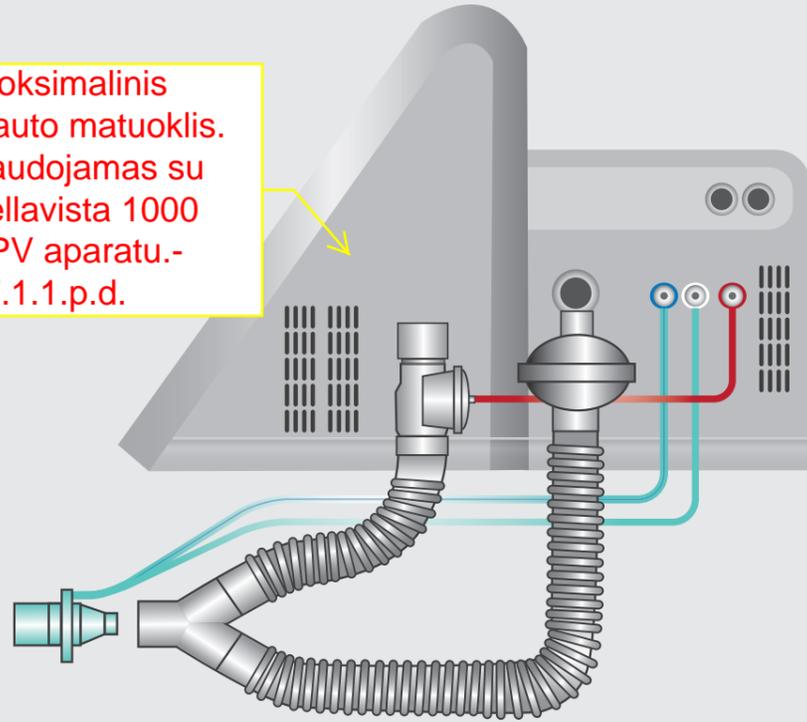**Step 3**
Connection to ventilator

Connect measurement lines as follows:

- blue strip / transparent measuring line: proximal pressure measurement port (blue)
- transparent measuring line: differential pressure measurement port (white/silver)

Proksimalinis srauto matuoklis. Naudojamas su Bellavista 1000 DPV aparatu.- 57.1.1.p.d.

Perform circuit check
For best accuracy, it is recommended to perform a circuit check including flow sensor calibration. To perform the flow sensor calibration, please follow the instructions on the ventilator. After the circuit check attach the calibration adapter to the measuring lines to prevent losing it.
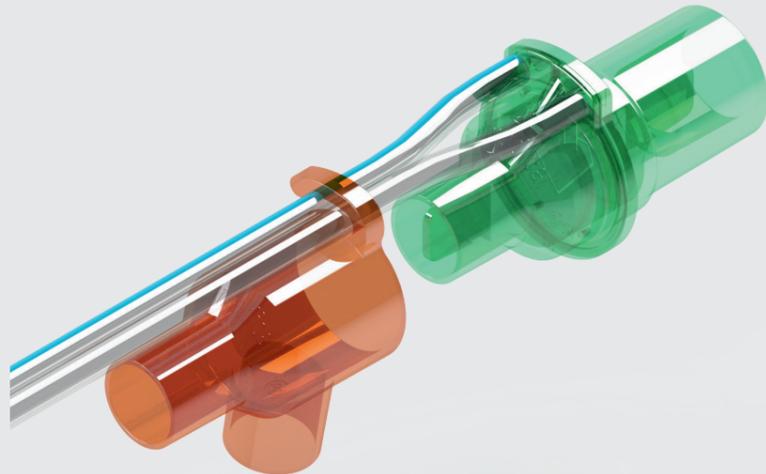
- Use the calibration adapter to turn the flow sensor for calibration in exhalation direction.
- Use the blind plug of the calibration adapter for the leakage test.
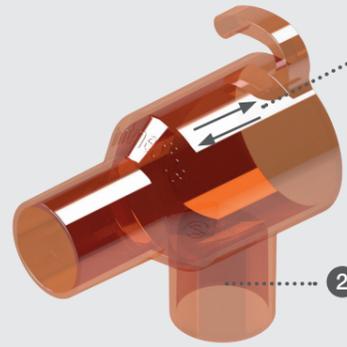
Du vamzdeliai - 57.1.3. p.d.

