

CLINICAL STUDY REPORT

A Multicenter, Randomized, Open-Label, Controlled Trial to Assess the Safety and Tolerability of Lucinactant for Inhalation in Preterm Neonates 26 to 28 Weeks PMA

Protocol Number: 03-CL-1401

Study Phase: 2a

Version: 1.0

Date of Report: 01 November 2017

Study Initiation Date: 15 January 2016

Study Completion Date: 08 July 2017

Study Early Termination Date: 08 July 2017

Investigational Product: AEROSURF™ (lucinactant for inhalation), comprised of lyophilized lucinactant and the AEROSURF Delivery System

IND Number: 119438

EudraCT Number: 2015-005624-26

Indication: Respiratory Distress Syndrome

Brief Description: Open-label dose escalation study (single dose with possible repeat) of lucinactant for inhalation compared to standard of care.

Sponsor: Windtree Therapeutics, Inc. (formerly Discovery Laboratories, Inc.)

Sponsor Contact: Steven G. Simonson, MD, MHS

Sponsor's Medical Officer: Steven G. Simonson, MD, MHS
Senior Vice President and Chief Medical Officer

Address: 2600 Kelly Road, Suite 100
Warrington, PA 18976
USA

Phone No.: (215) 488-9300

Fax No.: (215) 488-9301

See Appendix 16.1.4 for a complete list of all investigators and study centers. Relevant parties and author are listed in [Section 6](#).

This study was conducted in accordance with the *ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice (E6[R1])* (10 June 1996) and the *US Code of Federal Regulations, Title 21*, as well as all applicable local, state, and federal regulations and guidelines regarding the conduct of clinical studies. This report was written in accordance with *ICH Guideline: Structure and Content of Clinical Study Reports (E3)* (10 June 1996) and ISO 14155:2011 standard. Elements from ISO 14155:2011 for a Clinical Investigation Report have been incorporated into the ICH E3 format, as appropriate.

2. SYNOPSIS

Name of Sponsor/Company: Windtree Therapeutics, Inc. (formerly Discovery Laboratories, Inc.) 2600 Kelly Road Suite 100 Warrington, PA 18976, USA	Name of Finished Product: AEROSURF™ (lucinactant for inhalation) Lucinactant 30 mg TPL/ml (reconstituted)	Name of Active Ingredients: Dipalmitoylphosphatidylcholine (DPPC), palmitoyl-oleoyl-phosphatidylglycerol sodium salt (POPG, Na), palmitic acid (PA), and sinapultide (KL ₄ -peptide)
Title of Study: A Multicenter, Randomized, Open-Label, Controlled Trial to Assess the Safety and Tolerability of Lucinactant for Inhalation in Preterm Neonates 26 to 28 Weeks PMA		
Investigators and Study Centers: A total of 22 investigators from the United States (US), Canada, Chile and Poland received institutional review board (IRB), research ethics board (REB), or ethics committee (EC), and sponsor approval for participation in this study; subjects were enrolled at 15 study centers. The names of the investigators, addresses of the study centers, and copies of the investigators' curricula vitae are provided in Appendix 16.1.4.		
Publication (reference): None		
Study Period: 15 January 2016 – 08 July 2017 The study was terminated early on 08 July 2017	Phase of Development: 2a	
Objectives: The primary objective of this study was to evaluate the safety and tolerability of lucinactant for inhalation, administered as an aerosol in 4 escalating doses to a preterm, neonatal population 26 to 28 completed weeks post-menstrual age (PMA) receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS) compared with neonates receiving nCPAP alone. Safety and tolerability were evaluated using the same measures and assessments that were used in Study 03-CL-1201, in which lucinactant for inhalation was shown to be generally safe and well-tolerated in neonates 29 to 34 completed weeks PMA.		
Methodology: This multicenter, randomized, controlled, open-label, dose-escalation study, was conducted to evaluate the safety and tolerability of lucinactant for inhalation in conjunction with nCPAP in comparison with nCPAP alone in preterm neonates 26 to 28 completed weeks PMA with RDS. For this study, lucinactant for inhalation refers to the active investigational agent, lyophilized lucinactant, in combination with the prototype investigational delivery device, AEROSURF™ Delivery System (ADS). Reconstituted lyophilized lucinactant was aerosolized by the investigational device, ADS (using the capillary aerosol generator [CAG]), and introduced into the nCPAP circuit. Those randomized to the control arm continued to receive nCPAP alone. Dose assignments were unblinded, as the primary objective of this study was safety and tolerability. Preliminary efficacy endpoints were assessed as an exploratory objective. Preterm neonates between 26 and 28 completed weeks PMA who were within the first 20 hours after birth and who had successful implementation of controlled nCPAP within 90 minutes of birth were considered to be potential subjects. Before study enrollment, legal guardians were provided a written informed consent form (ICF) for each potential		

Name of Sponsor/Company:	Name of Finished Product:	Name of Active Ingredients:
Windtree Therapeutics, Inc. (formerly Discovery Laboratories, Inc.) 2600 Kelly Road Suite 100 Warrington, PA 18976, USA	AEROSURF™ (lucinactant for inhalation) Lucinactant 30 mg TPL/ml (reconstituted)	Dipalmitoylphosphatidylcholine (DPPC), palmitoyl-oleoyl- phosphatidylglycerol sodium salt (POPG, Na), palmitic acid (PA), and sinapultide (KL ₄ -peptide)
<p>subject. Qualification for study enrollment was established after confirmation that the subject had met all of the inclusion criteria and none of the exclusion criteria. The clinical criteria for enrollment could have been met prior to informed consent being obtained; however, no study-specific procedures that were not part of the usual standard care of the subject at the institution were performed until informed consent was provided by a legally authorized representative of the subject. Inclusion criteria to be met within the first 20 hours after birth included a required nCPAP of 5 to 6 cm H₂O and a fraction of inspired oxygen (FiO₂) within a range of 0.25 to 0.50 for at least 30 minutes to maintain oxygen saturation as determined by pulse oximetry (SpO₂) of 88% to 95%.</p> <p>As soon as study eligibility was confirmed and the informed consent was signed, subjects were randomized in a 1:1 ratio to either an active arm, to receive lucinactant for inhalation (1 of 4 intended dose groups enrolled sequentially) in conjunction with nCPAP, or a control arm, who received nCPAP alone. Doses of lucinactant for inhalation in each respective dosing group (Dosing Groups I through IV) were planned to be 50, 75, 100, or 150 mg total phospholipids (TPL)/kg administered over 30, 45, 60, or 90 minutes, respectively, and were administered within 2 hours of randomization. The study was terminated for administrative reasons (including resource limitations and the intent to study the 26-28 GA weeks PMA patients in an amendment to Study 03-CL-1202). Subjects were eligible to receive a repeat dose between 2 and 24 hours after the initial dose if subjects met repeat dosing criteria. The dose varied by the volume of the nominal dose of reconstituted lucinactant (30 mg TPL/ml) aerosolized and introduced into the nCPAP circuit, given over a predetermined time for each dose.</p> <p>After completion of enrollment of Dosing Group I and all subjects completed Study Day 7, a safety assessment (study-related adverse events [AEs], including adverse device effects [ADEs], serious adverse events [SAEs], and additional safety endpoints) was performed by an independent safety review committee (SRC). Following completion of enrollment within the dosing group, the lucinactant for inhalation dose was escalated for Dosing Group II (75 mg TPL/kg) and dosing Group III (100 mg TPL/kg). Subjects were followed through 36 weeks PMA, neonatal intensive care unit (NICU) discharge, hospital transfer, or death, whichever came first. The final study visit occurred at 36 weeks PMA or at time of discharge/transfer for all subjects.</p> <p>All enrolled subjects received study treatment in a neonatal intensive care unit (NICU), a specialized care center staffed by neonatologists, nurses, and respiratory therapists who are experienced in the delivery of emergent care to the preterm neonatal population. Neonates in the NICU are continuously monitored using advanced and sophisticated monitoring equipment, and there is ready and immediate access to equipment, medications, and skilled personnel that may be needed to address emergent developments. Interventions such as endotracheal intubation, mechanical ventilation, and surfactant administration were readily available to all study subjects if clinically indicated in accordance with the high level standard of care customary in the NICU.</p>		
<p>Number of Subjects (estimated and actual):</p> Number estimated: Approximately 64 Number enrolled/treated: 48/48 Number completing study: 48 Number discontinued: 0 Number discontinued due to adverse event (AE): 0		

<p>Name of Sponsor/Company: Windtree Therapeutics, Inc. (formerly Discovery Laboratories, Inc.) 2600 Kelly Road Suite 100 Warrington, PA 18976, USA</p>	<p>Name of Finished Product: AEROSURF™ (lucinactant for inhalation) Lucinactant 30 mg TPL/ml (reconstituted)</p>	<p>Name of Active Ingredients: Dipalmitoylphosphatidylcholine (DPPC), palmitoyl-oleoyl-phosphatidylglycerol sodium salt (POPG, Na), palmitic acid (PA), and sinapultide (KL₄-peptide)</p>								
<p>Diagnosis and Main Criteria for Entry:</p> <p>The study population consisted of preterm neonates from 26 to 28 completed weeks PMA with RDS. Subjects who met all of the following entry criteria were eligible for the study:</p> <ol style="list-style-type: none"> 1. Signed ICF from legally authorized representative; 2. Gestational age 26 to 28 completed weeks (28 weeks, 6 days) PMA; 3. Successful implementation of controlled nCPAP within 90 minutes after birth; 4. Spontaneous breathing; 5. Chest radiograph consistent with RDS; 6. Within the first 20 hours after birth, required an nCPAP of 5 to 6 cm H₂O and a FiO₂ of 0.25 to 0.50 that was clinically indicated for at least 30 minutes to maintain SpO₂ of 88% to 95%. Transient (<10 minutes) FiO₂ excursions below 0.25 or above 0.50 did not reset the 30 minute requirement. 										
<p>Test Product, Dose and Mode of Administration, and Batch Numbers:</p> <p>Reconstituted lyophilized lucinactant (30mg TPL/ml) was aerosolized by the prototype ADS (using CAG technology), and introduced into the nCPAP circuit. Those randomized to the control arm continued to receive nCPAP alone. The exposure time was based on the nominal dose. The nominal dose is the amount of lucinactant aerosolized by the ADS. Because of losses that occur as the lucinactant aerosol travels from the ADS to the patient interface, the emitted dose is approximately 35% of the nominal dose. The theoretical inhaled dose is the amount of the emitted dose that is likely to be inhaled, is estimated by product of the aerosol concentration, the minute ventilation of the neonate, and the administration time of the aerosol.</p> <p>Subjects randomized to the active study arm received aerosolized reconstituted lucinactant, in conjunction with nCPAP, within 2 hours of randomization through the ADS at 1 of 4 planned doses (50, 75, 100, or 150 mg TPL/kg) administered over 30, 45, 60, or 90 minutes, respectively, as shown below.</p> <table border="0"> <tr> <td data-bbox="186 1365 389 1396">Dosing Group I</td> <td data-bbox="422 1365 1445 1459"> <p><u>Active Arm</u> (n = 8): 50 mg TPL/kg administered over 30 minutes in conjunction with nCPAP 1 Repeat dose of 50 mg TPL/kg administered was allowed if repeat dosing criteria were met. <u>Control Arm</u> (n = 8): Continuous nCPAP</p> </td> </tr> <tr> <td data-bbox="186 1491 389 1522">Dosing Group II</td> <td data-bbox="422 1491 1445 1585"> <p><u>Active Arm</u> (n = 8): 75 mg TPL/kg administered over 45 minutes in conjunction with nCPAP 1 Repeat dose of 75 mg TPL/kg administered was allowed if repeat dosing criteria were met. <u>Control Arm</u> (n = 8): Continuous nCPAP</p> </td> </tr> <tr> <td data-bbox="186 1617 389 1648">Dosing Group III</td> <td data-bbox="422 1617 1445 1711"> <p><u>Active Arm</u> (n = 8): 100 mg TPL/kg administered over 60 minutes in conjunction with nCPAP 1 Repeat dose of 100 mg TPL/kg administered was allowed if repeat dosing criteria were met. <u>Control Arm</u> (n = 8): Continuous nCPAP</p> </td> </tr> <tr> <td data-bbox="186 1743 389 1774">Dosing Group IV</td> <td data-bbox="422 1743 1445 1837"> <p><u>Active Arm</u> (n = 8): 150 mg TPL/kg administered over 90 minutes in conjunction with nCPAP 1 Repeat dose of 150 mg TPL/kg administered was allowed if repeat dosing criteria were met. <u>Control Arm</u> (n = 8): Continuous nCPAP</p> </td> </tr> </table>			Dosing Group I	<p><u>Active Arm</u> (n = 8): 50 mg TPL/kg administered over 30 minutes in conjunction with nCPAP 1 Repeat dose of 50 mg TPL/kg administered was allowed if repeat dosing criteria were met. <u>Control Arm</u> (n = 8): Continuous nCPAP</p>	Dosing Group II	<p><u>Active Arm</u> (n = 8): 75 mg TPL/kg administered over 45 minutes in conjunction with nCPAP 1 Repeat dose of 75 mg TPL/kg administered was allowed if repeat dosing criteria were met. <u>Control Arm</u> (n = 8): Continuous nCPAP</p>	Dosing Group III	<p><u>Active Arm</u> (n = 8): 100 mg TPL/kg administered over 60 minutes in conjunction with nCPAP 1 Repeat dose of 100 mg TPL/kg administered was allowed if repeat dosing criteria were met. <u>Control Arm</u> (n = 8): Continuous nCPAP</p>	Dosing Group IV	<p><u>Active Arm</u> (n = 8): 150 mg TPL/kg administered over 90 minutes in conjunction with nCPAP 1 Repeat dose of 150 mg TPL/kg administered was allowed if repeat dosing criteria were met. <u>Control Arm</u> (n = 8): Continuous nCPAP</p>
Dosing Group I	<p><u>Active Arm</u> (n = 8): 50 mg TPL/kg administered over 30 minutes in conjunction with nCPAP 1 Repeat dose of 50 mg TPL/kg administered was allowed if repeat dosing criteria were met. <u>Control Arm</u> (n = 8): Continuous nCPAP</p>									
Dosing Group II	<p><u>Active Arm</u> (n = 8): 75 mg TPL/kg administered over 45 minutes in conjunction with nCPAP 1 Repeat dose of 75 mg TPL/kg administered was allowed if repeat dosing criteria were met. <u>Control Arm</u> (n = 8): Continuous nCPAP</p>									
Dosing Group III	<p><u>Active Arm</u> (n = 8): 100 mg TPL/kg administered over 60 minutes in conjunction with nCPAP 1 Repeat dose of 100 mg TPL/kg administered was allowed if repeat dosing criteria were met. <u>Control Arm</u> (n = 8): Continuous nCPAP</p>									
Dosing Group IV	<p><u>Active Arm</u> (n = 8): 150 mg TPL/kg administered over 90 minutes in conjunction with nCPAP 1 Repeat dose of 150 mg TPL/kg administered was allowed if repeat dosing criteria were met. <u>Control Arm</u> (n = 8): Continuous nCPAP</p>									

<p>Name of Sponsor/Company: Windtree Therapeutics, Inc. (formerly Discovery Laboratories, Inc.) 2600 Kelly Road Suite 100 Warrington, PA 18976, USA</p>	<p>Name of Finished Product: AEROSURF™ (lucinactant for inhalation) Lucinactant 30 mg TPL/ml (reconstituted)</p>	<p>Name of Active Ingredients: Dipalmitoylphosphatidylcholine (DPPC), palmitoyl-oleoyl-phosphatidylglycerol sodium salt (POPG, Na), palmitic acid (PA), and sinapultide (KL₄-peptide)</p>
<p>The study was terminated prior to subject enrollment for Dosing Group IV by the sponsor for administrative reasons (including resource limitations and the intent to study the 26-28 GA weeks PMA patients in an amendment to Study 03-CL-1202).</p> <p>The lot/batch numbers of lyophilized lucinactant for each dose (50, 75, and 100 mg TPL/kg) were as follows: All dosing groups included lots G15001 and G15003.</p>		
<p>Study Duration: First enrollment to last enrollment: 15 January 2016 to 14 May 2017. The planned duration of the study was from randomization through 36 weeks PMA, death, transfer, or discharge, whichever came first. The last subject's last visit was on 08 July 2017.</p>		
<p>Reference Therapy, Dose and Mode of Administration, and Batch Numbers: Subjects randomized to the control arms in all Dosing Groups received nCPAP alone. A total of 8 subjects were planned in each control arm of Dosing Groups I through IV; however, no subjects were enrolled in Dosing Group IV as the study was terminated by the sponsor for administrative reasons (including resource limitations and the intent to study the 26-28 GA weeks patients in an amendment to Study 03-CL-1202). Batch numbers are not applicable.</p>		
<p>Criteria for Evaluation:</p> <p><u>Efficacy (Exploratory):</u> Exploratory efficacy endpoints included the incidence of BPD, rate of survival without BPD at 36 weeks PMA, worsening of respiratory status (categorized as early if occurring ≤72 hours after birth or late if occurring >72 hours and ≤7 days after birth), and technical performance of the ADS (characterized indirectly through the subject's response to treatment and solicited feedback from the principal investigators [PIs] and relevant site-based study staff), physiological parameters (eg, FiO₂, PCO₂).</p> <p>Results for subjects without treatment interruptions and time to and incidence of intubation are described.</p> <p><u>Safety:</u> The primary endpoints of this study were derived from the safety evaluations reported from the time of randomization until 36 weeks PMA, death, transfer, or discharge, whichever came first. Safety endpoints included the following: survival (date of time of death, if applicable); AEs (including nasal excoriations by examination, evidence of lung air leak [eg, pneumothorax and pneumomediastinum], peri-dosing events [eg, bradycardia, desaturation, gagging/regurgitation, apnea, and pallor], and complications related to the placement of bi-nasal prongs); signs consistent with worsening respiratory status; concomitant medications; use of respiratory support and supplemental oxygen; complications of prematurity (eg, intraventricular hemorrhage [IVH], periventricular leukomalacia [PVL], pulmonary hemorrhage, necrotizing enterocolitis [NEC], patent ductus arteriosus [PDA],</p>		

<p>Name of Sponsor/Company: Windtree Therapeutics, Inc. (formerly Discovery Laboratories, Inc.) 2600 Kelly Road Suite 100 Warrington, PA 18976, USA</p>	<p>Name of Finished Product: AEROSURF™ (lucinactant for inhalation) Lucinactant 30 mg TPL/ml (reconstituted)</p>	<p>Name of Active Ingredients: Dipalmitoylphosphatidylcholine (DPPC), palmitoyl-oleoyl-phosphatidylglycerol sodium salt (POPG, Na), palmitic acid (PA), and sinapultide (KL₄-peptide)</p>
<p>sepsis, retinopathy of prematurity [ROP], and bronchopulmonary dysplasia [BPD]); physical examinations; tolerability of lucinactant for inhalation; incidence leading to withdrawal from study; arterial carbon dioxide (PCO₂) values, serum electrolyte measurements, body weight, vital signs, gastric liquid volume, defecation, SpO₂, and chest radiography.</p>		
<p>Statistical Methods:</p> <p>The statistical analyses of both the primary and secondary safety and tolerability objectives were based on all randomized preterm neonates in the study. In addition, data from all evaluable preterm neonates were analyzed for efficacy signals as an exploratory endpoint.</p> <p>All safety endpoint data captured from randomization to completion of Study Day 7 for active subjects, and all available safety endpoint data for nCPAP only subjects, were evaluated by the SRC. As this is an open-label study with no hypothesis testing, no adjustments for p-values were required or employed for the interim analysis.</p> <p>In addition, time to and incidence of intubation was added as an exploratory efficacy endpoint, and an analysis of subjects without treatment interruptions was added due to the unforeseen frequency of interruptions.</p>		
<p>Results:</p> <p>A total of 402 subjects 26-28 weeks GA were screened and 48 subjects (24 in the active groups and 24 in the nCPAP only group) were randomized into the study from 15 sites in 4 countries (US, Canada, Chile, and Poland). Subjects were typically white (32 [67%]) and not Hispanic (35 [73%]), with a mean gestational age of 27.3 and 27.5 weeks for active and nCPAP only groups, respectively. Approximately half of the subjects were male in the active group (11 [46%]); more than half were male in the nCPAP only group (16 [67%]).</p> <p>All 48 randomized subjects received treatment. Most subjects in the 50 and 100 mg TPL/kg received their full doses (7 [88%] and 6 [75%], respectively). Only 3 subjects in the 75 mg TPL/kg group received their full initial or repeat dose. In almost all cases, receiving less than a full dose was as a result of treatment interruptions. Interruptions primarily occurred due to surfactant clogged filters in the disposable components of the prototype ADS, and were more likely to occur in the 45 minute (ie, longer) treatments. No treatment interruptions resulted in loss of inspiratory flow or inability to maintain nCPAP.</p> <p>Efficacy:</p> <p>For this study, efficacy was considered an exploratory analysis. The primary purpose of the efficacy analysis was to determine the feasibility of certain efficacy measurements and to determine if there was any physiological evidence of aerosol delivery to the lungs; no statistical calculations or comparisons were planned.</p> <p>A total of 6 subjects (25%) in the nCPAP only group and no subjects in the active group developed BPD during the study. A post hoc statistical comparison was conducted using Chi-square which resulted in a p-value of 0.022.</p> <p>Overall, worsening of respiratory status occurred at comparable rates in active subjects (79%) vs. nCPAP only subjects (75%), and the individual criteria defining this endpoint occurred at a similar rate between the active groups and the nCPAP only group, with the exception of need for additional surfactant therapy and worsening respiratory</p>		

Name of Sponsor/Company:	Name of Finished Product:	Name of Active Ingredients:
Windtree Therapeutics, Inc. (formerly Discovery Laboratories, Inc.) 2600 Kelly Road Suite 100 Warrington, PA 18976, USA	AEROSURF™ (lucinactant for inhalation) Lucinactant 30 mg TPL/ml (reconstituted)	Dipalmitoylphosphatidylcholine (DPPC), palmitoyl-oleoyl-phosphatidylglycerol sodium salt (POPG, Na), palmitic acid (PA), and sinapultide (KL ₄ -peptide)
<p>status. By definition, need for additional surfactant therapy was reported only for subjects in the active treatments; this question was not applicable for subjects in the nCPAP only group. Worsening respiratory status was determined by the PI for 6 (25%) of the nCPAP only subjects and for 1 (4%) of the active subjects. Intubation was generally similar between the treatments (17 [71%] vs. 16 [67%] for active and control, respectively). If only subjects without treatment interruptions are considered, the rate of intubation for active subjects drops to 63% (4/7 [57%], 3/3 [100%], and 3/6 [50%] for 50, 75, and 100 mg TPL/kg, respectively). The median time until intubation due to nCPAP failure was slightly higher in the active groups (median of 8.9 hours) compared to the nCPAP only group (median of 5.8 hours).</p> <p>Baseline values for physiological measurements were similar in active subjects (mean FiO₂ of 0.34 and PCO₂ of 48.9 mmHg) and nCPAP only subjects (mean FiO₂ of 0.32 and PCO₂ of 50.5 mmHg).</p> <p>Over the 72-hour measurement period, there appears to be a dose-response for subjects in the 75 and 100 mg TPL/kg groups in decreases from baseline in FiO₂ values (approximately 10% decrease), whereas subjects in the nCPAP only group did not show a similar decrease (less than 5% decrease). No trends or consistent changes were noted for PCO₂ for any active treatment or control groups.</p> <p>Technical performance of the ADS was considered adequate. One detachment (noted before aerosol delivery began), and 1 incident of leakage was noted. No incidents of airway tubing obstructions, loss of inspiratory flow, or inability to maintain nCPAP were reported. There were 8 subjects with reports of automatic system shutdowns in the initial dose (1 for 50 mg TPL/kg, 4 for 75 mg TPL/kg and 3 for 100 mg TPL/kg) and 5 subjects with reports in the repeat dose (all for the 75 mg TPL/kg group). Automatic system shutdowns were predominantly due to an in-line filter clogging and the system responded appropriately in these cases.</p> <p>Safety:</p> <p>Lucinactant for inhalation was generally well-tolerated.</p> <p>All subjects experienced at least one AE. The most common TEAEs were neonatal apnea (17 [71%] and 19 [79%] subjects for active and nCPAP only groups, respectively), neonatal anemia (12 [50%] and 13 [54%]), desaturation (12 [50%] and 9 [38%]), patent ductus arteriosus (10 [42%] and 10 [42%]), and neonatal jaundice (9 [38%] and 11 [46%]). Most TEAEs were consistent between active and nCPAP only, with no differences exceeding 4 subjects in either direction, with the exception of dermatitis diaper (7 [29%] for active vs. 1 [4%] for control), retinopathy of prematurity (4 [17%] for active vs. 9 [38%] for control), and bronchopulmonary dysplasia (0 for active vs. 7 [29%] for control). One case of BPD reported as an adverse event, in the nCPAP only group, was not included in the BPD analysis as this subject was not on supplemental oxygen at 36 weeks PMA. The number of subjects with air leaks, which were an AE of special interest, was similar between active (5 [21%]) and nCPAP only (4 [17%]). For the air leak of pneumothorax, there were 2 (8%) active subjects compared to 3 (13%) control subjects reported.</p> <p>Peri-dosing AEs were experienced by 7 (29%) subjects, and related AEs were experienced by 9 (38%) subjects which, by definition, could only occur for subjects in the active group. No subjects reported complications related to the placement of bi-nasal prongs during the dosing period. There were two events reported as ADEs: one report of</p>		

Name of Sponsor/Company:	Name of Finished Product:	Name of Active Ingredients:
Windtree Therapeutics, Inc. (formerly Discovery Laboratories, Inc.) 2600 Kelly Road Suite 100 Warrington, PA 18976, USA	AEROSURF™ (lucinactant for inhalation) Lucinactant 30 mg TPL/ml (reconstituted)	Dipalmitoylphosphatidylcholine (DPPC), palmitoyl-oleoyl-phosphatidylglycerol sodium salt (POPG, Na), palmitic acid (PA), and sinapultide (KL ₄ -peptide)
<p>nasal inflammation (50 mg TPL/kg) and one report of desaturation (100 mg TPL/kg). Both ADEs, which were not serious, were considered mild, with the nasal inflammation reported as unrelated and the desaturation reported as related.</p> <p>There were SAEs experienced by 9 (38%) subjects in the active group and 6 (25%) in the nCPAP only group. One active subject (50 mg TPL/kg) had an SAE that was considered possibly related to study drug treatment. The other active subjects had SAEs that were considered unlikely related or not related to study drug treatment.</p> <p>There were 2 deaths in this study: 1 in the 50 mg TPL/kg group and 1 in the 75 mg TPL/kg group. The 2 deaths were considered unlikely related or not related, respectively, to study drug treatment. One death was as a result of pneumoperitoneum (Subject 11011, 75 mg TPL/kg, day-of-life [DOL] 10) and the other due to NEC and bowel perforation (Subject 12014, 50 mg TPL/kg, DOL 38).</p> <p>Overall, there were no treatment-related trends observed in physical examination findings or changes from baseline. In addition, there were no meaningful differences for temperature, respiratory rate, or heart rate at any of the selected time points.</p> <p>Approximately half (46%) of subjects on either active treatment or control received brief (< 10 minutes) positive pressure ventilation in the delivery room (DR).</p> <p>After dosing, there were no clinically significant differences between active and nCPAP only subjects for MV, supplemental O₂, CPAP settings, or complications of prematurity.</p>		

<p>Name of Sponsor/Company: Windtree Therapeutics, Inc. (formerly Discovery Laboratories, Inc.) 2600 Kelly Road Suite 100 Warrington, PA 18976, USA</p>	<p>Name of Finished Product: AEROSURF™ (lucinactant for inhalation) Lucinactant 30 mg TPL/ml (reconstituted)</p>	<p>Name of Active Ingredients: Dipalmitoylphosphatidylcholine (DPPC), palmitoyl-oleoyl-phosphatidylglycerol sodium salt (POPG, Na), palmitic acid (PA), and sinapultide (KL₄-peptide)</p>
<p>Discussion and Overall Conclusions: 15 January 2016 – 08 July 2017</p> <p>From 15 January 2016 to 08 July 2017, 48 preterm neonates 26 to 28 weeks PMA participated in this study. Baseline demographic and clinical characteristics of each group were generally similar between treatment groups</p> <p>Safety evaluations included assessment of AEs during dosing (peri-dosing events), AEs, ADEs, and SAEs that occurred throughout the duration of the study. No clinically relevant differences in AEs were noted for subjects in the active groups compared with subjects in the nCPAP only group. There were 2 deaths reported, considered by the PI to be unlikely related or not related to study drug treatment. Lucinactant for inhalation appeared to be well tolerated at all doses administered.</p> <p>The prototype ADS functioned as intended; however, an unanticipated high number of treatment interruptions was noted, mostly due to clogging of an in-line filter. When clogging occurred, the device functioned as designed and ceased aerosol delivery. Nonetheless, the use of the ADS for the delivery of reconstituted lucinactant in the study population and setting did not reveal any safety concerns.</p> <p>Exploratory efficacy assessment suggested that treatment with lucinactant for inhalation decreases the FiO₂ requirements, increases time to intubation, and decreases BPD in preterm neonates 26 to 28 weeks gestation PMA with RDS. When the dose is delivered as intended without treatment interruptions, CPAP failures and intubations may be reduced.</p> <p>Results of this study support further development of lucinactant for inhalation.</p>		
<p>Date of Report: 01 November 2017</p>		

3. TABLE OF CONTENTS

1. TITLE PAGE	1
2. SYNOPSIS	2
3. TABLE OF CONTENTS	10
LIST OF TABLES PRESENTED IN THE TEXT	14
LIST OF FIGURES PRESENTED IN THE TEXT	16
4. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS	17
5. ETHICS	19
5.1 Institutional Review Board or Independent Ethics Committee.....	19
5.2 Ethical Conduct of the Study	19
5.3 Informed Consent Form of Study Subject	20
5.4 Financial Disclosure.....	20
6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE	22
6.1 Key Study Personnel and Committees.....	22
6.2 Clinical Study Report Authors	24
7. INTRODUCTION.....	25
7.1 Development of Aerosolization Device for Lucinactant Delivery.....	26
7.2 Regulatory Agency Meetings.....	26
8. OBJECTIVES	28
9. INVESTIGATIONAL PLAN	29
9.1 Overall Study Design and Plan: Description.....	29
9.1.1 Study Duration	32
9.1.2 Duration of Subject Study Participation	32
9.2 Discussion of Study Design, Including the Choice of Control Groups	32
9.2.1 Rationale for Study Control	33
9.2.2 Active Dose Considerations.....	33
9.3 Selection of Study Population.....	34

9.3.1	Inclusion Criteria	34
9.3.2	Exclusion Criteria	34
9.3.3	Removal of Patients from Therapy or Assessment.....	35
9.4	Treatments.....	37
9.4.1	Treatments Administered.....	37
9.4.2	Identity of Investigational Product.....	38
9.4.3	Method of Assigning Study Subjects to Dosing Groups	43
9.4.4	Selection of Doses in the Study	44
9.4.5	Selection and Timing of Dose for Each Patient.....	47
9.4.6	Blinding/Masking	47
9.4.7	Prior and Concomitant Therapy.....	47
9.4.8	Treatment Compliance.....	47
9.5	Efficacy and Safety Variables	48
9.5.1	Efficacy and Safety Measurements Assessed and Flow Chart	48
9.5.2	Appropriateness of Measurements.....	62
9.5.3	Efficacy Variables.....	62
9.5.4	Drug Concentration Measurements	62
9.6	Data Quality Assurance.....	62
9.7	Statistical Methods Planned in the Protocol and Determination of Sample Size.....	63
9.7.1	Statistical and Analytical Plans.....	63
9.7.2	Determination of Sample Size	64
9.8	Changes in the Conduct of the Study or Planned Analyses	64
9.8.1	Changes in the Conduct of the Study.....	64
9.8.2	Changes in the Planned Analyses	70
10.	STUDY PATIENTS	71
10.1	Disposition of Patients	71
10.2	Protocol Deviations	72
11.	EXPLORATORY EFFICACY EVALUATION.....	73

11.1	Data Sets Analyzed	73
11.2	Demographic and Other Baseline Characteristics.....	73
11.3	Measurements of Treatment Compliance.....	75
11.4	Exploratory Efficacy Results and Tabulations of Individual Patient Data.....	76
11.4.1	Exploratory Analysis of Efficacy	76
11.4.2	Statistical/Analytical Issues	90
11.4.3	Tabulations of Individual Response Data.....	92
11.4.4	Drug Dose, Drug Concentration, and Relationships to Response	92
11.4.5	Drug-Drug and Drug-Disease Interactions	92
11.4.6	By-Subject Displays.....	92
11.4.7	Efficacy Conclusions.....	92
12.	SAFETY EVALUATION.....	94
12.1	Extent of Exposure	94
12.2	Adverse Events.....	94
12.2.1	Brief Summary of Adverse Events	94
12.2.2	Display of Adverse Events.....	95
12.2.3	Analysis of Adverse Events	99
12.2.4	Listing of Adverse Events by Patient.....	99
12.3	Deaths, Other Serious Adverse Events, and Other Significant Adverse Events	100
12.3.1	Listing of Deaths, Other Serious Adverse Events, and Other Significant Adverse Events	100
12.3.2	Narratives of Deaths, Other Serious Adverse Events, and Certain Other Significant Adverse Events	101
12.3.3	Analysis and Discussion of Deaths, Other Serious Adverse Events, and Other Significant Adverse Events	104
12.4	Clinical Laboratory Evaluation	104
12.4.1	Listing of Individual Laboratory Measurements by Patient and Each Abnormal Laboratory Value.....	105
12.4.2	Evaluation of Each Laboratory Parameter.....	105

12.5	Vital Signs, Physical Findings, and Other Observations Related to Safety.....	106
12.5.1	Physical Examination Findings.....	106
12.5.2	Vital Signs.....	107
12.5.3	Gastric Liquid Volume and Defecation	109
12.5.4	Clinical Assessments: Respiratory Parameters.....	109
12.5.5	Complications of Prematurity.....	113
12.6	Safety Conclusions.....	114
13.	DISCUSSION AND OVERALL CONCLUSIONS.....	115
14.	TABLES, FIGURES, AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT	116
14.1	Demographic Data Summary Tables and Summary Listings	116
14.2	Efficacy Data Summary Tables and Summary Graphs.....	771
14.3	Safety Data Summary Tables and Summary Listings.....	794
14.3.1	Displays of Adverse Events and Clinical Assessments	794
14.3.2	Listings of Deaths, Other Serious and Significant Adverse Events.....	1071
14.3.3	Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events 1076	
14.3.4	Abnormal Laboratory Value Listing (Each Subject).....	1097
15.	REFERENCE LIST.....	1098
	APPENDICES.....	1100

LIST OF TABLES PRESENTED IN THE TEXT

Table 6-1. Key Study Personnel 22

Table 6-2. Steering Committee Members 23

Table 6-3. Safety Review Committee Members and Affiliations 23

Table 9-1. Study Assignments by Dosing Groups 37

Table 9-2. Key Functions of ACU and ADP 39

Table 9-3. Components of Lucinactant 41

Table 9-4. Minute Ventilation Comparison Between Bide and Bhutani 46

Table 9-5. Dosing Duration (minutes) for Each Dosing Group 47

Table 9-6. Protocol Event Schedule 61

Table 10-1. Subject Disposition Summary (All Subjects) 71

Table 11-1. Subject Demographics (Intent-to-Treat Population) 73

Table 11-2. Maternal and Birth History (Intent-to-Treat Population) 74

Table 11-3. Summary of BPD and Survival without BPD at 36 Weeks PMA (Intent-to-Treat Population) 77

Table 11-4. Worsening Respiratory Status - Early (Intent-to-Treat Population) 78

Table 11-5. Time from Randomization until nCPAP Failure (Intent-to-Treat Population) 79

Table 11-6. Time from Randomization until Any Intubation (Intent-to-Treat Population) 79

Table 11-7. Time until nCPAP Failure, Without Treatment Interruptions 87

Table 12-1: Overview of Adverse Events 95

Table 12-2. Peri-Dosing Adverse Events, Initial Dose (Safety Population) 96

Table 12-3. Treatment-Emergent AEs by System Organ Class and Preferred Term Events Experienced by > 15% of Active or nCPAP Only Subjects 97

Table 12-4. TEAEs of Moderate or Severe Intensity by Treatment Group Experienced by > 10% of Subjects in any Column (Safety Population) 98

Table 12-5. Number of Subjects with Air Leaks (Safety Population) 101

Table 12-6. Subjects with SAEs (Safety Population) 102

Table 12-7. Serum Electrolytes (Safety Population) 24 Hours After Randomization 105

Table 12-8. Physical Examination Shift Table (Safety Population)..... 106

Table 12-9. Gastric Liquid Volume Post-Dose Administration and Number of Defecations 109

Table 12-10. Respiratory Support in the Delivery Room and Mechanical Ventilation 110

Table 12-11. Supplemental Oxygen 111

Table 12-12. CPAP Settings 112

Table 12-13. Complications of Prematurity..... 114

Table 14-1. Deaths and Serious Adverse Events 1076

LIST OF FIGURES PRESENTED IN THE TEXT

Figure 1. Schematic of Study Design 31

Figure 2. AEROSURF Delivery System 38

Figure 3. Intubation through 72 Hours from Randomization by Treatment (Intent-to-Treat Population)..... 80

Figure 4. Cumulative Time to nCPAP Failure from Randomization through 72 Hours (Intent-to-Treat Population) 81

Figure 5. Kaplan-Meier Curve for Time to Intubation from Randomization (Intent-to-Treat Population)..... 82

Figure 6. Capillary Aerosol Generator..... 83

Figure 7. Frit Filter and Filter Bubble Points vs. Flow Rate for 10 Micron Frit Filters 85

Figure 8. Intubation Through 72 Hours by Treatment (Subjects without Treatment Interruptions) 87

Figure 9. Kaplan-Meier Curve for Time to Intubation (Subjects without Treatment Interruptions) 88

Figure 10. FiO₂ Change from Baseline by Overall Treatment Group (Safety Population)..... 89

Figure 11. PCO₂ Change from Baseline by Overall Treatment Group (Intent-to-Treat Population) 90

Figure 12. Body Temperature – Change from Baseline Values (Safety Population)..... 107

Figure 13. Spontaneous Respirations – Change from Baseline Values (Safety Population)..... 108

Figure 14. Heart Rate – Change from Baseline Values (Safety Population)..... 108

4. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviations

Abbreviation	Description
ACU	AEROSURF Control Unit
AE	Adverse event
ADE	Adverse device effect
ADS	AEROSURF Delivery System
ADP	AEROSURF Delivery Pack
BPD	Bronchopulmonary dysplasia
CAG	Capillary aerosol generator
CFR	Code of Federal Regulations
CPAP/nCPAP	Continuous positive airway pressure/nasal CPAP
CRF/eCRF	Case report form/electronic CRF
DPPC	Dipalmitoylphosphatidylcholine
DR	Delivery room
FDA	Food and Drug Administration
FiO ₂	Fraction of inspired oxygen
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed consent form
ICH	International Conference on Harmonisation
IEC	Independent Ethics Committee
IRB	Institutional Review Board
IMV	Intermittent mechanical ventilation
IND	Investigational new drug
IPP	Intermittent positive pressure
ITT	Intent-to-Treat
IVH	Intraventricular hemorrhage
IWRS	Interactive web response system
KL ₄	21-amino acid hydrophobic synthetic peptide; also known as sinapultide
MMAD	Mass median aerodynamic diameter

Abbreviation	Description
MV	Mechanical ventilation
NDA	New drug application
NEC	Necrotizing enterocolitis
NICU	Neonatal intensive care unit
NOEL	No observed adverse effect level
O ₂	Oxygen
PA	Palmitic acid
PCO ₂	Partial pressure carbon dioxide
PDA	Patent ductus arteriosus
PI	Principal Investigator
PIE	Pulmonary interstitial emphysema
PMA	Post-menstrual age
POPG, Na	Palmitoyl-oleoyl-phosphatidylglycerol, sodium salt
PPV	Positive pressure ventilation
PROM	Premature rupture of membranes
PVL	Periventricular leukomalacia
REB	Research ethics board
RDS	Respiratory distress syndrome
ROP	Retinopathy of prematurity
SAE	Serious adverse event
SaO ₂	Oxygen saturation as measured by blood analysis
SIV	Site initiation visit
SpO ₂	Oxygen saturation as determined by pulse oximetry
SRC	Safety review committee
SRT	Surfactant replacement therapy
TORCH	Toxoplasmosis, rubella, cytomegalovirus, herpes simplex
TPL	Total phospholipids
UADE	Unanticipated adverse device effect
US	United States
V _m	Minute ventilation

5. ETHICS

5.1 Institutional Review Board or Independent Ethics Committee

The protocol, including any amendments and the informed consent form (ICF), was submitted to an institutional review board (IRB), research ethics board (REB), or ethics committee (EC) (collectively referred to as ECs in this report) at each investigational site for approval to conduct the study. Before the initiation of the study at each investigational site, a designee at the site forwarded to Windtree (formerly Discovery Laboratories, Inc.) a copy of the site's local EC approval to conduct the study. This approval referred to the study by exact protocol title and number and identified the documents reviewed and the date of review. A list of all ECs consulted is provided in Appendix 16.1.4.

Protocol and ICF modifications or changes were not implemented without prior written EC approval, except when the change(s) involved only logistical or administrative aspects of the study. Such modifications were submitted to the EC and written verification that the modification was submitted and subsequently approved was obtained. A site must receive approval from Windtree on any ICF modification before submission to the EC for approval and subsequent implementation at the study site. Protocol modifications (ie, amendments) were only enacted by Windtree.

The EC was informed of revisions to other study-related documents or study information that was originally submitted for review. Revised study documentation and related informational updates included, but were not limited to, the following:

- Serious and/or unexpected adverse events (AEs) occurring during the study (reported in accordance with the standard operating procedures (SOPs) and policies of the EC)
- Any new study information that may adversely affect subject safety or study conduct
- Annual study updates or EC requests for reassessment of the study
- Timely communication of significant actions and related findings from the SRC (to include study enrollment holds or expansion, protocol amendments, or early study closure).
- Notification of major study/site milestones to include study/site closure

5.2 Ethical Conduct of the Study

This study was conducted according to the United States (US) regulations and International Conference on Harmonisation (ICH) guidelines (21 Code of Federal Regulations [CFR] Part 50,

Protection of Human Subjects, 21 CFR Part 56, *Institutional Review Boards*, 21 CFR Part 312, *Investigational New Drug Application*, 21 CFR Part 54, *Financial Disclosure by Clinical Investigators*; 21 CFR Part 11, *Electronic Records; Electronic Signatures*; 21 CFR Part 812, *Investigational Device Exemptions*; and ICH E6(R1), *Guideline for Good Clinical Practice*) as well as all applicable local, state, and federal regulations and guidelines regarding the conduct of clinical studies. In addition, this study was conducted in accordance with the ethical principles included in the World Medical Assembly (WMA) Declaration of Helsinki, *Ethical Principles for Medical Research Involving Human Subjects* adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended most recently by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013.

5.3 Informed Consent Form of Study Subject

A signed ICF was obtained in accordance with the Declaration of Helsinki, ICH GCP, 21 CFR Part 50 Subpart B, 21 CFR 56, Subpart A), the Health Insurance Portability and Accountability Act (HIPAA), and local regulations.

The Principal Investigator (PI) prepared the ICF based on an ICF template provided by Windtree (see Appendix 16.1.3). Final versions of site-based ICFs were provided to Windtree or designee for approval before submission to the EC. The ICF generated by the PI was acceptable to Windtree and approved by the EC. The PI sent an EC-approved copy of the ICF to Windtree for the study file.

The subject's legally authorized guardian was provided an ICF describing this study and was provided sufficient information to make an informed decision about the subject's participation in this study. The formal consent of a subject's legally authorized guardian, using the EC-approved ICF (and any other locally required documents), was obtained before the performance of any study-related activity, including the cessation of any medications or procedures. The ICF was signed and dated, including the time of consent by the subject's legally authorized guardian, the investigator-designated research professional obtaining the consent, and, if applicable, an impartial witness.

5.4 Financial Disclosure

Clinical investigators were asked to disclose proprietary (eg, patent, licensing agreement) and financial (eg, stock options, royalty) interests as they pertain to Windtree, before participating in the study. In addition, clinical investigators were required to consult with Windtree before acquiring any financial interest in the company and to disclose any change in their proprietary or financial interests, if it occurs, during the course of the study and for 1 year following study

completion. The requirement for proprietary and financial disclosure also included any ownership by the spouse or any dependent subject of the clinical investigator.

6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

6.1 Key Study Personnel and Committees

Table 6-1 lists personnel critical to the conduct of the study, which was sponsored by Windtree.

Table 6-1. Key Study Personnel

Role/Responsibility	Name and Title
Medical Officer	Steven G. Simonson, MD, MHS Senior Vice President and Chief Medical Officer
Medical Monitors	Robert Segal, MD, FACP Senior Vice President, Clinical Development & Academic Affairs
	Paul Shore, MD Senior Director, Clinical Research
Clinical Operations	Christine E. Buben Senior Director, Clinical Operations
	Judy Varga Associate Director, Clinical Sciences
Biostatistics & Data Management	Phillip D. Simmons Executive Director, Biostatistics & Data Management
	Nancy J. Cameron Senior Manager, Clinical Data Management
Medical Device Development	Lawrence Weinstein Vice President, Medical Device Development
Clinical Supply Packaging	George Cox Vice President, Supply Chain

A total of 22 investigators from the US, Canada, Chile, and Poland received EC and sponsor approval for participation in this study; 15 centers enrolled subjects. The names and addresses of the investigators and copies of their curricula vitae, as well as the names of other important study personnel, are provided in Appendix 16.1.4.

The list of names and address of any third parties (eg, CROs, consultants, contractors) that contributed to the clinical investigation and a list of monitors is provided in Appendix 16.1.4.

A Steering Committee (SC), which also served as the Scientific Advisory Board (SAB), was established to help design the scientific aspects of the study and oversaw many aspects of this study, including protocol amendments and issues that arose during the conduct of the study. The SC member names and affiliations are listed in [Table 6-2](#).

Table 6-2. Steering Committee Members

Member	Affiliation
Neil N. Finer, MD; Chair	Emeritus Professor of Pediatrics, UCSD Medical Center
Brenda L. Bradley Poindexter, MD, FAAP	Professor of Pediatrics, University of Cincinnati
Richard Polin, MD	Professor of Pediatrics, Columbia University
Shahnaz Duara, MD	Professor of Pediatrics and Obstetrics & Gynecology, University of Miami School of Medicine
Andrea L. Lampland, MD	Asst. Prof. of Pediatrics, Univ. of Minnesota Dept. of Neonatology; Assoc. Director of Neonatology, Children’s Hospitals and Clinics of Minnesota – St. Paul

A Safety Review Committee (SRC) was established to review the safety data for this study. SRC member names and affiliations are listed in [Table 6-3](#). SRC responsibilities, authorities and procedures were documented in a SRC charter endorsed by members of the SRC. A copy of this charter can be found in Appendix 16.1.4.

Table 6-3. Safety Review Committee Members and Affiliations

Member	Affiliation
Richard Martin, MD; chair	Director, Neonatal Research Programs, Professor, Pediatrics, CWRU School of Med.
Donald M. Null, Jr., MD, FAAP	Medical Director, Neonatal Intensive Care Unit, UC Davis School of Medicine
Frank Mannino, MD	Medical Director of the Neonatal Intensive Care Unit, Professor of Pediatrics, UCSD
Mark Hudak, MD	Chief of Neonatology and Pediatric Critical Care; Professor & Chairman, Department of Pediatrics at University of Florida College of Medicine – Jacksonville
Wei Du, PhD (non-voting member)	Consulting Statistician Independent Statistical Analysis Consultant

The signature of the Responsible Medical Officer at Windtree is provided in Appendix 16.1.5.

6.2 Clinical Study Report Author

Phillip D. Simmons, Executive Director of Biostatistics & Data Management for Windtree prepared this report.

7. INTRODUCTION

The purpose of this study was to evaluate the safety and tolerability of a sequential, escalating dose of lucinactant for inhalation (a non-invasive, investigational drug-device combination product) administered in preterm neonates 26 weeks to 28 completed weeks (28 weeks 6 days) post-menstrual age (PMA) with respiratory distress syndrome (RDS), treated with nasal continuous positive airway pressure (nCPAP), in comparison with nCPAP alone.

Non-invasive surfactant delivery potentially addresses an unmet medical need by providing a means to deliver surfactant to preterm neonates with RDS treated with nCPAP, thereby providing surfactant therapy early in the disease course while avoiding the complications associated with endotracheal intubation for surfactant delivery.

This phase 2a study was designed to assess the safety and tolerability of a novel surfactant replacement therapy (SRT), lucinactant for inhalation, administered at select doses in preterm neonates 26 to 28 completed weeks PMA. A similar study, Study 03-CL-1201, in preterm neonates 29 to 34 completed weeks PMA, was conducted first to establish that lucinactant for inhalation is generally safe and well tolerated in that patient population. Similar to this study (03-CL-1401), Study 03-CL-1201 evaluated lucinactant for inhalation in a dose-escalation manner up to 75 mg total phospholipids (TPL)/kg, with a study extension up to 150 mg TPL/kg. Findings from these two studies (03-CL-1201 and 03-CL-1401) will contribute to the development and design of future investigations of this novel drug/device combination product.

Surfactant treatment has reduced mortality and morbidity in newborns with RDS. Intratracheal instillation of exogenous surfactant is a standard for the treatment of RDS⁽¹⁾, and the benefits of surfactant treatment, specifically early surfactant treatment, are well established⁽²⁾. However, instillation of surfactant into the lung requires endotracheal intubation, an invasive procedure that has potential deleterious effects. Efforts by neonatologists to avoid endotracheal intubation to reduce the volutrauma and barotrauma associated with airway inflation and deflation have focused on the use of nCPAP, reserving intubation and surfactant administration for the most severely ill neonates.

The use of nCPAP in preterm neonates with RDS has become widely accepted⁽³⁾ and national guidelines (American Association for Respiratory Care)⁽⁴⁾ exist for treatment of respiratory distress in preterm newborns. These guidelines outline several patient interface devices that can be used to deliver continuous airway pressure such as nasal masks, short bi-nasal prongs, and nasopharyngeal tubes. It has been demonstrated that nCPAP is effective in increasing functional residual capacity by stabilizing and improving alveolar function⁽⁵⁾ and in dilating the larynx⁽⁶⁾.

Devices that generate and deliver nCPAP, including patient interfaces such as nasal prongs, are specifically designed, manufactured, and cleared for use in neonates.

Although the use of nCPAP in preterm neonates is common, studies of nCPAP alone, including a meta-analysis of prophylactic nCPAP for preventing morbidity and mortality in very preterm neonates, have not shown a clear benefit of this approach⁽⁷⁾.

7.1 Development of Aerosolization Device for Lucinactant Delivery

Windtree developed a device using capillary aerosol generator (CAG) technology to aerosolize lucinactant. Pre-clinical studies using the CAG technology in spontaneously breathing preterm lambs receiving aerosolized lucinactant have demonstrated significant improvements in lung mechanics and gas exchange compared with lambs receiving CPAP alone. In addition, pilot clinical studies using aerosolized lucinactant delivered via a commercial nebulizer in neonates with RDS, as well as in adults with asthma and cystic fibrosis, have preliminarily demonstrated that aerosolized lucinactant is generally well-tolerated.

Data from a large neonatal database support the assumption that prophylactic use of aerosolized surfactant and nCPAP may reduce the need for intubation by 36% in neonates with a birth weight of 1001 to 1500 grams⁽³⁾. Because aerosolized surfactant is preferentially delivered to the ventilated parts of the lungs, it is essential to provide appropriate ventilatory support during aerosol delivery. Distribution of aerosol in the lungs has been limited by the technical constraints of currently available aerosol generators and system configurations. Compared with the endotracheal instillation surfactant administration route, efforts to aerosolize surfactants in clinical models have been largely unsuccessful because of the highly inefficient and limited dose delivery of currently available aerosol generators compared with the bolus administration route^(8,9). However, the CAG technology may allow for administration of aerosolized lucinactant to be deposited in the lungs of preterm neonates in potentially sufficient quantities to affect a therapeutic response analogous to that of endotracheal instillation surfactant administration. A prototype investigational device, AEROSURF™ Delivery System (ADS) utilizing the CAG technology has been developed and provides a high-density surfactant aerosol output, with an appropriate particle size (2 to 3 microns mass median aerodynamic diameter [MMAD]). The ADS was used in 3 clinical studies (Studies 03-CL-1201, 03-CL-1401 and 03-CL-1202) to aerosolize reconstituted lucinactant.

7.2 Regulatory Agency Meetings

Three meetings (1 pre-investigational new drug [pre-IND] meeting and 2 Type C meetings) were held with the US Food and Drug Administration (FDA) on 05 April 2006, 18 July 2007, and

20 April 2016, to discuss the proposed development program for lucinactant for inhalation. FDA feedback that impacted the development program was the need to demonstrate that dose escalation was initially safe in neonates 29 to 34 weeks PMA (Study 03-CL-1201) before proceeding to study a younger preterm population (ie, 26 to 28 weeks PMA) as per this study.

8. OBJECTIVES

The primary objective of this study was to evaluate the safety and tolerability of lucinactant for inhalation (30 mg TPL/ml), administered in 4 escalating theoretical inhaled doses of 50, 75, 100, and 150 mg TPL/kg to preterm neonates 26 weeks to 28 completed weeks (28 weeks 6 days) post-menstrual age (PMA), who were receiving nasal continuous positive airway pressure (nCPAP) for respiratory distress syndrome (RDS), compared to neonates receiving nCPAP alone.

The primary endpoints of this study were derived from the safety evaluations reported from the time of randomization until 36 weeks PMA or upon discharge. Safety and tolerability were evaluated using the same measures and assessments that were used in Study 03-CL-1201, which shows lucinactant for inhalation up to 150 mg/kg to be generally safe and well-tolerated in neonates 29 to 34 completed weeks PMA.

The secondary objective of this study was to determine the maximum tolerated dose of lucinactant as determined by the safety evaluations obtained within each dosing group, and to assess the feasibility of evaluating physiological pulmonary function parameters as a measure of improvement in clinical status in preterm neonates 26 to 28 completed weeks PMA who are receiving nCPAP for RDS, compared with preterm neonates receiving nCPAP alone.

The exploratory efficacy objective of this study was to demonstrate the ability to measure clinical effect. The endpoints specified are the same endpoints as Study 03-CL-1201, to allow for potential comparison and pooling of results.

9. INVESTIGATIONAL PLAN

9.1 Overall Study Design and Plan: Description

This was a multinational, multicenter, randomized, open-label, controlled dose-escalation study conducted to evaluate the safety and tolerability of a novel drug-device combination investigational product (lucinactant for inhalation), administered in conjunction with nCPAP in preterm neonates who are under the care and observation of a neonatal intensive care unit (NICU). The study explored escalating exposures of lucinactant for inhalation in a sequential manner through 4 planned unique dosing groups. All subjects randomized to the active study arms received the same concentration of study drug for different lengths of time. Subjects randomized to the control arm received nCPAP alone. The delivery of reconstituted lucinactant was facilitated by the prototype ADS in conjunction with a commercially-available nCPAP generator and patient interface.

Preterm neonates between 26 and 28 completed weeks PMA who were within the first 20 hours after birth and who had successful implementation of controlled nCPAP within 90 minutes of birth were considered to be potential subjects. Before study enrollment, legal guardians provided a written ICF for each potential subject. Qualification for study enrollment was established after confirmation that the subject met all of the inclusion criteria and none of the exclusion criteria. The clinical criteria for enrollment (eg, FiO₂, heart rate, O₂ saturation) may have been met prior to informed consent being obtained; however, no study-specific procedures that were not part of the usual standard care of the subject at the institution were to be performed until the ICF was signed by a legally authorized representative of the subject. As soon as study eligibility was confirmed and the ICF was signed, subjects were randomized. All study subjects were to be randomized within 20 hours after birth to either an active study arm or a control arm.

Subjects randomized to an active arm received 1 dose of lucinactant for inhalation, initiated within 2 hours of randomization through the prototype ADS administered over planned durations of 30, 45, 60, or 90 minutes (50, 75, 100, or 150 mg TPL/kg, respectively) in conjunction with nCPAP support. One additional treatment was allowed if subjects met the repeat dose criterion. Subjects randomized to a control arm were continued on nCPAP alone.

After all active subjects within Dosing Group I completed Study Day 7, a safety assessment (study-related AEs, including adverse device effects [ADEs], serious adverse events [SAEs], and additional safety endpoints) was performed by an independent SRC. Dosing was allowed to continue to the next higher dosing group (ie, Dosing Group II) immediately following completion of enrollment within the current dosing group. The SRC provided recommendations

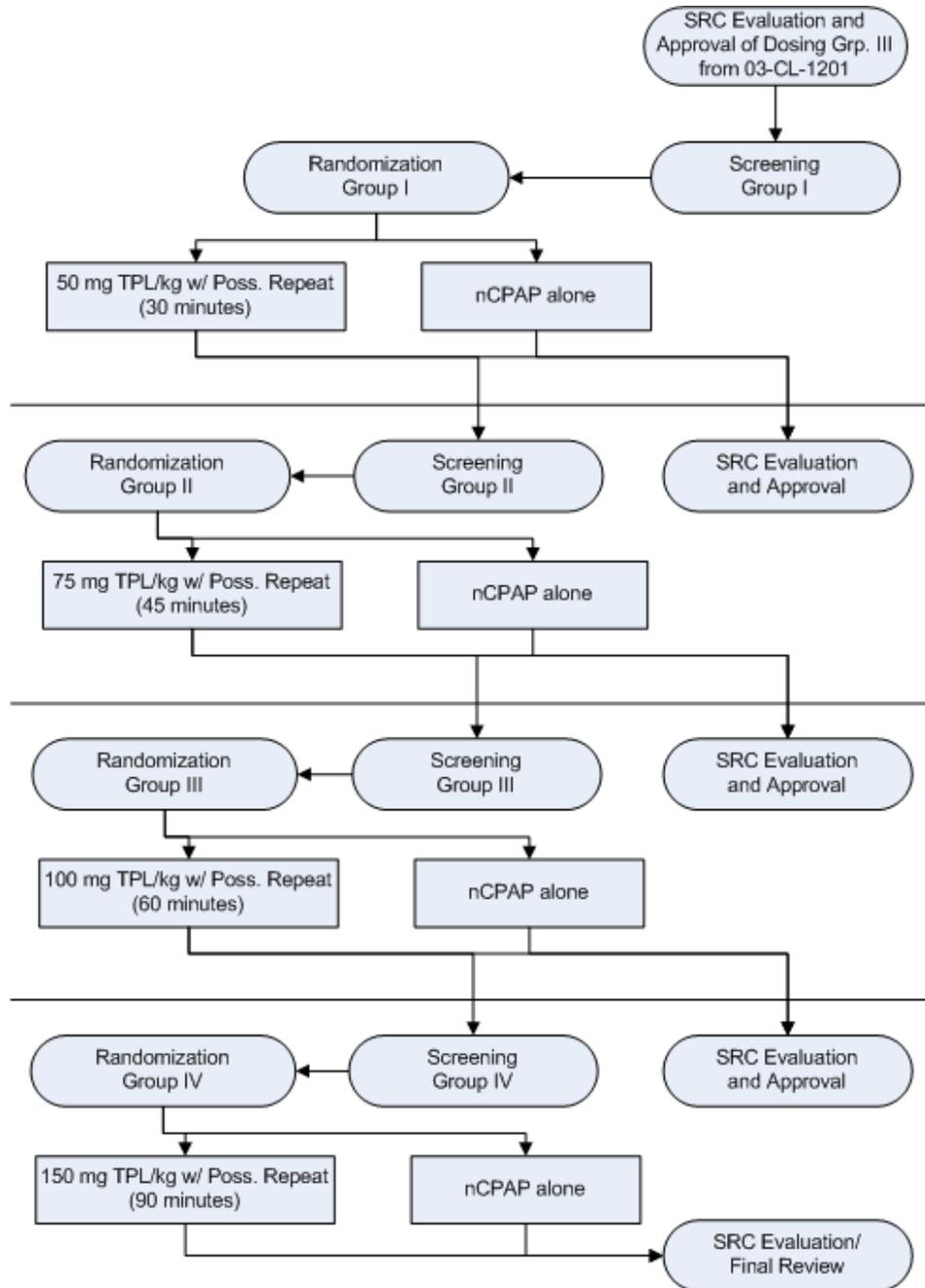
(eg, continue without any protocol modifications) following their review of the safety data. This process of continuing to the next higher dosing group and reviewing safety and tolerability was to be continued for the 100, and 150 mg TPL/kg group (ie, Dosing Groups III and IV, respectively). Subjects were followed for safety evaluations (including AEs and concomitant medications) until the subjects were 36 weeks PMA or were discharged. A final visit occurred at 36 weeks PMA or at time of discharge or withdrawal for all subjects.

All enrolled subjects received study treatment in a NICU, a specialized care center staffed by neonatologists, nurses, and respiratory therapists who were experienced in the delivery of emergent care to the preterm neonatal population. Neonates in the NICU were continuously monitored using advanced and sophisticated monitoring equipment, and there was ready and immediate access to equipment, medications, and skilled personnel that may have been needed to address emergent developments. Interventions such as endotracheal intubation, mechanical ventilation, and surfactant administration were readily available to all study subjects if clinically indicated in accordance with the high level standard of care customary in the NICU.

Dose assignments were unblinded, because the primary objective of this study was safety and tolerability. Preliminary efficacy endpoints were assessed as an exploratory objective.

The study schema is displayed in [Figure 1](#).

Figure 1. Schematic of Study Design



9.1.1 Study Duration

Recruitment occurred over a period of 16 months, with an average of approximately 0.2 subjects enrolled per month for each of the 15 enrolling study sites, or a rate of 0.7 subjects per week overall. The last subject completed all assessments and procedures 18 months from the time of the first subject enrolled. Thus the total duration of the study is 18 months.

9.1.2 Duration of Subject Study Participation

The total duration of study participation for each subject was from enrollment (≤ 20 hours from birth) to 36 weeks PMA. All subjects who completed all assessments and procedures up to and including the Final Visit (to occur at 36 weeks PMA, NICU discharge, or hospital transfer, whichever occurs first) are considered study completers.

Study participation consisted of the following study periods (assessments, procedures, and visits associated with each of these phases can be found in [Section 9.5](#)):

- Screening Period: to occur in a timely manner to allow for study randomization ≤ 20 hours from birth.
 - Study consent must be completed before any study-specific screening procedures that would not otherwise be performed in accordance with standard of care and local institutional practices.
- Primary Observation Period: time of randomization (T_0 on study) to 48 hours from randomization.
 - Includes: pre-treatment assessment, treatment period (30, 45, 60, or 90 minutes), followed by continual safety monitoring in accordance with local NICU procedures.
 - Study treatment must be initiated ≤ 22 hours from the time of birth
- Extended Observation Period: > 48 hours on study to completion on Study Day 7 (6 days after the day of randomization by calendar date) or until time of death or hospital transfer/discharge, whichever comes first.
- Final Observation Period: \geq Study Day 8 to 36 weeks PMA or discharge or until time of death or hospital transfer/discharge, whichever comes first.

9.2 Discussion of Study Design, Including the Choice of Control Groups

The ADS, using CAG technology, allows for administration of aerosolized reconstituted lucinactant to preterm neonates in sufficient quantities to affect a therapeutic response similar to the response demonstrated in surfactants administered by intratracheal instillation. A device that permits effective surfactant aerosolization to neonates receiving nCPAP support for the treatment of RDS may improve the success of nCPAP therapy.

9.2.1 Rationale for Study Control

nCPAP is widely utilized in the US for the treatment of RDS in preterm newborns, and current guidelines outline several patient interface devices that can be used to deliver continuous airway pressure such as nasal masks, short bi-nasal prongs, and nasopharyngeal tubes⁽⁴⁾. Thus, preterm neonates who, in accordance with current treatment practice, would be treated with nCPAP were appropriate controls for this study.

9.2.2 Active Dose Considerations

Lucinactant, administered as an intratracheal bolus at a dose of 175 mg TPL/kg (5.8 ml/kg of a 30 mg TPL/ml suspension) has been demonstrated to be safe and effective in the prevention of RDS in premature infants at high risk for RDS. [Surfaxin[®] (lucinactant) Intratracheal Suspension, NDA 021746]. Infants at high risk for RDS are presumed to be substantially or wholly surfactant deficient and require endotracheal intubation and mechanical ventilation. In contrast, the population of preterm infants who can be sustained by nCPAP, rather than endotracheal intubation and mechanical ventilation, likely represent a broad spectrum of varying degrees of surfactant insufficiency. While infants born at a lower gestational age are likely to be more surfactant insufficient compared with neonates born at higher gestational ages, a myriad of factors can also influence these degrees of surfactant insufficiency. Therefore, dosing algorithms based on gestational age, or birth weight as a surrogate for gestational age, would not necessarily represent the optimal method for estimating the dose of surfactant that should be administered to adequately treat RDS. Nevertheless, preterm neonates who can be sustained by nCPAP are unlikely to require a full replacement dose of SRT. Thus, it is likely that preterm neonates on nCPAP will require substantially less than the intratracheal bolus dose of 175 mg TPL/kg of lucinactant. In fact, based on a previously conducted clinical study of aerosolized lucinactant via a commercial nebulizer (Study KL4-CPAP-01), the target theoretical inhaled dose is likely to be in the range of 75 mg TPL/kg or higher.

The relative inefficiency of inhalation therapy must also be considered. Due to the viscoelastic properties of surfactant, it is highly likely that most, if not all, of the surfactant delivered as a bolus to the trachea will ultimately arrive in the alveoli, the site of action for surfactant. However, the entrainment of surfactant administered as an aerosol into the subglottic airway to the nasopharynx will vary depending on the characteristics of the aerosol, such as particle size and rate of administration, and the breathing characteristics of the individual neonate (eg, inspiratory and expiratory patterns, frequency, and tidal volume). The aerosol particle size and rate of administration can be kept constant; however, the rate of administration should be representative of the neonate's inspiratory flow to optimize the efficiency of aerosol entrainment.

Typically, inspiratory and expiratory patterns in preterm neonates will vary from breath to breath. However, breathing frequencies and tidal volumes are less variable in preterm populations. Minute ventilation, which is correlated to body surface area and therefore indirectly related to body weight, is the product of frequency and tidal volume. Therefore, minute ventilation can be used to estimate the theoretical inhaled dose of aerosolized surfactant normalized to body weight. The actual inhaled dose is likely to be less since some aerosolized surfactant will be expelled during exhalation or will deposit in the oropharynx and be swallowed into the stomach.

The safety of the total TPL load and volume of fluid that neonates received (and any potential for impact on serum electrolytes and acid-base balance) is supported both by prior toxicology studies and by preclinical and clinical experience.

9.3 Selection of Study Population

The study population was to consist of approximately 64 preterm neonates from 26 to 28 completed weeks PMA with RDS who were candidates for SRT and nCPAP in a NICU setting. Subjects were eligible to be enrolled at 1 of approximately 25 study sites in the US, Canada, Poland, and Chile.

9.3.1 Inclusion Criteria

Each subject must have met all of the following inclusion criteria to be enrolled in this study:

1. Signed ICF from legally authorized representative;
2. Gestational age 26 to 28 completed weeks PMA;
3. Successful implementation of controlled nCPAP within 90 minutes after birth;
4. Spontaneous breathing;
5. Chest radiograph consistent with RDS; and
6. Within the first 20 hours after birth, have an nCPAP of 5 to 6 cm H₂O to maintain SpO₂ of 88% to 95% with an FiO₂ of 0.25 to 0.50 that is clinically indicated for at least 30 minutes. Transient (<10 minutes) FiO₂ excursions below 0.25 or above 0.50 did not reset the 30 minute requirement.

9.3.2 Exclusion Criteria

Subjects meeting any of the following exclusion criteria were not to be enrolled in this study:

1. A heart rate that could not be stabilized above 100 beats/minutes within 5 minutes of birth;

2. Recurrent episodes of apnea that occurred after the initial newborn resuscitation period (ie, 10 minutes after birth) requiring intermittent positive pressure breaths using inflating pressures above the set CPAP pressure administered manually or mechanically through any patient interface;
3. A 5-minute Apgar score < 5;
4. Major congenital malformation(s) and cranial/facial abnormalities that preclude nCPAP, diagnosed antenatally or immediately after birth;
5. Other diseases or conditions potentially interfering with cardiopulmonary function (eg, hydrops fetalis or congenital infection such as TORCH);
6. Known or suspected chromosomal abnormality or syndrome;
7. Premature rupture of membranes (PROM) > 2 weeks;
8. Evidence of hemodynamic instability requiring vasopressors or steroids for hemodynamic support and/or presumed clinical sepsis;
9. A need for endotracheal intubation and/or mechanical ventilation; and
10. Had been administered any the following:
 - a) Any investigational agent or exposure to a medical device,
 - b) Any other surfactant agent, or
 - c) Steroid treatment (steroid exposure before birth is acceptable).

All subjects continued to meet entry criteria at the time of initiation of study therapy.

9.3.3 Removal of Patients from Therapy or Assessment

9.3.3.1 Treatment Discontinuation

The administration of lucinactant for inhalation may have been discontinued at any time in accordance with the clinical judgment of the PI or the wishes of the subject's legal guardian. In accordance with local institutional practices, a proven SRT must be made available to subjects demonstrating a clinical need following exposure to lucinactant for inhalation. Reasons for discontinuation of lucinactant for inhalation treatment may have been related to but not limited to the following:

- Device failure or malfunction, including error codes or treatment interruptions;
- Pulmonary hemorrhage or other AE/ADE;
- In the PI's best medical judgment, initiating or continuing the subject's exposure to lucinactant for inhalation was not in the best interest of the subject's safety, such as

hemodynamic instability. (Note: When medical judgment is the sole criteria for stopping therapy, a detailed narrative describing the clinical events and observations supporting the decision to stop therapy needs was to be documented.);

- Signs of respiratory deterioration as evidenced by an increased respiratory rate or an observed increase in respiratory effort (work of breathing) plus at least one of the following:
 - An $\text{FiO}_2 \geq 0.70$ or a sustained (≥ 10 minutes) increase from baseline by ≥ 0.30 to maintain oxyhemoglobin saturation ($\text{SpO}_2 \geq 88\%$),
 - A $\text{PCO}_2 > 70$ mm Hg or a progressive increase in PCO_2 from baseline to ≥ 20 mmHg above baseline and confirmed with a blood gas,
 - Recurring episodes of bradycardia defined as a heart rate of less than 100 bpm for ≥ 20 seconds,
 - A sustained apneic event, defined as apnea at least 20 seconds in duration and meeting at least one of the following: (1) $\text{HR} < 100$ bpm, (2) desaturation (oxygen saturation $< 80\%$), (3) requirement for IPP breaths using inflating pressures above the set CPAP pressure administered manually or mechanically through any patient interface.

9.3.3.2 Study Withdrawal

A subject was able to withdraw consent (through their legally authorized guardian) at any time without prejudice to further care.

If, at the end of the Final Study Period, the status of a subject was unknown, every effort was made to contact the subject's legally authorized guardian to determine the status of the subject. If the status of the subject had not been established in 28 days following exposure to study aerosol, the subject was considered lost to follow-up.

9.3.3.3 Early Study Termination

The study could have been terminated prematurely due to safety reasons by the SRC.

Additional reasons for study termination included, but were not limited to, the following:

- The local or national regulatory agency requested a termination of the study.
- It was determined that the risk level associated with the experimental drug was significant and warrants termination of the study.
- Windtree, for reasons other than safety, could have terminated the study at any time by written notice of intended termination provided at least 30 days before termination.

- The PI or EC, for reasons other than safety, could have terminated participation of a clinical site in the study by written notice of intended termination provided at least 30 days before termination.
- Any other clause described in the individual site Clinical Study Agreement (eg, if ICH GCP guidelines or other regulatory procedures were not followed or if enrollment rate was not sufficient to meet study goals).

9.3.3.4 Replacement of Subjects

Subjects who were withdrawn from the study were not replaced.

9.4 Treatments

9.4.1 Treatments Administered

Subjects were to be assigned to 1 of 4 dosing groups (Table 9-1).

Table 9-1. Study Assignments by Dosing Groups

Dosing Group	Study Assignment
Dosing Group I	<p><u>Active Arm:</u> (n = 8 subjects) Lucinactant for inhalation: 50 mg TPL/kg administered over 30 minutes with nCPAP 1 repeat dose was allowed if repeat dosing criteria are met</p> <p><u>Control Arm:</u> (n = 8 subjects) Continuous nCPAP</p>
Dosing Group II	<p><u>Active Arm:</u> (n = 8 subjects) Lucinactant for inhalation: 75 mg TPL/kg administered over 45 minutes with nCPAP 1 repeat dose was allowed if repeat dosing criteria are met</p> <p><u>Control Arm:</u> (n = 8 subjects) Continuous nCPAP</p>
Dosing Group III	<p><u>Active Arm:</u> (n = 8 subjects) Lucinactant for inhalation: 100 mg TPL/kg administered over 60 minutes with nCPAP 1 repeat dose was allowed if repeat dosing criteria are met</p> <p><u>Control Arm:</u> (n = 8 subjects) Continuous nCPAP</p>
Dosing Group IV	<p><u>Active Arm:</u> (n = 8 subjects) Lucinactant for inhalation: 150 mg TPL/kg administered over 90 minutes with nCPAP 1 repeat dose was allowed if repeat dosing criteria are met</p> <p><u>Control Arm:</u> (n = 8 subjects) Continuous nCPAP</p>

Note: Eligible subjects 26 to 28 weeks PMA were randomized into either the active or control arm in accordance with the dosing group enrolling at the time of subject randomization. Dosing Group IV was not conducted for administrative reasons (including resource limitations and the intent to study the 26-28 GA weeks patients in an amendment to Study 03-CL-1202)

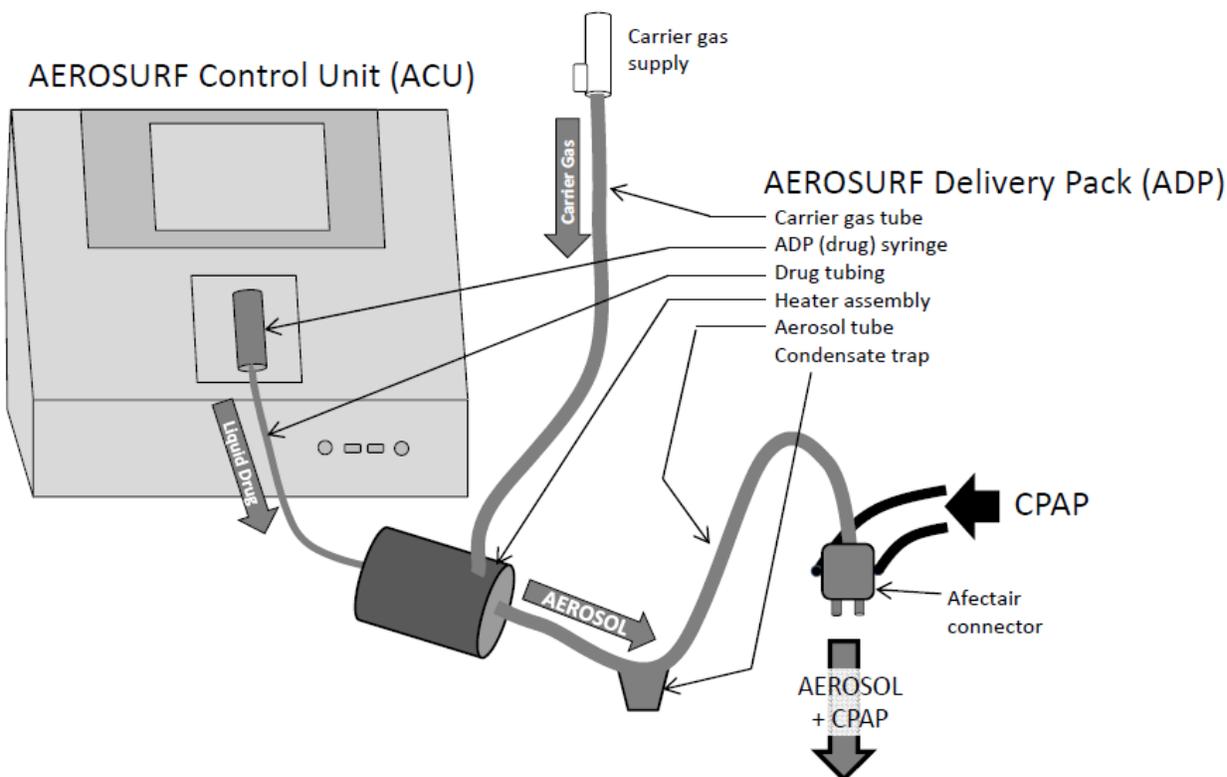
9.4.2 Identity of Investigational Product

9.4.2.1 AEROSURF Delivery System (ADS)

The prototype ADS creates and controls aerosolized surfactant (lucinactant for inhalation) through 2 components, the reusable AEROSURF Control Unit (ACU) (Section 9.4.2.1.1) and the disposable AEROSURF Delivery Pack (ADP) (Section 9.4.2.1.2). At the patient interface, two external flow sources are combined: humidified air from the CPAP system and carrier gas flow from the ADS (Figure 2). The ADS is designed for bedside use, and is mounted on a wheeled cart for easy transport. No changes to the device other than shelf life, including raw materials, software, components, storage conditions, or instructions for use, occurred during the conduct of this study. In December 2016, Windtree increased the shelf life of the ADP from 24 to 28 months from the date of manufacture.

A complete qualitative risk assessment has been completed to identify and mitigate potential safety risks associated with use of the prototype ADS.

Figure 2. AEROSURF Delivery System



The ADS aerosolizes reconstituted lucinactant through heat and pressure created within the CAG located within the heater assembly. The ADP is in-line to the ACU, and jointly these 2 components produce, control, and monitor the key elements necessary for the production of aerosolized surfactant (lucinactant for inhalation). A summary of the key functions each of the ADS components (ACU and ADP) contributes to the aerosolization of reconstituted lucinactant is provided in Table 9-2.

Table 9-2. Key Functions of ACU and ADP

Key Component	AEROSURF Control Unit	AEROSURF Delivery Pack
Carrier Gas ¹	N/A	Contains the carrier gas tube assembly that is connected to an external gas source.
Heater	Measures and controls the heater, which enables aerosol generation	Contains the heater assembly, placed in line with the Aerosol Control Unit to heat reconstituted lucinactant.
Lyophilized Lucinactant	Contains a chamber with a locking door mechanism to accept the filled syringe; prevents access to syringe chamber after aerosolization is started.	Includes a 60 ml syringe, which is filled to the maximum volume with reconstituted lucinactant.

¹ Carrier gas is an external flow source of oxygen and room air blends, at percentages that are in accordance with the study protocol, subject safety, and best medical judgment as directed by the PI.

9.4.2.1.1 AEROSURF Control Unit

The ACU contains a syringe pump mechanism integrated with control electronics and a temperature probe. The control electronics consists of embedded hardware and software with a touch screen interface that provides sequential instruction for (1) ADS set-up, (2) system operation, (3) safety interventions, and (4) temperature control. A cart is provided for use with the ACU. Materials and dimensions for the ACU are consistent with similar equipment used in critical care environments.

9.4.2.1.2 AEROSURF Delivery Pack

The ADP is a single-use, disposable pack containing a 60 ml syringe, the tube assembly, and the heater assembly. A summary of the ADP functions are provided in [Table 9-2](#).

9.4.2.1.2.1 ADP Set-up

Instructions for the proper set-up and connections of ADP components are provided in the ADS Operator’s Manual. Depending upon the dose, 1 or 2 ADPs will be required for each treatment.

The syringe is filled to maximum volume, regardless of the dose, with the reconstituted lucinactant suspension and placed in the syringe sleeve located in the ACU. To ensure full aerosol delivery, and proper functionality of the device, it is imperative that the syringe is filled to the maximum volume and all air bubbles are removed before placement into the device.

9.4.2.1.2.2 ADP Post Delivery Procedures

The ADP must be disengaged from the ACU after completion of aerosol delivery (as indicated on the ACU screen). Used ADPs were disposed of by sites according to local institutional practices, or returned to Windtree.

Instructions on proper removal of the ADP from the ADS are provided in the ADS Operator's Manual.

9.4.2.2 Delivery of On-Study Continuous Positive Airway Pressure

The use of nCPAP was implemented within 90 minutes of birth. On-site study staff was trained on the use and functionality of the nCPAP device for use during this study. The nCPAP device and training was provided by Windtree or qualified designee.

The use of nCPAP could have been preceded by intermittent positive pressure breaths using inflating pressures above the set nCPAP pressure administered manually or mechanically through a non-invasive patient interface (mask, nasal prongs) for no longer than 10 minutes after birth (eg, NeoPuff).

All local institutional policies and procedures relevant to the administration and safety surveillance of nCPAP must have been followed in conjunction with study specified procedures and assessments and in accordance with good clinical practice and judgment.

During the nCPAP delivery, subjects were to be closely monitored for complications related to placement of the patient interface (eg, bi-nasal prongs). Assessments included, but were not limited to, evaluations for the following conditions: bleeding, apparent obstruction of the nares, occlusion of interface requiring removal and replacement, nasal irritation (erythema of nares or septum, inflammation of nares or septum).

9.4.2.2.1 Set-up of Continuous Positive Airway Pressure System

The CPAP Operator's Manual provided details on the proper set-up and operation of the nCPAP device. These procedures, in conjunction with local institutional practices, must have been

followed to optimize subject safety, and to ensure consistent, therapeutic pressure that minimized resistance in the artificial and preterm neonate airways.

The essential procedures to further minimize resistance during nCPAP delivery were as follows:

1. Ensuring proper placement of the patient interface

Note: the device and subject interface used for nCPAP delivery during aerosol delivery were commercially available specifically for nCPAP delivery in neonates

2. Insertion of a gastric tube (open to air) after proper placement of the patient interface has been assessed.
3. Maintenance of the subject's neck position in a mild extension that is comfortable for the subject
4. Assessment of the need for nasal and oral airway suctioning and administer as needed

9.4.2.3 Formulation of the Study Drug

The complete list of ingredients for the drug product is shown in [Table 9-3](#).

Lyophilized lucinactant is a sterile, white, liposomal powder consisting of a 21-amino acid hydrophobic synthetic peptide (sinapultide, KL₄ peptide); the phospholipids dipalmitoyl-phosphatidylcholine (DPPC) and palmitoyloleoyl-phosphatidylglycerol, sodium salt (POPG, Na); and the fatty acid palmitic acid (PA). Immediately before dosing, lyophilized lucinactant is reconstituted with 10 ml of sterile water for injection at a concentration of 30 mg TPL/ml.

Table 9-3. Components of Lucinactant

Component	Amount (per ml)
Sinapultide ¹	0.862 mg
DPPC	22.50 mg
POPG, Na	7.50 mg
PA	4.05 mg
Sodium Chloride, USP	7.60 mg
Tromethamine, USP	2.42 mg
Sterile Water for Injection, USP	qs to 1 ml

Amount per ml for reconstituted lyophilized lucinactant.

Note: pH adjusted using glacial acetic acid, USP (United States Pharmacopeia).

¹ 21-residue synthetic peptide that mimics the function of SP-B

9.4.2.4 *Aerosol Characteristics*

The aerosol is generated at rate of approximately 20 μ l/second (1.2 ml/min). The mass median aerodynamic diameter (MMAD) of the aerosol is below 5.0 μ m. The gas that carries the aerosol to the subject has a nominal flow rate of 3 L/minute. A disposable fluid trap collects the condensed aerosol that was not transferred to the ventilation circuit (Figure 2). The specification for the aerosol temperature at the patient interface is 25°C to 38°C.

9.4.2.5 *Packaging and Labeling*

Lyophilized lucinactant was supplied in 30 ml glass vials packaged in cartons with foam inserts to reduce breakage.

Lyophilized lucinactant and the ADS were appropriately labeled with the country- or region-specific applicable regulatory requirements, to insure that users were aware that the drug product and device are for investigational use only.

9.4.2.5.1 Supply of Study Drug at the Site

Lyophilized lucinactant and ADPs were shipped directly to the investigational clinical study site pharmacies or to a designated location at the clinical study sites. A Clinical Supply Receipt Form accompanied the shipment. Study sites verified each shipment via the Clinical Supply Receipt Form and study IWRS, and reported study drug shipping temperatures to Windtree as outlined in the study manual.

Ancillary supplies (eg, CPAP system, nasal prongs, and high pressure hoses) were shipped directly to the investigational clinical study site NICU or to a designated location at the clinical study site. A Clinical Supply Receipt Form accompanied the shipment. Study sites verified each shipment to Windtree via the Clinical Supply Receipt Form.

9.4.2.5.2 Dispensing

Study supplies (study drug, ADP, and related study equipment) were dispensed in accordance with the subject's randomized dosing group (Section 9.4.1). The NICU pharmacist or designated study personal provided on-site storage, dispensing, reconciliation, and documentation of study supplies as outlined in the study manual. Study drug and ADP components (ie, ADP syringe and heater assembly) were fully reconciled at the end of the study. The study clinical site monitor provided oversight of these tasks and communicated any significant findings or indications of noncompliance to Windtree.

9.4.2.5.3 Storage of Lyophilized Lucinactant and AEROSURF Control Unit

Lyophilized lucinactant was stored in a secured area of the hospital pharmacy or NICU at 2°C to 8°C and protected from light until use. Study sites must have monitored and logged storage temperatures. All temperature excursions were to be reported to Windtree as outlined in the study manual.

The ACU and ADPs were delivered separately and were also stored in a secure location under the recommended storage conditions outlined in the ADS Operator's Manual.

9.4.2.6 Study Drug and Device Accountability

It was the responsibility of the PI and trained designee to ensure that all study supplies (vials of lyophilized lucinactant, all components of the ADS, and related equipment) were inventoried, appropriately stored in accordance with study guidance documents (eg, study protocol, ADS Operator's Manual), and used only for study subjects, by study trained staff.

9.4.2.6.1 Study Supply Accountability

The following guidelines were to be followed to ensure the storage and accountability of the study supplies was consistent with the study protocol:

- 1) Used or partially used vials of lyophilized lucinactant and ADPs must have been kept separate from unused supplies throughout the life of the study.
- 2) Designated study personnel returned all unused study drug vials and ADPs to the pharmacy or the clinical supply storage area immediately after the completion of study aerosol delivery.
- 3) Reconciliation of study supplies was performed at each study visit by the clinical site monitor and recorded appropriately in the pharmacy log and drug and device accountability records.
- 4) Storage conditions were assessed and documented by the clinical site monitor at each study visit (ensuring all supplies were kept in a secure area with restricted access).
- 5) Dispensing information must have been recorded in the inventory log and kept with the study site records throughout the study.
- 6) Designated study personnel (eg, pharmacists) supplied study drug or ADPs to study staff.

9.4.3 Method of Assigning Study Subjects to Dosing Groups

For each dosing group, preterm neonates who successfully met all eligibility criteria within the enrollment period (20 hours) were randomly assigned to 1 of 2 study arms (active or control)

(Section 9.4.1]). Subjects were randomized using centralized allocation by an interactive web response system (IWRS). Subjects from multiple births were randomized and enrolled independently.

The randomization code list was generated by Windtree Biometrics personnel and transmitted to the IWRS vendor. The code list used a block size of 4 for each dosing group.

The study dosing initiated in Dosing Group I (the lowest dose), and continued to Dosing Group II after completion of Group I enrollment. Each dosing group enrolled sequentially following completed enrollment of the previous dosing group. After all active subjects within each dosing group had completed 72 hours, the SRC reviewed the safety and tolerability of this dose.

If there appeared to be intolerability with a given dose or operational challenges administering a dose, the remaining subjects had the option of having the dose decreased to a previously administered dose, after consultation with the SRC.

The log files for the randomization programs with a copy of the randomization lists can be found in Appendix 16.1.7. BioClinica, Inc., had responsibility for the electronic data capture system (EDC) and randomization of subjects via the IWRS.

9.4.4 Selection of Doses in the Study

The safety of the TPL that was administered in this study was supported both by prior toxicology studies and by previous clinical experience with aerosolized lucinactant and liquid lucinactant.

9.4.4.1 Preclinical Experience Supporting Dose Rationale

Study MB 04-12812.01 evaluated the toxic effects of orally administered lucinactant in adult rabbits. A total of 14 daily doses of 600 mg TPL/kg lucinactant (20 ml/kg) or 20 ml/kg Tris/NaCl buffer were administered orally by lavage in 2 equal volumes (10 ml/kg) at 2- or 4-hour intervals to adult rabbits (2 males and 2 females per treatment group). No evidence of any toxic effect was found in any animals in this study.

Two completed non-clinical animal toxicology studies in pre-weaned rabbits (N107662) and pre-weaned rats (N107663) evaluated the acute toxicity of inhaled lucinactant (aerosolized by CAG technology). Rabbits and rats were exposed to aerosol on consecutive days by a nose-only inhalation exposure system. Aerosolized lucinactant low-, mid-, and high-dose groups were compared with air control and vehicle. Aerosolized lucinactant dose selections were based on the following; (1) potential human exposure (2) existing toxicity data (3) limitations imposed by the animal model (4) the exposure apparatus and its procedures, and (5) the stability of the

experimental atmosphere. A maximum feasible dose (determined by the achievable aerosol concentration, test animal airflow requirements, and the maximum length of exposure of the animals to the aerosol) was established based on these parameters and no-observed-adverse-effect-levels (NOAELs) were established to ensure adequate safety in preterm neonates.

The top dose of aerosolized reconstituted lucinactant planned was 150 mg TPL/kg, with a possible repeat dose of 150 mg TPL/kg (300 mg TPL/kg overall); preclinical studies provided a safety margin for this dose, whether delivered to the lungs or swallowed (including volume load and sodium load).

9.4.4.2 Clinical Experience Supporting Dose Rationale

Human subjects have been exposed to large daily volumes of lucinactant administered by intratracheal bronchial lavage. Study populations consisting of neonates with meconium aspiration syndrome and adults with acute respiratory distress syndrome (1710 ml), did not produce specific adverse events (AEs) compared to control groups^(10,11).

9.4.4.3 Calculation of the Theoretical Inhaled Dose

The emitted dose of aerosolized reconstituted lucinactant is the amount of aerosolized drug delivered to the subject at the orifice of the aerosol tube where it joins the patient nCPAP interface. The theoretical inhaled dose is the amount of aerosolized reconstituted lucinactant predicted to be inhaled by the subject. This inhaled dose is a function of the concentration of lucinactant in the aerosol, the amount of aerosol inhaled by the subject (estimated by the subject's minute ventilation, assuming that all gas inhaled by the subject contains the same concentration of aerosol), and the duration of exposure to the aerosol. Thus, the dose can be estimated using the following equation:

$$\text{Inhaled Dose} = C \times Vm/kg \times T \quad \text{Equation 1}$$

Where: C = Concentration of reconstituted lucinactant in aerosol (in mg TPL/L)
Vm/kg = Minute ventilation normalized to body weight (in L/min/kg)
T = Dose duration (in minutes)

All of the reconstituted lucinactant that flows through the ADS is aerosolized; however, since much of the aerosolized drug impacts within the aerosol tubing, only 35% reaches the patient interface. The emitted dose rate of the ADS is therefore the product of the flow rate of lucinactant through the CAG (1.2 mL/min), the concentration of the reconstituted lucinactant in

the dosing syringe (30 mg TPL/mL) and the fraction of the aerosolized dose that reaches the patient interface (35%):

$$\text{Emitted dose rate} = 1.2 \text{ mL/min} \times 30 \text{ mg TPL/mL} \times 0.35 = 12.6 \text{ mg TPL/min} \quad \text{Equation 2}$$

The aerosolized reconstituted lucinactant is carried to the patient interface by a gas (generally a mix of air and supplemental oxygen). The rate of flow of the carrier gas was chosen to be 3 L/min, which represents the typical peak inspiratory flow rate expected in the target population⁽¹²⁾. The concentration of aerosolized lucinactant in the carrier gas (C) is therefore the emitted dose rate (12.6 mg TPL/min) divided by the carrier gas flow rate (3 L/min).

$$C = \frac{12.6 \text{ mg TPL/min}}{3 \text{ L/min}} = 4.2 \text{ mg TPL/L} \quad \text{Equation 3}$$

Minute ventilation (Vm) of preterm neonates can be estimated based on body weight, as shown in [Table 9-4](#)^(13,14). When normalized to body weight, minute ventilation of the subjects expected to enroll in this study (750 to 2250 g) can be approximated as 0.4 L/min/kg.

Table 9-4. Minute Ventilation Comparison Between Bide and Bhutani

Weight (g)	Bide, et al. ⁽¹³⁾		Bhutani, et al. ⁽¹⁴⁾	
	Vm		Vm (50 th percentile)	
	(L/min/kg) ^a	(L/min)	(L/min/kg)	(L/min)
750	0.527	0.3954	0.4	0.3000
1000	0.499	0.4990	0.4	0.4000
1250	0.478	0.5977	0.4	0.5000
1500	0.462	0.6927	0.4	0.6000
1750	0.448	0.7847	0.4	0.7000
2000	0.437	0.8742	0.4	0.8000
2250	0.427	0.9616	0.4	0.9000
2500	0.419	1.0472	0.3	0.7500
2750	0.411	1.1312	0.3	0.8250

^a Calculated

Importantly, since Vm is approximately constant when normalized to body weight, the inhaled dose of aerosolized reconstituted lucinactant (*Equation 1*) becomes a function of exposure time regardless of body weight or gestational age. The time required to deliver the desired dose (T) can therefore be calculated by rearranging *Equation 1* in terms of T; that is, dividing the desired theoretical inhaled dose by the product of C (4.2 mg TPL/L) and Vm (0.4 L/min/kg). For

example, this calculation yields dose durations of 45 minutes to achieve a target theoretical inhaled dose of 75 mg TPL/kg and 60 minutes for a dose of 100 mg TPL/kg.

Table 9-5 provides a summary of the dosing durations for each dosing group.

Table 9-5. Dosing Duration (minutes) for Each Dosing Group

Weight (g)	Dosing Time (min)			
	Dosing Group I 50 mg TPL/kg	Dosing Group II 75 mg TPL/kg	Dosing Group III 100 mg TPL/kg	Dosing Group IV 150 mg TPL/kg
750 – 2750	30	45	60	90

Note: Based on Bhutani, et al.⁽¹⁴⁾

9.4.5 Selection and Timing of Dose for Each Patient

Study treatments began within 2 hours after randomization. For subjects randomized to the active study arm, the treatment dose (ie, drug exposure) was planned to be 50, 75, 100, or 150 mg TPL/kg (delivered over 30, 45, 60, or 90 minutes, respectively), in accordance with the subject’s dosing group. A repeat dose at the same level was allowed if the repeat dosing criterion was met (see Section 9.1 and Section 9.4.1).

9.4.6 Blinding/Masking

This study was an open-label study to determine the safety and tolerability of lucinactant for inhalation. No blinding or masking procedures were implemented.

9.4.7 Prior and Concomitant Therapy

Concomitant medications required for the general care of the subject were permitted, with the exception of investigational agents and investigational medical devices.

All concomitant medication and concurrent therapies were documented from birth until the time the subject completed the study (36 weeks PMA) or was withdrawn (Section 9.3.3.2). Dose, route, unit, frequency of administration, indication for administration, and dates of medication were captured.

9.4.8 Treatment Compliance

Study compliance was based on the actual delivery time of lucinactant for inhalation in comparison to the subject’s randomized aerosolization time. Aerosolization time was tracked by the ACU, which displayed a continual count of lucinactant exposure time throughout the aerosol

delivery period. The length of lucinactant exposure time (as observed through aerosol delivery and ACU display) was documented in the study electronic case report form (eCRF). The ACU also displayed an interface to allow for emergency aerosol discontinuation. PIs were to discontinue aerosol delivery if a potential safety risk to the subject was identified at any point during the aerosol delivery period.

The number of subjects randomized but not treated, and the number of subjects prematurely discontinued from aerosol delivery, were recorded in the eCRF (see [Section 10.1](#)). A sample CRF is provided in Appendix 16.1.2.

9.5 Efficacy and Safety Variables

9.5.1 Efficacy and Safety Measurements Assessed and Flow Chart

9.5.1.1 Safety Measurements Overview

The following measurements were documented in the eCRF:

1. Survival (date and time of death if applicable)
2. AEs, including ADEs
 - a. To include nasal excoriations by examination (≥ 24 hours to ≤ 7 days following aerosol exposure) and evidence of lung air leak (especially pneumothorax)
 - b. To be categorized as a peri-dosing event if onset of event was ≤ 2 hours from the time of initiating administration of lucinactant for inhalation
3. Signs consistent with worsening respiratory status
4. Concomitant medications
5. Use of respiratory support and supplemental oxygen, including the following:
 - a. Need for endotracheal intubation and mechanical ventilation
 - b. Need for intermittent positive pressure breaths using inflating pressures above the set CPAP pressure, administered manually or mechanically through any patient interface
 - c. nCPAP and fraction of inspired oxygen (FiO₂) requirements
6. Complications of prematurity (ie, intraventricular hemorrhage [IVH], periventricular leukomalacia [PVL], pulmonary hemorrhage, necrotizing enterocolitis [NEC], patent ductus arteriosus [PDA], sepsis, retinopathy of prematurity [ROP], bronchopulmonary dysplasia [BPD])
7. Physical examinations
8. Tolerability of lucinactant for inhalation
9. Incidence leading to withdrawal from study

10. Assessments of the following:

- a. PCO₂
- b. Serum electrolyte measurements
- c. Body weight
- d. Vital signs
- e. Gastric liquid volume
- f. Defecation
- g. Oxygen (O₂) saturation, as determined by pulse oximetry (SpO₂)
- h. Chest radiograph, as applicable

9.5.1.2 *Exploratory Efficacy Endpoints Overview*

Exploratory efficacy endpoints were evaluated from the time of lucinactant for inhalation initiation until the study completion (non-hypothesis testing) and included the following:

1. Incidence of BPD
2. Rate of survival without BPD at 36 weeks PMA
3. Worsening of respiratory status ([Section 9.5.1.3.16](#))
4. Technical performance of the ADS
 - The efficacy of the device delivery of aerosolized lucinactant was characterized indirectly through the subject's response to treatment and solicited feedback from PIs and relevant site-based study staff.
5. Physiological parameters (eg, FiO₂, PCO₂)

9.5.1.2.1 *Technical Performance of the Device Measurements*

The following measurements were captured in the eCRF:

1. Any issues associated with device tubing (eg, ventilator/CPAP tubing detachments, aerosol tube detachments, proximal pressure port obstruction, aerosol tube condensate obstruction)
2. Approximate volume (in ml) of liquid in all the traps
3. Aerosol or study drug leakage before the subject interface (eg, disconnect of the inspiratory circuitry)
4. Occurrence of alarm signals before, during, or after dosing that could have indicated a device malfunction
5. Any automatic system shutdowns
6. Loss of inspiratory flow to the neonate or inability to maintain nCPAP

7. ADS temperature alerts (high or low)

9.5.1.3 *Clinical Assessment Details*

The following clinical assessments were documented in the study eCRF. In addition, any clinical findings that were consistent with an AE were documented as such in the eCRF.

In addition to the clinical assessments outlined below, PIs provided continual clinical assessment and monitoring during the active delivery of lucinactant for inhalation. If at any point during the delivery of lucinactant for inhalation a potential safety risk to the subject was identified, aerosol delivery was to be discontinued by activating the ACU ‘stop treatment’ interface. Any significant clinical findings or observations were to have been documented and communicated to Windtree at the earliest time point possible.

9.5.1.3.1 Adverse Events

Information regarding the occurrence of AEs, including ADEs, was assessed from the time of completion of signed ICF until completion of Final Study Visit. All AEs were followed by the PI until resolution or for at least 30 days post-study if the subject was stable.

All AEs were assessed in all subjects throughout the study period (from enrollment to study withdrawal or completion) and documented in the study eCRF. Each AE was reported spontaneously or in response to general, non-directed discussion with the attending nurse or physician (eg, has there been any change in subject status since the last assessment period?). For each AE, the investigator obtained all information required to complete the AE page of the eCRF, in accordance with eCRF completion guidelines (provided separately by Windtree).

All AEs were followed until resolution or until a stable clinical end-point is reached, or for at least 30 days after the subject’s last day in the study if an AE was ongoing at the time the subject completes the study. All measures required for AE management and the ultimate outcome of the AE were recorded in the source document and reported on the AE page of the eCRF.

9.5.1.3.2 Vital Signs

Baseline vital signs (body temperature, respiratory rate, and heart rate) were documented within 15 minutes (\pm 5 minutes) before randomization and at the following time points from the time of randomization: 1, 3 (\pm 15 minutes), 6, 12 (\pm 1 hour), 18, 24, 36, and 48 hours (\pm 2 hours) post-randomization.

Subjects randomized to the active study arm had additional vital signs (respiratory rate and heart rate) documented every 5 minutes (± 2 minutes) during the administration of lucinactant for inhalation for Dosing Groups I and II. For Dosing Groups III and IV, vital signs were documented every 15 minutes (± 5 minutes) during treatment administration.

Subjects randomized to the nCPAP only arm had additional vital signs (respiratory rate and heart rate) documented 15 minutes (± 5 minutes) after randomization.

For all randomized subjects, daily vital sign assessments (body temperature, respiratory rate, and heart rate) were performed at 0800 hours (± 2 hours) from Study Day 3 to the completion of Study Day 7.

Sustained heart rate < 100 bpm for ≥ 20 seconds was noted as an AE of bradycardia in the study eCRF.

In this study, a sustained apnea event was defined as lasting ≥ 20 seconds and is coincident with at least one of the following: (1) HR < 100 bpm, (2) desaturation (oxygen saturation $< 80\%$), (3) requirement for intermittent positive pressure breaths using inflating pressures above the set CPAP pressure administered manually or mechanically through any patient interface.

9.5.1.3.3 Body Weight

The first body weight measurement obtained after randomization must have been recorded in the study eCRF. In addition, birth weight was documented in the study eCRF as part of the birth history.

9.5.1.3.4 Pulse Oximetry

SpO₂ was monitored continuously from the time of randomization until completion of Study Day 7. Sustained SpO₂ $< 80\%$ for ≥ 20 seconds was recorded as an AE of desaturation in the study eCRF.

9.5.1.3.5 FiO₂

FiO₂ values were recorded at different times throughout the study. At a minimum, FiO₂ values were: 1) recorded at specified time points while a subject is receiving nCPAP, 2) recorded every 12 hours when a subject is receiving other types of respiratory support or supplemental oxygen, 3) recorded every 15 minutes for 3 hours after randomization, and 4) recorded every 6 hours from randomization through 72 hours.

9.5.1.3.6 Monitoring of Carbon Dioxide Levels

PCO₂ measurements for subjects in both the active and control groups were provided through the use of continuous transcutaneous monitor.

PCO₂ monitoring was to be initiated following randomization (for subjects randomized to the active study arm, monitoring was to be initiated at least 30 minutes before the start of ADS delivery) and continue for 72 hours post randomization. The transcutaneous monitor was to be calibrated for accuracy against blood gas values (arterial, capillary or venous) at the time of initial set-up, and recalibrated as necessary in accordance with local institutional practices to ensure accuracy of the monitor output.

In the eCRF, PCO₂ values were recorded every 15 minutes through 3 hours after randomization, and every 6 hours from randomization through 72 hours.

9.5.1.3.7 Physical Examination

A complete physical examination was performed by either the PI or designee. The designee was a qualified member of the site-based study staff (such as a nurse practitioner, NICU nurse, or physician assistant); physical examinations performed at screening were reviewed and approved by the PI. Any new abnormal physical examination findings were to be documented as AEs in the eCRF and were followed by a physician or other qualified staff until resolution.

9.5.1.3.8 Serum Electrolytes

Serum electrolytes (Na⁺, Cl⁻, K⁺, and Total CO₂) were measured 24 hours following randomization (± 6 hours).

9.5.1.3.9 Chest Radiograph

A chest radiograph for the diagnosis of RDS was performed as part of the screening assessment.

A chest radiograph was also required during the first 7 study days for study subjects who met 1 or both of the following 2 criteria: (1) non-emergent intubation for any indication (in such instances, all efforts were made to obtain the chest radiograph prior to intubation, if the procedure did not delay or compromise the care of the subject) or (2) worsening of respiratory status (see [Section 9.5.1.3.16](#)).

9.5.1.3.10 Gastric Liquid Volume

Gastric liquid volume was assessed 30 minutes (\pm 15 minutes) following completion of lucinactant for inhalation administration. Enteral feedings were held during administration and for at least 1 hour following completion of lucinactant for inhalation administration.

9.5.1.3.11 Defecation

The number of stools within the first 24 hours following randomization was assessed and recorded in the study eCRF.

9.5.1.3.12 Medical Information

Relevant medical information, including maternal-birth history, pertinent respiratory history, medical history, and information regarding underlying diseases, was recorded at screening.

9.5.1.3.13 Concomitant Medications

Concomitant medications required for the general care of the subject were permitted, with the exception of investigational agents and investigational medical devices.

All concomitant medication and concurrent therapies were documented from birth until the time the subject completed the study (36 weeks PMA or discharge) or withdrew. Dose, route, unit, frequency of administration, indication for administration, and dates of medication were to be captured.

9.5.1.3.14 Use of Additional Surfactant Replacement Therapies

Following lucinactant for inhalation administration, commercially available SRTs consistent with the current standard of care were administered only in circumstances where it was in the best interest of subject's safety, and in the PI's best medical judgment. Subjects receiving commercially available SRT during study participation were considered treatment failures, and as such, were followed for safety follow-up until study completion.

9.5.1.3.15 Demographics

Demographic information (eg, gestational age, sex, race) were recorded at screening.

9.5.1.3.16 Worsening Respiratory Status

Subjects meeting the criteria of worsening respiratory status (outlined within this section) were followed for all safety evaluations until the time the subject completed the study (36 weeks PMA) or was withdrawn.

Refer to [Section 9.5.1.3.9](#) for required chest radiograph.

A subject was categorized as having worsening respiratory status if they met at least 1 of the following criteria:

1. The need for additional surfactant therapy following exposure to lucinactant for inhalation
2. A sustained $\text{FiO}_2 > 0.50$ for > 30 minutes to maintain an $\text{SpO}_2 > 90\%$
3. A $\text{PCO}_2 > 65$ mm Hg on ≥ 2 consecutive occasions
4. Persistent, arterial $\text{pH} < 7.20$ (if blood gas values were available and obtained for non-study related clinical assessment)
5. Any sustained apneic event defined as apnea ≥ 20 seconds and meeting at least one of the following criteria: (a) $\text{HR} < 100$ bpm, (b) desaturation ($\text{SpO}_2 < 80\%$), (c) requirement for IPP breaths using inflating pressures above the set CPAP pressure administered manually or mechanically through any patient interface
6. Intubation for any reason (except for elective surgical procedures)
7. $\text{nCPAP} > 7$ cm H_2O
8. Initiation of IPP breaths using inflating pressures above the set CPAP pressure administered manually or mechanically through any patient interface
9. Death while on study
10. The study PI determined that the subject had worsening respiratory status based on his or her best clinical judgment.
11. Worsening respiratory status was categorized as follows:
 - a. Early worsening: worsening respiratory status occurring ≤ 72 hours after birth
 - b. Late worsening: worsening respiratory status occurring > 72 hours and ≤ 7 days after birth

9.5.1.3.17 Respiratory Support and Oxygen Delivery

Study subjects were maintained on nCPAP from the time of randomization until they completed delivery of lucinactant for inhalation as outlined in [Section 9.4.2.2](#). The management of

respiratory support (including nCPAP) and oxygen delivery after the completion of lucinactant for inhalation delivery was at the discretion of the study PI.

During nCPAP delivery, subjects were closely monitored for complications related to placement of the patient interface (eg, bi-nasal prongs). Assessments were to include, but not be limited to, evaluation for the following conditions: bleeding, apparent obstruction of the nares, occlusion of interface requiring removal and replacement, nasal irritation (erythema of nares or septum, inflammation of nares or septum). Evidence of these conditions was reported as an AE and treated in accordance with local institutional practice.

FiO₂ values (regardless of mode of delivery) were recorded following randomization and continued for 72 hours post randomization.

9.5.1.3.18 Emergent Respiratory Support

Emergent endotracheal intubation and mechanical ventilation (MV), in accordance with local institutional guidance, were initiated at any time if deemed necessary for subject safety. In such instances, the subject was evaluated for worsening of respiratory status ([Section 9.5.1.3.16](#)).

Any clinical event indicating a need for MV, additional pressure support, or increases in supplemental oxygen was evaluated as a potential AE and reported in the study eCRF, if applicable.

9.5.1.3.19 Documentation during Primary and Extended Observation Period

From the time of randomization until completion of Study Day 7, the following were evaluated and documented in the study eCRF:

Mechanical ventilation: date and time of initiation and discontinuation, the mode, mean airway pressure, respiratory rate, set tidal volume (if appropriate), and FiO₂

- Documented every 12 hours (\pm 1 hour) until mechanical ventilation had been discontinued for > 24 hours

Pressure support (including nCPAP): date and time of initiation and discontinuation, PIP, respiratory rate, CPAP, flow rate, and FiO₂, as appropriate

- Primary Observation Period: documented at 1, 3 (\pm 15 minutes), 6, 12 (\pm 1 hour), 18, 24, 36, and 48 hours (\pm 2 hours) post randomization
- Extended Observation Period: documented every 12 hours (\pm 1 hour) until nCPAP had been discontinued for > 24 hours

Other supplemental oxygen ($\text{FiO}_2 > 21\%$; not delivered via bubble CPAP or MV): date and time of initiation and discontinuation, mode of delivery (eg, nasal cannula, oxygen hood), and FiO_2 , as appropriate.

- After the administration of lucinactant for inhalation, FiO_2 was documented every 12 hours (± 1 hour) until supplemental oxygen had been discontinued for > 24 hours

If respiratory support or oxygen delivery was reinitiated following discontinuation, then parameters were again captured every 12 hours until discontinuation.

9.5.1.3.20 Documentation during Final Observation Period

From Study Day 8 until the subject completed or was withdrawn from the study, the following were evaluated and documented in the study eCRF:

- Intubation and MV: date and time of initiation and discontinuation
- Pressure support (including nCPAP): date and time of initiation and discontinuation
- Supplemental oxygen: date and time of initiation and discontinuation, mode of delivery, and FiO_2
- Intubation Only: the date and time of intubation for any reason

9.5.1.3.21 Criteria for Acute Respiratory Deterioration

Subjects were closely monitored for signs and symptoms of acute respiratory deterioration throughout the study period. Any clinical signs of acute respiratory deterioration were treated in accordance with local institutional practices and under the best medical judgment of the study PI.

Acute respiratory deterioration was reported as an AE and, for study purposes, was defined by an increased respiratory rate or an observed increase in respiratory effort (work of breathing) plus at least one of the following criteria:

1. An $\text{FiO}_2 \geq 0.70$ or a sustained increase from baseline by ≥ 0.30 to maintain oxyhemoglobin saturation
2. A $\text{PCO}_2 > 70$ mm Hg or a progressive increase from baseline to ≥ 20 mm Hg above baseline and confirmed with a blood gas
3. Recurring episodes of bradycardia defined as a heart rate < 100 bpm for ≥ 20 seconds
4. A sustained apneic event, defined as apnea for at least 20 seconds in duration and meeting at least one of the following: (1) desaturation ($\text{SpO}_2 < 80\%$), (2) HR < 100 bpm, (3) requirement for IPP breaths using inflating pressures above the set CPAP pressure administered manually or mechanically through any patient interface
5. Endotracheal intubation for any reason (except elective surgical procedures)

6. Initiation of IPP breaths using inflating pressures above the set CPAP pressure administered manually or mechanically through any patient interface
7. nCPAP > 7 cm H₂O
8. Death while on study
9. The study PI determined that the subject had acute respiratory deterioration based on their best clinical judgment. (Note: When medical judgment was the sole criteria for stopping therapy, a detailed narrative describing the clinical events and observations supporting the decision to stop therapy were documented.

9.5.1.4 Evaluations by Visit

All of the following assessments were performed until the subject completed the study (36 weeks PMA) or was withdrawn. A Schedule of Events representing the required testing procedures and the associated timeframe to be performed for the duration of the study is outlined in [Section 9.5.1.5](#).

9.5.1.4.1 Screening Period

The following information was obtained for each subject before study enrollment:

1. A signed ICF
2. Maternal history, including the following:
 - a. Rupture of membranes (time relative to birth, type)
 - b. Chorioamnionitis (clinical)
 - c. Antenatal steroids (number of doses, time relative to birth)
3. Birth history, including the following:
 - a. Date and time of birth
 - b. Mode of delivery (vaginal, C-section)
 - c. Single or multiple birth (number)
 - d. Apgar score (assessed at 1 and 5 minutes)
 - e. Congenital anomaly
4. Medical History
5. Demographics, including the following:
 - a. Sex
 - b. Race
 - c. Ethnic origin

- d. Birth weight (grams)
- e. Gestational age (weeks)
6. Initial physical examination findings
7. Inclusion and exclusion criteria
8. Chest radiograph
9. Date and time of initial nCPAP or other type of controlled positive pressure ventilation

9.5.1.4.2 Primary Observation Period

The following were documented for each randomized subject during the Primary Observation Period of the study (≤ 48 hours after randomization [T_0]):

1. Date and time of randomization (T_0) and the study dosing group assignment
2. The date and time of the initiation and completion of aerosol delivery
3. All AEs, including ADEs
 - a. Included peri-dosing events (defined as an AE with an onset time ≤ 2 hours from the time of initiating administration of lucinactant for inhalation included, but were not limited to, the following:
 - Bradycardia (HR < 100 bpm for ≥ 20 seconds)
 - Desaturation ($SpO_2 < 80\%$ for ≥ 20 seconds)
 - Gagging/Regurgitation
 - Apnea (central, obstructive, or combined)
 - Pallor
 - Complications related to placement of bi-nasal prongs (bleeding, apparent obstruction of the nares, bi-nasal prongs occlusion requiring removal and replacement, nasal irritation [erythema of nares or septum, inflammation of nares or septum]).
4. Respiratory support and supplemental oxygen
5. nCPAP settings
6. FiO_2 values
7. Signs and symptoms consistent with worsening of respiratory status
8. Vital signs and SpO_2
9. PCO_2 values

10. Chest radiograph, as applicable
11. Gastric liquid volume
12. Serum electrolytes
13. Defecation (initial 24 hours following randomization)
14. Concomitant medications
15. Technical performance of the device
16. The use of pacifiers

9.5.1.4.3 Extended Observation Period:

The following assessments were performed during the Extended Observation Period of the study (> 48 hours to ≤ 6 days after date of randomization). Daily measurements were obtained as close to 0800 as possible:

1. Assessment and documentation of respiratory support and supplemental oxygen
2. Signs and symptoms consistent with worsening of respiratory status
3. Vital signs
4. SpO₂
5. Chest radiograph, as applicable
6. Incidence of AEs, including ADEs
7. Concomitant medications

9.5.1.4.4 Final Visit

The Final Visit (36 weeks PMA or discharge/transfer) included the following assessments:

1. Documentation of respiratory support and supplemental oxygen
2. AEs, including ADEs
3. Physical examination (including changes from baseline examination)
4. Occurrence or presence of the following (as applicable):
 - a. IVH (worst grade during hospitalization)
 - b. Cystic PVL during hospitalization
 - c. PDA and related treatments (surgery or pharmacologics)
 - d. NEC (stage and related treatments)

- e. Lung air leaks
 - f. Pulmonary hemorrhage
 - g. Acquired sepsis
 - h. Apnea
5. Incidence of BPD
 6. Incidence of ROP (documentation of onset and severity throughout study participation)
 7. Survival (date, time, and cause of death, if applicable)
 8. Date and time of transfer or discharge from the current hospital (if applicable)
 9. Concomitant medications

9.5.1.5 Protocol Event Schedule

The protocol event schedule is summarized in [Table 9-6](#).

Table 9-6. Protocol Event Schedule

Measurement/Procedure	Study Period				
	Screening	Primary Observation	Extended Observation	Final Observation	
		Days 1-2	Days 3-7	Day 8 to 36w PMA	Final Visit (36w PMA)
Informed Consent/HIPAA	X				
Inclusion/Exclusion Criteria	X				
Demographics	X				
Maternal/Birth History	X				
Physical Exam	X				X
Chest Radiograph ¹	X				
Randomization		X			
Lucinactant for inhalation		X			
Body Weight		X			
Defecation		X			
Vital Signs		X ²	X ²		
Monitoring of SpO ₂ ³		X	X		
Monitoring of PCO ₂ ⁴		X			
Respiratory support and O ₂ delivery	X	X	X	X ⁵	X ⁵
Serum Electrolytes		X			
Gastric Liquid Volume ⁶		X			
Peri-Dosing Events		X			
Adverse Events		X	X	X	X
Adverse Device Effects		X			
Concomitant Medication		X	X	X	X

¹ A chest radiograph prior to intubation was required if such a procedure does not delay or compromise emergent care.

² Vital signs were documented within 15 minutes (\pm 5 minutes) prior to randomization. For the active arms, vital signs were documented every 5 minutes (\pm 2 minutes) during dosing for Dosing Group I and II; every 15 minutes (\pm 5 minutes) during dosing for Dosing Group III and IV. For the control arms, vital signs were documented at 15 minutes (\pm 5 minutes) post randomization. In addition, recorded at 1, 3 (\pm 15 minutes), 6, 12 (\pm 1 hour), 18, 24, 36 and 48 hours (\pm 2 hours) post randomization and daily at 0800 (\pm 2 hours) on days 3 to 7 for all randomized subjects.

³ Continuous monitoring of oxygen saturations by pulse oximetry were initiated at the time of randomization and continued until completion of Study Day 7.

⁴ Continuous transcutaneous PCO₂ monitoring was initiated following randomization and at least 30 minutes prior to the start of ADS delivery, and continued for 72 hours post randomization.

⁵ Only the date and time.

⁶ Gastric liquid volume was assessed 30 minutes (\pm 15 minutes) following completion of lucinactant for inhalation administration.

9.5.2 Appropriateness of Measurements

The measures used to assess safety and tolerability were consistent with those used in conventional pulmonary surfactant and neonatal intensive care studies. In addition, measurements were included to account for potential issues that may result from aerosol administration, including a heightened concern over ingestion of aerosol product and potentially resultant electrolyte imbalances. All measures were selected with the assistance of the Windtree's SC and were reviewed by FDA.

9.5.3 Efficacy Variables

For this study, efficacy was included as an exploratory analysis; no statistical testing was performed. The goal for the efficacy measurements was to ensure that it would be feasible to collect and analyze this information.

The analysis of efficacy included multiple results; none were identified as primary. These measurements included the following:

1. Incidence of BPD
2. Rate of survival without BPD at 36 weeks PMA
3. Worsening of respiratory status
4. Technical performance of the ADS
5. Physiological Parameters

9.5.4 Drug Concentration Measurements

Because lucinactant is administered topically to its site of action (ie, the lungs) and is not appreciably absorbed systemically, no biological samples were taken and no pharmacokinetic studies were conducted.

9.6 Data Quality Assurance

A series of steps were taken to ensure the accuracy and reliability of data collected. All investigators selected were qualified in neonatology, the investigators and associated site staff members were trained on protocol procedures prior to study initiation, and periodic visits were made by the Windtree's in-house and contract clinical monitors.

Data were entered by site staff into eCRFs created and maintained by BioClinica, Inc., Newtown, PA, USA. The eCRFs were subjected to automatic electronic edit checks within the electronic data capture (EDC) system and were manually reviewed for accuracy against source documentation during on-site monitoring visits and by in-house Clinical Data Associates. All

discrepancies were resolved with the investigators or their designees, as appropriate. The eCRF database was transferred to Windtree by BioClinica where additional programmatic checks created by Windtree's Biometrics department were performed to ensure accuracy and completeness of data. All site and Windtree personnel using the EDC system received training from the BioClinica training department prior to use of the system. User's manuals for the EDC system were always available on-line.

This study was monitored by Windtree's in-house staff and contract personnel in accordance with ICH E6, *Guideline for Good Clinical Practice*, and 21 CFR Part 312. Additional details on study site monitoring can be found in Appendix 16.1.1, Protocol and Protocol Amendments.

Before site initiation, all participating PIs agreed to permit study-related monitoring, audits, EC reviews, as well as access and review of source data by Windtree or appointed designees. The PI is responsible for all study information obtained and documented on subjects. As such, the PI must review and verify all study data documented during the course of this study and ensure its completeness and accuracy.

9.7 Statistical Methods Planned in the Protocol and Determination of Sample Size

9.7.1 Statistical and Analytical Plans

A complete outline of the all planned analyses for the study, to include the handling of missing data, is provided in Statistical Analysis Plan (Appendix 16.1.9).

Approximately 64 subjects were to be enrolled into the study, with approximately 32 subjects randomized to the active surfactant arm and approximately 32 subjects randomized to the control (nCPAP only) arm. The sample size was based on the number of subjects necessary to evaluate the safety and tolerance of lucinactant for inhalation. Sample size calculations to demonstrate clinical effect were not performed because efficacy was an exploratory objective.

The statistical analysis was based on all randomized subjects in the study, ie, the Intent-to-Treat (ITT) population. In addition, all evaluable subjects were analyzed for efficacy signals. Evaluable subjects were those in whom complications of prematurity (eg, PDA, IVH, sepsis,) do not preclude assessment of efficacy signals (eg, improvement in oxygenation, need for intubation and IMV). For all variables, summary statistics were provided by dosing group, including frequency count and percentage for discrete or categorical variables, and mean, standard deviation, median, minimum, and maximum for continuous variables. In addition, time-to-event variables were summarized using Kaplan-Meier methodology. Incidence and rates of death, BPD, survival without BPD, and worst-stage ROP at 36 weeks PMA were summarized.

If no values were recorded in a given eCRF data field, they were treated as missing and not imputed.

In addition, time to and incidence of intubation were added as an exploratory efficacy endpoint, and an analysis of subjects without treatment interruptions was added due to the unforeseen frequency of interruptions. Results for subjects without treatment interruptions are described.

9.7.1.1 Interim Analyses

Following the completion of enrollment in each dose group, the SRC evaluated the tolerability and safety data upon completion of 72 hours for active subjects, and all available safety endpoint data for control subjects. An independent statistician, not a member of the committee, was responsible for the statistical analysis of the data to be reviewed at each meeting. The committee reviewed the AEs related to dosing and all AEs and device effects. The SRC had the authority to recommend suspending enrollment or not based on their independent review findings relevant to the safety of study subjects. At each review, the control subjects were summarized in aggregate.

