

## **Clinical trial results:**

An open-label, multicenter phase II study to compare the efficacy and safety of RAD001 as first-line followed by second-line sunitinib versus sunitinib as first-line followed by second-line RAD001 in the treatment of patients with metastatic renal cell carcinoma

Due to EudraCT system limitations, which EMA is aware of, results of crossover studies and data using 999 as data points are not accurately represented in this record. Please go to https://www.novctrd.com/CtrdWeb/home.nov for complete trial results

Summary		
Results information		
Trial information		
Trial identification	<b>,</b>	
Additional study identifiers		
Sponsors		
Paediatric regulatory details		

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

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Subjects enrolled per age group	

Subject disposition		
Recruitment		
Pre-assignment		
Period 1	<del> </del>	
Arms		
Arm title		
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Number of subjects in period 1		
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Period 2		
Arms		
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Number of subjects in period 2	

End points reporting groups				
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End point values				
Statistical analyses				
Statistical analysis title				

**End points** 

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Casandaniu Duanuasian fusa aum	wind combined (DEC C)
Secondary: Progression-free sur	vivai combined (PFS-C)

End point values					
Statistical analyses					
Constitution Occasion (OC)					
Secondary: Overall Survival (OS)					
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End point values					
Statistical analyses					
Secondary: Overall response rate (ORR) - First -Line (1-L)					

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End point values				
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Secondary: Duration of response	(DoR) - First	-Line (1-L)		
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Secondary: Time to definitive deterioration of the FKSI-DRS risk score by at least 3 score units by first-line drug				y at least 3
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point values				
Statistical analyses				
Secondary: Time to definitive de	terioration of	the FKSI-DR	S risk score b	y at least 3
score units by first and second-li	ne drugs com	bined		

End point values					
Statistical analyses					
Secondary: Time to definitive de	terioration of	the physical	functioning (	DE) scale of	
the EORTC QLQ-C30 - by First-Lin	ne (1L) drug	the physical	runctioning (	ri ) scale oi	
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Statistical analyses					

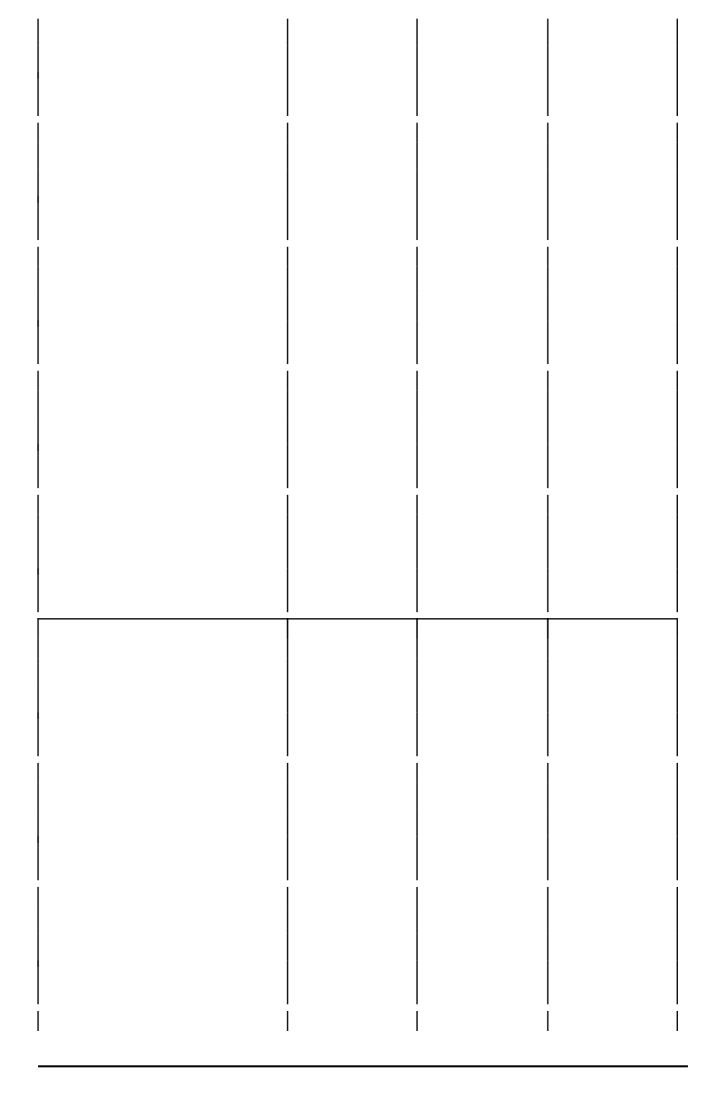
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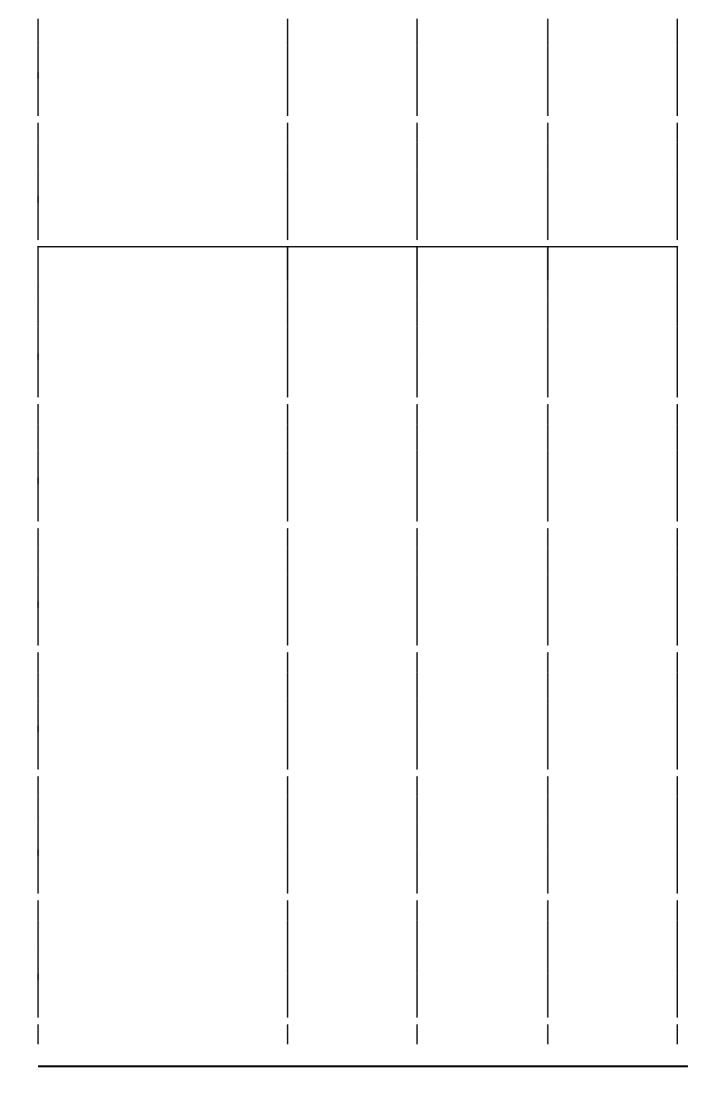
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Statistical analyses				

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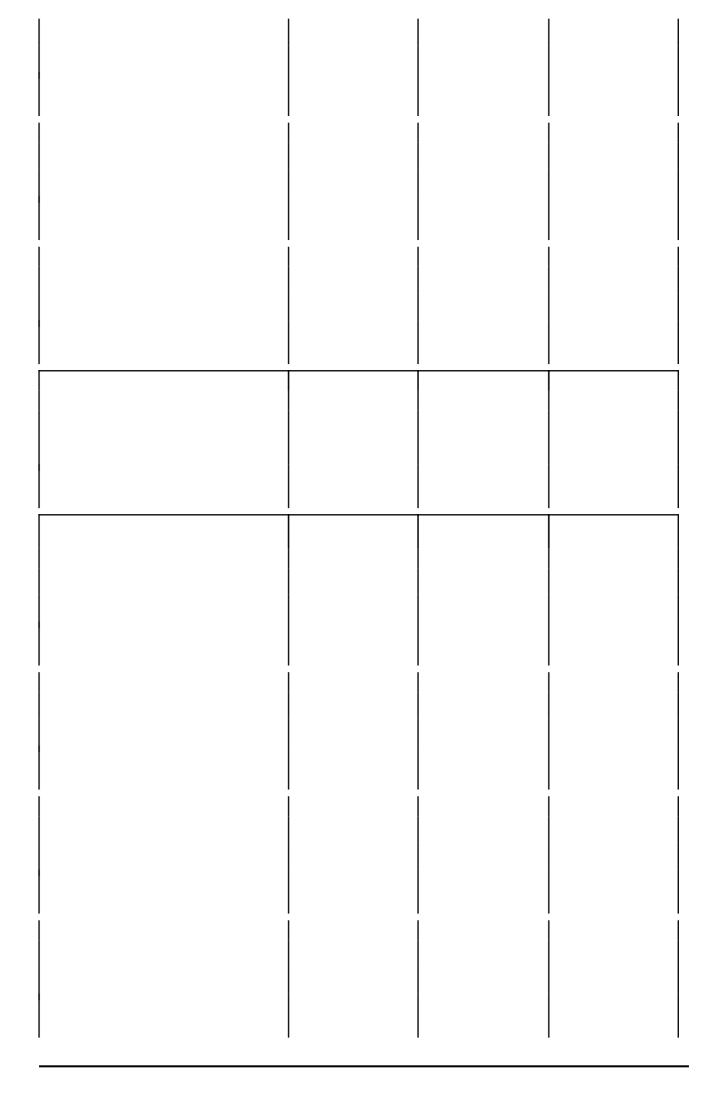
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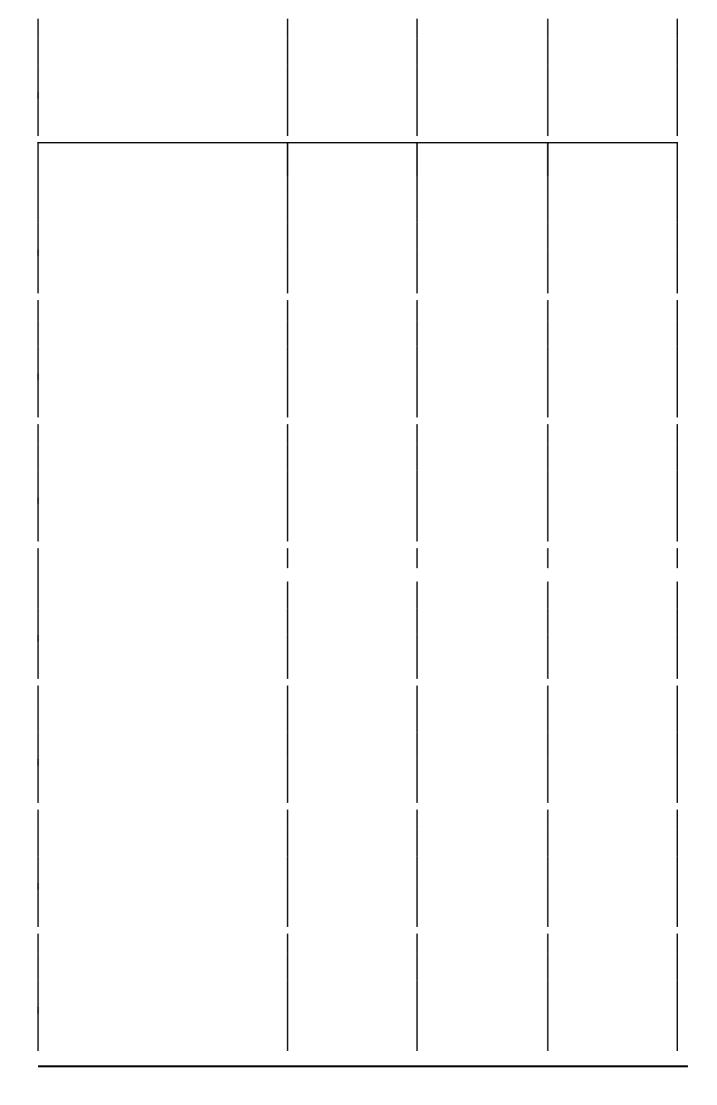
## **Adverse events Adverse events information Dictionary used Reporting groups** Serious adverse events

