



# User Manual

Tube

Heated Breathing Tube











LH1



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**1. Device Symbols**

|   |  |
|---|--|
|  | Manufacturer                                     |
|  | Follow Instructions for Use                      |
|  | Operating Instructions                           |
|  | Type BF Applied Part                             |
|  | DC Power   |
| <b>IPX2</b>   | Dripping (15° tilted)                            |
|  | Lot number                                       |
|  | Do not use the product if the package is damaged |
|  | WEEE Marking                                     |
|  | Use-by date                                      |
|  | Logo of BMC Medical Co., Ltd.                    |

## ***2. Warning, Caution and Important Tip***

### ***WARNING!***

Indicate the possibility of injury to the user or operator.

### ***CAUTION!***

Indicate the possibility of damage to the device.

### ***IMPORTANT TIP!***

Place emphasis on an operating characteristic.

Warnings, Cautions, and Important Tips appear throughout this manual as they apply.

## ***3. Intended Use***

The LH1 Heated Breathing Tube (Heated Breathing Tube for short) is heated air tubing intended for incorporation into respiratory therapy devices and humidifiers with conical ISO connectors (ISO 5356). And is intended to reducing or eliminating water condensation and/or pooling of water in the Heated Breathing Tube, and problems associated with such.

The Heated Breathing 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.

### ***WARNINGS!***

- This device is intended for adult use only.
- This product is not intended for patients with upper respiratory tract bypass.
- The device is intended for use by a single patient only.
- The instructions in this manual are not intended to supersede established medical protocols.
- When the device is connected with other devices to constitute the ME system, it shall meet the relevant requirements of IEC 60601-1-1 for the safety of medical electrical system.
- This device has no alarm function and is not applicable to the case where the alarm is required.
- Images shown are indicative only. If there is inconsistency between the image and actual product, the actual product shall govern.

#### 4. Specifications

|  |  |                              |                              |
|--|--|------------------------------|------------------------------|
| <b>Inner Diameter</b>                                | 19 mm  |                              |                              |
| <b>Length</b>  | The length under static (unstressed) condition in the horizontal plane is 1.8 m<br>Margin of Error: $\pm 10\%$                             |                              |                              |
| <b>Environmental Conditions</b>                      |  | <b>Operation</b>             | <b>Transport and Storage</b> |
|  | Temperature  | 5°C ~ 35°C                   | -25°C ~ 70°C                 |
|  | Humidity   | 15% ~ 93%,<br>Non-condensing | 15% ~ 93%,<br>Non-condensing |
|  | Atmospheric Pressure   | 760 ~ 1060 hPa               | 760 ~ 1060 hPa               |
| <b>Power Supply</b>                                  | DC Voltage   |                              | Load Power                   |
|  | 24 V   |                              | 18 W                         |
| <b>Air outlet Temperature</b>                        | At temperature 5°C ~ 30°C, air outlet temperature is less than 41°C.   |                              |                              |
| <b>Resistance to flow at rated flow</b>              | 30 l/min: < 0.06 hPa/l/min   |                              |                              |
| <b>Compliance standards</b>                          | 60 hPa: < 5 ml/hPa   |                              |                              |
| <b>Manufacture Date</b>                              | Refer to the nameplate   |                              |                              |
| <b>Service Life</b>                                  | The product's service life is six months if the use, maintenance, cleaning and disinfection are in strict accordance with the User Manual. |                              |                              |
| <b>Validity Term</b>                                 | 3 years  |                              |                              |
| <b>Type of Protection against Electric Shock</b>     | Not Applicable   |                              |                              |
| <b>Degree of Protection against Electric Shock</b>   | Type BF Applied Part   |                              |                              |
| <b>Degree of Protection against Ingress of Water</b> | IPX2   |                              |                              |

**Note:** The nominal rated flow of the product is 60 L/min, 0.2 kPa.

## 5. Features

The Heated Breathing Tube is composed of threaded tubing, adapter, heated wire and its port. The structure of the Heated Breathing Tube is shown in Fig. 5-1.

