English

User Manual

Auto CPAP / CPAP System

G3 A20 / G3 C20

CE 0123

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1. Symbols

1.1 Control Buttons

	Home Button
	Start/Stop Button
	Knob

1.2 Device Symbols

	Follow Instructions for Use
	Consult Instructions for Use
	Type BF Applied Part (mask and SpO_2 probe)
	Class II (Double Insulated)
	For Indoor Use Only
	AC Power
	DC Power
IP22	≥12.5 mm Diameter, Dripping (15° tilted)
	There is high voltage, beware of electric shock
	Hot Surface
	Alarm Inhibit (Low SpO_2 alarm is not available)
	Serial Number
	Manufacturer
	Authorized Representative in the European Community
	Maximum Water Level
	Disassembly is Prohibited

English

	Single Patient Multiple Use
	CE Marking
	Batch Code
	Non-Ionizing Radiation
	SD Card
	Marking of Electrical and Electronic Equipment
	Logo of BMC Medical Co., Ltd.
	Air Inlet
	Air Outlet
	Complies with RTCA DO-160 section 21, category M.
	Caution
	Medical Device
	Unique Device Identifier
	Model Number
	Made in China, date of manufacture
	Temperature Limit
	Humidity Limitation
	Atmospheric Pressure Limitation
	Importer Information

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!

Indicate the possibility that such operation may affect the effectiveness or ease of use of the device.

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

3. Intended Use

The G3 A20 / G3 C20 system is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of adults Obstructive Sleep Apnea (OSA) only, either in the hospital or at home.

The device is to be used only on the instruction of a licensed health care professional. Your home care provider will make the correct pressure settings according to your health care professional's prescription.

Several accessories are available to make your OSA treatment with the device as convenient and comfortable as possible. To ensure that you receive the safe, effective therapy prescribed for you, use only the manufacturer accessories.

WARNINGS!

• The device is intended for adults use only.
• The 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 the manufacturer accessories.
• Do not bring the device or accessories into a Magnetic Resonance (MR) environment as it may cause unacceptable risks to the patient or damage to the device or MR medical devices. The device and accessories have not been evaluated for safety in an MR environment.
• Do not use the device or accessories in an environment with electromagnetic equipment such as CT scanners, Diathermy, RFID and electromagnetic security systems (metal detectors) as it may cause unacceptable risks to the patient or damage to the device. Some electromagnetic sources may not be apparent, if you notice any unexplained changes in the performance of the device, if it makes unusual or harsh sounds, disconnect the power cord and stop using it. Contact your home care provider.
• Any serious incidents in relation to this device should be reported to the manufacturer and the competent authority in your country.

• The optional SpO_2 Kit used with the device together is intended to be used to obtain readings of SpO_2 value as part of routine checkups.
• Do not introduce fragrances or aromatherapy odors into the interior of the machine.
• If you discover foreign objects inside the device, tube, or mask, you should immediately stop using the device and contact the provider of your device.

CAUTIONS!

• The 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

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, dehydration 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

IMPORTANT TIPS!

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

CAUTION!

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

5. Clinical benefit

(1) The clinical benefit of CPAP therapy is a reduction in apneas, hypopneas and sleepiness, as well as improved quality of life.

(2) The clinical benefit of humidification is the reduction of positive airway pressure related side effects.

6. Specifications

Statement:

All requirements for the flowrate, volume and leakage

a) are expressed at STPD,

b) except for those associated with the VBS, which are expressed at BTPS.

Results are expressed as STPD (Standard Temperature and Pressure, Dry). Use the following table to convert the STPD flow setting to BTPS (Body Temperature and Pressure, Saturated) flow.

Accuracy may be reduced by the presence of leaks, supplemental oxygen, tidal volumes <100 mL or minute ventilation <3 L/min.

STPD to BTPS conversion

Altitude (m)	Ambient pressure (hPa)	STPD to BTPS conversion factor
0	1013.25	1.12
500	956.53	1.19
1000	902.41	1.27
1500	850.80	1.36
2000	801.60	1.45
2500	754.73	1.54
3000	710.11	1.65

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

Environmental Conditions

	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 hPa to 1060 hPa	760 hPa to 1060 hPa
Altitude	Sea level to 2300 m	Sea level to 2300 m

Note: The device can be operated or transported by airplane without the restriction of altitude.

Heated Humidifier

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

Maximum Operating Pressure: 40 hPa

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

Maximum Delivered Gas Temperature: ≤43°C

Heated Humidifier performance

Breathing Tube

Mask Pressure (hPa)	Nominal RH output % at 22°C (72°F) ambient temperature	Nominal system output mg/L AH[1], BTPS[2]
	Setting 5 (maximum setting)	Setting 5[3] (maximum setting)
4	100%	>12
10	100%	>12
20	100%	>12

[1] AH - Absolute Humidity in mg/L

[2] BTPS - Body Temperature Pressure Saturated

[3] Humidifier performance meets ISO 80601-2-74:2021 tested at 15°C to 35°C (59°F to 95°F).

Note: In accordance with ISO 80601-2-74:2021, the measurement uncertainty of the manufacturer's test equipment is ± 1 mg/L BTPS for measures of humidification output.

Cellular Module

ELS62-W

Transportation Requirements	Shock, severe vibration, and moisture should be avoided in transportation
Frequency Bands	LTE FDD Band[1] 1/Band 2/Band 3/Band 4/Band 5/Band 7/Band 8/Band 20/Band 28/Band 66 LTE TDD Band 38/Band 40/Band 41
Communication Mode	LTE Cat 1
RED/GCF/ANATEL	E1177-222014/10709/12747-22-05015

ELS62-E

Transportation Requirements	Shock, severe vibration, and moisture should be avoided in transportation
Frequency Bands	LTE Band[1] 1/Band 3/Band 7/Band 8/Band 20/Band 28
Communication Mode	LTE Cat 1
RED	E1177-222027

[1] The LTE bands supported by Cellular Module are defined above, while the following Table 1 describes the Receiver Input Sensitivity.

Table 1 Receiver Input Sensitivity

Parameter	Conditions	Min.	Typical	Unit
BW: 5 MHz, UL: Modulation: QPSK; NRB=6; DL: Modulation: QPSK; NRB=4;	LTE 2100 Band 1	-96.8	-101.5	dBm
	LTE 1900 Band 2	-94.8	-101.0	dBm
	LTE 1800 Band 3	-93.8	-100.5	dBm
	LTE 2100 Band 4	-96.8	-101.5	dBm
	LTE 850 Band 5	-94.8	-102.0	dBm
	LTE 2600 Band 7	-94.8	-100.5	dBm

English

	LTE 900 Band 8	-93.8	-102.5	dBm
	LTE 800 Band 20	-93.8	-102.5	dBm
	LTE 700 Band 28	-95.3	-102.0	dBm
	LTE 2300 Band 40	-96.8	-100.5	dBm
	LTE 2500 Band 41	-94.8	-101.0	dBm
	LTE 2100 Band 66	-96.3	-101.5	dBm

RED Requirements

The product complies with part Art. 3.1a./Art. 3.1b./Art. 3.2./Art. 3.3 of the RED Rules. Operation is subject to the following conditions:

(1) The protection of health and safety of persons and of domestic animals and the protection of property, including the objectives with respect to safety requirements set out in Directive 2014/35/EU, but with no voltage limit applying.

