# Luna® II qx

## USER MANUAL

Luna II QX CPAP / Luna II QX Auto CPAP

Model No LQX2000 / Model No LQX2A00

Internet Model

3B™ Medical, Inc.

www.3Bproducts.com

# Table of Contents

# 1. Introduction

Thank you for your purchase of the Luna II QX CPAP / Luna II QX Auto CPAP. 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

 Ramp Button

 Mute Button

 Knob

## 2.2 Device Symbols

 Follow Instructions for Use

 Operating Instructions

 Type BF Applied Part (mask)

 Class II (Double Insulated)

 AC Power

 DC Power

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

 Hot Surface

Serial Number of the Product

 Manufacturer

| | |
|---|---|
| EC REP | Authorized Representative in the European Community |
| | Disassembly is prohibited |
| CE 0123 | European CE Declaration of Conformity |
| LOT | Lot number |
| | Non-Ionizing Radiation |
| SD | SD Card |
| | WEEE Marking |
| | Air Inlet |
| | Air Outlet |
| BMC | Logo of BMC Medical Co., Ltd. |
| 3B | 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 II QX CPAP and Luna II QX Auto CPAP are intended to deliver positive pressure for the treatment of obstructive sleep apnea. The optional integrated heated humidifier is indicated for the humidification and warming of air from the flow generator. These devices are intended for single patient use by prescription in the home or hospital/institutional environment on adult patients.

***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.
• 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!***
• Federal law restricts this device to sale by or on the order of a physician.
• The device is intended for use by operators trained or experienced in similar equipment.
• The patient is an intended operator.
• Cleaning can be performed by the patient.

***IMPORTANT!***

• 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*

Studies have shown that the following pre-existing conditions may contraindicate the use of positive airway pressure therapy for some patients:

**Absolute Contraindications:** Pneumothorax, mediastinal emphysema; cerebrospinal fluid leak, traumatic brain injury, or pneumocephalus; shock caused by a variety of conditions before treatment; active epistaxis; upper gastrointestinal bleeding before treatment; coma or impaired consciousness making the use of mask during therapy impossible; giant vocal fold polyp, etc.

**Relative Contraindications:** Severe coronary heart disease complicated with left ventricular failure, acute otitis media, excessive respiratory secretions and weak cough, weak spontaneous breathing, nasal or oral tracheal intubation and tracheotomy, severe nasal congestion caused by a variety of conditions, lung bullae, and allergies to breathing masks, etc.

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

***IMPORTANTS!***

• An irregular sleep schedule, alcohol consumption, obesity, sleeping pills, or sedatives may aggravate your symptoms.

• Please use a mask which meets ISO 17510: 2015.

***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.

# 6. Specifications

***Device Size***

Dimensions: 274 mm × 184 mm × 115 mm

Weight: 1.9 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 $cmH_2O$ | 760 ～ 1060 $cmH_2O$ |

***Heated Humidifier***

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

Humidifier Output: No less than 10 mg $H_2O$/L

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

***Mode of Operation***

Continuous

***Work Mode***

For LQX2000: CPAP

For LQX2A00: CPAP, Auto

***SD Card***

The SD card can record patient data and fault information

***AC Power Consumption***

100 - 240 V ～, 50 / 60 Hz, Max 2 A

***Device offer to USB Communications Port***

5 V ⎓ 2.0 A

***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 20 $cmH_2O$ (in 0.5 $cmH_2O$ increments), ≤30 $cmH_2O$ under single fault conditions.

***Static Pressure Stability***

±0.5 $cmH_2O$

***Ramp***

The ramp time ranges from 0 to 60 minutes.

***Sound Pressure Level***

< 28 dB, when the device is working at the pressure of 10 $cmH_2O$.

***Sound Power Level***

< 38 dB, when the device is working at the pressure of 10 $cmH_2O$.

