

Clinical trial results:

A Phase 3, Randomized, Double-blind, Active Comparator-controlled, Multicenter Clinical Study to Evaluate the Safety, Tolerability, and Immunogenicity of V114 in Recipients of Allogeneic Hematopoietic Stem Cell Transplant (PNEU-STEM)

Summary	
Results information	
Trial information	
Trial identification	
Additional study identifiers	
Sponsors	
Paediatric regulatory details	

Results analysis stage	
General information about the tri	al
Population of trial subjects	
Subjects enrolled per country	
Subjects enrolled per age group	

Subject disposition Recruitment **Pre-assignment** Period 1 **Arms Arm title** Arm title

Number of subjects in period 1	

Reporting groups Reporting group values

Baseline characteristics

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End points End points reporting groups Primary: Adult Participants: Percentage of Participants With a Solicited Injection-site Adverse Event Following Any of the First 3 Doses With V114 or Prevnar 13™

End point values				
Statistical analyses				
Primary: Pediatric Participants: F	Percentage of	Darticinante	With a Solici	ted
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Primary: Adult Parti Adverse Event Follo	icipants: Percei	ntage of Pa e First 3 Do	rticipants Wit ses With V11	h a Solicited 4 or Prevnar	Systemic 13™
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Statistical analyses					
Primary: Pediatric P	Participants: Pe	rcentage of	Participants	With a Solici	ted Syste
Adverse Event Follo	wing Any of the	e First 3 Do	ses With V11	4 or Prevnar	13™
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Statistical analyses

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End point values				
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Statistical analyses				
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Up to Month 12 After Allogeneic	nts With a Va	ccine-related	Serious Adve	erse Event

Statistical analyses				
Primary: Geometric Mean C G (IgG) at 30 Days Followii	Concentration ng Dose 3 W	n (GMC) of S ith V114 or I	erotype-spec Prevnar 13™	ific Immunoglobuli (Day 90)
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End point values				
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Statistical analyses				
Statistical analyses				
Secondary: Adult Participants: Po	ercentage of	Participants V	Vith a Solicite	ed Injection-
site Adverse Event Following Vac	cination With	PNEUMOVA	८™23	
End point values				
Statistical analyses				
Secondary: Pediatric Participants	s: Percentage	of Participan	ts With a Sol	icited

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Statistical analyses							
Secondary: Pediatric Participants	s: Percentage	of Participan	ts With a Sol	icited			
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30 Days Following Dose 3 With \	/114 or Prevn	ar 13™ (Day	90)	c Activity de
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End point values				
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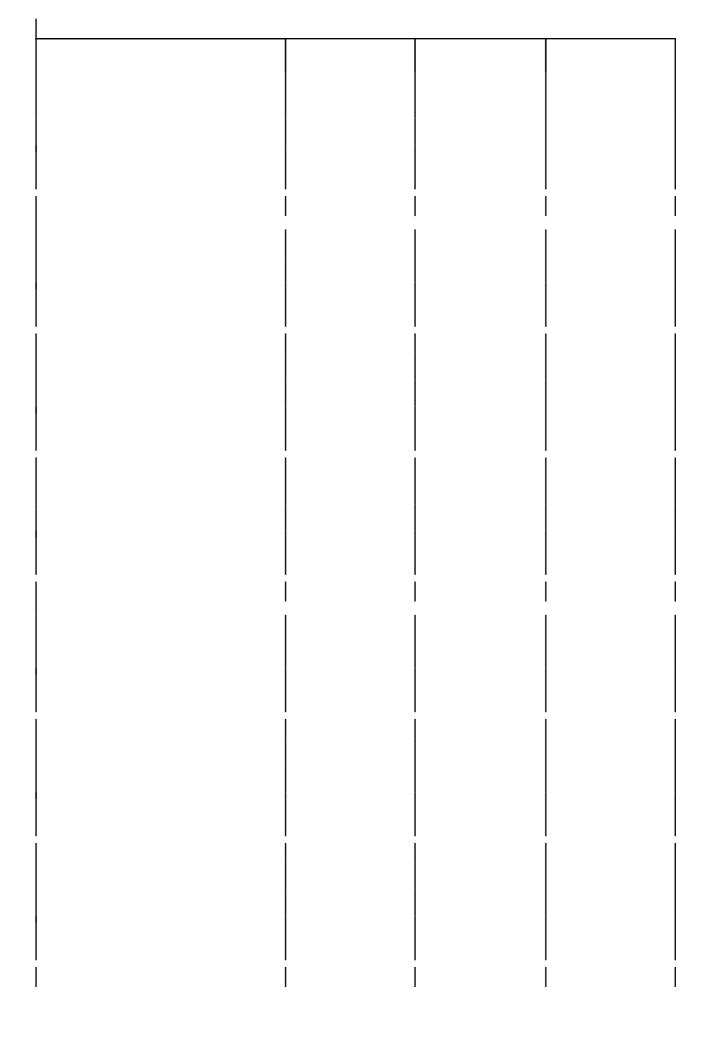
Statistical analyses							
Secondary: Percentage of Participants With Geometric Mean Fold Rises (GMFR) ≥4 in Serotype-specific IgG at 30 Days Following Dose 3 With V114 or Prevnar 13™							
in Serotype-specific IgG at 30 Da	pants With G ys Following	eometric Mea Dose 3 With	n Fold Rises V114 or Prev	(GMFR) ≥4 nar 13™			
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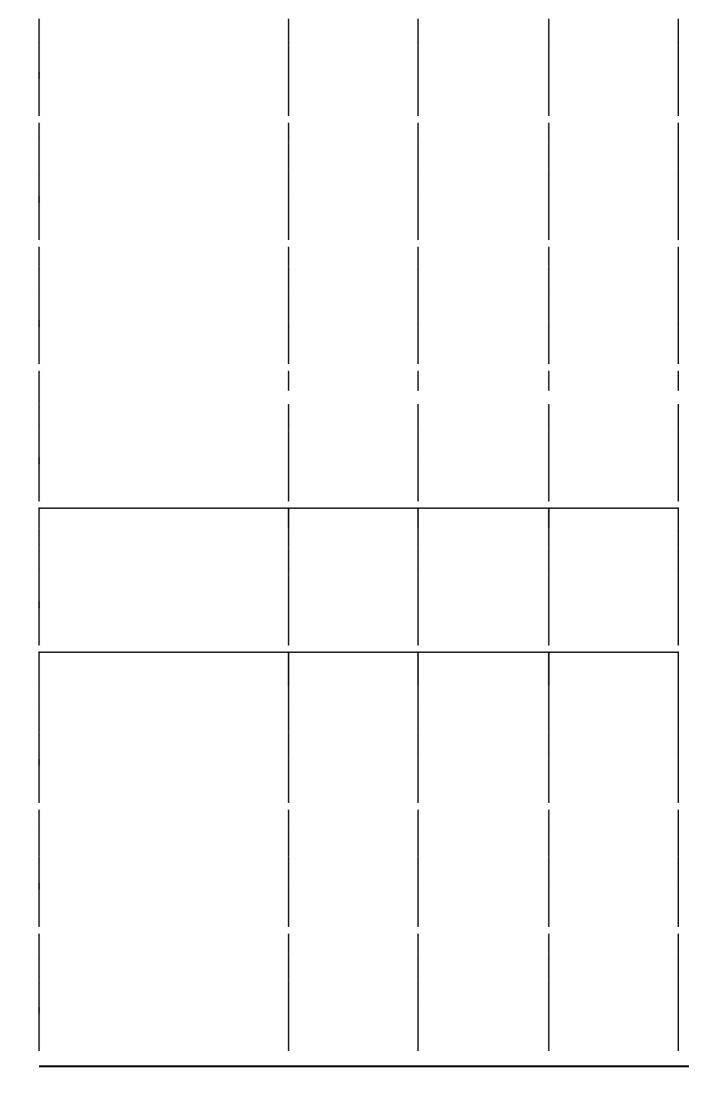
Statistical allalyses				
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	ipants With G 4 or Prevnar	MFR ≥4 in Se 13™ (Day 90)	rotype-specif	ic OPA at 30
	ipants With G 4 or Prevnar	MFR ≥4 in Se 13™ (Day 90)	rotype-specif	ic OPA at 30
	ipants With G 4 or Prevnar	MFR ≥4 in Se 13™ (Day 90)	rotype-specif	ic OPA at 30
	ipants With G 4 or Prevnar	MFR ≥4 in Se 13™ (Day 90)	rotype-specif	ic OPA at 30
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	ipants With G 4 or Prevnar	MFR ≥4 in Se 13™ (Day 90)	rotype-specif	ic OPA at 30
Secondary: Percentage of Partic Days Following Dose 3 With V11	ipants With G	MFR ≥4 in Se 13™ (Day 90)	rotype-specif	ic OPA at 30
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	ipants With G	MFR ≥4 in Se 13™ (Day 90)	rotype-specif	ic OPA at 30

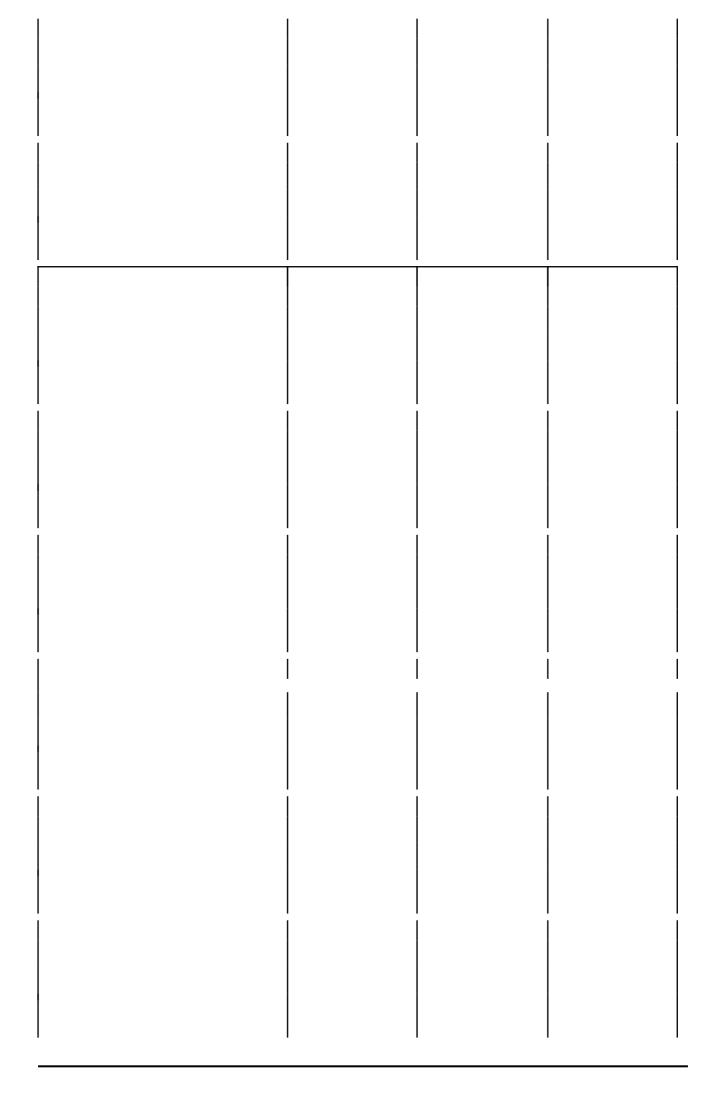
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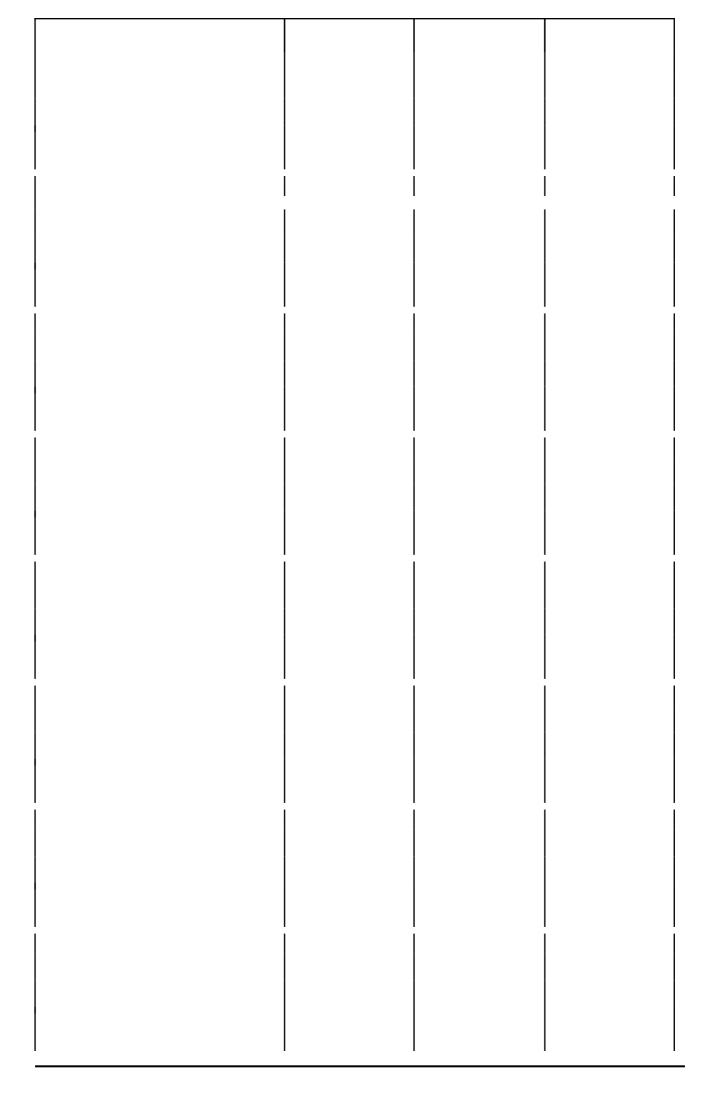
Statistical analyses		