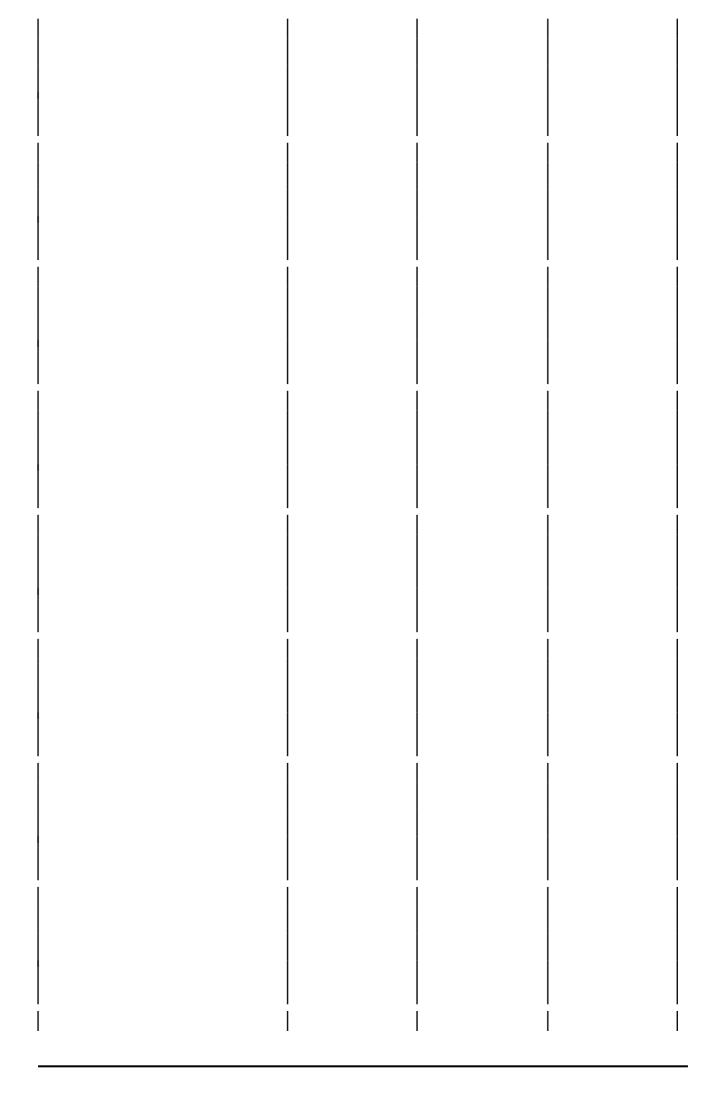


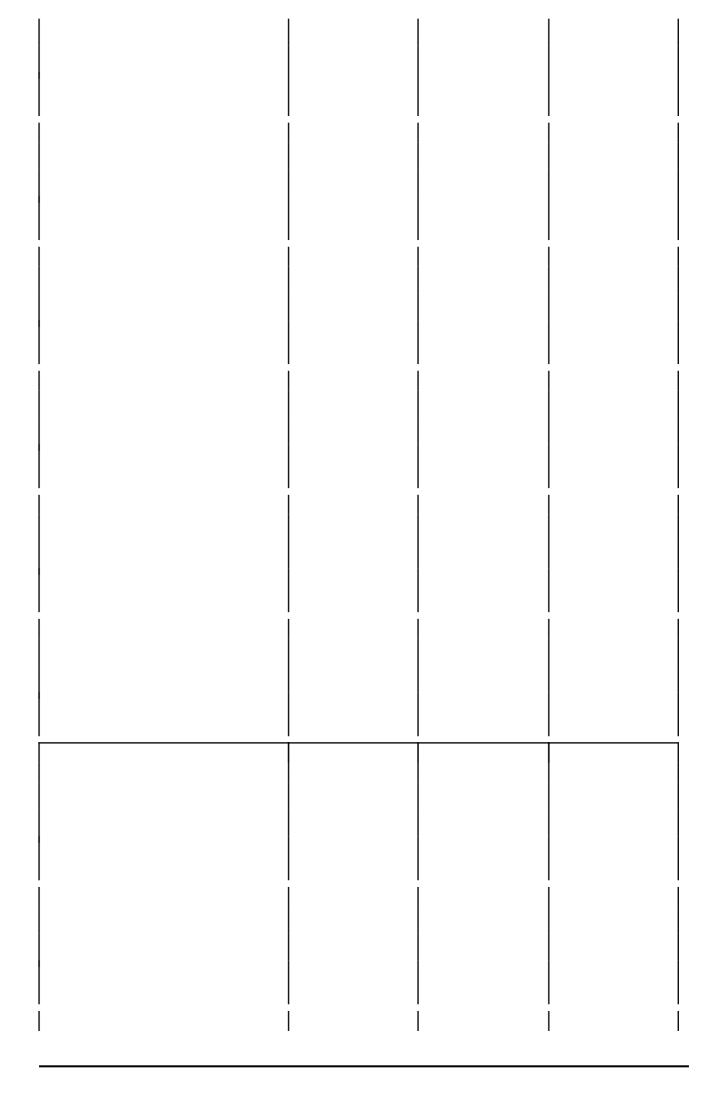


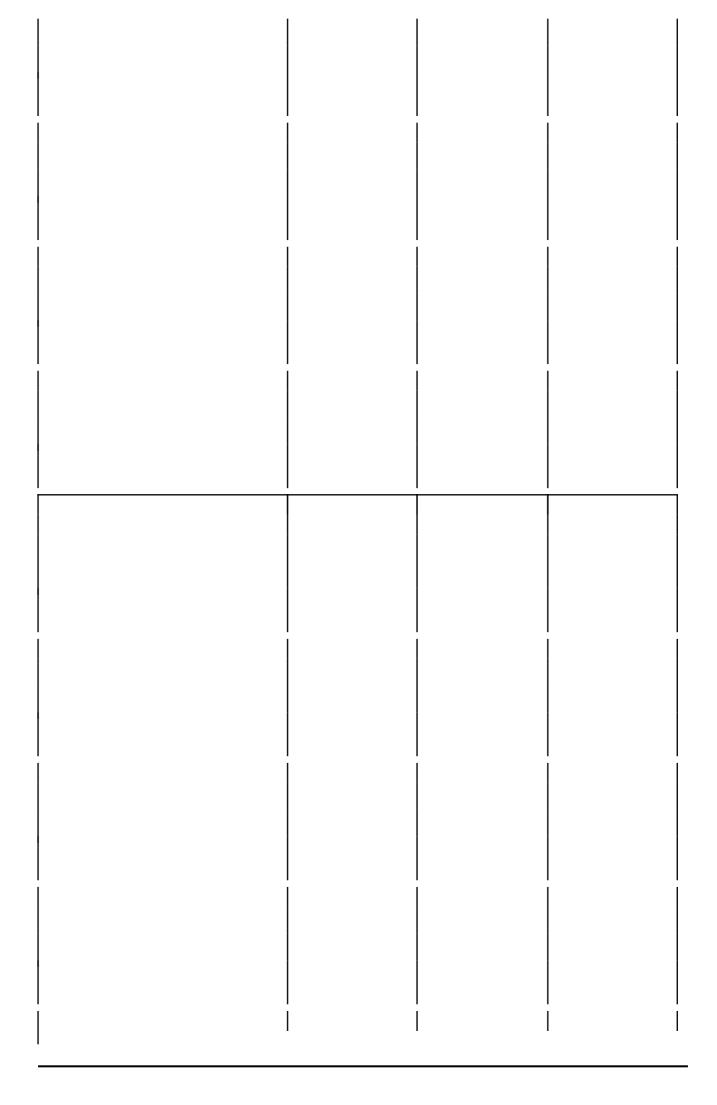


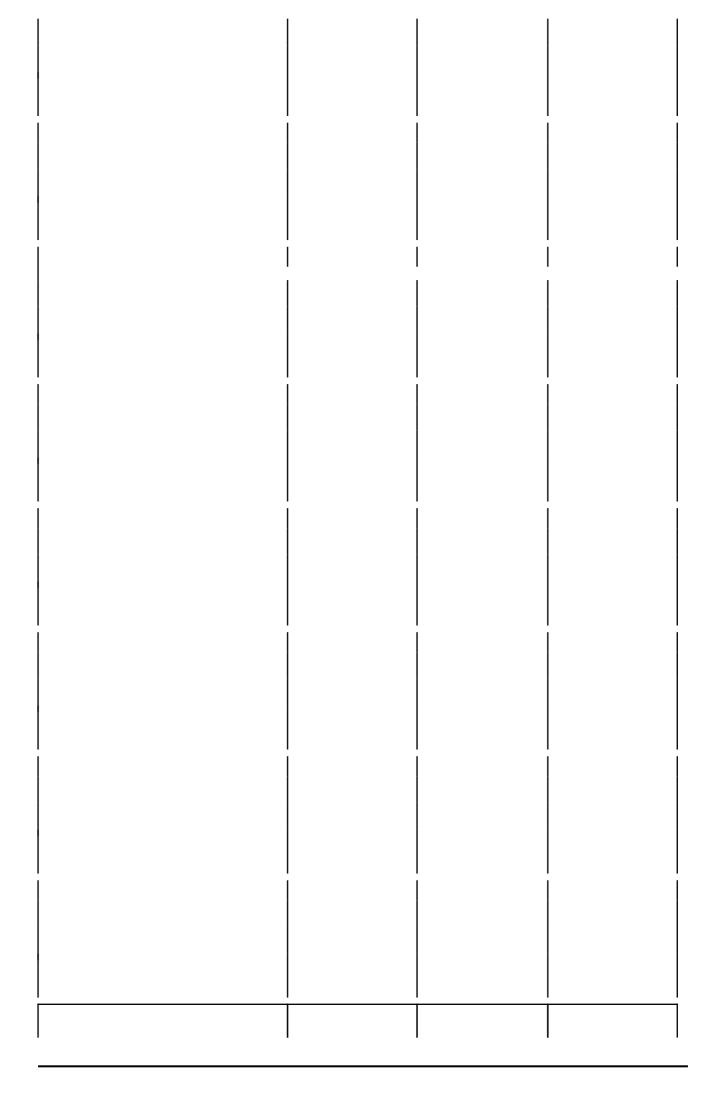


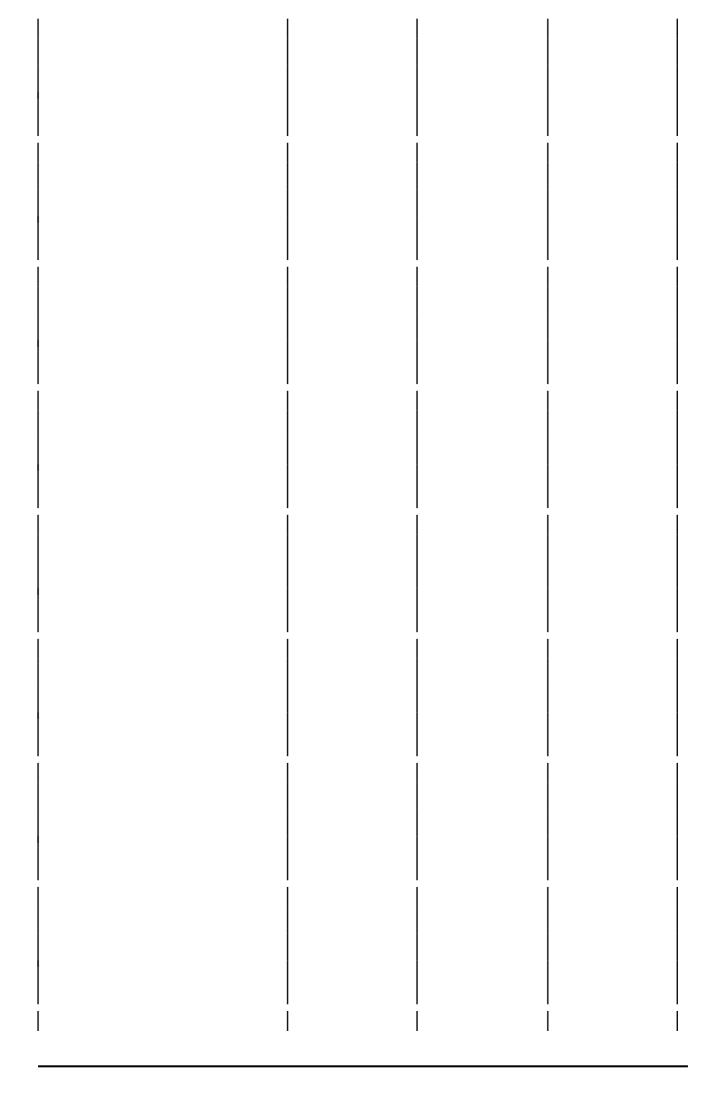


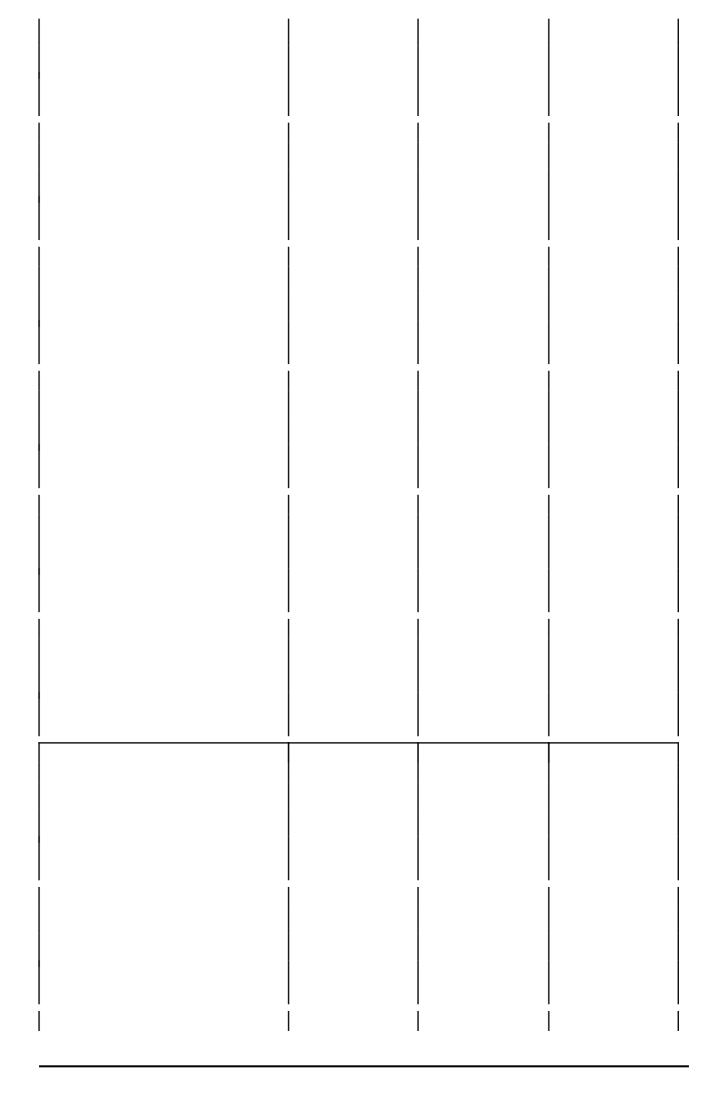


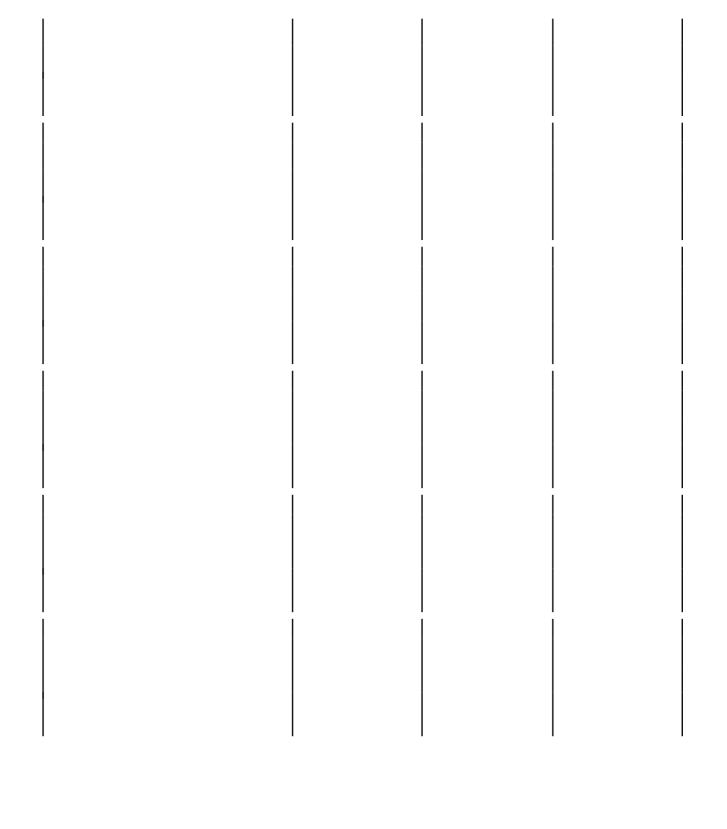




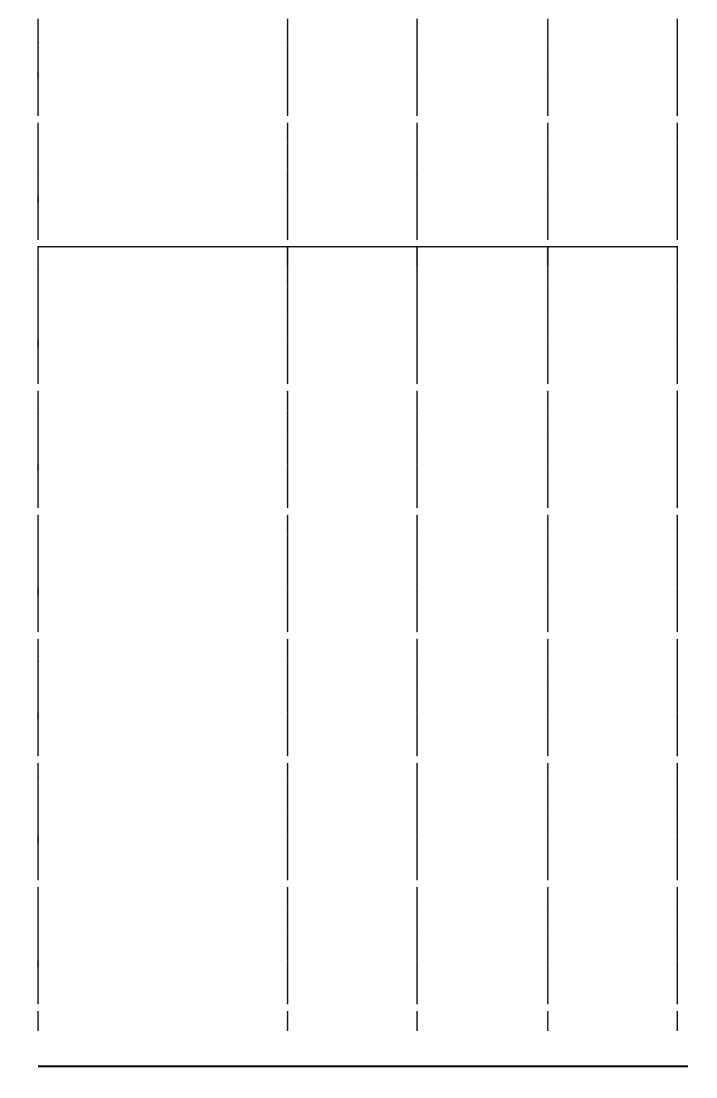