***Maximum Flow***

| Test Pressures ($cmH_2O$) | 4 | 10 | 15 | 20 |
|---|---|---|---|---|
| Measured Pressure at the Patient Connection Port ($cmH_2O$) | 3 | 9 | 14 | 19 |
| Average Flow at the Patient Connection Port (L/min) | 85 | 135 | 140 | 140 |

***Automatic leak compensation***

The pressure error ≤ ± 1 $cmH_2O$ when the air leakage is no more than 70 L / min.

***Pressure***

Range: 0 ～ 20 $cmH_2O$

Margin of Error: ± (0.4 $cmH_2O$ + 4%)

***Tube***

Length: 6 ft. (1.83 m)

***Maximum Delivered Gas Temperature***

≤ 43°C

***The Form and the Dimensions of the Patient Connection Port***

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

# 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. If your health care professional has prescribed ramp for you, you can press **the Ramp Button** to reduce the pressure and then gradually increase the pressure to the therapeutic pressure setting so that you can fall asleep more comfortably.

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

# 8. Glossary

***Apnea***
A condition marked by the cessation of spontaneous breathing.

***Auto***
Adjust CPAP pressure automatically to improve patient comfort based on monitoring of apnea and snoring events.

***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.

***CPAP***
Continuous 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.

***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*

<table>
<tr><th rowspan="2">Model</th><th colspan="4">Product Description</th></tr>
<tr><th>Product Contents</th><th>Optional Accessory</th><th>Work Mode</th><th>Maximum Work Pressure ($cmH_2O$)</th></tr>
<tr><td>LQX2A00</td><td>Device (3.5-inch TFT)</td><td rowspan="2">Tube, Mask,</td><td>CPAP, Auto</td><td rowspan="2">20</td></tr>
<tr><td>LQX2000</td><td>Device (2.4-inch TFT)</td><td>CPAP</td></tr>
</table>

# *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. |
|---|---|---|
| 1 | Device | 1 |
| 2 | Air Filter | 2 |
| 3 | Power Adapter | 1 |
| 4 | Power Cord | 1 |
| 5 | Tube | 1 |
| 6 | SD Card | 1 |
| 7 | Carrying Case | 1 |
| 8 | Enclosed Documents | 1 |

All parts and accessories are not made with 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. If the key components are replaced, the service life may be prolonged.

***IMPORTANTS!***

• 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.

***WARNINGS!***

• This device should only be used with the mask and accessories manufactured or recommended by 3B Medical, Inc. 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 wrap around the head or neck of the patient during sleep.

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

• Please contact 3B Medical, Inc. to obtain an SD card if needed.

# *11. System Features*

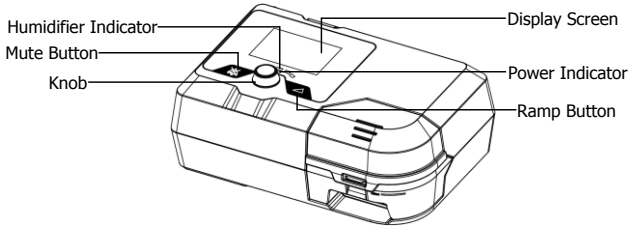


Fig. 11-1

| Name | Function |
|---|---|
| Humidifier Indicator | Indicate the humidity level. There are five levels in total. The number of indicator lights that light up is directly proportional to the humidity level. If the indicator lights are off, it means the humidifier is turned off |
| Mute Button | Press this button to mute the alert. However, if the problem causing the alert is not solved, the alert will sound again two minutes later |
| Knob | Start treatment and adjust device settings |
| Ramp Button | Enable the Ramp feature |
| Display Screen | Display menus for operation, messages, monitoring data, etc. |
| Power Indicator | Indicate the power supply status |

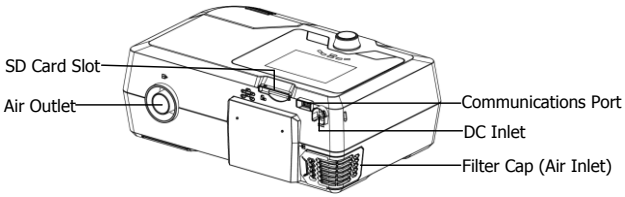


Fig. 11-2

| Name | Function |
|---|---|
| SD Card Slot | Insert the SD card into this slot |
| Air Outlet | Deliver pressurized air; connects to the tube |
| Communications Port | Connected to external equipment (Not for connection to un-recommended devices) |
| 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 |