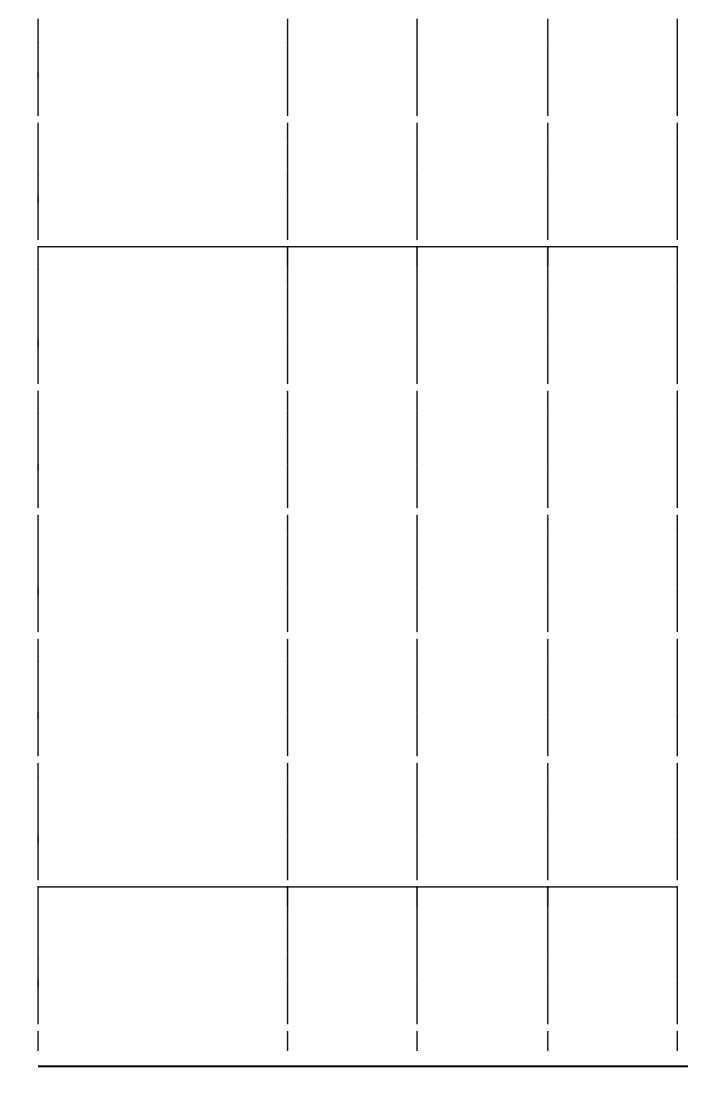
Adverse events Adverse events information Dictionary used Reporting groups Serious adverse events

