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User Manual

G3 B25A

Luna G3 BPAP 25A

CE0123

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1. Introduction

Thank you for your purchase of the Luna BPAP. 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)



Electric shock hazard



Hot Surface



Product Serial Number



Manufacturer



Authorized Representative in the European Community



Do not use the product if the package is damaged



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



Company logo

3. Warning, Caution and Important Tip

WARNING!

Indicates the possibility of injury to the user or operator.

CAUTION!

Indicates the possibility of damage to the device.

IMPORTANT TIP!

Places emphasis on an operating characteristic.

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

4. Intended Use

The Luna G3 BPAP 25A 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 adult use only.
- This device is not intended for life support.
- The instructions in this manual are not intended to supersede established medical protocols.
- 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 risk to the patient or damage to the device or MR medical devices. The device and accessories have not been evaluated for safety in an MR environment.
- Do not use the device or accessories in an environment with electromagnetic equipment such as CT scanners, Diathermy, RFID and electromagnetic security systems (metal detectors) as it may cause unacceptable risk to the patient or damage to the device. Some electromagnetic sources may not be apparent, if you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, disconnect the power cord and discontinue use. Contact your home care provider.

CAUTIONS!

- U. S. federal law restricts this device to sale by or on the order of a physician.
- The patient is the 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
- Ear or sinus discomfort
- 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

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 H₂O/L

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

Maximum Operating Pressure: 40 cmH₂O

Pressure Drop with Humidifier: < 0.4 cmH₂O at 60 LPM flow

Maximum Delivered Gas Temperature: ≤ 43°C

Mode of Operation

Continuous

Work Mode

CPAP, AutoCPAP, S, AutoS


SD Card

The SD card can record patient data and fault information

AC Power Consumption

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

4 to 25 cmH₂O (in 0.5 cmH₂O increments)

Under single fault conditions, ≤ 30 cmH₂O for CPAP and AutoCPAP mode, ≤ 40 cm for the rest of the modes.

Pressure Display Accuracy

$\pm(0.8 \text{ cmH}_2\text{O} + 4\%)$

Static Pressure Stability at 10 cmH₂O

$\pm 0.5 \text{ cmH}_2\text{O}$

Dynamic Pressure Stability

Pressures (cmH ₂ O)	10BPM	15BPM	20BPM
6.5	± 0.5	± 0.5	± 0.5
10	± 1	± 1	± 1
20	± 1	± 1	± 1

Device with humidification and 22mm Tube or Heated Tubing.

Ramp

The ramp time ranges from 0 to 60 minutes.

Sound Pressure Level

< 26 dB, when the device is working at the pressure of 10 cmH₂O.

Sound Power Level

< 34 dB, when the device is working at the pressure of 10 cmH₂O.

Maximum Flow

Test Pressures (cmH ₂ O)	4	10	15	20
Measured Pressure at the Patient Connection Port (cmH ₂ O)	3	9	14	19
Average Flow at the Patient Connection Port (L/min)	90	150	150	150

Air Tubing

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

The Form and the Dimensions of the Patient Connection Port

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

PM2.5 Filter

Efficiency: >90% for 2.5 micron dust

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	
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

Parameter		Min.	Max.	Unit	Remarks
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.

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.

AutoCPAP – Delivers CPAP therapy and provides an air pressure no less than the prescribed pressure based on the patient's needs.

S – A bi-level mode which responds to both 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 preset by home care provider.

AutoS – A bi-level mode which responds to both your inhalation and exhalation. The differential pressure of IPAP and EPAP are preset by home care provider. While working in auto feature, the device will automatically adjust the IPAP and EPAP if it detects an apnea.

8. Glossary

Apnea

A condition marked by the cessation of spontaneous breathing.

AutoCPAP

Adjust CPAP pressure automatically to improve patient comfort based on monitoring of sleep events, such as apnea, hypopnea etc.

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.

SmartC

With this feature, the device adjusts Treat P according to the patient's respiratory events during a certain time period.

SmartA

With this feature, the device adjusts Ramp P and Min APAP according to the patient's respiratory events during a certain time period.