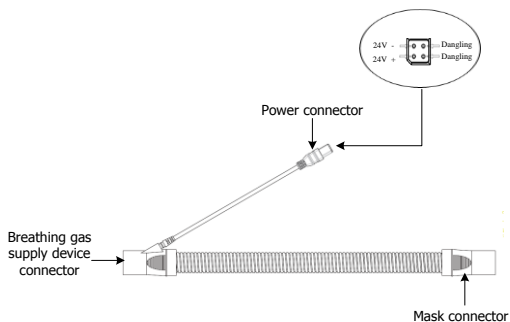


Fig. 5-1

### **WARNING!**

- This product should only be connected with mask type non-invasive breathing gas supply device or positive pressure breathing gas supply device (hereinafter referred to as breathing gas supply device) produced or authorized for use by BMC or recommended by prescription doctor. The use of incorrect breathing gas supply device may affect the the effectiveness of the treatment.

## 6. First Time Setup

### **WARNINGS!**

- When the indoor temperature exceeds 30°C, disconnect power supply of the Heated Breathing Tube, so as to avoid the high temperature of airflow and irritate the airway of patients.
- When the indoor humidity exceeds 80%, do not use the Heated Breathing Tube to prevent any condensation in the tubing from entering the patient's airway.
- Do not cover the Heated Breathing Tube with anything, including textile heat insulation sleeves, plastic sleeves, blankets, etc., to avoid excessive air temperature and irritate the airway of patients.
- Do not use the Heated Breathing Tube without airflow.
- When accidents occur during normal use, the product should be stopped immediately and appropriate emergency and corrective measures should be taken.
- If the DC voltage exceeds the range (refer to Part 4 "Power Supply"), the product will not work properly.
- If the Heated Breathing Tube is damaged (such as broken hole, kink, tear, exposed heated wire, etc.) or poor function, please do not repair and use it by yourself and replace it immediately.

**CAUTION!**

- Check the integrity of the product packaging, if the package is found damaged, please do not use this product.
- When using the product, make sure that patients are closely monitored.
- Check the product regularly and replace the product immediately if it is found to be contaminated or no longer applicable to its use intention.
- Do not pile too long tubes on the head of the bed, it is possible to entangle the head of the patient or neck in a deep sleep. The tubing should not be covered by the sheet or affected by the heating source (such as electric blanket), otherwise it may cause the deformation of the tubing to be dangerous.
- When the product is not connected to the patient, avoid foreign matter entering the inside of the Heated Breathing Tube.
- Before each use, the tubing should be checked for damage or foreign matter. If so, please replace the tubing immediately. Check whether the mask system is sealed.
- When the product is discarded, the treatment method of the high-molecular medical device shall be carried out for the harmless treatment.
- When connecting or disassembling Heated Breathing Tube with breathing gas supply device or nasal cannula, be sure to focus on the adapter and do not pull the threaded tubing.
- When using the Heated Breathing Tube, be sure to use with the humidifier, so as to avoid the gas temperature is too high.
- When using electrical products, you follow the usual safety measures.
- Do not use (microwave) oven, fan or any other appliances to dry the cleaned Heated Breathing Tube. Please refer to the cleaning instructions.
- Do not use a brush or any other object to clean the inner wall of the Heated Breathing Tube.
- Do not disassemble or intentionally damage the Heated Breathing Tube.
- When you want to permanently discard the Heated Breathing Tube, please clearly mark the used Heated Breathing Tube to avoid misuse by other patients.
- Do not use this product in an environment with flammable gases (such as narcotics) to avoid explosion.

**6.1 Connecting the Heated Breathing Tube to the Device**

- (1) Unpack and take out the product.
- (2) Connect the machine end port of Heated Breathing Tube and breathing gas supply device.
- (3) Connect the power connector of Heated Breathing Tube and the socket of breathing gas supply device as shown in Fig. 6-1.