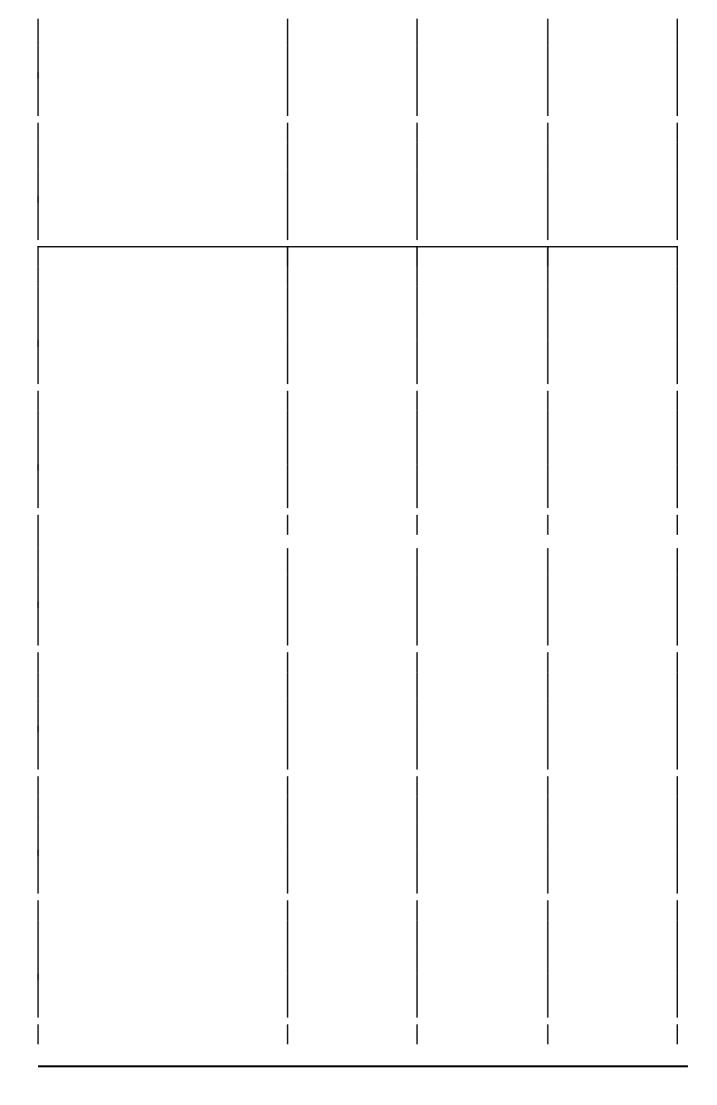


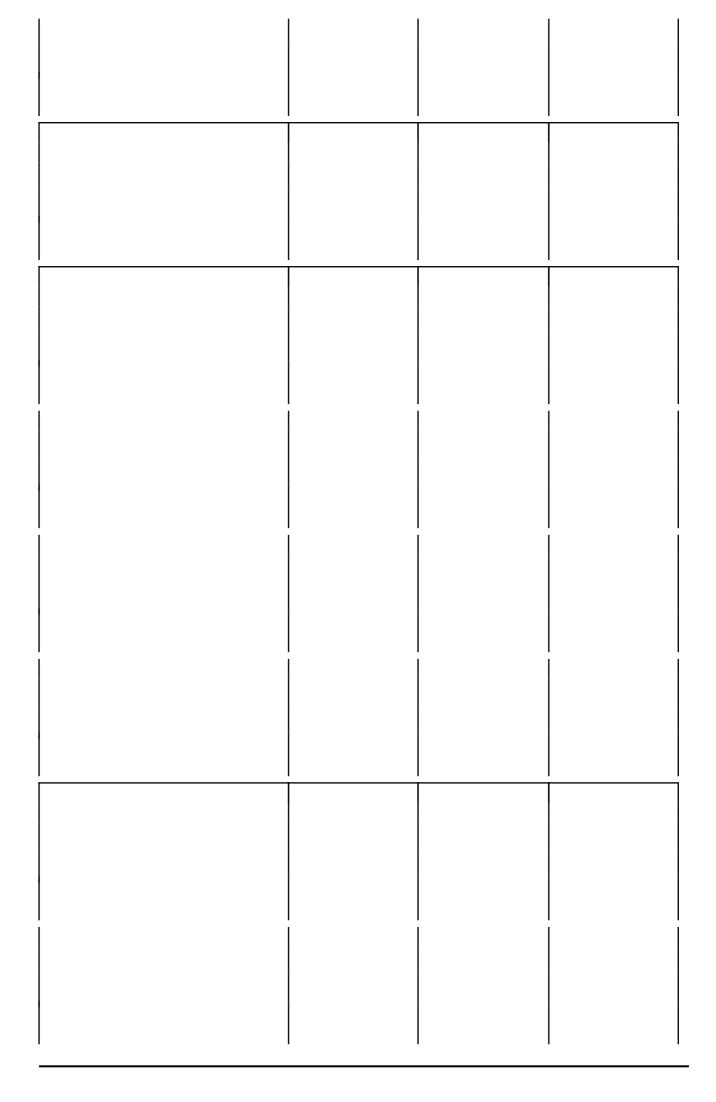


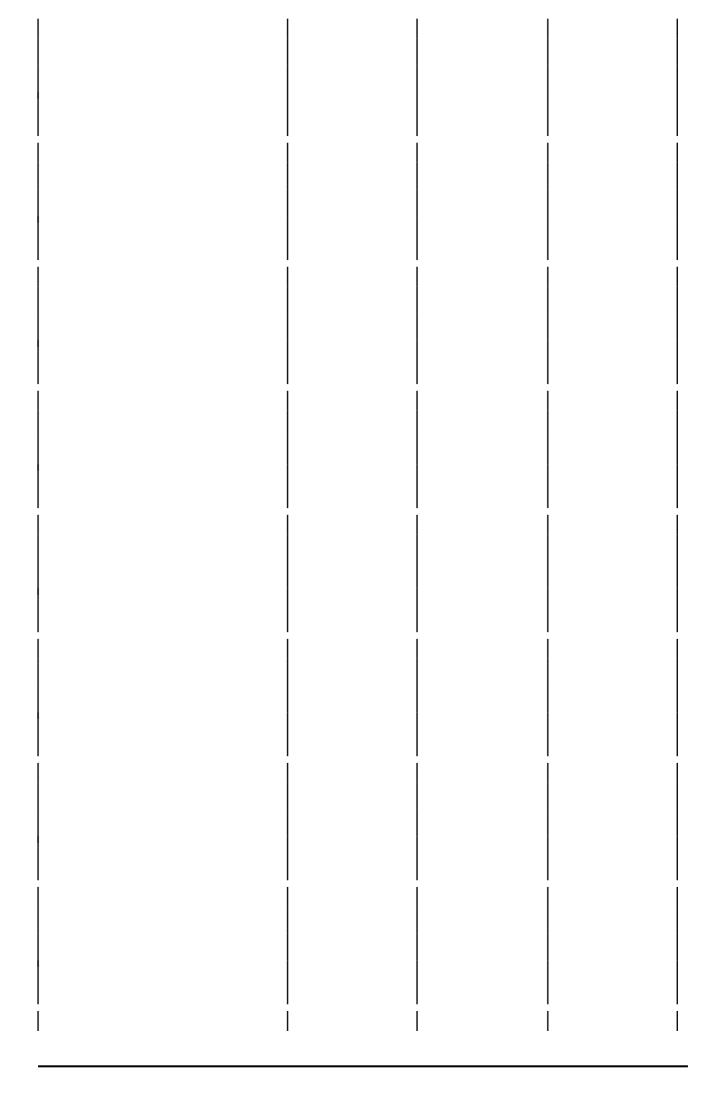






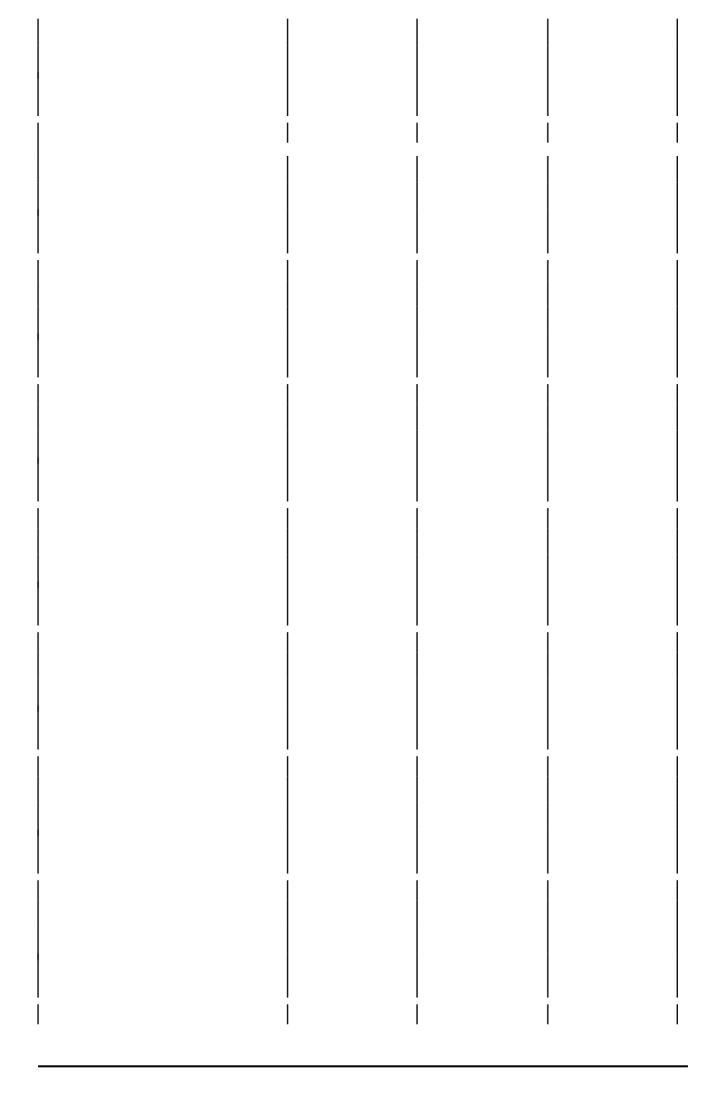


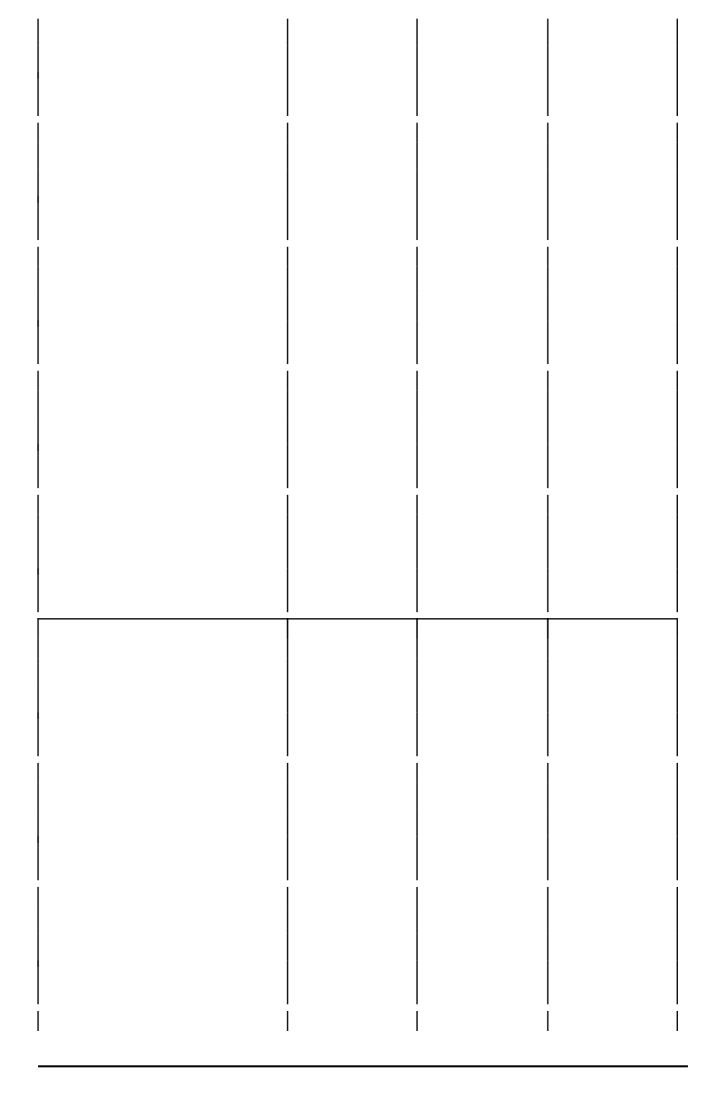


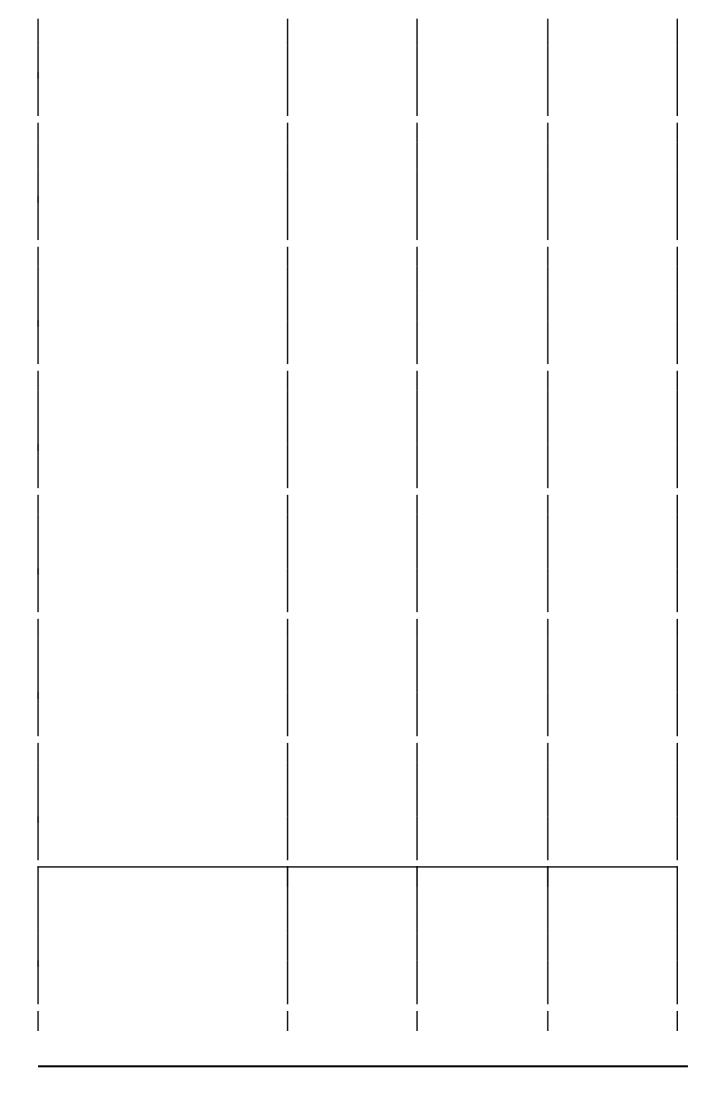




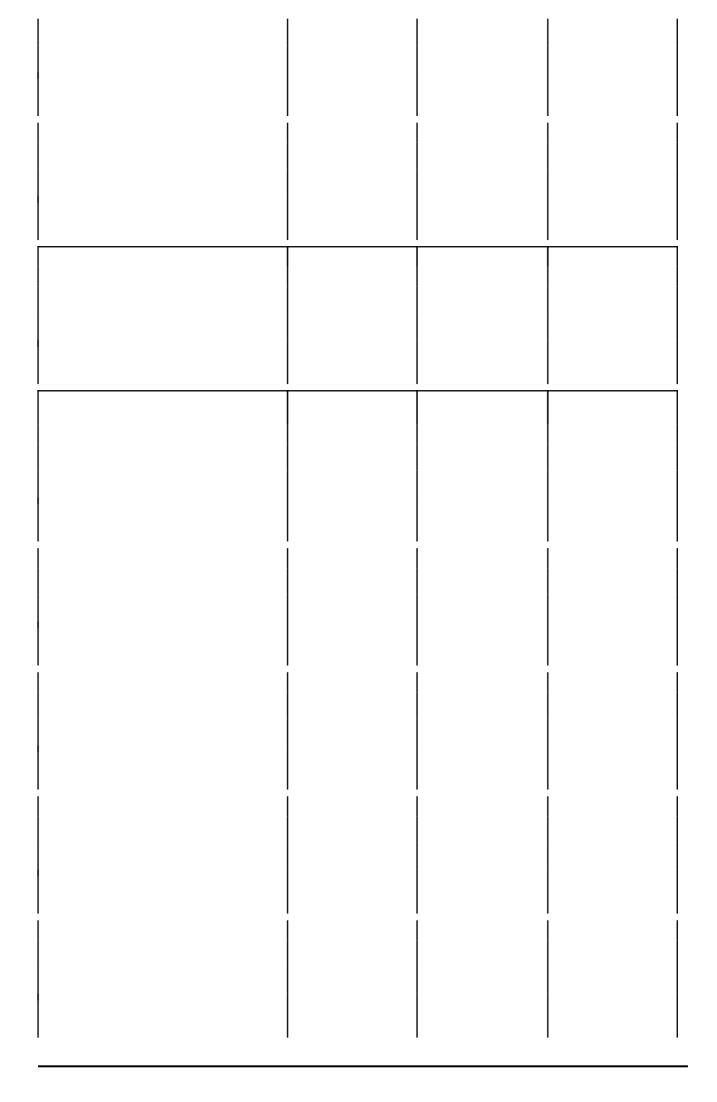


