User Manual

Luna® G3 BPAP System

Item No: LG3800-25VT / LG3800-30VT

Model No. G3 B25VT / G3 B30VT

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1. Introduction

Thank you for your purchase of the Luna® G3 BPAP System. This User Manual will introduce you to your device. Please read it carefully. If you experience any difficulties or problems during use, please contact your homecare provider or physician.

2. Symbols

2.1 Control Buttons

 Home Button

 Start / Stop Button

 Knob

2.2 Device Symbols

 Follow Instructions for Use

 Operating Instructions

 Type BF Applied Part (mask)

 Class II (Double Insulated)

 For indoor use only

 AC Power

 DC Power

IP22 ≥ 12.5 mm Diameter, Dripping (15° tilted)

 There is high voltage, beware of electric shock

 Hot Surface

 Serial Number of the Product

 Manufacturer

 Date of manufacture

	Use-by Date
	Authorized Representative in the European Community
	Do not use if package is damaged and consult instructions for use
	Disassembly is prohibited
	Maximum water level
	European CE Declaration of Conformity
	Product is intended for use by a single patient only
	Lot number
	Non-Ionizing Radiation
	SD Card
	WEEE Marking
	Air Inlet
	Air Outlet
	Indicates the possibility of injury to the user or operator
	MR Unsafe
	Logo of BMC Medical Co., Ltd.
	Logo of 3B Medical, Inc.

3. 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.

4. Intended Use

The Luna® G3 BPAP System is a Bi-level PAP (Bi-level Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA). The integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for single-patient use by prescription in the home or hospital/institutional environment on adult patients. It is to be used on patients > 66 lbs / 30 kg for whom CPAP therapy has been prescribed. The system can deliver bi-level therapy or auto bi-level therapy.

⚠***WARNINGS!***
• This device is intended for adults use only.
• This device is not intended for life support.
• The instructions in this manual are not intended to supersede established medical protocols.
• This device and accessories are intended for single patient. Please replace accessories when transfer the device to another patient.
• To ensure that you receive the safe, effective therapy prescribed for you, use only 3B Medical accessories.
• Do not bring the device or accessories into a Magnetic Resonance (MR) environment as it may cause unacceptable risks 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 risks 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 makes unusual or harsh sounds, disconnect the power cord and stop using it. Contact your home care provider.

CAUTIONS!

• This device is restricted to sale by or on the order of a physician.
• The patient is an intended operator.
• The device is intended for use by operators trained or experienced in similar equipment.
• Cleaning and disinfection can be performed by the patient.

IMPORTANT TIP!

• Read and understand the entire user manual before operating this system. If you have any questions concerning the use of this system, contact your home care provider or health care professional.

5. Contraindications

If you have any of the following conditions, tell your doctor before using this device:

• Insufficient respiratory drive to endure brief interruptions in non-invasive ventilation therapy
• Acute sinusitis or otitis media
• Epistaxis causing a risk of pulmonary aspiration
• Conditions predisposing to a risk of aspiration of gastric contents
• Impaired ability to clear secretions
• Hypotension or significant intravascular volume depletion
• Pneumothorax or pneumomediastinum
• Recent cranial trauma, cerebrospinal fluid leak or surgery
• Obviously uncooperative or extremely tense

The following side effects may occur during treatment:
- Dryness of the mouth, nose and throat
- Abdominal bloating
- Discomfort in the ears or sinuses
- Eye irritation
- Skin irritation due to the use of a mask
- Chest discomfort

CAUTION!

• Contact your health care professional if symptoms of sleep apnea recur. Contact your health care professional if you have any questions concerning your therapy.

IMPORTANT TIPS!

• An irregular sleep schedule, alcohol consumption, obesity, sleeping pills, or sedatives may aggravate your symptoms.
• Please use a mask which meets ISO 17510: 2015.

6. Specifications

Device Size

Dimensions (L x W x H): 265 mm × 145 mm × 114 mm

Weight: 1.7 kg

Water capacity: To maximum fill line 360 mL

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	5°C to 35°C (41˚F to 95˚F)	-25°C to 70°C (-13˚F to 158˚F)
Humidity:	15% to 93% Non-condensing	15% to 93% Non-condensing
Atmospheric Pressure:	760 ～ 1060 hPa	760 ～ 1060 hPa

This device automatically compensates pressure for altitude up to 2500 m.

Heated Humidifier

Humidifier Settings: off, Auto, 1 to 5 (95˚F to 154.4˚F / 35°C to 68°C)

Humidifier Output: No less than 15 mg H_2O/L

Environmental Conditions: Maximum airflow, 35°C, 15% relative humidity

Maximum Operating Pressure: 40 cmH_2O

Pressure Drop of Humidifier: < 0.4 cmH_2O at 60 LPM flow

Maximum Delivered Gas Temperature: ≤ 43°C

Mode of Operation

Continuous

Work Mode

CPAP, S, T, S/T

SD Card

The SD card can record patient data and fault information.

AC Power Consumption

100 V - 240 V ～, 50 Hz / 60 Hz, 2 A Max

Main device input

24 V, 3.33 A

Device offer to Heated Tubing Communications Port

24 V ⎓ 18 W

Type of Protection against Electric Shock

Class II Equipment

Degree of Protection against Electric Shock

Type BF Applied Part

Degree of Protection against Ingress of Water

IP22

Pressure Range

Model	Work Mode	Pressure Range
G3 B25VT	CPAP	4.0 ～ 20.0 cmH_2O
	S, T, S/T	IPAP: 4.0 ～ 25.0 cmH_2O; EPAP: 4.0 ～ 25.0 cmH_2O; in 0.5 cmH_2O increments.
G3 B30VT	CPAP	4.0 ～ 20.0 cmH_2O
	S, T, S/T	IPAP: 4.0 ～ 30.0 cmH_2O; EPAP: 4.0 ～ 25.0 cmH_2O; in 0.5 cmH_2O increments.

Under single fault conditions, ≤ 30 cmH_2O for CPAP mode, ≤ 40 cmH_2O for the other modes.

Pressure Display Accuracy

± (0.8 cmH_2O＋4%)

Static Pressure Stability

± 0.5 cmH_2O

Static pressure accuracy has a measurement uncertainty of 1.48%.

Dynamic Pressure Stability

Pressures (cmH_2O)	10 BPM	15 BPM	20 BPM
6.5	±0.5	±0.5	±0.5
10	±1	±1	±1
20	±1	±1	±1

Device with humidification and 22 mm Tubing or Heated Tubing.

Dynamic pressure accuracy has a measurement uncertainty of 2.85%.

Ramp

The ramp time ranges from 0 to 60 minutes.

Sound Pressure Level

< 26 dB (A), when the device is working at the pressure of 10 cmH_2O, Uncertainty: 2 dB (A).

Sound Power Level

< 34 dB (A), when the device is working at the pressure of 10 cmH_2O, Uncertainty: 2 dB (A).

Maximum Flow-LG3800-25VT

Test Pressures (cmH_2O)	4	10	15	20	25
Measured Pressure at the Patient Connection Port (cmH_2O)	3	9	14	19	24
Average Flow at the Patient Connection Port (L/min)	90	150	150	150	150
When the working pressure is set to the values listed in the table, the average flow rate at the patient end should be greater than 80% of the corresponding flow value in the table.					

Maximum Flow-LG3800-30VT

Test Pressures (cmH_2O)	4	11	17	24	30
Measured Pressure at the Patient Connection Port (cmH_2O)	3	10	16	23	29
Average Flow at the Patient Connection Port (L/min)	90	150	150	150	120
When the working pressure is set to the values listed in the table, the average flow rate at the patient end should be greater than 80% of the corresponding flow value in the table.					

Maximal Optical Output Power

Less than 1.5 mW maximum average.

Air Tubing

Air tubing	Length	Inner diameter
Tubing	6 ft.(1.83 m)	19 mm
Heated Tubing	6 ft.(1.83 m)	19 mm

The Form and the Dimensions of the Patient Connection Port

The 22 mm conical air outlet complies with ISO 5356-1.

Air filter

Type	Material	Average arrestance
Standard filter	Polyurethane	> 20% for 10 micron
PM2.5 filter	Polypropylene and Poly (ethylene terephthalate)	> 90% for 2.5 micron

Cellular Module

Transportation Requirements	Shock, severe vibration, and moisture should be avoided in transportation	
Frequency Bands	Bands[1] 2, 3, 4, 5, 8, 12, 13, 20, 28	
Communication Mode	LTE Cat M1/ NB1	
Effective Radiated Power LTE	LTE Cat M1/ NB1: ≤ +23 dBm (2100 mW), Class 3	
FCC ID	XPY2AGQN4NNN	
Security Measures	Authentication	Enforced on all data channels (outgoing and incoming)
	Encryption	Base 128 encoding

[1] The LTE bands supported by Cellular Module are defined in above, while the following Table 1 describes the Transmitting and Receiving frequencies.