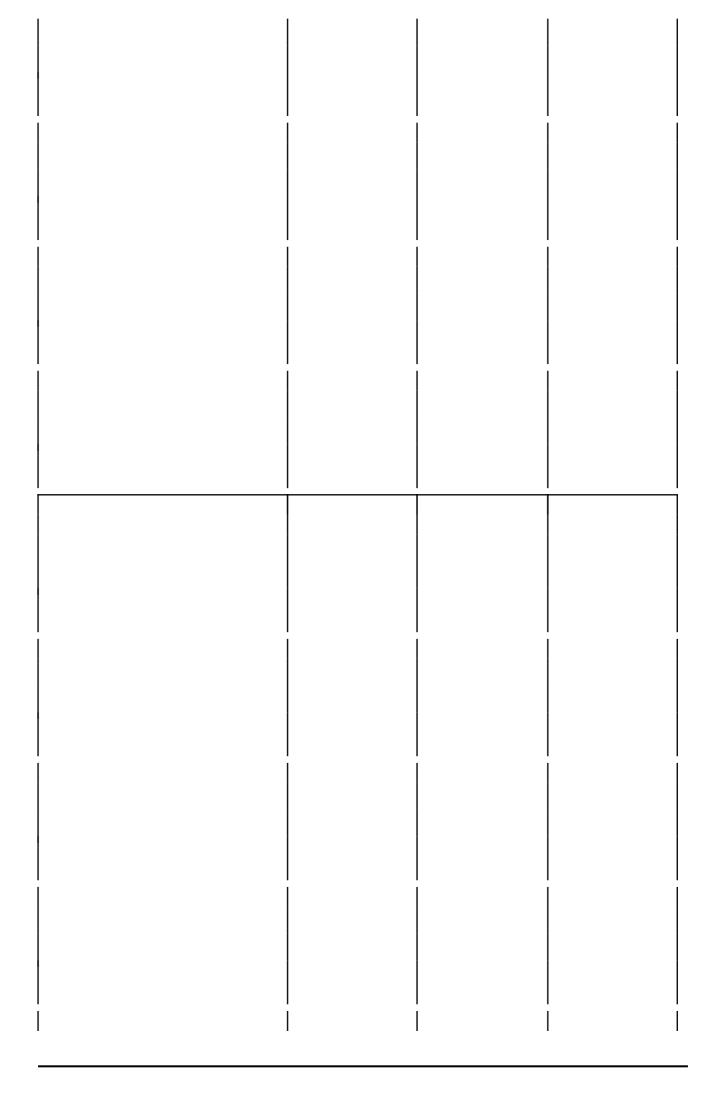


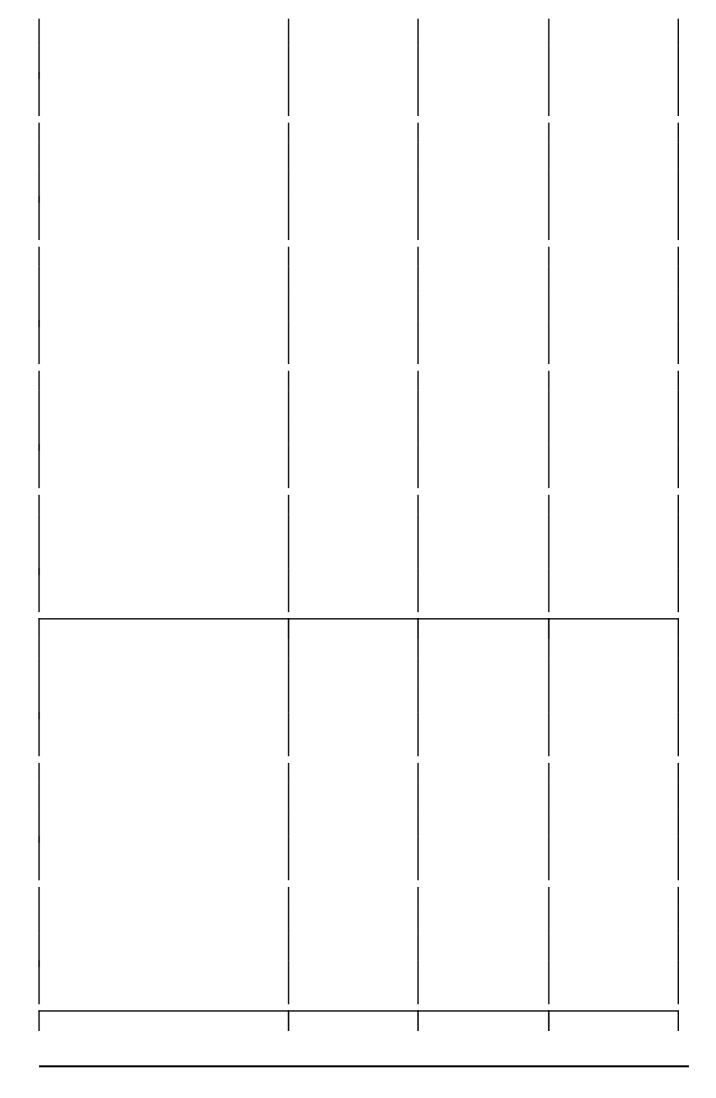


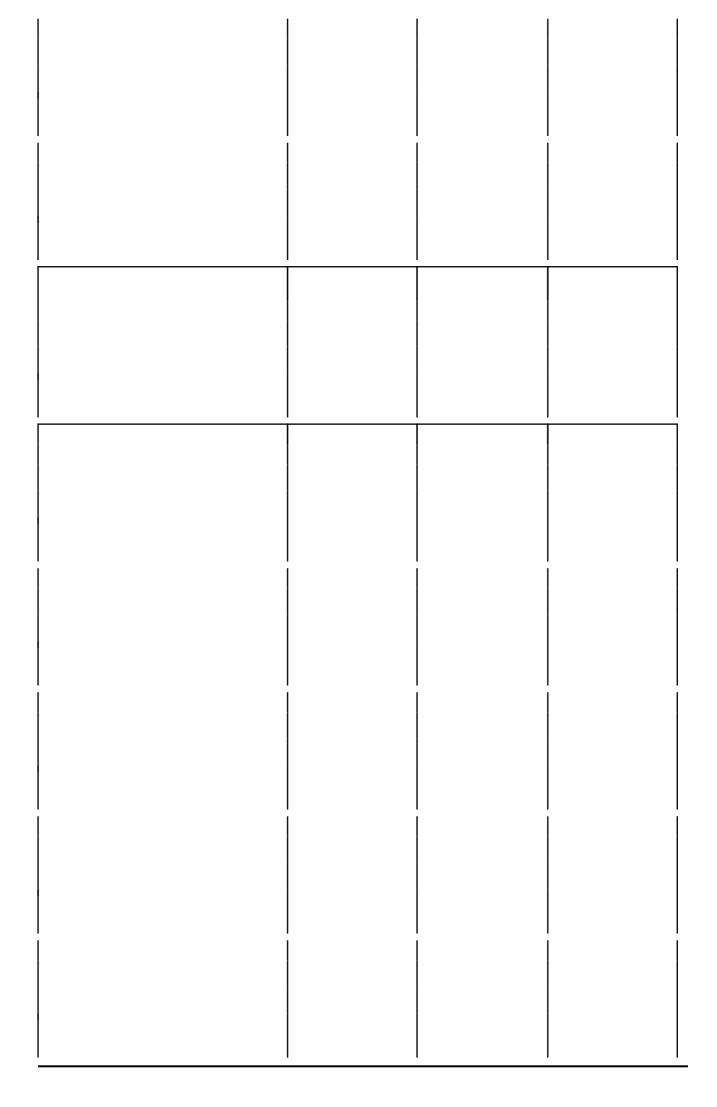


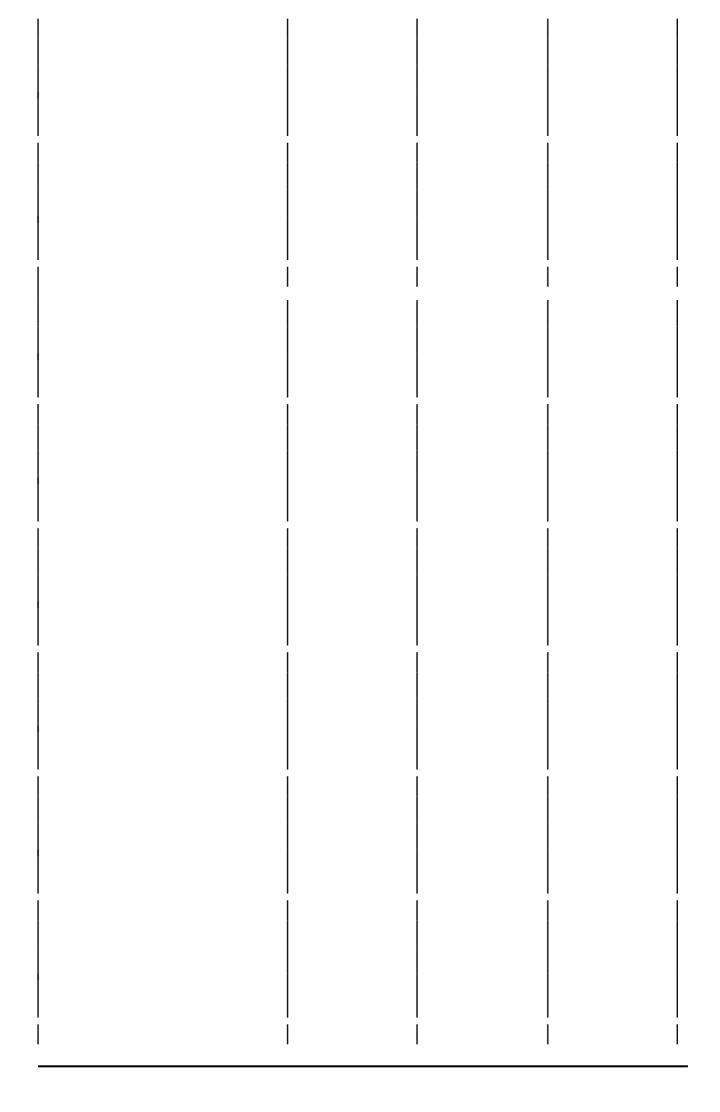


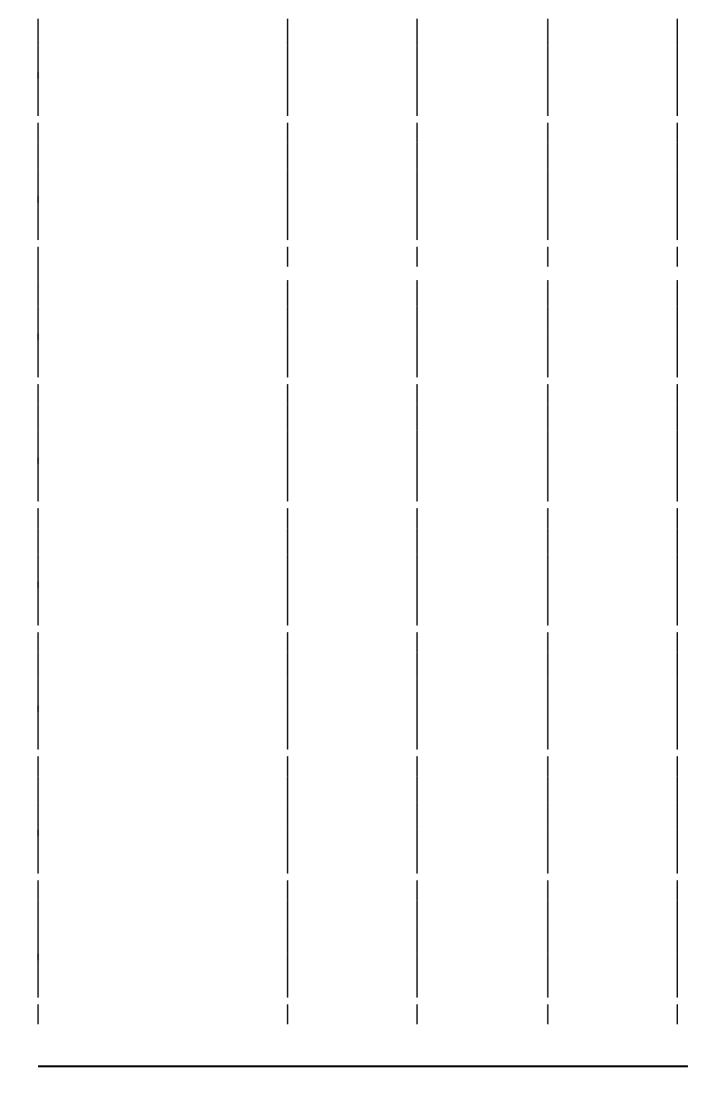


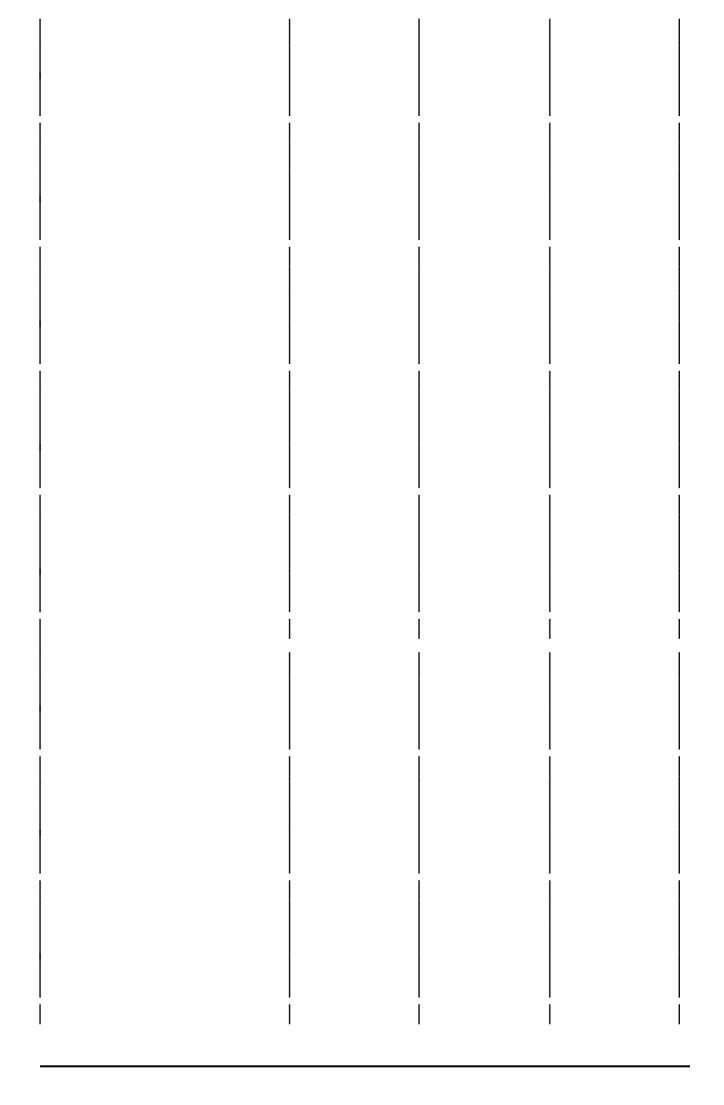




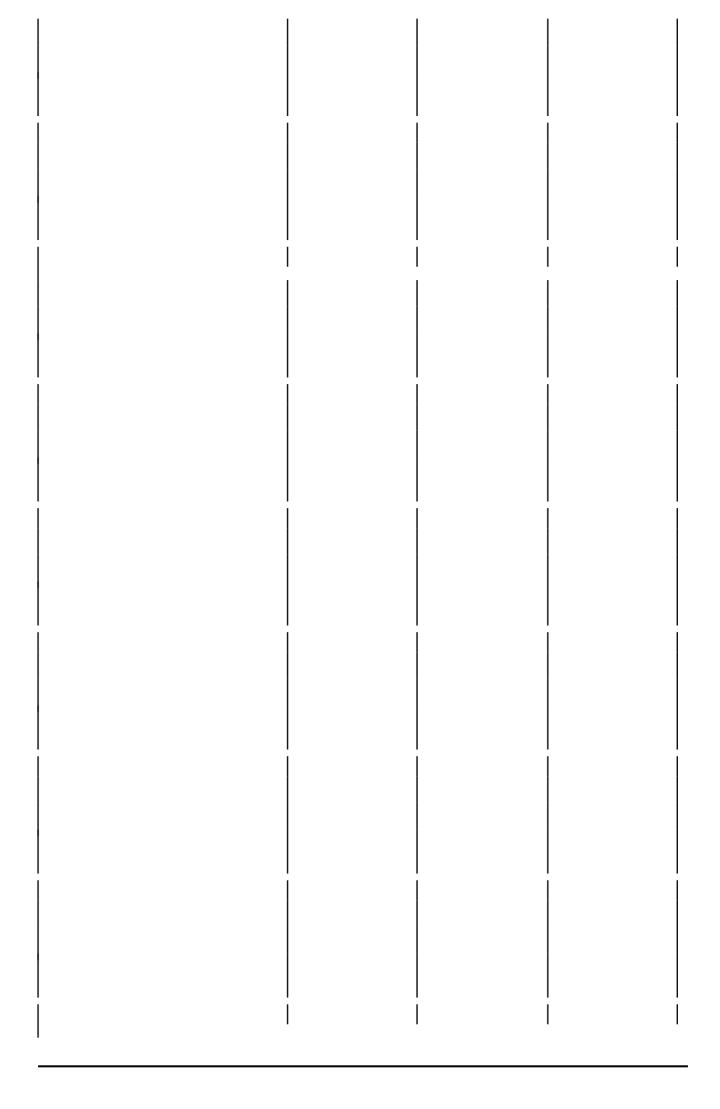


