English

ECE MEDİKAL

UYKU VE SOLUNUM CİHAZLARI

Respirox® BPAP System

G2S BPAP Series

User Manual

RespiroX®

www.respirox.com.tr

CE 0123

English

Table of Contents

English

English

1. Symbols

1.1 Control Buttons

 Ramp Button

 Mute 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 (15° tilted)

 There are high-pressure, be careful of electric shock

 Hot Surface

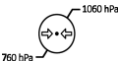
SN Serial Number of the Product

 Manufacturer

EC REP Authorized Representative in the European Community

 Do not use the product if the package is damaged

 Disassembly is prohibited

CE 0123	European CE Declaration of Conformity
	Product is intended for use by a single patient only
LOT	Lot number
	Non-Ionizing Radiation
	SD Card
	WEEE Marking
	Air Inlet
	Air Outlet
	Storage Temperature Range
	Storage Humidity Range
	Storage Atmospheric Pressure Range

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

Respirox® BPAP System (G2S BPAP Series) 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 patient by prescription in the home or hospital/institutional environment.
The optional SpO_2 module used with Respirox® G2S BPAP Series together is indicated for monitoring the patient's 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 ECE accessories.
• Do not bring the device or accessories into a Magnetic Resonance (MR) environment as it may cause unacceptable risk to the patient or damage to the device or MR medical devices. The device and accessories have not been evaluated for safety in an MR environment.
• Do not use the device or accessories in an environment with electromagnetic equipment such as CT scanners, Diathermy, RFID and electromagnetic security systems (metal detectors) as it may cause unacceptable risk to the patient or damage to the device. Some electromagnetic sources may not be apparent, if you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, disconnect the power cord and discontinue use. Contact your home care provider.

CAUTIONS!

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

IMPORTANT!

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

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

IMPORTANT!

• An irregular sleep schedule, alcohol consumption, obesity, sleeping pills, or sedatives may aggravate your symptoms.
• Please use the mask which meets ISO17510:2015 and ISO 18562.

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.

5. Specifications

Device Size

Dimensions: 274 mm × 184 mm × 115 mm

Weight: 1.9 kg

Water capacity: To maximum fill line 360mL

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 to 1060 hPa	760 to 1060 hPa

Heated Humidifier

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

Humidifier Output: No less than 10 mg H_2O/L

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

Maximum Delivered Gas Temperature: ≤ 43°C

Mode of Operation

Continuous

Work Mode

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

SD Card

SD card can record patient data and fault information.

AC Power Consumption

100 – 240 V ～ , 50 / 60 Hz, Max 2 A

Main Device offer to USB Communications Port

5 V ⎓ 2.0 A

Type of Protection against Electric Shock

Class II Equipment

Degree of Protection against Electric Shock

Type BF Applied Part

Degree of Protection against Ingress of Water

IP22

Pressure Range

IPAP: 4.0 ～ 20.0 hPa (only applies to G2S B20A, G2S B20S, G2S B20T);
4.0 ～ 25.0 hPa (only applies to G2S B25A, G2S B25S, G2S B25T, G2S B25VT, G2S LAB);
4.0 ～ 30.0 hPa (only applies to G2S B30T, G2S B30VT, G2S B30AT);
in 0.5 hPa increments.

EPAP: 4.0 ～ 20.0 hPa (only applies to G2S B20A, G2S B20S, G2S B20T);
4.0 ～ 25.0 hPa (only applies to G2S B25A, G2S B25S, G2S B25T, G2S B25VT, G2S B30T,

G2S B30VT, G2S B30AT, G2S LAB);
in 0.5 hPa increments.

CPAP mode: 4.0 ～ 20.0 hPa

Under single fault conditions, ≤ 30 hPa for CPAP 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

< 30 dB, when the device is working at the pressure of 10 hPa.

Sound Power Level

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

Maximum Flow

Test Pressure (hPa)	4	9	15	20	25
Measured Pressure at the Patient Connection Port (hPa)	3	8	14	19	24
Average Flow at the Patient Connection Port (L/min)	90	120	150	150	150

SpO_2

Range: 0 ～ 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: 40 ～ 240 BPM

Margin of Error: ±1%

Wavelengths

Red: 663 nanometers

Infrared: 890 nanometers

Maximal Optical Output Power

Less than 1.5 mW maximum average.

Tube

Length: 6 ft. (1.83 m)

The Form and the Dimensions of the Patient Connection Port

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

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 press **the Ramp Button** ⊿ to reduce the pressure and then gradually increase the pressure to the therapeutic pressure setting so that you can fall asleep more comfortably.

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

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.

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.

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.

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.

