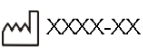
User Manual

Luna G3 Heated Tubing

LH1

Table of Contents

1. Device Symbols

	Caution, consult accompanying documents. Indicates a Warning or Caution and alerts you to a possible injury or explains special measures for the safe and effective use of the device.
	Manufacturer
	Follow Instructions for Use
	Consult instructions for use
	Type BF Applied Part
	DC Power
IPX2	Dripping (15° tilted)
	Batch code
	Do not use if package is damaged and consult instructions for use
	WEEE Marking
	Use-by date
	Date of manufacture
	Logo of BMC Medical Co., Ltd.
	Logo of REACT HEALTH

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 Luna G3 Heated Tubing (Heated Tubing 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 tubing, and problems associated with such.

The heated tubing 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 Tubing is single patient use 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.

• The Images shown are indicative only. If there is inconsistency between the image and the actual product, the actual product shall govern.

4. Specifications

<table>
<tr><td>Inner Diameter</td><td colspan="3">19 mm</td></tr>
<tr><td>Length</td><td colspan="3">The length under static (unstressed) condition in the horizontal plane is 1.8 m
Margin of Error: ±10%</td></tr>
<tr><td rowspan="4">Environmental Conditions</td><td></td><td>Operation</td><td>Transport and Storage</td></tr>
<tr><td>Temperature</td><td>5°C ～ 35°C</td><td>-25°C ～ 70°C</td></tr>
<tr><td>Humidity</td><td>15% ～ 93%,
Non-condensing</td><td>15% ～ 93%,
Non-condensing</td></tr>
<tr><td>Atmospheric Pressure</td><td>760 ～ 1060 hPa</td><td>760 ～ 1060 hPa</td></tr>
<tr><td rowspan="2">Power Supply</td><td colspan="2">DC Voltage</td><td>Load Power</td></tr>
<tr><td colspan="2">24 V</td><td>18 W</td></tr>
<tr><td>Air Outlet Temperature</td><td colspan="3">At temperature 5°C ～ 30°C, air outlet temperature is less than 41°C.</td></tr>
<tr><td rowspan="2">Airflow Resistance</td><td colspan="3">At 60 L/min flow rate, the airflow resistance is less than 0.2 kPa.</td></tr>
<tr><td colspan="3">At 30 L/min flow rate, the airflow resistance is less than 0.06 hPa/L/min.</td></tr>
<tr><td>Leakage</td><td colspan="3">At 6±0.3 kPa pressure, Leakage rate is less than 25 mL/min</td></tr>
<tr><td>Compliance</td><td colspan="3">At 6 kPa pressure, Compliance is less than 5 mL/hPa</td></tr>
<tr><td>Manufacture Date</td><td colspan="3">Refer to the nameplate</td></tr>
<tr><td>Service Life</td><td colspan="3">The product's service life is six months if the use, maintenance and cleaning are in strict accordance with the User Manual.</td></tr>
<tr><td>Shelf Life</td><td colspan="3">3 years</td></tr>
<tr><td>Type of Protection Against Electric Shock</td><td colspan="3">Not Applicable</td></tr>
<tr><td>Degree of Protection Against Electric Shock</td><td colspan="3">Type BF Applied Part</td></tr>
<tr><td>Degree of Protection Against Ingress of Water</td><td colspan="3">IPX2</td></tr>
</table>

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

5. Features

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

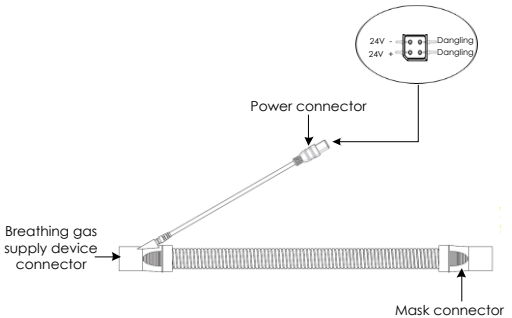


Fig. 5-1

⚠***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 REACT HEALTH or recommended by prescription doctor. The use of incorrect breathing gas supply device may affect the effectiveness of the treatment.

6. First Time Setup

⚠***WARNINGS!***

• When the indoor temperature exceeds 30°C, disconnect power supply of the heated tubing, 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 tubing to prevent any condensation in the tubing from entering the patient's airway.

• Do not cover the heated tubing 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 tubing 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 "Power Supply" in Chapter 4), the product will not work properly.

• If the heated tubing 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.

CAUTIONS!

• 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 suitable for its intended use.

• Do not stack excessively long tube at the head of the bed, as it may entangle the patient's head or neck during sleep. The tubing should not be covered by the sheet or affected by the heating source (e.g. electric blanket), otherwise it may cause the deformation of the tubing, which could be dangerous.

• When the product is not connected to the patient, avoid foreign matter entering the inside of the heated tubing.

• 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 tubing with breathing gas supply device or nasal cannula, be sure to hold it by the adapter and do not pull the threaded tubing.

• When using the heated tubing, be sure to use with the humidifier, so as to avoid the gas temperature is too high.

• When using electrical products, follow the usual safety measures.

• Do not use (microwave) oven, fan or any other appliances to dry the cleaned heated tubing. Please refer to the cleaning instructions.

• Do not use a brush or any other object to clean the inner wall of the heated tubing.

• Do not disassemble or intentionally damage the heated tubing.

• When you want to permanently discard the heated tubing, please clearly mark the used heated tubing 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 Tubing to the Device

(1) Unpack and take out the product.

(2) Connect the breathing gas supply device connector of heated tubing and breathing gas supply device.

(3) Connect the power connector of heated tubing and the socket of the breathing gas supply device as shown in Fig. 6-1.

