Instructions For Use HME with Oxygen Port

REF **RES027U0P**

SUNSET HEALTHCARE SOLUTIONS

1 Safety-related information

1.1 Intended use

Heat and moisture exchanger (HME) for humidifying respired gases for spontaneously breathing patients with tracheostomy. The integrated oxygen port is intended to administer supplementary oxygen.

Patient target groups

The product is intended for adults' and pediatric patients.

1.2 User group requirements

The term "user group" describes the user or personnel who have been assigned by the operating organization to perform a certain task on a product.

1.2.1 Duties of the operating organization

The operating organization must ensure the following:

- Every user group has the required qualifications (e.g., has undergone specialist training or acquired specialist knowledge through experience).
- Every user group has been trained to perform the task.
- Every user group has read and understood the relevant chapters in this document.

1.2.2 User groups

Clinical users

This user group operates the product in accordance with the intended use. Users have medical specialist knowledge in the application of the product.

1.3 Information on safety instructions

Safety instructions warn against hazards and provide instructions for safe use of the product. All safety instructions specify the type of danger and the consequences of failure to observe the safety instruction.

1.4 Safety instructions

1.4.1 Instructions for use

Failure to use the product in accordance with the information contained in these instructions for use may result in personal injury and property damage.

- Follow these instructions for use.
- Use this product only according to its intended use.
- Keep these instructions for use close to hand.
- Follow these instructions for use and those for any products used in conjunction with this product
- Follow these instructions for use and those for any products used in conjunction with this product. The instructions for use do not contain any information on the following points: – Risks that are obvious to users – Consequences of obvious improper use of the product – Potentially negative effects on patients with one or more illnesses.

1.4.2 Symbols and product labels

Failure to observe symbols and product labels may result in personal injury and property damage.

- Observe the symbols and product labels.

1.4.3 Single use

Reuse, reprocessing or sterilization may lead to failure of the medical device and to injury to the patient.

- The medical device was designed, tested and manufactured exclusively for single use and for a period of use not exceeding 24 hours. The medical device must not be reused, reprocessed or sterilized.
- Following use, the medical device must be disposed of in accordance with the administrative body's infection prevention policy.

1.4.4 Modifications to the product

Modifications to the product may lead to malfunctions and unforeseen risks. This may result in injury to the patient or the user or in property damage. Do not modify this product.

1.4.5 Ambient conditions

Operating the product under unsuitable ambient conditions may compromise its performance.

- When storing or operating this product, observe the permissible ranges for ambient temperature.

1.4.6 Components

Additional components in the breathing circuit such as filters or HME increase the dead space and result in the increase of compliance and resistance.

- The use of additional components therefore requires particular care and monitoring.

1.4.7 Patient safety

Medical devices that are damaged or incorrectly applied may lead to malfunctions or personal damage.

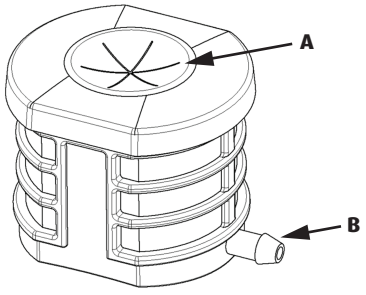
- To avoid contamination and soiling, keep the medical device packaged until ready to be used.
- Do not use the medical device if the packaging is damaged.
- Check all system components for obstructions, damage, and foreign matter before installation. Do not use damaged medical devices.
- Check that all connections are securely fitted and tight.
- Due to an increased risk of fire, oxygen therapy is not suitable for smokers.
- When administering oxygen, keep open flames, sparks, or other possible ignition sources away from the device.
- Regularly check the inside of the medical device for liquids or visible soiling (secretion). If liquids or visible soiling are found, replace the medical device if necessary.
- The oxygen port must only be used to introduce oxygen.
- Although this product has a Safety Valve (A), it should not be used on patients with heavy secretions

1.4.8 Use of humidifiers or medication nebulizers

When using an active humidifier or medication nebulizer, there is a risk of pressure build-up and insufficient patient ventilation.

- Do not use the product in combination with active humidifiers or medication nebulizers.

2 Overview



A Safety valve
B Oxygen port

2.1 Symbols

	Observe the instructions for use
	Expiration date
	Temperature limitation
	Do not reuse
	Do not use if package is damaged
REF	Part number
LOT	Lot number
QTY	Quantity
	Non-sterile
	Keep dry
	Keep away from sunlight
	Not made with natural rubber latex

3 Operation

1. Connect the heat and moisture exchanger to the tracheostomy tube.
2. Check that all connections are securely fitted and tight.

4 Period of use

The user is responsible for regularly replacing the medical device according to the administrative body's hygiene regulations. The medical device is intended for single use and must be replaced at least every 24 hours.

5 Disposal

This product must be disposed of in accordance with national regulations.

6 Technical data (DIN EN ISO 9360-1 and 9360-2)

Tidal volume (VT)

recommended range:	50 – 1000 ml.
Internal Volume	17 ml
Moisture loss:	VT = 250 ml: 9,0 mg/l T = 500 ml: 13,2 mg/l T = 750 ml: 14,2 mg/l T = 1000 ml: 15,5 mg/l

Pressure drop

Inspiration	Expiration
0,5 l/s = 0,09 cm H2O (~hPa)	0,5 l/s = 0,11 cm H2O (~hPa)
1,0 l/s = 0,26 cm H2O (~hPa)	1,0 l/s = 0,32 cm H2O (~hPa)
1,5 l/s = 0,54 cm H2O (~hPa)	1,5 l/s = 0,34 cm H2O (~hPa)

Weight	5g
Length	29mm

Connection: 15 mm female connector for ET tube. 5 mm connector for supplemental oxygen. Valve for forced inspiration/expiration (Type 302)

Material

Housing Polypropylene
HME medium Polyurethane
Valve Thermoplastic elastomer
Not made with natural rubber latex

Manufactured for
Sunset Healthcare Solutions
141 W Jackson Blvd Ste 1950
Chicago IL 60604
SunsetHCS.com

IFU-00108 REV 1.01
2025-01-22