9.7.2 Determination of Sample Size

The sample size was not based on statistical estimation for this phase 2 study. The number of subjects randomized (approximately 8 in each active group and approximately 8 in each control [nCPAP only] group) was considered sufficient to establish safety and tolerability before proceeding to the next higher dose. The total of approximately 32 subjects to be assigned to the active arm and approximately 32 subjects to be assigned to the control arm for the entire study was considered sufficient to assess overall safety and tolerability. Formal statistical sample size calculations were not performed.

9.8 Changes in the Conduct of the Study or Planned Analyses

9.8.1 Changes in the Conduct of the Study

There was 1 amendment to the protocol for this study. Major changes related to this amendment are summarized below. Where applicable, bold italics are used for additions, and strikethroughs are used for deletions. Administrative changes and typographical and formatting errors are not summarized here.

The original and amended protocol, along with summaries and rationales for the amendment, are provided in Appendix 16.1.1. The study was terminated early for administrative reasons (including resource limitations and the intent to study the 26-28 GA weeks PMA patients in an amendment to Study 03-CL-1202).

9.8.1.1 Amendment 1 (Dated 02 September 2015)

Location	Previous	Revised	Rationale
Protocol Summary, Study Design, Page 5	Subjects randomized to an active arm will receive 1 dose of lucinactant for inhalation within 2 hours of randomization through the investigational ADS device administered over 30, 45, 60, or 90 minutes in conjunction with nCPAP support.	Subjects randomized to an active arm will receive 1 dose of lucinactant for inhalation within 2 hours of randomization; <u>subjects must continue to meet entry criteria at the time of initiation of study therapy. Active study therapy will be administered</u> through the investigational ADS device administered over 30, 45, 60, or 90 minutes in conjunction with nCPAP support.	Additional requirement of meeting criteria at treatment initiation added.
Protocol Summary, Study Design, Pages 5-6	Subjects may be eligible to receive a repeat dose between 2 and 24 hours after the initial dose. Subjects randomized to a control arm will be continued on nCPAP alone.	Subjects may be eligible to receive a repeat dose between 2 and 24 hours after the initial dose <u>if subjects meet repeat dosing criteria, as described in the “Treatment Groups” section.</u> Subjects randomized to a control arm will be continued on nCPAP alone.	Additional clarification on repeat dose.
Protocol Summary, Study Design, Page 6	Prior to escalation to the next dose, a safety assessment will be performed by an independent SRC after each group has been enrolled. All subjects on the active arm will receive the same drug concentration of lucinactant for inhalation at the same rate. The dose will vary by the volume of the nominal dose of lucinactant (50 mg TPL/ml) aerosolized and introduced into the nCPAP circuit, given over a predetermined time for each dose.	Prior to escalation to the next dose, a <u>A</u> safety assessment will be performed by an independent SRC after each group has been enrolled. All subjects on the active arm will receive the same drug concentration of lucinactant for inhalation at the same rate. The dose will vary by the volume of the nominal dose of lucinactant (<u>30</u> 50 -mg TPL/ml) aerosolized and introduced into the nCPAP circuit, given over a predetermined time for each dose. <u>The lucinactant for inhalation delivery will be facilitated by the investigational ADS device in conjunction with a commercially available</u>	Escalation to the next dose group is no longer contingent on SRC review. Typo corrected (ie, 30 versus 50) and additional clarification language added.

Location	Previous	Revised	Rationale
		<u>nCPAP generator and patient interface.</u>	
Protocol Summary, Study Design, Page 6; Protocol Summary, Concomitant Medications, Page 10; Section 2.3.1, Duration of Subject Study Participation, Page 37		Completion of study clarified to be 36 weeks PMA, NICU discharge, hospital transfer, or death, whichever occurs first.	More clearly defines completion of study
Protocol Summary, Dosing Groups, Pages 8-9	... additional dosing groups. If the SRC concludes there are no safety concerns that would preclude proceeding to the next higher dose, dosing will commence in Dosing Group II.	... additional dosing groups. <u>Enrollment will continue in the next dosing group without pause from the previous dosing group; however, if the SRC identifies</u> concludes <u>there are no safety concerns that would preclude dosing, enrollment will stop until these safety concerns are addressed and the SRC recommends resuming enrollment.</u> proceeding to the next higher dose, dosing will commence in Dosing Group II.	SRC approval not required to advance to next dosing level. Additional sections not identified here were modified due to this change.
Protocol Summary, Dosing Groups, Page 9	Subjects meeting repeat dosing criteria will receive an additional treatment of the same dose. Repeat dosing will be allowed between 2 hours and 24 hours after completion of the initial dose if the FiO ₂ level is at least 0.35.	Subjects meeting <u>the repeat dosing criteria</u> on will receive an additional treatment of the same dose. Repeat dosing will be allowed between 2 hours and 24 hours after completion of the initial dose if <u>subjects require a sustained need for supplemental oxygen at or above the qualifying FiO₂ level for study entry (ie, 0.25) for is at least 0.3530 minutes to maintain SpO₂ of 88% to 95%.</u>	Repeat dosing criteria changed.
Protocol Summary, Concomitant Medications, Page 10	Commercially available SRTs, following lucinactant for inhalation administration, may be administered as medically indicated.	Commercially available SRTs, following lucinactant for inhalation administration <u>or control</u> , may be administered as medically	Additional clarifications added.

Location	Previous	Revised	Rationale
	Study subjects who receive any commercial SRT while on-study will be considered treatment failures, and as such, will continue to be followed for safety follow-up until study completion.	indicated. Study subjects who receive any commercial SRT while on-study will be considered treatment failures <u>but</u> , and as such, will continue to be followed for safety follow-up until study completion <u>(as per the protocol)</u> . <u>Postnatal steroids are not permitted unless clear medical need is determined</u> .	
Section 5.2.4, Sequential Dosing Scheme, Page 47	The study dosing will initiate in Dosing Group I (the lowest dose). Only after completion of the SRC review and subsequent approval (Section 6) will the study progress to Dosing Group II. After all active subjects within each dosing group have completed 72 hours, the SRC will review the safety and tolerability of this dose. Following SRC approval, dose escalation will proceed and subjects will be screened for the next dosing group.	The study dosing will initiate in Dosing Group I (the lowest dose), <u>and continue to Dosing Group II after completion of enrollment. Each dosing group will enroll sequentially following completed enrollment of the previous dosing group. Only after completion of the SRC review and subsequent approval (Section 6) will the study progress to Dosing Group II.</u> After all active subjects within each dosing group have completed 72 hours, the SRC will review the safety and tolerability of this dose. Following SRC approval, dose escalation will proceed and subjects will be screened for the next dosing group.	SRC approval not required to advance to next dosing level; sequential dosing rules still apply.
Section 5.2.5, Repeat Dosing, Page 47	The repeat dosing criterion is defined as: at least 2 hours, but no more than 24 hours, post dosing and a FiO ₂ level of at least 0.35.	The repeat dosing criterion is defined as at least 2 hours, but no more than 24 hours, <u>after post dosing and a the subject must require a sustained need for supplemental oxygen at or above the qualifying FiO₂ level for study entry (ie, 0.25) for of at least 0.35 at least 30 minutes to maintain SpO₂ of 88% to 95%.</u>	Repeat dosing criteria changed.

Location	Previous	Revised	Rationale
Section 5.3.3.2, ADP Post Delivery Procedures, Page 51	Instructions for of the return of the ADPs to Discovery are provided in the Study Manual.	<p><u>Study ADPs are required to be returned to 1 of 3 return facilities in accordance to the following categories.</u></p> <ol style="list-style-type: none"> 1. <u>Unused ADPs are shipped to Battelle at the time of site closure or at the request of Discovery (clinical site monitors will provide additional information to study sites on associated shipping procedures and addresses);</u> 2. <u>Used ADPs that are not associated device errors are picked-up by a specified vendor for destruction;</u> 3. <u>ADPs associated with device errors are shipped to Battelle, when requested by Discovery (further information regarding associated shipping procedures is made available to study sites at the time of the request).</u> <p><u>Further information and instructions on ADP shipping and accountability are provided in the Study Manual. Instructions for of the return of the ADPs to Discovery are provided in the Study Manual.</u></p>	Instructions for ADP returns were incomplete.

Location	Previous	Revised	Rationale
Section 6.2, Safety Enrollment Holds, Page 58	In addition, if a treated subject dies during or \leq 12 hours after aerosol administration, then an unscheduled meeting of the SRC will be called.	In addition, if a treated subject dies during <u>the first or \leq 12 hours following and related to lucinactant for inhalation after aerosol</u> administration, then an unscheduled meeting of the SRC will be called.	Clarification of when SRC meeting would be held following a death.
Section 8.2, Primary Observation Period, Page 69	<ul style="list-style-type: none"> • Bradycardia (as noted by HR < 100 bpm for \geq 20 seconds) (Section 7.1.1) • Desaturation (as noted by O₂ saturation < 80% for \geq 20 seconds) (Section 7.1.3) <p>Complications related to placement of bi-nasal prongs (bleeding, apparent obstruction of the nares, bi-nasal prongs occlusion requiring removal and replacement, nasal irritation).</p>	<ul style="list-style-type: none"> • Bradycardia (as noted by HR < 100 bpm for \geq 20 seconds) (Section 7.1.1) • Desaturation (as noted by O₂ saturation < 80% for \geq 20 seconds) (Section 7.1.3) • <u>Gagging/regurgitation</u> • <u>Apnea (central, obstructive, or combined) (Section 7.1.1)</u> • <u>Pallor</u> • Complications related to placement of bi-nasal prongs (bleeding, apparent obstruction of the nares, bi-nasal prongs occlusion requiring removal and replacement, nasal irritation). 	Clarification of peri-dosing events.

9.8.2 Changes in the Planned Analyses

Time to and incidence of intubation were included as an exploratory efficacy endpoint.

An analysis of subjects without treatment interruptions was added due to the unforeseen frequency of interruptions. Results for subjects without treatment interruptions are described.

The study was terminated early (08 July 2017) for administrative reasons (including resource limitations and the intent to study the 26-28 GA weeks PMA patients in an amendment to Study 03-CL-1202) after the completion of Dosing Group III.

10. STUDY PATIENTS

10.1 Disposition of Patients

A completed subject was defined as any subject who entered the study and was evaluated at 36 weeks PMA or discharge/transfer (whichever came first). A subject could have withdrawn consent (through their legally authorized guardian) at any time without prejudice to further care. Also, if the status of a subject is unknown at the Final Visit, every effort was to have been made to contact the subject's legally authorized guardian to determine the status of the subject. If the status of the subject had not been established in 28 days following exposure to study aerosol, the subject would have been considered lost to follow-up.

Due to administrative reasons (including resource limitations and the intent to study the 26-28 GA weeks PMA patients in an amendment to Study 03-CL-1202), this study was terminated by Windtree after the completion of Dosing Group III (08 July 2017). Thus, the doses summarized include 50, 75, and 100 mg TPL/kg; no subjects were enrolled in the 150 mg TPL/kg dosing group.

Table 10-1 presents the disposition of subjects in regards to population inclusion overall and by treatment group. A total of 402 subjects were screened and 48 (12%) subjects were randomized into this study from 15 January 2016 to 14 May 2017 at 15 of 22 active study centers in the US, Canada, Chile, and Poland. Safety analyses were based on the safety population (N=48), and exploratory efficacy analyses were based on the ITT population (N=48). Two subjects (1 in the 50 mg TPL/kg group and 1 in the 75 mg TPL/kg group) were withdrawn early from the study because the subjects died (see Section 12.3.1.1). For this study, the ITT and safety populations were the same because all subjects who were randomized to active treatment also received study drug.

Table 10-1. Subject Disposition Summary (All Subjects)

	Lucinaectant for Inhalation (mg TPL/kg)				nCPAP Only	Total
	50	75	100	All Active		
Intent-to-Treat	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)	48 (12%)
Safety Population	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)	48 (12%)
Early Termination	1 (13%)	1 (13%)	0	2 (8%)	0	2 (<1%)
Death	1 (13%)	1 (13%)	0	2 (8%)	0	2 (<1%)

Note: Percentages are based on total number in each column, except for total, which was based on total screened (402).
Source: Section 14.1, Summary Table 1.1 and Summary Table 1.2.

10.2 Protocol Deviations

Protocol violations and deviations are summarized in [Section 14.1](#), Summary Table 1.3. Violations and deviations were divided into 4 major categories: dosing issues (eg, not dosed within 2 hours of randomization), inclusion/exclusion issues (eg, chest radiograph not consistent with RDS), data issues (eg, evaluation time out of window), and other (eg, improper preparation of study drug, device not set up correctly). Only deviations for inclusion/exclusion issues and data issues were noted.

The data issues “Evaluation data not done or unknown” (100% for both active and nCPAP only) was the most prevalent deviation. No subjects were excluded because of protocol deviations or violations as efficacy was for exploratory purposes only. A list of protocol violations and deviations by subject is presented in [Section 14.1](#), Summary Listing 1.1.

11. EXPLORATORY EFFICACY EVALUATION

11.1 Data Sets Analyzed

The efficacy analysis dataset was the ITT population, defined as all subjects who were randomized. All safety analyses were based on the safety population, which was comprised of all subjects who received at least one dose of study drug. In this study, all subjects who were randomized received study drug (see also [Section 12](#)).

11.2 Demographic and Other Baseline Characteristics

[Table 11-1](#) presents, for all subjects, a summary of the demographic values. For subjects in the active group, slightly more than half (54%) were female and 50% were white, compared to subjects in the control group, where 33% were female and 83% were white. Ethnic origin, birth weight and mean gestational age were similar between groups; however, a larger proportion of subjects in the active group were at 26 weeks PMA (38%) compared to subjects in the nCPAP only group (25%).

Table 11-1. Subject Demographics (Intent-to-Treat Population)

Demographics	Statistic/Category	Total Active (N=24)	nCPAP Only (N=24)
Gender	Male	11 (46%)	16 (67%)
	Female	13 (54%)	8 (33%)
Race	White	12 (50%)	20 (83%)
	Black/African American	4 (17%)	1 (4%)
	Asian	3 (13%)	1 (4%)
	Other or Unknown	5 (21%)	2 (8%)
Ethnic Origin	Hispanic	6 (25%)	7 (29%)
Birth Weight (g)	n	24	24
	Mean (SE)	915 (39.1)	1005 (48.7)
	Median	893	1008
	Min, Max	540,1270	525,1460
Gestational Age (weeks)	n	24	24
	Mean (SE)	27.3 (0.17)	27.5 (0.16)
	Median	27.1	27.5
	Min, Max	26.1,28.9	26.3,28.9

Note: Percentages are based on total number of ITT subjects in each treatment group.

Source: [Section 14.1](#), *Summary Table 2.1*.

Table 11-2 presents a summary of maternal and birth history results, which are generally similar between treatment groups. There is a slight difference in the mode of delivery between treatments, but the directionality is the same and the difference is not considered clinically meaningful. All other parameters have very similar results.

Table 11-2. Maternal and Birth History (Intent-to-Treat Population)

Parameter	Statistic	Total Active (N=24)	nCPAP Only (N=24)
Ruptured Membranes (type)	Spontaneous, n (%)	9 (38%)	9 (38%)
	Artificial, n (%)	15 (63%)	15 (63%)
Chorioamnionitis	n (%)	1 (4%)	0 (0%)
Steroid Use, Maternal	n (%)	24 (100%)	21 (88%)
Mode of Delivery	Vaginal, n (%)	3 (13%)	7 (29%)
	C-section, n (%)	21 (88%)	17 (71%)
Birth Status	Single, n (%)	16 (67%)	19 (79%)
	Multiple, n (%)	8 (33%)	5 (21%)
Apgar Score at One Minute	Mean (SD)	5.8 (2.17)	5.8 (2.14)
	Median	6.0	6.0
	Min, Max	2, 9	1, 9
Apgar Score at Five Minutes	Mean (SD)	7.4 (1.72)	7.9 (1.25)
	Median	8.0	8.0
	Min, Max	1, 9	5, 9
Congenital Anomaly ¹	n (%)	1 (4%)	1 (4%)

Note: Percentages are based on total number of ITT subjects in each treatment group.

¹ Subject 11023 (100 mg/kg) reported an anomaly of 'Ambiguous genitalia; approved per Windtree'.
Subject 19004 (nCPAP Only) reported an anomaly of 'Vertebral anomaly, 11 pairs of ribs, dextrocardia, hypospadias'.

Source: Section 14.1, Summary Table 2.2 and Summary Table 2.3.

Summaries of concomitant medications are presented in Section 14.1, Summary Table 3.1. Medications were coded to generic drug name (eg, bacitracin) and medication category (eg, dermatologicals) using the World Health Organization (WHO) drug dictionary.

The most commonly received medication was caffeine, received by all subjects. Following caffeine, the most commonly received medications were ampicillin, gentamicin, and phytomenadione, which was given to a total of 37 subjects, 18 (75%) and 19 (79%) for ampicillin

and gentamicin for the active and control groups, respectively, and 17 (71%) and 20 (83%) for phytomenadione for the active and control groups, respectively. The most commonly received rescue surfactant was poractant alfa, which was received by 10 (42%) subjects in the active group and 8 (33%) in the nCPAP only group. For all surfactants combined, 17 (71%) were used by subjects in the Total Active group and 15 (63%) were used by subjects in the nCPAP Only group.

Medications were reviewed to ensure that no subject took an excluded medication during the study period.

11.3 Measurements of Treatment Compliance

All 48 randomized subjects received treatment. A total of 10 subjects had recorded in the eCRF that treatment was stopped prior to delivery of full dose. However, two subjects (09001 and 11025) received their full dose. Subject 09001 had an initial interruption after 6 minutes of dosing, but the treatment was restarted and thus the subject received more than their assigned dose of 50 mg TPL/kg. Subject 11025 reported a tubing detachment; however, this disconnection occurred before their treatment was started. Once the tubing was replaced, the subject received their full dose of 100 mg TPL/kg. Excluding these two, a total of 8 subjects did not receive their full dose ([Section 14.2](#), Summary Table 5.2.1 and Summary Table 5.2.2): 1 in the 50 mg TPL/kg group (Subjects 01033 – did not receive carrier gas for 6 minutes of 30 minute dose), 4 in the 75 mg TPL/kg group (Subjects 12023, 40003, 40006, and 42003), and 3 in the 100 mg TPL/kg group (Subjects 40014, 40016, and 42010). Subject 40016 received 59 minutes of dosing out of 60 minutes scheduled; while reported as early termination in the eCRF, this subject is considered to have received a full dose. Repeat treatments were terminated early for 5 subjects, all in the 75 mg TPL/kg group (Subjects 12023, 40003, 40006, 42003, and 51004). Subject 40006 had a supplemental dose after the interruption of their initial dose, which also was interrupted; however, the supplemental dose was listed as a “repeat” dose in the eCRF. Thus, a total of 4 repeat doses were interrupted. Based on the above, and for the purposes of analysis, a total of 8 subjects will be considered as having “treatment interruptions”; 2 from the US (Subjects 01033, 12023), 5 from Canada (Subjects 40003, 40006, 42003, 40014, 42010), and 1 from Poland (Subject 51004).

The most common reason for treatment termination was for a condition called “Syringe pressure out of range”, which resulted in the system automatically shutting down, as it is designed to do when this condition was detected. No terminations resulted in loss of inspiratory flow or inability to maintain nCPAP.

The average number of treatments and number of subjects with 1 or 2 treatments are shown in [Section 14.1](#), Summary Table 3.2. The average number of doses was between 1.5 and 1.9 for all dosing groups. A total of 4, 7, and 5 repeats were reported to have been given for the 50, 75, and 100 mg TPL/kg treatment groups, respectively. One “repeat” for the 75 mg TPL/kg treatments was actually a supplementary dose for the initial dose, but was recorded as a repeat in the eCRF.

The time from birth to first dose and from randomization to first dose are shown in [Section 14.1](#), Summary Table 3.3. For all active treatments, the mean and median time from birth to first dose was 7.3 and 5.5 hours, respectively. For time from randomization to first dose, the mean and median times were 1.6 and 1.5, respectively.

Because dosing was conducted at the clinical sites (typically in the NICU) and consisted of 1 or 2 treatments given to in-patient neonates, usual compliance measures (doses taken divided by doses prescribed) are not appropriate nor were they conducted.

11.4 Exploratory Efficacy Results and Tabulations of Individual Patient Data

11.4.1 Exploratory Analysis of Efficacy

The evaluation of efficacy was an exploratory endpoint in this study; no statistical testing or quantitative comparisons were performed between treatment groups or lucinactant for inhalation doses. The primary goal of the efficacy analysis was to evaluate the feasibility to measure a variety of efficacy endpoints.

Efficacy endpoints were evaluated from the time of lucinactant for inhalation initiation or randomization (for nCPAP only subjects) until the completion of Study Day 7 (36 weeks PMA for BPD endpoints).

1. Incidence of BPD at 36 weeks PMA
2. Rate of survival without BPD at 36 weeks PMA
3. Worsening of respiratory status
4. Technical performance of the ADS

In addition to measurements defined in [Section 9.5.1.2.1](#), the efficacy of the device delivery of aerosol was characterized indirectly through the subject’s response to treatment and solicited feedback from PIs and relevant site-based study staff.

5. Physiological measurements (FiO₂, PCO₂)
6. Time to and incidence of intubation was also evaluated as an exploratory efficacy endpoint.

11.4.1.1 BPD and Survival without BPD at 36 Weeks PMA

The numbers of subjects with BPD or who survived without BPD are shown in Table 11-3. No subjects in the active groups and 6 subjects in the nCPAP only group developed BPD during the study. An exploratory comparison between the active and control groups was significant at $p = 0.022$ from Fisher’s Exact Test. The incidence of survival without BPD was 22 (92%) and 18 (75%) subjects for the active and nCPAP only groups, respectively.

Table 11-3. Summary of BPD and Survival without BPD at 36 Weeks PMA (Intent-to-Treat Population)

	Lucinactant for Inhalation (mg TPL/kg)				nCPAP Only (N=24)
	50 (N=8)	75 (N=8)	100 (N=8)	Total Active (N=24)	
BPD	0	0	0	0	6 (25%)
Survival without BPD	7 (88%)	7 (88%)	8 (100%)	22 (92%)	18 (75%)

Source: [Section 14.2, Summary Table 4.2.](#)

Exploratory statistical comparison between Total Active and nCPAP Only groups resulted in a p-value of 0.022 (Fisher’s Exact Test).

11.4.1.2 Worsening of Respiratory Status

The numbers of subjects with early worsening respiratory status are presented in [Table 11-4](#). For the criteria defining these endpoints, this table shows the number of subjects who met each criterion at any time within 72 hours of randomization. A criterion met between 72 hours and 7 days would constitute late worsening. If a subject satisfied multiple criteria, or the same criteria multiple times, the subject would be counted according to the earliest criteria met.

Overall, worsening of respiratory status occurred at approximately the same rate in active subjects (79%) vs. nCPAP only subjects (75%), and the individual criteria defining this endpoint occurred were generally similar. Differences were noted for ‘Need for Additional Surfactant Use’ which occurred for 63% of the Total Active subjects and, by definition, for no nCPAP Only subjects. Also, the PI determination of worsening respiratory status was 4% for the Total Active Group and 25% for the nCPAP Only group. The rate of intubation for any reason varied between dosing groups, as discussed in [Section 11.4.1.3](#).

No subjects experienced late worsening without also experiencing early worsening.

Table 11-4. Worsening Respiratory Status - Early (Intent-to-Treat Population)

All Reasons	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Total of Subjects with Early Worsening	6 (75%)	7 (88%)	6 (75%)	19 (79%)	18 (75%)
Arterial pH less than 7.20	2 (25%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)
Desaturation less than 80%	2 (25%)	0 (0%)	1 (13%)	3 (13%)	2 (8%)
Heart Rate less 100 bpm	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
Initiation of intermittent PPV	3 (38%)	2 (25%)	1 (13%)	6 (25%)	3 (13%)
Intubation for any reason	5 (63%)	7 (88%)	4 (50%)	16 (67%)	14 (58%)
Need for additional surfactant therapy	5 (63%)	6 (75%)	4 (50%)	15 (63%)	0 (0%)
PCO ₂ is greater than 65%	1 (13%)	0 (0%)	0 (0%)	1 (4%)	2 (8%)
PI determines worsening respiratory status	0 (0%)	1 (13%)	0 (0%)	1 (4%)	6 (25%)
Required Intervention includes PPV	1 (13%)	0 (0%)	1 (13%)	2 (8%)	2 (8%)
Sustained FiO ₂ is greater than 0.50	4 (50%)	2 (25%)	2 (25%)	8 (33%)	7 (29%)
Sustained apnea event	2 (25%)	0 (0%)	1 (13%)	3 (13%)	3 (13%)
nCPAP is greater than 7 cmH ₂ O	1 (13%)	1 (13%)	2 (25%)	4 (17%)	3 (13%)

Note: Subjects may satisfy multiple criteria. The earliest criteria satisfied for a subject defined early vs. late. The 'Need for Additional Surfactant therapy' category is defined as 0 for nCPAP Only.

Source: [Section 14.2](#), *Summary Table 4.1.1*.

11.4.1.3 Incidence of and Time to Intubation

Lucinactant for inhalation is a noninvasive alternative to traditional, invasive SRT; therefore, intubation is the likely candidate as the primary efficacy endpoint in future studies. For this reason, intubation deserves particular discussion.

Time until nCPAP failure from randomization is shown in [Table 11-5](#). During the period of the first 72 hours after randomization, the number of nCPAP failures was nearly the same between the active groups and the control group (17 [71%] and 16 [67%], respectively). The median time until nCPAP failures was similar for the 50 and 100 mg TPL/kg groups (8.7 and 9.1 hours), but was higher in the 75 TPL mg/kg group (15.7 hours). For the total active group, the mean and median times to nCPAP failure were higher compared to the nCPAP Only group, at 10.6 and 8.9 compared to 8.6 and 5.8, respectively.

Table 11-5. Time from Randomization until nCPAP Failure (Intent-to-Treat Population)

	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Time until nCPAP Failure) ¹ (hours)	n	5	7	5	17	16
	Mean (SE)	10.2 (3.56)	12.2 (2.28)	8.8 (2.07)	10.6 (1.48)	8.6 (2.38)
	SD	7.95	6.03	4.63	6.09	9.51
	Median	8.7	15.7	9.1	8.9	5.8
	Min, Max	3.2 , 23.8	4.2 , 18.0	3.9 , 15.2	3.2 , 23.8	0.8 , 35.9

Source: [Section 14.2](#), Summary Table 4.3.2.

¹ Time is calculated from randomization

Time until any intubation from randomization, not just for nCPAP failure, is shown in [Table 11-6](#). The rates of intubation for any reason and at any time differed between dosing groups. Compared with the overall rate of intubations of 71% (17/24) in the nCPAP only group, intubation was slightly more common in the active treatment groups, particularly in the 75 mg TPL/kg group where 100% of subjects were intubated at any time. The median time until intubation was similar for the 50 and 100 mg TPL/kg groups (8.9 and 10.0 hours), but was higher in the 75 TPL mg/kg group (15.9 hours). The mean and median times to intubation were higher in the Total Active group compared to the nCPAP Only group, at 45.7 and 11.0 compared to 37.1 and 6.5, respectively, indicating that intubations in the active group started later than intubations in the control group.

Table 11-6. Time from Randomization until Any Intubation (Intent-to-Treat Population)

	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Time until Any Intubation) ¹ (hours)	n	7	8	6	21	17
	Mean (SE)	55.2 (36.72)	42.3 (30.18)	39.1 (30.35)	45.7 (18.01)	37.1 (28.85)
	SD	97.14	85.35	74.35	82.54	118.94
	Median	8.9	15.9	10.0	11.0	6.5
	Min, Max	3.2 , 270.0	4.2 , 253.1	3.9 , 190.6	3.2 , 270.0	0.2 , 497.3

Source: [Section 14.2](#), Summary Table 4.3.1.

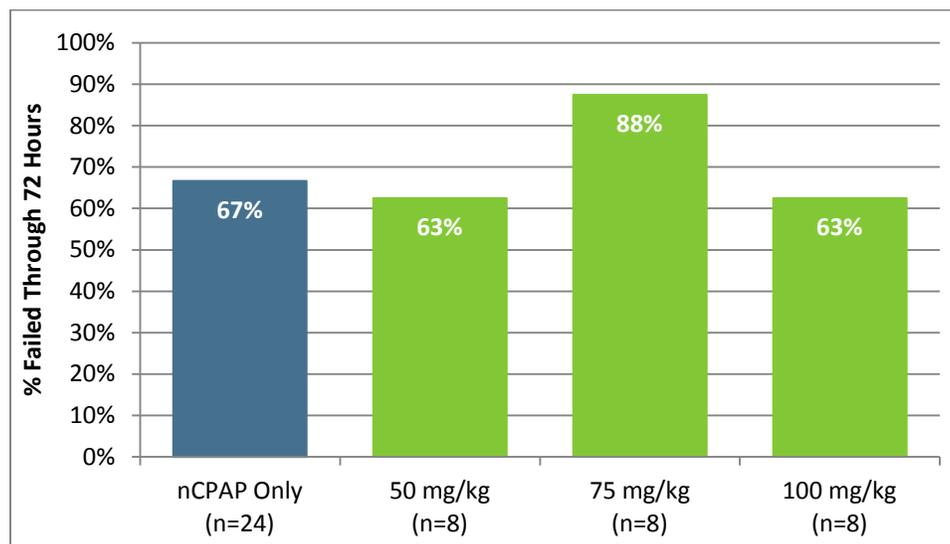
¹ Time is calculated from randomization

The critical time period is within 72 hours from birth. After 72 hours, neonates will normally be producing sufficient surfactant on their own; thus, intubation after this period is likely the result of causes other than respiratory distress syndrome. In addition, it is important to focus on intubation for the purpose of delivering mechanical ventilation or surfactant replacement therapy

(described as “nCPAP Failure”), as opposed to other reasons that were not a result of RDS, such as surgery. The rest of the efficacy results focus on intubations for nCPAP failure occurring within 72 hours from randomization.

Figure 3 shows the rate of intubations by each active treatment group and the control group. The group with the highest number of intubations was in the 75 mg TPL/kg group, where 7 out of 8 (88%) subjects were intubated within 72 hours of randomization. This was equal to the number of control subjects that were intubated in Dosing Group I, where 7 out of the 8 control subjects were intubated.

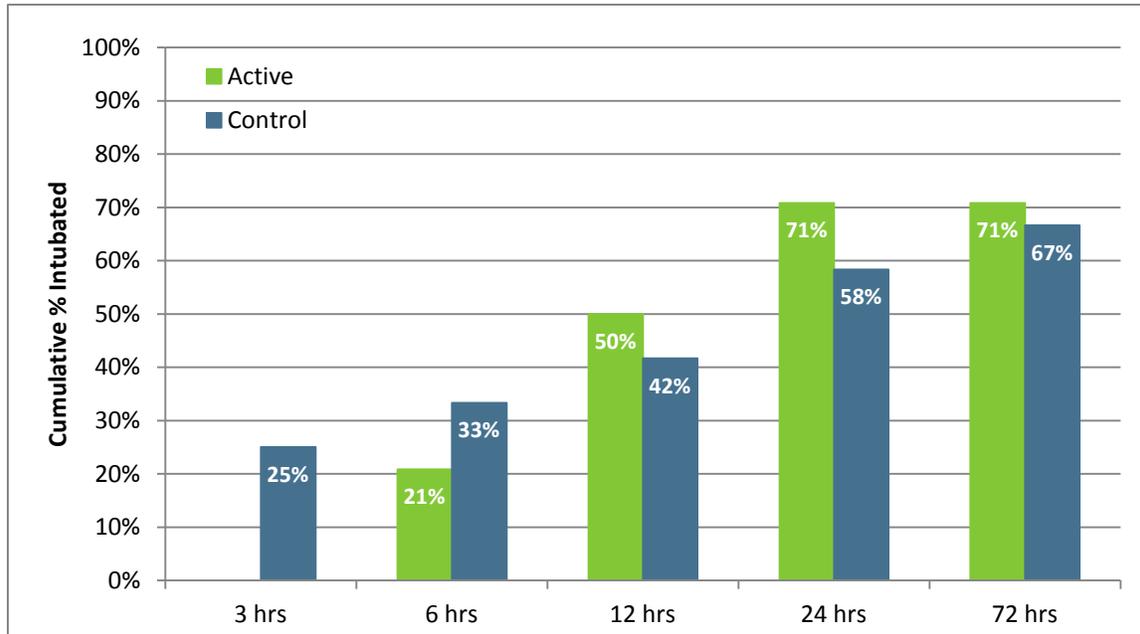
Figure 3. Intubation through 72 Hours from Randomization by Treatment (Intent-to-Treat Population)



Source: Section 14.2, Summary Graph 1.3.1.

Another way of viewing the time until intubation results is to compare treatment groups by the time periods of when intubation took place (Figure 4). This shows that while the number of intubations was similar, intubations in the active group occurred later than intubations in the nCPAP Only group. Through 3 hours from randomization, no subject in any of the active groups were intubated, whereas 6/24 (25%) subjects in the nCPAP only group had been intubated. Through 6 hours, 21% (5/24) and 33% (8/24) of subjects in the active and nCPAP only groups, respectively, had been intubated.

Figure 4. Cumulative Time to nCPAP Failure from Randomization through 72 Hours (Intent-to-Treat Population)

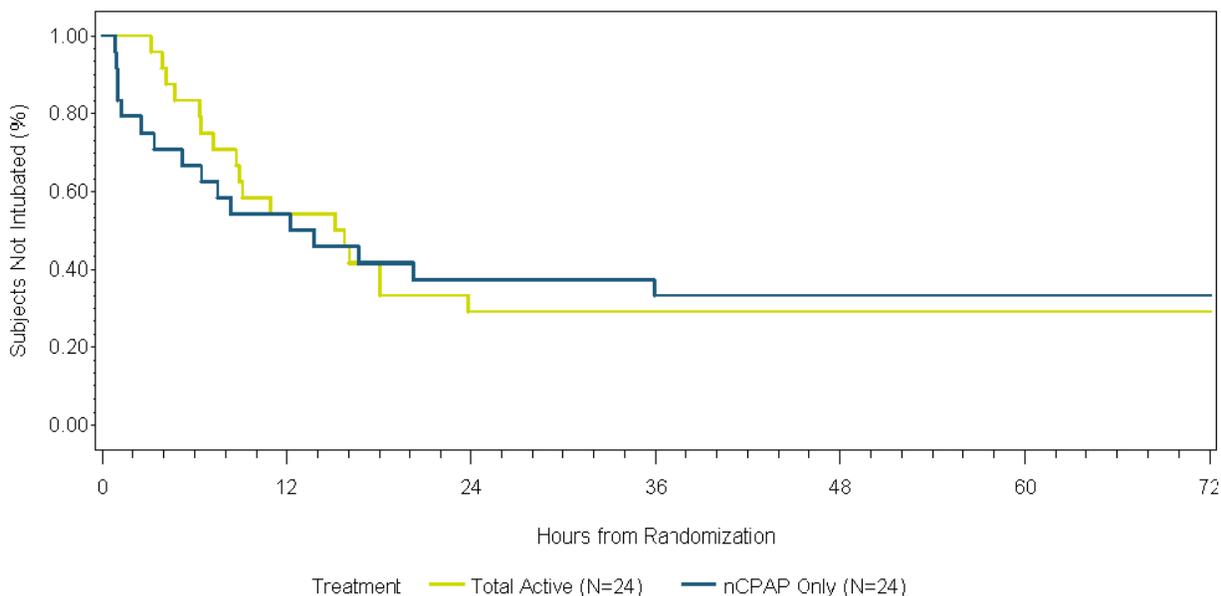


Source: [Section 14.2](#), *Summary Graph 1.1.2*.

A Kaplan-Meier (time-to-event) graph is used to show both incidence of and time to any intubation. [Figure 5](#) displays when each intubation occurred for the nCPAP only subjects and the active subjects.

The rate of intubation for the nCPAP only subjects is steep through 3 hours from randomization, where approximately half of the total number of subjects intubated in the control group occurred. All the intubations for the active subjects shown occurred between 3 and 24 hours after randomization. Thus, the initial intubations that occurred for the active subjects started later than those for nCPAP only subjects.

Figure 5. Kaplan-Meier Curve for Time to Intubation from Randomization (Intent-to-Treat Population)



Source: [Section 14.2, Summary Graph 1.1.](#)

11.4.1.4 Treatment Interruptions

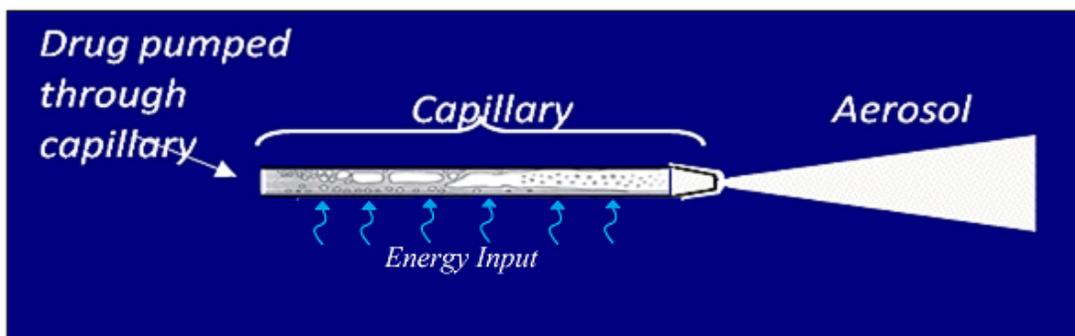
As a safety feature, the ADS was designed to shut down and interrupt treatment when conditions outside of normal, specified operating ranges are detected by the ADS. A treatment interruption occurs when the aerosol dose administration is terminated before the specified aerosolization treatment time completes. Treatment interruptions can also be initiated by a clinician, who wishes to stop treatment to otherwise take care of the patient.

In this study (Study 03-CL-1401), there were approximately 55 total ADPs used to administer doses to 24 active subjects. Of the 55 doses administered, 14 doses (25%) had a treatment interruption. The 14 interruptions impacted 8 of the 24 (33%) active enrollments; 10 of the 14 (71%) treatment interruptions were due to a condition identified as “syringe pressure out of range.” Syringe pressure out of range interruptions were unanticipated and were the cause of the vast majority of all treatment interruptions. They have been extensively assessed and will be mitigated by design in future iterations of the device. However, other types of interruptions may continue to occur in the future.

Filter Clogging

The CAG technology is shown in Figure 6. Syringe pressure out of range occurs when the system detects that the force (pressure) required to pump the reconstituted lucinactant through the device exceeds pre-set limits, indicating a clog in the system before the aerosol exits the capillary. When this clogging occurs, the system continues to produce aerosolized reconstituted lucinactant in the intended amount and concentration until the pre-set limits are exceeded. Once the limits are exceeded, aerosolization immediately stops and the system alarms, notifying the clinicians of the treatment interruption.

Figure 6. Capillary Aerosol Generator



Treatment Interruptions in Earlier Trials

Occurrences of treatment interruptions were infrequent in Study 03-CL-1201, with interruptions for the syringe pressure out of range occurring in approximately 3/60 (5%) of the doses delivered. Investigation into the syringe pressure out of range interruption concluded that the most likely cause was an assembly-related issue from the device manufacture. Prior to beginning enrollment in this study (Study 03-CL-1401) and Study 03-CL-1202, Windtree believed the specific cause for the syringe pressure out of range interruptions from Study 03-CL-1201 had been addressed. Therefore, the high level of clogging that occurred was unanticipated.

Interruption Events

Treatment interruptions due to clogging tended to occur later in the course of the aerosol administration of reconstituted lucinactant as the clogging is related to the volume of reconstituted lucinactant going through system. Thus, interruptions were most likely to occur in the 75 mg TPL/kg group. Other than being randomized to the higher dose group, no other known subject factor was associated with or had a role in the occurrence of a treatment interruption.

The prototype ADS used in the Phase 2 clinical program was designed to automatically stop aerosolization when any out of range condition occurred. Due to the nature of the prototype ADS, prior to restarting treatment, the ADS requires re-initialization, a replacement ADP, and a new syringe completely filled with reconstituted lyophilized lucinactant. Therefore, when an interruption occurred, in most cases, the subject was disconnected from the prototype ADS and returned to administration of nCPAP only. In order to ensure subjects with interruptions received the targeted dose within as short a time as possible, supplemental dosing guidelines were developed during the course of the study.

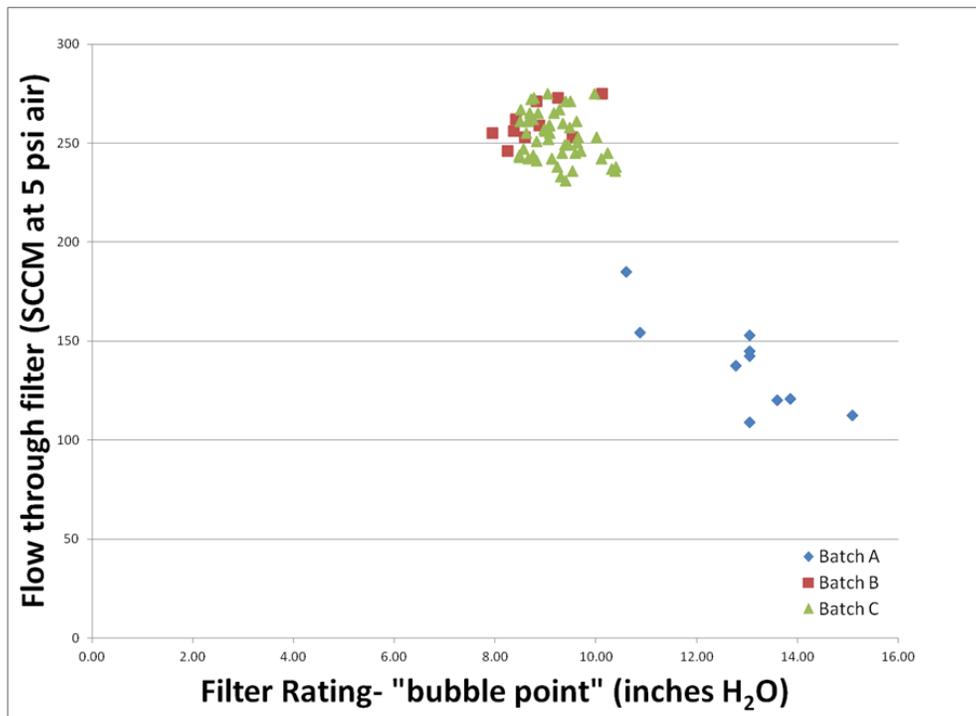
However, at the start of this study (Study 03-CL-1401) and Study 03-CL-1202, there were no supplemental dosing guidelines established. Shortly after the first reported interruptions, Windtree provided its internal support staff with supplemental dosing guidelines to instruct sites as interruptions occurred. These guidelines dictated supplemental doses to obtain a minimum percentage of the original targeted dose. When delivered, supplemental doses of lucinactant for inhalation were administered such that subjects were to receive 72 - 128% of the intended dosage.

Investigation and Mitigations on the Impact of Treatment Interruptions

Upon starting the investigation, Windtree identified several potential causes of the clogging. One of the potential causes was incomplete/improper reconstitution of lyophilized lucinactant prior to loading the ADS syringe. To minimize the likelihood that improper reconstitution would cause clogging, Windtree took immediate action and re-trained all sites on the importance of and proper methods for reconstituting lyophilized lucinactant. Despite this intervention, there was no change in the incidence of interruptions after this re-training and no systemic problems were identified during the re-training process.

Early in the investigation, focus went to the frit filter ([Figure 7](#)) as the most likely point of the clogging in the wetted path. Frit filter characteristics indicated that different batches of frit filters with the same filter rating or “bubble point” could have vastly different flow characteristics. As an example, a 10 micron frit filter will not let particles greater than 10 micron in diameter pass through the filter. For visualization, one can imagine two different 10 micron filters; one with one 10 micron pore and the other with one hundred 10 micron pores. With different manufacturer lots of 10 micron frit filters on hand, testing showed different flow characteristics between different lots of frit filters.

Figure 7. Frit Filter and Filter Bubble Points vs. Flow Rate for 10 Micron Frit Filters



Windtree determined that disposable ADPs had been built using three different lots of filters. The first group of ADPs, built with the first filter lot, was initially used in Study 03-CL-1201 and had a lower rate of clogging as compared to the ADPs manufactured with the second lot of filters. This first group was distributed only in the US, while the second group was shipped to

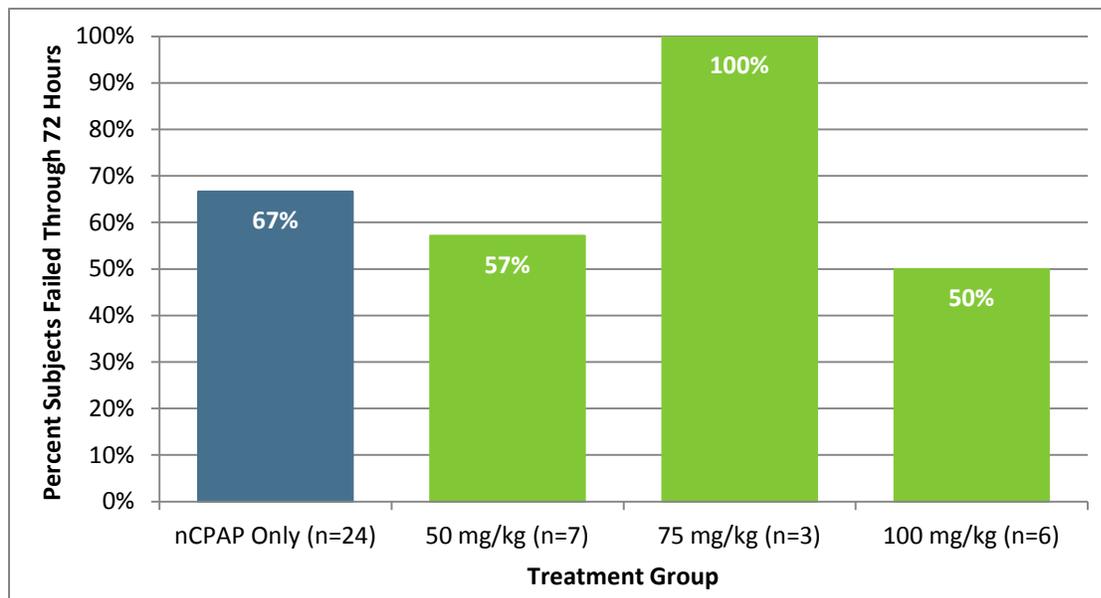
clinical sites in Poland, Canada, and Chile for use in the study. As a result, the rate of clogging in the US was lower compared to those other countries. Confirmation that the ADP group differences were causing the interruption rate differences was established in November 2016 when the ADPs manufactured with the third lot of filters became available and was shipped to all countries participating in the study. Due to lead time required for the manufacturing of ADPs, it was not possible to replace all ADPs at all sites.

Results Excluding Treatment Interruptions

The purpose of the clinical studies was to evaluate subject responses (safety, tolerability and efficacy) to the selected dose of lucinactant for inhalation in the expected time frame (eg, 75 mg TPL/kg in 45 min). When a treatment interruption occurred, the subject did not receive the targeted dose in the targeted time and the impact of the therapy on those subjects may not be representative of the expected results from the actual therapy as intended. As a result of this issue, Windtree determined that a review of the results without treatment interruptions would be appropriate. Therefore, an analysis excluding interruptions was added.

The number of nCPAP failures through 72 hours in subjects without treatment interruptions is shown in [Figure 8](#). Compared with [Figure 3](#), the rate of intubation was less for the 50 and 100 mg TPL/kg groups, although the rate of intubations for the 75 mg TPL/kg group increased to 100%. It is important to note that most interruptions occurred in the 75 mg TPL/kg group due to having the longest treatment time, and only 3 subjects in this group did not have an interruption.

Figure 8. Intubation Through 72 Hours by Treatment (Subjects without Treatment Interruptions)



Source: Section 14.2, Summary Graph 1.3.2.

The time until nCPAP failure for subjects without treatment interruptions is shown in Table 11-7. The median time until nCPAP failure was longer in each active group and all active combined (8.8 hours) compared to the nCPAP Only group (5.8 hours). The median time for the 75 mg TPL/kg group was the longest at 18 hours, and shortest for the 50 mg TPL/kg at 7.5 hours.

Table 11-7. Time until nCPAP Failure, Without Treatment Interruptions

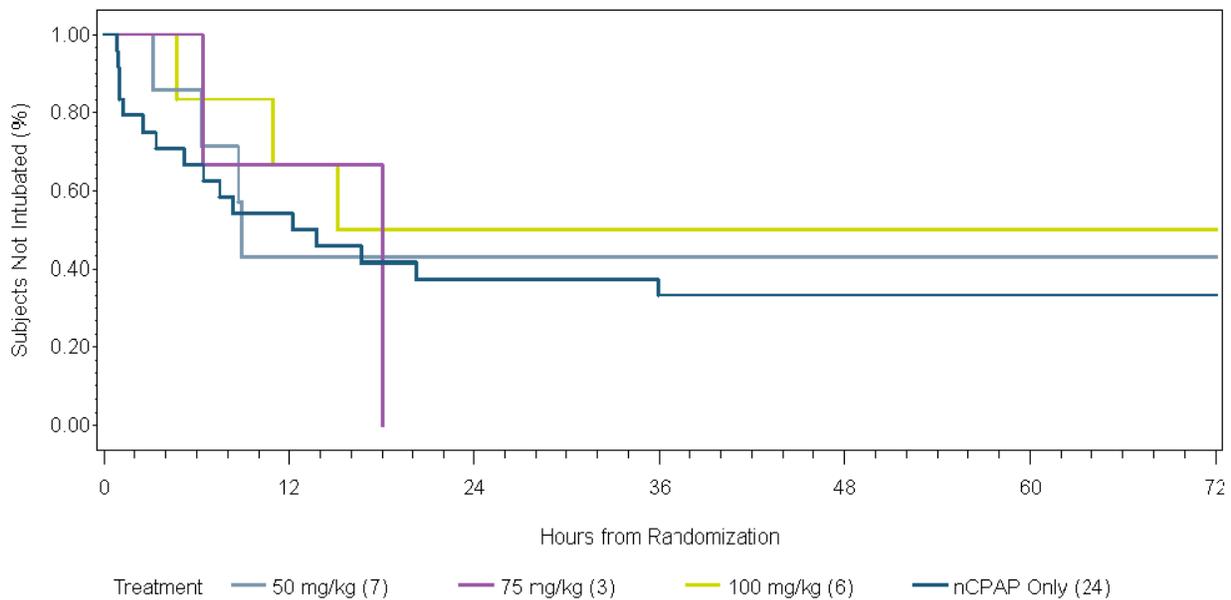
	Statistic	50 mg/kg (N=7)	75 mg/kg (N=3)	100 mg/kg (N=6)	Total Active (N=16)	nCPAP Only (N=24)
Time until nCPAP Failure (hours)	n	4	3	3	10	16
	Mean (SE)	6.8 (1.33)	14.1 (3.87)	10.3 (3.03)	10.0 (1.70)	8.6 (2.38)
	SD	2.66	6.71	5.25	5.37	9.51
	Median	7.5	18.0	11.0	8.8	5.8
	Min, Max	3.2 , 8.9	6.4 , 18.0	4.7 , 15.2	3.2 , 18.0	0.8 , 35.9

Source: Section 14.2, Summary Table 4.3.3.

Figure 9 displays the Kaplan-Meier graph of nCPAP failure for subjects without a treatment interruption. For the 75 mg TPL/kg group, all 3 subjects were intubated by 18 hours; however, the number and rate of intubations were less for both the 50 and 100 mg TPL/kg group, although

the lines for subjects in the 50 mg TPL/kg and the nCPAP Only groups did cross between 10 and 16 hours. Ultimately, the number of intubations for subjects in the 50 and 100 mg TPL/kg treatment groups is fewer compared to the number of subjects in the nCPAP Only group.

**Figure 9. Kaplan-Meier Curve for Time to Intubation
(Subjects without Treatment Interruptions)**



Source: [Section 14.2](#), *Summary Graph 1.2.1*.

11.4.1.5 Technical Performance of the ADS

Usability was found to be acceptable in this phase 2 device, with the only reported issue involving 2 user related assembly problems (at one site) with the aerosol tube set. This issue is believed to be resolved for the next-generation device, which will be verified with a formal usability test.

No incidents of obstructions, loss of inspiratory flow, or inability to maintain nCPAP were reported.

There were 5 reports of “automatic system shutdowns” in the eCRF: 4 for the 75 mg TPL/kg group, 3 for the 100 mg TPL/kg group, and 1 for the 50 mg TPL/kg group for the initial treatment, and 5 for the 75 mg TPL/kg group for a repeat treatment.

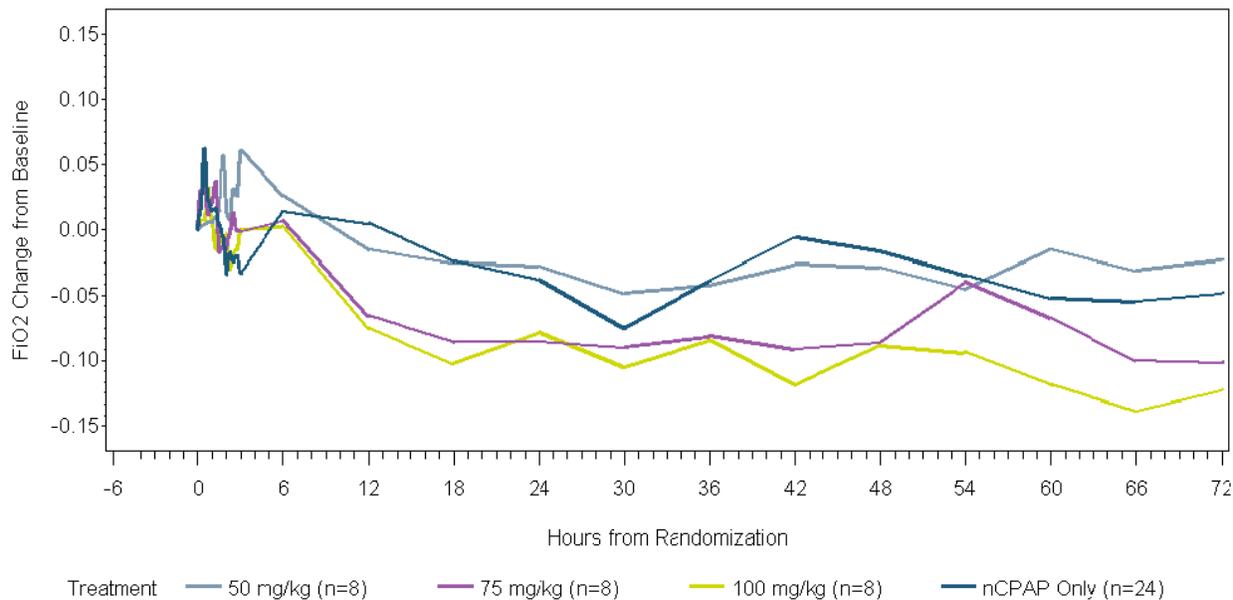
For the initial dose (Section 14.2, Summary Table 5.1.1), study drug leakage was reported 1 time for the 100 mg TPL/kg group as liquid around patient interface. No leakage was reported from the aerosol tubes or ACU.

11.4.1.6 Physiological Measurements

FiO₂ and PCO₂ were recorded every 15 minutes for 72 hours post randomization (subjects in the nCPAP only group). Selected results for FiO₂ and PCO₂ are shown in Figure 10 and Figure 11; complete results can be found in Section 14.3.1, Summary Table 7.5.1 and Summary Table 7.5.2.

Mean baseline values for FiO₂ ranged from 0.31 to 0.37 for the active groups and 0.32 for the control group. Over the 72-hour measurement period, subjects in the 75 and 100 mg TPL/kg treatment groups demonstrated greater decreases than the 50 mg TPL/kg and nCPAP Only treatment groups (Figure 10). These decreases were generally consistent from around 12 hours through 72 hours.

Figure 10. FiO₂ Change from Baseline by Overall Treatment Group (Safety Population)

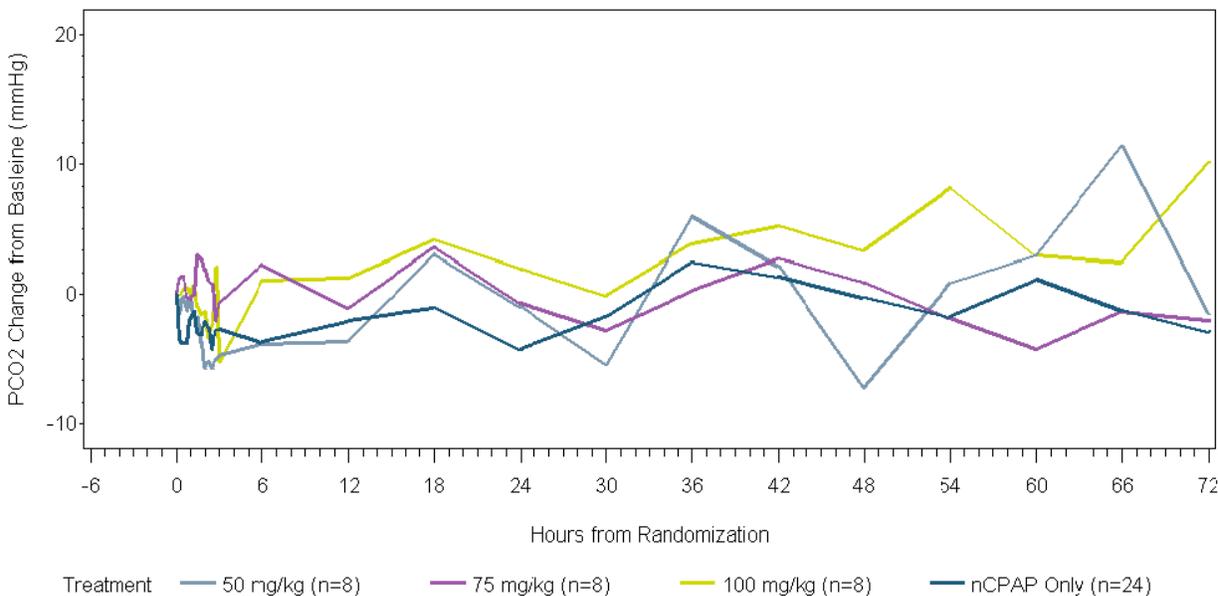


Source: Section 14.2, Summary Graph 2.1.2.

Mean baseline values for PCO₂ were 50.5 mmHg for the control group and ranged from 48.1 to 50.2 mmHg for the active groups. Results for all active groups combined and the nCPAP only group are represented graphically in Figure 11. This figure shows very little change in PCO₂

values over the entire 72-hour period for subjects in both groups, although there may be a slight increase in the 100 mg TPL/kg treatment group.

Figure 11. PCO₂ Change from Baseline by Overall Treatment Group (Intent-to-Treat Population)



Source: [Section 14.2, Summary Graph 2.2.2.](#)

11.4.2 Statistical/Analytical Issues

The statistical analysis plan (SAP), which contains additional analysis and a discussion of any statistical issues, can be found in Appendix 16.1.9. The SAP was approved prior to locking of the database.

11.4.2.1 Adjustments for Covariates

Because no statistical testing was conducted, adjustments for covariates were not applicable.

11.4.2.2 Handling of Dropouts or Missing Data

There were no reported dropouts during this study. All subjects completed the 36 Weeks PMA time point, were discharged or transferred from the hospital, or died. The final visit form was completed for all subjects.

Missing values represent a potential source of bias in a clinical trial. Hence, every effort was undertaken to fulfill all the requirements of the protocol concerning the collection and management of data; however, some missing data is inevitable. Nonetheless, because the primary objective of this study was safety and tolerability, no imputation or adjustment for missing data was done.

11.4.2.3 Interim Analyses and Data Monitoring

Pre-planned interim analyses for the purposes of safety reviews were conducted after completion of enrollment of each dosing group. Because this was an open-label study, there were no unblinding concerns. Also, because no a priori statistical analyses were conducted in this study, no statistical adjustments were necessary.

11.4.2.4 Safety Review Committee

A Safety Review Committee (SRC) was formed (see [Section 6.1](#) for committee membership) to evaluate the degree of risk involved in study subject participation within each dosing group to determine if study continuation in accordance with the current protocol held the potential to institute any undue harm, or threat to the safety and welfare of study subjects. Safety and tolerability data were assessed after enrollment was completed in each dosing group.

11.4.2.5 Multicenter Studies

A total of 15 out of the 22 centers activated enrolled subjects. Centers were located in the US, Canada, Poland, and Chile. Qualitative comparisons were not done and quantitative treatment-by-center interaction tests were not conducted.

11.4.2.6 Multiple Comparisons/Multiplicity

Because the efficacy analysis was exploratory in nature and because no statistical comparisons were performed, no adjustments for multiple comparisons or multiplicity were employed.

11.4.2.7 Use of an “Efficacy Subset” of Patients

No “Efficacy Subset” was used in this study. However, an analysis removing subjects with treatment interruptions was conducted to determine if interruptions adversely affected the exploratory efficacy assessments (see [Section 11.4.1.4](#)).

11.4.2.8 Active-Control Studies Intended to Show Equivalence

The control used in this study, nCPAP only, was not intended to show equivalence. Also, no statistical tests were performed for this study. Thus, confidence interval calculations for the comparison between the 2 treatments were not performed.

11.4.2.9 Examination of Subgroups

The small study sample size did not permit the examination of subgroups.

11.4.3 Tabulations of Individual Response Data

Summary listings for MV information (including discontinuations and restarts) and supplemental oxygen (including discontinuations and restarts) are provided in [Section 14.3](#). Because all data were provided electronically in Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) format, no other hardcopy listings are provided.

11.4.4 Drug Dose, Drug Concentration, and Relationships to Response

This was a dose-escalation study with no more than 8 subjects per active treatment. As a result, robust conclusions about drug/dose in relationship to response are difficult to establish. However, while small and potentially confounded by treatment interruptions, there appears to be a numerically greater reduction in nCPAP failure with increasing dose.

The drug concentration (30 mg TPL/ml) was the same for all subjects, with dose determined by time on therapy.

11.4.5 Drug-Drug and Drug-Disease Interactions

No apparent relationships between response and concomitant therapy or between response and past and/or concurrent illnesses were identified.

11.4.6 By-Subject Displays

Because all data are provided electronically in CDISC SDTM format, no by-subject displays are provided.

11.4.7 Efficacy Conclusions

Efficacy for this study was considered an exploratory analysis. The primary purpose of the efficacy analysis was to determine the feasibility of the efficacy measurements performed and to determine if there was any evidence of aerosol delivery to the lungs; no statistical calculations or comparisons were planned or performed.

Obtaining efficacy measurements proved feasible. Based upon the efficacy results, there was no qualitative evidence on rate of intubation; however, there was some evidence of effect in time to intubation, BPD, and FiO₂ requirements. The magnitude of the effect has not been determined and the study was not powered for comparisons between treatment groups.

In this study, 8 subjects experienced treatment interruptions that impacted study drug delivery, primarily due to a condition identified as “syringe pressure out of range.” Syringe pressure out of range interruptions were unanticipated and have been extensively assessed, Future iterations of the device will mitigate this condition, although other types of interruptions may continue to occur in the future.

Compared with all subjects, the rate of intubation was less for the 50 and 100 mg TPL/kg groups, when the subjects with treatment interruptions were removed. The number and rate of intubations were less for both the 50 and 100 mg TPL/kg group compared to the 75 mg TPL/kg and nCPAP only groups, although the lines for subjects in the 50 mg TPL/kg and the nCPAP only groups did cross between 10 and 16 hours. Ultimately, the number of intubations for subjects in the 50 and 100 mg TPL/kg treatment groups are fewer compared to the number and percent of subjects in the nCPAP only and the 75 mg TPL/kg groups. When lucinactant for inhalation is given as intended without treatment interruption, nCPAP failure and intubations may be reduced.

In summary, obtaining efficacy measurements proved to be feasible, and time to and incidence of intubation may be reasonable efficacy parameters for future studies. Exploratory efficacy assessment suggested that treatment with lucinactant for inhalation may decrease FiO₂, increase time to intubation, and decrease the incidence of BPD in preterm neonates 26 to 28 weeks PMA with RDS.

12. SAFETY EVALUATION

12.1 Extent of Exposure

All subjects randomized received study drug reconstituted to a concentration of 30 mg TPL/ml before aerosolization; dosages were determined by the length of the treatment. Most subjects in the 50 and 100 mg TPL/kg groups received their full treatments; 1 subject in the 50 mg TPL/kg group, 5 in the 75 mg TPL/kg group, and 2 in the 100 mg TPL/kg group did not receive their full treatments, with the most common reason being automatic device shutdown. No terminations were due to a device malfunction, and no terminations resulted in loss of inspiratory flow or inability to maintain nCPAP. See [Section 11.3](#) for details.

After completion of each dose group, the SRC concluded there were no safety concerns that would preclude proceeding to the next higher dose.

12.2 Adverse Events

Information regarding the occurrence of AEs, including ADEs, was assessed from the time of completion of signed ICF until completion of the Final Study Visit.

All AEs were assessed in all subjects throughout the study period (from enrollment to study withdrawal or completion) and documented in the study eCRF. Each AE was reported spontaneously or in response to general, non-directed discussion with the nurse or attending physician (eg, Has there been any change in subject status since the last assessment period?). For each AE, the investigator obtained all information required to complete the AE page of the eCRF, in accordance with eCRF completion guidelines (provided separately by Windtree).

All AEs were followed until resolution or until a stable clinical end-point is reached, or for at least 30 days after the subject's last day in the study if an AE was ongoing at the time the subject completed the study. All measures required for AE management and the ultimate outcome of the AE were recorded in the source document and reported on the AE page of the eCRF.

12.2.1 Brief Summary of Adverse Events

Adverse events were summarized as treatment-emergent adverse events (TEAEs). A TEAE was an AE that occurred after randomization or worsened in severity or frequency after randomization.

[Table 12-1](#) summarizes the overview of TEAEs observed in the safety population by overall treatment group. All subjects experienced at least one AE. Because this was an open-label study, treatment-related events and peri-dosing events are shown only for the active group. Related AEs

were experienced by 9 (38%) subjects and 1 incidence of nasal inflammation and 1 incidence of oxygen desaturation were reported as ADEs. A total of 9 (38%) active subjects and 6 (25%) nCPAP only subjects reported SAEs. Peri-dosing AEs were experienced by 7 (29%) subjects. The number of subjects with air leaks was similar between the active and control treatment groups, and a total of 2 active subjects (and no nCPAP only subjects) died during the study.

Table 12-1: Overview of Adverse Events

Adverse Events	Total Active (N=24)	nCPAP Only (N=24)
Subjects with a TEAE	24 (100%)	24 (100%)
Subjects with related AEs ^a	9 (38%)	0
Subjects with an ADE	2 (8%)	0
Subjects with a serious AE	9 (38%)	6 (25%)
Subjects with a peri-dosing AE ^b	7 (29%)	0
Subjects with an air leak	5 (21%)	4 (17%)
Subjects who discontinued due to an AE	0	0
Subjects who had died	2 (8%)	0

^a For AEs categorized as “Possibly Related” and “Related.”

^b Initial treatment.

Source: [Section 14.3.1](#), *Summary Tables 6.1.1, 6.2, 6.3.1, 6.3.3, 6.4.1, 6.5.1, and 6.6.*

AEs of special interest included bradycardia, desaturation, sustained apnea, complications related to placement of bi-nasal prongs, and air leak (especially pneumothorax) if they occurred within the primary observation period. Details are provided in [Section 12.3.1.3](#).

12.2.2 Display of Adverse Events

12.2.2.1 Peri-Dosing Adverse Events

Peri-dosing AEs were defined as AEs with an onset time ≤ 2 hours from the time of initiating administration of lucinactant for inhalation and are presented by treatment in [Table 12-2](#). Specific, predefined peri-dosing events included bradycardia, desaturation, apnea, pallor, gagging/regurgitation, and complications related to placement of bi-nasal prongs (ie, bleeding, nares obstruction, prongs occlusion, nasal irritation). Because nCPAP only subjects did not receive placebo or active comparator, and this was an open-label study, there were no peri-dosing events experienced by subjects in this group.

For peri-dosing events not involving the nasal prongs, 7 subjects in the total active group experienced peri-dosing events for the initial dose; these events included bradycardia (3 [13%])

subject), desaturation (6 [25%] subjects), and apnea (3 [13%] subjects). Peri-dosing events occurred in all dosage groups. For the repeat dose (Summary Table 6.1.2), only 2 incidences of desaturation for the 100 mg TPL/kg group were reported.

Table 12-2. Peri-Dosing Adverse Events, Initial Dose (Safety Population)

	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)
Any Event	1 (13%)	3 (38%)	3 (38%)	7 (29%)
Bradycardia	0	2 (25%)	1 (13%)	3 (13%)
Desaturation	1 (13%)	2 (25%)	3 (38%)	6 (25%)
Gagging/Regurgitation	0	0	0	0
Apnea	1 (13%)	1 (13%)	1 (13%)	3 (13%)
Pallor	0	0	0	0

Note: Percentages are based on the total number of subjects in each treatment group.

Note: Because nCPAP only subjects did not receive placebo or active comparator, there were no peri-dosing events experienced by subjects in this group.

Source: [Section 14.3.1](#), *Summary Table 6.1.1*.

No subjects reported complications related to the placement of bi-nasal prongs during the dosing period.

12.2.2.2 Adverse Device Effects

There were 2 ADEs reported in this study (see [Section 14.3.1](#), Summary Tables 6.5.1 and Summary Listing 2.4); neither event was considered serious. One involved a report of nasal inflammation (50 mg TPL/kg), considered unrelated to study treatment, and 1 report of oxygen desaturation (100 mg TPL/kg group), considered related to study treatment. Both events were considered mild.

12.2.2.3 Other Treatment-Emergent Adverse Events

TEAEs are summarized by the MedDRA preferred term and system organ class (SOC) by treatment group. TEAEs experienced by greater than 15% of subjects are summarized by SOC and treatment group in [Table 12-3](#). Most TEAEs were consistent between active and nCPAP only, with no differences exceeding 4 subjects in either direction, with the exception of retinopathy of prematurity (4 [17%] subjects in the total active group and 9 [38%] subjects in the nCPAP only group) and dermatitis diaper (7 [29%] subjects and 1 [4%] subjects for total active and nCPAP only, respectively).

Table 12-3. Treatment-Emergent AEs by System Organ Class and Preferred Term Events Experienced by > 15% of Active or nCPAP Only Subjects

System Organ Class(SOC) Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Any Event	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
Blood and lymphatic system disorders	6 (75%)	4 (50%)	2 (25%)	12 (50%)	13 (54%)
Anaemia neonatal	6 (75%)	4 (50%)	2 (25%)	12 (50%)	13 (54%)
Thrombocytopenia	2 (25%)	2 (25%)	0 (0%)	4 (17%)	4 (17%)
Congenital, familial and genetic disorders	3 (38%)	4 (50%)	4 (50%)	11 (46%)	11 (46%)
Patent ductus arteriosus	3 (38%)	3 (38%)	4 (50%)	10 (42%)	10 (42%)
Gastrointestinal disorders	6 (75%)	5 (63%)	1 (13%)	12 (50%)	6 (25%)
Constipation	5 (63%)	0 (0%)	1 (13%)	6 (25%)	2 (8%)
Infections and infestations	4 (50%)	4 (50%)	3 (38%)	11 (46%)	9 (38%)
Pneumonia	0 (0%)	2 (25%)	0 (0%)	2 (8%)	4 (17%)
Sepsis neonatal	2 (25%)	1 (13%)	1 (13%)	4 (17%)	4 (17%)
Investigations	3 (38%)	5 (63%)	7 (88%)	15 (63%)	11 (46%)
Oxygen saturation decreased	2 (25%)	4 (50%)	6 (75%)	12 (50%)	9 (38%)
Metabolism and nutrition disorders	7 (88%)	4 (50%)	1 (13%)	12 (50%)	12 (50%)
Feeding intolerance	3 (38%)	1 (13%)	1 (13%)	5 (21%)	1 (4%)
Hypernatraemia	1 (13%)	2 (25%)	0 (0%)	3 (13%)	4 (17%)
Hyponatraemia	3 (38%)	0 (0%)	0 (0%)	3 (13%)	7 (29%)
Metabolic acidosis	3 (38%)	0 (0%)	0 (0%)	3 (13%)	5 (21%)
Pregnancy, puerperium and perinatal conditions	6 (75%)	8 (100%)	7 (88%)	21 (88%)	22 (92%)
Bradycardia neonatal	0 (0%)	5 (63%)	3 (38%)	8 (33%)	9 (38%)
Intraventricular haemorrhage neonatal	0 (0%)	1 (13%)	3 (38%)	4 (17%)	3 (13%)
Jaundice neonatal	5 (63%)	3 (38%)	1 (13%)	9 (38%)	11 (46%)
Neonatal respiratory distress syndrome	1 (13%)	4 (50%)	2 (25%)	7 (29%)	10 (42%)
Retinopathy of prematurity	2 (25%)	1 (13%)	1 (13%)	4 (17%)	9 (38%)
Respiratory, thoracic and mediastinal disorders	8 (100%)	5 (63%)	7 (88%)	20 (83%)	23 (96%)
Apnoea neonatal	7 (88%)	4 (50%)	6 (75%)	17 (71%)	19 (79%)
Bronchopulmonary dysplasia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	7 (29%)
Nasal discomfort	2 (25%)	2 (25%)	0 (0%)	4 (17%)	3 (13%)
Pulmonary interstitial emphysema syndrome	3 (38%)	0 (0%)	1 (13%)	4 (17%)	3 (13%)
Skin and subcutaneous tissue disorders	4 (50%)	2 (25%)	1 (13%)	7 (29%)	3 (13%)
Dermatitis diaper	4 (50%)	2 (25%)	1 (13%)	7 (29%)	1 (4%)
Vascular disorders	1 (13%)	3 (38%)	0 (0%)	4 (17%)	6 (25%)
Hypotension	1 (13%)	2 (25%)	0 (0%)	3 (13%)	4 (17%)

Source: [Section 14.3.1](#), [Summary Table 6.3.1](#).

Adverse events for subjects without treatment interruptions are shown in [Section 14.3.1](#), [Summary Table 6.3.1.1](#). Nearly all percentages for the AEs were the same or within a few percentage points compared to [Summary Table 6.3.1](#). Thus, no meaningful difference was noted for these subjects compared to the entire safety population.

Adverse events by treatment group for events with moderate or severe intensity, for those events that occurred in at least 10% in either intensity for subjects in either total active or nCPAP only groups, are presented in Table 12-4. The complete summary for AEs with severity level is presented in [Section 14.3.1](#), Summary Table 6.3.2. No clinical relevant differences were noted for any comparisons of subjects in the active groups with those in the nCPAP only group, although a higher number of subjects (at least 3 subjects) for nCPAP only were noted for neonatal anemia, PDA, and BPD. The most common moderate and severe intensity AEs were neonatal RDS and PDA.

Table 12-4. TEAEs of Moderate or Severe Intensity by Treatment Group Experienced by > 10% of Subjects in any Column (Safety Population)

System Organ Class (SOC) Preferred Term	Total Active (N=24)		nCPAP Only (N=24)	
	Moderate	Severe	Moderate	Severe
Any Event	12 (50%)	6 (25%)	10 (42%)	7 (29%)
Blood and lymphatic system disorders	1 (4%)	0 (0%)	5 (21%)	0 (0%)
Anaemia neonatal	0 (0%)	0 (0%)	4 (17%)	0 (0%)
Congenital, familial and genetic disorders	2 (8%)	0 (0%)	6 (25%)	0 (0%)
Patent ductus arteriosus	2 (8%)	0 (0%)	6 (25%)	0 (0%)
Infections and infestations	7 (29%)	1 (4%)	7 (29%)	0 (0%)
Pneumonia	2 (8%)	0 (0%)	4 (17%)	0 (0%)
Pregnancy, puerperium, & perinatal conditions	4 (17%)	3 (13%)	8 (33%)	5 (21%)
Neonatal respiratory distress syndrome	4 (17%)	0 (0%)	3 (13%)	3 (13%)
Respiratory, thoracic, & mediastinal disorders	6 (25%)	1 (4%)	9 (38%)	4 (17%)
Apnoea neonatal	2 (8%)	0 (0%)	3 (13%)	0 (0%)
Bronchopulmonary dysplasia	0 (0%)	0 (0%)	3 (13%)	1 (4%)
PIE syndrome	3 (13%)	0 (0%)	2 (8%)	0 (0%)
Vascular disorders	2 (8%)	0 (0%)	4 (17%)	1 (4%)
Hypotension	2 (8%)	0 (0%)	4 (17%)	0 (0%)

Source: [Section 14.3.1](#), *Summary Table 6.3.2*.

Study treatment-related TEAEs by treatment group are presented in [Section 14.3.1](#), Summary Table 6.3.3, for all events. Because nCPAP only control subjects did not receive placebo or active comparator, there are no related events for this group. There were 8 (33%) subjects in the total active group with TEAEs possibly related and 1 (4%) subjects with TEAEs related to study drug. The events experienced by more than 1 subject included desaturation (5 [21%] subjects possibly related and 1 [4%] subject related), neonatal bradycardia (3 [13%] subjects possibly

related), neonatal apnea (4 [17%] subjects possibly related), and PIE syndrome (2 [8%] subjects possibly related).

12.2.3 Analysis of Adverse Events

All subjects experienced at least 1 TEAE. The most common TEAEs were neonatal apnea, neonatal anemia, desaturation, PDA, neonatal jaundice, neonatal bradycardia, neonatal RDS, diaper dermatitis, and constipation. No other TEAE was experienced by more than 5 subjects in either treatment group, with the exception of retinopathy of prematurity and hyponatremia, which also occurred in greater than 5 subjects in the nCPAP only group ([Section 14.3.1](#), Summary Table 6.3.5). Most TEAEs were consistent between active and nCPAP only groups, with no differences exceeding 4 subjects in either direction, except for retinopathy of prematurity, which was experienced by 4 subjects in the active group and 9 subjects in the nCPAP only group. The number of subjects with air leaks, which were an AE of special interest, was similar between active and nCPAP only subjects (see [Section 12.3.1.3.2](#)).

Overall, there were no TEAEs that would be considered unusual in this population. The incidence of TEAEs for the active groups compared with the nCPAP only groups was similar, and the incidence of TEAEs remained steady as dose increased ([Section 14.3.1](#), Summary Table 6.3.1, Summary Table 6.3.2, Summary Table 6.3.3, Summary Table 6.3.5, Summary Table 6.4.1, and Summary Table 6.5.1).

12.2.4 Listing of Adverse Events by Patient

In lieu of providing hard-copy AE listings by subject, Windtree is submitting electronic datasets that conform to the CDISC SDTM; the required AE tabulation data are contained in the AE dataset. The submission of electronic data fulfills the requirement for AE listings since, as stated in the CDISC SDTM Implementation Guide (version 3.2, 26 November 2013), “by submitting tabulations that conform to the standard structure, sponsors may benefit by no longer having to submit separate subject profiles or listings with a product marketing application.”

12.3 Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

12.3.1 Listing of Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

12.3.1.1 Deaths

There were 2 deaths reported in this study, 1 in the 50 mg TPL/kg group (NEC and bowel perforation) and 1 in the 75 mg TPL/kg group (pneumoperitoneum) ([Section 14.3.1](#), Summary Table 6.6 and [Section 14.3.2](#), Summary Listing 2.1.).

12.3.1.2 Other Serious Adverse Events

There were SAEs experienced by 9 (38%) subjects in the active group and 6 (25%) in the nCPAP only group. There were no differences greater than 1 between the active and nCPAP only treatment groups in the number of subjects with an SAE ([Section 14.3.1](#), Summary Table 6.4.1, and [Section 14.3.2](#), Summary Listing 2.2).

12.3.1.3 Other Significant Adverse Events

12.3.1.3.1 Adverse Events of Special Interest

AEs of special interest were defined as the following AEs if they occurred within the primary observation period: bradycardia (heart rate < 100 bpm for ≥ 20 seconds), desaturation (defined as SpO₂ < 80% for ≥ 20 seconds), sustained apnea (≥ 20 seconds), air leak (including pneumothorax and pneumomediastinum), and complications related to placement of bi-nasal prongs. Except for air leaks, these AEs constitute peri-dosing events, which are discussed in [Section 12.2.2.1](#). Air leaks are discussed below in [Section 12.3.1.3.2](#).

12.3.1.3.2 Air Leaks

The incidence of air leaks, either combined or individually, in active and nCPAP only groups was similar ([Table 12-5](#)) (see also [Section 14.3.1](#), Summary Table 6.2). Overall, 5 (21%) of active subjects experienced an air leak, of whom 2 had pneumothorax and 4 had pulmonary interstitial emphysema (PIE). In the nCPAP only group, 4 (17%) subjects were reported by the investigator as having air leak, 3 (13%) each with pneumothorax and PIE. The number of air leaks was similar for the 50 and 100 mg TPL/kg groups, while no subjects in the 75 mg TPL/kg group experienced an air leak.

Table 12-5. Number of Subjects with Air Leaks (Safety Population)

	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Total Subjects with Air Leaks ¹	3 (38%)	0 (0%)	2 (25%)	5 (21%)	4 (17%)
Pneumothorax	1 (13%)	0 (0%)	1 (13%)	2 (8%)	3 (13%)
PIE	3 (38%)	0 (0%)	1 (13%)	4 (17%)	3 (13%)

¹ Subjects may have had more than one type of air leak.

PIE = pulmonary interstitial emphysema.

Source: [Section 14.3.1](#), *Summary Table 6.2*.

12.3.2 Narratives of Deaths, Other Serious Adverse Events, and Certain Other Significant Adverse Events

Subjects who experienced SAEs are listed with the preferred term, severity, relationship, and outcome in [Table 12-6](#). Narratives can be found in [Section 14.3.3](#), and CRFs are provided in Appendix 16.3. A total of 29 SAEs were experienced by 15 subjects. The SAE for Subject 01040 (pneumothorax) was considered possibly related to study drug treatment; no other SAEs were considered possibly related or related to study treatment. Two deaths occurred during the course of the study (see [Section 12.3.3](#)). Subject 40001 (50 mg TPL/kg), Subject 11021 (100 mg TPL/kg), and Subjects 19004, 54017, 76002 (all nCPAP only) experienced SAEs that were still continuing at the end of the study; all other SAEs had recovered.

Table 12-6. Subjects with SAEs (Safety Population)

Treatment	Subject ID	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
50 mg/kg	01040	Pneumothorax	Left Pneumothorax	13JUN2016	18JUN2016	Moderate	Possibly	Recovered
	09001	Sepsis neonatal	CONS septicemia	21MAY2016	07JUN2016	Severe	Not Rel.	Recovered
	12014	NEC neonatal	NEC	05JUN2016	06JUN2016	Severe	Not Rel.	Died
	40001	Intestinal perforation	Spontaneous Intestinal perforation	07MAY2016	*	Severe	Unlikely	Continuing
75 mg/kg	11011	Pneumoperitoneum	pneumoperitoneum	04SEP2016	09SEP2016	Severe	Unlikely	Died
	50001	Neonatal RDS	Respiratory Failure	28SEP2016	03OCT2016	Moderate	Unlikely	Recovered
		Neonatal respiratory failure	Respiratory failure	13OCT2016	23OCT2016	Moderate	Not Rel.	Recovered
	51004	Pneumonia	Ventilator-associated pneumonia (VAP)	03AUG2016	17AUG2016	Moderate	Not Rel.	Recovered
		Neonatal RDS	respiratory failure	26JUL2016	03SEP2016	Moderate	Not Rel.	Recovered
100 mg/kg	11021	IVH neonatal	intraventricular hemorrhage	06NOV2016	*	Severe	Unlikely	Continuing
		Pneumothorax	pneumothorax	06NOV2016	15NOV2016	Severe	Unlikely	Recovered
	40015	IVH neonatal	Intraventricular Haemorrhage	23JAN2017	13MAR2017	Severe	Unlikely	Recovered
nCPAP only	11006	Pneumothorax	pneumothorax	07JUN2016	07JUN2016	Severe	Not Rel.	Recovered
	12006	Cardiac arrest	Cardiac Arrest	03MAR2016	03MAR2016	Severe	Not Rel.	Recovered
		Gastric perforation	Gastric perforation	03MAR2016	30MAR2016	Severe	Not Rel.	Recovered
		Neonatal respiratory failure	Hypoxic respiratory failure	03MAR2016	23MAR2016	Severe	Not Rel.	Recovered
		Traumatic liver injury	Liver laceration	03MAR2016	08MAR2016	Severe	Not Rel.	Recovered
		Hepatic haemorrhage	liver hemorrhage	03MAR2016	30MAR2016	Severe	Not Rel.	Recovered
		12010	Intestinal perforation	Bowel Perforation	24APR2016	16MAY2016	Severe	Not Rel.
	Laryngeal injury		Laryngeal Trauma Due to Intubation	18MAR2016	29MAR2016	Severe	Not Rel.	Recovered

Table 12-6. Subjects with SAEs (Safety Population)

Treatment	Subject ID	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	19004	NEC neonatal	Necrotizing Enterocolitis	01NOV2016	*	Severe	Not Rel.	Continuing
		Cardio-respiratory arrest	severe Bradycardia	31OCT2016	31OCT2016	Severe	Not Rel.	Recovered
	54017	Anaemia neonatal	anaemia	13DEC2016	*	Moderate	Not Rel.	Continuing
		Apnoea neonatal	apneas	07DEC2016	10DEC2016	Moderate	Not Rel.	Recovered
		Pneumonia	pneumonia	12DEC2016	22DEC2016	Moderate	Not Rel.	Recovered
		Neonatal RDS	worsening respiratory effort need of intubation	26NOV2016	26NOV2016	Severe	Not Rel.	Recovered
	76002	IVH neonatal	intraventricular hemorrhage	22DEC2016	*	Severe	Not Rel.	Continuing
		Pneumothorax	pneumothorax	21DEC2016	21DEC2016	Severe	Not Rel.	Recovered
		Shock	refractory shock	30DEC2016	03JAN2017	Severe	Not Rel.	Recovered

Source: [Section 14.3.2](#), *Summary Listing 2.2*.

12.3.3 Analysis and Discussion of Deaths, Other Serious Adverse Events, and Other Significant Adverse Events

Two deaths, one as a result of NEC with bowel perforation (Subject 12014, 50 mg TPL/kg) and one as a result of pneumoperitoneum (Subject 11011, 75 mg TPL/kg), occurred during the course of the study.

Neither death was considered related to study drug and neither occurred within 24 hours of study drug treatment. Narratives for these subjects are provided in [Section 14.3.3](#), and CRFs are provided in Appendix 16.3.

Air leak, in particular pneumothorax, was an AE of particular interest in this study (see [Section 12.3.1.3.2](#)). Because the various manifestations of air leak are pathophysiologically similar, it is reasonable to group them together for purposes of analysis. Further, seriousness of these air leaks generally was associated with management rather than severity; eg, pneumothoraces managed with a chest tube were generally reported as serious due to the additional intervention of the chest tube, whereas those managed conservatively with needle decompression were generally not reported as serious. The overall incidence of air leak was similar between active and nCPAP only subjects and occurred at a similar rate as dose increased.

12.4 Clinical Laboratory Evaluation

Serum electrolytes were measured 24 hours after randomization for all subjects. The results shown in [Table 12-7](#) demonstrate no clinically relevant differences between any active group and the nCPAP only group.

Table 12-7. Serum Electrolytes (Safety Population) 24 Hours After Randomization

Type	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Sodium (mEq/L)	n	8	8	8	24	24
	Mean (SE)	139.0 (2.25)	141.8 (2.37)	141.5 (1.18)	140.8 (1.14)	140.4 (1.21)
	Median	139.0	144.0	142.0	142.0	139.5
	Min, Max	128 , 148	128 , 149	136 , 146	128 , 149	130 , 150
Chloride (mEq/L)	n	8	8	8	24	23
	Mean (SE)	106.5 (1.24)	110.3 (2.50)	107.8 (1.08)	108.2 (1.01)	109.7 (1.81)
	Median	106.5	112.5	108.0	108.5	109.0
	Min, Max	102 , 112	94 , 118	103 , 112	94 , 118	98 , 141
Potassium (mEq/L)	n	8	8	7	23	24
	Mean (SE)	4.23 (0.103)	4.08 (0.323)	4.11 (0.378)	4.14 (0.157)	4.58 (0.200)
	Median	4.15	3.95	4.10	4.10	4.50
	Min, Max	3.8 , 4.8	2.9 , 5.5	2.6 , 5.7	2.6 , 5.7	3.0 , 6.6
Total CO ₂ (mEq/L)	n	8	8	5	21	21
	Mean (SE)	21.0 (1.21)	21.6 (0.61)	27.9 (6.77)	22.9 (1.68)	22.3 (1.25)
	Median	21.5	21.2	21.7	21.3	22.0
	Min, Max	13 , 24	19 , 24	20 , 55	13 , 55	15 , 44

Source: [Section 14.3.1](#), *Summary Table 7.2*.

12.4.1 Listing of Individual Laboratory Measurements by Patient and Each Abnormal Laboratory Value

In lieu of providing hard-copy listings by subject, Windtree is submitting electronic datasets that conform to the CDISC SDTM. The submission of electronic data fulfills the requirement for laboratory listings.

12.4.2 Evaluation of Each Laboratory Parameter

Because the only laboratory results are post-randomization electrolyte values and because there were no unexpected results, the detailed analyses that are typical for this section were not performed.

12.5 Vital Signs, Physical Findings, and Other Observations Related to Safety

12.5.1 Physical Examination Findings

Physical examination results from screening and final visit are presented in [Section 14.3.1](#), Summary Table 7.4.1. A shift table of physical examination results comparing screening to the final evaluation is presented in [Table 12-8](#) and [Section 14.3.1](#), Summary Table 7.4.2.

Table 12-8. Physical Examination Shift Table (Safety Population)

Organ System	Final Visit	Screening			
		Total Active (N=24)		nCPAP Only (N=24)	
		Normal	Abnormal	Normal	Abnormal
Abdominal	Normal	17 (71%)	2 (8%)	20 (83%)	1 (4%)
	Abnormal	3 (13%)	1 (4%)	2 (8%)	1 (4%)
Cardiac	Normal	19 (79%)	1 (4%)	20 (83%)	0 (0%)
	Abnormal	3 (13%)	0 (0%)	4 (17%)	0 (0%)
Extremities	Normal	18 (75%)	1 (4%)	17 (71%)	4 (18%)
	Abnormal	1 (4%)	0 (0%)	1 (5%)	0 (0%)
General Appearance (Skin)	Normal	16 (67%)	6 (25%)	12 (52%)	6 (26%)
	Abnormal	0 (0%)	0 (0%)	2 (9%)	3 (13%)
Genitalia and Perineum	Normal	19 (79%)	0 (0%)	17 (74%)	3 (13%)
	Abnormal	1 (4%)	1 (4%)	3 (13%)	0 (0%)
Head, Neck, Mouth	Normal	21 (88%)	0 (0%)	22 (92%)	1 (4%)
	Abnormal	1 (4%)	0 (0%)	0 (0%)	1 (4%)
Neurological	Normal	21 (88%)	0 (0%)	20 (83%)	2 (8%)
	Abnormal	2 (8%)	0 (0%)	2 (8%)	0 (0%)
Respiratory	Normal	2 (8%)	19 (79%)	1 (4%)	15 (63%)
	Abnormal	0 (0%)	2 (8%)	1 (4%)	7 (29%)

Note: Percentages calculated from the total number of responses for each category.

Source: [Section 14.3.1](#), [Summary Table 7.4.2](#).

The number of subjects in the upper right-hand corner of each 2x2 table shows the number of subjects that started abnormal and ended normal, whereas the lower left-hand corner (shaded) shows the number of subjects that started normal and ended abnormal. Thus, the upper right-hand corner indicates improvement, whereas the lower left-hand corner indicates worsening. For example, for the abdominal system category for Total Active, the upper right-

hand corner indicates that 2 subjects improved (started abnormal but ended normal), and the lower left-hand corner indicates that 3 subjects worsened (started normal but ended abnormal).

The largest changes occurred in the respiratory system, where both total active and nCPAP only showed a majority of subjects having improved. In all cases, changes were similar between total active and nCPAP only subjects. Overall, there were no clear treatment-related trends observed in physical examination findings or changes from baseline.

12.5.2 Vital Signs

Vital signs measurements were taken as described in [Section 9.5.1.3.2](#).

Results for vital signs are presented in [Section 14.3.1](#), Summary Table 7.1.1 to 7.1.3, and Summary Figures 3.1.1 to 3.3.2. In addition, results for change from baseline values are presented in [Figure 12](#), [Figure 13](#), and [Figure 14](#). There were no meaningful differences for temperature, respiratory rate, or heart rate at any of the selected time points.

Figure 12. Body Temperature – Change from Baseline Values (Safety Population)

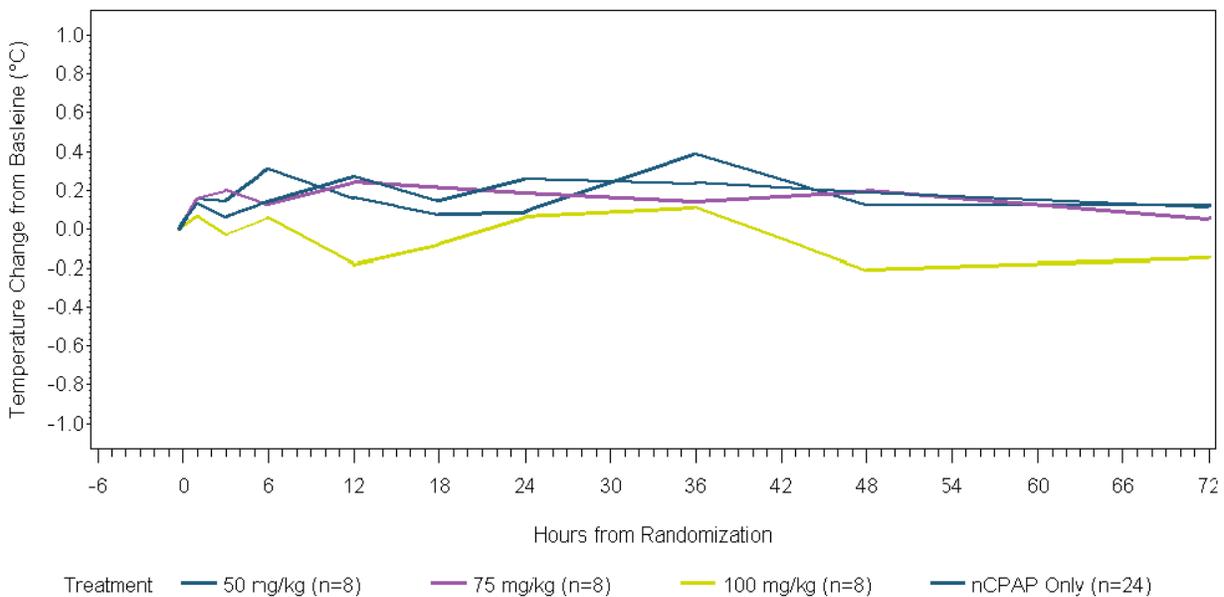


Figure 13. Spontaneous Respirations – Change from Baseline Values (Safety Population)

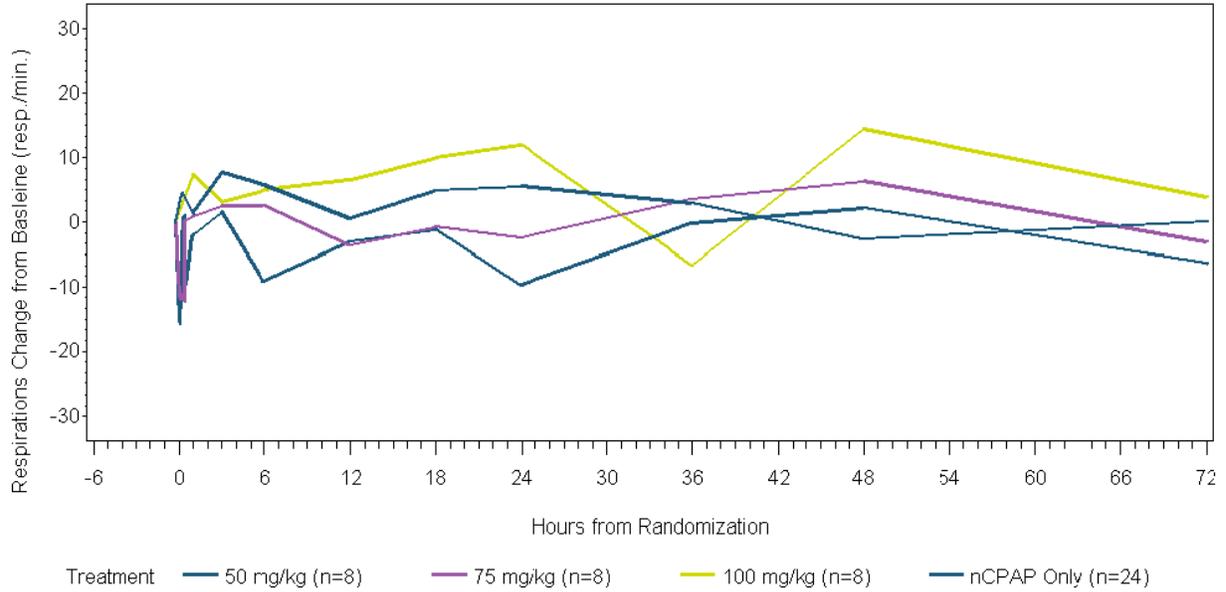
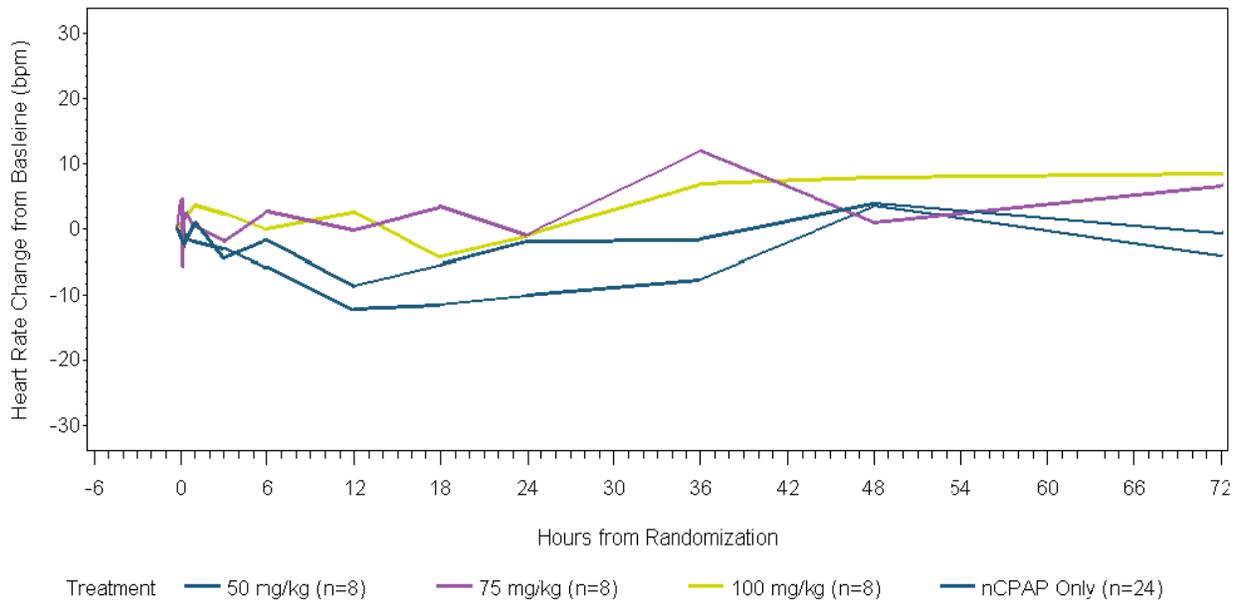


Figure 14. Heart Rate – Change from Baseline Values (Safety Population)



12.5.3 Gastric Liquid Volume and Defecation

The amount of gastric liquid post-dose administration and the number of defecations in the first 24 hours of life are shown in [Table 12-9](#) and are summarized in [Section 14.3.1](#), Summary Table 7.3. For the 50 and 100 mg TPL/kg doses, the gastric liquid volume had a median value of 0.0 ml; for the 75 mg TPL/kg dose, the median value was 0.75 ml. This value was half the maximum median value noted in the 03-CL-1201 study and was not considered clinically meaningful.

The number of defecations remained fairly consistent over the doses, which were similar to the number of defecations for subjects in the nCPAP only group.

Table 12-9. Gastric Liquid Volume Post-Dose Administration and Number of Defecations

	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
30 Minutes Post Dosing (ml)	n	8	8	7	23	N/A
	Mean (SE)	0.32 (0.277)	0.94 (0.467)	0.76 (0.558)	0.67 (0.248)	N/A
	Median	0.00	0.75	0.00	0.00	N/A
	Min, Max	0 , 2	0 , 4	0 , 4	0 , 4	N/A
30 Minutes Post Dosing (ml) - Repeat Dose	n	4	7	5	16	N/A
	Mean (SE)	0.00 (0.000)	0.99 (0.683)	0.64 (0.591)	0.63 (0.348)	N/A
	Median	0.00	0.40	0.00	0.00	N/A
	Min, Max	0 , 0	0 , 5	0 , 3	0 , 5	N/A
Number of Stools	n	8	8	8	24	24
	Mean (SE)	0.8 (0.25)	0.8 (0.41)	1.4 (0.73)	1.0 (0.29)	1.2 (0.29)
	Median	1.0	0.0	0.0	0.0	1.0
	Min, Max	0 , 2	0 , 3	0 , 5	0 , 5	0 , 5

12.5.4 Clinical Assessments: Respiratory Parameters

The number of subjects that received respiratory support in the delivery room (DR) and the use of mechanical ventilation are presented in [Table 12-10](#). Just under half of subjects in both total active and nCPAP only groups received respiratory support in the DR. The mean time on MV was, in general, slightly less for active treatments compared to nCPAP only; however, the median times were slightly higher for all treatments, at 6.9 days for total active compared to 4.8 days for nCPAP only. More than half of active subjects used SIMV, with MFV and volume ventilation also used. For nCPAP only subjects, modes of SIMV, HFV, volume ventilation, and

“other” modes were used. At initiation of MV, there was little difference between total active and nCPAP only in mean airway pressure (MAP) and FiO₂ values.

Table 12-10. Respiratory Support in the Delivery Room and Mechanical Ventilation

Assessment	Statistic	Lucinactant for Inhalation				nCPAP Only (N=24)
		50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	
Respiratory Support in DR ¹	n (%)	5 (63%)	3 (38%)	3 (38%)	11 (46%)	11 (46%)
Number of Subjects on MV						
Primary Period	n (%)	5 (63%)	6 (75%)	5 (63%)	16 (67%)	11 (46%)
Extended Period	n (%)	4 (50%)	5 (63%)	5 (63%)	14 (58%)	11 (46%)
Time on MV (Days)						
	n	7	7	6	20	14
	Mean (SE)	6.1 (1.61)	7.9 (3.19)	15.8 (10.87)	9.7 (3.41)	14.9 (4.84)
	Median	7.4	7.2	6.2	6.9	4.8
	Min, Max	0.1 , 11.1	-5.5 , 18.8	1.4 , 69.8	-5.5 , 69.8	-0.7 , 64.0
Initial Mode						
SIMV	n (%)	6 (75%)	5 (63%)	3 (38%)	14 (58%)	5 (21%)
HFV	n (%)	0 (0%)	1 (13%)	2 (25%)	3 (13%)	1 (4%)
Volume Ventilation	n (%)	1 (13%)	0 (0%)	1 (13%)	2 (8%)	3 (13%)
AC	n (%)	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
IMV	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	5 (21%)
At Initiation						
FiO ₂						
	n	6	7	6	19	13
	Mean (SE)	0.37 (0.061)	0.43 (0.049)	0.39 (0.057)	0.40 (0.031)	0.56 (0.071)
	Median	0.33	0.40	0.38	0.40	0.50
	Min, Max	0.23 , 0.59	0.25 , 0.63	0.21 , 0.6	0.21 , 0.63	0.21 , 1
MAP (cmH ₂ O)						
	n	5	7	6	18	13
	Mean (SE)	8.40 (1.208)	8.71 (0.747)	9.17 (0.749)	8.78 (0.482)	9.38 (0.572)
	Median	8.00	8.00	10.00	8.00	8.00
	Min, Max	6 , 13	7 , 12	6 , 11	6 , 13	7 , 14

Source: [Section 14.3.1](#), *Summary Table 7.6.1*

¹ Short-term positive pressure ventilation in the delivery room.

The number of subjects without a treatment interruption that received respiratory support in the delivery room (DR) and the use of mechanical ventilation are presented in [Section 14.3.1](#), *Summary Table 7.3*. Compared to the entire safety population, there were fewer subjects who received MV (16 vs. 13) and the time on MV was shorter (6.9 vs. 5.8 days); no other meaningful changes were noted.

Values for FiO₂, MAP, and respiration rates for subjects on MV from Day 1 to Day 7 (at 08:00 and 20:00) are presented in [Section 14.3.1](#), Summary Table 7.6.2. In general, FiO₂ values tended to be lower in the active treatments compared to control, especially at earlier timepoints. No consistent differences were noted for MAP or respiration rates.

The number of subjects and information on other supplemental oxygen (FiO₂ > 21%, not delivered via bubble CPAP or MV) is presented in [Table 12-11](#). No subjects received supplemental oxygen in the primary or extended period (through Day 7) for active or control groups. Through the end of the study, a total of 11 active subjects and 3 nCPAP only subjects received supplemental oxygen (no subjects in the 100 mg TPL/kg group received supplemental oxygen at any time). The total time on supplemental oxygen was slightly less for the active treatments compared to control (median of 8.5 days for total active vs. 14.0 days for nCPAP only). At initiation of supplemental oxygen, there was no perceived difference between active and control.

Table 12-11. Supplemental Oxygen

Statistic	Lucinactant for Inhalation				nCPAP	
	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	Only (N=24)	
No. of Subj. on Suppl. O₂						
Primary Period	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Extended Period	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Time on Suppl. Oxygen (Days)						
	n	7	4	0	11	3
	Mean (SE)	6.4 (3.12)	8.3 (3.16)	0 (0)	7.1 (2.21)	10.4 (5.28)
	Median	8.5	8.6	0	8.5	14.0
	Min, Max	-8.1 , 15.7	0.7 , 15.3	0, 0	-8.1 , 15.7	0.0 , 17.2
Initial Mode						
Nasal Cannula	n (%)	7 (88%)	3 (38%)	0 (0%)	10 (42%)	4 (17%)
Oxyhood	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other	n (%)	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
At Initiation						
FiO ₂	n	6	4	0	10	4
	Mean (SE)	0.26 (0.009)	0.44 (0.188)	0 (0)	0.33 (0.075)	0.28 (0.014)
	Median	0.25	0.25	0	0.25	0.28
	Min, Max	0.24 , 0.3	0.25 , 1	0, 0	0.24 , 1	0.25 , 0.3

Source: [Section 14.3.1](#), Summary Table 7.6.2.

Values for FiO₂ and mode, and respiration rates from Day 1 to Day 7 (at 08:00 and 20:00) are presented in [Section 14.3.1](#), Summary Table 7.7.2. However, while subjects did receive supplemental oxygen during the study, none received supplemental oxygen during the first 7 days, so there are no non-zero values in Summary Table 7.7.2.

CPAP settings (pressure and FiO₂) at 1, 3, 24, and 48 hours and Day 7 at 20:00 hours are shown in [Table 12-12](#). At all time points, including the initial values, the MAP and the FiO₂ values are similar between active and nCPAP only subjects.

Table 12-12. CPAP Settings

Time Point Analysis	Statistic	Lucinactant for Inhalation			Total Active (N=24)	nCPAP Only (N=24)
		50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)		
Initial						
MAP (cmH ₂ O)	n	7	8	8	23	24
	Mean (SE)	6.1 (0.67)	6.1 (0.35)	6.3 (0.53)	6.2 (0.29)	5.8 (0.20)
	Median	6.0	6.0	5.5	6.0	6.0
	Min, Max	5, 10	5, 8	5, 8	5, 10	5, 8
FiO ₂	n	7	8	8	23	24
	Mean (SE)	0.29 (0.020)	0.38 (0.068)	0.36 (0.041)	0.34 (0.028)	0.35 (0.018)
	Median	0.28	0.30	0.35	0.30	0.32
	Min, Max	0.25, 0.4	0.21, 0.8	0.21, 0.6	0.21, 0.8	0.25, 0.6
1 Hour Post Randomization						
MAP (cmH ₂ O)	n	8	8	8	24	20
	Mean (SE)	5.8 (0.16)	6.0 (0.19)	5.6 (0.18)	5.8 (0.10)	5.8 (0.09)
	Median	6.0	6.0	6.0	6.0	6.0
	Min, Max	5, 6	5, 7	5, 6	5, 7	5, 6
FiO ₂	n	8	8	8	24	20
	Mean (SE)	0.32 (0.022)	0.39 (0.043)	0.38 (0.034)	0.36 (0.020)	0.31 (0.015)
	Median	0.31	0.35	0.39	0.35	0.30
	Min, Max	0.25, 0.4	0.3, 0.65	0.21, 0.5	0.21, 0.65	0.24, 0.5
3 Hours Post Randomization						
MAP (cmH ₂ O)	n	7	8	8	23	20
	Mean (SE)	6.0 (0.22)	6.1 (0.23)	6.1 (0.40)	6.1 (0.17)	6.0 (0.19)
	Median	6.0	6.0	6.0	6.0	6.0
	Min, Max	5, 7	5, 7	5, 8	5, 8	4.9, 8
FiO ₂	n	7	8	8	23	20
	Mean (SE)	0.33 (0.056)	0.37 (0.043)	0.37 (0.038)	0.36 (0.025)	0.28 (0.017)
	Median	0.25	0.35	0.36	0.34	0.28
	Min, Max	0.21, 0.6	0.21, 0.62	0.21, 0.55	0.21, 0.62	0.21, 0.52

Table 12-12. CPAP Settings

Time Point Analysis	Statistic	Lucinactant for Inhalation			Total Active (N=24)	nCPAP Only (N=24)
		50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)		
24 Hours Post Randomization						
MAP (cmH ₂ O)	n	3	4	3	10	14
	Mean (SE)	6.7 (0.67)	5.8 (0.27)	5.7 (0.67)	6.0 (0.30)	5.7 (0.32)
	Median	6.0	6.0	5.0	6.0	6.0
	Min, Max	6, 8	5, 6.2	5, 7	5, 8	4, 8
FiO ₂	n	3	4	3	10	14
	Mean (SE)	0.24 (0.020)	0.23 (0.007)	0.32 (0.056)	0.26 (0.020)	0.27 (0.041)
	Median	0.24	0.24	0.30	0.24	0.23
	Min, Max	0.21, 0.28	0.21, 0.24	0.24, 0.43	0.21, 0.43	0.21, 0.8
48 Hours Post Randomization						
MAP (cmH ₂ O)	n	4	4	4	12	15
	Mean (SE)	6.0 (0.71)	5.8 (0.27)	6.0 (0.71)	5.9 (0.31)	5.8 (0.25)
	Median	5.5	6.0	5.5	6.0	6.0
	Min, Max	5, 8	5, 6.2	5, 8	5, 8	4, 8
FiO ₂	n	4	4	4	12	15
	Mean (SE)	0.26 (0.022)	0.24 (0.021)	0.32 (0.031)	0.27 (0.017)	0.25 (0.019)
	Median	0.25	0.22	0.33	0.26	0.21
	Min, Max	0.21, 0.31	0.21, 0.3	0.24, 0.38	0.21, 0.38	0.21, 0.5
Day 7, 20:00						
MAP (cmH ₂ O)	n	2	6	4	12	15
	Mean (SE)	5.0 (0.00)	5.4 (0.20)	5.3 (0.25)	5.3 (0.13)	5.2 (0.23)
	Median	5.0	5.3	5.0	5.0	5.0
	Min, Max	5, 5	5, 6	5, 6	5, 6	4, 7
FiO ₂	n	2	6	5	13	17
	Mean (SE)	0.21 (0.000)	0.22 (0.007)	0.21 (0.004)	0.21 (0.003)	0.22 (0.005)
	Median	0.21	0.21	0.21	0.21	0.21
	Min, Max	0.21, 0.21	0.21, 0.25	0.21, 0.23	0.21, 0.25	0.21, 0.28

Source: [Section 14.3.1](#), *Summary Table 7.8*

12.5.5 Complications of Prematurity

Complications of prematurity at the final visit are presented in [Section 14.3.1](#), Summary Table 7.9 and in [Table 12-13](#). There are no clinically important differences between results for subjects who received the active treatment compared to results for subjects who received nCPAP only. Slightly more total active subjects compared to nCPAP only subjects reported NEC (3 [13%] vs.

1 [4%], respectively); more nCPAP only subjects demonstrated ROP than total active subjects (9 [38%] vs. 4 [17%], respectively).

Table 12-13. Complications of Prematurity

Complications of Prematurity	Lucinactant for Inhalation				nCPAP Only
	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	Only (N=24)
No. of Subjects with any Complication	8 (100%)	7 (88%)	7 (88%)	22 (92%)	22 (92%)
Acquired Sepsis	2 (25%)	2 (25%)	2 (25%)	6 (25%)	5 (21%)
Air Leak	3 (38%)	0 (0%)	2 (25%)	5 (21%)	4 (17%)
Apnea	8 (100%)	5 (63%)	6 (75%)	19 (79%)	19 (79%)
Cystic PVL	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Patent Ductus Arteriosus	3 (38%)	3 (38%)	4 (50%)	10 (42%)	10 (42%)
Pulmonary Hemorrhage	1 (13%)	0 (0%)	1 (13%)	2 (8%)	1 (4%)
Intraventricular Hemorrhage	0 (0%)	1 (13%)	3 (38%)	4 (17%)	4 (17%)
Necrotizing Enterocolitis	1 (13%)	1 (13%)	1 (13%)	3 (13%)	1 (4%)
Retinopathy of Prematurity	2 (25%)	1 (13%)	1 (13%)	4 (17%)	9 (38%)

Source: [Section 14.3.1](#), *Summary Table 7.9*

12.6 Safety Conclusions

Lucinactant for inhalation was generally well tolerated. There were 2 deaths in this study, 1 in the 50 mg TPL/kg group and 1 in the 75 mg TPL/kg group, neither of which was related to study drug treatment.

All subjects experienced at least one AE, all of which were common occurrences in premature neonates. The incidence of TEAEs for the active groups compared with the nCPAP only group was generally similar, and the incidence of TEAEs remained steady as dose increased. Peri-dosing AEs were transient and generally mild. Complications of prematurity, including air leak, occurred at comparable rates between active and nCPAP only subjects.

Lucinactant for inhalation appeared to be well tolerated at all doses administered.

The ADS functioned as intended; however, a higher than expected number of treatment interruptions occurred due to clogging filters; this was especially prevalent in the 75 mg TPL/kg group, given the length of the treatment, where 5/8 subjects had at least 1 treatment that was prematurely interrupted.

13. DISCUSSION AND OVERALL CONCLUSIONS

From 15 January 2016 to 08 July 2017, 48 preterm neonates 26 to 28 weeks PMA participated in this study. Baseline demographic and clinical characteristics of each group were generally similar between treatment groups.

Safety evaluations included assessment of AEs during dosing (peri-dosing events), AEs, ADEs, and SAEs that occurred throughout the duration of the study. No clinically relevant differences in AEs were noted for subjects in the active groups compared with subjects in the nCPAP only group. There were 2 deaths reported, considered by the PI to be unrelated to lucinactant for inhalation. Lucinactant for inhalation appeared to be well-tolerated at all doses studied.

The ADS functioned as intended, despite higher than expected treatment interruptions. Use of this device for delivery of lucinactant for inhalation in the study population and setting did not reveal any safety concerns.

Exploratory efficacy assessments suggest that treatment with lucinactant for inhalation decreases the FiO₂ requirements, increases time to intubation, and decreases BPD in preterm neonates 26 to 28 weeks gestation PMA with RDS. When the dose is delivered as intended, without treatment interruptions, nCPAP failures and intubations may be reduced.

Results of this study indicate that further development of lucinactant for inhalation is warranted.

14. TABLES, FIGURES, AND GRAPHS REFERRED TO BUT NOT INCLUDED IN THE TEXT

14.1 Demographic Data Summary Tables and Summary Listings

Summary Tables

Table Number	Table Title
1.1	Subject Disposition – Study Populations – All Subjects
1.2	Subject Disposition – Study Completion/Termination Status – All Subjects
1.3	Subject Disposition – Protocol Deviations/Violations – All Subjects
2.1	Subject Demographics – Intent-to-Treat Population
2.2	Medical Information – Maternal History – Intent-to-Treat Population
2.3	Medical Information – Birth History – Intent-to-Treat Population
3.1	Concomitant Medications – Safety Population
3.2	Number of Treatments – Safety Population – Dosing Group IV and V
3.3	Time from Birth or Randomization to First Dose – Safety Population

Summary Listings

Listing Number	Listing Title
1.1	Protocol Violations/Deviations – All Subjects
1.2	First Body Weight Measurement After Randomization – All Subjects
3.1	Early Termination of Aerosol Treatment
4.1	Pre-Study/Concomitant Medications

Summary Table 1.1
Subject Disposition - Study Population
All Subjects

	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)	Total
Screened Subjects	N/A	N/A	N/A	N/A	N/A	402
Enrolled Subjects	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)	48 (12%)
Intent-to-Treat Population	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)	48 (12%)
Safety Population	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)	48 (12%)

Summary Table 1.2
Subject Disposition - Study Completion/Termination Status
All Subjects

Status	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Completed Study	7 (88%)	7 (88%)	8 (100%)	22 (92%)	24 (100%)
Not Completed Study	1 (13%)	1 (13%)	0 (0%)	2 (8%)	0 (0%)
Lost to Follow up	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Withdrawal of Consent	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Death	1 (13%)	1 (13%)	0 (0%)	2 (8%)	0 (0%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Note: Completed study includes 36 weeks PMA, discharge, or transfer.

Summary Table 1.3
Subject Disposition - Protocol Deviations/Violations
All Subjects

Deviation/Violation	Total Number of Events	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Any Deviation/Violation	6002	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
Inclusion/Exclusion Issues	1	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
A 5-minute Apgar score < 5	1	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Data Issues	6001	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
Evaluation data not done or unknown	5913	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
Evaluation time out of window	88	5 (63%)	3 (38%)	5 (63%)	13 (54%)	16 (67%)

Summary Table 2.1
Subject Demographics
Intent-to-Treat Population

Demographics	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Gender	Male	5 (63%)	3 (38%)	3 (38%)	11 (46%)	16 (67%)
	Female	3 (38%)	5 (63%)	5 (63%)	13 (54%)	8 (33%)
Race	White	3 (38%)	5 (63%)	4 (50%)	12 (50%)	20 (83%)
	Black/African American	1 (13%)	1 (13%)	2 (25%)	4 (17%)	1 (4%)
	Asian	2 (25%)	0 (0%)	1 (13%)	3 (13%)	1 (4%)
	Other or Unknown	2 (25%)	2 (25%)	1 (13%)	5 (21%)	2 (8%)
Ethnic Origin	Hispanic	3 (38%)	1 (13%)	2 (25%)	6 (25%)	7 (29%)
	Not Hispanic	5 (63%)	7 (88%)	6 (75%)	18 (75%)	17 (71%)
Birth Weight (g)	n	8	8	8	24	24
	Mean (SE)	1052 (61.8)	855 (29.9)	839 (79.5)	915 (39.1)	1005 (48.7)
	SD	174.7	84.6	224.9	191.5	238.8
	Median	1035	860	805	893	1008
	Min, Max	820 , 1270	720 , 966	540 , 1210	540 , 1270	525 , 1460
Gestational Age (weeks)	n	8	8	8	24	24
	Mean (SE)	27.6 (0.21)	27.2 (0.38)	27.2 (0.30)	27.3 (0.17)	27.5 (0.16)
	SD	0.61	1.06	0.84	0.84	0.76
	Median	27.3	26.8	27.2	27.1	27.5
	Min, Max	27 , 28.4	26.1 , 28.9	26.1 , 28.1	26.1 , 28.9	26.3 , 28.9

Note: Race categories with percentages < 10% in total active group were combined as 'Other'.

Summary Table 2.1
Subject Demographics
Intent-to-Treat Population

Demographics	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Gestational Age Distribution	26 wks PMA	0 (0%)	5 (63%)	4 (50%)	9 (38%)	6 (25%)
	27 wks PMA	5 (63%)	1 (13%)	2 (25%)	8 (33%)	10 (42%)
	28 wks PMA	3 (38%)	2 (25%)	2 (25%)	7 (29%)	8 (33%)

Note: Race categories with percentages < 10% in total active group were combined as 'Other'.

Summary Table 2.2
Medical Information - Maternal History
Intent-to-Treat Population

Maternal History	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Ruptured Membranes (type)	Spontaneous	3 (38%)	3 (38%)	3 (38%)	9 (38%)	9 (38%)
	Artificial	5 (63%)	5 (63%)	5 (63%)	15 (63%)	15 (63%)
Chorioamnionitis	Yes	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
	No	8 (100%)	8 (100%)	7 (88%)	23 (96%)	24 (100%)
Antenatal Steroids (# of subjects) (# of doses)	n	8	8	8	24	21
	Mean (SE)	1.8 (0.16)	1.9 (0.23)	1.6 (0.18)	1.8 (0.11)	2.1 (0.17)
	SD	0.46	0.64	0.52	0.53	0.77
	Median	2.0	2.0	2.0	2.0	2.0
	Min, Max	1, 2	1, 3	1, 2	1, 3	1, 4

Summary Table 2.3
Medical Information - Birth History
Intent-to-Treat Population

Birth History	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Mode of Delivery	Vaginal	0 (0%)	2 (25%)	1 (13%)	3 (13%)	7 (29%)
	C-section	8 (100%)	6 (75%)	7 (88%)	21 (88%)	17 (71%)
Birth Status	Single	4 (50%)	8 (100%)	4 (50%)	16 (67%)	19 (79%)
	Multiple	4 (50%)	0 (0%)	4 (50%)	8 (33%)	5 (21%)
Apgar Score at One Minute	n	8	8	8	24	24
	Mean (SE)	5.4 (0.89)	5.5 (0.80)	6.4 (0.65)	5.8 (0.44)	5.8 (0.44)
	SD	2.50	2.27	1.85	2.17	2.14
	Median	6.0	6.0	7.0	6.0	6.0
	Min, Max	2 , 9	2 , 8	3 , 8	2 , 9	1 , 9
Apgar Score at Five Minutes	n	8	8	8	24	24
	Mean (SE)	7.8 (0.25)	6.4 (0.86)	8.1 (0.40)	7.4 (0.35)	7.9 (0.25)
	SD	0.71	2.45	1.13	1.72	1.25
	Median	8.0	6.5	8.5	8.0	8.0
	Min, Max	7 , 9	1 , 9	6 , 9	1 , 9	5 , 9
Congenital Anomaly ¹	n (%)	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)

¹ Subject 11023 (100 mg/kg) reported an anomaly of 'Ambiguous genitalia; approved per Windtree'.