(2) An adequate level of electromagnetic compatibility as set out in Directive 2014/30/EU.

(3) Radio equipment shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference.

(4) Other special requirements.

English

Summary of Test Results

The EUT has been tested according to the following specifications:

Test Item	Standard Number & Version	Result
EMC	ETSI EN 301 489-1 V2.2.3 ETSI EN 301 489-52 V1.2.1	PASS
Radio LTE	ETSI EN 301 511 V12.5.1 ETSI EN 301 908-1 V15.1.1 ETSI EN 301 908-13 V13.2.1	PASS
Radio GSM		PASS
Radio LTE		PASS
Safety	EN 62368-1:2014+A11:2017	PASS
Health	EN IEC 62311:2020	PASS

WARNING!

• All other wireless technology emitters must be kept at least 30 cm (12 inches) away from the Cellular Module.

CAUTIONS!

• In accordance with network security requirements, the CPU on this equipment only supports our product software standards and is not compatible with other external software.

• Non-professionals are not authorized to upgrade software.

WiFi Kit

FCCID: 2ACSVHF-LPT270

Mode of Operation

Continuous

Work Mode

CPAP, AutoCPAP

SD Card

The SD card is capable of storing patient treatment data and error information.

AC Power Consumption

100 V to 240 V ~, 50 Hz/60 Hz, 2.5 A Max

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

Main device input

24 V, 3.33 A

24 V, 2.71 A

Power to Heated Tubing Communications Port

24 V ⎓ 18 W

Type of Protection Against Electric Shock

Class II Equipment

Degree of Protection Against Electric Shock

Type BF Applied Part

Degree of Protection Against Ingress of Water

IP22

Pressure Range

4 hPa to 20 hPa (in 0.5 hPa increments), ≤30 hPa under single fault conditions.

Static Pressure Stability

±0.5 hPa

Dynamic Pressure Stability

±(0.5 hPa + 5% of the set pressure)

Ramp

The ramp time ranges from 0 to 60 minutes.

The A-weighted sound pressure level and sound power level

When operating at a pressure of 10 hPa, the device's sound pressure level and sound power level shall not exceed the values listed in the table below.

Sound Pressure Level	Uncertainty	Sound Power Level	Uncertainty
28 dB(A)	2 dB(A)	36 dB(A)	2 dB(A)

Note: Declared dual-number noise emission values in accordance with ISO 4871:1996.

Maximum Flow

	Test Pressure				
	Pmin	Pmin + 1/4 (Pmax-Pmin)	Pmin + 1/2 (Pmax-Pmin)	Pmin + 3/4 (Pmax-Pmin)	Pmax
Test Pressures (hPa)	4	8	12	16	20
Measured Pressure at the Patient Connection Port (hPa)	3	7	11	15	19
Average Flow at the Patient Connection Port (L/min)	85	135	140	140	140
When the working pressure is set to the values listed in the table, the average flow rate at the patient end should be greater than 80% of the corresponding flow value in the table.					

Pressure

Range: 0 to 20 hPa

Margin of Error: ±(0.4 hPa + 4%)

SpO_2

Range: 35% to 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 bpm to 240 bpm

Margin of Error: ±2%

Wavelengths

Red: 663 nm

Infrared: 890 nm

Maximal Optical Output Power

Less than 1.5 mW maximum average.

Air Tubing

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

The Form and the Dimensions of the Patient Connection Port

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

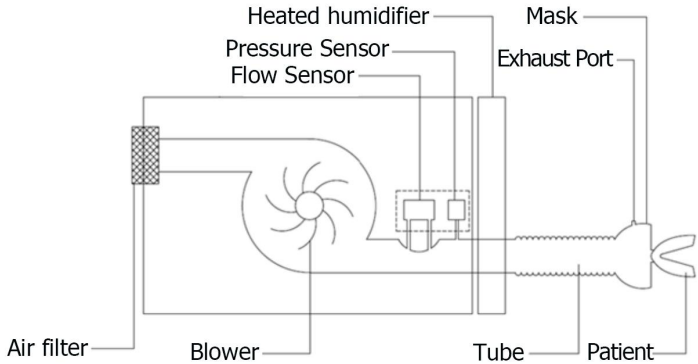
PM2.5 Filter

Efficiency: >90% for 2.5 micron dust

Power of heated plate

38 W

Ventilator Pneumatic System Schematic Diagram



Blower	The pneumatic drive component, which delivers therapeutic pressure to the patient during operation.
Pressure Sensor	Pressure sensing unit capable of real-time pressure value feedback.
Flow Sensor	Flow sensing unit providing real-time volumetric flow data.

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 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.

8. Glossary

Apnea

A condition marked by the cessation of spontaneous breathing.

AutoCPAP

Adjust CPAP pressure automatically to improve patient comfort based on monitoring of 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. This feature is always enabled.

SmartC

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

SmartA

In AutoCPAP mode, if SmartA is set to on, the device can adjust Initial P and Min APAP based on the patient's respiratory event during a certain time.

Initial P

Initial pressure.

Min APAP

Minimum Automatic Positive Airway Pressure.

CPAP

Continuous Positive Airway Pressure.

iCode

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

LPM

Liters Per Minute.

OSA

Obstructive Sleep Apnea.

Patient Menu

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

Ramp

A feature that increases patient comfort at the beginning of treatment. It begins from a low pressure and then gradually increases to the prescribed setting pressure so that 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".

CAUTION!

• Indexes such as Apnea, AHI, Hypopnea are only monitoring data provided by Sleep Apnea Therapy Device, not diagnostic parameters.

9. Model

Model	Product Description		Work Mode	Maximum Work Pressure (hPa)
	Product Contents	Optional Accessories		
G3 A20	Device (3.5-inch LCD)	Breathing Tube (optional), Mask (optional), SpO_2 Kit (optional), Pulse Oximeter Probe (optional), WiFi kit (optional), Cellular Module (optional), Heated Breathing Tube (optional), PM2.5 Filter (optional)	CPAP, AutoCPAP	20
G3 C20	Device (3.5-inch LCD)		CPAP	

10. Package Contents

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

No.	Articles	Qty.	Notes
1	Device	1	
2	Air Filter	2	
3	Power Adapter	1	
4	Power Cord	1	
5	WiFi kit (WL-500)	1	Optional
6	Cellular Module (WL-400)	1	Optional
7	Cellular Module (WL-600)	1	Optional
8	Mask	1	Optional
9	SpO_2 Kit (SP-100)	1	Optional
10	Pulse Oximeter Probe (S0010B-S)	1	Optional
11	Pulse Oximeter Probe (S0026N-L)	1	Optional
12	Breathing Tube	1	Optional
13	Heated Breathing Tube	1	Optional
14	PM2.5 Filter	1	Optional
15	SD Card	1	Optional
16	Carrying Case	1	Optional
17	Accompanying Documents	1	

English

All parts and accessories are not made of natural rubber latex.

The product's expected service life is five years from first date of use, if it is used, maintained, cleaned and disinfected in strict accordance with the User Manual.

The Heated Tubing expected service life of refer to the user manual of the heated tubing. The WiFi kit and Cellular Module expected service life is five years from first date of use. The SpO_2 Kit (SP-100) expected service life is five years from first date of use.

