User Manual

BPAP System

G3 B20A / G3 B25S / G3 B25A / G3 B25VT /

G3 B30VT / G3 B30SV / G3 LAB

CE0123

Table of Contents

1. Symbols

1.1 Control Buttons

	Home Button
	Start / Stop Button
	Knob

1.2 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 (15º tilted)
	There are high-pressure, be careful of electric shock
	Hot Surface
	Serial Number of the Product
	Manufacturer
	Authorized Representative in the European Community

	Do not use the product if the package is damaged
	Disassembly is prohibited
	Maximum water level
CE 0123	European CE Declaration of Conformity
	Product is intended for use by a single patient only
	Lot number
	Non-Ionizing Radiation
	SD Card
	WEEE Marking
	Logo of BMC Medical Co., Ltd.
	Air Inlet
	Air Outlet

2. Warning, Caution and Important Tip

WARNING!
Indicate the possibility of injury to the user or operator.

CAUTION!
Indicate the possibility of damage to the device.

IMPORTANT TIP!
Place emphasis on an operating characteristic.

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

3. Intended Use

The G3 B20A / B25S / B25A / B25VT / B30VT BPAP System is a Bi-level PAP (Bi-level Positive Airway Pressure) device, which is intended to provide non-invasive ventilation for patients with Obstructive Sleep Apnea (OSA) and Respiratory Insufficiency. These devices are intended for adult patients by prescription in the home or hospital/institutional environment. The G3 B30SV BPAP System is a Bi-level PAP (Bi-level Positive Airway Pressure) device, which is intended to provide non-invasive ventilation for patients with Obstructive Sleep Apnea (OSA), Central Sleep Apnea (CSA), Mixed Sleep Apnea (MSA), and periodic breathing. This device is intended for adult patients by prescription in the home or hospital/institutional environment.

The G3 LAB BPAP System is a Bi-level PAP (Bi-level Positive Airway Pressure) device, which is intended to provide non-invasive ventilation treatment and titration for patients with Obstructive Sleep Apnea (OSA), Central Sleep Apnea (CSA), Mixed Sleep Apnea (MSA), periodic breathing and Respiratory Insufficiency. This device is intended for adult patients by prescription in a clinical environment.

The optional SpO_2 module used with the G3 BPAP Series together is indicated for monitoring patients' SpO_2 and Pulse Rate auxiliarily.

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 BMC 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.

CAUTION!

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

IMPORTANT TIP!

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

4. 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.

5. 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 H_2O/L

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

Maximum Operating Pressure: 40 hPa

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

Maximum Delivered Gas Temperature: ≤ 43°C

Cellular Module

Receiver Frequency Band: 850/900/1800/1900MHz

FCCID：XMR201202M35

Max RF power output: 33.0 dBm

WiFi Kit

FCCID: AZY-HF-LPT200

Mode of Operation

Continuous

Work Mode

CPAP, AutoCPAP, S, AutoS, S/T, T

SD Card

The SD card can record patient data and fault information

AC Power Consumption

100 – 240 V ～, 50 / 60 Hz, 2.5A Max

100 – 240 V ～, 50 / 60 Hz, 2A Max

Main device input

24V, 3.33A

Device offer to Heated Tubing Communications Port

24 V ⎓ 18 W

Type of Protection against Electric Shock

Class II Equipment

Degree of Protection against Electric Shock

Type BF Applied Part

Degree of Protection against Ingress of Water

IP22

Pressure Range

Model	Work Mode	Pressure Range
G3 B20A G3 B25S G3 B25A G3 B25VT	CPAP	4.0 ～ 20.0 hPa
	S, AutoS, T, S/T	IPAP: 4.0 ～ 25.0 hPa; EPAP: 4.0 ～ 25.0 hPa; in 0.5 hPa increments.
G3 B30VT G3 B30SV	CPAP	4.0 ～ 20.0 hPa
	S, AutoS, T, S/T	IPAP: 4.0 ～ 30.0 hPa; EPAP: 4.0 ～ 25.0 hPa; in 0.5 hPa increments.
G3 LAB	CPAP, AutoCPAP	4.0 ～ 20.0 hPa
	S, AutoS, T, S/T	IPAP: 4.0 ～ 30.0 hPa; EPAP: 4.0 ～ 25.0 hPa; in 0.5 hPa increments.

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

Pressure Display Accuracy

±(0.8 hPa+4%)

Static Pressure Stability

±0.5 hPa

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 hPa.

Sound Power Level

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

Maximum Flow

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

SpO_2

Range: 35% ～ 100%

The margin of error for SpO_2 between 70% and 100% is ±3%. No strict accuracy requirements for SpO_2 below 70%.

Pulse Rate

Range: 30 ～ 240 BPM

Margin of Error: ±2%

Wavelengths

Red: 663 nanometers

Infrared: 890 nanometers

Maximal Optical Output Power

Less than 1.5 mw maximum average.

Air Tubing

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

6. 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 turn **the Knob** to reduce the pressure and then gradually increase the pressure to the therapeutic pressure setting so that you can fall asleep more comfortably.

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

S – A bi-level mode which responds to both your inhalation and exhalation by increasing pressure when you start to inhale and decreasing pressure when you start to exhale. There is no automatic delivery of 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 presetted by home care provider. While working in auto feature, the device will automatically adjust the IPAP and EPAP if it detects a sleep apnea.

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

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

7. 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. This feature is always enabled.

SmartC

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

SmartA

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

SmartB

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

ASV

Under S/T mode, ASV function can be set to be ASV, ASV Auto and Off. If this function is set to be ASV, the device will predict the minute ventilation according to the real-time collected air flow data, and adjust the IPAP according to the minute ventilation.

ASV Auto

Under S/T mode, ASV function can be set to be ASV, ASV Auto and Off. If this function is set to be ASV Auto, while achieving the ASV function, the respiratory events will be judged and the EPAP will be adjusted according to the respiratory events.

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.

