

CIRCUIT GUARD™ FILTER HME
THERMOFLO™ 1 FILTER HME

Package Insert

ThermoFlo 1 Filter and HME / CircuitGuard Filter and HME

Description

Single Patient Use Hygroscopic Condensing Humidifier and Filter for Anesthesia and Intensive Care Use

Indications: Protection of patients from excessive heat and moisture loss. Protection of patients and equipment from contamination. The device may either be used on the patient side or on the device side of the ventilator / anesthetic device and is used as a hygienic measure alternatively to decontamination of breathing system and / or breathing gas conveying parts of the ventilator.

The device is a breathing system filter and a Heat and Moisture Exchanger. The combination of a filter and a Heat and Moisture Exchanger offer the benefit of both product features. Heat and Moisture Exchangers are used as a conditioning system for mechanically ventilated patients whose upper airways are bypassed. In almost all cases of mechanical ventilation they are a fully valid alternative to heated humidifiers. The products are the only conditioning opportunity of breathing gases in cases of emergency ventilation or during transport since 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

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.

Directions for use:

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

Use with Closed Suction Systems:

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

Filtration Efficiency > 99.9%.

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

Manufactured for:
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