7. Glossary

Apnea

A condition marked by the cessation of spontaneous breathing.

Auto-CPAP

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

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

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		
G2S B20S	Main device (2.4-inch TFT)	Tube, Mask, Cellular Module, SpO_2 Kit, SpO_2&GPRS Kit	CPAP, S	20
G2S B20A	Main device (2.4-inch TFT)		CPAP, S, AutoS	20
G2S B20T	Main device (2.4-inch TFT)		CPAP, S, S/T, T	20
G2S B25S	Main device (3.5-inch TFT)		CPAP, S	25
G2S B25A	Main device (3.5-inch TFT)		CPAP, S, AutoS	25
G2S B25T	Main device (3.5-inch TFT)		CPAP, S, S/T, T	25
G2S B25VT	Main device (3.5-inch TFT)		CPAP, S, S/T, T	25
G2S LAB	Main device (3.5-inch TFT)		CPAP, S, AutoS, AutoCPAP, S/T, T	25
G2S B30T	Main device (3.5-inch TFT)		CPAP, S, S/T, T	30
G2S B30VT	Main device (3.5-inch TFT)		CPAP, S, S/T, T	30
G2S B30AT	Main device (3.5-inch TFT)		CPAP, S, AutoS, AutoCPAP, S/T, 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	Cellular Module	1	Optional
7	SpO_2 Kit	1	Optional
8	SpO_2&GPRS Kit	1	Optional
9	Tube	1	Optional
10	SD Card	1	Optional
11	Carrying Case	1	Optional
12	Accompanying Documents	1	
13	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.

SpO_2 Probe is applied part.

IMPORTANT!

• 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.

• The tube with a diameter of 15 mm or 22 mm is available.

WARNINGS!

• This device should only be used with the mask and accessories manufactured or recommended by ECE 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.

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

the patient.

• 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 ECE or your health care provider.

• Please contact ECE to obtain an SD card if needed.

10. System Features

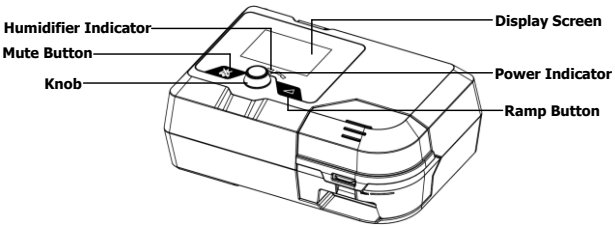


Fig. 10-1

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

CAUTION!

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

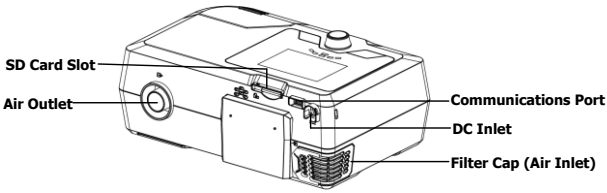


Fig. 10-2

Name	Function
SD Card Slot	Insert the SD card into this slot
Air Outlet	Deliver pressurized air; connects to the tube
Communications Port	Connected to external equipment (Not for connection to un-recommended devices)
DC Inlet	An inlet for the DC power supply
Filter Cap (Air Inlet)	Place the cap on the air filter, which is used to filter dust and pollen in the air entering the device

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!

• 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 objects (such as pests) are not blocking or entering 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

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

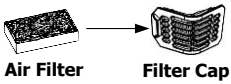


Fig. 11-1

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

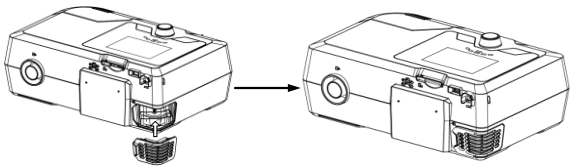


Fig. 11-2

CAUTIONS!

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

• Installing the air filter and filter cap, 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.

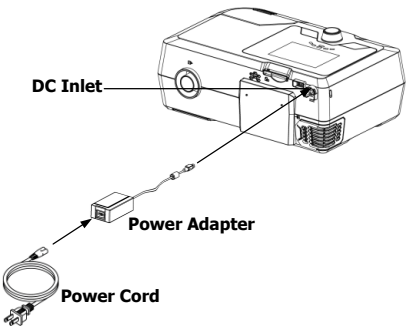


Fig. 11-3

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.

CAUTION!

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

IMPORTANT!

• 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) Assemble the power cord locker to the device directed by the positioning groove.

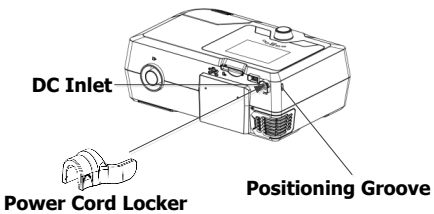


Fig. 11-4

(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.