8. Model

Model	Product Contents		Work Mode	Maximum Work Pressure (hPa)
	Main Device	Optional Accessory		
G3 B20A	Main device (3.5-inch TFT)	Tubing (optional), Mask (optional), SpO_2 Kit (optional), Finger clip Pulse Oximeter Sensor (optional), Finger cuff Pulse Oximeter Sensor (optional), Disposable Pulse Oximeter Sensor (optional), WiFi kit (optional), Cellular Module (optional), Heated Tubing (optional), PM2.5 Filter (optional)	CPAP, S, AutoS	20
G3 B25S	Main device (3.5-inch TFT)		CPAP, S	25
G3 B25A	Main device (3.5-inch TFT)		CPAP, S, AutoS	25
G3 B25VT	Main device (3.5-inch TFT)		CPAP, S, T, S/T	25
G3 B30VT	Main device (3.5-inch TFT)		CPAP, S, T, S/T	30
G3 B30SV□	Main device (3.5-inch TFT)		CPAP, S/T	30
G3 LAB	Main device (3.5-inch TFT)		CPAP, AutoCPAP, S, AutoS, T, S/T	30

9. 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.	Mask	1	Optional
6.	PM2.5 Filter	1	Optional
7.	WiFi kit	1	Optional
8.	Cellular Module	1	Optional
9.	SpO_2 Kit	1	Optional
10.	Finger clip Pulse Oximeter Sensor	1	Optional
11.	Finger cuff Pulse Oximeter Sensor	1	Optional
12.	Disposable Pulse Oximeter Sensor	1	Optional
13.	Tubing	1	Optional
14.	Heated Tubing	1	Optional
15.	SD Card	1	Optional
16.	Carrying Case	1	Optional
17.	Accompanying Documents	1	
18.	Power Cord Locker	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.

The Heated Tubing service life is six month. The WiFi kit and Cellular Module service life is one year.

SpO_2 Probe is applied part.

WARNINGS!

• This device should only be used with the mask and accessories manufactured or recommended by BMC 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 BMC or your health care provider.
• Please contact BMC to obtain an SD card if needed.

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.

10. System Features

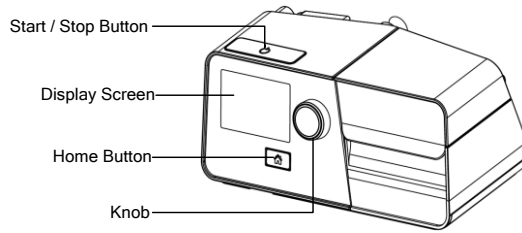

Fig. 10-1

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.

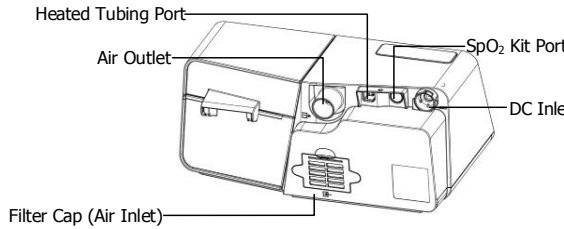

Fig. 10-2

Name	Function
Air Outlet	Deliver pressurized air; connects to the tubing
SpO_2 Kit Port (optional)	Connected to SpO_2 Kit (Not for connection to un-recommended devices)
Heated Tubing Port	Connected to the plug of the heated tubing
DC Inlet	An inlet for the DC power supply
Filter Cap (Air Inlet)	Place the cap on the air filter, which is used to filter dust and pollen in the air entering the device

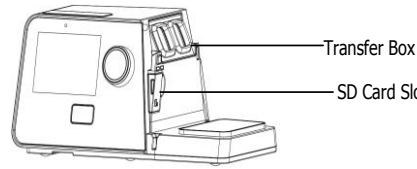

Fig. 10-3

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

11. First Time Setup

11.1 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 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.

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

(1) Attach the air filter to the filter cap, as shown in Fig. 11-1.

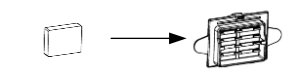

Fig. 11-1

(2) Install the filter cap containing the air filter to the device, as shown in Fig. 11-2.

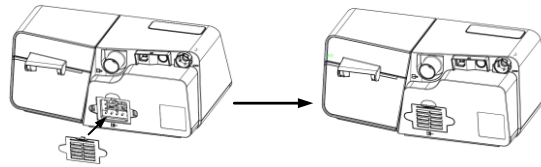

Fig. 11-2

(3) Change the air filter and filter cap to the PM2.5 filter, as shown in Fig. 11-3.

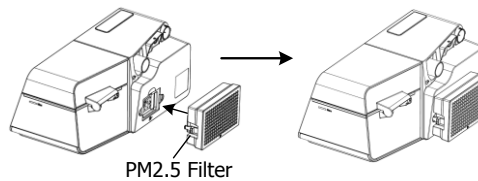

Fig. 11-3

CAUTION!

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

• Installing the air filter and filter cap or PM2.5 filter, device must be unplugged.

11.3 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.

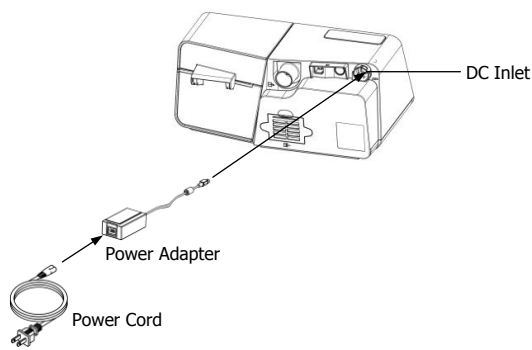

Fig. 11-4

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.

11.4 Connecting to Power Cord Locker

(1) Insert the power cord locker into the device, as shown in Fig. 11-5, and then rotated to the left for assembly to the device.

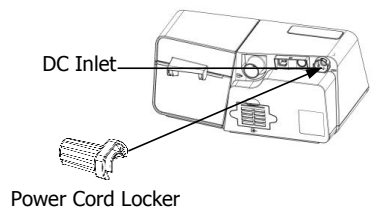

Fig. 11-5

(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.