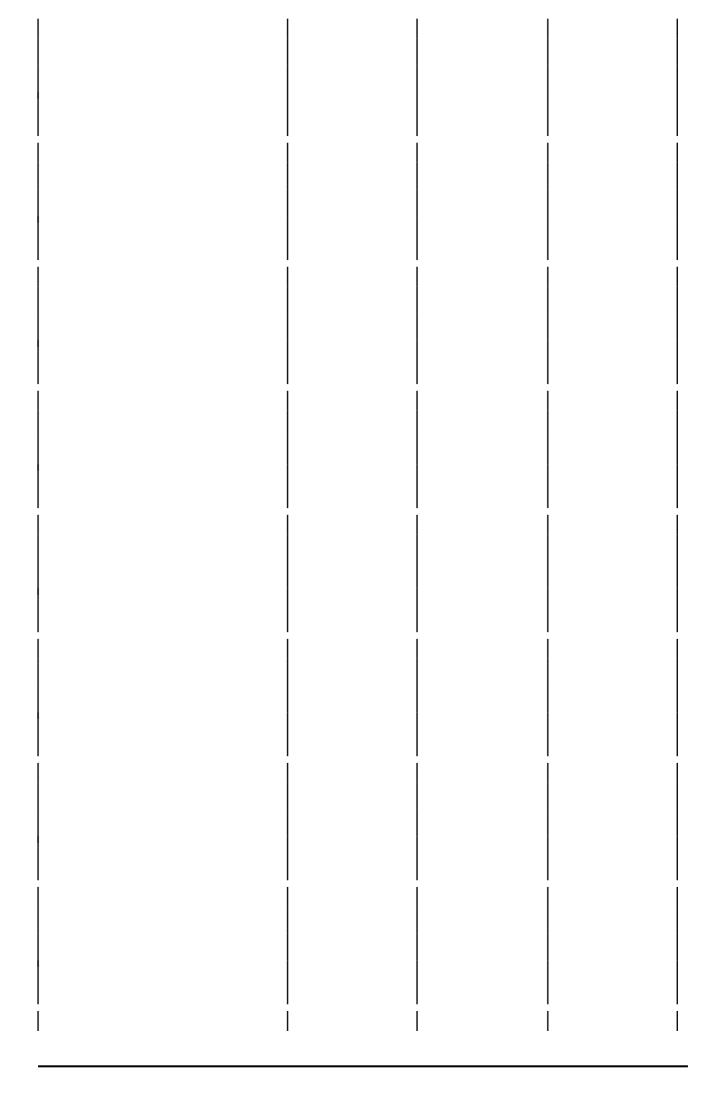


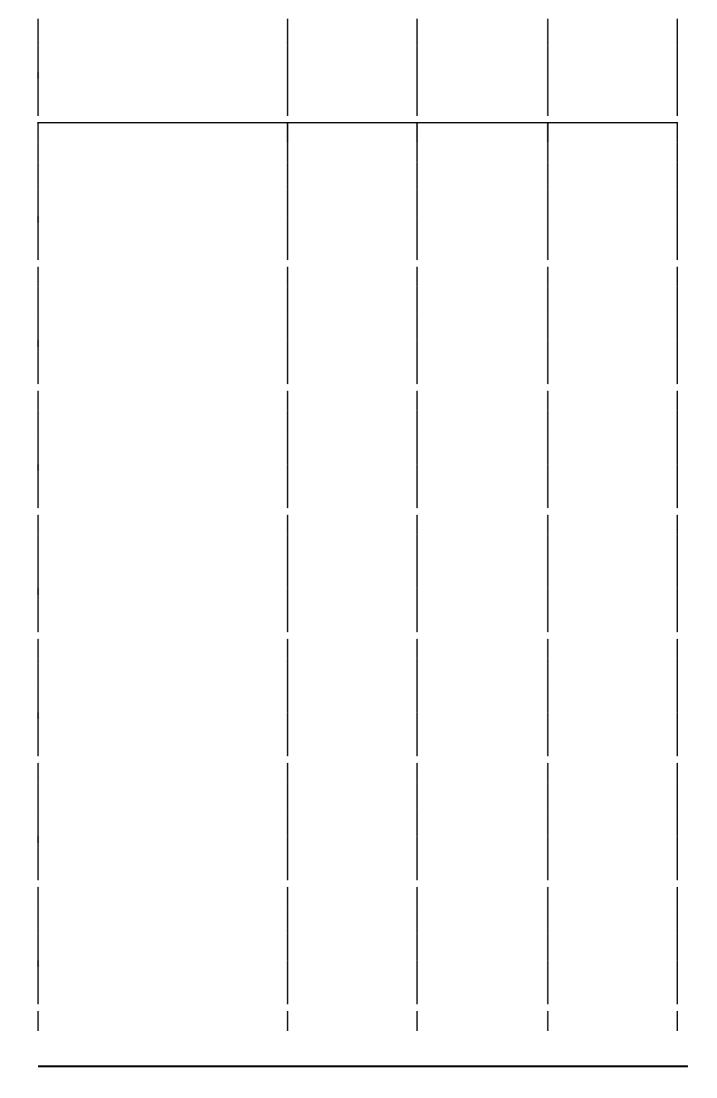






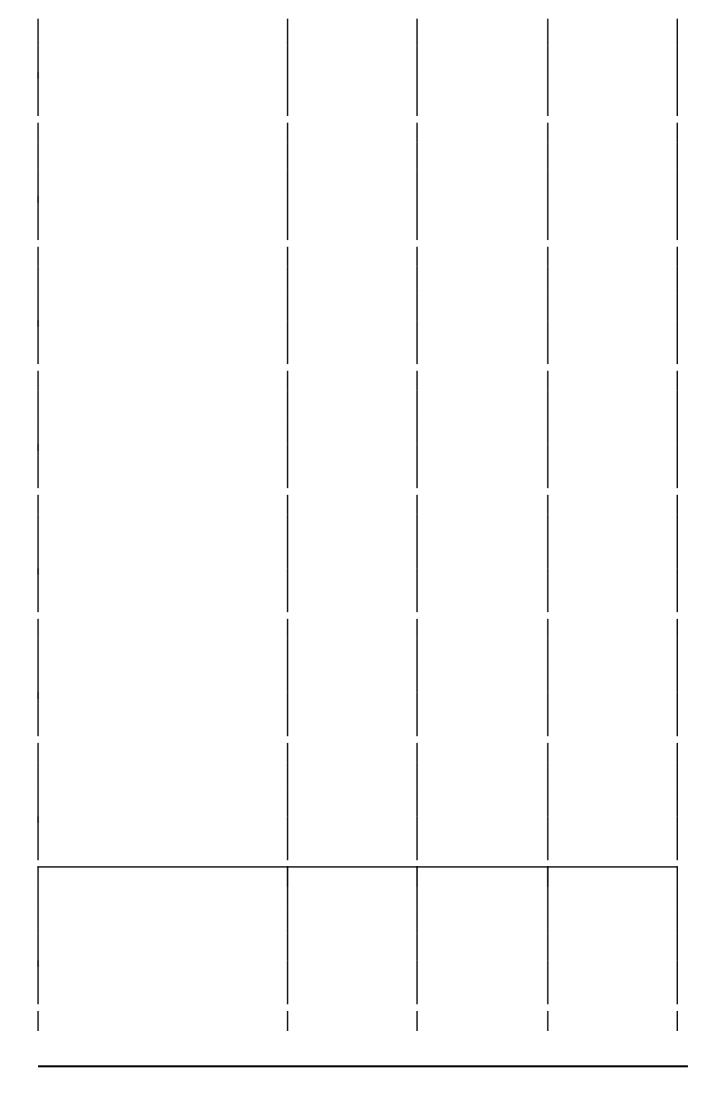








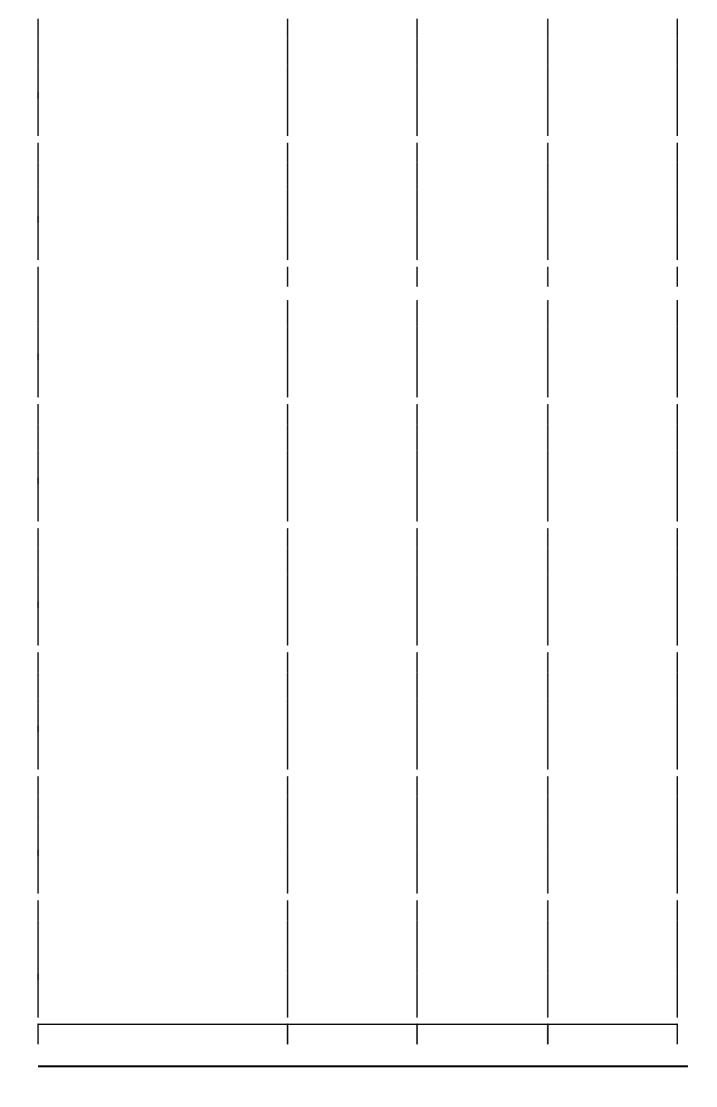


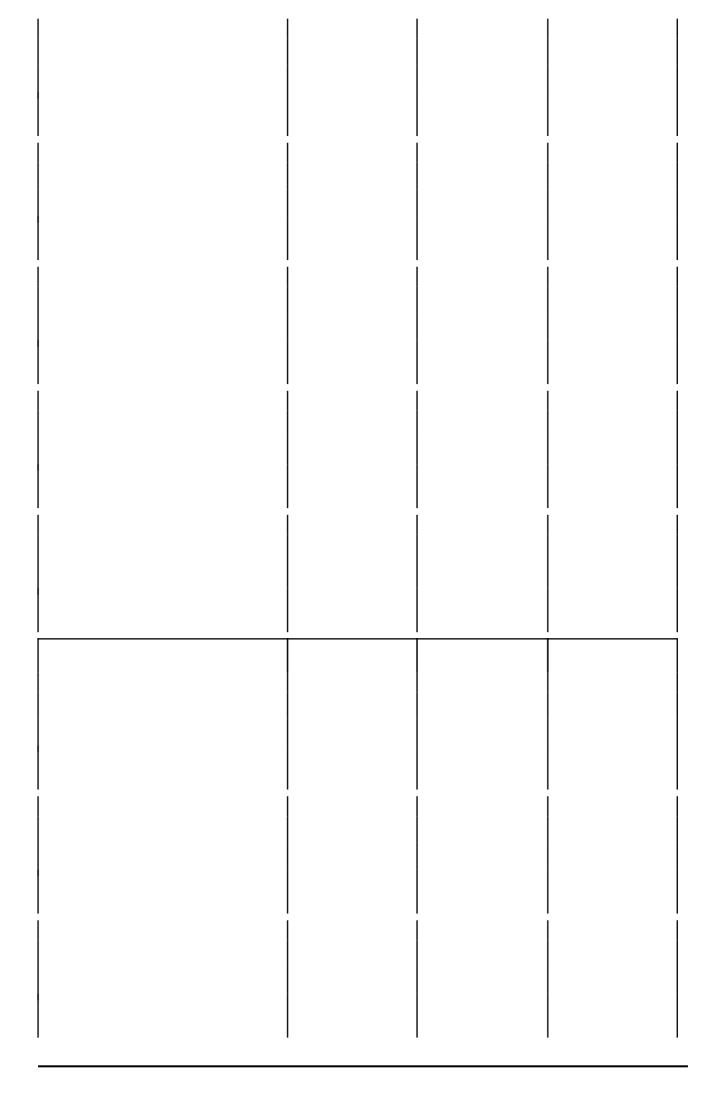


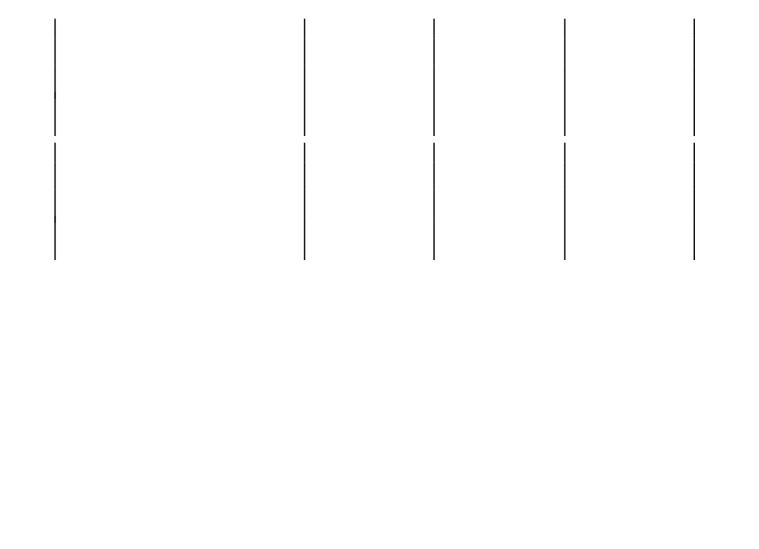


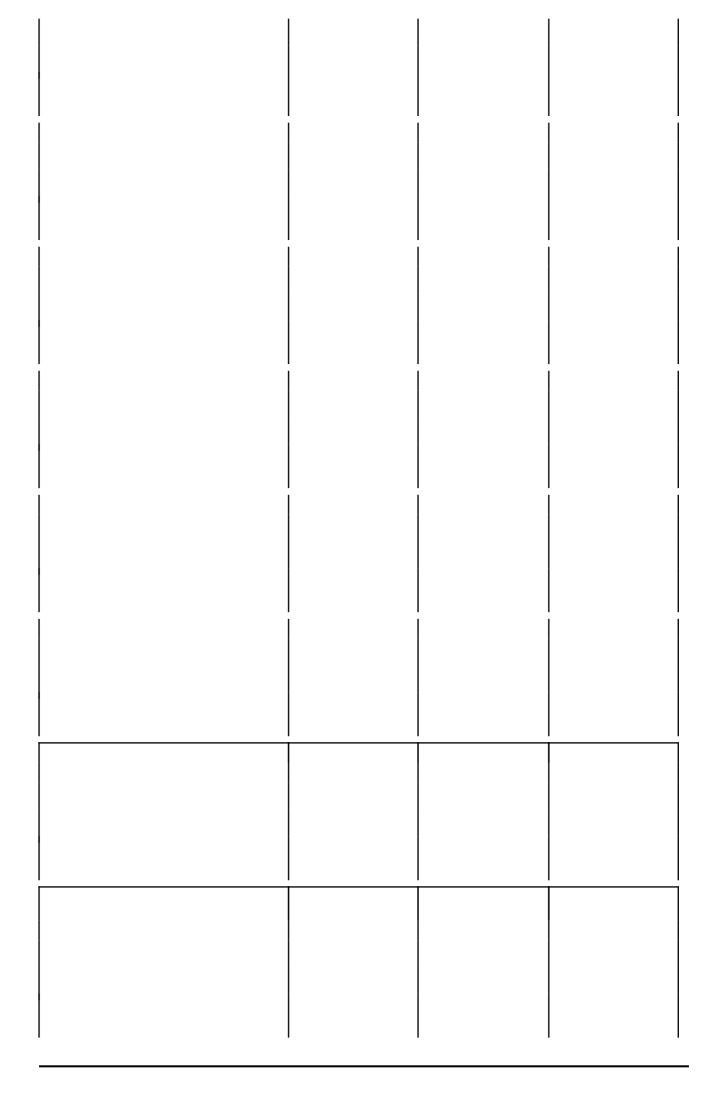


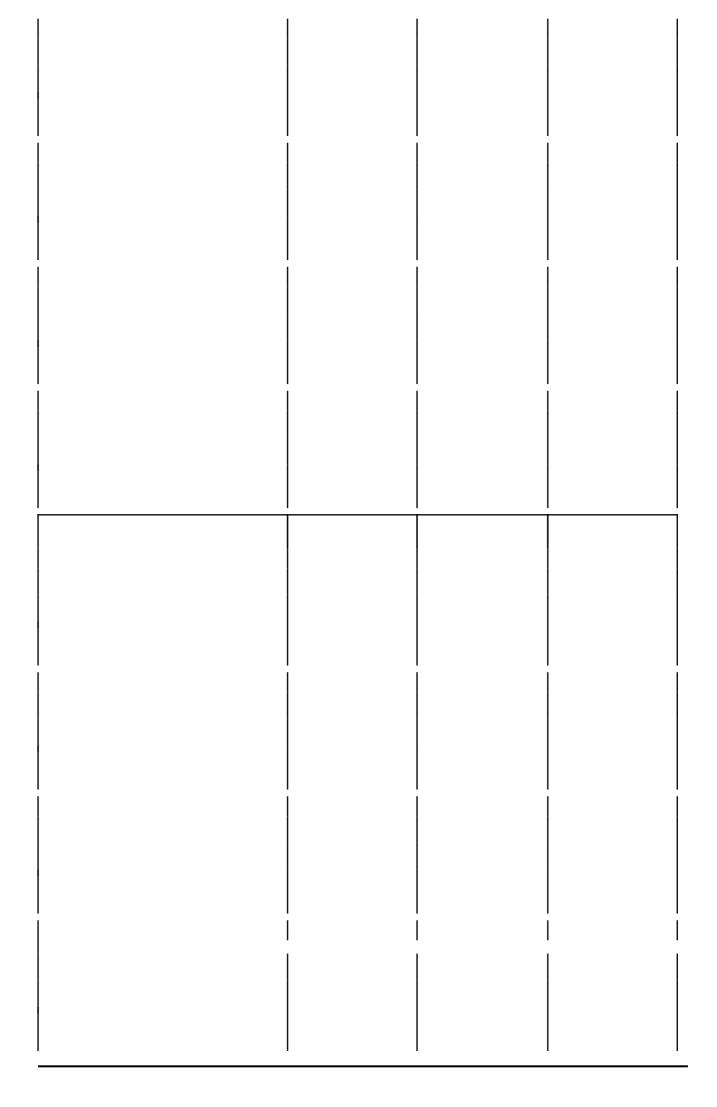
