

Technical Data Sheet

AirLife™ HMEFs

Product Codes and Product Description	M1004132 AirLife™ HMEF 750/S, Disposable M1010534 AirLife™ Angled HMEF 1000/S M1010538 AirLife™ Angled HMEF 750/S M1038637 AirLife™ HMEF 1000, Disposable M1038639 AirLife™ HMEF 750 M1043237 AirLife™ HEPA Filter, Disposable, Hydrophobic Pleated Bacterial/Viral Filter with Gas Sampling Port 8004231 AirLife™ HMEF Mini/S, Disposable 557019500 AirLife™ HMEF 1000/S With Flexible Tube and Double Swivel Elbow, Disposable 557021200 AirLife™ Uni-Filter, Disposable 557070100 AirLife™ HMEF 1000/S, Disposable 557070500 AirLife™ HMEF 500/S, Disposable 557070700 AirLife™ HMEF 500/S With Memoflex Tube, Disposable 557071500 AirLife™ HMEF 1000/S With Flexible Tube, Disposable 557071600 AirLife™ HMEF 1000/S and Flexible Tube, Disposable 557085500 AirLife™ HMEF 1000/S With Memoflex Tube, Disposable 8570203 AirLife™ HMEF 1000/S With Flexible Tube and Elbow Connector, Disposable M1005260 AirLife™ HMEF 750/S With Memoflex Tube																																		
General Product Description	Heat and moisture exchangers with integrated bacterial/viral filter (HMEF) are used for patients requiring humidification during anesthesia or ventilation. The HMEFs help protect the patient, healthcare personnel and equipment from various microorganisms present in the breathing circuit. The HMEFs are placed between the proximal end of the artificial airway and the Y-piece of the breathing circuit. Both straight and angled products are provided. Some HMEFs have a gas sampling port for gas monitoring. HMEFs are disposable devices																																		
Pack factor	<table border="0"> <tr><td>557070100</td><td>50</td></tr> <tr><td>M1010534</td><td>50</td></tr> <tr><td>M1010538</td><td>50</td></tr> <tr><td>M1038637</td><td>50</td></tr> <tr><td>M1038639</td><td>50</td></tr> <tr><td>M1004132</td><td>50</td></tr> <tr><td>M1005260</td><td>50</td></tr> <tr><td>557019500</td><td>30</td></tr> <tr><td>557070500</td><td>75</td></tr> <tr><td>8004231</td><td>50</td></tr> <tr><td>557070700</td><td>60</td></tr> <tr><td>557071500</td><td>30</td></tr> <tr><td>557071600</td><td>30</td></tr> <tr><td>557085500</td><td>40</td></tr> <tr><td>8570203</td><td>30</td></tr> <tr><td>M1043237</td><td>50</td></tr> <tr><td>557021200</td><td>45</td></tr> </table>	557070100	50	M1010534	50	M1010538	50	M1038637	50	M1038639	50	M1004132	50	M1005260	50	557019500	30	557070500	75	8004231	50	557070700	60	557071500	30	557071600	30	557085500	40	8570203	30	M1043237	50	557021200	45
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EAN/GTIN	557070100	EA	10885403286131	557070500	EA	10885403284144
	557070100	PAK	70885403286133	557070500	PAK	70885403284146
	M1010534	CS	50885403284210	8004231	EA	10885403284168
	M1010534	EA	10885403284212	8004231	PAK	70885403284160
	M1010538	CS	50885403284203	557070700	EA	10885403255755
	M1010538	EA	10885403284205	557070700	PAK	70885403255757
	M1038637	EA	10885403284427	557071500	EA	10885403255762
	M1038637	PAK	70885403284429	557071500	PAK	70885403255764
	M1038639	EA	10885403284434	557071600	EA	10885403255779
	M1038639	PAK	70885403284436	557071600	PAK	70885403255771
	M1004132	EA	10885403284151	557085500	EA	10885403255793
	M1004132	PAK	70885403284153	557085500	PAK	70885403255795
	M1005260	EA	10885403252952	8570203	EA	10885403255533
	M1005260	PAK	70885403252954	8570203	PAK	70885403255535
	557019500	EA	10885403255724	M1043237	EA	10885403287138
	557019500	PAK	70885403255726	M1043237	PAK	20885403287135
			557021200	EA	10885403284243	
			557021200	PAK	70885403284245	
Intended Use	The AirLife HMEF Mini, HMEF 500, HMEF 750 and HMEF 1000 (hereafter referred to as HMEFs) are HME/Filter combinations. HMEFs are disposable single-use devices indicated for patients requiring humidification during the delivery of ventilation gases. They provide filtration for reducing possible infection with potential for cross-contamination between patient and equipment. The HMEFs are for use in hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators. The HMEF 750, HMEF 500 and HMEF Mini can be used on adult and pediatric patients and the HMEF 1000 on adult patients. The HMEFs are indicated for use by qualified medical personnel only.					
Instructions for Use	Please refer to the Instructions for Use (IFU)					
Characteristics	The HMEFs are indicated for use by qualified medical personnel only. The device is intended for short term use for more than sixty minutes and less than thirty days as defined by section 1.1 of Annex IX of the Medical Device Directive 93/42/EEC					
Compatibility	Humidification and filtration products have a commonly used 15mm/22mm ISO 5356-1 standard ports. They may be connected to standard breathing circuits					
Shelf Life	Shelf life for all products is three years. Expiration date is printed on the product labeling					
Regulation	The passive humidification and filtration products are class IIa by rule 2, short term, non-invasive, and non-active					