Legend:
1 Flow direction
2 Blind plug

> ⓘ Best ventilation and highest accuracy of measurement will be achieved with initial inspection (circuit check including flow sensor calibration). Tight bends, kinks or dents must be avoided.
>
> Calibrate the iFlow 200 S before use. Repeat calibration if an alarm occurs.

FURTHER ACCESSORIES AND SPARE PARTS

The iFlow 200S has no accessories. Damaged iFlow 200S must be replaced. No maintenance is required.

Ask your local dealer or ordering contact data for replacement:

Tel: +65 6254 4110
E-Mail: webstore@imtmedical.com.sg

EC REP

MDSS GmbH
Schiffgraben 41
30175 Hannover

DISPOSAL

After usage the iFlow 200S must be handled as a contaminated item.

The device must be disposed according to local regulations. For information, contact your local environmental or public office and appropriate waste disposal companies. In this regard, waste is to be recycled or disposed of:

- without danger to human health
- without using procedures or methods harmful to the environment, particularly to the water, air, soil, flora and fauna
- without creating noise or smell

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iflow
the sensor
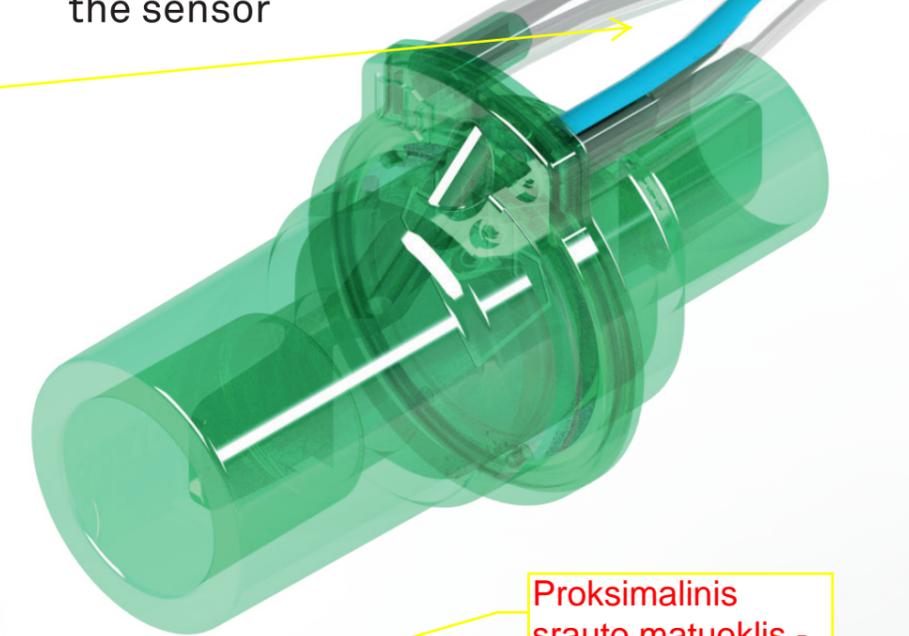
Proksimalinis srauto matuoklis - 57.1.p.d.

User manual
Proximal Flow Sensor – iFlow 200 S

imtmedical

SCOPE

This documentation is valid for the following product:
Proximal Flow Sensor (Adult/Pediatric, Single use), later on named as iFlow 200 S

The product is manufactured by imtmedical Pte. Ltd., 10 Jalan Kilang, Sime Darby Enterprise, Centre #07-01, Singapore 159410

INTENDED USE

The iFlow 200S is intended to be used as a device to measure continuous bi-directional patient air flow and airway pressure with imtmedical ventilators. The iFlow 200S is intended to be used only by appropriately trained personnel and can be used for the following types of ventilation:

- life supporting ventilation and non-life supporting ventilation
- invasive and non-invasive ventilation
- stationary and during intra-hospital patient transportation

SAFETY INSTRUCTIONS

This user manual uses the symbols below to specifically point out residual dangers during correct application and usage as well as important technical requirements. For a full understanding of the performance characteristics of this device please read carefully these Instructions before using the device.