Serious adverse events		

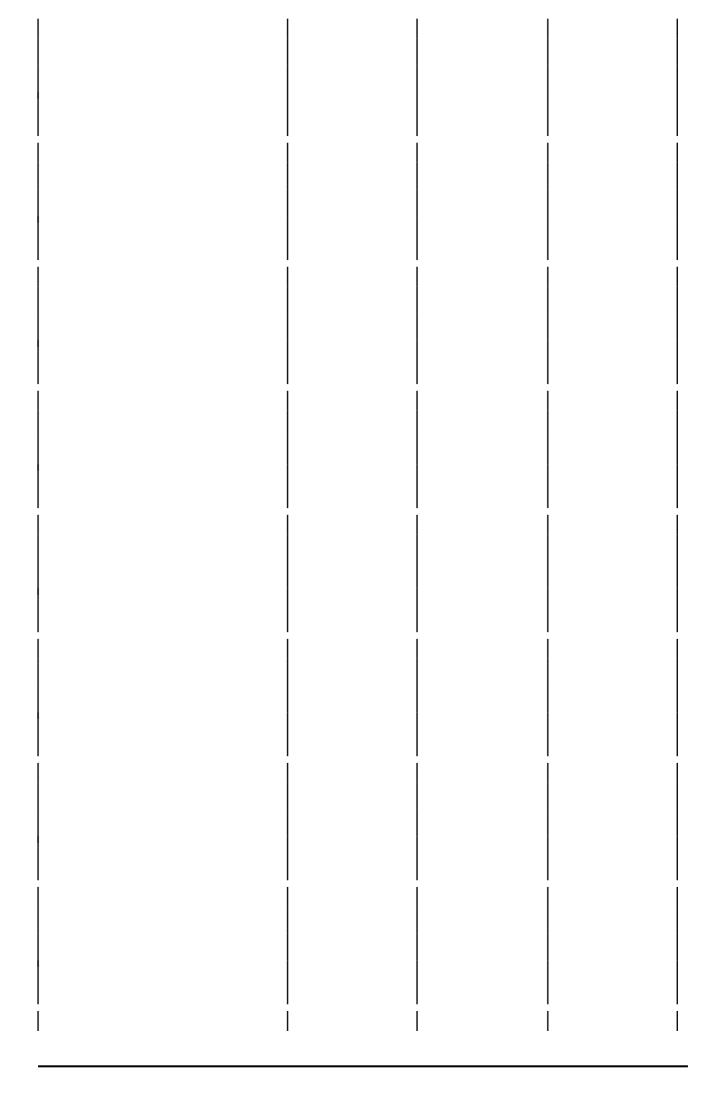




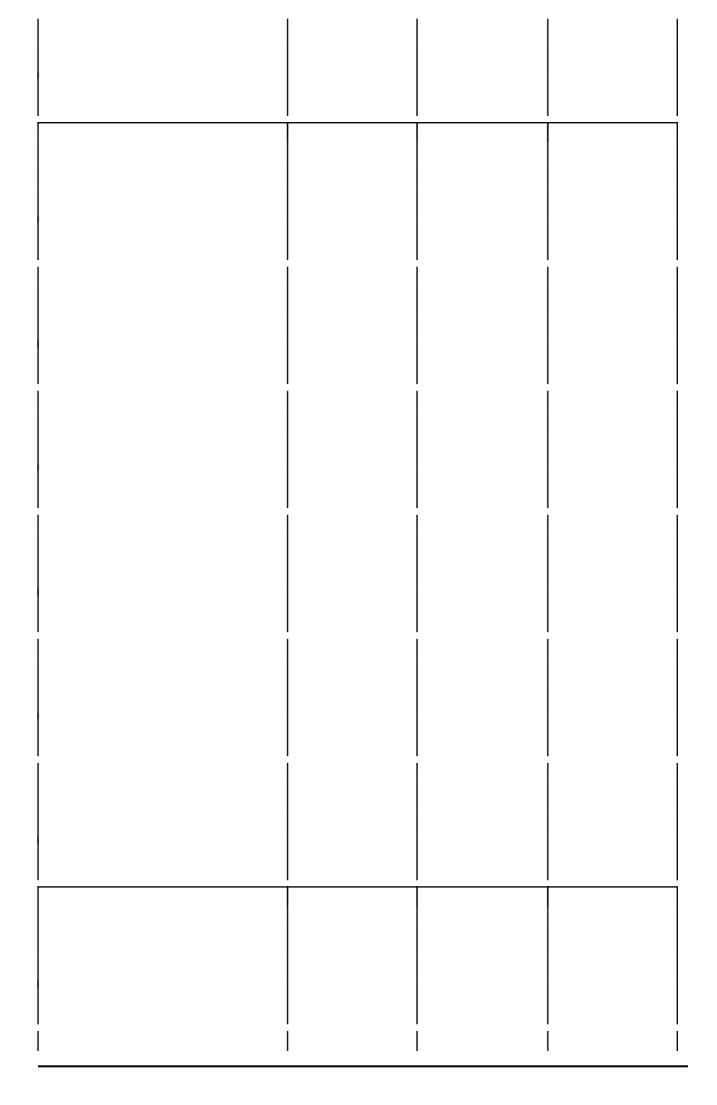


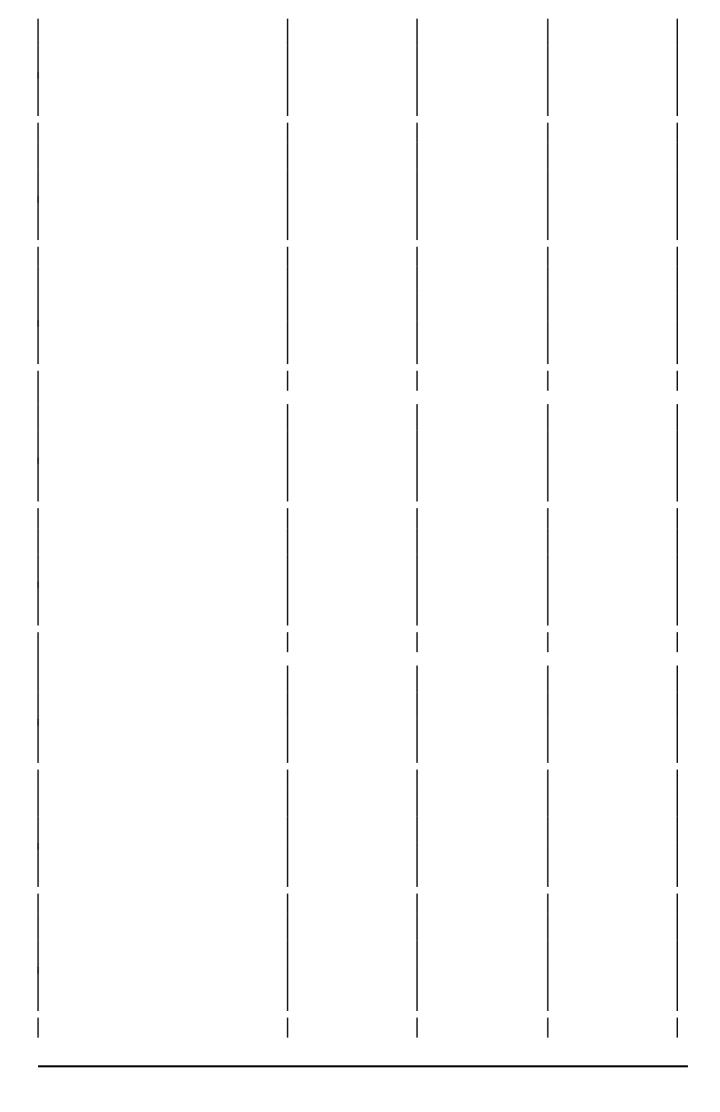


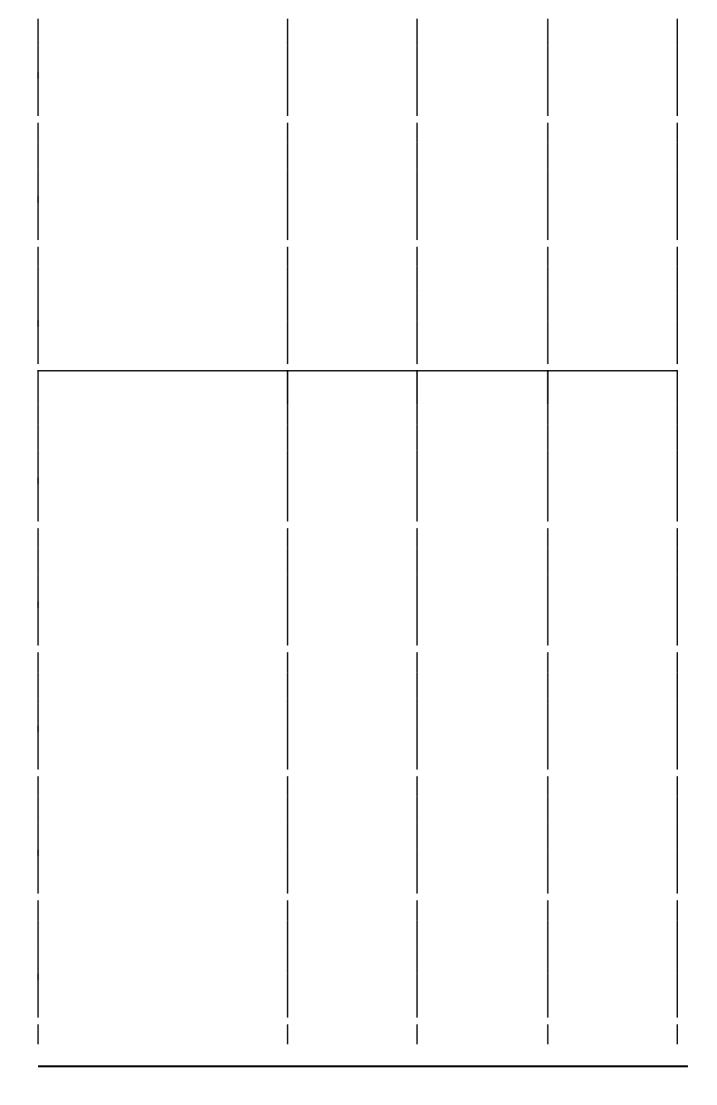




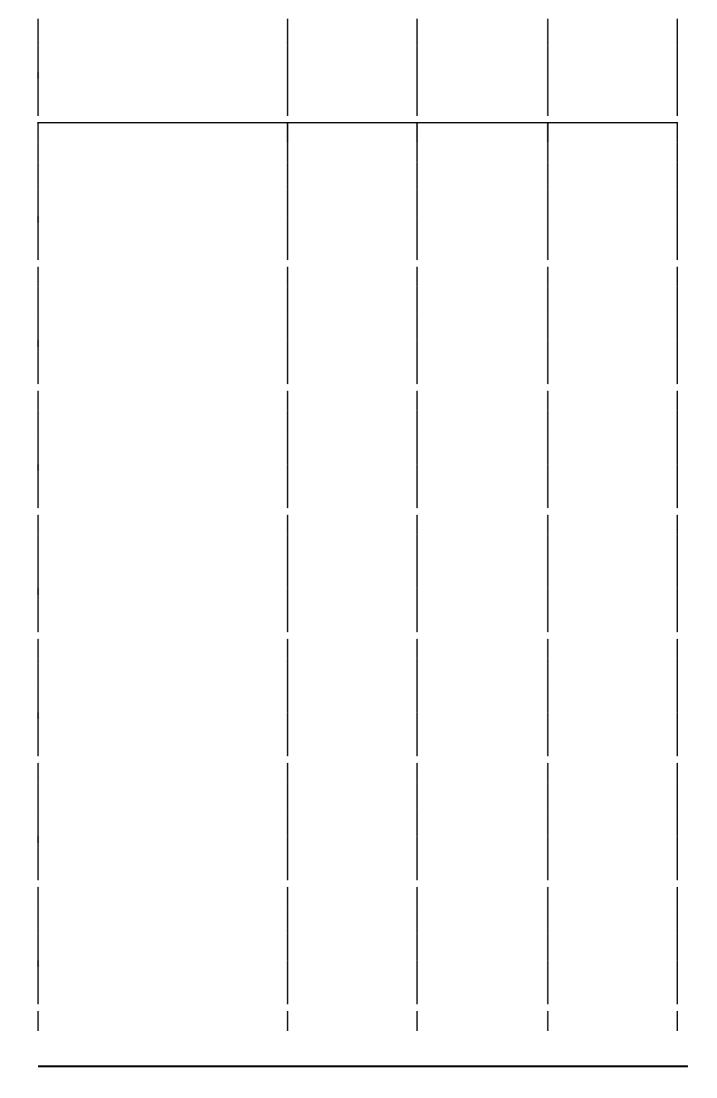




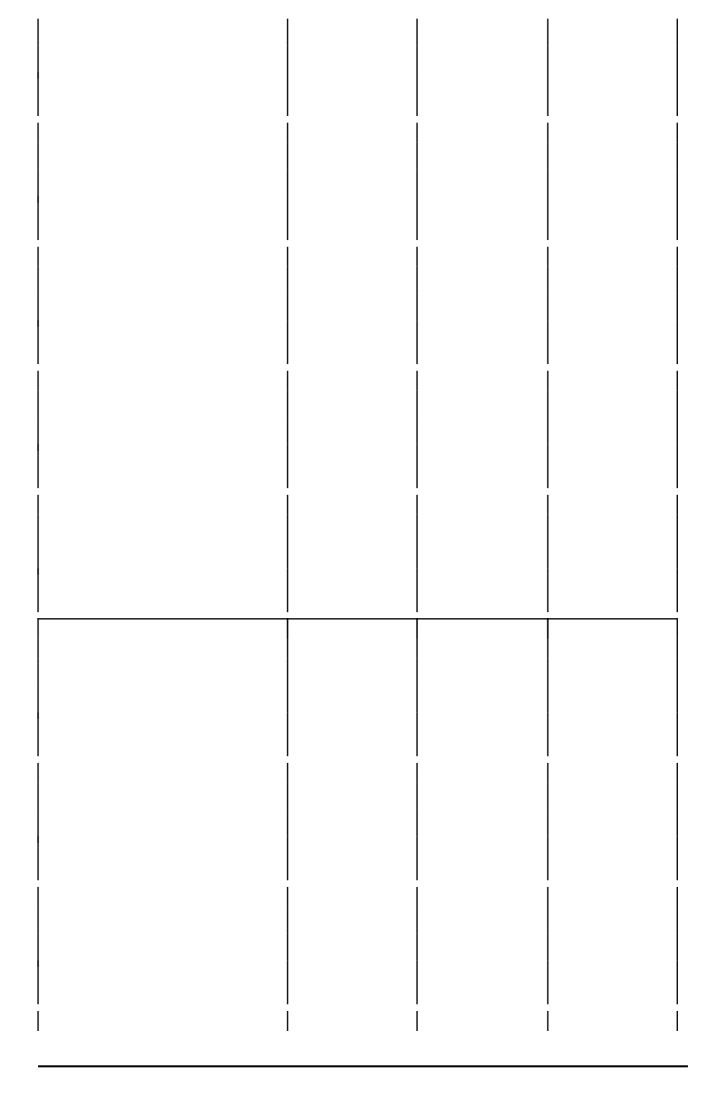