# *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!***

• 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 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 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*

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

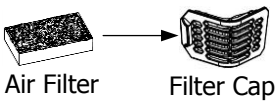


Fig. 12-1

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

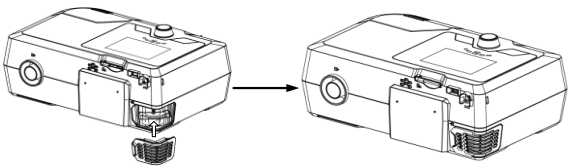

Fig. 12-2

***CAUTIONS!***

• The air filter must be in place when the device is operating.
• Installing the air filter and filter cap, device must be unplugged.

## *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.

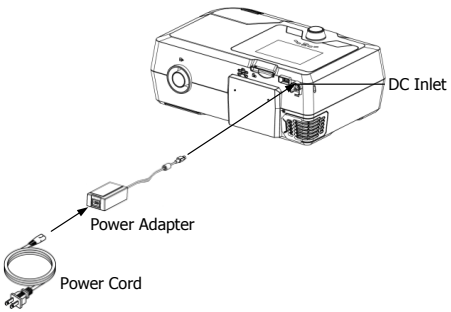


Fig. 12-3

***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.

***CAUTION!***

• Inspect the power cord often for any signs of damage. Replace a damaged cord immediately.

***IMPORTANTS!***

• 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 Assembling the Tube and Mask*

(1) Connect one end of the tube to the air outlet of the device, as shown in Fig. 12-4.

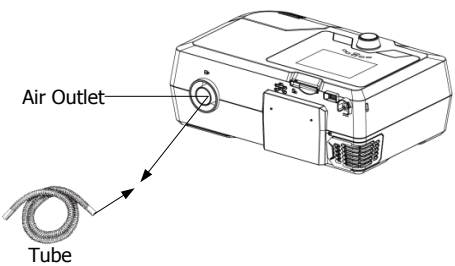


Fig. 12-4.

(2) Connect the other end of the tube to the mask according to the user manual for the mask.

***WARNINGS!***

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

• If you are using a mask with a separate exhalation port, connect the tube 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 $CO_2$ rebreathing, the patient should observe the following instructions:

- Use the accompanying tube and mask provided by 3B Medical, Inc.

- 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.

## *12.5 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 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 your Luna GII 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 does not exceed the work pressure of the device.

## *12.6 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. 12-5.

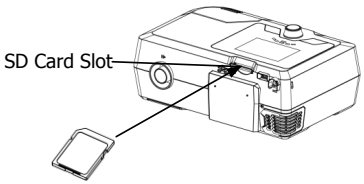


Fig. 12-5

If the SD card is inserted correctly, a symbol indicating correct insertion will appear in the Main Interface on the screen of the device, as shown in Fig. 12-6.

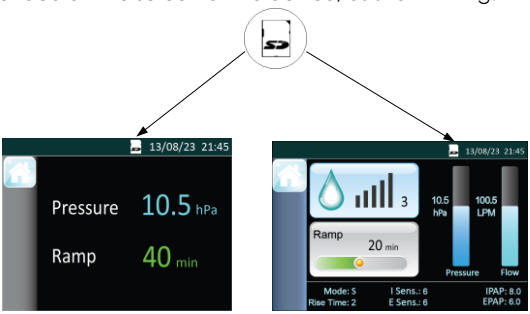


Fig. 12-6

If the SD card is inserted incorrectly, a symbol indicating incorrect insertion will appear in the Main Interface on the screen of the device, as shown in Fig. 12-7.