SmartB

With this feature, the device adjusts Ramp P and Min APAP according to the patient's respiratory event during a certain time.

CPAP

Continuous Positive Airway Pressure.

EPAP

Expiratory Positive Airway Pressure.

IPAP

Inspiratory Positive Airway Pressure.

iCode

A feature that is intended to give access to compliance and therapy management information. The "iCode" consists of six separate codes displayed in the Patient Menu, each code is a sequence of numbers. The "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 for the Ramp feature.

Ramp

A feature that may increase patient comfort when therapy is started. It can reduce pressure and then gradually increase the pressure to the prescription setting so 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	Product Contents		Work Mode	Maximum Work Pressure (cmH ₂ O)
	Main Device	Accessory		
B25A	Main device (3.5-inch TFT)	Adapter, Power Cord, Tubing, Cellular Module (optional), Heated Tubing (optional), PM2.5 Filter (optional)	CPAP, AutoCPAP, S, AutoS	25

10. Package Contents

After unpacking the system, make sure you have everything shown here (Different models of the product 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	
8	Heated Tubing	1	Optional
9	SD Card	1	
10	Carrying Case	1	
11	Accompanying Documents	1	

parts and accessories contain no natural rubber latex.

The product's service life is five years if the use, maintenance, cleaning and disinfection are in strict accordance with the User Manual.

The Heated Tubing service life is six months. The Cellular Module service life is one year.

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 therapy.
- The use of accessories other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.
- Do not pile up the long tubing at the head of the bed, as it may be a strangulation hazard.
- Do not connect any equipment to the device unless recommended by 3B MEDICAL or your health care provider.

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, always follow the instructions enclosed with the accessories.

11. System Features

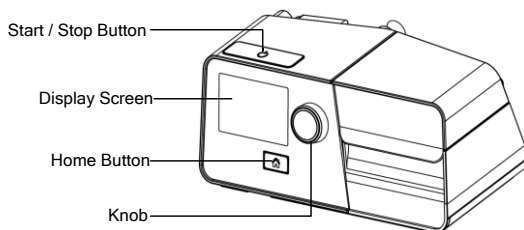


Fig. 11-1

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

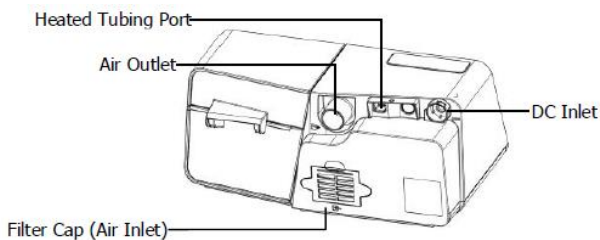


Fig. 11-2

Name	Function
Air Outlet	Deliver pressurized air; connect 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)	Cover and secure the air filter, which is used to filter dust and pollen in the air entering the device

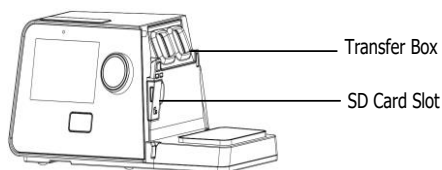


Fig. 11-3

Name	Function
Transfer Box	Connects the device to the water chamber
SD Card Slot	Insert the SD card into this slot

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 has entered the enclosure, disconnect the power cord and discontinue use. Contact your home care provider immediately.
- If the room temperature is warmer than 95°F (35°C), the airflow produced by the device may exceed 109.4°F (43°C). The room temperature must be kept below 95°F (35°C) while the patient uses 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 either very hot or very cold temperatures, allow it to adjust 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 to 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 build-up within the device, leading to the malfunctioning of the device.
- Air must flow freely around the device for it to work 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.