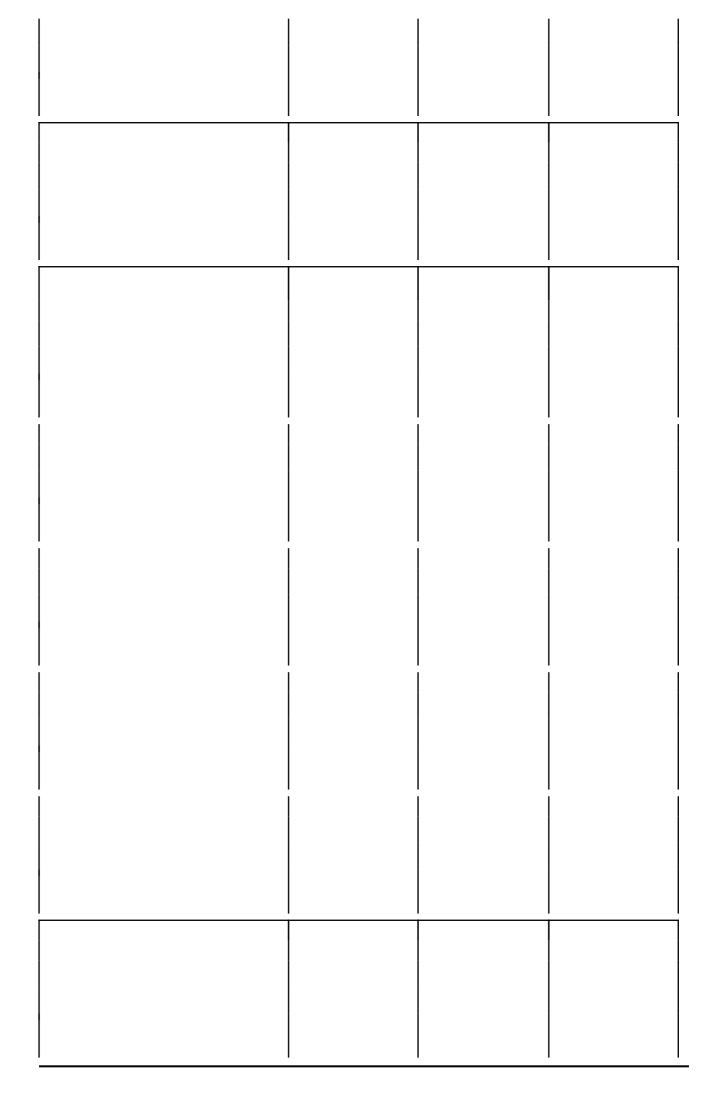


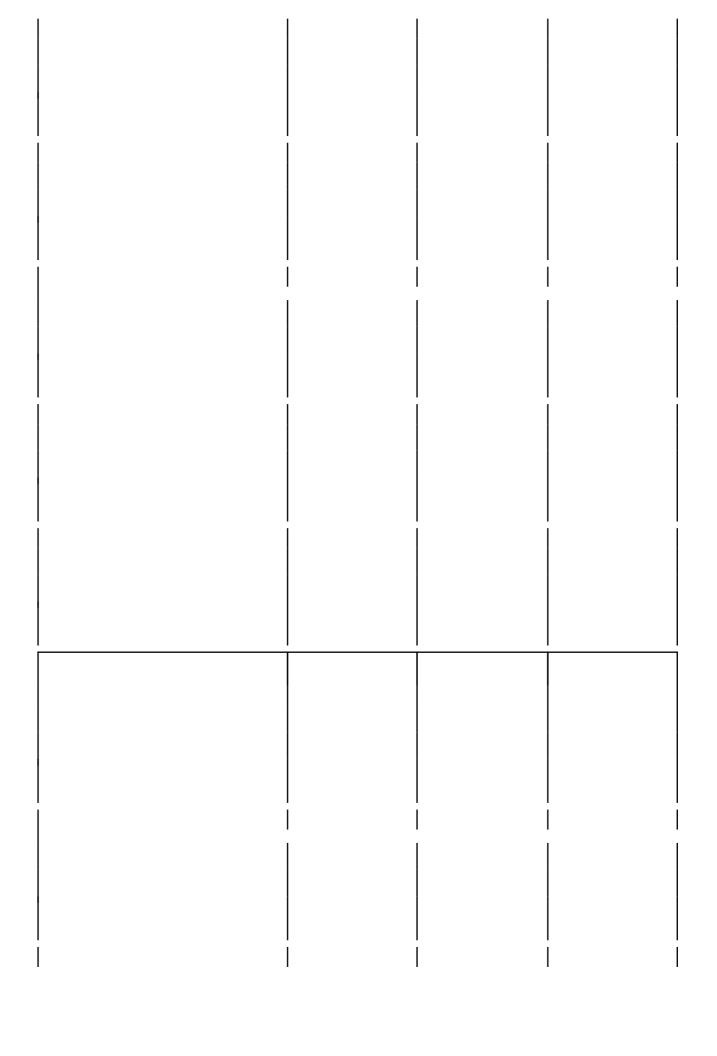


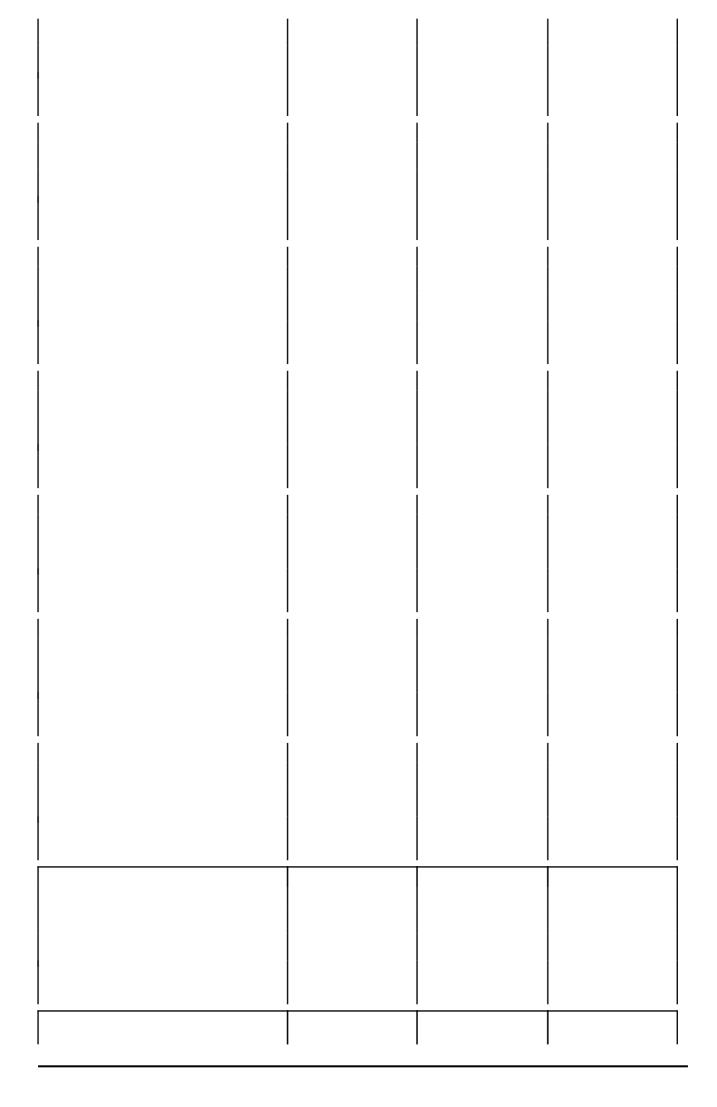


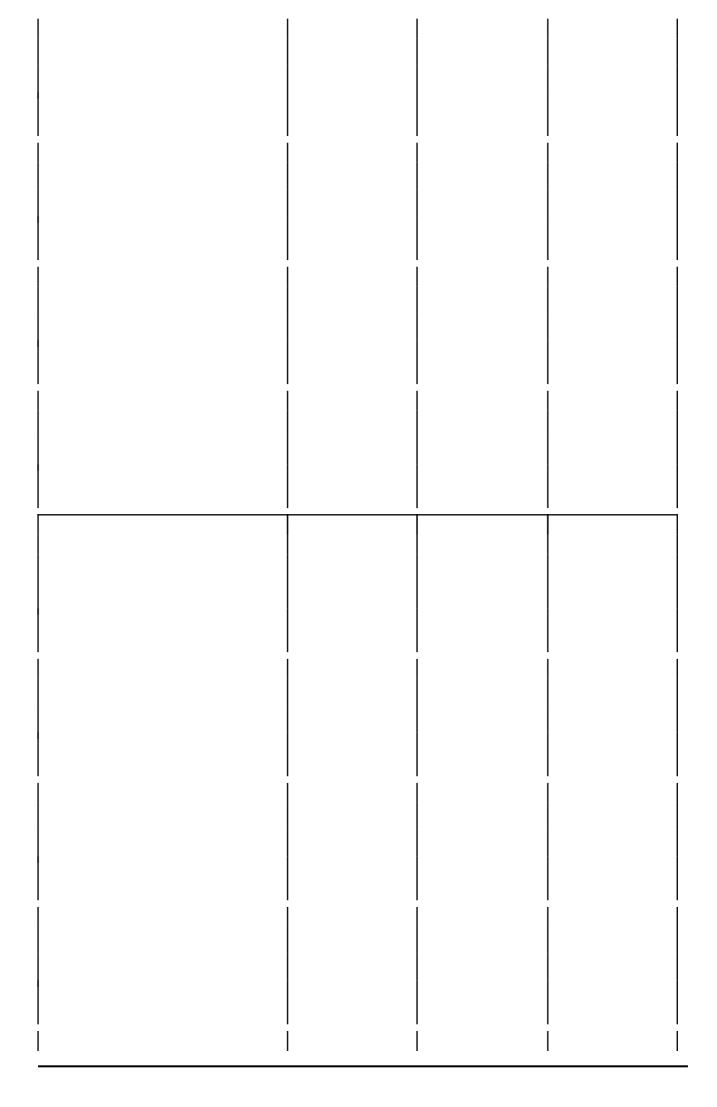
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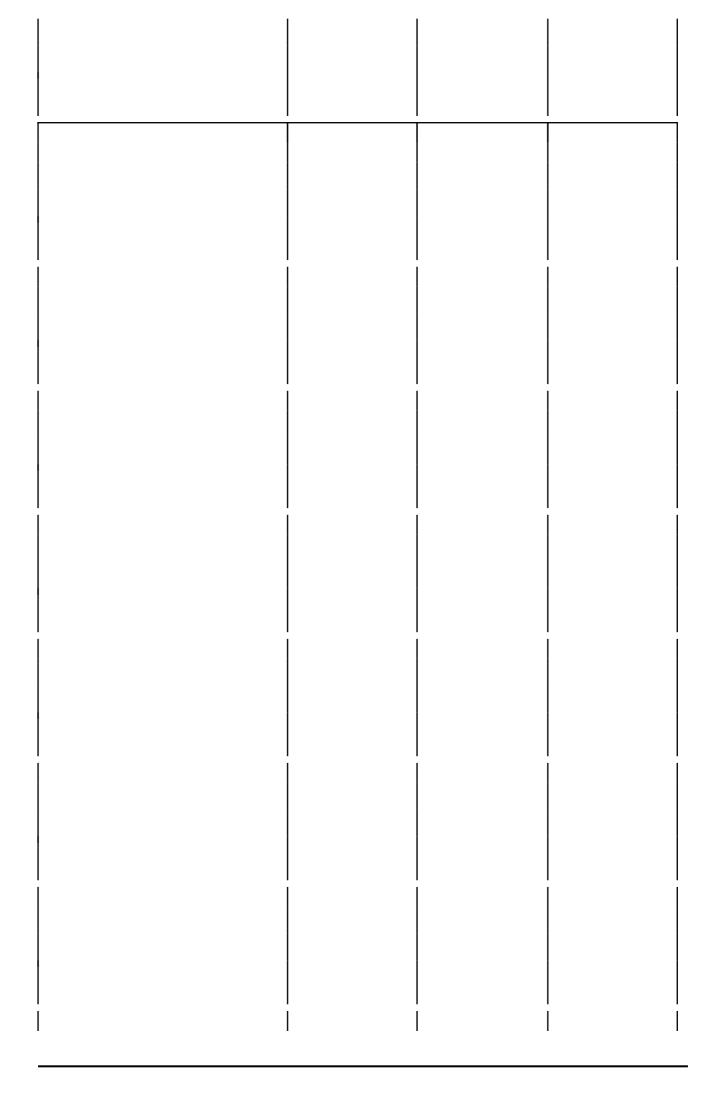