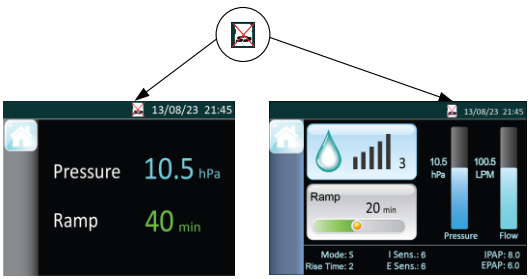


Fig. 12-7

***CAUTION!***

• If the SD card is not inserted, there will not be a symbol in the Main Interface on the 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.

## 12.7 Accessing Your Date and Report Generation

The Luna QX model platform has detailed reporting options. Using our smartphone apps, users can scan the QR Code that displays on the LCD for a full and detailed sleep report. Additionally, users can access the "Quick Report" option available on www.iCodeConnect.com to upload their SD card and print reports from the cloud without the need to install any software.

## 12.8 Starting Treatment

Connect the device to a power outlet, press **the Knob** , 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, Inc. 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 Tube

Connect the power cord, power adapter, and tube 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 tube for any damage or debris. If necessary, clean the tube to remove the debris. Replace any damaged tube. Make sure that the mask does not leak.

## 13.2 Adjusting the Tube

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

## 13.3 Turning on the Airflow

Press **the Knob** to turn on the airflow. The screen will display treatment pressure and other information.

## 13.4 Heating the Water

Pay attention to the humidifier indicator lights when using the humidifier. The

indicator lights indicate the On / Off state of the humidifier. It is off when all indicator lights go out.

***CAUTION!***

• Observe the water level of 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 Using the Ramp Button*

Every time **the Ramp Button** is pressed, the pressure will drop to the initial pressure, and then gradually rise to the prescribed treatment pressure according to the preset ramp time, so as to make the patient fall asleep easily. The screen displays a real-time countdown of the remaining ramp time in minutes.

***CAUTIONS!***

• You can press **the Ramp Button** as often as you wish during sleep.
• The ramp feature is not prescribed for all users.

## *13.6 Turning the Device Off*

Take off the mask and headgear, press and hold **the Knob** for two seconds, and the device will stop delivering air. Disconnect the power cord from the power outlet to power off the device.

***CAUTIONS!***

• Do not position the device where it is difficult to disconnect the device.
• To isolate the device from the supply mains, disconnect the plug.

# *14. Heated Humidifier*

The humidifier is available from your home care provider. 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*

Grab the water chamber, and pull it out of the device, as shown in the figure below.

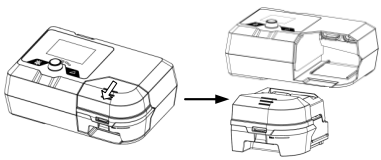

Fig. 14-1

***WARNING!***

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

### *14.1.2 Filling Water*

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.

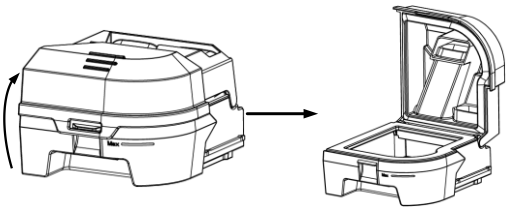

Fig. 14-2

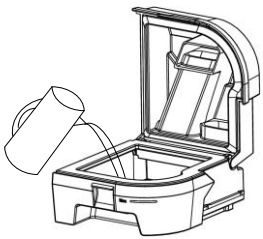

Fig. 14-3

***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.

### *14.1.3 Inserting the Water Chamber*

Close the cap after it is filled with water, as shown in Fig. 14-4, and return it to the device, as shown in Fig. 14-5.