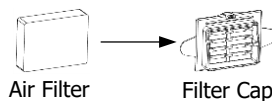


Fig. 12-1

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

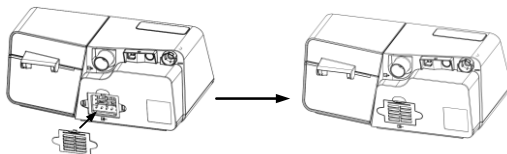


Fig. 12-2

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

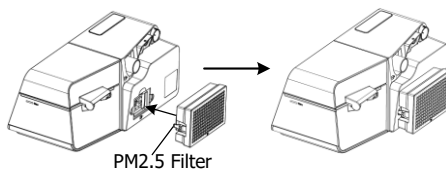


Fig. 12-3

CAUTIONS!

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

12.3 Connecting to Power

- (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.

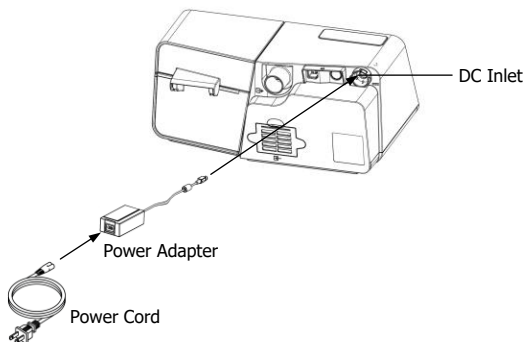



Fig. 12-4

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 is connected. The **Knob**  turns the blower On / Off.
- Use of the device at an AC voltage beyond the stated range (see Section 5 “AC Power Consumption”) may damage the device or cause device failure.
- Connect to appropriate power for proper operation of the device.
- Inspect the power cord often for any 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) Insert the power cord locker into the device, as shown in Fig. 12-5, and then rotated to the left for assembly to the device.

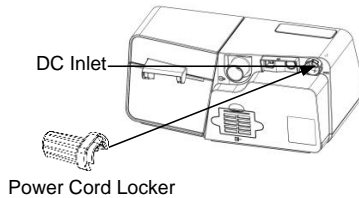


Fig. 12-5

(2) Open the power cord locker, plug the power cord to the power supply, and press the locker downward to fix the power cord into the power port.

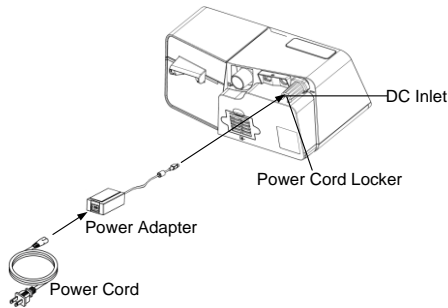


Fig. 12-6

The function of the locker is to prevent the power cord being displaced from the power port.

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. 12-7.

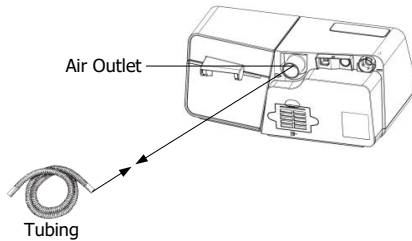


Fig. 12-7

(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. 12-8.

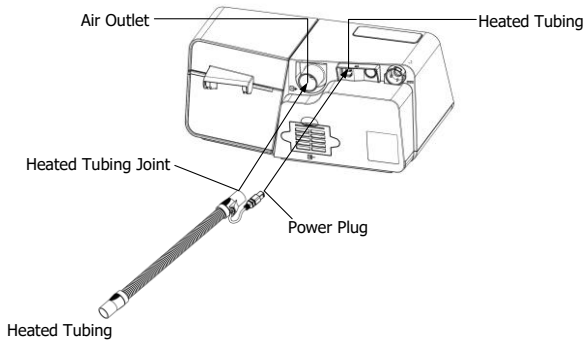



Fig. 12-8

If the heated tubing is connected correctly, the line next to the icon  will become a number in the Main Interface on the screen of the device, as shown in Fig. 12-9.

