

AIRLIFE® BV/HME FILTER

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

DEVICE MANUFACTURING SPECIFICATIONS

Product Family	AirLife HME/HCH
Manufacturer and Manufacturer Address	AirLife 2710 Northridge Dr. NW A Grand Rapids, MI 49544 USA
Country of Origin/Made In	China
FDA Product Code	BYD Condenser, Heat and Moisture (Artificial Nose)
Classification – Canada	Class II
Classification – Japan	Class II
GMDN Code	46816 - Heat/Moisture Exchanger/Microbial Medical Gas Filter
UMDNS Code	11712 – Filter, Bacteria
UNSPS Code	42272219 – Ventilator Heat or Moisture Exchangers or Filters
Usage	Replace every 24 hours or more frequently, as required, to avoid increased resistance due to accumulation of secretions.
Patient Population	Pediatric, Adult
Sterility	Non-Sterile; Packaging for non-sterile devices is intended to protect the product from dust and does not provide a sterile barrier.
Packaging	Individually Packaged in Polybag
Shelf Life	4 Years
Storage Conditions	Store in a Cool, Dry Place

Description: Heat and Moisture Exchanger (HME) is a passive humidification component that conserves a patient’s heat and moisture. HMEs are designed to capture the heat and moisture lost during exhalation and return it to the patient during inhalation.

Intended Purpose: The AirLife HME is intended to warm and humidify gases breathed by the patient within a respiratory circuit and artificial airway. The HMEF is also intended to function as a bacterial/viral filter in parallel with humidification. The BHME is intended for use on patients under ventilator care to effectively humidify and warm the inspired air according to the following product specifications and directions. Note that normal humidification efficiency is achieved after a few breaths.

Contraindications: Do not use with dehydrated patients, or patients with thick, tenacious secretions from the lungs and airways.



DEVICE MATERIAL

Component	Material
Housing	Thermoplastic Styrene-Butadiene Copolymers (SBC)
Filter Media	Technostat Electrostatic/ Polypropylene
Foam	Polyurethane (PU)
Gas Sampling Port	Thermoplastic Styrene-Butadiene Copolymers (SBC)
Luer Cap	High Density Polyethylene (HDPE)
Flexible Tubing	Polyethylene (PE)

Material Statement: The HME/HCHs are not manufactured with natural rubber latex, DEHP or BPA. The HME/HCH do not incorporate substances that may be considered a medicinal product. The HME/HCHs do not contain blood derivatives or materials derived from animal or human tissue.

Part Number	Description	UOM	QTY	GTIN
003003	Adult Hygroscopic Condenser Humidifier (HCH)	Each	1	10889483571545
		Case	50	30889483571549
003004	Type II Hygroscopic Condenser Humidier (HCH)	Each	1	10889483571569
		Case	50	30889483571563
003005	Adult Filtered Hygroscopic Condenser Humidifier (HCH) With Gas Sampling Port	Each	1	10889483571576
		Case	25	30889483571570
003006	Small Volume Filtered Hygroscopic Condenser Humidifier (HCH) With Gas Sampling Port	Each	1	10889483571583
		Case	50	30889483571587
003009	Adult Filtered Hygroscopic Condenser Humidifier (HCH) With Gas Sampling Port & 16 cm (6”) Flex Tube	Each	1	10889483571613
		Case	15	30889483571617
003020	Adult Nonfiltered Bypass Heat and Moisture Exchanger (BHME)	Each	1	10889483571651
		Case	25	30889483571655
003021	Adult Filtered Bypass Heat and Moisture Exchanger (BHME)	Each	1	10889483571668
		Case	25	30889483571662

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TECHNICAL SPECIFICATIONS - HME/HCH