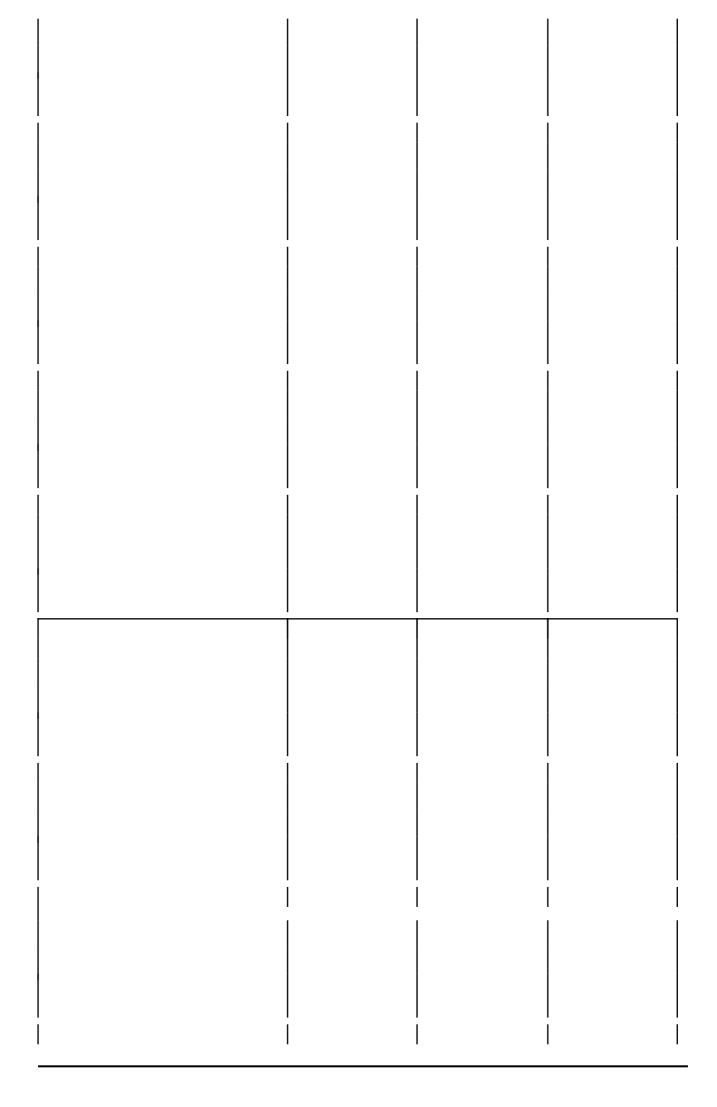


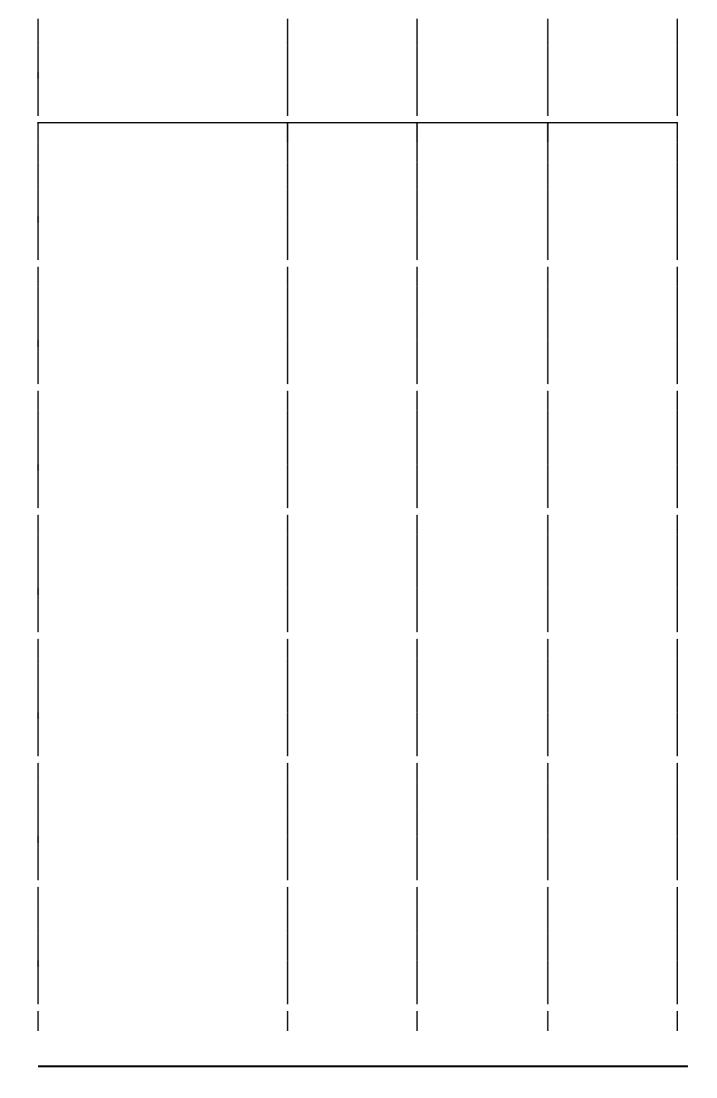






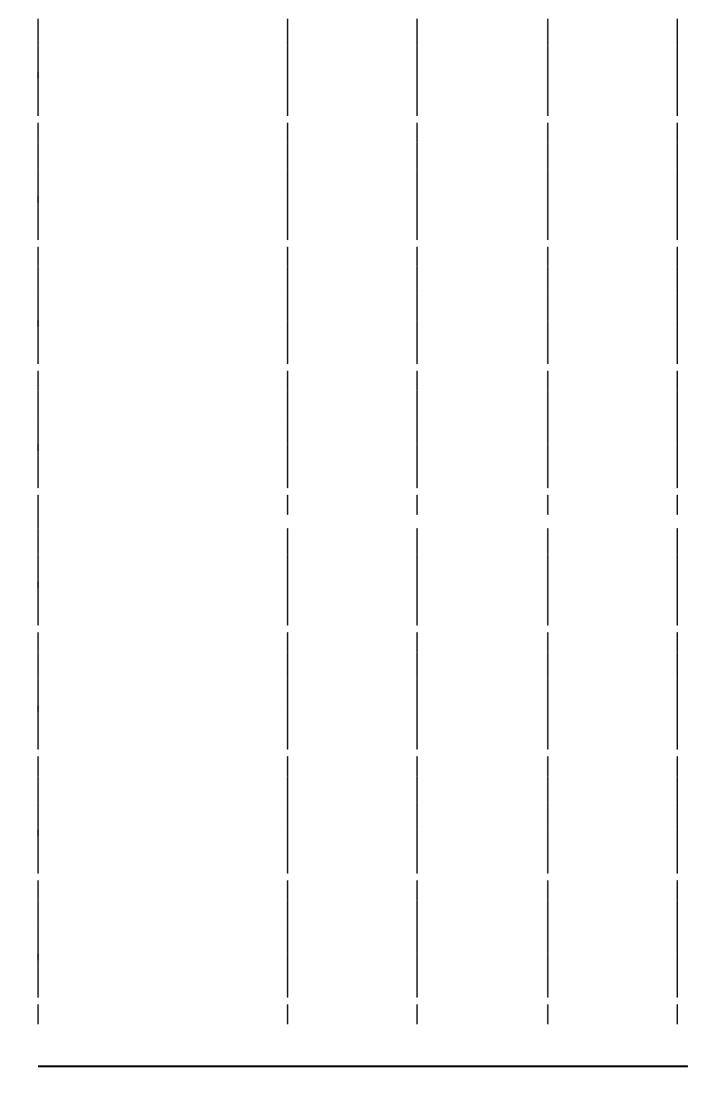


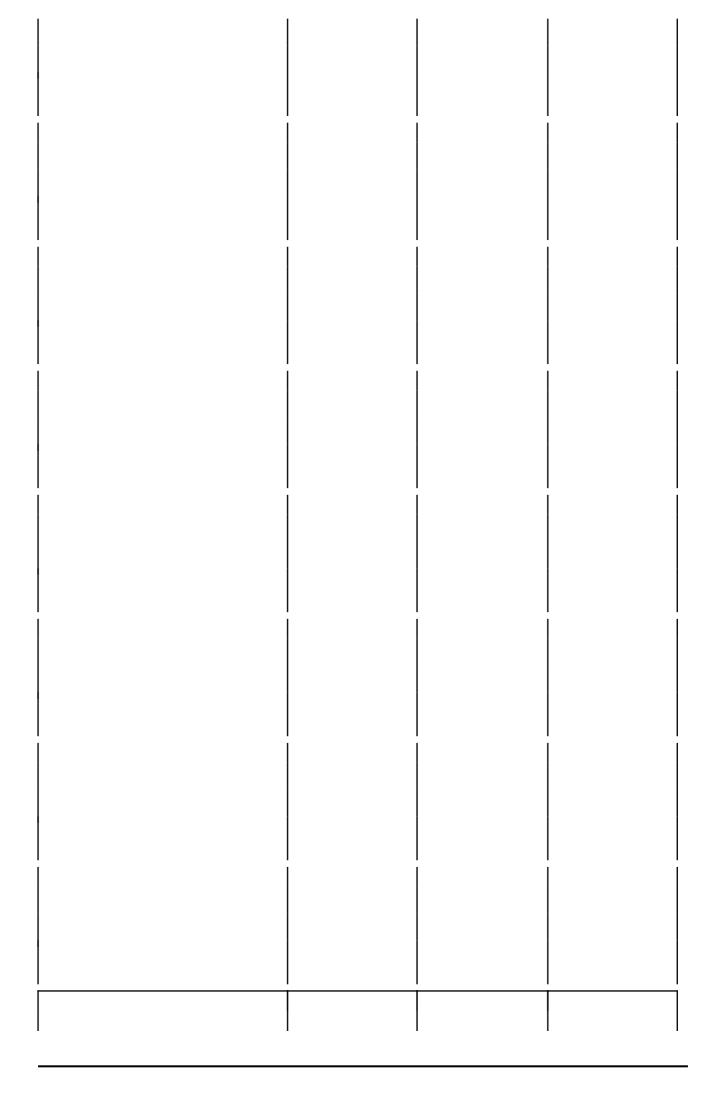




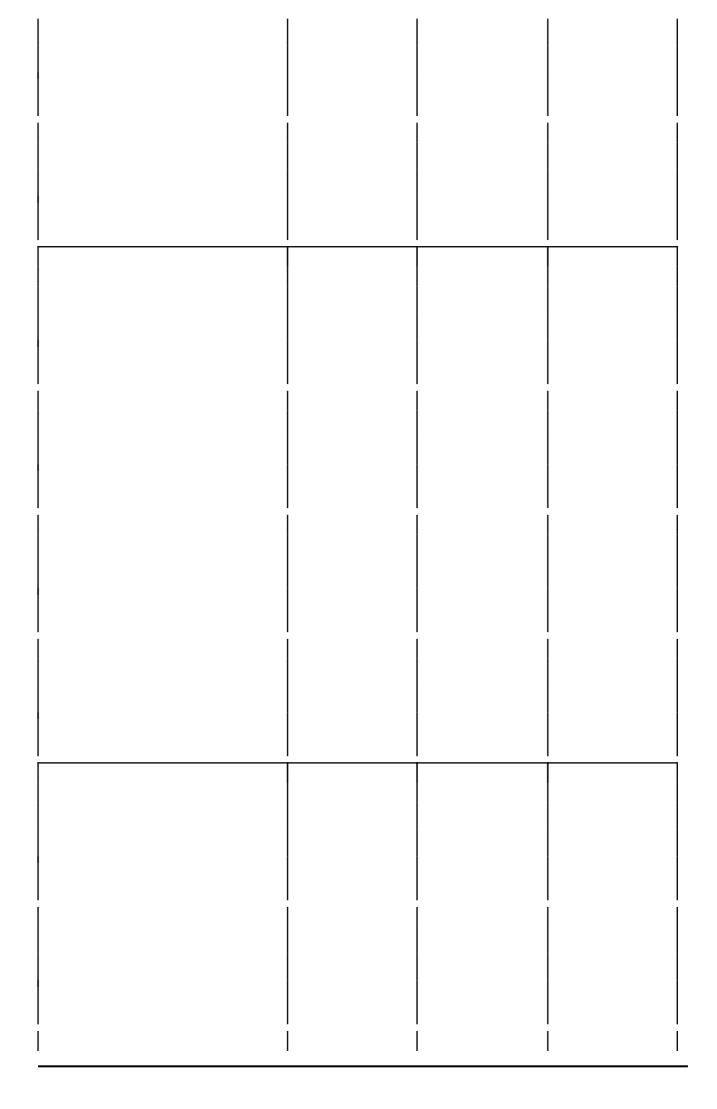




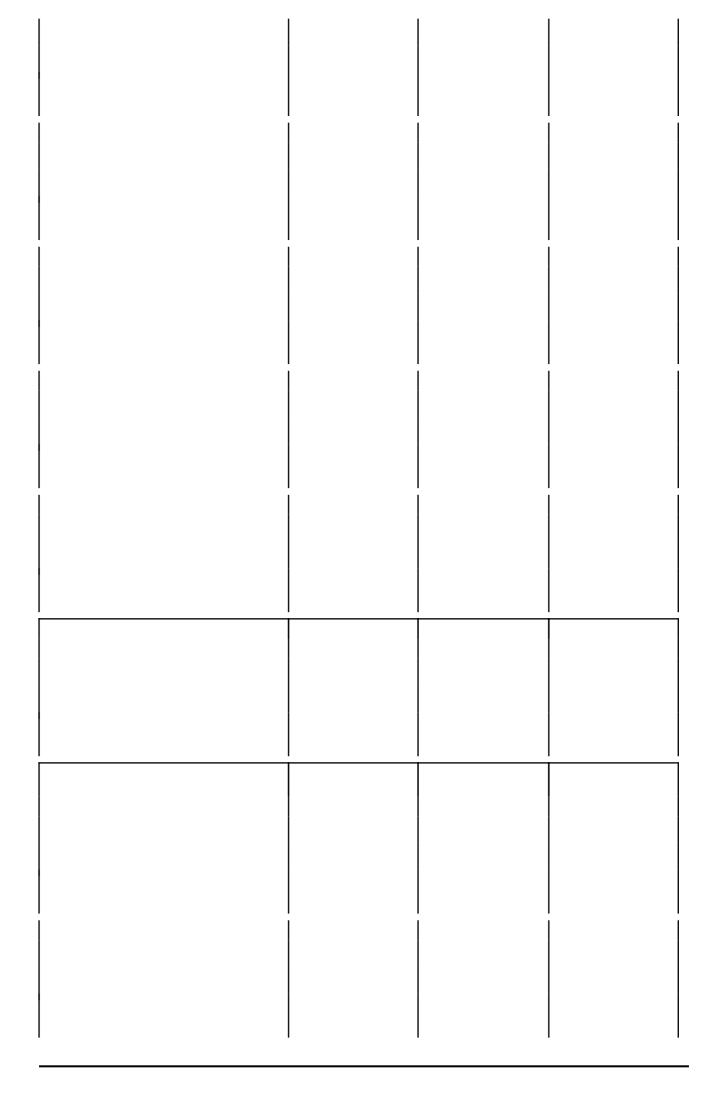


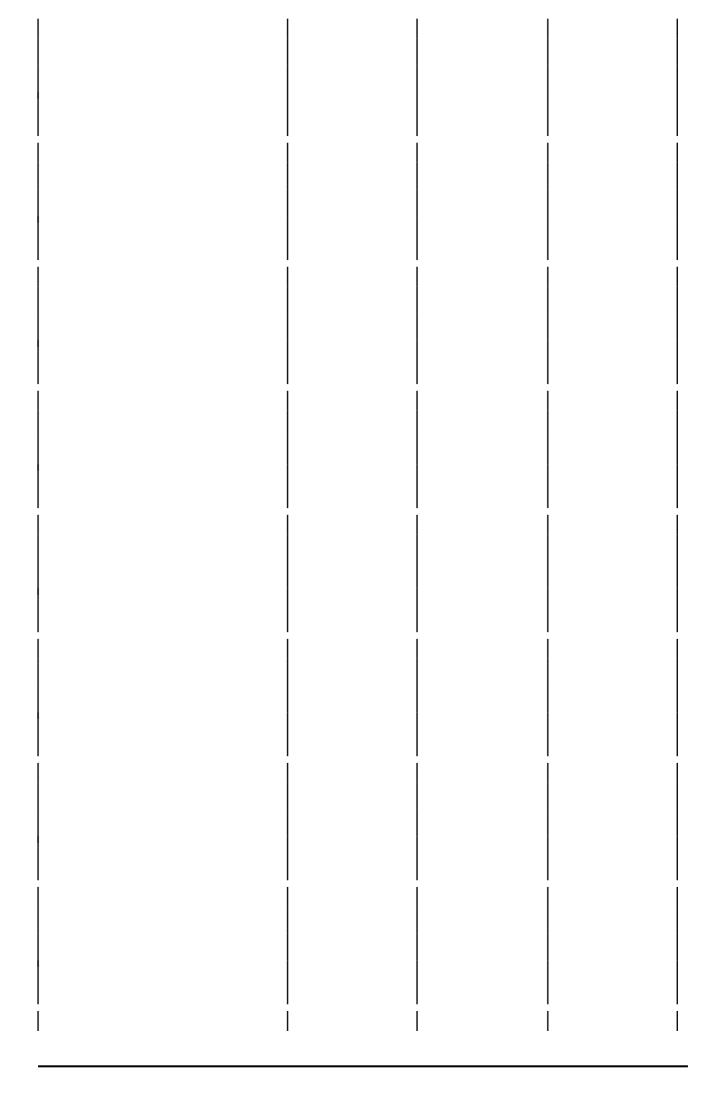


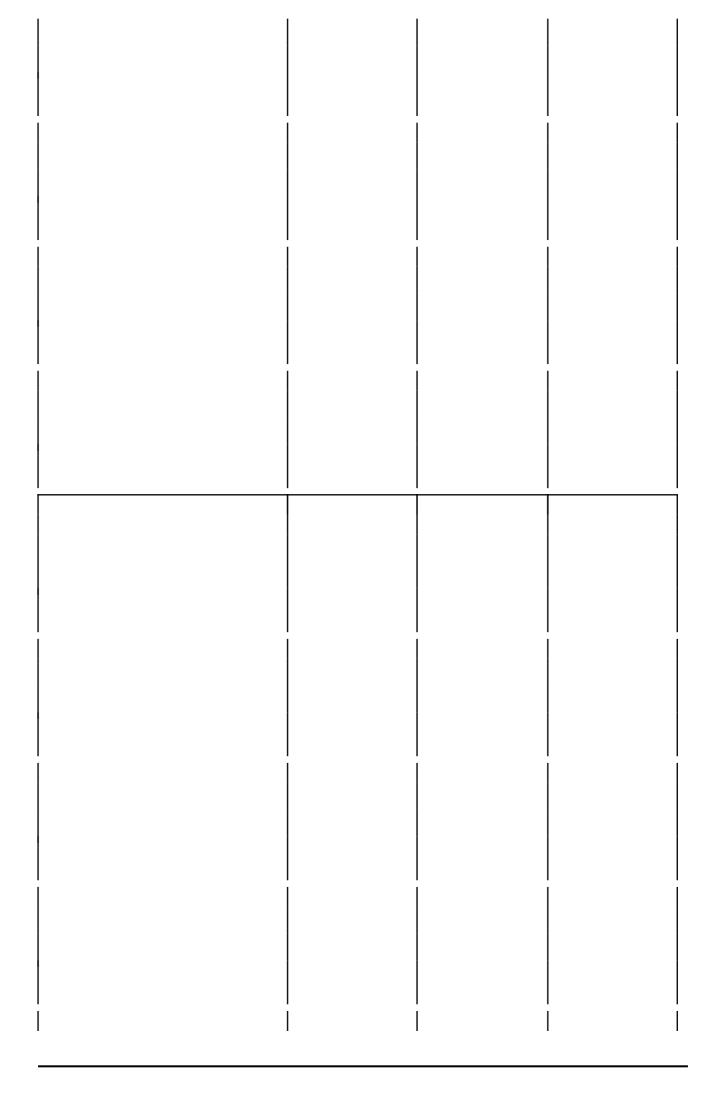