The expected service life of the water chamber is 6 months from first date of use, and the water chamber can withstand cleaning up to 180 times and disinfection 30 times.

Applied parts: SpO_2 Probe and mask are the applied parts of the device.

WARNINGS!

• The device should only be used with the mask and accessories manufactured or recommended by the manufacturer. The use of unsuitable masks and accessories may affect the performance of the device and impair the effectiveness of treatment.

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

• When the insulation layer of the SpO_2 probe cable is damaged, do not connect the probe to the patient.

• Do not stack the long tubing or SpO_2 Kit lead near the patient's neck, as it could wrap around

the patient's head or neck during sleep.

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

• Please contact the manufacturer for an SD card if needed.

• The manufacturer cannot guarantee the normal function of the device, nor the safety and effectiveness of the device when it exceeding the expected service life.

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 the device. When using optional accessories, be sure to follow the instructions that come with the accessories.

11. System Features

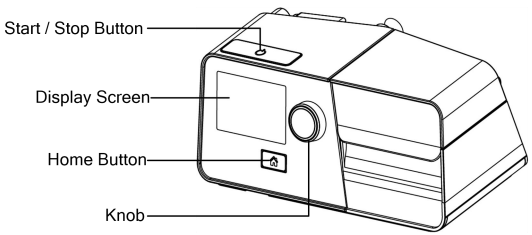


Fig. 11-1

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

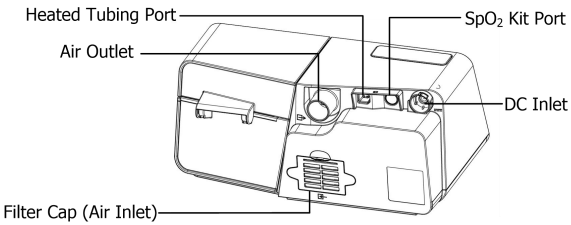


Fig. 11-2

Name	Function
Air Outlet	Deliver pressurized air; connects to the tubing.
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.

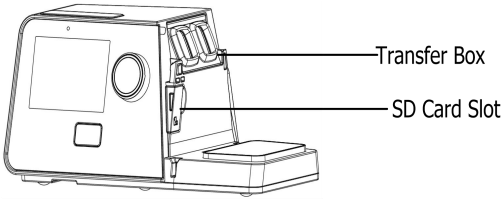


Fig. 11-3

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

CAUTION!

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

12. First Time Setup

12.1 Placing the Device

Place the device on a firm, flat surface.

WARNINGS!

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

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

CAUTIONS!

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

• Make sure the device is away from any heating or cooling equipment (e.g. forced air vents, radiators, or 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 or children away from the device and avoid small objects being inhaled or swallowed.

• To prevent the risk of explosion, the device must not be used in the presence of flammable gases (e.g. anesthetics).

• Tobacco smoke may cause tar to build-up in the device, which could lead to the malfunctioning of the device.

• Air must flow freely around the device to allow it to function properly.

• Do not move or tilt the device when there is water in the water chamber.

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

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



Fig. 12-1

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

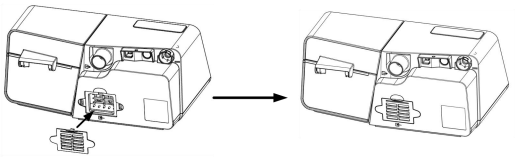


Fig. 12-2

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

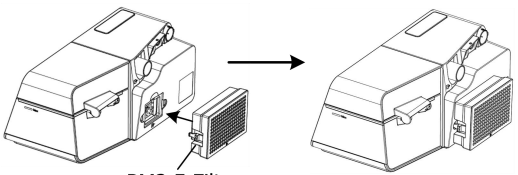


Fig. 12-3

CAUTIONS!

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

• Please change the air filter regularly and don't block it.

• Fire, open ignition source and smoking prohibited-the information is put on the device.

• Air filters provided by the manufacturer are recommended for use, otherwise foreign objects or odors may enter the device.

12.3 Connecting Power Supply

(1) Insert the plug of the power adapter into the DC Inlet on the back of the device.

(2) Connect the power cord to the power adapter.

(3) Plug the other end of the power cord into the power outlet.

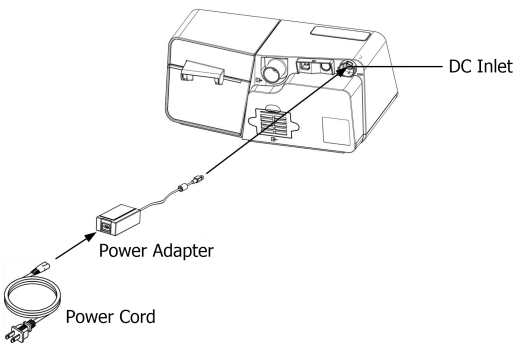


Fig. 12-4

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

WARNINGS!

• The device is powered on for use when the power cord and power adapter are connected. Press the **Start/Stop Button** ⏻ to turn the blower On/Off.

• Using the device at an AC voltage outside the specified range (see Section 6 "AC Power Consumption") may damage the device or cause device failure.

• Connect to the proper power source for proper operation of the device.

• Check the power cord frequently for signs of damage. Replace a damaged cord immediately.

IMPORTANT TIPS!

• After interruption and restoration of the power supply, the device will restore its pre-interruption working status automatically.

• To remove AC power, disconnect the power cord from the power outlet.

12.4 Assembling the Tubing/Heated Tubing and Mask

(1) Connect one end of the tubing to the air outlet of the device, as shown in Fig. 12-5.

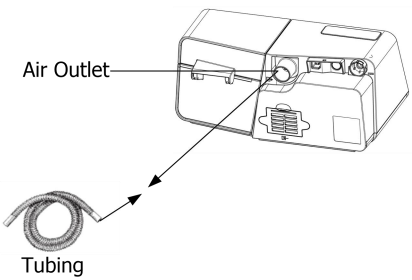


Fig. 12-5

(2) Connect the heated tubing joint to the air outlet of the device, and then insert the power plug into the heated tubing port on the back of the device, as shown in Fig. 12-6.

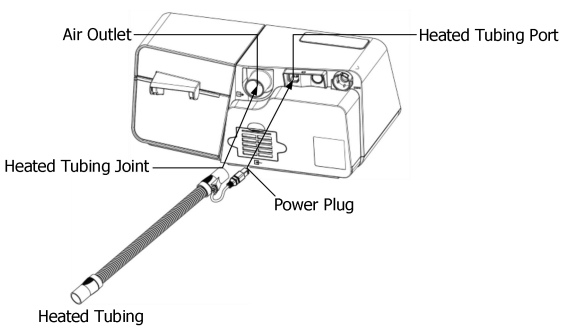


Fig. 12-6

If the heated tubing is connected correctly, the icon will become a number in the Main Interface on the screen of the device, as shown in Fig. 12-7.

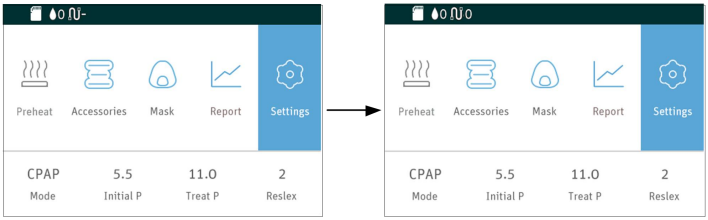


Fig. 12-7

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

There are five heat levels available, and the number of heat levels will appear on the main screen of the device. The number 3 next to the icon indicates the heat is adjusted to Level 3, as shown in Fig. 12-8.