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Biocompatibility	All materials are biocompatible, meeting skin irritation and sensitization requirements documents: DOC1591547, DOC1719945
Materials	<p>557070100: PP Thermoplastic Borealis RF825MO, POLYURETHANE (polyester based), Calciumchloride, Propyl 4-Hydroxybenzoate, Technostat 250, Polypropylene/Synth., EVA50%+LLDPE50%</p> <p>M1010534: PP Thermoplastic RF825MO, POLYURETHANE (polyester based), Calciumchloride, Propyl 4-Hydroxybenzoate, Technostat 250, Polypropylene/Synth., PP Borealis RF825MO, EVA50%+LLDPE50%</p> <p>M1038637: PP Thermoplastic Borealis RF825MO, POLYURETHANE (polyester based), Calciumchloride, Propyl 4-Hydroxybenzoate, Technostat 250, Polypropylene/Synth., PP, Borealis RF825MO</p> <p>M1004132: PP Thermoplastic Borealis RF825MO, PP Thermoplastic Borealis RF 825 P, Technostat 250, Polypropylene/Synth., Calciumchloride, Propyl 4-Hydroxybenzoate, POLYURETHANE BULPREN S75, EVA50%+LLDPE50%</p> <p>M1010538: PP Thermoplastic Borealis RF 825 P, Technostat 250, Polypropylene/Synth., Calciumchloride, Propyl 4-Hydroxybenzoate, POLYURETHANE BULPREN S75, PP Borealis RF825MO, EVA50%+LLDPE50%</p> <p>M1038639: PP Thermoplastic Borealis RF825 P, Technostat 250, Polypropylene/Synth., PP, Borealis RF825MO, Calciumchloride, Propyl 4-Hydroxybenzoate, POLYURETHANE BULPREN S75,</p> <p>557070500: PP, Borealis RF825MO, Borealis RF 856 P or equivalent, Technostat 250, Polypropylene/Synth., POLYURETHANE (polyester based), Kalciumchloride, Propyl 4-Hydroxybenzoate, EVA50%+LLDPE50%</p> <p>8004231: PP Borealis RF825MO, PP Borealis RF825MO, Technostat 250, Polypropylene/Synth., Polyurethane, Kalciumchloride, Propyl 4-Hydroxybenzoate, EVA50%+LLDPE50%</p> <p>557019500: EVA 1005 VN4 or equivalent -, PP Borealis RF825MO, PP Borealis RF825MO, Polyurethane, Kalciumchloride, Propyl 4-Hydroxybenzoate, EVA50%+LLDPE50%, Technostat 250, Polypropylene/Synth., PP, Silicone</p> <p>557070700: Clarified random polypropylene copolymer resin, Polyurethane (polyester based), Kalciumchloride, Propyl 4-Hydroxybenzoate, PP Borealis RF825MO, PP Borealis RF825MO, Technostat 250, Polypropylene/Synth., EVA50%+LLDPE50%</p> <p>557071500, 557071600: EVA 1005 VN4 or equivalent -, PP Borealis RF825MO, PP Borealis RF825MO, Polyurethane, Kalciumchloride, Propyl 4-Hydroxybenzoate, EVA50%+LLDPE50%, Technostat 250, Polypropylene/Synth.</p> <p>557085500: Clarified random polypropylene copolymer resin, PP Borealis RF825MO, PP Borealis RF825MO, Polyurethane, Kalciumchloride, Propyl 4-Hydroxybenzoate, EVA50%+LLDPE50%, Technostat 250, Polypropylene/Synth., EVA 1005 VN4 or equivalent</p> <p>8570203: EVA 1005 VN4 or equivalent -, PP Borealis RF825MO, PP Borealis RF825MO, Polyurethane, Kalciumchloride, Propyl 4-Hydroxybenzoate, EVA50%+LLDPE50%, Technostat 250, Polypropylene/Synth., Polypropylene</p> <p>M1005260: Clarified random Polypropylene copolymer resin, PP, Borealis RF825MO, PP Thermoplastic Borealis RF825P, Technostat 250 Polypropylene/Synth., Polyurethane Bulpren S75, Kalciumchloride, Propyl 4-Hydroxybenzoate, EVA50%+LLDPE50%</p> <p>M1045721: Polypropylene</p> <p>557021200: Polypropylene, Technostat 250, Polypropylene/synthetic</p>
Storage	There are no special storage conditions or handling requirements. Packaging for non-sterile devices is intended to protect the product from dust and does not provide a sterile barrier
GMDN Code	46816 Heat/moisture exchanger/microbial filter, non-sterile
Disposal	Dispose of in accordance with national and local authority regulations

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AirLife™ HMEFs

Does it contain PVC, DEHP and/or Latex	PVC Free, Latex Free, BPA Free, DEHP Free
Country of Origin	China
Legal Manufacturer	Vyaire Medical Finland 320 Oy, Kuortaneenkatu 2, FI-00510 Helsinki, Finland

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