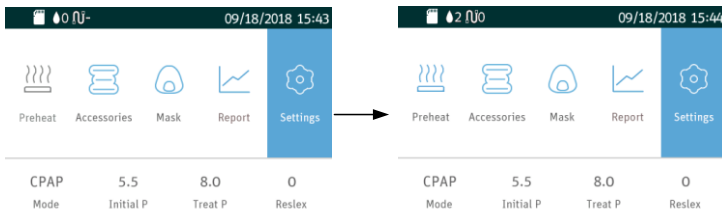




Fig. 12-9

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

There are five heat levels available, and the number of heat level will appear in the Main Interface on the screen of the device. The number 3 next to the icon  indicating the heat is adjusted to Level 3, as shown in Fig. 12-10.

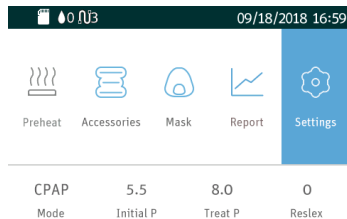


Fig. 12-10

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

WARNINGS!

- If multiple persons are going to use the device (e.g., rental devices), a low-resistance, main flow bacteria filter should be installed in-line between the device and tubing. Pressures must be verified by your home care provider when alternate or optional accessories are in place.
- 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 vented air is blowing 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.
- In order to minimize the risk of CO₂ rebreathing, the patient should observe the following instructions:
 - Use only 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 before turning off the device. Explanation of Warning: When the device is turned off, but the oxygen flow still exists, oxygen may accumulate within the device's enclosure and pose a fire hazard. Turning off the oxygen before turning off the device will prevent oxygen accumulation in the device and reduce the risk of fire. This warning applies to all 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 in the area near G3 BPAP 25A System or the oxygen container.
- Sources of oxygen should be located more than 1 m 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 should not exceed the work 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. 12-11.

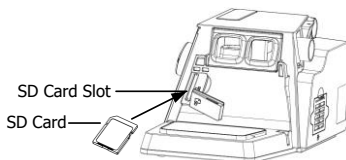




Fig. 12-11


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

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

CAUTIONS!

- If the SD card is not inserted, there will not be a symbol appear in the Main Interface on the screen of the device.
- To avoid data loss or any damage to the SD card, the SD card should 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, contact your physician or qualified medical personnel immediately.

13. Routine Use

13.1 Connecting the Tubing

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


CAUTION!

- Before each use, examine the tubing for any damage or debris. If necessary, clean the tubing to remove the debris. 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 during sleep. Adjust the mask and headgear until you have a comfortable fit and no airflow leaks 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 of the water chamber before using the humidifier. Make sure there is sufficient water in the water chamber, avoid heating the device with an empty water chamber.




13.5 Using the Ramp Feature

Every time the feature is enabled, the pressure will drop to the set initial pressure, and then gradually rise to the prescribed treatment pressure according to the preset ramp time, so as to ensure patient comfort. The screen displays a real-time countdown of the remaining ramp time in minutes.

CAUTIONS!

- You can use the ramp feature as often as you wish during sleep.
- The ramp feature is not prescribed for all users.

13.6 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 interface, as shown in the Fig. 13-2.

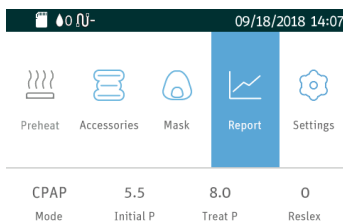



Fig. 13-1



Fig. 13-2

13.7 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 power off the device.

CAUTION!

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

14. Heated Humidifier

The humidifier is integrated into your device. The humidifier may 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

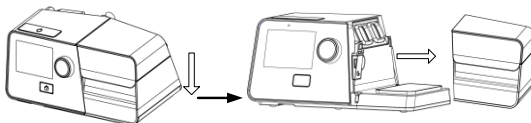


Fig. 14-1

⚠ WARNING!

- Turn the device off and allow approximately 15 minutes for the heater plate and water to cool.

14.1.2 Filling Water

(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.