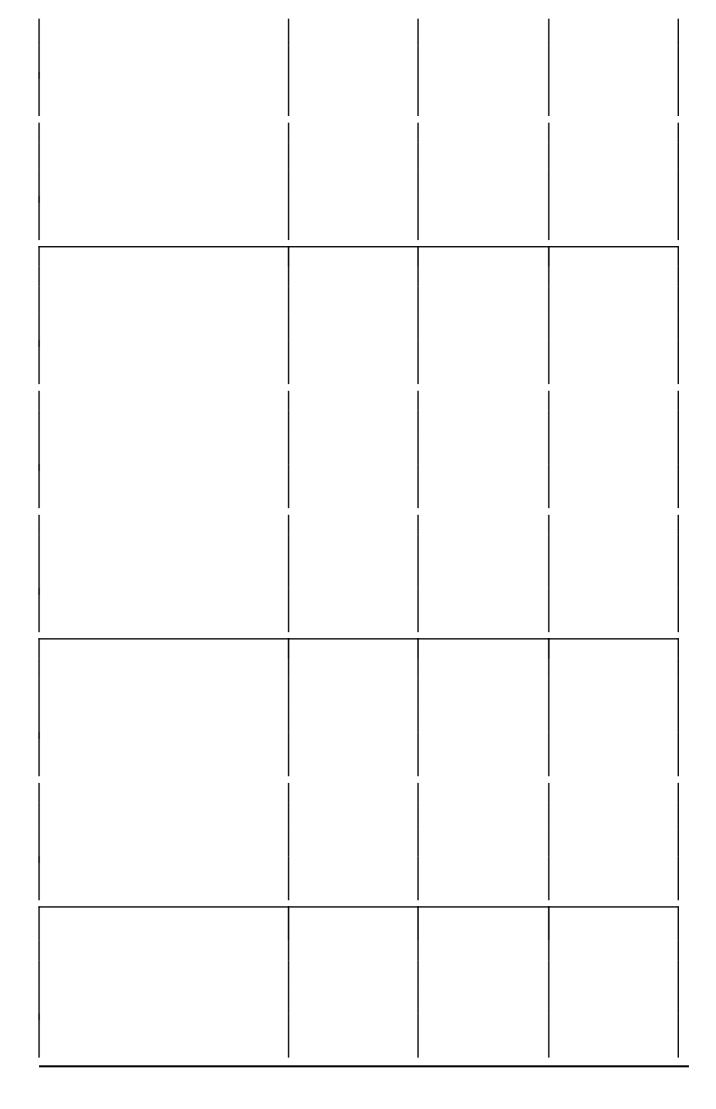


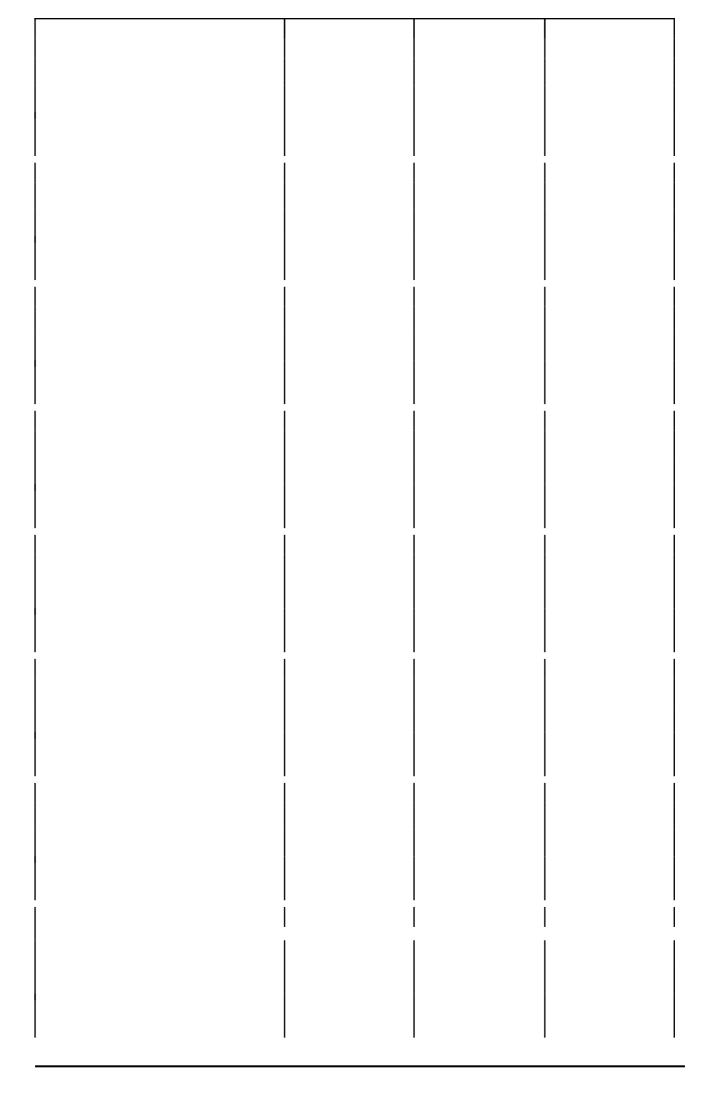


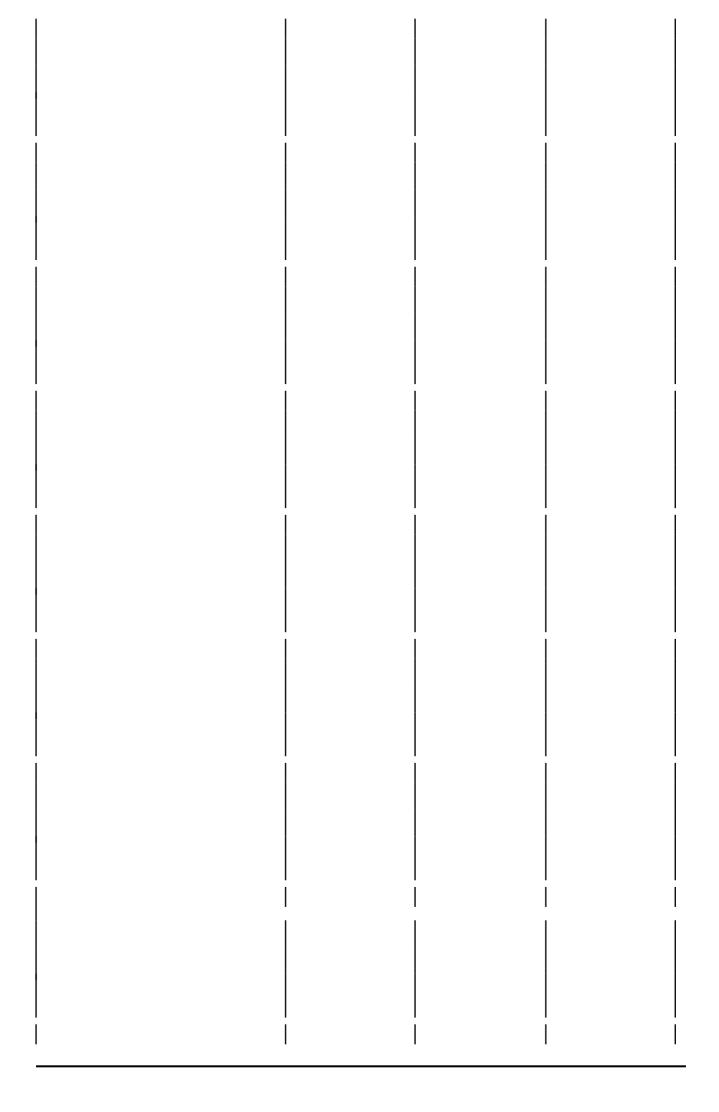


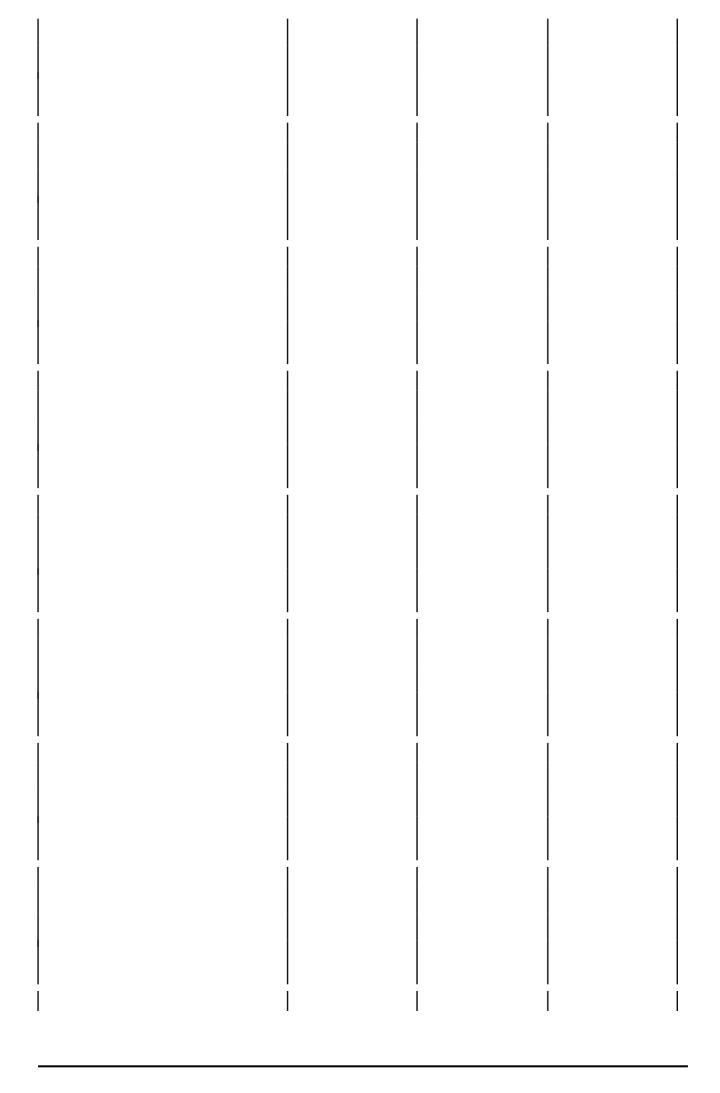


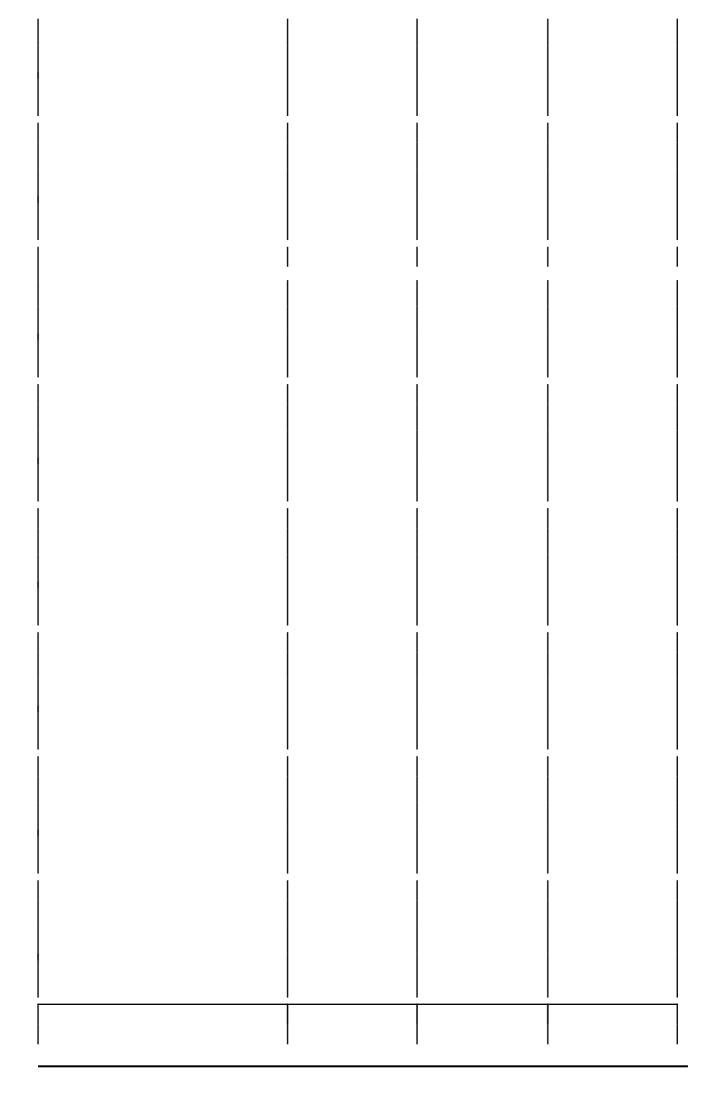




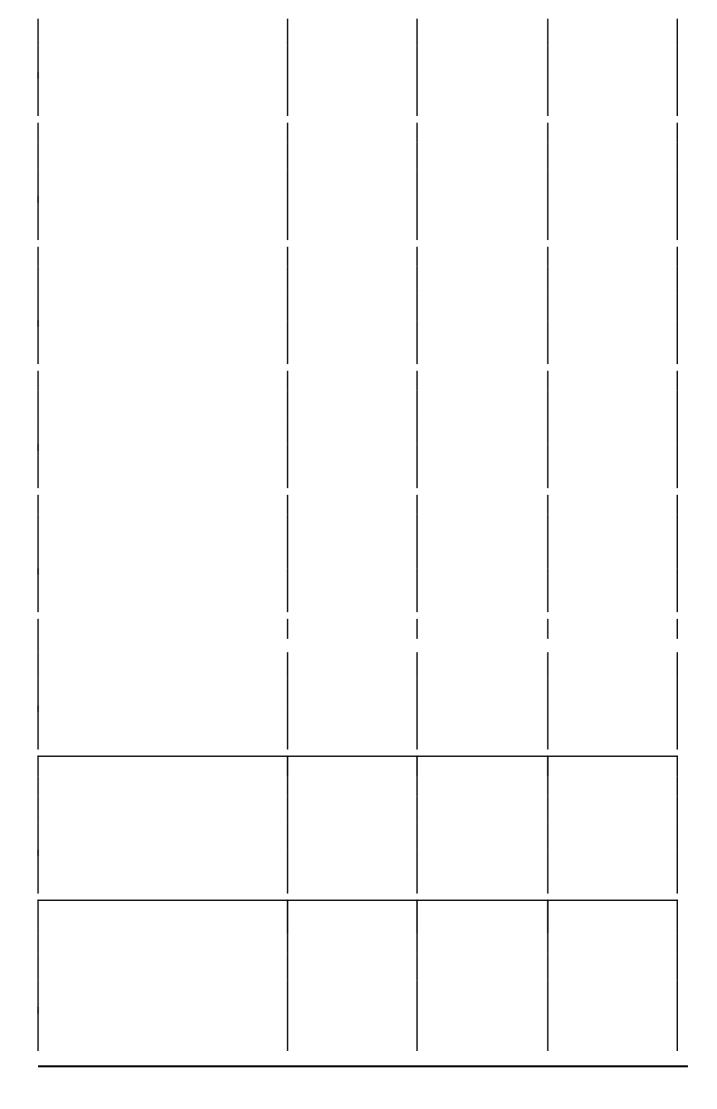


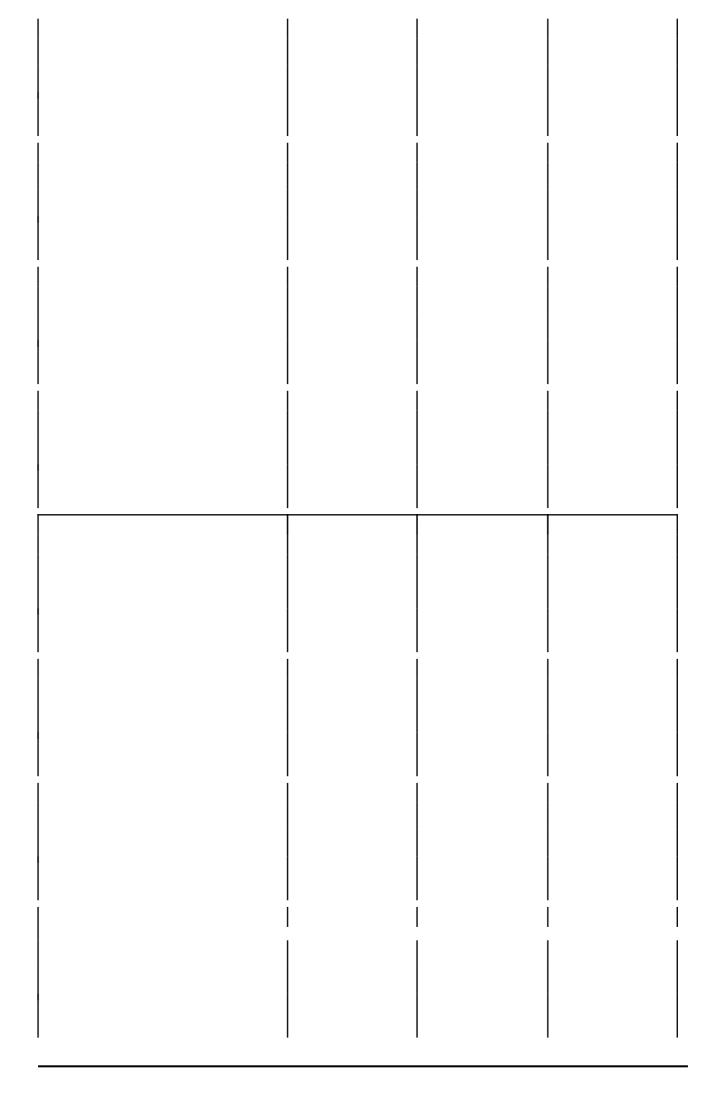


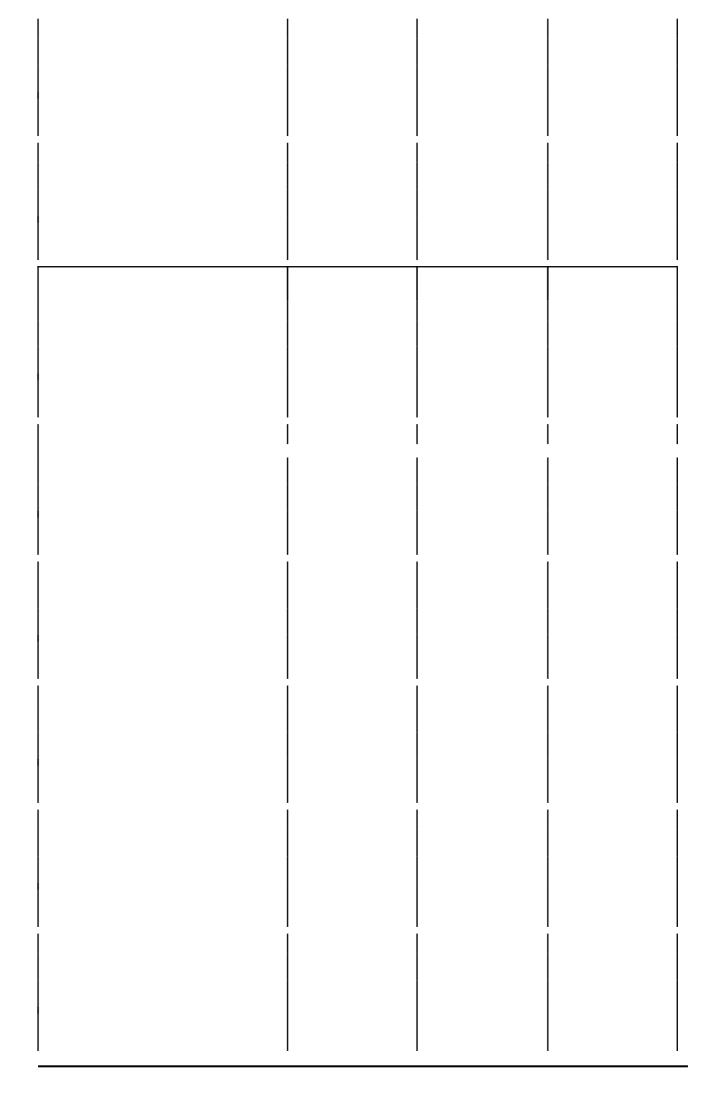


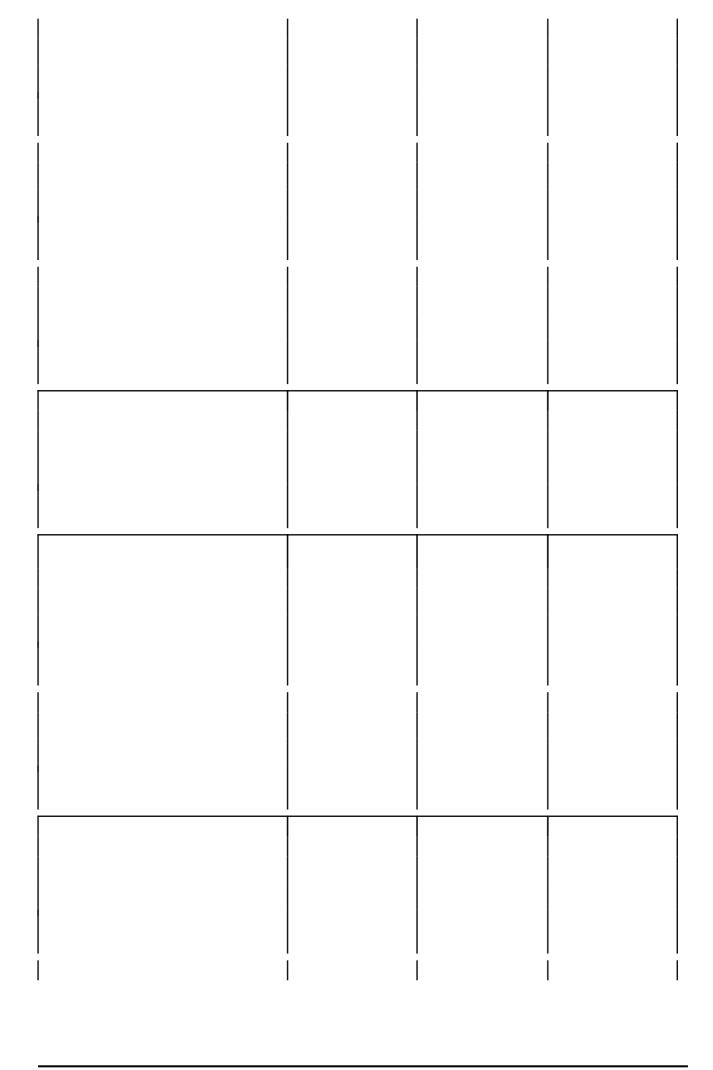


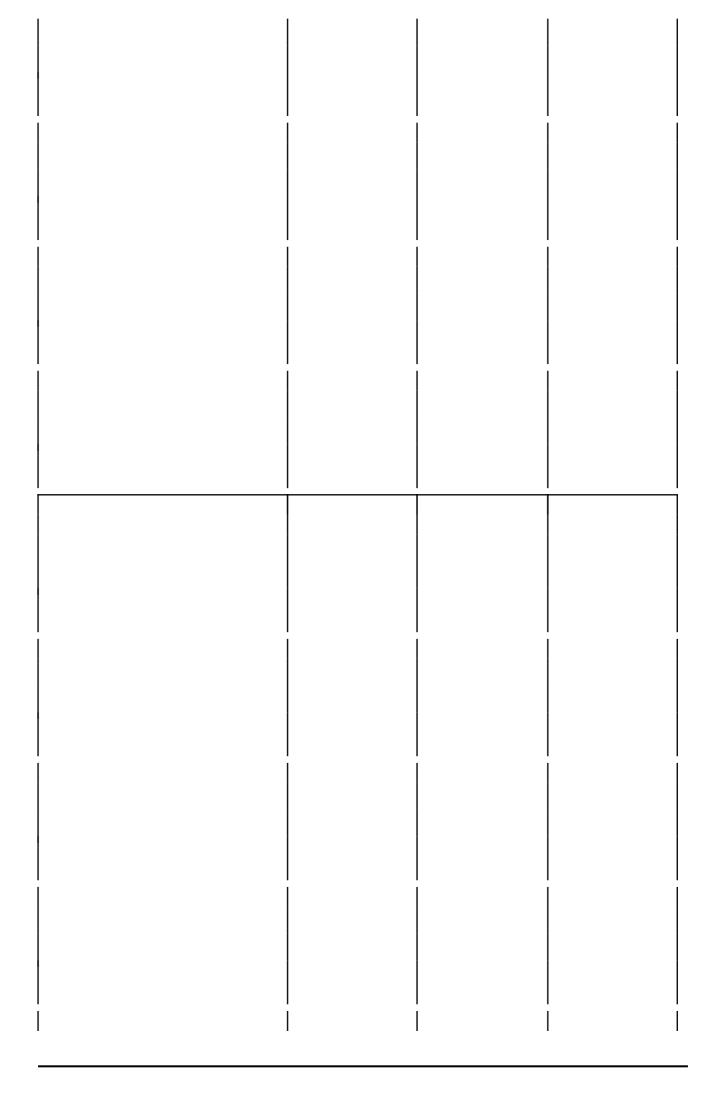
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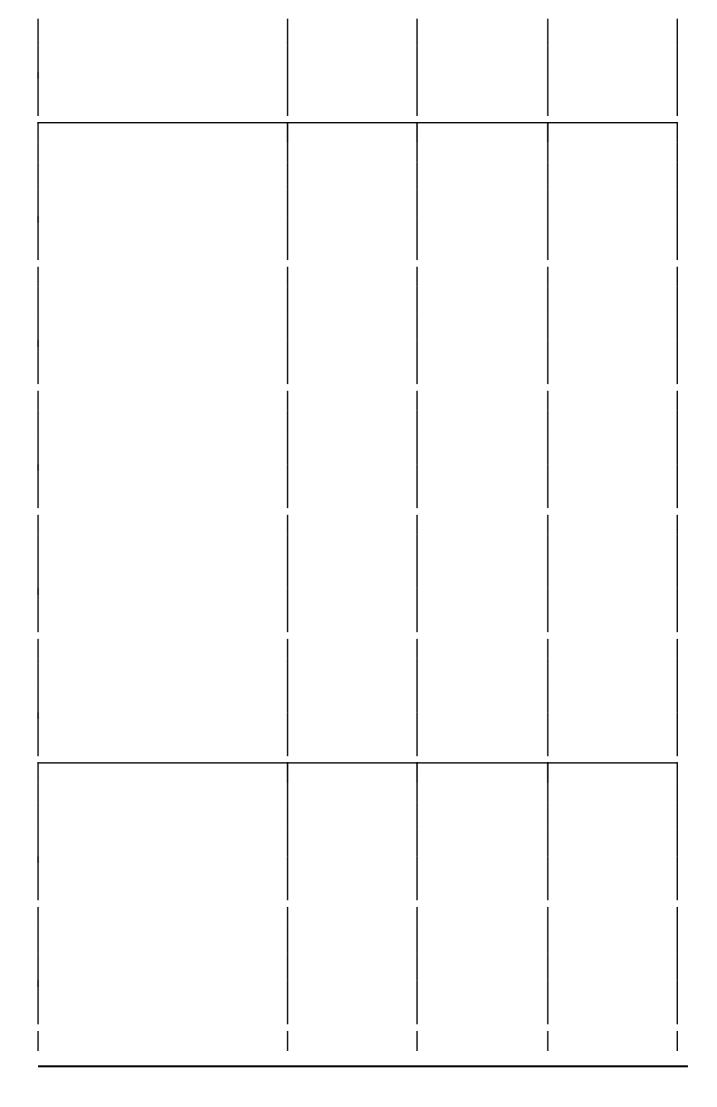