Fig. 12-8

(3) Connect the other end of the tubing to the mask according to the user manual of 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 the tubing. Pressures must be verified by your home care provider when using spare or optional accessories.

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

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

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

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

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

- 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.
• If condensation appears in the tube, remove then drain the tube; then reduce the humidification.
• To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used.

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 supply before turning off the device. Explanation of Warning: When the device is turned off, but the oxygen flow still remains, oxygen can accumulate inside the device's enclosure and pose a fire hazard. Turning off the oxygen supply before turning off the device will prevent oxygen accumulation in the device and reduce the risk of fire. This warning applies to CPAP devices.
• Oxygen supports combustion. Keep the device and the oxygen container away from heat, open flames, any oily substances, or other sources of ignition. DO NOT smoke in the area near G3 A20 / G3 C20 or the oxygen container.
• Sources of oxygen should be more than 1 m away from the device.
• When using oxygen with this system, a Pressure Valve must be placed in-line with the patient circuit between the device and the oxygen source. The pressure valve helps prevent the backflow of oxygen from the patient circuit into the device when the unit is off. Failure to use the pressure valve could result in a fire hazard.
• When the pressure valve is installed, the device's Auto On function will be disabled. Press the Start/Stop Button to initiate ventilation.
• Supplemental oxygen must not be used while smoking or in the presence of an open flame.
• When using the device with an oxygen supply, check the following:
Starting therapy - ensure the device is on and blowing air before the oxygen supply is turned on.
Stopping therapy - ensure the oxygen supply is turned off first, then the device.
This will ensure oxygen does not accumulate within the device and create a risk of fire.
• Do not connect the device to an unregulated or high-pressure oxygen source. The pressure of oxygen source does not exceed the working pressure of the device.

12.6 Inserting the SD Card (Only for the device equipped with SD Card)

Insert the SD card into the SD Card Slot, as shown in Fig. 12-9.

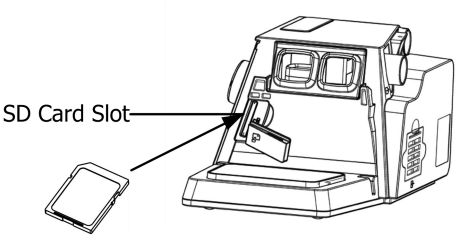


Fig. 12-9

If the SD card is properly inserted into the device, the correct insertion indicator will appear on the screen of the device.

CAUTIONS!

• If no SD card is inserted, the symbol will not appear 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 Starting Treatment

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

WARNINGS!

• Be sure that your home care provider follows your physician's instructions on adjusting the settings! These settings should not be tampered with by the patient. To order any accessories not included with the device, contact your home care provider.

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

13. Routine Use

13.1 Connecting the Tubing

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

CAUTION!

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

13.2 Adjusting the Tubing

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

13.3 Turning on the Airflow

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

13.4 Heating the Water

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

CAUTION!

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

13.5 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, to make it easy for the patient to fall asleep. The screen displays a real-time countdown of the remaining ramp time in minutes.

CAUTIONS!

• You can use the ramp feature as often as you wish during sleep.

• The ramp feature is not prescribed for all users.

13.6 Accessing the iCode

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



Fig. 13-1

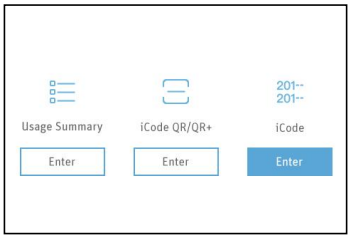


Fig. 13-2

13.7 Turning the Device Off

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

CAUTION!

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

14. Heated Humidifier

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

14.1 Filling the Water Chamber

14.1.1 Removing the Water Chamber

Press down the water chamber on the part closest to the machine and then remove it, as shown in Fig. 14-1.

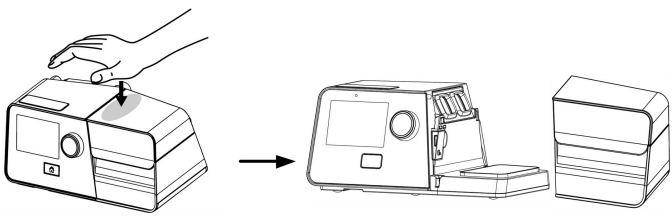


Fig. 14-1

WARNING!

• Turn the device off and allow the heating plate and water to cool for approximately 15 minutes before remove the Water Chamber.

14.1.2 Filling the Water

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

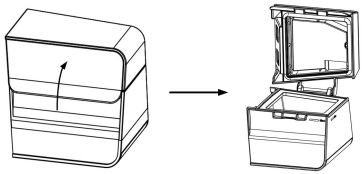


Fig. 14-2

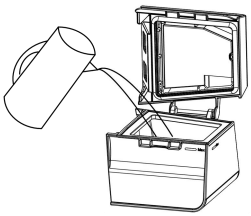


Fig. 14-3

WARNING!

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

CAUTIONS!

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

• Distilled water is recommended.

14.1.3 Putting the Water Chamber back

Close the cap when the water chamber is filled with water, as shown in Fig. 14-4, and put it back to the device, as shown in Fig. 14-5.

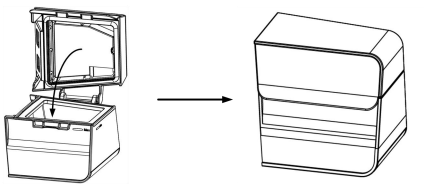


Fig. 14-4

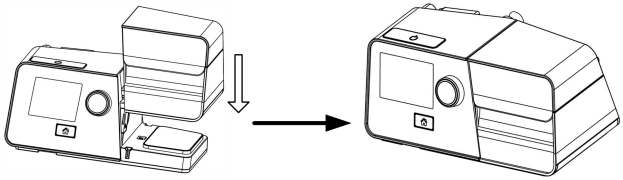


Fig. 14-5

WARNINGS!

• For safety, the device must be placed on a flat surface below the height of the patient's head when he is lying on a bed, so that the condensation flows back to the water chamber rather than remaining in the tubing which can cause droplet spraying.

• Do not use the humidifier at an altitude above 2300 m or outside a temperature range of 5°C (41°F) to 35°C (95°F). Using the humidifier outside of this temperature range or above this altitude can affect the quality of the therapy or injure the patient.

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 in Fig. 14-6, and pour any remaining water out of the water chamber.

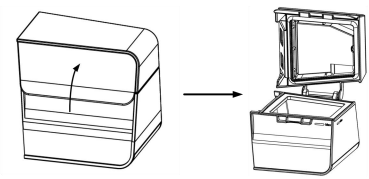


Fig. 14-6

CAUTION!

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

(3) **Putting the water chamber** back according to instructions in 14.1.3.

14.3 Setting the Humidity Level

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

There are multiple humidity levels available (such as Off, 1–5, Auto), and the number of humidity level will appear on the screen of the device.

