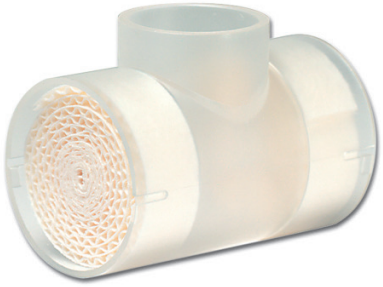
TECHNICAL SUMMARY SHEET

Portex™ Thermovent™ T Heat and Moisture Exchangere™



Product Description

Thermovent T is a sterile, single use heat and moisture exchanger which provides effective humidification for spontaneously breathing adult and paediatric patients whose upper airways are bypassed by a tracheal or tracheostomy tube.

Indications

The Portex Thermovent T is indicated for:

- Preserving humidity and minimising damage to tracheal epithelial cells.
- Reduction of heat loss through the bronco pulmonary tree.
- Helping to prevent thickened secretions and changes in lung function during long term anaesthesia or ventilatory support.

Contra-Indications

The device is intended for single use only and must not be re-used or cleaned. Wetting of the heat and moisture exchange elements with any cleaning solution may dangerously increase the resistance to breathing or may result in the retention of harmful residues or transmission of infectious agents.

Expert clinical judgement must be used in assessing the patient's humidification requirements. This device must be used as described in these instructions and in accordance with currently accepted medical techniques.

If a heat and moisture exchange element is displaced from the housing (for example by patient coughing), the device should be discarded and a new device used. Under no circumstances must replacement of the element be attempted.

The device may block if the patient develops copious secretions, pulmonary oedema or bleeding when the device is in use. If the device becomes blocked then it must be replaced. Under no circumstances should any attempt be made to clear or clean out the blockage as this may damage the heat and moisture exchange elements and could lead to further blockage.

Caution should be taken if this device is used on children as it contains components which may be removed and could be harmful if ingested or inhaled.

Precautions

As with all airway management products, the security of all connections and patency of the system and device should be checked prior to use.

This device should only be used with spontaneously breathing patients.

The effect of the additional deadspace volume of this device should be evaluated on an individual patient basis.

The device must not be used on conjunction with heated or nebulized water humidification systems or nebulizers

Device Classification

GMDN: 35530
Classification: Class IIa

Component Composition

Housing: Polypropylene HP371P Natural.
HME Media: Corrugated paper

Manufacturing Site Name and Address

ICU Medical, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442, USA

Country of Origin

Czech Republic

Sterilisation Method

Irradiation

Shelf-Life

5 years

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Labelling and Packaging

Packaging Dimensions			
Container Type	Length (mm)	Width (mm)	Height (mm)
Single Unit	115	55	24
Shelf Carton (50 units)	185	180	128
Transit Carton (600 units)	555	380	270

One Thermovent T unit is packaged per Multivac peel open blister. The label is printed with product specific information. Product is sterile, non-toxic and non-pyrogenic unless package is open, wet, or damaged. Discard if open, wet, or damaged. Fifty (50) units are packed per shelf carton, and twelve (12) shelf packs are packed per transit carton.

Product Specifications

Thermovent T Specifications		
Product Code	Moisture Output	Resistance to Flow
100/570/015	25 mg/L H_2O @ 10 breath/min Tidal volume 1,000 mL	0.9 hPa (cmH_2O) at gas flow rate 0.5 L/sec (30 L/min) 2.0 hPa (cmH_2O) at gas flow rate 1.0 L/sec (60 L/min) 3.5 hPa (cmH_2O) at gas flow rate 1.5 L/sec (90 L/min)

For more information, visit www.icumed.com or call +44 (0)845 850 0445

The product complies with current legislation and has the corresponding CE marking (2797).
For additional information, warnings and/or safety precautions, refer to the manufacturer's Instructions for Use.

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