

AIRLIFE® UNI-FILTERS

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

DEVICE MANUFACTURING SPECIFICATIONS

Reference	Filters, Disposable With or Without Sampling Port
Manufacturer Address	AirLife Finland Oy Kuortaneenkatu 2 FI-00510 Helsinki, Finland
Made In	China
Classification - US	Class II
FDA Product Code	CAH - Breathing Circuit Bacteria Filter
Classification - Australia	Class IIa
Australia Authorized Representative	AirLife Australia Holdings Pty Ltd.
Classification - Canada	Class II
Classification - Japan	Class II
Classification - South Africa	Class IIa
Classification - EU	Class IIa, Rule 2
CE Mark	CE 2797
EU Authorized Representative	Mt Promedt Consulting GmbH
EMDN Code	R040101, Ventilation Filter, Antibacterial & Antiviral
GMDN Code	60837, Microbial, Medical Gas Filter, Single-Use
UMDNS Code	11712, Filter, Bacteria
UNSPSC Code	42272219, Ventilator Heat or Moisture Exchangers or Filters
Usage	Single-Use, Change every 24 hours or more frequently as required.
Area of Use	Hospital, ICU, Anesthesia, During Transport, and with Resuscitators
Sterility	Non-Sterile. Packaging for non-sterile devices is intended to protect the product from dust and does not provide a sterile barrier.
Patient Population	Adult, Pediatric, Infant
Shelf Life	3 Years
Packaging	Individually Packaged in a Polybag
Storage Conditions	There are no special storage conditions or handling requirements.
Disposal Instructions	Dispose of all materials in accordance with local, state, and federal regulations.



DEVICE MATERIAL

Component	Material
Housing	Polypropylene
HME Element	Plastic

Biocompatibility Evaluation: All materials are biocompatible, meeting skin irritation and sensitization requirements. The B/V filters do not contain DEHP, natural rubber latex, or BPA. The B/V filters do not contain PVC. The B/V filters are REACH compliant and do not contain 3TG conflict minerals. The B/V filters do not contain blood derivatives or materials derived from animal or human tissue.

Description: Filters are used for reducing possible infection with potential for cross-contamination between patients and equipment. Filters shall be used in hospitals, ICU, anesthesia, respiratory therapy, during transport and with resuscitators for filtering particles including bacteria, viruses, and dust from CO₂ absorbers. Both straight and angled products are provided. Some filters come with a gas sampling port which allows for gas sampling. Filters shall be placed either between the proximal end of the artificial airway and the Y-piece of the breathing circuit or connected to the inspiratory/expiratory port of the ventilator or anesthesia system. Filters are disposable products.

Intended Purpose: Filters can be used to provide filtration for reducing possible cross contamination between patients and equipment. Filters are for use in the hospital, ICU, anesthesia, respiratory therapy, during transport, and with resuscitators for filtering particles including bacteria, viruses and dust from CO₂ absorbers. The filter with sampling port can also be used for gas sampling. Filters are indicated for use by qualified medical personnel only.

Contraindication: The Filters are contraindicated in patients producing fulminating, frothy secretions within their airways and lungs. When a filter is used in the exhalation limb in conjunction with a water bath humidifier, a water trap should be placed between the filter and the patient. Never position any filter in the inspiratory limb downstream of a water bath humidifier. Do not use the filter between the patient and any source of nebulized drugs. When nebulized drugs are administered, breathing resistance should be monitored and the filter should be replaced following standard hospital procedure.

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Filter Efficiency	557021200	M1003346	557022500	M1010541	M1003345
Bacterial	> 99.98%	> 99.99999%	99.9999%	99.9999%	99.999%
Viral	> 99.9%	99.999%	99.999%	99.999%	99.98%
Dead Space	60 mL	35 mL	35 mL	36 mL	22 mL
Weight	27 g	16 g	16 g	16 g	14 g
Pressure Drop	557021200	M1003346	557022500	M1010541	M1003345
@ 30 L/Min.	0.04 kPa (0.4 cm H ₂ O)	0.08 kPa (0.8 cm H ₂ O)	0.07 kPa (0.7 cm H ₂ O)	0.07 kPa (0.7 cm H ₂ O)	0.14 kPa (1.4 cm H ₂ O)
@ 60 L/Min.	0.08 kPa (0.8 cm H ₂ O)	0.22 kPa (2.2 cm H ₂ O)	0.19 kPa (1.9 cm H ₂ O)	0.19 kPa (1.9 cm H ₂ O)	0.32 kPa (3.2 cm H ₂ O)

Part Number	Description	UOM	Units/Case	GTIN/UDI
557021200	AirLife Uni-Filter, Disposable	Each	—	10889483586556
		Case	45	20889483586553
557022500	AirLife Uni-Filter/S, Disposable	Each	—	10889483586563
		Case	60	20889483586560
M1003345	AirLife Mini-Filter/S, Disposable	Each	—	10889483601495
		Case	50	20889483601492
M1003346	AirLife Uni-Filter Junior, Disposable	Each	—	10889483601501
		Case	50	20889483601508
M1010541	AirLife Angled Uni-Filter/S, Disposable	Each	—	10889483601587
		Case	50	20889483601584