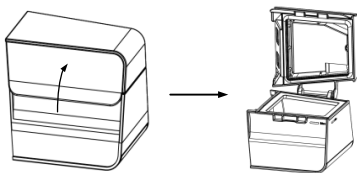


Fig. 14-2

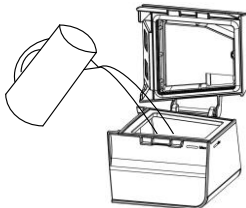


Fig. 14-3

(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.

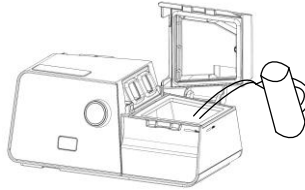


Fig. 14-4

⚠WARNING!

- Change water before every use and do not surpass the **MAX** fill 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 directly to fill the water.

14.1.3 Returning the Water Chamber

Close the cap after it is filled with water, as shown in Fig. 14-5, and return it to the device, as shown in Fig. 14-6.

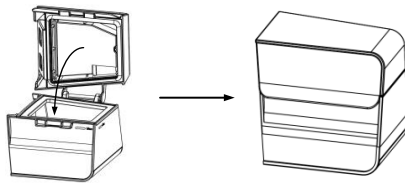


Fig. 14-5

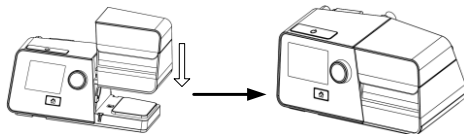


Fig. 14-6

⚠ WARNING!

- For safety purposes, the device must be placed on a flat surface at a level lower than the patient's head on a bed, so that the condensation flows back to the water chamber rather than remain in the tubing causing rainout.

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.

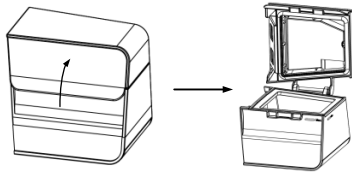



Fig. 14-7


CAUTION!

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

- (3) **Returning the Water Chamber** according to instructions in 14.1.3.

14.3 Setting the Humidity Level

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

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

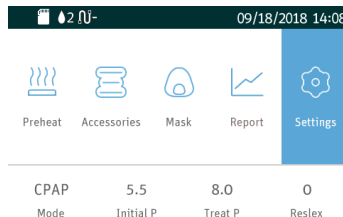


Fig. 14-8

⚠WARNING!

- Do not touch the heater plate of the device when it is working, otherwise you may get burned. Turn off the heat when the heated humidifier is not in use.

CAUTIONS!

- the humidity inside the mask is low when the water temperature is low.
- The greater the difference between the temperature inside the air tubing and room temperature is, the more likely condensation can occur inside the tubing.
- If there are only a few condensed water droplets inside the tubing in the morning after therapy, it means that the humidity level is appropriate; if there is lots of condensed water droplets inside the tubing and / or mask, it means that 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 25A with Cellular Module can wirelessly communicate with iCodeConnect®. 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 25A 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.

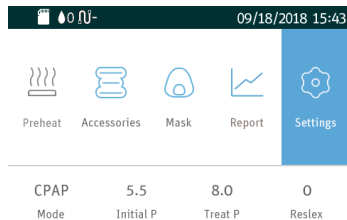






Fig. 15-1

(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

Note:

(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 appears in the Main Screen, as shown in Fig. 15-2 (the signal icons of different strength appear in a similar way).

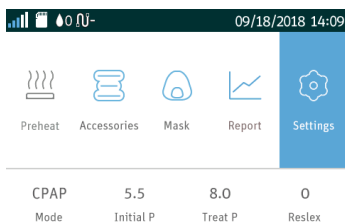


Fig. 15-2

The device screen will not show the signal icon 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 Navigating the Patient Menu

16.1.1 Accessing the Main Interface

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

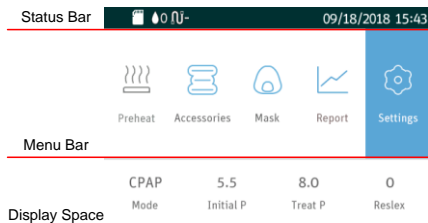


Fig. 16-1

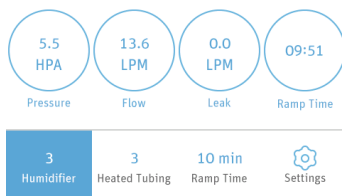


Fig. 16-2

Note: The above interface only applicable to the device, it does not activate the SmartC, SmartA or SmartB. If the SmartC, SmartA or SmartB is enabled, the symbol **S** will appear in the status bar at the top of the screen, as shown in Fig. 16-3.

