THERMOFLO™ HME
ThermoFlo™ 1 HME

Package Insert

Description
Single Patient Use Hygroscopic Condensing Humidifier and Intensive Care Use

Indications
Protection of patients from excessive heat and moisture loss. The ThermoFlo™ HME is a breathing system Heat and Moisture Exchanger. 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 product is the only conditioning opportunity of breathing gases in cases of emergency ventilation or during transport since heated humidified are almost impossible to use.
The products mentioned above are designed as disposable single patient use and should be changed at least every 24 hours.

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.

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.

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

Manufactured for:
ARC Medical, Inc.
4296 Cowan Road
Tucker, GA 30084
800-950-ARC1