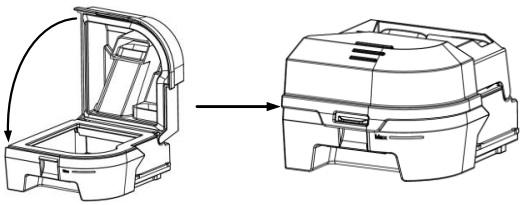

Fig. 14-4

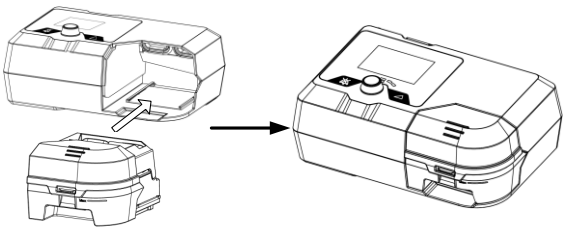

Fig. 14-5

***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.

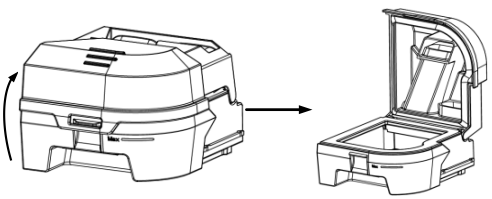

Fig. 14-6

***CAUTION!***

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

(3) **Inserting 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 on the screen of the device.

There are five humidity levels available, and the number of blue indicator lights that light up is directly proportional to the humidity level. If none of the indicator lights light up, it means that the heated humidifier is turned off.

The temperature of the water in the water chamber maintains a constant set level. Three indicator lights light up when the humidity is adjusted to Level 3, as shown in Fig. 14-7.

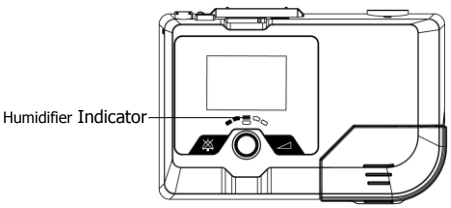


Fig. 14-7

***CAUTIONS!***

• Generally speaking, 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 easily condensation occurs 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.

***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.

# 15. Navigating the Patient Menu

## 15.1 Steps to Navigating the Patient Menu

### 15.1.1 Accessing the Main Interface

Connect the power cord and power adapter properly. The screen displays the Main Interface shown in Fig. 15-1(applies to LG2000), or the Main Interface shown in Fig. 15-2 (applies to LG2A00).


Fig. 15-1

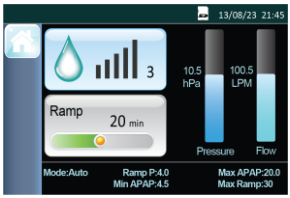


Fig. 15-2

### 15.1.2 Bringing up the Initial Setup Interface

From the Main Interface shown in Fig. 15-1 or Fig. 15-2, press and hold **the Ramp Button** for three seconds. The screen displays the Initial Setup Interface of the Patient Menu, as shown in Fig. 15-3.

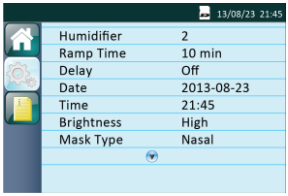


Fig. 15-3

The first icon on the left side of the screen indicates the Main Interface, the second icon indicates the Initial Setup Interface, and the third icon indicates the iCode Interface. As you turn **the Knob**, the cursor switches among the three icons, and the interface displayed on the screen changes accordingly.

### *15.1.3 Accessing the Setup Interface*

When the cursor is on the icon , the screen displays the Setup Interface. Access the Setup Interface by pressing **the Knob** . The first option on the Setup Interface is then displayed in blue, as shown in Fig. 15-4.

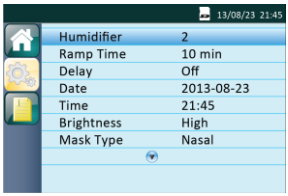


Fig. 15-4

### *15.1.4 Selecting Options*

As you turn **the Knob** clockwise, the cursor moves downwards from one option to another. As you turn it counterclockwise, the cursor moves upwards. When the cursor is on a certain option, press **the Knob** , and the option is then displayed in yellow, meaning that the option can now be adjusted, as shown by the **Humidifier** option in Fig. 15-5.