Subject 19004 (nCPAP Only) reported an anomaly of 'Vertebral anomaly, 11 pairs of ribs, Dextrocardia, Hypospadias'.

Summary Table 3.1
Concomitant Medications
Safety Population

Medication Category Drug Generic Name	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
ALL OTHER NON-THERAPEUTIC PRODUCTS	5 (63%)	3 (38%)	3 (38%)	11 (46%)	4 (17%)
BLOOD, CALF, DEPROT., LMW PORTION	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
SUCROSE	5 (63%)	2 (25%)	3 (38%)	10 (42%)	4 (17%)
ALL OTHER THERAPEUTIC PRODUCTS	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
ACETYLCYSTEINE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
NALOXONE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
ANALGESICS	5 (63%)	3 (38%)	0 (0%)	8 (33%)	9 (38%)
MORPHINE	5 (63%)	2 (25%)	0 (0%)	7 (29%)	6 (25%)
PARACETAMOL	0 (0%)	1 (13%)	0 (0%)	1 (4%)	4 (17%)
ANESTHETICS	5 (63%)	5 (63%)	5 (63%)	15 (63%)	14 (58%)
FENTANYL	4 (50%)	5 (63%)	5 (63%)	14 (58%)	11 (46%)
LIDOCAINE	2 (25%)	0 (0%)	1 (13%)	3 (13%)	5 (21%)
MARCAINE WITH EPINEPHRINE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
ANTI-ANEMIC PREPARATIONS	6 (75%)	5 (63%)	7 (88%)	18 (75%)	15 (63%)
EPOETIN ALFA	2 (25%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)
EPOETIN BETA	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
ERYTHROPOIETIN	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
FERROUS SULFATE	6 (75%)	4 (50%)	7 (88%)	17 (71%)	13 (54%)
FOLIC ACID	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
IRON	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)

Summary Table 3.1
Concomitant Medications
Safety Population

Medication Category Drug Generic Name	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
ANTIBACTERIALS FOR SYSTEMIC USE	8 (100%)	8 (100%)	6 (75%)	22 (92%)	20 (83%)
AMIKACIN	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
AMPICILLIN	7 (88%)	6 (75%)	5 (63%)	18 (75%)	19 (79%)
AZITHROMYCIN	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
BACITRACIN	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
BENZYLPENICILLIN SODIUM	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
CEFADROXIL	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
CEFAZOLIN	0 (0%)	1 (13%)	0 (0%)	1 (4%)	4 (17%)
CEFAZOLIN SODIUM	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
CEFEPIME	1 (13%)	0 (0%)	0 (0%)	1 (4%)	2 (8%)
CEFOTAXIME	4 (50%)	1 (13%)	0 (0%)	5 (21%)	1 (4%)
CEFOXITIN	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
CEFTAZIDIME	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
CLOXACILLIN	0 (0%)	1 (13%)	1 (13%)	2 (8%)	1 (4%)
GENTAMICIN	4 (50%)	8 (100%)	6 (75%)	18 (75%)	19 (79%)
MEROPENEM	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
METRONIDAZOLE	1 (13%)	1 (13%)	0 (0%)	2 (8%)	3 (13%)
NAFCILLIN	1 (13%)	0 (0%)	0 (0%)	1 (4%)	2 (8%)
OXACILLIN	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
PIP/TAZO	0 (0%)	2 (25%)	1 (13%)	3 (13%)	5 (21%)
TOBRAMYCIN	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
UNACID	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
VANCOMYCIN	3 (38%)	5 (63%)	3 (38%)	11 (46%)	11 (46%)

Summary Table 3.1
Concomitant Medications
Safety Population

Medication Category Drug Generic Name	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	3 (38%)	0 (0%)	2 (25%)	5 (21%)	2 (8%)
BACITRACIN	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
MUPIROCIN	1 (13%)	0 (0%)	1 (13%)	2 (8%)	1 (4%)
NEOSPORIN	1 (13%)	0 (0%)	1 (13%)	2 (8%)	0 (0%)
ANTIIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	1 (13%)	3 (38%)	1 (13%)	5 (21%)	7 (29%)
NATURES WAY PRIMADOPHILUS KIDS PROBIOTIC	0 (0%) 1 (13%)	1 (13%) 2 (25%)	0 (0%) 1 (13%)	1 (4%) 4 (17%)	0 (0%) 7 (29%)
ANTIEPILEPTICS	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
LEVETIRACETAM	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
PHENOBARBITAL	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
PHENYTOIN	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
ANTIFUNGALS FOR DERMATOLOGICAL USE	2 (25%)	2 (25%)	0 (0%)	4 (17%)	2 (8%)
NYSTATIN	2 (25%)	2 (25%)	0 (0%)	4 (17%)	2 (8%)
ANTIHEMORRHAGICS	7 (88%)	6 (75%)	4 (50%)	17 (71%)	20 (83%)
CRYOPRECIPITATE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
PHYTOMENADIONE	7 (88%)	6 (75%)	4 (50%)	17 (71%)	20 (83%)
ANTIMYCOTICS FOR SYSTEMIC USE	2 (25%)	1 (13%)	0 (0%)	3 (13%)	5 (21%)
FLUCONAZOLE	2 (25%)	1 (13%)	0 (0%)	3 (13%)	5 (21%)

Summary Table 3.1
Concomitant Medications
Safety Population

Medication Category Drug Generic Name	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
LIDOCAINE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
ANTISEPTICS AND DISINFECTANTS	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
CHLORHEXIDINE GLUCONATE	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
ANTITHROMBOTIC AGENTS	3 (38%)	2 (25%)	0 (0%)	5 (21%)	5 (21%)
ALTEPLASE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
HEPARIN	3 (38%)	2 (25%)	0 (0%)	5 (21%)	4 (17%)
BILE AND LIVER THERAPY	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
URSODEOXYCHOLIC ACID	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	7 (88%)	6 (75%)	7 (88%)	20 (83%)	22 (92%)
ALBUMIN HUMAN	1 (13%)	0 (0%)	0 (0%)	1 (4%)	3 (13%)
AMINO ACIDS NOS	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
AMINO ACIDS NOS W/CARBOHYDRATES NOS	7 (88%)	4 (50%)	3 (38%)	14 (58%)	15 (63%)
ARGININE	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
CALCIUM GLUCONATE	1 (13%)	0 (0%)	0 (0%)	1 (4%)	3 (13%)
FLEBOBAG RING LACT	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
GLUCOSE	2 (25%)	1 (13%)	0 (0%)	3 (13%)	5 (21%)
INTRALIPID	3 (38%)	2 (25%)	3 (38%)	8 (33%)	11 (46%)
NORMOSOL	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)

Summary Table 3.1
Concomitant Medications
Safety Population

Medication Category Drug Generic Name	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
PLASMA	1 (13%)	0 (0%)	1 (13%)	2 (8%)	3 (13%)
PLATELETS	2 (25%)	0 (0%)	0 (0%)	2 (8%)	4 (17%)
POTASSIUM CHLORIDE	0 (0%)	2 (25%)	0 (0%)	2 (8%)	3 (13%)
POTASSIUM PHOSPHATE MONOBASIC	1 (13%)	0 (0%)	0 (0%)	1 (4%)	2 (8%)
RED BLOOD CELLS	3 (38%)	3 (38%)	1 (13%)	7 (29%)	9 (38%)
SODIUM ACETATE	4 (50%)	1 (13%)	0 (0%)	5 (21%)	1 (4%)
SODIUM BICARBONATE	4 (50%)	2 (25%)	0 (0%)	6 (25%)	2 (8%)
SODIUM CHLORIDE	7 (88%)	3 (38%)	2 (25%)	12 (50%)	12 (50%)
SODIUM PHOSPHATE	2 (25%)	2 (25%)	1 (13%)	5 (21%)	2 (8%)
CARDIAC THERAPY	3 (38%)	7 (88%)	5 (63%)	15 (63%)	13 (54%)
ATROPINE	2 (25%)	4 (50%)	3 (38%)	9 (38%)	8 (33%)
DOBUTAMINE	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
DOBUTAMINE HYDROCHLORIDE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
DOPAMINE	1 (13%)	2 (25%)	0 (0%)	3 (13%)	5 (21%)
EPHEDRINE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
EPINEPHRINE	1 (13%)	1 (13%)	0 (0%)	2 (8%)	2 (8%)
IBUPROFEN	0 (0%)	2 (25%)	2 (25%)	4 (17%)	3 (13%)
INDOMETACIN	3 (38%)	2 (25%)	2 (25%)	7 (29%)	4 (17%)
MILRINONE	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
CONTRAST MEDIA	0 (0%)	0 (0%)	1 (13%)	1 (4%)	2 (8%)
IOHEXOL	0 (0%)	0 (0%)	1 (13%)	1 (4%)	2 (8%)
CORTICOSTEROIDS FOR SYSTEMIC USE	1 (13%)	2 (25%)	0 (0%)	3 (13%)	3 (13%)

Summary Table 3.1
Concomitant Medications
Safety Population

Medication Category Drug Generic Name	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
DEXAMETHASONE	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
HYDROCORTISONE	1 (13%)	2 (25%)	0 (0%)	3 (13%)	3 (13%)
COUGH AND COLD PREPARATIONS	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
DORNASE ALFA	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
DIURETICS	4 (50%)	3 (38%)	2 (25%)	9 (38%)	8 (33%)
ACETAZOLAMIDE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
ALDACTAZIDE A	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
CHLOROTHIAZIDE	0 (0%)	1 (13%)	1 (13%)	2 (8%)	2 (8%)
FUROSEMIDE	4 (50%)	2 (25%)	2 (25%)	8 (33%)	6 (25%)
SPIRONOLACTONE	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
DRUGS FOR ACID RELATED DISORDERS	0 (0%)	2 (25%)	0 (0%)	2 (8%)	1 (4%)
FAMOTIDINE	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
OMEPRAZOLE	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
DRUGS FOR CONSTIPATION	7 (88%)	3 (38%)	6 (75%)	16 (67%)	8 (33%)
GLYCEROL	7 (88%)	3 (38%)	6 (75%)	16 (67%)	8 (33%)
DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
DIMETICONE	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	0 (0%)	4 (50%)	2 (25%)	6 (25%)	5 (21%)
AMINOPHYLLINE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Summary Table 3.1
Concomitant Medications
Safety Population

Medication Category Drug Generic Name	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
BUDESONIDE	0 (0%)	3 (38%)	2 (25%)	5 (21%)	5 (21%)
DUOVENT	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
SALBUTAMOL	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
THEOPHYLLINE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
DRUGS USED IN DIABETES	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
INSULIN	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
EMOLLIENTS AND PROTECTIVES	3 (38%)	2 (25%)	2 (25%)	7 (29%)	5 (21%)
EMOLLIENTS AND PROTECTIVES	0 (0%)	0 (0%)	1 (13%)	1 (4%)	5 (21%)
ZINC OXIDE	3 (38%)	2 (25%)	1 (13%)	6 (25%)	1 (4%)
GENERAL NUTRIENTS	2 (25%)	2 (25%)	1 (13%)	5 (21%)	3 (13%)
GLUCOSE	2 (25%)	2 (25%)	1 (13%)	5 (21%)	3 (13%)
GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
AMPHOTERICIN B	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
IMMUNE SERA AND IMMUNOGLOBULINS	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
PALIVIZUMAB	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
MINERAL SUPPLEMENTS	1 (13%)	2 (25%)	0 (0%)	3 (13%)	2 (8%)
CALCIUM	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
MAGNESIUM CHLORIDE	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
MAGNESIUM HYDROXIDE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Summary Table 3.1
Concomitant Medications
Safety Population

Medication Category Drug Generic Name	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
MAGNESIUM SULFATE	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
ZINC SULFATE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
MUSCLE RELAXANTS	4 (50%)	4 (50%)	3 (38%)	11 (46%)	9 (38%)
ROCURONIUM	1 (13%)	1 (13%)	0 (0%)	2 (8%)	3 (13%)
SUXAMETHONIUM CHLORIDE	1 (13%)	3 (38%)	3 (38%)	7 (29%)	5 (21%)
VECURONIUM	2 (25%)	1 (13%)	0 (0%)	3 (13%)	2 (8%)
OPHTHALMOLOGICALS	7 (88%)	6 (75%)	7 (88%)	20 (83%)	18 (75%)
CYCLOMYDRIL	0 (0%)	2 (25%)	2 (25%)	4 (17%)	2 (8%)
CYCLOPENTOLATE W/PHENYLEPHRINE	6 (75%)	2 (25%)	5 (63%)	13 (54%)	9 (38%)
ERYTHROMYCIN	7 (88%)	4 (50%)	5 (63%)	16 (67%)	14 (58%)
LACRI-LUBE	2 (25%)	0 (0%)	0 (0%)	2 (8%)	1 (4%)
MACROGOL	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
MOXIFLOXACIN	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
PHENYLEPHRINE	0 (0%)	0 (0%)	2 (25%)	2 (8%)	1 (4%)
PHENYLEPHRINE HYDROCHLORIDE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
PROXYMETACAINE	1 (13%)	2 (25%)	3 (38%)	6 (25%)	1 (4%)
PROXYMETACAINE HYDROCHLORIDE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
TETRACAINE	0 (0%)	0 (0%)	3 (38%)	3 (13%)	2 (8%)
TIMOLOL MALEATE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
TROPICAMIDE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
OTHER HEMATOLOGICAL AGENTS	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
HYALURONIDASE	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)

Summary Table 3.1
Concomitant Medications
Safety Population

Medication Category Drug Generic Name	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
OTHER RESPIRATORY SYSTEM PRODUCTS	5 (63%)	7 (88%)	5 (63%)	17 (71%)	15 (63%)
BERACTANT	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
BOVINE LIPID EXTRACT SURFACTANT	0 (0%)	3 (38%)	3 (38%)	6 (25%)	4 (17%)
CALFACTANT	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
NITRIC OXIDE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
PORACTANT ALFA	5 (63%)	3 (38%)	2 (25%)	10 (42%)	8 (33%)
PSYCHOANALEPTICS	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
CAFFEINE	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
PSYCHOLEPTICS	3 (38%)	0 (0%)	0 (0%)	3 (13%)	4 (17%)
DEXMEDETOMIDINE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
LORAZEPAM	2 (25%)	0 (0%)	0 (0%)	2 (8%)	1 (4%)
MIDAZOLAM	1 (13%)	0 (0%)	0 (0%)	1 (4%)	3 (13%)
VACCINES	1 (13%)	2 (25%)	2 (25%)	5 (21%)	8 (33%)
BCG VACCINE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
HEPATITIS B VACCINE	1 (13%)	2 (25%)	2 (25%)	5 (21%)	8 (33%)
INFANRIX IPV+HIB	0 (0%)	0 (0%)	2 (25%)	2 (8%)	2 (8%)
PNEUMOCOCCAL VACCINE	0 (0%)	1 (13%)	2 (25%)	3 (13%)	2 (8%)
VACCIN IPAD D.T.C.	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
VITAMINS	7 (88%)	6 (75%)	8 (100%)	21 (88%)	21 (88%)
ASCORBIC ACID	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)

Summary Table 3.1
Concomitant Medications
Safety Population

Medication Category Drug Generic Name	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
COLECALCIFEROL	6 (75%)	6 (75%)	5 (63%)	17 (71%)	12 (50%)
FERROUS SULFATE W/VITAMINS NOS	1 (13%)	0 (0%)	2 (25%)	3 (13%)	2 (8%)
MULTIVITAMIN WITH MINERALS	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
MULTIVITAMINS	0 (0%)	1 (13%)	2 (25%)	3 (13%)	8 (33%)
RETINOL	2 (25%)	0 (0%)	0 (0%)	2 (8%)	7 (29%)
TOCOPHERYL ACETATE	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (17%)
VITAMIN B COMPLEX	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Summary Table 3.2
Number of Treatments
Safety Population

	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)
Number of Treatments	n	8	8	8	24
	Mean (SE)	1.5 (0.19)	1.9 (0.13)	1.6 (0.18)	1.7 (0.10)
	SD	0.53	0.35	0.52	0.48
	Min, Max	1 , 2	1 , 2	1 , 2	1 , 2
Number of Subjects by Treatment					
One Treatment	n	4	1	3	8
Two Treatments	n	4	7	5	16

Summary Table 3.3
Time from Birth or Randomization to First Dose
Safety Population

	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)
Time from Birth to First Dose (hr)	n	8	8	8	24
	Mean (SE)	5.1 (1.04)	8.1 (1.85)	8.5 (2.02)	7.3 (0.98)
	SD	2.95	5.22	5.71	4.82
	Median	4.0	6.0	6.5	5.5
	Min, Max	2 , 11	4 , 17	5 , 22	2 , 22
Time from Rand. to First Dose (hr)	n	8	8	8	24
	Mean (SE)	1.8 (0.31)	1.6 (0.18)	1.5 (0.27)	1.6 (0.15)
	SD	0.89	0.52	0.76	0.71
	Median	1.5	2.0	1.0	1.5
	Min, Max	1 , 3	1 , 2	1 , 3	1 , 3

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:04FEB2016:19:25:00 Stop:06FEB2016: 1:52:00	MV:TidalVolume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:06FEB2016: 1:52:00 Stop:10FEB2016:12:35:00	nCPAP:PIP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:14FEB2016:23:25:00 Stop:10MAR2016: 8:30:00	nCPAP:PIP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:04FEB2016:19:25:00 Stop:06FEB2016: 1:52:00	MV:TidalVolume
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:06FEB2016: 1:52:00 Stop:10FEB2016:12:35:00	nCPAP:PIP
01032	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:14FEB2016:23:25:00 Stop:10MAR2016: 8:30:00	nCPAP:PIP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05FEB2016:13:15:00 Stop:10FEB2016:11:05:00	MV:MAP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05FEB2016:13:15:00 Stop:10FEB2016:11:05:00	MV:TidalVolume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01033	50 mg/kg	Data Issues	Evaluation time out of window	5 Minutes	
01033	50 mg/kg	Data Issues	Evaluation time out of window	10 Minutes	
01033	50 mg/kg	Data Issues	Evaluation time out of window	15 Minutes	
01033	50 mg/kg	Data Issues	Evaluation time out of window	20 Minutes	
01033	50 mg/kg	Data Issues	Evaluation time out of window	25 Minutes	
01033	50 mg/kg	Data Issues	Evaluation time out of window	30 Minutes	
01033	50 mg/kg	Data Issues	Evaluation time out of window	3 hours (180 minutes) post randomization	
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	tcPCO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05FEB2016:13:15:00 Stop:10FEB2016:11:05:00	MV:MAP
01033	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05FEB2016:13:15:00 Stop:10FEB2016:11:05:00	MV:TidalVolume
01033	50 mg/kg	Data Issues	Evaluation time out of window	5 Minutes	
01033	50 mg/kg	Data Issues	Evaluation time out of window	10 Minutes	
01033	50 mg/kg	Data Issues	Evaluation time out of window	15 Minutes	
01033	50 mg/kg	Data Issues	Evaluation time out of window	20 Minutes	

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01033	50 mg/kg	Data Issues	Evaluation time out of window	25 Minutes	
01033	50 mg/kg	Data Issues	Evaluation time out of window	30 Minutes	
01033	50 mg/kg	Data Issues	Evaluation time out of window	3 hours (180 minutes) post randomization	
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours post randomization	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours post randomization	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours post randomization	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:13JUN2016:23:45:00 Stop:*	MV:TidalVolume
				*	

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours post randomization	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours post randomization	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours post randomization	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7	Spon. Resp. Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01040	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:13JUN2016:23:45:00 Stop:*, *	MV:TidalVolume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5	Spon. Resp. Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6	Spon. Resp. Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7	Spon. Resp. Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JUL2016:11:30:00 Stop:27JUL2016:9:05:00	nCPAP:PIP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JUL2016:11:30:00 Stop:27JUL2016:9:05:00	nCPAP:RespRate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:14JUN2016:1:02:00 Stop:*	* MV:MAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:14JUN2016:1:02:00 Stop:*	* MV:TidalVolume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21JUN2016:12:20:00 Stop:23JUN2016:10:38:00	nCPAP:PIP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21JUN2016:12:20:00 Stop:23JUN2016:10:38:00	nCPAP:RespRate
01041	50 mg/kg	Data Issues	Evaluation time out of window	60 hours post randomization	
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5	Spon. Resp. Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6	Spon. Resp. Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7	Spon. Resp. Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JUL2016:11:30:00 Stop:27JUL2016: 9:05:00	nCPAP:PIP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JUL2016:11:30:00 Stop:27JUL2016: 9:05:00	nCPAP:RespRate
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:14JUN2016: 1:02:00 Stop:*	* MV:MAP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:14JUN2016: 1:02:00 Stop:*	* MV:TidalVolume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21JUN2016:12:20:00 Stop:23JUN2016:10:38:00	nCPAP:PIP
01041	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21JUN2016:12:20:00 Stop:23JUN2016:10:38:00	nCPAP:RespRate
01041	50 mg/kg	Data Issues	Evaluation time out of window	60 hours post randomization	
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:12AUG2016:11:25:00 Stop:14AUG2016:14:55:00	MV:TidalVolume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:14AUG2016:14:55:00 Stop:*. *	nCPAP:FlowRate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:12AUG2016:11:25:00 Stop:14AUG2016:14:55:00	MV:TidalVolume
01042	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:14AUG2016:14:55:00 Stop:*. *	nCPAP:FlowRate
03006	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03006	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03006	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Start:16JAN2016:10:01:00 Stop:30JAN2016: 9:59:00	nCPAP:PIP
03006	Control	Data Issues	Evaluation data not done or unknown	Start:16JAN2016:10:01:00 Stop:30JAN2016: 9:59:00	nCPAP:RespRate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03006	Control	Data Issues	Evaluation time out of window	Vital Signs - 15 Minutes	
03006	Control	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
03006	Control	Data Issues	Evaluation time out of window	At the time of randomization	
03006	Control	Data Issues	Evaluation time out of window	15 minutes post randomization	
03006	Control	Data Issues	Evaluation time out of window	30 minutes post randomization	
03006	Control	Data Issues	Evaluation time out of window	45 minutes post randomization	
03006	Control	Data Issues	Evaluation time out of window	60 minutes post randomization	
03006	Control	Data Issues	Evaluation time out of window	1 hour 15 minutes (75 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	1 hour 30 minutes (90 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	1 hour 45 minutes (105 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	2 hours (120 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	2 hours 15 minutes (135 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	2 hours 30 minutes (150 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	2 hours 45 minutes (165 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	3 hours (180 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	30 hours post randomization	
03006	Control	Data Issues	Evaluation time out of window	24 Hours Post Randomization	
03006	Control	Data Issues	Evaluation time out of window	At the time of Randomization	
03006	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03006	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03006	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
03006	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
03006	Control	Data Issues	Evaluation data not done or unknown	Start:16JAN2016:10:01:00 Stop:30JAN2016: 9:59:00	nCPAP:PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03006	Control	Data Issues	Evaluation data not done or unknown	Start:16JAN2016:10:01:00 Stop:30JAN2016: 9:59:00	nCPAP:RespRate
03006	Control	Data Issues	Evaluation time out of window	Vital Signs - 15 Minutes	
03006	Control	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
03006	Control	Data Issues	Evaluation time out of window	At the time of randomization	
03006	Control	Data Issues	Evaluation time out of window	15 minutes post randomization	
03006	Control	Data Issues	Evaluation time out of window	30 minutes post randomization	
03006	Control	Data Issues	Evaluation time out of window	45 minutes post randomization	
03006	Control	Data Issues	Evaluation time out of window	60 minutes post randomization	
03006	Control	Data Issues	Evaluation time out of window	1 hour 15 minutes (75 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	1 hour 30 minutes (90 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	1 hour 45 minutes (105 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	2 hours (120 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	2 hours 15 minutes (135 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	2 hours 30 minutes (150 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	2 hours 45 minutes (165 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	3 hours (180 minutes) post randomization	
03006	Control	Data Issues	Evaluation time out of window	30 hours post randomization	
03006	Control	Data Issues	Evaluation time out of window	24 Hours Post Randomization	

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03006	Control	Data Issues	Evaluation time out of window	At the time of Randomization	
03013	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03013	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
03013	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Start:14AUG2016:13:54:00 Stop:*: *	nCPAP:PIP
03013	Control	Data Issues	Evaluation data not done or unknown	Start:14AUG2016:13:54:00 Stop:*: *	nCPAP:RespRate
03013	Control	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
03013	Control	Data Issues	Evaluation time out of window	30 hours post randomization	
03013	Control	Data Issues	Evaluation time out of window	At the time of Randomization	
03013	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03013	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
03013	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03013	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
03013	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
03013	Control	Data Issues	Evaluation data not done or unknown	Start:14AUG2016:13:54:00 Stop:*: *	nCPAP:PIP
03013	Control	Data Issues	Evaluation data not done or unknown	Start:14AUG2016:13:54:00 Stop:*: *	nCPAP:RespRate
03013	Control	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
03013	Control	Data Issues	Evaluation time out of window	30 hours post randomization	
03013	Control	Data Issues	Evaluation time out of window	At the time of Randomization	
08028	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08028	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08028	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
08028	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
08028	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
08028	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
08028	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
08028	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Start:15JUN2016:10:02:00 Stop:*: *	nCPAP:CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Start:15JUN2016:10:02:00 Stop:*: *	nCPAP:PIP
08028	Control	Data Issues	Evaluation data not done or unknown	Start:15JUN2016:10:02:00 Stop:*: *	nCPAP:RespRate
08028	Control	Data Issues	Evaluation data not done or unknown	Start:28MAY2016: 0:05:00 Stop:15JUN2016:10:01:00	nCPAP:FlowRate
08028	Control	Data Issues	Evaluation data not done or unknown	Start:28MAY2016: 0:05:00 Stop:15JUN2016:10:01:00	nCPAP:PIP
08028	Control	Data Issues	Evaluation data not done or unknown	Start:28MAY2016: 0:05:00 Stop:15JUN2016:10:01:00	nCPAP:RespRate
08028	Control	Data Issues	Evaluation data not done or unknown	Start:28MAY2016:16:00:00 Stop:27MAY2016:23:39:00	MV:TidalVolume
08028	Control	Data Issues	Evaluation time out of window	24 Hours Post Randomization	
08028	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08028	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08028	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
08028	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
08028	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
08028	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
08028	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
08028	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
08028	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
08028	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
08028	Control	Data Issues	Evaluation data not done or unknown	Start:15JUN2016:10:02:00 Stop:*: *	nCPAP:CPAP
08028	Control	Data Issues	Evaluation data not done or unknown	Start:15JUN2016:10:02:00 Stop:*: *	nCPAP:PIP
08028	Control	Data Issues	Evaluation data not done or unknown	Start:15JUN2016:10:02:00 Stop:*: *	nCPAP:RespRate
08028	Control	Data Issues	Evaluation data not done or unknown	Start:28MAY2016: 0:05:00 Stop:15JUN2016:10:01:00	nCPAP:FlowRate
08028	Control	Data Issues	Evaluation data not done or unknown	Start:28MAY2016: 0:05:00 Stop:15JUN2016:10:01:00	nCPAP:PIP
08028	Control	Data Issues	Evaluation data not done or unknown	Start:28MAY2016: 0:05:00 Stop:15JUN2016:10:01:00	nCPAP:RespRate
08028	Control	Data Issues	Evaluation data not done or unknown	Start:28MAY2016:16:00:00 Stop:27MAY2016:23:39:00	MV:TidalVolume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08028	Control	Data Issues	Evaluation time out of window	24 Hours Post Randomization	
08037	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
08037	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
08037	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
08037	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
08037	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08037	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
08037	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
08037	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
08037	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
08037	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08037	Control	Data Issues	Evaluation data not done or unknown	Start:24AUG2016:16:40:00 Stop:*. *	nCPAP:PIP
08037	Control	Data Issues	Evaluation data not done or unknown	Start:24AUG2016:16:40:00 Stop:*. *	nCPAP:RespRate
08037	Control	Data Issues	Evaluation data not done or unknown	Start:25AUG2016:10:38:00 Stop:28AUG2016:10:18:00	MV:TidalVolume
08037	Control	Data Issues	Evaluation data not done or unknown	Start:25AUG2016:10:38:00 Stop:28AUG2016:10:18:00	MV:tcPCO2
08037	Control	Data Issues	Evaluation data not done or unknown	Start:28AUG2016:10:19:00 Stop:14OCT2016:11:29:00	nCPAP:FlowRate
08037	Control	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
08037	Control	Data Issues	Evaluation time out of window	24 Hours Post Randomization	
08037	Control	Data Issues	Evaluation time out of window	At the time of Randomization	
08037	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
08037	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
08037	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
08037	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
08037	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08037	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
08037	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08037	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
08037	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
08037	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
08037	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
08037	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
08037	Control	Data Issues	Evaluation data not done or unknown	Start:24AUG2016:16:40:00 Stop:*: *	nCPAP:PIP
08037	Control	Data Issues	Evaluation data not done or unknown	Start:24AUG2016:16:40:00 Stop:*: *	nCPAP:RespRate
08037	Control	Data Issues	Evaluation data not done or unknown	Start:25AUG2016:10:38:00 Stop:28AUG2016:10:18:00	MV:TidalVolume
08037	Control	Data Issues	Evaluation data not done or unknown	Start:25AUG2016:10:38:00 Stop:28AUG2016:10:18:00	MV:tcPCO2
08037	Control	Data Issues	Evaluation data not done or unknown	Start:28AUG2016:10:19:00 Stop:14OCT2016:11:29:00	nCPAP:FlowRate
08037	Control	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
08037	Control	Data Issues	Evaluation time out of window	24 Hours Post Randomization	

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
08037	Control	Data Issues	Evaluation time out of window	At the time of Randomization	
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Temperature
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JUN2016:17:42:00 Stop:05JUN2016:19:00:00	SuppO2:FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21MAY2016:19:45:00 Stop:*: *	MV:FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21MAY2016:19:45:00 Stop:*: *	MV:TidalVolume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21MAY2016:19:45:00 Stop:*: *	MV:tcPCO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:23MAY2016:12:38:00 Stop:21MAY2016:19:45:00	nCPAP:CPAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:23MAY2016:12:38:00 Stop:21MAY2016:19:45:00	nCPAP:PIP
09001	50 mg/kg	Data Issues	Evaluation time out of window	48 Hours post randomization	
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Temperature
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JUN2016:17:42:00 Stop:05JUN2016:19:00:00	SuppO2:FiO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21MAY2016:19:45:00 Stop:*: *	MV:FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21MAY2016:19:45:00 Stop:*: *	MV:TidalVolume
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21MAY2016:19:45:00 Stop:*: *	MV:tcPCO2
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:23MAY2016:12:38:00 Stop:21MAY2016:19:45:00	nCPAP:CPAP
09001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:23MAY2016:12:38:00 Stop:21MAY2016:19:45:00	nCPAP:PIP
09001	50 mg/kg	Data Issues	Evaluation time out of window	48 Hours post randomization	
11005	Control	Data Issues	Evaluation data not done or unknown		Temperature
11005	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11005	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11005	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11005	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
11005	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Start:06JUN2016:19:00:00 Stop:08JUN2016:10:40:00	MV:TidalVolume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11005	Control	Data Issues	Evaluation data not done or unknown	Start:06JUN2016:19:00:00 Stop:08JUN2016:10:40:00	MV:tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	Start:08JUN2016:10:41:00 Stop:*: *	nCPAP:PIP
11005	Control	Data Issues	Evaluation time out of window	54 hours post randomization	
11005	Control	Data Issues	Evaluation data not done or unknown		Temperature
11005	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11005	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11005	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
11005	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
11005	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
11005	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11005	Control	Data Issues	Evaluation data not done or unknown	Start:06JUN2016:19:00:00 Stop:08JUN2016:10:40:00	MV:TidalVolume
11005	Control	Data Issues	Evaluation data not done or unknown	Start:06JUN2016:19:00:00 Stop:08JUN2016:10:40:00	MV:tcPCO2
11005	Control	Data Issues	Evaluation data not done or unknown	Start:08JUN2016:10:41:00 Stop:*: *	nCPAP:PIP
11005	Control	Data Issues	Evaluation time out of window	54 hours post randomization	

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11006	Control	Data Issues	Evaluation data not done or unknown		Temperature
11006	Control	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Temperature
11006	Control	Data Issues	Evaluation data not done or unknown	3 Hours post randomization	Temperature
11006	Control	Data Issues	Evaluation data not done or unknown	6 Hours post randomization	Temperature
11006	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11006	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11006	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
11006	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
11006	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Start:06JUN2016:15:45:00 Stop:10JUN2016:11:40:00	MV:TidalVolume
11006	Control	Data Issues	Evaluation data not done or unknown	Start:06JUN2016:15:45:00 Stop:10JUN2016:11:40:00	MV:tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	Start:10JUN2016:11:41:00 Stop:*, *	nCPAP:PIP
11006	Control	Data Issues	Evaluation time out of window	3 Hours post randomization	
11006	Control	Data Issues	Evaluation time out of window	30 hours post randomization	
11006	Control	Data Issues	Evaluation data not done or unknown		Temperature
11006	Control	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Temperature
11006	Control	Data Issues	Evaluation data not done or unknown	3 Hours post randomization	Temperature
11006	Control	Data Issues	Evaluation data not done or unknown	6 Hours post randomization	Temperature

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11006	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11006	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11006	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
11006	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
11006	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
11006	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11006	Control	Data Issues	Evaluation data not done or unknown	Start:06JUN2016:15:45:00 Stop:10JUN2016:11:40:00	MV:TidalVolume
11006	Control	Data Issues	Evaluation data not done or unknown	Start:06JUN2016:15:45:00 Stop:10JUN2016:11:40:00	MV:tcPCO2
11006	Control	Data Issues	Evaluation data not done or unknown	Start:10JUN2016:11:41:00 Stop:*: *	nCPAP:PIP
11006	Control	Data Issues	Evaluation time out of window	3 Hours post randomization	
11006	Control	Data Issues	Evaluation time out of window	30 hours post randomization	
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Heart Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Spon. Resp. Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Temperature
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Temperature
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:04SEP2016:21:25:00 Stop:06SEP2016: 3:56:00	MV:TidalVolume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:04SEP2016:21:25:00 Stop:06SEP2016: 3:56:00	MV:tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:06SEP2016: 3:57:00 Stop:08SEP2016:10:20:00	nCPAP:PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08SEP2016:10:22:00 Stop:01SEP2016:14:02:00	MV:TidalVolume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08SEP2016:10:22:00 Stop:01SEP2016:14:02:00	MV:tcPCO2
11011	75 mg/kg	Inc./Exc. Issues	A 5-minute Apgar score < 5	Screening Period	
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Heart Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Spon. Resp. Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Temperature
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Temperature
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:04SEP2016:21:25:00 Stop:06SEP2016: 3:56:00	MV:TidalVolume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:04SEP2016:21:25:00 Stop:06SEP2016: 3:56:00	MV:tcPCO2
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:06SEP2016: 3:57:00 Stop:08SEP2016:10:20:00	nCPAP:PIP
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08SEP2016:10:22:00 Stop:01SEP2016:14:02:00	MV:TidalVolume
11011	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08SEP2016:10:22:00 Stop:01SEP2016:14:02:00	MV:tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Heart Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Spon. Resp. Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Temperature
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Temperature
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	K+
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05NOV2016:18:45:00 Stop:11NOV2016:13:00:00	MV:TidalVolume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:11NOV2016:13:05:00 Stop:*: *	nCPAP:PIP
11021	100 mg/kg	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
11021	100 mg/kg	Data Issues	Evaluation time out of window	1 hour 30 minutes (90 minutes) post randomization	
11021	100 mg/kg	Data Issues	Evaluation time out of window	60 hours post randomization	
11021	100 mg/kg	Data Issues	Evaluation time out of window	1 Hour Post Randomization	
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Heart Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Spon. Resp. Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Temperature
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Temperature
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	K+
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05NOV2016:18:45:00 Stop:11NOV2016:13:00:00	MV:TidalVolume
11021	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:11NOV2016:13:05:00 Stop*: *	nCPAP:PIP
11021	100 mg/kg	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
11021	100 mg/kg	Data Issues	Evaluation time out of window	1 hour 30 minutes (90 minutes) post randomization	
11021	100 mg/kg	Data Issues	Evaluation time out of window	60 hours post randomization	
11021	100 mg/kg	Data Issues	Evaluation time out of window	1 Hour Post Randomization	
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Heart Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Spon. Resp. Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Temperature
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:01DEC2016:20:00:00 Stop*: *	nCPAP:PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:29NOV2016:19:05:00 Stop:01DEC2016:19:59:00	MV:TidalVolume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:29NOV2016:19:05:00 Stop:01DEC2016:19:59:00	MV:tcPCO2
11023	100 mg/kg	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
11023	100 mg/kg	Data Issues	Evaluation time out of window	3 Hours post randomization	
11023	100 mg/kg	Data Issues	Evaluation time out of window	30 Minutes Post Dosing	
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Heart Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Spon. Resp. Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Temperature
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:01DEC2016:20:00:00 Stop:*. *	nCPAP:PIP
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:29NOV2016:19:05:00 Stop:01DEC2016:19:59:00	MV:TidalVolume
11023	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:29NOV2016:19:05:00 Stop:01DEC2016:19:59:00	MV:tcPCO2
11023	100 mg/kg	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
11023	100 mg/kg	Data Issues	Evaluation time out of window	3 Hours post randomization	
11023	100 mg/kg	Data Issues	Evaluation time out of window	30 Minutes Post Dosing	
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Heart Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Spon. Resp. Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation time out of window	60 hours post randomization	
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Heart Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Spon. Resp. Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
11025	100 mg/kg	Data Issues	Evaluation time out of window	60 hours post randomization	
12004	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
12004	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
12004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
12004	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
12004	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12004	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Start:24MAR2016: 8:01:00 Stop:03APR2016:11:20:00	nCPAP:PIP
12004	Control	Data Issues	Evaluation time out of window	45 minutes post randomization	
12004	Control	Data Issues	Evaluation time out of window	2 hours 45 minutes (165 minutes) post randomization	
12004	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
12004	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
12004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
12004	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
12004	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
12004	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	tcPCO2
12004	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12004	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12004	Control	Data Issues	Evaluation data not done or unknown	Start:24MAR2016: 8:01:00 Stop:03APR2016:11:20:00	nCPAP:PIP
12004	Control	Data Issues	Evaluation time out of window	45 minutes post randomization	
12004	Control	Data Issues	Evaluation time out of window	2 hours 45 minutes (165 minutes) post randomization	
12006	Control	Data Issues	Evaluation data not done or unknown	48 Hours post randomization	Spon. Resp. Rate
12006	Control	Data Issues	Evaluation data not done or unknown	6 Hours post randomization	Temperature
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4	Spon. Resp. Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5	Spon. Resp. Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6	Spon. Resp. Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5	Temperature
12006	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12006	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
12006	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12006	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
12006	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
12006	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
12006	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
12006	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Start:03MAR2016: 7:01:00 Stop:23MAR2016: 8:45:00	MV:FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Start:03MAR2016: 7:01:00 Stop:23MAR2016: 8:45:00	MV:TidalVolume
12006	Control	Data Issues	Evaluation data not done or unknown	Start:03MAR2016: 7:01:00 Stop:23MAR2016: 8:45:00	MV:tcPCO2
12006	Control	Data Issues	Evaluation data not done or unknown	Start:23MAR2016: 8:46:00 Stop:*	nCPAP:FlowRate
12006	Control	Data Issues	Evaluation data not done or unknown	Start:23MAR2016: 8:46:00 Stop:*	nCPAP:PIP
12006	Control	Data Issues	Evaluation data not done or unknown	48 Hours post randomization	Spon. Resp. Rate
12006	Control	Data Issues	Evaluation data not done or unknown	6 Hours post randomization	Temperature
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4	Spon. Resp. Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5	Spon. Resp. Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6	Spon. Resp. Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5	Temperature
12006	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12006	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12006	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
12006	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
12006	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
12006	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
12006	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
12006	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
12006	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
12006	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Start:03MAR2016: 7:01:00 Stop:23MAR2016: 8:45:00	MV:FiO2
12006	Control	Data Issues	Evaluation data not done or unknown	Start:03MAR2016: 7:01:00 Stop:23MAR2016: 8:45:00	MV:TidalVolume
12006	Control	Data Issues	Evaluation data not done or unknown	Start:03MAR2016: 7:01:00 Stop:23MAR2016: 8:45:00	MV:tcPCO2
12006	Control	Data Issues	Evaluation data not done or unknown	Start:23MAR2016: 8:46:00 Stop:*. *	nCPAP:FlowRate
12006	Control	Data Issues	Evaluation data not done or unknown	Start:23MAR2016: 8:46:00 Stop:*. *	nCPAP:PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:04APR2016:10:00:00 Stop:18APR2016:10:00:00	SuppO2:FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12007	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:04APR2016:10:00:00 Stop:18APR2016:10:00:00	SuppO2:FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12010	Control	Data Issues	Evaluation data not done or unknown	18 Hours post randomization	Temperature
12010	Control	Data Issues	Evaluation data not done or unknown	24 Hours post randomization	Temperature
12010	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12010	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Start:17MAR2016:13:48:00 Stop:*	MV:MAP
				*	
12010	Control	Data Issues	Evaluation data not done or unknown	Start:17MAR2016:13:48:00 Stop:*	MV:TidalVolume
				*	
12010	Control	Data Issues	Evaluation data not done or unknown	Start:17MAR2016:13:48:00 Stop:*	MV:tcPCO2
				*	
12010	Control	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
12010	Control	Data Issues	Evaluation data not done or unknown	18 Hours post randomization	Temperature
12010	Control	Data Issues	Evaluation data not done or unknown	24 Hours post randomization	Temperature
12010	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12010	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12010	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
12010	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
12010	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12010	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12010	Control	Data Issues	Evaluation data not done or unknown	Start:17MAR2016:13:48:00 Stop:*: *	MV:MAP
12010	Control	Data Issues	Evaluation data not done or unknown	Start:17MAR2016:13:48:00 Stop:*: *	MV:TidalVolume
12010	Control	Data Issues	Evaluation data not done or unknown	Start:17MAR2016:13:48:00 Stop:*: *	MV:tcPCO2
12010	Control	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Spon. Resp. Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Screening Period	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Screening Period	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	nCPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JUN2016:17:45:00 Stop:*: *	MV:TidalVolume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JUN2016:17:45:00 Stop:*: *	MV:tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:09MAY2016:20:00:00 Stop:02JUN2016:12:00:00	nCPAP:PIP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:29APR2016:15:37:00 Stop:09MAY2016:19:59:00	MV:TidalVolume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:29APR2016:15:37:00 Stop:09MAY2016:19:59:00	MV:tcPCO2
12014	50 mg/kg	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
12014	50 mg/kg	Data Issues	Evaluation time out of window	3 hours (180 minutes) post randomization	
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Spon. Resp. Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Screening Period	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Screening Period	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	nCPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JUN2016:17:45:00 Stop:*: *	MV:TidalVolume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JUN2016:17:45:00 Stop:*: *	MV:tcPCO2
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:09MAY2016:20:00:00 Stop:02JUN2016:12:00:00	nCPAP:PIP
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:29APR2016:15:37:00 Stop:09MAY2016:19:59:00	MV:TidalVolume
12014	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:29APR2016:15:37:00 Stop:09MAY2016:19:59:00	MV:tcPCO2
12014	50 mg/kg	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
12014	50 mg/kg	Data Issues	Evaluation time out of window	3 hours (180 minutes) post randomization	
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6	Temperature
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07NOV2016:15:20:00 Stop:28NOV2016: 8:59:00	nCPAP:PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:10OCT2016:16:15:00 Stop:12OCT2016:19:59:00	MV:TidalVolume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:10OCT2016:16:15:00 Stop:12OCT2016:19:59:00	MV:tcPCO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:12OCT2016:20:00:00 Stop:22OCT2016: 1:09:00	nCPAP:FlowRate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:22OCT2016: 1:10:00 Stop:07NOV2016:15:19:00	MV:TidalVolume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:22OCT2016: 1:10:00 Stop:07NOV2016:15:19:00	MV:tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6	Temperature
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07NOV2016:15:20:00 Stop:28NOV2016: 8:59:00	nCPAP:PIP
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:10OCT2016:16:15:00 Stop:12OCT2016:19:59:00	MV:TidalVolume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:10OCT2016:16:15:00 Stop:12OCT2016:19:59:00	MV:tcPCO2
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:12OCT2016:20:00:00 Stop:22OCT2016: 1:09:00	nCPAP:FlowRate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:22OCT2016: 1:10:00 Stop:07NOV2016:15:19:00	MV:TidalVolume
12023	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:22OCT2016: 1:10:00 Stop:07NOV2016:15:19:00	MV:tcPCO2
12037	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12037	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Start:16DEC2016:13:15:00 Stop:31DEC2016:13:59:00	nCPAP:PIP
12037	Control	Data Issues	Evaluation time out of window	At the time of Randomization	
12037	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12037	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
12037	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
12037	Control	Data Issues	Evaluation data not done or unknown	Start:16DEC2016:13:15:00 Stop:31DEC2016:13:59:00	nCPAP:PIP
12037	Control	Data Issues	Evaluation time out of window	At the time of Randomization	
13016	Control	Data Issues	Evaluation data not done or unknown		Temperature
13016	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
13016	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
13016	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
13016	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
13016	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
13016	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
13016	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
13016	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
13016	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
13016	Control	Data Issues	Evaluation time out of window	2 hours 30 minutes (150 minutes) post randomizatio	
13016	Control	Data Issues	Evaluation time out of window	2 hours 45 minutes (165 minutes) post randomizatio	
13016	Control	Data Issues	Evaluation data not done or unknown		Temperature
13016	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
13016	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
13016	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
13016	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
13016	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
13016	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
13016	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
13016	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
13016	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
13016	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
13016	Control	Data Issues	Evaluation time out of window	2 hours 30 minutes (150 minutes) post randomizatio	
13016	Control	Data Issues	Evaluation time out of window	2 hours 45 minutes (165 minutes) post randomizatio	
19004	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
19004	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
19004	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
19004	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19004	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
19004	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19004	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19004	Control	Data Issues	Evaluation data not done or unknown	Start:28SEP2016:13:19:00 Stop:29OCT2016:10:26:00	nCPAP:PIP
19004	Control	Data Issues	Evaluation data not done or unknown	Start:31OCT2016: 9:45:00 Stop:*: *	MV:TidalVolume
19004	Control	Data Issues	Evaluation data not done or unknown	Start:31OCT2016: 9:45:00 Stop:*: *	MV:tcPCO2
19004	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
19004	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
19004	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
19004	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19004	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
19004	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
19004	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19004	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
19004	Control	Data Issues	Evaluation data not done or unknown	Start:28SEP2016:13:19:00 Stop:29OCT2016:10:26:00	nCPAP:PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19004	Control	Data Issues	Evaluation data not done or unknown	Start:31OCT2016: 9:45:00 Stop:*. *	MV:TidalVolume
19004	Control	Data Issues	Evaluation data not done or unknown	Start:31OCT2016: 9:45:00 Stop:*. *	MV:tcPCO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Heart Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Spon. Resp. Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Heart Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Spon. Resp. Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:20DEC2016: 8:39:00 Stop:21DEC2016:17:40:00	MV:TidalVolume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21DEC2016:17:41:00 Stop:*. *	nCPAP:PIP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Heart Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Spon. Resp. Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Heart Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Spon. Resp. Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:20DEC2016: 8:39:00 Stop:21DEC2016:17:40:00	MV:TidalVolume
19007	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21DEC2016:17:41:00 Stop:*. *	nCPAP:PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07MAY2016:13:12:00 Stop:*: *	MechanicalVentil

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40001	50 mg/kg	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40001	50 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07MAY2016:13:12:00 Stop:*: *	MechanicalVentil
40001	50 mg/kg	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08JUL2016: 7:00:00 Stop:21JUL2016:12:22:00	MechanicalVentil
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08JUL2016: 7:00:00 Stop:21JUL2016:12:22:00	MV:TidalVolume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21JUL2016:12:34:00 Stop:16AUG2016: 0:20:00	nCPAP:FlowRate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21JUL2016:12:34:00 Stop:16AUG2016: 0:20:00	nCPAP:PIP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08JUL2016: 7:00:00 Stop:21JUL2016:12:22:00	MechanicalVentil
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08JUL2016: 7:00:00 Stop:21JUL2016:12:22:00	MV:TidalVolume
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21JUL2016:12:34:00 Stop:16AUG2016: 0:20:00	nCPAP:FlowRate
40003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:21JUL2016:12:34:00 Stop:16AUG2016: 0:20:00	nCPAP:PIP
40004	Control	Data Issues	Evaluation data not done or unknown		Temperature
40004	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40004	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40004	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown		Temperature
40004	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40004	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
40004	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40004	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07SEP2016:13:10:00 Stop:11SEP2016:12:20:00	MechanicalVentil
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07SEP2016:13:10:00 Stop:11SEP2016:12:20:00	MV:TidalVolume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:11SEP2016:12:24:00 Stop:06OCT2016:20:18:00	nCPAP:FlowRate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:11SEP2016:12:24:00 Stop:06OCT2016:20:18:00	nCPAP:PIP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:24AUG2016:19:00:00 Stop:25AUG2016: 6:35:00	MV:TidalVolume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:25AUG2016: 6:43:00 Stop:07SEP2016:13:04:00	nCPAP:FlowRate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:25AUG2016: 6:43:00 Stop:07SEP2016:13:04:00	nCPAP:PIP
40006	75 mg/kg	Data Issues	Evaluation time out of window	60 hours post randomization	
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07SEP2016:13:10:00 Stop:11SEP2016:12:20:00	MechanicalVentil
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07SEP2016:13:10:00 Stop:11SEP2016:12:20:00	MV:TidalVolume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:11SEP2016:12:24:00 Stop:06OCT2016:20:18:00	nCPAP:FlowRate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:11SEP2016:12:24:00 Stop:06OCT2016:20:18:00	nCPAP:PIP
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:24AUG2016:19:00:00 Stop:25AUG2016: 6:35:00	MV:TidalVolume
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:25AUG2016: 6:43:00 Stop:07SEP2016:13:04:00	nCPAP:FlowRate
40006	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:25AUG2016: 6:43:00 Stop:07SEP2016:13:04:00	nCPAP:PIP
40006	75 mg/kg	Data Issues	Evaluation time out of window	60 hours post randomization	
40009	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40009	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40009	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40009	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Start:11OCT2016:16:01:00 Stop:07NOV2016:12:00:00	nCPAP:FlowRate
40009	Control	Data Issues	Evaluation data not done or unknown	Start:25SEP2016: 3:40:00 Stop:26SEP2016:15:54:00	MechanicalVentil
40009	Control	Data Issues	Evaluation data not done or unknown	Start:26SEP2016:15:55:00 Stop:26SEP2016:17:00:00	nCPAP:FlowRate
40009	Control	Data Issues	Evaluation data not done or unknown	Start:26SEP2016:15:55:00 Stop:26SEP2016:17:00:00	nCPAP:PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40009	Control	Data Issues	Evaluation data not done or unknown	Start:26SEP2016:17:53:00 Stop:11OCT2016:16:00:00	MechanicalVentil
40009	Control	Data Issues	Evaluation data not done or unknown	Start:26SEP2016:17:53:00 Stop:11OCT2016:16:00:00	MV:TidalVolume
40009	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40009	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
40009	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40009	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40009	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40009	Control	Data Issues	Evaluation data not done or unknown	Start:11OCT2016:16:01:00 Stop:07NOV2016:12:00:00	nCPAP:FlowRate
40009	Control	Data Issues	Evaluation data not done or unknown	Start:25SEP2016: 3:40:00 Stop:26SEP2016:15:54:00	MechanicalVentil
40009	Control	Data Issues	Evaluation data not done or unknown	Start:26SEP2016:15:55:00 Stop:26SEP2016:17:00:00	nCPAP:FlowRate
40009	Control	Data Issues	Evaluation data not done or unknown	Start:26SEP2016:15:55:00 Stop:26SEP2016:17:00:00	nCPAP:PIP
40009	Control	Data Issues	Evaluation data not done or unknown	Start:26SEP2016:17:53:00 Stop:11OCT2016:16:00:00	MechanicalVentil
40009	Control	Data Issues	Evaluation data not done or unknown	Start:26SEP2016:17:53:00 Stop:11OCT2016:16:00:00	MV:TidalVolume
40013	Control	Data Issues	Evaluation data not done or unknown		Temperature
40013	Control	Data Issues	Evaluation data not done or unknown	6 Hours post randomization	Temperature
40013	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40013	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40013	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Total CO2
40013	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40013	Control	Data Issues	Evaluation time out of window	1 hour 30 minutes (90 minutes) post randomization	
40013	Control	Data Issues	Evaluation time out of window	2 hours 30 minutes (150 minutes) post randomizatio	

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40013	Control	Data Issues	Evaluation time out of window	2 hours 45 minutes (165 minutes) post randomizatio	
40013	Control	Data Issues	Evaluation time out of window	3 hours (180 minutes) post randomization	
40013	Control	Data Issues	Evaluation data not done or unknown		Temperature
40013	Control	Data Issues	Evaluation data not done or unknown	6 Hours post randomization	Temperature
40013	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40013	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40013	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Total CO2
40013	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40013	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40013	Control	Data Issues	Evaluation time out of window	1 hour 30 minutes (90 minutes) post randomization	
40013	Control	Data Issues	Evaluation time out of window	2 hours 30 minutes (150 minutes) post randomizatio	
40013	Control	Data Issues	Evaluation time out of window	2 hours 45 minutes (165 minutes) post randomizatio	
40013	Control	Data Issues	Evaluation time out of window	3 hours (180 minutes) post randomization	
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Total CO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:09DEC2016: 0:24:00 Stop:15DEC2016:13:45:00	MechanicalVentil
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:09DEC2016: 0:24:00 Stop:15DEC2016:13:45:00	MV:TidalVolume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:14JAN2017: 9:00:00 Stop:19JAN2017:12:00:00	nCPAP:PIP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:14JAN2017: 9:00:00 Stop:19JAN2017:12:00:00	nCPAP:RespRate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start: 15DEC2016:14:00:00 Stop: 11JAN2017:12:00:00	nCPAP:FlowRate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Total CO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:09DEC2016: 0:24:00 Stop:15DEC2016:13:45:00	MechanicalVentil
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:09DEC2016: 0:24:00 Stop:15DEC2016:13:45:00	MV:TidalVolume
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:14JAN2017: 9:00:00 Stop:19JAN2017:12:00:00	nCPAP:PIP
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:14JAN2017: 9:00:00 Stop:19JAN2017:12:00:00	nCPAP:RespRate
40014	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:15DEC2016:14:00:00 Stop:11JAN2017:12:00:00	nCPAP:FlowRate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Heart Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Spon. Resp. Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Total CO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:04JAN2017: 6:40:00 Stop:05JAN2017:15:10:00	MechanicalVentil
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:04JAN2017: 6:40:00 Stop:05JAN2017:15:10:00	MV:TidalVolume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JAN2017:15:15:00 Stop:05JAN2017:22:00:00	nCPAP:FlowRate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JAN2017:15:15:00 Stop:05JAN2017:22:00:00	nCPAP:PIP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JAN2017:22:49:00 Stop:13JAN2017:14:20:00	MechanicalVentil
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:13JAN2017:14:23:00 Stop:*: *	nCPAP:FlowRate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:13JAN2017:14:23:00 Stop:*: *	nCPAP:PIP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Heart Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Reload Dose	Spon. Resp. Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	tcPCO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Total CO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:04JAN2017: 6:40:00 Stop:05JAN2017:15:10:00	MechanicalVentil
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:04JAN2017: 6:40:00 Stop:05JAN2017:15:10:00	MV:TidalVolume
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JAN2017:15:15:00 Stop:05JAN2017:22:00:00	nCPAP:FlowRate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JAN2017:15:15:00 Stop:05JAN2017:22:00:00	nCPAP:PIP
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:05JAN2017:22:49:00 Stop:13JAN2017:14:20:00	MechanicalVentil
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:13JAN2017:14:23:00 Stop:*: *	nCPAP:FlowRate
40015	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:13JAN2017:14:23:00 Stop:*: *	nCPAP:PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours post randomization	Temperature
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Total CO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours post randomization	Temperature
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Total CO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40016	100 mg/kg	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
40019	Control	Data Issues	Evaluation data not done or unknown		Temperature
40019	Control	Data Issues	Evaluation data not done or unknown	36 Hours post randomization	Temperature
40019	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40019	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40019	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Total CO2
40019	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40019	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40019	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
40019	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Start:16MAY2017:21:50:00 Stop:21MAY2017: 0:00:00	MV:TidalVolume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40019	Control	Data Issues	Evaluation data not done or unknown	Start:21MAY2017: 0:00:00 Stop:22MAY2017:14:00:00	nCPAP:PIP
40019	Control	Data Issues	Evaluation time out of window	1 hour 15 minutes (75 minutes) post randomization	
40019	Control	Data Issues	Evaluation data not done or unknown		Temperature
40019	Control	Data Issues	Evaluation data not done or unknown	36 Hours post randomization	Temperature
40019	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40019	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
40019	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Total CO2
40019	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
40019	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
40019	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
40019	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
40019	Control	Data Issues	Evaluation data not done or unknown	Start:16MAY2017:21:50:00 Stop:21MAY2017: 0:00:00	MV:TidalVolume
40019	Control	Data Issues	Evaluation data not done or unknown	Start:21MAY2017: 0:00:00 Stop:22MAY2017:14:00:00	nCPAP:PIP
40019	Control	Data Issues	Evaluation time out of window	1 hour 15 minutes (75 minutes) post randomization	
41002	Control	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Heart Rate
41002	Control	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Temperature
41002	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41002	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
41002	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
41002	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
41002	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Start:02DEC2016:15:25:00 Stop:*	nCPAP:PIP
				*	
41002	Control	Data Issues	Evaluation data not done or unknown	Start:27NOV2016:15:45:00 Stop:28NOV2016:12:45:00	MV:TidalVolume
41002	Control	Data Issues	Evaluation data not done or unknown	Start:27NOV2016:15:45:00 Stop:28NOV2016:12:45:00	MV:tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	Start:28NOV2016:12:45:00 Stop:30NOV2016:12:10:00	nCPAP:PIP
41002	Control	Data Issues	Evaluation data not done or unknown	Start:30NOV2016:12:30:00 Stop:02DEC2016:15:25:00	MV:TidalVolume
41002	Control	Data Issues	Evaluation data not done or unknown	Start:30NOV2016:12:30:00 Stop:02DEC2016:15:25:00	MV:tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Heart Rate
41002	Control	Data Issues	Evaluation data not done or unknown	1 Hour post randomization	Temperature
41002	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41002	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41002	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
41002	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
41002	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
41002	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
41002	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
41002	Control	Data Issues	Evaluation data not done or unknown	Start:02DEC2016:15:25:00 Stop:*	nCPAP:PIP
				*	
41002	Control	Data Issues	Evaluation data not done or unknown	Start:27NOV2016:15:45:00 Stop:28NOV2016:12:45:00	MV:TidalVolume
41002	Control	Data Issues	Evaluation data not done or unknown	Start:27NOV2016:15:45:00 Stop:28NOV2016:12:45:00	MV:tcPCO2
41002	Control	Data Issues	Evaluation data not done or unknown	Start:28NOV2016:12:45:00 Stop:30NOV2016:12:10:00	nCPAP:PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41002	Control	Data Issues	Evaluation data not done or unknown	Start:30NOV2016:12:30:00 Stop:02DEC2016:15:25:00	MV:TidalVolume
41002	Control	Data Issues	Evaluation data not done or unknown	Start:30NOV2016:12:30:00 Stop:02DEC2016:15:25:00	MV:tcPCO2
41005	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41005	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Start:03FEB2017:13:20:00 Stop:06FEB2017:14:19:00	MV:TidalVolume
41005	Control	Data Issues	Evaluation data not done or unknown	Start:03FEB2017:13:20:00 Stop:06FEB2017:14:19:00	MV:tcPCO2
41005	Control	Data Issues	Evaluation data not done or unknown	Start:06FEB2017:14:20:00 Stop:*, *	nCPAP:PIP
41005	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41005	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
41005	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
41005	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
41005	Control	Data Issues	Evaluation data not done or unknown	Start:03FEB2017:13:20:00 Stop:06FEB2017:14:19:00	MV:TidalVolume
41005	Control	Data Issues	Evaluation data not done or unknown	Start:03FEB2017:13:20:00 Stop:06FEB2017:14:19:00	MV:tcPCO2
41005	Control	Data Issues	Evaluation data not done or unknown	Start:06FEB2017:14:20:00 Stop:*, *	nCPAP:PIP
42001	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42001	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	CI-
42001	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Total CO2
42001	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42001	Control	Data Issues	Evaluation time out of window	Vital Signs - 15 Minutes	
42001	Control	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
42001	Control	Data Issues	Evaluation time out of window	60 minutes post randomization	
42001	Control	Data Issues	Evaluation time out of window	1 hour 15 minutes (75 minutes) post randomization	

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42001	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
42001	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42001	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Cl-
42001	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	Total CO2
42001	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
42001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42001	Control	Data Issues	Evaluation time out of window	Vital Signs - 15 Minutes	
42001	Control	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
42001	Control	Data Issues	Evaluation time out of window	60 minutes post randomization	
42001	Control	Data Issues	Evaluation time out of window	1 hour 15 minutes (75 minutes) post randomization	
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07AUG2016:15:40:00 Stop:14AUG2016:10:33:00	nCPAP:PIP
42003	75 mg/kg	Data Issues	Evaluation time out of window	1 Hour post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	30 minutes post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	45 minutes post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	60 minutes post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	1 hour 15 minutes (75 minutes) post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	1 hour 30 minutes (90 minutes) post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	1 hour 45 minutes (105 minutes) post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	2 hours (120 minutes) post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	2 hours 15 minutes (135 minutes) post randomizatio	
42003	75 mg/kg	Data Issues	Evaluation time out of window	2 hours 30 minutes (150 minutes) post randomizatio	
42003	75 mg/kg	Data Issues	Evaluation time out of window	2 hours 45 minutes (165 minutes) post randomizatio	

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42003	75 mg/kg	Data Issues	Evaluation time out of window	3 hours (180 minutes) post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	1 Hour Post Randomization	
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
42003	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07AUG2016:15:40:00 Stop:14AUG2016:10:33:00	nCPAP:PIP
42003	75 mg/kg	Data Issues	Evaluation time out of window	1 Hour post randomization	

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42003	75 mg/kg	Data Issues	Evaluation time out of window	30 minutes post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	45 minutes post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	60 minutes post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	1 hour 15 minutes (75 minutes) post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	1 hour 30 minutes (90 minutes) post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	1 hour 45 minutes (105 minutes) post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	2 hours (120 minutes) post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	2 hours 15 minutes (135 minutes) post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	2 hours 30 minutes (150 minutes) post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	2 hours 45 minutes (165 minutes) post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	3 hours (180 minutes) post randomization	
42003	75 mg/kg	Data Issues	Evaluation time out of window	1 Hour Post Randomization	
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3	Spon. Resp. Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4	Spon. Resp. Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5	Spon. Resp. Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6	Spon. Resp. Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7	Spon. Resp. Rate
42004	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
42004	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
42004	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
42004	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42004	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Start:05SEP2016:13:25:00 Stop:*	nCPAP:FlowRate
				*	
42004	Control	Data Issues	Evaluation data not done or unknown	Start:15AUG2016:21:50:00 Stop:*	MechanicalVentil
				*	
42004	Control	Data Issues	Evaluation time out of window	30 minutes post randomization	
42004	Control	Data Issues	Evaluation time out of window	60 minutes post randomization	
42004	Control	Data Issues	Evaluation time out of window	1 hour 45 minutes (105 minutes) post randomization	
42004	Control	Data Issues	Evaluation time out of window	2 hours (120 minutes) post randomization	
42004	Control	Data Issues	Evaluation time out of window	2 hours 15 minutes (135 minutes) post randomizatio	
42004	Control	Data Issues	Evaluation time out of window	3 hours (180 minutes) post randomization	
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3	Spon. Resp. Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4	Spon. Resp. Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5	Spon. Resp. Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6	Spon. Resp. Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7	Spon. Resp. Rate
42004	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
42004	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
42004	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
42004	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42004	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
42004	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
42004	Control	Data Issues	Evaluation data not done or unknown	Start:05SEP2016:13:25:00 Stop:*	nCPAP:FlowRate
				*	
42004	Control	Data Issues	Evaluation data not done or unknown	Start:15AUG2016:21:50:00 Stop:*	MechanicalVentil
				*	
42004	Control	Data Issues	Evaluation time out of window	30 minutes post randomization	
42004	Control	Data Issues	Evaluation time out of window	60 minutes post randomization	
42004	Control	Data Issues	Evaluation time out of window	1 hour 45 minutes (105 minutes) post randomization	
42004	Control	Data Issues	Evaluation time out of window	2 hours (120 minutes) post randomization	
42004	Control	Data Issues	Evaluation time out of window	2 hours 15 minutes (135 minutes) post randomization	
42004	Control	Data Issues	Evaluation time out of window	3 hours (180 minutes) post randomization	
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 Minutes post reload of dose	Heart Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 Minutes post reload of dose	Spon. Resp. Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08DEC2016: 8:07:00 Stop:20DEC2016:10:59:00	MechanicalVentil

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08DEC2016: 8:07:00 Stop:20DEC2016:10:59:00	MV:tcPCO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08DEC2016:18:50:00 Stop:*. *	MechanicalVentil
42010	100 mg/kg	Data Issues	Evaluation time out of window	30 Minutes Post Dosing	
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 Minutes post reload of dose	Heart Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 Minutes post reload of dose	Spon. Resp. Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08DEC2016: 8:07:00 Stop:20DEC2016:10:59:00	MechanicalVentil
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08DEC2016: 8:07:00 Stop:20DEC2016:10:59:00	MV:tcPCO2
42010	100 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08DEC2016:18:50:00 Stop:*. *	MechanicalVentil
42010	100 mg/kg	Data Issues	Evaluation time out of window	30 Minutes Post Dosing	
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:03OCT2016:23:25:00 Stop:13OCT2016: 7:50:00	nCPAP:FlowRate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07NOV2016:23:00:00 Stop:09NOV2016: 9:00:00	nCPAP:FlowRate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07NOV2016:23:00:00 Stop:09NOV2016: 9:00:00	nCPAP:PIP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07NOV2016:23:00:00 Stop:09NOV2016: 9:00:00	nCPAP:RespRate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:13OCT2016: 7:50:00 Stop:15OCT2016:11:15:00	MV:MAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:13OCT2016: 7:50:00 Stop:15OCT2016:11:15:00	MV:TidalVolume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:13OCT2016: 7:50:00 Stop:15OCT2016:11:15:00	MV:tcPCO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:15OCT2016:11:30:00 Stop:*, *	nCPAP:FlowRate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:28SEP2016:20:41:00 Stop:03OCT2016:23:25:00	MV:TidalVolume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:28SEP2016:20:41:00 Stop:03OCT2016:23:25:00	MV:tcPCO2
50001	75 mg/kg	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:03OCT2016:23:25:00 Stop:13OCT2016: 7:50:00	nCPAP:FlowRate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07NOV2016:23:00:00 Stop:09NOV2016: 9:00:00	nCPAP:FlowRate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07NOV2016:23:00:00 Stop:09NOV2016: 9:00:00	nCPAP:PIP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07NOV2016:23:00:00 Stop:09NOV2016: 9:00:00	nCPAP:RespRate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:13OCT2016: 7:50:00 Stop:15OCT2016:11:15:00	MV:MAP
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:13OCT2016: 7:50:00 Stop:15OCT2016:11:15:00	MV:TidalVolume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:13OCT2016: 7:50:00 Stop:15OCT2016:11:15:00	MV:tcPCO2
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:15OCT2016:11:30:00 Stop:*. *	nCPAP:FlowRate
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:28SEP2016:20:41:00 Stop:03OCT2016:23:25:00	MV:TidalVolume
50001	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:28SEP2016:20:41:00 Stop:03OCT2016:23:25:00	MV:tcPCO2
50001	75 mg/kg	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07AUG2016:20:20:00 Stop:08AUG2016: 9:10:00	nCPAP:FlowRate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08AUG2016: 9:10:00 Stop:11AUG2016:16:45:00	MV:TidalVolume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08AUG2016: 9:10:00 Stop:11AUG2016:16:45:00	MV:tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:11AUG2016:16:45:00 Stop:01SEP2016:10:30:00	nCPAP:FlowRate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:26JUL2016:20:20:00 Stop:07AUG2016:20:20:00	MV:TidalVolume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:26JUL2016:20:20:00 Stop:07AUG2016:20:20:00	MV:tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	36 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:07AUG2016:20:20:00 Stop:08AUG2016: 9:10:00	nCPAP:FlowRate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08AUG2016: 9:10:00 Stop:11AUG2016:16:45:00	MV:TidalVolume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:08AUG2016: 9:10:00 Stop:11AUG2016:16:45:00	MV:tcPCO2
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:11AUG2016:16:45:00 Stop:01SEP2016:10:30:00	nCPAP:FlowRate
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:26JUL2016:20:20:00 Stop:07AUG2016:20:20:00	MV:TidalVolume
51004	75 mg/kg	Data Issues	Evaluation data not done or unknown	Start:26JUL2016:20:20:00 Stop:07AUG2016:20:20:00	MV:tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54001	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54001	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
54001	Control	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
54001	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
54001	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54001	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
54001	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54001	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
54001	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
54001	Control	Data Issues	Evaluation time out of window	15 Minutes prior to randomization	
54002	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54002	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54002	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54002	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Start:15SEP2016: 1:00:00 Stop:04OCT2016: 9:00:00	nCPAP:PIP
54002	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54002	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54002	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
54002	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
54002	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54002	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	18 Hours Post Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
54002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54002	Control	Data Issues	Evaluation data not done or unknown	Start:15SEP2016: 1:00:00 Stop:04OCT2016: 9:00:00	nCPAP:PIP
54017	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54017	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
54017	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
54017	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
54017	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
54017	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
54017	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
54017	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
54017	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
54017	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
54017	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
54017	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
54017	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
54017	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
54017	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Start:10DEC2016: 4:15:00 Stop:15DEC2016:12:00:00	MechanicalVentil
54017	Control	Data Issues	Evaluation data not done or unknown	Start:10DEC2016: 4:15:00 Stop:15DEC2016:12:00:00	MV:tcPCO2
54017	Control	Data Issues	Evaluation data not done or unknown	Start:15DEC2016:12:00:00 Stop:05JAN2017:14:00:00	nCPAP:PIP
54017	Control	Data Issues	Evaluation data not done or unknown	Start:26NOV2016:10:00:00 Stop:26NOV2016:15:00:00	MechanicalVentil
54017	Control	Data Issues	Evaluation data not done or unknown	Start:26NOV2016:15:00:00 Stop:10DEC2016: 4:15:00	nCPAP:PIP
54017	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54017	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
54017	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
54017	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
54017	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
54017	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
54017	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
54017	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
54017	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54017	Control	Data Issues	Evaluation data not done or unknown	12 Hours Post Randomization	PIP
54017	Control	Data Issues	Evaluation data not done or unknown	24 Hours Post Randomization	PIP
54017	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
54017	Control	Data Issues	Evaluation data not done or unknown	36 Hours Post Randomization	PIP
54017	Control	Data Issues	Evaluation data not done or unknown	48 Hours Post Randomization	PIP
54017	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
54017	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	MAP
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
54017	Control	Data Issues	Evaluation data not done or unknown	Start:10DEC2016: 4:15:00 Stop:15DEC2016:12:00:00	MechanicalVentil
54017	Control	Data Issues	Evaluation data not done or unknown	Start:10DEC2016: 4:15:00 Stop:15DEC2016:12:00:00	MV:tcPCO2
54017	Control	Data Issues	Evaluation data not done or unknown	Start:15DEC2016:12:00:00 Stop:05JAN2017:14:00:00	nCPAP:PIP
54017	Control	Data Issues	Evaluation data not done or unknown	Start:26NOV2016:10:00:00 Stop:26NOV2016:15:00:00	MechanicalVentil
54017	Control	Data Issues	Evaluation data not done or unknown	Start:26NOV2016:15:00:00 Stop:10DEC2016: 4:15:00	nCPAP:PIP
76002	Control	Data Issues	Evaluation data not done or unknown		Temperature
76002	Control	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	24 Hours post randomization	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	36 Hours post randomization	Spon. Resp. Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	48 Hours post randomization	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Temperature
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
76002	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
76002	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Start:19JAN2017:23:54:00 Stop:26JAN2017:12:30:00	MV:TidalVolume
76002	Control	Data Issues	Evaluation data not done or unknown	Start:19JAN2017:23:54:00 Stop:26JAN2017:12:30:00	MV:tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	Start:21DEC2016:11:50:00 Stop:19JAN2017:23:54:00	MV:TidalVolume
76002	Control	Data Issues	Evaluation data not done or unknown	Start:21DEC2016:11:50:00 Stop:19JAN2017:23:54:00	MV:tcPCO2
76002	Control	Data Issues	Evaluation time out of window	At the time of Randomization	
76002	Control	Data Issues	Evaluation data not done or unknown		Temperature
76002	Control	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	24 Hours post randomization	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	36 Hours post randomization	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	48 Hours post randomization	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	15 Minutes prior to randomization	Temperature
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7	Spon. Resp. Rate
76002	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	At the time of randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	15 minutes post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	30 minutes post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	45 minutes post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	60 minutes post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	1 hour 15 minutes (75 minutes) post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	1 hour 30 minutes (90 minutes) post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	1 hour 45 minutes (105 minutes) post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours (120 minutes) post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomization	Room Air

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours 15 minutes (135 minutes) post randomizatio	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours 30 minutes (150 minutes) post randomizatio	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	2 hours 45 minutes (165 minutes) post randomizatio	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	3 hours (180 minutes) post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	6 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	12 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	18 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	24 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	30 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	36 hours post randomization	tcPCO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	42 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	48 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	54 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	60 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	66 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	Room Air
76002	Control	Data Issues	Evaluation data not done or unknown	72 hours post randomization	tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	1 Hour Post Randomization	PIP
76002	Control	Data Issues	Evaluation data not done or unknown	3 Hours Post Randomization	PIP
76002	Control	Data Issues	Evaluation data not done or unknown	6 Hours Post Randomization	PIP
76002	Control	Data Issues	Evaluation data not done or unknown	At the time of Randomization	PIP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Flow Rate

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	CPAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Flow Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	PIP Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	MAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	MAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	MAP
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	Set Tidal Volume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Respiratory Rate
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	Set Tidal Volume
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 1 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 2 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 3 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 4 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 5 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 6 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 08:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Study Day 7 20:00	FiO2
76002	Control	Data Issues	Evaluation data not done or unknown	Start:19JAN2017:23:54:00 Stop:26JAN2017:12:30:00	MV:TidalVolume
76002	Control	Data Issues	Evaluation data not done or unknown	Start:19JAN2017:23:54:00 Stop:26JAN2017:12:30:00	MV:tcPCO2
76002	Control	Data Issues	Evaluation data not done or unknown	Start:21DEC2016:11:50:00 Stop:19JAN2017:23:54:00	MV:TidalVolume

Summary Listing 1.1
Protocol Violations/Deviations
All Subjects

Subject ID	Treatment Group	Deviation Category	Deviation	Timepoint	Test (if applicable)
76002	Control	Data Issues	Evaluation data not done or unknown	Start:21DEC2016:11:50:00 Stop:19JAN2017:23:54:00	MV:tcPCO2
76002	Control	Data Issues	Evaluation time out of window	At the time of Randomization	

Summary Listing 1.2
First Body Weight Measurement after Randomization
All Subjects

Subject ID	Dosing Group	Treatment Group	Randomization Date/Time	Measurement Date	Measurement Time	Body Weight(Gram)
01032	Dosing Group I	50 mg/kg	04FEB2016:13:04:00	05FEB2016	5:10:00	825
01033	Dosing Group I	50 mg/kg	04FEB2016:13:27:00	05FEB2016	4:00:00	1050
01040	Dosing Group I	50 mg/kg	13JUN2016:14:51:00	14JUN2016	11:47:00	1260
01041	Dosing Group I	50 mg/kg	13JUN2016:16:21:00	14JUN2016	4:00:00	1130
09001	Dosing Group I	50 mg/kg	10MAY2016:13:47:00	11MAY2016	20:06:00	1240
12007	Dosing Group I	50 mg/kg	02MAR2016: 8:59:00	02MAR2016	15:04:00	970
12014	Dosing Group I	50 mg/kg	29APR2016:12:26:00	29APR2016	13:45:00	876
40001	Dosing Group I	50 mg/kg	04MAY2016:19:29:00	06MAY2016	*	936
03006	Dosing Group I	Control	15JAN2016:12:28:00	15JAN2016	20:00:00	1220
08028	Dosing Group I	Control	27MAY2016:17:13:00	27MAY2016	17:49:00	1100
11005	Dosing Group I	Control	06JUN2016:11:30:00	09JUN2016	20:00:00	740
11006	Dosing Group I	Control	06JUN2016:12:21:00	11JUN2016	5:00:00	750
12004	Dosing Group I	Control	29FEB2016:19:01:00	01MAR2016	20:00:00	750
12006	Dosing Group I	Control	01MAR2016:19:09:00	02MAR2016	20:00:00	820
12010	Dosing Group I	Control	17MAR2016:12:51:00	18MAR2016	14:21:00	524
42001	Dosing Group I	Control	30MAY2016:21:29:00	31MAY2016	*	1180
01042	Dosing Group II	75 mg/kg	11AUG2016:17:24:00	13AUG2016	1:00:00	820
11011	Dosing Group II	75 mg/kg	31AUG2016:19:58:00	02SEP2016	2:00:00	750
12023	Dosing Group II	75 mg/kg	30SEP2016: 3:07:00	30SEP2016	12:58:00	825
40003	Dosing Group II	75 mg/kg	07JUL2016:14:56:00	08JUL2016	20:00:00	763
40006	Dosing Group II	75 mg/kg	24AUG2016:14:50:00	25AUG2016	0:09:00	945
42003	Dosing Group II	75 mg/kg	18JUL2016:11:46:00	18JUL2016	*	1010
50001	Dosing Group II	75 mg/kg	28SEP2016:14:17:00	28SEP2016	14:30:00	720
51004	Dosing Group II	75 mg/kg	26JUL2016:13:07:00	26JUL2016	13:34:00	935

Summary Listing 1.2
First Body Weight Measurement after Randomization
All Subjects

Subject ID	Dosing Group	Treatment Group	Randomization Date/Time	Measurement Date	Measurement Time	Body Weight(Gram)
03013	Dosing Group II	Control	14AUG2016:11:01:00	14AUG2016	11:02:00	930
08037	Dosing Group II	Control	24AUG2016:15:06:00	27AUG2016	0:00:00	1150
19004	Dosing Group II	Control	27SEP2016:23:30:00	28SEP2016	21:00:00	640
40004	Dosing Group II	Control	18JUL2016:16:00:00	19JUL2016	20:09:00	1047
40009	Dosing Group II	Control	24SEP2016:22:27:00	28SEP2016	1:54:00	850
42004	Dosing Group II	Control	15AUG2016:20:58:00	16AUG2016	20:30:00	820
54001	Dosing Group II	Control	23JUL2016:13:33:00	23JUL2016	13:40:00	1320
54002	Dosing Group II	Control	02SEP2016:12:39:00	02SEP2016	13:00:00	1360
11021	Dosing Group III	100 mg/kg	05NOV2016:14:01:00	06NOV2016	2:00:00	940
11023	Dosing Group III	100 mg/kg	21NOV2016:20:28:00	24NOV2016	20:00:00	490
11025	Dosing Group III	100 mg/kg	27APR2017:11:31:00	28APR2017	2:00:00	970
19007	Dosing Group III	100 mg/kg	19DEC2016:21:40:00	20DEC2016	6:00:00	940
40014	Dosing Group III	100 mg/kg	08DEC2016:20:30:00	12DEC2016	0:56:00	644
40015	Dosing Group III	100 mg/kg	03JAN2017:15:30:00	07JAN2017	1:44:00	719
40016	Dosing Group III	100 mg/kg	23FEB2017:16:16:00	26FEB2017	12:01:00	670
42010	Dosing Group III	100 mg/kg	07DEC2016:23:02:00	08DEC2016	21:20:00	1140
12037	Dosing Group III	Control	30NOV2016: 2:48:00	01DEC2016	4:00:00	1040
13016	Dosing Group III	Control	17JAN2017:15:22:00	18JAN2017	0:00:00	840
40013	Dosing Group III	Control	30OCT2016:10:16:00	31OCT2016	0:01:00	1346
40019	Dosing Group III	Control	16MAY2017:13:30:00	20MAY2017	1:55:00	1191
41002	Dosing Group III	Control	27NOV2016:14:57:00	27NOV2016	18:10:00	800
41005	Dosing Group III	Control	13JAN2017:20:05:00	13JAN2017	20:52:00	1095
54017	Dosing Group III	Control	25NOV2016:17:21:00	25NOV2016	17:36:00	870
76002	Dosing Group III	Control	20DEC2016:23:36:00	21DEC2016	6:00:00	1050

Summary Listing 3.1
Early Termination of Aerosol Treatment

Treatment Group	Subject ID	Dose Date/Time	Dose end Date/Time	Stopped?	Primary Stopped Reason	Specify Other Reason	Additional Info
50 mg/kg	01032	04FEB2016: 16:26:00	04FEB2016: 16:56:00	No			
50 mg/kg	01033	04FEB2016: 15:19:00	04FEB2016: 15:43:00	Yes	Other	Full dose was not given because sweep gas (gas flow that carries the medication) not on for first 6 minutes	Only 24 minute tx given due to sweep gas (gas flow that carries medication) not being on for the first 6 minutes
50 mg/kg	01040	13JUN2016: 15:55:00	13JUN2016: 16:25:00	No			
50 mg/kg	01041	13JUN2016: 17:16:00	13JUN2016: 17:46:00	No			
75 mg/kg	01042	11AUG2016: 18:17:00	11AUG2016: 19:02:00	No			
50 mg/kg	09001	10MAY2016: 6:16:40:00	10MAY2016: 6:17:10:00	Yes	Device failure or malfunction, including error codes		Initial treatment started at 1455, device error codes at 6 minutes and 28 seconds, treatment stopped at 1501. Error code 5130 and 5010.
75 mg/kg	11011	31AUG2016: 21:41:00	31AUG2016: 22:26:00	No			
100 mg/kg	11021	05NOV2016: 16:00:00	05NOV2016: 17:24:00	No			
100 mg/kg	11023	21NOV2016: 22:18:00	21NOV2016: 23:33:00	No			

Summary Listing 3.1
Early Termination of Aerosol Treatment

Treatment Group	Subject ID	Dose Date/Time	Dose end Date/Time	Stopped?	Primary Stopped Reason	Specify Other Reason	Additional Info
100 mg/kg	11025	27APR2017: 14:27:00	27APR2017: 16:49:00	Yes	Other	tubing became disconnected from the ADP. Discussion between Dr. Leone and Jennifer Reed took place. Second syringe was given and a replacement syringe was ordered	the second syringe was started at 14:27 for 30 mins and the replacement dose was started at 16:19 for 30 mins
50 mg/kg	12007	02MAR201 6:10:08:00	02MAR201 6:10:38:00	No			
50 mg/kg	12014	29APR2016: 13:28:00	29APR2016: 13:58:00	No			
75 mg/kg	12023	30SEP2016: 5:43:00	30SEP2016: 6:22:00	Yes	Device failure or malfunction, including error codes		Error code 5300, 5130
100 mg/kg	19007	19DEC2016 :22:50:00	19DEC2016 :23:58:00	No			
50 mg/kg	40001	04MAY201 6:20:36:00	04MAY201 6:21:06:00	No			
75 mg/kg	40003	07JUL2016: 16:07:00	07JUL2016: 16:45:00	Yes	Device failure or malfunction, including error codes		Drug stopped at 16:45 due to device failure. Error code 5130 and 5010 were noted. Informed Christina Joseph, assigned R&D specialist.
75 mg/kg	40006	24AUG2016 :16:05:00	24AUG2016 :16:25:00	Yes	Device failure or malfunction, including error codes		Treatment stopped at 1613, Heart rate decreased to 80, PPV provided, resumed at 1617. At 1625 stopped due to temp probe error 5120

Summary Listing 3.1
Early Termination of Aerosol Treatment

Treatment Group	Subject ID	Dose Date/Time	Dose end Date/Time	Stopped?	Primary Stopped Reason	Specify Other Reason	Additional Info
100 mg/kg	40014	08DEC2016 :21:48:00	08DEC2016 :22:16:00	Yes	Device failure or malfunction, including error codes		After 4 minutes the machine had an error. Then R&D specialist told the investigator to use the second syringe, after 6 mins machine had the same error.
100 mg/kg	40015	03JAN2017: 16:37:00	03JAN2017: 17:44:00	No			
100 mg/kg	40016	23FEB2017: 17:08:00	23FEB2017: 18:21:00	Yes	Device failure or malfunction, including error codes		Error codes
75 mg/kg	42003	18JUL2016: 13:05:00	18JUL2016: 13:47:00	Yes	Device failure or malfunction, including error codes		Error codes at 12:45 prior to dose initiation: 5110, 5210, 5010 Error code at 41 min and 37 sec of dose: 5130
100 mg/kg	42010	08DEC2016 : 0:00:00	08DEC2016 : 1:09:00	Yes	Device failure or malfunction, including error codes		Error codes at 29 min 09 sec in first half of dose (5130, 5010) Error codes at 18 min 03 sec in second half of dose (5130, 5010)
75 mg/kg	50001	28SEP2016: 15:20:00	28SEP2016: 16:05:00	No			
75 mg/kg	51004	26JUL2016: 14:10:00	26JUL2016: 14:55:00	No			

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
50 mg/kg	01032	ALL OTHER NON-THERAPEUTIC PRODUCTS	SUCROSE	16FEB2016	16FEB2016	0.2	ml	No
		ALL OTHER NON-THERAPEUTIC PRODUCTS	SUCROSE	12MAR2016	12MAR2016	0.2	ml	No
		ANTIANEMIC PREPARATIONS	EPOETIN ALFA	25MAR2016		680	U	Yes
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	29FEB2016	25MAR2016	3	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	04FEB2016	07FEB2016	82	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFOTAXIME	04FEB2016	07FEB2016	40	mg	No
		ANTHEMORRHAGICS	PHYTOMENADIONE	04FEB2016	04FEB2016	1	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS	07FEB2016	09FEB2016	1	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	04FEB2016	24FEB2016	6	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	07FEB2016	07FEB2016	0.6	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	07MAR2016	07MAR2016	7	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	25MAR2016	25MAR2016	8	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM ACETATE	05FEB2016	12FEB2016	1	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	05FEB2016	05FEB2016	1.5	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	05FEB2016	06FEB2016	0.8	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	08FEB2016	08FEB2016	0.82	mEq	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	08FEB2016	08FEB2016	1	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	08FEB2016	08FEB2016	1	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	04FEB2016	05FEB2016	0.8	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM PHOSPHATE	09FEB2016	09FEB2016	0.8	mEq	No
		DIURETICS	FUROSEMIDE	15FEB2016	15FEB2016	0.5	mg	No
		DIURETICS	FUROSEMIDE	16FEB2016	16FEB2016	1	mg	No
		DIURETICS	FUROSEMIDE	17FEB2016	18FEB2016	1	mg	No
		DRUGS FOR CONSTIPATION	GLYCEROL	07FEB2016	08FEB2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	09FEB2016	11FEB2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	11FEB2016	14FEB2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	21FEB2016	21FEB2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	24FEB2016	24FEB2016	0.5	ml	No
		EMOLLIENTS AND PROTECTIVES	ZINC OXIDE	21MAR2016	21MAR2016	1	appl	No
		EMOLLIENTS AND PROTECTIVES	ZINC OXIDE	03APR2016	05APR2016	1	appl	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	08MAR2016	08MAR2016	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	22MAR2016	22MAR2016	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	29MAR2016	29MAR2016	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	29MAR2016	29MAR2016	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	04FEB2016	04FEB2016	1	appl	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	04FEB2016	04FEB2016	160	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		PSYCHOANALEPTICS	CAFFEINE	04FEB2016	04FEB2016	16	mg	No
		PSYCHOANALEPTICS	CAFFEINE	05FEB2016	16FEB2016	6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	17FEB2016	22FEB2016	8	mg	No
		PSYCHOANALEPTICS	CAFFEINE	23FEB2016	12MAR2016	8	mg	No
		VITAMINS	COLECALCIFEROL	23FEB2016		400	U	Yes
	01033	ALL OTHER NON-THERAPEUTIC PRODUCTS	SUCROSE	08MAR2016	08MAR2016	0.2	ml	No
		ANALGESICS	MORPHINE	05FEB2016	05FEB2016	0.05	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	29FEB2016		4.5	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	04FEB2016	11FEB2016	110	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFOTAXIME	04FEB2016	11FEB2016	55	mg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	04FEB2016	04FEB2016	1	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	04FEB2016	26FEB2016	7	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	07FEB2016	07FEB2016	11	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	05FEB2016	05FEB2016	2	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	05FEB2016	05FEB2016	2	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	04FEB2016	04FEB2016	10	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	04FEB2016	04FEB2016	11	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	04FEB2016	12FEB2016	0.8	ml/hr	No
		DIURETICS	FUROSEMIDE	16FEB2016	16FEB2016	1.2	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		DRUGS FOR CONSTIPATION	GLYCEROL	07FEB2016	07FEB2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	09FEB2016	12FEB2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	17FEB2016	21FEB2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	14MAR2016	14MAR2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	05APR2016	05APR2016	0.5	ml	No
		EMOLLIENTS AND PROTECTIVES	ZINC OXIDE	20MAR2016	21MAR2016	1	appl	No
		EMOLLIENTS AND PROTECTIVES	ZINC OXIDE	22MAR2016	22MAR2016	1	appl	No
		EMOLLIENTS AND PROTECTIVES	ZINC OXIDE	03APR2016	03APR2016	1	appl	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	08MAR2016	08MAR2016	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	22MAR2016	22MAR2016	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	29MAR2016	29MAR2016	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	29MAR2016	29MAR2016	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	04FEB2016	04FEB2016	1	appl	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	05FEB2016	05FEB2016	200	mg	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	06FEB2016	06FEB2016	120	mg	No
		PSYCHOANALEPTICS	CAFFEINE	04FEB2016	04FEB2016	22	mg	No
		PSYCHOANALEPTICS	CAFFEINE	05FEB2016	24FEB2016	9	mg	No
		PSYCHOANALEPTICS	CAFFEINE	25FEB2016	12MAR2016	10	mg	No
		VITAMINS	COLECALCIFEROL	23FEB2016		400	U	Yes
	01040	ALL OTHER NON-THERAPEUTIC PRODUCTS	SUCROSE	27JUN2016	27JUN2016	0.2	ml	No
		ANALGESICS	MORPHINE	14JUN2016	14JUN2016	0.12	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANALGESICS	MORPHINE	16JUN2016	19JUN2016	0.125	mg	No
		ANALGESICS	MORPHINE	20JUN2016	21JUN2016	0.1	mg	No
		ANESTHETICS	FENTANYL	17JUN2016	21JUN2016	1	mcg/kg/hr	No
		ANESTHETICS	FENTANYL	18JUN2016	18JUN2016	1	mcg	No
		ANTIEMETIC PREPARATIONS	FERROUS SULFATE	08JUL2016	29JUL2016	3	mg	No
		ANTIEMETIC PREPARATIONS	FERROUS SULFATE	30JUL2016		6	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	13JUN2016	20JUN2016	130	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFOTAXIME	13JUN2016	20JUN2016	65	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	30JUL2016	05AUG2016	10	mg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	13JUN2016	13JUN2016	1	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	13JUN2016	26JUN2016	6.7	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	21JUN2016	21JUN2016	14	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	22JUN2016	22JUN2016	14	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM ACETATE	14JUN2016	17JUN2016	1	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	14JUN2016	14JUN2016	1.3	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	13JUN2016	14JUN2016	1	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	17JUN2016	22JUN2016	2	ml/hr	No
		CARDIAC THERAPY	INDOMETACIN	15JUN2016	16JUN2016	0.3	mg	No
		DIURETICS	FUROSEMIDE	15JUL2016	15JUL2016	1.9	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		DRUGS FOR CONSTIPATION	GLYCEROL	16JUN2016	18JUN2016	1	sliver	No
		DRUGS FOR CONSTIPATION	GLYCEROL	21JUN2016	21JUN2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	22JUN2016	24JUN2016	0.5	ml	No
		EMOLLIENTS AND PROTECTIVES	ZINC OXIDE	05AUG2016		1	appl	Yes
		MUSCLE RELAXANTS	VECURONIUM	19JUN2016	19JUN2016	0.13	mg	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	13JUL2016	13JUL2016	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	26JUL2016	26JUL2016	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	13JUN2016	13JUN2016	1	appl	No
		OPHTHALMOLOGICALS	LACRI-LUBE	19JUN2016	19JUN2016	1	appl	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	14JUN2016	14JUN2016	160	mg	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	14JUN2016	14JUN2016	240	mg	No
		PSYCHOANALEPTICS	CAFFEINE	13JUN2016	13JUN2016	25	mg	No
		PSYCHOANALEPTICS	CAFFEINE	14JUN2016	25JUN2016	10	mg	No
		PSYCHOANALEPTICS	CAFFEINE	26JUN2016	25JUL2016	10	mg	No
		PSYCHOLEPTICS	LORAZEPAM	17JUN2016	17JUN2016	0.12	mg	No
		VITAMINS	COLECALCIFEROL	24JUN2016		400	U	Yes
	01041	ALL OTHER NON-THERAPEUTIC PRODUCTS	SUCROSE	27JUN2016	27JUN2016	0.2	ml	No
		ANALGESICS	MORPHINE	16JUN2016	19JUN2016	0.1	mg	No
		ANALGESICS	MORPHINE	21JUN2016	21JUN2016	0.1	mg	No
		ANESTHETICS	FENTANYL	16JUN2016	16JUN2016	0.6	mcg	No
		ANESTHETICS	FENTANYL	18JUN2016	21JUN2016	0.5	mcg/kg/hr	No
		ANTIANEMIC PREPARATIONS	FEROUS SULFATE	10JUL2016		6	mg	Yes

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	13JUN2016	15JUN2016	120	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFOTAXIME	13JUN2016	15JUN2016	60	mg	No
		ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	BACITRACIN	14JUN2016	20JUN2016	1	appl	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	13JUN2016	13JUN2016	1	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	13JUN2016	27JUN2016	6	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	13JUL2016	14JUL2016	20	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM ACETATE	14JUN2016	22JUN2016	1	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	13JUN2016	14JUN2016	1	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	02JUL2016	19JUL2016	1.5	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	20JUL2016	03AUG2016	1.5	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	03AUG2016		2	mEq	Yes
		DIURETICS	ALDACTAZIDE A	18JUL2016	27JUL2016	2	mg	No
		DIURETICS	ALDACTAZIDE A	27JUL2016	02AUG2016	2.2	mg	No
		DIURETICS	ALDACTAZIDE A	02AUG2016		2.4	mg	Yes
		DIURETICS	FUROSEMIDE	07JUL2016	07JUL2016	1.7	mg	No
		DIURETICS	FUROSEMIDE	18JUL2016	18JUL2016	2	mg	No
		DRUGS FOR CONSTIPATION	GLYCEROL	15JUN2016	16JUN2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	17JUN2016	18JUN2016	0.5	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		DRUGS FOR CONSTIPATION	GLYCEROL	22JUN2016	22JUN2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	29JUN2016	29JUN2016	0.5	ml	No
		MUSCLE RELAXANTS	VECURONIUM	16JUN2016	17JUN2016	0.1	mg	No
		MUSCLE RELAXANTS	VECURONIUM	18JUN2016	19JUN2016	0.1	mg	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	13JUL2016	13JUL2016	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	26JUL2016	26JUL2016	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	13JUN2016	13JUN2016	1	appl	No
		OPHTHALMOLOGICALS	LACRI-LUBE	19JUN2016	19JUN2016	1	appl	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	14JUN2016	14JUN2016	240	mg	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	15JUN2016	15JUN2016	120	mg	No
		PSYCHOANALEPTICS	CAFFEINE	13JUN2016	13JUN2016	24	mg	No
		PSYCHOANALEPTICS	CAFFEINE	14JUN2016	24JUN2016	9.4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	25JUN2016	01JUL2016	9	mg	No
		PSYCHOANALEPTICS	CAFFEINE	02JUL2016	08JUL2016	11	mg	No
		PSYCHOANALEPTICS	CAFFEINE	09JUL2016	14JUL2016	14.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	15JUL2016	26JUL2016	15	mg	No
		PSYCHOANALEPTICS	CAFFEINE	27JUL2016	27JUL2016	16	mg	No
		PSYCHOANALEPTICS	CAFFEINE	28JUL2016	07AUG2016	17	mg	No
		PSYCHOLEPTICS	LORAZEPAM	16JUN2016	16JUN2016	0.1	mg	No
		VITAMINS	COLECALCIFEROL	24JUN2016		400	U	Yes
	09001	ANTIANEMIC PREPARATIONS	EPOETIN ALFA	31MAY2016	06JUN2016	460	U	No
		ANTIANEMIC PREPARATIONS	EPOETIN ALFA	06JUN2016	09JUN2016	450	U	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	25MAY2016	31MAY2016	4.1	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	01JUN2016	09JUN2016	9.3	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	10JUN2016		5.3	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFEPIME	21MAY2016	22MAY2016	41.4	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFEPIME	22MAY2016	26MAY2016	69	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	21MAY2016	24MAY2016	20.5	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	24MAY2016	29MAY2016	20.5	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	29MAY2016	01JUN2016	20.5	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	01JUN2016	03JUN2016	20.5	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	03JUN2016	04JUN2016	17	mg	No
		ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	NEOSPORIN /00130801/	24MAY2016	10JUN2016	1	application	No
		ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	PROBIOTIC /07343501/	11MAY2016	14MAY2016	0.5	gm	No
		ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	PROBIOTIC /07343501/	16MAY2016	22MAY2016	0.5	gm	No
		ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	PROBIOTIC /07343501/	24MAY2016		0.5	gm	Yes
		ANTIHEMORRHAGICS	PHYTOMENADIONE	10MAY2016	10MAY2016	1	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	10MAY2016	11MAY2016	84	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	10MAY2016	12MAY2016	100	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	11MAY2016	12MAY2016	40.8	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	12MAY2016	13MAY2016	36	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	13MAY2016	15MAY2016	160.8	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	15MAY2016	16MAY2016	124.8	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	16MAY2016	17MAY2016	96	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	17MAY2016	18MAY2016	67.2	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	18MAY2016	19MAY2016	48	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	22MAY2016	23MAY2016	168	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	23MAY2016	24MAY2016	84	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	10MAY2016	11MAY2016	0.5	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	11MAY2016	12MAY2016	0.8	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	12MAY2016	13MAY2016	0.4	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	13MAY2016	17MAY2016	0.8	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	17MAY2016	18MAY2016	0.5	ml/hr	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	22MAY2016	23MAY2016	0.8	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	23MAY2016	24MAY2016	0.5	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM ACETATE	10MAY2016	12MAY2016	10	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	10MAY2016	10MAY2016	10	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	14MAY2016	14MAY2016	1	Enema	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	14MAY2016	15MAY2016		ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	21MAY2016	06JUN2016		ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	11MAY2016	11MAY2016	0.25	sliver	No
		DRUGS FOR CONSTIPATION	GLYCEROL	12MAY2016	12MAY2016	1	sliver	No
		DRUGS FOR CONSTIPATION	GLYCEROL	13MAY2016	13MAY2016	0.25	sliver	No
		DRUGS FOR CONSTIPATION	GLYCEROL	13MAY2016	13MAY2016	0.25	sliver	No
		DRUGS FOR CONSTIPATION	GLYCEROL	13MAY2016	14MAY2016	0.25	sliver	No
		GENERAL NUTRIENTS	GLUCOSE	10MAY2016	10MAY2016	2.5	ml	No
		GENERAL NUTRIENTS	GLUCOSE	10MAY2016	10MAY2016	200	ml	No
		GENERAL NUTRIENTS	GLUCOSE	13MAY2016	13MAY2016	4.5	ml/hr	No
		GENERAL NUTRIENTS	GLUCOSE	21MAY2016	22MAY2016	500	ml	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	08JUN2016		1	gtt	Yes
		OPHTHALMOLOGICALS	ERYTHROMYCIN	10MAY2016	10MAY2016	0.5	percent	No
		OPHTHALMOLOGICALS	PROXYMETACAINE	08JUN2016		1	gtt	Yes
		OTHER HEMATOLOGICAL AGENTS	HYALURONIDASE	24MAY2016	24MAY2016	150	U	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		PSYCHOANALEPTICS	CAFFEINE	10MAY2016	10MAY2016	25.4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	11MAY2016	12MAY2016	6.4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	12MAY2016	14MAY2016	6.4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	14MAY2016	19MAY2016	6.4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	19MAY2016	22MAY2016	6.4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	22MAY2016	24MAY2016	6.8	mg	No
		PSYCHOANALEPTICS	CAFFEINE	24MAY2016	03JUN2016	6.8	mg	No
		PSYCHOANALEPTICS	CAFFEINE	03JUN2016	09JUN2016	8.4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	09JUN2016	18JUN2016	10.6	mg	No
		VACCINES	HEPATITIS B VACCINE	10MAY2016	10MAY2016	0.5	ml	No
		VACCINES	HEPATITIS B VACCINE	10MAY2016	10MAY2016	156	U	No
		VACCINES	HEPATITIS B VACCINE	10JUN2016	10JUN2016	0.5	ml	No
		VITAMINS	COLECALCIFEROL	11MAY2016	14MAY2016	400	U	No
		VITAMINS	COLECALCIFEROL	16MAY2016		400	U	Yes
	12007	ALL OTHER NON-THERAPEUTIC PRODUCTS	SUCROSE	30MAR2016	05APR2016	0.2	ml	No
		ANALGESICS	MORPHINE	06MAR2016	06MAR2016	0.05	mg	No
		ANESTHETICS	LIDOCAINE	02MAR2016	21MAR2016	1	application	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	02MAR2016	04MAR2016	200	mg/kg/day	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	02MAR2016	04MAR2016	4.5	mg	No
		ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	MUPIROCIN	24MAR2016	02APR2016	1	application	No
		ANTIFUNGALS FOR DERMATOLOGICAL USE	NYSTATIN	26MAR2016	18APR2016	1	application	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	02MAR2016	02MAR2016	0.5	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIMYCOTICS FOR SYSTEMIC USE	FLUCONAZOLE	02MAR2016	18MAR2016	3	mg	No
		ANTITHROMBOTIC AGENTS	HEPARIN	02MAR2016	18MAR2016	50	U	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	02MAR2016	15MAR2016	120	mL/kg/day	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	15MAR2016	15MAR2016	0.5	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	02MAR2016	15MAR2016	3	g/kg/day	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	POTASSIUM PHOSPHATE MONOBASIC	16MAR2016	31MAR2016	25	mg/kg/day	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	06APR2016	06APR2016	20	ml/kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	15MAR2016	18MAR2016	2.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	06MAR2016	06MAR2016	0.5	ml	No
		MINERAL SUPPLEMENTS	MAGNESIUM CHLORIDE	15MAR2016	01APR2016	2	mEq/kg/mL	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	30MAR2016	30MAR2016	2	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	13APR2016	13APR2016	2	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	27APR2016	27APR2016	2	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	02MAR2016	02MAR2016	1.25	cm	No
		PSYCHOANALEPTICS	CAFFEINE	02MAR2016	02MAR2016	20	mg	No
		PSYCHOANALEPTICS	CAFFEINE	03MAR2016	12MAR2016	5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	07MAR2016	07MAR2016	10	mg	No
		PSYCHOANALEPTICS	CAFFEINE	13MAR2016	18APR2016	6	mg	No
		VITAMINS	COLECALCIFEROL	31MAR2016	31MAR2016	0.5	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		VITAMINS	FERROUS SULFATE W/VITAMINS NOS	01APR2016		0.5	mg	Yes
	12014	VITAMINS	RETINOL	02MAR2016		5000	U	Yes
		ANALGESICS	MORPHINE	29APR2016	29APR2016	0.1	mg/kg	No
		ANALGESICS	MORPHINE	02MAY2016	06JUN2016	0.05	mg/kg	No
		ANESTHETICS	FENTANYL	05JUN2016	05JUN2016	10	mcg	No
		ANESTHETICS	LIDOCAINE	02MAY2016	02MAY2016	1	application	No
		ANESTHETICS	LIDOCAINE	09MAY2016	09MAY2016	1	application	No
		ANTIEMETIC PREPARATIONS	FERROUS SULFATE	28MAY2016	04JUN2016	2.4	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	29APR2016	02MAY2016	5000	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	29APR2016	01MAY2016	4.5	mg/kg × 0.88 kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	07MAY2016	13MAY2016	4.9	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	NAFCILLIN	07MAY2016	14MAY2016	50	mg/kg/day	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	05JUN2016	06JUN2016	15	mg/kg	No
		ANTIFUNGALS FOR DERMATOLOGICAL USE	NYSTATIN	22MAY2016	06JUN2016	1	application	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	29APR2016	29APR2016	0.5	mg	No
		ANTIMYCOTICS FOR SYSTEMIC USE	FLUCONAZOLE	29APR2016	20MAY2016	3	mg/kg	No
		ANTITHROMBOTIC AGENTS	HEPARIN	01MAY2016	10MAY2016	0.5	ml/hr	No
		ANTITHROMBOTIC AGENTS	HEPARIN	05MAY2016	06JUN2016	0.6	ml	No
		BILE AND LIVER THERAPY	URSODEOXYCHOLIC ACID	03JUN2016	06OCT2016	20	mg/kg/day	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	ALBUMIN HUMAN	05JUN2016	05JUN2016	10	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	29APR2016	21MAY2016	137	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	CALCIUM GLUCONATE	05JUN2016	06JUN2016	100	mg/kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	29APR2016	30APR2016	2	g/kg/day	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	01MAY2016	20MAY2016	3	g/kg/day	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	05JUN2016	05JUN2016			No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	05JUN2016	05JUN2016			No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	05JUN2016	05JUN2016	2	mEq/kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	05JUN2016	05JUN2016	2	mEq/kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	05JUN2016	05JUN2016	2	mEq/kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	05JUN2016	05JUN2016	2	mEq/kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	05JUN2016	06JUN2016	15		No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	29APR2016	18MAY2016	2	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	01MAY2016	06JUN2016	2.5	mEq/mL	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM PHOSPHATE	04MAY2016	04MAY2016	10	mg/kg	No
		CARDIAC THERAPY	ATROPINE	05JUN2016	05JUN2016	0.2	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		CARDIAC THERAPY	DOBUTAMINE	05JUN2016	06JUN2016	15	mcg/kg/min	No
		CARDIAC THERAPY	DOPAMINE	05JUN2016	06JUN2016	26	mcg/min	No
		CARDIAC THERAPY	EPINEPHRINE	05JUN2016	05JUN2016	0.01	mg/kg	No
		CARDIAC THERAPY	INDOMETACIN	05MAY2016	07MAY2016	0.2	mg/kg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	05JUN2016	05JUN2016	100	mg	No
		DRUGS FOR CONSTIPATION	GLYCEROL	05MAY2016	05MAY2016	0.5	ml	No
		GENERAL NUTRIENTS	GLUCOSE	02MAY2016	03MAY2016	2	ml/hr	No
		GENERAL NUTRIENTS	GLUCOSE	05JUN2016	05JUN2016	7.6	ml/hr	No
		GENERAL NUTRIENTS	GLUCOSE	05JUN2016	06JUN2016	250	ml	No
		MUSCLE RELAXANTS	ROCURONIUM	05JUN2016	05JUN2016	1	mg	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	29APR2016	29APR2016	1.25	cm	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	29APR2016	29APR2016	2.2	ml	No
		PSYCHOANALEPTICS	CAFFEINE	29APR2016	29APR2016	20	mg/kg	No
		PSYCHOANALEPTICS	CAFFEINE	30APR2016	06JUN2016	5	mg/kg	No
		PSYCHOLEPTICS	MIDAZOLAM	05JUN2016	05JUN2016	0.1	mg/kg	No
		PSYCHOLEPTICS	MIDAZOLAM	06JUN2016	06JUN2016	1.3	mg	No
		VITAMINS	RETINOL	29APR2016	26MAY2016	5000	U	No
	40001	ANESTHETICS	FENTANYL	07MAY2016		2	mcg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	04MAY2016	06MAY2016	47	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	04MAY2016	06MAY2016	7.5	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	07MAY2016		7.7	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	METRONIDAZOLE	07MAY2016		7.2	mg	Yes

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	07MAY2016		9.6	mg	Yes
		ANTITHROMBOTIC AGENTS	HEPARIN	04MAY2016		50	U	Yes
		CARDIAC THERAPY	ATROPINE	07MAY2016	07MAY2016	0.19	ml	No
		CARDIAC THERAPY	INDOMETACIN	04MAY2016	06MAY2016	0.09	mg	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	07MAY2016	07MAY2016	0.095	ml	No
		PSYCHOANALEPTICS	CAFFEINE	06MAY2016		4.7	mg	Yes
75 mg/kg	01042	ANALGESICS	PARACETAMOL	12OCT2016	12OCT2016	20	mg	No
		ANTIEMETIC PREPARATIONS	FERROUS SULFATE	08SEP2016	08SEP2016	4.5	mg	No
		ANTIEMETIC PREPARATIONS	FERROUS SULFATE	11SEP2016		4.5	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	11AUG2016	13AUG2016	80	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFOTAXIME	11AUG2016	13AUG2016	40	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	09SEP2016	15SEP2016	4.8	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	09SEP2016	15SEP2016	22	mg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	11AUG2016	11AUG2016	1	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	11AUG2016	31AUG2016	5	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	09SEP2016	10SEP2016	7	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	14SEP2016	14SEP2016	7	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	19AUG2016	19AUG2016	16	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	14SEP2016	14SEP2016	18	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM ACETATE	11AUG2016	14AUG2016	1	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	12AUG2016	12AUG2016	0.85	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	12AUG2016	12AUG2016	1	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	11AUG2016	11AUG2016	1	ml/hr	No
		DIURETICS	FUROSEMIDE	14SEP2016	14SEP2016	1.2	mg	No
		DRUGS FOR ACID RELATED DISORDERS	OMEPRAZOLE	17SEP2016	02OCT2016	1.2	mg	No
		DRUGS FOR ACID RELATED DISORDERS	OMEPRAZOLE	07OCT2016		1.7	mg	Yes
		EMOLLIENTS AND PROTECTIVES	ZINC OXIDE	29SEP2016	02OCT2016	1	appl	No
		GENERAL NUTRIENTS	GLUCOSE	11AUG2016	11AUG2016	2	ml	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	13SEP2016	13SEP2016	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	27SEP2016	27SEP2016	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	05OCT2016	05OCT2016	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	11AUG2016	11AUG2016	1	appl	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	12AUG2016	12AUG2016	168	mg	No
		PSYCHOANALEPTICS	CAFFEINE	11AUG2016	11AUG2016	16	mg	No
		PSYCHOANALEPTICS	CAFFEINE	12AUG2016	13AUG2016	4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	14AUG2016	27AUG2016	6	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		PSYCHOANALEPTICS	CAFFEINE	28AUG2016	08SEP2016	7.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	09SEP2016	11SEP2016	9.4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	12SEP2016	23SEP2016	9.5	mg	No
		VACCINES	HEPATITIS B VACCINE	12OCT2016	12OCT2016	10	mcg	No
		VACCINES	PNEUMOCOCCAL VACCINE	12OCT2016	12OCT2016	0.5	ml	No
		VACCINES	VACCIN IPAD D.T.C.	12OCT2016	12OCT2016	0.5	ml	No
		VITAMINS	COLECALCIFEROL	03SEP2016	09SEP2016	200	U	No
		VITAMINS	COLECALCIFEROL	10SEP2016	14SEP2016	200	U	No
		VITAMINS	COLECALCIFEROL	23SEP2016		400	U	Yes
		VITAMINS	MULTIVITAMIN WITH MINERALS	15SEP2016	23SEP2016	1	ml	No
	11011	ANESTHETICS	FENTANYL	04SEP2016	04SEP2016	1.8	mcg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	31AUG2016	02SEP2016	92	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	31AUG2016	04SEP2016	4.6	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	MEROPENEM	09SEP2016	09SEP2016	27	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	PIP/TAZO	04SEP2016	09SEP2016	90	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	04SEP2016	09SEP2016	14	mg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	31AUG2016	31AUG2016	0.5	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	31AUG2016	09SEP2016	3	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	01SEP2016	09SEP2016	1	gm	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	NORMOSOL	08SEP2016	08SEP2016	250	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	POTASSIUM CHLORIDE	09SEP2016	09SEP2016	1	mEq	No
		CARDIAC THERAPY	DOPAMINE	07SEP2016	09SEP2016	10	mcg	No
		CARDIAC THERAPY	EPINEPHRINE	08SEP2016	08SEP2016	0.1	mg	No
		MINERAL SUPPLEMENTS	MAGNESIUM SULFATE	09SEP2016	09SEP2016	23	mg	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	31AUG2016	31AUG2016	1	application	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	01SEP2016	01SEP2016	2.3	ml	No
		PSYCHOANALEPTICS	CAFFEINE	31AUG2016	31AUG2016	18	mg	No
		PSYCHOANALEPTICS	CAFFEINE	01SEP2016	08SEP2016	4.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	08SEP2016	08SEP2016	18	mg	No
	12023	ANALGESICS	MORPHINE	10OCT2016	12OCT2016	20	mcg/kg/hr	No
		ANESTHETICS	FENTANYL	10OCT2016	10OCT2016	2.5	mcg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	30SEP2016	06OCT2016	200	mg/kg/day	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	22OCT2016	24OCT2016	200	mg/kg/day	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFAZOLIN	10OCT2016	10OCT2016	25	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFAZOLIN	10OCT2016	10OCT2016	25	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFTAZIDIME	24OCT2016	02NOV2016	150	mg/kg/day × 0.9 kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	30SEP2016	06OCT2016	4.5	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	22OCT2016	26NOV2016	4	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	31OCT2016	31OCT2016	4	mg/kg × 1.1 kg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIBACTERIALS FOR SYSTEMIC USE	TOBRAMYCIN	24OCT2016	30OCT2016	1.5	mg/kg × 0.9 kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	TOBRAMYCIN	30OCT2016	02NOV2016	1.5	mg/kg × 1.1 kg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	30SEP2016	30SEP2016	0.5	mg	No
		ANTIMYCOTICS FOR SYSTEMIC USE	FLUCONAZOLE	18OCT2016	04NOV2016	3	mg/kg	No
		ANTITHROMBOTIC AGENTS	HEPARIN	06OCT2016	10OCT2016	0.5	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	05OCT2016	06OCT2016	4.1	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	ARGININE	03NOV2016	06NOV2016	100	mg/kg × 1.2 kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	ARGININE	06NOV2016		1	mL/kg × 1.3 kg	Yes
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	FLEBOBAG RING LACT	10OCT2016	10OCT2016	10	ml/kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	FLEBOBAG RING LACT	11OCT2016	11OCT2016	10	ml/kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	30SEP2016	01OCT2016	3	g/kg/day	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	POTASSIUM CHLORIDE	05NOV2016	12NOV2016	2	mEq/kg/day × 1.3 kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	10OCT2016	10OCT2016	2	mEq/kg × 0.83 kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	06OCT2016	09OCT2016	1	ml/hr	No
		CARDIAC THERAPY	ATROPINE	10OCT2016	10OCT2016	0.02	mg/kg	No
		CARDIAC THERAPY	DOPAMINE	11OCT2016	11OCT2016	15	mcg/kg/min	No
		CARDIAC THERAPY	MILRINONE	10OCT2016	12OCT2016	0.375	mcg/kg/min	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		CORTICOSTEROIDS FOR SYSTEMIC USE	DEXAMETHASONE	04NOV2016	07NOV2016	0.075	mg/kg × 1.3 kg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	DEXAMETHASONE	07NOV2016	10NOV2016	0.05	mg/kg × 1.3 kg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	11OCT2016	11OCT2016	2	mg/kg × 0.83 kg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	11OCT2016	12OCT2016	1	mg/kg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	15OCT2016	15OCT2016	0.5	mg/kg × 0.9 kg	No
		COUGH AND COLD PREPARATIONS	DORNASE ALFA	24OCT2016	31OCT2016	2.5	mg	No
		DIURETICS	CHLOROTHIAZIDE	01NOV2016	08NOV2016	20	mg/kg/day × 1.2 kg	No
		DIURETICS	FUROSEMIDE	23OCT2016	24OCT2016	1	mg/kg × 0.9 kg	No
		DIURETICS	FUROSEMIDE	28OCT2016	28OCT2016	1	mg/kg × 1.1 kg	No
		DRUGS FOR ACID RELATED DISORDERS	FAMOTIDINE	06NOV2016	15NOV2016	0.5	mg/kg × 1.3 kg	No
		DRUGS FOR CONSTIPATION	GLYCEROL	01OCT2016	01OCT2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	02OCT2016	02OCT2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	15OCT2016	16OCT2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	20OCT2016	20OCT2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	23OCT2016	23OCT2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	27OCT2016	27OCT2016	0.5	ml	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	BUDESONIDE	01NOV2016		0.5	mg	Yes
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	SALBUTAMOL	28OCT2016	28OCT2016	2.5	mg	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	SALBUTAMOL	29OCT2016	29OCT2016	1.25	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		EMOLLIENTS AND PROTECTIVES	ZINC OXIDE	08OCT2016	08OCT2016	1	application	No
		MUSCLE RELAXANTS	ROCURONIUM	10OCT2016	10OCT2016	1	mg	No
		MUSCLE RELAXANTS	VECURONIUM	10OCT2016	10OCT2016	0.05	mg/kg	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	01NOV2016	01NOV2016	2	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	30SEP2016	30SEP2016	1.25	cm	No
		PSYCHOANALEPTICS	CAFFEINE	29SEP2016	29SEP2016	20	mg/kg × 0.83 kg	No
		PSYCHOANALEPTICS	CAFFEINE	30SEP2016	04OCT2016	5	mg/kg/day	No
		PSYCHOANALEPTICS	CAFFEINE	05OCT2016	12OCT2016	6	mg/kg/day × 0.83 kg	No
		PSYCHOANALEPTICS	CAFFEINE	05OCT2016	06NOV2016	6	mg/kg/day	No
		PSYCHOANALEPTICS	CAFFEINE	03NOV2016	03NOV2016	10	mg/kg × 1.2 kg	No
		PSYCHOANALEPTICS	CAFFEINE	06NOV2016	19NOV2016	6	mg/kg × 1.3 kg	No
	40003	ALL OTHER NON-THERAPEUTIC PRODUCTS	SUCROSE	11JUL2016	12AUG2016	0.5	ml	No
		ANESTHETICS	FENTANYL	08JUL2016	08JUL2016	2.4	mcg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	25JUL2016		3	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	07JUL2016	08JUL2016	3.8	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	07JUL2016	07JUL2016	6.1	mg	No
		CARDIAC THERAPY	ATROPINE	08JUL2016	08JUL2016	0.016	mg	No
		CARDIAC THERAPY	INDOMETACIN	07JUL2016	09JUL2016	0.076	mg	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	BUDESONIDE	21JUL2016		1	mg	Yes
		GENERAL NUTRIENTS	GLUCOSE	07JUL2016	08JUL2016	1.5	cc	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	08JUL2016	08JUL2016	1.6	mg	No
		OPHTHALMOLOGICALS	CYCLOMYDRIL	10AUG2016	10AUG2016	1	gtt	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		OPHTHALMOLOGICALS	PROXYMETACAINE	10AUG2016	10AUG2016	1	gtt	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	BOVINE LIPID EXTRACT SURFACTANT	08JUL2016	08JUL2016	4	ml	No
		PSYCHOANALEPTICS	CAFFEINE	09JUL2016	24JUL2016	4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	25JUL2016		5.3	mg	Yes
		VITAMINS	COLECALCIFEROL	24JUL2016		0.03	ml	Yes
	40006	ALL OTHER NON-THERAPEUTIC PRODUCTS	SUCROSE	25SEP2016	07OCT2016	0.5	ml	No
		ANESTHETICS	FENTANYL	24AUG2016	24AUG2016	2.9	mcg	No
		ANESTHETICS	FENTANYL	07SEP2016	07SEP2016	0.5	mcg	No
		ANESTHETICS	FENTANYL	07SEP2016	07SEP2016	1	mcg	No
		ANESTHETICS	FENTANYL	07SEP2016	07SEP2016	2.8	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	17SEP2016		4	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	24AUG2016	26AUG2016	48	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	24AUG2016	26AUG2016	7.7	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	05SEP2016	13SEP2016	7.2	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	METRONIDAZOLE	07SEP2016	13SEP2016	7	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	05SEP2016	15SEP2016	9	mg	No
		ANTIFUNGALS FOR DERMATOLOGICAL USE	NYSTATIN	22SEP2016	24SEP2016			No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	19SEP2016	07OCT2016	0.15	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM PHOSPHATE	20SEP2016		0.15	ml	Yes