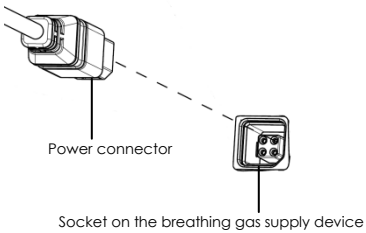


Fig. 6-1

(4) Connect the mask connector of heated tubing and the 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 Tubing from the Device

(1) Close the breathing gas supply device.
(2) Press and hold the power connector of the heated tubing to separate it from the socket on the breathing gas supply device.
(3) Disconnect the heated tubing 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 tubing, and the output power supply should meet the requirements of "Power Supply" in Chapter 4 of this manual.
(2) The socket on the breathing gas supply device must match the power connector of the heated tubing.

7. Cleaning and Maintenance

⚠***WARNINGS!***

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

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

Cleaning the Heated Tubing

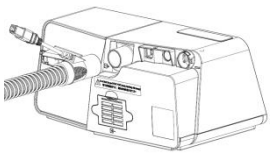


Fig. 7-1

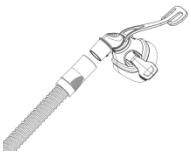


Fig. 7-2

(1) Remove the heated tubing from the device and the mask before cleaning.
(2) Hold the cuff of the heated tubing and gently pull it away from the device as shown in Fig. 7-1.
(3) Hold both the cuff of the heated tubing and the swivel of the mask, and gently pull them apart as shown in Fig. 7-2.
(4) Clean the components with a soft bristle brush for one minute while soaking them in a solution of Alconox diluted with warm water to 1% at 45 ~ 60°C. Pay particular attention to all crevices and cavities.
(5) Run the detergent solution through the air tubing repeatedly until no contamination is visible.
(6) Thoroughly rinse each component according to the detergent manufacturer's instructions.
(7) Thoroughly rinse the tubing in warm water (five liters per assembly) by immersing it completely for a minimum of one minute in duration.
(8) Repeat the rinse procedure two additional times using fresh water for a total of three rinses.
(9) Air dry out of direct sunlight and/or heat.
(10) Inspecting
Carry out a visual inspection of the components. If there are any obvious signs of deterioration (holes, tears or cracks, etc.), these parts should be discarded and replaced. A slight fade may occur, which is acceptable.

⚠***WARNINGS!***
• Please wash by hand.
• The Tubing should be cleaned daily.
• Failure to clean in accordance with the Manual may result in reduced performance of the heated tubing or reduced product life.
• After cleaning and prior to reuse, the Breathing Tubing should be inspected for holes, creases and tears.

8. Disposal

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

9. Technical Support

Please contact REACT HEALTH directly if you need the technical documents of the heated tubing for certain purposes such as maintenance or connection to other equipment. REACT HEALTH will provide the technical documents in whole or in part according to your needs.

10. EMC Requirements

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The heated tubing is intended for use in the electromagnetic environment specified below. The user of the heated tubing should ensure that it is used in such an environment.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>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</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">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</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>N/A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>N/A</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity			
The heated tubing is intended for use in the electromagnetic environment specified below. The user of the heated tubing should make sure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±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 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 IEC 61000-4-5	±1 kV Line(s) to line(s)	±1 kV 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 IEC 61000-4-11	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle 70% U_T; 25 / 30 cycles At 0° 0% U_T; 250 / 300 cycles	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle 70% U_T; 25 / 30 cycles At 0° 0% U_T; 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 Hz / 60 Hz) magnetic field 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_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity

The heated tubing is intended for use in the electromagnetic environment specified below. The user of the heated tubing should make sure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V (Effective value) 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. Recommended separation distance $d = 1.2\sqrt{p}$ $d = 1.2\sqrt{p}$ 80 MHz ~ 800 MHz $d = 2.3\sqrt{p}$ 800 MHz ~ 2.5 GHz 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). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz ~ 2.5 GHz	3 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] 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.
[b] Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

The heated tubing is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the heated tubing 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 (W)	150 kHz ~ 80 MHz $d = 1.2\sqrt{p}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{p}$	800 MHz ~ 2.5 GHz $d = 2.3\sqrt{p}$
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.
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!***

• During operation of the heated tubing, due to electrostatic interference, the following phenomena may occur:

(1) Temporary loss of function or degradation of performance, such as abnormal screen display. 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.

• This heated tubing should not be used in the vicinity of other electronic equipment such as diathermy, electrocautery and radio frequency identification (RFID), security systems (such as electromagnetic anti-theft systems and metal detectors), cell phone, transceiver or radio control products. If you have to do so, the heated tubing should be observed to verify normal operation.

• Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

• Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

• Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. In the above warning, "[ME EQUIPMENT or ME SYSTEM]" shall be replaced with the MODEL OR TYPE REFERENCE of the ME EQUIPMENT or ME SYSTEM.

• This heated tubing may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.
• The heated tubing may be interfered by the electromagnetic field of some known or unknown radio frequency transmitters in the environment during use. If interference occurs, please stay away from the interfered electromagnetic environment, or find and turn off the electromagnetic field interference source before continuing to use it.
• When the product is exposed to soldering, electro surgery, 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

REACT HEALTH 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 REACT HEALTH to the dealer. If the product fails to perform in accordance with the product specifications, REACT HEALTH will repair or replace, at its option, the defective material or part. REACT HEALTH will pay customary freight charges from REACT HEALTH 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.

REACT HEALTH 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:

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:
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Room 10, 17F, Building 4, Huiya Plaza, No.16 Lize Road, Fengtai District, 100073 Beijing,
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