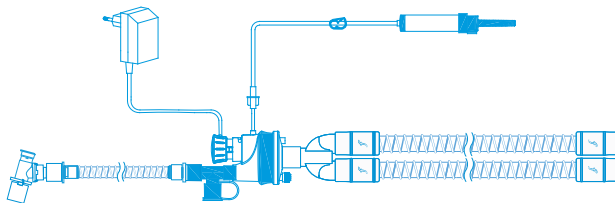


Hygrovent

GOLD

HYBRID HUMIDIFICATION DEVICE



INTENDED USE

This device is intended to provide a medium through which gases may pass to reduce the transmission of bacteria and viruses to and from patients with a breathing volume of 200-1200ml and/or provide humidification to those gases, in anesthesia and critical care in a hospital environment. The device is intended on being connected to HME Booster Heater. The device is intended on being used on a single patient up to 24hrs and is single use. It is to be used by trained users only.

DESCRIPTION

The Hygrovent Gold is a combined heat and moisture (HME) exchanger with a filter for bacteria and viruses that has a provision for adding extra heat and moisture. By adding this close to the patient heat and moisture management is very efficient, also because of the combination with the HME. The Hygrovent Gold can, in consultation with a doctor, replace other forms of active humidification. The device is intended for patients with a breathing volume of 200-1200ml and for patients undergoing artificial respiration in the ICU and during anesthesia. The device can only be used in combination with the HME Booster heating element.

PRECAUTIONS

- Do not use if packaging is opened or damaged
- The HME filter should only be used with patients who require humidification.
- During normal use the device consumes 1 drop of water per minute ($\pm 20\%$). In case the consumption is 2 drops per minute or more please replace the device.
- Check the condition of the X-ring on the HME Booster Heater prior to connecting the Hygrovent Gold.
- Ensure the water feed height above the filter is 0.8m with a corresponding flow range of 6-12ml/hour.
- The device should only be used with patients who require humidification.
- Mount the device without the use of lubricants or other fluids.
- Before use, visually inspect all connections to confirm they are secure. Immediately before each procedure, carry out a functional test of the breathing system to ensure there is no occlusion or leakage.
- Do not use filter longer than 24hrs.

WARNINGS AND CAUTIONS

- The HME filter should be replaced immediately if contaminated by secretions or haemoptysis, this can result in significantly increased resistance.
- Do not use the device in combination with other active humidifiers.
- Do not use the device in combination with explosive anesthetic gases.
- Consider total system dead space before use.
- Do not add moisture to the HME prior to use.
- Do not use an infusion pump or a pressurized infuser for the water supply to the Hygrovent Gold.
- Monitor the pressure-drop across the HME filter if it is being used in combination with medicine nebulizers.
- Replace the HME filter immediately if it becomes soiled, ventilation is compromised or significant pressure change is observed.
- Leakage around the endotracheal tube can cut down the effective humidification.
- Ensure tubing is not kinked or under excess strain.
- Ensure the system is not in permanent contact with bare skin.
- Do not touch the base of the heating element as it can become very hot
- Do not connect the water supply system to the CO₂ port on the machine side of the filter.
- Do not decontaminate / reprocess this device in any way. This includes rinsing, washing or decontamination using gas, heat, steam, or boiling water.
- Do not reuse this device. Reuse may result in hazards such as, but not limited to; cross contamination, damage to device and/or suboptimal performance.

INSTRUCTIONS FOR USE

1. Refer to manufacturer's instruction for correct set up of the HME Booster Heater device.
2. Engage the heating element in the cavity on the Hygrovent Gold HME filter rotating it to ensure a firm fit.
3. Wait for the HME Booster Heater to reach correct temperature indicated by a green light (refer to manufacturer's instructions).
4. Securely attach all connections using a 'push and twist' action to ensure a secure leak free connection.
5. Connect the device to the Y-piece of the breathing circuit.
6. Connect the catheter mount to the endotracheal tube.
7. Close the cap on the valved T-piece (Hygrovent Gold Comfort Plus Only).
8. Connect the (vented) spike to a water bag or bottle. Only use pure water (sterile or otherwise). The water source must be at least 0.8m above the heater connection port.
9. Open the clamp and let the system fill with water.
10. When the system is filled with water, device set up is complete.

STORAGE

Store in a cool, dry place out of direct sunlight.

DISPOSAL CONSIDERATIONS

After use, dispose of in accordance with local policies and / or as advised by your local healthcare provider.

Any serious incident that occurs in relation to the device should be reported to the manufacturer and the competent authority of the Member State of the user and/ or patient.

SYMBOL GLOSSARY



REF

Catalogue number



LOT

Batch code



Use-by date

MADE IN:

Country of origin



Date of Manufacture



CE
1639

Product conforms with
Directive 93/42/EEC



Do not
re-use



Consult instructions
for use



Caution



Do Not Use if
Packaging is Damaged

Rx Only

Caution: US Federal Law Restricts
this device to sale by, or on the order
of a physician



Product not made with
Phthalate DEHP



Non-sterile



Do not use
blade to open



Keep dry



Keep away
from sunlight



Recycle



Manufactured by



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