

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 regard to practice-orientated design, and with further development of the product.

Assessor:									
Hospital / Location:									
Sampling Line: (REF, TYP, 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?				
	Is the stated usage time clearly and easily understood? (Short Term Use or Long Term Use)				

No.	Question	Evaluation			Result/ Comments
		very good/ simple	good/ moderate	poor	
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?				
	Is the information within the Instructions for Use adequately explained?				
4.	Connect the sampling line to the monitor and evaluate if the connection is secure and stable.				
	Is the sampling line detected by the monitor and confirm that there are no error messages or alarms.				
5.	Attach the sampling line to the patient. What is your assessment of 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.	Is the information regarding product storage and disposal appropriate?				
Additional comments: 					
Signature & Date:					

This user product evaluation was initiated by:

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