Personnel

🛈 Usage only by trained personnel.

Responsibility and warranty

The manufacturer assumes no responsibility or warranty, nor will he accept any liability if the user or third parties:

- do not use the device as intended
- violate the technical specifications
- modify the device in any way (through modifications, changes, etc.)
- use the device with accessories not indicated in the related product documentation

🛈 Although the device is characterised by a high quality and safety standard as well as being built and tested according to state-of-the-art technology, injuries and serious consequences cannot be entirely excluded in case of inappropriate use or misuse of the device. Thus the manual should be read carefully and kept within easy reach of the device.

Single use products

🛈 Do not reuse single use products! These products should be used for one patient only! imtmedical single use products are designed for single use only and may compromise their intended function after reprocessing. Reprocessing a single use device may alter its characteristics from its original specifications and performance.

Potential for patient cross-contamination is one of the safety concerns associated with reuse. The risk of cross-contamination may increase due to the inability of the reprocessing system to completely remove viable micro-organisms. Viable micro-organisms may be transferred to the next patient.

Ventilator

The iFlow 200S is to be used only with systems making plausibility tests during operation. For higher accuracy, it is recommended to use devices which support initial inspection (circuit check and flow sensor calibration).

🛈 The ventilator should be equipped with monitoring and an alarm system that includes a technical alarm condition to warn of an obstructed inspiratory or expiratory breathing circuit.

Device label and symbols

The following labels and symbols can be found on the iFlow 200S and its packaging.

🛈	Consult Instruction for use	NON STERILE	Non-sterile
⊗	Do not re-use		Arrow, indicates the flow direction (patient side)
CE 0197	Conforms to directive 93/42/EEC as amended		Keep away from sunlight
⧖	Use-by date	☂	Keep dry
	Manufacturer		Temperature limit (see technical specification)
	Date of manufacture	%	Humidity limitation (see technical specification)
LOT	Batch code	=10	Box of ten
REF	Catalogue number	!	Warning; important information
EC REP	Authorised representative in the European community		

TECHNICAL SPECIFICATION

Parameter	Specification
Catalogue number	301.328.010
Life span	Single use (max. of 7 days)
Patient range	Pediatric to Adult • ≥ 6 kg body weight • 40–2500 mL tidal volume
Flow range	±200 L/min
Resistance	< 1.6 mbar/L/s, at 60 L/min
Dead space	10.25 mL
Weight	76 g (sensor + tube)
Measuring line length	1.92 m / 6 ft 4 in
Connectors	iFlow 200S: 22M & 15F / 15M Measuring line: ø 3 mm Calibration adapter: 22F × 15M / 15M blind plug
Material	MABS body, PET flap, PVC tubing (Latex, DEHP and Phtalate free)
Ambient conditions	Operating: +5–40°C (41–104°F) ≤ 100 % RH Storage: 0–50°C (32–122°F) 10–93 % RH, non-condensing
Gas compatibility	Air / O₂
Shelf life	2 years shelf life in original box
Scope of delivery	1 × iFlow 200S 1 × Calibration adapter
State of delivery	Clean, ready for clinical use
Quality management system	EN ISO 13485

All specifications ATP

🛈 Observe storage conditions: be aware, two year storage is usually the maximum and it also depends on the temperature cycles, and the level of exposure to light. With each exposure to water, light and high temperature, the risk of material deviation/deformation and material fatigue increases.

🛈 Do not use iFlow 200 S (Adult/Pediatric) for ventilation of an Neonatal/Infant patient.