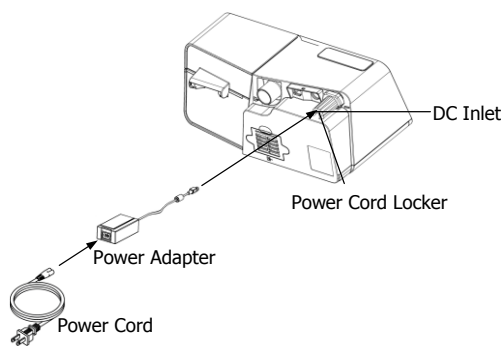

Fig. 11-6

The function of the locker is to prevent the power cord falling off from the power port.

11.5 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. 11-7.

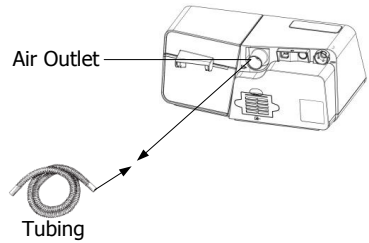

Fig. 11-7

(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. 11-8.

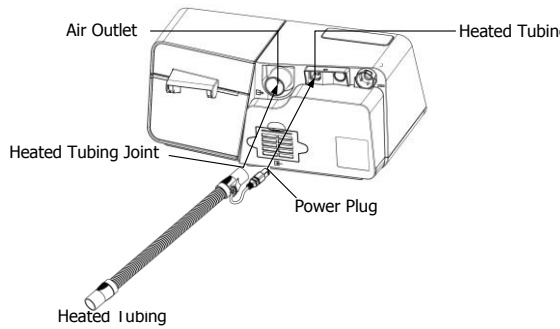

Fig. 11-8

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. 11-9.

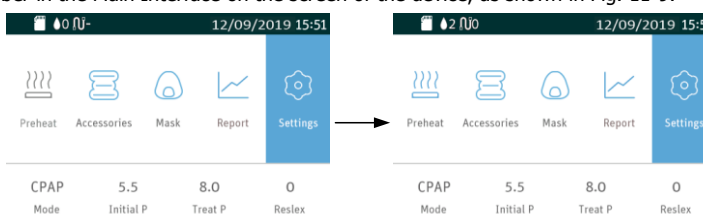

Fig. 11-9

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. 11-10.

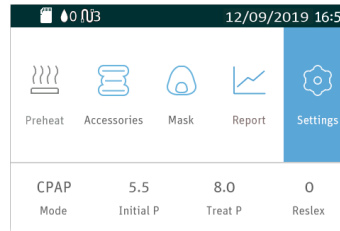

Fig. 11-10

(3) Connect the other end of the tubing to the mask according to the user manual for the mask. Wear 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 CO_2 rebreathing, the patient should observe the following instructions:

- Use the accompanying tubing and mask provided by BMC.
- 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.

11.6 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 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 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 does not exceed the work pressure of the device.

11.7 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. 11-11.

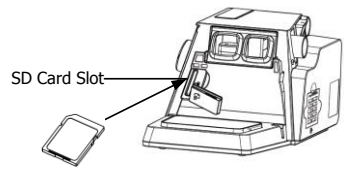

Fig. 11-11

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 can only be removed after the device stops delivering air.

11.8 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 BMC 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.

12. Routine Use

12.1 Connecting the Tubing

Connect the power cord, power adapter, and tubing properly according to the instructions in the First Time Setup (Chapter 11). 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.

12.2 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 until there are no airflow leaks around the mask.

12.3 Turning on the Airflow

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

12.4 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, and avoid heating the device with an empty water chamber.

12.5 Using the Ramp Feature

Every time the feature is enabled, 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 use the ramp feature as often as you wish during sleep.
- The ramp feature is not prescribed for all users.

12.6 Accessing the iCode

After the device is powered on, move the cursor to the icon by turning **the Knob**, as shown in the Fig. 12-1. Access the iCode information by pressing **the Knob**, the screen displays the iCode Inerface, as shown in the Fig. 12-2.

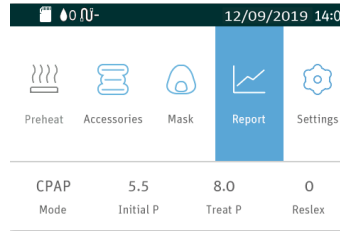

Fig. 12-1

Fig. 12-2

12.7 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.

13. 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.

13.1 Filling the Water Chamber

13.1.1 Removing the Water Chamber

Press down the water chamber, and then remove it, as shown in Fig. 13-1.

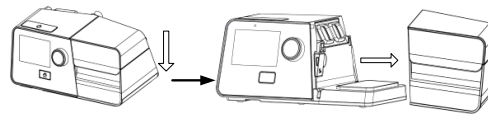

Fig. 13-1

WARNING!

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

13.1.2 Filling Water

(1) Open the cap, as shown in Fig. 13-2, and fill the water chamber with approximately 360 ml of water, as shown in Fig. 13-3. Make sure that the water does not exceed the maximum water level line.

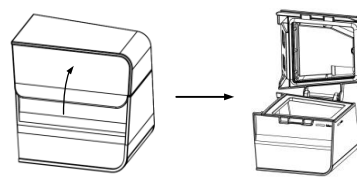

Fig. 13-2

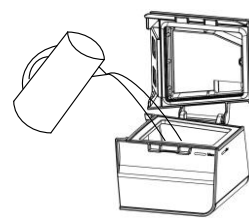

Fig. 13-3

(2) Open the cap, and fill the water chamber with approximately 360 ml of water, as shown in Fig. 13-4. Make sure that the water does not exceed the maximum water level line.

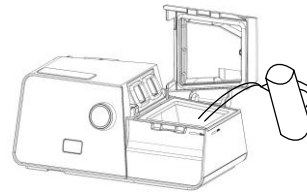

Fig. 13-4

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 that remove the water chamber from the device. The users can open the cap of the water chamber directly to fill the water.

