

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) | | | | |



VIAMED

Viamed Limited - 15 Station Road - Cross Hills
Keighley -West Yorkshire BD20 7DT - United Kingdom
Tel: +44 1535 634542 Fax: +44 1535 635582
Email: info@viamed.co.uk Website: www.viamed.co.uk

| 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? | | | | |
| | 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:

Viamed Ltd.
15 Station Road
Cross Hills
Keighley
West Yorkshire BD20 7DT
United Kingdom