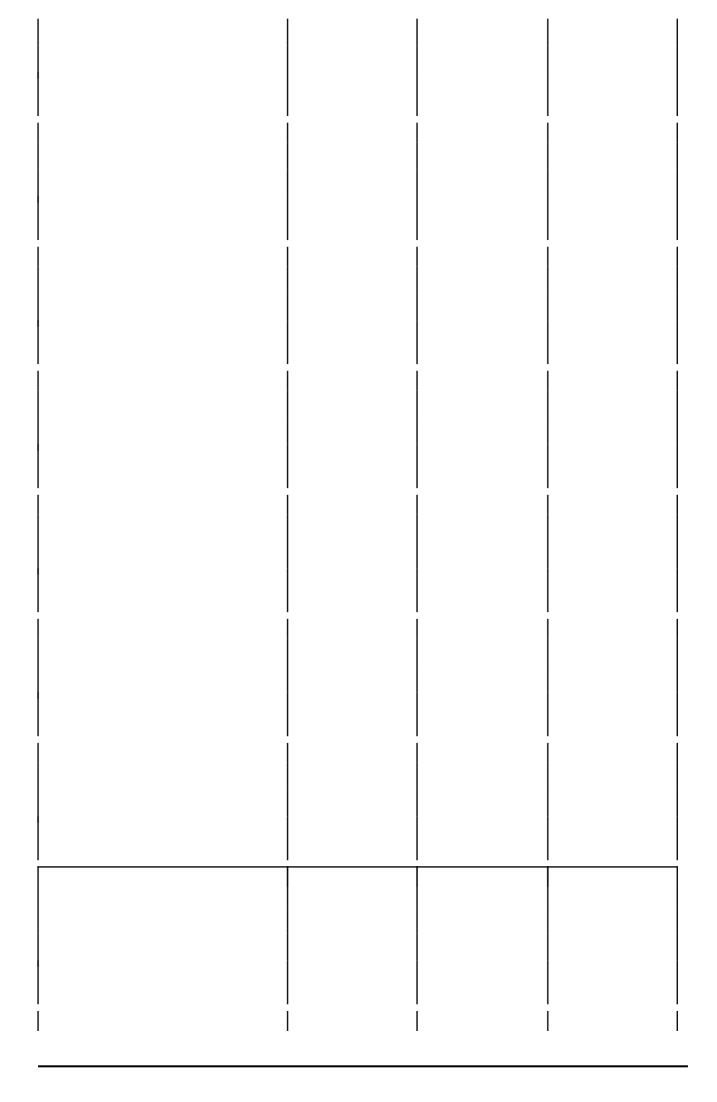


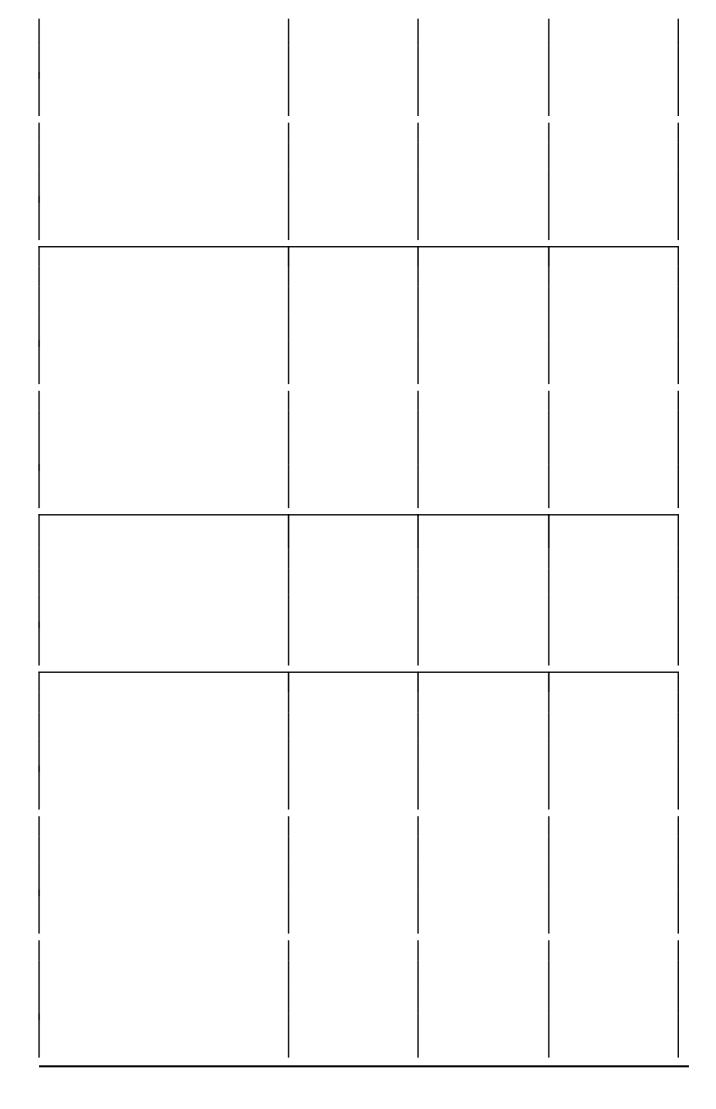


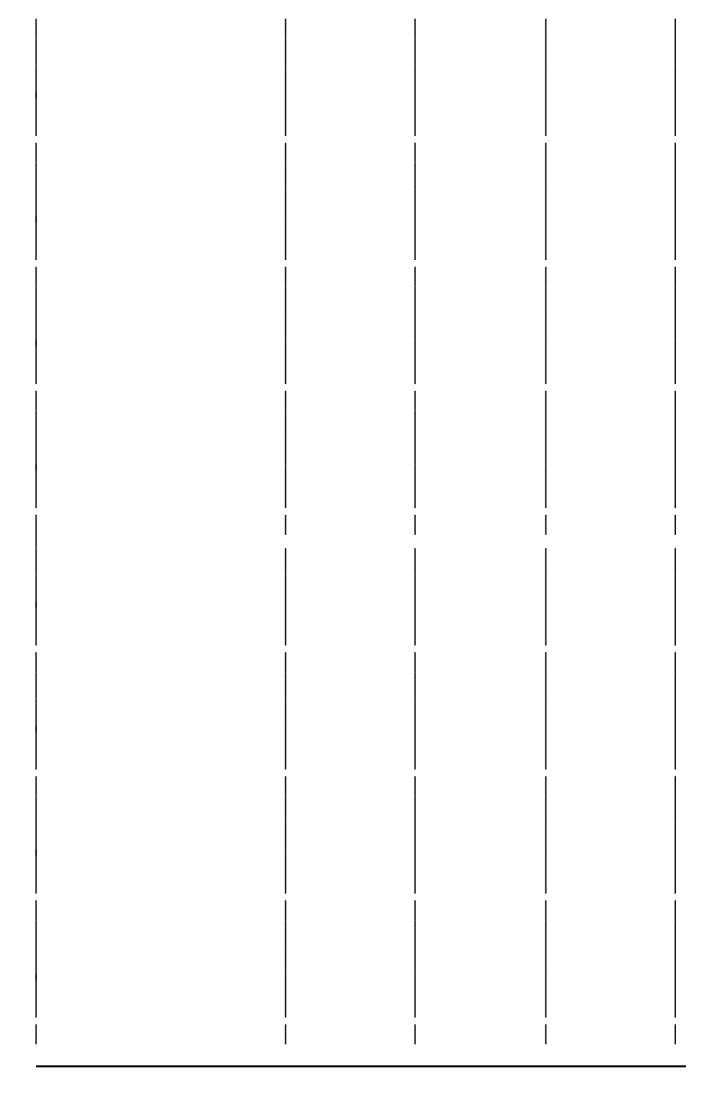


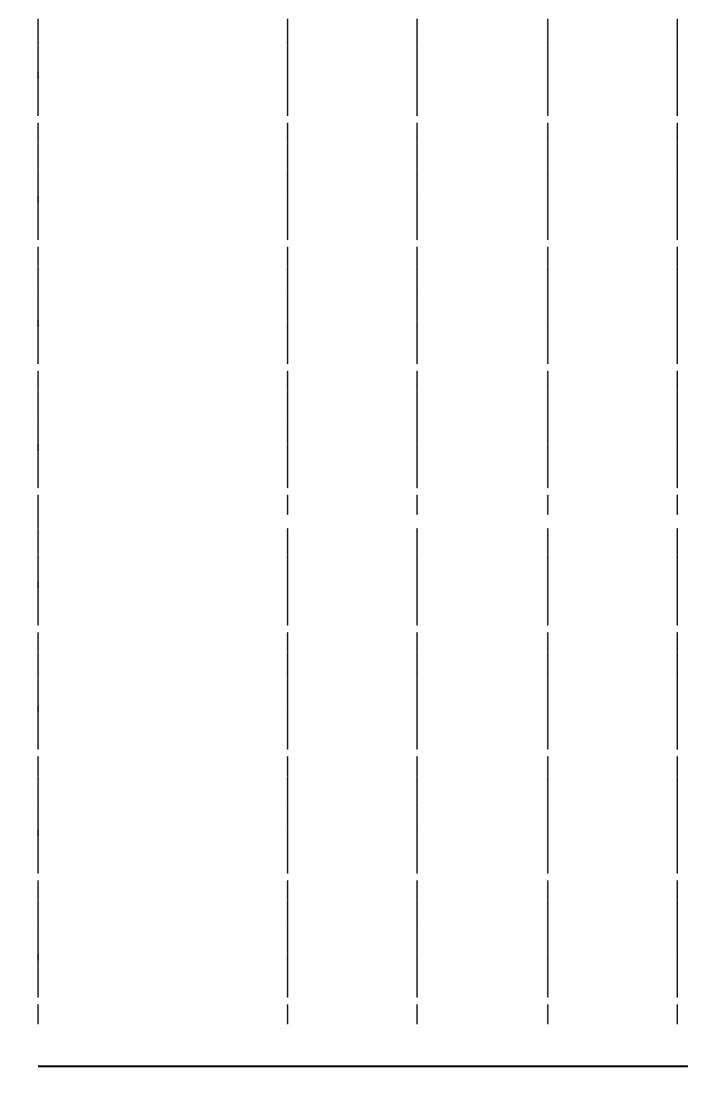


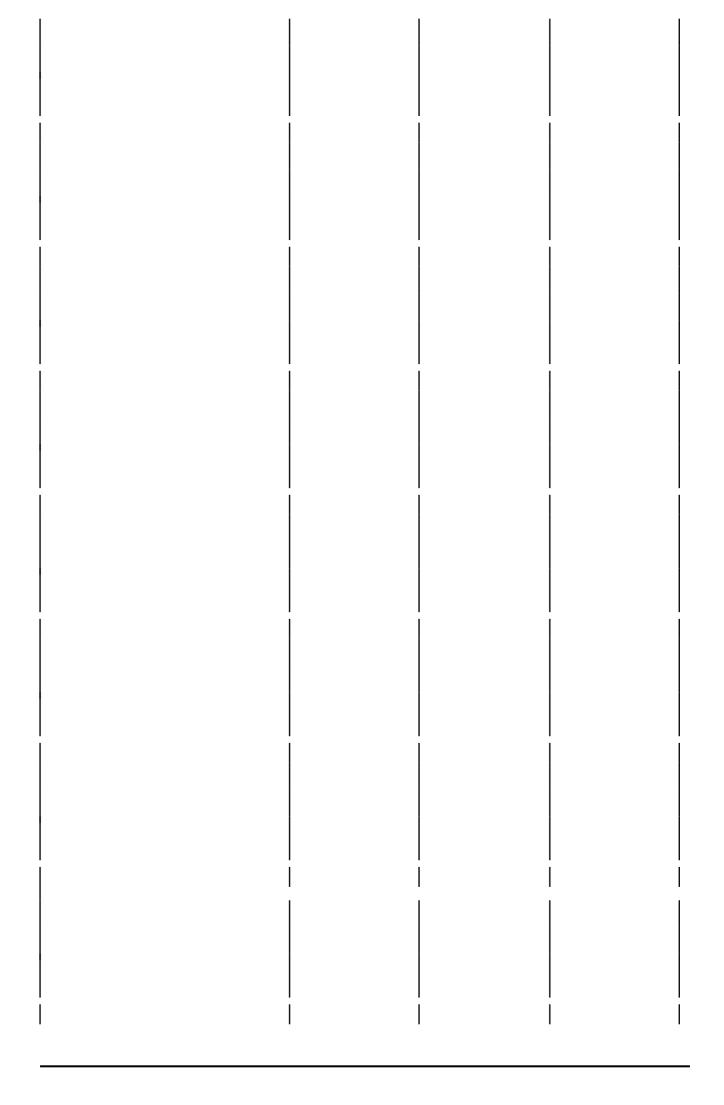




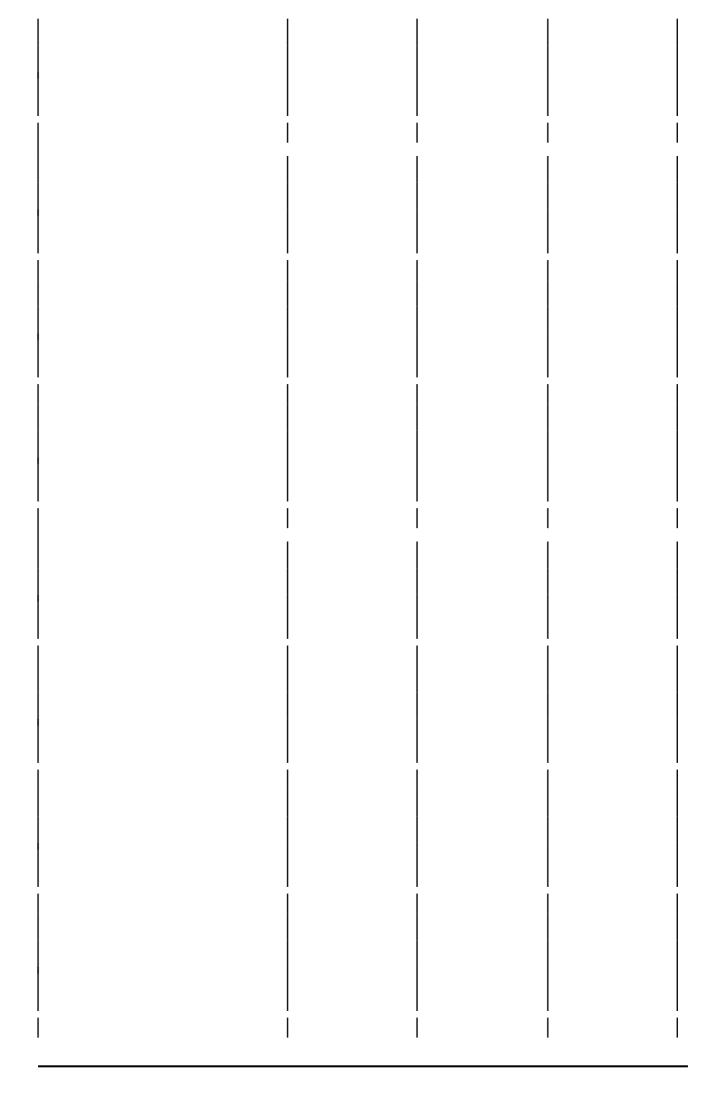


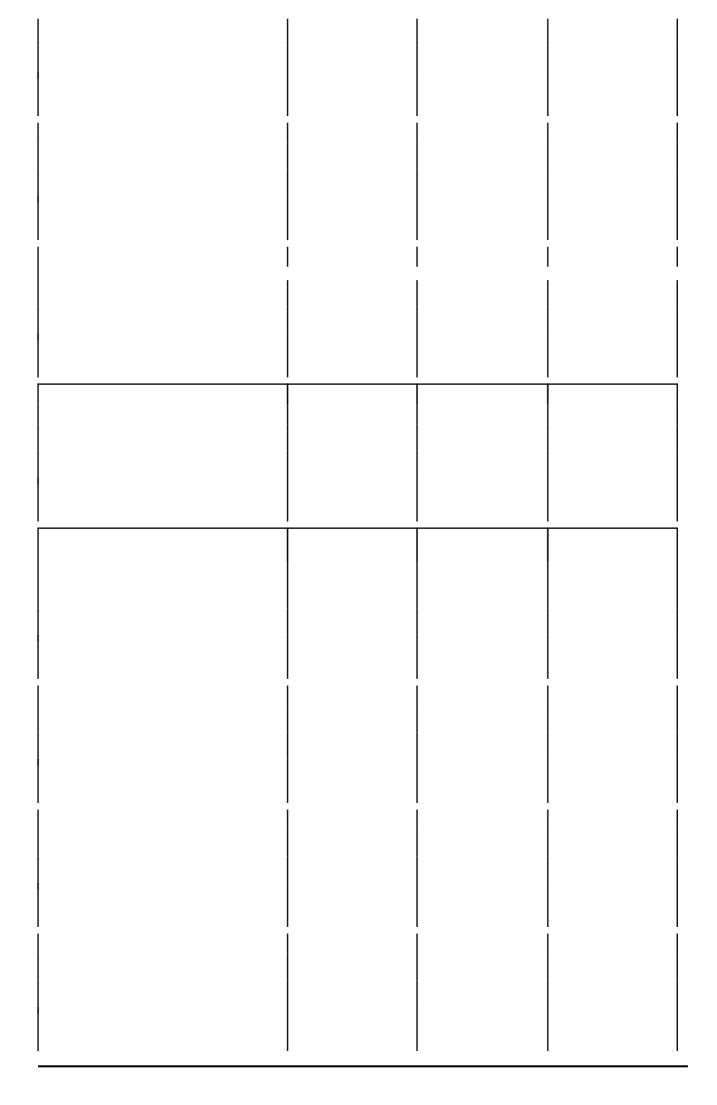


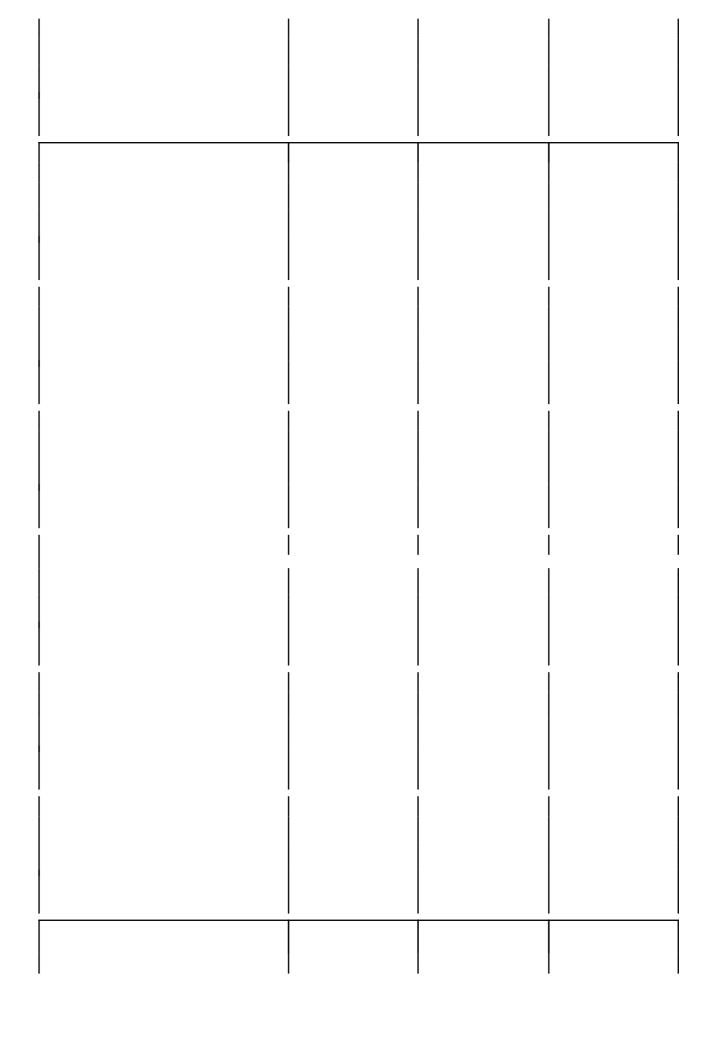