13.1.3 Returning the Water Chamber

Close the cap after it is filled with water, as shown in Fig. 13-5, and return it to the device, as shown in Fig. 13-6.

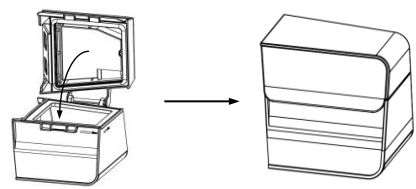

Fig. 13-5

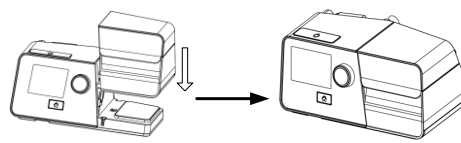

Fig. 13-6

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.

13.2 Emptying the Water Chamber

(1) **Removing the water chamber** according to instructions in 13.1.1.

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

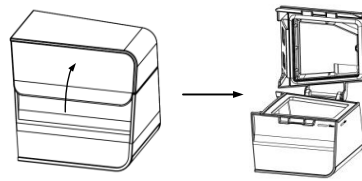

Fig. 13-7

CAUTION!

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

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

13.3 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. 13-8. The temperature of the water in the water chamber maintains a constant set level.

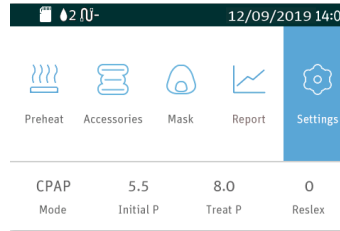

Fig. 13-8

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!

• 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.

14. Using the SpO_2 Kit

Connect the SpO_2 Kit to the device according to the user manual for the SpO_2 Kit. After the device is powered on, start the device, the screen of the device then displays the Main Interface shown in Fig. 14-1. The patient's blood oxygen saturation and pulse rate can be clearly seen during the course of therapy.

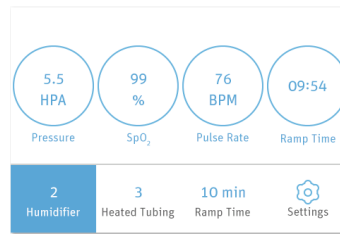

Fig. 14-1

For more details, please refer to the SpO_2 Kit user manual.

15. Using the Cellular Module and the WiFi kit

15.1 Connecting to Cellular Network

(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.

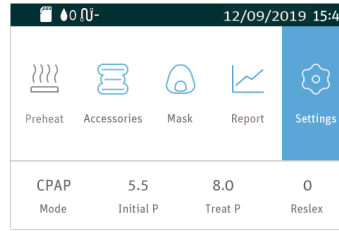

Fig. 15-1

(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).

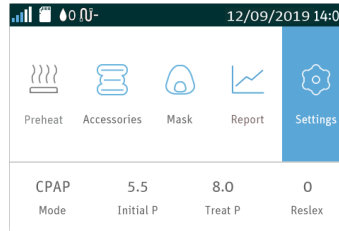

Fig. 15-2

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.

15.2 Connecting to WiFi Network

(1) Insert the WiFi kit into the device, and turn on the device. The device screen displays the Main Screen shown in Fig. 15-1. Turn **the Knob** until the cursor is on the icon , and the screen displays the Initial Setup Interface shown in Fig. 15-3. Press **the Knob** , and the first option on the Initial Setup Interface turns blue, as shown in Fig. 15-4.

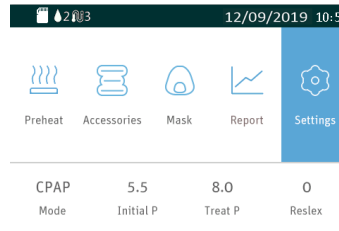

Fig. 15-3

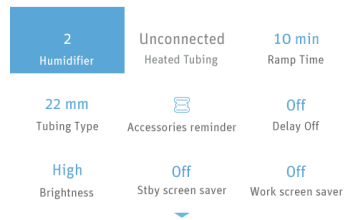

Fig. 15-4

(2) Turn **the Knob** until the cursor stays on the "**WiFi**" option, as shown in Fig. 15-5. Press **the Knob** , and the interface shown in Fig. 15-6 appears. Wait for 0-5 seconds to automatically access the "**WiFi**" setup interface.

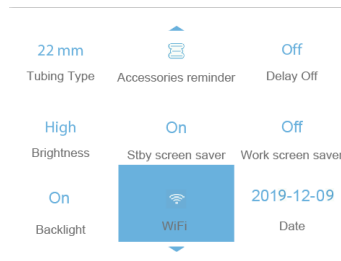

Fig. 15-5

Fig. 15-6

(3) The "**WiFi**" setup interface displays a certain number of available WiFi networks in a random order, as shown in Fig. 15-7. If a page turning symbol appears below the WiFi network list, it indicates that when the cursor is on the last WiFi network on that page, the user can turn **the Knob** to the right to see the remaining WiFi networks, as shown in figures 15-8. If the desired WiFi network is not listed, disconnect the device from the power supply, connect it to the power supply again, and then repeat steps (1) (2) to search for WiFi networks. Keep searching until the desired WiFi network is found.

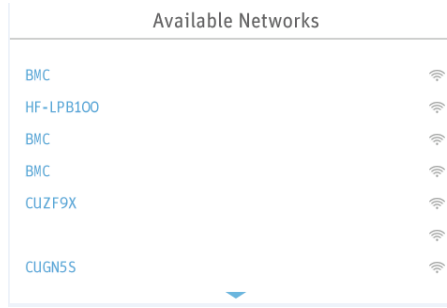

Fig. 15-7

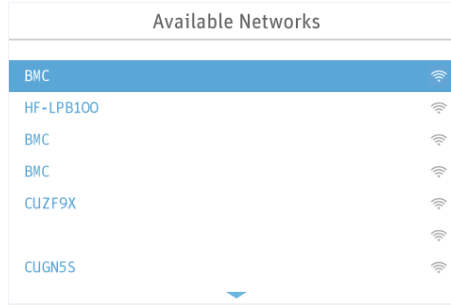

Fig. 15-8

Note: are page turning symbols.