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		CARDIAC THERAPY	ATROPINE	24AUG2016	24AUG2016	0.019	mg	No
		CARDIAC THERAPY	ATROPINE	07SEP2016	07SEP2016	0.018	mg	No
		CARDIAC THERAPY	INDOMETACIN	24AUG2016	25AUG2016	0.1	mg	No
		DRUGS FOR CONSTIPATION	GLYCEROL	11SEP2016	26SEP2016		NA	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	BUDESONIDE	03OCT2016		1	mg	Yes
		MINERAL SUPPLEMENTS	CALCIUM	19SEP2016		0.58	ml	Yes
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	24AUG2016	24AUG2016	1.9	mg	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	07SEP2016	07SEP2016	1.9	mg	No
		OPHTHALMOLOGICALS	CYCLOMYDRIL	28SEP2016	28SEP2016		4 drops in each eye	No
		OPHTHALMOLOGICALS	CYCLOMYDRIL	29SEP2016	29SEP2016		4 drops	No
		OPHTHALMOLOGICALS	CYCLOMYDRIL	05OCT2016	05OCT2016		in each eye	No
		OPHTHALMOLOGICALS	PROXYMETACAINE	28SEP2016	28SEP2016		4 drops	No
		OPHTHALMOLOGICALS	PROXYMETACAINE	29SEP2016	29SEP2016		4 drops	No
		OPHTHALMOLOGICALS	PROXYMETACAINE	05OCT2016	05OCT2016		1 drop	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	BOVINE LIPID EXTRACT SURFACTANT	24AUG2016	24AUG2016	4.8	ml	No
		PSYCHOANALEPTICS	CAFFEINE	24AUG2016	24AUG2016	10	mg	No
		PSYCHOANALEPTICS	CAFFEINE	25AUG2016	30AUG2016	5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	31AUG2016	11OCT2016	7.4	mg	No
		VITAMINS	COLECALCIFEROL	31AUG2016	05SEP2016	0.03	ml	No
		VITAMINS	COLECALCIFEROL	13SEP2016	13SEP2016	0.03	ml	No
	42003	ANESTHETICS	FENTANYL	19JUL2016	19JUL2016	2.25	mcg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	12AUG2016		3	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	CLOXACILLIN	07AUG2016	09AUG2016	70	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	07AUG2016	09AUG2016	7	mg	No
		ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	PROBIOTIC /07343501/	19JUL2016		0.5	gm	Yes
		ANTHEMORRHAGICS	PHYTOMENADIONE	17JUL2016	17JUL2016	0.5	mg	No
		CARDIAC THERAPY	ATROPINE	19JUL2016	19JUL2016	0.02	mg	No
		DRUGS FOR CONSTIPATION	GLYCEROL	26JUL2016	26JUL2016	1	sliver	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	19JUL2016	19JUL2016	1.8	mg	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	17JUL2016	17JUL2016	0.5	percent	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	BOVINE LIPID EXTRACT SURFACTANT	19JUL2016	19JUL2016	4.5	ml	No
		PSYCHOANALEPTICS	CAFFEINE	17JUL2016	17JUL2016	9	mg	No
		PSYCHOANALEPTICS	CAFFEINE	18JUL2016	28JUL2016	3.6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	28JUL2016	09AUG2016	4.2	mg	No
		PSYCHOANALEPTICS	CAFFEINE	08AUG2016	08AUG2016	1.3	mg	No
		PSYCHOANALEPTICS	CAFFEINE	09AUG2016	11AUG2016	5.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	11AUG2016	11AUG2016	1.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	12AUG2016		7	mg	Yes
		VITAMINS	COLECALCIFEROL	25JUL2016		400	IU	Yes
	50001	ALL OTHER NON-THERAPEUTIC PRODUCTS	BLOOD, CALF, DEPROT., LMW PORTION	21NOV2016	22NOV2016	1	LAYER	No
		ANTIANEMIC PREPARATIONS	FOLIC ACID	16OCT2016	12DEC2016	2.5	mg	No
		ANTIANEMIC PREPARATIONS	IRON	16OCT2016	19OCT2016	6	mg	No
		ANTIANEMIC PREPARATIONS	IRON	20OCT2016	01NOV2016	6	mg	No
		ANTIANEMIC PREPARATIONS	IRON	02NOV2016	08NOV2016	6	mg	No
		ANTIANEMIC PREPARATIONS	IRON	09NOV2016	22NOV2016	7	mg	No
		ANTIANEMIC PREPARATIONS	IRON	23NOV2016	04DEC2016	10	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIANEMIC PREPARATIONS	IRON	05DEC2016		10	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMIKACIN	13OCT2016	21OCT2016	14	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMIKACIN	02NOV2016	08NOV2016	20	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	28SEP2016	04OCT2016	3.5	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	UNACID	28SEP2016	03OCT2016	55	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	/00917901/ VANCOMYCIN	03OCT2016	05OCT2016	9	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	05OCT2016	08OCT2016	9.5	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	13OCT2016	24OCT2016	10	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	02NOV2016	09NOV2016	16	mg	No
		ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	PROBIOTIC	07OCT2016	06DEC2016	0.5	CAPSULES (1 000 000 000 cfu) OF LACTOBACILLUS	No
		ANTIFUNGALS FOR DERMATOLOGICAL USE	NYSTATIN	02OCT2016	04OCT2016	0.5	ml	No
		ANTIFUNGALS FOR DERMATOLOGICAL USE	NYSTATIN	05OCT2016	18OCT2016	0.5	ml	No
		ANTIFUNGALS FOR DERMATOLOGICAL USE	NYSTATIN	19OCT2016	25OCT2016	0.5	ml	No
		ANTIFUNGALS FOR DERMATOLOGICAL USE	NYSTATIN	26OCT2016	15NOV2016	0.5	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIHEMORRHAGICS	PHYTOMENADIONE	28SEP2016	28SEP2016	0.3	mg	No
		ANTITHROMBOTIC AGENTS	HEPARIN	28SEP2016	03OCT2016	1	U	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	28SEP2016	09NOV2016	1	MIX OF COMPONENTS ADJUSTED TO BABY REQUIREMENTS	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	31OCT2016	31OCT2016	21	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM PHOSPHATE	19OCT2016	23OCT2016	0.5	ml	No
		CARDIAC THERAPY	IBUPROFEN	30SEP2016	30SEP2016	7	mg	No
		CARDIAC THERAPY	IBUPROFEN	01OCT2016	02OCT2016	3.5	mg	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	DUOVENT	09NOV2016	18NOV2016	1	DOSE (INHALE FROM BABY HALER))	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	DUOVENT	18NOV2016	21NOV2016	1	DOSE (INHALE FROM BABYHALER)	No
		IMMUNE SERA AND IMMUNOGLOBULINS	PALIVIZUMAB	05DEC2016	05DEC2016	28	mg	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	28SEP2016	28SEP2016	1.8	ml	No
		PSYCHOANALEPTICS	CAFFEINE	28SEP2016	28SEP2016	7	mg	No
		PSYCHOANALEPTICS	CAFFEINE	29SEP2016	11OCT2016	3	mg	No
		PSYCHOANALEPTICS	CAFFEINE	12OCT2016	25OCT2016	4.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	26OCT2016	01NOV2016	5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	02NOV2016	08NOV2016	5.5	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		PSYCHOANALEPTICS	CAFFEINE	09NOV2016	15NOV2016	6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	16NOV2016	27NOV2016	6.5	mg	No
		VACCINES	HEPATITIS B VACCINE	28SEP2016	28SEP2016	0.5	ml	No
		VITAMINS	COLECALCIFEROL	25OCT2016	01NOV2016	1	gtt	No
		VITAMINS	COLECALCIFEROL	02NOV2016	03NOV2016	1	gtt	No
		VITAMINS	COLECALCIFEROL	04NOV2016	08NOV2016	2	gtt	No
		VITAMINS	COLECALCIFEROL	09NOV2016	15NOV2016	1	gtt	No
		VITAMINS	COLECALCIFEROL	16NOV2016	16NOV2016	2	gtt	No
		VITAMINS	COLECALCIFEROL	17NOV2016	06DEC2016	1	gtt	No
		VITAMINS	MULTIVITAMINS	12OCT2016	12DEC2016	0.5	CAPSULES (400 IU OF VIT D AND 25 ug of VIT K)	No
	51004	ANALGESICS	MORPHINE	27JUL2016	04AUG2016	20	microgram/kg/h	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	28JUL2016	03AUG2016	53	miligram/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	28JUL2016	30JUL2016	5	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	PIP/TAZO	03AUG2016	06AUG2016	95	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	PIP/TAZO	07AUG2016	17AUG2016	100	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	03AUG2016	08AUG2016	10	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	09AUG2016	17AUG2016	10	mg/kg	No
		ANTIIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	NATURES WAY PRIMADOPHILUS KIDS	16AUG2016	22SEP2016	2	gtt	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIEPILEPTICS	PHENOBARBITAL	27JUL2016	27JUL2016	10	mg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	26JUL2016	26JUL2016	0.4	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	03AUG2016	03AUG2016	16	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	12SEP2016	13SEP2016	30	ml	No
		CARDIAC THERAPY	IBUPROFEN	01AUG2016	03AUG2016	20	mg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	06AUG2016	13AUG2016	1	mg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	14AUG2016	16AUG2016	1	mg	No
		DIURETICS	SPIRONOLACTONE	01AUG2016	06AUG2016	1.5	mg/kg	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	BERACTANT	26JUL2016	26JUL2016	100	mg	No
		PSYCHOANALEPTICS	CAFFEINE	26JUL2016	11SEP2016	20	miligram/kg	No
		PSYCHOANALEPTICS	CAFFEINE	27JUL2016	28JUL2016	5	mg/kg	No
		PSYCHOANALEPTICS	CAFFEINE	29JUL2016	06AUG2016	7	mg/kg	No
		PSYCHOANALEPTICS	CAFFEINE	07AUG2016	17AUG2016	6	mg/kg	No
		PSYCHOANALEPTICS	CAFFEINE	18AUG2016	08SEP2016	7	mg	No
		PSYCHOANALEPTICS	CAFFEINE	09SEP2016	12SEP2016	10	mg	No
		VITAMINS	COLECALCIFEROL	16AUG2016		1000	U	Yes
100 mg/kg	11021	ANTIANEMIC PREPARATIONS	FERROUS SULFATE	06DEC2016		6	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	05NOV2016	08NOV2016	94	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	05NOV2016	07NOV2016	4.7	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	22NOV2016	24NOV2016	3.9	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	22NOV2016	24NOV2016	15	mg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	05NOV2016	05NOV2016	0.3	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	05NOV2016	20NOV2016	3.1	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	06NOV2016	22NOV2016	0.12	ml	No
		DIURETICS	FUROSEMIDE	30NOV2016	30NOV2016	1.1	mg	No
		DIURETICS	FUROSEMIDE	15DEC2016	15DEC2016	1.6	mg	No
		DRUGS FOR CONSTIPATION	GLYCEROL	09NOV2016	09NOV2016	0.25	1/4 suppository	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	13DEC2016	13DEC2016	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	05NOV2016	05NOV2016	1	one application to each eye	No
		OPHTHALMOLOGICALS	PHENYLEPHRINE	13DEC2016	13DEC2016	1	gtt	No
		OPHTHALMOLOGICALS	TETRACAINE	13DEC2016	13DEC2016	1	gtt	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	05NOV2016	05NOV2016	2.3	ml	No
		PSYCHOANALEPTICS	CAFFEINE	05NOV2016	05NOV2016	20	mg	No
		PSYCHOANALEPTICS	CAFFEINE	06NOV2016	06NOV2016	4.7	mg	No
		PSYCHOANALEPTICS	CAFFEINE	10NOV2016	10NOV2016	20	mg	No
		PSYCHOANALEPTICS	CAFFEINE	12NOV2016	22NOV2016	4.5	mg	No
		VACCINES	HEPATITIS B VACCINE	06JAN2017	06JAN2017	0.5	ml	No
		VACCINES	INFANRIX IPV+HIB	07JAN2017	07JAN2017	0.5	ml	No
		VACCINES	PNEUMOCOCCAL VACCINE	06JAN2017	06JAN2017	0.5	ml	No
		VITAMINS	MULTIVITAMINS	22DEC2016		1	ml	Yes

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
	11023	ANTIANEMIC PREPARATIONS	FERROUS SULFATE	18DEC2016	05JAN2017	3.4	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	29NOV2016	01DEC2016	2.2	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	OXACILLIN	01DEC2016	09DEC2016	26	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	PIP/TAZO	06JAN2017	13JAN2017	97	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	29NOV2016	01DEC2016	8.8	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	06JAN2017	13JAN2017	14.6	mg	No
		ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	MUPIROCIN	24JAN2017	31JAN2017	1	application	No
		ANTHEMORRHAGICS	PHYTOMENADIONE	21NOV2016	21NOV2016	0.2	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	21NOV2016	24JAN2017	6.1	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	22NOV2016	22JAN2017	18.1	ml	No
		CARDIAC THERAPY	IBUPROFEN	30NOV2016	02DEC2016	5.1	mg	No
		DIURETICS	CHLOROTHIAZIDE	16DEC2016	18DEC2016	3.5	mg	No
		DIURETICS	FUROSEMIDE	29NOV2016	29NOV2016	0.3	mg	No
		DIURETICS	FUROSEMIDE	13DEC2016	13DEC2016	0.7	mg	No
		DRUGS FOR CONSTIPATION	GLYCEROL	19DEC2016	19DEC2016	0.25	suppository	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	24JAN2017	24JAN2017	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	21NOV2016	21NOV2016	1	application	No
		OPHTHALMOLOGICALS	PHENYLEPHRINE	24JAN2017	24JAN2017	1	gtt	No
		OPHTHALMOLOGICALS	TETRACAINE	24JAN2017	24JAN2017	1	gtt	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		PSYCHOANALEPTICS	CAFFEINE	21NOV2016	21NOV2016	5.4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	22NOV2016	29NOV2016	2.7	mg	No
		PSYCHOANALEPTICS	CAFFEINE	01DEC2016	11DEC2016	2.7	mg	No
		PSYCHOANALEPTICS	CAFFEINE	12DEC2016	12DEC2016	3.2	mg	No
		PSYCHOANALEPTICS	CAFFEINE	13DEC2016	15DEC2016	3.2	mg	No
		PSYCHOANALEPTICS	CAFFEINE	16DEC2016	24DEC2016	3.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	25DEC2016	29DEC2016	3.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	30DEC2016	05JAN2017	4.4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	06JAN2017	22JAN2017	4.4	mg	No
		VACCINES	HEPATITIS B VACCINE	20JAN2017	20JAN2017	0.5	ml	No
		VACCINES	INFANRIX IPV+HIB	21JAN2017	21JAN2017	0.5	ml	No
		VACCINES	PNEUMOCOCCAL VACCINE	21JAN2017	21JAN2017	0.5	ml	No
		VITAMINS	MULTIVITAMINS	12DEC2016		0.5	ml	Yes
	11025	ANTIANEMIC PREPARATIONS	FERROUS SULFATE	11MAY2017		3	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	26APR2017	29APR2017	107	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	26APR2017	28APR2017	5.4	mg	No
		ANTHEMORRHAGICS	PHYTOMENADIONE	26APR2017	26APR2017	0.5	mg	No
		ANTISEPTICS AND DISINFECTANTS	CHLORHEXIDINE GLUCONATE	12JUN2017	12JUN2017		one CHG bath	No
		ANTISEPTICS AND DISINFECTANTS	CHLORHEXIDINE GLUCONATE	14JUN2017	14JUN2017		one	No
		ANTISEPTICS AND DISINFECTANTS	CHLORHEXIDINE GLUCONATE	21JUN2017	21JUN2017		bath	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	26APR2017	08MAY2017	5.4	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	27APR2017	05MAY2017	0.67	ml	No
		CONTRAST MEDIA	IOHEXOL	29APR2017	29APR2017	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	02MAY2017	02MAY2017	0.25	suppository	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	23MAY2017	23MAY2017	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	06JUN2017	06JUN2017	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	26APR2017	26APR2017	1	eye ointment	No
		OPHTHALMOLOGICALS	TETRACAINE	06JUN2017	06JUN2017	1	gtt	No
		OPHTHALMOLOGICALS	TETRACAINE	20JUN2017	20JUN2017	1	gtt	No
		PSYCHOANALEPTICS	CAFFEINE	30APR2017	30APR2017	22	mg	No
		PSYCHOANALEPTICS	CAFFEINE	01MAY2017	05MAY2017	5.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	06MAY2017	21MAY2017	6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	22MAY2017	08JUN2017	7	mg	No
		VITAMINS	COLECALCIFEROL	10MAY2017		400	IU	Yes
	19007	ANESTHETICS	FENTANYL	19DEC2016	21DEC2016	0.9	mcg	No
		ANESTHETICS	FENTANYL	20DEC2016	20DEC2016	1.9	mcg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	19DEC2016	21DEC2016	85	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	19DEC2016	21DEC2016	4.3	mg	No
		EMOLLIENTS AND PROTECTIVES	ZINC OXIDE	27DEC2016	09FEB2017	1	application	No
		GENERAL NUTRIENTS	GLUCOSE	19DEC2016	19DEC2016	1.7	ml	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	18JAN2017	18JAN2017	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	08FEB2017	08FEB2017	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	19DEC2016	19DEC2016	1	application	No
		OPHTHALMOLOGICALS	PROXYMETACAINE	18JAN2017	18JAN2017	1	gtt	No
		OPHTHALMOLOGICALS	PROXYMETACAINE	08FEB2017	08FEB2017	1	gtt	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	20DEC2016	20DEC2016	120	mg	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	21DEC2016	21DEC2016	1.5	ml	No
		PSYCHOANALEPTICS	CAFFEINE	19DEC2016	19DEC2016	21.25	mg	No
		PSYCHOANALEPTICS	CAFFEINE	20DEC2016	24DEC2016	8.6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	25DEC2016	02JAN2017	8.2	mg	No
		PSYCHOANALEPTICS	CAFFEINE	03JAN2017	11JAN2017	9.6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	12JAN2017	18JAN2017	13.6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	19JAN2017	25JAN2017	15.4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	26JAN2017	28JAN2017	18.4	mg	No
		VITAMINS	FERROUS SULFATE W/VITAMINS NOS	09JAN2017	07FEB2017	0.25	ml	No
	40014	ALL OTHER NON-THERAPEUTIC PRODUCTS	SUCROSE	12DEC2016	07JAN2017	0.5	ml	No
		ANESTHETICS	FENTANYL	09DEC2016	09DEC2016	2.1	mg	No
		ANESTHETICS	FENTANYL	12DEC2016	12DEC2016	1.8	mg	No
		ANESTHETICS	FENTANYL	13DEC2016	13DEC2016	1.3	mcg	No
		ANESTHETICS	LIDOCAINE	11JAN2017	11JAN2017	0.5	gm	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	23DEC2016	02JAN2017	2	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	28DEC2016	02JAN2017	0.14	ml	No
		CARDIAC THERAPY	ATROPINE	09DEC2016	09DEC2016	0.014	mg	No
		CARDIAC THERAPY	ATROPINE	12DEC2016	12DEC2016	0.012	mg	No
		DRUGS FOR CONSTIPATION	GLYCEROL	29DEC2016	29JAN2017		l	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	BUDESONIDE	24DEC2016	20JAN2017	1	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	BUDESONIDE	20JAN2017	21JAN2017	1	mg	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	BUDESONIDE	21JAN2017		1	mg	Yes
		IMMUNE SERA AND IMMUNOGLOBULINS	PALIVIZUMAB	11JAN2017	11JAN2017	18	mg	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	09DEC2016	09DEC2016	1.4	mg	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	12DEC2016	12DEC2016	1.2	mg	No
		OPHTHALMOLOGICALS	CYCLOMYDRIL	02JAN2017	02JAN2017	1	1 drop to each eye	No
		OPHTHALMOLOGICALS	PROXYMETACAINE	02JAN2017	02JAN2017	1	1 drop in each eye	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	BOVINE LIPID EXTRACT SURFACTANT	09DEC2016	09DEC2016	3	ml	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	BOVINE LIPID EXTRACT SURFACTANT	09DEC2016	09DEC2016	3.38	ml	No
		PSYCHOANALEPTICS	CAFFEINE	08DEC2016	08DEC2016	6.7	mg	No
		PSYCHOANALEPTICS	CAFFEINE	10DEC2016	19DEC2016	3.3	mg	No
		PSYCHOANALEPTICS	CAFFEINE	20DEC2016	30DEC2016	3.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	31DEC2016	12JAN2017	4.3	mg	No
		PSYCHOANALEPTICS	CAFFEINE	13JAN2017	19JAN2017	6.4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	20JAN2017		7.2	mg	Yes
		VITAMINS	COLECALCIFEROL	18DEC2016	02JAN2017	0.03	ml	No
		VITAMINS	COLECALCIFEROL	03JAN2017	30JAN2017	0.03	ml	No
		VITAMINS	FERROUS SULFATE W/VITAMINS NOS	03JAN2017	16JAN2017	3	mg	No
		VITAMINS	FERROUS SULFATE W/VITAMINS NOS	17JAN2017	30JAN2017	4	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
	40015	ALL OTHER NON-THERAPEUTIC PRODUCTS	SUCROSE	03JAN2017	30JAN2017	0.5	ml	No
		ANESTHETICS	FENTANYL	04JAN2017	04JAN2017	2.1	mg	No
		ANESTHETICS	FENTANYL	05JAN2017	05JAN2017	2.1	mcg	No
		ANESTHETICS	FENTANYL	07JAN2017	07JAN2017	0.7	mcg	No
		ANESTHETICS	FENTANYL	09JAN2017	09JAN2017	0.76	mcg	No
		ANESTHETICS	FENTANYL	10JAN2017	10JAN2017	0.8	mcg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	19JAN2017		2	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	03JAN2017	05JAN2017	3.8	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	03JAN2017	03JAN2017	6.1	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	16JAN2017		0.1	ml	Yes
		CARDIAC THERAPY	ATROPINE	04JAN2017	04JAN2017	0.014	mg	No
		CARDIAC THERAPY	ATROPINE	05JAN2017	05JAN2017	0.014	mg	No
		CARDIAC THERAPY	INDOMETACIN	03JAN2017	05JAN2017	0.076	mg	No
		DRUGS FOR CONSTIPATION	GLYCEROL	07JAN2017	07JAN2017		1	No
		DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS	DIMETICONE	22JAN2017	01FEB2017			No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	04JAN2017	04JAN2017	1.4	mg	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	05JAN2017	05JAN2017	1.4	mg	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	BOVINE LIPID EXTRACT SURFACTANT	04JAN2017	04JAN2017	4	cc	No
		PSYCHOANALEPTICS	CAFFEINE	03JAN2017	03JAN2017	7.6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	05JAN2017	14JAN2017	3.8	mg	No
		PSYCHOANALEPTICS	CAFFEINE	15JAN2017	22JAN2017	3.3	mg	No
		PSYCHOANALEPTICS	CAFFEINE	23JAN2017		3.7	mg	Yes

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		VITAMINS	COLECALCIFEROL	16JAN2017		0.03	ml	Yes
	40016	ALL OTHER NON-THERAPEUTIC PRODUCTS	SUCROSE	26FEB2017	04APR2017	0.5	ml	No
		ANESTHETICS	FENTANYL	28FEB2017	28FEB2017	0.7	mcg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	10MAR2017	15MAR2017	2	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	16MAR2017	03APR2017	3	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	04APR2017		4	mg	Yes
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM PHOSPHATE	16MAR2017		0.06	ml	Yes
		CARDIAC THERAPY	INDOMETACIN	23FEB2017	25FEB2017	0.07	mg	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	BUDESONIDE	10MAR2017		1	mg	Yes
		EMOLLIENTS AND PROTECTIVES	EMOLLIENTS AND PROTECTIVES	24FEB2017	01MAR2017	2	ml	No
		OPHTHALMOLOGICALS	CYCLOMYDRIL	28MAR2017	28MAR2017		1 drop to each eye	No
		OPHTHALMOLOGICALS	CYCLOMYDRIL	05APR2017	05APR2017		1 drop to each eye	No
		OPHTHALMOLOGICALS	MACROGOL	09MAR2017	02APR2017			No
		OPHTHALMOLOGICALS	PROXYMETACAINE	28MAR2017	28MAR2017		1 drop to each eye	No
		OPHTHALMOLOGICALS	PROXYMETACAINE	05APR2017	05APR2017		1 drop to each eye	No
		PSYCHOANALEPTICS	CAFFEINE	23FEB2017	23FEB2017	6.7	mg	No
		PSYCHOANALEPTICS	CAFFEINE	25FEB2017	06MAR2017	3.3	mg	No
		PSYCHOANALEPTICS	CAFFEINE	07MAR2017	10MAR2017	3.3	mg	No
		PSYCHOANALEPTICS	CAFFEINE	11MAR2017	22MAR2017	3.7	mg	No
		PSYCHOANALEPTICS	CAFFEINE	23MAR2017		4.8	mg	Yes
		VITAMINS	COLECALCIFEROL	06MAR2017	27MAR2017	0.03	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		VITAMINS	COLECALCIFEROL	28MAR2017		0.03	ml	Yes
	42010	ANESTHETICS	FENTANYL	08DEC2016	08DEC2016	3	mcg	No
		ANESTHETICS	FENTANYL	08DEC2016	08DEC2016	3	mcg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	04JAN2017	29JAN2017	1.5	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	30JAN2017		4.5	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	07DEC2016	14DEC2016	60	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CLOXACILLIN	24DEC2016	26DEC2016	65	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	07DEC2016	13DEC2016	6	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	24DEC2016	24DEC2016	6.5	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	26DEC2016	02JAN2017	14	mg	No
		ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	NEOSPORIN /00130801/	27JAN2017	03FEB2017	1	gtt	No
		ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	PROBIOTIC /07343501/	08DEC2016	10DEC2016	0.5	gm	No
		ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	PROBIOTIC /07343501/	16DEC2016	01FEB2017	0.5	gm	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	07DEC2016	07DEC2016	0.5	mg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	10DEC2016	10DEC2016	1	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	10DEC2016	10DEC2016	18	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	10DEC2016	10DEC2016	18	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	12DEC2016	12DEC2016	12	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	15DEC2016	15DEC2016	20	ml	No
		CARDIAC THERAPY	ATROPINE	08DEC2016	08DEC2016	0.02	mg	No
		CARDIAC THERAPY	ATROPINE	08DEC2016	08DEC2016	0.02	mg	No
		CARDIAC THERAPY	IBUPROFEN	12DEC2016	12DEC2016	12	mg	No
		CARDIAC THERAPY	IBUPROFEN	13DEC2016	14DEC2016	6	mg	No
		DRUGS FOR CONSTIPATION	GLYCEROL	11DEC2016	11DEC2016	1	sliver	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	08DEC2016	08DEC2016	2.4	mcg	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	08DEC2016	08DEC2016	2.4	mg	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	18JAN2017	18JAN2017	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	31JAN2017	31JAN2017	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	07DEC2016	07DEC2016	1	gtt	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	BOVINE LIPID EXTRACT SURFACTANT	08DEC2016	08DEC2016	6	ml	No
		PSYCHOANALEPTICS	CAFFEINE	07DEC2016	07DEC2016	12	mg	No
		PSYCHOANALEPTICS	CAFFEINE	08DEC2016	16DEC2016	5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	17DEC2016	20DEC2016	5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	21DEC2016	21DEC2016	6.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	21DEC2016	30DEC2016	5.2	mg	No
		PSYCHOANALEPTICS	CAFFEINE	26DEC2016	26DEC2016	6.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	31DEC2016	03JAN2017	6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	04JAN2017	09JAN2017	6.5	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		PSYCHOANALEPTICS	CAFFEINE	10JAN2017	10JAN2017	9.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	10JAN2017	16JAN2017	8	mg	No
		PSYCHOANALEPTICS	CAFFEINE	16JAN2017	16JAN2017	1	mg	No
		PSYCHOANALEPTICS	CAFFEINE	17JAN2017	17JAN2017	9	mg	No
		PSYCHOANALEPTICS	CAFFEINE	18JAN2017	27JAN2017	10	mg	No
		PSYCHOANALEPTICS	CAFFEINE	28JAN2017		12	mg	Yes
		VITAMINS	COLECALCIFEROL	19DEC2016		400	IU	Yes
nCPAP Only	03006	ANTIANEMIC PREPARATIONS	FERROUS SULFATE	28JAN2016	03FEB2016	2	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	03FEB2016	09FEB2016	2.5	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	09FEB2016		3	mg	Yes
		ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	PROBIOTIC /07343501/	31JAN2016	05FEB2016	0.5	capsule	No
		ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	PROBIOTIC /07343501/	06FEB2016	25FEB2016	1	capsule	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	15JAN2016	23JAN2016	1	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	18JAN2016	23JAN2016	3.782	gm	No
		DRUGS FOR CONSTIPATION	GLYCEROL	16JAN2016	19JAN2016	0.2	ml	No
		EMOLLIENTS AND PROTECTIVES	EMOLLIENTS AND PROTECTIVES	22JAN2016	01FEB2016	1	application	No
		EMOLLIENTS AND PROTECTIVES	ZINC OXIDE	21JAN2016	29JAN2016	1	application	No
		OPHTHALMOLOGICALS	CYCLOMYDRIL	01MAR2016	01MAR2016	1	gtt	No
		OPHTHALMOLOGICALS	PROXYMETACAINE HYDROCHLORIDE	01MAR2016	01MAR2016	2	gtt	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	16JAN2016	16JAN2016	3	ml	No
		PSYCHOANALEPTICS	CAFFEINE	15JAN2016	24JAN2016	13	mg	No
		PSYCHOANALEPTICS	CAFFEINE	25JAN2016	03FEB2016	12.4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	04FEB2016	09FEB2016	14.8	mg	No
		PSYCHOANALEPTICS	CAFFEINE	10FEB2016		17.2	mg	Yes
	03013	ANALGESICS	MORPHINE	17AUG2016	17AUG2016	0.45	mg	No
		ANALGESICS	PARACETAMOL	14AUG2016	16AUG2016	8	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	14AUG2016	15AUG2016	47	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	14AUG2016	14AUG2016	4.64	mg	No
		ANTIIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	PROBIOTIC /07343501/	15AUG2016	30AUG2016	1	capsule	No
		ANTHEMORRHAGICS	PHYTOMENADIONE	14AUG2016	14AUG2016	0.3	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	14AUG2016	22AUG2016	2.9	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	14AUG2016	22AUG2016	1.36	gm	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	28AUG2016	30AUG2016	0.44	mEq	No
		CARDIAC THERAPY	INDOMETACIN	30AUG2016	31AUG2016	0.22	mg	No
		DRUGS FOR CONSTIPATION	GLYCEROL	17AUG2016	15SEP2016	0.2	ml	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	14AUG2016	14AUG2016	1	strip	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	14AUG2016	14AUG2016	2.35	ml	No
		PSYCHOANALEPTICS	CAFFEINE	14AUG2016	21SEP2016	8.8	mg	No
		VITAMINS	MULTIVITAMINS	24AUG2016	30AUG2016	0.5	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
	08028	ANALGESICS	MORPHINE	10JUN2016	12JUN2016	0.11	mg	No
		ANESTHETICS	FENTANYL	28MAY2016	28MAY2016	2.22	mcg	No
		ANESTHETICS	FENTANYL	10JUN2016	10JUN2016	10	mcg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	28MAY2016	30MAY2016	111	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFAZOLIN	10JUN2016	12JUN2016	27.75	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	28MAY2016	28MAY2016	5.55	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	03JUN2016	04JUN2016	11	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	04JUN2016	05JUN2016	11.1	mg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	27MAY2016	27MAY2016	0.5	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	27MAY2016	28MAY2016	4.6	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	28MAY2016	16JUN2016	4.9	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	28MAY2016	15JUN2016	0.8	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	POTASSIUM CHLORIDE	08JUN2016	09JUN2016	1.16	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	28MAY2016	01JUN2016	1	ml	No
		CARDIAC THERAPY	ATROPINE	28MAY2016	28MAY2016	0.02	mg	No
		CARDIAC THERAPY	IBUPROFEN	01JUN2016	01JUN2016	10.1	mg	No
		CARDIAC THERAPY	IBUPROFEN	02JUN2016	02JUN2016	5.05	mg	No
		CARDIAC THERAPY	IBUPROFEN	03JUN2016	05JUN2016	5.55	mg	No
		CARDIAC THERAPY	IBUPROFEN	06JUN2016	06JUN2016	5.15	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		DIURETICS	FUROSEMIDE	08JUN2016	09JUN2016	1.16	mg	No
		DIURETICS	FUROSEMIDE	10JUN2016	10JUN2016	1.11	mg	No
		MUSCLE RELAXANTS	VECURONIUM	10JUN2016	10JUN2016	0.15	mg	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	05JUL2016	21JUL2016	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	27MAY2016	27MAY2016	1	application to both eyes	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	CALFACTANT	27MAY2016	27MAY2016	3	ml	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	CALFACTANT	28MAY2016	28MAY2016	3.33	ml	No
		PSYCHOANALEPTICS	CAFFEINE	27MAY2016	27MAY2016	22.2	mg	No
		PSYCHOANALEPTICS	CAFFEINE	28MAY2016	16JUN2016	5.55	mg	No
		PSYCHOANALEPTICS	CAFFEINE	17JUN2016		22.13	mg	Yes
		VACCINES	HEPATITIS B VACCINE	28JUN2016	28JUN2016	0.5	ml	No
		VITAMINS	MULTIVITAMINS	17JUN2016	29JUN2016	0.5	ml	No
		VITAMINS	MULTIVITAMINS	30JUN2016	20JUL2016	1	ml	No
	08037	ANESTHETICS	FENTANYL	24AUG2016	24AUG2016	1	mcg	No
		ANESTHETICS	FENTANYL	25AUG2016	25AUG2016	1.15	mcg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	24AUG2016	26AUG2016	115	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	24AUG2016	24AUG2016	5.75	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	PIP/TAZO	06SEP2016	08SEP2016	123	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	06SEP2016	08SEP2016	12.3	mg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	24AUG2016	24AUG2016	0.5	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	24AUG2016	01SEP2016	2.8	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	05SEP2016	11SEP2016	6.6	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	05SEP2016	05SEP2016	7	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	24AUG2016	31AUG2016	0.7	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	05SEP2016	09SEP2016	0.8	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	POTASSIUM CHLORIDE	10OCT2016	19OCT2016	1	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	24AUG2016	28AUG2016	0.5	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	12SEP2016	14SEP2016	0.7	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	14SEP2016	16SEP2016	1.3	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	16SEP2016	19SEP2016	1.45	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	19SEP2016	29SEP2016	1.58	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	29SEP2016	19OCT2016	2.5	mEq	No
		CARDIAC THERAPY	ATROPINE	24AUG2016	24AUG2016	0.02	mg	No
		CARDIAC THERAPY	ATROPINE	25AUG2016	25AUG2016	0.02	mg	No
		DIURETICS	FUROSEMIDE	11SEP2016	11SEP2016	1.35	mg	No
		DIURETICS	FUROSEMIDE	07OCT2016	09OCT2016	4.5	mg	No
		DIURETICS	FUROSEMIDE	11OCT2016	17OCT2016	4.5	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	29SEP2016	29SEP2016	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	12OCT2016	12OCT2016	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	19OCT2016	19OCT2016	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	24AUG2016	24AUG2016	1	application	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	CALFACTANT	24AUG2016	24AUG2016	3.45	ml	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	CALFACTANT	25AUG2016	25AUG2016	3.45	ml	No
		PSYCHOANALEPTICS	CAFFEINE	24AUG2016	24AUG2016	23	mg	No
		PSYCHOANALEPTICS	CAFFEINE	25AUG2016	01SEP2016	8.63	mg	No
		PSYCHOANALEPTICS	CAFFEINE	02SEP2016	04SEP2016	8.7	mg	No
		PSYCHOANALEPTICS	CAFFEINE	05SEP2016	11SEP2016	8.7	mg	No
		PSYCHOANALEPTICS	CAFFEINE	12SEP2016	02OCT2016	8.7	mg	No
		PSYCHOANALEPTICS	CAFFEINE	03OCT2016	06OCT2016	10.6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	07OCT2016	16OCT2016	17	mg	No
		VACCINES	HEPATITIS B VACCINE	23SEP2016	23SEP2016	5	mcg	No
		VITAMINS	MULTIVITAMINS	12SEP2016		0.5	ml	Yes
	11005	ANTIANEMIC PREPARATIONS	FERROUS SULFATE	22JUN2016	06JUL2016	2	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	07JUL2016		11	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	06JUN2016	08JUN2016	96	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	06JUN2016	08JUN2016	4.8	mg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	06JUN2016	06JUN2016	0.3	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	06JUN2016	17JUN2016	3.2	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	06JUN2016	16JUN2016	0.6	gm	No
		CONTRAST MEDIA	IOHEXOL	08JUN2016	08JUN2016	0.5	ml	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	06JUN2016	06JUN2016		0.5%	No
		OPHTHALMOLOGICALS	TETRACAINE	12JUL2016	12JUL2016	1	gtt	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	NITRIC OXIDE	06JUN2016	07JUN2016	20	PPM (parts per million)	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	06JUN2016	06JUN2016	2.4	ml	No
		PSYCHOANALEPTICS	CAFFEINE	06JUN2016	06JUN2016	20	mg	No
		PSYCHOANALEPTICS	CAFFEINE	10JUN2016	10JUN2016	19	mg	No
		PSYCHOANALEPTICS	CAFFEINE	11JUN2016	12JUN2016	5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	13JUN2016	17JUN2016	6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	18JUN2016	31JUL2016	6.6	mg	No
		VACCINES	HEPATITIS B VACCINE	11AUG2016	11AUG2016	0.5	ml	No
		VACCINES	INFANRIX IPV+HIB	10AUG2016	10AUG2016	0.5	ml	No
		VACCINES	PNEUMOCOCCAL VACCINE	12AUG2016	12AUG2016	0.5	ml	No
		VITAMINS	MULTIVITAMINS	22JUN2016		1	ml	Yes
	11006	ANESTHETICS	LIDOCAINE	07JUN2016	07JUN2016	1	ml	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	22JUN2016	06JUL2016	1.8	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	07JUL2016		4	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	06JUN2016	08JUN2016	82	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	06JUN2016	08JUN2016	4.1	mg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	06JUN2016	06JUN2016	0.2	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	06JUN2016	17JUN2016	2.7	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	07JUN2016	16JUN2016	0.1	ml	No
		CONTRAST MEDIA	IOHEXOL	08JUN2016	08JUN2016	0.5	ml	No
		EMOLLIENTS AND PROTECTIVES	EMOLLIENTS AND PROTECTIVES	30JUL2016	01AUG2016		applied to diaper rash q 3 hours prn	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	12JUL2016	12JUL2016	2	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	19JUL2016	19JUL2016	2	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	02AUG2016	02AUG2016	2	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	09AUG2016	09AUG2016	2	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	06JUN2016	06JUN2016	0.5	percent	No
		OPHTHALMOLOGICALS	PHENYLEPHRINE	12JUL2016	12JUL2016	2	gtt	No
		OPHTHALMOLOGICALS	PHENYLEPHRINE	19JUL2016	19JUL2016	2	gtt	No
		OPHTHALMOLOGICALS	PHENYLEPHRINE	02AUG2016	02AUG2016	2	gtt	No
		OPHTHALMOLOGICALS	PHENYLEPHRINE	09AUG2016	09AUG2016	2	gtt	No
		OPHTHALMOLOGICALS	TETRACAINE	12JUL2016	12JUL2016	1	gtt	No
		OPHTHALMOLOGICALS	TETRACAINE	19JUL2016	19JUL2016	1	gtt	No
		OPHTHALMOLOGICALS	TETRACAINE	02AUG2016	02AUG2016	1	gtt	No
		OPHTHALMOLOGICALS	TETRACAINE	09AUG2016	09AUG2016	1	gtt	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	NITRIC OXIDE	07JUN2016	09JUN2016	20	PPM (parts per million)	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	06JUN2016	06JUN2016	2	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		PSYCHOANALEPTICS	CAFFEINE	10JUN2016	10JUN2016	16	mg	No
		PSYCHOANALEPTICS	CAFFEINE	11JUN2016	12JUN2016	4.1	mg	No
		PSYCHOANALEPTICS	CAFFEINE	13JUN2016	18JUN2016	5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	19JUN2016	01AUG2016	5	mg	No
		PSYCHOLEPTICS	MIDAZOLAM	07JUN2016	07JUN2016	0.04	mg	No
		VACCINES	HEPATITIS B VACCINE	11AUG2016	11AUG2016	0.5	ml	No
		VACCINES	INFANRIX IPV+HIB	10AUG2016	10AUG2016	0.5	ml	No
		VACCINES	PNEUMOCOCCAL VACCINE	12AUG2016	12AUG2016	0.5	ml	No
		VITAMINS	MULTIVITAMINS	22JUN2016		1	ml	Yes
	12004	ANALGESICS	MORPHINE	08MAR2016	08MAR2016	0.05	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	29FEB2016	10MAR2016	200	mg/kg/day	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	29FEB2016	03MAR2016	4.5	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	08MAR2016	10MAR2016	4	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	08MAR2016	10MAR2016	4	mg/kg	No
		ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	BACITRACIN	08MAR2016	29MAR2016			No
		ANTHEMORRHAGICS	PHYTOMENADIONE	29FEB2016	29FEB2016	0.5	mg	No
		ANTHEMORRHAGICS	PHYTOMENADIONE	29FEB2016	29FEB2016	0.5	mg	No
		ANTIMYCOTICS FOR SYSTEMIC USE	FLUCONAZOLE	01MAR2016	25MAR2016	3	mg/kg	No
		ANTITHROMBOTIC AGENTS	HEPARIN	29FEB2016	08MAR2016	50	ml	No
		ANTITHROMBOTIC AGENTS	HEPARIN	08MAR2016	08MAR2016	0.6	unit/mL	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	29FEB2016	26MAR2016	150	ml/kg/day (highest dose recorded)	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	29FEB2016	25MAR2016	3	g/kg/day	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	POTASSIUM PHOSPHATE MONOBASIC	19APR2016	26APR2016	20	mg/kg/day	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	14MAR2016	14MAR2016	20	ml/kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	27MAR2016	27MAR2016	20	ml/kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	08MAR2016	28MAR2016	1	ml	No
		DRUGS FOR ACID RELATED DISORDERS	FAMOTIDINE	11MAR2016	11MAR2016	0.5	mg/kg	No
		DRUGS FOR CONSTIPATION	GLYCEROL	02MAR2016	02MAR2016	0.5	ml	No
		GENERAL NUTRIENTS	GLUCOSE	29FEB2016	29FEB2016	80	mL/kg/day	No
		GENERAL NUTRIENTS	GLUCOSE	21MAR2016	21MAR2016	0.5	ml/kg	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	30MAR2016	27APR2016	2	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	29FEB2016	29FEB2016	1.25	cm	No
		PSYCHOANALEPTICS	CAFFEINE	29FEB2016	29FEB2016	20	mg/kg	No
		PSYCHOANALEPTICS	CAFFEINE	01MAR2016	19APR2016	5	mg/kg	No
		VACCINES	HEPATITIS B VACCINE	01MAR2016	01MAR2016	0.5	ml	No
		VITAMINS	COLECALCIFEROL	28MAR2016	04APR2016	200	U	No
		VITAMINS	FERROUS SULFATE W/VITAMINS NOS	05APR2016		0.5	ml	Yes
		VITAMINS	RETINOL	02MAR2016	29MAR2016	5000	U	No
	12006	ANALGESICS	MORPHINE	03MAR2016	14APR2016	10	mcg/kg/hr	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANESTHETICS	FENTANYL	03MAR2016	08MAR2016	2.5	mcg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	01MAR2016	11MAR2016	80	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	BACITRACIN	08MAR2016	08MAR2016	50000	U	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFAZOLIN	08MAR2016		20	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFOXITIN	03MAR2016	03MAR2016	32	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	01MAR2016	11MAR2016	3.6	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	METRONIDAZOLE	03MAR2016	09MAR2016	6	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	METRONIDAZOLE	26APR2016	29APR2016	30	mg/kg/day	No
		ANTIBACTERIALS FOR SYSTEMIC USE	NAFCILLIN	26APR2016	29APR2016	150	mg/kg/day	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	01MAR2016	01MAR2016	0.5	mg	No
		ANTIMYCOTICS FOR SYSTEMIC USE	FLUCONAZOLE	04MAR2016	12MAR2016	3	mg/kg	No
		ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC.	LIDOCAINE	02MAR2016	28MAR2016	1	Application	No
		ANTITHROMBOTIC AGENTS	HEPARIN	01MAR2016	17MAR2016	50	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	ALBUMIN HUMAN	03MAR2016	03MAR2016	1	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	01MAR2016	02MAR2016	63	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	01MAR2016	02MAR2016	78	ml/kg/day	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	02MAR2016	03MAR2016	96	ml/kg/day	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	03MAR2016	04MAR2016	102	mL/kg/day	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	04MAR2016	05MAR2016	114	mL/kg/day	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	05MAR2016		105	mL/kg/hr	Yes
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	CALCIUM GLUCONATE	03MAR2016	08MAR2016	20	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	01MAR2016	01MAR2016	1.6	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	03MAR2016	03MAR2016	3.2	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	01MAR2016	02MAR2016	0.033	g/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	01MAR2016	02MAR2016	0.033	gram/hour	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	04MAR2016		0.066	g/hr	Yes
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	03MAR2016	03MAR2016	5	ml/hour	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	06MAR2016	06MAR2016	5	ml/hr	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	03MAR2016	10MAR2016			No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	17MAR2016	17MAR2016	20	ml/kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	26APR2016	26APR2016	20	mg/kg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		CARDIAC THERAPY	DOPAMINE	03MAR2016	03MAR2016	5	mcg/kg/min	No
		CARDIAC THERAPY	EPHEDRINE	03MAR2016	03MAR2016	0.5	mg	No
		CARDIAC THERAPY	EPINEPHRINE	03MAR2016	03MAR2016	2	mcg	No
		DIURETICS	CHLOROTHIAZIDE	28APR2016	04MAY2016	10	mg/kg/day	No
		DRUGS FOR CONSTIPATION	GLYCEROL	30MAR2016	30MAR2016	0.5	ml	No
		MUSCLE RELAXANTS	ROCURONIUM	03MAR2016	03MAR2016	1	mg	No
		MUSCLE RELAXANTS	VECURONIUM	03MAR2016	09MAR2016	0.1	mg/kg/hr	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	01MAR2016	01MAR2016	1.25	cc	No
		OPHTHALMOLOGICALS	LACRI-LUBE	05MAR2016	09MAR2016	1	application	No
		PSYCHOANALEPTICS	CAFFEINE	01MAR2016	01MAR2016	16	mg	No
		PSYCHOANALEPTICS	CAFFEINE	02MAR2016	29MAR2016	5	mg	No
		VITAMINS	RETINOL	02MAR2016	28MAR2016	5000	U	No
	12010	ALL OTHER THERAPEUTIC PRODUCTS	ACETYLCYSTEINE	08APR2016	08APR2016	1	ml	No
		ALL OTHER THERAPEUTIC PRODUCTS	ACETYLCYSTEINE	08APR2016	08APR2016	1	ml	No
		ALL OTHER THERAPEUTIC PRODUCTS	ACETYLCYSTEINE	09APR2016	09APR2016	1	ml	No
		ALL OTHER THERAPEUTIC PRODUCTS	ACETYLCYSTEINE	25APR2016	25APR2016	1	ml	No
		ALL OTHER THERAPEUTIC PRODUCTS	ACETYLCYSTEINE	08MAY2016	08MAY2016	1	ml	No
		ANALGESICS	MORPHINE	17MAR2016	17MAR2016	0.1	mg/kg	No
		ANALGESICS	MORPHINE	24MAR2016	29MAR2016	0.05	mg/kg	No
		ANALGESICS	MORPHINE	04APR2016		20	mcg/kg/hr	Yes
		ANALGESICS	MORPHINE	05APR2016	10APR2016	0.026	mg	No
		ANALGESICS	MORPHINE	10APR2016	10APR2016	0.1	mg/kg × 0.7 kg	No
		ANESTHETICS	FENTANYL	04APR2016	04APR2016	2.5	mcg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANESTHETICS	FENTANYL	24APR2016	24APR2016	2.5	mcg	No
		ANESTHETICS	LIDOCAINE	23MAR2016	08APR2016	1	application	No
		ANESTHETICS	MARCAINE WITH EPINEPHRINE /00879801/	24APR2016	24APR2016	0.2	ml	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	17MAR2016	24MAR2016	53	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFAZOLIN	04APR2016	04APR2016	20	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFAZOLIN	04APR2016	04APR2016	25	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	17MAR2016	23MAR2016	4.5	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	22APR2016		4	mg/kg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	METRONIDAZOLE	23MAR2016	29MAR2016	7.5	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	METRONIDAZOLE	24APR2016	30APR2016	7.5	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	NAFCILLIN	22APR2016	30APR2016	75	mg/kg/day	No
		ANTIBACTERIALS FOR SYSTEMIC USE	PIP/TAZO	29MAR2016	05APR2016	150	mg/kg/day	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	24MAR2016	26APR2016	15	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	24APR2016	26APR2016	15	mg/kg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	17MAR2016	17MAR2016	0.5	mg	No
		ANTIMYCOTICS FOR SYSTEMIC USE	FLUCONAZOLE	18MAR2016	18MAR2016	3	mg/kg	No
		ANTIMYCOTICS FOR SYSTEMIC USE	FLUCONAZOLE	20MAR2016		12	mg/kg	Yes

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIMYCOTICS FOR SYSTEMIC USE	FLUCONAZOLE	01APR2016	05APR2016	3	mg/kg	No
		ANTITHROMBOTIC AGENTS	HEPARIN	17MAR2016		0.5	ml/hr	Yes
		ANTITHROMBOTIC AGENTS	HEPARIN	22MAR2016		0.6	ml	Yes
		BILE AND LIVER THERAPY	URSODEOXYCHOLIC ACID	14APR2016	21APR2016	10	mg/kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	18MAR2016		196	ml	Yes
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	18MAR2016		0.2	g/kg/day	Yes
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	21MAR2016	21MAR2016	2.5	g/kg/day	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	22MAR2016	31MAR2016	3	g/kg/day	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	23MAR2016	23MAR2016			No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	POTASSIUM PHOSPHATE MONOBASIC	19MAY2016		8.75	mg	Yes
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	18MAR2016	18MAR2016			No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM PHOSPHATE	24MAR2016	24MAR2016	10	mg/kg	No
		CARDIAC THERAPY	ATROPINE	17MAR2016	17MAR2016	0.1	mg	No
		CARDIAC THERAPY	DOPAMINE	18MAR2016	19MAR2016	5	mcg/kg/min	No
		CARDIAC THERAPY	DOPAMINE	04APR2016		40	mg	Yes
		CARDIAC THERAPY	INDOMETACIN	24MAR2016	30MAR2016	0.2	mg/kg	No
		CARDIAC THERAPY	INDOMETACIN	25MAR2016	25MAR2016	0.25	mg/kg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	DEXAMETHASONE	11APR2016		1.4	mg/kg/day	Yes
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	08APR2016	10APR2016	1	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	10APR2016	11APR2016	0.75	mg/kg	No
		DIURETICS	FUROSEMIDE	23MAR2016	03APR2016	1	mg/kg	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	BUDESONIDE	19APR2016		0.25	mg	Yes
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	SALBUTAMOL	06APR2016	08APR2016	2.5	mg	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	SALBUTAMOL	25APR2016	25APR2016	2.5	mg	No
		MUSCLE RELAXANTS	ROCURONIUM	04APR2016	04APR2016	1	mg	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	17MAR2016	17MAR2016	1.25	cm	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	17MAR2016	17MAR2016	2.5	ml/kg	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	19MAR2016	19MAR2016	1.25	ml/kg	No
		PSYCHOANALEPTICS	CAFFEINE	17MAR2016	17MAR2016	20	mg	No
		PSYCHOANALEPTICS	CAFFEINE	18MAR2016	06APR2016	5	mg/kg	No
		PSYCHOLEPTICS	MIDAZOLAM	06APR2016	11APR2016	0.1	mg/kg	No
		VITAMINS	RETINOL	19MAR2016	08APR2016	5000	U	No
	12037	ANESTHETICS	LIDOCAINE	30NOV2016	16DEC2016	1	1 application	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	09JAN2017	18JAN2017	2	mg/kg/DAY	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	19JAN2017		3	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	29NOV2016	06DEC2016	200	mg/kg/day	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	29NOV2016	05DEC2016	4.5	mg/kg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	04JAN2017	04JAN2017	15	mg/kg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	29NOV2016	29NOV2016	1	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	30NOV2016	19DEC2016	7.9	mL/kg/day	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	29NOV2016	29NOV2016	2	ml/kg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	30NOV2016		3	g/kg/day	Yes
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	06DEC2016	06DEC2016			No
		DRUGS FOR CONSTIPATION	GLYCEROL	09DEC2016	09DEC2016	0.5	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	11DEC2016	11JAN2017	0.5	ml	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	29NOV2016	29NOV2016	1.25	cm	No
		PSYCHOANALEPTICS	CAFFEINE	30NOV2016	30NOV2016	20	mg/kg	No
		PSYCHOANALEPTICS	CAFFEINE	04DEC2016	17DEC2016	5	mg/kg/day	No
		PSYCHOANALEPTICS	CAFFEINE	18DEC2016	31DEC2016	6	mg/kg/day	No
		PSYCHOANALEPTICS	CAFFEINE	01JAN2017		7	mg/kg	Yes
		VITAMINS	COLECALCIFEROL	09JAN2017		400	U	Yes
		VITAMINS	RETINOL	30NOV2016	16DEC2016	5000	U	No
	13016	ALL OTHER NON-THERAPEUTIC PRODUCTS	SUCROSE	14MAR2017		0.25	ml	Yes
		ANALGESICS	PARACETAMOL	14MAR2017	14MAR2017	30.81	mg	No
		ANALGESICS	PARACETAMOL	15MAR2017	15MAR2017	30.17	mg	No
		ANALGESICS	PARACETAMOL	18MAR2017	18MAR2017	30	mg	No
		ANESTHETICS	LIDOCAINE	15MAR2017	15MAR2017	1	application	No
		ANESTHETICS	LIDOCAINE	16MAR2017	16MAR2017	1	application	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	31JAN2017	02FEB2017	2.85	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	08FEB2017	20FEB2017	3.3	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	21FEB2017	03MAR2017	4.35	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	04MAR2017	19MAR2017	4.8	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	17JAN2017	19JAN2017	98	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	18MAR2017		223.2	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFEPIME	15MAR2017		100	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFTAZIDIME	15MAR2017	15MAR2017	100	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	17JAN2017	18JAN2017	2.95	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	26JAN2017	28JAN2017	2.95	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	02FEB2017	03FEB2017	2.9	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	14MAR2017	14MAR2017	8.2	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	OXACILLIN	26JAN2017	27JAN2017	25	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	OXACILLIN	14MAR2017	15MAR2017	51	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	17JAN2017	17JAN2017	15	mcg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	02FEB2017	07FEB2017	14.4	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	07FEB2017	09FEB2017	15.45	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	15MAR2017	18MAR2017	30.3	mcg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	MUPIROCIN	16FEB2017	20FEB2017	1	application	No
		ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE	MUPIROCIN	23MAR2017		1	application	Yes
		ANTIHEMORRHAGICS	PHYTOMENADIONE	17JAN2017	17JAN2017	1	mg	No
		ANTIMYCOTICS FOR SYSTEMIC USE	FLUCONAZOLE	17JAN2017	23JAN2017	5.22	mg	No
		ANTITHROMBOTIC AGENTS	ALTEPLASE	20MAR2017	20MAR2017	1	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	17JAN2017	18JAN2017	3.2	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	18JAN2017	24JAN2017	3.1	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	03FEB2017	07FEB2017	5.17	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	24JAN2017	25JAN2017	1.2	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	02FEB2017	03FEB2017	5.8	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	18JAN2017	24JAN2017	0.41	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	INTRALIPID /00272201/	03FEB2017	07FEB2017	0.42	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	POTASSIUM CHLORIDE	27FEB2017	28FEB2017	1.6	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	POTASSIUM CHLORIDE	28FEB2017	20MAR2017	1.6	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	POTASSIUM CHLORIDE	20MAR2017		2.04	mg	Yes

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	17JAN2017	21JAN2017	1.3	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	09MAR2017	20MAR2017	1.8	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	20MAR2017		2.04	mg	Yes
		DIURETICS	ACETAZOLAMIDE	03MAR2017	04MAR2017	8	mg	No
		DIURETICS	CHLOROTHIAZIDE	05MAR2017	17MAR2017	8.5	mg	No
		DIURETICS	CHLOROTHIAZIDE	17MAR2017		11	mg	Yes
		DIURETICS	FUROSEMIDE	20FEB2017	20FEB2017	2.9	mg	No
		DIURETICS	FUROSEMIDE	21FEB2017	21FEB2017	2.8	mg	No
		DIURETICS	FUROSEMIDE	22FEB2017	22FEB2017	2.9	mg	No
		DIURETICS	FUROSEMIDE	02MAR2017	03MAR2017	3.4	mg	No
		DIURETICS	FUROSEMIDE	04MAR2017	04MAR2017	1.7	mg	No
		DIURETICS	SPIRONOLACTONE	05MAR2017	17MAR2017	3.34	mg	No
		DIURETICS	SPIRONOLACTONE	18MAR2017	20MAR2017	4.38	mg	No
		DIURETICS	SPIRONOLACTONE	21MAR2017		2.18	mg	Yes
		DRUGS FOR CONSTIPATION	GLYCEROL	28JAN2017	28JAN2017	0.44	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	06MAR2017	06MAR2017	0.85	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	16MAR2017	16MAR2017	1.01	ml	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	BUDESONIDE	17MAR2017		0.25	mg	Yes
		GENERAL NUTRIENTS	GLUCOSE	17JAN2017	17JAN2017	1	ml	No
		GENERAL NUTRIENTS	GLUCOSE	17JAN2017	17JAN2017	2	ml	No
		GENERAL NUTRIENTS	GLUCOSE	18JAN2017	19JAN2017	0.4	ml	No
		GENERAL NUTRIENTS	GLUCOSE	07FEB2017	10FEB2017	1	ml	No
		GENERAL NUTRIENTS	GLUCOSE	17MAR2017	20MAR2017	1	ml/hr	No
		GENERAL NUTRIENTS	GLUCOSE	21MAR2017		1.5	ml	Yes

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	13FEB2017		1	gtt	Yes
		OPHTHALMOLOGICALS	ERYTHROMYCIN	20JAN2017	20JAN2017	1	ribbon	No
		PSYCHOANALEPTICS	CAFFEINE	17JAN2017	17JAN2017	19.6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	17JAN2017	24JAN2017	9.8	mg	No
		PSYCHOANALEPTICS	CAFFEINE	25JAN2017	02FEB2017	9	mg	No
		PSYCHOANALEPTICS	CAFFEINE	02FEB2017	02FEB2017	9.6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	03FEB2017	08FEB2017	9.6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	09FEB2017	11FEB2017	11	mg	No
		PSYCHOANALEPTICS	CAFFEINE	12FEB2017	23FEB2017	12	mg	No
		PSYCHOANALEPTICS	CAFFEINE	24FEB2017	03MAR2017	14	mg	No
		PSYCHOANALEPTICS	CAFFEINE	03MAR2017		16	mg	Yes
		VITAMINS	FERROUS SULFATE W/VITAMINS NOS	20MAR2017		0.5	ml	Yes
		VITAMINS	MULTIVITAMINS	31JAN2017	02FEB2017	0.5	ml	No
		VITAMINS	MULTIVITAMINS	08FEB2017	20MAR2017	0.5	ml	No
	19004	ALL OTHER THERAPEUTIC PRODUCTS	NALOXONE	31OCT2016	31OCT2016	0.11	mg	No
		ANALGESICS	MORPHINE	31OCT2016	01NOV2016	0.055	mg	No
		ANESTHETICS	FENTANYL	04OCT2016	04OCT2016	0.7	mcg	No
		ANESTHETICS	FENTANYL	31OCT2016	31OCT2016	2.1	mcg	No
		ANESTHETICS	FENTANYL	01NOV2016	05NOV2016	2.6	mcg	No
		ANESTHETICS	FENTANYL	03NOV2016		3	mcg	Yes
		ANESTHETICS	FENTANYL	03NOV2016	03NOV2016	5	mcg	No
		ANESTHETICS	FENTANYL	07NOV2016		2	mcg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFAZOLIN	24NOV2016		35	mg	Yes

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFEPIME	02NOV2016	24NOV2016	72	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	31OCT2016	15NOV2016	4.2	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	METRONIDAZOLE	31OCT2016	31OCT2016	15.9	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	METRONIDAZOLE	31OCT2016	04NOV2016	8.5	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	PIP/TAZO	01NOV2016	16NOV2016	80	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	TOBRAMYCIN	23NOV2016	30NOV2016	300	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	31OCT2016	01NOV2016	10.6	mg	No
		ANTIEPILEPTICS	PHENOBARBITAL	24NOV2016		7.15	mg	Yes
		ANTIFUNGALS FOR DERMATOLOGICAL USE	NYSTATIN	02OCT2016	03OCT2016	0	powder	No
		ANTHEMORRHAGICS	CRYOPRECIPITATE	04NOV2016	04NOV2016	10	ml	No
		ANTHEMORRHAGICS	PHYTOMENADIONE	27SEP2016	27SEP2016	0.5	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	ALBUMIN HUMAN	05OCT2016	05OCT2016	0.6	gm	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	ALBUMIN HUMAN	01NOV2016	01NOV2016	1.06	gm	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	ALBUMIN HUMAN	01NOV2016	01NOV2016	1.06	gm	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	ALBUMIN HUMAN	01NOV2016	04NOV2016	1.06	gm	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	ALBUMIN HUMAN	05NOV2016	12NOV2016	1.95	gm	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	ALBUMIN HUMAN	25NOV2016	25NOV2016	1.56	gm	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	CALCIUM GLUCONATE	22OCT2016	12NOV2016	200	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	02NOV2016	02NOV2016	16	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	03NOV2016	03NOV2016	15	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	03NOV2016	03NOV2016	16.7	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	03NOV2016	03NOV2016	30	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	04NOV2016	04NOV2016	17	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	05NOV2016	05NOV2016	11	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	06NOV2016	06NOV2016	10	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	06NOV2016	06NOV2016	10	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	07NOV2016	07NOV2016	10	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	21NOV2016	21NOV2016	20	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	01NOV2016	01NOV2016	10	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	01NOV2016	01NOV2016	20	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	02NOV2016	02NOV2016	10	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	02NOV2016	02NOV2016	15	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	02NOV2016	02NOV2016	22	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	03NOV2016	03NOV2016	15	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	03NOV2016	03NOV2016	15	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	03NOV2016	03NOV2016	30	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	04NOV2016	04NOV2016	16	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	04NOV2016	04NOV2016	22	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	05NOV2016	05NOV2016	20	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	06NOV2016	06NOV2016	20	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	06NOV2016	06NOV2016	20	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	06NOV2016	06NOV2016	20	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	07NOV2016	07NOV2016	20	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	10NOV2016	10NOV2016	20	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	03OCT2016	03OCT2016	9	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	11OCT2016	12OCT2016	12	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	18OCT2016	18OCT2016	13	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	31OCT2016	31OCT2016	15	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	31OCT2016	31OCT2016	16	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	02NOV2016	02NOV2016	15	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	02NOV2016	02NOV2016	15	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	03NOV2016	03NOV2016	25	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	04NOV2016	04NOV2016	16	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	04NOV2016	04NOV2016	24	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	07NOV2016	07NOV2016	15	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	14NOV2016	14NOV2016	20	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	19NOV2016	19NOV2016	18	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	26NOV2016	26NOV2016	24	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM ACETATE	17OCT2016	18OCT2016	3	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	06OCT2016	06OCT2016	6.6	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	20OCT2016	24OCT2016	2	mEq	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	26OCT2016	30OCT2016	3	mEq	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	31OCT2016	31OCT2016	10.6	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	01NOV2016	01NOV2016	10.6	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	01NOV2016	01NOV2016	12.9	ml	No
		CARDIAC THERAPY	DOPAMINE	03OCT2016	04OCT2016	3	mcg/kg/min	No
		CARDIAC THERAPY	DOPAMINE	05OCT2016	06OCT2016	3	mcg/kg/min	No
		CARDIAC THERAPY	DOPAMINE	31OCT2016	04NOV2016	15	mcg/kg/hr	No
		CARDIAC THERAPY	DOPAMINE	04NOV2016	12NOV2016	3	mcg/kg/hr	No
		CARDIAC THERAPY	DOPAMINE	12NOV2016	16NOV2016	10	mcg/kg/hr	No
		CARDIAC THERAPY	DOPAMINE	16NOV2016	21NOV2016	7	mcg/kg/hr	No
		CARDIAC THERAPY	DOPAMINE	23NOV2016	27NOV2016	12	mcg/kg/hr	No
		CARDIAC THERAPY	INDOMETACIN	01OCT2016	02OCT2016	0.12	mg/kg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	01NOV2016	06NOV2016	1.3	mg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	06NOV2016		0.8	mg	Yes
		DIURETICS	FUROSEMIDE	01NOV2016		2	mg	Yes
		DIURETICS	FUROSEMIDE	01NOV2016	01NOV2016	1.1	mg	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	BUDESONIDE	29OCT2016	23NOV2016	0.25	mg	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	SALBUTAMOL	15NOV2016	19NOV2016	1.25	mg	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	SALBUTAMOL	15NOV2016	23NOV2016	2.5	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	SALBUTAMOL	26NOV2016	26NOV2016	2.5	mg	No
		GENERAL NUTRIENTS	GLUCOSE	01NOV2016	02NOV2016	15	gm	No
		MINERAL SUPPLEMENTS	MAGNESIUM HYDROXIDE	22OCT2016	29OCT2016	0.4	ml	No
		MINERAL SUPPLEMENTS	MAGNESIUM HYDROXIDE	30OCT2016	31OCT2016	0.5	ml	No
		MUSCLE RELAXANTS	ROCURONIUM	03NOV2016	03NOV2016	1	mg	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	26OCT2016	26OCT2016	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	23NOV2016	23NOV2016	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	27SEP2016	27SEP2016	5	mg/gram ophth	No
		OPHTHALMOLOGICALS	PROXYMETACAINE	26OCT2016	26OCT2016	1	gtt	No
		OPHTHALMOLOGICALS	PROXYMETACAINE	23NOV2016	23NOV2016	1	gtt	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	28SEP2016	28SEP2016	1.5	ml	No
		PSYCHOANALEPTICS	CAFFEINE	27SEP2016	27SEP2016	15	mg	No
		PSYCHOANALEPTICS	CAFFEINE	28SEP2016	10OCT2016	6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	10OCT2016	16OCT2016	7.8	mg	No
		PSYCHOANALEPTICS	CAFFEINE	17OCT2016	18OCT2016	8.8	mg	No
		PSYCHOANALEPTICS	CAFFEINE	18OCT2016	20OCT2016	8.75	mg	No
		PSYCHOANALEPTICS	CAFFEINE	20OCT2016	29OCT2016	8.6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	29OCT2016	31OCT2016	10.2	mg	No
		PSYCHOANALEPTICS	CAFFEINE	06NOV2016	14NOV2016	10	mg	No
		PSYCHOLEPTICS	DEXMEDETOMIDINE	31OCT2016		1	mcg/kg/hr	Yes
		PSYCHOLEPTICS	LORAZEPAM	07NOV2016		0.1	mg	Yes
		VITAMINS	COLECALCIFEROL	30OCT2016	31OCT2016	400	U	No
	40004	ALL OTHER NON-THERAPEUTIC PRODUCTS	SUCROSE	22JUL2016	25JUL2016	0.5	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	01AUG2016		3	mg	Yes
		ANTITHROMBOTIC AGENTS	HEPARIN	18JUL2016	19JUL2016	0.5	units/ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	25JUL2016		0.18	ml	Yes
		EMOLLIENTS AND PROTECTIVES	EMOLLIENTS AND PROTECTIVES	30JUL2016	03AUG2016	1	gtt	No
		PSYCHOANALEPTICS	CAFFEINE	18JUL2016		5.5	mg	Yes
		VITAMINS	COLECALCIFEROL	25JUL2016		0.03	ml	Yes
	40009	ANESTHETICS	FENTANYL	25SEP2016	25SEP2016	3	mg	No
		ANESTHETICS	FENTANYL	06OCT2016	06OCT2016	0.94	mcg	No
		ANESTHETICS	FENTANYL	07OCT2016	07OCT2016	0.97	mcg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	10OCT2016	15OCT2016	3	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	16OCT2016	07NOV2016	4	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	08NOV2016		5	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	24SEP2016	26SEP2016	49.5	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	24SEP2016	26SEP2016	7.9	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	02OCT2016	04OCT2016	7.3	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	MEROPENEM	04OCT2016	09OCT2016	17.5	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	MEROPENEM	09OCT2016	15OCT2016	42	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	02OCT2016	04OCT2016	9.1	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	02OCT2016	02OCT2016	8.5	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	03OCT2016	03OCT2016	4.5	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	03OCT2016	03OCT2016	4.5	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM PHOSPHATE	22OCT2016		0.08	ml	Yes
		CARDIAC THERAPY	ATROPINE	25SEP2016	25SEP2016	0.02	mg	No
		CARDIAC THERAPY	INDOMETACIN	24SEP2016	26SEP2016	0.1	mg	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	BUDESONIDE	11OCT2016		1	mg	Yes
		EMOLLIENTS AND PROTECTIVES	EMOLLIENTS AND PROTECTIVES	25SEP2016	30SEP2016		NA	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	25SEP2016	25SEP2016	2	mg	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	BOVINE LIPID EXTRACT SURFACTANT	25SEP2016	25SEP2016	5	ml	No
		PSYCHOANALEPTICS	CAFFEINE	24SEP2016	24SEP2016	9.9	mg	No
		PSYCHOANALEPTICS	CAFFEINE	26SEP2016	08OCT2016	5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	09OCT2016	16OCT2016	5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	17OCT2016	03NOV2016	6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	03NOV2016		7.3	mg	Yes
		VITAMINS	COLECALCIFEROL	08OCT2016		0.03	ml	Yes
	40013	ALL OTHER NON-THERAPEUTIC PRODUCTS	SUCROSE	05NOV2016	05NOV2016	0.5	ml	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	07NOV2016		1	mg	Yes
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	07NOV2016		0.13	ml	Yes
		DRUGS FOR CONSTIPATION	GLYCEROL	31OCT2016	31OCT2016		1	No
		PSYCHOANALEPTICS	CAFFEINE	29OCT2016	29OCT2016	15	mg	No
		PSYCHOANALEPTICS	CAFFEINE	31OCT2016	02NOV2016	7.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	03NOV2016		7.5	mg	Yes
		VITAMINS	COLECALCIFEROL	04NOV2016	06NOV2016	0.03	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		VITAMINS	MULTIVITAMINS	07NOV2016		1	ml	Yes
		VITAMINS	TOCOPHERYL ACETATE	07NOV2016		1	ml	Yes
	40019	ALL OTHER NON-THERAPEUTIC PRODUCTS	SUCROSE	20MAY2017	12JUN2017	0.5	ml	No
		ANESTHETICS	FENTANYL	16MAY2017	16MAY2017	1	mcg	No
		ANESTHETICS	FENTANYL	16MAY2017	16MAY2017	2.2	mg	No
		ANESTHETICS	FENTANYL	17MAY2017	21MAY2017	2	mcg/ml	No
		ANESTHETICS	FENTANYL	18MAY2017	18MAY2017	1	mcg	No
		ANESTHETICS	FENTANYL	22MAY2017	22MAY2017	1.1	mg	No
		ANESTHETICS	LIDOCAINE	16MAY2017	16MAY2017	1	ml	No
		ANESTHETICS	LIDOCAINE	17MAY2017	17MAY2017	1	ml	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	06JUN2017	11JUN2017	3	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	12JUN2017	20JUN2017	4	mg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	21JUN2017		5	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	17MAY2017	20MAY2017	55	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	17MAY2017	19MAY2017	8.8	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	03JUN2017	20JUN2017	0.18	ml	No
		CARDIAC THERAPY	ATROPINE	16MAY2017	16MAY2017	0.22	ml	No
		EMOLLIENTS AND PROTECTIVES	EMOLLIENTS AND PROTECTIVES	22MAY2017	26MAY2017		NA	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	16MAY2017	16MAY2017	2.2	mg	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	BOVINE LIPID EXTRACT SURFACTANT	16MAY2017	16MAY2017	6.6	cc	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	BOVINE LIPID EXTRACT SURFACTANT	18MAY2017	18MAY2017	5.5	cc	No
		PSYCHOANALEPTICS	CAFFEINE	16MAY2017	16MAY2017	11	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		PSYCHOANALEPTICS	CAFFEINE	17MAY2017	30MAY2017	5.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	01JUN2017	08JUN2017	6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	09JUN2017		7.6	mg	Yes
		VITAMINS	COLECALCIFEROL	03JUN2017	20JUN2017	0.03	ml	No
		VITAMINS	COLECALCIFEROL	22JUN2017	25JUN2017	0.03	ml	No
	41002	ANESTHETICS	FENTANYL	27NOV2016	27NOV2016	1.6	mcg	No
		ANESTHETICS	FENTANYL	30NOV2016	30NOV2016	1.5	mcg	No
		ANTIANEMIC PREPARATIONS	IRON	18DEC2016		3	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	30NOV2016	02DEC2016	40	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	02DEC2016	03DEC2016	40	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	30NOV2016	03DEC2016	4	mg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	27NOV2016	27NOV2016	0.5	mg	No
		CARDIAC THERAPY	ATROPINE	27NOV2016	27NOV2016	0.02	mg	No
		CARDIAC THERAPY	ATROPINE	30NOV2016	30NOV2016	0.02	mg	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	27NOV2016	27NOV2016	1.6	mg	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	30NOV2016	30NOV2016	1.5	mg	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	28DEC2016	28DEC2016	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	27NOV2016	27NOV2016	5	mg	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	BOVINE LIPID EXTRACT SURFACTANT	27NOV2016	27NOV2016	4	ml	No
		PSYCHOANALEPTICS	CAFFEINE	28NOV2016	28NOV2016	8	mg	No
		PSYCHOANALEPTICS	CAFFEINE	29NOV2016	06DEC2016	4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	07DEC2016	21DEC2016	4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	21DEC2016		6	mg	Yes

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
	41005	ANTIANEMIC PREPARATIONS	IRON	07FEB2017	16FEB2017	3	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	13JAN2017	15JAN2017	55	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFOTAXIME	22JAN2017	24JAN2017	55	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CLOXACILLIN	21JAN2017	22JAN2017	54	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	13JAN2017	13JAN2017	5.5	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	21JAN2017	21JAN2017	5.5	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	23JAN2017	02FEB2017	5.5	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	03FEB2017	04FEB2017	19	mg	No
		ANTIFUNGALS FOR DERMATOLOGICAL USE	NYSTATIN	19FEB2017		1	ml	Yes
		ANTIHEMORRHAGICS	PHYTOMENADIONE	13JAN2017	13JAN2017	0.5	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	16FEB2017	16FEB2017	20	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	14JAN2017	14JAN2017	11	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	03FEB2017	03FEB2017	12	ml	No
		DRUGS FOR CONSTIPATION	GLYCEROL	16JAN2017	17JAN2017	0.25	sliver	No
		DRUGS FOR CONSTIPATION	GLYCEROL	19FEB2017	19FEB2017	0.25	sliver	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	15FEB2017	15FEB2017	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	13JAN2017	13JAN2017	5	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		PSYCHOANALEPTICS	CAFFEINE	13JAN2017	13JAN2017	11	mg	No
		PSYCHOANALEPTICS	CAFFEINE	14JAN2017	20JAN2017	5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	21JAN2017	21JAN2017	5.4	mg	No
		PSYCHOANALEPTICS	CAFFEINE	22JAN2017	31JAN2017	5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	31JAN2017	31JAN2017	6.2	mg	No
		PSYCHOANALEPTICS	CAFFEINE	01FEB2017	03FEB2017	6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	04FEB2017	04FEB2017	6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	05FEB2017	16FEB2017	6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	17FEB2017		7	mg	Yes
	42001	ANESTHETICS	FENTANYL	30MAY2016	30MAY2016	3	mcg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	27JUN2016		1.5	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	30MAY2016	01JUN2016	60	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	30MAY2016	30MAY2016	6	mg	No
		ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	PROBIOTIC /07343501/	31MAY2016		0.5	gm	Yes
		ANTIHEMORRHAGICS	PHYTOMENADIONE	30MAY2016	30MAY2016	0.5	mg	No
		CARDIAC THERAPY	ATROPINE	30MAY2016	30MAY2016	0.02	mg	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	30MAY2016	30MAY2016	2.4	mg	No
		OPHTHALMOLOGICALS	CYCLOMYDRIL	11JUL2016	11JUL2016	1	gtt	No
		OPHTHALMOLOGICALS	ERYTHROMYCIN	30MAY2016	30MAY2016	0.5	%	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	BOVINE LIPID EXTRACT SURFACTANT	30MAY2016	30MAY2016	6	ml	No
		PSYCHOANALEPTICS	CAFFEINE	30MAY2016	30MAY2016	12	mg	No
		PSYCHOANALEPTICS	CAFFEINE	31MAY2016		4.2	mg	Yes
		VITAMINS	COLECALCIFEROL	04JUN2016		400	IU	Yes

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
	42004	ANESTHETICS	FENTANYL	15AUG2016	15AUG2016	2	mcg	No
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	13SEP2016		3	mg	Yes
		ANTIDIARRHEALS, INTESTINAL	PROBIOTIC	18AUG2016		0.5	gm	Yes
		ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	/07343501/					
		ANTIHEMORRHAGICS	PHYTOMENADIONE	17AUG2016	17AUG2016	0.5	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	17AUG2016	17AUG2016	12	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	16AUG2016	18AUG2016	0.1	mmoL/kg/hr	No
		CARDIAC THERAPY	ATROPINE	15AUG2016	15AUG2016	0.02	mg	No
		CARDIAC THERAPY	DOPAMINE	15AUG2016	18AUG2016		mcg/kg/min	No
		CARDIAC THERAPY	IBUPROFEN	18AUG2016	18AUG2016	8	mg	No
		CARDIAC THERAPY	IBUPROFEN	19AUG2016	20AUG2016	4	mg	No
		CARDIAC THERAPY	IBUPROFEN	25AUG2016	25AUG2016	9	mg	No
		CARDIAC THERAPY	IBUPROFEN	26AUG2016	27AUG2016	4.5	mg	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	15AUG2016	15AUG2016	1.6	mg	No
		MUSCLE RELAXANTS	SUXAMETHONIUM CHLORIDE	15AUG2016	15AUG2016	1.6	mg	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	29SEP2016	29SEP2016	1	gtt	No
		OPHTHALMOLOGICALS	CYCLOPENTOLATE W/PHENYLEPHRINE	06OCT2016	06OCT2016	1	gtt	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	15AUG2016	15AUG2016	4	ml	No
		PSYCHOANALEPTICS	CAFFEINE	15AUG2016	15AUG2016	8	mg	No
		PSYCHOANALEPTICS	CAFFEINE	16AUG2016	05SEP2016	3.2	mg	No
		PSYCHOANALEPTICS	CAFFEINE	05SEP2016	05SEP2016	5.5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	06SEP2016	12SEP2016	4.4	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		PSYCHOANALEPTICS	CAFFEINE	13SEP2016	17SEP2016	5	mg	No
		PSYCHOANALEPTICS	CAFFEINE	17SEP2016	28SEP2016	6	mg	No
		PSYCHOANALEPTICS	CAFFEINE	28SEP2016	28SEP2016	1	mg	No
		PSYCHOANALEPTICS	CAFFEINE	29SEP2016		7	mg	Yes
		VITAMINS	COLECALCIFEROL	24AUG2016		400	IU	Yes
	54001	ANALGESICS	PARACETAMOL	25JUL2016	26JUL2016	8	mg	No
		ANTIANEMIC PREPARATIONS	EPOETIN BETA	10AUG2016		250	250IU/kg	Yes
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	05AUG2016		0.4	ml	Yes
		ANTIANEMIC PREPARATIONS	FOLIC ACID	02AUG2016		0.1	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	23JUL2016	25JUL2016	70	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	23JUL2016	25JUL2016	6.5	mg	No
		ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	PROBIOTIC /07343501/	05AUG2016		5	gtt	Yes
		ANTIHEMORRHAGICS	PHYTOMENADIONE	23JUL2016	23JUL2016	0.5	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	23JUL2016	28JUL2016			No
		CARDIAC THERAPY	IBUPROFEN	29JUL2016	31JUL2016	12	mg	No
		OPHTHALMOLOGICALS	PHENYLEPHRINE HYDROCHLORIDE	22AUG2016	12SEP2016	1	gtt	No
		OPHTHALMOLOGICALS	TIMOLOL MALEATE	12SEP2016		1	gtt	Yes
		OPHTHALMOLOGICALS	TROPICAMIDE	22AUG2016	12SEP2016	1	gtt	No
		PSYCHOANALEPTICS	CAFFEINE	23JUL2016	23JUL2016	26	mg	No
		PSYCHOANALEPTICS	CAFFEINE	24JUL2016	16AUG2016	10	mg	No
		VACCINES	BCG VACCINE	06SEP2016	06SEP2016	0.05	ml	No
		VACCINES	HEPATITIS B VACCINE	23JUL2016	23AUG2016	0.5	ml	No
		VITAMINS	ASCORBIC ACID	02AUG2016		2	gtt	Yes

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		VITAMINS	COLECALCIFEROL	31JUL2016		500	U	Yes
		VITAMINS	RETINOL	02AUG2016		1	gtt	Yes
		VITAMINS	TOCOPHERYL ACETATE	02AUG2016		1	gtt	Yes
	54002	ANTIANEMIC PREPARATIONS	EPOETIN BETA	16SEP2016		500	U	Yes
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	14SEP2016		0.2	ml	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	02SEP2016	06SEP2016	68	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	02SEP2016	06SEP2016	7	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	18OCT2016	24OCT2016	9	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	18OCT2016	25OCT2016	22	mg	No
		ANTIIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	PROBIOTIC /07343501/	12SEP2016		3	gtt	Yes
		ANTIHEMORRHAGICS	PHYTOMENADIONE	02SEP2016	02SEP2016	0.3	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	02SEP2016	09SEP2016			No
		PSYCHOANALEPTICS	CAFFEINE	02SEP2016	02SEP2016	27	mg	No
		PSYCHOANALEPTICS	CAFFEINE	03SEP2016	12OCT2016	10	mg	No
		VACCINES	BCG VACCINE	10OCT2016	10OCT2016	0.05	ml	No
		VACCINES	HEPATITIS B VACCINE	02SEP2016	04OCT2016	0.5	ml	No
		VITAMINS	ASCORBIC ACID	07SEP2016		3	gtt	Yes
		VITAMINS	COLECALCIFEROL	07SEP2016		800	U	Yes
		VITAMINS	RETINOL	07SEP2016		1	gtt	Yes
		VITAMINS	TOCOPHERYL ACETATE	07SEP2016		1	gtt	Yes
	54017	ANALGESICS	PARACETAMOL	28NOV2016	05DEC2016	13	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIANEMIC PREPARATIONS	ERYTHROPOIETIN	26DEC2016		400	IU	Yes
		ANTIANEMIC PREPARATIONS	FERROUS SULFATE	24DEC2016		6	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	25NOV2016	30NOV2016	87	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	25NOV2016	29NOV2016	4.3	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	GENTAMICIN	12DEC2016	14DEC2016	4	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	PIP/TAZO	15DEC2016	22DEC2016	100	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	12DEC2016	14DEC2016	10	mg	No
		ANTIIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS	PROBIOTIC /07343501/	18DEC2016	01JAN2017	5	gtt	No
		ANTHEMORRHAGICS	PHYTOMENADIONE	25NOV2016	25NOV2016	0.2	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	25NOV2016	14DEC2016	4	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	13DEC2016	13DEC2016	15	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	30DEC2016	30DEC2016	26	ml	No
		DIURETICS	SPIRONOLACTONE	18JAN2017		4	mg	Yes
		OPHTHALMOLOGICALS	MOXIFLOXACIN	01DEC2016	14DEC2016	1	gtt	No
		OTHER RESPIRATORY SYSTEM PRODUCTS	PORACTANT ALFA	26NOV2016	26NOV2016	170	mg	No
		PSYCHOANALEPTICS	CAFFEINE	25NOV2016	25NOV2016	18	mg	No
		PSYCHOANALEPTICS	CAFFEINE	26NOV2016		7	mg	Yes
		VACCINES	HEPATITIS B VACCINE	25NOV2016	27DEC2016	0.5	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		VITAMINS	COLECALCIFEROL	23DEC2016		800	IU	Yes
		VITAMINS	RETINOL	23DEC2016		1	gtt	Yes
		VITAMINS	TOCOPHERYL ACETATE	23DEC2016		1	gtt	Yes
		VITAMINS	VITAMIN B COMPLEX	30DEC2016		1	gtt	Yes
	76002	ANESTHETICS	FENTANYL	21DEC2016	21DEC2016	1	gamma	No
		ANESTHETICS	FENTANYL	21DEC2016	24DEC2016	95	gammas	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMIKACIN	21JAN2017	22JAN2017	18	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMIKACIN	24JAN2017	01FEB2017	21	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	21DEC2016	21DEC2016	100	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AMPICILLIN	22DEC2016	24DEC2016	150	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AZITHROMYCIN	08FEB2017	10FEB2017	16	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AZITHROMYCIN	13FEB2017	15FEB2017	18	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AZITHROMYCIN	17FEB2017	17FEB2017	19	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	AZITHROMYCIN	22FEB2017		18	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	BENZYL PENICILLIN SODIUM	22DEC2016	02JAN2017	51000	U	No
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFADROXIL	02FEB2017		30	mg	Yes
		ANTIBACTERIALS FOR SYSTEMIC USE	CEFAZOLIN SODIUM	27DEC2016	29DEC2016	25	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIBACTERIALS FOR SYSTEMIC USE	MEROPENEM	30DEC2016	07JAN2017	40	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	MEROPENEM	09JAN2017	13JAN2017	40	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	PIP/TAZO	22JAN2017	01FEB2017	140	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	30DEC2016	07JAN2017	10	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	09JAN2017	12JAN2017	11	mg	No
		ANTIBACTERIALS FOR SYSTEMIC USE	VANCOMYCIN	22JAN2017	24JAN2017	14	mg	No
		ANTIPILEPTICS	LEVETIRACETAM	03JAN2017	06JAN2017	5	mg	No
		ANTIPILEPTICS	LEVETIRACETAM	06JAN2017	16JAN2017	10	mg	No
		ANTIPILEPTICS	LEVETIRACETAM	16JAN2017		28	mg	Yes
		ANTIPILEPTICS	PHENOBARBITAL	22DEC2016	22DEC2016	20	mg	No
		ANTIPILEPTICS	PHENOBARBITAL	22DEC2016	22DEC2016	20	mg	No
		ANTIPILEPTICS	PHENOBARBITAL	23DEC2016	27DEC2016	1.5	mg	No
		ANTIPILEPTICS	PHENOBARBITAL	29DEC2016	30DEC2016	1.5	mg	No
		ANTIPILEPTICS	PHENOBARBITAL	30DEC2016	04JAN2017	2	mg	No
		ANTIPILEPTICS	PHENOBARBITAL	07JAN2017	10JAN2017	4	mg	No
		ANTIPILEPTICS	PHENOBARBITAL	13JAN2017	18JAN2017	4	mg	No
		ANTIPILEPTICS	PHENOBARBITAL	19JAN2017	27JAN2017	2.7	mg	No
		ANTIPILEPTICS	PHENOBARBITAL	28JAN2017	13FEB2017	3	mg	No
		ANTIPILEPTICS	PHENOBARBITAL	14FEB2017		4	mg	Yes
		ANTIPILEPTICS	PHENYTOIN	28DEC2016	28DEC2016	15	mg	No
		ANTIPILEPTICS	PHENYTOIN	28DEC2016	28DEC2016	20	mg	No
		ANTIPILEPTICS	PHENYTOIN	29DEC2016	29DEC2016	4	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		ANTIEPILEPTICS	PHENYTOIN	30DEC2016	15JAN2017	6	mg	No
		ANTIEPILEPTICS	PHENYTOIN	16JAN2017	16JAN2017	4.5	mg	No
		ANTIEPILEPTICS	PHENYTOIN	17JAN2017	17JAN2017	3.3	mg	No
		ANTIEPILEPTICS	PHENYTOIN	18JAN2017	18JAN2017	2.5	mg	No
		ANTIEPILEPTICS	PHENYTOIN	19JAN2017	20JAN2017	2	mg	No
		ANTIEPILEPTICS	PHENYTOIN	21JAN2017	21JAN2017	1.5	mg	No
		ANTIEPILEPTICS	PHENYTOIN	22JAN2017	22JAN2017	1	mg	No
		ANTIHEMORRHAGICS	CRYOPRECIPITATE	23DEC2016	23DEC2016	10	ml	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	20DEC2016	20DEC2016	0.5	ml	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	21DEC2016	22DEC2016	1	mg	No
		ANTIHEMORRHAGICS	PHYTOMENADIONE	01JAN2017	03JAN2017	1	mg	No
		ANTIMYCOTICS FOR SYSTEMIC USE	FLUCONAZOLE	14JAN2017	26JAN2017	14	mg	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	ALBUMIN HUMAN	31DEC2016	01JAN2017	5	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	ALBUMIN HUMAN	02JAN2017	02JAN2017	6	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	ALBUMIN HUMAN	08JAN2017	10JAN2017	6	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS	21DEC2016	21DEC2016	19	cc	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	21DEC2016	25DEC2016	303	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	AMINO ACIDS NOS W/CARBOHYDRATES NOS/07403901/	25DEC2016	16JAN2017	2911	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	CALCIUM GLUCONATE	21DEC2016	22DEC2016	2	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	20DEC2016	21DEC2016	9	cc	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	21DEC2016	21DEC2016	48	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	24DEC2016	25DEC2016	91.2	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	31DEC2016	01JAN2017	63	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	03JAN2017	03JAN2017	43	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	GLUCOSE	08JAN2017	09JAN2017	79	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	21DEC2016	21DEC2016	10	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLASMA	01JAN2017	01JAN2017	11	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	PLATELETS	23DEC2016	23DEC2016	15	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	21DEC2016	22DEC2016	10	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	22DEC2016	23DEC2016	10	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	24DEC2016	24DEC2016	10	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	30DEC2016	31DEC2016	10	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	01JAN2017	01JAN2017	11	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	09JAN2017	10JAN2017	11	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	12JAN2017	12JAN2017	12	cc	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	RED BLOOD CELLS	24JAN2017	24JAN2017	14	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM BICARBONATE	31DEC2016	31DEC2016	1.1	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	22DEC2016	22DEC2016	10	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	22DEC2016	22DEC2016	10	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	28DEC2016	28DEC2016	2.9	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	30DEC2016	30DEC2016	1.8	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	30DEC2016	30DEC2016	10	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	30DEC2016	30DEC2016	20	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	31DEC2016	31DEC2016	11	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	05JAN2017	05JAN2017	13	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	06JAN2017	06JAN2017	12	ml	No
		BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS	SODIUM CHLORIDE	09JAN2017	09JAN2017	15	ml	No
		CARDIAC THERAPY	DOBUTAMINE HYDROCHLORIDE	30DEC2016	31DEC2016	1920	gammas	No
		CARDIAC THERAPY	DOPAMINE	22DEC2016	26DEC2016	816	gammas	No
		CARDIAC THERAPY	DOPAMINE	30DEC2016	03JAN2017	1880	gammas	No
		CARDIAC THERAPY	DOPAMINE	09JAN2017	10JAN2017	25	gammas	No
		CARDIAC THERAPY	EPINEPHRINE	30DEC2016	30DEC2016	0.1	ml	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		CARDIAC THERAPY	EPINEPHRINE	30DEC2016	02JAN2017	72	gammas	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	DEXAMETHASONE	16JAN2017	16JAN2017	0.8	mg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	DEXAMETHASONE	26JAN2017	26JAN2017	0.9	mg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	30DEC2016	31DEC2016	1	mg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	31DEC2016	02JAN2017	1	mg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	02JAN2017	03JAN2017	1	ml	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	03JAN2017	04JAN2017	1	mg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	04JAN2017	05JAN2017	1	mg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	09JAN2017	10JAN2017	1.3	mg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	10JAN2017	11JAN2017	1	mg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	11JAN2017	12JAN2017	0.7	mg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	12JAN2017	13JAN2017	0.5	mg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	13JAN2017	15JAN2017	0.3	ml	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	15JAN2017	16JAN2017	0.2	mg	No
		CORTICOSTEROIDS FOR SYSTEMIC USE	HYDROCORTISONE	16JAN2017	17JAN2017	0.2	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		DIURETICS	FUROSEMIDE	31DEC2016	31DEC2016	0.6	ml	No
		DIURETICS	FUROSEMIDE	01JAN2017	01JAN2017	1	mg	No
		DIURETICS	FUROSEMIDE	01JAN2017	01JAN2017	1	ml	No
		DIURETICS	FUROSEMIDE	08JAN2017	09JAN2017	1	mg	No
		DIURETICS	FUROSEMIDE	09JAN2017	09JAN2017	1.5	mg	No
		DIURETICS	FUROSEMIDE	09JAN2017	09JAN2017	3.5	mg	No
		DIURETICS	FUROSEMIDE	10JAN2017	10JAN2017	0.7	mg	No
		DIURETICS	FUROSEMIDE	13JAN2017	14JAN2017	1.3	mg	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	AMINOPHYLLINE	20DEC2016	20DEC2016	6	mg	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	AMINOPHYLLINE	21DEC2016	16JAN2017	2	mg	No
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	BUDESONIDE	02FEB2017		1	Puff	Yes
		DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	THEOPHYLLINE	19FEB2017	23FEB2017	4	mg	No
		DRUGS USED IN DIABETES	INSULIN	21DEC2016	22DEC2016	0.57	IU	No
		DRUGS USED IN DIABETES	INSULIN	24DEC2016	26DEC2016	0.72	IU	No
		DRUGS USED IN DIABETES	INSULIN	30DEC2016	01JAN2017	1.2	IU	No
		GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS	AMPHOTERICIN B	11JAN2017	13JAN2017	1.2	mg	No
		MINERAL SUPPLEMENTS	ZINC SULFATE	16JAN2017		4	gtt	Yes
		OTHER RESPIRATORY SYSTEM PRODUCTS	BERACTANT	21DEC2016	22DEC2016	4.1	cc	No
		PSYCHOANALEPTICS	CAFFEINE	16JAN2017	11FEB2017	14	mg	No
		PSYCHOANALEPTICS	CAFFEINE	12FEB2017	18FEB2017	18	mg	No
		PSYCHOANALEPTICS	CAFFEINE	23FEB2017		20	mg	Yes
		PSYCHOLEPTICS	MIDAZOLAM	21DEC2016	21DEC2016	0.1	mg	No

Summary Listing 4.1
Pre-Study/Concomitant Medications

Treatment Group	Subject ID	Medication Category	Drug Generic Name	Start Date	Stop Date	Dose	Unit	Ongoing?
		PSYCHOLEPTICS	MIDAZOLAM	29DEC2016	29DEC2016	0.2	mg	No
		PSYCHOLEPTICS	MIDAZOLAM	29DEC2016	03JAN2017	14.5	mg	No
		PSYCHOLEPTICS	MIDAZOLAM	30DEC2016	30DEC2016	0.3	mg	No
		PSYCHOLEPTICS	MIDAZOLAM	08JAN2017	09JAN2017	0.2	mg	No
		PSYCHOLEPTICS	MIDAZOLAM	08JAN2017	09JAN2017	3.9	mg	No
		VITAMINS	MULTIVITAMINS	18JAN2017		400	IU	Yes

14.2 Efficacy Data Summary Tables and Summary Graphs

Summary Tables

Table Number	Table Title
4.1.1	Exploratory Efficacy Analysis – Early Worsening of Respiratory Status Criteria – Intent-to-Treat Population
4.1.2	Exploratory Efficacy Analysis – Late Worsening of Respiratory Status Criteria – Intent-to-Treat Population
4.2	Exploratory Efficacy Analysis – Summary of BPD and Survival without BPD at 36 Weeks PMA – Intent-to-Treat Population
4.3.1	Exploratory Efficacy Analysis – Time until Any Intubation – Intent-to-Treat Population
4.3.2	Exploratory Efficacy Analysis – Time until nCPAP Failure
4.3.3	Exploratory Efficacy Analysis – Time until nCPAP Failure – Without Treatment Interruptions
5.1.1	Investigational Device – Technical Performance of the Device – Initial Dose – Intent-to-Treat Population
5.1.2	Investigational Device – Technical Performance – Repeat Dose – Intent-to-Treat Population
5.2.1	Investigational Device – Investigational Product Administration – Initial Dose – Safety Population
5.2.2	Investigational Device – Investigational Product Administration – Repeat Dose – Safety Population

Summary Graphs

Graph Number	Graph Title
1.1	Time Until Intubation – Total Active and Control – Intent-to-Treat Population
1.1.1	Time Until Intubation – Total Active and Control without Treatment Interruptions – Intent-to-Treat Population
1.1.2	nCPAP Failure (Intubation) by Time Period – Through 72 Hours
1.2	Time Until Intubation – Intent-to-Treat Population

Summary Graphs

Graph Number	Graph Title
1.2.1	Time Until Intubation – Without Treatment Interruptions – Intent-to-Treat Population
1.3.1	nCPAP Failure (Intubation) by Treatment Group– Through 72 Hours
1.3.2	nCPAP Failure (Intubation) by Treatment Group– Subjects without Dosing Interruptions
2.1.1	Oxygenation – FiO ₂ – Observed Values – Intent-to-Treat Population
2.1.2	Oxygenation – FiO ₂ – Change from Baseline Values – Intent-to-Treat Population
2.2.1	Oxygenation – PCO ₂ – Observed Values – Intent-to-Treat Population
2.2.2	Oxygenation – PCO ₂ – Change from Baseline Values – Intent-to-Treat Population

Summary Table 4.1.1
Exploratory Efficacy Analysis
Early Worsening of Respiratory Status Criteria
Intent-to-Treat Population

All Reasons	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Total of Subjects with Early Worsening	6 (75%)	7 (88%)	6 (75%)	19 (79%)	18 (75%)
Arterial pH less than 7.20	2 (25%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)
Desaturation less than 80%	2 (25%)	0 (0%)	1 (13%)	3 (13%)	2 (8%)
Heart Rate less 100 bpm	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
Initiation of intermittent PPV	3 (38%)	2 (25%)	1 (13%)	6 (25%)	3 (13%)
Intubation for any reason	5 (63%)	7 (88%)	4 (50%)	16 (67%)	14 (58%)
Need for additional surfactant therapy	5 (63%)	6 (75%)	4 (50%)	15 (63%)	0 (0%)
PCO ₂ is greater than 65%	1 (13%)	0 (0%)	0 (0%)	1 (4%)	2 (8%)
PI determines worsening respiratory status	0 (0%)	1 (13%)	0 (0%)	1 (4%)	6 (25%)
Required Intervention includes PPV	1 (13%)	0 (0%)	1 (13%)	2 (8%)	2 (8%)
Sustained FiO ₂ is greater than 0.50	4 (50%)	2 (25%)	2 (25%)	8 (33%)	7 (29%)
Sustained apnea event	2 (25%)	0 (0%)	1 (13%)	3 (13%)	3 (13%)
nCPAP is greater than 7 cmH ₂ O	1 (13%)	1 (13%)	2 (25%)	4 (17%)	3 (13%)

Note: Subjects may satisfy multiple criteria.

'Need for additional surfactant therapy' defined as 0 for nCPAP Only.

Summary Table 4.1.2
Exploratory Efficacy Analysis
Late Worsening of Respiratory Status Criteria
Intent-to-Treat Population

All Reasons	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Total of Subjects with Late Worsening	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Summary Table 4.2
Exploratory Efficacy Analysis
Summary of BPD and Survival Without BPD at 36 Weeks PMA
Intent-to-Treat Population

	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
BPD	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	6 (25%)
Survived without BPD	n (%)	7 (88%)	7 (88%)	8 (100%)	22 (92%)	18 (75%)

Summary Table 4.3.1
Exploratory Efficacy Analysis
Time until Any Intubation
Intent-to-Treat Population

Statistic		50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Time until Any Intubation (hours)	n	7	8	6	21	17
	Mean (SE)	55.2 (36.72)	42.3 (30.18)	39.1 (30.35)	45.7 (18.01)	37.1 (28.85)
	SD	97.14	85.35	74.35	82.54	118.94
	Median	8.9	15.9	10.0	11.0	6.5
	Min, Max	3.2 , 270.0	4.2 , 253.1	3.9 , 190.6	3.2 , 270.0	0.2 , 497.3

Summary Table 4.3.2
Exploratory Efficacy Analysis
Time until nCPAP Failure

Statistic		50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Time until nCPAP Failure (hours)	n	5	7	5	17	16
	Mean (SE)	10.2 (3.56)	12.2 (2.28)	8.8 (2.07)	10.6 (1.48)	8.6 (2.38)
	SD	7.95	6.03	4.63	6.09	9.51
	Median	8.7	15.7	9.1	8.9	5.8
	Min, Max	3.2 , 23.8	4.2 , 18.0	3.9 , 15.2	3.2 , 23.8	0.8 , 35.9

Summary Table 4.3.3
Exploratory Efficacy Analysis
Time until nCPAP Failure - Without Treatment Interruptions

	Statistic	50 mg/kg (N=7)	75 mg/kg (N=3)	100 mg/kg (N=6)	Total Active (N=16)	nCPAP Only (N=24)
Time until nCPAP Failure (hours)	n	4	3	3	10	16
	Mean (SE)	6.8 (1.33)	14.1 (3.87)	10.3 (3.03)	10.0 (1.70)	8.6 (2.38)
	SD	2.66	6.71	5.25	5.37	9.51
	Median	7.5	18.0	11.0	8.8	5.8
	Min, Max	3.2 , 8.9	6.4 , 18.0	4.7 , 15.2	3.2 , 18.0	0.8 , 35.9

Summary Table 5.1.1
Investigational Device
Technical Performance of Device - Initial Dose
Intent-to-Treat Population

Technical Performance of Device	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)
Number of Automatic System Shutdowns	n (%)	1 (13%)	4 (50%)	3 (38%)	8 (33%)
Number of Detachments ¹	n (%)	0 (0%)	0 (0%)	1 (13%)	1 (4%)
Number of Obstructions ²	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Study Drug Aerosol/Liquid Leakage	n (%)	0 (0%)	0 (0%)	1 (13%)	1 (4%)
Loss of Inspiratory Flow	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Inability to maintain nCPAP	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Number of Times Error Codes Noted	n (%)	1 (13%)	4 (50%)	3 (38%)	8 (33%)
Occurrence of Alarm Signals					
Before Dosing	n (%)	0 (0%)	2 (25%)	0 (0%)	2 (8%)
During Dosing	n (%)	1 (13%)	4 (50%)	3 (38%)	8 (33%)
After Dosing	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Volume of Liquid (ml)	n	8	8	8	24
	Mean (SE)	12.0 (1.43)	13.8 (1.19)	18.4 (3.17)	14.7 (1.30)
	SD	4.04	3.37	8.98	6.36
	Median	11.0	13.5	22.0	13.5
	Min, Max	8 , 20	8 , 19	4 , 27	4 , 27

Note: A total of 6 subjects experienced back-pressure errors (1 for 50 mg/kg, 3 for 75 mg/kg, 2 for 100 mg/kg).

¹ Ventilator/CPAP or Aerosol Tubing Detachments.

² Proximal Pressure Port or Aerosol Tube Condensate Obstruction.

Summary Table 5.1.2
Investigational Device
Technical Performance of Device - Repeat Dose
Intent-to-Treat Population

Technical Performance of Device	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)
Number of Automatic System Shutdowns	n (%)	0 (0%)	5 (63%)	0 (0%)	5 (21%)
Number of Detachments ¹	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Number of Obstructions ²	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Study Drug Aerosol/Liquid Leakage	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Loss of Inspiratory Flow	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Inability to maintain nCPAP	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Number of Times Error Codes Noted	n (%)	0 (0%)	5 (63%)	0 (0%)	5 (21%)
Occurrence of Alarm Signals					
Before Dosing	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
During Dosing	n (%)	0 (0%)	5 (63%)	0 (0%)	5 (21%)
After Dosing	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Volume of Liquid (ml)	n	8	8	8	24
	Mean (SE)	12.0 (1.43)	13.8 (1.19)	18.4 (3.17)	14.7 (1.30)
	SD	4.04	3.37	8.98	6.36
	Median	11.0	13.5	22.0	13.5
	Min, Max	8 , 20	8 , 19	4 , 27	4 , 27

Note: ¹ Ventilator/CPAP or Aerosol tubing Detachments.

² Proximal Pressure Port or Aerosol tube Condensate Obstruction.

Summary Table 5.2.1
Investigational Device
Investigational Product Administration - Initial Dose
Safety Population

	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)
Initial Dosing Completed	7 (88%)	4 (50%)	4 (50%)	15 (63%)
Any Early Termination	1 (13%)	4 (50%)	4 (50%)	9 (38%)
Device Failure or Malfunction	0 (0%)	4 (50%)	3 (38%)	7 (29%)
Signs of Acute Respiratory Deterioration	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Pulmonary Hemorrhage	0 (0%)	0 (0%)	0 (0%)	0 (0%)
PI's Medical Judgment	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other	1 (13%)	0 (0%)	1 (13%)	2 (8%)
Number of Subjects using the Following:				
Pacifiers	0 (0%)	2 (25%)	2 (25%)	4 (17%)
Gastric Tube	6 (75%)	5 (63%)	8 (100%)	19 (79%)
Chin Strap	0 (0%)	0 (0%)	0 (0%)	0 (0%)

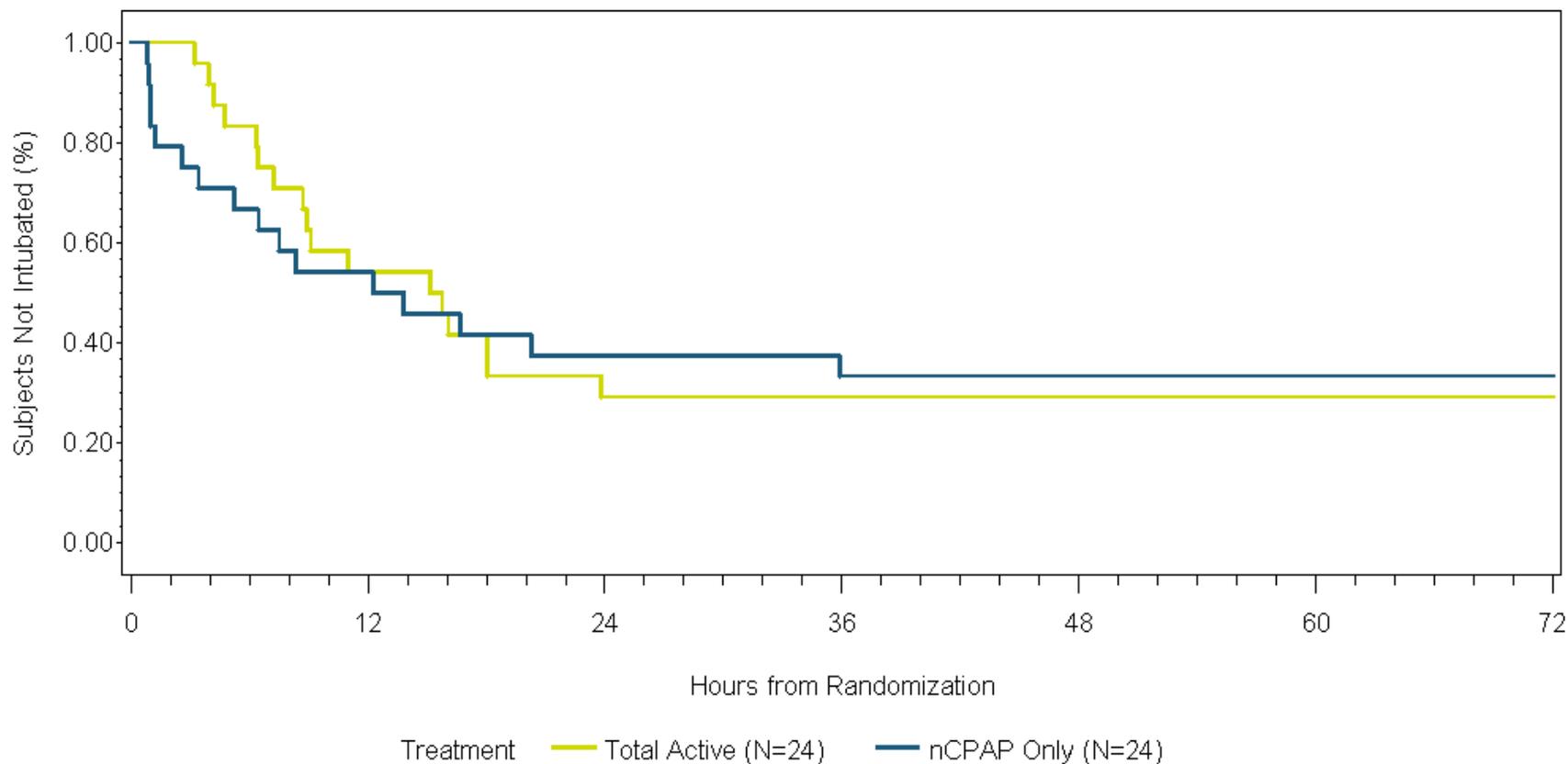
Note: 'Device Failure or Malfunction' includes automatic shut downs due to a detected error condition.

Summary Table 5.2.2
Investigational Device
Investigational Product Administration - Repeat Dose
Safety Population

	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)
Repeat Dosing Completed	4 (50%)	2 (25%)	5 (63%)	11 (46%)
Any Early Termination	1 (13%)	4 (50%)	4 (50%)	9 (38%)
Device Failure or Malfunction	0 (0%)	5 (63%)	0 (0%)	5 (21%)
Signs of Acute Respiratory Deterioration	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Pulmonary Hemorrhage	0 (0%)	0 (0%)	0 (0%)	0 (0%)
PI's Medical Judgment	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Number of Subjects using the Following:				
Pacifiers	0 (0%)	2 (25%)	2 (25%)	4 (17%)
Gastric Tube	6 (75%)	5 (63%)	8 (100%)	19 (79%)
Chin Strap	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Note: 'Device Failure or Malfunction' includes automatic shut downs due to a detected error condition.