Technical Data	003003	003004	003005	003006	003009
Tidal Volume	250–1250 mL	80–600 mL	250–1250 mL	70–600 mL	250–1250 mL
Dead Space	31 mL	21 mL	59 mL	22 mL	80 mL
Weight	13 g	8 g	38 g	17 g	46 g
Compliance @ 7 kPa (71 cmH ₂ O)	0.30 ml/kPa	—	0.64 ml/kPa	—	0.92 ml/kPa
Y-Piece Connection	15F mm	15F mm	15F/22M mm	15F mm	15F/22M mm
Patient Connection	15F mm/22M mm	15F mm/22M mm	15F mm/22M mm	15F mm/22M mm	15F mm
Sampling Port	—	—	Yes - Luer	Yes - Luer	Yes
Bacterial	—	—	99.999%	99.998%	99.999%
Viral	—	—	99.98%	99.99%	99.98%
NaCL Penetration Before Use	—	—	3.06% @ 30 LPM	5.36% @ 15 LPM	3.34% @ 30 LPM
Resistance					
@ Flow 0.5 L/s	1.0 cmH ₂ O	0.8 cmH ₂ O	0.9 cmH ₂ O	—	1.0 cmH ₂ O
@ Flow 1.0 L/s	2.5 cmH ₂ O	2.4 cmH ₂ O	2.1 cmH ₂ O	—	2.7 cmH ₂ O
@ Flow 1.5 L/s	4.8 cmH ₂ O	—	3.7 cmH ₂ O	—	5.1 cmH ₂ O
@ Flow 9 L/s	—	—	—	0.4 cmH ₂ O	—
@ Flow 15 L/s	—	—	—	0.8 cmH ₂ O	—
@ Flow 30 L/s	—	—	—	1.8 cmH ₂ O	—
Moisture Output					
Tidal Volume = 250 mL	37 mg H ₂ O/L	30.6 mg H ₂ O/L	36 mg H ₂ O/L	31.5 mg H ₂ O/L	36 mg H ₂ O/L
Tidal Volume = 500 mL	35 mg H ₂ O/L	30 mg H ₂ O/L	33 mg H ₂ O/L	30.3 mg H ₂ O/L	33 mg H ₂ O/L
Tidal Volume = 600 mL	—	29 mg H ₂ O/L	—	25.6 mg H ₂ O/L	—
Tidal Volume = 750 mL	32 mg H ₂ O/L	—	31 mg H ₂ O/L	—	31 mg H ₂ O/L
Tidal Volume = 1000 mL	30 mg H ₂ O/L	—	28 mg H ₂ O/L	—	28 mg H ₂ O/L
Tidal Volume = 1250 mL	27 mg H ₂ O/L	—	27 mg H ₂ O/L	—	27 mg H ₂ O/L
Moisture Loss					
Tidal Volume = 250 mL	7 mg H ₂ O/L	—	8 mg H ₂ O/L	—	8 mg H ₂ O/L
Tidal Volume = 500 mL	9 mg H ₂ O/L	—	11 mg H ₂ O/L	—	11 mg H ₂ O/L
Tidal Volume = 750 mL	12 mg H ₂ O/L	—	13 mg H ₂ O/L	—	13 mg H ₂ O/L
Tidal Volume = 1000 mL	14 mg H ₂ O/L	—	16 mg H ₂ O/L	—	16 mg H ₂ O/L
Tidal Volume = 1250 mL	17 mg H ₂ O/L	—	17 mg H ₂ O/L	—	17 mg H ₂ O/L
Number Per Case	50/Case	50/Case	25/Case	50/Case	15/Case

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TECHNICAL SPECIFICATIONS - BYPASS HME

Technical Data		003020	003021	
Tidal Volume		250-1250 mL	250 -1250 mL	
Dead Space		68 mL	68 mL	
Weight		43 g	44 g	
Y-Piece Connection		15F mm	15F mm	
Patient Connection (ETT)		15F/22M mm	15F/22M mm	
Bacterial		—	99.999%	
Viral		—	99.99%	
NaCL		—	95%	
MR Conditional		3-Tesla or less	3-Tesla or less	
Compliance @ 7 kPa (71 cmH ₂ O)		0.68 mL/kPa	0.68 mL/kPa	
Resistance	Before Use	After Use	Before Use	After Use
@ Flow 0.5 L/s	0.6 cmH ₂ O	0.7 cmH ₂ O	1.3 cmH ₂ O	1.5 cmH ₂ O
@ Flow 1.0 L/s	1.6 cmH ₂ O	2.0 cmH ₂ O	3.3 cmH ₂ O	4.0 cmH ₂ O
@ Flow 1.5 L/s	3.3 cmH ₂ O	4.5 cmH ₂ O	6.1 cmH ₂ O	6.0 cmH ₂ O
Moisture Loss				
Tidal Volume = 250 mL	9.1 mg H ₂ O/L		8.7 mg H ₂ O/L	
Tidal Volume = 500 mL	10.6 mg H ₂ O/L		11.1 mg H ₂ O/L	
Tidal Volume = 750 mL	12.9 mg H ₂ O/L		12.9 mg H ₂ O/L	
Tidal Volume = 1000 mL	14.3 mg H ₂ O/L		14.7 mg H ₂ O/L	
Tidal Volume = 1250 mL	14.9 mg H ₂ O/L		15.7 mg H ₂ O/L	
Number Per Case	25/Case		25/Case	