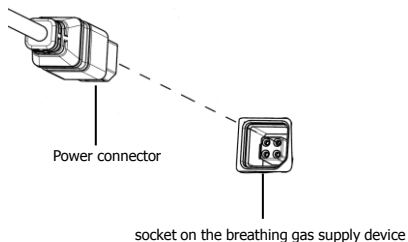


Fig. 6-1

(4) Connect the mask connector of Heated Breathing Tube and mask.

**CAUTION!**

- Before each use of the product, test the product according to the instructions of the device manufacturer to ensure that the product is compatible with the device and that the product is free of air leakage and blockage.

**6.2 Removing the Heated Breathing Tube from the Device**

- (1) Close the breathing gas supply device.
- (2) Press and hold the power connector the Heated Breathing Tube to separate it from the socket on the breathing gas supply device.
- (3) Disconnect the Heated Breathing Tube from breathing gas supply device and accessories.

**6.3 Requirements for breathing gas supply device**

- (1) The breathing gas supply device should have current limitation when supplying power to the Heated Breathing Tube, and the output power supply should meet the requirements of "Power Supply" in part 4 of this manual.
- (2) The socket on the breathing gas supply device must match the power connector of the Heated Breathing Tube.

**7. Cleaning and Maintenance**

**WARNINGS!**

- Regular cleaning of the device and its accessories is very important for the prevention of respiratory infections.
- To avoid electric shock, always unplug the device before cleaning.
- Use mild soap that is nontoxic to humans.
- Do not use irritating soap, detergent, solvent or alcohol clean the tubing.
- Do not reconnect the Heated Breathing Tube until it is completely dry.



- Do not wash Heated Breathing Tube with dish-washing machine.
- The power connector of the Heated Breathing Tube should not have any contact with any liquid and a disposable medical cleaning cloth or paper is used to remove any visible dirt.

### ***7.1 Cleaning the Heated Breathing Tube***

- (1) Before cleaning, remove all connecting parts, then clean the tubing in warm water which contains washing liquid, and then rinse it in clean water thoroughly.
- (2) Tap gently to remove excess moisture from the connector port.
- (3) Suspend the Heated Breathing Tube with openings at both ends facing the floor.
- (4) Air-dry the tubing, and avoid direct sunlight.

#### ***WARNINGS!***

- Please wash by hand.
- If the Heated Breathing Tube is damaged (such as broken hole, tear, exposed heated wire, etc.) or poor function, please do not repair and use it by yourself and replace it immediately.
- Failure to clean in accordance with the Manual may result in reduced performance of the Heated Breathing Tube or reduced product life.

### ***7.2 Disinfection of the Heated Breathing Tube***

If the cleaning instructions in Clause 7.1 are strictly followed, it is generally not necessary to disinfect the Heated Breathing Tube. When the product is contaminated, please clean it according to the cleaning method in Clause 7.1, before disinfecting according to the following scheme.

- (1) Immerse the Heated Breathing Tube in 0.55% O-phthalaldehyde for 12 min.
- (2) After immersing, rinse it in clean water thoroughly.
- (3) Tap gently to remove excess moisture from the connector port.
- (4) Suspend the Heated Breathing Tube with the openings at both ends facing the floor.
- (5) Air-dry the tubing, and avoid direct sunlight.

#### ***WARNING!***

- No sterilization is required by the product.

#### ***CAUTIONS!***

- BMC has used the following disinfectants to verify the disinfection cycle of the Heated Breathing Tube, and the number of cycles of verified disinfection is 100 times.
- Disinfectants generally damage the surface of materials and shorten the service life of the product. Attention should be paid to the instructions for use of the disinfectants; the right ones should be selected as applicable as possible, and the recommendations of the disinfectant manufacturer should be followed.
- If the Heated Breathing Tube is found to have any damage (such as fracture and rupture) after disinfection, it needs to be replaced in time. It is normal for the Heated Breathing Tube to become slightly discolored.
- After disinfection, please be sure to always rinse it thoroughly with clear water to prevent residual disinfectant from damaging skin and respiratory tractor causing allergic reaction.