Summary Figure 1.1
Time until Intubation - Total Active and Control
Intent-to-Treat Population



Summary Figure 1.1.1
Time until Intubation - Total Active and Control Without Treatment Interruptions
Intent-to-Treat Population

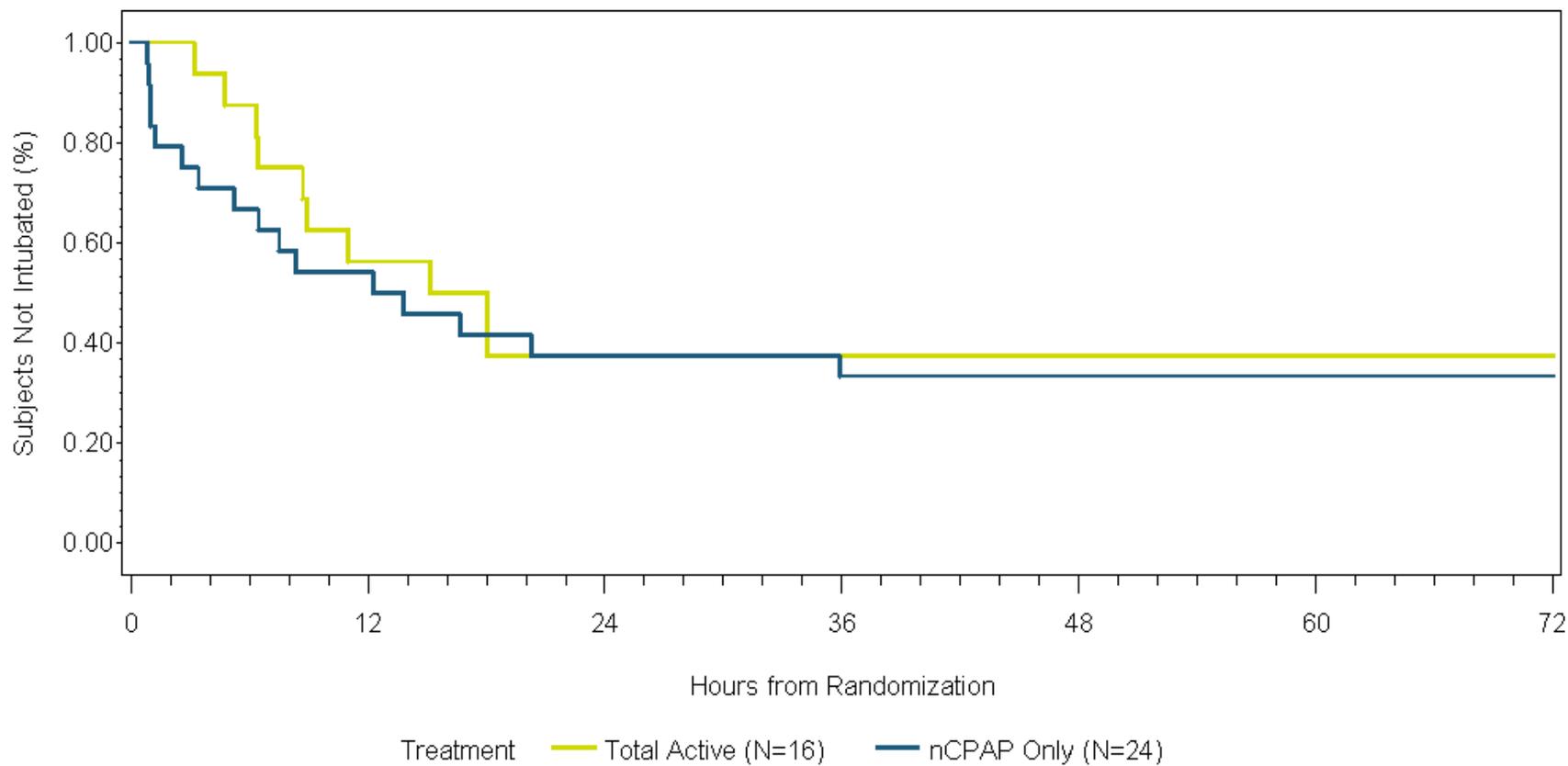
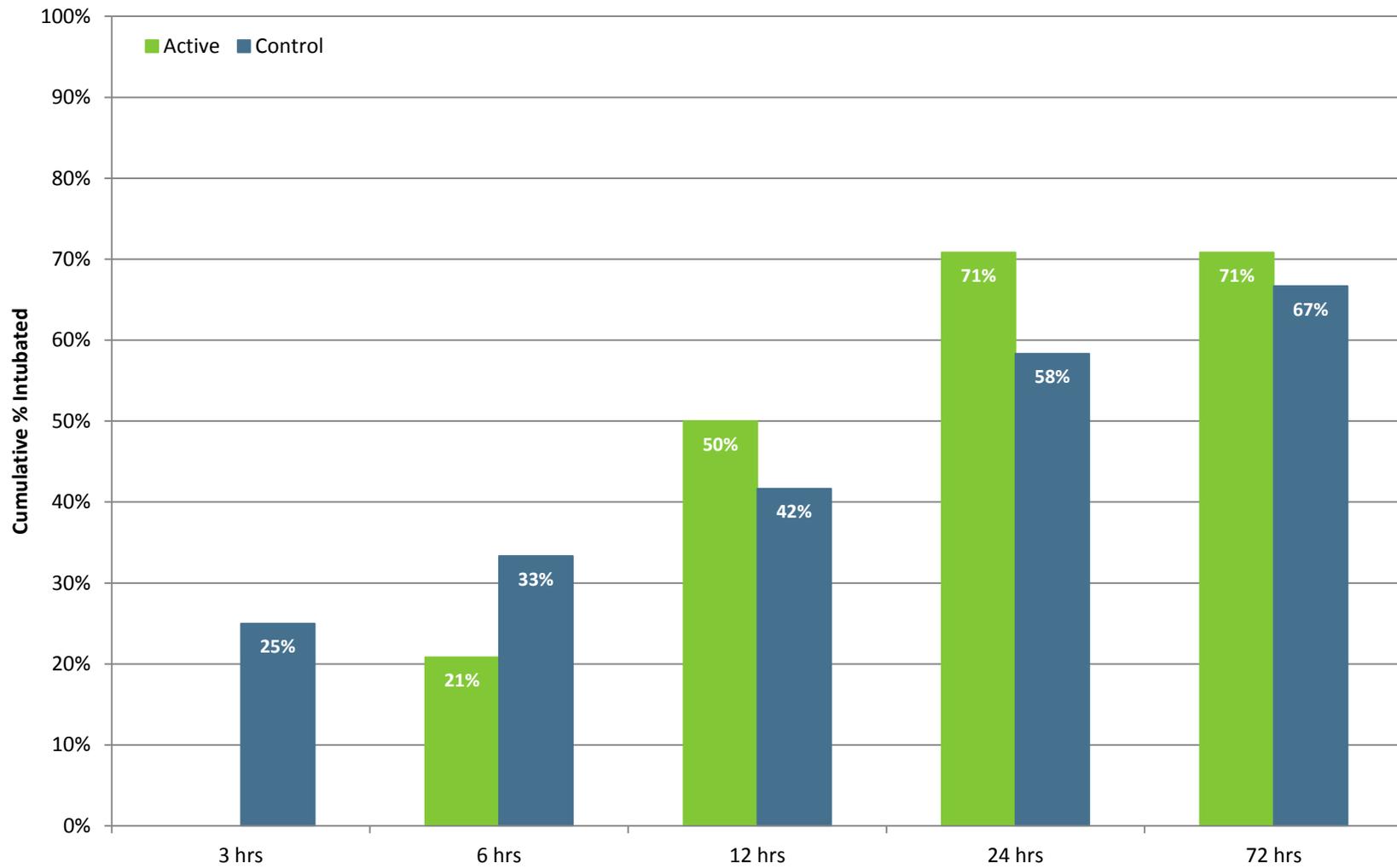
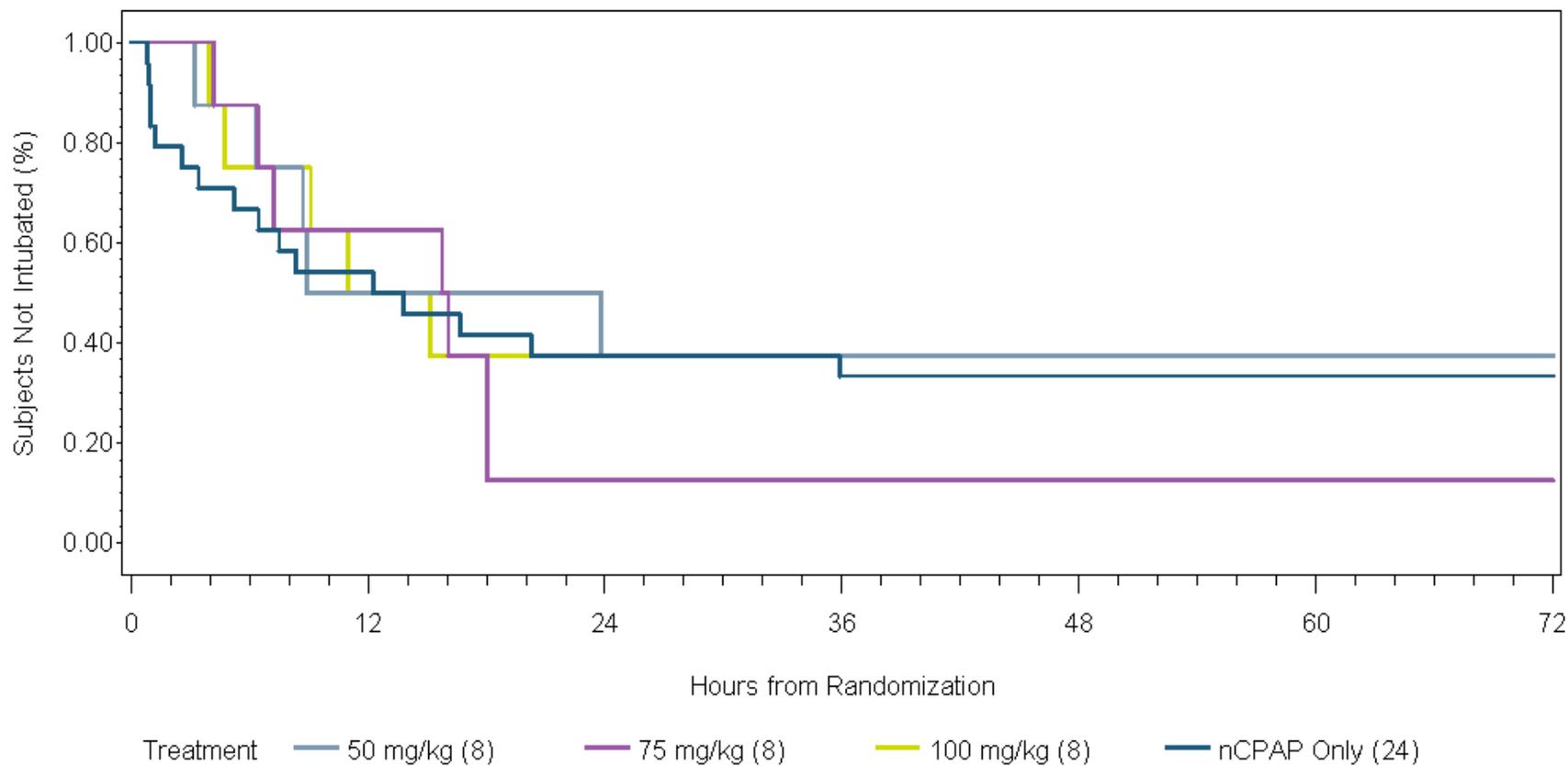


Figure 1.1.2
nCPAP Failure (Intubation) by Time Period
Through 72 Hours



Summary Figure 1.2
Time until Intubation
Intent-to-Treat Population



Summary Figure 1.2.1
Time until Intubation - Without Treatment Interruptions
Intent-to-Treat Population

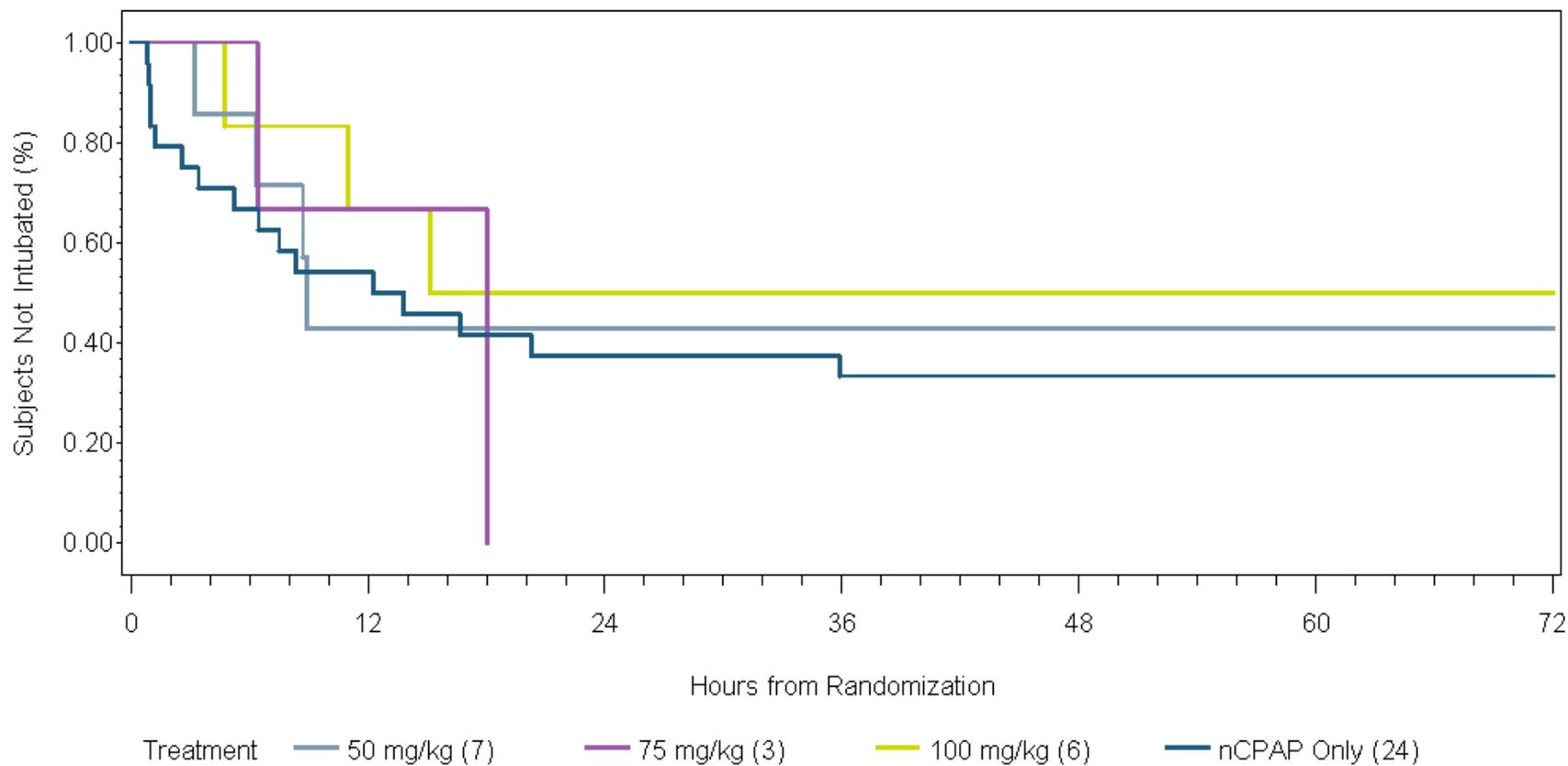


Figure 1.3.1
nCPAP Failures (Intubation) by Treatment Group
Through 72 Hours

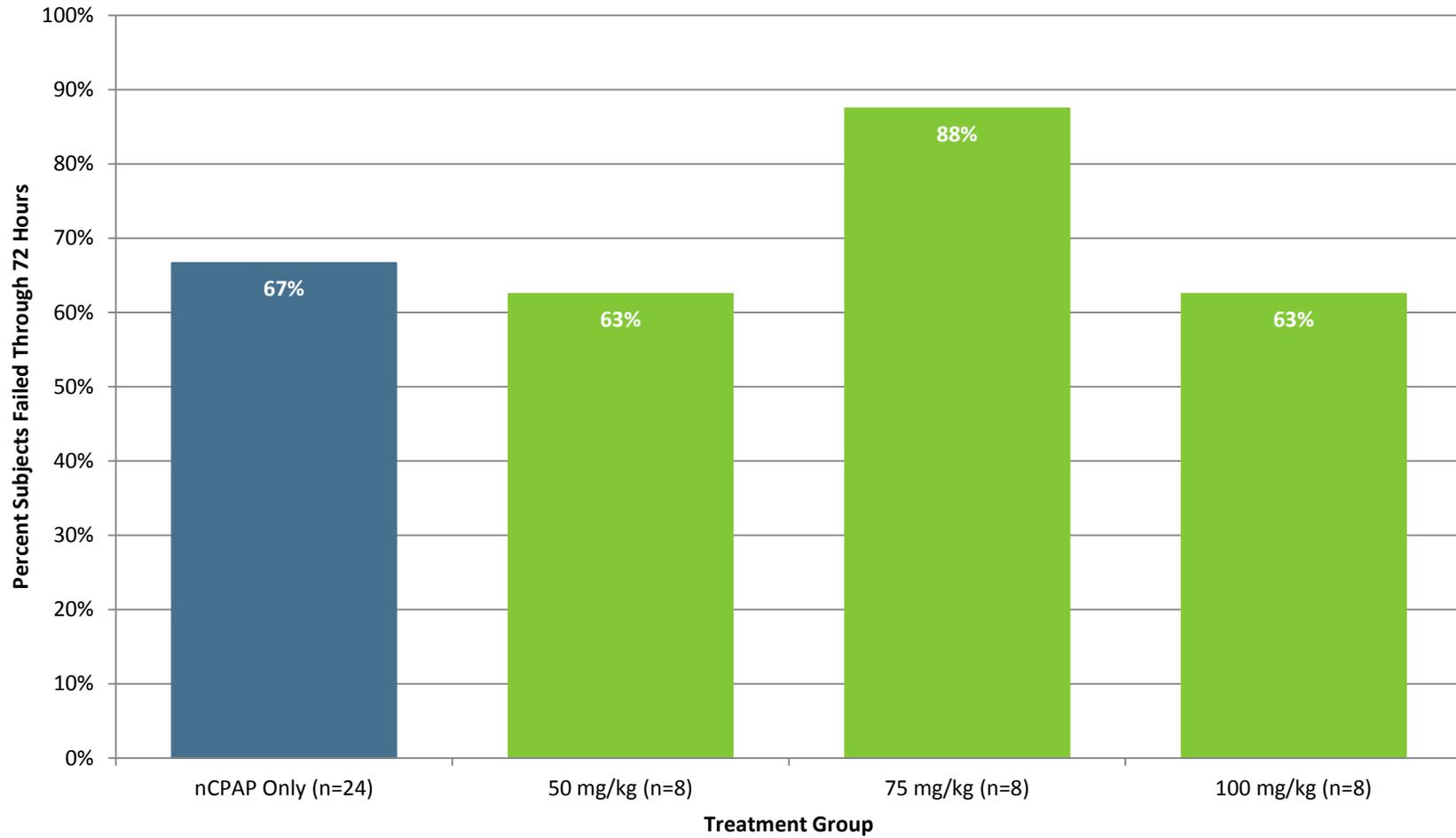
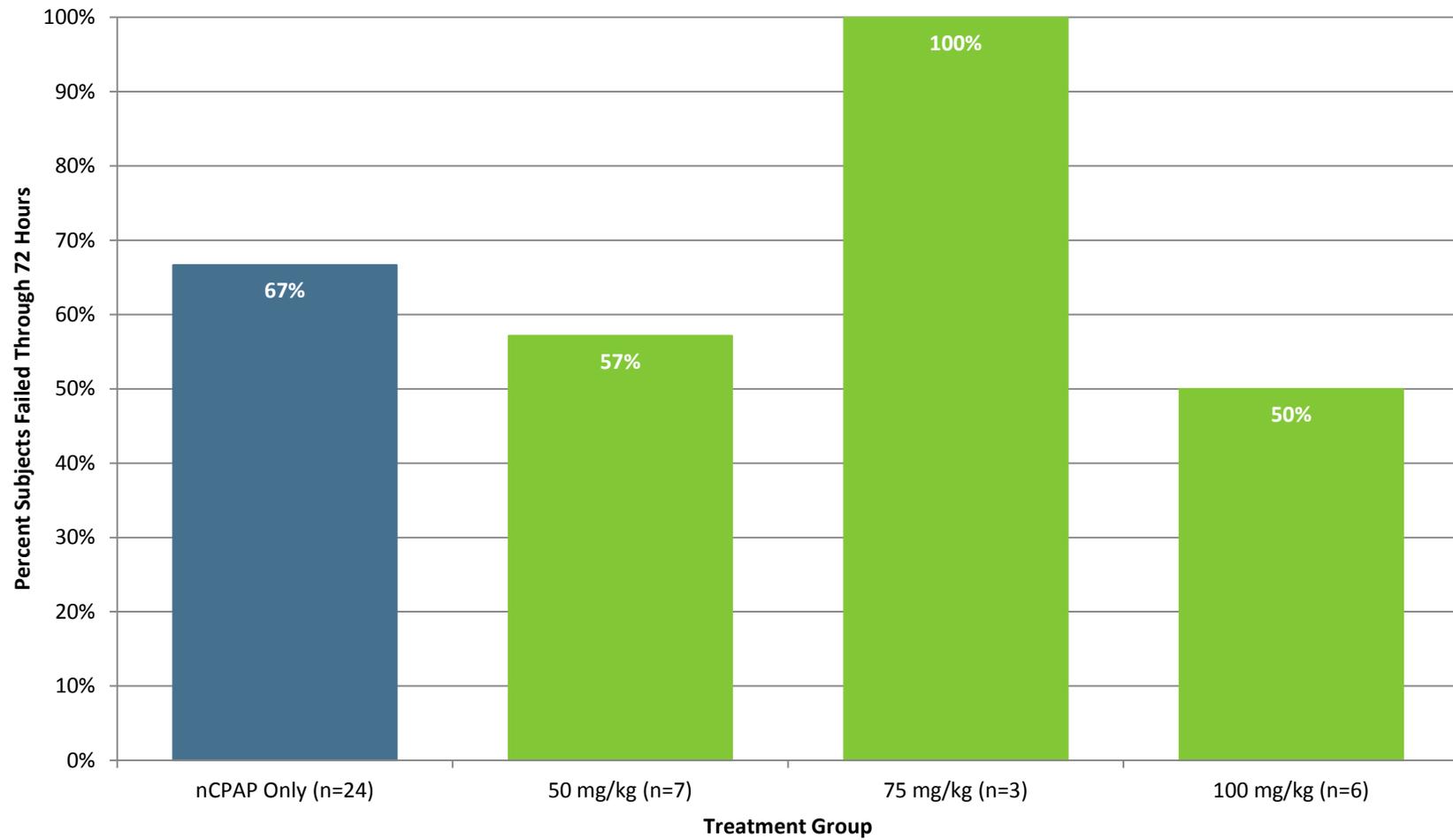
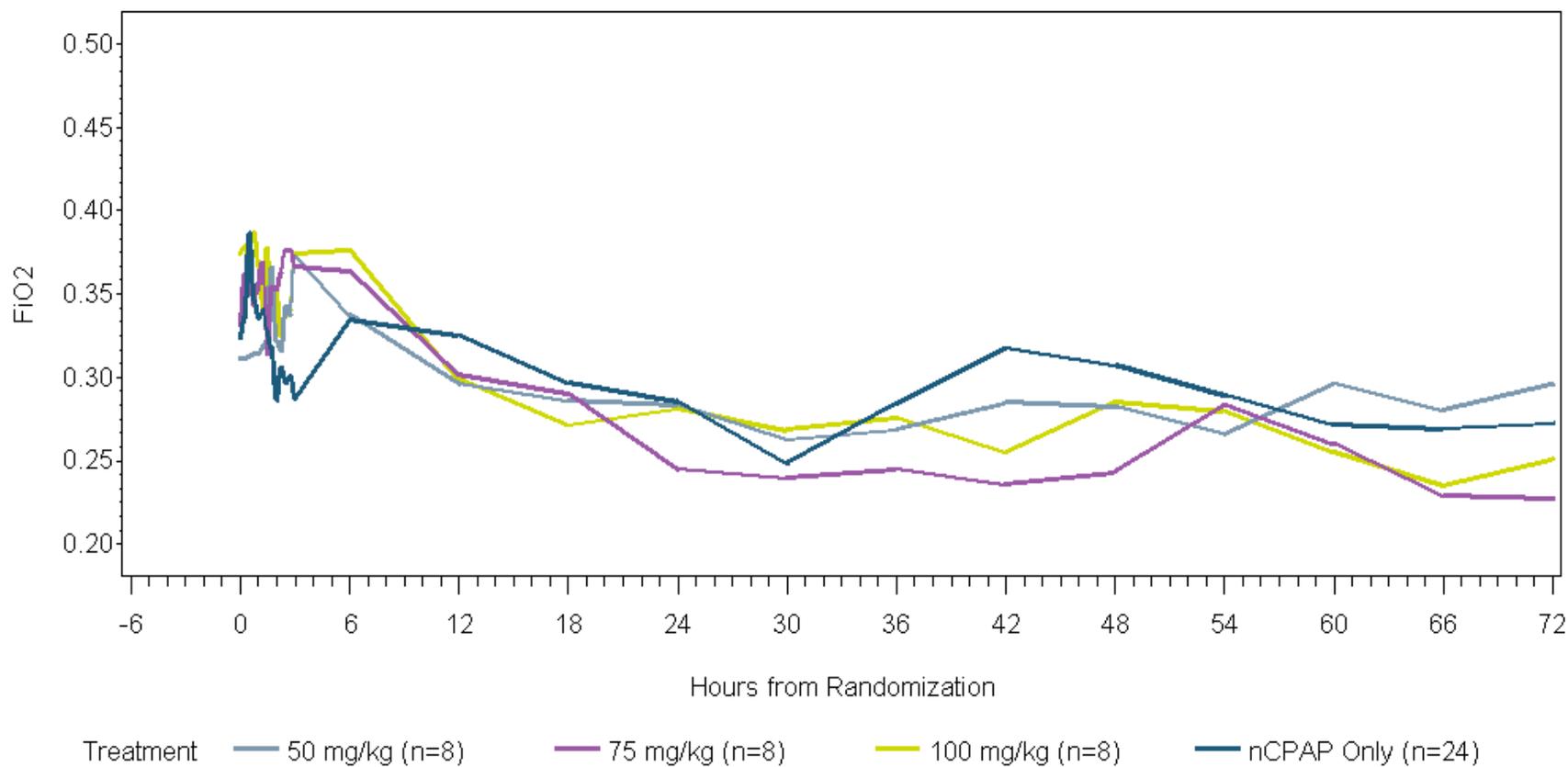


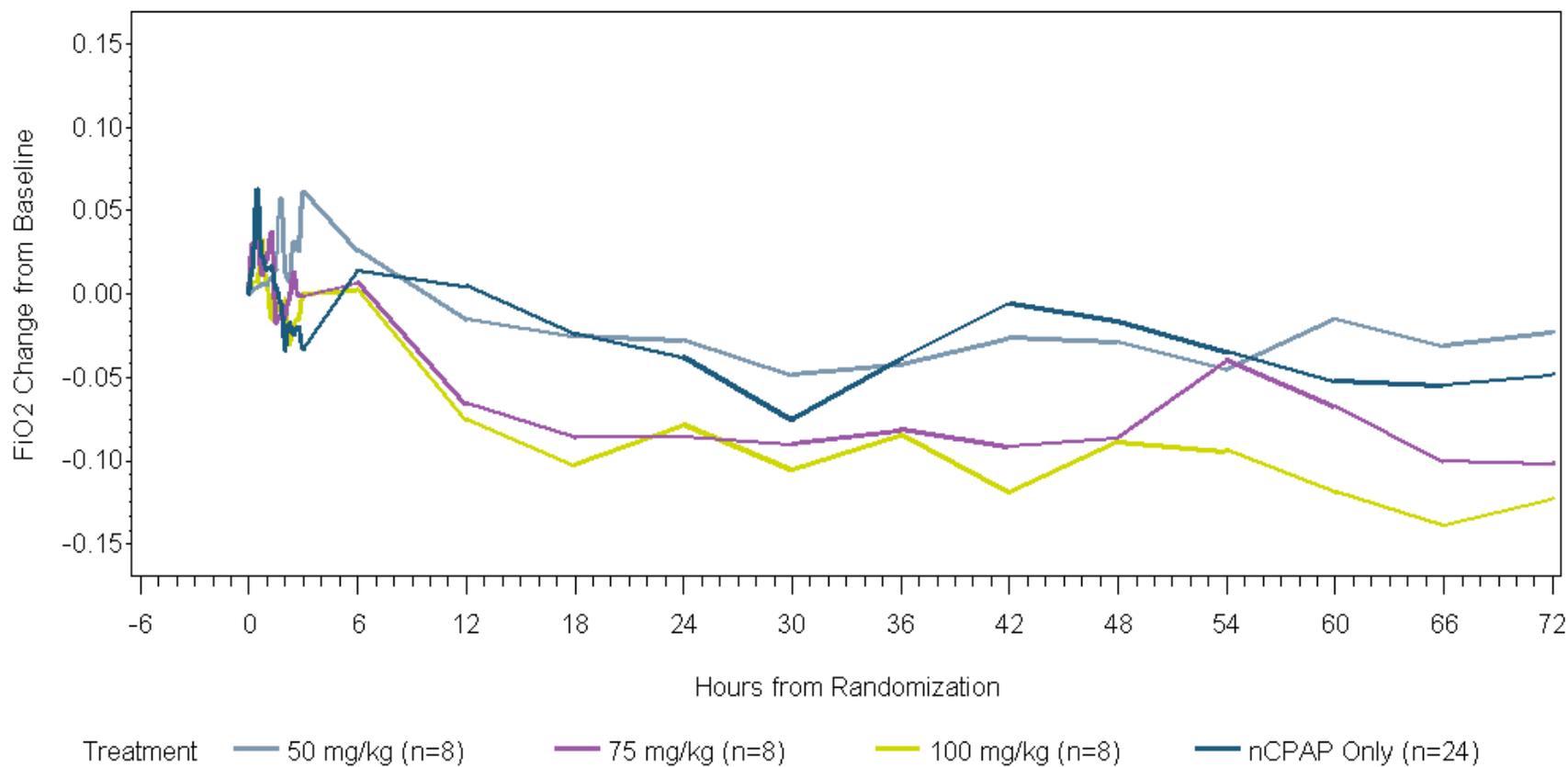
Figure 1.3.2
nCPAP Failures (Intubation) by Treatment Group
Subjects without Dosing Interruptions



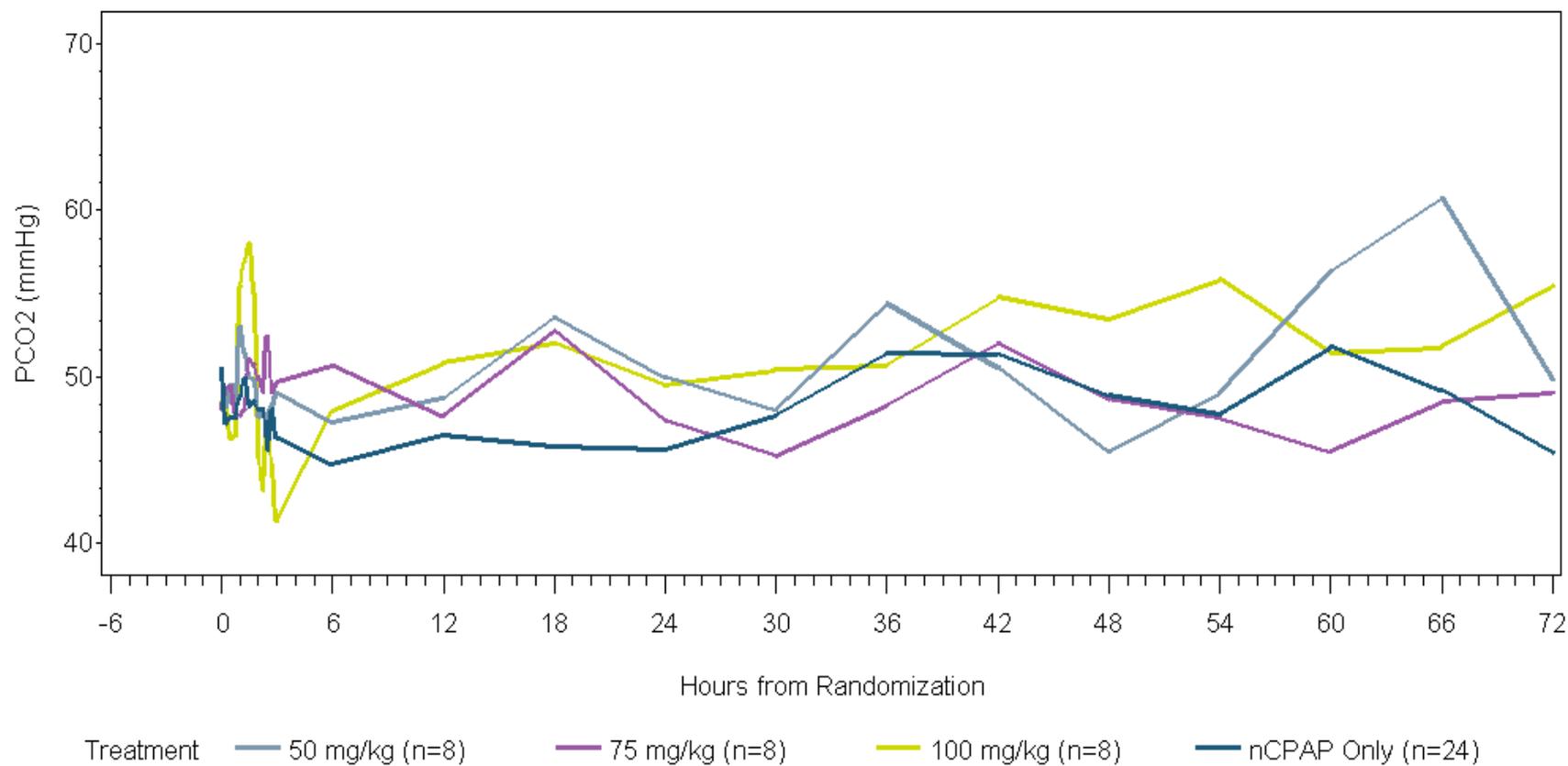
Summary Figure 2.1.1
Oxygenation - FiO2 - Observed Values
Intent-to-Treat Population



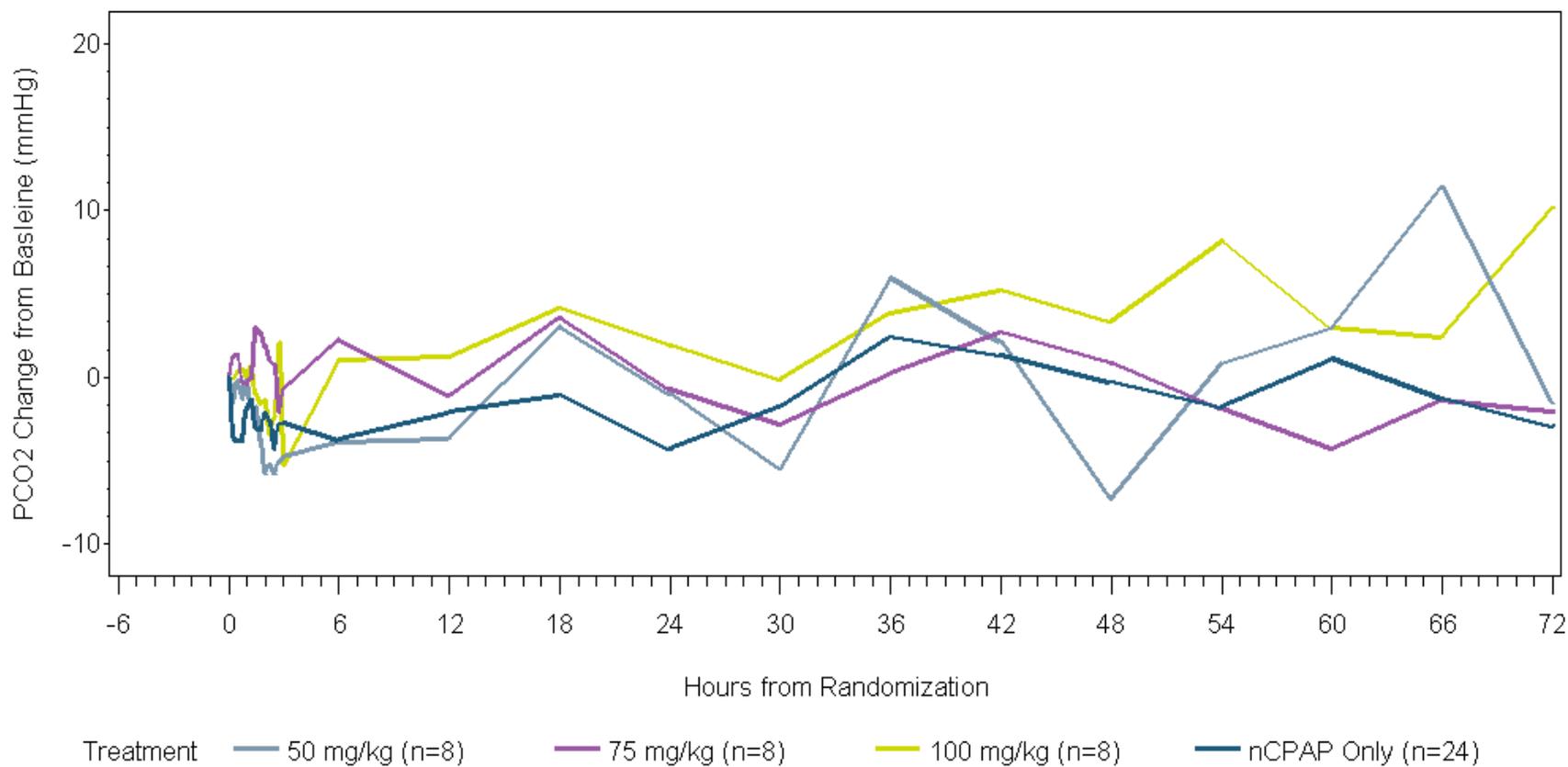
Summary Figure 2.1.2
Oxygenation - FiO2 - Change from Baseline Values
Intent-to-Treat Population



Summary Figure 2.2.1
Oxygenation - tcPCO₂ - Observed Values
Intent-to-Treat Population



Summary Figure 2.2.2
Oxygenation - tcPCO₂ - Change from Baseline
Intent-to-Treat Population



14.3 Safety Data Summary Tables and Summary Listings

14.3.1 Displays of Adverse Events and Clinical Assessments

Summary Tables

Table Number	Table Title
6.1.1	Peri-Dosing Adverse Events – Initial Dose – Safety Population
6.1.2	Peri-Dosing Adverse Events – Repeat Dose – Safety Population
6.2	Air Leak – Safety Population
6.3.1	Treatment-Emergent Adverse Events by System Organ Class and Preferred Term – Safety Population
6.3.2	Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Severity – Safety Population
6.3.3	Treatment-Emergent Adverse Events by System Organ Class, Preferred Term, and Relationship – Safety Population
6.3.4	Treatment-Emergent Adverse Events by Severity and Relationship to Study Drug – Safety Population
6.3.5	Treatment-Emergent Adverse Events by Preferred Term in Descending Order by Total Active Group – Safety Population
6.4.1	Serious Adverse Events by Preferred Term Displayed in Descending Order of Frequency – Safety Population
6.5.1	Adverse Device Effects by System Organ Class and Preferred Term – Safety Population
6.6	All-Cause Mortality – Safety Population
7.1.1	Clinical Assessments – Vital Signs – Body Temperature – Safety Population
7.1.2	Clinical Assessments – Vital Signs – Respiration Rate – Safety Population
7.1.3	Clinical Assessments – Vital Signs – Heart Rate – Safety Population
7.2	Clinical Assessments – Serum Electrolytes – Safety Population
7.3	Clinical Assessments – Gastric Liquid Volume and Defecation – Safety Population
7.4.1	Clinical Assessments – Physical Examination Findings – Safety Population

Summary Tables

Table Number	Table Title
7.4.2	Clinical Assessments – Physical Examination Findings: Shift Table – Safety Population
7.5.1	Clinical Assessments – Respiratory Parameters – FiO ₂ – Safety Population
7.5.2	Clinical Assessments – Respiratory Parameters – PCO ₂ – Safety Population
7.6.1	Clinical Assessments – Respiratory Support – Mechanical Ventilation – Safety Population
7.6.2	Clinical Assessments – Respiratory Parameters – Mechanical Ventilation – Safety Population
7.7.1	Clinical Assessments – Respiratory Support – Supplemental Oxygen – Safety Population
7.7.2	Clinical Assessments – Respiratory Parameters – Supplemental Oxygen – Safety Population
7.8	Clinical Assessments – Respiratory Parameters – nCPAP Settings – Safety Population
7.9	Clinical Assessments – Complications of Prematurity – Safety Population

Summary Listings

Listing Number	Listing Title
2.3	Any Adverse Events
2.4	Adverse Device Effects
5.1	Respiratory Support – Mechanical Ventilation Information by Subject
5.2	Respiratory Support – Supplemental Oxygen Information by Subject
5.3	Respiratory Support – nCPAP Setting Information by Subject

Summary Graphs

Graph Number	Graph Title
3.1.1	Vital Signs – Body Temperature – Observed Values – Intent-to-Treat Population
3.1.2	Vital Signs – Body Temperature – Change from Baseline Values – Intent-to-Treat Population
3.2.1	Vital Signs – Spontaneous Respiratory Rate – Observed Values – Intent-to-Treat Population
3.2.2	Vital Signs – Spontaneous Respiratory Rate – Change from Baseline Values – Intent-to-Treat Population
3.3.1	Vital Signs – Heart Rate – Observed Values – Intent-to-Treat Population
3.3.2	Vital Signs – Heart Rate – Change from Baseline Values – Intent-to-Treat Population

Summary Table 6.1.1
Peri-Dosing Adverse Events - Initial Dose
Safety Population

Peri-Dosing Event	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Total Number of Subjects with peri-dosing event	1 (13%)	3 (38%)	3 (38%)	7 (29%)	0 (0%)
Bradycardia	0 (0%)	2 (25%)	1 (13%)	3 (13%)	0 (0%)
Desaturation	1 (13%)	2 (25%)	3 (38%)	6 (25%)	0 (0%)
Gagging/regurgitation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Apnea	1 (13%)	1 (13%)	1 (13%)	3 (13%)	0 (0%)
Pallor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Complications Related to Placement of Bi-Nasal Prongs	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Bleeding	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Apparent Obstruction of the Nares	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Occlusion Requiring Removal and Replacement	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Nasal Irritation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Summary Table 6.1.2
Peri-Dosing Adverse Events - Repeat Dose
Safety Population

Peri-Dosing Event	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Total Number of Subjects with peri-dosing event	0 (0%)	0 (0%)	2 (25%)	2 (8%)	0 (0%)
Bradycardia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Desaturation	0 (0%)	0 (0%)	2 (25%)	2 (8%)	0 (0%)
Gagging/regurgitation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Apnea (centual, obstructive, or combined)	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Pallor	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Complications Related to Placement of Bi-Nasal Prongs	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Bleeding	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Apparent Obstruction of the Nares	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Occlusion Requiring Removal and Replacement	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Nasal Irritation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Summary Table 6.2
Air Leak
Safety Population

	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Subjects with Air Leak	3 (38%)	0 (0%)	2 (25%)	5 (21%)	4 (17%)
Type of air leak					
Pneumothorax	1 (13%)	0 (0%)	1 (13%)	2 (8%)	3 (13%)
Pulmonary Interstitial Emphysema (PIE)	3 (38%)	0 (0%)	1 (13%)	4 (17%)	3 (13%)

Summary Table 6.3.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population

System Organ Class(SOC) Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Any Event	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
Blood and lymphatic system disorders	6 (75%)	4 (50%)	2 (25%)	12 (50%)	13 (54%)
Anaemia neonatal	6 (75%)	4 (50%)	2 (25%)	12 (50%)	13 (54%)
Bandaemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Coagulopathy	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Leukocytosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Leukopenia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Neutropenia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Thrombocytopenia	2 (25%)	2 (25%)	0 (0%)	4 (17%)	4 (17%)
Thrombocytosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardiac disorders	0 (0%)	1 (13%)	1 (13%)	2 (8%)	3 (13%)
Arrhythmia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardiac arrest	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardio-respiratory arrest	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Tachycardia	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Congenital, familial and genetic disorders	3 (38%)	4 (50%)	4 (50%)	11 (46%)	11 (46%)
Atrial septal defect	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Cardiac septal defect	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hydrocele	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Patent ductus arteriosus	3 (38%)	3 (38%)	4 (50%)	10 (42%)	10 (42%)
Endocrine disorders	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Adrenal insufficiency	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages calculated from column totals.

Summary Table 6.3.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population

System Organ Class(SOC) Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Gastrointestinal disorders	6 (75%)	5 (63%)	1 (13%)	12 (50%)	6 (25%)
Abdominal distension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Abdominal pain	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Constipation	5 (63%)	0 (0%)	1 (13%)	6 (25%)	2 (8%)
Gastric haemorrhage	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Gastric hypomotility	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Gastric perforation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Gastrointestinal hypomotility	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Gastroesophageal reflux disease	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Haematemesis	2 (25%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)
Inguinal hernia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Intestinal perforation	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Pneumoperitoneum	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Salivary hypersecretion	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Umbilical hernia	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Vomiting	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
General disorders and administration site conditions	5 (63%)	0 (0%)	1 (13%)	6 (25%)	5 (21%)
Endotracheal intubation complication	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
Face oedema	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Hypothermia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Oedema	3 (38%)	0 (0%)	0 (0%)	3 (13%)	1 (4%)
Pain	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Pyrexia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages calculated from column totals.

Summary Table 6.3.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population

System Organ Class(SOC) Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Hepatobiliary disorders	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (17%)
Cholestasis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Gallbladder disorder	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Infections and infestations	4 (50%)	4 (50%)	3 (38%)	11 (46%)	9 (38%)
Bacteraemia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Bacterial disease carrier	0 (0%)	0 (0%)	2 (25%)	2 (8%)	0 (0%)
Conjunctivitis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Enterococcal sepsis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Fungal skin infection	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Nosocomial infection	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Pneumonia	0 (0%)	2 (25%)	0 (0%)	2 (8%)	4 (17%)
Pneumonia klebsiella	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pneumonia staphylococcal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Sepsis neonatal	2 (25%)	1 (13%)	1 (13%)	4 (17%)	4 (17%)
Septic shock	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Urinary tract infection	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Urinary tract infection enterococcal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Urosepsis	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Injury, poisoning and procedural complications	2 (25%)	2 (25%)	0 (0%)	4 (17%)	4 (17%)
Blister	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Ear abrasion	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Hepatic haemorrhage	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Infusion site extravasation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Laceration	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)

Note: Percentages calculated from column totals.

Summary Table 6.3.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population

System Organ Class(SOC) Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Laryngeal injury	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Skin abrasion	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Tracheal injury	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Traumatic liver injury	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Investigations	3 (38%)	5 (63%)	7 (88%)	15 (63%)	11 (46%)
Anticonvulsant drug level above therapeut	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Blood urea increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardiac murmur	2 (25%)	1 (13%)	0 (0%)	3 (13%)	1 (4%)
Coagulation time prolonged	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Neutrophil count increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Oxygen saturation decreased	2 (25%)	4 (50%)	6 (75%)	12 (50%)	9 (38%)
PO2 increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Reticulocyte count increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Metabolism and nutrition disorders	7 (88%)	4 (50%)	1 (13%)	12 (50%)	12 (50%)
Dehydration	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Electrolyte imbalance	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Feeding intolerance	3 (38%)	1 (13%)	1 (13%)	5 (21%)	1 (4%)
Fluid retention	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hypercalcaemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Hyperchloraemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	3 (13%)
Hyperglycaemia	1 (13%)	2 (25%)	0 (0%)	3 (13%)	3 (13%)
Hyperkalaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Hypermagnesaemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Hypernatraemia	1 (13%)	2 (25%)	0 (0%)	3 (13%)	4 (17%)

Note: Percentages calculated from column totals.

Summary Table 6.3.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population

System Organ Class(SOC) Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Hypertriglyceridaemia	1 (13%)	1 (13%)	0 (0%)	2 (8%)	2 (8%)
Hypoalbuminaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Hypocalcaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Hypochloraemia	2 (25%)	1 (13%)	0 (0%)	3 (13%)	3 (13%)
Hypoglycaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Hypokalaemia	0 (0%)	2 (25%)	0 (0%)	2 (8%)	3 (13%)
Hypomagnesaemia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Hyponatraemia	3 (38%)	0 (0%)	0 (0%)	3 (13%)	7 (29%)
Hypophosphataemia	2 (25%)	0 (0%)	0 (0%)	2 (8%)	1 (4%)
Hypovolaemia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Metabolic acidosis	3 (38%)	0 (0%)	0 (0%)	3 (13%)	5 (21%)
Metabolic alkalosis	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Osteopenia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Vitamin D deficiency	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Nervous system disorders	1 (13%)	0 (0%)	0 (0%)	1 (4%)	2 (8%)
Hypotonia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Lethargy	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Periventricular leukomalacia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Seizure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pregnancy, puerperium and perinatal conditions	6 (75%)	8 (100%)	7 (88%)	21 (88%)	22 (92%)
Agitation neonatal	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Bradycardia neonatal	0 (0%)	5 (63%)	3 (38%)	8 (33%)	9 (38%)
Fixed bowel loop	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Intraventricular haemorrhage neonatal	0 (0%)	1 (13%)	3 (38%)	4 (17%)	3 (13%)

Note: Percentages calculated from column totals.

Summary Table 6.3.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population

System Organ Class(SOC) Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Jaundice neonatal	5 (63%)	3 (38%)	1 (13%)	9 (38%)	11 (46%)
Necrotising enterocolitis neonatal	1 (13%)	1 (13%)	1 (13%)	3 (13%)	1 (4%)
Neonatal respiratory distress syndrome	1 (13%)	4 (50%)	2 (25%)	7 (29%)	10 (42%)
Neonatal respiratory failure	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Periventricular haemorrhage neonatal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Retinopathy of prematurity	2 (25%)	1 (13%)	1 (13%)	4 (17%)	9 (38%)
Small for dates baby	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Renal and urinary disorders	0 (0%)	1 (13%)	0 (0%)	1 (4%)	3 (13%)
Azotaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Haematuria	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Oliguria	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
Renal failure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Respiratory, thoracic and mediastinal disorders	8 (100%)	5 (63%)	7 (88%)	20 (83%)	23 (96%)
Apnoea neonatal	7 (88%)	4 (50%)	6 (75%)	17 (71%)	19 (79%)
Bronchopulmonary dysplasia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	7 (29%)
Chronic respiratory failure	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Hypercapnia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
Nasal discomfort	2 (25%)	2 (25%)	0 (0%)	4 (17%)	3 (13%)
Neonatal respiratory failure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Neonatal tachypnoea	1 (13%)	0 (0%)	1 (13%)	2 (8%)	2 (8%)
Pneumothorax	1 (13%)	0 (0%)	1 (13%)	2 (8%)	3 (13%)
Pulmonary haemorrhage	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
Pulmonary hypertension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pulmonary interstitial emphysema syndrome	3 (38%)	0 (0%)	1 (13%)	4 (17%)	3 (13%)

Note: Percentages calculated from column totals.

Summary Table 6.3.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population

System Organ Class(SOC) Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Pulmonary oedema neonatal	1 (13%)	1 (13%)	0 (0%)	2 (8%)	2 (8%)
Respiratory acidosis	2 (25%)	0 (0%)	0 (0%)	2 (8%)	1 (4%)
Respiratory alkalosis	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Respiratory tract haemorrhage	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Skin and subcutaneous tissue disorders	4 (50%)	2 (25%)	1 (13%)	7 (29%)	3 (13%)
Dermatitis diaper	4 (50%)	2 (25%)	1 (13%)	7 (29%)	1 (4%)
Rash	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Vascular disorders	1 (13%)	3 (38%)	0 (0%)	4 (17%)	6 (25%)
Haemangioma	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Hypertension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hypotension	1 (13%)	2 (25%)	0 (0%)	3 (13%)	4 (17%)
Shock	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages calculated from column totals.

Summary Table 6.3.1.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population - Without Treatment Interruptions

System Organ Class(SOC) Preferred Term	50 mg/kg (N=7)	75 mg/kg (N=3)	100 mg/kg (N=6)	Total Active (N=16)	nCPAP Only (N=24)
Any Event	7 (100%)	3 (100%)	6 (100%)	16 (100%)	24 (100%)
Blood and lymphatic system disorders	5 (71%)	2 (67%)	1 (17%)	8 (50%)	13 (54%)
Anaemia neonatal	5 (71%)	2 (67%)	1 (17%)	8 (50%)	13 (54%)
Bandaemia	1 (14%)	0 (0%)	0 (0%)	1 (6%)	1 (4%)
Coagulopathy	1 (14%)	0 (0%)	0 (0%)	1 (6%)	1 (4%)
Leukocytosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Leukopenia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Neutropenia	1 (14%)	0 (0%)	0 (0%)	1 (6%)	1 (4%)
Thrombocytopenia	1 (14%)	2 (67%)	0 (0%)	3 (19%)	4 (17%)
Thrombocytosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardiac disorders	0 (0%)	0 (0%)	1 (17%)	1 (6%)	3 (13%)
Arrhythmia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardiac arrest	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardio-respiratory arrest	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Tachycardia	0 (0%)	0 (0%)	1 (17%)	1 (6%)	0 (0%)
Congenital, familial and genetic disorders	2 (29%)	2 (67%)	3 (50%)	7 (44%)	11 (46%)
Atrial septal defect	0 (0%)	1 (33%)	1 (17%)	2 (13%)	0 (0%)
Cardiac septal defect	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hydrocele	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Patent ductus arteriosus	2 (29%)	1 (33%)	3 (50%)	6 (38%)	10 (42%)
Endocrine disorders	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Adrenal insufficiency	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages calculated from column totals.

Summary Table 6.3.1.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population - Without Treatment Interruptions

System Organ Class(SOC) Preferred Term	50 mg/kg (N=7)	75 mg/kg (N=3)	100 mg/kg (N=6)	Total Active (N=16)	nCPAP Only (N=24)
Gastrointestinal disorders	5 (71%)	3 (100%)	1 (17%)	9 (56%)	6 (25%)
Abdominal distension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Abdominal pain	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Constipation	4 (57%)	0 (0%)	1 (17%)	5 (31%)	2 (8%)
Gastric hypomotility	1 (14%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)
Gastric perforation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Gastroesophageal reflux disease	0 (0%)	1 (33%)	0 (0%)	1 (6%)	0 (0%)
Haematemesis	2 (29%)	0 (0%)	0 (0%)	2 (13%)	0 (0%)
Inguinal hernia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Intestinal perforation	1 (14%)	0 (0%)	0 (0%)	1 (6%)	1 (4%)
Pneumoperitoneum	0 (0%)	1 (33%)	0 (0%)	1 (6%)	0 (0%)
Umbilical hernia	0 (0%)	1 (33%)	1 (17%)	2 (13%)	0 (0%)
Vomiting	1 (14%)	0 (0%)	0 (0%)	1 (6%)	1 (4%)
General disorders and administration site conditions	4 (57%)	0 (0%)	0 (0%)	4 (25%)	4 (17%)
Endotracheal intubation complication	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Face oedema	1 (14%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)
Hypothermia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Oedema	2 (29%)	0 (0%)	0 (0%)	2 (13%)	1 (4%)
Pain	1 (14%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)
Pyrexia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hepatobiliary disorders	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (17%)
Cholestasis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Gallbladder disorder	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages calculated from column totals.

Summary Table 6.3.1.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population - Without Treatment Interruptions

System Organ Class(SOC) Preferred Term	50 mg/kg (N=7)	75 mg/kg (N=3)	100 mg/kg (N=6)	Total Active (N=16)	nCPAP Only (N=24)
Infections and infestations	3 (43%)	1 (33%)	2 (33%)	6 (38%)	9 (38%)
Bacteraemia	0 (0%)	1 (33%)	0 (0%)	1 (6%)	1 (4%)
Bacterial disease carrier	0 (0%)	0 (0%)	2 (33%)	2 (13%)	0 (0%)
Conjunctivitis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Enterococcal sepsis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Fungal skin infection	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Nosocomial infection	0 (0%)	1 (33%)	0 (0%)	1 (6%)	0 (0%)
Pneumonia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (17%)
Pneumonia klebsiella	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pneumonia staphylococcal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Sepsis neonatal	1 (14%)	0 (0%)	1 (17%)	2 (13%)	4 (17%)
Septic shock	1 (14%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)
Urinary tract infection	1 (14%)	0 (0%)	0 (0%)	1 (6%)	1 (4%)
Urinary tract infection enterococcal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Injury, poisoning and procedural complications	2 (29%)	0 (0%)	0 (0%)	2 (13%)	4 (17%)
Blister	1 (14%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)
Hepatic haemorrhage	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Infusion site extravasation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Laceration	1 (14%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)
Laryngeal injury	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Skin abrasion	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Traumatic liver injury	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Investigations	2 (29%)	3 (100%)	5 (83%)	10 (63%)	11 (46%)

Note: Percentages calculated from column totals.

Summary Table 6.3.1.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population - Without Treatment Interruptions

System Organ Class(SOC) Preferred Term	50 mg/kg (N=7)	75 mg/kg (N=3)	100 mg/kg (N=6)	Total Active (N=16)	nCPAP Only (N=24)
Anticonvulsant drug level above therapeut	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Blood urea increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardiac murmur	1 (14%)	1 (33%)	0 (0%)	2 (13%)	1 (4%)
Neutrophil count increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Oxygen saturation decreased	2 (29%)	2 (67%)	5 (83%)	9 (56%)	9 (38%)
PO2 increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Reticulocyte count increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Metabolism and nutrition disorders	6 (86%)	3 (100%)	1 (17%)	10 (63%)	12 (50%)
Dehydration	1 (14%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)
Electrolyte imbalance	1 (14%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)
Feeding intolerance	2 (29%)	0 (0%)	1 (17%)	3 (19%)	1 (4%)
Fluid retention	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hypercalcaemia	1 (14%)	0 (0%)	0 (0%)	1 (6%)	1 (4%)
Hyperchloraemia	1 (14%)	0 (0%)	0 (0%)	1 (6%)	3 (13%)
Hyperglycaemia	1 (14%)	1 (33%)	0 (0%)	2 (13%)	3 (13%)
Hyperkalaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Hypermagnesaemia	1 (14%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)
Hypernatraemia	1 (14%)	1 (33%)	0 (0%)	2 (13%)	4 (17%)
Hypertriglyceridaemia	1 (14%)	0 (0%)	0 (0%)	1 (6%)	2 (8%)
Hypoalbuminaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Hypocalcaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Hypochloraemia	2 (29%)	0 (0%)	0 (0%)	2 (13%)	3 (13%)
Hypoglycaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Hypokalaemia	0 (0%)	2 (67%)	0 (0%)	2 (13%)	3 (13%)
Hypomagnesaemia	0 (0%)	1 (33%)	0 (0%)	1 (6%)	1 (4%)

Note: Percentages calculated from column totals.

Summary Table 6.3.1.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population - Without Treatment Interruptions

System Organ Class(SOC) Preferred Term	50 mg/kg (N=7)	75 mg/kg (N=3)	100 mg/kg (N=6)	Total Active (N=16)	nCPAP Only (N=24)
Hyponatraemia	3 (43%)	0 (0%)	0 (0%)	3 (19%)	7 (29%)
Hypophosphataemia	2 (29%)	0 (0%)	0 (0%)	2 (13%)	1 (4%)
Hypovolaemia	0 (0%)	1 (33%)	0 (0%)	1 (6%)	0 (0%)
Metabolic acidosis	2 (29%)	0 (0%)	0 (0%)	2 (13%)	5 (21%)
Osteopenia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Vitamin D deficiency	0 (0%)	1 (33%)	0 (0%)	1 (6%)	0 (0%)
Nervous system disorders	1 (14%)	0 (0%)	0 (0%)	1 (6%)	2 (8%)
Hypotonia	1 (14%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)
Lethargy	1 (14%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)
Periventricular leukomalacia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Seizure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pregnancy, puerperium and perinatal conditions	5 (71%)	3 (100%)	5 (83%)	13 (81%)	22 (92%)
Agitation neonatal	0 (0%)	0 (0%)	1 (17%)	1 (6%)	0 (0%)
Bradycardia neonatal	0 (0%)	1 (33%)	3 (50%)	4 (25%)	9 (38%)
Fixed bowel loop	1 (14%)	0 (0%)	0 (0%)	1 (6%)	0 (0%)
Intraventricular haemorrhage neonatal	0 (0%)	1 (33%)	2 (33%)	3 (19%)	3 (13%)
Jaundice neonatal	4 (57%)	2 (67%)	1 (17%)	7 (44%)	11 (46%)
Necrotising enterocolitis neonatal	1 (14%)	0 (0%)	1 (17%)	2 (13%)	1 (4%)
Neonatal respiratory distress syndrome	1 (14%)	1 (33%)	1 (17%)	3 (19%)	10 (42%)
Neonatal respiratory failure	0 (0%)	1 (33%)	0 (0%)	1 (6%)	0 (0%)
Periventricular haemorrhage neonatal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Retinopathy of prematurity	1 (14%)	1 (33%)	0 (0%)	2 (13%)	9 (38%)
Small for dates baby	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages calculated from column totals.

Summary Table 6.3.1.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population - Without Treatment Interruptions

System Organ Class(SOC) Preferred Term	50 mg/kg (N=7)	75 mg/kg (N=3)	100 mg/kg (N=6)	Total Active (N=16)	nCPAP Only (N=24)
Renal and urinary disorders	0 (0%)	1 (33%)	0 (0%)	1 (6%)	3 (13%)
Azotaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Haematuria	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Oliguria	0 (0%)	1 (33%)	0 (0%)	1 (6%)	2 (8%)
Renal failure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Respiratory, thoracic and mediastinal disorders	7 (100%)	2 (67%)	5 (83%)	14 (88%)	23 (96%)
Apnoea neonatal	6 (86%)	1 (33%)	5 (83%)	12 (75%)	19 (79%)
Bronchopulmonary dysplasia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	7 (29%)
Hypercapnia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Nasal discomfort	0 (0%)	1 (33%)	0 (0%)	1 (6%)	1 (4%)
Nasal inflammation	2 (29%)	0 (0%)	0 (0%)	2 (13%)	2 (8%)
Neonatal respiratory failure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Neonatal tachypnoea	1 (14%)	0 (0%)	1 (17%)	2 (13%)	2 (8%)
Pneumothorax	1 (14%)	0 (0%)	1 (17%)	2 (13%)	3 (13%)
Pulmonary haemorrhage	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pulmonary hypertension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pulmonary interstitial emphysema syndrome	2 (29%)	0 (0%)	1 (17%)	3 (19%)	3 (13%)
Pulmonary oedema neonatal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Respiratory acidosis	2 (29%)	0 (0%)	0 (0%)	2 (13%)	1 (4%)
Respiratory alkalosis	1 (14%)	0 (0%)	0 (0%)	1 (6%)	1 (4%)
Skin and subcutaneous tissue disorders	3 (43%)	1 (33%)	1 (17%)	5 (31%)	3 (13%)
Dermatitis diaper	3 (43%)	1 (33%)	1 (17%)	5 (31%)	1 (4%)
Rash	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)

Note: Percentages calculated from column totals.

Summary Table 6.3.1.1
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population - Without Treatment Interruptions

System Organ Class(SOC) Preferred Term	50 mg/kg (N=7)	75 mg/kg (N=3)	100 mg/kg (N=6)	Total Active (N=16)	nCPAP Only (N=24)
Vascular disorders	1 (14%)	2 (67%)	0 (0%)	3 (19%)	6 (25%)
Haemangioma	0 (0%)	1 (33%)	0 (0%)	1 (6%)	1 (4%)
Hypertension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hypotension	1 (14%)	1 (33%)	0 (0%)	2 (13%)	4 (17%)
Shock	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Any Event	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
Mild	1 (13%)	2 (25%)	3 (38%)	6 (25%)	7 (29%)
Moderate	4 (50%)	5 (63%)	3 (38%)	12 (50%)	10 (42%)
Severe	3 (38%)	1 (13%)	2 (25%)	6 (25%)	7 (29%)
Blood and lymphatic system disorders	7 (88%)	4 (50%)	2 (25%)	13 (54%)	16 (67%)
Mild	6 (75%)	4 (50%)	2 (25%)	12 (50%)	11 (46%)
Moderate	1 (13%)	0 (0%)	0 (0%)	1 (4%)	5 (21%)
Anaemia neonatal	6 (75%)	4 (50%)	2 (25%)	12 (50%)	13 (54%)
Mild	6 (75%)	4 (50%)	2 (25%)	12 (50%)	9 (38%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (17%)
Bandaemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Coagulopathy	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Leukocytosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Leukopenia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Neutropenia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Thrombocytopenia	2 (25%)	2 (25%)	0 (0%)	4 (17%)	4 (17%)
Mild	1 (13%)	2 (25%)	0 (0%)	3 (13%)	2 (8%)
Moderate	1 (13%)	0 (0%)	0 (0%)	1 (4%)	2 (8%)
Thrombocytosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardiac disorders	0 (0%)	1 (13%)	1 (13%)	2 (8%)	3 (13%)
Mild	0 (0%)	1 (13%)	1 (13%)	2 (8%)	1 (4%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Arrhythmia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardiac arrest	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardio-respiratory arrest	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Tachycardia	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Mild	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Congenital, familial and genetic disorders	3 (38%)	4 (50%)	4 (50%)	11 (46%)	12 (50%)
Mild	3 (38%)	3 (38%)	3 (38%)	9 (38%)	6 (25%)
Moderate	0 (0%)	1 (13%)	1 (13%)	2 (8%)	6 (25%)
Atrial septal defect	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Mild	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Cardiac septal defect	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hydrocele	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Patent ductus arteriosus	3 (38%)	3 (38%)	4 (50%)	10 (42%)	10 (42%)
Mild	3 (38%)	2 (25%)	3 (38%)	8 (33%)	4 (17%)
Moderate	0 (0%)	1 (13%)	1 (13%)	2 (8%)	6 (25%)
Endocrine disorders	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Adrenal insufficiency	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Gastrointestinal disorders	9 (113%)	5 (63%)	1 (13%)	15 (63%)	6 (25%)
Mild	6 (75%)	4 (50%)	1 (13%)	11 (46%)	4 (17%)
Moderate	2 (25%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)
Severe	1 (13%)	1 (13%)	0 (0%)	2 (8%)	2 (8%)
Abdominal distension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Abdominal pain	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Constipation	5 (63%)	0 (0%)	1 (13%)	6 (25%)	2 (8%)
Mild	5 (63%)	0 (0%)	1 (13%)	6 (25%)	2 (8%)
Gastric haemorrhage	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Gastric hypomotility	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Moderate	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Gastric perforation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Gastrointestinal hypomotility	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Moderate	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Gastroesophageal reflux disease	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Haematemesis	2 (25%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)
Mild	2 (25%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)
Inguinal hernia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Intestinal perforation	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Severe	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Pneumoperitoneum	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Severe	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Salivary hypersecretion	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Umbilical hernia	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Mild	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Vomiting	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
General disorders and administration site conditions	5 (63%)	0 (0%)	1 (13%)	6 (25%)	4 (17%)
Mild	5 (63%)	0 (0%)	1 (13%)	6 (25%)	4 (17%)
Endotracheal intubation complication	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
Mild	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
Face oedema	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Hypothermia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Oedema	3 (38%)	0 (0%)	0 (0%)	3 (13%)	1 (4%)
Mild	3 (38%)	0 (0%)	0 (0%)	3 (13%)	1 (4%)
Pain	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Pyrexia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hepatobiliary disorders	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (17%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cholestasis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Gallbladder disorder	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Infections and infestations	4 (50%)	5 (63%)	4 (50%)	13 (54%)	11 (46%)
Mild	1 (13%)	1 (13%)	3 (38%)	5 (21%)	4 (17%)
Moderate	2 (25%)	4 (50%)	1 (13%)	7 (29%)	7 (29%)
Severe	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Bacteraemia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Moderate	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Bacterial disease carrier	0 (0%)	0 (0%)	2 (25%)	2 (8%)	0 (0%)
Mild	0 (0%)	0 (0%)	2 (25%)	2 (8%)	0 (0%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Conjunctivitis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Enterococcal sepsis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Fungal skin infection	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Nosocomial infection	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Pneumonia	0 (0%)	2 (25%)	0 (0%)	2 (8%)	4 (17%)
Moderate	0 (0%)	2 (25%)	0 (0%)	2 (8%)	4 (17%)
Pneumonia klebsiella	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pneumonia staphylococcal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Sepsis neonatal	2 (25%)	1 (13%)	1 (13%)	4 (17%)	4 (17%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	2 (8%)
Moderate	0 (0%)	1 (13%)	1 (13%)	2 (8%)	2 (8%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Severe	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Septic shock	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Moderate	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Urinary tract infection	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Moderate	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Urinary tract infection enterococcal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Urosepsis	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Mild	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Injury, poisoning and procedural complications	2 (25%)	2 (25%)	0 (0%)	4 (17%)	4 (17%)
Mild	2 (25%)	2 (25%)	0 (0%)	4 (17%)	2 (8%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Blister	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Ear abrasion	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Hepatic haemorrhage	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Infusion site extravasation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Laceration	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Laryngeal injury	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Skin abrasion	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Tracheal injury	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Traumatic liver injury	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Investigations	3 (38%)	5 (63%)	7 (88%)	15 (63%)	11 (46%)
Mild	3 (38%)	5 (63%)	7 (88%)	15 (63%)	10 (42%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Anticonvulsant drug level above therapeut	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Blood urea increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardiac murmur	2 (25%)	1 (13%)	0 (0%)	3 (13%)	1 (4%)
Mild	2 (25%)	1 (13%)	0 (0%)	3 (13%)	1 (4%)
Coagulation time prolonged	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Mild	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Neutrophil count increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Oxygen saturation decreased	2 (25%)	4 (50%)	6 (75%)	12 (50%)	9 (38%)
Mild	2 (25%)	4 (50%)	6 (75%)	12 (50%)	9 (38%)
PO2 increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Reticulocyte count increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Metabolism and nutrition disorders	9 (113%)	6 (75%)	1 (13%)	16 (67%)	13 (54%)
Mild	7 (88%)	4 (50%)	1 (13%)	12 (50%)	11 (46%)
Moderate	2 (25%)	2 (25%)	0 (0%)	4 (17%)	2 (8%)
Dehydration	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Electrolyte imbalance	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Feeding intolerance	3 (38%)	1 (13%)	1 (13%)	5 (21%)	1 (4%)
Mild	1 (13%)	1 (13%)	1 (13%)	3 (13%)	1 (4%)
Moderate	2 (25%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)
Fluid retention	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hypercalcaemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Hyperchloraemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	3 (13%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	3 (13%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Hyperglycaemia	1 (13%)	2 (25%)	0 (0%)	3 (13%)	3 (13%)
Mild	1 (13%)	2 (25%)	0 (0%)	3 (13%)	2 (8%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hyperkalaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Hypermagnesaemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Hypernatraemia	1 (13%)	2 (25%)	0 (0%)	3 (13%)	4 (17%)
Mild	1 (13%)	2 (25%)	0 (0%)	3 (13%)	4 (17%)
Hypertriglyceridaemia	1 (13%)	1 (13%)	0 (0%)	2 (8%)	2 (8%)
Mild	1 (13%)	1 (13%)	0 (0%)	2 (8%)	2 (8%)
Hypoalbuminaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Hypocalcaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Hypochloraemia	2 (25%)	1 (13%)	0 (0%)	3 (13%)	3 (13%)
Mild	2 (25%)	1 (13%)	0 (0%)	3 (13%)	3 (13%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Hypoglycaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Hypokalaemia	0 (0%)	2 (25%)	0 (0%)	2 (8%)	3 (13%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	3 (13%)
Moderate	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Hypomagnesaemia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Hyponatraemia	3 (38%)	0 (0%)	0 (0%)	3 (13%)	7 (29%)
Mild	3 (38%)	0 (0%)	0 (0%)	3 (13%)	6 (25%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hypophosphataemia	2 (25%)	0 (0%)	0 (0%)	2 (8%)	1 (4%)
Mild	2 (25%)	0 (0%)	0 (0%)	2 (8%)	1 (4%)
Hypovolaemia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Moderate	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Metabolic acidosis	3 (38%)	0 (0%)	0 (0%)	3 (13%)	5 (21%)
Mild	3 (38%)	0 (0%)	0 (0%)	3 (13%)	3 (13%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Metabolic alkalosis	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Osteopenia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Vitamin D deficiency	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Nervous system disorders	1 (13%)	0 (0%)	0 (0%)	1 (4%)	3 (13%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hypotonia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Lethargy	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Periventricular leukomalacia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Seizure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pregnancy, puerperium and perinatal conditions	8 (100%)	9 (113%)	10 (125%)	27 (113%)	33 (138%)
Mild	6 (75%)	7 (88%)	7 (88%)	20 (83%)	20 (83%)
Moderate	1 (13%)	2 (25%)	1 (13%)	4 (17%)	8 (33%)
Severe	1 (13%)	0 (0%)	2 (25%)	3 (13%)	5 (21%)
Agitation neonatal	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Mild	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Bradycardia neonatal	0 (0%)	5 (63%)	3 (38%)	8 (33%)	9 (38%)
Mild	0 (0%)	5 (63%)	3 (38%)	8 (33%)	7 (29%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Fixed bowel loop	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Intraventricular haemorrhage neonatal	0 (0%)	1 (13%)	3 (38%)	4 (17%)	3 (13%)
Mild	0 (0%)	1 (13%)	1 (13%)	2 (8%)	2 (8%)
Severe	0 (0%)	0 (0%)	2 (25%)	2 (8%)	1 (4%)
Jaundice neonatal	5 (63%)	3 (38%)	1 (13%)	9 (38%)	11 (46%)
Mild	5 (63%)	3 (38%)	1 (13%)	9 (38%)	9 (38%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Necrotising enterocolitis neonatal	1 (13%)	1 (13%)	1 (13%)	3 (13%)	1 (4%)
Mild	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Severe	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Neonatal respiratory distress syndrome	1 (13%)	4 (50%)	2 (25%)	7 (29%)	10 (42%)
Mild	0 (0%)	2 (25%)	1 (13%)	3 (13%)	4 (17%)
Moderate	1 (13%)	2 (25%)	1 (13%)	4 (17%)	3 (13%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Neonatal respiratory failure	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Moderate	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Periventricular haemorrhage neonatal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Retinopathy of prematurity	2 (25%)	1 (13%)	1 (13%)	4 (17%)	9 (38%)
Mild	2 (25%)	1 (13%)	1 (13%)	4 (17%)	7 (29%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Small for dates baby	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Renal and urinary disorders	0 (0%)	1 (13%)	0 (0%)	1 (4%)	5 (21%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	3 (13%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Azotaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Haematuria	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Oliguria	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
Renal failure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Respiratory, thoracic and mediastinal disorders	10 (125%)	6 (75%)	10 (125%)	26 (108%)	33 (138%)
Mild	8 (100%)	5 (63%)	6 (75%)	19 (79%)	20 (83%)
Moderate	2 (25%)	1 (13%)	3 (38%)	6 (25%)	9 (38%)
Severe	0 (0%)	0 (0%)	1 (13%)	1 (4%)	4 (17%)
Apnoea neonatal	7 (88%)	4 (50%)	6 (75%)	17 (71%)	19 (79%)
Mild	7 (88%)	4 (50%)	4 (50%)	15 (63%)	16 (67%)
Moderate	0 (0%)	0 (0%)	2 (25%)	2 (8%)	3 (13%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Bronchopulmonary dysplasia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	7 (29%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Chronic respiratory failure	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Moderate	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Hypercapnia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Moderate	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Nasal discomfort	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Nasal inflammation	2 (25%)	0 (0%)	0 (0%)	2 (8%)	2 (8%)
Mild	2 (25%)	0 (0%)	0 (0%)	2 (8%)	2 (8%)
Nasal mucosal ulcer	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Neonatal respiratory failure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Neonatal tachypnoea	1 (13%)	0 (0%)	1 (13%)	2 (8%)	2 (8%)
Mild	1 (13%)	0 (0%)	1 (13%)	2 (8%)	1 (4%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pneumothorax	1 (13%)	0 (0%)	1 (13%)	2 (8%)	3 (13%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Moderate	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Severe	0 (0%)	0 (0%)	1 (13%)	1 (4%)	2 (8%)
Pulmonary haemorrhage	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
Moderate	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
Pulmonary hypertension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pulmonary interstitial emphysema syndrome	3 (38%)	0 (0%)	1 (13%)	4 (17%)	3 (13%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Moderate	2 (25%)	0 (0%)	1 (13%)	3 (13%)	2 (8%)
Pulmonary oedema neonatal	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Respiratory acidosis	2 (25%)	0 (0%)	0 (0%)	2 (8%)	1 (4%)
Mild	2 (25%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Respiratory alkalosis	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Mild	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Moderate	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Respiratory tract haemorrhage	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Mild	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Skin and subcutaneous tissue disorders	4 (50%)	2 (25%)	1 (13%)	7 (29%)	3 (13%)
Mild	4 (50%)	2 (25%)	1 (13%)	7 (29%)	3 (13%)
Dermatitis diaper	4 (50%)	2 (25%)	1 (13%)	7 (29%)	1 (4%)
Mild	4 (50%)	2 (25%)	1 (13%)	7 (29%)	1 (4%)
Rash	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Vascular disorders	1 (13%)	3 (38%)	0 (0%)	4 (17%)	8 (33%)
Mild	0 (0%)	2 (25%)	0 (0%)	2 (8%)	3 (13%)
Moderate	1 (13%)	1 (13%)	0 (0%)	2 (8%)	4 (17%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.2
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
Safety Population

System Organ Class(SOC) Preferred Term Highest Severity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Haemangioma	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Hypertension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Mild	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hypotension	1 (13%)	2 (25%)	0 (0%)	3 (13%)	4 (17%)
Mild	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Moderate	1 (13%)	1 (13%)	0 (0%)	2 (8%)	4 (17%)
Shock	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Severe	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages are calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Any Event	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
Not Related	5 (63%)	2 (25%)	2 (25%)	9 (38%)	24 (100%)
Unlikely Related	1 (13%)	3 (38%)	2 (25%)	6 (25%)	0 (0%)
Possibly Related	2 (25%)	3 (38%)	3 (38%)	8 (33%)	0 (0%)
Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Blood and lymphatic system disorders	6 (75%)	4 (50%)	2 (25%)	12 (50%)	13 (54%)
Not Related	6 (75%)	4 (50%)	2 (25%)	12 (50%)	13 (54%)
Anaemia neonatal	6 (75%)	4 (50%)	2 (25%)	12 (50%)	13 (54%)
Not Related	6 (75%)	4 (50%)	2 (25%)	12 (50%)	13 (54%)
Bandaemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Coagulopathy	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Leukocytosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Leukopenia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Neutropenia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Thrombocytopenia	2 (25%)	2 (25%)	0 (0%)	4 (17%)	4 (17%)
Not Related	2 (25%)	2 (25%)	0 (0%)	4 (17%)	4 (17%)
Thrombocytosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardiac disorders	0 (0%)	1 (13%)	1 (13%)	2 (8%)	3 (13%)
Not Related	0 (0%)	1 (13%)	1 (13%)	2 (8%)	3 (13%)
Arrhythmia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardiac arrest	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardio-respiratory arrest	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Tachycardia	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Not Related	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Congenital, familial and genetic disorders	3 (38%)	4 (50%)	4 (50%)	11 (46%)	11 (46%)
Not Related	3 (38%)	4 (50%)	2 (25%)	9 (38%)	11 (46%)
Unlikely Related	0 (0%)	0 (0%)	2 (25%)	2 (8%)	0 (0%)
Atrial septal defect	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Not Related	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Cardiac septal defect	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hydrocele	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Patent ductus arteriosus	3 (38%)	3 (38%)	4 (50%)	10 (42%)	10 (42%)
Not Related	3 (38%)	3 (38%)	2 (25%)	8 (33%)	10 (42%)
Unlikely Related	0 (0%)	0 (0%)	2 (25%)	2 (8%)	0 (0%)
Endocrine disorders	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Adrenal insufficiency	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Gastrointestinal disorders	6 (75%)	5 (63%)	1 (13%)	12 (50%)	6 (25%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Not Related	5 (63%)	4 (50%)	0 (0%)	9 (38%)	6 (25%)
Unlikely Related	1 (13%)	1 (13%)	1 (13%)	3 (13%)	0 (0%)
Abdominal distension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Abdominal pain	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Constipation	5 (63%)	0 (0%)	1 (13%)	6 (25%)	2 (8%)
Not Related	5 (63%)	0 (0%)	0 (0%)	5 (21%)	2 (8%)
Unlikely Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Gastric haemorrhage	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Not Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Gastric hypomotility	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Unlikely Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Gastric perforation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Gastrointestinal hypomotility	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Gastroesophageal reflux disease	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Not Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Haematemesis	2 (25%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)
Not Related	2 (25%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)
Inguinal hernia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Intestinal perforation	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Unlikely Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Pneumoperitoneum	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Unlikely Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Salivary hypersecretion	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Not Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Umbilical hernia	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Not Related	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Vomiting	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
General disorders and administration site conditions	5 (63%)	0 (0%)	1 (13%)	6 (25%)	4 (17%)
Not Related	5 (63%)	0 (0%)	1 (13%)	6 (25%)	4 (17%)
Endotracheal intubation complication	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
Not Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
Face oedema	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Hypothermia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Oedema	3 (38%)	0 (0%)	0 (0%)	3 (13%)	1 (4%)
Not Related	3 (38%)	0 (0%)	0 (0%)	3 (13%)	1 (4%)
Pain	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Pyrexia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hepatobiliary disorders	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (17%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (17%)
Cholestasis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Gallbladder disorder	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Infections and infestations	4 (50%)	4 (50%)	3 (38%)	11 (46%)	9 (38%)
Not Related	4 (50%)	4 (50%)	2 (25%)	10 (42%)	9 (38%)
Unlikely Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Bacteraemia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Not Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Bacterial disease carrier	0 (0%)	0 (0%)	2 (25%)	2 (8%)	0 (0%)
Not Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Unlikely Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Conjunctivitis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Enterococcal sepsis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Fungal skin infection	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Nosocomial infection	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Not Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Pneumonia	0 (0%)	2 (25%)	0 (0%)	2 (8%)	4 (17%)
Not Related	0 (0%)	2 (25%)	0 (0%)	2 (8%)	4 (17%)
Pneumonia klebsiella	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pneumonia staphylococcal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Sepsis neonatal	2 (25%)	1 (13%)	1 (13%)	4 (17%)	4 (17%)
Not Related	2 (25%)	1 (13%)	1 (13%)	4 (17%)	4 (17%)
Septic shock	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Urinary tract infection	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Urinary tract infection enterococcal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Urosepsis	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Not Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Injury, poisoning and procedural complications	2 (25%)	2 (25%)	0 (0%)	4 (17%)	4 (17%)
Not Related	2 (25%)	1 (13%)	0 (0%)	3 (13%)	4 (17%)
Unlikely Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Blister	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Ear abrasion	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Not Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Hepatic haemorrhage	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Infusion site extravasation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Laceration	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Laryngeal injury	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Skin abrasion	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Tracheal injury	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Unlikely Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Traumatic liver injury	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Investigations	3 (38%)	5 (63%)	7 (88%)	15 (63%)	11 (46%)
Not Related	2 (25%)	3 (38%)	4 (50%)	9 (38%)	11 (46%)
Possibly Related	1 (13%)	2 (25%)	2 (25%)	5 (21%)	0 (0%)
Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Anticonvulsant drug level above therapeut	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Blood urea increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Cardiac murmur	2 (25%)	1 (13%)	0 (0%)	3 (13%)	1 (4%)
Not Related	2 (25%)	1 (13%)	0 (0%)	3 (13%)	1 (4%)
Coagulation time prolonged	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Not Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Neutrophil count increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Oxygen saturation decreased	2 (25%)	4 (50%)	6 (75%)	12 (50%)	9 (38%)
Not Related	1 (13%)	2 (25%)	3 (38%)	6 (25%)	9 (38%)
Possibly Related	1 (13%)	2 (25%)	2 (25%)	5 (21%)	0 (0%)
Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
PO2 increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Reticulocyte count increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Metabolism and nutrition disorders	7 (88%)	4 (50%)	1 (13%)	12 (50%)	12 (50%)
Not Related	7 (88%)	3 (38%)	1 (13%)	11 (46%)	12 (50%)
Unlikely Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Dehydration	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Electrolyte imbalance	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Feeding intolerance	3 (38%)	1 (13%)	1 (13%)	5 (21%)	1 (4%)
Not Related	3 (38%)	1 (13%)	1 (13%)	5 (21%)	1 (4%)
Fluid retention	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hypercalcaemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Hyperchloraemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	3 (13%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	3 (13%)
Hyperglycaemia	1 (13%)	2 (25%)	0 (0%)	3 (13%)	3 (13%)
Not Related	1 (13%)	2 (25%)	0 (0%)	3 (13%)	3 (13%)
Hyperkalaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Hypermagnesaemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Hypernatraemia	1 (13%)	2 (25%)	0 (0%)	3 (13%)	4 (17%)
Not Related	1 (13%)	2 (25%)	0 (0%)	3 (13%)	4 (17%)
Hypertriglyceridaemia	1 (13%)	1 (13%)	0 (0%)	2 (8%)	2 (8%)
Not Related	1 (13%)	1 (13%)	0 (0%)	2 (8%)	2 (8%)
Hypoalbuminaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Hypocalcaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Hypochloraemia	2 (25%)	1 (13%)	0 (0%)	3 (13%)	3 (13%)
Not Related	2 (25%)	1 (13%)	0 (0%)	3 (13%)	3 (13%)
Hypoglycaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Hypokalaemia	0 (0%)	2 (25%)	0 (0%)	2 (8%)	3 (13%)
Not Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	3 (13%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Unlikely Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Hypomagnesaemia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Unlikely Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Hyponatraemia	3 (38%)	0 (0%)	0 (0%)	3 (13%)	7 (29%)
Not Related	3 (38%)	0 (0%)	0 (0%)	3 (13%)	7 (29%)
Hypophosphataemia	2 (25%)	0 (0%)	0 (0%)	2 (8%)	1 (4%)
Not Related	2 (25%)	0 (0%)	0 (0%)	2 (8%)	1 (4%)
Hypovolaemia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Unlikely Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Metabolic acidosis	3 (38%)	0 (0%)	0 (0%)	3 (13%)	5 (21%)
Not Related	3 (38%)	0 (0%)	0 (0%)	3 (13%)	5 (21%)
Metabolic alkalosis	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Not Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Osteopenia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Vitamin D deficiency	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Not Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Nervous system disorders	1 (13%)	0 (0%)	0 (0%)	1 (4%)	2 (8%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	2 (8%)
Hypotonia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Lethargy	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Periventricular leukomalacia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Seizure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pregnancy, puerperium and perinatal conditions	6 (75%)	8 (100%)	7 (88%)	21 (88%)	22 (92%)
Not Related	6 (75%)	4 (50%)	3 (38%)	13 (54%)	22 (92%)
Unlikely Related	0 (0%)	2 (25%)	3 (38%)	5 (21%)	0 (0%)
Possibly Related	0 (0%)	2 (25%)	1 (13%)	3 (13%)	0 (0%)
Agitation neonatal	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Not Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Bradycardia neonatal	0 (0%)	5 (63%)	3 (38%)	8 (33%)	9 (38%)
Not Related	0 (0%)	3 (38%)	2 (25%)	5 (21%)	9 (38%)
Possibly Related	0 (0%)	2 (25%)	1 (13%)	3 (13%)	0 (0%)
Fixed bowel loop	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Intraventricular haemorrhage neonatal	0 (0%)	1 (13%)	3 (38%)	4 (17%)	3 (13%)
Not Related	0 (0%)	1 (13%)	1 (13%)	2 (8%)	3 (13%)
Unlikely Related	0 (0%)	0 (0%)	2 (25%)	2 (8%)	0 (0%)
Jaundice neonatal	5 (63%)	3 (38%)	1 (13%)	9 (38%)	11 (46%)
Not Related	5 (63%)	3 (38%)	1 (13%)	9 (38%)	11 (46%)
Necrotising enterocolitis neonatal	1 (13%)	1 (13%)	1 (13%)	3 (13%)	1 (4%)
Not Related	1 (13%)	1 (13%)	0 (0%)	2 (8%)	1 (4%)
Unlikely Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Neonatal respiratory distress syndrome	1 (13%)	4 (50%)	2 (25%)	7 (29%)	10 (42%)
Not Related	1 (13%)	2 (25%)	2 (25%)	5 (21%)	10 (42%)
Unlikely Related	0 (0%)	2 (25%)	0 (0%)	2 (8%)	0 (0%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Neonatal respiratory failure	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Not Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Periventricular haemorrhage neonatal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Retinopathy of prematurity	2 (25%)	1 (13%)	1 (13%)	4 (17%)	9 (38%)
Not Related	2 (25%)	1 (13%)	0 (0%)	3 (13%)	9 (38%)
Unlikely Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Small for dates baby	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Renal and urinary disorders	0 (0%)	1 (13%)	0 (0%)	1 (4%)	3 (13%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Unlikely Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Azotaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Haematuria	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Oliguria	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Unlikely Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Renal failure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Respiratory, thoracic and mediastinal disorders	8 (100%)	5 (63%)	7 (88%)	20 (83%)	23 (96%)
Not Related	6 (75%)	4 (50%)	3 (38%)	13 (54%)	23 (96%)
Unlikely Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Possibly Related	2 (25%)	1 (13%)	3 (38%)	6 (25%)	0 (0%)
Apnoea neonatal	7 (88%)	4 (50%)	6 (75%)	17 (71%)	19 (79%)
Not Related	6 (75%)	3 (38%)	2 (25%)	11 (46%)	19 (79%)
Unlikely Related	0 (0%)	0 (0%)	2 (25%)	2 (8%)	0 (0%)
Possibly Related	1 (13%)	1 (13%)	2 (25%)	4 (17%)	0 (0%)
Bronchopulmonary dysplasia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	7 (29%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	7 (29%)
Chronic respiratory failure	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Not Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Hypercapnia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
Not Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Nasal discomfort	2 (25%)	2 (25%)	0 (0%)	4 (17%)	3 (13%)
Not Related	2 (25%)	2 (25%)	0 (0%)	4 (17%)	3 (13%)
Neonatal respiratory failure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Neonatal tachypnoea	1 (13%)	0 (0%)	1 (13%)	2 (8%)	2 (8%)
Not Related	1 (13%)	0 (0%)	1 (13%)	2 (8%)	2 (8%)
Pneumothorax	1 (13%)	0 (0%)	1 (13%)	2 (8%)	3 (13%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Unlikely Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Possibly Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Pulmonary haemorrhage	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
Not Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
Pulmonary hypertension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pulmonary interstitial emphysema syndrome	3 (38%)	0 (0%)	1 (13%)	4 (17%)	3 (13%)
Not Related	2 (25%)	0 (0%)	0 (0%)	2 (8%)	3 (13%)
Possibly Related	1 (13%)	0 (0%)	1 (13%)	2 (8%)	0 (0%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Pulmonary oedema neonatal	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
Not Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
Respiratory acidosis	2 (25%)	0 (0%)	0 (0%)	2 (8%)	1 (4%)
Not Related	2 (25%)	0 (0%)	0 (0%)	2 (8%)	1 (4%)
Respiratory alkalosis	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Not Related	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Respiratory tract haemorrhage	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Not Related	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Skin and subcutaneous tissue disorders	4 (50%)	2 (25%)	1 (13%)	7 (29%)	3 (13%)
Not Related	4 (50%)	2 (25%)	1 (13%)	7 (29%)	3 (13%)
Dermatitis diaper	4 (50%)	2 (25%)	1 (13%)	7 (29%)	1 (4%)
Not Related	4 (50%)	2 (25%)	1 (13%)	7 (29%)	1 (4%)
Rash	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Vascular disorders	1 (13%)	3 (38%)	0 (0%)	4 (17%)	6 (25%)
Not Related	1 (13%)	2 (25%)	0 (0%)	3 (13%)	6 (25%)

Note: Percentages calculated from column totals.

Summary Table 6.3.3
Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Relationship
Safety Population

System Organ Class(SOC) Preferred Term Highest Relationship	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Unlikely Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Haemangioma	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Not Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Hypertension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hypotension	1 (13%)	2 (25%)	0 (0%)	3 (13%)	4 (17%)
Not Related	1 (13%)	1 (13%)	0 (0%)	2 (8%)	4 (17%)
Unlikely Related	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Shock	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Not Related	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Percentages calculated from column totals.

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
nCPAP Only												
Abdominal distension	13016 (x1)											
Abdominal pain	54001 (x1)											
Adrenal insufficiency					19004 (x1)							
Anaemia neonatal	03006 (x1)				12004 (x1)							
Anaemia neonatal	12006 (x1)				12010 (x1)							
Anaemia neonatal	12037 (x1)				54017 (x1)							
Anaemia neonatal	13016 (x1)				76002 (x3)							
Anaemia neonatal	19004 (x1)											
Anticonvulsant drug level above therapeut					76002 (x1)							
Apnoea neonatal	03013 (x1)				08037 (x1)							
Apnoea neonatal	11005 (x1)				12010 (x1)							
Apnoea neonatal	11006 (x1)				54017 (x1)							
Apnoea neonatal	12004 (x1)											
Apnoea neonatal	12006 (x1)											
Arrhythmia	42001 (x1)											
Azotaemia	76002 (x1)											
Bacteraemia					13016 (x1)							
Bandaemia	12006 (x1)											
Blood urea increased	13016 (x1)											
Bradycardia neonatal	13016 (x1)				12004 (x1)							
Bradycardia neonatal	40004 (x1)				12010 (x1)							
Bradycardia neonatal	40009 (x1)											
Bradycardia neonatal	40013 (x1)											
Bradycardia neonatal	40019 (x1)											

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
Bronchopulmonary dysplasia	08028 (x1)				12006 (x2)				19004 (x1)			
Bronchopulmonary dysplasia	13016 (x1)				12010 (x1)							
Bronchopulmonary dysplasia	42004 (x1)				76002 (x1)							
Cardiac arrest									12006 (x1)			
Cardiac murmur	12004 (x1)											
Cardiac septal defect	08037 (x1)											
Cardio-respiratory arrest									19004 (x1)			
Cholestasis	12010 (x1)								19004 (x1)			
Cholestasis	40013 (x1)											
Coagulopathy					76002 (x1)							
Conjunctivitis	54017 (x1)											
Constipation	03006 (x1)											
Constipation	13016 (x1)											
Dermatitis diaper	03006 (x1)											
Endotracheal intubation complication	40009 (x1)											
Enterococcal sepsis	13016 (x1)											
Feeding intolerance	12037 (x1)											
Fluid retention	54017 (x1)											
Fungal skin infection	41005 (x1)											
Gallbladder disorder	12004 (x1)											
Gastric perforation									12006 (x1)			
Haemangioma	54001 (x1)											
Haematuria	76002 (x1)											
Hepatic haemorrhage									12006 (x1)			
Hydrocele	19004 (x1)											

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
Hypercalcaemia	13016 (x1)											
Hypercapnia	13016 (x3)				03006 (x1)							
Hyperchloraemia	12004 (x1)											
Hyperchloraemia	12037 (x1)											
Hyperchloraemia	13016 (x1)											
Hyperglycaemia	12006 (x1)				76002 (x1)							
Hyperglycaemia	13016 (x1)											
Hyperglycaemia	76002 (x2)											
Hyperkalaemia	03013 (x1)											
Hyperkalaemia	76002 (x1)											
Hypernatraemia	12037 (x1)											
Hypernatraemia	13016 (x2)											
Hypernatraemia	41005 (x1)											
Hypernatraemia	76002 (x1)											
Hypertension	12004 (x1)											
Hypertriglyceridaemia	13016 (x1)											
Hypertriglyceridaemia	76002 (x2)											
Hypoalbuminaemia	12010 (x1)											
Hypoalbuminaemia	19004 (x1)											
Hypoalbuminaemia	76002 (x1)											
Hypocalcaemia	19004 (x1)											
Hypocalcaemia	76002 (x1)											
Hypochloraemia	12004 (x1)											
Hypochloraemia	12010 (x1)											
Hypochloraemia	13016 (x2)											
Hypoglycaemia	12004 (x1)											

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
Hypoglycaemia	13016 (x1)											
Hypoglycaemia	19004 (x1)											
Hypokalaemia	12006 (x1)											
Hypokalaemia	12010 (x1)											
Hypokalaemia	13016 (x2)											
Hypomagnesaemia	19004 (x1)											
Hyponatraemia	12004 (x1)				76002 (x1)							
Hyponatraemia	12010 (x1)											
Hyponatraemia	12037 (x1)											
Hyponatraemia	19004 (x1)											
Hyponatraemia	40009 (x1)											
Hypophosphataemia	12010 (x1)											
Hypotension	76002 (x1)				12006 (x1)							
Hypotension					12010 (x1)							
Hypotension					42004 (x1)							
Hypotension					76002 (x3)							
Hypothermia	03013 (x1)											
Hypothermia	13016 (x1)											
Infusion site extravasation	40009 (x1)											
Inguinal hernia	03006 (x1)											
Inguinal hernia	13016 (x1)											
Intestinal perforation									12010 (x1)			
Intraventricular haemorrhage neonatal	19004 (x1)								76002 (x1)			
Intraventricular haemorrhage neonatal	54002 (x1)											
Jaundice neonatal	03006 (x1)				54001 (x1)							

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
Jaundice neonatal	08037 (x1)				54002 (x1)							
Jaundice neonatal	12006 (x2)											
Jaundice neonatal	12010 (x1)											
Jaundice neonatal	19004 (x1)											
Laryngeal injury									12010 (x1)			
Leukocytosis	13016 (x1)											
Leukopenia	12010 (x1)											
Leukopenia	76002 (x1)											
Metabolic acidosis	12004 (x1)				42004 (x1)							
Metabolic acidosis	12006 (x1)				76002 (x1)							
Metabolic acidosis	12037 (x1)											
Nasal discomfort	12004 (x1)											
Nasal inflammation	40004 (x1)											
Nasal inflammation	41005 (x1)											
Necrotising enterocolitis neonatal									19004 (x2)			
Neonatal respiratory distress syndrome	03006 (x1)				08028 (x1)				11005 (x1)			
Neonatal respiratory distress syndrome	19004 (x1)				08037 (x2)				11006 (x1)			
Neonatal respiratory distress syndrome	41005 (x1)				12006 (x2)				54017 (x1)			
Neonatal respiratory distress syndrome	42001 (x1)											
Neonatal respiratory failure					12010 (x1)				12006 (x1)			
Neonatal tachypnoea	12004 (x1)				12004 (x1)							
Neonatal tachypnoea	12037 (x1)											

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
Neutropenia	12006 (x1)											
Neutrophil count increased	13016 (x1)											
Oedema	12037 (x1)											
Oliguria	12010 (x1)											
Oliguria	19004 (x1)											
Osteopenia	12006 (x1)											
Osteopenia	19004 (x1)											
Oxygen saturation decreased	13016 (x1)											
Oxygen saturation decreased	40004 (x1)											
Oxygen saturation decreased	40009 (x2)											
Oxygen saturation decreased	40013 (x1)											
Oxygen saturation decreased	40019 (x2)											
PO2 increased	13016 (x1)											
Patent ductus arteriosus	12037 (x1)				03013 (x1)							
Patent ductus arteriosus	41002 (x1)				08028 (x1)							
Patent ductus arteriosus	41005 (x1)				19004 (x1)							
Patent ductus arteriosus	76002 (x1)				42004 (x1)							
Patent ductus arteriosus					54001 (x1)							
Periventricular haemorrhage neonatal	54001 (x1)											
Periventricular leukomalacia									19004 (x1)			
Pneumonia					19004 (x1)							
Pneumonia					54002 (x1)							
Pneumonia					54017 (x1)							
Pneumonia					76002 (x1)							
Pneumonia klebsiella					19004 (x1)							

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
Pneumonia staphylococcal					19004 (x1)							
Pneumothorax	40019 (x1)								11006 (x1)			
Pneumothorax									76002 (x1)			
Pulmonary haemorrhage					42004 (x1)							
Pulmonary hypertension					76002 (x1)							
Pulmonary interstitial emphysema syndrome	40019 (x1)				08028 (x1)							
Pulmonary interstitial emphysema syndrome					76002 (x1)							
Pulmonary oedema neonatal	12006 (x1)				12010 (x1)							
Pyrexia	13016 (x1)											
Rash	19004 (x1)											
Rash	54001 (x1)											
Renal failure	76002 (x1)				19004 (x1)							
Renal failure					76002 (x1)							
Respiratory acidosis	76002 (x1)				76002 (x1)							
Respiratory alkalosis					76002 (x2)							
Reticulocyte count increased	13016 (x1)											
Retinopathy of prematurity	08037 (x1)				13016 (x1)							
Retinopathy of prematurity	11005 (x1)				54002 (x1)							
Retinopathy of prematurity	11006 (x1)											
Retinopathy of prematurity	12006 (x1)											
Retinopathy of prematurity	19004 (x1)											
Seizure	76002 (x1)				76002 (x1)							
Sepsis neonatal	12037 (x1)				12010 (x1)							
Sepsis neonatal	41005 (x1)				40009 (x1)							
Shock									76002 (x1)			

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
Skin abrasion	42001 (x1)											
Small for dates baby	03013 (x1)											
Thrombocytopenia	12006 (x1)				12010 (x1)							
Thrombocytopenia	76002 (x1)				19004 (x1)							
Thrombocytosis	13016 (x1)											
Traumatic liver injury									12006 (x1)			
Urinary tract infection					76002 (x2)							
Urinary tract infection enterococcal	13016 (x1)											
Vomiting	40019 (x1)											
50 mg/kg												
Anaemia neonatal	01033 (x1)											
Anaemia neonatal	01040 (x1)											
Anaemia neonatal	01041 (x1)											
Anaemia neonatal	09001 (x1)											
Anaemia neonatal	12007 (x1)											
Apnoea neonatal	01032 (x1)											
Apnoea neonatal	01033 (x1)											
Apnoea neonatal	01040 (x1)											
Apnoea neonatal	01041 (x1)											
Apnoea neonatal	09001 (x1)											
Apnoea neonatal											12007 (x1)	
Bandaemia	12014 (x1)											
Blister	09001 (x1)											
Cardiac murmur	01033 (x1)											

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
Cardiac murmur	01040 (x1)											
Coagulopathy	01040 (x1)											
Constipation	01032 (x3)											
Constipation	01033 (x4)											
Constipation	01040 (x2)											
Constipation	01041 (x3)											
Constipation	09001 (x1)											
Dehydration	01032 (x1)											
Dermatitis diaper	01032 (x1)											
Dermatitis diaper	01033 (x2)											
Dermatitis diaper	01040 (x1)											
Dermatitis diaper	12014 (x1)											
Electrolyte imbalance	12014 (x1)											
Face oedema	40001 (x1)											
Feeding intolerance	09001 (x1)				01032 (x1)							
Feeding intolerance					01033 (x1)							
Fixed bowel loop	09001 (x1)											
Gastric hypomotility							40001 (x1)					
Gastrointestinal hypomotility					01033 (x1)							
Haematemesis	09001 (x1)											
Haematemesis	40001 (x1)											
Hypercalcaemia	01032 (x1)											
Hyperchloraemia	12014 (x1)											
Hyperglycaemia	12014 (x1)											
Hypermagnesaemia	01032 (x1)											
Hypernatraemia	09001 (x1)											

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
Hypertriglyceridaemia	12014 (x1)											
Hypochloraemia	12007 (x1)											
Hypochloraemia	12014 (x1)											
Hyponatraemia	01041 (x1)											
Hyponatraemia	12007 (x1)											
Hyponatraemia	12014 (x1)											
Hypophosphataemia	01032 (x1)											
Hypophosphataemia	12014 (x1)											
Hypotension					12014 (x1)							
Hypotonia	09001 (x1)											
Intestinal perforation										40001 (x1)		
Jaundice neonatal	01033 (x1)											
Jaundice neonatal	01040 (x1)											
Jaundice neonatal	01041 (x1)											
Jaundice neonatal	09001 (x1)											
Jaundice neonatal	12014 (x1)											
Laceration	01041 (x1)											
Lethargy	09001 (x1)											
Metabolic acidosis	01032 (x1)											
Metabolic acidosis	01033 (x1)											
Metabolic acidosis	01040 (x1)											
Nasal inflammation	12007 (x1)											
Nasal inflammation	40001 (x2)											
Necrotising enterocolitis neonatal									12014 (x1)			
Neonatal respiratory distress syndrome					12014 (x1)							

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
Neonatal tachypnoea	01041 (x1)											
Neutropenia	12014 (x1)											
Oedema	01032 (x1)											
Oedema	01033 (x1)											
Oedema	01041 (x1)											
Oxygen saturation decreased	01040 (x1)											
Oxygen saturation decreased	12007 (x1)											
Oxygen saturation decreased			12007 (x1)									
Pain	12014 (x1)											
Patent ductus arteriosus	01033 (x1)											
Patent ductus arteriosus	01040 (x1)											
Patent ductus arteriosus	01041 (x1)											
Pneumothorax								01040 (x1)				
Pulmonary interstitial emphysema syndrome	01033 (x1)				01041 (x1)							
Pulmonary interstitial emphysema syndrome								01040 (x1)				
Respiratory acidosis	09001 (x1)											
Respiratory acidosis	12014 (x1)											
Respiratory alkalosis	12014 (x1)											
Retinopathy of prematurity	01032 (x1)											
Retinopathy of prematurity	01033 (x1)											
Sepsis neonatal	01033 (x1)								09001 (x1)			
Septic shock					12014 (x1)							
Thrombocytopenia	09001 (x1)				01033 (x1)							
Urinary tract infection					01040 (x1)							
Vomiting	09001 (x1)											

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
75 mg/kg												
Anaemia neonatal	01042 (x1)											
Anaemia neonatal	12023 (x1)											
Anaemia neonatal	50001 (x2)											
Anaemia neonatal	51004 (x2)											
Apnoea neonatal	01042 (x1)											
Apnoea neonatal	12023 (x1)											
Apnoea neonatal	40006 (x1)											
Apnoea neonatal	42003 (x1)											
Apnoea neonatal				01042 (x1)								
Atrial septal defect	01042 (x1)											
Bacteraemia					50001 (x1)							
Bradycardia neonatal	12023 (x1)											
Bradycardia neonatal	40003 (x1)											
Bradycardia neonatal	40006 (x1)											
Bradycardia neonatal	42003 (x2)											
Bradycardia neonatal				11011 (x1)								
Bradycardia neonatal				40006 (x1)								
Cardiac murmur	01042 (x1)											
Chronic respiratory failure					12023 (x1)							
Dermatitis diaper	01042 (x1)											
Dermatitis diaper	12023 (x1)											
Ear abrasion	42003 (x1)											
Feeding intolerance	12023 (x1)											
Gastric haemorrhage	40003 (x1)											

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
Gastroesophageal reflux disease	01042 (x1)											
Haemangioma	50001 (x1)											
Hypercapnia					12023 (x1)							
Hyperglycaemia	01042 (x1)											
Hyperglycaemia	12023 (x1)											
Hypernatraemia	01042 (x1)											
Hypernatraemia	12023 (x1)											
Hypertriglyceridaemia	12023 (x1)											
Hypochloraemia	12023 (x1)											
Hypokalaemia					01042 (x1)							
Hypokalaemia		11011 (x1)										
Hypomagnesaemia		11011 (x1)										
Hypotension	12023 (x1)											
Hypotension						11011 (x1)						
Hypovolaemia						11011 (x1)						
Intraventricular haemorrhage neonatal	50001 (x1)											
Jaundice neonatal	01042 (x1)											
Jaundice neonatal	12023 (x1)											
Jaundice neonatal	50001 (x1)											
Metabolic alkalosis	12023 (x1)											
Nasal discomfort	50001 (x1)											
Nasal mucosal ulcer	12023 (x1)											
Necrotising enterocolitis neonatal	42003 (x1)											

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
Neonatal respiratory distress syndrome	40003 (x1)				51004 (x1)							
Neonatal respiratory distress syndrome		42003 (x1)				50001 (x1)						
Neonatal respiratory failure					50001 (x1)							
Nosocomial infection	50001 (x1)											
Oliguria		11011 (x1)										
Oxygen saturation decreased	40003 (x1)											
Oxygen saturation decreased	40006 (x1)											
Oxygen saturation decreased	50001 (x1)											
Oxygen saturation decreased			11011 (x1)									
Oxygen saturation decreased			40006 (x2)									
Patent ductus arteriosus	50001 (x1)				12023 (x1)							
Patent ductus arteriosus	51004 (x1)											
Pneumonia					12023 (x1)							
Pneumonia					51004 (x1)							
Pneumoperitoneum										11011 (x1)		
Pulmonary oedema neonatal	12023 (x1)											
Retinopathy of prematurity	50001 (x1)											
Salivary hypersecretion	12023 (x1)											
Sepsis neonatal					40006 (x1)							
Tachycardia	12023 (x1)											
Thrombocytopenia	01042 (x1)											
Thrombocytopenia	50001 (x1)											
Tracheal injury		40003 (x1)										
Umbilical hernia	50001 (x1)											
Vitamin D deficiency	50001 (x1)											

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
100 mg/kg												
Agitation neonatal	19007 (x1)											
Anaemia neonatal	19007 (x1)											
Anaemia neonatal	42010 (x1)											
Apnoea neonatal	40015 (x2)											
Apnoea neonatal	40016 (x1)											
Apnoea neonatal				11021 (x2)								
Apnoea neonatal				11023 (x1)								
Apnoea neonatal		42010 (x1)						11023 (x1)				
Apnoea neonatal								11025 (x1)				
Atrial septal defect	19007 (x1)											
Bacterial disease carrier	11023 (x1)											
Bacterial disease carrier		11025 (x1)										
Bradycardia neonatal	40015 (x1)											
Bradycardia neonatal	40016 (x1)											
Bradycardia neonatal				11021 (x3)								
Coagulation time prolonged	42010 (x1)											
Constipation		11025 (x1)										
Dermatitis diaper	40015 (x1)											
Endotracheal intubation complication	40014 (x1)											
Feeding intolerance	40016 (x1)											
Intraventricular haemorrhage neonatal	42010 (x1)											
Intraventricular haemorrhage neonatal										11021 (x1)		

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
Intraventricular haemorrhage neonatal												40015 (x1)
Jaundice neonatal	19007 (x1)											
Necrotising enterocolitis neonatal		11023 (x1)										
Neonatal respiratory distress syndrome	40014 (x2)				11023 (x1)							
Neonatal tachypnoea	40016 (x1)											
Oxygen saturation decreased	40014 (x2)											
Oxygen saturation decreased	40015 (x1)											
Oxygen saturation decreased	40016 (x1)											
Oxygen saturation decreased			11021 (x2)									
Oxygen saturation decreased			11023 (x3)									
Oxygen saturation decreased			19007 (x1)									
Oxygen saturation decreased				19007 (x1)								
Patent ductus arteriosus	19007 (x1)				42010 (x1)							
Patent ductus arteriosus		11021 (x1)										
Patent ductus arteriosus		11023 (x1)										
Pneumothorax												11021 (x1)
Pulmonary haemorrhage					42010 (x1)							
Pulmonary interstitial emphysema syndrome							11025 (x1)					
Respiratory tract haemorrhage	40014 (x1)											
Retinopathy of prematurity		42010 (x1)										
Sepsis neonatal					11023 (x1)							
Tachycardia	40015 (x1)											

Summary Table 6.3.4
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term by Severity and Relationship to Study Treatment
Safety Population

Treatment Preferred Term Relationship:	Severity											
	Mild				Moderate				Severe			
	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related	Not Rel.	Unlikely	Possibly	Related
Umbilical hernia	11025 (x1)											
Urosepsis	42010 (x1)											

Summary Table 6.3.5
Treatment-Emergent Adverse Events by Preferred Term in Descending Order of Frequency
Safety Population

Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Apnoea neonatal	7 (88%)	4 (50%)	6 (75%)	17 (71%)	19 (79%)
Anaemia neonatal	6 (75%)	4 (50%)	2 (25%)	12 (50%)	13 (54%)
Oxygen saturation decreased	2 (25%)	4 (50%)	6 (75%)	12 (50%)	9 (38%)
Patent ductus arteriosus	3 (38%)	3 (38%)	4 (50%)	10 (42%)	10 (42%)
Jaundice neonatal	5 (63%)	3 (38%)	1 (13%)	9 (38%)	11 (46%)
Bradycardia neonatal	0 (0%)	5 (63%)	3 (38%)	8 (33%)	9 (38%)
Neonatal respiratory distress syndrome	1 (13%)	4 (50%)	2 (25%)	7 (29%)	10 (42%)
Dermatitis diaper	4 (50%)	2 (25%)	1 (13%)	7 (29%)	1 (4%)
Constipation	5 (63%)	0 (0%)	1 (13%)	6 (25%)	2 (8%)
Feeding intolerance	3 (38%)	1 (13%)	1 (13%)	5 (21%)	1 (4%)
Retinopathy of prematurity	2 (25%)	1 (13%)	1 (13%)	4 (17%)	9 (38%)
Sepsis neonatal	2 (25%)	1 (13%)	1 (13%)	4 (17%)	4 (17%)
Thrombocytopenia	2 (25%)	2 (25%)	0 (0%)	4 (17%)	4 (17%)
Intraventricular haemorrhage neonatal	0 (0%)	1 (13%)	3 (38%)	4 (17%)	3 (13%)
Pulmonary interstitial emphysema syndrome	3 (38%)	0 (0%)	1 (13%)	4 (17%)	3 (13%)
Hyponatraemia	3 (38%)	0 (0%)	0 (0%)	3 (13%)	7 (29%)
Metabolic acidosis	3 (38%)	0 (0%)	0 (0%)	3 (13%)	5 (21%)
Hypernatraemia	1 (13%)	2 (25%)	0 (0%)	3 (13%)	4 (17%)
Hypotension	1 (13%)	2 (25%)	0 (0%)	3 (13%)	4 (17%)
Hyperglycaemia	1 (13%)	2 (25%)	0 (0%)	3 (13%)	3 (13%)
Hypochloraemia	2 (25%)	1 (13%)	0 (0%)	3 (13%)	3 (13%)
Cardiac murmur	2 (25%)	1 (13%)	0 (0%)	3 (13%)	1 (4%)
Necrotising enterocolitis neonatal	1 (13%)	1 (13%)	1 (13%)	3 (13%)	1 (4%)

Note: Sorted by total active group.

Summary Table 6.3.5
Treatment-Emergent Adverse Events by Preferred Term in Descending Order of Frequency
Safety Population

Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Oedema	3 (38%)	0 (0%)	0 (0%)	3 (13%)	1 (4%)
Pneumonia	0 (0%)	2 (25%)	0 (0%)	2 (8%)	4 (17%)
Hypokalaemia	0 (0%)	2 (25%)	0 (0%)	2 (8%)	3 (13%)
Pneumothorax	1 (13%)	0 (0%)	1 (13%)	2 (8%)	3 (13%)
Hypertriglyceridaemia	1 (13%)	1 (13%)	0 (0%)	2 (8%)	2 (8%)
Nasal inflammation	2 (25%)	0 (0%)	0 (0%)	2 (8%)	2 (8%)
Neonatal tachypnoea	1 (13%)	0 (0%)	1 (13%)	2 (8%)	2 (8%)
Hypophosphataemia	2 (25%)	0 (0%)	0 (0%)	2 (8%)	1 (4%)
Respiratory acidosis	2 (25%)	0 (0%)	0 (0%)	2 (8%)	1 (4%)
Atrial septal defect	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Bacterial disease carrier	0 (0%)	0 (0%)	2 (25%)	2 (8%)	0 (0%)
Haematemesis	2 (25%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)
Tachycardia	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Umbilical hernia	0 (0%)	1 (13%)	1 (13%)	2 (8%)	0 (0%)
Hyperchloraemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	3 (13%)
Hypercapnia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
Neonatal respiratory failure	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
Oliguria	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
Pulmonary oedema neonatal	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
Bacteraemia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Bandaemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Coagulopathy	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Endotracheal intubation complication	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)

Note: Sorted by total active group.

Summary Table 6.3.5
Treatment-Emergent Adverse Events by Preferred Term in Descending Order of Frequency
Safety Population

Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Haemangioma	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Hypercalcaemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Hypomagnesaemia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Intestinal perforation	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Nasal discomfort	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Neutropenia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Pulmonary haemorrhage	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
Respiratory alkalosis	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Urinary tract infection	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Vomiting	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Agitation neonatal	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Blister	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Chronic respiratory failure	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Coagulation time prolonged	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Dehydration	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Ear abrasion	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Electrolyte imbalance	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Face oedema	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Fixed bowel loop	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Gastric haemorrhage	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Gastric hypomotility	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Gastrointestinal hypomotility	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Gastroesophageal reflux disease	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)

Note: Sorted by total active group.

Summary Table 6.3.5
Treatment-Emergent Adverse Events by Preferred Term in Descending Order of Frequency
Safety Population

Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Hypermagnesaemia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Hypotonia	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Hypovolaemia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Laceration	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Lethargy	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Metabolic alkalosis	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Nasal mucosal ulcer	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Nosocomial infection	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Pain	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Pneumoperitoneum	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Respiratory tract haemorrhage	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Salivary hypersecretion	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Septic shock	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Tracheal injury	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Urosepsis	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Vitamin D deficiency	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Bronchopulmonary dysplasia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	7 (29%)
Cholestasis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Hypoalbuminaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Hypoglycaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Hyperkalaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Hypocalcaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Hypothermia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)

Note: Sorted by total active group.

Summary Table 6.3.5
Treatment-Emergent Adverse Events by Preferred Term in Descending Order of Frequency
Safety Population

Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Inguinal hernia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Leukopenia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Osteopenia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Rash	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Renal failure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Abdominal distension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Abdominal pain	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Adrenal insufficiency	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Anticonvulsant drug level above therapeut	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Arrhythmia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Azotaemia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Blood urea increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardiac arrest	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardiac septal defect	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardio-respiratory arrest	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Conjunctivitis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Enterococcal sepsis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Fluid retention	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Fungal skin infection	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Gallbladder disorder	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Gastric perforation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Haematuria	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hepatic haemorrhage	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Sorted by total active group.

Summary Table 6.3.5
Treatment-Emergent Adverse Events by Preferred Term in Descending Order of Frequency
Safety Population

Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Hydrocele	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hypertension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Infusion site extravasation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Laryngeal injury	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Leukocytosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Neutrophil count increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
PO2 increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Periventricular haemorrhage neonatal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Periventricular leukomalacia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pneumonia klebsiella	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pneumonia staphylococcal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pulmonary hypertension	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pyrexia	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Reticulocyte count increased	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Seizure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Shock	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Skin abrasion	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Small for dates baby	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Thrombocytosis	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Traumatic liver injury	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Urinary tract infection enterococcal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Sorted by total active group.

Summary Table 6.4.1
Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population

System Organ Class(SOC) Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Any Event	4 (50%)	3 (38%)	2 (25%)	9 (38%)	6 (25%)
Blood and lymphatic system disorders	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Anaemia neonatal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardiac disorders	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Cardiac arrest	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardio-respiratory arrest	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Gastrointestinal disorders	1 (13%)	1 (13%)	0 (0%)	2 (8%)	2 (8%)
Gastric perforation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Intestinal perforation	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Pneumoperitoneum	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Infections and infestations	1 (13%)	1 (13%)	0 (0%)	2 (8%)	1 (4%)
Pneumonia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Sepsis neonatal	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Injury, poisoning and procedural complications	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
Hepatic haemorrhage	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Laryngeal injury	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Traumatic liver injury	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pregnancy, puerperium and perinatal conditions	1 (13%)	2 (25%)	2 (25%)	5 (21%)	3 (13%)
Intraventricular haemorrhage neonatal	0 (0%)	0 (0%)	2 (25%)	2 (8%)	1 (4%)
Necrotising enterocolitis neonatal	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)

Summary Table 6.4.1
Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
Safety Population

System Organ Class(SOC) Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Neonatal respiratory distress syndrome	0 (0%)	2 (25%)	0 (0%)	2 (8%)	1 (4%)
Neonatal respiratory failure	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Respiratory, thoracic and mediastinal disorders	1 (13%)	0 (0%)	1 (13%)	2 (8%)	4 (17%)
Apnoea neonatal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Neonatal respiratory failure	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Pneumothorax	1 (13%)	0 (0%)	1 (13%)	2 (8%)	2 (8%)
Vascular disorders	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Shock	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Summary Table 6.4.2
Serious Treatment-Emergent Adverse Events by Preferred Term in Descending Order of Frequency
Safety Population

Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Pneumothorax	1 (13%)	0 (0%)	1 (13%)	2 (8%)	2 (8%)
Intraventricular haemorrhage neonatal	0 (0%)	0 (0%)	2 (25%)	2 (8%)	1 (4%)
Neonatal respiratory distress syndrome	0 (0%)	2 (25%)	0 (0%)	2 (8%)	1 (4%)
Intestinal perforation	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Necrotising enterocolitis neonatal	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)
Neonatal respiratory failure	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Pneumonia	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
Pneumoperitoneum	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Sepsis neonatal	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Anaemia neonatal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Apnoea neonatal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardiac arrest	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Cardio-respiratory arrest	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Gastric perforation	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Hepatic haemorrhage	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Laryngeal injury	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Shock	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Traumatic liver injury	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)

Note: Sorted by total active group.