The number 2 next to the icon indicates that the humidity is adjusted to Level 2, as shown in Fig. 14-7. The water temperature in the water chamber is maintained at a constant set level.

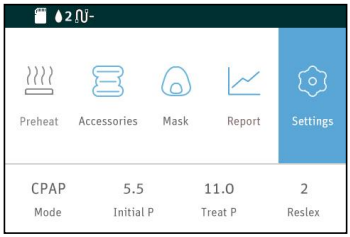


Fig. 14-7

WARNING!

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

CAUTIONS!

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

• Condensation inside the tubing is more likely to occur as the difference between the air tubing temperature and room temperature increases.

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

15. 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. 15-1. The patient's blood oxygen saturation and pulse rate can be clearly seen during the course of treatment.



Fig. 15-1

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

16. Connecting to Cellular Module or WiFi Network

16.1 Connecting to Cellular Module Network

(1) Connect the power supply. The device screen displays the Main Interface shown in Fig. 16-1.



Fig. 16-1

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

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

Table 2 Description of Cellular Module Icons

Icon	Description
	Strong Cellular Module signal
	Moderate Cellular Module signal
	Weak Cellular Module signal
	No Cellular Module signal found

Notes:

(1) When the Cellular Module signal is weak, data transmission may become slow and even stop.

(2) The Cellular Module will keep searching for Cellular Module signals until one is found.

If the Cellular Module signal is strong, the Cellular Module icon will appear on the screen, as shown in Fig. 16-2 (the Cellular Module icons of different strength appear in a similar way).

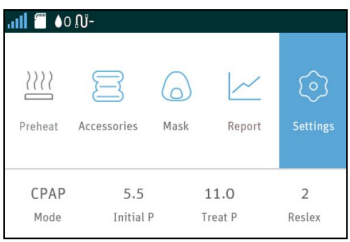


Fig. 16-2

English

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

WARNING!

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

16.2 Connecting to WiFi Network

(1) Connect the power supply. Turn the **Knob** until the cursor is on the icon , and the screen displays the Main Interface shown in Fig. 16-3. Press the **Knob** , and the first option on the Initial Setup Interface turns blue, as shown in Fig. 16-4.

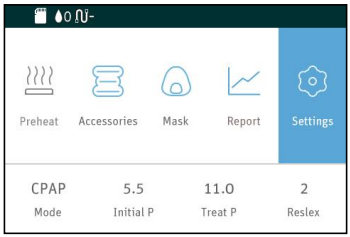


Fig. 16-3

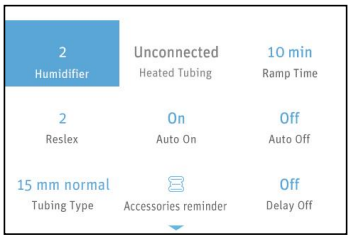


Fig. 16-4

(2) Turn the **Knob** until the cursor stays on the **WiFi** option, as shown in Fig. 16-5. Press the **Knob** , and the interface shown in Fig. 16-6 appears. Wait for 0-5 seconds to automatically access the WiFi setup interface.

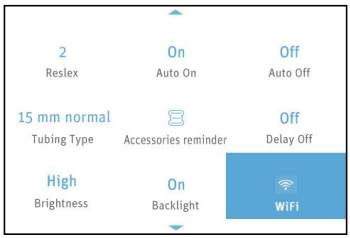


Fig. 16-5



Fig. 16-6

(3) The WiFi setup interface displays a certain number of available WiFi networks in a random order, as shown in Fig. 16-7. 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 Fig. 16-8. 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. 16-7



Fig. 16-8

Note: are page turning symbols.

If no WiFi networks are found, the WiFi setup interface displays "**No WiFi signal available**", as shown in Fig. 16-9.



Fig. 16-9

(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 to 9, as shown in Fig. 16-10. After the password is entered, turn the **Knob** until the cursor stays on the **Confirmation Key** Enter. Press the **Knob** to connect to the WiFi network, as shown in Fig. 16-11. At this moment, the user must not perform any operations, and should wait 0 to 15 seconds for the connection result.

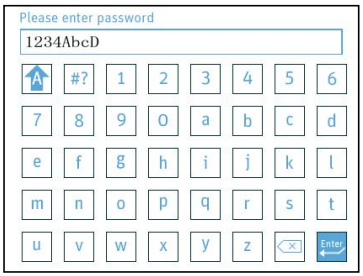


Fig. 16-10

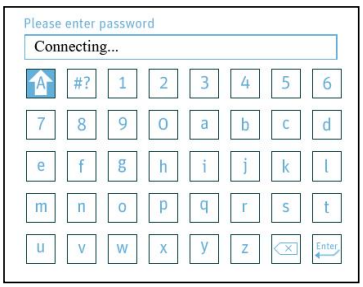


Fig. 16-11

If the WiFi network is connected successfully, the screen will return to the WiFi setup interface, and the WiFi symbol color will become blue, as shown in Fig. 16-12. If connection to the WiFi network fails, the password input box displays "**Connection Failed!**" as shown in Fig. 16-13.

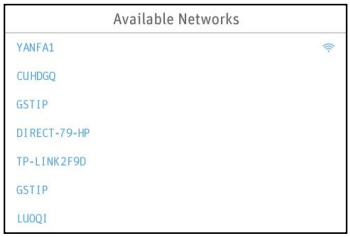


Fig. 16-12

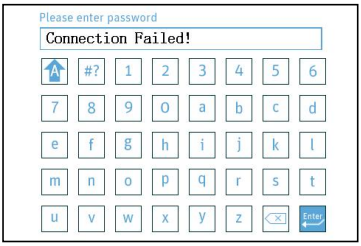


Fig. 16-13

To switch from one 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** Enter. Press the **Knob** to connect to the network.

17. Navigating the Patient Menu

17.1 Steps to Navigate the Patient Menu

17.1.1 Accessing the Main Interface

Connect the power cord and power adapter properly. The screen displays the Main Interface shown in Fig. 17-1.

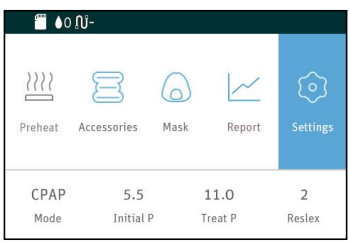


Fig. 17-1

Note: The above interface is only applicable to devices that do not have the modes of SmartC or SmartA activated. If SmartC or SmartA is enabled, the symbol S will appear in the status

English

bar at the top of the screen, as shown in Fig. 17-2.



Fig. 17-2

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

Note: As the humidity is turned off, the Preheat Function Icon will turn gray.

17.1.2 Bringing up the Initial Setup Interface

After the screen displays the Main Interface shown in Fig. 17-1, turn the **Knob**. When the cursor is on the icon, press the **Knob**, and the screen displays the Initial Setup Interface of the Patient Menu, as shown in Fig. 17-3.

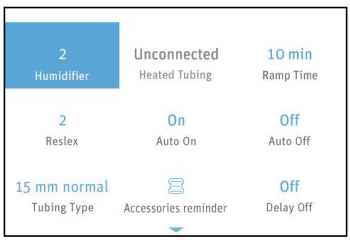


Fig. 17-3

Note: The **Heated Tubing** option can only be adjusted when the device is connected to a heated tubing, as shown in Fig. 17-4.