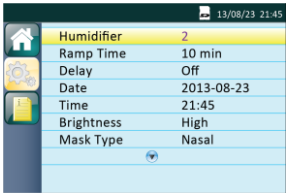


Fig. 15-5

### *15.1.5 Adjusting Options*

Adjust the option by turning **the Knob** . As shown in Fig. 15-5, the **Humidifier** option is selected. As you turn **the Knob** clockwise, the numbering increases, indicating a higher humidity level. As you turn **the Knob** counterclockwise, the numbering decreases, indicating a lower humidity level. The **Humidifier** option is still displayed in yellow, as shown in Fig. 15-6.

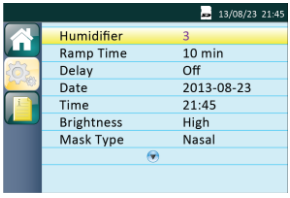


Fig. 15-6

### *15.1.6 Confirming Adjustments*

Confirm your adjustment to an option by pressing **the Knob** . The option is then displayed in blue, as shown in Fig. 15-7.

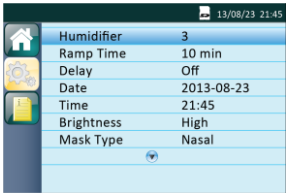


Fig. 15-7

### *15.1.7 Turning Pages*

When the cursor is on **Mask Type**, the last option shown in Fig. 15-7, the remaining options will appear on a new page if you continue to turn **the Knob** clockwise, as shown in Fig. 15-8.

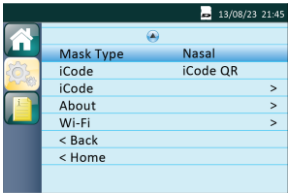


Fig. 15-8

Note: are page turning symbols.

### *15.1.8 Exiting the Patient Menu*

(1) Returning to the Initial Setup Interface

Move the cursor to the **Back** option by turning **the Knob** , as shown in Fig. 15-9.


Fig. 15-9

Press **the Knob** , the cursor jumps to the second icon on the left side of the screen. The screen displays the Initial Setup Interface, as shown in Fig. 15-10.

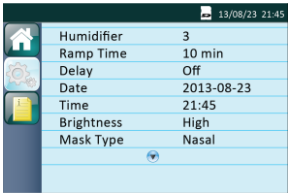


Fig. 15-10

(2) Returning to the Main Interface

Move the cursor to the **Home** option by turning **the Knob** , as shown in Fig. 15-11.


Fig. 15-11

Press **the Knob** to exit the Patient Menu. The screen will display the Main Interface shown in Fig. 15-1 or Fig. 15-2.

## *15.2 Options of the Patient Menu and Corresponding Descriptions*

| Option | Range | Description |
|---|---|---|
| Humidifier | Off, 1 ～ 5 | There are five humidity levels available. As the numbering increases, the humidity rises accordingly. "Off" means the humidifier is turned off. The default setting is "**2**" |
| 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 numbering is, the more pressure the device reduces. "Off" means this feature is disabled. The default setting is "**Off**" |
| Ramp Time | 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 default setting is "**10 minutes**". The screen displays a real-time countdown of the remaining ramp time in minutes |
| 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 $cmH_2O$) after you press **the Knob** 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 airfolw stops delivering air instantly after you press **the Knob**. The default setting is "**Off**" |
| Date | 2000-01-01 — 2099-12-31 | Set date by adjusting this option |
| Time | 00:00 — 23:59 | Set time by adjusting this option |
| Brightness | High / Low | Setting screen brightness by adjusting this option. The default setting is "**High**" |

| | | |
|---|---|---|
| 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, Inc. 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 |
| Use Time | 0 ～ 50000 h | Use Time displays how long has the device been used by the patient |
| About | —— | Displays related information of the device (Model, SN, Version, ID). This is read-only and cannot be edited |