Summary Table 6.5.1
Adverse Device Effect Events by System Organ Class and Preferred Term
Safety Population

System Organ Class(SOC) Preferred Term	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Any Event	1 (13%)	0 (0%)	1 (13%)	2 (8%)	0 (0%)
Investigations	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Oxygen saturation decreased	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Respiratory, thoracic and mediastinal disorders	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Nasal inflammation	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)

Summary Table 6.6
All-Cause Mortality
Safety Population

	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Mortality	1 (13%)	1 (13%)	0 (0%)	2 (8%)	0 (0%)
Primary Reason for Death:					
NEC and bowel perforation	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
Pneumoperitoneum	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)

Summary Table 7.1.1
Clinical Assessments
Vital Signs - Body Temperature
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
15 Minutes prior to randomization (Baseline)						
Observed	n	8	7	7	22	22
	Mean (SE)	36.7 (0.06)	36.6 (0.17)	36.9 (0.13)	36.7 (0.07)	36.6 (0.07)
	SD	0.17	0.44	0.34	0.34	0.33
	Median	36.8	36.5	36.8	36.8	36.7
	Min, Max	36.4 , 36.9	35.9 , 37.1	36.6 , 37.6	35.9 , 37.6	36 , 37.2
15 Minutes post randomization						
Observed	n	N/A	N/A	N/A	N/A	16
	Mean (SE)	N/A	N/A	N/A	N/A	36.7 (0.08)
	SD	N/A	N/A	N/A	N/A	0.33
	Median	N/A	N/A	N/A	N/A	36.8
	Min, Max	N/A	N/A	N/A	N/A	36 , 37.1
Change from Baseline	n	N/A	N/A	N/A	N/A	16
	Mean (SE)	N/A	N/A	N/A	N/A	0.1 (0.08)
	SD	N/A	N/A	N/A	N/A	0.32
	Median	N/A	N/A	N/A	N/A	0.0
	Min, Max	N/A	N/A	N/A	N/A	-0.6 , 1
1 Hour post randomization						
Observed	n	7	7	6	20	23
	Mean (SE)	36.9 (0.13)	36.7 (0.10)	37.0 (0.11)	36.9 (0.07)	36.6 (0.14)
	SD	0.35	0.25	0.27	0.31	0.68
	Median	36.8	36.7	37.1	36.8	36.7

Summary Table 7.1.1
Clinical Assessments
Vital Signs - Body Temperature
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	36.5 , 37.3	36.2 , 37	36.6 , 37.3	36.2 , 37.3	34.3 , 37.6
Change from Baseline	n	7	7	6	20	21
	Mean (SE)	0.2 (0.15)	0.2 (0.11)	0.1 (0.10)	0.1 (0.07)	0.1 (0.10)
	SD	0.39	0.30	0.25	0.31	0.46
	Median	0.0	0.2	0.0	0.0	0.1
	Min, Max	-0.2 , 0.9	-0.2 , 0.7	-0.3 , 0.4	-0.3 , 0.9	-0.7 , 1.5
3 Hours post randomization Observed	n	8	8	8	24	23
	Mean (SE)	36.9 (0.15)	36.7 (0.11)	36.9 (0.19)	36.8 (0.09)	36.6 (0.10)
	SD	0.43	0.31	0.55	0.43	0.48
	Median	37.0	36.6	36.8	36.8	36.7
	Min, Max	36.3 , 37.3	36.2 , 37.2	36.3 , 38	36.2 , 38	35 , 37.1
Change from Baseline	n	8	7	7	22	22
	Mean (SE)	0.2 (0.16)	0.2 (0.12)	-0.0 (0.27)	0.1 (0.11)	0.1 (0.10)
	SD	0.46	0.32	0.73	0.51	0.47
	Median	0.2	0.3	0.1	0.1	0.1
	Min, Max	-0.5 , 0.9	-0.3 , 0.6	-1 , 1.2	-1 , 1.2	-0.7 , 0.9
6 Hours post randomization Observed	n	8	8	8	24	21
	Mean (SE)	37.0 (0.13)	36.7 (0.13)	36.9 (0.14)	36.9 (0.08)	36.8 (0.10)
	SD	0.37	0.38	0.39	0.39	0.45

Summary Table 7.1.1
Clinical Assessments
Vital Signs - Body Temperature
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	37.0	36.7	37.0	36.9	36.8
	Min, Max	36.5 , 37.8	36.1 , 37.2	36.4 , 37.5	36.1 , 37.8	35.5 , 37.666666667
Change from Baseline	n	8	7	7	22	20
	Mean (SE)	0.3 (0.14)	0.1 (0.24)	0.1 (0.20)	0.2 (0.11)	0.1 (0.14)
	SD	0.41	0.65	0.53	0.52	0.62
	Median	0.3	0.3	0.3	0.3	0.1
	Min, Max	-0.4 , 1	-1 , 0.8	-1 , 0.5	-1 , 1	-1.3 , 1.555555556
12 Hours post randomization Observed	n	8	8	8	24	24
	Mean (SE)	36.9 (0.08)	36.8 (0.12)	36.7 (0.05)	36.8 (0.05)	36.8 (0.14)
	SD	0.22	0.34	0.13	0.24	0.69
	Median	36.9	36.8	36.7	36.8	36.9
	Min, Max	36.6 , 37.2	36.4 , 37.3	36.944444444	36.5 , 36.4 , 37.3	34 , 37.9
Change from Baseline	n	8	7	7	22	22
	Mean (SE)	0.2 (0.09)	0.2 (0.13)	-0.2 (0.13)	0.1 (0.07)	0.3 (0.11)
	SD	0.24	0.35	0.35	0.35	0.52
	Median	0.2	0.3	-0.1	0.2	0.2
	Min, Max	-0.2 , 0.5	-0.5 , 0.5	-0.9 , 0.2	-0.9 , 0.5	-0.5 , 1.9
18 Hours post randomization						

Summary Table 7.1.1
Clinical Assessments
Vital Signs - Body Temperature
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Observed	n	8	8	8	24	23
	Mean (SE)	36.8 (0.08)	36.7 (0.11)	36.9 (0.12)	36.8 (0.06)	36.7 (0.11)
	SD	0.24	0.32	0.34	0.29	0.52
	Median	36.8	36.7	37.0	36.8	36.8
	Min, Max	36.5 , 37.2	36.4 , 37.4	36.3 , 37.3	36.3 , 37.4	34.5 , 37.2
Change from Baseline	n	8	7	7	22	21
	Mean (SE)	0.1 (0.12)	0.2 (0.11)	-0.1 (0.21)	0.1 (0.09)	0.1 (0.07)
	SD	0.33	0.30	0.56	0.41	0.32
	Median	0.0	0.2	-0.1	0.1	0.1
	Min, Max	-0.2 , 0.8	-0.2 , 0.6	-1 , 0.5	-1 , 0.8	-0.4 , 0.8
24 Hours post randomization Observed	n	8	8	8	24	23
	Mean (SE)	36.8 (0.07)	36.8 (0.06)	36.8 (0.17)	36.8 (0.06)	36.8 (0.09)
	SD	0.20	0.18	0.47	0.30	0.41
	Median	36.8	36.8	36.8	36.8	36.9
	Min, Max	36.5 , 37.1	36.5 , 37	37.3333333333	37.3333333333	35.9 , 37.4
Change from Baseline	n	8	7	7	22	21
	Mean (SE)	0.1 (0.08)	0.2 (0.14)	0.1 (0.17)	0.1 (0.07)	0.3 (0.09)
	SD	0.23	0.38	0.46	0.35	0.44
	Median	0.1	0.1	0.2	0.1	0.2
	Min, Max	-0.2 , 0.4	-0.2 , 0.7	-0.8 , 0.6	-0.8 , 0.7	-0.7 , 1.2777777778

Summary Table 7.1.1
Clinical Assessments
Vital Signs - Body Temperature
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
36 Hours post randomization						
Observed	n	8	8	7	23	23
	Mean (SE)	37.1 (0.16)	36.8 (0.10)	36.9 (0.09)	36.9 (0.07)	36.8 (0.07)
	SD	0.45	0.27	0.24	0.35	0.32
	Median	37.0	36.8	37.0	36.9	36.9
	Min, Max	36.6 , 37.8	36.4 , 37.3	36.5 , 37.2	36.4 , 37.8	36.2 , 37.4
Change from Baseline	n	8	7	6	21	21
	Mean (SE)	0.4 (0.15)	0.1 (0.16)	0.1 (0.09)	0.2 (0.08)	0.2 (0.11)
	SD	0.43	0.41	0.22	0.38	0.51
	Median	0.2	0.2	0.2	0.2	0.2
	Min, Max	-0.1 , 0.9	-0.3 , 0.7	-0.2222222222 , 0.3	-0.3 , 0.9	-1 , 1.2
48 Hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	36.8 (0.06)	36.8 (0.08)	36.7 (0.09)	36.8 (0.04)	36.8 (0.05)
	SD	0.17	0.22	0.26	0.22	0.26
	Median	36.9	36.7	36.7	36.7	36.9
	Min, Max	36.6 , 37.1	36.5 , 37.2	36.3 , 37.2	36.3 , 37.2	36 , 37.2
Change from Baseline	n	8	7	7	22	22
	Mean (SE)	0.1 (0.09)	0.2 (0.14)	-0.2 (0.08)	0.0 (0.07)	0.2 (0.08)
	SD	0.24	0.38	0.22	0.33	0.39
	Median	0.1	0.3	-0.2	0.0	0.1

Summary Table 7.1.1
Clinical Assessments
Vital Signs - Body Temperature
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	-0.2 , 0.5	-0.4 , 0.7	-0.444444444 , 0.2	-0.444444444 , 0.7	-0.5 , 1.1
Study Day 3						
Observed	n	8	8	8	24	24
	Mean (SE)	36.8 (0.09)	36.7 (0.12)	36.8 (0.07)	36.8 (0.06)	36.8 (0.08)
	SD	0.27	0.35	0.21	0.27	0.40
	Median	36.8	36.6	36.8	36.7	36.7
	Min, Max	36.6 , 37.4	36.4 , 37.3	36.4 , 37.1	36.4 , 37.4	36 , 37.333333333
Change from Baseline	n	8	7	7	22	22
	Mean (SE)	0.1 (0.15)	0.1 (0.19)	-0.1 (0.15)	0.0 (0.09)	0.1 (0.12)
	SD	0.41	0.50	0.40	0.43	0.58
	Median	0.0	0.1	-0.2	-0.1	0.0
	Min, Max	-0.2 , 1	-0.7 , 0.7	-0.9 , 0.3	-0.9 , 1	-0.7 , 1.3
Study Day 4						
Observed	n	8	8	8	24	24
	Mean (SE)	37.0 (0.12)	36.8 (0.10)	36.7 (0.09)	36.8 (0.06)	36.9 (0.08)
	SD	0.35	0.29	0.26	0.32	0.37
	Median	36.8	36.8	36.7	36.8	37.0
	Min, Max	36.7 , 37.7	36.4 , 37.3	36.3 , 37.111111111	36.3 , 37.7	36.4 , 38
Change from Baseline	n	8	7	7	22	22
	Mean (SE)	0.3 (0.10)	0.2 (0.14)	-0.2 (0.20)	0.1 (0.09)	0.3 (0.10)

Summary Table 7.1.1
Clinical Assessments
Vital Signs - Body Temperature
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	0.29	0.37	0.53	0.44	0.48
	Median	0.3	0.0	-0.1	0.1	0.2
	Min, Max	-0.1 , 0.8	-0.1 , 0.8	-1.3 , 0.3	-1.3 , 0.8	-0.6 , 1.4
Study Day 5						
Observed	n	7	8	8	23	23
	Mean (SE)	37.0 (0.09)	36.6 (0.06)	36.7 (0.10)	36.7 (0.06)	36.8 (0.06)
	SD	0.23	0.18	0.28	0.28	0.27
	Median	37.0	36.6	36.8	36.8	36.8
	Min, Max	36.7 , 37.4	36.3 , 36.8	36.1 , 37	36.1 , 37.4	36.1 , 37.5
Change from Baseline						
	n	7	7	7	21	21
	Mean (SE)	0.3 (0.14)	0.1 (0.14)	-0.1 (0.15)	0.1 (0.09)	0.2 (0.10)
	SD	0.37	0.36	0.39	0.40	0.45
	Median	0.3	0.1	-0.0	0.0	0.1
	Min, Max	-0.1 , 1	-0.5 , 0.6	-1 , 0.2	-1 , 1	-0.7 , 0.9
Study Day 6						
Observed	n	7	7	8	22	24
	Mean (SE)	36.8 (0.14)	36.7 (0.06)	36.8 (0.09)	36.8 (0.06)	36.8 (0.06)
	SD	0.37	0.17	0.26	0.27	0.31
	Median	36.8	36.6	36.8	36.8	36.8
	Min, Max	36.4 , 37.5	36.6 , 37	36.5 , 37.2	36.4 , 37.5	36.1 , 37.44444444

Summary Table 7.1.1
Clinical Assessments
Vital Signs - Body Temperature
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Change from Baseline	n	7	6	7	20	22
	Mean (SE)	0.2 (0.19)	0.1 (0.15)	-0.1 (0.14)	0.0 (0.09)	0.2 (0.09)
	SD	0.50	0.37	0.37	0.42	0.43
	Median	0.1	0.1	-0.1	0.0	0.1
	Min, Max	-0.4 , 1.1	-0.3 , 0.7	-0.8 , 0.4	-0.8 , 1.1	-0.6 , 1.3333333333
Study Day 7 Observed	n	7	8	8	23	24
	Mean (SE)	36.9 (0.05)	36.8 (0.09)	36.9 (0.13)	36.9 (0.06)	36.8 (0.05)
	SD	0.14	0.25	0.38	0.27	0.23
	Median	36.9	36.8	36.8	36.9	36.8
	Min, Max	36.6 , 37	36.5 , 37.1	36.6 , 37.6	36.5 , 37.6	36.5 , 37.666666667
Change from Baseline	n	7	7	7	21	22
	Mean (SE)	0.2 (0.09)	0.2 (0.21)	-0.1 (0.13)	0.1 (0.09)	0.2 (0.09)
	SD	0.23	0.56	0.36	0.40	0.44
	Median	0.2	0.0	0.0	0.1	0.1
	Min, Max	-0.1 , 0.6	-0.6 , 0.9	-0.7 , 0.4444444444	-0.7 , 0.9	-0.4 , 1.5555555556

Summary Table 7.1.2
Clinical Assessments
Vital Signs - Respiration Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
15 Minutes prior to randomization (Baseline)						
Observed	n	7	7	8	22	23
	Mean (SE)	59.7 (5.41)	52.9 (5.93)	51.0 (2.38)	54.4 (2.68)	48.5 (2.73)
	SD	14.31	15.69	6.72	12.59	13.08
	Median	57.0	50.0	49.5	51.5	50.0
	Min, Max	38 , 86	36 , 80	43 , 65	36 , 86	29 , 81
5 Minutes post treatment						
Observed	n	8	8	N/A	16	N/A
	Mean (SE)	43.4 (3.43)	42.9 (3.02)	N/A	43.1 (2.21)	N/A
	SD	9.71	8.54	N/A	8.84	N/A
	Median	44.0	41.0	N/A	41.0	N/A
	Min, Max	25 , 55	28 , 55	N/A	25 , 55	N/A
Change from Baseline	n	7	7	N/A	14	N/A
	Mean (SE)	-15.6 (7.23)	-11.7 (7.99)	N/A	-13.6 (5.21)	N/A
	SD	19.14	21.14	N/A	19.48	N/A
	Median	-11.0	-1.0	N/A	-8.5	N/A
	Min, Max	-46 , 10	-52 , 7	N/A	-52 , 10	N/A
10 Minutes post treatment						
Observed	n	8	8	N/A	16	N/A
	Mean (SE)	44.4 (4.92)	43.4 (5.22)	N/A	43.9 (3.47)	N/A
	SD	13.91	14.75	N/A	13.86	N/A
	Median	42.5	45.0	N/A	42.5	N/A

Summary Table 7.1.2
Clinical Assessments
Vital Signs - Respiration Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	30 , 73	26 , 63	N/A	26 , 73	N/A
Change from Baseline	n	7	7	N/A	14	N/A
	Mean (SE)	-13.3 (8.06)	-11.9 (8.92)	N/A	-12.6 (5.78)	N/A
	SD	21.34	23.59	N/A	21.62	N/A
	Median	-8.0	-11.0	N/A	-10.0	N/A
	Min, Max	-52 , 9	-54 , 20	N/A	-54 , 20	N/A
15 Minutes post treatment Observed	n	8	8	0	16	23
	Mean (SE)	48.5 (3.39)	43.3 (4.85)	0 (0)	45.9 (2.94)	53.2 (2.63)
	SD	9.58	13.72	0	11.75	12.62
	Median	51.0	44.0	0	50.0	54.0
	Min, Max	35 , 60	21 , 64	0 , 0	21 , 64	33 , 78
Change from Baseline	n	7	7	0	14	22
	Mean (SE)	-9.3 (6.32)	-11.1 (8.04)	0 (0)	-10.2 (4.92)	4.5 (3.41)
	SD	16.73	21.27	0	18.41	15.98
	Median	-8.0	-15.0	0	-11.5	4.0
	Min, Max	-35 , 13	-42 , 13	0 , 0	-42 , 13	-20 , 49
20 Minutes post treatment Observed	n	8	8	N/A	16	N/A
	Mean (SE)	55.9 (6.60)	43.6 (4.15)	N/A	49.8 (4.09)	N/A
	SD	18.67	11.75	N/A	16.34	N/A

Summary Table 7.1.2
Clinical Assessments
Vital Signs - Respiration Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	47.5	47.0	N/A	47.0	N/A
	Min, Max	38 , 88	27 , 56	N/A	27 , 88	N/A
Change from Baseline	n	7	7	N/A	14	N/A
	Mean (SE)	-1.3 (6.94)	-11.0 (6.11)	N/A	-6.1 (4.64)	N/A
	SD	18.37	16.16	N/A	17.37	N/A
	Median	-3.0	-13.0	N/A	-11.0	N/A
	Min, Max	-19 , 34	-36 , 11	N/A	-36 , 34	N/A
25 Minutes post treatment Observed	n	8	8	N/A	16	N/A
	Mean (SE)	57.3 (6.16)	41.9 (3.18)	N/A	49.6 (3.89)	N/A
	SD	17.43	8.98	N/A	15.57	N/A
	Median	52.5	39.5	N/A	48.0	N/A
	Min, Max	33 , 78	30 , 54	N/A	30 , 78	N/A
Change from Baseline	n	7	7	N/A	14	N/A
	Mean (SE)	1.0 (8.78)	-12.1 (7.79)	N/A	-5.6 (5.93)	N/A
	SD	23.24	20.62	N/A	22.18	N/A
	Median	-7.0	-3.0	N/A	-5.0	N/A
	Min, Max	-29 , 37	-44 , 9	N/A	-44 , 37	N/A
30 Minutes post treatment Observed	n	8	8	N/A	16	N/A
	Mean (SE)	48.5 (2.28)	54.3 (4.75)	N/A	51.4 (2.65)	N/A

Summary Table 7.1.2
Clinical Assessments
Vital Signs - Respiration Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	6.46	13.45	N/A	10.61	N/A
	Median	47.5	50.0	N/A	47.5	N/A
	Min, Max	36 , 56	42 , 74	N/A	36 , 74	N/A
Change from Baseline	n	7	7	N/A	14	N/A
	Mean (SE)	-9.4 (6.10)	0.3 (9.28)	N/A	-4.6 (5.50)	N/A
	SD	16.14	24.54	N/A	20.58	N/A
	Median	-8.0	6.0	N/A	-7.0	N/A
	Min, Max	-39 , 14	-36 , 31	N/A	-39 , 31	N/A
35 Minutes post treatment Observed	n	N/A	8	N/A	8	N/A
	Mean (SE)	N/A	45.5 (2.96)	N/A	45.5 (2.96)	N/A
	SD	N/A	8.38	N/A	8.38	N/A
	Median	N/A	45.5	N/A	45.5	N/A
	Min, Max	N/A	35 , 59	N/A	35 , 59	N/A
Change from Baseline	n	N/A	7	N/A	7	N/A
	Mean (SE)	N/A	-7.6 (8.52)	N/A	-7.6 (8.52)	N/A
	SD	N/A	22.53	N/A	22.53	N/A
	Median	N/A	4.0	N/A	4.0	N/A
	Min, Max	N/A	-45 , 16	N/A	-45 , 16	N/A
40 Minutes post treatment Observed	n	N/A	8	N/A	8	N/A

Summary Table 7.1.2
Clinical Assessments
Vital Signs - Respiration Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	N/A	56.4 (4.78)	N/A	56.4 (4.78)	N/A
	SD	N/A	13.53	N/A	13.53	N/A
	Median	N/A	57.5	N/A	57.5	N/A
	Min, Max	N/A	38 , 76	N/A	38 , 76	N/A
Change from Baseline	n	N/A	7	N/A	7	N/A
	Mean (SE)	N/A	4.4 (6.69)	N/A	4.4 (6.69)	N/A
	SD	N/A	17.70	N/A	17.70	N/A
	Median	N/A	8.0	N/A	8.0	N/A
	Min, Max	N/A	-24 , 26	N/A	-24 , 26	N/A
45 Minutes post treatment Observed	n	N/A	8	N/A	8	N/A
	Mean (SE)	N/A	48.4 (4.80)	N/A	48.4 (4.80)	N/A
	SD	N/A	13.57	N/A	13.57	N/A
	Median	N/A	47.5	N/A	47.5	N/A
	Min, Max	N/A	28 , 72	N/A	28 , 72	N/A
Change from Baseline	n	N/A	7	N/A	7	N/A
	Mean (SE)	N/A	-4.0 (8.65)	N/A	-4.0 (8.65)	N/A
	SD	N/A	22.90	N/A	22.90	N/A
	Median	N/A	3.0	N/A	3.0	N/A
	Min, Max	N/A	-40 , 29	N/A	-40 , 29	N/A
1 Hour post randomization						

Summary Table 7.1.2
Clinical Assessments
Vital Signs - Respiration Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Observed	n	8	8	6	22	24
	Mean (SE)	55.4 (5.84)	52.5 (5.02)	58.3 (8.40)	55.1 (3.47)	50.0 (3.65)
	SD	16.53	14.20	20.58	16.27	17.88
	Median	56.0	45.5	55.5	52.0	44.5
	Min, Max	36 , 80	38 , 75	33 , 88	33 , 88	28 , 120
Change from Baseline	n	7	7	6	20	23
	Mean (SE)	-2.0 (10.82)	0.9 (3.64)	7.3 (9.52)	1.8 (4.72)	1.3 (4.26)
	SD	28.63	9.63	23.31	21.13	20.42
	Median	-1.0	0.0	5.0	0.5	1.0
	Min, Max	-46 , 42	-12 , 15	-23 , 40	-46 , 42	-28 , 80
3 Hours post randomization Observed	n	8	8	8	24	24
	Mean (SE)	58.0 (5.32)	56.4 (5.09)	54.1 (3.63)	56.2 (2.64)	56.1 (3.08)
	SD	15.05	14.39	10.26	12.91	15.10
	Median	56.0	59.0	55.0	57.0	55.5
	Min, Max	35 , 86	34 , 77	36 , 68	34 , 86	34 , 81
Change from Baseline	n	7	7	8	22	23
	Mean (SE)	1.6 (7.74)	2.4 (5.16)	3.1 (4.45)	2.4 (3.21)	7.7 (3.26)
	SD	20.47	13.66	12.60	15.04	15.63
	Median	2.0	-2.0	5.5	2.5	1.0
	Min, Max	-39 , 22	-13 , 23	-16 , 20	-39 , 23	-8 , 48

Summary Table 7.1.2
Clinical Assessments
Vital Signs - Respiration Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
6 Hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	55.4 (5.62)	57.8 (3.67)	56.0 (4.78)	56.4 (2.63)	54.4 (2.90)
	SD	15.90	10.38	13.52	12.90	14.19
	Median	53.5	60.0	54.0	58.5	53.0
	Min, Max	39 , 89	41 , 74	44 , 85	39 , 89	30 , 85
Change from Baseline	n	7	7	8	22	23
	Mean (SE)	-9.1 (7.63)	2.6 (8.07)	5.0 (6.11)	-0.3 (4.19)	5.7 (3.70)
	SD	20.19	21.35	17.30	19.64	17.76
	Median	-7.0	7.0	3.0	-1.5	6.0
	Min, Max	-47 , 21	-35 , 26	-21 , 39	-47 , 39	-33 , 45
12 Hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	59.1 (5.84)	52.6 (6.43)	57.6 (5.51)	56.5 (3.33)	49.2 (3.73)
	SD	16.51	18.19	15.59	16.30	18.27
	Median	62.0	57.0	61.0	59.0	50.0
	Min, Max	25 , 76	21 , 76	34 , 79	21 , 79	16 , 98
Change from Baseline	n	7	7	8	22	23
	Mean (SE)	-3.0 (11.21)	-3.6 (5.85)	6.6 (5.48)	0.3 (4.39)	0.6 (3.60)
	SD	29.67	15.49	15.51	20.59	17.26
	Median	0.0	-11.0	9.5	0.5	-4.0
	Min, Max	-61 , 38	-21 , 24	-18 , 30	-61 , 38	-27 , 36

Summary Table 7.1.2
Clinical Assessments
Vital Signs - Respiration Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
18 Hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	59.9 (4.60)	54.0 (3.85)	61.0 (6.42)	58.3 (2.87)	53.7 (3.09)
	SD	13.02	10.90	18.16	14.07	15.12
	Median	59.5	49.5	65.5	59.0	50.0
	Min, Max	44 , 84	40 , 67	40 , 86	40 , 86	20 , 82
Change from Baseline	n	7	7	8	22	23
	Mean (SE)	-1.1 (8.08)	-0.7 (6.68)	10.0 (7.43)	3.0 (4.24)	4.9 (3.79)
	SD	21.38	17.66	21.02	19.90	18.20
	Median	6.0	-1.0	12.0	3.0	8.0
	Min, Max	-42 , 20	-34 , 23	-24 , 40	-42 , 40	-39 , 37
24 Hours post randomization						
Observed	n	7	8	8	23	23
	Mean (SE)	54.9 (6.62)	51.8 (4.06)	63.0 (5.78)	56.6 (3.20)	54.1 (3.16)
	SD	17.52	11.49	16.34	15.33	15.18
	Median	62.0	51.5	62.5	58.0	54.0
	Min, Max	24 , 70	33 , 70	35 , 85	24 , 85	24 , 91
Change from Baseline	n	6	7	8	21	23
	Mean (SE)	-9.7 (7.56)	-2.4 (8.06)	12.0 (7.68)	1.0 (4.75)	5.6 (4.59)
	SD	18.51	21.31	21.73	21.77	22.03
	Median	-11.5	7.0	12.0	8.0	5.0

Summary Table 7.1.2
Clinical Assessments
Vital Signs - Respiration Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	-33 , 14	-34 , 27	-30 , 39	-34 , 39	-45 , 58
36 Hours post randomization						
Observed	n	7	8	8	23	23
	Mean (SE)	64.7 (3.94)	57.1 (5.78)	44.4 (4.11)	55.0 (3.17)	51.5 (3.17)
	SD	10.44	16.35	11.64	15.18	15.19
	Median	67.0	56.0	41.0	60.0	50.0
	Min, Max	43 , 74	37 , 87	33 , 64	33 , 87	20 , 82
Change from Baseline	n	6	7	8	21	23
	Mean (SE)	-0.2 (5.57)	3.6 (9.51)	-6.6 (5.10)	-1.4 (3.96)	3.0 (4.05)
	SD	13.64	25.16	14.42	18.15	19.40
	Median	5.5	7.0	-11.0	0.0	6.0
	Min, Max	-22 , 11	-30 , 44	-30 , 15	-30 , 44	-35 , 42
48 Hours post randomization						
Observed	n	7	8	8	23	22
	Mean (SE)	65.0 (4.49)	61.8 (4.74)	65.5 (5.16)	64.0 (2.69)	45.8 (3.46)
	SD	11.87	13.41	14.59	12.90	16.25
	Median	62.0	57.5	62.5	60.0	43.5
	Min, Max	48 , 84	49 , 85	47 , 88	47 , 88	15 , 72
Change from Baseline	n	6	7	8	21	22
	Mean (SE)	2.2 (3.03)	6.3 (9.08)	14.5 (6.60)	8.2 (4.01)	-2.6 (4.23)
	SD	7.41	24.01	18.68	18.35	19.86

Summary Table 7.1.2
Clinical Assessments
Vital Signs - Respiration Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	2.5	10.0	13.0	7.0	0.5
	Min, Max	-9 , 12	-31 , 42	-8 , 40	-31 , 42	-39 , 32
Study Day 3						
Observed	n	7	8	8	23	22
	Mean (SE)	56.1 (4.45)	51.4 (7.91)	55.0 (4.87)	54.1 (3.37)	49.0 (3.28)
	SD	11.78	22.36	13.78	16.18	15.39
	Median	57.0	58.5	57.5	57.0	48.0
	Min, Max	44 , 79	0 , 72	30 , 77	0 , 79	16 , 88
Change from Baseline	n	6	7	8	21	22
	Mean (SE)	-6.3 (6.89)	-3.0 (9.56)	4.0 (5.79)	-1.3 (4.24)	0.1 (3.86)
	SD	16.87	25.29	16.38	19.41	18.09
	Median	-4.5	5.0	8.5	3.0	3.5
	Min, Max	-29 , 17	-42 , 21	-22 , 29	-42 , 29	-38 , 34
Study Day 4						
Observed	n	7	8	8	23	21
	Mean (SE)	65.9 (5.84)	63.5 (17.40)	52.4 (5.39)	60.3 (6.42)	49.3 (2.94)
	SD	15.46	49.23	15.25	30.77	13.48
	Median	67.0	56.0	52.5	57.0	50.0
	Min, Max	40 , 86	0 , 171	38 , 82	0 , 171	27 , 72
Change from Baseline	n	6	7	8	21	21
	Mean (SE)	1.8 (7.85)	-4.7 (8.97)	1.4 (6.01)	-0.5 (4.21)	0.5 (3.82)

Summary Table 7.1.2
Clinical Assessments
Vital Signs - Respiration Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	19.24	23.74	16.99	19.28	17.52
	Median	-1.0	-4.0	-7.0	-4.0	0.0
	Min, Max	-19 , 25	-42 , 35	-14 , 33	-42 , 35	-39 , 40
Study Day 5						
Observed	n	5	8	8	21	21
	Mean (SE)	48.8 (5.49)	52.3 (7.85)	43.5 (5.30)	48.1 (3.76)	48.0 (2.14)
	SD	12.28	22.21	15.00	17.23	9.81
	Median	51.0	58.0	46.0	53.0	50.0
	Min, Max	32 , 64	0 , 73	19 , 65	0 , 73	23 , 64
Change from Baseline						
	n	4	7	8	19	21
	Mean (SE)	-12.5 (8.29)	-2.1 (8.03)	-7.5 (5.79)	-6.6 (4.08)	-0.9 (3.45)
	SD	16.58	21.24	16.38	17.79	15.82
	Median	-7.5	-2.0	-10.0	-7.0	0.0
	Min, Max	-35 , 0	-42 , 22	-29 , 16	-42 , 22	-32 , 24
Study Day 6						
Observed	n	5	8	8	21	21
	Mean (SE)	44.2 (8.73)	46.1 (7.49)	54.8 (6.82)	49.0 (4.29)	45.4 (2.50)
	SD	19.52	21.18	19.30	19.64	11.45
	Median	50.0	49.5	55.5	50.0	43.0
	Min, Max	12 , 64	0 , 72	28 , 86	0 , 86	23 , 64
Change from Baseline						
	n	4	7	8	19	21

Summary Table 7.1.2
Clinical Assessments
Vital Signs - Respiration Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	-13.3 (7.50)	-5.7 (7.79)	3.8 (8.06)	-3.3 (4.75)	-3.5 (4.09)
	SD	15.00	20.62	22.81	20.69	18.73
	Median	-9.5	2.0	-1.0	-4.0	-2.0
	Min, Max	-34 , 0	-42 , 17	-27 , 43	-42 , 43	-49 , 28
Study Day 7 Observed	n	5	8	8	21	22
	Mean (SE)	52.8 (5.67)	49.3 (8.71)	51.8 (5.28)	51.0 (3.93)	45.5 (2.23)
	SD	12.68	24.64	14.94	18.03	10.44
	Median	53.0	52.0	54.0	53.0	46.0
	Min, Max	37 , 68	0 , 80	29 , 76	0 , 80	25 , 73
Change from Baseline	n	4	7	8	19	22
	Mean (SE)	-8.8 (5.45)	-6.6 (8.74)	0.8 (7.36)	-3.9 (4.50)	-3.4 (3.30)
	SD	10.90	23.12	20.83	19.61	15.49
	Median	-12.0	0.0	5.0	1.0	-4.5
	Min, Max	-18 , 7	-42 , 17	-32 , 33	-42 , 33	-39 , 30

Summary Table 7.1.3
Clinical Assessments
Vital Signs - Heart Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
15 Minutes prior to randomization (Baseline)						
Observed	n	8	7	8	23	24
	Mean (SE)	156.4 (4.46)	147.3 (3.31)	149.9 (4.39)	151.3 (2.43)	151.3 (2.95)
	SD	12.63	8.77	12.41	11.66	14.46
	Median	158.0	149.0	150.5	151.0	147.5
	Min, Max	130 , 170	131 , 159	126 , 166	126 , 170	126 , 170
5 Minutes post treatment						
Observed	n	8	8	N/A	16	N/A
	Mean (SE)	155.6 (5.10)	151.4 (5.13)	N/A	153.5 (3.54)	N/A
	SD	14.41	14.51	N/A	14.14	N/A
	Median	156.5	149.0	N/A	154.0	N/A
	Min, Max	125 , 174	133 , 180	N/A	125 , 180	N/A
Change from Baseline	n	8	7	N/A	15	N/A
	Mean (SE)	-0.8 (4.01)	4.6 (4.31)	N/A	1.7 (2.92)	N/A
	SD	11.34	11.41	N/A	11.30	N/A
	Median	-1.0	2.0	N/A	2.0	N/A
	Min, Max	-16 , 19	-13 , 21	N/A	-16 , 21	N/A
10 Minutes post treatment						
Observed	n	8	8	N/A	16	N/A
	Mean (SE)	157.3 (5.34)	142.6 (9.66)	N/A	149.9 (5.66)	N/A
	SD	15.12	27.33	N/A	22.63	N/A
	Median	161.0	150.0	N/A	153.0	N/A

Summary Table 7.1.3
Clinical Assessments
Vital Signs - Heart Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	126 , 174	80 , 171	N/A	80 , 174	N/A
Change from Baseline	n	8	7	N/A	15	N/A
	Mean (SE)	0.9 (3.71)	-5.6 (11.37)	N/A	-2.1 (5.50)	N/A
	SD	10.48	30.08	N/A	21.30	N/A
	Median	3.5	4.0	N/A	4.0	N/A
	Min, Max	-16 , 14	-73 , 12	N/A	-73 , 14	N/A
15 Minutes post treatment Observed	n	8	8	0	16	23
	Mean (SE)	153.6 (6.38)	147.5 (4.02)	0 (0)	150.6 (3.73)	149.7 (2.66)
	SD	18.04	11.38	0	14.91	12.76
	Median	156.0	147.5	0	150.0	148.0
	Min, Max	115 , 177	134 , 169	0 , 0	115 , 177	129 , 175
Change from Baseline	n	8	7	0	15	23
	Mean (SE)	-2.8 (4.86)	0.1 (3.94)	0 (0)	-1.4 (3.09)	-2.3 (2.21)
	SD	13.75	10.43	0	11.97	10.60
	Median	-1.5	1.0	0	1.0	-3.0
	Min, Max	-18 , 22	-19 , 11	0 , 0	-19 , 22	-25 , 17
20 Minutes post treatment Observed	n	8	8	N/A	16	N/A
	Mean (SE)	155.3 (5.14)	149.1 (3.48)	N/A	152.2 (3.10)	N/A
	SD	14.54	9.85	N/A	12.41	N/A

Summary Table 7.1.3
Clinical Assessments
Vital Signs - Heart Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	155.5	149.0	N/A	151.5	N/A
	Min, Max	126 , 175	135 , 168	N/A	126 , 175	N/A
Change from Baseline	n	8	7	N/A	15	N/A
	Mean (SE)	-1.1 (4.16)	1.7 (2.25)	N/A	0.2 (2.40)	N/A
	SD	11.78	5.96	N/A	9.31	N/A
	Median	-2.5	-1.0	N/A	-1.0	N/A
	Min, Max	-15 , 20	-4 , 10	N/A	-15 , 20	N/A
25 Minutes post treatment Observed	n	8	8	N/A	16	N/A
	Mean (SE)	155.5 (5.38)	149.3 (3.33)	N/A	152.4 (3.16)	N/A
	SD	15.20	9.41	N/A	12.63	N/A
	Median	155.0	146.0	N/A	152.5	N/A
	Min, Max	126 , 177	140 , 169	N/A	126 , 177	N/A
Change from Baseline	n	8	7	N/A	15	N/A
	Mean (SE)	-0.9 (4.54)	2.4 (2.42)	N/A	0.7 (2.62)	N/A
	SD	12.84	6.40	N/A	10.15	N/A
	Median	-2.0	1.0	N/A	0.0	N/A
	Min, Max	-15 , 22	-4 , 10	N/A	-15 , 22	N/A
30 Minutes post treatment Observed	n	8	8	N/A	16	N/A
	Mean (SE)	154.9 (4.73)	149.9 (3.55)	N/A	152.4 (2.93)	N/A

Summary Table 7.1.3
Clinical Assessments
Vital Signs - Heart Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	13.39	10.05	N/A	11.72	N/A
	Median	157.5	152.0	N/A	154.0	N/A
	Min, Max	125 , 168	133 , 164	N/A	125 , 168	N/A
Change from Baseline	n	8	7	N/A	15	N/A
	Mean (SE)	-1.5 (3.53)	2.0 (1.88)	N/A	0.1 (2.06)	N/A
	SD	9.99	4.97	N/A	7.98	N/A
	Median	0.0	2.0	N/A	2.0	N/A
	Min, Max	-16 , 13	-6 , 10	N/A	-16 , 13	N/A
35 Minutes post treatment						
Observed	n	N/A	8	N/A	8	N/A
	Mean (SE)	N/A	151.4 (4.06)	N/A	151.4 (4.06)	N/A
	SD	N/A	11.49	N/A	11.49	N/A
	Median	N/A	152.0	N/A	152.0	N/A
	Min, Max	N/A	136 , 167	N/A	136 , 167	N/A
Change from Baseline	n	N/A	7	N/A	7	N/A
	Mean (SE)	N/A	3.1 (2.56)	N/A	3.1 (2.56)	N/A
	SD	N/A	6.77	N/A	6.77	N/A
	Median	N/A	5.0	N/A	5.0	N/A
	Min, Max	N/A	-8 , 10	N/A	-8 , 10	N/A
40 Minutes post treatment						
Observed	n	N/A	8	N/A	8	N/A

Summary Table 7.1.3
Clinical Assessments
Vital Signs - Heart Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	N/A	149.3 (3.18)	N/A	149.3 (3.18)	N/A
	SD	N/A	8.99	N/A	8.99	N/A
	Median	N/A	149.5	N/A	149.5	N/A
	Min, Max	N/A	137 , 163	N/A	137 , 163	N/A
Change from Baseline	n	N/A	7	N/A	7	N/A
	Mean (SE)	N/A	1.0 (2.01)	N/A	1.0 (2.01)	N/A
	SD	N/A	5.32	N/A	5.32	N/A
	Median	N/A	2.0	N/A	2.0	N/A
	Min, Max	N/A	-5 , 8	N/A	-5 , 8	N/A
45 Minutes post treatment Observed	n	N/A	8	N/A	8	N/A
	Mean (SE)	N/A	150.8 (2.02)	N/A	150.8 (2.02)	N/A
	SD	N/A	5.73	N/A	5.73	N/A
	Median	N/A	151.0	N/A	151.0	N/A
	Min, Max	N/A	144 , 158	N/A	144 , 158	N/A
Change from Baseline	n	N/A	7	N/A	7	N/A
	Mean (SE)	N/A	2.7 (2.35)	N/A	2.7 (2.35)	N/A
	SD	N/A	6.21	N/A	6.21	N/A
	Median	N/A	2.0	N/A	2.0	N/A
	Min, Max	N/A	-6 , 13	N/A	-6 , 13	N/A
1 Hour post randomization						

Summary Table 7.1.3
Clinical Assessments
Vital Signs - Heart Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Observed	n	8	8	6	22	23
	Mean (SE)	154.4 (5.38)	148.5 (3.39)	157.5 (1.86)	153.1 (2.40)	153.2 (2.58)
	SD	15.21	9.58	4.55	11.26	12.36
	Median	157.5	147.5	159.5	155.5	155.0
	Min, Max	123 , 172	133 , 162	150 , 162	123 , 172	123 , 169
Change from Baseline	n	8	7	6	21	23
	Mean (SE)	-2.0 (3.62)	0.4 (3.09)	3.7 (3.13)	0.4 (1.91)	1.0 (1.98)
	SD	10.23	8.18	7.66	8.77	9.51
	Median	-6.5	2.0	3.0	0.0	2.0
	Min, Max	-12 , 17	-12 , 14	-4 , 15	-12 , 17	-15 , 20
3 Hours post randomization Observed	n	8	8	8	24	24
	Mean (SE)	153.4 (4.75)	146.5 (2.63)	152.3 (4.80)	150.7 (2.39)	146.8 (2.46)
	SD	13.45	7.45	13.58	11.73	12.06
	Median	156.5	146.5	155.5	154.0	147.5
	Min, Max	123 , 168	136 , 156	131 , 167	123 , 168	114 , 165
Change from Baseline	n	8	7	8	23	24
	Mean (SE)	-3.0 (3.01)	-1.9 (2.98)	2.4 (4.48)	-0.8 (2.05)	-4.5 (3.49)
	SD	8.52	7.88	12.67	9.84	17.12
	Median	-4.5	-3.0	4.5	-2.0	-2.5
	Min, Max	-11 , 13	-11 , 7	-15 , 18	-15 , 18	-56 , 26

Summary Table 7.1.3
Clinical Assessments
Vital Signs - Heart Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
6 Hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	150.6 (5.14)	150.4 (2.31)	149.9 (3.81)	150.3 (2.17)	149.5 (1.88)
	SD	14.55	6.55	10.76	10.62	9.19
	Median	153.0	149.0	148.0	151.0	151.5
	Min, Max	118 , 167	144 , 159	134 , 171	118 , 171	133 , 164
Change from Baseline	n	8	7	8	23	24
	Mean (SE)	-5.8 (3.83)	2.7 (3.07)	0.0 (4.40)	-1.2 (2.26)	-1.8 (2.93)
	SD	10.85	8.12	12.44	10.84	14.38
	Median	-6.5	0.0	0.5	-4.0	-2.0
	Min, Max	-19 , 12	-5 , 14	-17 , 18	-19 , 18	-36 , 26
12 Hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	144.1 (2.17)	148.5 (2.60)	152.5 (3.88)	148.4 (1.79)	142.7 (2.80)
	SD	6.15	7.35	10.97	8.76	13.69
	Median	143.5	148.0	151.5	147.5	145.0
	Min, Max	134 , 155	138 , 159	136 , 169	134 , 169	92 , 165
Change from Baseline	n	8	7	8	23	24
	Mean (SE)	-12.3 (3.30)	-0.1 (2.66)	2.6 (3.06)	-3.4 (2.19)	-8.6 (3.70)
	SD	9.35	7.03	8.65	10.50	18.13
	Median	-10.5	0.0	2.0	-3.0	-5.0
	Min, Max	-25 , 4	-13 , 7	-12 , 15	-25 , 15	-69 , 18

Summary Table 7.1.3
Clinical Assessments
Vital Signs - Heart Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
18 Hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	144.9 (4.79)	152.3 (3.56)	145.6 (4.27)	147.6 (2.44)	145.8 (2.58)
	SD	13.55	10.07	12.07	11.94	12.63
	Median	147.5	149.0	148.5	149.0	143.5
	Min, Max	122 , 162	140 , 166	125 , 162	122 , 166	120 , 172
Change from Baseline	n	8	7	8	23	24
	Mean (SE)	-11.5 (3.76)	3.4 (3.50)	-4.3 (4.22)	-4.4 (2.49)	-5.5 (2.87)
	SD	10.64	9.27	11.95	11.95	14.07
	Median	-8.0	1.0	-4.5	-5.0	-7.5
	Min, Max	-28 , 2	-7 , 13	-19 , 13	-28 , 13	-30 , 24
24 Hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	146.4 (3.84)	146.4 (2.26)	148.9 (4.76)	147.2 (2.09)	149.3 (2.33)
	SD	10.86	6.39	13.47	10.25	11.43
	Median	144.0	144.5	151.0	145.5	147.5
	Min, Max	135 , 170	140 , 159	132 , 165	132 , 170	129 , 180
Change from Baseline	n	8	7	8	23	24
	Mean (SE)	-10.0 (4.43)	-0.9 (4.45)	-1.0 (4.96)	-4.1 (2.72)	-2.0 (3.03)
	SD	12.54	11.77	14.03	13.03	14.86
	Median	-12.0	5.0	0.5	-7.0	-2.5

Summary Table 7.1.3
Clinical Assessments
Vital Signs - Heart Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	-26 , 11	-19 , 11	-25 , 15	-26 , 15	-29 , 38
36 Hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	148.8 (3.84)	160.1 (5.74)	156.8 (4.25)	155.2 (2.77)	149.7 (2.69)
	SD	10.87	16.23	12.02	13.56	13.18
	Median	146.0	157.0	156.5	156.0	149.0
	Min, Max	133 , 166	134 , 189	141 , 179	133 , 189	123 , 172
Change from Baseline						
	n	8	7	8	23	24
	Mean (SE)	-7.6 (2.80)	12.0 (5.38)	6.9 (4.39)	3.4 (2.92)	-1.6 (3.69)
	SD	7.93	14.22	12.40	14.01	18.09
	Median	-10.5	7.0	6.0	3.0	-1.5
	Min, Max	-15 , 3	-2 , 36	-8 , 29	-15 , 36	-37 , 41
48 Hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	159.9 (4.67)	152.1 (5.19)	157.8 (3.18)	156.6 (2.54)	155.3 (3.61)
	SD	13.20	14.69	9.00	12.43	17.68
	Median	157.5	153.0	158.0	154.5	155.5
	Min, Max	142 , 179	126 , 179	147 , 169	126 , 179	100 , 189
Change from Baseline						
	n	8	7	8	23	24
	Mean (SE)	3.5 (5.22)	1.0 (3.09)	7.9 (4.09)	4.3 (2.45)	4.0 (3.95)
	SD	14.76	8.16	11.57	11.77	19.33

Summary Table 7.1.3
Clinical Assessments
Vital Signs - Heart Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	0.5	-1.0	9.5	4.0	6.5
	Min, Max	-13 , 24	-9 , 13	-15 , 21	-15 , 24	-60 , 42
Study Day 3						
Observed	n	8	8	8	24	24
	Mean (SE)	152.3 (3.14)	155.5 (3.81)	158.4 (4.12)	155.4 (2.11)	150.7 (3.08)
	SD	8.89	10.77	11.65	10.35	15.09
	Median	151.5	154.0	157.5	154.0	150.5
	Min, Max	142 , 168	134 , 168	141 , 178	134 , 178	112 , 188
Change from Baseline	n	8	7	8	23	24
	Mean (SE)	-4.1 (5.58)	6.7 (2.55)	8.5 (4.81)	3.6 (2.83)	-0.6 (3.04)
	SD	15.78	6.75	13.61	13.57	14.89
	Median	-6.0	6.0	6.0	3.0	-1.0
	Min, Max	-21 , 24	-5 , 15	-7 , 28	-21 , 28	-24 , 34
Study Day 4						
Observed	n	8	8	8	24	24
	Mean (SE)	163.8 (4.30)	149.1 (11.84)	156.3 (4.34)	156.4 (4.42)	156.6 (2.53)
	SD	12.15	33.49	12.28	21.66	12.40
	Median	166.0	160.5	157.0	160.5	157.5
	Min, Max	146 , 179	70 , 178	137 , 177	70 , 179	130 , 190
Change from Baseline	n	8	7	8	23	24
	Mean (SE)	7.4 (3.75)	13.1 (4.15)	6.4 (4.65)	8.8 (2.40)	5.3 (2.94)

Summary Table 7.1.3
Clinical Assessments
Vital Signs - Heart Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	10.61	10.99	13.16	11.52	14.39
	Median	11.5	14.0	4.0	11.0	0.5
	Min, Max	-13 , 18	0 , 33	-14 , 27	-14 , 33	-22 , 43
Study Day 5						
Observed	n	7	8	8	23	24
	Mean (SE)	156.4 (4.34)	161.0 (2.49)	157.8 (1.69)	158.5 (1.65)	155.4 (2.95)
	SD	11.49	7.03	4.77	7.93	14.43
	Median	159.0	163.0	158.0	159.0	155.0
	Min, Max	136 , 171	152 , 169	150 , 164	136 , 171	121 , 181
Change from Baseline						
	n	7	7	8	22	24
	Mean (SE)	0.1 (3.37)	13.0 (3.23)	7.9 (4.20)	7.0 (2.32)	4.1 (3.54)
	SD	8.91	8.54	11.87	10.89	17.36
	Median	0.0	15.0	4.0	5.5	3.0
	Min, Max	-10 , 16	-4 , 21	-3 , 30	-10 , 30	-27 , 39
Study Day 6						
Observed	n	7	8	8	23	24
	Mean (SE)	162.4 (3.98)	152.8 (6.66)	168.6 (5.67)	161.2 (3.44)	158.8 (2.91)
	SD	10.53	18.84	16.04	16.48	14.24
	Median	166.0	149.5	163.5	164.0	158.0
	Min, Max	146 , 172	126 , 179	150 , 193	126 , 193	132 , 190
Change from Baseline						
	n	7	7	8	22	24

Summary Table 7.1.3
Clinical Assessments
Vital Signs - Heart Rate
Safety Population

Time Point Analysis	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	6.1 (3.38)	9.3 (5.31)	18.8 (4.99)	11.7 (2.83)	7.5 (3.69)
	SD	8.93	14.04	14.11	13.29	18.05
	Median	6.0	8.0	18.5	9.5	7.0
	Min, Max	-6 , 19	-8 , 30	0 , 43	-8 , 43	-33 , 47
Study Day 7 Observed	n	7	8	8	23	24
	Mean (SE)	167.1 (3.78)	162.4 (5.32)	170.9 (4.30)	166.8 (2.64)	160.6 (2.08)
	SD	10.01	15.05	12.17	12.64	10.18
	Median	168.0	167.0	169.0	168.0	160.0
	Min, Max	156 , 185	139 , 180	157 , 197	139 , 197	141 , 180
Change from Baseline	n	7	7	8	22	24
	Mean (SE)	10.9 (4.23)	13.7 (4.98)	21.0 (5.79)	15.5 (2.98)	9.3 (3.19)
	SD	11.20	13.17	16.39	13.95	15.63
	Median	9.0	18.0	22.0	18.5	12.0
	Min, Max	-3 , 26	-10 , 31	-9 , 47	-10 , 47	-29 , 33

Summary Table 7.2
Clinical Assessments
Serum Electrolytes
Safety Population

Type	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Sodium	n	8	8	8	24	24
	Mean (SE)	139.0 (2.25)	141.8 (2.37)	141.5 (1.18)	140.8 (1.14)	140.4 (1.21)
	SD	6.37	6.69	3.34	5.57	5.93
	Median	139.0	144.0	142.0	142.0	139.5
	Min, Max	128 , 148	128 , 149	136 , 146	128 , 149	130 , 150
Chloride	n	8	8	8	24	23
	Mean (SE)	106.5 (1.24)	110.3 (2.50)	107.8 (1.08)	108.2 (1.01)	109.7 (1.81)
	SD	3.51	7.07	3.06	4.95	8.68
	Median	106.5	112.5	108.0	108.5	109.0
	Min, Max	102 , 112	94 , 118	103 , 112	94 , 118	98 , 141
Potassium	n	8	8	7	23	24
	Mean (SE)	4.23 (0.103)	4.08 (0.323)	4.11 (0.378)	4.14 (0.157)	4.58 (0.200)
	SD	0.292	0.913	1.001	0.755	0.981
	Median	4.15	3.95	4.10	4.10	4.50
	Min, Max	4 , 5	3 , 6	3 , 6	3 , 6	3 , 7
Total CO ₂	n	8	8	5	21	21
	Mean (SE)	21.0 (1.21)	21.6 (0.61)	27.9 (6.77)	22.9 (1.68)	22.3 (1.25)
	SD	3.42	1.72	15.15	7.71	5.72
	Median	21.5	21.2	21.7	21.3	22.0
	Min, Max	13 , 24	19 , 24	20 , 55	13 , 55	15 , 44

Summary Table 7.3
Clinical Assessments
Gastric Liquid Volume and Defecation
Safety Population

	Statistics	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
30 Minutes Post Dosing (ml)	n	8	8	7	23	N/A
	Mean (SE)	0.32 (0.277)	0.94 (0.467)	0.76 (0.558)	0.67 (0.248)	N/A
	SD	0.784	1.321	1.476	1.191	N/A
	Median	0.00	0.75	0.00	0.00	N/A
	Min, Max	0, 2	0, 4	0, 4	0, 4	N/A
30 Minutes Post Dosing (ml) - Repeat Dose	n	4	7	5	16	N/A
	Mean (SE)	0.00 (0.000)	0.99 (0.683)	0.64 (0.591)	0.63 (0.348)	N/A
	SD	0.000	1.808	1.322	1.392	N/A
	Median	0.00	0.40	0.00	0.00	N/A
	Min, Max	0, 0	0, 5	0, 3	0, 5	N/A
Number of Stools	0	3 (38%)	5 (63%)	5 (63%)	13 (54%)	11 (46%)
	1	4 (50%)	1 (13%)	0 (0%)	5 (21%)	4 (17%)
	2	1 (13%)	1 (13%)	1 (13%)	3 (13%)	5 (21%)
	3	0 (0%)	1 (13%)	0 (0%)	1 (4%)	2 (8%)
	4	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
	5	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
	n	8	8	8	24	24
	Mean (SE)	0.8 (0.25)	0.8 (0.41)	1.4 (0.73)	1.0 (0.29)	1.2 (0.29)
	SD	0.71	1.16	2.07	1.40	1.44
	Median	1.0	0.0	0.0	0.0	1.0
Min, Max	0, 2	0, 3	0, 5	0, 5	0, 5	

Summary Table 7.4.1
Clinical Assessments
Physical Examinations Findings
Safety Population

Time Point	Finding	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Screening Period	Subjects with at least 1 PE Finding	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
	Abdominal	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
	Normal	5 (63%)	8 (100%)	8 (100%)	21 (88%)	22 (92%)
	Abnormal	3 (38%)	0 (0%)	0 (0%)	3 (13%)	2 (8%)
	Cardiac	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
	Normal	7 (88%)	8 (100%)	8 (100%)	23 (96%)	24 (100%)
	Abnormal	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
	Extremities	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
	Normal	8 (100%)	8 (100%)	7 (88%)	23 (96%)	20 (83%)
	Abnormal	0 (0%)	0 (0%)	1 (13%)	1 (4%)	4 (17%)
	Genitalia and Perineum	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
	Normal	8 (100%)	8 (100%)	7 (88%)	23 (96%)	20 (83%)
	Abnormal	0 (0%)	0 (0%)	1 (13%)	1 (4%)	4 (17%)
	General Appearance (Skin)	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
	Not Done	1 (13%)	0 (0%)	0 (0%)	1 (4%)	0 (0%)
	Normal	4 (50%)	6 (75%)	6 (75%)	16 (67%)	14 (58%)
	Abnormal	3 (38%)	2 (25%)	2 (25%)	7 (29%)	10 (42%)

Summary Table 7.4.1
Clinical Assessments
Physical Examinations Findings
Safety Population

Time Point	Finding	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Head, Neck, Mouth	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
	Normal	8 (100%)	8 (100%)	8 (100%)	24 (100%)	22 (92%)
	Abnormal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
	Neurological	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
	Normal	8 (100%)	8 (100%)	8 (100%)	24 (100%)	22 (92%)
	Abnormal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
	Respiratory	8 (100%)	8 (100%)	8 (100%)	24 (100%)	24 (100%)
	Normal	1 (13%)	0 (0%)	1 (13%)	2 (8%)	2 (8%)
	Abnormal	7 (88%)	8 (100%)	7 (88%)	22 (92%)	22 (92%)
Final Observation Period	Subjects with at least 1 PE Finding	8 (100%)	7 (88%)	8 (100%)	23 (96%)	24 (100%)
	Abdominal	8 (100%)	7 (88%)	8 (100%)	23 (96%)	24 (100%)
	Normal	6 (75%)	6 (75%)	7 (88%)	19 (79%)	21 (88%)
	Abnormal	2 (25%)	1 (13%)	1 (13%)	4 (17%)	3 (13%)
	Cardiac	8 (100%)	7 (88%)	8 (100%)	23 (96%)	24 (100%)
	Normal	6 (75%)	7 (88%)	7 (88%)	20 (83%)	20 (83%)
	Abnormal	2 (25%)	0 (0%)	1 (13%)	3 (13%)	4 (17%)
	Extremities	8 (100%)	7 (88%)	8 (100%)	23 (96%)	24 (100%)

Summary Table 7.4.1
Clinical Assessments
Physical Examinations Findings
Safety Population

Time Point	Finding	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Not Done	2 (25%)	1 (13%)	0 (0%)	3 (13%)	2 (8%)
	Normal	6 (75%)	5 (63%)	8 (100%)	19 (79%)	21 (88%)
	Abnormal	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
	Genitalia and Perineum	8 (100%)	7 (88%)	8 (100%)	23 (96%)	24 (100%)
	Not Done	1 (13%)	1 (13%)	0 (0%)	2 (8%)	1 (4%)
	Normal	7 (88%)	6 (75%)	6 (75%)	19 (79%)	20 (83%)
	Abnormal	0 (0%)	0 (0%)	2 (25%)	2 (8%)	3 (13%)
	General Appearance (Skin)	8 (100%)	7 (88%)	8 (100%)	23 (96%)	24 (100%)
	Not Done	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
	Normal	8 (100%)	7 (88%)	8 (100%)	23 (96%)	18 (75%)
	Abnormal	0 (0%)	0 (0%)	0 (0%)	0 (0%)	5 (21%)
	Head, Neck, Mouth	8 (100%)	7 (88%)	8 (100%)	23 (96%)	24 (100%)
	Not Done	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
	Normal	8 (100%)	5 (63%)	8 (100%)	21 (88%)	23 (96%)
	Abnormal	0 (0%)	1 (13%)	0 (0%)	1 (4%)	1 (4%)
	Neurological	8 (100%)	7 (88%)	8 (100%)	23 (96%)	24 (100%)
	Normal	6 (75%)	7 (88%)	8 (100%)	21 (88%)	22 (92%)
	Abnormal	2 (25%)	0 (0%)	0 (0%)	2 (8%)	2 (8%)

Summary Table 7.4.1
Clinical Assessments
Physical Examinations Findings
Safety Population

Time Point	Finding	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Respiratory	8 (100%)	7 (88%)	8 (100%)	23 (96%)	24 (100%)
	Normal	7 (88%)	6 (75%)	8 (100%)	21 (88%)	16 (67%)
	Abnormal	1 (13%)	1 (13%)	0 (0%)	2 (8%)	8 (33%)

Summary Table 7.4.2
Clinical Assessments
Physical Examinations Findings: Shift Table
Safety Population

Organ System	Final Visit:	Baseline:	Screening							
			50 mg/kg (N=8)		75 mg/kg (N=8)		100 mg/kg (N=8)		nCPAP Only (N=24)	
			Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Abdominal										
	Normal		4 (50%)	2 (25%)	6 (86%)	0 (0%)	7 (88%)	0 (0%)	20 (83%)	1 (4%)
	Abnormal		1 (13%)	1 (13%)	1 (14%)	0 (0%)	1 (13%)	0 (0%)	2 (8%)	1 (4%)
Cardiac										
	Normal		5 (63%)	1 (13%)	7 (100%)	0 (0%)	7 (88%)	0 (0%)	20 (83%)	0 (0%)
	Abnormal		2 (25%)	0 (0%)	0 (0%)	0 (0%)	1 (13%)	0 (0%)	4 (17%)	0 (0%)
Extremities										
	Normal		6 (100%)	0 (0%)	5 (83%)	0 (0%)	7 (88%)	1 (13%)	17 (77%)	4 (18%)
	Abnormal		0 (0%)	0 (0%)	1 (17%)	0 (0%)	0 (0%)	0 (0%)	1 (5%)	0 (0%)
General Appearance (Skin)										
	Normal		4 (57%)	3 (43%)	6 (86%)	1 (14%)	6 (75%)	2 (25%)	12 (52%)	6 (26%)
	Abnormal		0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (9%)	3 (13%)
Genitalia and Perineum										
	Normal		7 (100%)	0 (0%)	6 (100%)	0 (0%)	6 (75%)	0 (0%)	17 (74%)	3 (13%)
	Abnormal		0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (13%)	1 (13%)	3 (13%)	0 (0%)

Note: The lower left cell in the 2x2 result for each body system indicates a worsening from baseline.

Summary Table 7.4.2
Clinical Assessments
Physical Examinations Findings: Shift Table
Safety Population

Organ System	Final Visit:	Baseline:	Screening							
			50 mg/kg (N=8)		75 mg/kg (N=8)		100 mg/kg (N=8)		nCPAP Only (N=24)	
			Normal	Abnormal	Normal	Abnormal	Normal	Abnormal	Normal	Abnormal
Head, Neck, Mouth										
	Normal		8 (100%)	0 (0%)	5 (83%)	0 (0%)	8 (100%)	0 (0%)	22 (92%)	1 (4%)
	Abnormal		0 (0%)	0 (0%)	1 (17%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Neurological										
	Normal		6 (75%)	0 (0%)	7 (100%)	0 (0%)	8 (100%)	0 (0%)	20 (83%)	2 (8%)
	Abnormal		2 (25%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)	0 (0%)
Respiratory										
	Normal		1 (13%)	6 (75%)	0 (0%)	6 (86%)	1 (13%)	7 (88%)	1 (4%)	15 (63%)
	Abnormal		0 (0%)	1 (13%)	0 (0%)	1 (14%)	0 (0%)	0 (0%)	1 (4%)	7 (29%)

Note: The lower left cell in the 2x2 result for each body system indicates a worsening from baseline.

Summary Table 7.5.1
Clinical Assessments
Respiratory Parameters - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
At the time of randomization						
Observed (Baseline)	n	8	7	8	23	24
	Mean (SE)	0.31 (0.020)	0.33 (0.027)	0.37 (0.025)	0.34 (0.014)	0.32 (0.012)
	SD	0.058	0.071	0.072	0.069	0.061
	Median	0.31	0.30	0.37	0.33	0.30
	Min, Max	0.25 , 0.40	0.25 , 0.45	0.27 , 0.47	0.25 , 0.47	0.25 , 0.45
15 minutes post randomization						
Observed	n	7	7	7	21	23
	Mean (SE)	0.31 (0.023)	0.36 (0.030)	0.38 (0.033)	0.35 (0.017)	0.34 (0.020)
	SD	0.060	0.079	0.089	0.078	0.095
	Median	0.30	0.37	0.38	0.35	0.30
	Min, Max	0.25 , 0.40	0.25 , 0.45	0.25 , 0.50	0.25 , 0.50	0.25 , 0.65
Change from Baseline						
	n	7	7	7	21	23
	Mean (SE)	0.00 (0.003)	0.03 (0.028)	0.01 (0.008)	0.01 (0.009)	0.02 (0.013)
	SD	0.008	0.073	0.021	0.044	0.063
	Median	0.00	0.00	0.00	0.00	0.00
	Min, Max	0.00 , 0.02	-0.05 , 0.18	-0.02 , 0.04	-0.05 , 0.18	-0.05 , 0.29
30 minutes post randomization						
Observed	n	7	7	7	21	24
	Mean (SE)	0.31 (0.023)	0.36 (0.034)	0.37 (0.028)	0.35 (0.017)	0.39 (0.039)
	SD	0.062	0.089	0.074	0.076	0.190
	Median	0.30	0.33	0.38	0.33	0.31

Summary Table 7.5.1
Clinical Assessments
Respiratory Parameters - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	0.25 , 0.40	0.25 , 0.48	0.25 , 0.47	0.25 , 0.48	0.24 , 1.00
Change from Baseline	n	7	7	7	21	24
	Mean (SE)	0.00 (0.003)	0.03 (0.020)	0.01 (0.009)	0.01 (0.007)	0.06 (0.035)
	SD	0.008	0.052	0.025	0.034	0.172
	Median	0.00	0.05	0.00	0.00	0.00
	Min, Max	0.00 , 0.02	-0.05 , 0.11	-0.02 , 0.06	-0.05 , 0.11	-0.05 , 0.60
45 minutes post randomization Observed	n	7	7	6	20	24
	Mean (SE)	0.31 (0.024)	0.34 (0.028)	0.39 (0.048)	0.35 (0.019)	0.35 (0.029)
	SD	0.064	0.073	0.117	0.086	0.141
	Median	0.30	0.32	0.37	0.32	0.30
	Min, Max	0.25 , 0.40	0.25 , 0.45	0.25 , 0.57	0.25 , 0.57	0.21 , 0.90
Change from Baseline	n	7	7	6	20	24
	Mean (SE)	0.01 (0.004)	0.01 (0.015)	0.03 (0.036)	0.02 (0.012)	0.02 (0.028)
	SD	0.010	0.040	0.088	0.052	0.138
	Median	0.00	0.00	0.00	0.00	0.00
	Min, Max	0.00 , 0.02	-0.05 , 0.05	-0.02 , 0.21	-0.05 , 0.21	-0.19 , 0.60
60 minutes post randomization Observed	n	7	7	7	21	23
	Mean (SE)	0.31 (0.024)	0.35 (0.024)	0.37 (0.034)	0.34 (0.016)	0.34 (0.033)
	SD	0.064	0.063	0.090	0.073	0.159

Summary Table 7.5.1
Clinical Assessments
Respiratory Parameters - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	0.30	0.32	0.38	0.32	0.30
	Min, Max	0.25 , 0.40	0.30 , 0.45	0.21 , 0.47	0.21 , 0.47	0.21 , 1.00
Change from Baseline	n	7	7	7	21	23
	Mean (SE)	0.01 (0.004)	0.02 (0.009)	0.01 (0.017)	0.01 (0.006)	0.01 (0.034)
	SD	0.010	0.024	0.044	0.029	0.162
	Median	0.00	0.01	0.00	0.00	0.00
	Min, Max	0.00 , 0.02	0.00 , 0.05	-0.06 , 0.09	-0.06 , 0.09	-0.19 , 0.70
1 hour 15 minutes (75 minutes) post randomization						
Observed	n	7	7	6	20	22
	Mean (SE)	0.32 (0.026)	0.37 (0.039)	0.34 (0.037)	0.34 (0.019)	0.34 (0.038)
	SD	0.068	0.103	0.090	0.086	0.180
	Median	0.30	0.31	0.34	0.32	0.30
	Min, Max	0.25 , 0.42	0.25 , 0.50	0.21 , 0.48	0.21 , 0.50	0.21 , 1.00
Change from Baseline	n	7	7	6	20	22
	Mean (SE)	0.01 (0.007)	0.04 (0.018)	-0.02 (0.011)	0.01 (0.009)	0.02 (0.039)
	SD	0.017	0.046	0.028	0.038	0.182
	Median	0.00	0.04	0.00	0.00	-0.01
	Min, Max	0.00 , 0.04	0.00 , 0.13	-0.06 , 0.01	-0.06 , 0.13	-0.24 , 0.70
1 hour 30 minutes (90 minutes) post randomization						
Observed	n	7	7	8	22	22
	Mean (SE)	0.32 (0.032)	0.31 (0.026)	0.38 (0.040)	0.34 (0.020)	0.33 (0.031)

Summary Table 7.5.1
Clinical Assessments
Respiratory Parameters - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	0.085	0.068	0.114	0.093	0.146
	Median	0.26	0.30	0.35	0.31	0.30
	Min, Max	0.25 , 0.42	0.25 , 0.45	0.21 , 0.55	0.21 , 0.55	0.21 , 0.90
Change from Baseline	n	7	7	8	22	22
	Mean (SE)	0.01 (0.017)	-0.02 (0.012)	0.00 (0.019)	0.00 (0.010)	0.00 (0.032)
	SD	0.044	0.033	0.054	0.045	0.150
	Median	0.00	0.00	0.01	0.00	-0.01
	Min, Max	-0.04 , 0.10	-0.06 , 0.03	-0.07 , 0.08	-0.07 , 0.10	-0.19 , 0.60
1 hour 45 minutes (105 minutes) post randomization						
Observed	n	7	8	6	21	22
	Mean (SE)	0.37 (0.046)	0.35 (0.043)	0.35 (0.046)	0.36 (0.025)	0.32 (0.031)
	SD	0.123	0.121	0.113	0.114	0.146
	Median	0.42	0.32	0.32	0.33	0.29
	Min, Max	0.21 , 0.50	0.21 , 0.60	0.21 , 0.55	0.21 , 0.60	0.21 , 0.90
Change from Baseline	n	7	7	6	20	22
	Mean (SE)	0.06 (0.039)	-0.01 (0.017)	-0.01 (0.023)	0.01 (0.017)	-0.01 (0.033)
	SD	0.104	0.044	0.056	0.077	0.153
	Median	0.04	0.00	-0.01	0.00	-0.01
	Min, Max	-0.05 , 0.25	-0.09 , 0.05	-0.07 , 0.08	-0.09 , 0.25	-0.20 , 0.60
2 hours (120 minutes) post randomization						
Observed	n	7	8	6	21	23

Summary Table 7.5.1
Clinical Assessments
Respiratory Parameters - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	0.32 (0.045)	0.35 (0.043)	0.35 (0.047)	0.34 (0.025)	0.29 (0.015)
	SD	0.119	0.122	0.115	0.114	0.072
	Median	0.25	0.31	0.33	0.31	0.28
	Min, Max	0.21 , 0.50	0.21 , 0.60	0.21 , 0.55	0.21 , 0.60	0.21 , 0.45
	Change from Baseline	n	7	7	6	20
	Mean (SE)	0.01 (0.025)	-0.01 (0.018)	-0.00 (0.024)	-0.00 (0.012)	-0.03 (0.014)
	SD	0.066	0.047	0.058	0.056	0.069
	Median	0.00	0.00	-0.01	0.00	-0.02
	Min, Max	-0.05 , 0.10	-0.09 , 0.03	-0.06 , 0.08	-0.09 , 0.10	-0.19 , 0.09
	2 hours 15 minutes (135 minutes) post randomization	n	7	8	6	21
Observed	Mean (SE)	0.32 (0.047)	0.36 (0.042)	0.33 (0.033)	0.34 (0.024)	0.31 (0.019)
	SD	0.124	0.119	0.081	0.108	0.088
	Median	0.25	0.34	0.32	0.30	0.29
	Min, Max	0.21 , 0.50	0.21 , 0.60	0.21 , 0.45	0.21 , 0.60	0.21 , 0.49
	Change from Baseline	n	7	7	6	20
	Mean (SE)	0.01 (0.026)	-0.00 (0.025)	-0.03 (0.016)	-0.01 (0.013)	-0.02 (0.018)
	SD	0.069	0.067	0.040	0.060	0.084
	Median	-0.04	0.00	-0.02	-0.01	-0.01
	Min, Max	-0.05 , 0.10	-0.09 , 0.10	-0.09 , 0.02	-0.09 , 0.10	-0.19 , 0.15

2 hours 30 minutes (150 minutes) post randomization

Summary Table 7.5.1
Clinical Assessments
Respiratory Parameters - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Observed	n	8	8	6	22	23
	Mean (SE)	0.34 (0.045)	0.38 (0.041)	0.34 (0.031)	0.35 (0.023)	0.30 (0.017)
	SD	0.126	0.116	0.077	0.107	0.084
	Median	0.33	0.38	0.35	0.37	0.30
	Min, Max	0.21 , 0.50	0.21 , 0.60	0.21 , 0.44	0.21 , 0.60	0.21 , 0.50
Change from Baseline	n	8	7	6	21	23
	Mean (SE)	0.03 (0.029)	0.01 (0.027)	-0.02 (0.012)	0.01 (0.015)	-0.02 (0.017)
	SD	0.083	0.072	0.030	0.068	0.081
	Median	0.01	0.00	-0.01	0.00	-0.02
	Min, Max	-0.05 , 0.17	-0.09 , 0.12	-0.06 , 0.02	-0.09 , 0.17	-0.19 , 0.12
2 hours 45 minutes (165 minutes) post randomization Observed	n	8	8	6	22	23
	Mean (SE)	0.34 (0.046)	0.38 (0.051)	0.34 (0.034)	0.35 (0.026)	0.30 (0.018)
	SD	0.131	0.145	0.083	0.121	0.084
	Median	0.33	0.35	0.35	0.35	0.30
	Min, Max	0.21 , 0.50	0.21 , 0.70	0.21 , 0.46	0.21 , 0.70	0.21 , 0.52
Change from Baseline	n	8	7	6	21	23
	Mean (SE)	0.03 (0.030)	-0.00 (0.025)	-0.01 (0.012)	0.01 (0.015)	-0.02 (0.017)
	SD	0.086	0.066	0.029	0.067	0.081
	Median	-0.01	0.00	-0.00	0.00	-0.02
	Min, Max	-0.05 , 0.17	-0.09 , 0.10	-0.06 , 0.02	-0.09 , 0.17	-0.19 , 0.11

Summary Table 7.5.1
Clinical Assessments
Respiratory Parameters - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
3 hours (180 minutes) post randomization						
Observed	n	8	8	8	24	23
	Mean (SE)	0.37 (0.068)	0.37 (0.043)	0.37 (0.038)	0.37 (0.028)	0.29 (0.017)
	SD	0.191	0.120	0.107	0.138	0.082
	Median	0.32	0.35	0.36	0.36	0.28
	Min, Max	0.21 , 0.70	0.21 , 0.62	0.21 , 0.55	0.21 , 0.70	0.21 , 0.52
Change from Baseline	n	8	7	8	23	23
	Mean (SE)	0.06 (0.054)	-0.00 (0.025)	0.00 (0.016)	0.02 (0.021)	-0.03 (0.017)
	SD	0.154	0.066	0.047	0.102	0.082
	Median	-0.02	0.00	0.00	0.00	-0.03
	Min, Max	-0.05 , 0.37	-0.09 , 0.10	-0.06 , 0.08	-0.09 , 0.37	-0.20 , 0.12
6 hours post randomization						
Observed	n	8	8	8	24	23
	Mean (SE)	0.34 (0.057)	0.36 (0.037)	0.38 (0.033)	0.36 (0.024)	0.33 (0.047)
	SD	0.162	0.104	0.095	0.119	0.224
	Median	0.30	0.36	0.34	0.33	0.28
	Min, Max	0.21 , 0.70	0.22 , 0.54	0.28 , 0.50	0.21 , 0.70	0.21 , 1.00
Change from Baseline	n	8	7	8	23	23
	Mean (SE)	0.03 (0.055)	0.01 (0.029)	0.00 (0.024)	0.01 (0.022)	0.01 (0.042)
	SD	0.156	0.077	0.066	0.104	0.201
	Median	-0.02	-0.01	0.01	0.00	-0.04
	Min, Max	-0.10 , 0.38	-0.08 , 0.12	-0.09 , 0.13	-0.10 , 0.38	-0.24 , 0.60

Summary Table 7.5.1
Clinical Assessments
Respiratory Parameters - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
12 hours post randomization						
Observed	n	8	8	8	24	23
	Mean (SE)	0.30 (0.040)	0.30 (0.041)	0.30 (0.024)	0.30 (0.020)	0.33 (0.038)
	SD	0.114	0.117	0.068	0.098	0.181
	Median	0.26	0.26	0.30	0.28	0.25
	Min, Max	0.21 , 0.53	0.21 , 0.55	0.21 , 0.40	0.21 , 0.55	0.21 , 1.00
Change from Baseline	n	8	7	8	23	23
	Mean (SE)	-0.02 (0.048)	-0.07 (0.028)	-0.08 (0.032)	-0.05 (0.022)	0.00 (0.036)
	SD	0.137	0.074	0.090	0.104	0.172
	Median	-0.07	-0.05	-0.08	-0.05	-0.02
	Min, Max	-0.14 , 0.23	-0.22 , 0.00	-0.18 , 0.05	-0.22 , 0.23	-0.24 , 0.65
18 hours post randomization						
Observed	n	8	8	8	24	23
	Mean (SE)	0.29 (0.032)	0.29 (0.045)	0.27 (0.029)	0.28 (0.020)	0.30 (0.037)
	SD	0.090	0.129	0.081	0.098	0.176
	Median	0.26	0.26	0.24	0.25	0.23
	Min, Max	0.21 , 0.45	0.21 , 0.60	0.21 , 0.45	0.21 , 0.60	0.21 , 1.00
Change from Baseline	n	8	7	8	23	23
	Mean (SE)	-0.03 (0.033)	-0.09 (0.024)	-0.10 (0.040)	-0.07 (0.020)	-0.02 (0.035)
	SD	0.094	0.063	0.113	0.096	0.169
	Median	-0.02	-0.09	-0.14	-0.09	-0.04

Summary Table 7.5.1
Clinical Assessments
Respiratory Parameters - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	-0.14 , 0.15	-0.17 , -0.01	-0.26 , 0.10	-0.26 , 0.15	-0.24 , 0.65
24 hours post randomization						
Observed	n	8	8	7	23	24
	Mean (SE)	0.28 (0.033)	0.25 (0.016)	0.28 (0.029)	0.27 (0.015)	0.29 (0.029)
	SD	0.093	0.044	0.077	0.073	0.143
	Median	0.26	0.24	0.25	0.24	0.23
	Min, Max	0.21 , 0.50	0.21 , 0.35	0.21 , 0.43	0.21 , 0.50	0.21 , 0.80
Change from Baseline						
	n	8	7	7	22	24
	Mean (SE)	-0.03 (0.026)	-0.09 (0.018)	-0.08 (0.040)	-0.06 (0.017)	-0.04 (0.029)
	SD	0.072	0.046	0.105	0.079	0.140
	Median	-0.03	-0.09	-0.07	-0.06	-0.04
	Min, Max	-0.14 , 0.10	-0.14 , -0.01	-0.22 , 0.08	-0.22 , 0.10	-0.24 , 0.44
30 hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	0.26 (0.021)	0.24 (0.023)	0.27 (0.019)	0.26 (0.012)	0.25 (0.014)
	SD	0.060	0.065	0.054	0.059	0.069
	Median	0.25	0.22	0.25	0.25	0.21
	Min, Max	0.21 , 0.40	0.21 , 0.40	0.21 , 0.35	0.21 , 0.40	0.21 , 0.50
Change from Baseline						
	n	8	7	8	23	24
	Mean (SE)	-0.05 (0.027)	-0.09 (0.020)	-0.11 (0.035)	-0.08 (0.017)	-0.08 (0.017)
	SD	0.077	0.054	0.098	0.080	0.082

Summary Table 7.5.1
Clinical Assessments
Respiratory Parameters - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	-0.05	-0.09	-0.14	-0.06	-0.07
	Min, Max	-0.17 , 0.07	-0.17 , -0.02	-0.22 , 0.05	-0.22 , 0.07	-0.24 , 0.15
36 hours post randomization						
Observed	n	8	8	7	23	24
	Mean (SE)	0.27 (0.019)	0.25 (0.021)	0.28 (0.022)	0.26 (0.012)	0.28 (0.036)
	SD	0.055	0.059	0.057	0.056	0.179
	Median	0.26	0.22	0.27	0.25	0.22
	Min, Max	0.21 , 0.38	0.21 , 0.38	0.21 , 0.35	0.21 , 0.38	0.21 , 1.00
Change from Baseline	n	8	7	7	22	24
	Mean (SE)	-0.04 (0.028)	-0.08 (0.024)	-0.08 (0.032)	-0.07 (0.016)	-0.04 (0.038)
	SD	0.079	0.064	0.085	0.076	0.186
	Median	-0.02	-0.07	-0.13	-0.07	-0.07
	Min, Max	-0.17 , 0.05	-0.17 , 0.02	-0.17 , 0.05	-0.17 , 0.05	-0.24 , 0.70
42 hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	0.29 (0.027)	0.24 (0.013)	0.26 (0.018)	0.26 (0.012)	0.32 (0.044)
	SD	0.076	0.038	0.051	0.058	0.214
	Median	0.27	0.21	0.24	0.26	0.23
	Min, Max	0.21 , 0.45	0.21 , 0.30	0.21 , 0.35	0.21 , 0.45	0.21 , 1.00
Change from Baseline	n	8	7	8	23	24
	Mean (SE)	-0.03 (0.039)	-0.09 (0.025)	-0.12 (0.034)	-0.08 (0.020)	-0.01 (0.044)

Summary Table 7.5.1
Clinical Assessments
Respiratory Parameters - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	0.111	0.065	0.096	0.098	0.214
	Median	-0.03	-0.09	-0.13	-0.09	-0.06
	Min, Max	-0.17 , 0.20	-0.17 , 0.03	-0.25 , 0.00	-0.25 , 0.20	-0.24 , 0.70
48 hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	0.28 (0.021)	0.24 (0.013)	0.29 (0.025)	0.27 (0.012)	0.31 (0.038)
	SD	0.058	0.038	0.071	0.058	0.188
	Median	0.28	0.24	0.27	0.25	0.24
	Min, Max	0.21 , 0.40	0.21 , 0.30	0.21 , 0.40	0.21 , 0.40	0.21 , 1.00
Change from Baseline	n	8	7	8	23	24
	Mean (SE)	-0.03 (0.029)	-0.09 (0.028)	-0.09 (0.032)	-0.07 (0.018)	-0.02 (0.039)
	SD	0.083	0.075	0.091	0.085	0.191
	Median	-0.01	-0.09	-0.10	-0.06	-0.07
	Min, Max	-0.15 , 0.07	-0.17 , 0.05	-0.22 , 0.05	-0.22 , 0.07	-0.24 , 0.70
54 hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	0.27 (0.019)	0.28 (0.060)	0.28 (0.022)	0.28 (0.021)	0.29 (0.028)
	SD	0.053	0.169	0.063	0.104	0.136
	Median	0.25	0.23	0.28	0.25	0.23
	Min, Max	0.21 , 0.35	0.21 , 0.70	0.21 , 0.40	0.21 , 0.70	0.21 , 0.78
Change from Baseline	n	8	7	8	23	24

Summary Table 7.5.1
Clinical Assessments
Respiratory Parameters - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	-0.05 (0.028)	-0.04 (0.052)	-0.09 (0.036)	-0.06 (0.022)	-0.03 (0.030)
	SD	0.079	0.139	0.103	0.106	0.145
	Median	-0.01	-0.08	-0.09	-0.06	-0.07
	Min, Max	-0.17 , 0.02	-0.17 , 0.25	-0.26 , 0.05	-0.26 , 0.25	-0.24 , 0.48
60 hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	0.30 (0.033)	0.26 (0.035)	0.26 (0.022)	0.27 (0.017)	0.27 (0.022)
	SD	0.094	0.098	0.063	0.085	0.105
	Median	0.30	0.23	0.25	0.24	0.23
	Min, Max	0.21 , 0.50	0.21 , 0.50	0.21 , 0.40	0.21 , 0.50	0.21 , 0.65
Change from Baseline						
	n	8	7	8	23	24
	Mean (SE)	-0.02 (0.040)	-0.07 (0.028)	-0.12 (0.038)	-0.07 (0.022)	-0.05 (0.023)
	SD	0.113	0.075	0.106	0.106	0.115
	Median	0.01	-0.07	-0.14	-0.06	-0.07
	Min, Max	-0.17 , 0.17	-0.17 , 0.05	-0.26 , 0.05	-0.26 , 0.17	-0.24 , 0.35
66 hours post randomization						
Observed	n	8	8	8	24	24
	Mean (SE)	0.28 (0.024)	0.23 (0.008)	0.24 (0.011)	0.25 (0.010)	0.27 (0.020)
	SD	0.068	0.022	0.031	0.049	0.098
	Median	0.26	0.22	0.22	0.23	0.24
	Min, Max	0.21 , 0.40	0.21 , 0.26	0.21 , 0.28	0.21 , 0.40	0.21 , 0.65

Summary Table 7.5.1
Clinical Assessments
Respiratory Parameters - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Change from Baseline	n	8	7	8	23	24
	Mean (SE)	-0.03 (0.033)	-0.10 (0.029)	-0.14 (0.024)	-0.09 (0.019)	-0.05 (0.022)
	SD	0.094	0.076	0.068	0.089	0.109
	Median	-0.03	-0.09	-0.13	-0.09	-0.07
	Min, Max	-0.17 , 0.07	-0.22 , 0.00	-0.24 , -0.06	-0.24 , 0.07	-0.24 , 0.35
72 hours post randomization Observed	n	7	8	8	23	23
	Mean (SE)	0.30 (0.040)	0.23 (0.008)	0.25 (0.018)	0.26 (0.014)	0.27 (0.025)
	SD	0.105	0.023	0.050	0.069	0.119
	Median	0.25	0.22	0.24	0.23	0.23
	Min, Max	0.21 , 0.48	0.21 , 0.27	0.21 , 0.35	0.21 , 0.48	0.21 , 0.78
Change from Baseline	n	7	7	8	22	23
	Mean (SE)	-0.02 (0.050)	-0.10 (0.027)	-0.12 (0.023)	-0.08 (0.021)	-0.05 (0.028)
	SD	0.133	0.071	0.066	0.099	0.133
	Median	-0.04	-0.09	-0.12	-0.08	-0.07
	Min, Max	-0.19 , 0.15	-0.22 , -0.02	-0.22 , -0.04	-0.22 , 0.15	-0.24 , 0.48

Summary Table 7.5.1.1
Clinical Assessments
Respiratory Parameters before Intubation - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
At the time of randomization						
Observed (Baseline)	n	7	7	6	20	17
	Mean (SE)	0.32 (0.021)	0.33 (0.027)	0.40 (0.027)	0.35 (0.016)	0.35 (0.014)
	SD	0.056	0.071	0.066	0.069	0.056
	Median	0.32	0.30	0.39	0.35	0.35
	Min, Max	0.25 , 0.40	0.25 , 0.45	0.30 , 0.47	0.25 , 0.47	0.26 , 0.45
15 minutes post randomization						
Observed	n	6	7	5	18	15
	Mean (SE)	0.32 (0.024)	0.36 (0.030)	0.41 (0.035)	0.36 (0.018)	0.36 (0.026)
	SD	0.058	0.079	0.079	0.077	0.101
	Median	0.31	0.37	0.40	0.38	0.35
	Min, Max	0.25 , 0.40	0.25 , 0.45	0.30 , 0.50	0.25 , 0.50	0.25 , 0.65
Change from Baseline						
	n	6	7	5	18	15
	Mean (SE)	0.00 (0.003)	0.03 (0.028)	0.01 (0.009)	0.02 (0.011)	0.02 (0.020)
	SD	0.008	0.073	0.019	0.046	0.078
	Median	0.00	0.00	0.00	0.00	0.00
	Min, Max	0.00 , 0.02	-0.05 , 0.18	0.00 , 0.04	-0.05 , 0.18	-0.05 , 0.29
30 minutes post randomization						
Observed	n	6	7	5	18	16
	Mean (SE)	0.32 (0.025)	0.36 (0.034)	0.39 (0.028)	0.36 (0.018)	0.44 (0.053)

Summary Table 7.5.1.1
Clinical Assessments
Respiratory Parameters before Intubation - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	0.060	0.089	0.062	0.075	0.212
	Median	0.31	0.33	0.40	0.36	0.38
	Min, Max	0.25 , 0.40	0.25 , 0.48	0.30 , 0.47	0.25 , 0.48	0.28 , 1.00
Change from Baseline	n	6	7	5	18	16
	Mean (SE)	0.01 (0.003)	0.03 (0.020)	0.01 (0.012)	0.02 (0.008)	0.10 (0.051)
	SD	0.008	0.052	0.026	0.036	0.203
	Median	0.00	0.05	0.00	0.00	0.00
	Min, Max	0.00 , 0.02	-0.05 , 0.11	0.00 , 0.06	-0.05 , 0.11	-0.05 , 0.60
45 minutes post randomization						
Observed	n	6	7	4	17	16
	Mean (SE)	0.33 (0.026)	0.34 (0.028)	0.43 (0.058)	0.36 (0.021)	0.38 (0.040)
	SD	0.063	0.073	0.116	0.087	0.159
	Median	0.31	0.32	0.43	0.32	0.35
	Min, Max	0.25 , 0.40	0.25 , 0.45	0.30 , 0.57	0.25 , 0.57	0.21 , 0.90
Change from Baseline	n	6	7	4	17	16
	Mean (SE)	0.01 (0.004)	0.01 (0.015)	0.05 (0.053)	0.02 (0.013)	0.04 (0.042)
	SD	0.010	0.040	0.105	0.055	0.167
	Median	0.00	0.00	0.00	0.00	0.00
	Min, Max	0.00 , 0.02	-0.05 , 0.05	0.00 , 0.21	-0.05 , 0.21	-0.19 , 0.60

Summary Table 7.5.1.1
Clinical Assessments
Respiratory Parameters before Intubation - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
60 minutes post randomization						
Observed	n	6	7	5	18	12
	Mean (SE)	0.33 (0.026)	0.35 (0.024)	0.40 (0.030)	0.36 (0.016)	0.34 (0.018)
	SD	0.063	0.063	0.067	0.067	0.063
	Median	0.31	0.32	0.40	0.35	0.31
	Min, Max	0.25 , 0.40	0.30 , 0.45	0.30 , 0.47	0.25 , 0.47	0.28 , 0.50
Change from Baseline	n	6	7	5	18	12
	Mean (SE)	0.01 (0.004)	0.02 (0.009)	0.02 (0.018)	0.02 (0.006)	0.01 (0.013)
	SD	0.010	0.024	0.039	0.025	0.043
	Median	0.00	0.01	0.00	0.00	0.00
	Min, Max	0.00 , 0.02	0.00 , 0.05	0.00 , 0.09	0.00 , 0.09	-0.06 , 0.12
1 hour 15 minutes (75 minutes) post randomization						
Observed	n	6	7	4	17	11
	Mean (SE)	0.33 (0.027)	0.37 (0.039)	0.37 (0.040)	0.36 (0.020)	0.31 (0.013)
	SD	0.066	0.103	0.081	0.084	0.042
	Median	0.31	0.31	0.35	0.32	0.30
	Min, Max	0.25 , 0.42	0.25 , 0.50	0.30 , 0.48	0.25 , 0.50	0.25 , 0.40
Change from Baseline	n	6	7	4	17	11
	Mean (SE)	0.01 (0.007)	0.04 (0.018)	-0.01 (0.011)	0.02 (0.009)	-0.01 (0.007)
	SD	0.018	0.046	0.022	0.037	0.025

Summary Table 7.5.1.1
Clinical Assessments
Respiratory Parameters before Intubation - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	0.00	0.04	0.00	0.00	0.00
	Min, Max	0.00 , 0.04	0.00 , 0.13	-0.04 , 0.01	-0.04 , 0.13	-0.06 , 0.02
1 hour 30 minutes (90 minutes) post randomization						
Observed	n	6	7	6	19	11
	Mean (SE)	0.34 (0.035)	0.31 (0.026)	0.41 (0.044)	0.35 (0.021)	0.32 (0.022)
	SD	0.086	0.068	0.107	0.092	0.072
	Median	0.33	0.30	0.39	0.31	0.30
	Min, Max	0.25 , 0.42	0.25 , 0.45	0.30 , 0.55	0.25 , 0.55	0.25 , 0.50
Change from Baseline						
	n	6	7	6	19	11
	Mean (SE)	0.02 (0.020)	-0.02 (0.012)	0.01 (0.023)	0.00 (0.011)	0.00 (0.017)
	SD	0.048	0.033	0.056	0.046	0.055
	Median	0.00	0.00	0.02	0.00	0.00
	Min, Max	-0.04 , 0.10	-0.06 , 0.03	-0.07 , 0.08	-0.07 , 0.10	-0.07 , 0.14
1 hour 45 minutes (105 minutes) post randomization						
Observed	n	6	8	4	18	11
	Mean (SE)	0.34 (0.048)	0.35 (0.043)	0.37 (0.059)	0.35 (0.027)	0.31 (0.018)
	SD	0.118	0.121	0.119	0.113	0.060
	Median	0.34	0.32	0.32	0.32	0.30
	Min, Max	0.21 , 0.50	0.21 , 0.60	0.30 , 0.55	0.21 , 0.60	0.25 , 0.45

Summary Table 7.5.1.1
Clinical Assessments
Respiratory Parameters before Intubation - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Change from Baseline	n	6	7	4	17	11
	Mean (SE)	0.02 (0.027)	-0.01 (0.017)	-0.00 (0.032)	0.00 (0.014)	-0.01 (0.013)
	SD	0.066	0.044	0.064	0.056	0.044
	Median	0.02	0.00	-0.01	0.00	0.00
	Min, Max	-0.05 , 0.10	-0.09 , 0.05	-0.07 , 0.08	-0.09 , 0.10	-0.07 , 0.09
2 hours (120 minutes) post randomization Observed	n	6	8	4	18	11
	Mean (SE)	0.34 (0.048)	0.35 (0.043)	0.38 (0.059)	0.35 (0.027)	0.31 (0.022)
	SD	0.118	0.122	0.117	0.113	0.072
	Median	0.33	0.31	0.33	0.32	0.30
	Min, Max	0.21 , 0.50	0.21 , 0.60	0.30 , 0.55	0.21 , 0.60	0.24 , 0.45
Change from Baseline	n	6	7	4	17	11
	Mean (SE)	0.02 (0.028)	-0.01 (0.018)	-0.00 (0.030)	0.00 (0.014)	-0.01 (0.016)
	SD	0.068	0.047	0.060	0.057	0.052
	Median	0.01	0.00	-0.01	0.00	-0.01
	Min, Max	-0.05 , 0.10	-0.09 , 0.03	-0.06 , 0.08	-0.09 , 0.10	-0.08 , 0.09
2 hours 15 minutes (135 minutes) post randomization Observed	n	6	8	4	18	11
	Mean (SE)	0.33 (0.051)	0.36 (0.042)	0.34 (0.037)	0.35 (0.025)	0.33 (0.025)
	SD	0.125	0.119	0.074	0.108	0.083

Summary Table 7.5.1.1
Clinical Assessments
Respiratory Parameters before Intubation - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	0.33	0.34	0.32	0.32	0.30
	Min, Max	0.21 , 0.50	0.21 , 0.60	0.29 , 0.45	0.21 , 0.60	0.24 , 0.45
Change from Baseline	n	6	7	4	17	11
	Mean (SE)	0.01 (0.030)	-0.00 (0.025)	-0.04 (0.019)	-0.00 (0.015)	0.01 (0.020)
	SD	0.072	0.067	0.039	0.063	0.065
	Median	-0.01	0.00	-0.02	0.00	-0.01
	Min, Max	-0.05 , 0.10	-0.09 , 0.10	-0.09 , 0.00	-0.09 , 0.10	-0.07 , 0.15
2 hours 30 minutes (150 minutes) post randomization						
Observed	n	7	8	4	19	11
	Mean (SE)	0.36 (0.049)	0.38 (0.041)	0.36 (0.029)	0.37 (0.025)	0.33 (0.024)
	SD	0.130	0.116	0.059	0.107	0.078
	Median	0.40	0.38	0.35	0.37	0.30
	Min, Max	0.21 , 0.50	0.21 , 0.60	0.30 , 0.44	0.21 , 0.60	0.24 , 0.45
Change from Baseline	n	7	7	4	18	11
	Mean (SE)	0.04 (0.033)	0.01 (0.027)	-0.02 (0.010)	0.02 (0.017)	0.00 (0.018)
	SD	0.088	0.072	0.021	0.071	0.061
	Median	0.02	0.00	-0.01	0.00	0.00
	Min, Max	-0.05 , 0.17	-0.09 , 0.12	-0.04 , 0.00	-0.09 , 0.17	-0.07 , 0.12

2 hours 45 minutes (165 minutes) post randomization

Summary Table 7.5.1.1
Clinical Assessments
Respiratory Parameters before Intubation - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Observed	n	7	8	4	19	10
	Mean (SE)	0.36 (0.049)	0.38 (0.051)	0.37 (0.034)	0.37 (0.028)	0.32 (0.021)
	SD	0.130	0.145	0.068	0.121	0.066
	Median	0.40	0.35	0.35	0.36	0.30
	Min, Max	0.21 , 0.50	0.21 , 0.70	0.30 , 0.46	0.21 , 0.70	0.24 , 0.45
Change from Baseline	n	7	7	4	18	10
	Mean (SE)	0.04 (0.033)	-0.00 (0.025)	-0.01 (0.009)	0.01 (0.016)	0.00 (0.017)
	SD	0.088	0.066	0.019	0.069	0.053
	Median	0.02	0.00	-0.00	0.00	-0.02
	Min, Max	-0.05 , 0.17	-0.09 , 0.10	-0.04 , 0.00	-0.09 , 0.17	-0.06 , 0.11
3 hours (180 minutes) post randomization Observed	n	7	8	6	21	10
	Mean (SE)	0.40 (0.073)	0.37 (0.043)	0.40 (0.040)	0.39 (0.030)	0.31 (0.023)
	SD	0.194	0.120	0.098	0.138	0.074
	Median	0.38	0.35	0.39	0.37	0.30
	Min, Max	0.21 , 0.70	0.21 , 0.62	0.30 , 0.55	0.21 , 0.70	0.21 , 0.45
Change from Baseline	n	7	7	6	20	10
	Mean (SE)	0.08 (0.060)	-0.00 (0.025)	0.01 (0.019)	0.03 (0.024)	-0.00 (0.019)
	SD	0.160	0.066	0.047	0.107	0.060
	Median	0.00	0.00	0.00	0.00	-0.03

Summary Table 7.5.1.1
Clinical Assessments
Respiratory Parameters before Intubation - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	-0.05 , 0.37	-0.09 , 0.10	-0.04 , 0.08	-0.09 , 0.37	-0.07 , 0.12
6 hours post randomization						
Observed	n	6	7	4	17	8
	Mean (SE)	0.38 (0.070)	0.38 (0.039)	0.39 (0.051)	0.38 (0.030)	0.30 (0.019)
	SD	0.171	0.103	0.101	0.123	0.054
	Median	0.34	0.36	0.39	0.36	0.30
	Min, Max	0.21 , 0.70	0.22 , 0.54	0.30 , 0.49	0.21 , 0.70	0.21 , 0.41
Change from Baseline						
	n	6	6	4	16	8
	Mean (SE)	0.06 (0.069)	0.01 (0.034)	0.02 (0.042)	0.03 (0.029)	-0.01 (0.021)
	SD	0.170	0.084	0.083	0.118	0.060
	Median	0.02	-0.01	0.00	0.00	-0.03
	Min, Max	-0.10 , 0.38	-0.08 , 0.12	-0.07 , 0.13	-0.10 , 0.38	-0.07 , 0.11
12 hours post randomization						
Observed	n	3	5	2	10	6
	Mean (SE)	0.27 (0.017)	0.35 (0.055)	0.33 (0.025)	0.32 (0.029)	0.43 (0.117)
	SD	0.030	0.124	0.035	0.092	0.285
	Median	0.27	0.32	0.33	0.30	0.34
	Min, Max	0.24 , 0.30	0.23 , 0.55	0.30 , 0.35	0.23 , 0.55	0.21 , 1.00
Change from Baseline						
	n	3	4	2	9	6

Summary Table 7.5.1.1
Clinical Assessments
Respiratory Parameters before Intubation - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	-0.08 (0.045)	-0.02 (0.010)	-0.02 (0.015)	-0.04 (0.017)	0.11 (0.110)
	SD	0.078	0.021	0.021	0.050	0.270
	Median	-0.10	-0.02	-0.02	-0.02	0.01
	Min, Max	-0.14 , 0.01	-0.05 , 0.00	-0.03 , 0.00	-0.14 , 0.01	-0.07 , 0.65
18 hours post randomization						
Observed	n	3	3	1	7	3
	Mean (SE)	0.30 (0.049)	0.37 (0.115)	0.30 (0)	0.33 (0.049)	0.31 (0.040)
	SD	0.085	0.200	0	0.130	0.069
	Median	0.27	0.27	0.30	0.27	0.35
	Min, Max	0.24 , 0.40	0.24 , 0.60	0.30 , 0.30	0.24 , 0.60	0.23 , 0.35
Change from Baseline						
	n	3	2	1	6	3
	Mean (SE)	-0.04 (0.048)	-0.02 (0.010)	0.00 (0)	-0.03 (0.023)	-0.01 (0.026)
	SD	0.084	0.014	0	0.056	0.045
	Median	0.00	-0.02	0.00	-0.01	-0.01
	Min, Max	-0.14 , 0.01	-0.03 , -0.01	0.00 , 0.00	-0.14 , 0.01	-0.05 , 0.04
24 hours post randomization						
Observed	n	3	1	1	5	2
	Mean (SE)	0.34 (0.081)	0.24 (0)	0.30 (0)	0.31 (0.048)	0.51 (0.290)
	SD	0.140	0	0	0.108	0.410
	Median	0.28	0.24	0.30	0.28	0.51

Summary Table 7.5.1.1
Clinical Assessments
Respiratory Parameters before Intubation - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	0.24 , 0.50	0.24 , 0.24	0.30 , 0.30	0.24 , 0.50	0.22 , 0.80
Change from Baseline	n	3	1	1	5	2
	Mean (SE)	-0.01 (0.071)	-0.01 (0)	0.00 (0)	-0.01 (0.039)	0.19 (0.250)
	SD	0.122	0	0	0.086	0.354
	Median	0.02	-0.01	0.00	0.00	0.19
	Min, Max	-0.14 , 0.10	-0.01 , -0.01	0.00 , 0.00	-0.14 , 0.10	-0.06 , 0.44
30 hours post randomization Observed	n	2	1	1	4	3
	Mean (SE)	0.23 (0.020)	0.23 (0)	0.35 (0)	0.26 (0.031)	0.28 (0.040)
	SD	0.028	0	0	0.062	0.070
	Median	0.23	0.23	0.35	0.24	0.28
	Min, Max	0.21 , 0.25	0.23 , 0.23	0.35 , 0.35	0.21 , 0.35	0.21 , 0.35
Change from Baseline	n	2	1	1	4	3
	Mean (SE)	-0.09 (0.080)	-0.02 (0)	0.05 (0)	-0.04 (0.047)	-0.04 (0.018)
	SD	0.113	0	0	0.094	0.031
	Median	-0.09	-0.02	0.05	-0.02	-0.03
	Min, Max	-0.17 , -0.01	-0.02 , -0.02	0.05 , 0.05	-0.17 , 0.05	-0.07 , -0.01
36 hours post randomization Observed	n	2	1	1	4	2

Summary Table 7.5.1.1
Clinical Assessments
Respiratory Parameters before Intubation - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	0.24 (0.025)	0.27 (0)	0.35 (0)	0.27 (0.029)	0.43 (0.220)
	SD	0.035	0	0	0.058	0.311
	Median	0.24	0.27	0.35	0.27	0.43
	Min, Max	0.21 , 0.26	0.27 , 0.27	0.35 , 0.35	0.21 , 0.35	0.21 , 0.65
Change from Baseline	n	2	1	1	4	2
	Mean (SE)	-0.09 (0.085)	0.02 (0)	0.05 (0)	-0.03 (0.049)	0.11 (0.180)
	SD	0.120	0	0	0.099	0.255
	Median	-0.09	0.02	0.05	0.01	0.11
	Min, Max	-0.17 , 0.00	0.02 , 0.02	0.05 , 0.05	-0.17 , 0.05	-0.07 , 0.29
42 hours post randomization Observed	n	2	1	1	4	1
	Mean (SE)	0.24 (0.030)	0.28 (0)	0.30 (0)	0.27 (0.019)	0.21 (0)
	SD	0.042	0	0	0.039	0
	Median	0.24	0.28	0.30	0.28	0.21
	Min, Max	0.21 , 0.27	0.28 , 0.28	0.30 , 0.30	0.21 , 0.30	0.21 , 0.21
Change from Baseline	n	2	1	1	4	1
	Mean (SE)	-0.08 (0.090)	0.03 (0)	0.00 (0)	-0.03 (0.046)	-0.07 (0)
	SD	0.127	0	0	0.093	0
	Median	-0.08	0.03	0.00	0.01	-0.07
	Min, Max	-0.17 , 0.01	0.03 , 0.03	0.00 , 0.00	-0.17 , 0.03	-0.07 , -0.07

Summary Table 7.5.1.1
Clinical Assessments
Respiratory Parameters before Intubation - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
48 hours post randomization						
Observed	n	2	1	1	4	1
	Mean (SE)	0.26 (0.025)	0.30 (0)	0.30 (0)	0.28 (0.017)	0.21 (0)
	SD	0.035	0	0	0.033	0
	Median	0.26	0.30	0.30	0.29	0.21
	Min, Max	0.23 , 0.28	0.30 , 0.30	0.30 , 0.30	0.23 , 0.30	0.21 , 0.21
Change from Baseline	n	2	1	1	4	1
	Mean (SE)	-0.07 (0.085)	0.05 (0)	0.00 (0)	-0.02 (0.045)	-0.07 (0)
	SD	0.120	0	0	0.089	0
	Median	-0.07	0.05	0.00	0.01	-0.07
	Min, Max	-0.15 , 0.02	0.05 , 0.05	0.00 , 0.00	-0.15 , 0.05	-0.07 , -0.07
54 hours post randomization						
Observed	n	2	1	1	4	1
	Mean (SE)	0.23 (0.020)	0.25 (0)	0.30 (0)	0.25 (0.018)	0.21 (0)
	SD	0.028	0	0	0.037	0
	Median	0.23	0.25	0.30	0.25	0.21
	Min, Max	0.21 , 0.25	0.25 , 0.25	0.30 , 0.30	0.21 , 0.30	0.21 , 0.21
Change from Baseline	n	2	1	1	4	1
	Mean (SE)	-0.09 (0.080)	0.00 (0)	0.00 (0)	-0.05 (0.042)	-0.07 (0)

Summary Table 7.5.1.1
Clinical Assessments
Respiratory Parameters before Intubation - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	0.113	0	0	0.083	0
	Median	-0.09	0.00	0.00	-0.01	-0.07
	Min, Max	-0.17 , -0.01	0.00 , 0.00	0.00 , 0.00	-0.17 , 0.00	-0.07 , -0.07
60 hours post randomization						
Observed	n	2	1	1	4	1
	Mean (SE)	0.25 (0.040)	0.25 (0)	0.25 (0)	0.25 (0.016)	0.21 (0)
	SD	0.057	0	0	0.033	0
	Median	0.25	0.25	0.25	0.25	0.21
	Min, Max	0.21 , 0.29	0.25 , 0.25	0.25 , 0.25	0.21 , 0.29	0.21 , 0.21
Change from Baseline						
	n	2	1	1	4	1
	Mean (SE)	-0.07 (0.100)	0.00 (0)	-0.05 (0)	-0.05 (0.044)	-0.07 (0)
	SD	0.141	0	0	0.088	0
	Median	-0.07	0.00	-0.05	-0.03	-0.07
	Min, Max	-0.17 , 0.03	0.00 , 0.00	-0.05 , -0.05	-0.17 , 0.03	-0.07 , -0.07
66 hours post randomization						
Observed	n	2	1	1	4	1
	Mean (SE)	0.23 (0.010)	0.25 (0)	0.21 (0)	0.23 (0.009)	0.21 (0)
	SD	0.014	0	0	0.018	0
	Median	0.23	0.25	0.21	0.23	0.21
	Min, Max	0.22 , 0.24	0.25 , 0.25	0.21 , 0.21	0.21 , 0.25	0.21 , 0.21

Summary Table 7.5.1.1
Clinical Assessments
Respiratory Parameters before Intubation - FiO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Change from Baseline	n	2	1	1	4	1
	Mean (SE)	-0.09 (0.070)	0.00 (0)	-0.09 (0)	-0.07 (0.036)	-0.07 (0)
	SD	0.099	0	0	0.073	0
	Median	-0.09	0.00	-0.09	-0.06	-0.07
	Min, Max	-0.16 , -0.02	0.00 , 0.00	-0.09 , -0.09	-0.16 , 0.00	-0.07 , -0.07
72 hours post randomization Observed	n	1	1	1	3	1
	Mean (SE)	0.23 (0)	0.23 (0)	0.21 (0)	0.22 (0.007)	0.21 (0)
	SD	0	0	0	0.012	0
	Median	0.23	0.23	0.21	0.23	0.21
	Min, Max	0.23 , 0.23	0.23 , 0.23	0.21 , 0.21	0.21 , 0.23	0.21 , 0.21
Change from Baseline	n	1	1	1	3	1
	Mean (SE)	-0.15 (0)	-0.02 (0)	-0.09 (0)	-0.09 (0.038)	-0.07 (0)
	SD	0	0	0	0.065	0
	Median	-0.15	-0.02	-0.09	-0.09	-0.07
	Min, Max	-0.15 , -0.15	-0.02 , -0.02	-0.09 , -0.09	-0.15 , -0.02	-0.07 , -0.07

Summary Table 7.5.2
Clinical Assessments
Respiratory Parameters - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
At the time of randomization						
Observed (Baseline)	n	6	6	6	18	15
	Mean (SE)	50.2 (3.72)	48.1 (2.68)	48.5 (4.60)	48.9 (2.05)	50.5 (3.24)
	SD	9.12	6.56	11.28	8.68	12.55
	Median	45.0	46.8	48.5	47.0	49.0
	Min, Max	44 , 65	39 , 57	31 , 62	31 , 65	31 , 81
15 minutes post randomization						
Observed	n	4	6	5	15	14
	Mean (SE)	48.3 (3.07)	49.3 (3.14)	48.3 (5.82)	48.7 (2.28)	47.2 (2.78)
	SD	6.13	7.69	13.01	8.82	10.39
	Median	48.5	46.6	49.0	47.2	48.0
	Min, Max	42 , 54	42 , 62	31 , 62	31 , 62	30 , 65
Change from Baseline						
	n	4	6	5	15	14
	Mean (SE)	-1.5 (4.57)	1.2 (1.02)	-0.0 (0.67)	0.1 (1.21)	-3.6 (1.29)
	SD	9.15	2.51	1.49	4.70	4.82
	Median	-2.0	1.0	0.4	0.4	-2.3
	Min, Max	-12 , 10	-2 , 5	-3 , 1	-12 , 10	-17 , 1
30 minutes post randomization						
Observed	n	4	6	4	14	13
	Mean (SE)	49.5 (2.78)	49.4 (2.61)	46.3 (6.39)	48.6 (2.12)	47.5 (3.02)
	SD	5.57	6.38	12.79	7.92	10.90
	Median	48.5	46.2	45.3	46.7	49.0

Summary Table 7.5.2
Clinical Assessments
Respiratory Parameters - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	44 , 57	44 , 59	33 , 62	33 , 62	30 , 67
Change from Baseline	n	4	6	4	14	13
	Mean (SE)	-0.3 (5.82)	1.3 (0.95)	0.3 (1.04)	0.6 (1.58)	-3.8 (1.49)
	SD	11.64	2.34	2.08	5.91	5.38
	Median	0.5	1.5	0.9	1.4	-4.0
	Min, Max	-15 , 13	-2 , 5	-2 , 2	-15 , 13	-15 , 4
45 minutes post randomization Observed	n	4	6	4	14	13
	Mean (SE)	48.5 (2.40)	47.8 (3.09)	46.5 (5.64)	47.6 (2.03)	47.6 (3.42)
	SD	4.80	7.57	11.29	7.58	12.34
	Median	47.5	46.0	45.6	46.5	45.8
	Min, Max	44 , 55	37 , 57	34 , 61	34 , 61	32 , 74
Change from Baseline	n	4	6	4	14	13
	Mean (SE)	-1.3 (5.62)	-0.3 (0.89)	0.5 (1.03)	-0.3 (1.52)	-3.8 (2.44)
	SD	11.24	2.18	2.06	5.69	8.81
	Median	0.0	0.0	0.2	0.0	-4.8
	Min, Max	-16 , 11	-4 , 2	-1 , 3	-16 , 11	-19 , 11
60 minutes post randomization Observed	n	5	6	6	17	16
	Mean (SE)	53.0 (4.16)	47.7 (2.22)	55.4 (8.96)	52.0 (3.37)	48.7 (2.75)
	SD	9.30	5.45	21.94	13.89	11.02

Summary Table 7.5.2
Clinical Assessments
Respiratory Parameters - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	50.0	48.1	47.8	49.5	47.6
	Min, Max	43 , 67	39 , 54	39 , 99	39 , 99	35 , 75
Change from Baseline	n	4	6	5	15	13
	Mean (SE)	-0.3 (6.47)	-0.4 (1.84)	0.1 (2.70)	-0.2 (1.89)	-1.9 (2.07)
	SD	12.95	4.52	6.04	7.33	7.48
	Median	1.5	-0.1	0.5	0.0	-4.0
	Min, Max	-17 , 13	-7 , 7	-8 , 8	-17 , 13	-16 , 13
1 hour 15 minutes (75 minutes) post randomization						
Observed	n	5	6	6	17	18
	Mean (SE)	51.4 (4.23)	48.1 (2.02)	56.9 (9.94)	52.2 (3.68)	49.9 (2.52)
	SD	9.45	4.95	24.34	15.17	10.67
	Median	50.0	49.5	47.9	50.0	50.0
	Min, Max	41 , 65	40 , 54	39 , 105	39 , 105	34 , 70
Change from Baseline	n	4	6	5	15	13
	Mean (SE)	-1.8 (5.65)	-0.0 (1.90)	0.7 (2.35)	-0.3 (1.71)	-1.3 (2.43)
	SD	11.30	4.65	5.25	6.63	8.75
	Median	-2.0	0.5	1.9	1.0	-3.0
	Min, Max	-15 , 12	-7 , 5	-5 , 8	-15 , 12	-15 , 14
1 hour 30 minutes (90 minutes) post randomization						
Observed	n	6	6	6	18	19
	Mean (SE)	50.0 (3.44)	51.0 (3.56)	58.0 (12.60)	53.0 (4.32)	48.3 (2.37)

Summary Table 7.5.2
Clinical Assessments
Respiratory Parameters - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	8.41	8.72	30.86	18.35	10.33
	Median	48.0	49.0	47.6	48.5	48.1
	Min, Max	42 , 66	39 , 62	36 , 120	36 , 120	28 , 65
Change from Baseline	n	5	6	5	16	14
	Mean (SE)	-1.8 (4.21)	3.0 (2.97)	-1.0 (3.39)	0.2 (1.96)	-3.1 (2.38)
	SD	9.42	7.28	7.58	7.84	8.90
	Median	1.0	2.8	1.7	1.6	-3.0
	Min, Max	-17 , 7	-8 , 14	-13 , 6	-17 , 14	-16 , 15
1 hour 45 minutes (105 minutes) post randomization						
Observed	n	6	6	6	18	18
	Mean (SE)	49.8 (3.30)	50.7 (3.23)	55.0 (10.18)	51.9 (3.54)	48.5 (2.34)
	SD	8.08	7.90	24.93	15.03	9.94
	Median	49.0	51.0	45.1	49.0	47.7
	Min, Max	42 , 65	39 , 61	39 , 105	39 , 105	30 , 66
Change from Baseline	n	4	6	5	15	13
	Mean (SE)	-3.8 (6.13)	2.7 (1.91)	-1.6 (4.89)	-0.5 (2.34)	-3.1 (2.51)
	SD	12.26	4.68	10.94	9.05	9.05
	Median	0.5	2.3	0.3	0.5	-2.0
	Min, Max	-21 , 5	-4 , 8	-20 , 9	-21 , 9	-21 , 10
2 hours (120 minutes) post randomization						
Observed	n	5	6	5	16	19

Summary Table 7.5.2
Clinical Assessments
Respiratory Parameters - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	47.6 (4.55)	50.0 (2.61)	45.2 (2.46)	47.7 (1.83)	48.0 (2.13)
	SD	10.16	6.40	5.51	7.31	9.29
	Median	48.0	49.5	45.7	47.0	47.6
	Min, Max	37 , 62	42 , 61	38 , 53	37 , 62	33 , 61
Change from Baseline	n	4	6	5	15	13
	Mean (SE)	-5.8 (5.15)	1.9 (2.15)	-1.4 (4.65)	-1.3 (2.21)	-2.2 (2.31)
	SD	10.31	5.26	10.40	8.57	8.31
	Median	-7.0	3.2	2.9	2.9	-1.0
Min, Max	-17 , 8	-8 , 7	-19 , 7	-19 , 8	-24 , 9	
2 hours 15 minutes (135 minutes) post randomization Observed	n	5	6	5	16	18
	Mean (SE)	48.0 (4.32)	49.1 (2.13)	43.2 (1.90)	46.9 (1.69)	48.0 (2.34)
	SD	9.67	5.22	4.24	6.76	9.94
	Median	43.0	49.3	44.2	46.0	47.3
Min, Max	39 , 62	42 , 56	39 , 47	39 , 62	34 , 67	
Change from Baseline	n	4	6	5	15	13
	Mean (SE)	-5.3 (6.88)	1.0 (1.41)	-3.4 (5.52)	-2.1 (2.53)	-2.6 (2.19)
	SD	13.77	3.45	12.34	9.79	7.89
	Median	-4.0	0.9	-1.0	-0.8	-1.0
Min, Max	-23 , 10	-4 , 6	-24 , 8	-24 , 10	-25 , 7	
2 hours 30 minutes (150 minutes) post randomization						

Summary Table 7.5.2
Clinical Assessments
Respiratory Parameters - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Observed	n	5	7	6	18	19
	Mean (SE)	47.6 (4.08)	52.4 (4.17)	46.8 (3.43)	49.2 (2.24)	45.7 (2.74)
	SD	9.13	11.02	8.39	9.50	11.94
	Median	45.0	49.0	45.0	47.0	46.9
	Min, Max	38 , 62	42 , 74	37 , 60	37 , 74	23 , 75
Change from Baseline	n	4	6	5	15	14
	Mean (SE)	-5.8 (6.14)	0.8 (1.50)	-2.4 (4.95)	-2.0 (2.30)	-4.3 (3.21)
	SD	12.28	3.68	11.06	8.92	12.03
	Median	-3.5	2.5	1.3	1.3	-1.6
	Min, Max	-22 , 6	-5 , 4	-21 , 6	-22 , 6	-32 , 12
2 hours 45 minutes (165 minutes) post randomization Observed	n	5	7	4	16	19
	Mean (SE)	48.2 (3.80)	49.1 (3.66)	44.7 (2.65)	47.7 (2.03)	48.0 (2.56)
	SD	8.50	9.68	5.30	8.11	11.16
	Median	46.0	47.0	46.7	46.5	46.0
	Min, Max	41 , 62	37 , 68	37 , 48	37 , 68	35 , 76
Change from Baseline	n	4	6	4	14	13
	Mean (SE)	-5.0 (6.42)	-2.1 (1.09)	2.1 (2.36)	-1.7 (1.96)	-2.8 (2.55)
	SD	12.83	2.66	4.72	7.33	9.18
	Median	-1.5	-2.0	2.8	-1.3	-3.0
	Min, Max	-23 , 6	-5 , 2	-4 , 6	-23 , 6	-25 , 13

Summary Table 7.5.2
Clinical Assessments
Respiratory Parameters - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
3 hours (180 minutes) post randomization						
Observed	n	6	7	5	18	19
	Mean (SE)	49.0 (3.14)	49.7 (2.97)	41.3 (2.18)	47.1 (1.80)	46.3 (2.20)
	SD	7.69	7.87	4.87	7.65	9.58
	Median	48.5	47.0	40.0	46.6	44.6
	Min, Max	40 , 62	41 , 63	37 , 49	37 , 63	34 , 67
Change from Baseline	n	4	6	5	15	14
	Mean (SE)	-4.8 (6.26)	-0.7 (2.04)	-5.2 (5.67)	-3.3 (2.49)	-2.7 (2.58)
	SD	12.53	5.00	12.67	9.66	9.65
	Median	-1.0	1.4	-5.1	0.9	-3.0
	Min, Max	-22 , 5	-7 , 4	-25 , 6	-25 , 6	-27 , 15
6 hours post randomization						
Observed	n	7	7	7	21	18
	Mean (SE)	47.2 (2.02)	50.7 (2.46)	47.9 (2.53)	48.6 (1.33)	44.7 (1.71)
	SD	5.35	6.50	6.68	6.09	7.24
	Median	47.0	51.0	49.0	48.0	44.9
	Min, Max	40 , 56	42 , 60	37 , 58	37 , 60	32 , 60
Change from Baseline	n	5	6	5	16	13
	Mean (SE)	-3.9 (4.97)	2.3 (2.56)	1.0 (2.60)	-0.1 (1.97)	-3.7 (2.85)
	SD	11.11	6.26	5.81	7.90	10.27
	Median	1.0	1.3	1.0	1.0	-2.1
	Min, Max	-23 , 4	-6 , 12	-5 , 7	-23 , 12	-33 , 11

Summary Table 7.5.2
Clinical Assessments
Respiratory Parameters - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
12 hours post randomization						
Observed	n	7	7	8	22	16
	Mean (SE)	48.7 (3.37)	47.7 (3.19)	50.8 (2.79)	49.1 (1.73)	46.5 (2.22)
	SD	8.92	8.44	7.90	8.11	8.88
	Median	50.0	47.1	50.8	49.8	45.5
	Min, Max	32 , 58	39 , 62	36 , 62	32 , 62	32 , 68
Change from Baseline	n	5	6	6	17	13
	Mean (SE)	-3.6 (3.87)	-1.1 (2.27)	1.2 (4.55)	-1.0 (2.05)	-2.1 (3.86)
	SD	8.65	5.57	11.14	8.44	13.92
	Median	0.8	-2.0	2.0	0.8	-3.0
	Min, Max	-14 , 4	-7 , 8	-12 , 19	-14 , 19	-34 , 21
18 hours post randomization						
Observed	n	7	7	7	21	18
	Mean (SE)	53.6 (4.39)	52.8 (3.08)	52.0 (2.80)	52.8 (1.92)	45.8 (4.93)
	SD	11.61	8.15	7.40	8.79	20.94
	Median	52.0	56.1	53.0	53.0	42.4
	Min, Max	32 , 65	42 , 61	43 , 63	32 , 65	0 , 101
Change from Baseline	n	5	6	5	16	13
	Mean (SE)	3.0 (4.45)	3.6 (2.36)	4.1 (4.36)	3.6 (1.99)	-1.1 (6.03)
	SD	9.96	5.79	9.75	7.95	21.73
	Median	6.0	4.0	10.0	5.5	-1.0

Summary Table 7.5.2
Clinical Assessments
Respiratory Parameters - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	-12 , 15	-6 , 11	-9 , 13	-12 , 15	-37 , 52
24 hours post randomization						
Observed	n	7	6	6	19	20
	Mean (SE)	50.0 (4.15)	47.4 (4.40)	49.5 (1.97)	49.0 (2.05)	45.6 (1.65)
	SD	10.97	10.77	4.82	8.95	7.39
	Median	52.0	47.0	51.7	52.0	45.0
	Min, Max	32 , 68	32 , 59	42 , 55	32 , 68	36 , 62
Change from Baseline	n	5	6	5	16	14
	Mean (SE)	-1.0 (4.37)	-0.7 (3.78)	1.9 (3.95)	0.0 (2.19)	-4.3 (3.51)
	SD	9.77	9.26	8.83	8.75	13.15
	Median	3.0	-1.5	3.0	2.5	-3.0
	Min, Max	-12 , 8	-13 , 13	-10 , 12	-13 , 13	-36 , 18
30 hours post randomization						
Observed	n	6	6	8	20	20
	Mean (SE)	48.0 (4.10)	45.3 (4.16)	50.5 (2.47)	48.2 (1.96)	47.7 (2.55)
	SD	10.05	10.19	6.99	8.76	11.41
	Median	50.6	46.8	52.8	49.5	47.6
	Min, Max	33 , 58	30 , 56	38 , 59	30 , 59	30 , 74
Change from Baseline	n	4	5	6	15	14
	Mean (SE)	-5.5 (2.94)	-2.8 (2.39)	-0.1 (3.84)	-2.5 (1.86)	-1.7 (3.90)
	SD	5.89	5.35	9.41	7.22	14.58

Summary Table 7.5.2
Clinical Assessments
Respiratory Parameters - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	-6.5	-1.0	-0.5	-3.0	-6.0
	Min, Max	-11 , 2	-9 , 3	-13 , 12	-13 , 12	-30 , 26
36 hours post randomization						
Observed	n	7	7	7	21	21
	Mean (SE)	54.4 (4.51)	48.3 (3.44)	50.7 (2.25)	51.1 (2.01)	51.4 (3.40)
	SD	11.93	9.11	5.96	9.21	15.57
	Median	54.0	48.0	54.0	54.0	48.0
	Min, Max	38 , 67	37 , 60	42 , 56	37 , 67	32 , 90
Change from Baseline	n	5	6	5	16	15
	Mean (SE)	5.9 (4.08)	0.3 (3.04)	3.8 (3.88)	3.1 (2.05)	2.4 (4.79)
	SD	9.13	7.45	8.68	8.18	18.57
	Median	6.7	-0.5	7.0	2.5	4.0
	Min, Max	-6 , 19	-11 , 12	-7 , 12	-11 , 19	-32 , 28
42 hours post randomization						
Observed	n	6	6	7	19	20
	Mean (SE)	50.6 (5.53)	52.0 (2.59)	54.8 (2.76)	52.6 (2.09)	51.4 (2.47)
	SD	13.54	6.33	7.30	9.11	11.04
	Median	50.3	54.0	56.0	55.0	49.0
	Min, Max	35 , 70	40 , 58	45 , 66	35 , 70	35 , 74
Change from Baseline	n	4	5	5	14	14
	Mean (SE)	2.2 (9.36)	2.7 (4.50)	5.2 (4.07)	3.4 (3.16)	1.3 (3.72)

Summary Table 7.5.2
Clinical Assessments
Respiratory Parameters - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	18.73	10.07	9.09	11.81	13.91
	Median	-0.7	-2.0	7.0	2.5	1.7
	Min, Max	-16 , 26	-8 , 14	-5 , 15	-16 , 26	-34 , 22
48 hours post randomization						
Observed	n	6	5	7	18	19
	Mean (SE)	45.5 (4.10)	48.6 (3.58)	53.4 (3.49)	49.5 (2.20)	48.9 (2.09)
	SD	10.05	8.00	9.23	9.34	9.13
	Median	49.0	50.2	53.0	50.6	47.0
	Min, Max	26 , 53	36 , 58	40 , 64	26 , 64	34 , 66
Change from Baseline	n	4	4	5	13	13
	Mean (SE)	-7.3 (5.72)	0.9 (4.69)	3.4 (4.98)	-0.7 (3.01)	-0.3 (4.39)
	SD	11.44	9.38	11.13	10.87	15.82
	Median	-8.0	3.4	2.0	1.0	1.0
	Min, Max	-18 , 5	-12 , 9	-9 , 19	-18 , 19	-41 , 24
54 hours post randomization						
Observed	n	6	6	6	18	18
	Mean (SE)	49.0 (5.01)	47.5 (5.84)	55.9 (4.33)	50.8 (2.90)	47.8 (2.12)
	SD	12.27	14.29	10.60	12.30	9.00
	Median	56.1	46.0	60.7	54.6	45.5
	Min, Max	30 , 58	32 , 71	42 , 67	30 , 71	34 , 69
Change from Baseline	n	4	5	5	14	13

Summary Table 7.5.2
Clinical Assessments
Respiratory Parameters - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	0.8 (6.95)	-1.9 (5.91)	8.2 (4.02)	2.5 (3.21)	-1.8 (4.11)
	SD	13.89	13.22	8.99	11.99	14.81
	Median	1.6	-3.0	11.0	6.6	1.0
	Min, Max	-14 , 14	-16 , 14	-5 , 19	-16 , 19	-39 , 23
60 hours post randomization						
Observed	n	6	6	6	18	19
	Mean (SE)	56.3 (3.80)	45.5 (4.84)	51.4 (3.89)	51.1 (2.52)	51.8 (3.52)
	SD	9.31	11.86	9.52	10.68	15.33
	Median	57.5	46.6	51.3	53.0	51.0
	Min, Max	40 , 68	29 , 62	41 , 61	29 , 68	34 , 100
Change from Baseline						
	n	4	5	5	14	13
	Mean (SE)	3.0 (4.97)	-4.3 (5.42)	2.9 (3.50)	0.4 (2.67)	1.1 (3.65)
	SD	9.93	12.11	7.83	9.99	13.16
	Median	3.0	-10.0	1.7	-2.7	2.0
	Min, Max	-7 , 13	-12 , 17	-7 , 12	-12 , 17	-30 , 16
66 hours post randomization						
Observed	n	7	6	7	20	17
	Mean (SE)	60.7 (3.62)	48.5 (3.38)	51.8 (4.00)	53.9 (2.35)	49.2 (3.23)
	SD	9.59	8.28	10.60	10.51	13.31
	Median	62.0	48.8	57.0	55.7	47.0
	Min, Max	48 , 74	38 , 59	35 , 66	35 , 74	28 , 74

Summary Table 7.5.2
Clinical Assessments
Respiratory Parameters - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Change from Baseline	n	5	5	6	16	12
	Mean (SE)	11.4 (4.73)	-1.4 (4.11)	2.5 (7.13)	4.0 (3.38)	-1.2 (4.40)
	SD	10.57	9.19	17.47	13.53	15.24
	Median	5.0	2.0	1.3	4.5	0.0
	Min, Max	4 , 28	-12 , 8	-23 , 23	-23 , 28	-29 , 23
72 hours post randomization Observed	n	6	6	7	19	14
	Mean (SE)	49.8 (3.82)	49.1 (5.88)	55.4 (4.98)	51.7 (2.80)	45.5 (2.86)
	SD	9.37	14.40	13.17	12.20	10.69
	Median	50.5	48.5	57.0	54.0	46.6
	Min, Max	37 , 62	33 , 68	40 , 80	33 , 80	26 , 61
Change from Baseline	n	4	5	5	14	11
	Mean (SE)	-1.5 (4.50)	-2.0 (7.63)	10.1 (7.37)	2.5 (4.03)	-2.9 (5.54)
	SD	9.00	17.05	16.48	15.06	18.39
	Median	-4.0	-3.0	16.4	-2.0	6.0
	Min, Max	-9 , 11	-21 , 23	-8 , 31	-21 , 31	-37 , 24

Summary Table 7.5.2.1
Clinical Assessments
Respiratory Parameters before Intubation - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
At the time of randomization						
Observed (Baseline)	n	6	6	6	18	15
	Mean (SE)	50.2 (3.72)	48.1 (2.68)	48.5 (4.60)	48.9 (2.05)	50.5 (3.24)
	SD	9.12	6.56	11.28	8.68	12.55
	Median	45.0	46.8	48.5	47.0	49.0
	Min, Max	44 , 65	39 , 57	31 , 62	31 , 65	31 , 81
15 minutes post randomization						
Observed	n	4	6	5	15	14
	Mean (SE)	48.3 (3.07)	49.3 (3.14)	48.3 (5.82)	48.7 (2.28)	47.2 (2.78)
	SD	6.13	7.69	13.01	8.82	10.39
	Median	48.5	46.6	49.0	47.2	48.0
	Min, Max	42 , 54	42 , 62	31 , 62	31 , 62	30 , 65
Change from Baseline						
	n	4	6	5	15	14
	Mean (SE)	-1.5 (4.57)	1.2 (1.02)	-0.0 (0.67)	0.1 (1.21)	-3.6 (1.29)
	SD	9.15	2.51	1.49	4.70	4.82
	Median	-2.0	1.0	0.4	0.4	-2.3
	Min, Max	-12 , 10	-2 , 5	-3 , 1	-12 , 10	-17 , 1
30 minutes post randomization						
Observed	n	4	6	4	14	13
	Mean (SE)	49.5 (2.78)	49.4 (2.61)	46.3 (6.39)	48.6 (2.12)	47.5 (3.02)

Summary Table 7.5.2.1
Clinical Assessments
Respiratory Parameters before Intubation - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	5.57	6.38	12.79	7.92	10.90
	Median	48.5	46.2	45.3	46.7	49.0
	Min, Max	44 , 57	44 , 59	33 , 62	33 , 62	30 , 67
Change from Baseline	n	4	6	4	14	13
	Mean (SE)	-0.3 (5.82)	1.3 (0.95)	0.3 (1.04)	0.6 (1.58)	-3.8 (1.49)
	SD	11.64	2.34	2.08	5.91	5.38
	Median	0.5	1.5	0.9	1.4	-4.0
	Min, Max	-15 , 13	-2 , 5	-2 , 2	-15 , 13	-15 , 4
45 minutes post randomization						
Observed	n	4	6	4	14	13
	Mean (SE)	48.5 (2.40)	47.8 (3.09)	46.5 (5.64)	47.6 (2.03)	47.6 (3.42)
	SD	4.80	7.57	11.29	7.58	12.34
	Median	47.5	46.0	45.6	46.5	45.8
	Min, Max	44 , 55	37 , 57	34 , 61	34 , 61	32 , 74
Change from Baseline	n	4	6	4	14	13
	Mean (SE)	-1.3 (5.62)	-0.3 (0.89)	0.5 (1.03)	-0.3 (1.52)	-3.8 (2.44)
	SD	11.24	2.18	2.06	5.69	8.81
	Median	0.0	0.0	0.2	0.0	-4.8
	Min, Max	-16 , 11	-4 , 2	-1 , 3	-16 , 11	-19 , 11

Summary Table 7.5.2.1
Clinical Assessments
Respiratory Parameters before Intubation - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
60 minutes post randomization						
Observed	n	5	6	6	17	16
	Mean (SE)	53.0 (4.16)	47.7 (2.22)	55.4 (8.96)	52.0 (3.37)	48.7 (2.75)
	SD	9.30	5.45	21.94	13.89	11.02
	Median	50.0	48.1	47.8	49.5	47.6
	Min, Max	43 , 67	39 , 54	39 , 99	39 , 99	35 , 75
Change from Baseline	n	4	6	5	15	13
	Mean (SE)	-0.3 (6.47)	-0.4 (1.84)	0.1 (2.70)	-0.2 (1.89)	-1.9 (2.07)
	SD	12.95	4.52	6.04	7.33	7.48
	Median	1.5	-0.1	0.5	0.0	-4.0
	Min, Max	-17 , 13	-7 , 7	-8 , 8	-17 , 13	-16 , 13
1 hour 15 minutes (75 minutes) post randomization						
Observed	n	5	6	6	17	18
	Mean (SE)	51.4 (4.23)	48.1 (2.02)	56.9 (9.94)	52.2 (3.68)	49.9 (2.52)
	SD	9.45	4.95	24.34	15.17	10.67
	Median	50.0	49.5	47.9	50.0	50.0
	Min, Max	41 , 65	40 , 54	39 , 105	39 , 105	34 , 70
Change from Baseline	n	4	6	5	15	13
	Mean (SE)	-1.8 (5.65)	-0.0 (1.90)	0.7 (2.35)	-0.3 (1.71)	-1.3 (2.43)
	SD	11.30	4.65	5.25	6.63	8.75

Summary Table 7.5.2.1
Clinical Assessments
Respiratory Parameters before Intubation - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	-2.0	0.5	1.9	1.0	-3.0
	Min, Max	-15 , 12	-7 , 5	-5 , 8	-15 , 12	-15 , 14
1 hour 30 minutes (90 minutes) post randomization						
Observed	n	6	6	6	18	19
	Mean (SE)	50.0 (3.44)	51.0 (3.56)	58.0 (12.60)	53.0 (4.32)	48.3 (2.37)
	SD	8.41	8.72	30.86	18.35	10.33
	Median	48.0	49.0	47.6	48.5	48.1
	Min, Max	42 , 66	39 , 62	36 , 120	36 , 120	28 , 65
Change from Baseline	n	5	6	5	16	14
	Mean (SE)	-1.8 (4.21)	3.0 (2.97)	-1.0 (3.39)	0.2 (1.96)	-3.1 (2.38)
	SD	9.42	7.28	7.58	7.84	8.90
	Median	1.0	2.8	1.7	1.6	-3.0
	Min, Max	-17 , 7	-8 , 14	-13 , 6	-17 , 14	-16 , 15
1 hour 45 minutes (105 minutes) post randomization						
Observed	n	6	6	6	18	18
	Mean (SE)	49.8 (3.30)	50.7 (3.23)	55.0 (10.18)	51.9 (3.54)	48.5 (2.34)
	SD	8.08	7.90	24.93	15.03	9.94
	Median	49.0	51.0	45.1	49.0	47.7
	Min, Max	42 , 65	39 , 61	39 , 105	39 , 105	30 , 66

Summary Table 7.5.2.1
Clinical Assessments
Respiratory Parameters before Intubation - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Change from Baseline	n	4	6	5	15	13
	Mean (SE)	-3.8 (6.13)	2.7 (1.91)	-1.6 (4.89)	-0.5 (2.34)	-3.1 (2.51)
	SD	12.26	4.68	10.94	9.05	9.05
	Median	0.5	2.3	0.3	0.5	-2.0
	Min, Max	-21 , 5	-4 , 8	-20 , 9	-21 , 9	-21 , 10
2 hours (120 minutes) post randomization						
Observed	n	5	6	5	16	19
	Mean (SE)	47.6 (4.55)	50.0 (2.61)	45.2 (2.46)	47.7 (1.83)	48.0 (2.13)
	SD	10.16	6.40	5.51	7.31	9.29
	Median	48.0	49.5	45.7	47.0	47.6
	Min, Max	37 , 62	42 , 61	38 , 53	37 , 62	33 , 61
Change from Baseline	n	4	6	5	15	13
	Mean (SE)	-5.8 (5.15)	1.9 (2.15)	-1.4 (4.65)	-1.3 (2.21)	-2.2 (2.31)
	SD	10.31	5.26	10.40	8.57	8.31
	Median	-7.0	3.2	2.9	2.9	-1.0
	Min, Max	-17 , 8	-8 , 7	-19 , 7	-19 , 8	-24 , 9
2 hours 15 minutes (135 minutes) post randomization						
Observed	n	5	6	5	16	18
	Mean (SE)	48.0 (4.32)	49.1 (2.13)	43.2 (1.90)	46.9 (1.69)	48.0 (2.34)
	SD	9.67	5.22	4.24	6.76	9.94

Summary Table 7.5.2.1
Clinical Assessments
Respiratory Parameters before Intubation - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	43.0	49.3	44.2	46.0	47.3
	Min, Max	39 , 62	42 , 56	39 , 47	39 , 62	34 , 67
Change from Baseline	n	4	6	5	15	13
	Mean (SE)	-5.3 (6.88)	1.0 (1.41)	-3.4 (5.52)	-2.1 (2.53)	-2.6 (2.19)
	SD	13.77	3.45	12.34	9.79	7.89
	Median	-4.0	0.9	-1.0	-0.8	-1.0
	Min, Max	-23 , 10	-4 , 6	-24 , 8	-24 , 10	-25 , 7
2 hours 30 minutes (150 minutes) post randomization						
Observed	n	5	7	6	18	19
	Mean (SE)	47.6 (4.08)	52.4 (4.17)	46.8 (3.43)	49.2 (2.24)	45.7 (2.74)
	SD	9.13	11.02	8.39	9.50	11.94
	Median	45.0	49.0	45.0	47.0	46.9
	Min, Max	38 , 62	42 , 74	37 , 60	37 , 74	23 , 75
Change from Baseline	n	4	6	5	15	14
	Mean (SE)	-5.8 (6.14)	0.8 (1.50)	-2.4 (4.95)	-2.0 (2.30)	-4.3 (3.21)
	SD	12.28	3.68	11.06	8.92	12.03
	Median	-3.5	2.5	1.3	1.3	-1.6
	Min, Max	-22 , 6	-5 , 4	-21 , 6	-22 , 6	-32 , 12
2 hours 45 minutes (165 minutes) post randomization						

Summary Table 7.5.2.1
Clinical Assessments
Respiratory Parameters before Intubation - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Observed	n	5	7	4	16	19
	Mean (SE)	48.2 (3.80)	49.1 (3.66)	44.7 (2.65)	47.7 (2.03)	48.0 (2.56)
	SD	8.50	9.68	5.30	8.11	11.16
	Median	46.0	47.0	46.7	46.5	46.0
	Min, Max	41 , 62	37 , 68	37 , 48	37 , 68	35 , 76
Change from Baseline	n	4	6	4	14	13
	Mean (SE)	-5.0 (6.42)	-2.1 (1.09)	2.1 (2.36)	-1.7 (1.96)	-2.8 (2.55)
	SD	12.83	2.66	4.72	7.33	9.18
	Median	-1.5	-2.0	2.8	-1.3	-3.0
	Min, Max	-23 , 6	-5 , 2	-4 , 6	-23 , 6	-25 , 13
3 hours (180 minutes) post randomization Observed	n	6	7	5	18	19
	Mean (SE)	49.0 (3.14)	49.7 (2.97)	41.3 (2.18)	47.1 (1.80)	46.3 (2.20)
	SD	7.69	7.87	4.87	7.65	9.58
	Median	48.5	47.0	40.0	46.6	44.6
	Min, Max	40 , 62	41 , 63	37 , 49	37 , 63	34 , 67
Change from Baseline	n	4	6	5	15	14
	Mean (SE)	-4.8 (6.26)	-0.7 (2.04)	-5.2 (5.67)	-3.3 (2.49)	-2.7 (2.58)
	SD	12.53	5.00	12.67	9.66	9.65
	Median	-1.0	1.4	-5.1	0.9	-3.0

Summary Table 7.5.2.1
Clinical Assessments
Respiratory Parameters before Intubation - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	-22 , 5	-7 , 4	-25 , 6	-25 , 6	-27 , 15
6 hours post randomization						
Observed	n	7	7	7	21	18
	Mean (SE)	47.2 (2.02)	50.7 (2.46)	47.9 (2.53)	48.6 (1.33)	44.7 (1.71)
	SD	5.35	6.50	6.68	6.09	7.24
	Median	47.0	51.0	49.0	48.0	44.9
	Min, Max	40 , 56	42 , 60	37 , 58	37 , 60	32 , 60
Change from Baseline	n	5	6	5	16	13
	Mean (SE)	-3.9 (4.97)	2.3 (2.56)	1.0 (2.60)	-0.1 (1.97)	-3.7 (2.85)
	SD	11.11	6.26	5.81	7.90	10.27
	Median	1.0	1.3	1.0	1.0	-2.1
	Min, Max	-23 , 4	-6 , 12	-5 , 7	-23 , 12	-33 , 11
12 hours post randomization						
Observed	n	7	7	8	22	16
	Mean (SE)	48.7 (3.37)	47.7 (3.19)	50.8 (2.79)	49.1 (1.73)	46.5 (2.22)
	SD	8.92	8.44	7.90	8.11	8.88
	Median	50.0	47.1	50.8	49.8	45.5
	Min, Max	32 , 58	39 , 62	36 , 62	32 , 62	32 , 68
Change from Baseline	n	5	6	6	17	13

Summary Table 7.5.2.1
Clinical Assessments
Respiratory Parameters before Intubation - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	-3.6 (3.87)	-1.1 (2.27)	1.2 (4.55)	-1.0 (2.05)	-2.1 (3.86)
	SD	8.65	5.57	11.14	8.44	13.92
	Median	0.8	-2.0	2.0	0.8	-3.0
	Min, Max	-14 , 4	-7 , 8	-12 , 19	-14 , 19	-34 , 21
18 hours post randomization						
Observed	n	7	7	7	21	18
	Mean (SE)	53.6 (4.39)	52.8 (3.08)	52.0 (2.80)	52.8 (1.92)	45.8 (4.93)
	SD	11.61	8.15	7.40	8.79	20.94
	Median	52.0	56.1	53.0	53.0	42.4
	Min, Max	32 , 65	42 , 61	43 , 63	32 , 65	0 , 101
Change from Baseline						
	n	5	6	5	16	13
	Mean (SE)	3.0 (4.45)	3.6 (2.36)	4.1 (4.36)	3.6 (1.99)	-1.1 (6.03)
	SD	9.96	5.79	9.75	7.95	21.73
	Median	6.0	4.0	10.0	5.5	-1.0
	Min, Max	-12 , 15	-6 , 11	-9 , 13	-12 , 15	-37 , 52
24 hours post randomization						
Observed	n	7	6	6	19	20
	Mean (SE)	50.0 (4.15)	47.4 (4.40)	49.5 (1.97)	49.0 (2.05)	45.6 (1.65)
	SD	10.97	10.77	4.82	8.95	7.39
	Median	52.0	47.0	51.7	52.0	45.0

Summary Table 7.5.2.1
Clinical Assessments
Respiratory Parameters before Intubation - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	32 , 68	32 , 59	42 , 55	32 , 68	36 , 62
Change from Baseline	n	5	6	5	16	14
	Mean (SE)	-1.0 (4.37)	-0.7 (3.78)	1.9 (3.95)	0.0 (2.19)	-4.3 (3.51)
	SD	9.77	9.26	8.83	8.75	13.15
	Median	3.0	-1.5	3.0	2.5	-3.0
	Min, Max	-12 , 8	-13 , 13	-10 , 12	-13 , 13	-36 , 18
30 hours post randomization Observed	n	6	6	8	20	20
	Mean (SE)	48.0 (4.10)	45.3 (4.16)	50.5 (2.47)	48.2 (1.96)	47.7 (2.55)
	SD	10.05	10.19	6.99	8.76	11.41
	Median	50.6	46.8	52.8	49.5	47.6
	Min, Max	33 , 58	30 , 56	38 , 59	30 , 59	30 , 74
Change from Baseline	n	4	5	6	15	14
	Mean (SE)	-5.5 (2.94)	-2.8 (2.39)	-0.1 (3.84)	-2.5 (1.86)	-1.7 (3.90)
	SD	5.89	5.35	9.41	7.22	14.58
	Median	-6.5	-1.0	-0.5	-3.0	-6.0
	Min, Max	-11 , 2	-9 , 3	-13 , 12	-13 , 12	-30 , 26
36 hours post randomization Observed	n	7	7	7	21	21

Summary Table 7.5.2.1
Clinical Assessments
Respiratory Parameters before Intubation - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	54.4 (4.51)	48.3 (3.44)	50.7 (2.25)	51.1 (2.01)	51.4 (3.40)
	SD	11.93	9.11	5.96	9.21	15.57
	Median	54.0	48.0	54.0	54.0	48.0
	Min, Max	38 , 67	37 , 60	42 , 56	37 , 67	32 , 90
Change from Baseline	n	5	6	5	16	15
	Mean (SE)	5.9 (4.08)	0.3 (3.04)	3.8 (3.88)	3.1 (2.05)	2.4 (4.79)
	SD	9.13	7.45	8.68	8.18	18.57
	Median	6.7	-0.5	7.0	2.5	4.0
	Min, Max	-6 , 19	-11 , 12	-7 , 12	-11 , 19	-32 , 28
42 hours post randomization Observed	n	6	6	7	19	20
	Mean (SE)	50.6 (5.53)	52.0 (2.59)	54.8 (2.76)	52.6 (2.09)	51.4 (2.47)
	SD	13.54	6.33	7.30	9.11	11.04
	Median	50.3	54.0	56.0	55.0	49.0
	Min, Max	35 , 70	40 , 58	45 , 66	35 , 70	35 , 74
Change from Baseline	n	4	5	5	14	14
	Mean (SE)	2.2 (9.36)	2.7 (4.50)	5.2 (4.07)	3.4 (3.16)	1.3 (3.72)
	SD	18.73	10.07	9.09	11.81	13.91
	Median	-0.7	-2.0	7.0	2.5	1.7
	Min, Max	-16 , 26	-8 , 14	-5 , 15	-16 , 26	-34 , 22

Summary Table 7.5.2.1
Clinical Assessments
Respiratory Parameters before Intubation - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
48 hours post randomization						
Observed	n	6	5	7	18	19
	Mean (SE)	45.5 (4.10)	48.6 (3.58)	53.4 (3.49)	49.5 (2.20)	48.9 (2.09)
	SD	10.05	8.00	9.23	9.34	9.13
	Median	49.0	50.2	53.0	50.6	47.0
	Min, Max	26 , 53	36 , 58	40 , 64	26 , 64	34 , 66
Change from Baseline	n	4	4	5	13	13
	Mean (SE)	-7.3 (5.72)	0.9 (4.69)	3.4 (4.98)	-0.7 (3.01)	-0.3 (4.39)
	SD	11.44	9.38	11.13	10.87	15.82
	Median	-8.0	3.4	2.0	1.0	1.0
	Min, Max	-18 , 5	-12 , 9	-9 , 19	-18 , 19	-41 , 24
54 hours post randomization						
Observed	n	6	6	6	18	18
	Mean (SE)	49.0 (5.01)	47.5 (5.84)	55.9 (4.33)	50.8 (2.90)	47.8 (2.12)
	SD	12.27	14.29	10.60	12.30	9.00
	Median	56.1	46.0	60.7	54.6	45.5
	Min, Max	30 , 58	32 , 71	42 , 67	30 , 71	34 , 69
Change from Baseline	n	4	5	5	14	13
	Mean (SE)	0.8 (6.95)	-1.9 (5.91)	8.2 (4.02)	2.5 (3.21)	-1.8 (4.11)

Summary Table 7.5.2.1
Clinical Assessments
Respiratory Parameters before Intubation - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	13.89	13.22	8.99	11.99	14.81
	Median	1.6	-3.0	11.0	6.6	1.0
	Min, Max	-14 , 14	-16 , 14	-5 , 19	-16 , 19	-39 , 23
60 hours post randomization						
Observed	n	6	6	6	18	19
	Mean (SE)	56.3 (3.80)	45.5 (4.84)	51.4 (3.89)	51.1 (2.52)	51.8 (3.52)
	SD	9.31	11.86	9.52	10.68	15.33
	Median	57.5	46.6	51.3	53.0	51.0
	Min, Max	40 , 68	29 , 62	41 , 61	29 , 68	34 , 100
Change from Baseline						
	n	4	5	5	14	13
	Mean (SE)	3.0 (4.97)	-4.3 (5.42)	2.9 (3.50)	0.4 (2.67)	1.1 (3.65)
	SD	9.93	12.11	7.83	9.99	13.16
	Median	3.0	-10.0	1.7	-2.7	2.0
	Min, Max	-7 , 13	-12 , 17	-7 , 12	-12 , 17	-30 , 16
66 hours post randomization						
Observed	n	7	6	7	20	17
	Mean (SE)	60.7 (3.62)	48.5 (3.38)	51.8 (4.00)	53.9 (2.35)	49.2 (3.23)
	SD	9.59	8.28	10.60	10.51	13.31
	Median	62.0	48.8	57.0	55.7	47.0
	Min, Max	48 , 74	38 , 59	35 , 66	35 , 74	28 , 74

Summary Table 7.5.2.1
Clinical Assessments
Respiratory Parameters before Intubation - tcPCO₂
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Change from Baseline	n	5	5	6	16	12
	Mean (SE)	11.4 (4.73)	-1.4 (4.11)	2.5 (7.13)	4.0 (3.38)	-1.2 (4.40)
	SD	10.57	9.19	17.47	13.53	15.24
	Median	5.0	2.0	1.3	4.5	0.0
	Min, Max	4 , 28	-12 , 8	-23 , 23	-23 , 28	-29 , 23
72 hours post randomization Observed	n	6	6	7	19	14
	Mean (SE)	49.8 (3.82)	49.1 (5.88)	55.4 (4.98)	51.7 (2.80)	45.5 (2.86)
	SD	9.37	14.40	13.17	12.20	10.69
	Median	50.5	48.5	57.0	54.0	46.6
	Min, Max	37 , 62	33 , 68	40 , 80	33 , 80	26 , 61
Change from Baseline	n	4	5	5	14	11
	Mean (SE)	-1.5 (4.50)	-2.0 (7.63)	10.1 (7.37)	2.5 (4.03)	-2.9 (5.54)
	SD	9.00	17.05	16.48	15.06	18.39
	Median	-4.0	-3.0	16.4	-2.0	6.0
	Min, Max	-9 , 11	-21 , 23	-8 , 31	-21 , 31	-37 , 24

Summary Table 7.6.1
Clinical Assessments
Respiratory Support - Mechanical Ventilation
Safety Population

Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Respiratory Support in the DR	n (%)	5 (63%)	3 (38%)	3 (38%)	11 (46%)	11 (46%)
Number of Subjects on MV						
Primary Observation Period	n (%)	5 (63%)	6 (75%)	5 (63%)	16 (67%)	11 (46%)
Extended Observation Period	n (%)	4 (50%)	5 (63%)	5 (63%)	14 (58%)	11 (46%)
Time on MV (Days)						
	n	7	7	6	20	14
	Mean (SE)	6.1 (1.61)	7.9 (3.19)	15.8 (10.87)	9.7 (3.41)	14.9 (4.84)
	SD	4.25	8.44	26.63	15.24	18.12
	Median	7.4	7.2	6.2	6.9	4.8
	Min, Max	0.1 , 11.1	-5.5 , 18.8	1.4 , 69.8	-5.5 , 69.8	-0.7 , 64.0
MV Initial Mode						
IMV	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
SIMV	n (%)	6 (75%)	5 (63%)	3 (38%)	14 (58%)	5 (21%)
AC	n (%)	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
HFV	n (%)	0 (0%)	1 (13%)	2 (25%)	3 (13%)	1 (4%)
Volume Ventilation (including volmue guarantee)	n (%)	1 (13%)	0 (0%)	1 (13%)	2 (8%)	3 (13%)
Other	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	5 (21%)
At Initiation						
FiO ₂	n	6	7	6	19	13
	Mean (SE)	0.37 (0.061)	0.43 (0.049)	0.39 (0.057)	0.40 (0.031)	0.56 (0.071)
	SD	0.150	0.130	0.140	0.134	0.256

Note: Subject may receive multiple mechanical ventilation in different modes.

