

L1 Breathing Tube

User Manual

 Before using the product, please read this user manual through carefully and completely.

riangle Warnings and precautions:

- Please keep this user manual for future reference.
- Always hold the tube at the cuffs, when connecting or disconnecting to the therapy device, humidifier and mask.
- The tube must not be heated (> 60°C / > 140°F).
- The tube is for single patient use only.
- After washing, the tube must not be dried with an oven (microwave), a hairdryer or other appliances. See cleaning instructions.
- The interior of the tube must not be cleaned with brushes or other objects, as it can damage the tube.
- Do not disassemble the tube or damage it.
- Do not insert or drop any object into the openings of the tube as it can damage the tube.
- Do not place objects on the tube as it can damage the tube.
- If the tube is damaged (holes, creases, tears, etc.) or malfunctioning, please do not repair it yourself or continue using it. Replace the tube immediately. Label the old tube so that it is not used by another patient before its final disposal.
- Images shown are indicative only. If there is inconsistency between the image and actual product, the actual product shall govern.

Intended use

The tube is intended for use with respiratory therapy devices and humidifiers with conical ISO connectors (ISO 5356). The tube is designed to transport breathing gasses from the flow generator or humidifier to the patient.

The tube is indicated for non-invasive respiratory therapy in the home, hospital or sleep-lab setting by a single adult patient. It can also be used in conjunction with supplemental oxygen.

Cleaning

⚠ Warnings:

- Do not use harsh soaps, detergents, solvents or alcohols to clean the tube.
- 2. Do not clean the tube in a dishwasher.
- After cleaning and prior to reuse, the tube should be inspected for holes, creases and tears.
- 4. The tube should be cleaned daily.

Cleaning instructions

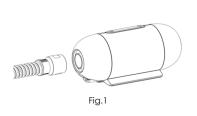




Fig.2

- 1. Remove the tube from the device and mask before cleaning.
- 2. Hold the cuff of the tube and gently pull it away from the device as shown in Fig.1.
- 3. Hold both the cuff of the tube and the swivel of the mask, then gently pull apart as shown in Fig.2.

- 4. Soak the tube in 2% soapy water at 35°C to 40°C for 10 minutes, then clean the inside and outside surfaces with a soft brush 5 times, and rinse it with sterile water for 5 minutes.
- Gently tap the tube to remove excess moisture from the connector ports. Hang the tube so that both ends of the opening face the floor, let the tube naturally dry, out of direct sunlight.
- 6. Inspection

Please perform a visual inspection of the tube. If any visible deterioration is apparent (holes, tears or cracks, etc.), the tube should be discarded and replaced. Slight discoloration may occur, which is acceptable.

Product specifications

| Tube | Length | Internal diameter | Compliance standards | Resistance to flow at rated flow |
|------|--------|----------------------|----------------------|----------------------------------|
| D15 | 1.8 m | 15 mm | 60 hPa: < 5 mL/hPa | 30 L/min: < 0.06 hPa/L/min |

Operating conditions:

Ambient Temperature: 5°C to 35°C (41°F to 95°F)

Relative humidity: 15% to 93%

Atmospheric Pressure: 760 to 1060 hPa Storage and transport conditions:

Storage temperature: -25°C to 70°C (-13°F to 158°F)

Relative humidity: 15% to 93%

Atmospheric Pressure: 760 to 1060 hPa

The tube should be transported and stored in the original packaging and protected from dust and exposure to direct sunlight.

Disposal

The tube, packaging and the required user manual can be disposed of along with the household waste.

Service life

Under normal maintenance and usage, the expected service life of the tube is 6 months. The shelf life of the tube is 3 years. The tube should be discarded after 6 months of use.

Warranty

It is warranted that the tube shall be free from defects in material and workmanship for a period of ninety (90) days from the date of purchase by the initial consumer. To exercise the rights under this warranty, contact the local authorized dealers.

The tube is a consumable and must be checked before first use otherwise warranty claims are excluded. Warranty expires, if:

- Interventions, modifications, extensions, calibration, repairs and maintenance are carried out by persons who are not authorized by the manufacturer.
- Other manufacturers' accessories and spare parts are used that have not been approved by the manufacturer for use the product.
- The product is used other than as described in the user manual.
- Wearing parts are worn.
- Product damages are caused by force majeure (e.g. by lightning).
- The hygiene and cleaning instructions described in the user manual have not been complied with.

System and packaging



Caution



Manufacturer



Consult instructions for use or consult electronic instructions for use

Batch code



Do not use if package is damaged and consult instructions for use



Use-by date



Model number

UDI

Unique device identifier



Medical device



Made in China



Temperature limit



Humidity limitation



Atmospheric pressure limitation

Manufactured for: **REACT HEALTH**

5101 Fruitville Rd., Suite 200 Sarasota, FL 34232 T: (863) 226-6285

For additional information, please visit our Patient Portal at: www.reacthealth.com

Manufacturer:

BMC Medical Co., Ltd.

Room 10, 17F, Building 4, Huiya Plaza, No.16 Lize Road, Fengtai

District, 100073 Beijing, PEOPLE'S REPUBLIC OF CHINA

URL: en.bmc-medical.com E-mail: intl@bmc-medical.com

Tel: +86-10-51663880

Fax: +86-10-51663880 Ext. 810