## 8. Disposal

When the device reaches the end of its service life, dispose of the device and packaging in accordance with local laws and regulations.

## 9. Technical Support

Please contact BMC directly if you need the technical documents of the Heated Breathing Tube for certain purposes such as maintenance or connection to other equipment. BMC will provide the technical documents in whole or in part according to your needs.


## 10. EMC Requirements

| <b>Guidance and manufacturer's declaration - electromagnetic emissions</b>  |                   |   |
|---|-------------------|---|
| The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment. |                   |   |
| <b>Emissions Test</b>   | <b>Compliance</b> | <b>Electromagnetic Environment - Guidance</b>   |
| RF emissions<br>CISPR 11  | Group 1           | The device uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment   |
| RF emissions<br>CISPR 11  | Class B           | The device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes |
| Harmonic emissions<br>IEC 61000-3-2   | N/A               |   |
| Voltage fluctuations<br>/ flicker emissions<br>IEC 61000-3-3  | N/A               |   |

### **WARNINGS!**

- During operation of the device, due to electrostatic interference, the following phenomena may occur:
  - (1) Temporary loss of function or degradation of performance, such as abnormal screen display, etc. The device will recover to normal after being restarted;
  - (2) Automatic restart of the device. These phenomena will not affect the normal use of the device, and will not cause permanent performance degradation or function loss of the device.

| <b>Guidance and manufacturer's declaration - electromagnetic immunity</b>  |  |  |   |
|--|--|--|---|
| The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment. |  |  |   |
| <b>Immunity Test</b>   | <b>IEC 60601 Test Level</b>  | <b>Compliance Level</b>  | <b>Electromagnetic Environment - Guidance</b>   |
| Electrostatic discharge (ESD)<br><br>IEC 61000-4-2   | ±8 kV contact<br><br>±15 kV air  | ±8 kV contact<br><br>±15 kV air  | Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%   |
| Electrical fast transient / burst<br><br>IEC 61000-4-4   | ±2 kV for power supply lines   | ±2 kV for power supply lines   | Mains power quality should be that of a typical commercial or hospital environment  |
| Surge<br><br>IEC 61000-4-5   | ±1 kV<br>Line (s) to line (s)  | ±1 kV<br>Line (s) to line (s)  | Mains power quality should be that of a typical commercial or hospital environment  |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br><br>IEC 61000-4-11   | 0% $U_i$ ; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0% $U_i$ ; 1 cycle<br><br>70% $U_i$ ; 25 / 30 cycles<br>At 0°<br><br>0% $U_i$ ; 250 / 300 cycles | 0% $U_i$ ; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0% $U_i$ ; 1 cycle<br><br>70% $U_i$ ; 25 / 30 cycles<br>At 0°<br><br>0% $U_i$ ; 250 / 300 cycles | Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery |
| Power frequency (50 / 60 Hz) magnetic field<br><br>IEC 61000-4-8   | 30 A/m   | 30 A/m   | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment  |
| Note: $U_i$ is the AC mains voltage prior to application of the test level.  |  |  |   |

| <b>Guidance and manufacturer's declaration - electromagnetic immunity</b>   |   |                         |   |
|---|---|-------------------------|---|
| The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.  |   |                         |   |
| <b>Immunity Test</b>  | <b>IEC 60601 Test Level</b>               | <b>Compliance Level</b> | <b>Electromagnetic Environment - Guidance</b>   |
| Conducted RF<br>IEC<br>61000-4-6  | 3 V (Effective value)<br>150 kHz ~ 80 MHz | 3 V (Effective value)   | Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$d = 1.2\sqrt{p}$<br>$d = 1.2\sqrt{p}$ 80 MHz ~ 800 MHz<br>$d = 2.3\sqrt{p}$ 800 MHz ~ 2.5 GHz<br>Where $p$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol:  |
| Radiated RF<br>IEC<br>61000-4-3   | 3 V/m<br>80 MHz ~ 2.5 GHz                 | 3 V/m                   |   |
| <p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>  |   |                         |   |
| <p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.</p> <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.</p> |   |                         |   |