Summary Table 7.6.1
Clinical Assessments
Respiratory Support - Mechanical Ventilation
Safety Population

Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
MAP (cmH ₂ O)	Median	0.33	0.40	0.38	0.40	0.50
	Min, Max	0 , 1	0 , 1	0 , 1	0 , 1	0 , 1
	n	5	7	6	18	13
	Mean (SE)	8.40 (1.208)	8.71 (0.747)	9.17 (0.749)	8.78 (0.482)	9.38 (0.572)
	SD	2.702	1.976	1.835	2.045	2.063
	Median	8.00	8.00	10.00	8.00	8.00
	Min, Max	6 , 13	7 , 12	6 , 11	6 , 13	7 , 14

Note: Subject may receive multiple mechanical ventilation in different modes.

Summary Table 7.6.1.1
Clinical Assessments
Respiratory Support - Mechanical Ventilation
Safety Population - Without Treatment Interruptions

Assessment	Statistic	50 mg/kg (N=7)	75 mg/kg (N=3)	100 mg/kg (N=6)	Total Active (N=16)	nCPAP Only (N=24)
Respiratory Support in the DR	n (%)	4 (57%)	1 (33%)	2 (33%)	7 (44%)	11 (46%)
Number of Subjects on MV						
Primary Observation Period	n (%)	4 (57%)	2 (67%)	3 (50%)	9 (56%)	11 (46%)
Extended Observation Period	n (%)	3 (43%)	3 (100%)	3 (50%)	9 (56%)	11 (46%)
Time on MV (Days)						
	n	6	3	4	13	14
	Mean (SE)	6.3 (1.89)	1.3 (3.69)	4.6 (1.77)	4.6 (1.33)	14.9 (4.84)
	SD	4.62	6.39	3.55	4.81	18.12
	Median	7.5	2.1	3.9	5.8	4.8
	Min, Max	0.1 , 11.1	-5.5 , 7.2	1.4 , 9.0	-5.5 , 11.1	-0.7 , 64.0
MV Initial Mode						
IMV	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
SIMV	n (%)	5 (71%)	3 (100%)	3 (50%)	11 (69%)	5 (21%)
HFV	n (%)	0 (0%)	0 (0%)	1 (17%)	1 (6%)	1 (4%)
Volume Ventilation (including volmue guarantee)	n (%)	1 (14%)	0 (0%)	0 (0%)	1 (6%)	3 (13%)
Other	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	5 (21%)
At Initiation						
FiO ₂	n	5	3	4	12	13
	Mean (SE)	0.35 (0.068)	0.38 (0.073)	0.46 (0.055)	0.39 (0.038)	0.56 (0.071)
	SD	0.152	0.126	0.111	0.132	0.256
	Median	0.26	0.40	0.45	0.40	0.50
	Min, Max	0.23 , 0.59	0.25 , 0.50	0.35 , 0.60	0.23 , 0.60	0.21 , 1.00

Note: Subject may receive multiple mechanical ventilation in different modes.

Summary Table 7.6.1.1
Clinical Assessments
Respiratory Support - Mechanical Ventilation
Safety Population - Without Treatment Interruptions

Assessment	Statistic	50 mg/kg (N=7)	75 mg/kg (N=3)	100 mg/kg (N=6)	Total Active (N=16)	nCPAP Only (N=24)
MAP (cmH ₂ O)	n	5	3	4	12	13
	Mean (SE)	8.40 (1.208)	7.67 (0.333)	9.25 (1.109)	8.50 (0.609)	9.38 (0.572)
	SD	2.702	0.577	2.217	2.111	2.063
	Median	8.00	8.00	10.00	8.00	8.00
	Min, Max	6.00 , 13.00	7.00 , 8.00	6.00 , 11.00	6.00 , 13.00	7.00 , 14.00

Note: Subject may receive multiple mechanical ventilation in different modes.

Summary Table 7.6.2
Clinical Assessments
Respiratory Parameters - Mechanical Ventilation
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Day 1 08:00						
MAP (cmH ₂ O)	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
FiO ₂	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Respiratory Rate (RPM)	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Day 1 20:00						
MAP (cmH ₂ O)	n	2	3	1	6	4
	Mean (SE)	9.7 (3.30)	8.8 (0.43)	8.8 (0)	9.1 (0.89)	8.2 (0.67)
	SD	4.67	0.75	0	2.19	1.34

Summary Table 7.6.2
Clinical Assessments
Respiratory Parameters - Mechanical Ventilation
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	9.7	8.4	8.8	8.6	8.0
	Min, Max	6.4 , 13.0	8.4 , 9.7	8.8 , 8.8	6.4 , 13.0	7.0 , 10.0
FiO ₂	n	2	3	1	6	4
	Mean (SE)	0.25 (0.015)	0.43 (0.067)	0.50 (0)	0.38 (0.054)	0.61 (0.228)
	SD	0.021	0.115	0	0.132	0.456
	Median	0.25	0.50	0.50	0.40	0.61
	Min, Max	0.23 , 0.26	0.30 , 0.50	0.50 , 0.50	0.23 , 0.50	0.21 , 1.00
Respiratory Rate (RPM)	n	2	3	1	6	4
	Mean (SE)	39 (23.5)	33 (6.7)	66 (0)	41 (8.5)	58 (21.5)
	SD	33.2	11.5	0	20.9	43.0
	Median	39	40	66	40	67
	Min, Max	15 , 62	20 , 40	66 , 66	15 , 66	0 , 99
Day 2 08:00						
MAP (cmH ₂ O)	n	4	3	3	10	8
	Mean (SE)	8.3 (0.99)	9.8 (1.15)	10.1 (0.95)	9.3 (0.59)	9.9 (0.46)
	SD	1.97	1.99	1.65	1.88	1.31
	Median	8.0	9.4	9.3	9.2	10.0
	Min, Max	6.3 , 11.0	8.1 , 12.0	9.0 , 12.0	6.3 , 12.0	8.0 , 12.0
FiO ₂	n	4	4	3	11	8
	Mean (SE)	0.30 (0.050)	0.48 (0.127)	0.32 (0.070)	0.37 (0.054)	0.26 (0.037)

Summary Table 7.6.2
Clinical Assessments
Respiratory Parameters - Mechanical Ventilation
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	0.100	0.254	0.121	0.181	0.105
	Median	0.25	0.48	0.30	0.30	0.21
	Min, Max	0.25 , 0.45	0.21 , 0.75	0.21 , 0.45	0.21 , 0.75	0.21 , 0.50
Respiratory Rate (RPM)	n	4	2	1	7	5
	Mean (SE)	22 (6.1)	34 (3.5)	65 (0)	32 (6.8)	51 (5.2)
	SD	12.2	4.9	0	18.0	11.6
	Median	20	34	65	30	47
	Min, Max	10 , 39	30 , 37	65 , 65	10 , 65	40 , 68
Day 2 20:00						
MAP (cmH ₂ O)	n	5	3	5	13	7
	Mean (SE)	8.1 (0.67)	9.3 (1.04)	9.1 (0.50)	8.7 (0.39)	10.3 (0.89)
	SD	1.50	1.80	1.12	1.41	2.35
	Median	7.1	9.4	9.6	9.4	10.0
	Min, Max	7.0 , 10.0	7.4 , 11.0	7.7 , 10.0	7.0 , 11.0	6.6 , 14.0
FiO ₂	n	5	4	5	14	8
	Mean (SE)	0.28 (0.025)	0.26 (0.048)	0.26 (0.027)	0.27 (0.018)	0.34 (0.096)
	SD	0.057	0.095	0.060	0.066	0.272
	Median	0.26	0.21	0.23	0.25	0.22
	Min, Max	0.24 , 0.38	0.21 , 0.40	0.21 , 0.35	0.21 , 0.40	0.21 , 1.00
Respiratory Rate (RPM)	n	4	3	2	9	5

Summary Table 7.6.2
Clinical Assessments
Respiratory Parameters - Mechanical Ventilation
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	27 (12.0)	44 (12.3)	58 (14.5)	39 (7.9)	34 (6.3)
	SD	24.0	21.4	20.5	23.6	14.1
	Median	17	37	58	37	37
	Min, Max	10 , 62	27 , 68	43 , 72	10 , 72	10 , 47
Day 3 08:00						
MAP (cmH ₂ O)	n	4	4	5	13	10
	Mean (SE)	9.1 (1.39)	8.6 (0.86)	9.4 (0.44)	9.0 (0.49)	9.7 (0.78)
	SD	2.79	1.72	0.97	1.77	2.47
	Median	8.2	8.0	10.0	8.5	9.8
	Min, Max	6.9 , 13.0	7.3 , 11.0	8.2 , 10.2	6.9 , 13.0	6.3 , 14.5
FiO ₂	n	4	4	5	13	10
	Mean (SE)	0.29 (0.033)	0.24 (0.021)	0.25 (0.022)	0.26 (0.015)	0.40 (0.076)
	SD	0.067	0.043	0.050	0.054	0.241
	Median	0.29	0.22	0.21	0.23	0.34
	Min, Max	0.21 , 0.37	0.21 , 0.30	0.21 , 0.31	0.21 , 0.37	0.21 , 1.00
Respiratory Rate (RPM)	n	3	3	2	8	6
	Mean (SE)	27 (12.3)	47 (10.4)	51 (4.0)	41 (6.7)	46 (4.8)
	SD	21.4	18.0	5.7	18.9	11.7
	Median	20	52	51	49	45
	Min, Max	10 , 51	27 , 62	47 , 55	10 , 62	30 , 64

Summary Table 7.6.2
Clinical Assessments
Respiratory Parameters - Mechanical Ventilation
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Day 3 20:00						
MAP (cmH ₂ O)	n	4	4	3	11	9
	Mean (SE)	8.3 (0.71)	9.2 (1.36)	8.6 (0.74)	8.7 (0.55)	11.5 (0.89)
	SD	1.42	2.72	1.28	1.81	2.68
	Median	8.1	9.0	8.3	8.3	11.0
	Min, Max	7.1 , 10.0	6.8 , 12.0	7.5 , 10.0	6.8 , 12.0	9.0 , 16.0
FiO ₂	n	4	4	3	11	9
	Mean (SE)	0.33 (0.058)	0.37 (0.127)	0.23 (0.023)	0.32 (0.049)	0.38 (0.069)
	SD	0.115	0.253	0.040	0.164	0.208
	Median	0.29	0.27	0.21	0.27	0.28
	Min, Max	0.25 , 0.50	0.21 , 0.75	0.21 , 0.28	0.21 , 0.75	0.21 , 0.78
Respiratory Rate (RPM)	n	3	2	1	6	5
	Mean (SE)	16 (2.0)	48 (26.0)	54 (0)	33 (10.2)	37 (8.9)
	SD	3.5	36.8	0	25.0	19.9
	Median	14	48	54	21	35
	Min, Max	14 , 20	22 , 74	54 , 54	14 , 74	12 , 60
Day 4 08:00						
MAP (cmH ₂ O)	n	4	4	4	12	9
	Mean (SE)	8.4 (0.81)	8.8 (1.01)	9.5 (0.50)	8.9 (0.44)	11.0 (0.93)
	SD	1.61	2.01	1.00	1.52	2.79

Summary Table 7.6.2
Clinical Assessments
Respiratory Parameters - Mechanical Ventilation
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	8.5	8.7	10.0	9.8	11.0
	Min, Max	6.6 , 10.0	6.9 , 11.0	8.0 , 10.0	6.6 , 11.0	6.0 , 14.0
FiO ₂	n	4	4	4	12	9
	Mean (SE)	0.34 (0.031)	0.29 (0.043)	0.24 (0.013)	0.29 (0.020)	0.34 (0.052)
	SD	0.063	0.085	0.026	0.071	0.157
	Median	0.35	0.28	0.24	0.26	0.27
	Min, Max	0.25 , 0.40	0.21 , 0.40	0.21 , 0.27	0.21 , 0.40	0.21 , 0.65
Respiratory Rate (RPM)	n	3	2	1	6	5
	Mean (SE)	33 (18.7)	50 (28.0)	29 (0)	38 (11.7)	41 (7.5)
	SD	32.4	39.6	0	28.7	16.8
	Median	16	50	29	26	32
	Min, Max	12 , 70	22 , 78	29 , 29	12 , 78	27 , 68
Day 4 20:00						
MAP (cmH ₂ O)	n	4	3	4	11	10
	Mean (SE)	8.4 (0.68)	9.3 (1.23)	8.9 (0.72)	8.8 (0.45)	10.8 (0.77)
	SD	1.36	2.14	1.44	1.49	2.44
	Median	8.3	10.0	9.3	9.0	9.8
	Min, Max	7.0 , 10.0	6.9 , 11.0	7.0 , 10.0	6.9 , 11.0	8.0 , 14.2
FiO ₂	n	4	3	4	11	10
	Mean (SE)	0.39 (0.070)	0.29 (0.043)	0.24 (0.013)	0.31 (0.032)	0.31 (0.055)

Summary Table 7.6.2
Clinical Assessments
Respiratory Parameters - Mechanical Ventilation
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	0.141	0.074	0.025	0.107	0.175
	Median	0.37	0.32	0.25	0.27	0.28
	Min, Max	0.23 , 0.57	0.21 , 0.35	0.21 , 0.27	0.21 , 0.57	0.21 , 0.80
Respiratory Rate (RPM)	n	3	1	1	5	6
	Mean (SE)	21 (10.0)	22 (0)	40 (0)	25 (6.6)	50 (9.9)
	SD	17.3	0	0	14.9	24.3
	Median	12	22	40	22	52
	Min, Max	10 , 41	22 , 22	40 , 40	10 , 41	23 , 88
Day 5 08:00						
MAP (cmH ₂ O)	n	4	3	4	11	10
	Mean (SE)	7.9 (0.71)	9.6 (1.48)	9.8 (1.02)	9.1 (0.60)	10.0 (0.71)
	SD	1.42	2.57	2.05	2.01	2.25
	Median	7.3	10.0	10.3	9.5	9.2
	Min, Max	7.0 , 10.0	6.9 , 12.0	7.0 , 11.6	6.9 , 12.0	7.0 , 14.0
FiO ₂	n	4	3	4	11	10
	Mean (SE)	0.39 (0.062)	0.24 (0.021)	0.26 (0.023)	0.30 (0.031)	0.30 (0.045)
	SD	0.123	0.036	0.047	0.101	0.142
	Median	0.41	0.23	0.27	0.28	0.24
	Min, Max	0.23 , 0.50	0.21 , 0.28	0.21 , 0.30	0.21 , 0.50	0.21 , 0.68
Respiratory Rate (RPM)	n	2	1	1	4	6

Summary Table 7.6.2
Clinical Assessments
Respiratory Parameters - Mechanical Ventilation
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	22 (10.0)	22 (0)	54 (0)	30 (9.0)	39 (6.3)
	SD	14.1	0	0	18.0	15.5
	Median	22	22	54	27	38
	Min, Max	12 , 32	22 , 22	54 , 54	12 , 54	20 , 64
Day 5 20:00						
MAP (cmH ₂ O)	n	4	3	4	11	8
	Mean (SE)	8.1 (0.68)	9.8 (1.33)	10.4 (0.95)	9.4 (0.59)	9.8 (0.80)
	SD	1.37	2.31	1.90	1.96	2.26
	Median	7.7	10.0	10.8	9.8	9.5
	Min, Max	6.8 , 10.0	7.4 , 12.0	7.9 , 12.0	6.8 , 12.0	7.0 , 13.0
FiO ₂	n	4	3	4	11	8
	Mean (SE)	0.36 (0.093)	0.28 (0.038)	0.24 (0.011)	0.29 (0.036)	0.29 (0.034)
	SD	0.186	0.067	0.022	0.119	0.097
	Median	0.31	0.30	0.24	0.25	0.27
	Min, Max	0.21 , 0.60	0.21 , 0.34	0.21 , 0.26	0.21 , 0.60	0.21 , 0.47
Respiratory Rate (RPM)	n	3	1	1	5	4
	Mean (SE)	18 (5.2)	20 (0)	34 (0)	21 (4.3)	49 (10.7)
	SD	9.0	0	0	9.5	21.3
	Median	13	20	34	20	50
	Min, Max	12 , 28	20 , 20	34 , 34	12 , 34	27 , 69

Summary Table 7.6.2
Clinical Assessments
Respiratory Parameters - Mechanical Ventilation
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Day 6 08:00						
MAP (cmH ₂ O)	n	4	4	4	12	7
	Mean (SE)	8.2 (0.62)	8.8 (0.94)	10.6 (1.21)	9.2 (0.59)	10.0 (0.90)
	SD	1.24	1.88	2.43	2.03	2.38
	Median	7.9	8.7	11.8	9.0	9.8
	Min, Max	7.1 , 10.0	7.0 , 10.8	7.0 , 12.0	7.0 , 12.0	7.0 , 13.2
FiO ₂	n	4	4	4	12	7
	Mean (SE)	0.26 (0.028)	0.23 (0.023)	0.22 (0.005)	0.24 (0.012)	0.30 (0.048)
	SD	0.055	0.045	0.010	0.042	0.126
	Median	0.26	0.21	0.21	0.21	0.25
	Min, Max	0.21 , 0.31	0.21 , 0.30	0.21 , 0.23	0.21 , 0.31	0.21 , 0.55
Respiratory Rate (RPM)	n	3	2	1	6	3
	Mean (SE)	15 (3.7)	30 (9.5)	60 (0)	27 (7.8)	55 (9.7)
	SD	6.4	13.4	0	19.1	16.8
	Median	12	30	60	21	64
	Min, Max	10 , 22	20 , 39	60 , 60	10 , 60	36 , 66
Day 6 20:00						
MAP (cmH ₂ O)	n	4	4	4	12	6
	Mean (SE)	8.1 (0.66)	8.7 (1.16)	9.7 (1.26)	8.8 (0.59)	10.4 (0.72)
	SD	1.31	2.32	2.52	2.03	1.77

Summary Table 7.6.2
Clinical Assessments
Respiratory Parameters - Mechanical Ventilation
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	7.8	8.5	10.5	9.0	10.0
	Min, Max	7.0 , 10.0	6.5 , 11.3	6.0 , 11.6	6.0 , 11.6	8.4 , 13.0
FiO ₂	n	4	4	4	12	6
	Mean (SE)	0.26 (0.033)	0.21 (0.000)	0.21 (0.000)	0.23 (0.012)	0.30 (0.053)
	SD	0.066	0.000	0.000	0.041	0.129
	Median	0.23	0.21	0.21	0.21	0.26
	Min, Max	0.21 , 0.35	0.21 , 0.21	0.21 , 0.21	0.21 , 0.35	0.21 , 0.55
Respiratory Rate (RPM)	n	2	2	1	5	3
	Mean (SE)	29 (19.0)	42 (26.5)	61 (0)	40 (11.9)	54 (8.8)
	SD	26.9	37.5	0	26.5	15.2
	Median	29	42	61	48	51
	Min, Max	10 , 48	15 , 68	61 , 61	10 , 68	40 , 70
Day 7 08:00						
MAP (cmH ₂ O)	n	4	2	4	10	6
	Mean (SE)	8.0 (0.72)	10.6 (0.60)	9.5 (1.24)	9.1 (0.62)	9.7 (0.69)
	SD	1.44	0.85	2.48	1.98	1.68
	Median	7.8	10.6	10.2	9.7	9.0
	Min, Max	6.6 , 10.0	10.0 , 11.2	6.0 , 11.5	6.0 , 11.5	8.4 , 13.0
FiO ₂	n	4	2	4	10	6
	Mean (SE)	0.26 (0.028)	0.24 (0.010)	0.22 (0.005)	0.24 (0.012)	0.28 (0.031)

Summary Table 7.6.2
Clinical Assessments
Respiratory Parameters - Mechanical Ventilation
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	0.055	0.014	0.010	0.038	0.076
	Median	0.26	0.24	0.21	0.22	0.25
	Min, Max	0.21 , 0.31	0.23 , 0.25	0.21 , 0.23	0.21 , 0.31	0.21 , 0.40
Respiratory Rate (RPM)	n	2	0	1	3	3
	Mean (SE)	24 (13.5)	0 (0)	55 (0)	34 (13.1)	45 (3.5)
	SD	19.1	0	0	22.6	6.1
	Median	24	0	55	37	44
	Min, Max	10 , 37	0, 0	55 , 55	10 , 55	40 , 52
Day 7 20:00						
MAP (cmH ₂ O)	n	3	2	3	8	6
	Mean (SE)	8.6 (0.72)	9.4 (1.70)	9.9 (0.38)	9.3 (0.47)	9.5 (0.56)
	SD	1.25	2.40	0.66	1.33	1.38
	Median	8.0	9.4	10.0	9.6	9.0
	Min, Max	7.7 , 10.0	7.7 , 11.1	9.2 , 10.5	7.7 , 11.1	8.0 , 12.0
FiO ₂	n	3	2	3	8	6
	Mean (SE)	0.35 (0.037)	0.22 (0.010)	0.29 (0.067)	0.30 (0.032)	0.32 (0.078)
	SD	0.064	0.014	0.116	0.090	0.190
	Median	0.38	0.22	0.23	0.26	0.25
	Min, Max	0.28 , 0.40	0.21 , 0.23	0.21 , 0.42	0.21 , 0.42	0.21 , 0.70
Respiratory Rate (RPM)	n	1	1	0	2	3

Summary Table 7.6.2
Clinical Assessments
Respiratory Parameters - Mechanical Ventilation
Safety Population

Time Point	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	77 (0)	42 (0)	0 (0)	60 (17.5)	50 (5.5)
	SD	0	0	0	24.7	9.5
	Median	77	42	0	60	50
	Min, Max	77 , 77	42 , 42	0 , 0	42 , 77	40 , 59

Summary Table 7.7.1
Clinical Assessments
Respiratory Support - Supplemental Oxygen
Safety Population

Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Number of Subjects on SO						
Primary Observation Period	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Extended Observation Period	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Time on SO (Days)						
	n	7	4	0	11	3
	Mean (SE)	6.4 (3.12)	8.3 (3.16)	0 (0)	7.1 (2.21)	10.4 (5.28)
	SD	8.24	6.32	0	7.32	9.15
	Median	8.5	8.6	0	8.5	14.0
	Min, Max	-8.1 , 15.7	0.7 , 15.3	0, 0	-8.1 , 15.7	0.0 , 17.2
SO Initial Mode						
Nasal Cannula	n (%)	7 (88%)	3 (38%)	0 (0%)	10 (42%)	4 (17%)
Oxyhood	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Simple Face Mask	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Non-Rebreathing Face Mask	n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other	n (%)	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
FiO ₂ at Initiation						
	n	6	4	0	10	4
	Mean (SE)	0.26 (0.009)	0.44 (0.188)	0 (0)	0.33 (0.075)	0.28 (0.014)
	SD	0.022	0.375	0	0.236	0.029
	Median	0.25	0.25	0	0.25	0.28
	Min, Max	0 , 0	0 , 1	0, 0	0 , 1	0 , 0

Note: Subject may receive multiple supplemental oxygen in different modes.

Summary Table 7.7.2
Clinical Assessments
Respiratory Parameters - Supplemental Oxygen
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Day 1 08:00						
FiO ₂	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Mode						
Day 1 20:00						
FiO ₂	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Mode						
Day 2 08:00						
FiO ₂	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Mode						
Day 2 20:00						

Summary Table 7.7.2
Clinical Assessments
Respiratory Parameters - Supplemental Oxygen
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
FiO ₂	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Mode						
Day 3 08:00 FiO ₂	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Mode						
Day 3 20:00 FiO ₂	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Mode						
Day 4 08:00 FiO ₂	n	0	0	0	0	0

Summary Table 7.7.2
Clinical Assessments
Respiratory Parameters - Supplemental Oxygen
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Mode						
Day 4 20:00						
FiO ₂	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Mode						
Day 5 08:00						
FiO ₂	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Mode						
Day 5 20:00						
FiO ₂	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Summary Table 7.7.2
Clinical Assessments
Respiratory Parameters - Supplemental Oxygen
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Mode						
Day 6 08:00						
FiO ₂	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Mode						
Day 6 20:00						
FiO ₂	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Mode						
Day 7 08:00						
FiO ₂	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0

Summary Table 7.7.2
Clinical Assessments
Respiratory Parameters - Supplemental Oxygen
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Mode						
Day 7 20:00						
FiO ₂	n	0	0	0	0	0
	Mean (SE)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	SD	0	0	0	0	0
	Median	0	0	0	0	0
	Min, Max	0, 0	0, 0	0, 0	0, 0	0, 0
Mode						

Summary Table 7.8
Clinical Assessments
Respiratory Parameters - nCPAP Settings
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Initiation						
MAP (cmH ₂ O)	n	7	8	8	23	24
	Mean (SE)	6.1 (0.67)	6.1 (0.35)	6.3 (0.53)	6.2 (0.29)	5.8 (0.20)
	SD	1.77	0.99	1.49	1.37	0.97
	Median	6.0	6.0	5.5	6.0	6.0
	Min, Max	5.0 , 10.0	5.0 , 8.0	5.0 , 8.0	5.0 , 10.0	5.0 , 8.0
FiO ₂	n	7	8	8	23	24
	Mean (SE)	0.29 (0.020)	0.38 (0.068)	0.36 (0.041)	0.34 (0.028)	0.35 (0.018)
	SD	0.053	0.193	0.117	0.136	0.088
	Median	0.28	0.30	0.35	0.30	0.32
	Min, Max	0.25 , 0.40	0.21 , 0.80	0.21 , 0.60	0.21 , 0.80	0.25 , 0.60
At the time of Randomization						
MAP (cmH ₂ O)	n	7	8	8	23	24
	Mean (SE)	5.7 (0.18)	6.0 (0.19)	5.5 (0.19)	5.7 (0.11)	5.8 (0.08)
	SD	0.49	0.53	0.53	0.54	0.41
	Median	6.0	6.0	5.5	6.0	6.0
	Min, Max	5.0 , 6.0	5.0 , 7.0	5.0 , 6.0	5.0 , 7.0	5.0 , 6.0
FiO ₂	n	8	8	8	24	24
	Mean (SE)	0.31 (0.020)	0.35 (0.028)	0.37 (0.025)	0.34 (0.015)	0.32 (0.013)
	SD	0.058	0.078	0.072	0.071	0.062
	Median	0.31	0.34	0.37	0.34	0.30

Note: Subjects may receive multiple nCPAP setting in different modes.

Summary Table 7.8
Clinical Assessments
Respiratory Parameters - nCPAP Settings
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	0.25 , 0.40	0.25 , 0.45	0.27 , 0.47	0.25 , 0.47	0.25 , 0.45
1 Hour Post Randomization						
MAP (cmH ₂ O)	n	8	8	8	24	20
	Mean (SE)	5.8 (0.16)	6.0 (0.19)	5.6 (0.18)	5.8 (0.10)	5.8 (0.09)
	SD	0.46	0.53	0.52	0.51	0.41
	Median	6.0	6.0	6.0	6.0	6.0
	Min, Max	5.0 , 6.0	5.0 , 7.0	5.0 , 6.0	5.0 , 7.0	5.0 , 6.0
FiO ₂	n	8	8	8	24	20
	Mean (SE)	0.32 (0.022)	0.39 (0.043)	0.38 (0.034)	0.36 (0.020)	0.31 (0.015)
	SD	0.061	0.120	0.096	0.097	0.065
	Median	0.31	0.35	0.39	0.35	0.30
	Min, Max	0.25 , 0.40	0.30 , 0.65	0.21 , 0.50	0.21 , 0.65	0.24 , 0.50
3 Hours Post Randomization						
MAP (cmH ₂ O)	n	7	8	8	23	20
	Mean (SE)	6.0 (0.22)	6.1 (0.23)	6.1 (0.40)	6.1 (0.17)	6.0 (0.19)
	SD	0.58	0.64	1.13	0.79	0.83
	Median	6.0	6.0	6.0	6.0	6.0
	Min, Max	5.0 , 7.0	5.0 , 7.0	5.0 , 8.0	5.0 , 8.0	4.9 , 8.0
FiO ₂	n	7	8	8	23	20
	Mean (SE)	0.33 (0.056)	0.37 (0.043)	0.37 (0.038)	0.36 (0.025)	0.28 (0.017)

Note: Subjects may receive multiple nCPAP setting in different modes.

Summary Table 7.8
Clinical Assessments
Respiratory Parameters - nCPAP Settings
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	0.149	0.120	0.107	0.121	0.077
	Median	0.25	0.35	0.36	0.34	0.28
	Min, Max	0.21 , 0.60	0.21 , 0.62	0.21 , 0.55	0.21 , 0.62	0.21 , 0.52
6 Hours Post Randomization						
MAP (cmH ₂ O)	n	7	7	6	20	18
	Mean (SE)	6.0 (0.22)	6.0 (0.31)	6.0 (0.37)	6.0 (0.16)	6.0 (0.18)
	SD	0.58	0.82	0.89	0.73	0.77
	Median	6.0	6.0	6.0	6.0	6.0
	Min, Max	5.0 , 7.0	5.0 , 7.0	5.0 , 7.0	5.0 , 7.0	4.9 , 8.0
FiO ₂	n	7	7	6	20	18
	Mean (SE)	0.35 (0.064)	0.36 (0.044)	0.37 (0.037)	0.36 (0.028)	0.28 (0.020)
	SD	0.168	0.116	0.091	0.124	0.086
	Median	0.30	0.36	0.34	0.34	0.26
	Min, Max	0.21 , 0.70	0.22 , 0.54	0.28 , 0.49	0.21 , 0.70	0.21 , 0.54
12 Hours Post Randomization						
MAP (cmH ₂ O)	n	4	5	5	14	16
	Mean (SE)	5.8 (0.25)	6.1 (0.50)	6.1 (0.61)	6.0 (0.27)	6.0 (0.18)
	SD	0.50	1.12	1.37	1.02	0.72
	Median	6.0	6.0	5.3	6.0	6.0
	Min, Max	5.0 , 6.0	5.0 , 8.0	5.0 , 8.0	5.0 , 8.0	5.0 , 8.0

Note: Subjects may receive multiple nCPAP setting in different modes.

Summary Table 7.8
Clinical Assessments
Respiratory Parameters - nCPAP Settings
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
FiO ₂	n	4	5	5	14	16
	Mean (SE)	0.26 (0.019)	0.35 (0.055)	0.31 (0.033)	0.31 (0.024)	0.27 (0.017)
	SD	0.039	0.124	0.073	0.091	0.067
	Median	0.26	0.32	0.30	0.29	0.25
	Min, Max	0.21 , 0.30	0.23 , 0.55	0.21 , 0.40	0.21 , 0.55	0.21 , 0.40
18 Hours Post Randomization						
MAP (cmH ₂ O)	n	4	5	4	13	15
	Mean (SE)	5.8 (0.25)	5.5 (0.22)	5.8 (0.48)	5.7 (0.17)	5.9 (0.26)
	SD	0.50	0.50	0.96	0.62	1.00
	Median	6.0	5.6	5.5	6.0	6.0
	Min, Max	5.0 , 6.0	5.0 , 6.0	5.0 , 7.0	5.0 , 7.0	4.0 , 8.0
FiO ₂	n	4	5	4	13	15
	Mean (SE)	0.28 (0.042)	0.32 (0.079)	0.30 (0.055)	0.30 (0.035)	0.26 (0.018)
	SD	0.084	0.177	0.111	0.124	0.071
	Median	0.26	0.24	0.26	0.24	0.23
	Min, Max	0.21 , 0.40	0.21 , 0.63	0.21 , 0.45	0.21 , 0.63	0.21 , 0.45
24 Hours Post Randomization						
MAP (cmH ₂ O)	n	3	4	3	10	14
	Mean (SE)	6.7 (0.67)	5.8 (0.27)	5.7 (0.67)	6.0 (0.30)	5.7 (0.32)
	SD	1.15	0.54	1.15	0.94	1.19
	Median	6.0	6.0	5.0	6.0	6.0

Note: Subjects may receive multiple nCPAP setting in different modes.

Summary Table 7.8
Clinical Assessments
Respiratory Parameters - nCPAP Settings
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Min, Max	6.0 , 8.0	5.0 , 6.2	5.0 , 7.0	5.0 , 8.0	4.0 , 8.0
FiO ₂	n	3	4	3	10	14
	Mean (SE)	0.24 (0.020)	0.23 (0.007)	0.32 (0.056)	0.26 (0.020)	0.27 (0.041)
	SD	0.035	0.015	0.097	0.065	0.154
	Median	0.24	0.24	0.30	0.24	0.23
	Min, Max	0.21 , 0.28	0.21 , 0.24	0.24 , 0.43	0.21 , 0.43	0.21 , 0.80
36 Hours Post Randomization MAP (cmH ₂ O)	n	3	4	3	10	14
	Mean (SE)	6.3 (0.88)	5.3 (0.24)	5.7 (0.67)	5.7 (0.33)	6.1 (0.31)
	SD	1.53	0.48	1.15	1.05	1.14
	Median	6.0	5.1	5.0	5.1	6.0
	Min, Max	5.0 , 8.0	5.0 , 6.0	5.0 , 7.0	5.0 , 8.0	4.0 , 8.0
FiO ₂	n	3	4	3	10	14
	Mean (SE)	0.23 (0.017)	0.23 (0.015)	0.31 (0.023)	0.25 (0.015)	0.23 (0.006)
	SD	0.029	0.030	0.040	0.049	0.022
	Median	0.21	0.21	0.30	0.24	0.21
	Min, Max	0.21 , 0.26	0.21 , 0.27	0.27 , 0.35	0.21 , 0.35	0.21 , 0.28
48 Hours Post Randomization MAP (cmH ₂ O)	n	4	4	4	12	15
	Mean (SE)	6.0 (0.71)	5.8 (0.27)	6.0 (0.71)	5.9 (0.31)	5.8 (0.25)

Note: Subjects may receive multiple nCPAP setting in different modes.

Summary Table 7.8
Clinical Assessments
Respiratory Parameters - nCPAP Settings
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	SD	1.41	0.54	1.41	1.09	0.96
	Median	5.5	6.0	5.5	6.0	6.0
	Min, Max	5.0 , 8.0	5.0 , 6.2	5.0 , 8.0	5.0 , 8.0	4.0 , 8.0
FiO ₂	n	4	4	4	12	15
	Mean (SE)	0.26 (0.022)	0.24 (0.021)	0.32 (0.031)	0.27 (0.017)	0.25 (0.019)
	SD	0.044	0.043	0.061	0.058	0.074
	Median	0.25	0.22	0.33	0.26	0.21
	Min, Max	0.21 , 0.31	0.21 , 0.30	0.24 , 0.38	0.21 , 0.38	0.21 , 0.50
Day 3 08:00						
MAP (cmH ₂ O)	n	4	4	3	11	14
	Mean (SE)	6.3 (0.63)	5.5 (0.29)	6.0 (1.00)	5.9 (0.34)	5.7 (0.27)
	SD	1.26	0.58	1.73	1.14	0.99
	Median	6.0	5.5	5.0	6.0	6.0
	Min, Max	5.0 , 8.0	5.0 , 6.0	5.0 , 8.0	5.0 , 8.0	4.0 , 8.0
FiO ₂	n	4	4	3	11	14
	Mean (SE)	0.25 (0.024)	0.23 (0.010)	0.31 (0.037)	0.26 (0.016)	0.22 (0.006)
	SD	0.048	0.021	0.064	0.054	0.021
	Median	0.24	0.23	0.35	0.24	0.21
	Min, Max	0.21 , 0.31	0.21 , 0.25	0.24 , 0.35	0.21 , 0.35	0.21 , 0.28

Day 3 20:00

Note: Subjects may receive multiple nCPAP setting in different modes.

Summary Table 7.8
Clinical Assessments
Respiratory Parameters - nCPAP Settings
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
MAP (cmH ₂ O)	n	4	4	5	13	15
	Mean (SE)	6.0 (0.71)	5.8 (0.25)	7.0 (1.14)	6.3 (0.49)	5.6 (0.22)
	SD	1.41	0.50	2.55	1.75	0.83
	Median	5.5	6.0	6.0	6.0	6.0
	Min, Max	5.0 , 8.0	5.0 , 6.0	5.0 , 11.0	5.0 , 11.0	4.0 , 7.0
FiO ₂	n	4	4	5	13	15
	Mean (SE)	0.26 (0.030)	0.24 (0.011)	0.27 (0.026)	0.26 (0.014)	0.24 (0.010)
	SD	0.061	0.022	0.058	0.049	0.039
	Median	0.26	0.24	0.25	0.25	0.21
	Min, Max	0.21 , 0.32	0.21 , 0.26	0.21 , 0.35	0.21 , 0.35	0.21 , 0.33
Day 4 08:00 MAP (cmH ₂ O)	n	4	4	4	12	14
	Mean (SE)	5.5 (0.29)	5.8 (0.25)	6.0 (0.71)	5.8 (0.25)	5.5 (0.25)
	SD	0.58	0.50	1.41	0.87	0.93
	Median	5.5	6.0	5.5	6.0	5.7
	Min, Max	5.0 , 6.0	5.0 , 6.0	5.0 , 8.0	5.0 , 8.0	4.0 , 7.0
FiO ₂	n	4	4	4	12	15
	Mean (SE)	0.25 (0.018)	0.23 (0.010)	0.25 (0.023)	0.24 (0.010)	0.23 (0.009)
	SD	0.035	0.019	0.047	0.034	0.035
	Median	0.25	0.22	0.25	0.23	0.21
	Min, Max	0.21 , 0.28	0.21 , 0.25	0.21 , 0.30	0.21 , 0.30	0.21 , 0.31

Note: Subjects may receive multiple nCPAP setting in different modes.

Summary Table 7.8
Clinical Assessments
Respiratory Parameters - nCPAP Settings
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Day 4 20:00						
MAP (cmH ₂ O)	n	3	5	4	12	13
	Mean (SE)	5.7 (0.33)	5.4 (0.23)	5.8 (0.75)	5.6 (0.26)	5.4 (0.24)
	SD	0.58	0.52	1.50	0.89	0.87
	Median	6.0	5.2	5.0	5.1	5.0
	Min, Max	5.0 , 6.0	5.0 , 6.0	5.0 , 8.0	5.0 , 8.0	4.0 , 7.0
FiO ₂	n	3	5	4	12	14
	Mean (SE)	0.21 (0.000)	0.23 (0.010)	0.23 (0.012)	0.22 (0.006)	0.24 (0.011)
	SD	0.000	0.022	0.024	0.020	0.042
	Median	0.21	0.21	0.22	0.21	0.21
	Min, Max	0.21 , 0.21	0.21 , 0.25	0.21 , 0.26	0.21 , 0.26	0.21 , 0.33
Day 5 08:00						
MAP (cmH ₂ O)	n	3	5	4	12	12
	Mean (SE)	5.7 (0.33)	5.4 (0.24)	5.5 (0.50)	5.5 (0.19)	5.2 (0.22)
	SD	0.58	0.53	1.00	0.67	0.75
	Median	6.0	5.1	5.0	5.1	5.0
	Min, Max	5.0 , 6.0	5.0 , 6.0	5.0 , 7.0	5.0 , 7.0	4.0 , 6.0
FiO ₂	n	3	5	4	12	14
	Mean (SE)	0.21 (0.000)	0.23 (0.009)	0.22 (0.005)	0.22 (0.005)	0.23 (0.008)
	SD	0.000	0.020	0.010	0.016	0.030

Note: Subjects may receive multiple nCPAP setting in different modes.

Summary Table 7.8
Clinical Assessments
Respiratory Parameters - nCPAP Settings
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Median	0.21	0.23	0.21	0.21	0.21
	Min, Max	0.21 , 0.21	0.21 , 0.25	0.21 , 0.23	0.21 , 0.25	0.21 , 0.30
Day 5 20:00						
MAP (cmH ₂ O)	n	3	5	4	12	14
	Mean (SE)	5.7 (0.33)	5.7 (0.45)	5.3 (0.25)	5.5 (0.21)	5.3 (0.19)
	SD	0.58	1.01	0.50	0.74	0.69
	Median	6.0	6.0	5.0	5.5	5.0
	Min, Max	5.0 , 6.0	4.4 , 7.0	5.0 , 6.0	4.4 , 7.0	4.0 , 6.0
FiO ₂	n	3	5	4	12	16
	Mean (SE)	0.21 (0.000)	0.23 (0.022)	0.21 (0.000)	0.22 (0.009)	0.23 (0.010)
	SD	0.000	0.049	0.000	0.032	0.039
	Median	0.21	0.21	0.21	0.21	0.21
	Min, Max	0.21 , 0.21	0.21 , 0.32	0.21 , 0.21	0.21 , 0.32	0.21 , 0.33
Day 6 08:00						
MAP (cmH ₂ O)	n	3	4	4	11	15
	Mean (SE)	5.7 (0.33)	5.9 (0.52)	5.3 (0.25)	5.6 (0.22)	5.5 (0.29)
	SD	0.58	1.03	0.50	0.74	1.12
	Median	6.0	6.0	5.0	6.0	5.0
	Min, Max	5.0 , 6.0	4.5 , 7.0	5.0 , 6.0	4.5 , 7.0	4.0 , 8.0
FiO ₂	n	3	4	4	11	17

Note: Subjects may receive multiple nCPAP setting in different modes.

Summary Table 7.8
Clinical Assessments
Respiratory Parameters - nCPAP Settings
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
	Mean (SE)	0.21 (0.000)	0.23 (0.022)	0.22 (0.005)	0.22 (0.008)	0.23 (0.014)
	SD	0.000	0.045	0.010	0.027	0.057
	Median	0.21	0.21	0.21	0.21	0.21
	Min, Max	0.21 , 0.21	0.21 , 0.30	0.21 , 0.23	0.21 , 0.30	0.21 , 0.44
Day 6 20:00						
MAP (cmH ₂ O)	n	3	4	3	10	16
	Mean (SE)	5.7 (0.33)	5.6 (0.59)	5.3 (0.33)	5.5 (0.25)	5.4 (0.25)
	SD	0.58	1.18	0.58	0.79	1.00
	Median	6.0	5.5	5.0	5.5	5.5
	Min, Max	5.0 , 6.0	4.3 , 7.0	5.0 , 6.0	4.3 , 7.0	3.7 , 7.0
FiO ₂						
	n	3	4	4	11	18
	Mean (SE)	0.21 (0.000)	0.25 (0.035)	0.21 (0.000)	0.22 (0.013)	0.23 (0.011)
	SD	0.000	0.070	0.000	0.042	0.046
	Median	0.21	0.21	0.21	0.21	0.21
	Min, Max	0.21 , 0.21	0.21 , 0.35	0.21 , 0.21	0.21 , 0.35	0.21 , 0.40
Day 7 08:00						
MAP (cmH ₂ O)	n	3	6	3	12	16
	Mean (SE)	5.3 (0.33)	5.5 (0.36)	5.3 (0.33)	5.4 (0.20)	5.3 (0.23)
	SD	0.58	0.87	0.58	0.69	0.92
	Median	5.0	5.3	5.0	5.0	5.0
	Min, Max	5.0 , 6.0	4.6 , 7.0	5.0 , 6.0	4.6 , 7.0	3.9 , 7.0

Note: Subjects may receive multiple nCPAP setting in different modes.

Summary Table 7.8
Clinical Assessments
Respiratory Parameters - nCPAP Settings
Safety Population

Time Point Assessment	Statistic	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
FiO ₂	n	3	6	4	13	18
	Mean (SE)	0.21 (0.000)	0.23 (0.015)	0.21 (0.000)	0.22 (0.007)	0.22 (0.005)
	SD	0.000	0.037	0.000	0.025	0.022
	Median	0.21	0.21	0.21	0.21	0.21
	Min, Max	0.21 , 0.21	0.21 , 0.30	0.21 , 0.21	0.21 , 0.30	0.21 , 0.28
Day 7 20:00 MAP (cmH ₂ O)	n	2	6	4	12	15
	Mean (SE)	5.0 (0.00)	5.4 (0.20)	5.3 (0.25)	5.3 (0.13)	5.2 (0.23)
	SD	0.00	0.49	0.50	0.45	0.88
	Median	5.0	5.3	5.0	5.0	5.0
	Min, Max	5.0 , 5.0	5.0 , 6.0	5.0 , 6.0	5.0 , 6.0	4.0 , 7.0
FiO ₂	n	2	6	5	13	17
	Mean (SE)	0.21 (0.000)	0.22 (0.007)	0.21 (0.004)	0.21 (0.003)	0.22 (0.005)
	SD	0.000	0.016	0.009	0.012	0.019
	Median	0.21	0.21	0.21	0.21	0.21
	Min, Max	0.21 , 0.21	0.21 , 0.25	0.21 , 0.23	0.21 , 0.25	0.21 , 0.28

Note: Subjects may receive multiple nCPAP setting in different modes.

Summary Table 7.9
Clinical Assessments
Complications of Prematurity
Safety Population

Complications of Prematurity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Number of Subjects with any Complication	8 (100%)	7 (88%)	7 (88%)	22 (92%)	22 (92%)
Acquired Sepsis	2 (25%)	2 (25%)	2 (25%)	6 (25%)	5 (21%)
Air Leak	3 (38%)	0 (0%)	2 (25%)	5 (21%)	4 (17%)
Apnea	8 (100%)	5 (63%)	6 (75%)	19 (79%)	19 (79%)
Cystic Periventricular Leukomalacia (PVL)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Patent Ductus Arteriosus (PDA)	3 (38%)	3 (38%)	4 (50%)	10 (42%)	10 (42%)
Pulmonary Hemorrhage	1 (13%)	0 (0%)	1 (13%)	2 (8%)	1 (4%)
Intraventricular Hemorrhage (IVH)	0 (0%)	1 (13%)	3 (38%)	4 (17%)	4 (17%)
Grade I	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
Grade II	0 (0%)	1 (13%)	1 (13%)	2 (8%)	2 (8%)
Grade III	0 (0%)	0 (0%)	1 (13%)	1 (4%)	0 (0%)
Grade IV	0 (0%)	0 (0%)	1 (13%)	1 (4%)	1 (4%)
Necrotizing Enterocolitis (NEC)	1 (13%)	1 (13%)	1 (13%)	3 (13%)	1 (4%)
Stage I	0 (0%)	1 (13%)	0 (0%)	1 (4%)	0 (0%)
Stage IIA	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Stage IIB	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Stage IIIA	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Stage IIIB	1 (13%)	0 (0%)	0 (0%)	1 (4%)	1 (4%)

Summary Table 7.9
Clinical Assessments
Complications of Prematurity
Safety Population

Complications of Prematurity	50 mg/kg (N=8)	75 mg/kg (N=8)	100 mg/kg (N=8)	Total Active (N=24)	nCPAP Only (N=24)
Retinopathy of Prematurity (ROP)	2 (25%)	1 (13%)	1 (13%)	4 (17%)	9 (38%)
Stage I	2 (25%)	1 (13%)	1 (13%)	4 (17%)	6 (25%)
Stage II	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (13%)
Stage III	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Stage IV	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE	SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
50 mg/kg	01032	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea of Prematurity	11FEB2016	*	Mild	NotRelated	Continuing
	01032	No	Pregnancy, puerperium and perinatal conditions	Retinopathy of prematurity	Retinopathy of Prematurity	08MAR2016	*	Mild	NotRelated	Continuing
	01032	No	Gastrointestinal disorders	Constipation	constipation	24FEB2016	24FEB2016	Mild	NotRelated	Recovered
	01032	No	Gastrointestinal disorders	Constipation	constipation	21FEB2016	22FEB2016	Mild	NotRelated	Recovered
	01032	No	Gastrointestinal disorders	Constipation	constipation	07FEB2016	14FEB2016	Mild	NotRelated	Recovered
	01032	No	Metabolism and nutrition disorders	Dehydration	dehydration	05FEB2016	09FEB2016	Mild	NotRelated	Recovered
	01032	No	Skin and subcutaneous tissue disorders	Dermatitis diaper	diaper rash	03APR2016	*	Mild	NotRelated	Continuing
	01032	No	General disorders and administration site	Oedema	edema	16FEB2016	21FEB2016	Mild	NotRelated	Recovered
	01032	No	Metabolism and nutrition disorders	Feeding intolerance	feeding intolerance	05FEB2016	24FEB2016	Moderate	NotRelated	Recovered
	01032	No	Metabolism and nutrition disorders	Hypercalcaemia	hypercalcemia	08FEB2016	11FEB2016	Mild	NotRelated	Recovered
	01032	No	Metabolism and nutrition disorders	Hypermagnesaemia	hypermagnesemia	05FEB2016	12FEB2016	Mild	NotRelated	Recovered
	01032	No	Metabolism and nutrition disorders	Hypophosphataemia	hypophosphatemia	08FEB2016	11FEB2016	Mild	NotRelated	Recovered
	01032	No	Metabolism and nutrition disorders	Metabolic acidosis	metabolic acidosis	04FEB2016	10FEB2016	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	01033	No Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea of Prematurity	12FEB2016	15MAR2016	Mild	NotRelated	Recovered
	01033	No Gastrointestinal disorders	Constipation	Constipation	14MAR2016	15MAR2016	Mild	NotRelated	Recovered
	01033	No Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	Hyperbilirubinemia	05FEB2016	18FEB2016	Mild	NotRelated	Recovered
	01033	No Congenital, familial and genetic disorders	Patent ductus arteriosus	Patent Ductus Arteriosis	09FEB2016	*	Mild	NotRelated	Continuing
	01033	No Respiratory, thoracic and mediastinal	Pulmonary interstitial emphysema syndrome	Pulmonary Interstitial	07FEB2016	*	Mild	NotRelated	Continuing
	01033	No Pregnancy, puerperium and perinatal conditions	Retinopathy of prematurity	Retinopathy of Prematurity	08MAR2016	*	Mild	NotRelated	Continuing
	01033	No Blood and lymphatic system disorders	Anaemia neonatal	anemia	13FEB2016	*	Mild	NotRelated	Continuing
	01033	No Infections and infestations	Sepsis neonatal	clinical sepsis	07FEB2016	12FEB2016	Mild	NotRelated	Recovered
	01033	No Gastrointestinal disorders	Constipation	constipation	05APR2016	05APR2016	Mild	NotRelated	Recovered
	01033	No Gastrointestinal disorders	Constipation	constipation	17FEB2016	21FEB2016	Mild	NotRelated	Recovered
	01033	No Gastrointestinal disorders	Constipation	constipation	07FEB2016	12FEB2016	Mild	NotRelated	Recovered
	01033	No Gastrointestinal disorders	Gastrointestinal hypomotility	decreased peristalsis	07FEB2016	*	Moderate	NotRelated	Improved
	01033	No Skin and subcutaneous tissue disorders	Dermatitis diaper	diaper rash	03APR2016	03APR2016	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	01033	No Skin and subcutaneous tissue disorders	Dermatitis diaper	diaper rash	22MAR2016	23MAR2016	Mild	NotRelated	Recovered
	01033	No General disorders and administration site	Oedema	edema	15FEB2016	19FEB2016	Mild	NotRelated	Recovered
	01033	No Metabolism and nutrition disorders	Feeding intolerance	feeding intolerance	12FEB2016	03MAR2016	Moderate	NotRelated	Recovered
	01033	No Metabolism and nutrition disorders	Metabolic acidosis	metabolic acidosis	05FEB2016	05FEB2016	Mild	NotRelated	Recovered
	01033	No Investigations	Cardiac murmur	systolic murmur heard over right	05APR2016	*	Mild	NotRelated	Continuing
	01033	No Blood and lymphatic system disorders	Thrombocytopenia	thrombocytopenia	06FEB2016	15FEB2016	Moderate	NotRelated	Recovered
	01040	Yes Respiratory, thoracic and mediastinal	Pneumothorax	Left Pneumothorax	13JUN2016	18JUN2016	Moderate	PossiblyRelated	Recovered
	01040	No Congenital, familial and genetic disorders	Patent ductus arteriosus	Patent Ductus Arteriosus	15JUN2016	*	Mild	NotRelated	Improved
	01040	No Blood and lymphatic system disorders	Anaemia neonatal	anemia	18JUN2016	*	Mild	NotRelated	Continuing
	01040	No Respiratory, thoracic and mediastinal	Apnoea neonatal	apnea of prematurity	14JUN2016	*	Mild	NotRelated	Continuing
	01040	No Blood and lymphatic system disorders	Coagulopathy	coagulopathy	21JUN2016	23JUN2016	Mild	NotRelated	Recovered
	01040	No Gastrointestinal disorders	Constipation	constipation	21JUN2016	26JUN2016	Mild	NotRelated	Recovered
	01040	No Gastrointestinal disorders	Constipation	constipation	16JUN2016	21JUN2016	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	01040	No	Investigations	Oxygen saturation decreased	desaturations	15JUL2016	16JUL2016	Mild	NotRelated	Recovered
	01040	No	Skin and subcutaneous tissue disorders	Dermatitis diaper	diaper rash	04AUG2016	*	Mild	NotRelated	Improved
	01040	No	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	hyperbilirubinemia	14JUN2016	17JUN2016	Mild	NotRelated	Recovered
	01040	No	Metabolism and nutrition disorders	Metabolic acidosis	metabolic acidosis	14JUN2016	15JUN2016	Mild	NotRelated	Recovered
	01040	No	Investigations	Cardiac murmur	murmur: SEM, Grade (2/6)	01JUL2016	*	Mild	NotRelated	Continuing
	01040	No	Respiratory, thoracic and mediastinal	Pulmonary interstitial emphysema syndrome	pulmonary interstitial	13JUN2016	22JUN2016	Moderate	PossiblyRelated	Recovered
	01040	No	Infections and infestations	Urinary tract infection	urinary tract infection-E Coli	29JUL2016	05AUG2016	Moderate	NotRelated	Recovered
	01041	No	Respiratory, thoracic and mediastinal	Neonatal tachypnoea	Intermittent tachypnea	13JUN2016	04AUG2016	Mild	NotRelated	Recovered
	01041	No	Congenital, familial and genetic disorders	Patent ductus arteriosus	PDA	14JUN2016	07JUL2016	Mild	NotRelated	Recovered
	01041	No	Blood and lymphatic system disorders	Anaemia neonatal	anemia	01JUL2016	*	Mild	NotRelated	Continuing
	01041	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	apnea of prematurity	14JUN2016	*	Mild	NotRelated	Continuing
	01041	No	Gastrointestinal disorders	Constipation	constipation	29JUN2016	29JUN2016	Mild	NotRelated	Recovered
	01041	No	Gastrointestinal disorders	Constipation	constipation	22JUN2016	23JUN2016	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	01041	No Gastrointestinal disorders	Constipation	constipation	15JUN2016	18JUN2016	Mild	NotRelated	Recovered
	01041	No General disorders and administration site	Oedema	edema	18JUL2016	*	Mild	NotRelated	Continuing
	01041	No Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	hyperbilirubinemia	15JUN2016	17JUN2016	Mild	NotRelated	Recovered
	01041	No Metabolism and nutrition disorders	Hyponatraemia	hyponatremia	02JUL2016	*	Mild	NotRelated	Improved
	01041	No Respiratory, thoracic and mediastinal	Pulmonary interstitial emphysema syndrome	pulmonary interstitial	15JUN2016	21JUN2016	Moderate	NotRelated	Recovered
	01041	No Injury, poisoning and procedural	Laceration	skin tear right abdomen	14JUN2016	20JUN2016	Mild	NotRelated	Recovered
	09001	No Pregnancy, puerperium and perinatal conditions	Fixed bowel loop	Abdominal loops	13MAY2016	13MAY2016	Mild	NotRelated	Recovered
	09001	No Blood and lymphatic system disorders	Anaemia neonatal	Anemia	22MAY2016	24JUN2016	Mild	NotRelated	Recovered
	09001	No Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea of prematurity	12MAY2016	20JUN2016	Mild	NotRelated	Recovered
	09001	No Gastrointestinal disorders	Haematemesis	Blood in emesis	13MAY2016	13MAY2016	Mild	NotRelated	Recovered
	09001	Yes Infections and infestations	Sepsis neonatal	CONS septicemia	21MAY2016	07JUN2016	Severe	NotRelated	Recovered
	09001	No Gastrointestinal disorders	Constipation	Constipation	11MAY2016	17MAY2016	Mild	NotRelated	Recovered
	09001	No Metabolism and nutrition disorders	Hypernatraemia	Elevated sodium (Na+) level	11MAY2016	11MAY2016	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	09001	No Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	Hyperbilirubinemia	13MAY2016	21MAY2016	Mild	NotRelated	Recovered
	09001	No Nervous system disorders	Hypotonia	Hypotonia	21MAY2016	21MAY2016	Mild	NotRelated	Recovered
	09001	No Gastrointestinal disorders	Vomiting	Intermittent emesis	11MAY2016	25MAY2016	Mild	NotRelated	Recovered
	09001	No Injury, poisoning and procedural	Blister	Left wrist blister/skin	24MAY2016	13JUN2016	Mild	NotRelated	Recovered
	09001	No Nervous system disorders	Lethargy	Lethargy	21MAY2016	21MAY2016	Mild	NotRelated	Recovered
	09001	No Metabolism and nutrition disorders	Feeding intolerance	Poor feeder	10MAY2016	*	Mild	NotRelated	Continuing
	09001	No Respiratory, thoracic and mediastinal	Respiratory acidosis	Respiratory acidosis	21MAY2016	22MAY2016	Mild	NotRelated	Recovered
	09001	No Blood and lymphatic system disorders	Thrombocytopenia	Thrombocytopenia	22MAY2016	02JUN2016	Mild	NotRelated	Recovered
	12007	No Blood and lymphatic system disorders	Anaemia neonatal	Anemia of prematurity	07APR2016	02MAY2016	Mild	NotRelated	Recovered
	12007	No Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea	02MAR2016	02MAR2016	Mild	PossiblyRelated	Recovered
	12007	No Investigations	Oxygen saturation decreased	Desaturation	04APR2016	18APR2016	Mild	NotRelated	Recovered
	12007	No Investigations	Oxygen saturation decreased	Desaturation	02MAR2016	02MAR2016	Mild	PossiblyRelated	Recovered
	12007	No Metabolism and nutrition disorders	Hypochloraemia	hypochloremia	09MAR2016	16MAR2016	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	12007	No Metabolism and nutrition disorders	Hyponatraemia	hyponatremia	09MAR2016	30MAR2016	Mild	NotRelated	Recovered
	12007	No Respiratory, thoracic and mediastinal	Nasal inflammation	nasal irritation	24MAR2016	02APR2016	Mild	NotRelated	Recovered
	12014	No Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	Acute respiratory failure	29APR2016	05JUN2016	Moderate	NotRelated	Worsened
	12014	No Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea	29APR2016	05JUN2016	Mild	NotRelated	Worsened
	12014	No Respiratory, thoracic and mediastinal	Respiratory alkalosis	Mild respiratory alkalosis	04MAY2016	05MAY2016	Mild	NotRelated	Recovered
	12014	Yes Pregnancy, puerperium and perinatal conditions	Necrotising enterocolitis neonatal	NEC	05JUN2016	06JUN2016	Severe	NotRelated	Died
	12014	No General disorders and administration site	Pain	Pain	29APR2016	06JUN2016	Mild	NotRelated	Worsened
	12014	No Blood and lymphatic system disorders	Anaemia neonatal	anemia of prematurity	02MAY2016	06JUN2016	Mild	NotRelated	Worsened
	12014	No Blood and lymphatic system disorders	Bandaemia	bandemia	04MAY2016	06MAY2016	Mild	NotRelated	Recovered
	12014	No Skin and subcutaneous tissue disorders	Dermatitis diaper	diaper rash	22MAY2016	02JUN2016	Mild	NotRelated	Recovered
	12014	No Metabolism and nutrition disorders	Electrolyte imbalance	electrolyte imbalance	05JUN2016	06JUN2016	Mild	NotRelated	Worsened
	12014	No Metabolism and nutrition disorders	Hyperchloraemia	hyperchloremia	01MAY2016	01MAY2016	Mild	NotRelated	Recovered
	12014	No Metabolism and nutrition disorders	Hyperglycaemia	hyperglycemia	02MAY2016	11MAY2016	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	12014	No Metabolism and nutrition disorders	Hypertriglyceridaemia	hypertriglyceridemia	04MAY2016	07MAY2016	Mild	NotRelated	Recovered
	12014	No Metabolism and nutrition disorders	Hypochloraemia	hypochloremia	04MAY2016	06MAY2016	Mild	NotRelated	Recovered
	12014	No Metabolism and nutrition disorders	Hyponatraemia	hyponatremia	01MAY2016	01MAY2016	Mild	NotRelated	Recovered
	12014	No Metabolism and nutrition disorders	Hypophosphataemia	hypophosphotemia	04MAY2016	04MAY2016	Mild	NotRelated	Recovered
	12014	No Vascular disorders	Hypotension	hypotension	05JUN2016	06JUN2016	Moderate	NotRelated	Worsened
	12014	No Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	indirect hyperbilirubinemia	01MAY2016	05MAY2016	Mild	NotRelated	Recovered
	12014	No Blood and lymphatic system disorders	Neutropenia	neutropenia	30APR2016	06MAY2016	Mild	NotRelated	Recovered
	12014	No Respiratory, thoracic and mediastinal	Respiratory acidosis	respiratory acidosis	01MAY2016	03MAY2016	Mild	NotRelated	Recovered
	12014	No Infections and infestations	Septic shock	septic shock	05JUN2016	06JUN2016	Moderate	NotRelated	Worsened
	40001	No Gastrointestinal disorders	Haematemesis	Coffee ground (altered blood) from	05MAY2016	05MAY2016	Mild	NotRelated	Recovered
	40001	No Gastrointestinal disorders	Gastric hypomotility	Decreased gut motility	06MAY2016	*	Moderate	UnlikelyRelated	Continuing
	40001	No General disorders and administration site	Face oedema	Face edema	06MAY2016	*	Mild	NotRelated	Continuing
	40001	No Respiratory, thoracic and mediastinal	Nasal inflammation	Nasal Irritation	06MAY2016	*	Mild	NotRelated	Continuing

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE	SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	40001	No	Respiratory, thoracic and mediastinal	Nasal inflammation	Nasal Irritation (Nasal Septum)	05MAY2016	05MAY2016	Mild	NotRelated	Recovered
	40001	Yes	Gastrointestinal disorders	Intestinal perforation	Spontaneous Intestinal perforation	07MAY2016	*	Severe	UnlikelyRelated	Continuing
75 mg/kg	01042	No	Gastrointestinal disorders	Gastrooesophageal reflux disease	Gastrooesophageal reflux	14SEP2016	*	Mild	NotRelated	Improved
	01042	No	Blood and lymphatic system disorders	Anaemia neonatal	anemia	13AUG2016	*	Mild	NotRelated	Improved
	01042	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	apnea	11AUG2016	11AUG2016	Mild	PossiblyRelated	Recovered
	01042	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	apnea of prematurity	13AUG2016	08OCT2016	Mild	NotRelated	Recovered
	01042	No	Skin and subcutaneous tissue disorders	Dermatitis diaper	diaper rash	29SEP2016	02OCT2016	Mild	NotRelated	Recovered
	01042	No	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	hyperbilirubinemia	13AUG2016	24AUG2016	Mild	NotRelated	Recovered
	01042	No	Metabolism and nutrition disorders	Hyperglycaemia	hyperglycemia	12AUG2016	12AUG2016	Mild	NotRelated	Recovered
	01042	No	Metabolism and nutrition disorders	Hypernatraemia	hypernatremia	13AUG2016	15AUG2016	Mild	NotRelated	Recovered
	01042	No	Metabolism and nutrition disorders	Hypokalaemia	hypokalemia	12AUG2016	14AUG2016	Moderate	NotRelated	Recovered
	01042	No	Investigations	Cardiac murmur	murmur: SEM, Grade (1/6)	12SEP2016	17SEP2016	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	01042	No Congenital, familial and genetic disorders	Atrial septal defect	patent foramen ovale	15AUG2016	*	Mild	NotRelated	Continuing
	01042	No Blood and lymphatic system disorders	Thrombocytopenia	thrombocytopenia	13AUG2016	24AUG2016	Mild	NotRelated	Recovered
	11011	No Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Bradycardia	31AUG2016	31AUG2016	Mild	PossiblyRelated	Recovered
	11011	No Investigations	Oxygen saturation decreased	Desaturation	31AUG2016	31AUG2016	Mild	PossiblyRelated	Recovered
	11011	No Renal and urinary disorders	Oliguria	decreased urine output	07SEP2016	07SEP2016	Mild	UnlikelyRelated	Recovered
	11011	No Metabolism and nutrition disorders	Hypokalaemia	hypokalemia	09SEP2016	09SEP2016	Mild	UnlikelyRelated	Recovered
	11011	No Metabolism and nutrition disorders	Hypomagnesaemia	hypomagnesemia	09SEP2016	09SEP2016	Mild	UnlikelyRelated	Recovered
	11011	No Vascular disorders	Hypotension	hypotension	07SEP2016	09SEP2016	Moderate	UnlikelyRelated	Continuing
	11011	No Metabolism and nutrition disorders	Hypovolaemia	hypovolemia	08SEP2016	09SEP2016	Moderate	UnlikelyRelated	Continuing
	11011	Yes Gastrointestinal disorders	Pneumoperitoneum	pneumoperitoneum	04SEP2016	09SEP2016	Severe	UnlikelyRelated	Died
	12023	No Blood and lymphatic system disorders	Anaemia neonatal	Anemia of prematurity	09OCT2016	*	Mild	NotRelated	Continuing
	12023	No Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea of prematurity	30SEP2016	*	Mild	NotRelated	Continuing
	12023	No Respiratory, thoracic and mediastinal	Chronic respiratory failure	Chronic respiratory failure	30SEP2016	*	Moderate	NotRelated	Continuing

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	12023	No Metabolism and nutrition disorders	Feeding intolerance	Feeding difficulties in newborn	03OCT2016	*	Mild	NotRelated	Continuing
	12023	No Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	Hyperbilirubinemia	30SEP2016	*	Mild	NotRelated	Continuing
	12023	No Metabolism and nutrition disorders	Hyperglycaemia	Hyperglycemia	12OCT2016	14OCT2016	Mild	NotRelated	Recovered
	12023	No Metabolism and nutrition disorders	Hypernatraemia	Hyperosmolality with hyponatremia	02OCT2016	09OCT2016	Mild	NotRelated	Recovered
	12023	No Metabolism and nutrition disorders	Hypertriglyceridaemia	Hypertriglyceridemia	09OCT2016	*	Mild	NotRelated	Continuing
	12023	No Metabolism and nutrition disorders	Hypochloraemia	Hypochloremia	06OCT2016	*	Mild	NotRelated	Continuing
	12023	No Infections and infestations	Pneumonia	Pneumonia	22OCT2016	26OCT2016	Moderate	NotRelated	Recovered
	12023	No Respiratory, thoracic and mediastinal	Nasal mucosal ulcer	Skin ulcer of nose	07OCT2016	*	Mild	NotRelated	Continuing
	12023	No Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	bradycardia	03OCT2016	*	Mild	NotRelated	Continuing
	12023	No Skin and subcutaneous tissue disorders	Dermatitis diaper	diaper rash	07OCT2016	*	Mild	NotRelated	Continuing
	12023	No Respiratory, thoracic and mediastinal	Hypercapnia	hypercarbia	22OCT2016	01NOV2016	Moderate	NotRelated	Recovered
	12023	No Vascular disorders	Hypotension	hypotension	10OCT2016	16OCT2016	Mild	NotRelated	Recovered
	12023	No Metabolism and nutrition disorders	Metabolic alkalosis	metabolic alkalosis	06OCT2016	*	Mild	NotRelated	Continuing

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	12023	No	Congenital, familial and genetic disorders	Patent ductus arteriosus	moderate PDA with left to right shunting	03OCT2016	*	Moderate	NotRelated	Continuing
	12023	No	Gastrointestinal disorders	Salivary hypersecretion	oral secretions	28OCT2016	31OCT2016	Mild	NotRelated	Recovered
	12023	No	Respiratory, thoracic and mediastinal	Pulmonary oedema neonatal	pulmonary edema	28OCT2016	20NOV2016	Mild	NotRelated	Recovered
	12023	No	Cardiac disorders	Tachycardia	tachycardia	01NOV2016	*	Mild	NotRelated	Continuing
	40003	No	Gastrointestinal disorders	Gastric haemorrhage	Blood tinged residual noted in	09JUL2016	12JUL2016	Mild	NotRelated	Recovered
	40003	No	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	Early worsening of respiratory status	08JUL2016	21JUL2016	Mild	NotRelated	Recovered
	40003	No	Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Intermittent Bradycardia	10JUL2016	01AUG2016	Mild	NotRelated	Recovered
	40003	No	Investigations	Oxygen saturation decreased	Intermittent destaurations	08JUL2016	12AUG2016	Mild	NotRelated	Recovered
	40003	No	Injury, poisoning and procedural	Tracheal injury	Scant blood tinged endo tracheal tube	10JUL2016	18JUL2016	Mild	UnlikelyRelated	Recovered
	40006	No	Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Bradycardia (peri-dosing)	24AUG2016	24AUG2016	Mild	PossiblyRelated	Recovered
	40006	No	Infections and infestations	Sepsis neonatal	Culture negative septic episode	05SEP2016	15SEP2016	Moderate	NotRelated	Recovered
	40006	No	Investigations	Oxygen saturation decreased	Destaturation (peri-dosing)	24AUG2016	24AUG2016	Mild	PossiblyRelated	Recovered
	40006	No	Investigations	Oxygen saturation decreased	Inadequate oxygen saturation	24AUG2016	24AUG2016	Mild	PossiblyRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	40006	No Respiratory, thoracic and mediastinal	Apnoea neonatal	Intermittent Apnea	26AUG2016	11OCT2016	Mild	NotRelated	Recovered
	40006	No Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Intermittent bradycardia	26AUG2016	11OCT2016	Mild	NotRelated	Recovered
	40006	No Investigations	Oxygen saturation decreased	Intermittent desaturation	24AUG2016	10OCT2016	Mild	NotRelated	Recovered
	42003	No Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Bradycardia	28JUL2016	28JUL2016	Mild	NotRelated	Recovered
	42003	No Injury, poisoning and procedural	Ear abrasion	Ear lobe abrasion/tear (right)	29JUL2016	01AUG2016	Mild	NotRelated	Recovered
	42003	No Pregnancy, puerperium and perinatal conditions	Necrotising enterocolitis neonatal	NEC - stage I	08AUG2016	08AUG2016	Mild	NotRelated	Recovered
	42003	No Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	Respiratory distress	07AUG2016	14AUG2016	Mild	UnlikelyRelated	Recovered
	42003	No Respiratory, thoracic and mediastinal	Apnoea neonatal	apnea	07AUG2016	07AUG2016	Mild	NotRelated	Recovered
	42003	No Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	bradycardia	07AUG2016	07AUG2016	Mild	NotRelated	Recovered
	50001	No Blood and lymphatic system disorders	Anaemia neonatal	Anemia of prematurity	20OCT2016	01NOV2016	Mild	NotRelated	Recovered
	50001	No Blood and lymphatic system disorders	Anaemia neonatal	Anemia of prematurity	05DEC2016	*	Mild	NotRelated	Continuing
	50001	No Infections and infestations	Bacteraemia	Bacteraemia/Sepsis.	13OCT2016	23OCT2016	Moderate	NotRelated	Recovered
	50001	No Respiratory, thoracic and mediastinal	Nasal discomfort	Decubitus at the base of the nasal	13OCT2016	05DEC2016	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	50001	No	Investigations	Oxygen saturation decreased	Desaturations	07NOV2016	22NOV2016	Mild	NotRelated	Recovered
	50001	No	Vascular disorders	Haemangioma	Haemangioma of left thigh	25NOV2016	*	Mild	NotRelated	Continuing
	50001	No	Pregnancy, puerperium and perinatal conditions	Intraventricular haemorrhage neonatal	Intraventricular haemorrhage (2nd	13OCT2016	31OCT2016	Mild	NotRelated	Recovered
	50001	No	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	JAUNDICE	29SEP2016	03OCT2016	Mild	NotRelated	Recovered
	50001	No	Infections and infestations	Nosocomial infection	Nosocomial infection	02NOV2016	09NOV2016	Mild	NotRelated	Recovered
	50001	No	Congenital, familial and genetic disorders	Patent ductus arteriosus	PATENT ARTERIAL DUCT	30SEP2016	04OCT2016	Mild	NotRelated	Recovered
	50001	Yes	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	RESPIRATORY FAILURE	28SEP2016	03OCT2016	Moderate	UnlikelyRelated	Recovered
	50001	Yes	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory failure	Respiratory failure	13OCT2016	23OCT2016	Moderate	NotRelated	Recovered
	50001	No	Pregnancy, puerperium and perinatal conditions	Retinopathy of prematurity	Retinopathy of prematurity (1st	23NOV2016	*	Mild	NotRelated	Continuing
	50001	No	Gastrointestinal disorders	Umbilical hernia	Umbilical hernia	05DEC2016	*	Mild	NotRelated	Continuing
	50001	No	Metabolism and nutrition disorders	Vitamin D deficiency	VITAMIN D DEFICIENCY	24OCT2016	17NOV2016	Mild	NotRelated	Recovered
	50001	No	Blood and lymphatic system disorders	Thrombocytopenia	thrombocytopenia of prematurity	30SEP2016	07OCT2016	Mild	NotRelated	Recovered
	51004	No	Congenital, familial and genetic disorders	Patent ductus arteriosus	Patent Ductus Arteriosus	31JUL2016	04AUG2016	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE	SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	51004	Yes	Infections and infestations	Pneumonia	Ventilator-associated pneumonia (VAP)	03AUG2016	17AUG2016	Moderate	NotRelated	Recovered
	51004	No	Blood and lymphatic system disorders	Anaemia neonatal	anemia	03AUG2016	03AUG2016	Mild	NotRelated	Recovered
	51004	No	Blood and lymphatic system disorders	Anaemia neonatal	anemia	12SEP2016	12SEP2016	Mild	NotRelated	Recovered
	51004	Yes	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	respiratory failure	26JUL2016	03SEP2016	Moderate	NotRelated	Recovered
100 mg/kg	11021	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea	05NOV2016	05NOV2016	Mild	PossiblyRelated	Recovered
	11021	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea	05NOV2016	05NOV2016	Mild	PossiblyRelated	Recovered
	11021	No	Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Bradycardia	05NOV2016	05NOV2016	Mild	PossiblyRelated	Recovered
	11021	No	Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Bradycardia	05NOV2016	05NOV2016	Mild	PossiblyRelated	Recovered
	11021	No	Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Bradycardia	05NOV2016	05NOV2016	Mild	PossiblyRelated	Recovered
	11021	No	Investigations	Oxygen saturation decreased	Desaturation	05NOV2016	05NOV2016	Mild	PossiblyRelated	Recovered
	11021	No	Investigations	Oxygen saturation decreased	Desaturation	05NOV2016	05NOV2016	Mild	PossiblyRelated	Recovered
	11021	No	Congenital, familial and genetic disorders	Patent ductus arteriosus	Patent Ductus Arteriosus	09NOV2016	13JAN2017	Mild	UnlikelyRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	11021	Yes	Pregnancy, puerperium and perinatal conditions	Intraventricular haemorrhage neonatal	intraventricular hemorrhage	06NOV2016	*	Severe	UnlikelyRelated	Continuing
	11021	Yes	Respiratory, thoracic and mediastinal	Pneumothorax	pneumothorax	06NOV2016	15NOV2016	Severe	UnlikelyRelated	Recovered
	11023	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea of prematurity	22NOV2016	02FEB2017	Moderate	UnlikelyRelated	Recovered
	11023	No	Investigations	Oxygen saturation decreased	During Dose 1, subject experienced	21NOV2016	21NOV2016	Mild	PossiblyRelated	Recovered
	11023	No	Investigations	Oxygen saturation decreased	During Dose 1, subject experienced	21NOV2016	21NOV2016	Mild	PossiblyRelated	Recovered
	11023	No	Investigations	Oxygen saturation decreased	During repeat dose, subject experienced	22NOV2016	22NOV2016	Mild	PossiblyRelated	Recovered
	11023	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	During repeat dose, subject experienced	22NOV2016	22NOV2016	Mild	PossiblyRelated	Recovered
	11023	No	Infections and infestations	Bacterial disease carrier	MSSA colonization	17JAN2017	06FEB2017	Mild	NotRelated	Recovered
	11023	No	Congenital, familial and genetic disorders	Patent ductus arteriosus	Patent Ductus Arteriosus	28NOV2016	13DEC2016	Mild	UnlikelyRelated	Recovered
	11023	No	Infections and infestations	Sepsis neonatal	Sepsis	29NOV2016	05DEC2016	Moderate	NotRelated	Recovered
	11023	No	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	Worsening respiratory status	29NOV2016	29NOV2016	Moderate	NotRelated	Recovered
	11023	No	Pregnancy, puerperium and perinatal conditions	Necrotising enterocolitis neonatal	medical NEC	06JAN2017	*	Mild	UnlikelyRelated	Improved
	11025	No	Infections and infestations	Bacterial disease carrier	MSSA skin colonization	15MAY2017	*	Mild	UnlikelyRelated	Continuing

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	11025	No Respiratory, thoracic and mediastinal	Apnoea neonatal	apnea of prematurity	30APR2017	*	Moderate	UnlikelyRelated	Continuing
	11025	No Gastrointestinal disorders	Constipation	constipation	28APR2017	02MAY2017	Mild	UnlikelyRelated	Recovered
	11025	No Gastrointestinal disorders	Umbilical hernia	reducible umbilical hernia	06JUN2017	*	Mild	NotRelated	Continuing
	11025	No Respiratory, thoracic and mediastinal	Pulmonary interstitial emphysema syndrome	right pulmonary interstitial	29APR2017	*	Moderate	PossiblyRelated	Continuing
	19007	No Pregnancy, puerperium and perinatal conditions	Agitation neonatal	Agitation requiring sedation	21DEC2016	23DEC2016	Mild	NotRelated	Recovered
	19007	No Blood and lymphatic system disorders	Anaemia neonatal	Anemia of Prematurity	30JAN2017	*	Mild	NotRelated	Continuing
	19007	No Investigations	Oxygen saturation decreased	Desaturation	19DEC2016	19DEC2016	Mild	Related	Recovered
	19007	No Investigations	Oxygen saturation decreased	Desturation	20DEC2016	20DEC2016	Mild	PossiblyRelated	Recovered
	19007	No Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	Hyperbilirubinemia	20DEC2016	03JAN2017	Mild	NotRelated	Recovered
	19007	No Congenital, familial and genetic disorders	Patent ductus arteriosus	Patent Ductus Arteriosus	02JAN2017	*	Mild	NotRelated	Continuing
	19007	No Congenital, familial and genetic disorders	Atrial septal defect	Patent Foramen Ovale	02JAN2017	*	Mild	NotRelated	Continuing
	40014	No Respiratory, thoracic and mediastinal	Respiratory tract haemorrhage	Bloody secretions from the	09DEC2016	09DEC2016	Mild	NotRelated	Recovered
	40014	No Investigations	Oxygen saturation decreased	Desaturation	09DEC2016	09DEC2016	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	40014	No	General disorders and administration site	Endotracheal intubation complication	Inadvertent extubation	12DEC2016	12DEC2016	Mild	NotRelated	Recovered
	40014	No	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	Increased respiratory distress	09DEC2016	09DEC2016	Mild	NotRelated	Recovered
	40014	No	Investigations	Oxygen saturation decreased	Intermittent desaturation	11DEC2016	30JAN2017	Mild	NotRelated	Recovered
	40014	No	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	Worsening RDS	09DEC2016	09DEC2016	Mild	NotRelated	Recovered
	40015	No	Skin and subcutaneous tissue disorders	Dermatitis diaper	Diaper rash	22JAN2017	01FEB2017	Mild	NotRelated	Recovered
	40015	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Intermittent Apnea	05JAN2017	02FEB2017	Mild	NotRelated	Recovered
	40015	No	Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Intermittent Bradycardia	05JAN2017	02FEB2017	Mild	NotRelated	Recovered
	40015	No	Cardiac disorders	Tachycardia	Intermittent Sinus tachycardia	07JAN2017	02FEB2017	Mild	NotRelated	Recovered
	40015	No	Investigations	Oxygen saturation decreased	Intermittent desaturation	05JAN2017	02FEB2017	Mild	NotRelated	Recovered
	40015	Yes	Pregnancy, puerperium and perinatal conditions	Intraventricular haemorrhage neonatal	Intraventricular Haemorrhage	23JAN2017	13MAR2017	Severe	UnlikelyRelated	Recovered
	40015	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Profound Apnea episode	05JAN2017	05JAN2017	Mild	NotRelated	Recovered
	40016	No	Metabolism and nutrition disorders	Feeding intolerance	Feeding intolerance	25FEB2017	26FEB2017	Mild	NotRelated	Recovered
	40016	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Intermittent Apnea	26FEB2017	*	Mild	NotRelated	Continuing

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	40016	No	Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Intermittent Bradycardia	24FEB2017	*	Mild	NotRelated	Continuing
	40016	No	Investigations	Oxygen saturation decreased	Intermittent Desaturations	24FEB2017	*	Mild	NotRelated	Continuing
	40016	No	Respiratory, thoracic and mediastinal	Neonatal tachypnoea	Intermittent Tachypnea	24FEB2017	*	Mild	NotRelated	Continuing
	42010	No	Blood and lymphatic system disorders	Anaemia neonatal	Anemia	15DEC2016	19DEC2016	Mild	NotRelated	Recovered
	42010	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea	08DEC2016	20DEC2016	Mild	UnlikelyRelated	Recovered
	42010	No	Investigations	Coagulation time prolonged	Elevated clotting time	09DEC2016	13DEC2016	Mild	NotRelated	Recovered
	42010	No	Congenital, familial and genetic disorders	Patent ductus arteriosus	Patent ductus arteriosus	12DEC2016	*	Moderate	NotRelated	Improved
	42010	No	Respiratory, thoracic and mediastinal	Pulmonary haemorrhage	Pulmonary Hemorrhage	09DEC2016	17DEC2016	Moderate	NotRelated	Recovered
	42010	No	Pregnancy, puerperium and perinatal conditions	Retinopathy of prematurity	Retinopathy of Prematurity	31JAN2017	*	Mild	UnlikelyRelated	Continuing
	42010	No	Pregnancy, puerperium and perinatal conditions	Intraventricular haemorrhage neonatal	Small left subependymal	12DEC2016	21DEC2016	Mild	NotRelated	Recovered
	42010	No	Infections and infestations	Urosepsis	Urosepsis	24DEC2016	02JAN2017	Mild	NotRelated	Recovered
nCPAP only	03006	No	Blood and lymphatic system disorders	Anaemia neonatal	Anemia of Prematurity	28JAN2016	*	Mild	NotRelated	Continuing

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	03006	No	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	Chronic Respiratory Insufficiency of	14FEB2016	*	Mild	NotRelated	Continuing
	03006	No	Gastrointestinal disorders	Constipation	Constipation	16JAN2016	19JAN2016	Mild	NotRelated	Recovered
	03006	No	Skin and subcutaneous tissue disorders	Dermatitis diaper	Diaper Rash	21JAN2016	01FEB2016	Mild	NotRelated	Recovered
	03006	No	Respiratory, thoracic and mediastinal	Hypercapnia	Hypercapnia	16JAN2016	16JAN2016	Moderate	NotRelated	Recovered
	03006	No	Gastrointestinal disorders	Inguinal hernia	Inguinal hernia-right	06MAR2016	*	Mild	NotRelated	Continuing
	03006	No	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	Jaundice	16JAN2016	28JAN2016	Mild	NotRelated	Recovered
	03013	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea of Prematurity	15AUG2016	09OCT2016	Mild	NotRelated	Recovered
	03013	No	Metabolism and nutrition disorders	Hyperkalaemia	Hyperkalemia	15AUG2016	16AUG2016	Mild	NotRelated	Recovered
	03013	No	Congenital, familial and genetic disorders	Patent ductus arteriosus	Patent ductus arteriosis	29AUG2016	14OCT2016	Moderate	NotRelated	Recovered
	03013	No	Pregnancy, puerperium and perinatal conditions	Small for dates baby	Poor growth	28AUG2016	30AUG2016	Mild	NotRelated	Recovered
	03013	No	General disorders and administration site	Hypothermia	hypothermia	18AUG2016	18AUG2016	Mild	NotRelated	Recovered
	08028	No	Respiratory, thoracic and mediastinal	Bronchopulmonary dysplasia	Bronchopulmonary dysplasia	20JUL2016	*	Mild	NotRelated	Continuing
	08028	No	Respiratory, thoracic and mediastinal	Pulmonary interstitial emphysema syndrome	Pulmonary Interstitial	09JUN2016	13JUN2016	Moderate	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	08028	No	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	Respiratory distress syndrome	28MAY2016	20JUL2016	Moderate	NotRelated	Worsened
	08028	No	Congenital, familial and genetic disorders	Patent ductus arteriosus	patent ductus arteriosus	31MAY2016	10JUN2016	Moderate	NotRelated	Recovered
	08037	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea	24AUG2016	24AUG2016	Moderate	NotRelated	Recovered
	08037	No	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	Hyperbilirubinemia	25AUG2016	31AUG2016	Mild	NotRelated	Recovered
	08037	No	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	Worsening respiratory status	24AUG2016	25AUG2016	Moderate	NotRelated	Recovered
	08037	No	Pregnancy, puerperium and perinatal conditions	Retinopathy of prematurity	retinopathy of prematurity right eye	12OCT2016	*	Mild	NotRelated	Continuing
	08037	No	Congenital, familial and genetic disorders	Cardiac septal defect	small secundum type atrial septal defect	21OCT2016	*	Mild	NotRelated	Continuing
	08037	No	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	worsening RDS	25AUG2016	28AUG2016	Moderate	NotRelated	Recovered
	11005	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea of Prematurity	10JUN2016	31JUL2016	Mild	NotRelated	Recovered
	11005	No	Pregnancy, puerperium and perinatal conditions	Retinopathy of prematurity	Retinopathy of Prematurity	12JUL2016	09AUG2016	Mild	NotRelated	Recovered
	11005	No	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	worsening respiratory distress	06JUN2016	08JUN2016	Severe	NotRelated	Recovered
	11006	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea of Prematurity	10JUN2016	01AUG2016	Mild	NotRelated	Recovered
	11006	No	Pregnancy, puerperium and perinatal conditions	Retinopathy of prematurity	Retinopathy of Prematurity	19JUL2016	*	Mild	NotRelated	Improved

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	11006	Yes	Respiratory, thoracic and mediastinal	Pneumothorax	pneumothorax	07JUN2016	07JUN2016	Severe	NotRelated	Recovered
	11006	No	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	worsening respiratory distress	06JUN2016	10JUN2016	Severe	NotRelated	Recovered
	12004	No	Investigations	Cardiac murmur	2/6 systolic murmur LSB	10MAR2016	*	Mild	NotRelated	Continuing
	12004	No	Blood and lymphatic system disorders	Anaemia neonatal	Anemia of Prematurity	06MAR2016	30APR2016	Moderate	NotRelated	Recovered
	12004	No	Hepatobiliary disorders	Gallbladder disorder	Enlarged gallbladder	10MAR2016	11APR2016	Mild	NotRelated	Recovered
	12004	No	Metabolism and nutrition disorders	Hyperchloraemia	Hyperchloremia	16MAR2016	16MAR2016	Mild	NotRelated	Recovered
	12004	No	Vascular disorders	Hypertension	Hypertension	10MAR2016	10MAR2016	Mild	NotRelated	Recovered
	12004	No	Metabolism and nutrition disorders	Hypochloraemia	Hypochloremia	12MAR2016	16MAR2016	Mild	NotRelated	Recovered
	12004	No	Metabolism and nutrition disorders	Hyponatraemia	Hyponatremia	12MAR2016	15MAR2016	Mild	NotRelated	Recovered
	12004	No	Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Intermittent Bradycardia	29FEB2016	04APR2016	Moderate	NotRelated	Recovered
	12004	No	Respiratory, thoracic and mediastinal	Neonatal tachypnoea	Intermittent Tachycardia	06MAR2016	28MAR2016	Moderate	NotRelated	Recovered
	12004	No	Respiratory, thoracic and mediastinal	Neonatal tachypnoea	Intermittent Tachypnea	29FEB2016	30MAR2016	Mild	NotRelated	Recovered
	12004	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Intermittent apnea	29FEB2016	*	Mild	NotRelated	Continuing

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE	SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	12004	No	Metabolism and nutrition disorders	Hypoglycaemia	Intermittent hypoglycemia	29FEB2016	25MAR2016	Mild	NotRelated	Recovered
	12004	No	Metabolism and nutrition disorders	Metabolic acidosis	Metabolic acidosis	01MAR2016	17MAR2016	Mild	NotRelated	Recovered
	12004	No	Respiratory, thoracic and mediastinal	Nasal discomfort	small erythematous lesion left nares	08MAR2016	29MAR2016	Mild	NotRelated	Recovered
	12006	No	Blood and lymphatic system disorders	Anaemia neonatal	Anemia	03MAR2016	*	Mild	NotRelated	Continuing
	12006	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea of prematurity	05MAR2016	*	Mild	NotRelated	Continuing
	12006	Yes	Cardiac disorders	Cardiac arrest	Cardiac Arrest	03MAR2016	03MAR2016	Severe	NotRelated	Recovered
	12006	No	Respiratory, thoracic and mediastinal	Bronchopulmonary dysplasia	Chronic lung disease	30MAR2016	*	Moderate	NotRelated	Improved
	12006	Yes	Gastrointestinal disorders	Gastric perforation	Gastric perforation	03MAR2016	30MAR2016	Severe	NotRelated	Recovered
	12006	No	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	Hyperbilirubinemia	03MAR2016	08MAR2016	Mild	NotRelated	Recovered
	12006	No	Metabolism and nutrition disorders	Hyperglycaemia	Hyperglycemia	03MAR2016	04MAR2016	Mild	NotRelated	Recovered
	12006	No	Metabolism and nutrition disorders	Hypokalaemia	Hypokalemia	27APR2016	02MAY2016	Mild	NotRelated	Recovered
	12006	No	Vascular disorders	Hypotension	Hypotension	03MAR2016	30MAR2016	Moderate	NotRelated	Recovered
	12006	Yes	Respiratory, thoracic and mediastinal	Neonatal respiratory failure	Hypoxic respiratory failure	03MAR2016	23MAR2016	Severe	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	12006	Yes	Injury, poisoning and procedural	Traumatic liver injury	Liver laceration	03MAR2016	08MAR2016	Severe	NotRelated	Recovered
	12006	No	Blood and lymphatic system disorders	Neutropenia	Neutropenia	04MAR2016	11MAR2016	Mild	NotRelated	Recovered
	12006	No	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	Respiratory Failure	03MAR2016	30MAR2016	Moderate	NotRelated	Recovered
	12006	No	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	Respiratory distress syndrome	01MAR2016	30MAR2016	Moderate	NotRelated	Recovered
	12006	No	Pregnancy, puerperium and perinatal conditions	Retinopathy of prematurity	Retinopathy of prematurity	30MAR2016	*	Mild	NotRelated	Continuing
	12006	No	Blood and lymphatic system disorders	Bandaemia	bandemia	26APR2016	04MAY2016	Mild	NotRelated	Recovered
	12006	No	Respiratory, thoracic and mediastinal	Bronchopulmonary dysplasia	bronchopulmonary dysplasia	04MAY2016	04MAY2016	Moderate	NotRelated	Recovered
	12006	Yes	Injury, poisoning and procedural	Hepatic haemorrhage	liver hemorrhage	03MAR2016	30MAR2016	Severe	NotRelated	Recovered
	12006	No	Metabolism and nutrition disorders	Metabolic acidosis	metabolic acidosis	03MAR2016	10MAR2016	Mild	NotRelated	Recovered
	12006	No	Metabolism and nutrition disorders	Osteopenia	osteopenia of prematurity	27APR2016	*	Mild	NotRelated	Continuing
	12006	No	Respiratory, thoracic and mediastinal	Pulmonary oedema neonatal	pulmonary edema	26APR2016	03MAY2016	Mild	NotRelated	Recovered
	12006	No	Blood and lymphatic system disorders	Thrombocytopenia	thrombocytopenia	26APR2016	27APR2016	Mild	NotRelated	Recovered
	12006	No	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	unconjugated hyperbilirubinemia	02MAR2016	08MAR2016	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE	SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	12010	No	Blood and lymphatic system disorders	Anaemia neonatal	Anemia	18MAR2016	*	Moderate	NotRelated	Continuing
	12010	Yes	Gastrointestinal disorders	Intestinal perforation	Bowel Perforation	24APR2016	16MAY2016	Severe	NotRelated	Recovered
	12010	No	Respiratory, thoracic and mediastinal	Bronchopulmonary dysplasia	Bronchopulmonary dysplasia	17APR2016	*	Moderate	NotRelated	Continuing
	12010	No	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	Hyperbilirubinemia	18MAR2016	29MAR2016	Mild	NotRelated	Recovered
	12010	No	Metabolism and nutrition disorders	Hypochloraemia	Hypochloremia	18MAR2016	05APR2016	Mild	NotRelated	Recovered
	12010	No	Metabolism and nutrition disorders	Hypokalaemia	Hypokalemia	05APR2016	24APR2016	Mild	NotRelated	Recovered
	12010	No	Metabolism and nutrition disorders	Hyponatraemia	Hyponatremia	18MAR2016	*	Mild	NotRelated	Continuing
	12010	No	Metabolism and nutrition disorders	Hypophosphataemia	Hypophosphatemia	30MAR2016	*	Mild	NotRelated	Continuing
	12010	No	Vascular disorders	Hypotension	Hypotension	19MAR2016	21MAR2016	Moderate	NotRelated	Recovered
	12010	No	Respiratory, thoracic and mediastinal	Neonatal respiratory failure	Hypoxic Respiratory Failure	07APR2016	*	Moderate	NotRelated	Continuing
	12010	No	Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Intermittent Bradycardia	17MAR2016	*	Moderate	NotRelated	Continuing
	12010	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Intermittent apnea (of prematurity)	17MAR2016	*	Moderate	NotRelated	Continuing
	12010	Yes	Injury, poisoning and procedural	Laryngeal injury	Laryngeal Trauma Due to Intubation	18MAR2016	29MAR2016	Severe	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE	SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	12010	No	Blood and lymphatic system disorders	Leukopenia	Leukopenia	18MAR2016	29MAR2016	Mild	NotRelated	Recovered
	12010	No	Renal and urinary disorders	Oliguria	Oliguria	19MAR2016	20MAR2016	Mild	NotRelated	Recovered
	12010	No	Respiratory, thoracic and mediastinal	Pulmonary oedema neonatal	Pulmonary Edema	19MAR2016	*	Moderate	NotRelated	Continuing
	12010	No	Infections and infestations	Sepsis neonatal	Sepsis	29MAR2016	*	Moderate	NotRelated	Continuing
	12010	No	Blood and lymphatic system disorders	Thrombocytopenia	Thrombocytopenia	23MAR2016	*	Moderate	NotRelated	Continuing
	12010	No	Hepatobiliary disorders	Cholestasis	cholestasis	29MAR2016	*	Mild	NotRelated	Continuing
	12010	No	Metabolism and nutrition disorders	Hypoalbuminaemia	hypoalbuminemia	18MAR2016	*	Mild	NotRelated	Continuing
	12037	No	Blood and lymphatic system disorders	Anaemia neonatal	Anemia of prematurity	06DEC2016	*	Mild	NotRelated	Continuing
	12037	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea of prematurity	30NOV2016	*	Mild	NotRelated	Continuing
	12037	No	Metabolism and nutrition disorders	Feeding intolerance	Feeding problem of newborn	03DEC2016	*	Mild	NotRelated	Continuing
	12037	No	Metabolism and nutrition disorders	Hyponatraemia	Hyponatremia	12DEC2016	14DEC2016	Mild	NotRelated	Recovered
	12037	No	Metabolism and nutrition disorders	Hyperchloraemia	hyperchloremia	01DEC2016	06DEC2016	Mild	NotRelated	Recovered
	12037	No	Metabolism and nutrition disorders	Hypernatraemia	hypernatremia	01DEC2016	06DEC2016	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	12037	No Respiratory, thoracic and mediastinal	Neonatal tachypnoea	intermittent tachypnea	15JAN2017	*	Mild	NotRelated	Continuing
	12037	No Metabolism and nutrition disorders	Metabolic acidosis	metabolic acidosis	03DEC2016	*	Mild	NotRelated	Continuing
	12037	No General disorders and administration site	Oedema	mild labial edema	29DEC2016	*	Mild	NotRelated	Continuing
	12037	No Congenital, familial and genetic disorders	Patent ductus arteriosus	patent ductus arteriosus	02DEC2016	*	Mild	NotRelated	Continuing
	12037	No Infections and infestations	Sepsis neonatal	sepsis	01DEC2016	06DEC2016	Mild	NotRelated	Recovered
	13016	No Pregnancy, puerperium and perinatal conditions	Retinopathy of prematurity	ROP S2 Z2	27FEB2017	*	Moderate	NotRelated	Continuing
	13016	No Blood and lymphatic system disorders	Anaemia neonatal	anemia of prematurity	06MAR2017	27MAR2017	Mild	NotRelated	Recovered
	13016	No Respiratory, thoracic and mediastinal	Bronchopulmonary dysplasia	developing chronic lung disease	26JAN2017	*	Mild	NotRelated	Continuing
	13016	No Investigations	Neutrophil count increased	elevated ANC	18JAN2017	01FEB2017	Mild	NotRelated	Recovered
	13016	No Investigations	Blood urea increased	elevated BUN	17JAN2017	03FEB2017	Mild	NotRelated	Recovered
	13016	No Respiratory, thoracic and mediastinal	Hypercapnia	elevated CO2	27FEB2017	09MAR2017	Mild	NotRelated	Recovered
	13016	No Respiratory, thoracic and mediastinal	Hypercapnia	elevated CO2	20MAR2017	27MAR2017	Mild	NotRelated	Recovered
	13016	No Respiratory, thoracic and mediastinal	Hypercapnia	elevated CO2	16MAR2017	17MAR2017	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	13016	No	Blood and lymphatic system disorders	Leukocytosis	elevated WBC	18JAN2017	19JAN2017	Mild	NotRelated	Recovered
	13016	No	Metabolism and nutrition disorders	Hyperchloraemia	elevated chloride	17JAN2017	18JAN2017	Mild	NotRelated	Recovered
	13016	No	Blood and lymphatic system disorders	Thrombocytosis	elevated platelets	01FEB2017	13FEB2017	Mild	NotRelated	Recovered
	13016	No	Investigations	Reticulocyte count increased	elevated retic count	06MAR2017	27MAR2017	Mild	NotRelated	Recovered
	13016	No	Metabolism and nutrition disorders	Hypertriglyceridaemia	elevated triglycerides	20JAN2017	22JAN2017	Mild	NotRelated	Recovered
	13016	No	Infections and infestations	Urinary tract infection enterococcal	enterococcus faecalis,	14MAR2017	29MAR2017	Mild	NotRelated	Recovered
	13016	No	Infections and infestations	Enterococcal sepsis	entrobacter cloacae, klebsiella	14MAR2017	29MAR2017	Mild	NotRelated	Recovered
	13016	No	General disorders and administration site	Pyrexia	fever	26JAN2017	28JAN2017	Mild	NotRelated	Recovered
	13016	No	Investigations	PO2 increased	high PaO2	02FEB2017	08FEB2017	Mild	NotRelated	Recovered
	13016	No	Metabolism and nutrition disorders	Hypercalcaemia	hpyercalcemia	21JAN2017	22JAN2017	Mild	NotRelated	Recovered
	13016	No	Metabolism and nutrition disorders	Hyperglycaemia	hyperglycemia	03FEB2017	04FEB2017	Mild	NotRelated	Recovered
	13016	No	Metabolism and nutrition disorders	Hypernatraemia	hypernatremia	17JAN2017	18JAN2017	Mild	NotRelated	Recovered
	13016	No	Metabolism and nutrition disorders	Hypernatraemia	hypernatremia	18JAN2017	19JAN2017	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	13016	No Metabolism and nutrition disorders	Hypoglycaemia	hypoglycemia	17JAN2017	17JAN2017	Mild	NotRelated	Recovered
	13016	No Gastrointestinal disorders	Abdominal distension	intermittent abdominal distention	18JAN2017	09MAR2017	Mild	NotRelated	Recovered
	13016	No Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	intermittent bradycardia	17JAN2017	*	Mild	NotRelated	Continuing
	13016	No Gastrointestinal disorders	Constipation	intermittent constipation	28JAN2017	16MAR2017	Mild	NotRelated	Recovered
	13016	No Investigations	Oxygen saturation decreased	intermittent desaturation	17JAN2017	*	Mild	NotRelated	Continuing
	13016	No Metabolism and nutrition disorders	Hypochloraemia	low chloride	27FEB2017	09MAR2017	Mild	NotRelated	Recovered
	13016	No Metabolism and nutrition disorders	Hypochloraemia	low chloride	20MAR2017	23MAR2017	Mild	NotRelated	Recovered
	13016	No Metabolism and nutrition disorders	Hypokalaemia	low potassium	27FEB2017	28FEB2017	Mild	NotRelated	Recovered
	13016	No Metabolism and nutrition disorders	Hypokalaemia	low potassium	03FEB2017	04FEB2017	Mild	NotRelated	Recovered
	13016	No General disorders and administration site	Hypothermia	low temperature	14MAR2017	18MAR2017	Mild	NotRelated	Recovered
	13016	No Gastrointestinal disorders	Inguinal hernia	right inguinal hernia	14MAR2017	*	Mild	NotRelated	Continuing
	13016	No Infections and infestations	Bacteraemia	staphylococcus epidermidis sepsis	02FEB2017	09FEB2017	Moderate	NotRelated	Recovered
	19004	No Endocrine disorders	Adrenal insufficiency	Adrenal Insufficiency	22NOV2016	*	Moderate	NotRelated	Continuing

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	19004	No Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea of prematurity	27SEP2016	*	Mild	NotRelated	Continuing
	19004	No Respiratory, thoracic and mediastinal	Bronchopulmonary dysplasia	Bronchopulmonary dysplasia	28NOV2016	*	Severe	NotRelated	Continuing
	19004	No Pregnancy, puerperium and perinatal conditions	Intraventricular haemorrhage neonatal	Grade 1 IVH (Germinal Matrix	07OCT2016	*	Mild	NotRelated	Continuing
	19004	No Congenital, familial and genetic disorders	Hydrocele	Hydrocele, left	31OCT2016	*	Mild	NotRelated	Continuing
	19004	No Metabolism and nutrition disorders	Hypocalcaemia	Hypocalcemia	21OCT2016	*	Mild	NotRelated	Continuing
	19004	No Metabolism and nutrition disorders	Hypomagnesaemia	Hypomagnesemia	22OCT2016	25NOV2016	Mild	NotRelated	Recovered
	19004	No Metabolism and nutrition disorders	Hyponatraemia	Hyponatremia	17OCT2016	31OCT2016	Mild	NotRelated	Recovered
	19004	No Hepatobiliary disorders	Cholestasis	Intrahepatic Cholestasis	22NOV2016	*	Severe	NotRelated	Continuing
	19004	Yes Pregnancy, puerperium and perinatal conditions	Necrotising enterocolitis neonatal	Necrotizing Enterocolitis	01NOV2016	*	Severe	NotRelated	Continuing
	19004	No Pregnancy, puerperium and perinatal conditions	Necrotising enterocolitis neonatal	Necrotizing Enterocolitis	31OCT2016	01NOV2016	Severe	NotRelated	Worsened
	19004	No Metabolism and nutrition disorders	Hypoglycaemia	Neonatal hypoglycemia	01NOV2016	02NOV2016	Mild	NotRelated	Recovered
	19004	No Metabolism and nutrition disorders	Osteopenia	Osteopenia of Prematurity	17OCT2016	*	Mild	NotRelated	Continuing
	19004	No Nervous system disorders	Periventricular leukomalacia	Periventricular leukomalacia	28NOV2016	*	Severe	NotRelated	Continuing

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	19004	No	Infections and infestations	Pneumonia klebsiella	Pneumonia due to Klebsiella	22NOV2016	*	Moderate	NotRelated	Continuing
	19004	No	Infections and infestations	Pneumonia	Pneumonia due to proteus mirabilis	22NOV2016	*	Moderate	NotRelated	Continuing
	19004	No	Infections and infestations	Pneumonia staphylococcal	Pneumonia due to staphylococcus	22NOV2016	*	Moderate	NotRelated	Continuing
	19004	No	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	RDS requiring surfactant therapy	28SEP2016	28SEP2016	Mild	NotRelated	Recovered
	19004	No	Skin and subcutaneous tissue disorders	Rash	Rash to groin and behind ears	02OCT2016	03OCT2016	Mild	NotRelated	Recovered
	19004	No	Renal and urinary disorders	Renal failure	Renal insufficiency	01NOV2016	*	Moderate	NotRelated	Continuing
	19004	No	Renal and urinary disorders	Oliguria	Renal insufficiency: decreased UOP	03OCT2016	06OCT2016	Mild	NotRelated	Recovered
	19004	No	Pregnancy, puerperium and perinatal conditions	Retinopathy of prematurity	Retinopathy of prematurity	23NOV2016	*	Mild	NotRelated	Continuing
	19004	No	Blood and lymphatic system disorders	Thrombocytopenia	Thrombocytopenia	01NOV2016	28NOV2016	Moderate	NotRelated	Recovered
	19004	No	Blood and lymphatic system disorders	Anaemia neonatal	anemia of prematurity	02OCT2016	*	Mild	NotRelated	Continuing
	19004	No	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	hyperbilirubinemia	29SEP2016	02OCT2016	Mild	NotRelated	Recovered
	19004	No	Metabolism and nutrition disorders	Hypoalbuminaemia	hypoalbuminemia	31OCT2016	22NOV2016	Mild	NotRelated	Recovered
	19004	No	Congenital, familial and genetic disorders	Patent ductus arteriosus	patent ductus arteriosus	01OCT2016	*	Moderate	NotRelated	Continuing