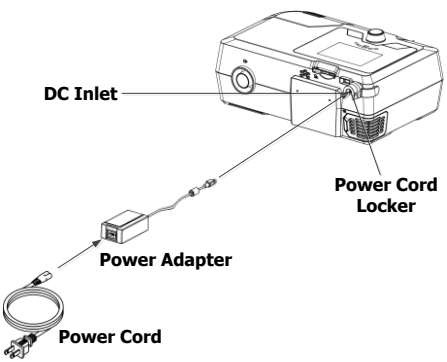


Fig. 11-5

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

11.5 Assembling the Tube and Mask

(1) Connect one end of the tube to the air outlet of the main device, as shown in Fig. 11-6.

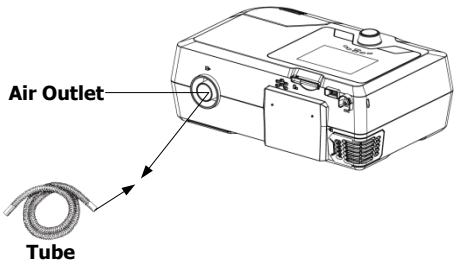


Fig. 11-6

(2) Connect the other end of the tube 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 tube. 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 tube.

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

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

• In order to minimize the risk of CO_2 rebreathing, the patient should observe the following instructions:

- Use the accompanying tube and mask provided by ECE.
- 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.

CAUTION!

• When using the tube with a diameter of 15mm, set the tube of the Patient Menu to 15 mm (see Section 14.2 "Options of the Patient Menu and Corresponding Descriptions").

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 most 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 Respirox® 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. 11-7.

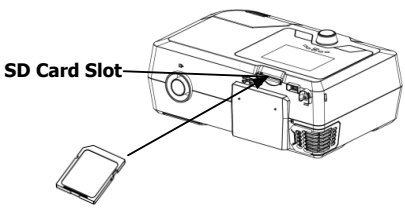


Fig. 11-7

If the SD card is inserted correctly, a symbol indicating correct insertion will appear in the Main Interface on the screen of the device, as shown in Fig. 11-8.

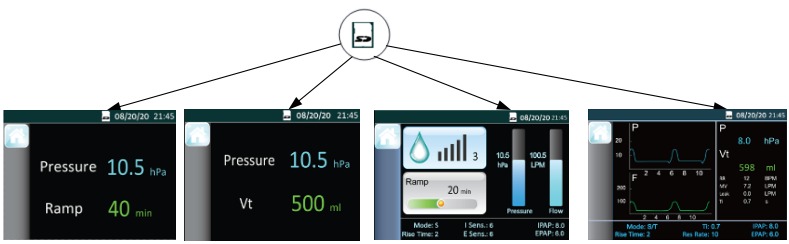


Fig. 11-8

If the SD card is inserted incorrectly, a symbol indicating incorrect insertion will appear in the Main Interface on the screen of the device, as shown in Fig. 11-9.

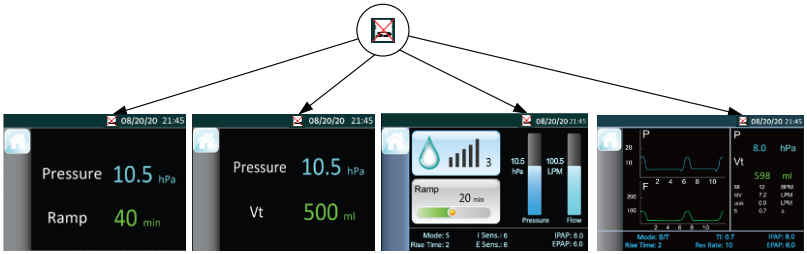


Fig. 11-9

CAUTION!

• 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 main device stops delivering air.

11.8 Using the Optional Kits

Optional Kits contain KS-CM01 SpO_2 Kit, WL-200 Cellular Module and SG-200 SpO_2&GPRS Kit. For more details, please refer to the corresponding user manual.

CAUTIONS!

• No SpO_2 alarm when configuring the SG-200 SpO_2&GPRS Kit and KS-CM01 SpO_2 Kit.

• The device can only use the SG-200 SpO_2&GPRS Kit, KS-CM01 SpO_2 Kit and WL-200 Cellular Module which configured for the device.

• When the power failure, no special operation is required after restore power supply. The device will continue to work according to the setting before.

11.9 Starting Treatment

Connect the device to a power outlet, press **the Knob** , and the device will start delivering air.