Table 1 Transmitting and Receiving frequencies

Parameter		Min.	Max.	Unit	Remarks
Frequency range FDD Band 12 (700 MHz)	Uplink	699	716	MHz	Module transmit
	Downlink	729	746	MHz	Module receive
Frequency range FDD Band 28 (700 MHz)	Uplink	703	748	MHz	Module transmit
	Downlink	758	803	MHz	Module receive
Frequency range FDD Band 13 (700 MHz)	Uplink	777	787	MHz	Module transmit
	Downlink	746	756	MHz	Module receive
Frequency range FDD Band 20 (800 MHz)	Uplink	832	862	MHz	Module transmit
	Downlink	791	821	MHz	Module receive
Frequency range FDD Band 5 (850 MHz)	Uplink	824	849	MHz	Module transmit
	Downlink	869	894	MHz	Module receive
Frequency range FDD Band 8 (900 MHz)	Uplink	880	915	MHz	Module transmit
	Downlink	925	960	MHz	Module receive
Frequency range FDD Band 4 (1700 MHz)	Uplink	1710	1755	MHz	Module transmit
	Downlink	2110	2155	MHz	Module receive
Frequency range FDD Band 3 (1800 MHz)	Uplink	1710	1785	MHz	Module transmit
	Downlink	1805	1880	MHz	Module receive
Frequency range FDD Band 2 (1900 MHz)	Uplink	1850	1910	MHz	Module transmit
	Downlink	1930	1990	MHz	Module receive

⚠***WARNING!***

• All other wireless technology emitters must be kept at least 2 meters from the Cellular Module.

CAUTION!

• Considering the requirements of network security, the cpu on this equipment only supports the standard of our product software and does not support the operation of other foreign software.

7. Available Therapies

The device delivers the following therapies:

CPAP – Delivers Continuous Positive Airway Pressure; CPAP maintains a constant level of pressure throughout the breathing cycle.

S – A bi-level mode which responds to both your inhalation and exhalation by increasing pressure when you start to inhale and decreasing pressure when you start to exhale. There is no automatic delivery of breathing gas if you do not inhale. IPAP (Inspiratory Positive Airway Pressure) and EPAP (Expiratory Positive Airway Pressure) are preset by a home care provider.

T – A bi-level mode in which the device automatically starts inhalation and exhalation, and automatically controls the time of inhalation and that of exhalation according to the preset parameter.

S/T – A bi-level mode which responds to both your inhalation and exhalation by increasing pressure when you start to inhale and decreasing pressure when you start to exhale. If you do not start inhaling within a set time, the device will automatically start the process of inhalation. When the device starts the process of inhalation, it controls the time of inhalation and automatically decreases the pressure for exhalation within a set time.

8. Glossary

Apnea

A condition marked by the cessation of spontaneous breathing.

Auto Off

When this feature is enabled, the device automatically discontinues therapy whenever the mask is removed.

Auto On

With this feature, the device automatically initiates therapy when you breathe into the mask. This feature is always enabled.

SmartC

In CPAP mode, if SmartC is set to on, the device can adjust Treat P based on the patient's respiratory event during a certain time.

CPAP

Continuous Positive Airway Pressure.

EPAP

Expiratory Positive Airway Pressure.

IPAP

Inspiratory Positive Airway Pressure.

Target Vt

Target tidal volume

S mode

A bi-level mode which responds to both your inhalation and exhalation by increasing pressure when you start to inhale and decreasing pressure when you start to exhale. There is no automatic delivery of a breath you do not inhale. IPAP (Inspiratory Positive Airway Pressure) and EPAP (Expiratory Positive Airway Pressure) are pre-set by home care provider.

T mode

A bi-level mode which the device automatically starts inhalation and exhalation, automatically controls the time of inhalation and that of exhalation according to the preset parameter.

S/T mode

A bi-level mode which responds to both your inhalation and exhalation by increasing pressure when you start to inhale and decreasing pressure when you start to exhale. If you do not start inhaling within a set time, the device automatically starts inhalation. When the device starts inhalation, it controls the time of inhalation and automatically decreases the pressure for exhalation within a set time.

Vt

Tidal volume

MV

Minuite ventilation

I Sensitivity

Inspiratory Sensitivity

E Sensitivity

Expiratory Sensitivity

Ti

Inspiratory Time

Leak

Leakage in the gas of device

iCode

A feature designed to give access to compliance and therapy management information. "iCode" consists of six separate codes displayed in the Patient Menu, each code being a sequence of numbers. "iCode QR" and "iCode QR+" display two-dimensional codes.

LPM

Liters Per Minute.

OSA

Obstructive Sleep Apnea.

Patient Menu

The display mode in which you can change patient-adjustable device settings, such as the starting pressure of the Ramp feature.

Ramp

A feature that increases patient comfort at the beginning of treatment. It reduces the pressure and then gradually increases it to the prescribed setting so that the patient can fall asleep more comfortably.

Rise Time

The time it takes for the device to change from EPAP to IPAP. You can adjust this time for your comfort.

Res Rate

Respiratory Rate. Number of breaths per minute.

Reslex

A therapy feature that is enabled by your home care provider to provide pressure relief during exhalation.

Standby State

The state of the device when power is applied but the airflow is turned off.

min

Means the time unit "minute".

h

Means the time unit "hour".

yy mm dd / mm dd yy / dd mm yy

Denotes date.

9. Model

Model No.	Item No.	Product Contents		Work Mode	Maximum Work Pressure (cmH_2O)
		Main Device	Optional Accessory		
G3 B25VT	LG3800-25VT	Main device (3.5-inch TFT)	Power Adapter, Power Cord, Tubing (optional), Cellular Module (optional), Heated Tubing (optional), PM2.5 Filter (optional)	CPAP, S, T, S/T	25
G3 B30VT	LG3800-30VT	Main device (3.5-inch TFT)		CPAP, S, T, S/T	30

10. Package Contents

After unpacking the system, make sure you have everything shown here (Different models of the device may contain different components):

No.	Articles	Qty.	Notes
1	Device	1	
2	Air Filter	2	
3	Power Adapter	1	
4	Power Cord	1	
5	PM2.5 Filter	1	Optional
6	Cellular Module	1	Optional
7	Tubing	1	Optional
8	Heated Tubing	1	Optional
9	SD Card	1	Optional
10	Carrying Case	1	Optional
11	Accompanying Documents	1	
12	Power Cord Locker	1	

All parts and accessories are made of no natural rubber latex.

The expected service life of the device is five years if the device is used, maintained, cleaned and disinfected in strict accordance with the User Manual. The shelf life of the device is ten years.

The expected service life of the Tubing and the Heated Tubing is six months. The shelf life of the Tubing and the Heated Tubing is 3 years.

The expected service life of the Water Chamber is 6 months.

⚠***WARNINGS!***

• This device should only be used with the mask and accessories manufactured or recommended by 3B Medical or with those recommended by your prescribing physician. The use of inappropriate masks and accessories may affect the performance of the device and impair the effectiveness of treatment.

• The use of accessories other than those specified, except for cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or reduced immunity of the equipment or system.

• Do not stack the long tubing at the head of the bed, as it may wrap around the head or neck of the patient during sleep and become an entanglement or strangle hazard.

• Do not attach any equipment to the device unless recommended by 3B Medical or your health care provider.

• All parts and accessories shall meet ISO80601-2-70 and the specific standards. Masks shall meet ISO 17510:2015. The breathing tube shall meet ISO 5367:2014. The filters between the device and the patient shall conform to ISO 23328-1:2003 and ISO 23328-2:2002.

• Exceeding the Expected Service life, our company cannot guarantee the normal function of the device, nor the safety and effectiveness of the device.

IMPORTANT TIPS!

• If any of the above parts are missing, contact your home care provider.

• Contact your home care provider for additional information on the available accessories of this device. When using optional accessories, be sure to follow the instructions that come with the accessories.

11. System Features

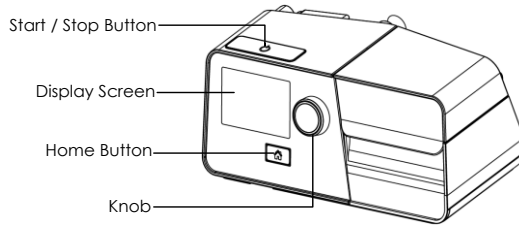

Fig. 11-1

Name	Function
Start / Stop Button	Start / Stop delivering air.
Display Screen	Display operation menus, information, monitoring data, etc.
Home Button	Return to the previous menu or main interface.
Knob	Adjust device settings.