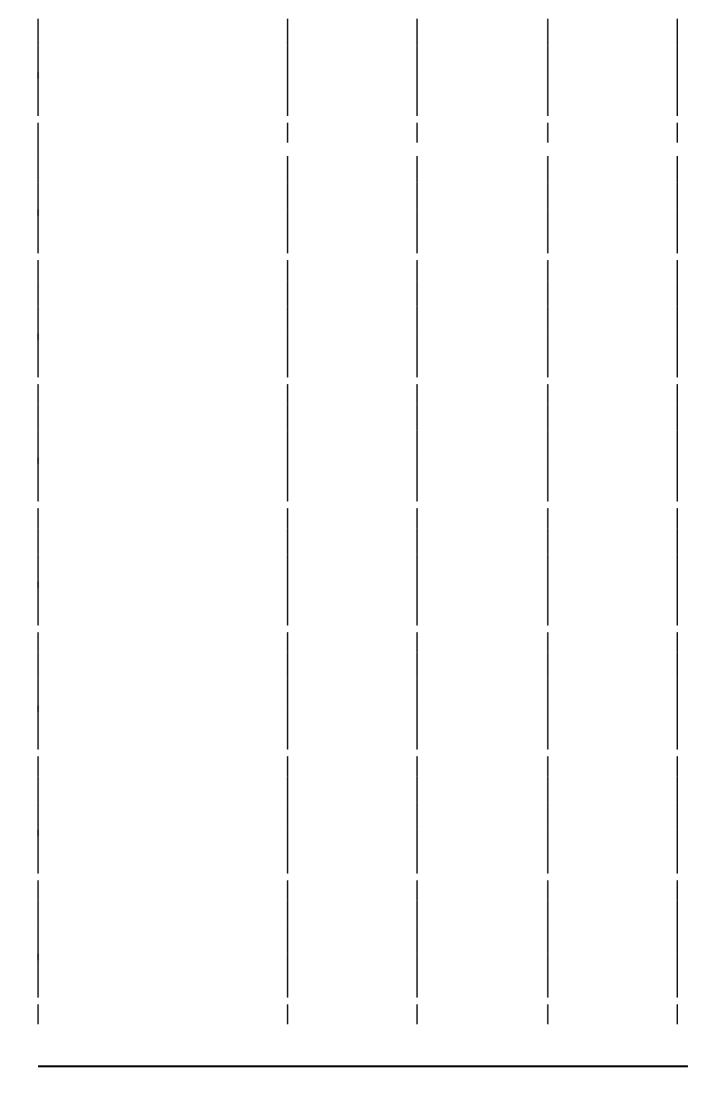


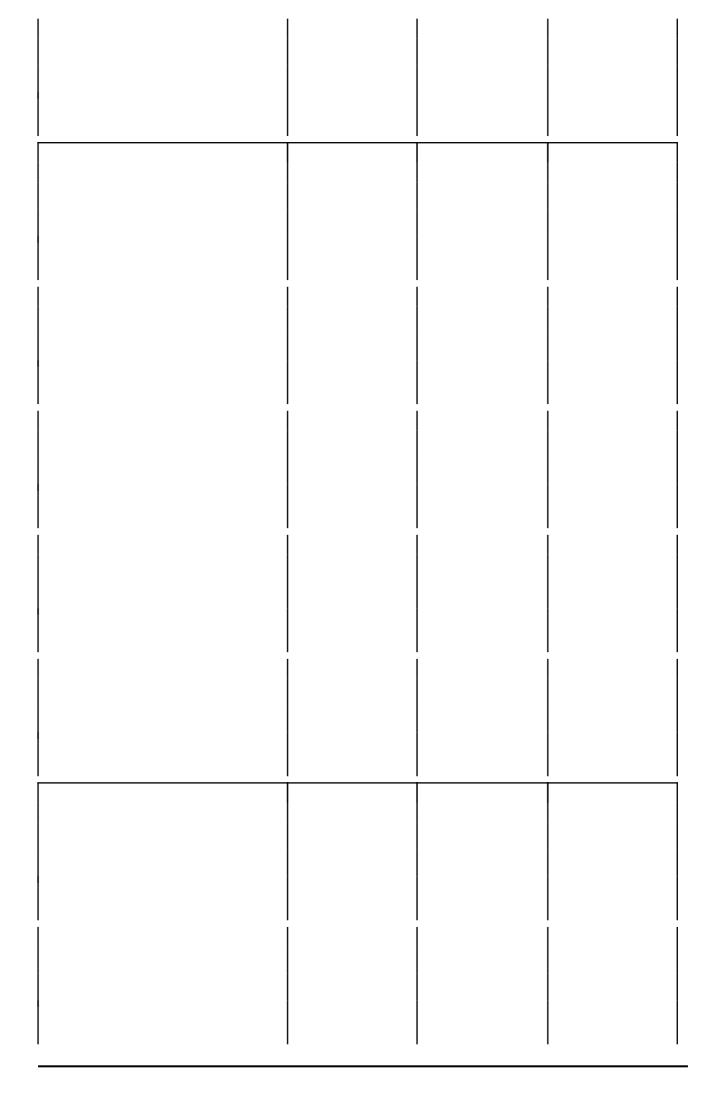
Serious adverse events				

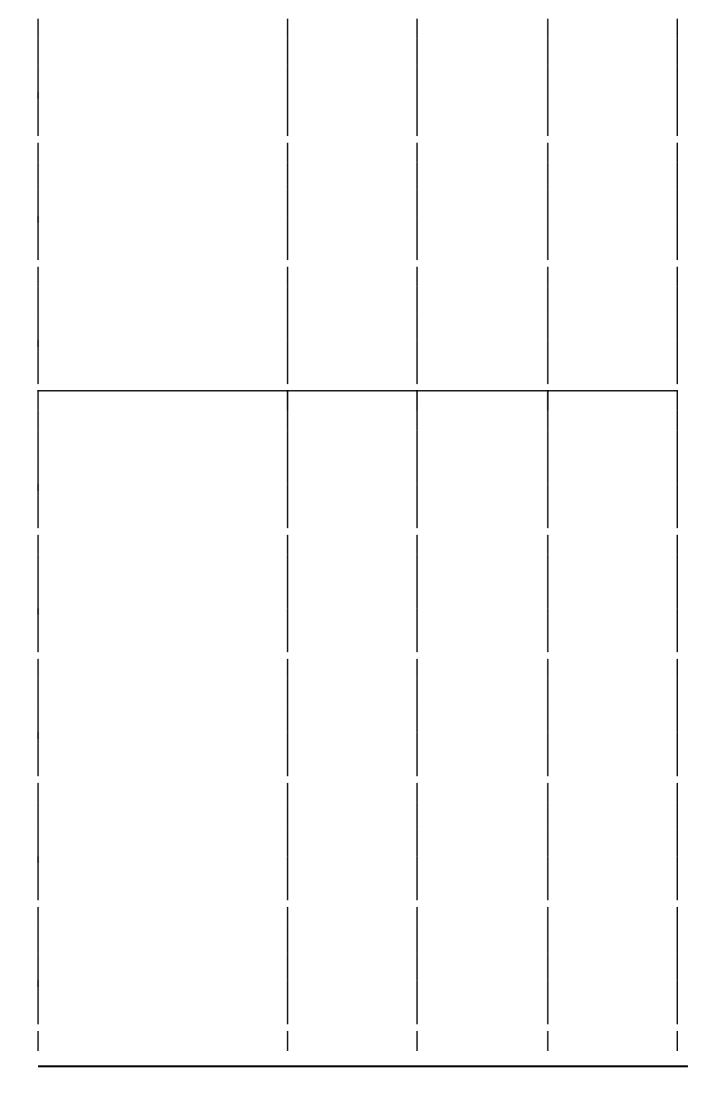


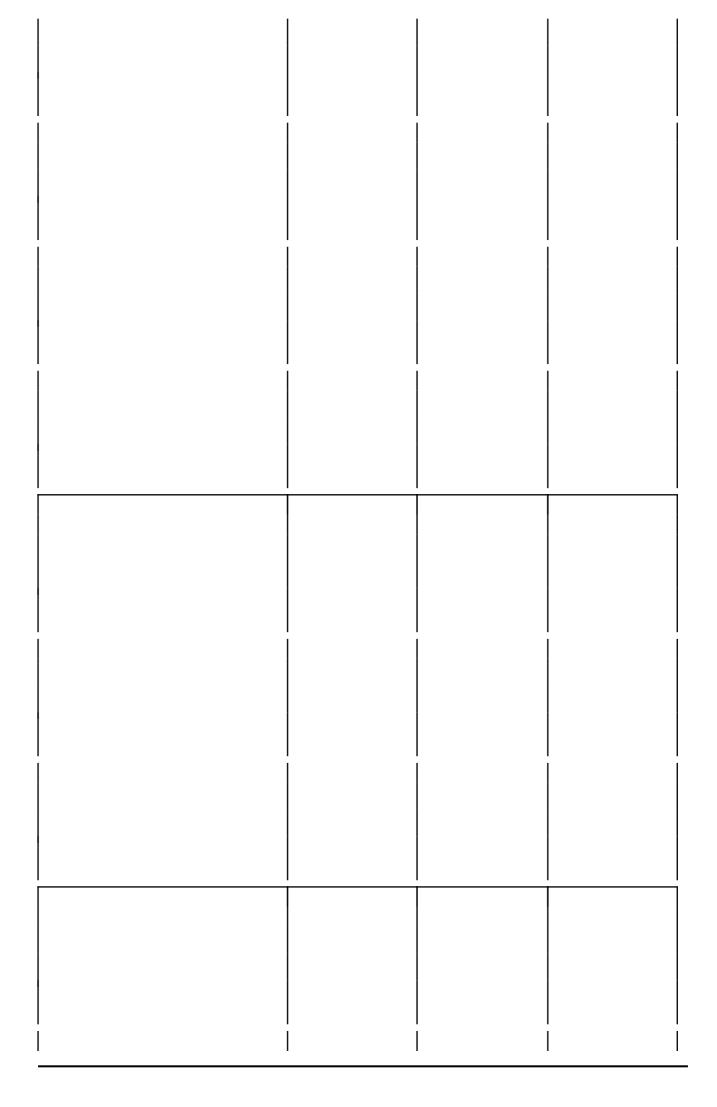


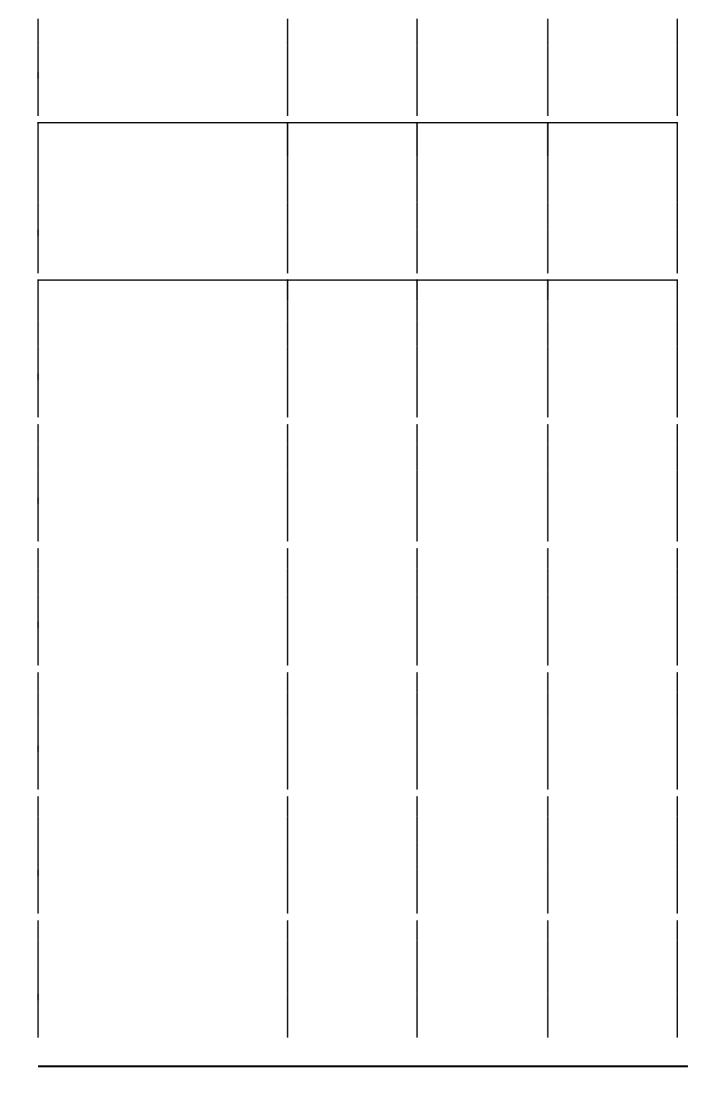


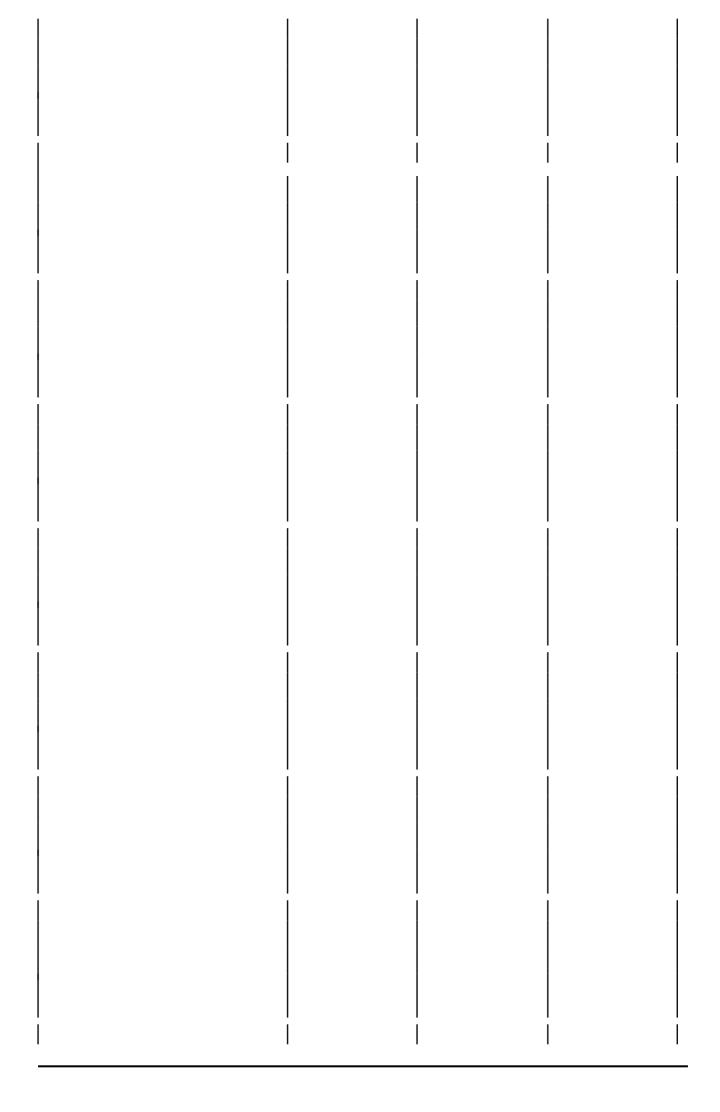


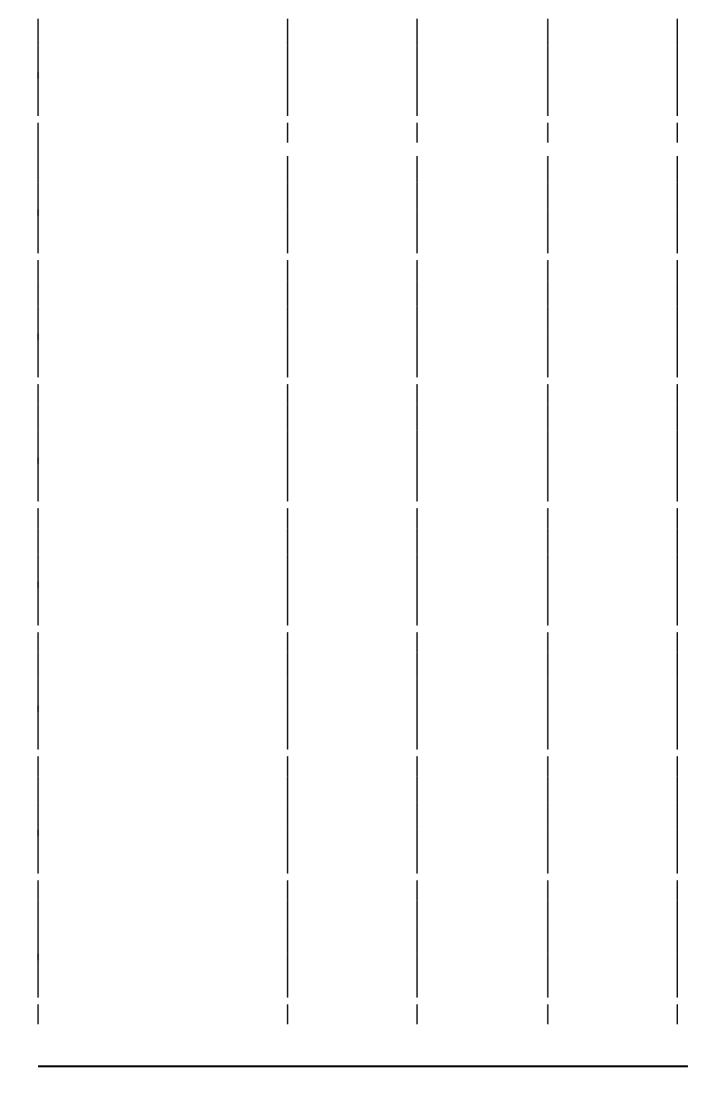


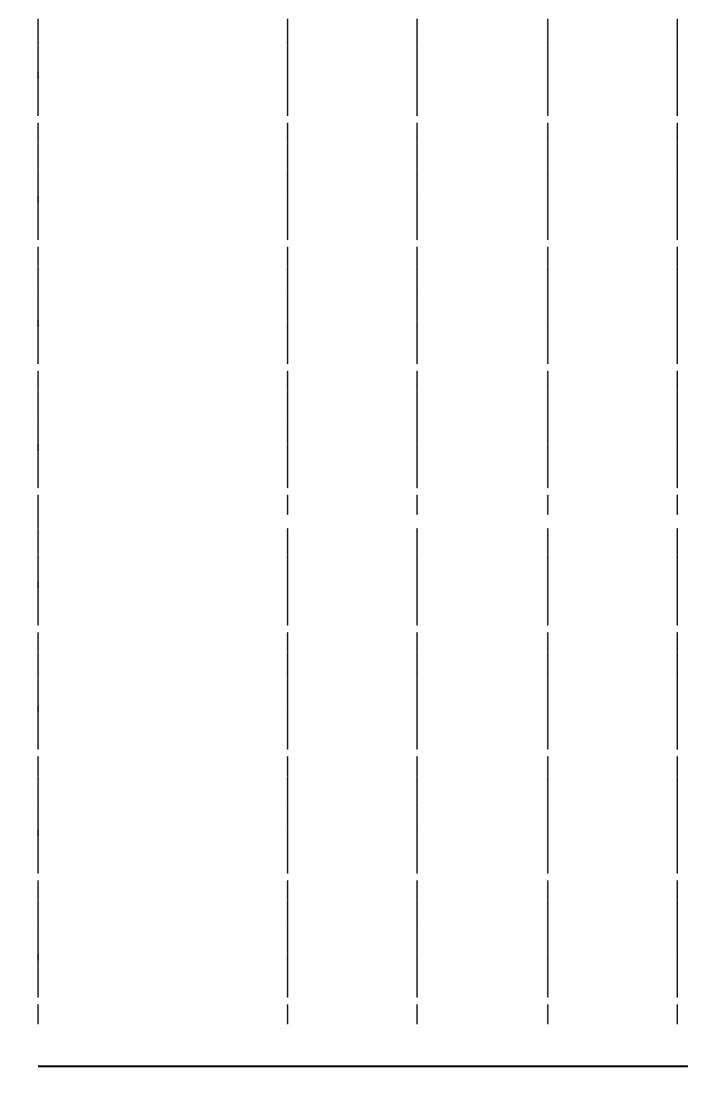