WARNINGS!

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

• DO NOT connect any ancillary equipment to this device unless recommended by ECE 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 Tube

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

12.2 Adjusting the Tube

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

12.3 Turning on the Airflow

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

12.4 Heating the Water

Pay attention to the humidifier indicator lights when using the humidifier. The indicator lights indicate the On / Off state of the humidifier. It is off when all indicator lights go out.

CAUTION!

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

12.5 Using the Ramp Button

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

CAUTIONS!

• You can press **the Ramp Button** as often as you wish during sleep.

• The ramp feature is not prescribed for all users.

12.6 Turning the Device Off

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

CAUTIONS!

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

• To isolate the device from the supply mains, disconnect the plug.

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

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

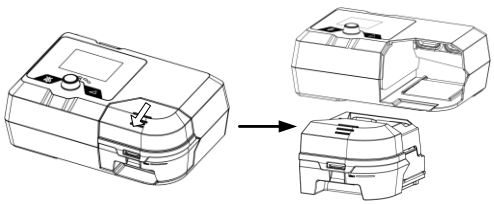


Fig. 13-1

WARNING!

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

13.1.2 Filling Water

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.

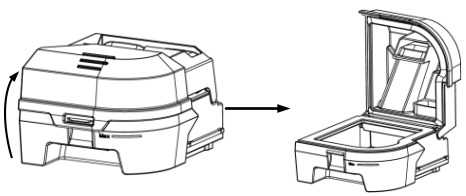


Fig. 13-2

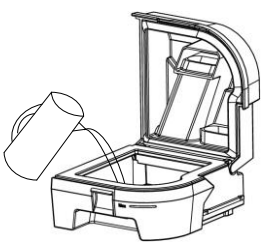


Fig. 13-3

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.

13.1.3 Inserting the Water Chamber

Close the cap after it is filled with water, as shown in Fig. 13-4, and return it to the device, as shown in Fig. 13-5.

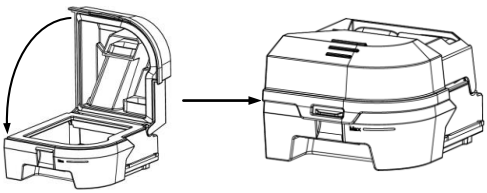


Fig. 13-4

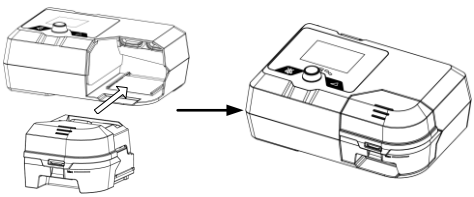


Fig. 13-5

WARNING!

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

CAUTIONS!

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

• Take precautions to protect furniture from water damage.

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.

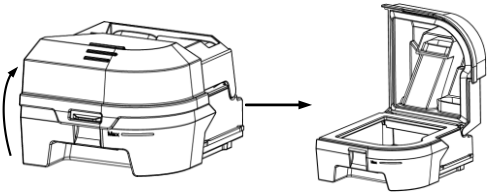


Fig. 13-6

CAUTION!

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

(3) **Inserting the Water Chamber** according to instructions in 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 on the screen of the device.

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

The temperature of the water in the water chamber maintains a constant set level. Three indicator lights light up when the humidity is adjusted to Level 3, as shown in Fig. 13-7.

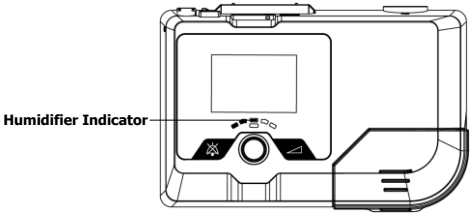


Fig. 13-7

CAUTIONS!

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

• The greater the difference between the temperature inside the air tubing and room temperature is, the more easily condensation occurs inside the tubing.

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

WARNING!

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

14. Navigating the Patient Menu

14.1 Steps to Navigating the Patient Menu

14.1.1 Accessing the Main Interface

Connect the power cord and power adapter properly. The screen displays the Main Interface shown in Fig. 14-1, or the Main Interface shown in Fig. 14-2, or the Main Interface shown in Fig. 14-3, or the Main Interface shown in Fig. 14-4.

Fig. 14-1

Note: The above interface only applies to G2S B20S, G2S B20A.

Fig. 14-2

Note: The above interface only applies to G2S B20T.

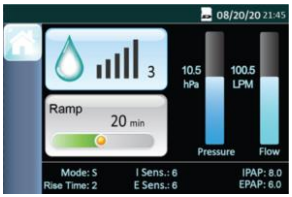


Fig. 14-3

Note: The above interface only applies to G2S B25A and G2S B25S.