## *16. Alert*

| Alert Message | Description |
|---|---|
| Power Failure!!! | An audible alert will sound in 6 s if the device is accidentally disconnected from power when it is delivering air.<br>Note:<br>(1) The alert will not sound if power failure occurs when the device is in standby state.<br>(2) No alert message on the screen during a power failure |
| Device Fault!!! | An audible alert will sound if no airflow comes out of the machine; the screen will display "**Device Fault!!!**" |
| Leak!! | When the airflow is on, an audible alert will sound in 40 s if the air leak rate is excessive; the screen will display "**Leak!!**" |
| Low Input Voltage!! | If the voltage supplied by power adaptor is lower than 22V, an audible alert will sound and the screen will display "**Low Input Voltage!!**" |
| Humidifier Failure!! | When humidifier is applied, an audible alert will sound when the humidifier fails to work; the screen will display "**Humidifier Failure!!**" |
| Please Change Filter! | When the Filter Alert feature is enabled, an audible alert will sound if the preset replacement time reaches but without replacing the air filter; the screen will display "**Please Change Filter!**" |
| SD Card Full! | The screen will display "**SD Card Full!**" if the SD card has reached its maximum capacity |
| Reinsert SD card! | The screen will display "**Reinsert SD card!**" if the SD card fails to work |

# 17. 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 tube 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, so you do not get burned.

• The device shall not be serviced or maintained while in use with a patient.

• Sterilization of this device and its components other than recommended is not permitted.

• 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.

## 17.1 Cleaning the Mask and Headgear

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

## 17.2 Cleaning the Water Chamber

(1) **Opening the Water Chamber:** Open the cap of the water chamber, as shown in Fig. 17-1.

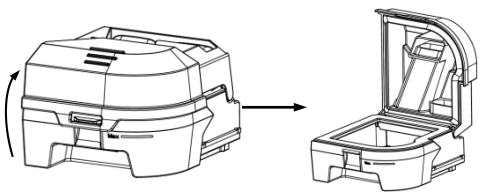

Fig. 17-1

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

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

• Inspect the water chamber for any leak or damage. Replace the water chamber if any damage is present.

• It is recommended to do daily cleaning of the water chamber.

## *17.3 Cleaning the Enclosure*

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

***CAUTIONS!***

• The device can 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.

## *17.4 Cleaning the Tube*

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

(2) Clean the tube in warm water which contains washing liquid, and then rinse it in clean water thoroughly.

(3) After cleaning, air-dry the tube in a cool, well-ventilated area, and avoid direct sunlight. It takes approximately 30 minutes to completely air-dry the tube. Check whether the tube is completely dry before re-use.

***CAUTION!***

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

## *17.5 Replacing the Air Filter*

(1) Open the air filter cap to remove the air filter.

(2) Put the new air filter in the filter area, and then place the filter cap back properly.

***CAUTIONS!***

• To avoid material damage, do not place the spare air filter in direct sunlight, humid environments, or temperatures below the freezing point. The air filter should be replaced every 2 weeks (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.

• Replacing the air filter and filter cap, device must be unplugged.

# *18. 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 5), the accuracy of the leakage alert will be affected.

(1) Use the 3B medical, Inc. carrying case to carry the device and accessories along with you. 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 the types of the power sockets in your destination. Bring, if necessary, a power socket adaptor which can be purchased in electronics stores.

(3) Remember to bring a spare air filter and the emergency documents (filled and signed by your physician) about this device. If you plan to travel by air, remember to bring the multi-language emergency documents about respiratory therapy, in case that the border and customs officers in your destination country inspect the device. With the emergency documents, 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 along with you to help security personnel understand the device.

# *19. 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, Inc. -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.

## *20. Technical Support*

Please contact 3B medical, Inc. 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, Inc. will provide the circuit diagram and / or other technical documents in whole or in part according to your needs.