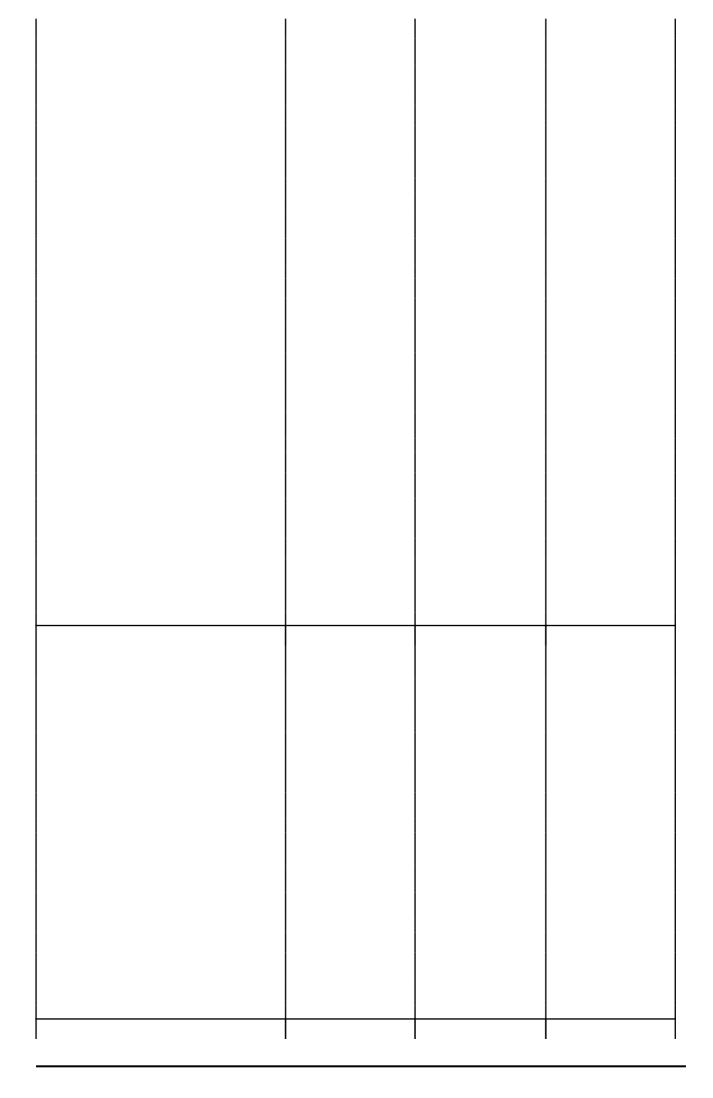




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Non-serious adverse events			

Non-serious adverse events		

Non-serious adverse events		



Non-serious adverse events		



More information

Substantial protocol amendments (globally)

Date	Amendment

Interruptions (globally)

Limitations and caveats