| <b>Recommended separation distances between portable and mobile RF communications equipment and the device</b>   |                                       |                                       |  |
|--|---------------------------------------|---------------------------------------|--|
| The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment. |                                       |                                       |  |
| Rated maximum output of transmitter<br>W   | 150 kHz ~ 80 MHz<br>$d = 1.2\sqrt{P}$ | 80 MHz ~ 800 MHz<br>$d = 1.2\sqrt{P}$ | 800 MHz ~ 2.5 GHz<br>$d = 2.3\sqrt{P}$ |
| 0.01   | 0.12                                  | 0.12                                  | 0.23                                   |
| 0.1  | 0.38                                  | 0.38                                  | 0.73                                   |
| 1  | 1.2                                   | 1.2                                   | 2.3                                    |
| 10   | 3.80                                  | 3.80                                  | 7.28                                   |
| 100  | 12                                    | 12                                    | 23                                     |
| Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.<br>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.  |                                       |                                       |  |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.   |                                       |                                       |  |

**WARNINGS!**

- This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.
- The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.
- Even if other equipment meets the emission requirements of corresponding national standards, the product may still be interfered by other equipment.
- Do not bring the device or accessories into a Magnetic Resonance (MR) environment as it may cause unacceptable risk to the patient or damage to the device or MR medical devices. The device and accessories have not been evaluated for safety in an MR environment.
- Do not use the device or accessories in an environment with electromagnetic equipment such as CT scanners, Diathermy, RFID and electromagnetic security systems (metal detectors) as it may cause unacceptable risk to the patient or damage to the device. Some electromagnetic sources may not be apparent, if you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, disconnect the power cord and discontinue use. Contact your home care provider.
- When the product is exposed to soldering, electrosurgery, defibrillation, X-ray (γ ray), infrared radiation, transient electromagnetic field, including nuclear magnetic resonance (MRI) and radio interference environment, the product may be damaged.

## **11. Limited Warranty**

BMC Medical Co., Ltd. warrants that the device shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for three (3) months from the date of sale by BMC Medical Co., Ltd. to the dealer. If the product fails to perform in accordance with the product specifications, BMC Medical Co., Ltd. will repair or replace, at its option, the defective material or part. BMC Medical Co., Ltd. will pay customary freight charges from BMC Medical Co., Ltd. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

BMC MEDICAL CO., LTD. DISCLAIMS ALL LIABILITY FOR ECONOMIC LOSS, LOSS OF PROFITS, OVERHEAD OR CONSEQUENTIAL DAMAGES WHICH MAY BE CLAIMED TO ARISE FROM ANY SALE OR USE OF THIS PRODUCT. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

To exercise the rights under this warranty, contact the local authorized dealers or:

### **MANUFACTURER:**

#### **BMC Medical Co., Ltd.**

Room 110 Tower A Fengyu Building, No. 115 Fucheng Road, Haidian, 100036 Beijing,  
PEOPLE'S REPUBLIC OF CHINA

URL: [en.bmc-medical.com](http://en.bmc-medical.com)

E-mail: [intl@bmc-medical.com](mailto:intl@bmc-medical.com)

Tel: +86-10-51663880

Fax: +86-10-51663880 Ext. 810

### **Contract Manufacturer:**

#### **BMC (Tianjin) Medical Co., Ltd.**

2/F North Area and 3/F, Building No.4, No.1 Xinxing Road, Wuqing District, (301700)  
Tianjin, P.R.China

Tel: +86-22-82939881

### **UKAR:**

#### **Wellkang Ltd.**

16 Castle St, Dover, CT16 1PW, England, UK