## *21. Disposal*

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

# 22. 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.

## 22.1 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, leading to nasal mucosa irritation and subsequent dryness and swelling | Increase the humidity setting of the device.<br>Contact your physician, and continue treatment unless the physician suggests the opposite |
| Dry mouth and throat | Probably because 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 markings on the patient's face.<br>Add additional filling to the mask so it does not leak.<br>Contact your equipment supplier for an appropriate mask. Add additional filling to the mask if necessary |
| | 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 | Contract your equipment supplier for a correct-size mask |

| | | |
|---|---|---|
| | The patient is allergic to the materials of the mask | Contact your physician and equipment supplier.<br>Use a mask which is not made with natural rubber latex.<br>Place a lining between the skin and mask |
| Water in mask | When the humidifier is used, the humidified air tends to condense in the cold tube and mask if the room temperature is low | Turn the humidity setting down, or raise the room temperature. Place the tube under the quilt, or use the tube cover.<br>Hang the tube loosely, and the lowest part of the tube 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 determined according to the patient's conditions, and cannot treat sleep apnea if the treatment pressure is set too low | It takes a maximum of four weeks to adapt to pressurized air.<br>Relax and breathe through the nose. If the problem still exists, contact your physician |
| Obstructive sleep apnea symptoms recur | Probably because the patient sleeps with his or her mouth open, and the pressurized air goes out via the mouth, leading to blockage in the respiratory tract | Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details |
| The device is too noisy | The tube is not connected properly | Reconnect the tube 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 15.6 Replacing the Air 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 |

## *22.2 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 tube is not connected properly | Reconnect the tube properly |
| | There may be holes in the mask or pressure sensing tube | 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 16.6 Replacing the Air 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 |

# *23. 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<br>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<br>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<br>IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions<br>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)<br><br>IEC 61000-4-2 | ±8 kV contact<br><br>±15 kV air | ±8 kV contact<br><br>±15 kV air | Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% |
| Electrical fast transient / burst<br><br>IEC 61000-4-4 | ±2 kV for power supply lines | ±2 kV for power supply lines | Mains power quality should be that of a typical commercial or hospital environment |
| Surge<br><br>IEC 61000-4-5 | ±1 kV<br>line(s) to line(s) | ±1 kV<br>line(s) to line(s) | Mains power quality should be that of a typical commercial or hospital environment |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br><br>IEC 61000-4-11 | 0% $U_T$; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0% $U_T$; 1 cycle<br><br>70% $U_T$; 25 / 30 cycle<br>At 0°<br><br>0% $U_T$; 250 / 300 cycle | 0% $U_T$; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0% $U_T$; 1 cycle<br><br>70% $U_T$; 25 / 30 cycle<br>At 0°<br><br>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<br><br>IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment |
| Note: $U_T$ 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<br><br>Radiated RF IEC 61000-4-3 | 3 V<br>0.15 MHz ~ 80 MHz<br>6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz<br><br>10 V/m<br>80 MHz to 2.7 GHz | 3 V<br>0.15 MHz ~ 80 MHz<br>6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz<br><br>10 V/m<br>80 MHz to 2.7 GHz | Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distance**<br>$d = 1.17\sqrt{p}$<br>$d = 0.35\sqrt{p}$ 80 MHz to 800 MHz<br>$d = 0.70\sqrt{p}$ 800 MHz to 2.5 GHz<br>Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b]<br>Interference may occur in the vicinity of equipment marked with the following symbol: |

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.<br>**Recommended separation distance**<br>$E = \frac{6}{d}\sqrt{P}$<br>Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| 450 | 2 | 0.3 | 28 | 28 | |
| 710<br>745<br>780 | 0.2 | 0.3 | 9 | 9 | |
| 810<br>870<br>930 | 2 | 0.3 | 28 | 28 | |
| 1720<br>1845<br>1970 | 2 | 0.3 | 28 | 28 | |
| 2450 | 2 | 0.3 | 28 | 28 | |
| 5240<br>5500<br>5785 | 0.2 | 0.3 | 9 | 9 | |

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.

# *24. 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.
203 Avenue A NW, Suite 300
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

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www.3Bproducts.com