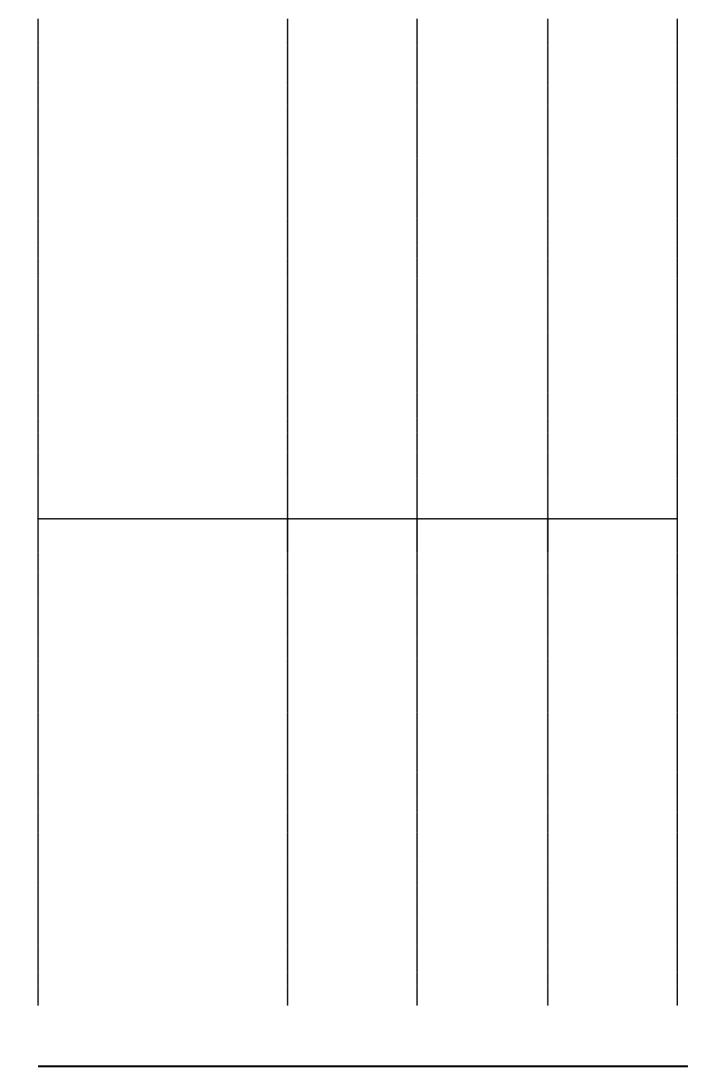


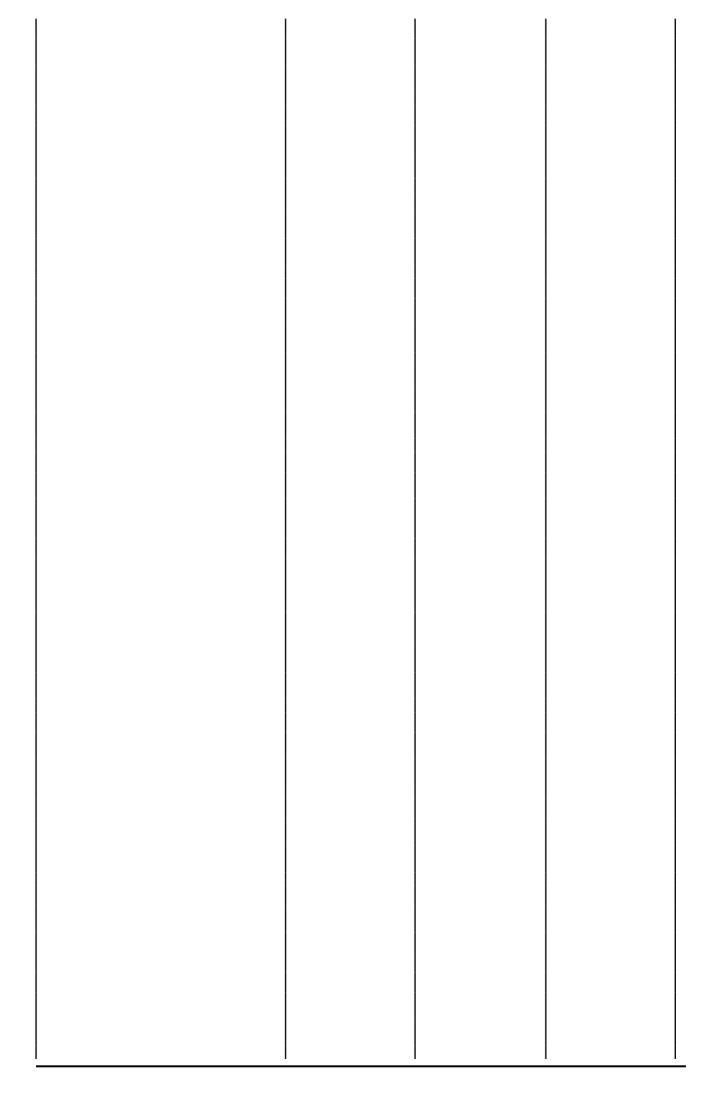


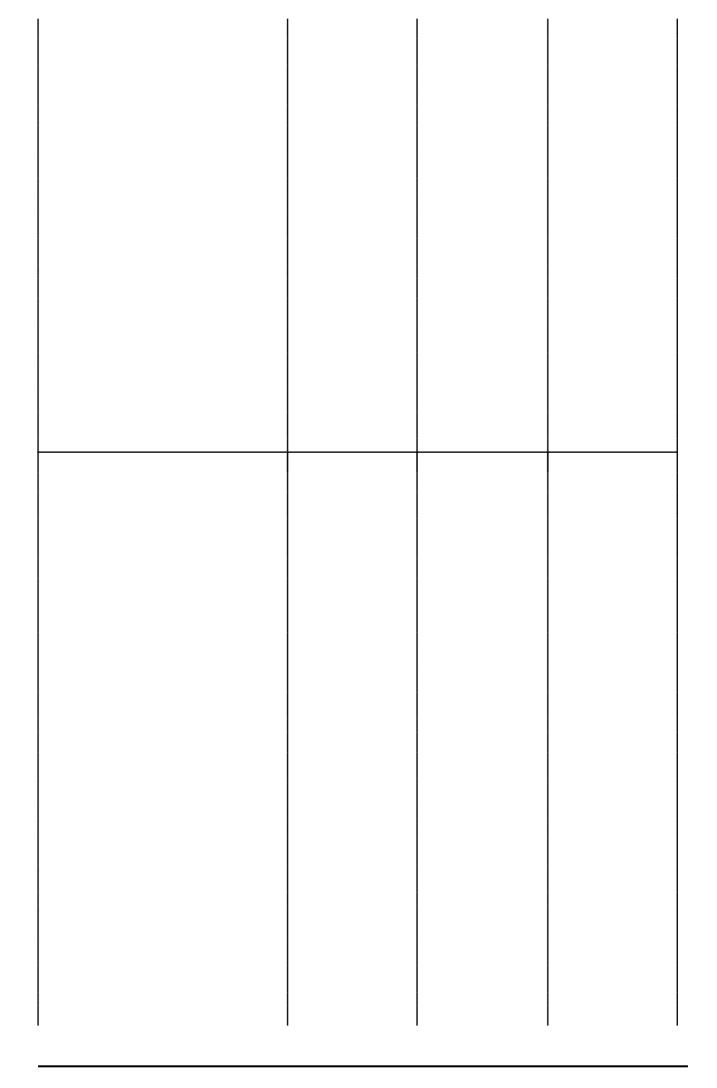


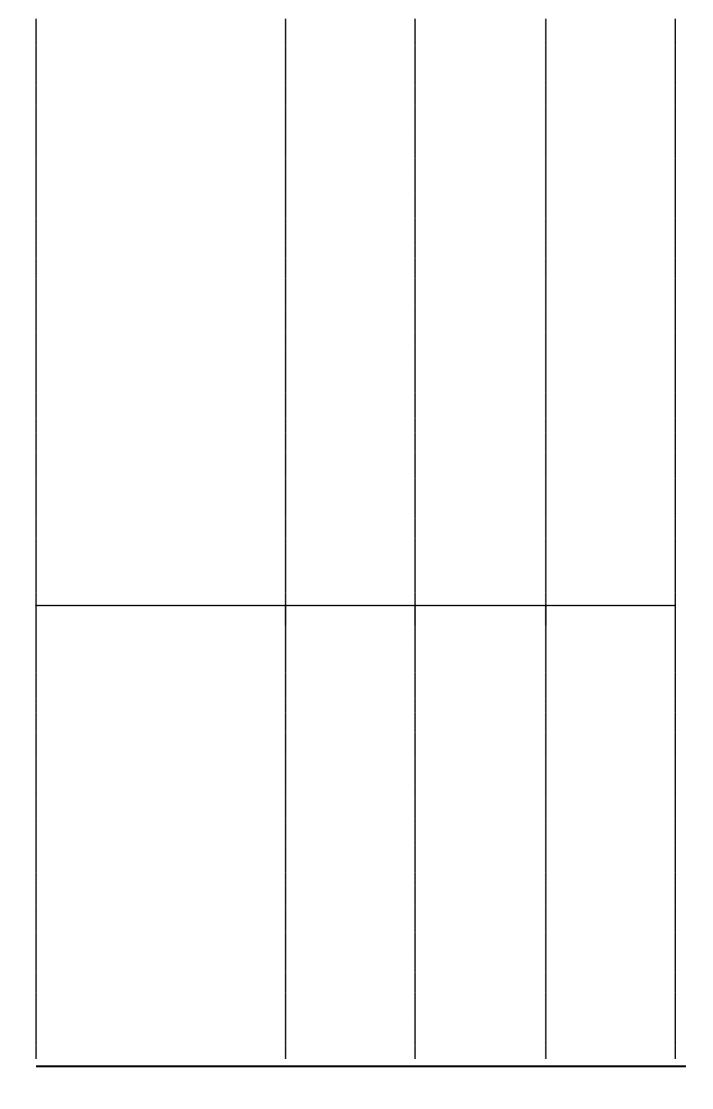
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Non-serious adverse events		



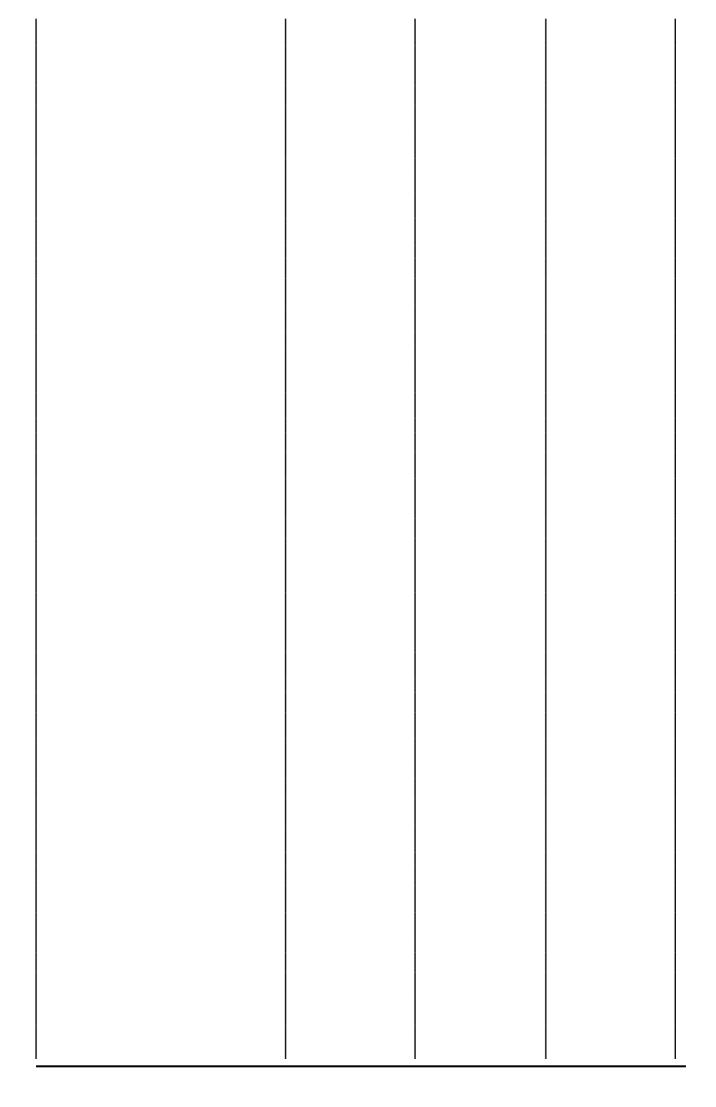