If no WiFi networks are found, the "**WiFi**"setup interface displays "**No Available WiFi**", as shown in Fig. 15-9.

Fig. 15-9

(4) After the desired WiFi network is found, press the **Knob**, turn **the Knob** to select this WiFi network. Press **the Knob** to access the WiFi password input interface. The password is at least 8 characters in length, and can contain uppercase and lowercase English letters and digits 0 ～ 9, as shown in Fig. 15-10. After the password is entered, turn **the Knob** until the cursor stays on the **Confirmation Key**. Press **the Knob** to connect to the WiFi network, as shown in Fig. 15-11. At this moment, the user must not perform any operations, and should wait 0-15 seconds for the connection result.

Fig. 15-10

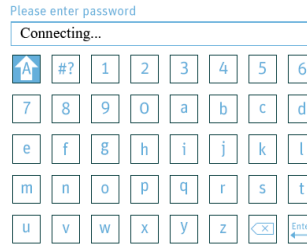

Fig. 15-11

If the WiFi network is connected successfully, the screen will return to the "**WiFi**" setup interface, displaying "**connected**" to the right of the WiFi network name, and the WiFi symbol will become blue, as shown in Fig. 15-12. If connection to the WiFi network fails, the password input box displays "**Connection Failed!**" as shown in Fig. 15-13.

Fig. 8-13

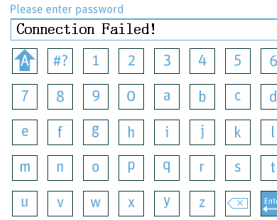

Fig. 8-14

To switch from one successfully connected WiFi network to another, select the desired new network and enter the correct password to connect to it.

If the desired WiFi network is a public network that does not require a password, turn **the Knob** directly after accessing the password input interface until the cursor stays on the **Confirmation Key**. Press **the Knob** to connect to the network.

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 properly, the screen displays the Main Interface shown in Fig. 16-1. Press **the Start / Stop Button**, and the device will start delivering air, the screen displays the Main Interface shown in Fig. 16-2 (Applicable to G3 B20A, G3 B25S, G3 B25A models) or Fig. 16-3 (Applicable to G3 B25VT、G3 B30VT、G3 B30SV、G3 LAB、MBC-790-30ATHmodels).

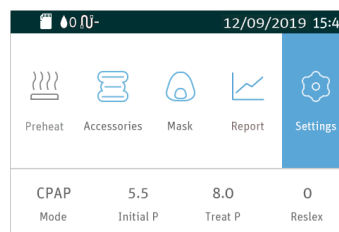

Fig. 16-1

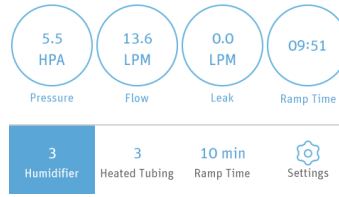

Fig. 16-2

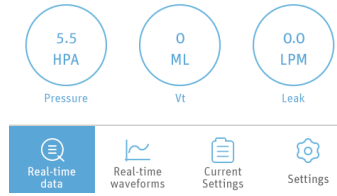

Fig. 16-3

Note: The above interface only applicable to the device does not activate the SmartC, SmartA or SmartB. If the SmartC, SmartA or SmartB is enabled, and the symbol S will appear in the status bar at the top of the screen, as shown in Fig. 16-4.

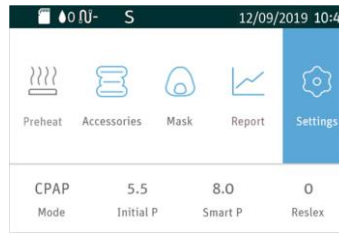

Fig. 16-4

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

Note: As the humidity levels is off, the Preheat Function Icon will become gray, as shown in Fig. 16-2.

16.1.2 Bringing up the Initial Setup Interface

After the display 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. 16-5.

Fig. 16-5

Note: The **Heated Tubing** option can only be adjusted when the device is connected to the Heated Tubing, as shown in Fig. 16-6.

Fig. 16-6

16.1.3 Selecting Options

As you turn **the Knob** clockwise, the cursor moves downwards from one option to another. When the cursor is on a certain option, press **the Knob**, and the color of the option is changed, meaning that the option can now be adjusted, as shown by the **Humidifier** option in Fig. 16-7.

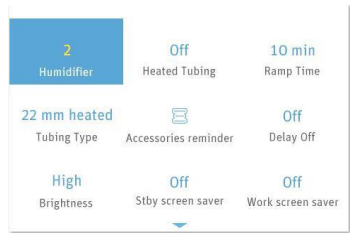

Fig. 16-7

16.1.4 Adjusting Options

Adjust the option by turning **the Knob**. As shown in Fig. 16-7, 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 leve, as shown in Fig. 16-8.

Fig. 16-8

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. 16-9.

Fig. 16-9

16.1.6 Turning Pages

When the cursor is on **Work screen saver**, the last option shown in Fig. 16-9, the remaining options will appear on a new page if you continue to turn **the Knob** clockwise, as shown in Fig. 16-10.