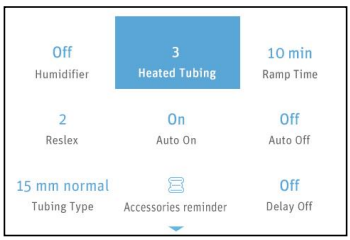


Fig. 17-4

English

17.1.3 Selecting Options

As you turn the **Knob** clockwise, the cursor moves from one option to another. When the cursor is on a certain option, press the **Knob**, and the color of the option will change, meaning that the option is now adjustable, as shown in Fig. 17-5 by the **Humidifier** option.

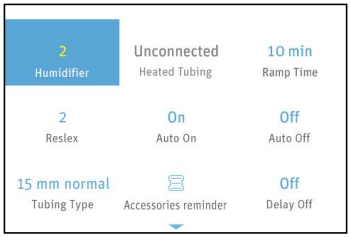


Fig. 17-5

17.1.4 Adjusting Options

Adjust the option by turning the **Knob**. As shown in Fig. 17-6, the **Humidifier** option is selected. As you turn the **Knob** clockwise, the number increases, indicating a higher humidity level. As you turn the **Knob** counterclockwise, the number decreases, indicating a lower humidity level, as shown in Fig. 17-6.

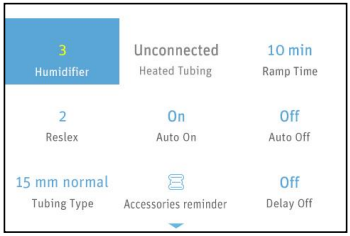


Fig. 17-6

17.1.5 Confirming Adjustments

Press the **Knob** to confirm your adjustment of a particular option. The option is then displayed in white, as shown in Fig. 17-7.

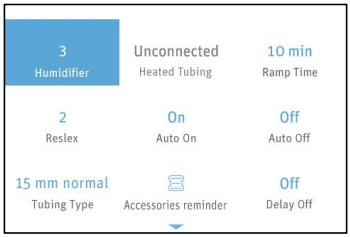


Fig. 17-7

17.1.6 Turning Pages

When the cursor is on **Delay Off**, the last option shown in Fig. 17-7, the remaining options will appear on a new page if you continue to turn the **Knob** clockwise, as shown in Fig. 17-8.

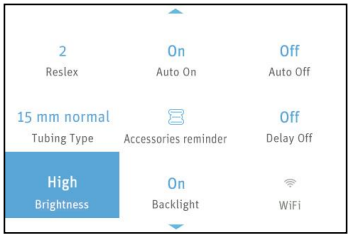


Fig. 17-8

Note: are page turning symbols.

17.1.7 Exiting the Patient Menu

The users can press the **Home button** to return to the Main Interface shown in Fig. 17-1.

17.2 Options in the Patient Menu and Corresponding Descriptions

Option	Range	Description
Preheat	On/Off	Set humidifier to preheat by adjusting this option. This feature is automatically turned off after 30 minutes.
Accessories	——	Reset the use time of the filter, tubing and mask.
Mask	——	Choose a mask type or test that the mask is worn correctly.
Report	——	Choose to view the usage summary or iCode/iCode QR/iCode QR+.
Humidifier	Off/Auto/ 1 to 5	There are five humidity levels available. As the number increases, the humidity rises accordingly. "Off" means the humidifier is turned off.
Heated Tubing	Off/1 to 5	There are five heat levels available. As the number increases, the heat rises accordingly. "Off" means the heat is turned off. Note: **Heated Tubing** is displayed in the patient menu only when a heated tubing is connected.
Ramp Time	Auto/ 0 to Max Ramp	In order to increase comfort and help the patient fall asleep easily, the pressure can be increased gradually, when the Ramp feature is enabled. The ramp time during which the initial pressure rises to the preset treatment pressure can be adjusted.
Reslex	Off/1 to 3	This feature enables the device to automatically reduce the treatment pressure when the patient exhales, so as to make the patient more comfortable. The higher the number, the more pressure the device reduces. "Off" means this feature is disabled.
Auto On	On/Off	This feature enables the device to start automatically and deliver air at a preset pressure after the patient takes a few deep breaths with the mask on.
Auto Off	On/Off	This feature enables the device to automatically discontinue the therapy and shut off when the mask is removed.
Tubing Type	15 mm normal/ 19 mm normal/ 15 mm heated/ 19 mm heated	There are four tubing types available.

English

Option	Range	Description
Accessories reminder	30 days/ 60 days/ 180 days/ 365 days/ Off	This function is used for setting filter reminder, tube reminder and mask reminder.
Delay Off	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 Button** to discontinue the treatment. In this process, the vapor left in the water chamber will be blown away to avoid any damage to the device. When this feature is set to "Off", which means it is disabled, the device will stop delivering air instantly after you press the **Start/Stop Button**.
Brightness	High/Low	Setting the brightness of the screen by adjusting this option.
Backlight	Auto/On	The backlight of the LCD screen can be set to "Auto" or "On". Turn the **Knob** to choose between the two modes. If it is set to "Auto", the backlight will be turned off automatically after 30 seconds of inactivity. If it is set to "On", the backlight will be always on.
WiFi	——	Connect to WiFi network by adjusting this option.
Language	English/Español/ Português/ Deutsch/ 中文（简体）/ Français/ Polski/Italiano/ Türkçe/Русский/ Nederlands/ Ελληνικά/ 한국어	Turn the **Knob** to choose among these available languages. The setting is only valid when the device is inserted a SD card with language pack.
Used Time	0 to 50000 h	Use Time displays how long has the device been used by the patient. The use time can be erased.
About	——	Displays related information of the device (Model, SN, Version, ID). This is read-only and cannot be edited.

18. Alert

Alert Message	Description
Power Failure!!!	An audible alert will sound in 6 s if the device is accidentally disconnected from power supply when it is delivering air. Note: (1) The alert will not sound if power failure occurs when the device is in standby state. (2) No alert message will appear 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 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 22 V, 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 reminder feature is enabled, an audible alert will sound if the preset replacement time is reached but the air filter is not replaced; the screen will display "**Please change filter!**".
Please replace tubing!	When the tubing reminder feature is enabled, an audible alert will sound if the preset replacement time is reached but the tubing; the screen will display "**Please replace tubing!**".
Please replace mask!	When the Mask reminder feature is enabled, an audible alert will sound if the preset replacement time is reached but the mask is not replaced; the screen will display "**Please replace mask!**".
SD Card Full!	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.
SpO_2 Faults!	Disconnect the SpO_2 Probe from the SpO_2 Probe equipment and place it in series with a circuit with which each SpO_2 Probe wire can be opened or shorted to any other SpO_2 Probe wire. The screen will display **"SpO_2 Faults!"**.

English

19. 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 and disinfection.

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

• Before cleaning and disinfection, check that the device is disconnected from the power supply, whether the power cord is unplugged, and whether the water chamber of the device has cooled down. Make sure that the heating plate has cooled down to room temperature, so that you do not get burned.

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

• The device shall not be serviced or maintained while a patient is using it.

• 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.

• Disinfection of this device and its components other than recommended is not permitted, otherwise the manufacturer will not be able to verify the safety or performance of the device.

