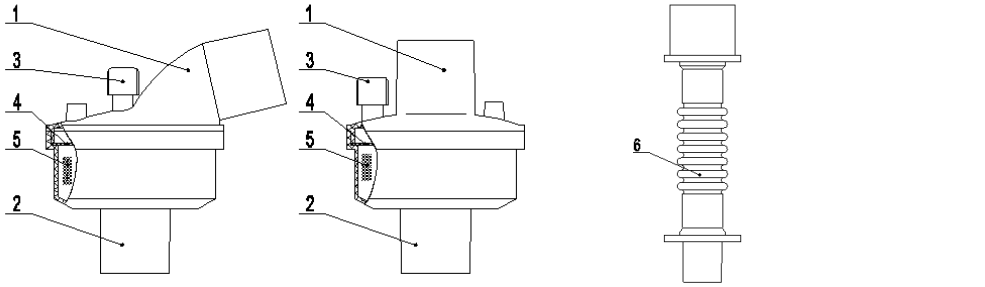
Disposable heat and moisture exchange filter
（with absorbent paper）

[Product name]: Disposable heat and moisture exchange filter

[Type]: GLQ-Q-A、GLQ-Q-AG、GLQ-Q-A1、GLQ-Q-A1G、GLQ-Q-B、GLQ-Q-BG、GLQ-Q-B1、GLQ-Q-B1G

[Product structure and components]: upper casing、lower casing、protective cap、filter membrane、absorbent paper、telescopic pipe(optional)



A: bend type　　B: straight type　　G: telescopic pipe(optional)

1. upper casing　2. lower casing　3. protective cap　4. filter membrane
5. absorbent paper　6. 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. Moreover, the product also has the function of heat and humidity insulation, so that patients can breathe more comfortable.

1、Moisture loss:

The moisture loss of pediatric products shall have no more than 17.5mg/L when the moisture volume is 250mL .

The moisture loss of adult products shall have no more than 19.5mg/L when the moisture volume is 500mL .

2、Pressure Drop:

Under the flow rate of 15L/min for pediatric products, the pressure drop at both ends shall not be greater than 0.1kpa .

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 62.4mL(approx) ； Pediatric type: 30.5mL(approx).

4、Filtration efficiency:

1）The product's filtration rate of suspended particles above≥0.3μm shall be ≥ 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. 气体泄漏应不超过 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.

[Clinical benefits]： When breathing, filter gas particles, foreign bodies, bacteria and viruses to avoid secondary infection to patients, and the product has the function of heat and humidity insulation, so that patients breathe more comfortable (GLQ-Q-V and GLQ-Q-VG are not applicable for the performance of heat preservation and moisture preservation).

[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 with absorbent paper suitable for patients who have established artificial airway to exchange heat and humidity of the gas they breathe and filter particles, bacteria and viruses.

[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, PaC02.
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 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]:

MD	Medical Device		Do not use if package is damaged
	Single Sterile barrier system	STERILE EO	Sterilized using ethylene oxide

UDI	Unique Device Identifier	CE 0123	European Conformity		
	Consult instructions for use		Caution	REF	Catalogue number
	Keep away from sunlight		Do not re-use	LOT	Batch code
	Manufacturer		Keep dry		Date of manufacture
EC REP	Authorized Representative in the European Community				Use-by date

[Storage and shipping]:

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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