MD

Breathing Tube

User’s Manual

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The website of Electronic manual is http://www.rescomf.com/en/pro_show.asp?cid=238&id=2803

1.Understanding the Breathing Tube

1.1 Intended Use

Breathing tube is intended to be combined with a respiratory therapy devices and humidifiers to provide air connection between positive pressure ventilation and patient interface. It is intended for single-patient in homes, hospitals.

Indications: It is the same with the ventilators or humidifiers, please refer to the users' manual of ventilators or humidifiers connected to breathing tube.

Intended patient: It is used by adult patients receiving respiratory support via positive pressure ventilation.

Contraindications: Not found, please refer to the users' manual of ventilators or humidifiers connected to breathing tube.

Intended user: The intended users are adults who are capable of understanding general operation of the device and the content of instruction manual, and can be either doctors or lay persons.(Intended delivered volume ≥300ml).

1.2 Models and material:

Model:TRS Series

Include: TRS15-12,Length:0.4m , 1.0m

TRS15-15 , Length:0.35m

TRS22-15,Length:0.4m，0.6m，1.0m，1.8m，2.0m

TRS22-19,Length:0.4m，0.45m，0.6m，1.0m，1.8m，2.0m

Structural composition: The product is composed of thread tube and tube joint.

TRS22-15 Set:Length:1.8m

TRS22-19 Set:Length:1.8m

Structural composition: The product is composed of thread tube and tube joint.

Optional accessories are as follows：0.4~0.6m Tubing、CPAP Pressure Line、T-junction、tube support and tube sleeve.

Material:

Tube body is made of POE、PP；

Tube inferfaceis made of TPE、PP、POE；

Optional parts:CPAP Pressure Line is made of PVC, T-junction is made of PC, tube support is made of aluminum-magnesium alloy, and the tube sleeve is made of velvet.

1.3 Warnings and attentions:



Warnings:

Product Instruction

(1) No matter how long the storage time is , clean the tubing thoroughly before storage.
(2) Do not use solutions containing bleach, alcohol, fragrances, moisturizing lotions, fungicides or essential oils to clean the tubing.
(3) Do not expose the tubing to direct sunlight, which may lead to product deterioration.



Attentions:

(1) Please read the instructions before use;
(2) Check the integrity of product packaging before use, and do not use if the packaging is found damaged;

(3) When using the product in a medical setting, ensure that the patient is closely monitored;
(4) Check the product regularly and replace it immediately if it is found to be contaminated or has became unsuitable for its intended use.
(5) Avoid foreign matter entering the breathing tube to cause blockage.
(6) Potential safety hazards and use restrictions: In case of biological incompatible hazards or other hazards, please stop using it immediately and consult your doctor for treatment.
(7) In case of any accident during the correct use of the product, please stop using it immediately and consult your doctor for treatment.
(8) In the process of use, always pay attention to the connection air tightness between the breathing tube and the connecting equipment, and replace a new tube in time when there is air leakage.
(9) In case of any adverse events that may occur during the use of the product,please stop using it immediately and consult your doctor for treatment.
(10) Combined use device information:
The breathing tube only can used with approved respiratory therapy equipment (such as ventilator) and the patient interface (Mask or cannula) according to Medical device directive 93/42/EEC or Medical device regulation 2017/745. The breathing tube is not coaxial breathing set. Their connector size shall be comply with ISO standard, so that the breathing tube can be attached to their connector socket with good connection.

1.4 Performance Index:

(1) Appearance
The appearance of the tubing should be round, smooth,free from obvious spots and mechanical damage. Interior should be kept clean and unobstructed.
(2) Connection
The tubing cuffs is connected to 22mm or 15mm external tapered connector.
(3) Resistance to flow
Those breathing tubes supplied ready for adult use,flow resistance limit is less than 0,06 hPa/l/min at At flow 30 l/min.
The pressure at the flow rate stated when the breathing tube is suspended over the metal cylinder shall not exceed 150% of the value obtained when the tube is straight.
(4) Leakage
Leakage from breathing tubes shall not exceed 10ml/min at (60 ±3) hPa.
(5) Compliance
Those breathing tubes supplied ready for adult use,Compliance limit is less than 5ml/hPa At pressure 60 ±3 hPa.
(6) Axial strength of breathing tube
Those breathing tubes shall withstand an axial force of 45 N.

2.Use and Care

2.1 Installation and Use
(1) Open the package and take out the product;
(2) Connect the product to the breathing air supply equipment and mask and other accessories, ensure that there is no air leakage and loosening;
(3) Before each use of the product, please test the product in accordance with the equipment manufacturer’s guidelines to ensure that the product is compatible with the equipment and no leaks or blockages.
2.2 Replacement instructions:
(1) Turn off the breathing air supply equipment.
(2) Disconnect the connection between breathing tube and the breathing air supply equipment and accessories.
(3) Follow the steps in the installation instructions to install the new breathing tube.