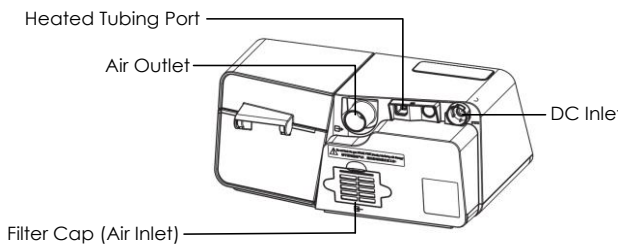

Fig. 11-2

Name	Function
Air Outlet	Deliver pressurized air; connects to the tubing.
Heated Tubing Port	Connected to the plug of the heated tubing.
DC Inlet	An inlet for the DC power supply.
Filter Cap (Air Inlet)	Place the cap on the air filter, which is used to filter dust and pollen in the air entering the device.

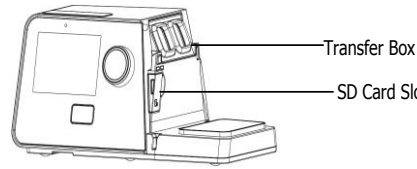

Fig. 11-3

Name	Function
Transfer Box	For the connection of the water chamber to the device.
SD Card Slot	Insert the SD card into this slot.

CAUTION!

• The pictures in this manual are only for reference, if they are different from the material objects, the latter shall prevail.

12. First Time Setup

12.1 Placing the Device

Place the device on a firm, flat surface.

⚠***WARNINGS!***

• If the device has been dropped or mishandled, if the enclosure is broken, or if water enters the enclosure, disconnect the power cord and discontinue use. Contact your home care provider immediately.

• If the room temperature is above 95°F (35°C), the airflow generated by the device may exceed 109.4°F (43°C). The room temperature must be kept below 95°F (35°C) while the patient is using the device.

CAUTIONS!

• Always ensure that the device is placed in an area where the screen and indicators are clearly visible.

• If the device has been exposed to very hot or very cold temperatures, allow it to acclimate to room temperature (approximately 2 hours) before beginning setup.

• Make sure the device is away from any heating or cooling equipment (e.g., forced air vents, radiators, air conditioners).

• The device is not suitable for use in high humidity environments. Make sure that no water enters the device.

• Make sure that bedding, curtains, or other items are not blocking the filter or vents of the device.

• Keep pets, pests or children away from the device and avoid small objects being inhaled or swallowed.

• To avoid explosion, this device must not be used in the presence of flammable gases (e.g. anesthetics).
• Tobacco smoke may cause tar to build up in the device, which could lead to the malfunctioning of the device.
• Air must flow freely around the device to allow it to function properly.

12.2 Installing the Air Filter and Filter Cap / PM2.5 Filter

(1) Attach the air filter to the filter cap, as shown in Fig. 12-1.

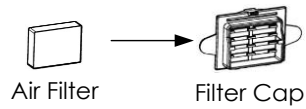

Fig. 12-1

(2) Install the filter cap containing the air filter to the device, as shown in Fig. 12-2.

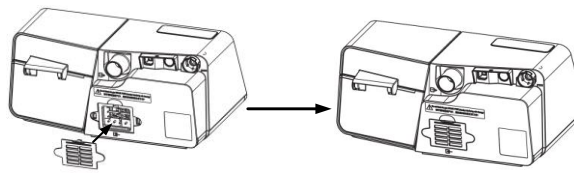

Fig. 12-2

(3) Change the air filter and filter cap to the PM2.5 filter, as shown in Fig. 12-3.

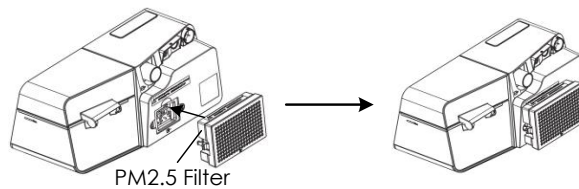

Fig. 12-3

⚠***WARNINGS!***

• Do not block the gas INTAKE PORT, thereby interfering with the therapy.
• Nebulization or humidification can increase the resistance of breathing system filters and the operator must monitor the breathing system filter frequently for increased resistance and blockage to ensure the delivery of the therapeutic pressure.

CAUTIONS!

• The air filter or the PM2.5 filter must be in place when the device is operating.
• The device must be unplugged when installing the air filter and filter cap or PM2.5 filter.

12.3 Connecting Power Supply

(1) Insert the plug of the power adapter into the DC Inlet on the back of the device.
(2) Connect the power cord to the power adapter.
(3) Plug the other end of the power cord into the power outlet.

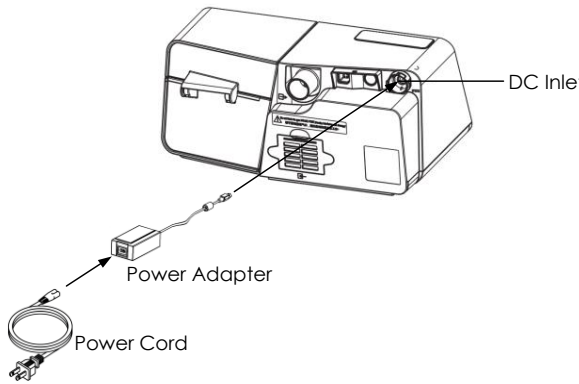

Fig. 12-4

Note: *The length of the power cord and power adapter is 1.5 m and 1.8 m respectively without the function of preventing electromagnetic interference.*

⚠***WARNINGS!***

• The device is powered on for use when the power cord and power adapter are connected. Use **the Knob** to turn the blower On / Off.
• Using the device at an AC voltage beyond the specified range (see Section 5 "AC Power Consumption") may damage the device or cause device failure.
• Connect to the proper power source for proper operation of the device.
• Check the power cord frequently for signs of damage. Replace a damaged cord immediately.

IMPORTANT TIPS!

• After interruption and restoration of the power supply, the device will restore its pre-interruption working status automatically.
• To remove AC power, disconnect the power cord from the power outlet.

12.4 Connecting to Power Cord Locker

(1) Connect the device to power supply in accordance with *12.3 Connecting Power Supply*.

(2) Clip the narrow end of the power cord locker to the cord of the power adapter, as shown in Fig. 12-5.

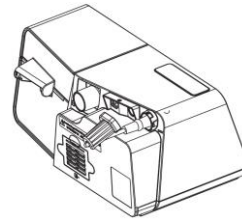

Fig. 12-5

(3) Insert the power cord locker into the buckle of DC inlet, as shown in Fig. 12-6.

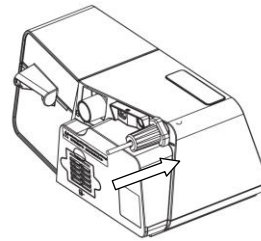

Fig. 12-6

(4) Press the power cord locker downward to fix power cord into the port, as shown in Fig. 12-7.

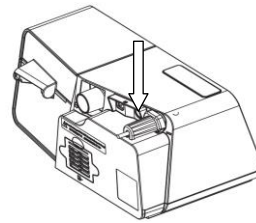

Fig. 12-7

The function of the locker is to prevent the power cord from falling out of the power port. After installation, you must make sure that the power adapter cable is stuck in the slot at the narrow end of the power cord locker.

12.5 Assembling the Tubing / Heated Tubing and Mask

(1) Connect one end of the tubing to the air outlet of the device, as shown in Fig. 12-8.

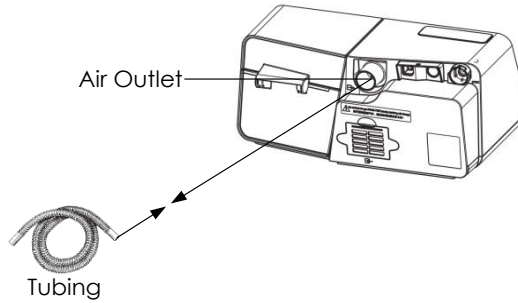

Fig. 12-8

(2) Connect the heated tubing joint to the air outlet of the device, and then insert the power plug into the heated tubing port on the back of the device, as shown in Fig. 12-9.

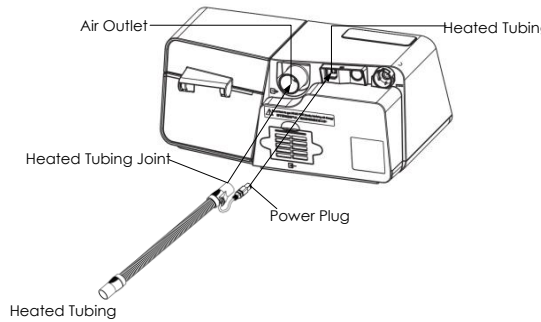

Fig. 12-9

CAUTION!

• As the ambient temperature decreases, the humidifier can be reduced to improve or avoid condensation in the pipeline. If the ambient temperature is too low, in order to avoid condensation, it is recommended to use the heated tubing.

If the heated tubing is connected correctly, the line next to the icon will become a number on the main screen of the device, as shown in Fig. 12-10.