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	19004	Yes	Cardiac disorders	Cardio-respiratory arrest	severe Bradycardia	31OCT2016	31OCT2016	Severe	NotRelated	Recovered
	40004	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Intermittent Apnea	19JUL2016	03AUG2016	Mild	NotRelated	Recovered
	40004	No	Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Intermittent Bradycardia	18JUL2016	03AUG2016	Mild	NotRelated	Recovered
	40004	No	Investigations	Oxygen saturation decreased	Intermittent Desaturations	18JUL2016	02AUG2016	Mild	NotRelated	Recovered
	40004	No	Respiratory, thoracic and mediastinal	Nasal inflammation	Nasal Irritation	19JUL2016	19JUL2016	Mild	NotRelated	Recovered
	40009	No	Infections and infestations	Sepsis neonatal	Ecoli sepsis (presented as	02OCT2016	15OCT2016	Moderate	NotRelated	Recovered
	40009	No	Investigations	Oxygen saturation decreased	Inadequate oxygen saturation	25SEP2016	11OCT2016	Mild	NotRelated	Recovered
	40009	No	General disorders and administration site	Endotracheal intubation complication	Inadvertent extubation	26SEP2016	26SEP2016	Mild	NotRelated	Recovered
	40009	No	Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Intermittent Bradycardia	26SEP2016	08NOV2016	Mild	NotRelated	Recovered
	40009	No	Investigations	Oxygen saturation decreased	Intermittent Desaturation	25SEP2016	08NOV2016	Mild	NotRelated	Recovered
	40009	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Intermittent apnea	26SEP2016	08NOV2016	Mild	NotRelated	Recovered
	40009	No	Metabolism and nutrition disorders	Hyponatraemia	hyponatremia	02OCT2016	06OCT2016	Mild	NotRelated	Recovered
	40009	No	Injury, poisoning and procedural	Infusion site extravasation	peripheral IV infiltration	07OCT2016	07OCT2016	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	40013	No	Hepatobiliary disorders	Cholestasis	Cholestasis (increased direct	05NOV2016	*	Mild	NotRelated	Continuing
	40013	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Intermittent Apnea	02NOV2016	03NOV2016	Mild	NotRelated	Recovered
	40013	No	Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Intermittent Bradycardia	31OCT2016	07NOV2016	Mild	NotRelated	Recovered
	40013	No	Investigations	Oxygen saturation decreased	Intermittent Desaturation	30OCT2016	04NOV2016	Mild	NotRelated	Recovered
	40019	No	Respiratory, thoracic and mediastinal	Pneumothorax	Bilateral pneumothoraces	16MAY2017	20MAY2017	Mild	NotRelated	Recovered
	40019	No	Investigations	Oxygen saturation decreased	Failure to maintain oxygen saturation	16MAY2017	20MAY2017	Mild	NotRelated	Recovered
	40019	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Intermittent Apnea	21MAY2017	*	Mild	NotRelated	Continuing
	40019	No	Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Intermittent Bradycardia	21MAY2017	*	Mild	NotRelated	Continuing
	40019	No	Investigations	Oxygen saturation decreased	Intermittent Desaturations	16MAY2017	*	Mild	NotRelated	Continuing
	40019	No	Respiratory, thoracic and mediastinal	Pulmonary interstitial emphysema syndrome	Pulmonary Interstitial	16MAY2017	22MAY2017	Mild	NotRelated	Recovered
	40019	No	Gastrointestinal disorders	Vomiting	Vomiting bilious aspirates	21MAY2017	24MAY2017	Mild	NotRelated	Recovered
	41002	No	Blood and lymphatic system disorders	Anaemia neonatal	Anemia	18DEC2016	*	Mild	NotRelated	Continuing
	41002	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea of prematurity	30NOV2016	*	Mild	NotRelated	Continuing

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	41002	No Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	Hyperbilirubinemia	28NOV2016	01DEC2016	Mild	NotRelated	Recovered
	41002	No Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Intermittent bradycardia	30NOV2016	*	Mild	NotRelated	Continuing
	41002	No Investigations	Oxygen saturation decreased	Intermittent desaturations	29NOV2016	*	Mild	NotRelated	Continuing
	41002	No Congenital, familial and genetic disorders	Patent ductus arteriosus	Small patent ductus arteriosus	29NOV2016	01DEC2016	Mild	NotRelated	Recovered
	41005	No Infections and infestations	Sepsis neonatal	Acquired sepsis	22JAN2017	05FEB2017	Mild	NotRelated	Recovered
	41005	No Blood and lymphatic system disorders	Anaemia neonatal	Anemia	06FEB2017	*	Mild	NotRelated	Continuing
	41005	No Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea of prematurity	15JAN2017	*	Mild	NotRelated	Continuing
	41005	No Infections and infestations	Fungal skin infection	Fungal yeast infection behind left	19FEB2017	*	Mild	NotRelated	Continuing
	41005	No Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	Hyperbilirubinemia	15JAN2017	19JAN2017	Mild	NotRelated	Recovered
	41005	No Metabolism and nutrition disorders	Hypernatraemia	Hypernatremia	15JAN2017	17JAN2017	Mild	NotRelated	Recovered
	41005	No Metabolism and nutrition disorders	Hyponatraemia	Hyponatremia	03FEB2017	*	Mild	NotRelated	Continuing
	41005	No Pregnancy, puerperium and perinatal conditions	Bradycardia neonatal	Intermittent bradycardia	15JAN2017	*	Mild	NotRelated	Continuing
	41005	No Respiratory, thoracic and mediastinal	Nasal inflammation	Nasal Irritation and bruising	14JAN2017	18JAN2017	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	41005	No	Congenital, familial and genetic disorders	Patent ductus arteriosus	Small PDA	07FEB2017	12FEB2017	Mild	NotRelated	Recovered
	41005	No	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	Worsening respiratory status >7	03FEB2017	06FEB2017	Mild	NotRelated	Recovered
	42001	No	Cardiac disorders	Arrhythmia	Arrhythmia	05JUN2016	14JUN2016	Mild	NotRelated	Recovered
	42001	No	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	Early worsening respiratory status	30MAY2016	31MAY2016	Mild	NotRelated	Recovered
	42001	No	Injury, poisoning and procedural	Skin abrasion	Skin abrasion on bridge of nose	01JUN2016	05JUN2016	Mild	NotRelated	Recovered
	42004	No	Respiratory, thoracic and mediastinal	Bronchopulmonary dysplasia	BPD	14OCT2016	*	Mild	NotRelated	Continuing
	42004	No	Investigations	Oxygen saturation decreased	Desaturation	03OCT2016	03OCT2016	Mild	NotRelated	Recovered
	42004	No	Vascular disorders	Hypotension	Hypotension	15AUG2016	18AUG2016	Moderate	NotRelated	Recovered
	42004	No	Metabolism and nutrition disorders	Metabolic acidosis	Metabolic acidosis	16AUG2016	18AUG2016	Moderate	NotRelated	Recovered
	42004	No	Congenital, familial and genetic disorders	Patent ductus arteriosus	Patent Ductus Arteriosus	17AUG2016	*	Moderate	NotRelated	Improved
	42004	No	Respiratory, thoracic and mediastinal	Pulmonary haemorrhage	pulmonary hemorrhage	17AUG2016	27AUG2016	Moderate	NotRelated	Recovered
	54001	No	Congenital, familial and genetic disorders	Patent ductus arteriosus	Patent ductus arteriosus	29JUL2016	03SEP2016	Moderate	NotRelated	Recovered
	54001	No	Pregnancy, puerperium and perinatal conditions	Periventricular haemorrhage neonatal	Periventricular haemorrhage stage	29JUL2016	*	Mild	NotRelated	Continuing

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	54001	No Gastrointestinal disorders	Abdominal pain	abdomen pain	25JUL2016	26JUL2016	Mild	NotRelated	Recovered
	54001	No Blood and lymphatic system disorders	Anaemia neonatal	anaemia	10AUG2016	*	Mild	NotRelated	Continuing
	54001	No Respiratory, thoracic and mediastinal	Apnoea neonatal	apnea	09AUG2016	09AUG2016	Mild	NotRelated	Recovered
	54001	No Respiratory, thoracic and mediastinal	Apnoea neonatal	apnea	07AUG2016	07AUG2016	Mild	NotRelated	Recovered
	54001	No Investigations	Oxygen saturation decreased	desaturation spO2	03AUG2016	03AUG2016	Mild	NotRelated	Recovered
	54001	No Vascular disorders	Haemangioma	haemangioma on the back skin	10SEP2016	*	Mild	NotRelated	Continuing
	54001	No Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	hyperbilirubinemia	24JUL2016	28JUL2016	Moderate	NotRelated	Recovered
	54001	No Skin and subcutaneous tissue disorders	Rash	rash on the skin on neck and face	10SEP2016	12SEP2016	Mild	NotRelated	Recovered
	54001	No Pregnancy, puerperium and perinatal conditions	Retinopathy of prematurity	retinopathy of prematurity I degree	05SEP2016	19SEP2016	Mild	NotRelated	Recovered
	54002	No Pregnancy, puerperium and perinatal conditions	Intraventricular haemorrhage neonatal	Intraventricular haemorrhage stage	05SEP2016	*	Mild	NotRelated	Continuing
	54002	No Blood and lymphatic system disorders	Anaemia neonatal	anaemia	16SEP2016	*	Mild	NotRelated	Continuing
	54002	No Respiratory, thoracic and mediastinal	Apnoea neonatal	apneas	04SEP2016	04SEP2016	Mild	NotRelated	Recovered
	54002	No Investigations	Oxygen saturation decreased	desaturations	03SEP2016	*	Mild	NotRelated	Improved

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	54002	No	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	hyperbilirubinemia	03SEP2016	10SEP2016	Moderate	NotRelated	Recovered
	54002	No	Infections and infestations	Pneumonia	pneumonia	18OCT2016	25OCT2016	Moderate	NotRelated	Recovered
	54002	No	Pregnancy, puerperium and perinatal conditions	Retinopathy of prematurity	retinopathy of prematurity	03OCT2016	*	Moderate	NotRelated	Continuing
	54017	Yes	Blood and lymphatic system disorders	Anaemia neonatal	anaemia	13DEC2016	*	Moderate	NotRelated	Continuing
	54017	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	apneas	15DEC2016	17DEC2016	Mild	NotRelated	Recovered
	54017	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	apneas	27NOV2016	04DEC2016	Mild	NotRelated	Recovered
	54017	Yes	Respiratory, thoracic and mediastinal	Apnoea neonatal	apneas	07DEC2016	10DEC2016	Moderate	NotRelated	Recovered
	54017	No	Infections and infestations	Conjunctivitis	conjunctivitis	01DEC2016	14DEC2016	Mild	NotRelated	Recovered
	54017	No	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	hyperbilirubinemia	26NOV2016	27NOV2016	Mild	NotRelated	Recovered
	54017	No	Congenital, familial and genetic disorders	Patent ductus arteriosus	patent ductus arteriosus	28NOV2016	05DEC2016	Moderate	NotRelated	*
	54017	Yes	Infections and infestations	Pneumonia	pneumoniae	12DEC2016	22DEC2016	Moderate	NotRelated	Recovered
	54017	No	Metabolism and nutrition disorders	Fluid retention	retention of water	17JAN2017	*	Mild	NotRelated	Continuing
	54017	No	Pregnancy, puerperium and perinatal conditions	Retinopathy of prematurity	retinopathy of prematurity	09JAN2017	*	Mild	NotRelated	Continuing

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome	
	54017	Yes	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	worsening respiratory effort	26NOV2016	26NOV2016	Severe	NotRelated	Recovered
	76002	No	Blood and lymphatic system disorders	Anaemia neonatal	Anemia	24JAN2017	24JAN2017	Mild	NotRelated	Recovered
	76002	No	Respiratory, thoracic and mediastinal	Apnoea neonatal	Apnea	25FEB2017	25FEB2017	Mild	NotRelated	Recovered
	76002	No	Respiratory, thoracic and mediastinal	Bronchopulmonary dysplasia	Bronchopulmonary dysplasia	17JAN2017	*	Moderate	NotRelated	Continuing
	76002	No	Blood and lymphatic system disorders	Coagulopathy	Coagulation disorder	21DEC2016	21DEC2016	Moderate	NotRelated	Recovered
	76002	No	Respiratory, thoracic and mediastinal	Respiratory acidosis	Compensated respiratory acidosis	20JAN2017	22JAN2017	Mild	NotRelated	Recovered
	76002	No	Respiratory, thoracic and mediastinal	Respiratory acidosis	Compensated respiratory acidosis	18JAN2017	19JAN2017	Moderate	NotRelated	Recovered
	76002	No	Nervous system disorders	Seizure	Convulsive Syndrome	22DEC2016	30DEC2016	Moderate	NotRelated	Recovered
	76002	No	Nervous system disorders	Seizure	Convulsive syndrome	06JAN2017	08JAN2017	Mild	NotRelated	Recovered
	76002	No	Renal and urinary disorders	Azotaemia	Hyperazoemia	03JAN2017	17JAN2017	Mild	NotRelated	Recovered
	76002	No	Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	Hyperbilirubin	21DEC2016	23DEC2016	Mild	NotRelated	Recovered
	76002	No	Metabolism and nutrition disorders	Hyperglycaemia	Hyperglycemia	24DEC2016	25DEC2016	Mild	NotRelated	Recovered
	76002	No	Metabolism and nutrition disorders	Hyperglycaemia	Hyperglycemia	21DEC2016	22DEC2016	Mild	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE	SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	76002	No	Metabolism and nutrition disorders	Hyperglycaemia	Hyperglycemia	30DEC2016	01JAN2017	Moderate	NotRelated	Recovered
	76002	No	Metabolism and nutrition disorders	Hyperkalaemia	Hyperkalemia	21DEC2016	23DEC2016	Mild	NotRelated	Recovered
	76002	No	Metabolism and nutrition disorders	Hypernatraemia	Hyponatremia	02JAN2017	04JAN2017	Mild	NotRelated	Recovered
	76002	No	Metabolism and nutrition disorders	Hypertriglyceridaemia	Hypertriglyceridemia	24DEC2016	26DEC2016	Mild	NotRelated	Recovered
	76002	No	Metabolism and nutrition disorders	Hypertriglyceridaemia	Hypertriglyceridemia	31DEC2016	10JAN2017	Mild	NotRelated	Recovered
	76002	No	Metabolism and nutrition disorders	Hypoalbuminaemia	Hypoalbuminemia	22DEC2016	12JAN2017	Mild	NotRelated	Recovered
	76002	No	Metabolism and nutrition disorders	Hypocalcaemia	Hypocalcemia	21DEC2016	21DEC2016	Mild	NotRelated	Recovered
	76002	No	Metabolism and nutrition disorders	Hyponatraemia	Hyponatremia	28DEC2016	01JAN2017	Moderate	NotRelated	Recovered
	76002	No	Vascular disorders	Hypotension	Hypotension	06JAN2017	06JAN2017	Mild	NotRelated	Recovered
	76002	No	Vascular disorders	Hypotension	Hypotension	22DEC2016	26DEC2016	Moderate	NotRelated	Recovered
	76002	No	Vascular disorders	Hypotension	Hypotension	05JAN2017	05JAN2017	Moderate	NotRelated	Recovered
	76002	No	Vascular disorders	Hypotension	Hypotension	09JAN2017	10JAN2017	Moderate	NotRelated	Recovered
	76002	No	Investigations	Anticonvulsant drug level above therapeut	Increased levels of phenobarbital	27DEC2016	01FEB2017	Moderate	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	76002	No Blood and lymphatic system disorders	Leukopenia	Leukopenia	23DEC2016	30DEC2016	Mild	NotRelated	Recovered
	76002	No Congenital, familial and genetic disorders	Patent ductus arteriosus	Patent ductus arteriosus	23DEC2016	30DEC2016	Mild	NotRelated	Recovered
	76002	No Respiratory, thoracic and mediastinal	Pulmonary interstitial emphysema syndrome	Pulmonar Interstitial emphysema	28DEC2016	01JAN2017	Moderate	NotRelated	Recovered
	76002	No Respiratory, thoracic and mediastinal	Pulmonary hypertension	Pulmonary Hypertension	21DEC2016	24DEC2016	Moderate	NotRelated	Recovered
	76002	No Renal and urinary disorders	Renal failure	Renal insufficiency	08JAN2017	12JAN2017	Moderate	NotRelated	Recovered
	76002	No Respiratory, thoracic and mediastinal	Respiratory alkalosis	Respiratory alkalosis	10JAN2017	10JAN2017	Moderate	NotRelated	Recovered
	76002	No Respiratory, thoracic and mediastinal	Respiratory alkalosis	Respiratory alkalosis	17JAN2017	18JAN2017	Moderate	NotRelated	Recovered
	76002	No Blood and lymphatic system disorders	Thrombocytopenia	Thrombocytopenia	22DEC2016	26DEC2016	Mild	NotRelated	Recovered
	76002	No Infections and infestations	Urinary tract infection	Urinary tract infection by candida	09JAN2017	26JAN2017	Moderate	NotRelated	Recovered
	76002	No Blood and lymphatic system disorders	Anaemia neonatal	aenemia	21DEC2016	24DEC2016	Moderate	NotRelated	Recovered
	76002	No Blood and lymphatic system disorders	Anaemia neonatal	aenemia	30DEC2016	01JAN2017	Moderate	NotRelated	Recovered
	76002	No Blood and lymphatic system disorders	Anaemia neonatal	anemia	09JAN2017	10JAN2017	Mild	NotRelated	Recovered
	76002	No Blood and lymphatic system disorders	Anaemia neonatal	anemia	12JAN2017	17JAN2017	Moderate	NotRelated	Recovered

Summary Listing 2.3
Any Adverse Events

Treatment	Subject ID	SAE SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	76002	No Infections and infestations	Pneumonia	bronchoneumonia by serratia and	22JAN2017	02FEB2017	Moderate	NotRelated	Recovered
	76002	No Renal and urinary disorders	Haematuria	hematuria	01JAN2017	02JAN2017	Mild	NotRelated	Recovered
	76002	Yes Pregnancy, puerperium and perinatal conditions	Intraventricular haemorrhage neonatal	intraventricular hemorrhage (IVH)	22DEC2016	*	Severe	NotRelated	Continuing
	76002	No Metabolism and nutrition disorders	Metabolic acidosis	metabolic acidosis	31DEC2016	01JAN2017	Moderate	NotRelated	Recovered
	76002	Yes Respiratory, thoracic and mediastinal	Pneumothorax	pneumothorax	21DEC2016	21DEC2016	Severe	NotRelated	Recovered
	76002	Yes Vascular disorders	Shock	refractory shock	30DEC2016	03JAN2017	Severe	NotRelated	Recovered
	76002	No Renal and urinary disorders	Renal failure	renal insufficiency	24DEC2016	28DEC2016	Mild	NotRelated	Recovered
	76002	No Infections and infestations	Urinary tract infection	urinary tract infection by serratia	22JAN2017	02FEB2017	Moderate	NotRelated	Recovered

Summary Listing 5.1
Respiratory Support - Mechanical Ventilation Information by subject

Treatment Group	Subject ID	On MV?	Start Date	Start Time	End Date	End Time	Reason	RS Mode	Other Mode	MAP	Resp Rate	FiO ₂	
50 mg/kg	01032	No	04FEB2016	19:25:00	06FEB2016	1:52:00	Need for high FiO2	SIMV		6	15	0.26	
	01033	No	05FEB2016	13:15:00	10FEB2016	11:05:00	need for higher fio2 and support	SIMV			35	0.50	
	01040	No	13JUN2016	23:45:00	21JUN2016	10:25:00	respiratory distress	SIMV		8	25	0.59	
	01041	No	14JUN2016	1:02:00	21JUN2016	12:20:00	Respiratory distress	SIMV				20	0.40
	09001	No	21MAY2016	19:45:00	01JUN2016	23:00:00	Reason unknown.	SIMV		8	40		
	12014	No	29APR2016	15:37:00	09MAY2016	19:59:00	respiratory failure	SIMV		13	62	0.23	
	12014	No	05JUN2016	17:45:00	06JUN2016	0:52:00	respiratory failure	SIMV		11	35	0.40	
	40001	No	07MAY2016	13:12:00	07MAY2016	14:30:00	Baby had spontaneous intestinal perforation.	Volume Ventilation (including volume guarantee)		7			0.25
75 mg/kg	01042	No	12AUG2016	11:25:00	14AUG2016	14:55:00	increasing respiratory distress	SIMV		8	20	0.25	
	11011	No	04SEP2016	21:25:00	06SEP2016	3:56:00	intubation for placement of abdominal drain	SIMV		7	79	0.40	
	11011	No	08SEP2016	10:22:00	01SEP2016	14:02:00	worsening respiratory status	SIMV		11	52	0.25	
	12023	No	10OCT2016	16:15:00	12OCT2016	19:59:00	intubated due PDA closer	SIMV		11	47	0.40	
	12023	No	22OCT2016	1:10:00	07NOV2016	15:19:00	worsening hypercarbia	SIMV		10	30	0.44	
	40003	No	08JUL2016	7:00:00	21JUL2016	12:22:00	Worsening Respiratory Status	HFV		12		0.63	
	40006	No	24AUG2016	19:00:00	25AUG2016	6:35:00	Surfactant Administration	AC		7	20	0.30	
	40006	No	07SEP2016	13:10:00	11SEP2016	12:20:00	Intubated for culture negative septic episode	HFV		8		0.57	
	50001	No	28SEP2016	20:41:00	03OCT2016	23:25:00	excessive respiratory effort	SIMV		8	40	0.50	
	50001	No	13OCT2016	7:50:00	15OCT2016	11:15:00	respiratory insufficiency	SIMV				40	0.60
	51004	No	26JUL2016	20:20:00	07AUG2016	20:20:00	improvement of respiratory efficiency	SIMV		8	40	0.50	
	51004	No	08AUG2016	9:10:00	11AUG2016	16:45:00	respiratory failure	SIMV		9	35	0.30	
100 mg/kg	11021	No	05NOV2016	18:45:00	11NOV2016	13:00:00	escalating fio2 requirements	SIMV		11	47	0.60	
	11023	No	29NOV2016	19:05:00	01DEC2016	19:59:00	worsening respiratory status	SIMV		10	92	0.35	

Summary Listing 5.1
Respiratory Support - Mechanical Ventilation Information by subject

Treatment Group	Subject ID	On MV?	Start Date	Start Time	End Date	End Time	Reason	RS Mode	Other Mode	MAP	Resp Rate	FiO ₂
	19007	No	20DEC2016	8:39:00	21DEC2016	17:40:00	intubated for curosurf administration and started on mechanical ventilation	SIMV		6.	72	0.50
	40014	No	09DEC2016	0:24:00	15DEC2016	13:45:00	Increased respiratory failure	HFV		8		0.30
	40015	No	04JAN2017	6:40:00	05JAN2017	15:10:00	Respiratory Failure	HFV		10		0.40
	40015	No	05JAN2017	22:49:00	13JAN2017	14:20:00	Intubated for respiratory failure	Volume Ventilation (including volume guarantee)		12		0.28
	42010	No	08DEC2016	8:07:00	20DEC2016	10:59:00	Intubated for surfactant administration	Volume Ventilation (including volume guarantee)		10		0.21
	42010	No	08DEC2016	18:50:00	04FEB2017	11:50:00	Reintubated for apneas	Volume Ventilation (including volume guarantee)		8		0.21
nCPAP Only	08028	No	28MAY2016	16:00:00	27MAY2016	23:39:00	Required mechanical intubation for increased work of breathing and FiO ₂ . 2nd dose of surfactant administered as well.	Other	volume targeted SIMV	10	35	0.21
	08037	No	25AUG2016	10:38:00	28AUG2016	10:18:00	escalation of care	SIMV		11	40	0.55
	11005	No	06JUN2016	19:00:00	08JUN2016	10:40:00	increasing fiO ₂ requirements	SIMV		8.	33	1.00
	11006	No	06JUN2016	15:45:00	10JUN2016	11:40:00	worsening respiratory distress	SIMV		8.	51	0.50
	12006	No	03MAR2016	7:01:00	23MAR2016	8:45:00	hypoxic respiratory failure	HFV		8	28	
	12010	No	17MAR2016	13:48:00	20MAY2016	13:00:00	Acute respiratory failure	Other	NAVA		62	0.40
	19004	No	31OCT2016	9:45:00	28NOV2016	18:08:00	infant received fentanyl for intubation, had severe bradycardia, bag mask ventilation provided during code until infant could be intubated with ETT corresponds with AE NEC	SIMV		14	50	.99
	40009	No	25SEP2016	3:40:00	26SEP2016	15:54:00	Respiratory Failure	Volume Ventilation (including volume guarantee)		8		0.76

Summary Listing 5.1
Respiratory Support - Mechanical Ventilation Information by subject

Treatment Group	Subject ID	On MV?	Start Date	Start Time	End Date	End Time	Reason	RS Mode	Other Mode	MAP	Resp Rate	FiO ₂
	40009	No	26SEP2016	17:53:00	11OCT2016	16:00:00	Failed Extubation	HFV		9		0.67
	40019	No	16MAY2017	21:50:00	21MAY2017	0:00:00	Increasing oxygen requirement	Other	HFJV	11	39	0.48
	41002	No	27NOV2016	15:45:00	28NOV2016	12:45:00	Worsening respiratory status	Other	CMV	9	56	0.40
	41002	No	30NOV2016	12:30:00	02DEC2016	15:25:00	Increased oxygen requirement and work of breathing	AC		6	45	0.27
	41005	No	03FEB2017	13:20:00	06FEB2017	14:19:00	Worsening respiratory status, increased apneas.	Other	CMV	7	60	0.40
	42004	No	15AUG2016	21:50:00	05SEP2016	13:24:00	FiO ₂ = 0.80	Volume Ventilation (including volume guarantee)		8.		0.60
	54017	No	26NOV2016	10:00:00	26NOV2016	15:00:00	surfactant administration	Volume Ventilation (including volume guarantee)		12		0.21
	54017	No	10DEC2016	4:15:00	15DEC2016	12:00:00	apneas	Volume Ventilation (including volume guarantee)		14		0.30
	76002	No	21DEC2016	11:50:00	19JAN2017	23:54:00	respiratory failure	SIMV		8	40	0.75
	76002	No	19JAN2017	23:54:00	26JAN2017	12:30:00	respiratory failure	SIMV		7	40	0.35

Summary Listing 5.2
Respiratory Support - Supplemental Oxygen Information by subject

Treatment Group	Subject ID	On O ₂	Start Date	Start Time	End Date	End Time	Reason	RS Mode	Other Mode	FiO ₂
50 mg/kg	01032	No	14FEB2016	3:19:00	14FEB2016	23:25:00	increased oxygen requirements, maintain sats 88-95%	Nasal Cannula		0.25
	01032	No	18MAR2016	15:13:00	19MAR2016	7:35:00	maintain sats 88-95%	Nasal Cannula		0.25
	01033	No	10FEB2016	11:05:00	10FEB2016	12:22:00	on minimal settings on the vent, requires less support	Nasal Cannula		0.25
	01033	No	14FEB2016	3:21:00	20FEB2016	7:20:00	Low oxygen saturation	Nasal Cannula		0.25
	01033	No	21FEB2016	11:32:00	22FEB2016	5:10:00	low oxygen sats	Nasal Cannula		0.28
	01033	No	23FEB2016	17:02:00	01MAR2016	7:15:00	low sats	Nasal Cannula		0.29
	01033	No	04MAR2016	3:20:00	04MAR2016	6:57:00	need for more support	Nasal Cannula		0.23
	01033	No	05MAR2016	15:40:00	06MAR2016	7:18:00	low sats	Nasal Cannula		0.25
	01033	No	08MAR2016	19:53:00	09MAR2016	0:44:00	low sats	Nasal Cannula		0.24
	01033	No	12MAR2016	12:55:00	13MAR2016	12:26:00	moved to low flow at 1.0	Nasal Cannula		1.00
	01040	No	21JUN2016	10:25:00	23JUN2016	14:30:00	Extubated to HFNC	Nasal Cannula		0.25
	01040	No	16JUL2016	3:52:00	16JUL2016	23:53:00	oxygen placed to maintain sats 88-95%	Nasal Cannula		0.30
	01040	No	20JUL2016	7:10:00	27JUL2016	12:38:00	to maintain sats 88-95%	Nasal Cannula		0.23
	01041	No	28JUN2016	3:38:00	05JUL2016	11:30:00	Placed on oxygen to maintain sats 88-95%	Nasal Cannula		0.25
	01041	No	27JUL2016	9:05:00	28JUL2016	14:32:00	weaned off cpap	Nasal Cannula		0.25
	09001	No	31MAY2016	17:00:00	23MAY2016	12:38:00	Reason unknown.	Nasal Cannula		0.24
	09001	No	05JUN2016	17:42:00	05JUN2016	19:00:00	Reason unknown. Set at 25 mL/min.	Nasal Cannula		
	12007	No	04APR2016	10:00:00	18APR2016	10:00:00	Desaturation	Nasal Cannula		
	12014	No	02JUN2016	12:05:00	05JUN2016	17:44:00	wean to nasal cannula	Nasal Cannula		0.30
	75 mg/kg	01042	No	22AUG2016	9:00:00	22AUG2016	19:01:00	requiring less support	Nasal Cannula	
01042		No	24AUG2016	10:30:00	03SEP2016	8:27:00	needs O2 to maintain sats	Nasal Cannula		0.25
01042		No	10SEP2016	14:44:00	10SEP2016	16:35:00	needs O2 to maintain sats	Nasal Cannula		0.40
01042		No	15SEP2016	15:19:00	16SEP2016	3:32:00	needs O2 to maintain sats	Nasal Cannula		0.25
01042		No	21SEP2016	7:20:00	21SEP2016	11:15:00	needs O2 to maintain sats	Nasal Cannula		0.24
12023		No	28NOV2016	9:00:00	04DEC2016	8:51:00	wean to HFNC	Nasal Cannula		0.25
42003		No	06AUG2016	21:40:00	07AUG2016	15:39:00	low flow nasal cannula started at a flow of 0.04L/min for low lying saturations	Nasal Cannula		1.00
50001		No	03NOV2016	23:00:00	07NOV2016	23:00:00	trying to disconnect from non invasive support	Other	incubator mode	0.25

Summary Listing 5.2
Respiratory Support - Supplemental Oxygen Information by subject

Treatment Group	Subject ID	On O ₂	Start Date	Start Time	End Date	End Time	Reason	RS Mode	Other Mode	FiO ₂
	50001	No	09NOV2016	9:00:00	20NOV2016	15:00:00	respiratory improvement	Other	incubator with oxygen servo control	0.25
nCPAP Only	03013	No	16SEP2016	12:31:00	30SEP2016	11:35:00	Changed to heated high flow nasal cannula from bubble CPAP	Nasal Cannula		0.25
	12037	No	15DEC2016	11:08:00	16DEC2016	13:14:00	wean to HFNC	Nasal Cannula		0.25
	12037	No	31DEC2016	14:00:00	16JAN2017	17:00:00	wean to HFNC	Nasal Cannula		0.28
	19004	No	31OCT2016	9:00:00	31OCT2016	9:24:00	decreased support clinically indicated	Nasal Cannula		0.30
	76002	No	24FEB2017	12:30:00	28FEB2017		clinical improvement	Nasal Cannula		0.30

Summary Listing 5.3
Respiratory Support - nCPAP Setting Information by subject

Treatment Group	Subject ID	On nCPAP?	Start Date	Start Time	End Date	End Time	Reason	Type of Resp. Support	RS Mode	Other Mode	PIP	FiO ₂	Resp Rate	CPAP	Flow Rate
50 mg/kg	01032	No	06FEB2016	1:52:00	10FEB2016	12:35:00	stable on minimal settings	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.32	65	6	9
	01032	No	14FEB2016	23:25:00	10MAR2016	8:30:00	respiratory insufficiency	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.25	81	6	9
	01041	No	21JUN2016	12:20:00	23JUN2016	10:38:00	extubated to CPAP	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.24		5	9
	01041	No	05JUL2016	11:30:00	27JUL2016	9:05:00	Respiratory insufficiency	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.21		5	8
	09001	No	23MAY2016	12:38:00	21MAY2016	19:45:00	Reason unknown.	nCPAP	HFNC (e.g., Vapotherm, Neotech RAM Cannula)			0.21	44		2
	12014	No	09MAY2016	20:00:00	02JUN2016	12:00:00	wean to NCPAP	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.25	44	7	8
75 mg/kg	01042	No	14AUG2016	14:55:00	22AUG2016	9:00:00	extubated to NIMV	nCPAP	NIPPV		20	0.21	25	6	
	11011	No	06SEP2016	3:57:00	08SEP2016	10:20:00	respiratory staus improved	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.21	38	5	6
	12023	No	12OCT2016	20:00:00	22OCT2016	1:09:00	weaned to NIPPV	nCPAP	NIPPV		21	0.34	30	9	
	12023	No	07NOV2016	15:20:00	28NOV2016	8:59:00	wean to CPAP	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.28	45	6	8
	40003	No	21JUL2016	12:34:00	16AUG2016	0:20:00	Extubated to CPAP	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.25	68	8	
	40006	No	25AUG2016	6:43:00	07SEP2016	13:04:00	Extubated to CPAP	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.21	50	5	
	40006	No	11SEP2016	12:24:00	06OCT2016	20:18:00	Extubated	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.21	36	7	
	42003	No	19JUL2016	4:30:00	06AUG2016	21:39:00	Extubated post surfactant administration	nCPAP	NIPPV		9	0.29	20	5	9
	42003	No	07AUG2016	15:40:00	14AUG2016	10:33:00	cpap for increased work of breathing	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.21	46	4	8

Summary Listing 5.3
Respiratory Support - nCPAP Setting Information by subject

Treatment Group	Subject ID	On nCPAP?	Start Date	Start Time	End Date	End Time	Reason	Type of Resp. Support	RS Mode	Other Mode	PIP	FiO ₂	Resp Rate	CPAP	Flow Rate
	50001	No	03OCT2016	23:25:00	13OCT2016	7:50:00	planned extubation and non invasive support due to respiratory improvement	nCPAP	NIPPV		17	0.30	25	5	
	50001	No	15OCT2016	11:30:00	03NOV2016	23:00:00	planned extubation due to respiratory improvement	nCPAP	NIPPV		16	0.25	25	6	
	50001	No	07NOV2016	23:00:00	09NOV2016	9:00:00	desaturations	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.22		6	
	51004	No	07AUG2016	20:20:00	08AUG2016	9:10:00	improvement in respiratory efficiency	nCPAP	NIPPV		18	0.33	40	6	
	51004	No	11AUG2016	16:45:00	01SEP2016	10:30:00	Respiratory insufficiency	nCPAP	NIPPV		20	0.25	45	6	
100 mg/kg	11021	No	11NOV2016	13:05:00	13JAN2017	7:54:00	improving respiratory status	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.27	57	5	6
	11023	No	01DEC2016	20:00:00	26JAN2017	13:21:00	improved respiratory status	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.22	43	5	5
	19007	No	21DEC2016	17:41:00	24JAN2017	11:30:00	Subject breathing improved. Was extubated and placed on nCPAP	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.23	42	6	8
	40014	No	15DEC2016	14:00:00	11JAN2017	12:00:00	Extubated	nCPAP	Other	Non Invasive HFO	12	0.26	10	10	
	40014	No	14JAN2017	9:00:00	19JAN2017	12:00:00	Increase Work of breathing (WOB)	nCPAP	Other	High Flow		0.21		5	5
	40015	No	05JAN2017	15:15:00	05JAN2017	22:00:00	Extubated	nCPAP	Other	NIVHFO		0.30	10	10	
	40015	No	13JAN2017	14:23:00	01FEB2017	12:00:00	Extubated	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.21	34	7	
	42010	No	20DEC2016	11:00:00	02FEB2017	11:04:00	Extubated	nCPAP	NIPPV		7	0.31	20	4	11
	42010	No	08DEC2016	10:55:00	08DEC2016	18:49:00	Extubated post surfactant	nCPAP	NIPPV		9	0.21	20	5	12

Summary Listing 5.3
Respiratory Support - nCPAP Setting Information by subject

Treatment Group	Subject ID	On nCPAP?	Start Date	Start Time	End Date	End Time	Reason	Type of Resp. Support	RS Mode	Other Mode	PIP	FiO ₂	Resp Rate	CPAP	Flow Rate
nCPAP Only	03006	No	16JAN2016	10:01:00	30JAN2016	9:59:00	extubated to nCPAP	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.28		6	6
	08028	No	28MAY2016	0:05:00	15JUN2016	10:01:00	infant was placed back onto nCPAP after brief intubation for surfactant administration	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.35		6	
	08028	No	15JUN2016	10:02:00	20JUL2016	15:20:00	decrease in respiratory support	nCPAP	HFNC (e.g., Vapotherm, Neotech RAM Cannula)			0.30			6
	08037	No	28AUG2016	10:19:00	14OCT2016	11:29:00	decrease in respiratory support	nCPAP	NIPPV		20	0.30	20	6	
	08037	No	24AUG2016	16:40:00	22OCT2016	8:47:00	went back onto bCPAP after intubated for surfactant administration	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.21		6	10
	11005	No	08JUN2016	10:41:00	12AUG2016	12:50:00	improving respiratory status	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.50	49	5	7
	11006	No	10JUN2016	11:41:00	12AUG2016	12:45:00	improving respiratory condition	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.25	45	5	6
	12006	No	23MAR2016	8:46:00	04MAY2016	13:31:00	weaned to nCPAP	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.25	33	5	
	12037	No	16DEC2016	13:15:00	31DEC2016	13:59:00	increase FiO ₂	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.40	29	5	8

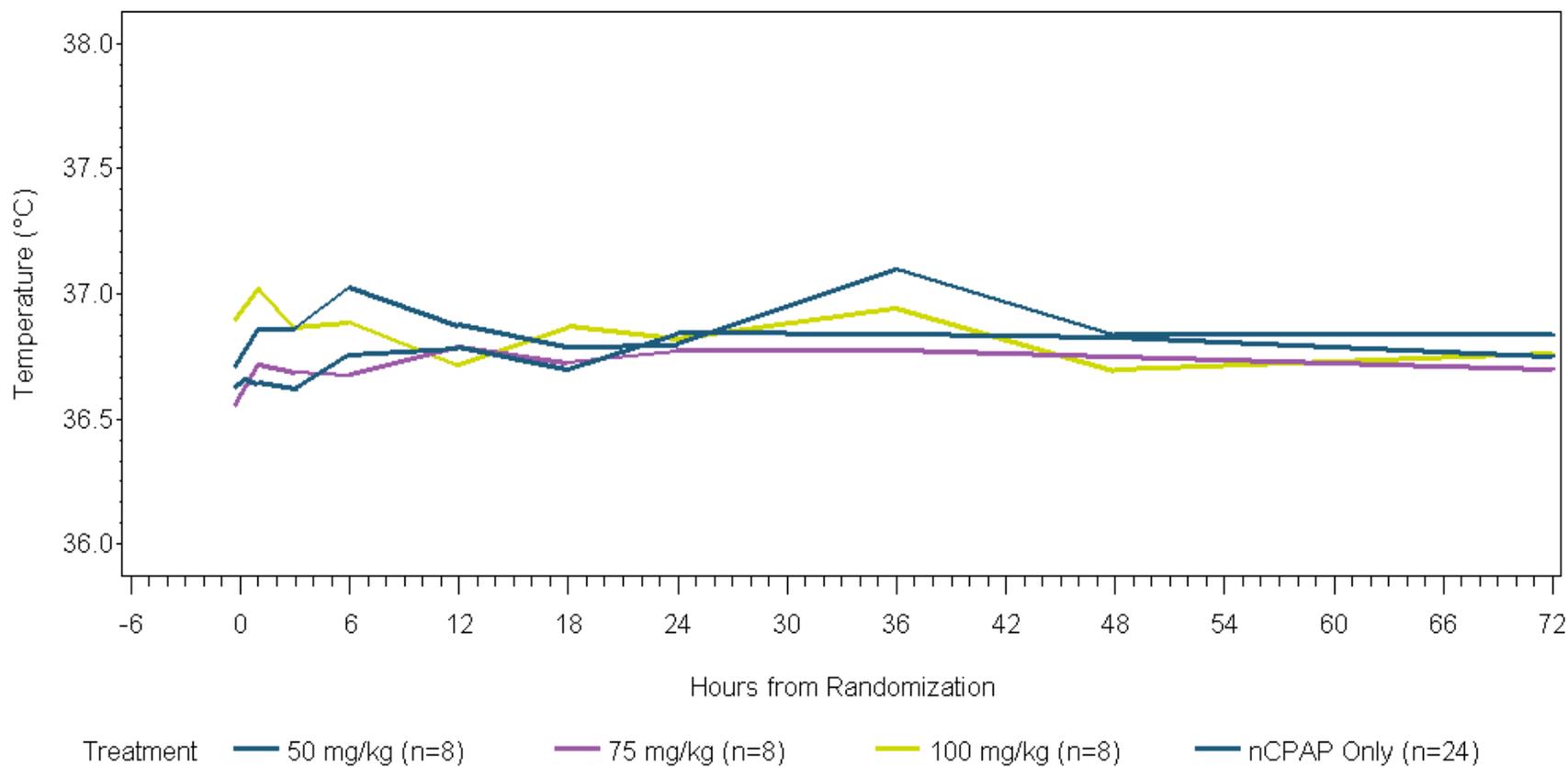
Summary Listing 5.3
Respiratory Support - nCPAP Setting Information by subject

Treatment Group	Subject ID	On nCPAP?	Start Date	Start Time	End Date	End Time	Reason	Type of Resp. Support	RS Mode	Other Mode	PIP	FiO ₂	Resp Rate	CPAP	Flow Rate
	19004	No	28SEP2016	13:19:00	29OCT2016	10:26:00	Intubation only to administer Curosurf only. Infant was on NCPAP and was placed on NCPAP after Curosurf administration. Infant never placed on mechanical ventilation. ETT start stop time unknown	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.24	37	6	8
	40009	No	26SEP2016	15:55:00	26SEP2016	17:00:00	Extubated	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.25	72	8	
	40009	No	11OCT2016	16:01:00	07NOV2016	12:00:00	Extubated	nCPAP	Other	NiVHFo	14	0.36	10	10	
	40019	No	21MAY2017	0:00:00	22MAY2017	14:00:00	Extubated	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.21	40	6	10
	41002	No	28NOV2016	12:45:00	30NOV2016	12:10:00	Improving respiratory status	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.21	42	5	9
	41002	No	02DEC2016	15:25:00	30DEC2016	10:39:00	Improving respiratory status	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.30	62	6	9
	41005	No	06FEB2017	14:20:00	22FEB2017	11:53:00	Improving respiratory status	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.21	56	6	8
	42001	No	30MAY2016	22:50:00	13JUL2016	14:55:00	Extubated post surfactant administration	nCPAP	NIPPV		7	0.23	20	4	9
	42004	No	05SEP2016	13:25:00	14OCT2016	13:00:00	Extubation	nCPAP	NIPPV		20	0.33	50	8	
	54002	No	15SEP2016	1:00:00	04OCT2016	9:00:00	need of respiratory support	nCPAP	HFNC (e.g., Vapotherm, Neotech RAM Cannula)			0.21	40	5	4
	54017	No	26NOV2016	15:00:00	10DEC2016	4:15:00	breathing support	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.30	40	6	8

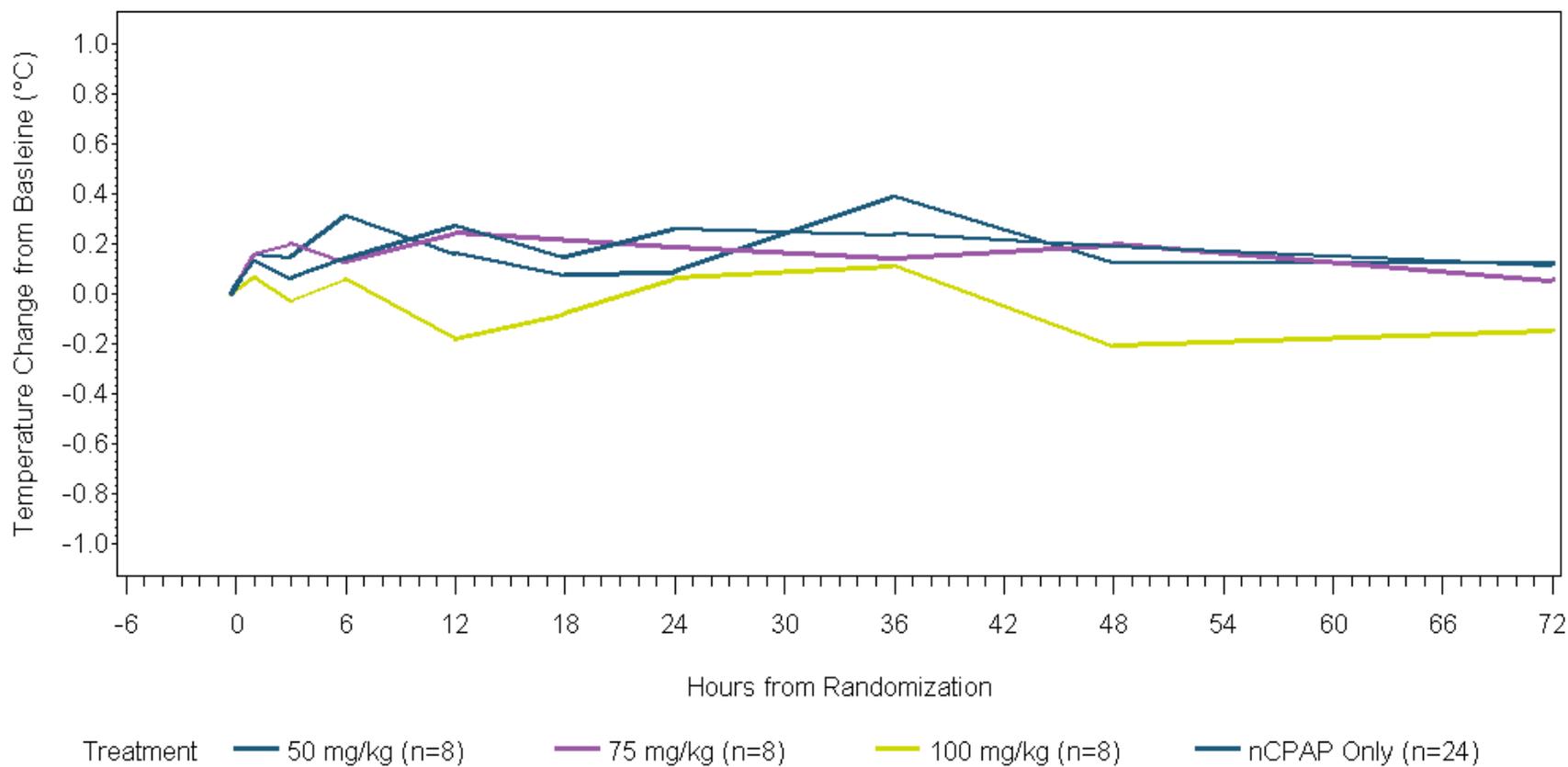
Summary Listing 5.3
Respiratory Support - nCPAP Setting Information by subject

Treatment Group	Subject ID	On nCPAP?	Start Date	Start Time	End Date	End Time	Reason	Type of Resp. Support	RS Mode	Other Mode	PIP	FiO ₂	Resp Rate	CPAP	Flow Rate
	54017	No	15DEC2016	12:00:00	05JAN2017	14:00:00	breathing support only	nCPAP	CPAP (e.g. Bubble, ventilator driven)			0.26	35	5	8
	76002	No	17JAN2017	11:00:00	21DEC2016	11:50:00	clinical improvement	nCPAP	NIPPV		20	0.35	40	6	6
	76002	No	26JAN2017	12:30:00	24FEB2017	12:30:00	clinical improvement	nCPAP	NIPPV		20	0.45	40	6	6

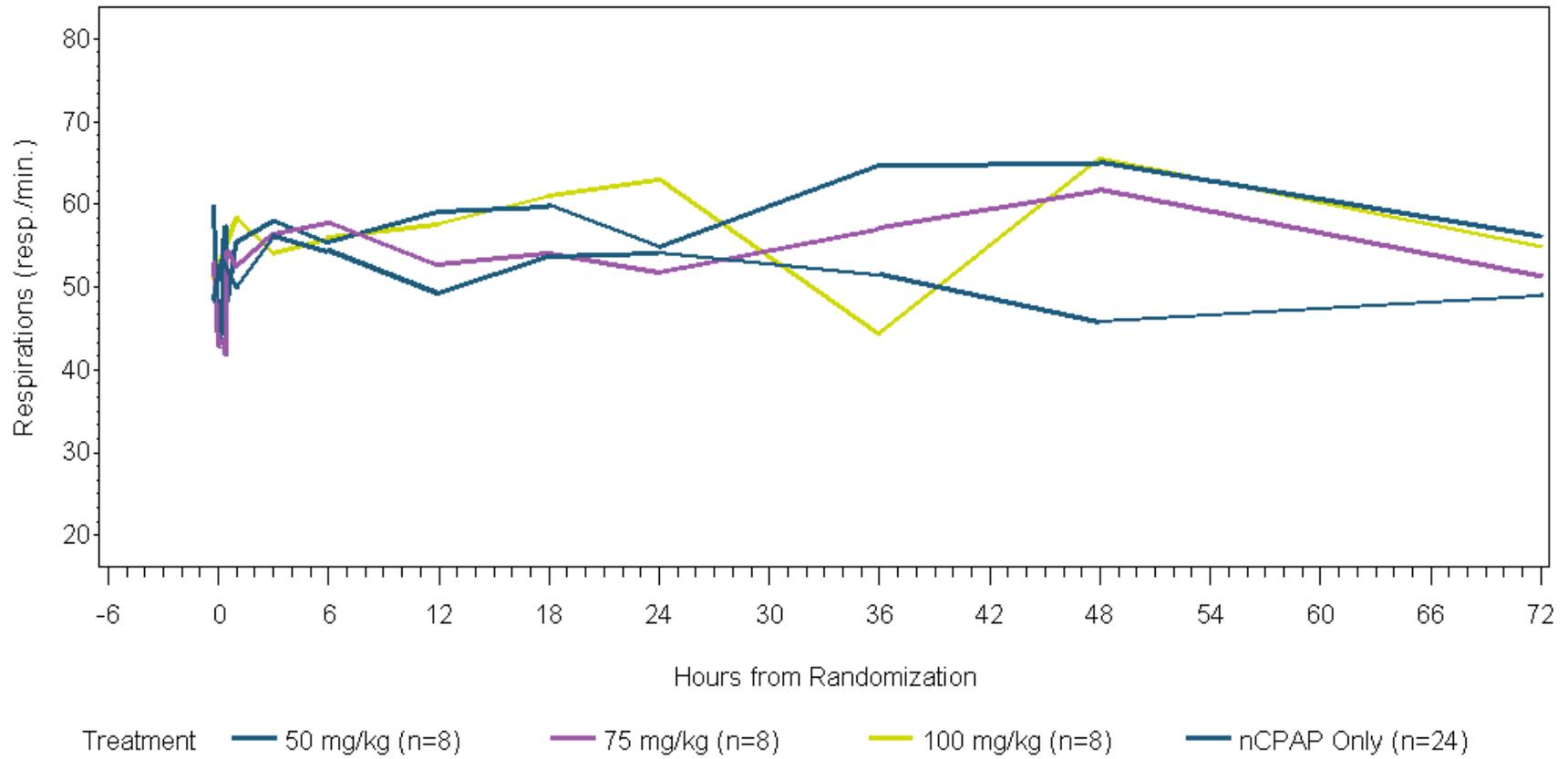
Summary Figure 3.1.1
Vital Signs - Body Temperature - Observed Values
Intent-to-Treat Population



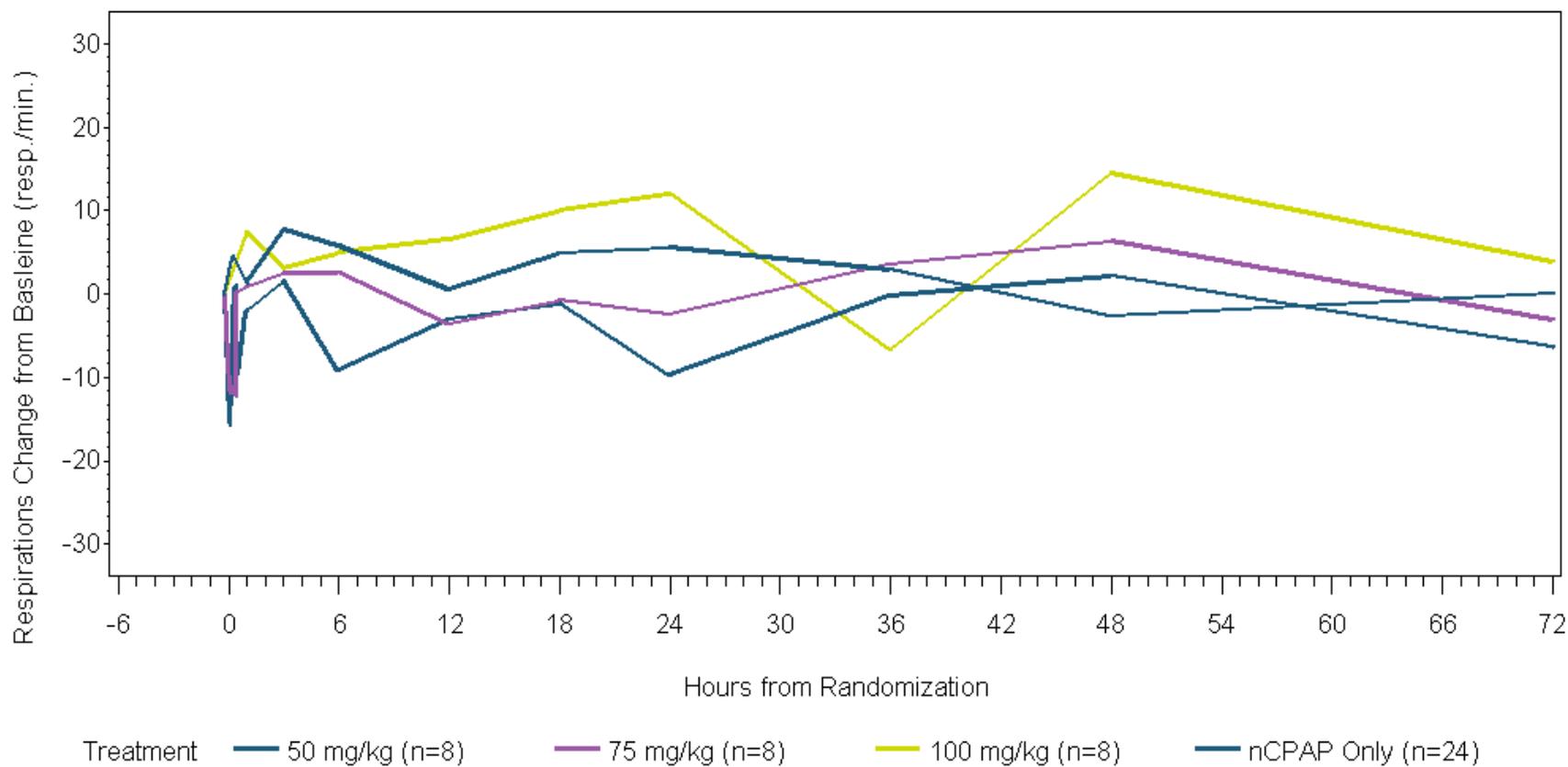
Summary Figure 3.1.2
Vital Signs - Body Temperature - Change from Baseline Values
Intent-to-Treat Population



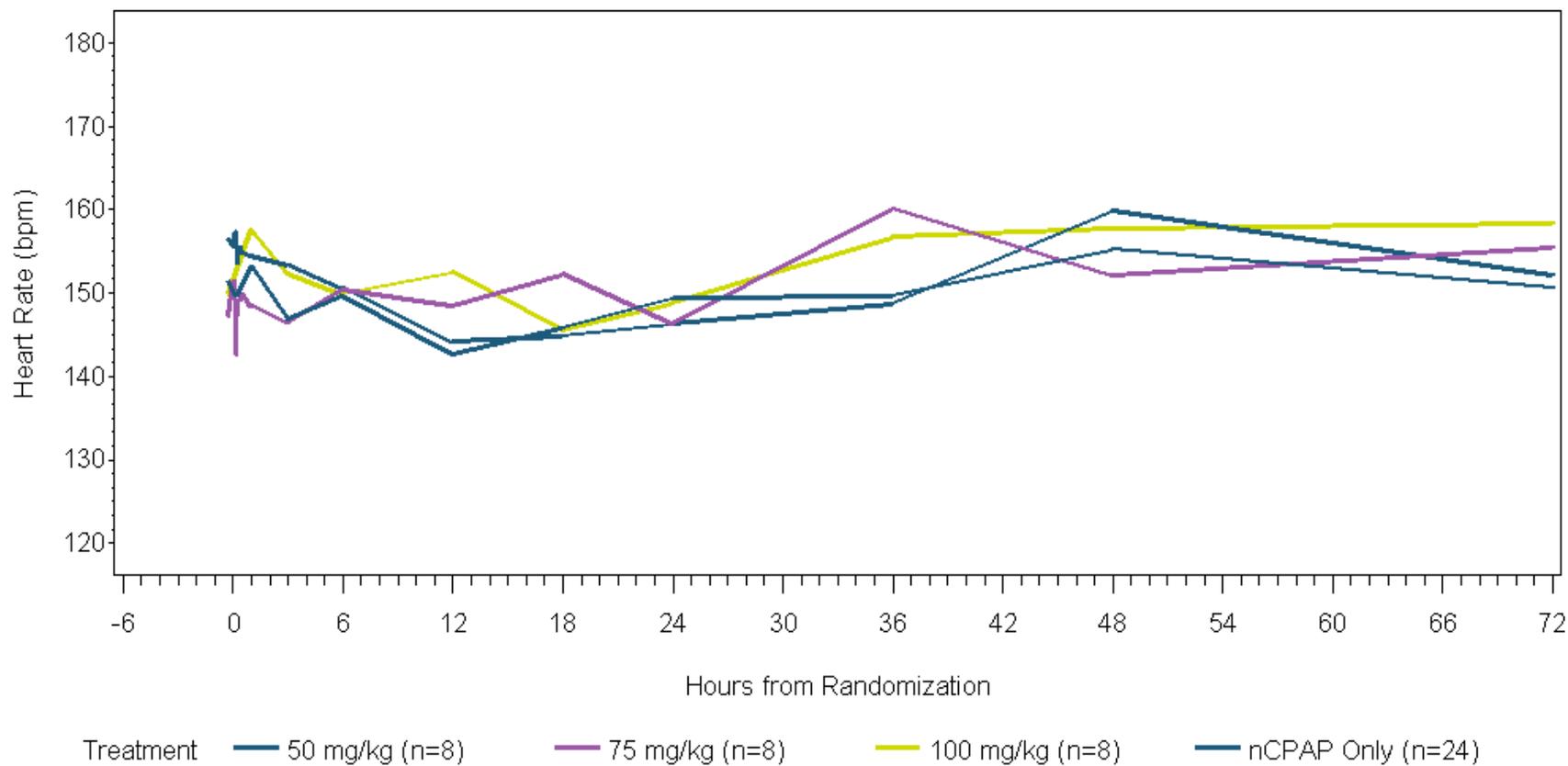
Summary Figure 3.2.1
Vital Signs - Spontaneous Respiratory Rate - Observed Values
Intent-to-Treat Population



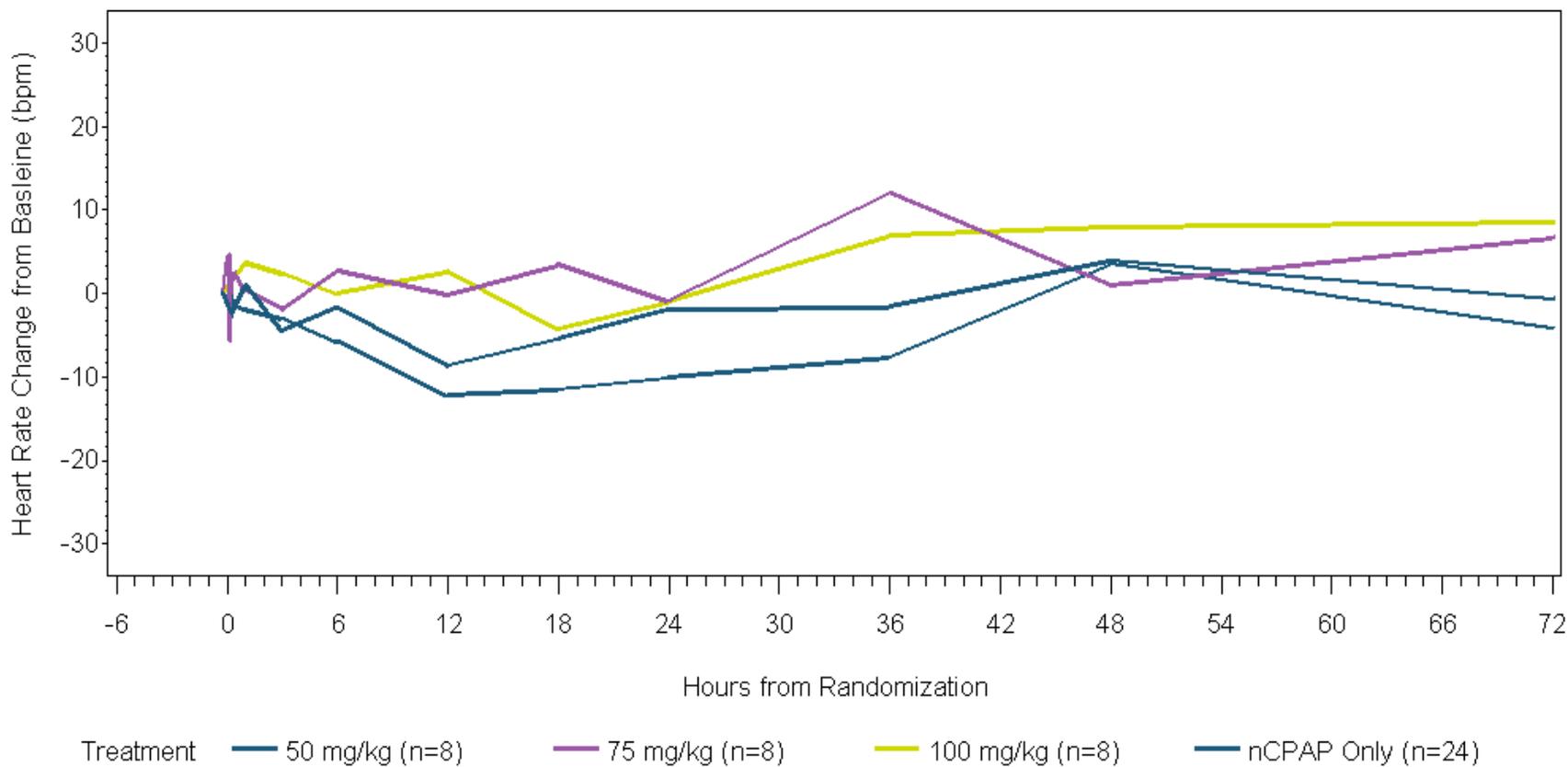
Summary Figure 3.2.2
Vital Signs - Spontaneous Respiratory Rate - Change from Baseline
Intent-to-Treat Population



Summary Figure 3.3.1
Vital Signs - Heart Rate - Observed Values
Intent-to-Treat Population



Summary Figure 3.3.2
Vital Signs - Heart Rate - Change from Baseline Values
Intent-to-Treat Population



14.3.2 Listings of Deaths, Other Serious and Significant Adverse Events

Summary Listings

Listing Number	Listing Title
2.1	All-Cause Mortality
2.2	Serious Adverse Events

Summary Listing 2.1
All-Cause Mortality

Subject ID	Treatment	Death Date	Death Time	Death Reason
11011	75 mg/kg	09SEP2016	13:50:00	Pneumoperitoneum
12014	50 mg/kg	06JUN2016	0:52:00	NEC and bowel perforation

Summary Listing 2.2
Serious Adverse Events

Treatment	Subject ID	SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
50 mg/kg	01040	Respiratory, thoracic and mediastinal disorders	Pneumothorax	Left Pneumothorax	13JUN2016	18JUN2016	Moderate	Possibly	Recovered
	09001	Infections and infestations	Sepsis neonatal	CONS septicemia	21MAY2016	07JUN2016	Severe	NotRel.	Recovered
	12014	Pregnancy, puerperium and perinatal conditions	Necrotising enterocolitis neonatal	NEC	05JUN2016	06JUN2016	Severe	NotRel.	Died
	40001	Gastrointestinal disorders	Intestinal perforation	Spontaneous Intestinal perforation	07MAY2016	*	Severe	Unlikely	Continuing
75 mg/kg	11011	Gastrointestinal disorders	Pneumoperitoneum	pneumoperitoneum	04SEP2016	09SEP2016	Severe	Unlikely	Died
	50001	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	RESPIRATORY FAILURE	28SEP2016	03OCT2016	Moderate	Unlikely	Recovered
	50001	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory failure	Respiratory failure	13OCT2016	23OCT2016	Moderate	NotRel.	Recovered
	51004	Infections and infestations	Pneumonia	Ventilator-associated pneumonia (VAP)	03AUG2016	17AUG2016	Moderate	NotRel.	Recovered
	51004	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	respiratory failure	26JUL2016	03SEP2016	Moderate	NotRel.	Recovered
100 mg/kg	11021	Pregnancy, puerperium and perinatal conditions	Intraventricular haemorrhage neonatal	intraventricular hemorrhage	06NOV2016	*	Severe	Unlikely	Continuing
	11021	Respiratory, thoracic and mediastinal disorders	Pneumothorax	pneumothorax	06NOV2016	15NOV2016	Severe	Unlikely	Recovered
	40015	Pregnancy, puerperium and perinatal conditions	Intraventricular haemorrhage neonatal	Intraventricular Haemorrhage	23JAN2017	13MAR2017	Severe	Unlikely	Recovered

Summary Listing 2.2
Serious Adverse Events

Treatment	Subject ID	SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
nCPAP only	11006	Respiratory, thoracic and mediastinal disorders	Pneumothorax	pneumothorax	07JUN2016	07JUN2016	Severe	NotRel.	Recovered
	12006	Cardiac disorders	Cardiac arrest	Cardiac Arrest	03MAR2016	03MAR2016	Severe	NotRel.	Recovered
	12006	Gastrointestinal disorders	Gastric perforation	Gastric perforation	03MAR2016	30MAR2016	Severe	NotRel.	Recovered
	12006	Respiratory, thoracic and mediastinal disorders	Neonatal respiratory failure	Hypoxic respiratory failure	03MAR2016	23MAR2016	Severe	NotRel.	Recovered
	12006	Injury, poisoning and procedural complications	Traumatic liver injury	Liver laceration	03MAR2016	08MAR2016	Severe	NotRel.	Recovered
	12006	Injury, poisoning and procedural complications	Hepatic haemorrhage	liver hemorrhage	03MAR2016	30MAR2016	Severe	NotRel.	Recovered
	12010	Gastrointestinal disorders	Intestinal perforation	Bowel Perforation	24APR2016	16MAY2016	Severe	NotRel.	Recovered
	12010	Injury, poisoning and procedural complications	Laryngeal injury	Laryngeal Trauma Due to Intubation	18MAR2016	29MAR2016	Severe	NotRel.	Recovered
	19004	Pregnancy, puerperium and perinatal conditions	Necrotising enterocolitis neonatal	Necrotizing Enterocolitis	01NOV2016	*	Severe	NotRel.	Continuing
	19004	Cardiac disorders	Cardio-respiratory arrest	severe Bradycardia	31OCT2016	31OCT2016	Severe	NotRel.	Recovered
	54017	Blood and lymphatic system disorders	Anaemia neonatal	anaemia	13DEC2016	*	Moderate	NotRel.	Continuing
	54017	Respiratory, thoracic and mediastinal disorders	Apnoea neonatal	apneas	07DEC2016	10DEC2016	Moderate	NotRel.	Recovered

Summary Listing 2.2
Serious Adverse Events

Treatment	Subject ID	SOC	Preferred Term	Verbatim Term	Start Date	End Date	Severity	Relationship	Outcome
	54017	Infections and infestations	Pneumonia	pneumoniae	12DEC2016	22DEC2016	Moderate	NotRel.	Recovered
	54017	Pregnancy, puerperium and perinatal conditions	Neonatal respiratory distress syndrome	worsening respiratory effort	26NOV2016	26NOV2016	Severe	NotRel.	Recovered
	76002	Pregnancy, puerperium and perinatal conditions	Intraventricular haemorrhage neonatal	intraventricular hemorrhage (IVH)	22DEC2016	*	Severe	NotRel.	Continuing
	76002	Respiratory, thoracic and mediastinal disorders	Pneumothorax	pneumothorax	21DEC2016	21DEC2016	Severe	NotRel.	Recovered
	76002	Vascular disorders	Shock	refractory shock	30DEC2016	03JAN2017	Severe	NotRel.	Recovered

14.3.3 Narratives of Deaths, Other Serious and Certain Other Significant Adverse Events

Table 14-1 lists the subjects who died or had other SAEs for which a narrative is provided.

Table 14-1. Deaths and Serious Adverse Events

Subject ID	Death or SAE	Subject ID	Death or SAE
01040	SAE	19004 ^a	SAE
09001	SAE	40001	SAE
11006	SAE	40015	SAE
11011	Death	50001 ^a	SAE
11021 ^a	SAE	51004 ^a	SAE
12006 ^a	SAE	54017 ^a	SAE
12010 ^a	SAE	76002 ^a	SAE
12014	Death		

^a Subject had multiple SAEs recorded separately in the safety database.

14.3.3.1 Deaths

Subject ID: 11011

ARISg ID#: DSC201609-000009

SAE: Pneumoperitoneum

Subject 11-011 was a white female born at 26 1/7 weeks gestational age (GA) with birth weight (BW) 0.91 kg. The subject was randomized into the study on 31-AUG-2016 at 19:58, receiving a single study treatment of lucinactant for inhalation 75 mg/kg at 21:41 when she was approximately 6 hours old, which was well tolerated. Concomitant medications included caffeine, Curosurf, ampicillin, and gentamicin.

On 09-SEP-2016 (day-of-life [DOL] #10), the subject experienced the fatal event of Pneumoperitoneum, which was severe in intensity and was judged by the investigator as being unlikely related to the study drug and not to the study device.

On 01-SEP-2016 (DOL #2), the subject was intubated and received poractant alfa due to increasing oxygen requirement and desaturations. The subject was treated with ampicillin and gentamicin for suspected sepsis at birth until culture results came back negative on 02-SEP-2016 (DOL #3). The subject had patent ductus arteriosus (PDA) not being treated with any medication, apnea of prematurity (treated with caffeine) and hyperbilirubinemia (treated with phototherapy).

On the evening of 04-SEP-2016 (DOL #5) the subject's respirations were supported with nCPAP with FiO₂ 0.21, and she was not being fed. On exam, she was noted to have a distended abdomen. An abdominal X-ray (AXR) revealed free intraperitoneal air (pneumoperitoneum). She was then intubated and Penrose drain placed surgically at the bedside. The subject was stable after the drain was placed and she was extubated to nCPAP on 06-SEP-2016 (DOL #7).

On 07-SEP-2016 (DOL #8), the subject had decreased urine output, hypotension and hypovolemia (all reported as non-serious AEs). She received fluid boluses and was started on dopamine with improvement in urine output and blood pressure. On 08-SEP-2016, (DOL #9) the subject began having apnea with deep bradycardia, and bloody drainage was noted from the Penrose drain. She was intubated, and had bright red blood suctioned from the endotracheal tube consistent with pulmonary hemorrhage. She was treated with blood transfusions and intra-tracheal epinephrine.

On 09-SEP-2016 (DOL #10) in the morning, the subject had worsening hypotension and difficulty maintaining adequate oxygenation, and was found to have disseminated intravascular coagulation (DIC). Exploratory laparotomy was planned, however cancelled as she developed persistent bradycardia and hypoxemia. After discussion with the parents, the decision was made to limit further resuscitation efforts and the subject died on the same day.

On 09-SEP-2016 (DOL #10), the event of pneumoperitoneum was considered fatal.

Subject ID: 12014

ARISg ID#: DSC201606-000006

SAE: Necrotizing Enterocolitis

Subject 12-014 is an Asian male born at 27 0/7 weeks GA with BW 0.75 kg. The subject was randomized into the study on 29-APR-2016 at 12:26, receiving a single study treatment of lucinactant for inhalation 50 mg/kg at 13:28 when he was approximately 5 hours old, which was well tolerated. Concomitant medications included caffeine, ferrous sulfate, Nystatin, and ursodiol. His active problems included bronchopulmonary dysplasia (BPD), PDA treated with indomethacin, and indirect hyperbilirubinemia (reported as a non-serious AE) treated with ursodiol.

On 05-JUN-2016 (DOL #38), the subject experienced the fatal event of necrotizing enterocolitis of severe intensity, judged by the investigator as being not related to the study drug and not related to the study device.

On 29-APR-2016 (DOL #1) about 1 hour after completion of study treatment he developed acute respiratory failure (reported as a non-serious AE) and he was intubated for surfactant administration. Intubation was straightforward, but pink frothy fluid consistent with pulmonary edema was noted transiently in the endotracheal tube immediately after intubation. The subject improved and no further pulmonary edema was noted. Hemorrhagic pulmonary edema was reported as a non-serious adverse event (AE).

The subject had been described as doing well, receiving bolus feeds which were well tolerated. AXR on 02-JUN-2016 (DOL #35) showed slightly increased gaseous distension but was otherwise normal.

On the morning of 05-JUN-2016 (DOL #38), the usual morning exam was normal. Around noon, the baby had emesis, which was typical for him, but exam was normal. Feeds were held for an hour then resumed. At approximately 17:00-18:00, the bedside nurse called the physician to evaluate the baby. At that time, the baby was found to be dusky with agonal breathing, and pulses were not palpable. He was intubated immediately, intraosseous lines were placed and he was resuscitated with fluids, blood products and resuscitative medications. AXR at 18:07 showed significant pneumatosis throughout the majority of the intestinal tract with portal venous air tracking. Emergent laparotomy was done at the bedside, with brief cardiopulmonary resuscitation (CPR) being required just before incision. A perforation in the mid-small bowel was found. After laparotomy the baby transiently improved on inotropic support, but he deteriorated, developed refractory DIC with bleeding from all vascular access sites and mucosa due to septic shock with hypotension (both as a result of NEC and reported as non-serious AEs), and again required resuscitation. After discussion with the parents, life support was withdrawn and the subject died on 06-JUN-2016 (DOL #39) at 00:52.

On 06-JUN-2016 (DOL #39), the outcome of the event necrotizing enterocolitis was fatal.

14.3.3.2 Other Serious Adverse Events

Subject ID: 01040

ARISg ID#: DSC201606-000008

SAE: Left Pneumothorax

Subject 01-040 is a white male born at 28 3/7 weeks GA with BW 1.26 kg. The subject was randomized into the study on 13-JUN-2016 at 14:51, receiving the initial study treatment of lucinactant for inhalation 50 mg/kg at 15:55 when he was approximately 2 hours old, which was well tolerated. The subject received a repeat study treatment on 13-JUN-2016 at 20:35.

Concomitant medications included ampicillin, cefotaxime, caffeine, erythromycin, and phytomenadione.

On 13-JUN-2016 (DOL #1), the subject experienced the important medical event of left pneumothorax, which was moderate severity and was judged by the investigator as being possibly related to the study drug and not related to the study device. The same day, the subject experienced the non-serious AE of pulmonary interstitial emphysema (PIE) of moderate severity.

The subject's mother had been admitted prenatally for observation due to a diagnosis of Ehlers-Danlos syndrome (a genetic disorder causing weakened connective tissue, which places the mother at risk for uterine rupture) and twin gestation. The subject (twin B) and his sibling (twin A) were delivered by Caesarian section.

On 13-JUN-2016 (DOL #1) after birth, the subject was placed on bubble nCPAP of 5 cmH₂O with FiO₂ of 0.25. At 14:59, a chest X-ray (CXR) was consistent with RDS and showed no air leak. At 20:35 when the subject received the second dose of study therapy, FiO₂ had been increased to 0.4. A CXR at 23:11 showed moderate RDS, probable early PIE and small left sided pneumothorax. FiO₂ had increased to 0.6 so at 23:40, the subject was intubated.

On 14-JUN-2016 (DOL #2) at 00:05, a post-intubation CXR was unchanged, still showing moderate RDS, probable early PIE, and small left pneumothorax. At 00:25, the subject was placed on mechanical ventilation (MV) and given a dose of intratracheal poractant. A follow up CXR at 05:51 showed a small-to-moderate-sized left side pneumothorax. At 06:22, an 8.0 Fr chest tube was inserted. At 06:55, FiO₂ was down to 0.6 and a CXR at 07:41 showed that the pneumothorax had resolved and PIE was still present. At 09:55, a second dose of poractant was given; at that time the subject was on high-frequency jet ventilation (HFJV) and FiO₂ was down to 0.23.

On 18-JUN-2016 (DOL #6), the outcome of the event left pneumothorax was considered resolved.

On 09-AUG-2016 (DOL #27), the Investigator noted that the subject had tested positive for the gene associated with Ehlers-Danlos syndrome Type 4, which can present in childhood with spontaneous pneumothorax. The subject's sibling (Subject 01-041) also tested positive for the Ehlers-Danlos syndrome Type 4 gene, and also experienced a non-serious AE of PIE on DOL #3.

Subject ID: 09001

ARISg ID#: DSC201609-000010

SAE: CONS (Coagulase Negative Staphylococcal) Septicemia

Subject 09-001 is a black female born at 28 1/7 weeks GA with BW 1.270 kg. The subject was randomized into the study on 10-MAY-2016 at 13:47, receiving the initial study treatment of lucinactant for inhalation 50 mg/kg at 16:40 when she was approximately 4.5 hours old, which was well tolerated. The subject received a repeat study treatment on 10-MAY-2016 at 20:20. Concomitant medications included caffeine, cholecalciferol, total parenteral nutrition (TPN) and probiotic.

On 21-MAY-2016 (DOL #12), the subject experienced the life-threatening event of CONS (Coagulase Negative Staphylococcal) septicemia, which was of severe intensity and was judged by the investigator as being not related to the study drug and not related to the study device.

On 21-MAY-2016 (DOL #12) at 18:48 hours, the subject was found to be hypotonic, lethargic, and in respiratory distress requiring high flow nasal cannula (HFNC) for respiratory support with increased FiO₂ from 0.28 to 0.36; all were reported as non-serious AEs. Laboratory tests showed a mixed acidosis, increased white blood cell count (WBC) at $29.3 \times 10^3/\mu\text{L}$ (reference range 5-21 $\times 10^3/\mu\text{L}$), mild anemia with hemoglobin of 10.7 g/dL (reference range 14.5-22.5 g/dL) and thrombocytopenia with platelet count of $91 \times 10^3/\mu\text{L}$ (reference range 150-400 $\times 10^3/\mu\text{L}$) (both reported as non-serious AEs), and elevated C-reactive protein (CRP) at 18.2 mg/dL. CXR was consistent with RDS, with no air leak. Blood cultures were drawn, which subsequently grew coagulase-negative *Staphylococcus*. At 19:29, the subject continued to have significant respiratory acidosis (reported as a non-serious AE), FiO₂ had increased to 0.38 and she had episodes of apnea, so she was intubated and placed on MV. Antibiotics were started with cefepime and vancomycin. A urine culture grew no bacteria, and a sputum culture showed no white blood cells (WBCs) on Gram stain and grew rare normal respiratory flora with few *Klebsiella pneumoniae* and *Citrobacter freundii* complex.

On 23-MAY-2016 (DOL #13), the subject was extubated to HFNC and tube feedings were begun. A blood culture drawn that day did not grow any bacteria.

On 28-MAY-2016 (DOL #19), the outcome of the event "CONS septicemia" was reported as recovered.

Subject ID: 11006

ARISg ID#: DSC201606-000007

SAE: Pneumothorax

Subject 11-006 is a Hispanic male born at 26 3/7 weeks GA with BW 0.81 kg. The subject was randomized into the study on 06-JUN-2016 at 12:21 and was assigned to receive nCPAP only (control). Concomitant medications included ampicillin, gentamicin, and nitric oxide (NO).

On 07-JUN-2016 (DOL #2), the subject experienced the life-threatening event of pneumothorax, which was of severe intensity and was judged by the investigator as being not related to the study drug and not related to the study device.

On 06-JUN-2016 (DOL #1) shortly after birth at 07:07, the subject was placed on bubble nCPAP at 5 cmH₂O for respiratory support. A CXR at 08:26 showed RDS with no air leak. At 8 hours of life (approximately 15:00), the subject developed worsening respiratory distress (reported as a non-serious AE) with FiO₂ increased to 0.5-0.6, so the subject was intubated at 15:45. A post-intubation CXR at 16:39 showed no air leak. The subject received endotracheal surfactant at 16:30 but continued to have a high oxygen requirement despite mechanical ventilation, so was started on NO with improvement in oxygen requirement.

On 07-JUN-2016 (DOL #2) at 22 hours of life, the subject had increased respiratory distress and his oxygen requirement increased. A CXR revealed a left pneumothorax. A chest tube was placed at 06:50 and pneumothorax was effectively drained. Subsequently, the subject's respiratory status improved and he was able to be weaned from mechanical ventilation and ultimately extubated back to bubble nCPAP with FiO₂ 0.25.

On 09-JUN-2016 (DOL #4), the chest tube was removed at 14:45 hours. On 10-JUN-2016 the subject was extubated to bubble nasal CPAP.

On 07-JUN-2016 (DOL #2), the event of pneumothorax was considered resolved.

Subject ID: 11021

ARISg ID#: DSC201611-000015

SAE: Pneumothorax

ARISg ID#: DSC201611-000016

SAE: Intraventricular Hemorrhage

Subject 11-021 is a Hispanic male born at 26 1/7 weeks GA with BW 0.94 kg. The subject was randomized into the study on 05-NOV-2016 at 14:01, receiving a single study treatment of

lucinactant for inhalation 100 mg TPL/kg at 16:00 when he was approximately 8 hours old, which was well tolerated. Concomitant medications included ampicillin, gentamicin, and caffeine.

On 06-NOV-2016 (DOL #2), the subject experienced the important medical events of pneumothorax and intraventricular hemorrhage, both of which were of severe intensity and judged by the investigator as being unlikely related to the study drug and not related to the study device.

On 05-NOV-2016 (DOL #1), in the delivery room, the subject was resuscitated initially with nCPAP at 5 cmH₂O and FiO₂ 0.3 via NeoPuff™. The subject was noted to have respiratory distress with heart rate (HR) <100 beats per min (bpm), so positive pressure ventilation (PPV) was given from 1-6 min of life with the NeoPuff, initially with peak inspiratory pressure (PIP) 20 cmH₂O/positive end-expiratory pressure (PEEP) 5 cmH₂O and FiO₂ 0.4, but then increased to 23/5 cmH₂O with FiO₂ 1.0. The subject then switched to nCPAP via nasal prongs and FiO₂ was weaned to 0.30-0.35. FiO₂ gradually increased up to 0.50. CXRs at 10:37 and 10:46 showed RDS with no air leak. The subject's FiO₂ was 0.50 when study treatment was administered. Upon completion of study treatment, FiO₂ remained at 0.55-0.60 and ultimately was increased to 0.90 to maintain SaO₂ 90-95%. The subject was intubated at 18:45, placed on MV, and given endotracheal surfactant. No CXR was done prior to intubation due to medical urgency, but post-intubation CXR at 19:47 showed RDS with no air leak. Empiric antibiotics were started with ampicillin and gentamicin for possible sepsis.

On 06-NOV-2016 (DOL #2), CXRs at 00:19 and 03:12 showed no air leak, with appropriately positioned endotracheal tube and vascular catheters. At 12:39, increased FiO₂ prompted a CXR, which revealed a moderate sized anterior right pneumothorax. At 13:19, a CXR showed revealed bilateral pneumothoraces. A right chest tube was placed, and a CXR at 14:33 showed persistent moderately large left pneumothorax with resolved right pneumothorax after chest tube placement. That day, a routine head ultrasound revealed bilateral intraventricular hemorrhages (IVH) which were grade 2 on the right and grade 1 on the left; the subject was reported to have no neurological symptoms suggestive of IVH.

The pneumothoraces persisted intermittently on CXRs from 07-NOV-2016 (DOL #3) to 10-NOV-2016 (DOL #6), but CXRs on and after 11-NOV-2016 (DOL #7) showed no pneumothorax. On 22-NOV-2016 (DOL #18), a CXR showed RDS with mild PIE but no pneumothorax. On 23-NOV-2016 (DOL #19), a CXR showed prominent lung markings with no focal consolidation but no air leak.

On 08-NOV-2016 (DOL #4), a follow-up head ultrasound revealed interval worsening of the IVHs to grade 4 bilaterally. A repeat head ultrasound on 12-NOV-2016 (DOL #8) showed evolving bilateral grade 4 IVH with increasing cystic changes and resultant ex-vacuo dilation of the ventricular system. Electroencephalograms (EEGs) performed on 14-NOV-2016 (DOL #10) and 15-NOV-2016 (DOL #11), revealed no definitive abnormalities. On 02-DEC-2016 (DOL #28), there were no changes in IVH status.

On 15-NOV-2016 (DOL #11), the outcome of the event pneumothorax was reported as resolved. The intraventricular hemorrhage was reported as continuing at the end of the study (13-JAN-2017; DOL #69).

Subject ID: 12006

ARISg ID#: DSC201603-000001

SAE: Gastric Perforation, Hypoxic Respiratory Failure, Liver Laceration, Hemorrhage, Cardiac Arrest

Subject 12-006 is a Hispanic female born at 27 2/7 weeks GA with BW 0.785 kg. The subject was randomized into the study on 01-MAR-2016 at 19:09 and was assigned to receive nCPAP only (control). Concomitant medications included ampicillin, gentamicin, caffeine, poractant alpha, and phytomenadione.

On 03-MAR-2016 (DOL #3), the subject experienced the life-threatening and important medical events of gastric perforation, hypoxic respiratory failure, liver laceration, hemorrhage, and cardiac arrest, which were all of severe intensity and were judged by the investigator as being not related to the study drug and not related to the study device.

On 01-MAR-2016 (DOL #1), the subject was born and respirations were supported with bubble nCPAP at 6 cmH₂O and FiO₂ 0.3. Through 02-MAR-2016 (DOL #2) she was doing well, receiving nutrition with TPN. A CXR/abdominal X-ray (AXR) showed improved lung aeration and normal bowel gas pattern with no free air, and a nasogastric (NG) tube whose tip was in the stomach.

On 03-MAR-2016 (DOL #3) in the morning, the subject developed abdominal distention with increasing oxygen requirement, with SpO₂ only in the high 70's despite FiO₂ rising from 0.3 overnight to 0.65. At 06:30, the subject was found to be hypotensive with a blood pressure of 57/34 mmHg (reported as a non-serious AE) and had meconium noted on physical examination; laboratory values showed a low-normal platelet count at 158 ×10³/μL and normal hemoglobin at 16.8 g/L. At 06:55, the subject experienced hypoxic respiratory failure and was intubated. The

subject was placed on HFJV and intratracheal poractant was given. AXR/CXR at 07:31 showed massive pneumoperitoneum and increased patchy opacities in the lungs without air leak.

That day at 09:33, an exploratory laparotomy was done which revealed a large perforation of the greater curvature of the stomach from gastroesophageal (GE) junction to the mid-stomach. The perforation itself was repaired with significant difficulty. During the procedure, despite intraoperative measures to protect the liver, the subject experienced a liver laceration with significant subcapsular dissecting hematoma that led to intraoperative bleeding with hemorrhagic cardiac arrest. CPR along with blood transfusion successfully restored circulation. The wound was packed with thrombostatic agents and surgical sponges, and the abdomen left open with a black sponge negative-pressure wound therapy (NPWT) apparatus overlying. The subject was described as being hemodynamically unstable, in critical condition, and under observation for sepsis. She was anemic with hemoglobin of 4.5 g/dL (reference range 12-16.5) and hematocrit of 12.8 % (reference range 42.0-52.0).

On 06-MAR-2016 (DOL #6), the subject was less anemic, with a hemoglobin of 10.6 g/dL and hematocrit of 31.1 %, and was thrombocytopenic with a platelet count of $88 \times 10^9/L$ (reference range 130-460). On 08-MAR-2016 (DOL #8), the liver was not bleeding so the NPWT was removed and the fascia and skin were closed. The subject remained intubated on MV, taking nothing by mouth (NPO) and receiving nutrition via TPN, and was described as being in stable condition awaiting return of normal bowel function.

On 03-MAR-2016 (DOL #3), the outcome of the event cardiac arrest was considered resolved. On 08-MAR-2016 (DOL #8), the outcome of the event liver laceration was considered resolved. On 23-MAR-2016 (DOL #23), the outcome of the event hypoxic respiratory failure was considered resolved. On 30-MAR-2016 (DOL #30), the outcomes of the events hemorrhage and gastric perforation were considered resolved.

Subject ID: 12010

ARISg ID#: DSC201604-000002

SAE: Laryngeal Trauma Due To Intubation

ARISg ID#: DSC201604-000003

SAE: Bowel Perforation

Subject 12-010 is a Hispanic male born at 26 6/7 weeks GA with BW 0.585 kg. The subject was randomized into the study on 17-MAR-2016 at 12:51 and was assigned to receive nCPAP only (control). Concomitant medications at the time of the first event included ampicillin, gentamicin,

caffeine and indomethacin, and at the time of the second event included albuterol, budesonide, caffeine, cyclopentolate/phenylephrine, fluconazole, gentamicin, heparin hydrocortisone, lipid emulsion, metronidazole, furosemide and morphine.

On 18-MAR-2016 (DOL #2), the subject experienced the important medical event of “laryngeal trauma due to intubation” which was of moderate severity. On 24-APR-2016 (DOL #39), the subject experienced the life-threatening event of bowel perforation, which was of severe intensity and prolonged hospitalization. Both events were judged by the investigator as being not related to the study drug and not related to the study device.

On 17-MAR-2016 (DOL #1) after birth, the subject’s respirations were supported with nCPAP. At 13:48 hours, due to worsening respiratory status from RDS, the subject was successfully intubated and a dose of intratracheal surfactant was given.

On 18-MAR-2016 (DOL #2), the subject developed increased oxygen requirement. A CXR was consistent with RDS so a second dose of intratracheal surfactant was given. At 23:18, laboratory tests showed anemia, with hemoglobin of 7.2 g/dL (reference range 14.5-22.5) and hematocrit of 22.0 % (reference range 45.0-67.0). The subject developed severe apnea, bradycardia and hypoxemia, the subject was re-intubated; however, intubation required 3 attempts. During intubation, blood was visualized in the oral cavity and bloody secretions in endotracheal tube; no blood, petechiae or purulent discharge was noticed on the vocal cords. Lung sounds were equal bilaterally, and a CXR was not suggestive of pulmonary hemorrhage. The subject was kept intubated, placed on high-frequency oscillatory ventilation (HFOV) and an additional dose of surfactant was given. The subject was transfused with packed red blood cells (PRBCs), fresh frozen plasma (FFP), and platelets. No further pulmonary bleeding was noted from the ETT tube. The bleeding was initially concerning for pulmonary hemorrhage and had been reported as a serious AE, but later was determined to be due to traumatic intubation and so the term was changed to “Laryngeal Trauma Due To Intubation”.

From 29-MAR-2016 (DOL #13) to 31-MAR-2016 (DOL #15), the subject was treated with indomethacin for PDA, and was NPO receiving TPN during treatment. On 31-MAR-2016 (DOL #15), the subject developed hypotension, pulmonary edema with respiratory failure requiring MV, and metabolic acidosis. The subject was found to have a large PDA (over half the size of the descending aorta) despite having been treated with indomethacin. The subject was placed on inotropic support and was deteriorating hemodynamically.

On 03-APR-2016 (DOL #18), the subject remained hypotensive on pressors and on HFOV, so PDA ligation was performed at the bedside on 04-APR-2016 (DOL #19). The left lung was

described by the cardiothoracic surgeons as hemorrhagic, possibly from the PDA or from the traumatic intubation. The subject's PDA resolved after ligation on the same day. Subsequently, the subject was stable on neutrally-activated ventilatory assistance (NAVA) and recovered from the PDA. The PDA had initially been reported as a serious AE, but was changed to a concurrent condition as PDA is a congenital condition which was present before the subject was enrolled.

On 22-APR-2016 (DOL #37), CXR/AXRs revealed no specific finding of NEC or bowel obstruction. On 23-APR-2016 (DOL #38), a CXR/AXR showed no radiological finding concerning for NEC, but an AXR later that same day showed nonspecific new focal gaseous distention of the left hemi abdominal bowel loops, with no intra-abdominal free air or portal venous gas.

On 24-APR-2016, the subject's AXR showed intra-abdominal free air, and a fixed, obstructive bowel gas pattern that also suggested the possibility of NEC. The subject was diagnosed with bowel perforation and a Penrose drain was placed surgically.

On 29-MAR-2016, the outcome of the event "laryngeal trauma due to intubation" was considered to be resolved. On 16-MAY-2016, outcome of the event bowel perforation was considered to be resolved.

Subject ID: 19004

ARISg ID#: DSC201611-000013

SAE: Necrotizing Enterocolitis, Severe Bradycardia

Subject 19-004 is a black male born at 27 1/7 weeks GA with BW 1.29 kg. The subject was randomized into the study on 27-SEP-2016 at 23:30 and was assigned to receive nCPAP only (control). Concomitant medications included budesonide, caffeine, cholecalciferol, magnesium hydroxide, calcium gluconate, and sodium chloride. The subject's relevant medical history included PDA, apnea of prematurity, persistent pulmonary hypertension of the newborn (PPHN), grade 1 IVH, and several congenital anomalies including dextrocardia with partial anomalous pulmonary venous return, congenital vertebral anomaly, congenital absence of rib, tethered cord, sacral agenesis, and hypospadias. The PDA and IVH were reported as non-serious AEs.

On 31-OCT-2016 (DOL #35), the subject experienced the life-threatening event of severe bradycardia. The same day, the subject experienced the non-serious AE of necrotizing enterocolitis, which became life-threatening on 01-NOV-2016 (DOL #36) and was upgraded to

serious. Both events were of severe intensity and were judged by the investigator as being not related to the study drug and not related to the study device.

On 31-OCT-2016 (DOL #35), the subject had been receiving special care feed (20 mL every 3 hours) via orogastric (OG) tube. That day in the morning, the subject developed abdominal distension and tenderness. A kidney, ureter and bladder X-ray (KUB) showed extensive pneumatosis intestinalis in the left side of abdomen, which worsened on repeat KUB a few hours later. Laboratory studies showed a mixed acidosis and a CBC that was initially normal but later showed a low WBC at 2.6 K/ μ L (reference range 6-17 K/ μ L) with elevated bands at 25% (reference range 0-9%) and low-normal platelet count at 194 K/ μ L. Blood and urine cultures were drawn. The subject was diagnosed with NEC.

Elective intubation was attempted. At 09:18 hours, the subject was noted to have chest wall rigidity after administration of a fentanyl bolus, which is an uncommon but reported adverse drug reaction of fentanyl. Despite PPV with FiO₂ 1.0, the subject's HR and SpO₂ fell. Two attempts at intubation were unsuccessful. The subject received naloxone, but HR continued to be dangerously low at 48. CPR was started at 09:24 while PPV with FiO₂ 1.0 continued. At 09:27, the subject was successfully intubated and CPR was stopped. At 09:30, the subject was placed on MV and vital signs returned to normal limits.

On 01-NOV-2016 (DOL #36), the subject was made NPO on TPN, an NG drainage (Replogle) tube was placed, and antibiotics were started with vancomycin and gentamicin. The subject received massive fluid resuscitation with crystalloid, colloid and PRBCs, and dopamine was started to maintain blood pressure. The subject's perfusion and acidosis worsened so resuscitation continued, hydrocortisone was started for hypotension, and the subject was changed from conventional MV to HFOV. Piperacillin-tazobactam was added and diuresis was begun with furosemide. That day, hypoglycemia, renal insufficiency and thrombocytopenia were reported as non-serious AEs. On 02-NOV-2016 (DOL #37), HFOV was felt to be unsuccessful so he was returned to conventional MV at high settings with improvement. The subject continued to receive blood products for anemia and thrombocytopenia. Additional antimicrobials were added with cefepime and metronidazole to treat NEC.

On 03-NOV-2016 (DOL #38), an exploratory laparotomy was performed due to the subject's extensive and ongoing inflammatory response. Half to three-quarters of the ileum and a small spot of jejunum were removed due to necrosis; the ileocecal valve was preserved. A loop jejunostomy and ileoileostomy were created. Resuscitation with crystalloid, colloid and blood products continued after surgery, requiring ongoing diuresis.

On 04-NOV-2016 (DOL #39), the subject developed DIC with excessive bleeding so phytomenadione was started. DIC was initially reported as a separate serious AE, but the Investigator later determined it was part of the event of Necrotizing Enterocolitis.

On 22-NOV-2016 (DOL #57), the non-serious AEs of adrenal insufficiency; intrahepatic cholestasis; pneumonias due to *Klebsiella pneumoniae*, *Proteus mirabilis*, and *Staphylococcus aureus*; and retinopathy of prematurity (ROP) were reported. On 28-NOV-2016 (DOL #63), the non-serious AEs of BPD and periventricular leukomalacia (PVL) were reported.

On 09-DEC-2016 (DOL #74), the subject was described as having short gut syndrome.

On 31-OCT-2016 (DOL #4), the event of severe bradycardia was considered resolved. On 21/Feb/2017 (DOL #148), the event of necrotizing enterocolitis was considered resolved with permanent sequelae.

Subject ID: 40001

ARISg ID#: DSC201605-000005

SAE: Spontaneous Intestinal Perforation

Subject 40-001 is an Asian male born at 27 1/7 weeks GA with BW 0.94 kg. The subject was randomized into the study on 04-MAY-2016 at 19:29, receiving a single study treatment of lucinactant for inhalation at 20:36 when he was approximately 8 hours old, which was well tolerated. Concomitant medications included caffeine, indomethacin, vancomycin, gentamicin and metronidazole.

On 07-MAY-2016 (DOL #4), the subject experienced the life-threatening event of spontaneous intestinal perforation, which was of severe intensity and was judged by the investigator as being unlikely related to the study drug and not related to the study device.

On 04-MAY-2016 (DOL #1) after resuscitation with bag-mask ventilation for 4 minutes, the subject's respirations were supported with nCPAP 8 cmH₂O with FiO₂ 0.21. At 13:51, when the subject was 1 hour old, he was initiated on donor human breast milk. After study consent was obtained, the subject was transitioned to bubble nCPAP at 6 cmH₂O with 0.28 FiO₂, which was reduced to 0.21 after study treatment.

On 05-MAY-2016 (DOL #2), FiO₂ was gradually increased to 0.29 and nCPAP to 8 cmH₂O by afternoon. At 16:00, the subject had yellow emesis but the belly was described as being clinically fine. The subject continued to have bilious gastric aspirates so at 22:00 was made NPO.

On 06-MAY-2016 (DOL #3), the subject's abdomen was described as slightly distended but soft. He continued to have some bilious gastric aspirates and stooling was stimulated with a glycerin suppository, but an AXR was felt to be reassuring so his feeds were continued. At 12:00, another AXR showed a suspicious shadow but no definite perforation.

On 07-MAY-2016 (DOL #4), the subject developed bilious aspirates, poor stooling and abdominal distension, but a clinical condition that was otherwise described as "pretty stable" on nCPAP. Laboratory studies showed a mild respiratory acidosis and normal WBC and CRP. The subject was made NPO and started on antimicrobials with vancomycin, gentamicin and metronidazole. An AXR at 11:20 revealed pneumoperitoneum without pneumatosis or signs of NEC. Per the site's standard practice, the subject was transferred to a separate medical center (Hospital for Sick Children, Toronto, ON, Canada) for further management, and was intubated electively for transport.

On 13-JUN-2016 (DOL #40), the event intestinal perforation was considered not resolved, since the outcome could not be determined after transfer to the separate medical center and no further information was expected.

Subject ID: 40015

ARISg ID#: DSC201701-000002

SAE: Intraventricular Hemorrhage

Subject 40-015 is an Asian female born at 26 4/7 weeks GA with BW 0.760 kg. The subject was randomized into the study on 03-JAN-2017 at 15:30, receiving the initial study treatment of lucinactant for inhalation 100 mg TPL/kg at 16:37 when she was approximately 4 hours old, which was well tolerated. The subject received a repeat study treatment on 03-JAN-2017 at HH:MM. Concomitant medications included caffeine, probiotic, cholecalciferol, elemental iron and sodium chloride.

On 23-JAN-2017, the subject experienced the important medical event of intraventricular hemorrhage, which was of severe intensity and was judged by the investigator as being unlikely related to the study drug and not related to the study device.

On 03-JAN-2017 (DOL #1), the subject was born with Apgar scores of 7 and 9 at 1 and 5 minutes of life (respectively) and birth with good tone; however, some bruising was noticed on the trunk due to difficult delivery. The subject responded well to initial resuscitation with bag and mask, and was then placed on bubble nCPAP. Over the next several hours, she required increased oxygen so she was intubated; intubation required approximately 4 attempts. She was

given intratracheal surfactant at 18 hours of life. On 04-JAN-2017 (DOL #2), she was extubated to nCPAP. On 05-JAN-2017 (DOL #5), non-serious AEs of intermittent apnea, intermittent bradycardia, intermittent desaturation, and profound apnea episode were reported.

On 06-JAN-2017 (DOL #4), the subject required increased nCPAP settings and developed apnea so was intubated and placed on HFOV. That day, a routine cranial ultrasound was done, which revealed bilateral sub-ependymal hemorrhages, with a large IVH on the right and smaller IVH on left. On 13-JAN-2017 (DOL #11), a repeat cranial ultrasound revealed a large IVH with some mild ventriculomegaly and possible increased echogenicity in parenchyma.

On 23-JAN-2017 (DOL #21), a repeat cranial ultrasound revealed severe bilateral ventriculomegaly with a small parenchymal periventricular cyst suggestive of periventricular leukomalacia. The subject was described as otherwise stable on nCPAP for apnea of prematurity. That day, the event was reported as a serious AE because of the severe ventriculomegaly, which was presumed to be a consequence of the initial IVH detected on 06-JAN-2017 (DOL #4) and which carried risks of requiring surgical intervention or neurodevelopmental sequelae.

On 13-MAR-2017 (DOL #70), a cranial ultrasound showed improved ventriculomegaly, and the event of intraventricular hemorrhage was considered resolved.

Subject ID: 50001

ARISg ID#: DSC201609-000011

SAE: Respiratory Failure

ARISg ID#: DSC201611-000014

SAE: Respiratory Failure

Subject 50-001 is a white female born at 26 2/7 weeks GA with BW 0.72 kg. The subject was randomized into the study on 28-SEP-2016 at 14:17, receiving the initial study treatment of lucinactant for inhalation 75 mg TPL/kg at 15:20 when she was approximately 4.5 hours old, which was well tolerated. The subject received a repeat study treatment at 19:14. Concomitant medications at the time of the first event included ampicillin/sulbactam, gentamicin, and caffeine; and at the time of the second event included caffeine, Nystatin, cholecalciferol, phytomenadione, and probiotic.

On 28-SEP-2016 (DOL #1), the subject experienced the important medical event of respiratory failure, which was of moderate severity and was judged by the investigator as being unlikely related to the study drug and not related to the study device. On 13-OCT-2016 (DOL #16), the subject experienced a second important medical event of Respiratory Failure, which was of

moderate severity and was judged by the investigator as being not related to the study drug and not related to the study device.

On 28-SEP-2016 (DOL #1), the subject was born via caesarian delivery and was placed on nCPAP with FiO₂ 0.3. After receiving 2 doses of study drug, the subject's FiO₂ increased to 0.5. The subject was intubated, placed on MV and given a dose of intratracheal surfactant, after which FiO₂ was reduced to 0.21. No CXR was performed prior to intubation as the Investigator felt it would take too much time; however, a post-surfactant CXR showed no air leak. Antibiotics were started with ampicillin/sulbactam and gentamicin for the suspicion of inborn infection.

Over the next days, FiO₂ and MV parameters were gradually reduced, and the subject was extubated to NIV on 03-OCT-2016 (DOL #6). On 04-OCT-2016 (DOL #7), gentamicin was stopped. The subject was treated with ibuprofen due to PDA.

On 13-OCT-2016 (DOL #16), the subject developed apneas and was intubated, after which the subject's condition stabilized and FiO₂ was reduced to 0.21. Laboratory tests showed an increased CRP at 3.04 mg/dL (reference range <1.0 mg/dL) and respiratory acidosis. A blood culture was drawn, which subsequently grew *Staphylococcus haemolyticus*, and cultures of endotracheal tube discharge grew *Enterococcus faecalis*, *Klebsiella oxytoca* and coagulase negative *Staphylococcus*. The same day, non-serious AEs of bacteremia and IVH were reported.

On 02-NOV-2016 (DOL #36), a non-serious AE of nosocomial infection was reported. Ampicillin/sulbactam was discontinued on 03-NOV-2016 (DOL #37).

On 03-OCT-2016 (DOL #6), the first event of respiratory failure was considered to be resolved. On 23-OCT-2016 (DOL #26), the second event of respiratory failure was considered to be resolved.

Subject ID: 51004

ARISg ID#: DSC201611-000012

SAE: Respiratory Failure, Ventilator-Associated Pneumonia

Subject 51-004 is a white male born at 28 6/7 weeks GA with BW 0.935 kg. The subject was randomized into the study on 26-JUL-2016, receiving the initial study treatment of lucinactant for inhalation 75 mg TPL/kg at 14:10 when he was approximately 3.5 hours old, which was well tolerated. The subject received a repeat study treatment at 17:52. Concomitant medications at the time of the first event included caffeine and phytomenadione, and at the time of the second event included caffeine, spironolactone, ibuprofen, morphine and TPN.

On 26-JUL-2016 (DOL #1), the subject experienced the important and life-threatening medical event of respiratory failure. On 03-AUG-2016 (DOL #9), the subject experienced the important medical event of ventilator-associated pneumonia. Both events were of moderate severity and were judged by the investigator as being not related to the study drug and not related to the study device

On 26-JUL-2016 (DOL #1), 2 hours after study drug administration, the subject developed worsening respiratory insufficiency with increased oxygen requirement and respiratory effort. At 20:20, the subject was intubated, placed on MV, and given intratracheal surfactant. Following surfactant treatment, FiO₂ was reduced to 0.21; however, the subject remained on MV due to worsening respiratory parameters.

On 31-JUL-2016 (DOL #6), a non-serious AE of PDA was reported, and the subject was started on ibuprofen.

On 01-AUG-2016 (DOL #7), the subject was described as unstable, with increasing need for oxygen due to desaturations. A CXR showed inflammatory changes, and CBC and CRP were normal. Antibiotics were started with vancomycin and piperacillin/tazobactam. A bronchoalveolar lavage (BAL) was performed, and cultures subsequently grew $>5 \times 10^4$ CFU of *Staphylococcus haemolyticus*.

After a few days of treatment with antibiotics, the subject was improved. A BAL on 08-AUG-2016 (DOL #14) grew no bacteria. Antibiotics were stopped after 14 days. On 02-SEP-2016 (DOL #39), the subject was breathing spontaneously without support.

On 17-AUG-2016 (DOL #23), the event ventilator-associated pneumonia was considered to be resolved. On 03-SEP-2016 (DOL #40), the event respiratory failure was considered to be resolved.

Subject ID: 54017

ARISg ID#: DSC201702-000003

SAE: Pneumonia, Apneas

ARISg ID#: DSC201702-000004

SAE: Anaemia

ARISg ID#: DSC201702-000005

SAE: Respiratory Distress Syndrome Need of Surfactant Administration

Subject 54-017 is a white female born at 28 1/7 weeks GA with BW 0.87 kg. The subject was randomized into the study on 25-NOV-2016 at 17:21 and was assigned to receive nCPAP only (control).

On 26-NOV-2016 (DOL #2), the subject experienced the event of “respiratory distress syndrome need of surfactant administration,” which was of severe intensity and caused persistent or significant disability. On 07-DEC-2016 (DOL #13), the subject experienced the important medical event of apneas which was of moderate severity. On 12-DEC-2016 (DOL #18), the subject experienced the event of pneumonia, which was moderate severity and caused persistent or significant disability. On 13-DEC-2016 (DOL #19), the subject experienced the event of anaemia, which was of moderate severity and caused persistent or significant disability. All events were judged by the investigator as being not related to the study drug and not related to the study device.

On 26-NOV-2016 (DOL #2), the subject experienced worsening respiratory effort and required $FiO_2 >0.4$. The subject’s CXR was consistent with RDS. The subject was intubated and given intratracheal surfactant.

On 27-NOV-2016 (DOL #3), a non-serious AE of apneas of mild severity was recorded. On 28-NOV-2016 (DOL #4), a non-serious AE of PDA of moderate severity was recorded. On 07-DEC-2016 (DOL # 13), the subject developed apneas and so was intubated and placed on MV. On that date, the AE of apneas was upgraded to serious. She remained on MV for 5 days and received no other medication for the treatment. She was extubated on 10-DEC-2016 (DOL #16). Another non-serious AE of apneas of mild severity was recorded on 15-DEC-2016 (DOL #21).

On 12-DEC-2016 (DOL #18), the subject developed worsening of breathing and was intubated and antibiotics were started with gentamicin and vancomycin. The subject’s CRP was increased to 41 mg/dL (reference range: 0-5 mg/dL). Secretions from respiratory tract were cultured and subsequently grew *Klebsiella pneumonia*. The subject was diagnosed with ventilator-associated

pneumonia. The subject was treated with gentamicin and vancomycin until 14-DEC-2016 (DOL #20), and with piperacillin/tazobactam from 15-DEC-2016 (DOL #21) to 22-DEC-2016 (DOL #28).

On 13-DEC-2016 (DOL #19), the subject was found to anemic with a hemoglobin that was low at 8.8 g/dL (reference range: 10-14 g/dL), so she was transfused with PRBCs. Medical therapy for anemia was started with iron on 24-DEC-2016 (DOL #30) and with erythropoietin on 26-DEC-2016 (DOL #32). On 30-DEC-2016 (DOL #36), the subject's hemoglobin was again low at 8.1 g/dL so another transfusion with PRBCs was given. On 25-JAN-2017 (DOL #62), the subject's hemoglobin and hematocrit were normal at 10.6 g/dL and 30.7 %, respectively. On 19-JAN-2017 (DOL #55), when the subject had reached 36 weeks PMA, the hemoglobin and hematocrit were normal at 11.4 g/dL and 35.3 %, respectively.

On 26-NOV-2016 (DOL #2), the event “respiratory distress syndrome need of surfactant administration” was considered to be resolved. On 10-DEC-2016 (DOL #16), the event apneas was considered to be resolved. On 22-DEC-2016 (DOL #28), the event pneumonia was considered to be resolved. The event anaemia was considered to be continuing at the end of the study.

Subject ID: 76002

ARISg ID#: DSC201612-000017

SAE: Pneumothorax

ARISg ID#: DSC201612-000018

SAE: Intraventricular Hemorrhage

ARISg ID#: DSC201701-000001

SAE: Refractory Shock

Subject 76-002 is a Hispanic male born at 26 2/7 weeks GA with BW 1.025 kg. The subject was randomized into the study on 20-DEC-2016 at 23:36 and was assigned to receive nCPAP only (control). Concomitant medications at the time of the first event included aminophylline, phytomenadione, ampicillin, and amikacin; at the time of the second event also included penicillin, TPN, fentanyl, dopamine and insulin; and at the time of the third event included aminophylline, penicillin, cefazolin, phenobarbital, phenytoin and midazolam.

On 21-DEC-2016 (DOL #2), the subject experienced the life-threatening event of pneumothorax. On 22-DEC-2016 (DOL #3), the subject experienced the life-threatening event of intraventricular hemorrhage, which also prolonged hospitalization and was associated with persistent or significant disability. On 30-DEC-2016 (DOL #11), the subject experienced the

important and life-threatening event of refractory shock, which was also associated with persistent or significant disability. All events were of severe intensity and were judged by the investigator as being not related to the study drug and not related to the study device.

On 20-DEC-2016 (DOL #1), the subject was born in a good condition via emergency cesarean section due to breech presentation. The reason for preterm labor was unknown, but congenital infection was suspected. The subject's mother had a negative venereal disease research laboratory test (VDRL) test, 3 months prior to delivery. However, the intrapartum VDRL test was reported positive after enrollment, at approximately 17 hours of life. The subject was treated with penicillin from 22-DEC-2016 to 02-JAN-2017 (DOL #3 to #14) for probable congenital syphilis; however, the definite confirmation of congenital syphilis is done by a committee of specialists of the regional health service, which meets twice a year and had not yet met at the time of this report.

After birth, the subject was diagnosed with RDS and stabilized on conventional nCPAP at 6 cmH₂O with FiO₂ 0.30. At 58 min of life, the subject was switched from conventional nCPAP to bubble nCPAP with the same settings. Empiric antibiotics were started with ampicillin and amikacin, and apnea of prematurity was treated empirically with aminophylline. The subject was found to be coagulopathic, with prolonged PT of 23.5 sec (reference range: 12.8-17.4 sec) and aPTT of 82.8 sec (reference range: 23.6-35 sec), and anemic with a low hematocrit of 41% (reference range: 45-71%); coagulopathy and anemia were both reported as non-serious AEs. The subject was given phytonadione and was transfused with FFP.

On 21-DEC-2016 (DOL #2) in the morning, the subject developed progressive respiratory deterioration, with tachypnea, retractions, and increased FiO₂ to 0.50. nCPAP was increased to 7 cmH₂O without any improvement, and breath sounds were found to be unequal. At 11:20, the subject was intubated and placed initially on conventional MV but escalated to HFOV with FiO₂ 1.0. CXR prior to intubation was not possible due to the subject's condition, but a post-intubation CXR showed a right pneumothorax. At 13:00, needle decompression of the chest was performed and a chest tube was placed, which resulted in stabilization of the subject's clinical condition. The subject was given 3 doses of intratracheal surfactant. The same day, pulmonary hypertension of moderate severity was reported as a non-serious AE. On 28-DEC-2016 (DOL #9), a non-serious AE of PIE of moderate severity was reported; no specific treatment was described.

On 22-DEC-2016 (DOL #3), the subject remained anemic with a low hematocrit of 26%, and was also found to have thrombocytopenia (reported as a non-serious AE) with a low platelet count of 105 ×10³/μL (reference range: 150-550 ×10³/μL). At 20:40, the subject developed

“hugging” movements of the extremities with EEG tracing consistent with seizure (reported as a non-serious AE), so was treated with a dose of phenobarbital. At 23:15, the subject experienced a non-clinical seizure, so was treated with a second dose of phenobarbital, which stopped the seizure at 23:30. The subject was diagnosed with convulsive syndrome which in conjunction with the new anemia was suspected to be secondary to intracranial hemorrhage. Penicillin was started for probable congenital syphilis as described above, and dopamine was started for hypotension (reported as a non-serious AE), which was stopped on 26-DEC-2016 (DOL #7).

On 24-DEC-2016 (DOL #5), a non-serious AE of renal insufficiency of mild severity was reported. On 27-DEC-2016 (DOL #8), the subject was initiated on therapy with cefazolin for uroprophylaxis. The subject subsequently had 2 non-serious AEs of urinary tract infection of moderate severity, reported on 09-JAN-2017 (DOL #21) and 22-JAN-2017 (DOL #34).

On 26-DEC-2016 (DOL # 7), a cranial ultrasound showed a grade IV IVH on the left and grade III on the right with moderate mass effect. On 27-DEC-2016 (DOL #8), his phenobarbital level was high at 80.9 µg/mL (reference range: 15-40 µg/mL), which was reported as a non-serious AE. On 28-DEC-2016 (DOL #9), antiepileptic therapy was started with phenytoin and midazolam. His sodium level was found to be extremely low at 117 mEq/L (reference range: 135-145 mEq/L) treated?. On 29-DEC-2016 (DOL #10), antiepileptic therapy was started with phenobarbital. An additional non-serious AE of seizure was reported on 06-JAN-2017 (DOL #18).

On 30-DEC-2016 (DOL #11) at 00:00, the subject developed hypotension and metabolic acidosis. He was fluid resuscitated, placed on HFOV with FiO₂ 1.0, and started on inotropic and corticosteroid support. At 12:20, the subject had a pulmonary hemorrhage and cardiorespiratory arrest that responded to 3 minutes of cardiac massage with 1 dose of epinephrine. Laboratory tests showed an elevated glucose of 390 mg/dL (reference range: 50-60 mg/dL) and lactic acid of 29.4 mg/dL (reference range: 4.0-19.8 mg/dL), which is common after cardiac arrest. A blood culture was drawn which did not grow any bacteria.

On 02-JAN-2017 (DOL #14), the subject’s hemodynamics improved and vasoactive drugs were weaned. On 03-JAN-2017 (DOL #15), he had adequate hemodynamics and diuresis, and no acidosis while on MV so vasoactive support was stopped.

On 21-DEC-2016 (DOL #2), the event pneumothorax was considered to be resolved. On 03-JAN-2017 (DOL #15) the event refractory shock was considered to be resolved. On 12-JUN-2017 (DOL #175), the event intraventricular hemorrhage was considered to be not resolved at 36 weeks of gestational age.

14.3.4 Abnormal Laboratory Value Listing (Each Subject)

Not applicable.

15. REFERENCE LIST

1. Soll RF, Merritt TA, Hallman M. Surfactant in the prevention and treatment of respiratory distress syndrome. In Boynton BR, Carlo WA, Jobe AH, editors. *New Therapies for Neonatal Respiratory Failure; A Physiological Approach*. Cambridge: Cambridge University Press; 1994. p. 49-80.
2. Engle WA; American Academy of Pediatrics Committee on Fetus and Newborn. Surfactant-replacement therapy for respiratory distress in the preterm and term neonate. *Pediatrics*. 2008; 121(2): p. 419-432.
3. Vermont Oxford Network. Annual VLBW Database Summary 2002. 2003.
4. AARC Clinical Practice Guidelines. Application of continuous positive airway pressure to neonates via nasal prongs, nasopharyngeal tube, or nasal mask - 2004 revision and update. *Respiratory Care*. 2004; 19(9): p. 1100-1108.
5. Lewis JF, Ikegami M, Jobe AH, Absolom D. Physiologic responses and distribution of aerosolized surfactant (Survanta[®]) in a nonuniform pattern of lung injury. *Am Rev Respir Dis*. 1993; 147(6 pt 1): p. 1364-1370.
6. Gaon P, Lee S, Hannan S, Ingram D, Milner AD. Assessment of effect of nasal continuous positive pressure on laryngeal opening using fibre optic laryngoscopy. *Arch Dis Child Fetal Neonatal Ed*. 1999; 80(3): p. F230-F232.
7. Subramaniam P, Ho JJ, Davis PG. Prophylactic nasal continuous positive airways pressure for preventing morbidity and mortality in very preterm infants. *Cochrane Database Syst Rev*. 2016;(6).
8. Morley, CJ; Davis, PG; Doyle, LW; Brion, LP; Hascoet, JM; Carlin, JB; COIN Trial Investigators. Nasal CPAP or intubation at birth for very preterm infants. *N Engl J Med*. 2008 Feb 14; 358(7): p. 700-708.
9. Arroe M, Pedersen-Bjergaard L, Albertsen P, Bode S, Greisen G, Jonsbo F, et al. Inhalation of aerosolized surfactant (Exosurf[®]) to neonates treated with nasal continuous positive airway pressure. *Prenat Neonat Med*. 1998; 3: p. 346-352.
10. Wiswell TE, Knight GR, Finer NN, Donn SM, Desai H, Walsh WF, et al. A multicenter, randomized, controlled trial comparing Surfaxin (lucinactant) lavage with standard of care for treatment of meconium aspiration syndrome. *Pediatrics*. 2002; 109(6): p. 1081-1087.

11. Wiswell TE, Smith RM, Katz LB, Mastroianni L, Wong DY, Willms D, et al. Bronchopulmonary segmental lavage with Surfaxin (KL₄-surfactant) for acute respiratory distress syndrome. *Am J Respir Crit Care Med.* 1999; 160(4): p. 1188-1195.
12. Mazela J, Merritt TA, Finer NN. Aerosolized surfactants. *Curr Opin Pediatr.* 2007; 19(2): p. 155-162.
13. Bide RS, Armour S, Yee E. Allometric respiration/body mass data for animals to be used for estimates of inhalation toxicity to young adult humans. *J Appl Tox.* 2000; 20(4): p. 273-290.
14. Bhutani VK, Sivieri EM. Pulmonary function and graphics. In Goldsmith JP, Karotkin EH, editors. *Assisted Ventilation of the Neonate.* 4th ed.: Saunders; 2003.

APPENDICES

16.1 Study Information

16.1.1 Protocol, Protocol Amendments, and ADS Operator's Manual

The original protocol, protocol amendment and change document are provided.

The ADS Operator's Manual (instructions for use) is provided.

16.1.2 Sample Case Report Form

A sample case report form is provided.

16.1.3 List of Independent Ethics Committees or Institutional Review Boards and Representative Written Information for Patient and Sample Consent Form

The names and addresses of participating Institutional Review Boards, Ethics Committees and Research Ethics Boards are provided in Appendix 16.1.4. Copies of the sample informed consent forms used during the study are provided.

16.1.4 List and Description of Investigators and Other Important Participants in the Study, Including Curricula Vitae

The list of investigators and sites are provided. Curricula vitae (CVs) for each Principal Investigator are also provided. CVs for sub-investigators are available upon request.

The list of names and address of any third parties (eg, CROs, consultants, contractors) that contributed to the clinical investigation and a list of monitors is also provided.

16.1.5 Signatures of Principal or Coordinating Investigator(s) and Sponsor's Responsible Medical Officer

The signatures of the sponsor's responsible medical officer and coordinating investigator are provided.

16.1.6 Listing of Patients Receiving Test Drug(s)/Investigational Product(s) From Specific Batches, Where More Than One Batch was Used

Two batches of lyophilized lucinactant (Lots G15001 and G15003) were used for this study. A list of patients and batches used for the study is provided.

16.1.7 Randomization Scheme and Codes

The randomization scheme and codes are provided.

16.1.8 Audit Certificates, if Available

Not applicable.

16.1.9 Documentation of Statistical Methods

The final statistical analysis plan is provided.

16.1.10 Documentation of Interlaboratory Standardization Methods and Quality Assurance Procedures, if Used

Not Applicable.

16.1.11 Publications Based on the Study

None.

16.1.12 Important Publications Referenced in the Report

All referenced publications are provided.

16.2 Patient Data Listings

All data are provided electronically in Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) format.

16.3 Case Report Forms

The CRFs for subjects who died and/or who had an SAE are provided. No subjects withdrew from the study due to an adverse event.

16.4 Individual Patient Data Listings

All data are provided electronically in CDISC SDTM format.