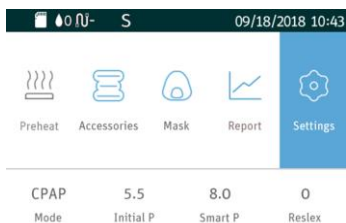








Fig. 16-3

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

Note: If the humidity level is 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 the Fig. 16-1, turn **the knob** . When the cursor is on the icon , press **the knob** , 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 the 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 the desired option, press **the Knob** , and the background color of the option will change, meaning that the option can now be adjusted, 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 numerals increase, indicating a higher humidity level. As you turn **the Knob**  counterclockwise, the numerals decrease, indicating a lower humidity level, as shown in Fig. 16-7.



Fig. 16-7

16.1.5 Confirming Adjustments



Confirm your adjustment to an option by pressing **the Knob** . 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.

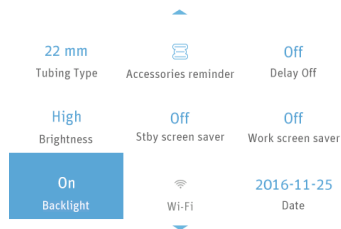





Fig. 16-9




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 of the Patient Menu and Corresponding Descriptions

Option	Range	Description
Humidifier	Off,Auto, 1 ~ 5	There are five humidity levels available. As the numbers increase, the humidity rises accordingly. "Off" means the humidifier is turned off.
Preheat	On / Off	Set humidifier to preheat by adjusting this option. This feature automatically turns 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 the user more comfortable. The higher the number is, the more pressure the device reduces. "Off" means this feature is disabled.
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 it is connected.
Ramp Time	Auto, 0 - Max Ramp	In order to increase comfort and help the patient fall asleep easily, the pressure can increase gradually when the Ramp feature is enabled. The ramp time during which the initial pressure rises to the prescribed treatment pressure can be adjusted. As you turn the Knob  to the nearest point, the numbering increases or decreases by five minutes. 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 cmH ₂ O) after you press the Start / Stop  to discontinue treatment. This will blow off the vapor left in the water chamber to avoid any damage to the device. When this feature is set to "Off," which means it is disabled, the airflow stops delivering air instantly after you press the Start / Stop  .
Date	2000-01-01 — 2099-12-31	Set date by adjusting this option.

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 time format
Date Format	yy mm dd / mm dd yy / dd mm yy	Turn the Knob  to choose date formats
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 turn off automatically after 30 seconds of inactivity. If it is set to "On," the backlight will always be on.
Mask Fitting Test	Start the Mask Fitting Test	Test whether the mask is worn correctly, the screen will display the "great" icon if it passes the fit test, otherwise the screen will display the "need to adjust" icon.
Brightness	High / Low	Set screen brightness by adjusting this option.
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). The default mask type is " Nasal ," but the patient can choose other suitable masks as well. When selecting masks other than the above three types of 3B MEDICAL masks, the patient can identify the masks as other.
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 sequences of numbers, and the iCode QR / iCode QR + mode displays data in two-dimensional codes.
Consumables Reminder	30 days/60 days/180 days/1 year/off	This function is used for setting filter reminder, tube reminder and mask reminder. Patient can set the use time of filter, tube and mask. This is for replacement reminders.
Language	English	The default setting is " English ".
Use Time	0 ~ 50000 h	Use Time displays how long the device been used by the patient. The use time can be restored to factory settings.
Consumables Alert	—	Reset the use time of the filter, tubing and mask.
About	—	Displays related information of the device (Model, SN, Version, ID). This is read-only and cannot be edited.