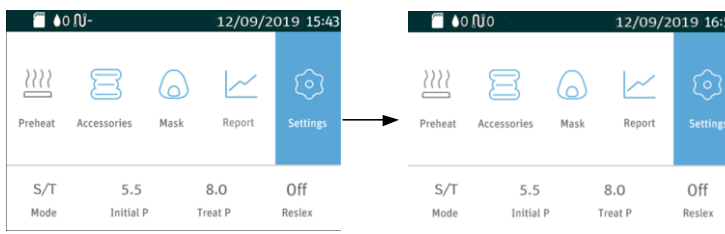

Fig. 12-10

Turn **the Knob** to turn the heated tubing on or off and to adjust the heat level according to the instructions in the Patient Menu of the device.

There are five heat levels available, and the number of heat levels will appear on the main screen of the device. The number 3 next to the icon indicates that the heat is adjusted to Level 3, as shown in Fig. 12-11.

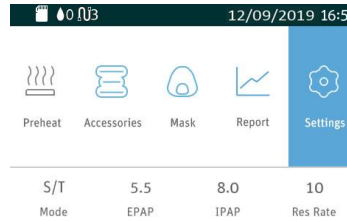

Fig. 12-11

(3) Connect the other end of the tubing to the mask according to the user manual of the mask.

⚠***WARNINGS!***

• If you are using a mask with a built-in exhalation port, connect the mask's connector to the tubing.

• If you are using a mask with a separate exhalation port, connect the tubing to the exhalation port. Position the exhalation port so that the released air blows away from your face. Connect the mask's connector to the exhalation port.

• If you are using a full-face mask (a mask covering both your mouth and nose), the mask must be equipped with a safety (entrainment) valve.

• To minimize the risk of CO_2 rebreathing, the patient should observe the following instructions:

- Use the accompanying tubing and mask provided by 3B Medical.

- Do not wear the mask for more than a few minutes while the device is not operating.

- Use only masks with vent holes. Do not block or try to seal the vent holes in the exhalation port.

12.6 Using Oxygen with the Device

Oxygen may be added at the mask connection. Please observe the instructions listed below when using oxygen with the device.

⚠***WARNINGS!***

• Connect the oxygen tube to the oxygen inlet of the mask.

• The oxygen supply must comply with the local regulations for medical oxygen.

• Turn on the device before turning on the oxygen. Turn off the oxygen supply

before turning off the device. Explanation of Warning: When the device is turned off, but the oxygen flow remains, oxygen can accumulate inside the device's enclosure and pose a fire hazard. Turning off the oxygen supply before turning off the device will prevent oxygen accumulation in the device and reduce the risk of fire. This warning applies to CPAP devices.

• Oxygen supports combustion. Keep the device and the oxygen container away from heat, open flames, any oily substances, or other sources of ignition. DO NOT smoke near the Luna® G3 BPAP System or the oxygen container.

• Sources of oxygen should be more than 1 m away from the device.

• When using oxygen with this system, a Pressure Valve must be placed in-line with the patient circuit between the device and the oxygen source. The pressure valve helps prevent the backflow of oxygen from the patient circuit into the device when the unit is off. Failure to use the pressure valve could result in a fire hazard.

• Do not connect the device to an unregulated or high-pressure oxygen source. The pressure of oxygen source does not exceed the working pressure of the device.

12.7 Inserting the SD Card (Only for the device that equipped with SD card)

Insert the SD card into the SD Card Slot, as shown in Fig. 12-12.

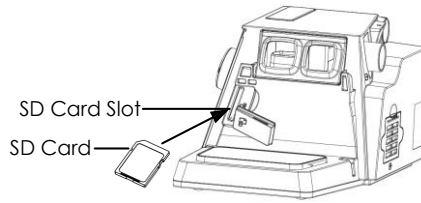

Fig. 12-12

If the SD card is inserted correctly, a symbol indicating correct insertion will appear on the main screen of the device.

If the SD card is inserted incorrectly, a symbol indicating incorrect insertion will appear on the main screen of the device.

CAUTIONS!

• If no SD card is inserted, neither of the symbols will appear on the main screen of the device.

• To avoid data loss or any damage to the SD card, the SD card can only be removed after the device stops delivering air.

12.8 Starting Treatment

Connect the device to a power outlet, press **the Start / Stop Button**  and the device will start delivering air.

⚠***WARNINGS!***

• Be sure to follow your physician's instructions on adjusting the settings! To order any accessories not included with this device, contact your equipment supplier.

• DO NOT connect any ancillary equipment to this device unless recommended by 3B Medical or your physician. If you suffer from chest discomfort, shortness of breath, stomach bloating, or severe headache when using the device, contract your physician or qualified medical personnel immediately.

13. Routine Use

13.1 Connecting the Tubing

Connect the power cord, power adapter, and tubing properly in accordance with the instructions in the First Time Setup (Chapter 12). Connect the mask and headgear according to the user manual of the mask.

CAUTION!

• Before each use, examine the tubing for any damage or foreign object. If necessary, clean the tubing to remove the foreign object. Replace any damaged tubing. Make sure that the mask does not leak.

13.2 Adjusting the Tubing

Lie down on your bed, and adjust the tubing so it is free to move if you turn over during sleep. Adjust the mask and headgear until you have a comfortable fit and until there is no airflow leakage around the mask.

13.3 Turning on the Airflow

Press **the Start / Stop Button**  to turn on the airflow. The screen will display treatment pressure and other information.

13.4 Heating the Water

Pay attention to the number next to the icon  when using the humidifier. The number indicate the On / Off state of the humidifier. It is off when the number next to the icon is 0.

CAUTION!

• Observe the water level in the water chamber before using the humidifier. Make sure there is sufficient water in the water chamber, and avoid heating the device with an empty water chamber.

13.5 Accessing the iCode

After the device is powered on, move the cursor to the icon by turning **the Knob**, as shown in the Fig. 13-1. Access the iCode information by pressing **the Knob**, the screen displays the iCode Inerface, as shown in the Fig. 13-2.

Fig. 13-1

Fig. 13-2

13.6 Turning the Device Off

Take off the mask and headgear, press **the Start / Stop Button**, and the device will stop delivering air. Disconnect the power cord from the power outlet to turn off the device.

CAUTION!

• Do not position the device where it is difficult to disconnect the device.

14. Heated Humidifier

The humidifier can be obtained from your home care provider. The humidifier can reduce nasal dryness and irritation by adding moisture (and heat if applicable) to the airflow.

14.1 Filling the Water Chamber

14.1.1 Removing the Water Chamber

Press down the water chamber, and then remove it, as shown in Fig. 14-1.

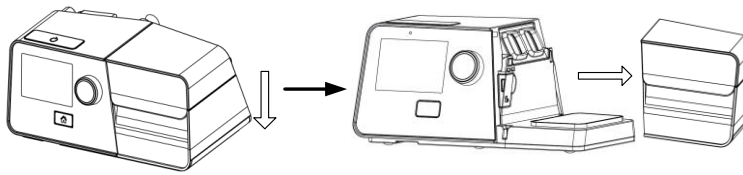

Fig. 14-1

⚠***WARNING!***

• Turn the device off and the heating plate and water to cool for approximately 15 minutes.

14.1.2 Filling the Water Chamber

(1) Open the cap, as shown in Fig. 14-2, and fill the water chamber with approximately 360 mL of water, as shown in Fig. 14-3. Make sure that the water does not exceed the maximum water level line.

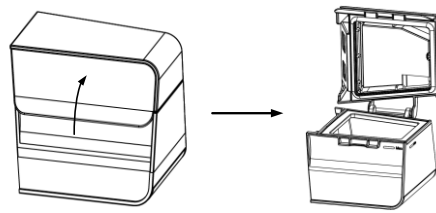

Fig. 14-2

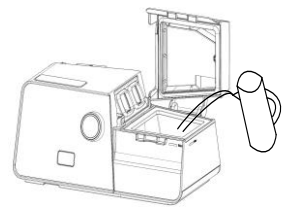

Fig. 14-3

(2) Open the cap, and fill the water chamber with approximately 360 ml of water, as shown in Fig. 14-4. Make sure that the water does not exceed the maximum water level line.

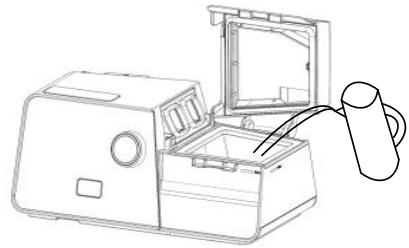

Fig. 14-4

⚠***WARNING!***

• Change water before every use and do not surpass the maximum water level line.

CAUTIONS!

• Empty the water chamber when the heated humidifier is not in use.

• Distilled water is recommended.

IMPORTANT TIP!

• It is not necessary to remove the water chamber from the device. The users can open the cap of the water chamber with it being attatched to the divice to fill it with water.

14.1.3 Putting the Water Chamber back

Close the cap when the water chamber filled with water, as shown in Fig. 14-5, and put it back to the device, as shown in Fig. 14-6.