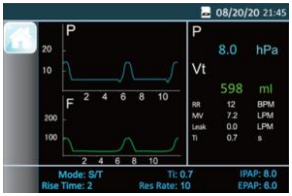


Fig. 14-4

Note: The above interface only applies to G2S B25T, G2S B25VT, G2S B30T, G2S B30VT, G2S B30AT and G2S LAB.

14.1.2 Bringing up the Initial Setup Interface

From the Main Interface shown in Fig. 14-1 or Fig. 14-2 or Fig. 14-3 or Fig. 14-4, press and hold **the Ramp Button** for three seconds. The screen displays the Initial Setup Interface of the Patient Menu, as shown in Fig. 14-5.

Fig. 14-5

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

14.1.3 Accessing the Setup Interface

When the cursor is on the icon, the screen displays the Setup Interface. Access the Setup Interface by pressing **the Knob**. The first option on the Setup Interface is then displayed in blue, as shown in Fig. 14-6.

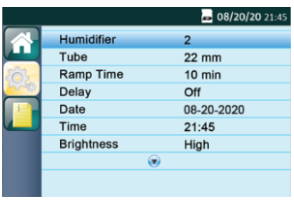


Fig. 14-6

14.1.4 Selecting Options

As you turn **the Knob** clockwise, the cursor moves downwards from one option to another. As you turn it counterclockwise, the cursor moves upwards. When the cursor is on a certain option, press **the Knob**, and the option is then displayed in yellow, meaning that the option can now be adjusted, as shown by the **Humidifier** option in Fig. 14-7.

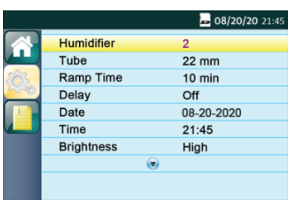


Fig. 14-7

14.1.5 Adjusting Options

Adjust the option by turning **the Knob** . As shown in Fig. 14-7, 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 level. The **Humidifier** option is still displayed in yellow, as shown in Fig. 14-8.

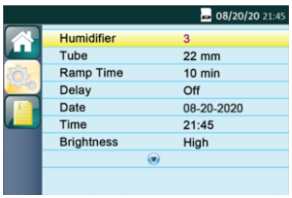


Fig. 14-8

14.1.6 Confirming Adjustments

Confirm your adjustment to an option by pressing **the Knob** . The option is then displayed in blue, as shown in Fig. 14-9.

Fig. 14-9

14.1.7 Turning Pages

When the cursor is on **Mask Type**, the last option shown in Fig. 14-9, the remaining options will appear on a new page if you continue to turn **the Knob** clockwise, as shown in Fig. 14-10.

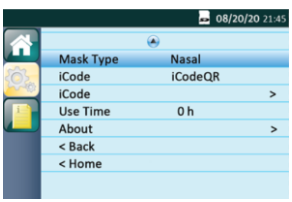


Fig. 14-10

Note: are page turning symbols.

14.1.8 Exiting the Patient Menu

(1) Returning to the Initial Setup Interface

Move the cursor to the **Back** option by turning **the Knob** , as shown in Fig. 14-11.

Fig. 14-11

Press **the Knob**, the cursor jumps to the second icon on the left side of the screen. The screen displays the Initial Setup Interface, as shown in Fig. 14-12.

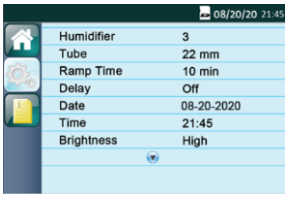


Fig. 14-12

(2) Returning to the Main Interface

Move the cursor to the **Home** option by turning **the Knob**, as shown in Fig. 14-13.

Fig. 14-13

Press **the Knob** to exit the Patient Menu. The screen will display the Main Interface shown in Fig. 14-1 or Fig. 14-2 or Fig. 14-3 or Fig. 14-4.