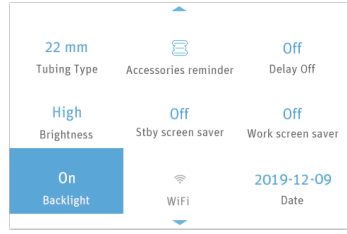

Fig. 16-10

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 six humidity levels available. As the numbering increases, the humidity rises accordingly. "Off" means the humidifier is turned off.
Preheat	On / Off	Set humidifier to preheat by adjusting this option. This feature 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 numbering 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 numbering 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 seconds. The screen displays a real-time countdown of the remaining ramp time in seconds
Delay	On / Off	When the humidifier is on, this feature allows the airflow to continue for about 15 minutes at a low pressure (about 2 hPa) after you press **the Start / Stop** to discontinue 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 Start / Stop**.
Date	2000-01-01 — 2099-12-31	Set date by adjusting this option
Date Format	yy mm dd / mm dd yy / dd mm yy	Turn **the Knob** to choose among three date formats.
Time	00:00 — 23:59	Set time by adjusting this option

Time Format	12-hour / 24-hour	Turn **the Knob** to choose between the two time formats.
Brightness	High / Low	Setting screen brightness by adjusting this option.
Backlight	Auto / On	The backlight of the LCD screen can be set to "Auto" or "On." Turn **the Knob** to choose between the two modes. If it is set to "Auto," the backlight will turn off automatically after 30 seconds of inactivity. If it is set to "On," the backlight will always be on.
Mask Type	Full Face; Nasal; Pillow; Other	There are three mask types available, Full Face (full-face mask), Nasal (nasal mask), and Pillow (nasal pillow mask). When selecting masks other than the above three types of BMC masks, the patient can identify the masks as other.
Mask Fititing Test	Start the Mask Fititing Test	Test whether the mask is worn correctly,the screen will display the "great" icon if it is qualified, otherwise the screen will display the "need to adjust" icon.
iCode	iCode, iCode QR, iCode QR +	iCode provides access to the patient's compliance data during a recent time period. The iCode mode displays data in sequences of numbers, and the iCode QR / iCode QR + mode displays data in two-dimensional codes
WiFi	——	Connect to WiFi network by adjusting this option
Use Time	0 ～ 50000 h	Use Time displays how long has the device been used by the patient. The use time can be erased
Consumables Reminder	——	Reset the use time of the filter, tubing and mask
Consumables Reminder	30 days/60 days/180 days/1 year/off	This function is used for setting filter reminder, tube reminder and mask reminder. After opening, can set the use time of filter, tube and mask.
Language	English/ Español/ Português/ Deutsch/ 中文（简体）/Français/ Polski/ Italiana/Türk/ Русский/ Nederlands/ Ελληνικά/ 한국어	Turn **the Knob** to choose among the two languages available. The setting is only valid when the device is inserted a SD card with language pack.
About	——	Displays related information of the device (Model, SN, Version, ID). This is read-only and cannot be edited.

17. Alarm

This chapter describes device alarms and the responses operators make to different alarms.

After running, disconnect the device from the power supply by unplugging the power cord, an audible alarm sounds like "beep beep beep, beep-beep, beep beep beep, beep-beep", which means the alarming system of the device works normally.

17.1 Grading for Alarming and Description

The grading for alarming and description of this equipment is presented as follows:

Grade	Sign of Grading	Description
High	!!!	Requires operator to make instant response
Intermediate	!!	Requires operator to make instant on-time response
Low	!	Requires operator to be more cautious about the change of the state of equipment

17.2 Visual Alarming

The grading for the visual alarming is expressed by the background of the alarming information on the top of the screen and the color of the LED light under the silence key, which is described as follows:

Grade	Visual	Description
High	Red	Red light flickers—high-grade alarming
Intermediate	Yellow	Yellow light flickers—intermediate alarming
Low	Yellow	Yellow light indicates in a fixed manner—low-grade alarming

17.3 Auditory Alarming

In the case of alarming, the alarming sounds at different grades will occur and are described as follows:

Grade	Auditory	Description
High	●●● ●● ●●● ●●	beep beep beep beep-beep beep beep beep beep beep
Intermediate	● ● ●	beep beep beep
Low	●	beep

In accordance with the requirements of the relevant standards, the volume of the audible alarm signal meets the requirements, and the sound pressure range of the measured auditory alarm signal is described as follows:

Alarm Condition	Measured sound pressure level（dB）	A-weighted sound pressure level averaged over the measurement surface（dB）	Remarks
High priority	52.2	38.5	Maximum volume
Median priority	51.8	39.6	Maximum volume
Low priority	51.8	37.2	Maximum volume

17.4 Alarming Silence

When the breathing machine sounds an alarm, press the home button ⌂ and it will become silent for 100 to 120 seconds and then the alarm sounds again immediately after the end of the silence; if the home button is re-pressed during the silence period, the alarm sound will resume.

17.5 Alarming Information and Description

Alarm Message	Alarm Priority	Alarm Type	Description
Power Failure!!!	High Priority	Technology Alarm	An audible alarm will sound in 6s if the device is accidentally disconnected from power when it is delivering air. Alarming duration time is no less than 30s. **Note:** (1) The alarm will not sound if power failure occurs when the device is in standby state. (2) No alarm message on the screen during a power failure
Device fault!!!	High Priority	Technology Alarm	An audible alarm will sound if no airflow comes out of the machine; the screen will display "**Device fault!!!**"
Tube disconnected!!! (only applies to G3 B25VT, G3 B30VT, G3 B30SV and G3 LAB)	High Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the tube accidentally detached, the screen will display "**Tube disconnected!!!**"
High Pressure!!!	High Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the airway pressure exceeds the warning threshold; the screen will display "**High Pressure!!!**". **Note:** The thresholds for different models: Off, 5 ～ 26 hPa applies to G3 B25VT, in 0.5 hPa increments, the default setting is "**25 hPa**". Off, 5 ～ 31 hPa applies to G3 B30VT, G3 B30SV and G3 LAB, in 0.5 hPa increments, the default setting is "**30 hPa**"

