

VersaStream®

Usability Questionnaire

Objective:

As a potential user, may we ask you to complete this questionnaire by reviewing the supplied instructions for use and evaluating the safety aspects of the product during use. The questions form part of our manufacturing risk analysis and your independent assessment will assist us in regards to practice-orientated design and further development of the product.

Assessor:									
Hospital / Location:									
Sampling Line: (REF, LOT)									
Connected to: Device / Monitor.									
Environmental Conditions									
Usage Time									
Gas administered	None	O ₂	N ₂ O	Des	Sev	Enf	Iso	Hal	Other

No.	Question	Evaluation			
		(Tick which statement applies and add result/comments as appropriate)			
		Very Good/ Simple	Good/ Moderate	Poor	Result/Comments
1.	How clear are the Instructions for Use?				
	Are the warnings, contraindications and safety notes easily understood and are they appropriate?				
	Is the patient type and weight clearly stated and easily understood?	Yes		No	
	Is the stated usage time clear and easily understood? (Short Term Use or Long Term Use)				

No.	Question	Evaluation			
		(Tick which statement applies and add result/comments as appropriate)			
		Very Good/ Simple	Good/ Moderate	Poor	Result/Comments
2.	State the usual clinical application of the sampling line (critical patient monitoring, patient transport monitoring, emergency medicine...)	--	--	--	
3.	What is your assessment regarding the legibility of the labelling and markings?				
	How well is the information within the Instructions for Use explained?				
4.	Connect the sampling line to the monitor. How secure and stable is the connection?				
	Is the sampling line detected by the monitor?	Yes		No	
	Are there any error messages or alarms? If so, please describe.	Yes		No	
5.	Attach the sampling line to the patient. How clear did you find the handling and application instructions in the Instructions for Use?				
6.	What is your assessment of the quality of the capnogram and the measurement accuracy?				
7.	How appropriate is the information regarding product storage and disposal?				
Additional comments:					
Signature & Date:					

This user product evaluation was initiated by:

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