14.2 Options of the Patient Menu and Corresponding Descriptions

Option	Range	Description
Humidifier	Off, 1 ～ 5	There are five humidity levels available. As the numbering increases, the humidity rises accordingly. "Off" means the humidifier is turned off
Tube	15 mm / 22 mm	Setting diameter of the tube by adjusting this option
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
Ramp Time	0 - Max Ramp	In order to increase comfort and help the patient fall asleep easily, the pressure can increase gradually, when the Ramp feature is enabled. The ramp time during which the initial pressure rises to the prescribed treatment pressure can be adjusted. As you turn **the Knob** to the nearest point, the numbering increases or decreases by five minutes. The screen displays a real-time countdown of the remaining ramp time in minutes
Delay	On / Off	When the humidifier is on, this feature allows the airflow to continue for about 15 minutes at a low pressure (about 2 hPa) after you press **the Knob** to discontinue treatment. This will blow off the vapor left in the humidifier to avoid any damage to the device. When this feature is set to "Off," which means it is disabled, the airfolw stops delivering air instantly after you press **the Knob**
Date	2000-01-01 — 2099-12-31	Set date by adjusting this option
Time	00:00 — 23:59	Set time by adjusting this option
Brightness	High / Low	Setting screen brightness by adjusting this option
Mask Type	Full Face; Nasal; Pillow; Other	There are three mask types available, Full Face (full-face mask), Nasal (nasal mask), and Pillow (nasal pillow mask). The patient should choose suitable masks. When selecting masks other than the above three types of masks, the patient can identify the masks as **Other**
iCode	iCode, iCode QR, iCode QR+	iCode provides access to the patient's compliance data during a recent time period. The iCode mode displays data in sequences of numbers, and the iCode QR / iCode QR + mode displays data in two-dimensional codes
Use Time	0 ～ 50000 h	Use Time displays how long has the device been used by the patient. The use time can be erased
About	Model; SN; Firmware version; ID; PIN	Show the relevant information about the device, this is only for users to view, can not be modified. Model: the device model; SN: Serial Number of the device; Firmware version: Software version of the device; ID: Contains information such as gallery and language; PIN: Personal identification code

15. 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 alert sounds like "beep beep beep, beep beep, beep beep beep, beep beep", which means the alarming system of the device works normally.

15.1 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

15.2 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

15.3 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

15.4 Alarming Silence

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

15.5 Alarming Information and Description

Alarm Message	Alarm Priority	Alarm Type	Description
Power Failure!!!	High Priority	Technology Alarm	An audible alert will sound in 6 s if the device is accidentally disconnected from power when it is delivering air. Alarming duration time is no less than 30 s. **Note:** (1) The alert will not sound if power failure occurs when the device is in standby state. (2) No alert message on the screen during a power failure
Device fault!!!	High Priority	Technology Alarm	An audible alert will sound if no airflow comes out of the machine; the screen will display "**Device fault!!!**"
Tube disconnected!!! (only applies to G2S B20T, G2S B25T, G2S B25VT, G2S B30T, G2S B30VT, G2S B30AT and G2S LAB)	High Priority	Function Alarm	When the airflow is on, an audible alert will sound if the tube accidentally detached, the screen will display "**Tube disconnected!!!**"

Alarm Message	Alarm Priority	Alarm Type	Description
High Pressure!!!	High Priority	Function Alarm	When the airflow is on, an audible alert will sound if the airway pressure exceeds the warning threshold; the screen will display "**High Pressure!!!**". **Note:** The thresholds for different models: Off, 5 ～ 21 hPa applies to G2S B20T, in 0.5 hPa increments, the default setting is "**20 hPa**". Off, 5 ～ 26 hPa applies to G2S B25T, G2S B25VT and G2S LAB, in 0.5 hPa increments, the default setting is "**25 hPa**" Off, 5 ～ 31 hPa applies to G2S B30T, G2S B30VT and G2S B30AT, in 0.5 hPa increments, the default setting is "**30 hPa**"
Low Pressure!!	Middle Priority	Function Alarm	When the airflow is on, an audible alert 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 ～ 19 hPa applies to G2S B20T, in 0.5 hPa increments, the default setting is "**4 hPa**". Off, 3 ～ 24 hPa applies to G2S B25T, G2S B25VT and G2S LAB, in 0.5 hPa increments, the default setting is "**4 hPa**" Off, 3 ～ 29 hPa applies to G2S B30T, G2S B30VT and G2S B30AT, in 0.5 hPa increments, the default setting is "**4 hPa**"
Low RR!!! (only applies to G2S B20T, G2S B25T, G2S B25VT, G2S B30T, G2S B30VT, G2S B30AT and G2S LAB)	High Priority	Function Alarm	When the airflow is on, an audible alert 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