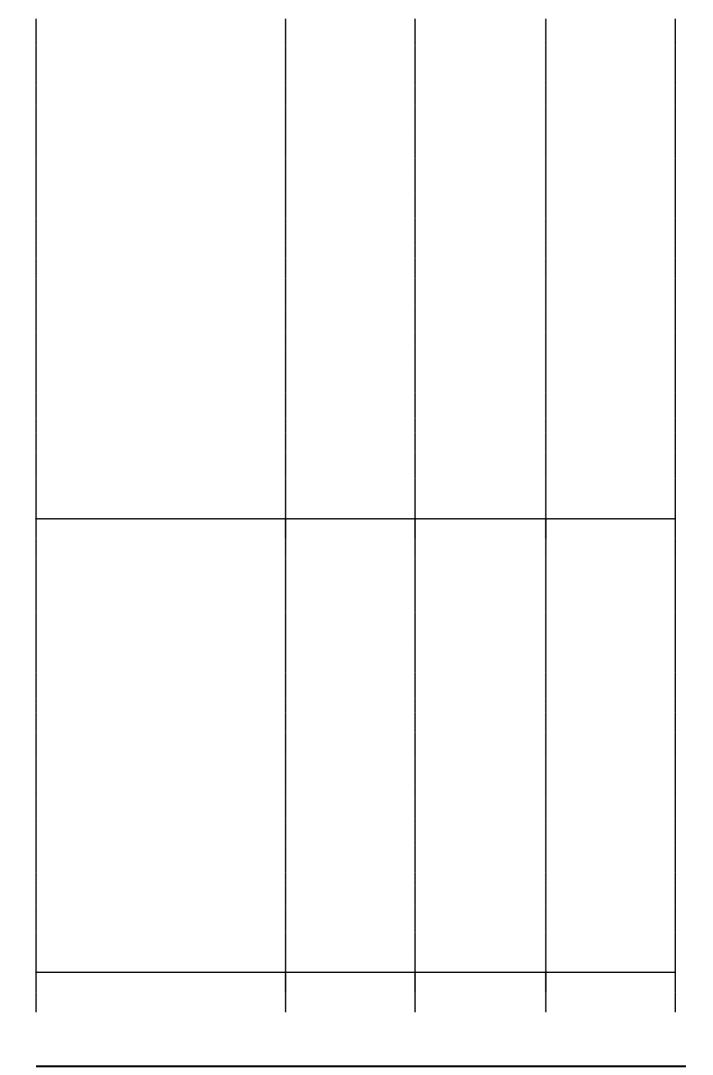


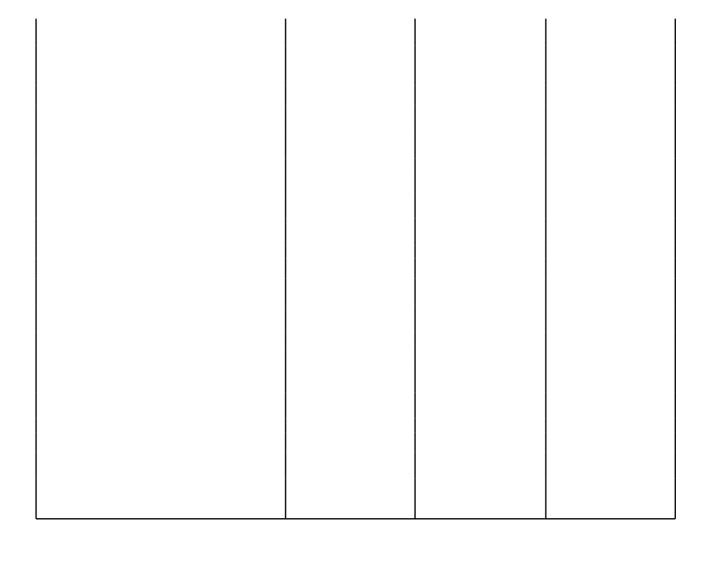


Non-serious adverse events		
Non-serious adverse events		

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## **More information**

## Substantial protocol amendments (globally)

Date	Amendment			
Interruptions (globally)				

Limitations and caveats						