17. Alert

Alert Message	Description
Power Failure!!!	<p>An audible alert will sound in 6s if the device is accidentally disconnected from power when it is delivering air.</p> <p>Note:</p> <p>(1) The alert will not sound if power failure occurs when the device is in standby state.</p> <p>(2) No alert message displayed during a power failure.</p>
Device fault!!!	<p>An audible alert will sound if no airflow comes out of the machine; the screen will display "Device fault!!!".</p>
Leak!!	<p>When the airflow is on, an audible alert will sound if the air leak rate exceeds 150 L/min; the screen will display "Leak!!".</p>
Low Input Voltage!!	<p>If the voltage supplied by power adaptor is lower than 22V, an audible alert will sound and the screen will display "Low Input Voltage!!".</p>
Humidifier Failure!!	<p>When humidifier is connected, an audible alert will sound if the humidifier fails to work in 10 minutes; the screen will display "Humidifier Failure!!".</p>
Please Change Filter!	<p>When the Filter Alert feature is enabled, an audible alert will sound if the preset replacement time is reached but the air filter hasn't been replaced; the screen will display "Please Change Filter!". The default setting is "Off".</p>
Please Change Tube!	<p>When the tubing Alert feature is enabled, an audible alert will sound if the preset replacement time is reached but the tubing hasn't been replaced; the screen will display "Please Change Tube!".</p>
Please Change Mask!	<p>When the Mask Alert feature is enabled, an audible alert will sound if the preset replacement time is reached but the mask hasn't been replaced; the screen will display "Please Change Mask!".</p>
SD Card Full!	<p>The screen will display "SD Card Full!" if the SD card has reached its maximum capacity.</p>
Reinsert SD card!	<p>The screen will display "Reinsert SD card!" if the SD card fails to work.</p>

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 whether the device has been disconnected from the power supply, whether the power cord has been unplugged, and whether the water chamber of the device has cooled down. Make sure the plate has cooled down to room temperature, to avoid the risk of burns.
- Do not open or modify the device. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorized service agent.

CAUTIONS!

- Overheating of the materials could lead to early fatigue of these 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 higher than 80°C (176°F). High temperatures could reduce product life.
- Do not immerse the device in any fluids.

18.1 Cleaning the Mask and Headgear

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

18.2 Cleaning the Water Chamber

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

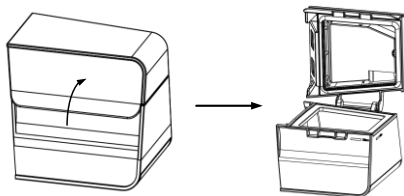


Fig. 18-1

(2) **Cleaning the Water Chamber:** You may also clean the water chamber with a soft cloth (dip the soft cloth in liquid soap if necessary), rinse it thoroughly, and then wipe it dry with a soft cloth.

(3) **Replacing the Water Chamber** according to instructions found in 14.1.3.

⚠️ 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 thoroughly 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.
- Inspect the water chamber for any leak or damage. Replace the water chamber if any damage is present.
- It is recommended to clean the water chamber and change the water daily.

18.3 Cleaning the Transfer Box

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

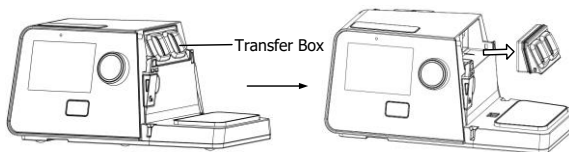


Fig. 18-2

(2) **Cleaning the Transfer Box:** Rinse the transfer box thoroughly in clean water. You may also clean the transfer box with a soft cloth (dip the soft cloth in liquid soap if necessary), rinse it thoroughly, and then wipe it dry with a soft cloth.

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

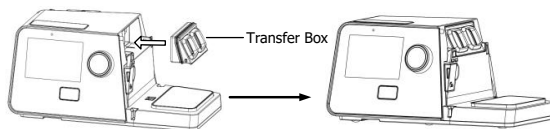


Fig. 18-3

CAUTION!

