

PM-HME Attaches to a Tracheostomy Tube

INSTRUCTIONS FOR USE

Only one copy of these Instructions for Use is provided per package. These Instructions for Use must be kept in an accessible location for all users.

MADE IN USA

CAUTION:

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

Rx only



Not made with natural rubber latex



Single use only



Non-sterile



Keep dry



Medical device



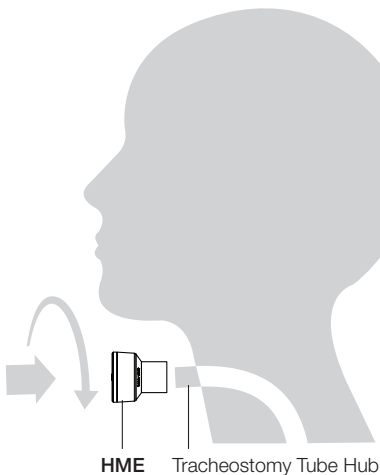
Instructions for use



WARNING: NOT FOR USE DURING MECHANICAL VENTILATION

PassyMuir®

Heat Moisture Exchanger (PM-HME)



INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The Passy Muir Heat Moisture Exchanger (HME) is a non-sterile, lightweight, single patient use device intended to be positioned on a tracheostomy tube to warm and humidify gases breathed in by a patient.

INDICATIONS FOR USE

For spontaneously breathing patients with a tracheostomy where warm and humidified inspiratory gases are desired.

Environment of use - clinical settings including hospital, sub-acute, rehabilitation, outpatient, pre-hospital, skilled nursing, long-term care, and the home setting.






PATIENT POPULATION

The PM-HME is intended for spontaneously breathing tracheostomy patients. The intended users are healthcare professionals trained in the care of patients with a tracheostomy, including physicians, nurses, speech-language pathologists, physiotherapists, and respiratory therapists, as well as patients and caregivers under the supervision of a healthcare professional.

CONTRAINDICATIONS

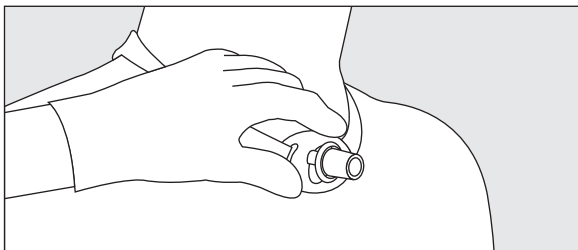
- Patients using the PM-HME must be able to remove the PM-HME themselves as needed OR should be monitored by a trained healthcare provider or caregiver.
- **Do not use** the PM-HME during mechanical ventilation.
- **Do not use** the PM-HME with a suction catheter.
- **Do not use** the PM-HME as a connector for tubing, adapters, accessories, or other connections to the hub of the tracheostomy tube.
- **Do not use** the PM-HME in conjunction with humidifiers or nebulizers.
- **Do not use** the PM-HME on laryngectomy patients.
- **Do not use** the PM-HME with medicated aerosols.
- **Do not use** the PM-HME with any flow delivery system including High-Flow or any other device connection.
- **Do not use** the PM-HME with patients having a low tidal volume (<50mL) as it may cause (Carbon Dioxide) CO₂ retention.

WARNINGS & PRECAUTIONS

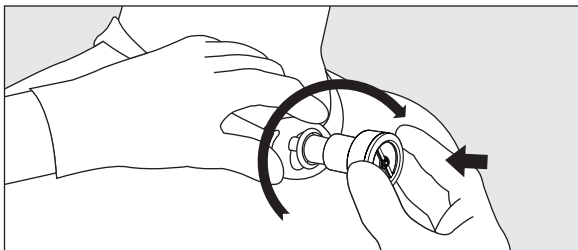
-  **CAUTION:** Federal law restricts this device to sale by or on the order of a physician.
-  **WARNING:** DO NOT use a PM-HME if saturated or clogged as it may prevent or obstruct breathing.
-  **WARNING:** DO NOT use a PM-HME if it is damaged, as the device will not operate as intended.
-  **WARNING:** When used continuously on the patient, the PM-HME must be changed every 24 hours or more frequently as required.
-  **CAUTION:** The PM-HME is designed for single use only and should not be cleaned, sterilized, or reused.

PLACEMENT

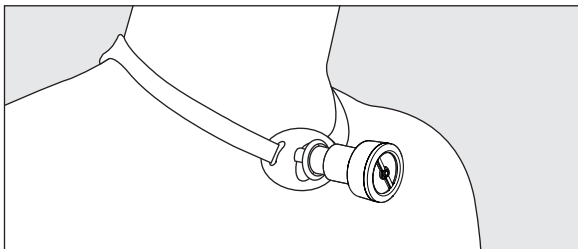
The following instructions are for the placement of the Passy Muir Heat Moisture Exchanger (PM-HME).



Step 1: Using universal precautions and appropriate Personal Protective Equipment (PPE), stabilize the patient's tracheostomy tube.



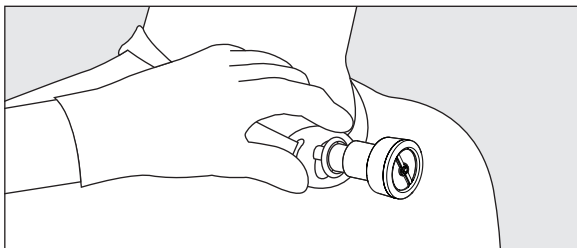
Step 2: Place the PM-HME gently onto the 15mm hub of the tracheostomy tube with a gentle quarter turn clockwise (to the right) while placing it onto the hub. Do not PUSH the PM-HME onto the tracheostomy tube hub.



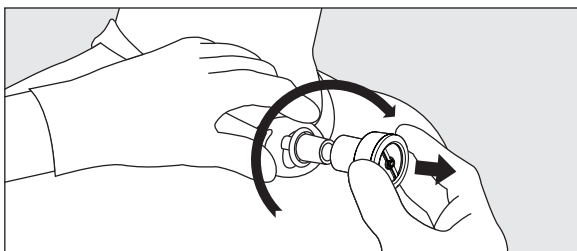
Step 3: Monitor the patient's respiratory status and assess for changes from baseline parameters.

REMOVAL

The following instructions are for the removal of the Passy Muir Heat Moisture Exchanger (PM-HME).



Step 1: Using universal precautions and appropriate PPE, stabilize the patient's tracheostomy tube.



Step 2: Remove the PM-HME with a gentle quarter turn clockwise (to the right) while gently removing the PM-HME from the 15mm hub.

STORAGE & DISPOSAL

- Store at room temperature and away from direct sunlight.
- Discard the PM-HME as medical waste per applicable national regulations and facility policy.

TECHNICAL SPECIFICATIONS

Tidal Volume (V_t)	> 50 mL
Dead Space (Internal Volume)	4.9 mL
Pressure Drop*	10 LPM - 0.1 hPa
	30 LPM - 0.7 hPa
	60 LPM - 2.0 hPa
Moisture Loss at $V_t = 1000\text{ml}^*$	20.6 mg/L
Moisture Loss at $V_t = 150\text{ml}^{**}$	9.6 mg/L
Connector	15F (ISO 15 mm)
Height	33 mm
Diameter	30 mm
Weight	5.2 g

* Tested in accordance with ISO 9360

** Test adapted from ISO 9360

Note: Minor condensation in the bag is typical and does not affect the use or safety of the device.



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