

Technical Information

SpiroTrue®H

Disposable flow sensor used to measure the airflow in the breathing system of the patient for use with Hamilton ventilators.



Sensor technical data:

- Measuring principle: differential pressure measurement
- Flow range: 0 to 180 L/min
- Accuracy: ± 25 ml/s or $\pm 20\%$ (whichever is greater) of sensor signal, uncalibrated (manufacturing tolerances)
- CE marking: Designed in accordance with Annex I of 93/42/EEC and (EU)2017/745(MDR)
- Classification: Class IIa, according to 93/42/EC, Annex IX and (EU)2017/745(MDR), Annex VIII
- Quality control acc. to: DIN EN ISO 13485
- Materials: DEHP FREE, LATEX FREE
 - Sensor body: MABS
 - Flap: PET
 - ISO Adaptor: MABS
 - Hook: PP
 - Tubing: DEHP FREE PVC
- Sensor weight: $\leq 9,5$ g (without sensor tube)
- Dead space: ≤ 10 mL (functional)
- Resistance: $< 0,03$ cmH₂O/(L/min) in the range of 0 to 100 L/min;
 $< 0,04$ cmH₂O/(L/min) across the entire range;
- Connections:
 - Sensor: 15M/15M - DIN EN ISO 5356-1
 - ISO Adaptor: 15F/22M – 15F/22M, DIN EN ISO 5356-1
- Biocompatibility evaluation: DIN EN ISO 10993-1 and DIN EN ISO 18562-1
- Non-sterile packaged

Recommended operating conditions:

- Temperature: 10°C to 40°C
- Relative humidity: 5 to 95%, non-condensing
- Atmospheric pressure: 700hPa to 1060hPa

Recommended storage conditions:

- Temperature: -20°C to 50°C
- Humidity (r.H.): 5% to 95%
- Atmospheric pressure: 700hPa to 1060hPa
- Storage period: ≤ 3 years (unopened, away from direct sunlight)

Compatibility:

- SpiroTrue®H is compatible with Hamilton single use flow sensor PN: 279331

Notes:

- The flow sensor must be calibrated within the basic device (ventilator) prior to patient use.
- The flow sensor calibration must be performed in accordance with the instructions for use of basic device (ventilator). Observe the selected gas/gas-mixture type.
- A preoperational device system check must be performed according to the instructions for use of basic device (ventilator) prior to patient use.
- Alignment, operation and sensor change must be carried out in accordance with the relevant device-specific instruction manual considering the hospital's infection control regulations.
- For further information, refer to the product-specific accompanying documentation.

Ordering information:

- REF 1030132000 – Box of 6pcs: SpiroTrue®H with 2m±0,05m double PVC tube, incl. hook and adaptor

Ordering information for SpiroTrue®H as component for Manufacturers of OEM Breathing Systems:

- REF 4030131003 – 1pcs SpiroTrue®H with 2m±0,05m double PVC tube. Packed in PE Bag 20pcs/Bag; 200pcs/Box

Manufacturer information:



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