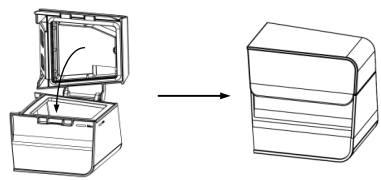

Fig. 14-5

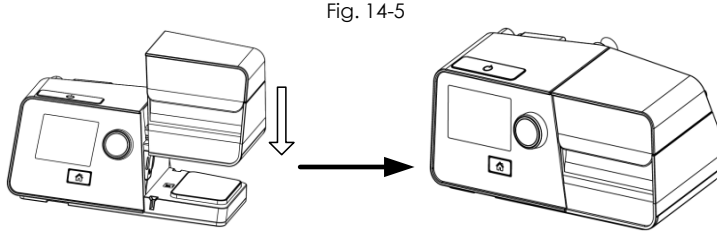

Fig. 14-6

⚠***WARNING!***

• For safety, the device must be placed on a flat surface below the height of the patient's head when he is lying on a bed, so that the condensation flows back to

the water chamber rather than remaining in the tubing which can cause droplet spraying.

CAUTIONS!

• Avoid moving or tilting the device when the water chamber has water in it.

• Take precautions to protect furniture from water damage.

14.2 Emptying the Water Chamber

(1) **Removing the water chamber** according to instructions in 14.1.1.

(2) **Emptying the water chamber:** Open the cap, as shown below, and pour any remaining water out of the water chamber.

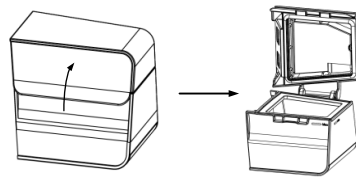

Fig. 14-7

CAUTION!

• Empty and air-dry the water chamber when the device is not in use.

(3) **Putting the Water Chamber back** according to instructions in 13.1.3.

14.3 Setting the Humidity Level

After the device is powered on, turn **the Knob** to turn the heated humidifier on or off and to adjust the humidity level according to instructions in the Patient Menu of the device.

There are five humidity levels available, and the number of humidity level will appear on the main screen of the device. The number 2 next to the icon indicates that the humidity is adjusted to Level 2, as shown in Fig. 14-8. The water temperature in the water chamber is maintained at a constant set level.

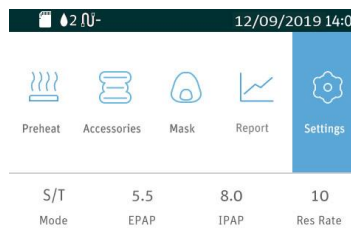

Fig. 14-8

⚠***WARNING!***

• Do not touch the heating plate of the device when it is in operation, otherwise you may get burned. Stop heating when the heated humidifier is not in use.

CAUTIONS!

• Generally speaking, the humidity level inside the mask is low when the water temperature is low.

• The greater the difference between the temperature inside the air tubing and the room temperature, the more likely condensation will occur in the tubing.

• If there is only a small amout of condensed water droplets in the tubing in the morning after treatment, the humidity level is appropriate; if there is a large amount of condensed water droplets inside the tubing and / or the mask, the humidity level is too high and should be set lower; Nasal dryness means that the humidity level is too low and should be set higher.

15. Using the Cellular Module

The Luna® G3 BPAP System with a Cellular Module can wirelessly communicate with the iCodeConnect. The iCodeconnect is intended to augment the standard follow-up care of patients diagnosed with obstructive sleep apnea by displaying usage and therapeutic information that has been transmitted from the patient's Luna® G3 BPAP System therapy device to the clinician or healthcare professional.

(1) Insert the Cellular Module into the device, and turn on the device. The device screen displays the Main Screen shown in Fig. 15-1.

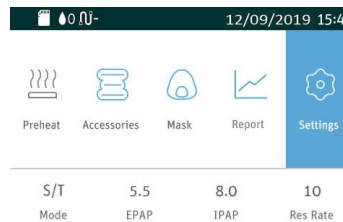

Fig. 15-1

(2) The Cellular Module starts searching for signals in a few seconds. Once a signal is found, the module will automatically connect to it, and a signal icon will appear in the status bar at the top of the device screen.

There are four different signal icons, as listed in Table 2:

Table 2 Description of Signal Icons

Icon	Description
	Strong signal
	Moderate signal
	Weak signal
	No signal found

Notes:
(1) When the signal is weak, data transmission may become slow and even stop.
(2) The Cellular Module will keep searching for signals until one is found.

If the signal is strong, the signal icon will appear on the Main Screen, as shown in Fig. 15-2 (the signal icons of different strength appear in a similar way).

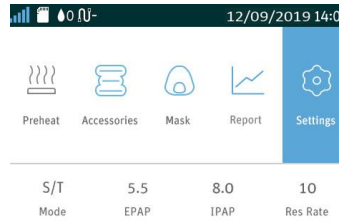

Fig. 15-2

No signal icon will appear on the screen, if the Cellular Module is connected to the device improperly or if the Module is not working properly.

⚠***WARNING!***

• To ensure successful data transmission through the Cellular Module, computers, televisions, radios or similar devices should not be placed near the Cellular Module.

16. Navigating the Patient Menu

16.1 Steps to Navigate the Patient Menu

16.1.1 Accessing the Main Interface

Connect the power cord and power adapter properly, and the screen displays the Main Interface shown in Fig. 16-1. Press **the Start / Stop Button**  , and the device will start to deliver air. The screen displays the Main Interface as shown in Fig. 16-2.

Fig. 16-1

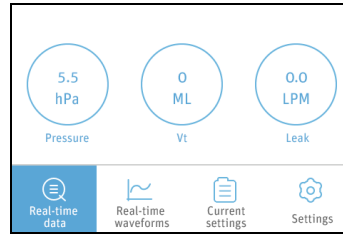

Fig. 16-2

Note: The above interface is only applicable to the devices do not have the mode of SmartC activated. If the SmartC is enabled, the symbol S will appear in the status bar at the top of the screen, as shown in Fig. 16-3.

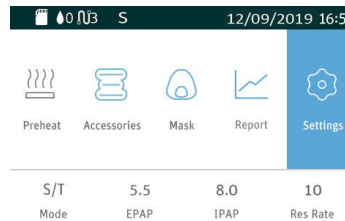

Fig. 16-3

The first icon on the upper part of the screen is the Preheat Function Icon, the second icon indicates the Accessories, and the third icon is the Mask Setup Icon, the fourth icon is the Report Interface Icon, the fifth icon is the Initial Setup Icon. As you turn **the Knob**, the cursor will switch among the five icons, and the interface displayed on the screen changes accordingly.

Note: If the humidifier is turned off, the Preheat Icon will turn gray, as shown in Fig. 16-3.

16.1.2 Bringing up the Initial Setup Interface

After the screen displays the Main Interface shown in Fig. 16-1, turn **the Knob**. When the cursor is on the icon, press **the Knob**, and the screen displays the Initial Setup Interface of the Patient Menu, as shown in Fig. 16-4.

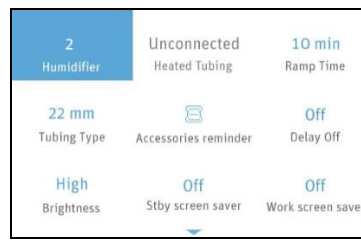

Fig. 16-4

Note: The **Heated Tubing** option can only be adjusted when the device is connected to a Heated Tubing, as shown in Fig. 16-5.

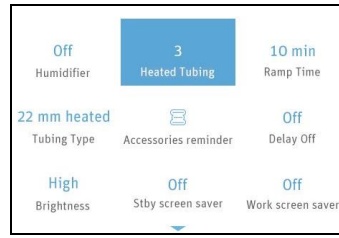

Fig. 16-5

16.1.3 Selecting Options

As you turn **the Knob** clockwise, the cursor moves downwards from one option to another. When the cursor is on a certain option, press **the Knob**, and the color of the option will change, meaning that the option is now ajustable, as shown by the **Humidifier** option in Fig. 16-6.

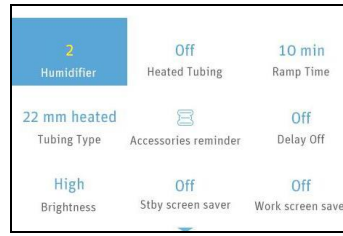

Fig. 16-6

16.1.4 Adjusting Options

Adjust the option by turning **the Knob**. As shown in Fig. 16-6, the **Humidifier** option is selected. As you turn **the Knob** clockwise, the numbe increases, indicating a higher humidity level. As you turn **the Knob** counterclockwise, the numbe decreases, indicating a lower humidity level, as shown in Fig. 16-7.