2.3 Processing instruction

<table>
<tr><td colspan="3">Manufacturer: GuangDong EDA Technology Co., Ltd.
Method:See in below table
Symbol:N.A.
Devices:This processing instruction is suitable for all models of Breathing Tube.
Processing requirements for first and interval use: Have to clean and disinfect the tube before first use, or when no use over than one week.</td></tr>
<tr><td colspan="2">Limitations on processing</td><td>Reuse: 30 times
● These devices are designed for 30 repeated uses when in accordance with reprocessing instructions. These devices are supplied non-sterile as indicated on the packaging labels. Process through cleaning and disinfection after each use. Care in use and handling will help ensure the useful life.
● It is recommended to establish a procedural review (before and after each use) by which the breathing tube showing such damage or wear are either sent for refurbishing, discarded and/or replaced.</td></tr>
<tr><td colspan="3">INSTRUCTIONS</td></tr>
<tr><td colspan="2">Initial treatment at the point of use</td><td>Step 1:
Press the Start/Stop button of the ventilator to stop breathing tube and ventilator, then turn off the power of ventilator.
Step 2: Remove the tube from the breathing machine before cleaning.
Step 3: Rinse the tube with clean water until no obvious soil stay in the tube when there is obvious soil or contamination in the tube after detaching the tube from ventilator.</td></tr>
<tr><td colspan="2">Preparation before cleaning</td><td>Step 1: Please check the breathing tube for any damage before cleaning. If there are any holes, tear or crack, the tube should be replaced after dissemble the tube.
Step 2： Please check if there is dirt, blood or sputum scab in the tube, it must be cleaned within half an hour.
Step 3: Prepare Liquid container which can accommodate the tube, Enzyme-containing cleaning solution (5mL cleaning solution /1L water) and an effective chlorine solution containing 500mg/L.</td></tr>
<tr><td rowspan="2">Cleaning:</td><td>Automated</td><td>N.A. The product cannot be automatically cleaned, which may cause product damage (it may case pipe wrinkles or damage, and tube aging et.,) and affect product performance.</td></tr>
<tr><td>Manual</td><td>Step 1： Please use clean water to wash the dirt, blood or sputum scab and other dirt in the tube firstly.
Step 2： Soak the tube in enzyme-containing cleaning solution (5mL cleaning solution /1L water) for 2-3 minutes, then rinse with clean water. Suggest using the clean enzymatic detergent from GETINGE.
Step 3：After cleaning, check that there is no dirt, blood or sputum scab inside the tube and other dirt can be disinfected. Otherwise, please repeat above Step 1 to Step 2.
Note:
● Do not soak tube in hot water, alcohol, non-designated disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed one hours soaking in ANY solution.</td></tr>
</table>

		● Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents to wash the tubes, they will damage the tubes. ● Manual cleaning effect has its instability, it is recommended to strictly follow the instructions when cleaning.
Disinfection:	Automated	N.A. The product cannot be automatically cleaned, which may cause product damage (it may case pipe wrinkles or damage, and tube aging et.,) and affect product performance.
	Manual	**Step 1:** Soak the cleaned tube with an effective chlorine solution containing 500mg/L for 30~35 minutes to disinfect it; The tube must be completely immersed in disinfectant during immersion disinfection. **Step 2:** After soaking, rinse with pure water or cold boiled water and soak for 30 minutes. Note： Manual disinfection effect has its instability, it is recommended to strictly follow the instructions during disinfection.
Drying		**Step 1:**Then hang the tubes vertically in a ventilated environment for more than 4 hours to air dry. **Step 2:** After drying, check that the tubes are free from blood stains, stains, damage, aging and cracks.
Maintenance, inspection and testing		Then install the breathing tube to the ventilator to confirm it can work normally when you power on the ventilator.
Packaging		The tubes after disinfection are stored in clean and dry containers or clean bags for use. Do not wear gloves with talcum powder when packing to prevent talcum powder from entering the tube inside; When packing, check whether the articles are complete to prevent missing parts.
Sterilization		N.A.
Storage		Storage temperature : -20℃～65℃; Relative humidity : ≤95%,non-condensing； Atmospheric pressure:70Kpa~106Kpa Storage conditions : Keep in the original packaging, protected from dust and avoid exposure to direct sunlight.

Please record the number of uses in the following table after each use:

Number of uses	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Mark "√" after each use															
Number of uses	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Mark "√" after each use															

Precautions:

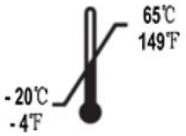
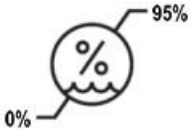
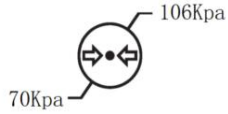
1. Disinfectants generally damage the surface of the material and shorten the product life. Attention should be paid to the instruction of disinfectants, choose the disinfectant recommended by our company as much as possible, and follow the disinfectant manufacturer's recommendations.
2. If any breakage is found in the tubing after disinfection, it should be replaced promptly. Slight discoloration of the tubing may occur after disinfection, which is a normal phenomenon.
3.Thoroughly clean the tubing after the disinfection , in case of residual disinfectant damage to the skin and respiratory tract, or cause allergic reactions.

4.The company has used the effective chlorine content of 500mg/L disinfectant to carry out disinfection cycle verification of the breathing tube, the verified circulation disinfection times is 30 times.

Attentions:

- Care and maintenance: Clean after each use, dry with air and keep in the ventilated area.
- Transportation:No request.
- Product Validity period and recommended life time:The validity period of the product is 5 years.
  In the case of use, maintaining and cleaning in accordance with the instructions, the recommended life time of the product is 6 months.
- Optional parts:0.4~0.6m Tube and tee-junction can be together with breathing tube in reprocessing. The Piezometric tube, circuit holder, and tube sleeve require only cleaning with purified water followed by air-drying. These parts are designated as non-critical devices per Spaulding classification and do not require sterilization or disinfection.
- This product does not require sterilization.

3.Illustration of graphic symbols

Caution! Refer to the attached documents	Latex Free	Batch code	Use-by date
			
Non-sterile	Non-sterile	Follow the user' manual	Date of manufacture
			
Manufacturer	Catalogue number	Temperature Limit	Humidity Limitation
			
Atmospheric pressure limitation	Medical Device	Unique device identifier	Authorized Representative in European Community.
			

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