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

18.4 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) Clean the tubing in warm water and mild soap, and then rinse it in clean water thoroughly.
- (3) After cleaning, air-dry the tubing in a cool, well-ventilated area, and avoid direct sunlight. It takes approximately 30 minutes to completely air-dry the tubing. Ensure the tubing is completely dry before re-use.

CAUTION!

- It is recommended to clean the tubing once a week.

18.6 Replacing the Air Filter / PM2.5 Filter

- (1) Open the air filter cap to remove the air filter. Attach the air filter to the filter cap, as shown in Fig. 18-4.

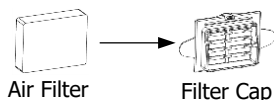


Fig. 18-4

- (2) Install the filter cap containing the air filter to the device, as shown in Fig. 18-5.

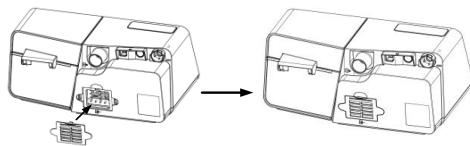


Fig. 18-5

(3) Disassemble the PM2.5 Filter from the device, as shown in Fig. 18-6.

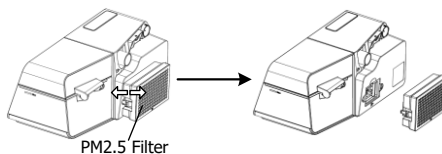


Fig. 18-6

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

CAUTIONS!

- Empty the water chamber before packing the device for your trip; in order to prevent any remaining water from entering the device.
- Using the device at an incorrect elevation setting could result in airflow pressures higher than the prescribed setting. Always verify the elevation setting when traveling or relocating.
- If the device is used when the atmospheric pressure is out of the stated range (See Section 6), the accuracy of the leakage alert will be affected.

(1) Use the 3B MEDICAL carrying case to carry the device and accessories as a carry on. Do not put them in your checked baggage.

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

(3) Remember to bring a spare air filter and the emergency documents (filled and

signed by your physician) regarding this device. If you plan to travel by air, remember to bring the multi-language emergency documents about respiratory therapy in case border and customs officers in your destination country inspect the device. With the emergency documents, you can provide documentation 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 along with you to help security personnel understand the device.

20. Transferring the Device to Another Patient

If the device is transferred to another patient, components in close contact with the previous owner, including the mask, headgear, tubing, and air 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 servicing.

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, discontinue use. Contact your home care provider.
- If the device malfunctions, 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

Electrical product components contain chemical substance which may pollute environment, 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 have with the device and possible solutions to those problems. If none of the corrective actions solve the problem, 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 airflow, the air becomes cold, leading to nasal mucosa irritation and subsequent dryness and swelling.	Increase the humidity setting of the device. Contact your physician, and follow treatment physician suggestions.
Dry mouth and throat	The patient sleeps with his or her mouth open, and the pressurized air goes out via the mouth, leading to nasal and throat dryness.	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 size or model may not be correct, or the mask is not positioned correctly, thereby leading to air leakage.	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. Contact your equipment supplier for an appropriate mask. .
	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 with 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, 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	treatment pressure is a prescription, and cannot 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 (see 18.7 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 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 (see 18.7 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 25A 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, 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 1M 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 alarms, 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

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

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
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 V 0.15 MHz ~ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz</p> <p>10 V/m 80 MHz to 2.7 GHz</p>	<p>3 V 0.15 MHz ~ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz</p> <p>10 V/m 80 MHz to 2.7 GHz</p>	<p>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.</p> <p>Recommended separation distance</p> <p>$d = 1.17\sqrt{P}$</p> <p>$d = 0.35\sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 0.70\sqrt{P}$ 800 MHz to 2.5 GHz</p> <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).</p> <p>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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^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.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 10 V/m.</p>			

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					
870	2	0.3	28	28	
930	2	0.3	28	28	
1720					
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					

Note 1: 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 or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.
- The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.
- This device may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

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:

3B Medical, Inc.

Winter Haven, FL 33881

T: (863) 226-6285

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