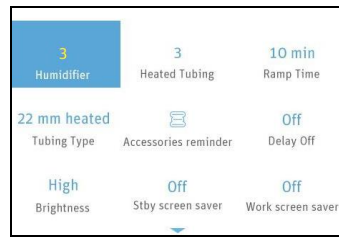

Fig. 16-7

16.1.5 Confirming Adjustments

Press **the Knob** to confirm your adjustment for a particular option. The option is

then displayed in white, as shown in Fig. 16-8.

Fig. 16-8

16.1.6 Turning Pages

When the cursor is on **Work screen saver**, the last option shown in Fig. 16-8, the remaining options will appear on a new page if you continue to turn **the Knob** clockwise, as shown in Fig. 16-9.

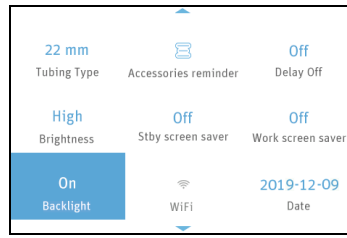

Fig. 16-9

Note: are page turning symbols.

16.1.7 Exiting the Patient Menu

The users can press **the Home** to return to the Main Interface shown in Fig. 16-1.

16.2 Options in the Patient Menu and Corresponding Descriptions

Option	Range	Description
Humidifier	Off, Auto, 1 ～ 5	There are six humidity levels available. As the number increases, the humidity rises accordingly. "Off" means the humidifier is turned off.
Preheat	On / Off	Set humidifier to preheat by adjusting this option. This feature is automatically turned off after 30 minutes.
Reslex	Off, 1 ～ 3	This feature enables the device to automatically reduce the treatment pressure when the patient exhales, so as to make him more comfortable. The higher the number, the more pressure the device reduces. "Off" means this feature is disabled.
Auto on	On / Off	If this function is turned on, the device will automatically start delivering air under preset pressure after the patient puts on a breathing mask and takes several deep breaths. Click to select "On" or "Off".
Auto off	On / Off	If this function is turned on, the device will automatically stop delivering air and shut down after the patient takes off the breathing mask. Click to select "On" or "Off".
Tubing type	15 mm / 22 mm	You can choose one of two types of tubing, 15mm and 22mm tubing.
Stby screen saver	On /Off	You can choose to turn it on or off. After turning it on, if there is no operation on the standby interface for a period of time, it will enter the screen saver interface, displaying the date, time, humidifier gear and heating Tubing connection.
Work screen saver	On /Off	You can choose to turn it on or off. After turning it on, if there is no operation on the working interface for a period of time, it will enter the screen saver interface, displaying the date, time, humidifier gear and heating Tubing connection.
Wifi	——	After selecting to enter, you can view the list of WiFi names, or manually add WiFi, and then connect.
Heated Tubing	Off, 1 ～ 5	There are five heat levels available. As the number increases, the heat rises accordingly. "Off" means the heat is turned off. Note: **Heated Tubing** is displayed in the patient menu only when a heated tubing is connected.

Ramp Time	Auto, 0 ～ Max Ramp	In order to increase comfort and help the patient fall asleep easily, the pressure can be increased gradually, when the Ramp feature is enabled. The ramp time during which the initial pressure rises to the preset treatment pressure can be adjusted. As you turn **the Knob** to the nearest point, the number increases or decreases by five seconds. The screen displays a real-time countdown of the remaining ramp time in seconds.
Delay	On / Off	When the humidifier is on, this feature allows the airflow to continue for about 15 minutes at a low pressure (about 2 hPa) after you press **the Start / Stop** to discontinue the treatment. In this process, the vapor left in the water chamber will be blown away to avoid any damage to the device. When this feature is set to "Off," which means it is disabled, the device will stop delivering air instantly after you press **the Start / Stop**.
Date	2000-01-01 — 2099-12-31	Set date by adjusting this option.
Date Format	yy mm dd / mm dd yy / dd mm yy	Turn **the Knob** to choose among three date formats.

Option	Range	Description
Time	00:00 — 23:59	Set time by adjusting this option.
Time Format	12-hour / 24-hour	Turn **the Knob** to choose between two time formats.
Brightness	High / Low	Set the brightness of the screen by adjusting this option.
Backlight	Auto / On	The backlight of the LCD screen can be set to "Auto" or "On." Turn **the Knob** to choose between the two modes. If it is set to "Auto," the backlight will be turned off automatically after 30 seconds of inactivity. If it is set to "On," the backlight will be always on.
Mask Type	Full Face; Nasal; Pillow; Other	There are three mask types available, Full Face (full-face mask), Nasal (nasal mask), and Pillow (nasal pillow mask). When selecting masks other than the above three types of 3B Medical masks, the patient can set the mask type as Other.
Mask Fitting Test	Start the Mask Fitting Test	Test whether the mask is worn correctly,the screen will display the "great" icon if it is qualified, otherwise the screen will display the "need to adjust" icon.
iCode	iCode, iCode QR, iCode QR+	iCode provides access to the patient's compliance data during a recent time period. The iCode mode displays data in number sequence, and the iCode QR / iCode QR+ mode displays data in two-dimensional codes.
Used Time	0 ～ 50000 h	Used Time displays how long has the device been used by the patient. The used time can be erased.
Accessories	——	Reset the use time of the filter, tubing and mask.
Accessories reminder	30 days/60 days/180 days/1 year/off	This function is used to set filter reminder, tube reminder and mask reminder. After opening, can set the use time of filter, tube and mask.
Language	English	The default setting is "**English**".
About	——	Displays related information of the device (Model, SN, Version, ID). This is read-only and cannot be edited.

17. Alert

Alert Message	Alert Priority	Alert Type	Description
Power Failure!!!	High Priority	Technology Alert	An audible Alert will sound in 6s if the device is accidentally disconnected from power supply when it is delivering air. Alerting duration time is no less than 30 s. **Notes:** (1) The Alert will not sound if power failure occurs when the device is in standby state. (2) No Alert message will appearon the screen during a power failure.
Device fault!!!	High Priority	Technology Alert	An audible Alert will sound if no airflow comes out of the machine; the screen will display "**Device fault!!!**".
Tube disconnected!!!	High Priority	Function Alert	When the airflow is on, an audible Alert will sound if the tube accidentally detached, the screen will display "**Tube disconnected!!!**".
High Pressure!!!	High Priority	Function Alert	When the airflow is on, an audible Alert will sound if the airway pressure exceeds the Alert limit; the screen will display "**High Pressure!!!**". **Note:** The thresholds for different models: Off, 5 ～ 26 hPa applies to G3 B25VT, in 0.5 hPa increments, the default setting is "**25 hPa**". Off, 5 ～ 31 hPa applies to G3 B30VT in 0.5 hPa increments, the default setting is "**30 hPa**".
Low Pressure!!	Middle Priority	Function Alert	When the airflow is on, an audible Alert will sound if the airway pressure is below the Alert limit; the screen will display "**Low Pressure!!**". Note: The limens for different models: Off,3 ～ 24 hPa applies to G3 B25VT, in 0.5 hPa increments, the default setting is "**4 hPa**". Off, 3 ～ 29 hPa applies to G3 B30VT in 0.5 hPa increments, the default setting is "**4 hPa**".
Low RR!!!	High Priority	Function Alert	When the airflow is on, an audible Alert will sound if the respiratory rate is below the Alert limit; the screen will display "**Low RR!!!**".

			Setting range: Off, 4 ～ 40 BPM, in 1 BPM increments, the default setting is "**6 BPM**". **Note:** This function is available under the work mode of S/T or T.
Leak!!	Middle Priority	Function Alert	When the airflow is on, an audible Alert will sound if the air leak rate exceeds 150 L/min; the screen will display "**Leak!!**". The Alerting duration time is no less than 30 s.
Mask Blocked!!	Middle Priority	Function Alert	When the airflow is on, an audible Alert will sound if the vents of the mask are blocked; the screen will display "**Mask Blocked!!**".
Low MV!!	Middle Priority	Function Alert	When the airflow is on, an audible Alert will sound if the minute volume is below the Alert limit; the screen will display "**Low MV!!**". Setting range: Off, 1 ～ 30 L/min, in 1 L/min increments, the default setting is "**1 L/min**".
Low Input Voltage!!	Middle Priority	Technology Alert	If the voltage supplied by power adaptor is lower than 22 V, an audible Alert will sound and the screen will display "**Low Input Voltage!!**".
High RR!!	Middle Priority	Function Alert	When the airflow is on, an audible Alert will sound if the respiratory rate exceeds the Alert limit; the screen will display "**High RR!!**". Setting range: Off, the setting value of Low RR ～ 80 BPM, in 1 BPM increments, the default setting is "**40 BPM**". **Note:** This function is avaliable under the work mode of S/T or T.
Humidifier Failure!!	Middle Priority	Function Alert	When humidifier is applied, an audible Alert will sound when the humidifier fails to work in 10 minutes; the screen will display "**Humidifier Failure!!**".
Please change filter!	Low Priority	Technology Alert	When the Filter Alert feature is enabled, an audible Alert will sound if the preset replacement time is reached but the air filter is not replaced; the screen will display "**Please change filter!**". The default setting is "**Off**".

