



Instructions for Use

REV: A/1

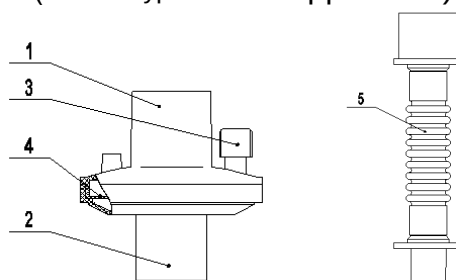
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Disposable heat and moisture exchange filter (without absorbent paper)

[Product name]: Disposable heat and moisture exchange filter

[Type]: GLQ-Q-V、GLQ-Q-VG

[Product structure and components]: upper casing、lower casing、protective cap、filter membrane、absorbent paper(“v: thin type” is not applicable)、telescopic pipe(optional)



1. upper casing 2. lower casing 3. protective cap 4. filter membrane
5. telescopic pipe(optional)

[Performance characteristics of the device]: Disposable heat and moisture exchange filter has a suitable port to connect to the patient and the machine side, has certain defensive, sealing, low respiratory resistance characteristics. It is mainly used to filter gas particles, foreign bodies, bacteria and viruses in the process of breathing, so as to avoid secondary infection to patients. the product are not applicable for the performance of heat preservation and moisture preservation.

1、Moisture loss: NA.

2、Pressure Drop:

Under the flow rate of 30L/min for adult products, the pressure drop at both ends shall not be greater than 0.2kpa.

3、Internal Volume: Adult type 30.4mL(approx);

4、Filtration efficiency:

1) The product's filtration rate of suspended particles $\geq 0.3 \mu m$ shall be $\geq 99\%$.

2) Bacterial Filtration Efficiency (BFE) is 99.9%.

3) Viral Filtration Efficiency (VFE) is 99.9%.

5、Gas leakage:

The flowrate of gas leakage shall not exceed 25mL/min.

6、Compliance:

The compliance of the product shall not exceed 1mL/kPa.

[CMR/endocrine-disrupting substances] : This product has no CMR/endocrine-disrupting substances precipitation.

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[Clinical benefits]: When breathing, filter gas particles, foreign bodies, bacteria and viruses to avoid secondary infection to patients.

[Measuring function accuracy]: NA.

[Device connection instructions]: This medical device can be connected with ventilator and its pipeline, anesthesia machine and its pipeline, gas intubation pipeline, etc.

[Sterile]: The product is sterilized by EO.

[Shelf life]: 5 years.

[Target population]: Adults and children.

[Intended user]: Professional trained medical staff.

[Intended purpose]: The products without absorbent paper suitable for patients who have established artificial airway to filter particles, bacteria and viruses of the gas they breathe.

[Instruction for use]:

- 1.First inspect the integrity of the package, and then remove product from the sterile package, and inspect the integrity of product.
- 2.Connect to equipment or pipe according to interface type. When a telescopic pipe is needed, connect the telescopic pipe to the disposable heat and moisture exchange filter first, and then connect to equipment or pipe according to interface type.
3. Adjust equipment parameters, start auxiliary breathing or anesthesia operation.
4. Replace the heat and humidity exchanger every 24 hours based on actual requirements.

[Indications]:

Mechanical ventilation, surgical anesthesia, laryngeal surgery, airway management, etc.

[Contra-indications/Limitation]:

Infants, patients with pulmonary insufficiency or at risk of airway obstruction should be used with caution or contraindicated.

[Complications / Risks]:

The filter may increases the patient airway resistance, reduce the air throughput, affect ventilate, should continuously monitoring SpO₂, arterial blood gases, airway pressure, PaCO₂.

Cross infection: The filtration efficiency of this product for bacteria and viruses is 99.9%, The risk of cross-infection during clinical use cannot be absolutely avoided.

[Adverse Event Feedback and Measures]: A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the

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manufacturer and the competent authority of the Member State in which the user and/or patient is established.



[Notices and warning]:

1. For single patient and single-use only. Not to be re-sterilized or reused, in which case performance of device can be affected, and risk of cross infection is increased.
2. Inspect the integrity of packaging before use. Do not use if any single packaging is damaged.
3. For safety reasons, the device should only be operated by medical personnel, not non-professionals.
4. Patient signs should be monitored during use, and measures should be taken immediately if abnormal monitoring is found.
5. Please replace, discard and destroy the product after it reaches the age of use.
6. Sterilized with EO. Sterilization is valid for 5 years.
7. To be used before the expiry date on sealed package.
8. **Warning:** In clinical anesthesia use, it should be noted that HME has a certain adsorption and filtration of anesthetic gas, and the anesthetic effect of patients should be observed during anesthesia use.
9. **Warning:** HME is not recommended for clinical inhalation of atomization or humidification
10. **Warning:** In order to meet the requirements of environmental protection, the used products should be collected in a centralized manner according to the regulations of the local medical waste disposal department. When medical waste is destroyed, the environment must not be damaged.
11. **Warning:** Do not use if the product is contaminated or damaged.

[Key symbols]:

	Medical Device		Do not use if package is damaged		
	Single Sterile barrier system		Sterilized using ethylene oxide		
	Unique Device Identifier		European Conformity		
	Consult instructions for use		Caution		Catalogue number
	Keep away from sunlight		Do not re-use		Batch code
	Manufacturer		Keep dry		Date of manufacture
	Authorized Representative in the European Community				Use-by date

[Storage and shipping]:

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1. Avoid heavy pressure. Keep away from direct sunlight and rain.
2. Fragile、handle with care.
3. Stored in dry, ventilated and clean environment and free of corrosive gases.

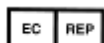


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