• In order to prevent cross-infection of patients or contamination of equipment, BSF (Breathing System Filter) that meets ISO 23328-1:2003 and ISO 23328-2:2002 standards and has medical device registration certificates can be used.

(1) BSF need to be replaced before different patients using this device.

(2) When using the BSF, please install and operate it according to the instructions of the BSF, and pay attention to adjust the output pressure setting of the device according to resistance of the BSF to ensure delivering normal treatment pressure.

(3) Atomization or humidification will increase the resistance of the BSF. The operator must often monitor the resistance increase and blockage of the BSF to ensure delivering normal treatment pressure.

• If you use ozone or other cleaning and disinfection methods that are not recommended by BMC, BMC will not be able to verify the safety or performance of the equipment.

CAUTIONS!

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

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

• Do not clean with water above 80°C (176°F) or dry the device and its accessories in an environment with temperature above 80°C (176°F). High temperatures could reduce product life.

• Do not immerse the device in any fluids.

• Disinfectants tend to damage the materials and reduce the life of components. Try to select the appropriate disinfectant, and follow the disinfectant manufacturer's instructions and recommendations.
• After disinfection, visually inspect the headgear, mask or SpO_2 Probe for any visible signs of deterioration or breakage. Replace any damaged component immediately.

19.1 Cleaning

Accessories that need to be cleaned	**Detergent**
Mask and Headgear	See Mask Manual for details
SpO_2 Probe	Isopropanol (70%-concentration)
Water chamber and Transfer box	Alconox (diluted at 1%)
Tubing	See Tubing Manual for details
Air Filter	-

19.1.1 Cleaning the Mask and Headgear

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

19.1.2 Cleaning the SpO_2 Probe

Preparation before cleaning
Preparation tools: spotless soft gauze, purified water.
(1) Dip a piece of spotless soft gauze into 70%-concentration isopropanol solution, and gently wipe the surface of the SpO_2 Probe for 2 minutes.
(2) Scrub the SpO_2 Probe surface with another piece of spotless soft gauze having dipped in fresh water (purified water is recommended) for 2 minutes.
(3) Dry the SpO_2 Probe by wiping all surfaces with a piece of spotless and dry soft gauze.
Note: The temperature of isopropanol solution and water should be controlled at 5°C to 40°C.

19.1.3 Cleaning the Water Chamber and Transfer Box

Preparation before cleaning
Preparation tools: soft bristle brush, drinking quality water, mild liquid detergent.

(1) Remove the Water Chamber and Transfer Box
Firstly remove the Water Chamber according to instructions in 14.1.1.
Then remove the transfer box, as shown in Fig. 19-1.

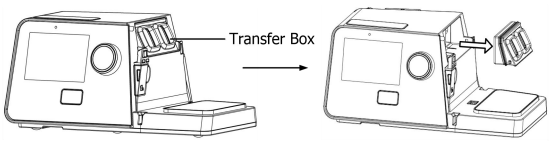


Fig. 19-1

(2) Cleaning the Water Chamber and Transfer Box

a. Open the Water Chamber as shown in Fig. 19-2.

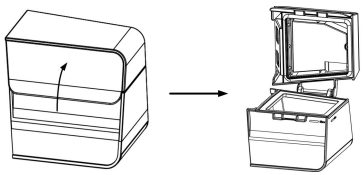


Fig. 19-2

b. Rinse the Water Chamber and Transfer Box with running water for at least 2 minutes.

c. Immerse the Water Chamber and Transfer Box into the detergent for at least 5 minutes. Clean the water chamber and Transfer Box with a soft bristled brush for at least 1 minute while soaking in detergent solution. Pay particular attention to all crevices and cavities.

Detergent: Alconox

Concentration: 1:100

Temperature: 45°C to 60°C (113°F to 140°F)

d. Then rinse with running water for 5 minutes. Wipe it dry with a soft cloth or air dry out of direct sunlight.

(3) Putting the Water Chamber and Transfer Box back

Firstly, put back the Transfer Box as shown in Figure 19-3, then put back the Water Chamber according to instructions in 14.1.3.

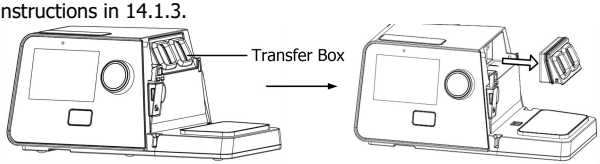


Fig. 19-3

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. To make sure that no water enters the device, make sure to disconnect the water chamber from the device prior to cleaning.

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

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

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

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

19.1.4 Cleaning the Tubing

For details, refer to the cleaning instructions in the user manual for the L1 and LH1.

19.1.5 Cleaning and Replacing the Air Filter/PM2.5 Filter

(1) Attach the air filter to the filter cap, as shown in Fig. 19-4.

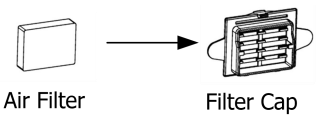


Fig. 19-4

(2) Install the filter cap containing the air filter to the device, as shown in Fig. 19-5.

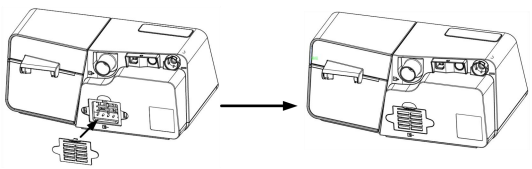


Fig. 19-5

(3) Change the air filter and filter cap to the PM2.5 filter, as shown in Fig. 19-6.

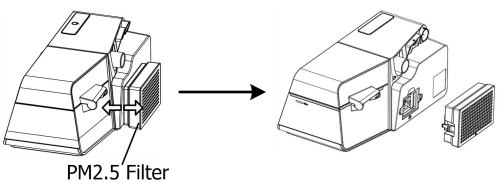


Fig. 19-6

(4) When the air filter is dirty, it can be cleaned as follows:

Preparation tools: tap water [5°C to 35°C (41°F to 95°F)].

Rinse the air filter for at least 2 minutes under running tap water at 5°C to 35°C (41°F to 95°F).

When cleaning, gently press the air filter, but do not pull on the air filter.

After cleaning, place the air filter in a cool place to dry and avoid direct sunlight.

Allow the air filter to air dry completely before reinstalling it.

CAUTION: Never install a wet filter into the device. You must ensure sufficient drying time for the cleaned filter.

The air filter is recommended to be replaced rather than cleaned frequently, and the number of cleaning times per month is not more than 4 times when used in harsh environments.

The PM2.5 filter is not washable.

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.

• Please replace the manufacturer-recommended filter periodically; Please clean the reusable air filter if it is contaminated.

19.2 Disinfection

Accessories that need to be disinfected	**Chemical Disinfection**	**High Temperature Disinfection**
Mask and Headgear	See Mask Manual for details	See Mask Manual for details
SpO_2 Probe	1:10 bleach solution (5%-concentration sodium hypochlorite liquor) Temperature: 5°C to 40°C	—
Water chamber and Transfer box	CIDEX® OPA solution at 0.55% concentration Temperature: 20°C	water at 90°C to 92°C
Tubing	See Tubing Manual for details	See Tubing Manual for details

19.2.1 Disinfecting the mask and headband

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

19.2.2 Disinfection of the SpO_2 Probe

(1) Before using each time, dip a piece of spotless soft gauze into 1:10 bleach solution (5%-concentration sodium hypochlorite liquor), and gently scrub the SpO_2 Probe for 2 minutes for disinfection.