Please replace tubing!	Low Priority	Technology Alert	When the tubing Alert feature is enabled, an audible Alert will sound if the preset replacement time is reached but the tubing is not replaced; the screen will display "**Please replace tubing!**".
Please replace mask!	Low Priority	Technology Alert	When the Mask Alert feature is enabled, an audible Alert will sound if the preset replacement time is reached but the mask is not replaced; the screen will display "**Please replace mask!**".
SD Card Full!	Low Priority	Technology Alert	The screen will display "**SD Card Full!**" if the SD card has reached its maximum capacity.
Reinsert SD card!	Low Priority	Technology Alert	The screen will display "**Reinsert SD card!**" if the SD card fails to work.

18. Cleaning

⚠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.

• Follow the manufacturer's instructions on cleaning the mask and tubing and on determining the frequency of cleaning.

• Before cleaning, check that the device is disconnected from the power supply,the power cord is unplugged, and whether the water chamber of the device has cooled down. Make sure that the heating plate has cooled down to room temperature, to aviod burns.

• Do not open or modify the device. There are no user serviceable parts inside. Repairs and service should only be performed by an authorized service agent.

• Avoid the use of any CPAP cleaner or disinfection device that relies on ozone (i.e. activated oxygen). Device warranty may terminate if the damage is caused by the use of an ozone cleaner.

• In order to prevent contamination of the device, use only manufacturer-approved filters on this device conforming to ISO 23328-1:2003 and ISO 23328-2:2002 standards.

CAUTIONS!

• Overheating of the materials could lead to early fatigue of the materials.

• Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing moisturizing agents or antimicrobials should not be used either. These solutions may harden cleaned

materials or reduce their lifespan.

• Do not clean or dry the device and its accessories when the temperature is above 80°C (176°F). High temperatures could reduce product life.

• Do not immerse the device in any fluids.

18.1 Cleaning the Water Chamber

(1) **Opening the Water Chamber:** Open the cap of the water chamber, as shown in Fig. 18-1.

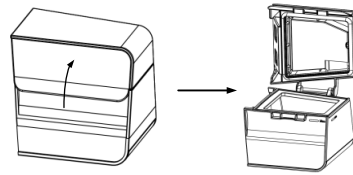

Fig. 18-1

(2) **Cleaning the Water Chamber:** You may clean the water chamber with a soft cloth which will not scratch it (dip the soft cloth in liquid soap if necessary). Rinse the water chamber thoroughly, then wipe it dry with a soft cloth.

(3) **Putting the Water Chamber back** according to instructions in 13.1.3.

⚠WARNINGS!

• Emptying and cleaning the water chamber daily will help prevent mold and bacteria growth.

• Allow the water in the chamber to cool down to room temperature before removing it from the device.

CAUTIONS!

• Clean the water chamber only after the water in it cools. Make sure that no water enters the device.

• After cleaning, rinse the water chamber throughly in clean water to make sure that no soap residue is left; then wipe it dry with a lint-free cloth, so as to prevent calcareous accumulations.

• Check the water chamber for any leak or damage. Replace the water chamber if there is any damage.

• It is recommended to clean the water chamber and change the water daily.

18.2 Cleaning the Transfer Box

(1) **Removing the Transfer Box:** First remove the water chamber from the device, then remove the transfer box, as shown in Fig. 18-2.

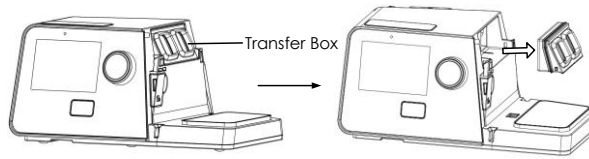

Fig. 18-2

(2) **Cleaning the Transfer Box:** Rinse the transfer box throughly in clean water. You may also clean the transfer box with a soft cloth which will not scratch it (dip the soft cloth in liquid soap if necessary). Rinse the transfer box thoroughly, then wipe it dry with a soft cloth.

(3) **Returning the Transfer Box:** As shown in Fig. 18-3.

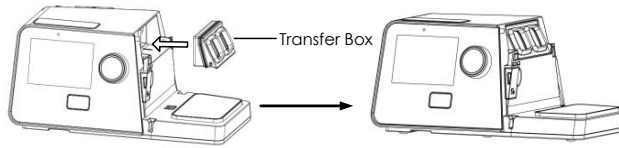

Fig. 18-3

CAUTION!

• It is recommended to clean the transfer box once a week.

18.3 Cleaning the Mask and Headgear

For details, refer to the cleaning instructions in the user manual of the mask.

18.4 Cleaning the Enclosure

Wipe the surface of the device with a soft, slightly damp cloth.

CAUTIONS!

• The device should only be used after the enclosure is dry, so that no moisture enters the device.

• It is recommended to clean the enclosure once a week.

18.5 Cleaning the Tubing

(1) Remove the tubing from the device and mask before cleaning.

(2) Hold the cuff of the tubing and gently pull it away from the device as shown in Fig. 18-4. Or disconnect the power of the heated tubing, then hold the cuff of the heated tubing and pull it away from the device, as shown in Fig. 18-5.

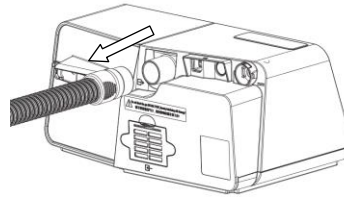

Fig. 18-4

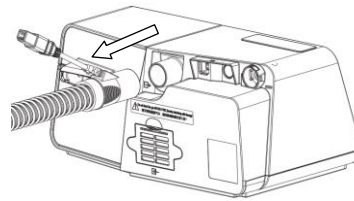

Fig. 18-5

(3) Hold both the cuff of the air tubing and the swivel of the mask, then gently pull apart as shown in Fig. 18-6.

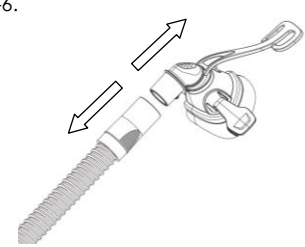

Fig. 18-6

(4) Clean the components with a soft bristled brush for one minute while soaking in detergent solution (see the table below). Pay particular attention to all crevices and cavities.

Detergent	Water temperature	Tubing	Heated Tubing
Alconox™ (diluted at 1%)	Warm water (approx 113 to 140°F or 45 to 60°C)	√	√

(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 drinking quality 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

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

⚠***WARNINGS!***

• Please wash by hand.

•The tubing should be cleaned daily.

• If the heated tubing 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 tubing or reduced product life.

• After cleaning and prior to reuse, the Breathing Tubing should be inspected for holes, creases and tears.

18.6 Replacing the Air Filter / PM2.5 Filter

(1) Open the air filter cap to remove the air filter. Attach a new air filter to the filter cap, as shown in Fig. 18-7.

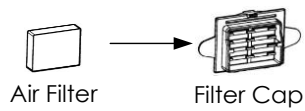

Fig. 18-7

(2) Install the filter cap containing the air filter to the device, as shown in Fig. 18-8.

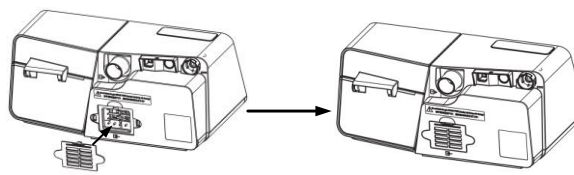

Fig. 18-8

(3) Disassemble the PM2.5 Filter from the device, as shown in Fig. 18-9. Then change a new one.

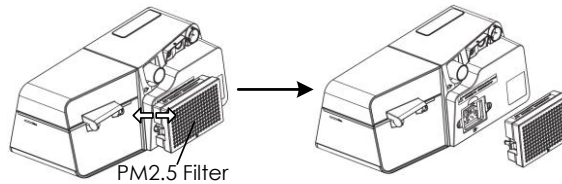

Fig. 18-9

CAUTIONS!

• To avoid material damage, do not place the spare air filter / PM2.5 Filter in direct sunlight, humid environments, or temperatures below the freezing point. The air filter / PM2.5 Filter should be replaced every 6 months (It may be replaced more frequently based on actual sanitary conditions).

• Operating the device with a dirty air filter may stop it from working properly and may cause damage to the device.

19. Traveling with the Device

(1) Use the carrying case to carry the device and accessories along with you. Do not put them in your checked baggage.

(2) This device operates on a power supply of 100 V - 240 V and 50 Hz / 60 Hz, and is suitable for use in any country in the world. No special adjustment is required, but you will need to find out the types of the power sockets at your destination. If necessary, bring a power socket adaptor which can be purchased at electronics stores.

