

HEAT MOISTURE EXCHANGERS

DISPOSABLE | SINGLE USE | LATEX FREE | DEHP FREE | NON-STERILE

DEVICE MANUFACTURING SPECIFICATIONS

Product Family	Heat Moisture Exchangers
Company	AirLife
Manufacturer and Manufacturer Address	SunMed LLC 2710 Northridge Dr. NW, Suite A Grand Rapids, MI 49544 USA
Country of Origin/Made In	China
Classification – US	Class I
FDA Product Code	BYD
Classification – Canada	Class II
Classification – EU	Class IIa
CE Mark	CE 2797/BSI Group
EU Authorized Representative	MT Promedt Consulting GmbH
EMDN Code	R040102 - Antibacterial & Antiviral Respiratory Filters Humidifiers
GMDN Code	35530 – Heat/Moisture Exchangers
UMDNS Code	15645 – Humidifiers, Heat or Moisture Exchangers
UNSPSC Code	42272219 – Ventilator Heat or Moisture Exchanger or Filter
Patient Population	Pediatric, Adult
Usage	Disposable, Single Use Up to 24 Hours
Sterility	Non-Sterile
Packaging	Individually Packaged, 50/Case
Shelf Life	5 Years
Storage Conditions	-20°C (-4°F) to 50°C (122°F)
Disposal Instructions	Safely dispose of device in accordance with local, state, and federal regulations.

Description: The Heat Moisture Exchanger (HME) devices are used to provide passive humidification of dry gas supplied to patients. The device is comprised of a foam cylinder inside a plastic housing. The foam cylinder traps and stores heat and moisture from a patient's expired air to humidify the inspired gas. The Heat Moisture Exchangers Filter (HMEF) includes a bacteria/viral filter to mitigate the transmission of micro-contaminants in gases being expired from the patients. The HME/HMEF are available in different sizes and shapes with or without a female Luer sampling port.

Intended Purpose: A heat and moisture exchanger (HME) is intended to warm and humidify gases breathed by the patient within a respiratory circuit and artificial airway.

Area of Use: Hospitals, sub-acute, medical clinics, pre-hospital, home, surgical centers, and skilled nursing facilities.

Contraindications: None known.



DEVICE MATERIAL

Component	Material
Top & Bottom Housing	Polypropylene
Filter Media	Polypropylene, Blended Synthetic Fiber

Material Statement: The HMEs do not incorporate medicinal substances, human blood or plasma, or animal tissue. They do not contain natural rubber latex and natural rubber latex is not used in the manufacturing process or packaging components. They do not contain DEHP or BPA.

Part Number	UOM	GTIN
FH603006	Each	1088948308093
	Case	3088948308093
FH603007	Each	1088948308186
	Case	3088948308186
FH603014	Each	1088948310332
	Case	3088948310332
FH603021	Each	1088948311033
	Case	3088948311033
FH603023	Each	1088948309635
	Case	3088948309635
FH603023F	Each	1088948307943
	Case	3088948307943
FH603028	Each	1088948316897
	Case	3088948316897

TECHNICAL SPECIFICATIONS

Part	Description	Port	Tubing	Min Tidal Volume	Max Tidal Volume	Moisture Output @ VT 500 mL	Deadspace	Pressure Drop @ 30 LPM
FH603006	Large Round	—	—	250 mL	1500 mL	31.3 mg H ₂ O/L	40.5 mL	< 1 cm H ₂ O
FH603007	Large Round	Yes	—	250 mL	1500 mL	31.3 mg H ₂ O/L	40.5 mL	< 1 cm H ₂ O
FH603014	Small Angled	Yes	—	150 mL	1000 mL	30.2 mg H ₂ O/L	36.6 mL	< 1 cm H ₂ O
FH603021	Small Straight	Yes	—	150 mL	1000 mL	30.2 mg H ₂ O/L	30.1 mL	< 1 cm H ₂ O
FH603023	Small Straight	—	—	150 mL	1000 mL	30.2 mg H ₂ O/L	30.1 mL	< 1 cm H ₂ O
FH603023F	Small Straight	—	6 mm x 15 mm I.D. Flexible	150 mL	1000 mL	30.2 mg H ₂ O/L	30.1 mL	< 1 cm H ₂ O
FH603028	Pediatric Straight	Yes	—	150 mL	500 mL	24.5 mg H ₂ O/L	19.7 mL	< 1 cm H ₂ O