(2) After disinfection, scrub the SpO_2 Probe with another piece of spotless gauze having dipped into fresh water (purified water is recommended) for 2 minutes, and then change a piece of spotless gauze having dipped into fresh water (purified water is recommended) and scrub the surface of the blood oxygen probe for 2 minutes, and finally wipe them dry with a piece of spotless dry gauze.

Note: The temperature of sodium hypochlorite liquor and fresh water should be controlled at 5°C to 40°C.

19.2.3 Disinfection of the Water Chamber and Transfer Box

Preparation before disinfection

Preparation tools: soft bristle brush, drinking quality water, applicable disinfectant.

Generally speaking, if you have strictly followed the above cleaning instructions, you do not have to disinfect the device and/or the water chamber. If the device is contaminated or used in

clinical trials, you can purchase disinfectants from a home medical equipment company to disinfect the device.

In the following procedures, only one disinfection process needs to be performed at one time.

Chemical Disinfection:

(1) Clean the water chamber or the transfer box by the steps in the cleaning instructions.

(2) Put the CIDEX® OPA solution at 0.55% concentration into a plastic box, so that the water chamber or the transfer box can be completely submerged.

(3) Immerse the water chamber or the transfer box in CIDEX® OPA solution at 0.55% concentration for 12 min.

(4) Rinse 3 times the water chamber or transfer box with 8 L purified water to remove the residual disinfectant.

(5) Wipe the water chamber or transfer box dry with a soft cloth or air dry out of direct sunlight.

High Temperature Disinfection (water at 90°C to 92°C):

(1) Clean the water chamber or the transfer box by the steps in cleaning instructions.

(2) Open the cap of the water chamber, and then immerse the water chamber in the water tank. Heat the water and hold between 90°C to 92°C and immerse the water chamber or the transfer box for at least 5min.

(3) Wipe the water chamber or the transfer box dry with a soft cloth or air dry them away from direct sunlight.

19.2.4 Disinfection the Tubing

For details, refer to the disinfection instructions in the user manuals of the L1 and LH1.

20. Traveling with the Device

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

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

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

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

CAUTIONS!

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

• If the device is used when the atmospheric pressure is outside the specified range (See Section 6), the accuracy of the leak alert will be affected.

21. Transferring the Device to Another Patient

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

22. Reordering

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

WARNINGS!

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

• If the device fails to work properly, contact your home care provider immediately. Never attempt to open the enclosure of the device. Repairs and adjustments must be performed by the manufacturer-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.

23. Technical Support

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

24. Disposal

This product complies with the requirements of Directives 2011/65/EU and (EU) 2015/863 (RoHs) on the restriction of hazardous substances.

According to the European Directive 2012/19/EU (WEEE) on electrical and electronic equipment, products cannot be discarded indiscriminately and must be disposed of in accordance with the laws and regulations of the country in which disposal occurs.

The crossed-out wheeled bin symbol  indicates that the product bearing this symbol may not be disposed of together with general household waste, but instead requires separate disposal. This requirement for separate disposal is based on the European Directive 2012/19/EU for electrical and electronic equipment. You can hand in the product at a municipal collection point, for example. This reduces the impact on natural resources and prevents contamination of the environment through the release of hazardous substances.

For further information regarding product disposal, please contact your specialist distributor.

25. Troubleshooting

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

25.1 Common Problems in Patients and Corresponding Solutions

Problem	Possible Cause	Solution(s)
Dry, cold, runny, and blocked nose; having a cold	The nose reacts to the airflow and cold. Due to fast airflow, the air becomes cold, resulting in the irritation of nasal mucosa and subsequent dryness and swelling.	Increase the humidity setting of the device. Contact your physician and continue treatment unless the physician suggests the opposite.
Dry mouth and throat	It may be because the patient sleeps with the mouth open, and the pressurized air flows out through the mouth, causing dryness of the nasal passage and throat.	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details.
Eye irritation	The mask may not be the correct size or type, or the mask may be incorrectly positioned resulting in an air leak.	Narrow the distance between the forehead support of the mask and the forehead. Note that adjusting the mask too tight may leave marks on the patient's face. Add additional filling to the mask so it does not leak. Contact your home care provider 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.	Contact your home care provider for a correct-size mask.
	The patient may be allergic to the materials of the mask.	Contact your physician and home care provider. Use a mask that is not made of 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 make sure that the lowest part of the tubing should be lower than the patient's head.
Nasal, sinus, or ear pain	Sinus or middle ear inflammation.	Contact your physician immediately.
Discomfort due to inability to adapt to the treatment pressure	The patient will feel uncomfortable when the treatment pressure is higher than 13 hPa. However, the treatment pressure is determined by the patient's conditions, and the device will not be able to treat sleep apnea if the treatment pressure is set too low.	It takes a maximum of four weeks for the patient to adapt to pressurized air. Relax and breathe through the nose. If the problem still exists, contact your physician.
Obstructive sleep apnea symptoms reappear	It may be because the patient sleeps with the mouth open, and the pressurized air flows out through the mouth, causing a 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 19.1.5 Cleaning and Replacing the Air Filter/PM2.5 Filter), and clean the air inlet.
		Place the device in an area where air flows freely, and make sure that the device is at least 20 centimeters away from the wall, curtain, or other things.

English

25.2 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 home care provider for repair.
	Cannot find any cause.	Contact your home care provider.
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 home care provider.
	It is a faulty device.	Contact your home care provider.
The device produces very low pressures	The air inlet of the device may be blocked.	Replace the air filter (see 19.1.5 Cleaning and 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.

26. EMC Requirements

Guidance and manufacturer's declaration - electromagnetic emissions	
The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.	
Emissions Test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies

WARNINGS!

• The 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 must do so, the device should be observed to verify normal operation.

• The use of accessories and power cord which are not 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.

• The device may be interfered with by other equipments, even if those equipments comply with CISPR EMISSION requirements.

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

• This device is not intended for use with MRI equipment and is not allowed to be used in MR environments.

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**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines
Surge IEC 61000-4-5	±1 kV Line(s) to line(s)	±1 kV Line(s) to line(s)
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
Power frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
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**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V 0.15 MHz to 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 to 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
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 to 80 MHz $d = 1.17\sqrt{p}$	80 MHz to 800 MHz $d = 0.35\sqrt{p}$	800 MHz to 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
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					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: 
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.					

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 ensure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**
Proximity magnetic fields IEC 61000-4-39	See Tab 1	See Tab 1

Tab 1

Test frequency	**Modulation**	**Immunity Test Level (A/m)**
30 kHz [a)]	Pulse modulation [b)] CW	8
134.2 kHz	Pulse modulation [b)] 2.1 kHz	65 [c)]
13.56 MHz	50 kHz	7.5 [c)]
[a)] This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT. [b)] This carrier shall be modulated using a 50% duty cycle square wave signal. [c)] r.m.s., before modulation is applied.		

27. 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 device and three (3) months for all accessories from the date of sale by BMC Medical Co., Ltd. to the distributor. 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 distributor 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 distributors or:

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