(3) Remember to bring a spare air filter and emergency documentation (filled and signed by your physician) about this device. If you plan to travel by air, remember to bring the multilingual emergency documentation about respiratory therapy, in case that the border and customs officers in your destination country inspect the device. With emergency documentation, you can prove to them that it is a medical device.

(4) Security Stations: For convenience at security stations, there is a note on the bottom of the device stating that it is medical equipment. It may be helpful to bring this manual with you to help security personnel understand the device.

CAUTION!

• Empty the water chamber before packing the device for your trip; to prevent any remaining water from entering the device.

20. Transferring the Device to Another Patient

If the device is transferred to another patient, components in close contact with the previous user, including the mask, headgear, tubing, water chamber and air filter/ PM2.5 Filter, should be replaced to prevent cross-infection.

21. Reordering

Contact your home care provider to order accessories or replacement filters.
The device does not require routine service.

⚠***WARNINGS!***

• If you notice any unexplained changes in the performance of the device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, please stop using the device and. Contact your home care provider.

• If the device fails to work properly, contact your home care provider immediately. Never attempt to open the enclosure of the device. Repairs and adjustments must be performed by 3B Medical-authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.

• If necessary, contact your local authorized dealer or 3B Medical, Inc. for technical support and documents.

22. Technical Support

Please contact 3B Medical directly if you need the circuit diagram of the device and the list of components for certain purposes such as maintenance or connection to other equipment. 3B Medical will provide the circuit diagram and / or other technical documents in whole or in part according to your needs.

23. Disposal

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

24. Troubleshooting

The table below lists common problems you may encounter with the device and possible solutions to resolve them. If none of the corrective actions solve the problem, please contact your home care provider.

24.1 Common Problems in Patients and Corresponding Solutions

Problem	Possible Cause	Solution (s)
Dry, cold, runny, and blocked nose; having a cold	The nose reacts to the airflow and cold. Due to fast airflow, the air becomes cold, resulting in the irritation of nasal mucosa and subsequent dryness and swelling	Increase the humidity setting of the device. Contact your physician, and continue treatment unless the physician suggests otherwise
Dry mouth and throat	Pressurized air flows out through the mouth, causing dryness of nasal passage and throat	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details
Eye irritation	The mask may not be the correct size or type, or the mask may be incorrectly positioned resulting in an air leak	Narrow the distance between the forehead support of the mask and the forehead. Note that adjusting the mask too tight may leave marks on the patient's face
	Mask cushion (the soft part of the mask) hardens	Replace the mask or mask cushion
Facial reddening	The mask is too tight	Loosen the headgear
	The distance between the forehead support of the mask and the forehead is not correct	Try a different distance. The angle and size of the forehead support differ according to the type of masks
	Wrong mask size	Contact your equipment supplier for a correct-size mask
	The patient is allergic to the materials of the mask	Contact your physician and equipment supplier. Use a mask which is not made of natural rubber latex. Place a lining between the skin and mask

Problem	Possible Cause	Solution (s)
Water in mask	When the humidifier is used, the humidified air tends to condense in the cold tubing and mask if the room temperature is low	Turn the humidity setting down, or raise the room temperature. Place the tubing under the quilt, or use the tubing cover. Hang the tubing loosely, and make sure that the lowest part of the tubing should be lower than the patient's head
Nasal, sinus, or ear pain	Sinus or middle ear inflammation	Contact your physician immediately
Discomfort due to inability to adapt to the treatment pressure	The patient will feel uncomfortable when the treatment pressure is higher than 13 cmH_2O. However, the treatment pressure is a prescription, and the device will not be able to treat sleep apnea if the treatment pressure is set too low	Patients may experience a variance in time to acclimate to their therapy. If the problem persists, contact your physician or home care company for assistance
Obstructive sleep apnea symptoms recur	There are many causes of recurring symptoms including weight change, medication or alcohol, and poor mask fit	Contact your physician for assistance
The device is too noisy	The tubing is not connected properly	Reconnect the tubing properly
Air delivered from the device is abnormally hot	The air inlet of the device may be partially blocked, leading to insufficient airflow into the device	Replace the air filter (refer to 18.6 Replacing the Air Filter / PM2.5 Filter), and clean the air inlet
		Place the device in an area where air flows freely, and make sure that the device is at least 20 centimeters away from the wall, curtain, or other things

24.2 Common Problems in the Device and Corresponding Solutions

Problem	Possible Cause	Solution(s)
The device does not work when it is turned on	The Auto On / Off feature is enabled	Take a few deep breaths with the mask on, and the device will start automatically
	Power is not connected properly	Ensure that the power cord, power adapter, and the device are connected properly
	There is no voltage	Check whether a power outage occurs by turning on a light or other means. If you are sure the fuse in the device is broken, contact your equipment supplier for repair
	Cannot find any cause	Contact your equipment supplier
The device is working, but the pressure inside the mask differs from the set treatment pressure	The tubing is not connected properly	Reconnect the tubing properly
	There may be holes in the mask or pressure sensing tubing	Contact your equipment supplier
	It is a faulty device	Contact your equipment supplier
The device produces very low pressures	The air inlet of the device may be blocked	Replace the air filter (refer to 18.6 Replacing the Air Filter / PM2.5 Filter), and clean the air inlet. Make sure the air inlet is unblocked
	The treatment pressure has been changed accidentally	Contact your physician
	When the Ramp feature is enabled, it takes some time for the initial pressure to rise to the treatment pressure. This is normal	If necessary, disable the Ramp feature, or set the ramp time shorter
After the device is turned on, the screen displays intermittently, or displays nothing at all	The operating system of the device needs to be readjusted or restarted	Unplug the power cord of the device, and re-plug it 20 seconds later
The device is in standby, and will not start	The operating system of the device needs to be readjusted or restarted	Unplug the power cord of the device, and re-plug it 20 seconds later

25. Information of QoS

The data transmission between the Luna® G3 BPAP System with a Cellular Module and iCodeConnect is a daily transmission. The Cellular Module transmits the following four types of data: Therapy summary data in a defined period of time, compliance data, system settings, and device information.
This process is not real time communication.
The size of the data transmitted to Cellular Module per second is no more than 1k in normal condition, and no more than 1 M within 8 hours per night.

Acceptable latency
As the user information is not viewed by the doctor in real time, sometimes it can be delayed for 24 or more hours.

Acceptable level of probability for loss of information within the network
The data has little effects on treatment effectiveness. These are key data, and their integrity should be ensured, but they do not involve real-time control of therapeutic medical devices, and do not rely on network quality.

Wrong transmission of the information described in sections above data will be abandoned based on a checking mechanism, and correct data will be sent continuously until received completely.

The data transmission protocol between the module and the server includes unpacking information and ID value, which ensure the completeness of the data transmission.

Signal priorities of the network
The therapy device itself does not have high-priority medical device alert, and its treatment of patients does not rely on wireless communications.
Based on the above analysis, the Cellular Module has low requirements for QoS.

26. EMC Requirements

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">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.</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>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity			
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.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±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 cycle At 0° 0% U_T; 250 / 300 cycle	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 cycle At 0° 0% U_T; 250 / 300 cycle	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 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 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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz ~ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz ~ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	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** $d = 1.17\sqrt{p}$ $d = 0.35\sqrt{p}$ 80 MHz to 800 MHz $d = 0.70\sqrt{p}$ 800 MHz to 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	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	

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 10 V/m.

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

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 W	150 kHz ~ 80 MHz $d = 1.17\sqrt{p}$	80 MHz ~ 800 MHz $d = 0.35\sqrt{p}$	800 MHz ~ 2.5 GHz $d = 0.70\sqrt{p}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.70
10	3.70	1.11	2.22
100	11.7	3.50	7.00

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.

Recommended separation distances between RF wireless communications equipment

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 RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency MHz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless 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** $E = \frac{6}{d}\sqrt{P}$ 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

⚠***WARNINGS!***

• This device 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 device 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 reduced 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 Luna® G3 BPAP System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

• This device may be interfered with by other equipment, even if the equipment complies with CISPR EMISSION requirements.

• The device 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, 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.

• During the operation of the device, due to electrostatic interference, the following phenomena may occur: (1) Temporary loss of function or performance degradation, such as abnormal screen display, etc. The device will return to normal after being restarted; (2) Automatic restart of the device. These phenomena will not affect the normal use of the device, nor will they cause permanent performance degradation or loss of function of the device.

27. Limited Warranty

3B Medical, Inc. warrants that the device shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years for main unit and three (3) months for all accessories from the date of sale by 3B Medical, Inc. to the dealer. If the product fails to perform in accordance with the product specifications, 3B Medical, Inc. will repair or replace, at its option, the defective material or part. 3B Medical, Inc. will pay customary freight charges from 3B Medical, Inc. 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.

3B MEDICAL, Inc. 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:

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F: (863) 226-6284

For additional information, please visit our Patient Portal at:
www.3Bproducts.com
icodeconnect.com – Web-based cloud for report generation and storage

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