

ThermoFlo[®] Heat and Moisture Exchanger (HME)

Instructions for Use

Description

Single-patient-use hygroscopic condensing humidifier and intensive care use.

Indications

- Protection of patients from excessive heat and moisture loss.
- The products mentioned are designed as disposable, single-patient-use products and should be changed at least every 24 hours.

The ThermoFlo[®] Heat and Moisture Exchanger (HME) is used as a conditioning system for mechanically ventilated patients whose upper airways are bypassed. HMEs are a fully valid alternative to heated humidifiers for almost all cases of mechanical ventilation. They are the only conditioning opportunity of breathing gases in cases of emergency ventilation or during transport, as heated humidifiers are almost impossible to use.

Contraindications

1. Do not use in conjunction with conventional heated water humidifiers.
2. Patients on this device should be closely monitored. If complications are observed, the device should be removed or replaced.
3. Device must be changed every 24 hours or more frequently if secretions accumulate.
4. The additional dead space for this device must be taken into consideration when used.
5. Do not use in patients whose expiratory volume is 8% less than inspiratory volume.

Warnings

- Device is intended for single-patient-use and should not be cleaned or reused. Do not sterilize.
- Check for clear airflow prior to use.
- Use appropriate alarms and visually monitor patients on life support equipment.

Precautions

The device provides for “self-humidification” by the patient. Patients must be evaluated accordingly.

Note: The use of this product is not intended to modify the breathing circuit manufacturer’s recommended instructions for use, e.g., disposal or cleaning and disinfection after use.

Instructions for Use

Connect device securely to breathing system between mask and Y-piece of the circuit. Check for secure connections.

Product Code	Description	Tidal Volume Range	Dead Space	Moisture Output	Resistance @ 30 L/min
6061	ThermoFlo® Heat and Moisture Exchanger (Small)	100–1000 mL	32 mL	> 30.8 mg/L @ 500 mL Vt	< 1.3 cm H ₂ O
6071	ThermoFlo® Heat and Moisture Exchanger	300–1500 mL	90 mL (with connectors)	> 30.5 mg/L @ 500 mL Vt	< 0.4 cm H ₂ O

Closed Suction Systems

We recommend following the manufacturer's suggested procedure for lavaging the patient. This will prevent any excess lavaging solution from entering the filter system. If excess lavaging solution does enter the device and resistance is increased, the device must be replaced.

Caution: Federal law restricts this device to sale by or on the order of a physician.