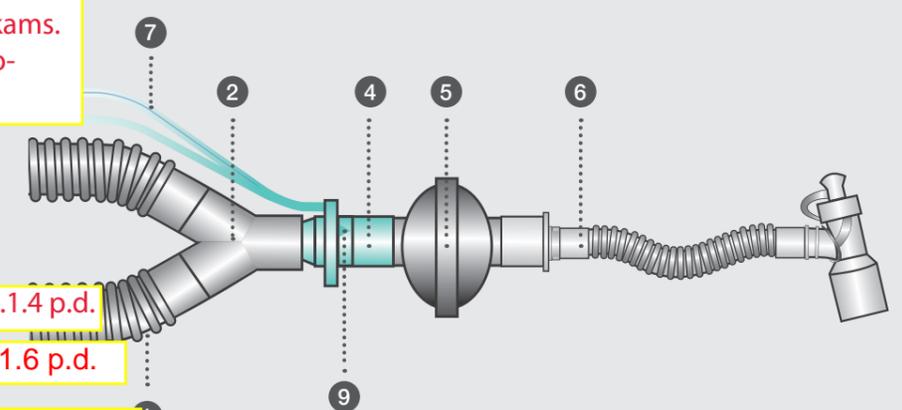## CONNECTION TO VENTILATOR

Step 1
Visual inspection

- no obstruction
- no deformation of flap or housing
- no cracks
- no kinked measuring lines
- calibration adapter included

Step 2
Connection to circuit

- Connect the iFlow 200 S sensor to the Y-piece of the breathing circuit.
- The triangle (Pos. 9) should face towards the patient.
- Measuring lines on top, to prevent liquids and condensation from entering.
- Ensure measuring lines are firmly connected.

...nt connection with iFlow 200S and HME filter

...graphy and iFlow 200S

Annotations (Lithuanian):
- Skirtas naudoti: suaugusiems, vaikams. ≥ 6 kg kūno svorio- 57.1.2 p.d.
- Įpūtimo tūris - 57.1.4 p.d.
- Srauto greitis - 57.1.6 p.d.
- Negyvoji zona - 57.1.5 p.d.
- Matavimo vamzdelių ilgis - 57.1.9 p.d.
- Pajungimas prie paciento - 57.1.8 p.d.
- Pajungimas į prietaisą - 57.1.7 p.d.
- Kalibravimo priedėlis - 57.1.10. p.d.
- Medžiaga - PVC. Be latekso, DEHP ir ftalatų 57.1.3. p.d.
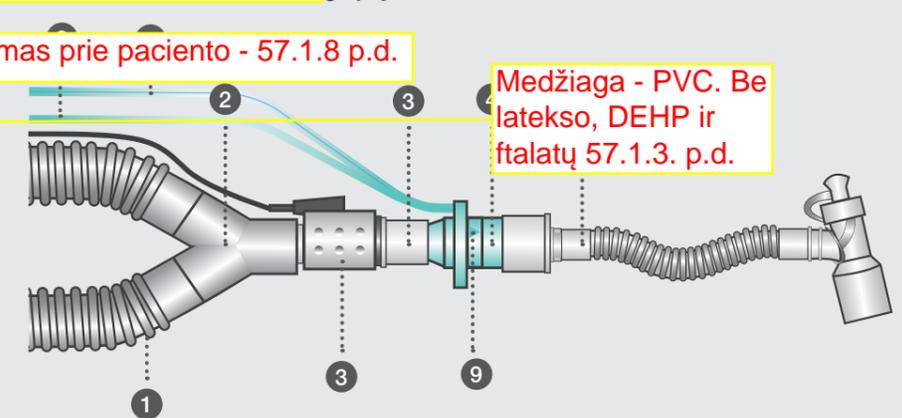
Legend:

1. Breathing circuit, connection to ventilator
2. Y-piece
3. Optional capnography sensor with airway adapter
4. iFlow 200S (Twin tube measuring line connections always on top, to prevent liquids from entering)
5. Optional HME filter
6. Flexible tube, connection to patient
7. Proximal measuring line (colour code: blue strip / transparent)
8. Differential measuring line (transparent)
9. Triangle, indicates the flow direction