Alarm Message	Alarm Priority	Alarm Type	Description
Low SpO_2!!!	High Priority	Function Alarm	When SpO_2 Kit is applied, an audible alert will 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 alert will sound if the air leak rate exceeds 150 L/min; the screen will display "**Leak!!**". The alarming duration time is no less than 30 s
Mask Blocked!! (only applies to G2S B20T, G2S B25T , G2S B25VT, G2S B30T, G2S B30VT, G2S B30AT and G2S LAB)	Middle Priority	Function Alarm	When the airflow is on, an audible alert will sound if the vents of the mask are blocked; the screen will display "**Mask Blocked!!**"
Low MV!! (only applies to G2S B20T, G2S B25T , G2S B25VT, G2S B30T, G2S B30VT, G2S B30AT and G2S LAB)	Middle Priority	Function Alarm	When the airflow is on, an audible alert 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 22 V, an audible alert will sound and the screen will display "**Low Input Voltage!!**"
High RR!! (only applies to G2S B20T, G2S B25T , G2S B25VT, G2S B30T, G2S B30VT, G2S B30AT and G2S LAB)	Middle Priority	Function Alarm	When the airflow is on, an audible alert 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

Alarm Message	Alarm Priority	Alarm Type	Description
Humidifier Failure!!	Middle Priority	Function Alarm	When humidifier is applied, an audible alert will sound when the humidifier fails to work in 10 minutes; the screen will display "**Humidifier Failure!!**"
Please Change Filter!	Low Priority	Technology Alarm	When the Filter Alert feature is enabled, an audible alert will sound if the preset replacement time reaches but without replacing the air filter; the screen will display "**Please Change Filter!**". The default setting is "**Off**".
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 1 s.

15.6 Reposition of Alarming

After the elimination of the alrming 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.

15.7 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.

16. 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 tube and on determining the frequency of cleaning.

• Before cleaning, check whether the device has been disconnected from the power supply, whether the power cord has been unplugged, and whether the water chamber of the humidifier has cooled down. Make sure the heater 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.

16.1 Cleaning the Mask and Headgear

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

16.2 Cleaning the Optional Kits

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

CAUTIONS!

• It is recommended to clean the SpO_2&GPRS Kit / SpO_2 Kit / Cellular Module once a week.

16.3 Cleaning the Water Chamber

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

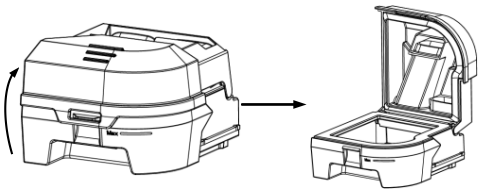


Fig. 16-1

(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.

16.4 Cleaning the Enclosure

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

CAUTION!

• 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.

16.5 Cleaning the Tube

(1) Remove the tube from the device and mask before cleaning.
(2) Clean the tube in warm water which contains washing liquid, and then rinse it in clean water thoroughly.
(3) After cleaning, air-dry the tube in a cool, well-ventilated area, and avoid direct sunlight. It takes approximately 30 minutes to completely air-dry the tube. Check whether the tube is completely dry before re-use.

CAUTIONS!

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

16.6 Replacing the Air Filter

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

CAUTIONS!

• To avoid material damage, do not place the spare air filter in direct sunlight, humid environments, or temperatures below the freezing point. The air filter should be replaced every 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.
• Replacing the air filter and filter cap, device must be unplugged.

16.7 Disinfection

Generally speaking, if you have strictly followed the above cleaning instructions, you do not have to disinfect the device and / or humidifier. 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 16.3 "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:

See the Disinfection section of the kit user manual for more information on the disinfection of the SpO_2 Probe.

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 tube, 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.

17. Traveling with the Device

CAUTIONS!

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

• Using the device at an incorrect elevation setting could result in airflow pressures higher than the prescribed setting. Always verify the elevation setting when traveling or relocating.

• If the device is used when the atmospheric pressure is out of the stated range (See Section 5), the accuracy of the leakage alert will be affected.

(1) Use the ECE 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.

18. 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, tube, and air filter, should be replaced to prevent cross-infection.

19. Reordering

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

WARNINGS!

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

• If the device malfunctions, contact your home care provider immediately. Never attempt to open the enclosure of the device. Repairs and adjustments must be performed by ECE-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 ECE TIBBİ CİHAZLAR VE MEDİKAL SAN.TİC. A.Ş for technical support and documents.

20. Technical Support

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

21. Disposal

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

22. Troubleshooting

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

22.1 Common Problems in Patients and Corresponding Solutions

Problem	Possible Cause	Solution (s)
Dry, cold, runny, and blocked nose; having a cold	The nose reacts to the airflow and cold. Due to fast airflow, the air becomes cold, leading to nasal mucosa irritation and subsequent dryness and swelling	Increase the humidity setting of the humidifier 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 latex-free mask Place a lining between the skin and mask