Low Pressure!!	Middle Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the airway pressure is below the warning limen; the screen will display "**Low Pressure!!**". Note: The limens for different models: Off,3 ～ 24 hPa applies to G3 B25VT, in 0.5 hPa increments, the default setting is "**4 hPa**". Off, 3 ～ 29 hPa applies to G3 B30VT, G3 B30SV and G3 LAB, in 0.5 hPa increments, the default setting is "**4 hPa**"
Low RR!!! (only applies to G3 B25VT, G3 B30VT, G3 B30SV and G3 LAB)	High Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the respiratory rate is below the limen; the screen will display "**Low RR!!!**". Setting range: Off, 4 ～ 40 BPM, in 1 BPM increments, the default setting is "**6 BPM**". **Note:** This function is available under the work mode of S/T or T
Low SpO_2!!!	High Priority	Function Alarm	When SpO_2 Kit is applied, an audible alarmwill sound when the value of SpO_2 is lower than the warning threshold; the screen will display "**Low SpO_2!!!**". Setting range: Off, 70% ～ 100%, in 1% increments, the default setting is "**85%**". **Note:** This function is available only when the device is equipped with SpO_2 Kit
Leak!!	Middle Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the air leak rate exceeds 150 L/min; the screen will display "**Leak!!**". The alarming duration time is no less than 30s.
Mask Blocked!! (only applies to G3 B25VT, G3 B30VT, G3 B30SV and G3 LAB)	Middle Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the vents of the mask are blocked; the screen will display "**Mask Blocked!!**"
Low MV!! (only applies to G3 B25VT, G3 B30VT, G3 B30SV and G3 LAB)	Middle Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the minute volume is below the warning limen; the screen will display "**Low MV!!**". Setting range: Off, 1 ～ 30 L/min, in 1 L/min increments, the default setting is

			"**1 L/min**"
Low Input Voltage!!	Middle Priority	Technology Alarm	If the voltage supplied by power adaptor is lower than 22V, an audible alarm will sound and the screen will display "**Low Input Voltage!!**"
High RR!! (only applies to G3 B25VT, G3 B30VT, G3 B30SV and G3 LAB)	Middle Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the respiratory rate exceeds the threshold; the screen will display "**High RR!!**". Setting range: Off, the setting value of Low RR ～ 80 BPM, in 1 BPM increments, the default setting is "**40 BPM**". **Note:** This function is avaliable under the work mode of S/T or T
Humidifier Failure!!	Middle Priority	Function Alarm	When humidifier is applied, an audible alarm will sound when the humidifier fails to work in 10 minutes; the screen will display "**Humidifier Failure!!**"
Please Change Filter!	Low Priority	Technology Alarm	When the Filter Alarm feature is enabled, an audible alarm will sound if the preset replacement time reaches but without replacing the air filter; the screen will display "**Please Change Filter!**". The default setting is "**Off**".
Please Change Tube!	Low Priority	Technology Alarm	When the tubing Alarm feature is enabled, an audible alarm will sound if the preset replacement time reaches but without replacing the tubing; the screen will display "**Please Change Tube!**"
Please Change Mask!	Low Priority	Technology Alarm	When the Mask Alarm feature is enabled, an audible alarm will sound if the preset replacement time reaches but without replacing the mask; the screen will display "**Please Change Mask!**"
SD Card Full!	Low Priority	Technology Alarm	The screen will display "**SD Card Full!**" if the SD card has reached its maximum capacity
Reinsert SD card!	Low Priority	Technology Alarm	The screen will display "**Reinsert SD card!**" if the SD card fails to work

Note: the delay time of alarming system of this device is no more than 1s.

17.6 Reposition of Alarming

After the elimination of the alarming faults, the residual alarming information still exists (alarming information is shown on the top of the screen without any visual and auditory alarming), and turn the button leftwards or rightwards to reduce the residual alarming information.

17.7 Alarming Journal

The alarming journal is designed for the breathing machine to record the latest 6 alarming information. Reserved inside the machine, the alarming journal will not be lost after the power supply interruption and the latest alarming will replace the former one with 6 reserved.

WARNINGS!

• Prior to the use of equipment, the oeprators should examine the current alarming pre-arrangement to check if it is applicable to each case of patient, and such pre-arrangement can only be changed by the professional doctors and must not be modified by the patients at home.

• In the case of the suspension of the power or the power loss for no less than 30 seconds, it will restore the last set alarming value on the next oepration.

CAUTION!

• The information of alarming journal will be maintained when the device is powered down, but the instantaneous time of power down will not be recorded.

17.8 Alarming Verification

Turn on the device, and then check the alarming system of the device at any time.

Tube disconnected alarm test

(1) When the device is working normally, adjust the device to the appropriate patient settings. Remove the tube thar connected to the air outlet of the device, and then confirm whether the tube disconnected alarm occurs.

(2) Press the home button and it will become silent for 100 to 120 seconds. If the alarm state has not been eliminated, and then the alarm sounds again immediately after the end of the silence.

(3) Reinstall the tube.

(4) Turn the button leftwards or rightwards to reduce the residual alarming information.

Mask Blocked alarm test

(1) When the device is working normally, adjust the device to the appropriate patient settings. Block the vent hole of the mask for 35 seconds by hand or soft cloth, and then confirm whether the mask blocked alarm occurs.

(2) Press the home button and it will become silent for 100 to 120 seconds. If the alarm state has not been eliminated, and then the alarm sounds again immediately after the end of the silence.
(3) Turn the button leftwards or rightwards to reduce the residual alarming information.

Low minute ventilation alarm test

(1) Connect the device to the simulated lung.
(2) Observe the value of minute ventilation displayed on the screen.
(3) Make the alarm value of the minute ventilation larger than the displayed value, and then confirm whether the alarm of low minute ventilation occurs.
(4) Press the home button and it will become silent for 100 to 120 seconds. If the alarm state has not been eliminated, and then the alarm sounds again immediately after the end of the silence.
(5) Turn the button leftwards or rightwards to reduce the residual alarming information.
(6) Set the alarm setting of the low minute ventilation as "Off".

Power failure alarm test

(1) Confirm whether an audible alarm will sound in 6s when the device is accidentally disconnected from power during it is delivering air.
(2) Reconnect the power supply, and then confirm if the device restarts delivering air.

WARNING!

• Adjust the device to the appropriate patient settings after the test and before use.

