



Gas Samling Line H

en Instruction for Use

Disposable, 2.5m/8ft

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| REF | 8090121313V |
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| # | 4421517 |
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Indications for Use

The Gas Sampling Line H are intended for continuous monitoring of expired and inspired respiratory gases. The Gas Sampling Line H are single patient use devices with a cumulative duration of use of up to 24 hours.

The Gas Sampling Line H are for use with Sedana Medical Anaesthetic Conserving Devices (AnaConDa), with adult, pediatric and infant patients. The Gas Sampling Line H are intended for continuous monitoring of Carbon Dioxide (CO₂), Oxygen (O₂), Sevoflurane, Isoflurane and respiratory rate in professional/hospital care environments, such as operating rooms and intensive care units (ICU).

The Gas Sampling Line H are intended for use by qualified medical personnel only. Prescription use only.

Warnings

Warning: Only for use with anaesthetic agents Sevoflurane and Isoflurane. Do not use with any other anaesthetic agents.

Warning: Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.

Warning: Do not cut or remove any part of the sampling line. Cutting the sampling line could lead to erroneous readings.

Warning: Due to risk of cross contamination, do not re-use.

Warning: Loose or damaged connections may compromise ventilation or cause an inaccurate measurement of respiratory gases. Securely connect all components and check connections for leaks according to standard clinical procedures.

Warning: Check tubing regularly during use to ensure that no kinks are present. Kinked tubing may cause inaccurate measurement.

Cautions

Caution: Do not attempt to clean, disinfect, sterilize or rinse any part of the sampling line with liquids.

Caution: Dispose of sampling lines in accordance with standard operating procedures or local regulations for the disposal of contaminated medical waste.

Notes

Note: For accuracy specifications and further instructions, warnings and cautions, please consult the gas monitor instructions for use.

Instructions for Use

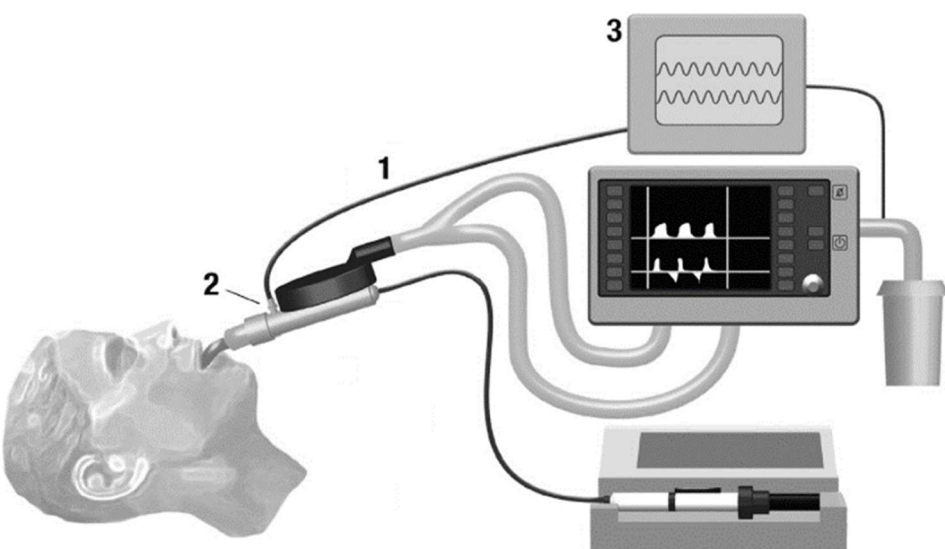


Figure 1

1. Connect the Gas Sampling Line (1) to the AnaConDa gas monitor sampling port (2) as shown in Figure 1. Rotate the Luer connector clockwise for a secure fit to ensure that there is no leakage of gases at the connection point.
2. Connect the Gas Sampling Line (1) to the respiratory gas monitor (3). Rotate the Luer connector clockwise for a secure fit to ensure that there is no leakage of gases at the connection point.
4. After connection of the sampling line, check that gas values appear on the monitor display.

Environmental Specification

Operating temperature: +10 °C to +40 °C (50 °F to 104 °F)

Storage temperature: -25 °C to +60 °C (-13 °F to 140 °F)

Atmospheric pressure: 660 to 1060 hPa (495 to 795 mmHg)

Ambient Humidity: 10 to 95% RH (non-condensing)

Reporting of serious incidents





















If there is a *serious incident* in connection with the use of this product, this should be reported. The incident should be reported to the manufacturer and the health authority or the competent authority for the installation site of the product. A *serious incident* is when there is a **death or a temporary or permanent serious deterioration in the health of a patient, user or other person.**

Send an email to the following manufacturer address: prrc@bluepoint-medical.com

When doing so, please provide the following information:

- Order number and model designation of the product as indicated on the product
- Serial number/batch number of the product
- Date of the *serious incident*
- Description of the *serious incident*, including its impact on the patient or any injury
- Your contact details (institution, address, contact name (substitute), title and phone number)

Symbols

| | |
|---|--|
|  | Do not reuse |
|  | Not made with natural rubber latex |
|  | Not made with DEHP |
|  | Do not use if package is open or damaged |
|  | Keep dry |
|  | Temperature limitation |
|  | Humidity limitation |
|  | Atmospheric pressure limitation |
|  | Consult instructions for use |
|  | Keep away from sunlight |
|  | CE-Conformité Européene mark, 0482-notified body |
|  | Medical Device |
|  | Date of manufacture |
|  | Manufacturer |
|  | Catalogue number |
|  | Lot number |
|  | Use by |
|  | Gas inlet |
|  | Do not connect a syringe |
|  | Consult accompanying documents |

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