Problem	Possible Cause	Solution (s)
Water in mask	When the humidifier is used, the humidified air tends to condense in the cold tube and mask if the room temperature is low	Turn the humidity setting down, or raise the room temperature Place the tube under the quilt, or use the tube cover Hang the tube loosely, and the lowest part of the tube should be lower than the patient's head
Nasal, sinus, or ear pain	Sinus or middle ear inflammation	Contact your physician immediately
Discomfort due to inability to adapt to the treatment pressure	The patient will feel uncomfortable when the treatment pressure is higher than 13 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 tube is not connected properly	Reconnect the tube properly
Air delivered from the device is abnormally hot	The air inlet of the device may be partially blocked, leading to insufficient airflow into the device	Replace the air filter (see 16.6 Replacing the Air Filter), and clean the air inlet Place the device in an area where air flows freely, and make sure the device is at least 20 centimeters away from the wall, curtain, or other things

22.2 Common Problems in the Device and Corresponding Solutions

Problem	Possible Cause	Solution (s)
The device does not work when it is turned on	The Auto On / Off feature is enabled	Take a few deep breaths with the mask on, and the device will start automatically
	Power is not connected properly	Ensure that the power cord, power adapter, and the device are connected properly
	There is no voltage	Check whether a power outage occurs by turning on a light or other means. If you are sure the fuse in the device is broken, contact your equipment supplier for repair
	Cannot find any cause	Contact your equipment supplier
The device is working, but the pressure inside the mask differs from the set treatment pressure	The tube is not connected properly	Reconnect the tube properly
	There may be holes in the mask or pressure sensing tube	Contact your equipment supplier
	It is a faulty device	Contact your equipment supplier
The device produces very low pressures	The air inlet of the device may be blocked	Replace the air filter (see 16.6 Replacing the Air Filter), and clean the air inlet. Make sure the air inlet is unblocked
	The treatment pressure has been changed accidentally	Contact your physician
	When the Ramp feature is enabled, it takes some time for the initial pressure to rise to the treatment pressure. This is normal	If necessary, disable the Ramp feature, or set the ramp time shorter
After the device is turned on, the screen displays intermittently, or displays nothing at all	The operating system of the device needs to be readjusted or restarted	Unplug the power cord of the device, and re-plug it 20 seconds later
The device is in standby, and will not start	The operating system of the device needs to be readjusted or restarted	Unplug the power cord of the device, and re-plug it 20 seconds later

23. EMC Requirements

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

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±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 ±1 kV for input / output lines	±2 kV for power supply lines ±1 kV for input / output 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) ±2 kV common mode	±1 kV line (s) to line (s) ±2 kV common mode	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 a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz ~ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz ~ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{p}$ $d = 0.35\sqrt{p}$ 80 MHz to 800 MHz $d = 0.70\sqrt{p}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 10 V/m.

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

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

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

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

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

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

Recommended separation distances between RF wireless communications equipment

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

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

Note 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.

24. Limited Warranty

ECE TIBBİ CİHAZLAR VE MEDİKAL SAN.TİC. A.Ş 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 ECE TIBBİ CİHAZLAR VE MEDİKAL SAN.TİC. A.Ş to the dealer. If the product fails to perform in accordance with the product specifications, ECE TIBBİ CİHAZLAR VE MEDİKAL SAN.TİC. A.Ş will repair or replace, at its option, the defective material or part. ECE TIBBİ CİHAZLAR VE MEDİKAL SAN.TİC. A.Ş will pay customary freight charges from ECE TIBBİ CİHAZLAR VE MEDİKAL SAN.TİC. A.Ş 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.

ECE TIBBİ CİHAZLAR VE MEDİKAL SAN.TİC. A.Ş 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:

MANUFACTURER:
BMC Medical Co., Ltd.
Room 110 Tower A Fengyu Building, No. 115 Fucheng Road,
Haidian, 100036 Beijing, PEOPLE'S REPUBLIC OF CHINA
Tel: +86-10-51663880
Fax: +86-10-51663880 Ext. 810
URL: en.bmc-medical.com
E-mail: intl@bmc-medical.com

MANUFACTURING SITE:
BMC (Tianjin) Medical Co., Ltd.
2/F North Area and 3/F, Building No.4, No.1 Xinxing Road,
Wuqing District, 301700 Tianjin, PEOPLE'S REPUBLIC OF CHINA
Tel: +86-22-82939881

EU AUTHORISED REPRESENTATIVE:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestraβe 80, 20537 Hamburg, Germany
Tel: 0049-40-2513175
Fax: 0049-40-255726

IMPORTER:
ECE TIBBI CIHAZLAR VE MEDIKAL SAN.TIC. A.S.
MALTEPE MAH. HASTANE YOLU SOK. 6, ZEYTINBURNU-ISTANBUL 34010 TURKEY
Tel: 444 78 96
www.ecemedikal.com.tr, www.respirox.com.tr

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