18. Cleaning and Disinfection

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, so you do not get burned.
• 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 SpO_2 Kit

For details, refer to the cleaning instructions in the user manual for the SpO_2 Kit.

18.3 Cleaning the Water Chamber

(1) **Opening the Water Chamber:** Open the cap of the water chamber, as shown in Fig. 16-1.

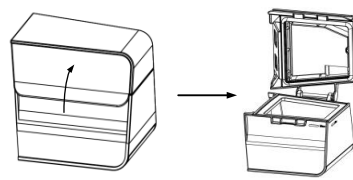

Fig. 18-1

(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 13.1.3.

WARNINGS!

• Emptying and cleaning the water chamber daily will help prevent mold and bacteria growth.
• Allow the water in the chamber to cool down to room temperature before removing it from the device.

CAUTIONS!

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

18.4 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.

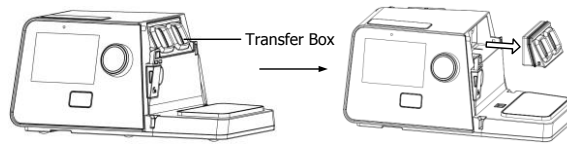

Fig. 18-2

(2) **Cleaning the Transfer Box:** Rinse the transfer box throughly in clean water. You may also clean the transfer box with a soft cloth which does not scratch it (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.

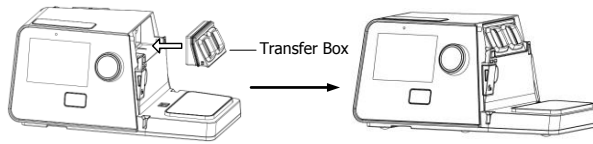

Fig. 18-3

CAUTION!

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

18.5 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.

18.6 Cleaning the Tubing

(1) Remove the tubing from the device and mask before cleaning.
(2) Clean the tubing in warm water which contains washing liquid, 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. Check whether the tubing is completely dry before re-use.

CAUTION!

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

18.7 Replacing the Air Filter / PM2.5 Filter

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

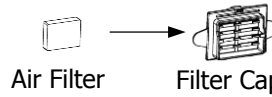

Fig. 18-4

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

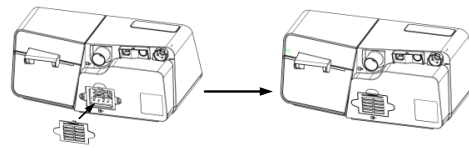

Fig. 18-5

(3) Change the air filter and filter cap to the PM2.5 filter, as shown in Fig. 18-6.

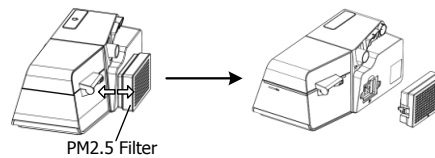

Fig. 18-6

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.

18.8 Disinfection

Generally speaking, if you have strictly followed the above cleaning instructions, you do not have to disinfect the device and / or water chamber. If the device is contaminated or used in clinical trials, you may purchase disinfectants from a home medical equipment company to disinfect the device.

Disinfection of the Water Chamber:

Prior to disinfection, clean the water chamber according to Section 18.3 "Cleaning the Water Chamber". The disinfection methods are as follows:

(1) Heat disinfection: Disinfect the water chamber by immersing it in tap water at 75°C±2°C for 30 minutes.

(2) Use mild disinfectants.

Disinfection of the SpO_2 Probe:

For details, refer to the disinfection instructions in the user manual for the SpO_2 Kit.

CAUTIONS!

• Disinfectants tend to damage materials and reduce the life of components. Try to select the appropriate disinfectant, and follow the disinfectant manufacturer's instructions and recommendations.

• After disinfection, check the disinfected component for any signs of damage. Replace any damaged component immediately.

WARNINGS!

• After disinfection, rinse any disinfected component in clean water thoroughly, especially components in close contact with the patient such as the mask, headgear, and tubing, so as to prevent disinfectant residuals from damaging the skin or respiratory tract or causing allergies.

• 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.

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 5), the accuracy of the leakage alarm will be affected.

(1) Use the BMC 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.

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 BMC -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 BMC Medical Co., Ltd., for technical support and documents.

22. Technical Support

Please contact BMC 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. BMC will provide the circuit diagram and / or other technical documents in whole or in part according to your needs.

23. Disposal

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

24. Troubleshooting

The table below lists common problems you may 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 fast 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 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. Add additional filling to the mask so it does not leak. 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. Use a mask which is not made with natural rubber latex. 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 tubing and mask if the room temperature is low	Turn the humidity setting down, or raise the room temperature. Place the tubing under the quilt, or use the tubing cover. Hang the tubing loosely, and the lowest part of the tubing should be lower than the patient's head
Nasal, sinus, or ear pain	Sinus or middle ear inflammation	Contact your physician immediately
Discomfort due to inability to adapt to the treatment pressure	The patient will feel uncomfortable when the treatment pressure is higher than 13 hPa. 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. 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 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. EMC Requirements

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

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

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V 0.15 MHz ～ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 10 V/m 80 MHz to 2.7 GHz	3 V 0.15 MHz ～ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 10 V/m 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. **Recommended separation distance** $d = 1.17\sqrt{p}$ $d = 0.35\sqrt{p}$ 80 MHz to 800 MHz $d = 0.70\sqrt{p}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applied. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. [b] Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 10 V/m.			

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

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

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

Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Recommended separation distances between RF wireless communications equipment

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency MHz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					

Note 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.

26. Limited Warranty

BMC Medical Co., Ltd. warrants that the device shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one (1) year for main unit and three (3) months for all accessories from the date of sale by BMC Medical Co., Ltd. to the dealer. If the product fails to perform in accordance with the product specifications, BMC Medical Co., Ltd. will repair or replace, at its option, the defective material or part. BMC Medical Co., Ltd. will pay customary freight charges from BMC Medical Co., Ltd. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

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

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

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