User Manual

Sleep Apnea Therapy Device and Accessories

Auto CPAP System

M1 Mini

CE 0123

Table of Contents

1. Symbols

1.1 Control Buttons

Bluetooth Button

Start/Stop Button

1.2 Device Symbols

	Follow Instructions for Use	LOT	Lot number
	Operating Instructions		Manufacturer
	Type BF Applied Part (mask)		Manufacturing date
	Class II (Double Insulated)	EC REP	Authorized Representative in the European Community
	AC Power	CE 0123	European CE Declaration of Conformity
	DC Power	Bluetooth®	Bluetooth logo
IP22	≥12.5 mm Diameter, Dripping (15º tilted)		Nonionizing radiation
SN	Serial Number of the Product	BMC	Logo of BMC Medical Co., Ltd.
	Aircraft use		

CAUTION!

• The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by BMC is under license. Other trademarks and trade names are those of their respective owners.

2. Warning, Caution and Important Tip

WARNING!

Indicate the possibility of injury to the user or operator.

CAUTION!

Indicate the possibility of damage to the device.

IMPORTANT TIP!

Place emphasis on an operating characteristic.

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

3. Intended Use

The M1 Mini Auto CPAP 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 BMC accessories.

WARNINGS!

• The device is intended for adult use only.

• The device is not intended for life support.

• The instructions in this manual are not intended to supersede established medical protocols.

• Do not bring the device or accessories into a Magnetic Resonance (MR) environment as it may cause unacceptable risk to the patient or damage to the device or MR medical devices. The device and accessories have not been evaluated for safety in an MR environment.

• Do not use the device or accessories in an environment with electromagnetic equipment such as CT scanners, Diathermy, RFID and electromagnetic security systems (metal detectors) as it may cause unacceptable risk to the patient or damage to the device. Some electromagnetic sources may not be apparent, if you notice any unexplained changes in the performance of the device, if it is making unusual or harsh sounds, disconnect the power cord and discontinue use. Contact your home care provider.

CAUTION!

• The device is restricted to sale by or on the order of a physician.

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.

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

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, 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!

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

• Please use the mask which meets ISO 17510: 2015 and ISO 18562 series standard.

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: 159 mm × 66 mm × 72 mm

Weight: < 400 g

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:	≤ 93% Non-condensing	≤ 93% Non-condensing
Atmospheric Pressure:	760 ～ 1060 hPa	760 ～ 1060 hPa

Mode of Operation

Continuous

Work Mode

CPAP, AutoCPAP

AC Power Consumption

100 - 240 V AC, 50 / 60 Hz, 1.0 A max

Main device input

19 V, 1.26 A

Type of Protection Against Electric Shock

Class II Equipment

Degree of Protection Against Electric Shock

Type BF Applied Part

Degree of Protection Against Ingress of Water

IP22

Pressure Range

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

Pressure Display Accuracy

0 to 20 hPa，Margin of Error：±(0.5 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 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	125	110	110	95
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.					

Air Tubing

Air tubing	Length	Inner diameter
Tubing	6 ft.(1.83 m)	15 mm
Tubing	6 ft.(1.83 m)	19 mm

The Form and the Dimensions of the Patient Connection Port

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

Air filter

Filtration efficiency: > 20% for 10 micron

Material: Non-woven fabric and Polyester

Aircraft use

BMC confirms that the device meets the Federal Aviation Administration (FAA) requirements (RTCA/DO-160, section 20, category T and section 21, category M) for all phases of air travel.

Bluetooth authentication information

Product name: Auto CPAP System

Model: M1 Mini

DID: D051679

QDID: 154506

Bluetooth module

Technology used: Bluetooth

Connection types: GATT

Frequency: 2400 to 2483 MHz

Max RF power output: +4 dBm

Operating range: 10 m (Class 2)

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.

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

7. Glossary

Apnea

A condition marked by the cessation of spontaneous breathing.

AutoCPAP

Adjust CPAP pressure automatically to improve patient comfort based on monitoring of 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.

CPAP

Continuous Positive Airway Pressure.

LPM

Liters Per Minute.

OSA

Obstructive Sleep Apnea.

Patient Menu

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

Ramp

A feature that may increase patient comfort when therapy is started. It can reduce pressure and then gradually increase the pressure to the prescription setting so the patient can fall asleep more comfortably.

Reslex

A therapy feature that is enabled by you or 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

Means the date.

8. Model

Model	Product Description				
	Product Contents	**Optional Accessory 1**	**Optional Accessory 2**	**Work Mode**	**Maximum Work Pressure (hPa)**
M1 Mini	Main device, Mini series ventilator control software (LightTrip App)	Tubing	Mask	CPAP, AutoCPAP	20

9. Package Contents

After unpacking the system, make sure you have everything shown here:

No.	Articles	Qty.	Notes
1	Main Device	1	
2	Tubing	1	Optional
3	Mask	1	Optional
4	Air Filter	2	
5	Power Adapter	1	
6	Storage bag	1	Optional
7	Carrying Case	1	Optional
8	Accompanying Documents	1	

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

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

According to the power adapter standards of different countries, different power adapters are configured.

IMPORTANTS!

• If any of the above parts are missing, contact your home care provider.

• Contact your home care provider for additional information on the available accessories of the device. When using optional accessories, always follow the instructions enclosed with the accessories.

WARNING!

• The device should only be used with the mask and accessories manufactured or recommended by BMC or with those recommended by your prescribing physician. The use of inappropriate masks and accessories may affect the performance of the device and impair the effectiveness of therapy.

10. System Features

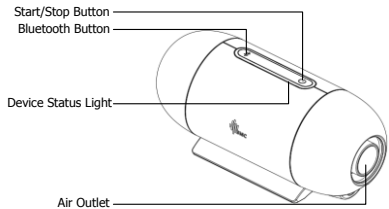

Fig. 10-1

Name	Function
Start/Stop Button	Press this button to Start / Stop delivering air. The indicator light is white.
Bluetooth Button	Press this button to control Bluetooth status: When Bluetooth is off, press this button to turn on the Bluetooth function; when Bluetooth is on, double click this button to turn off the Bluetooth function. The indicator light is blue.
Air Outlet	Deliver pressurized air; connected to the tube.
Device Status Light	This light is white in normal state and orange in case of prompt message.

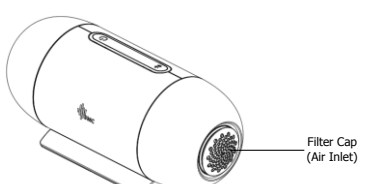

Fig. 10-2

Name	Function
Filter Cap (Air Inlet)	Place the cap on the air filter, which is used to filter dust and pollen in the air entering the device.

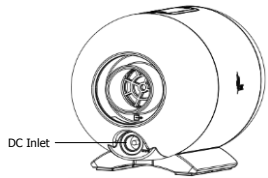

Fig. 10-3

Name	Function
DC Inlet	An inlet for the DC power supply.

11. First Time Setup

11.1 Download LightTrip App software

Search and download LightTrip App in the App store.

Support Android platform and IOS platform.

11.2 Placing the Device

Place the device on a firm, flat surface. The anti-skid pad installed at the bottom of the device is convenient for fixing the device.

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 (20°C, approximately 2 hours) before beginning setup.

• Make sure the device is away from any heating or cooling equipment (e.g., forced air vents, radiators, air conditioners).

• The device is not suitable for use in high humidity environments. Make sure that no water enters the device.

• Make sure that bedding, curtains, or other items are not blocking the filter or vents of the device.

• Keep pets, pests or children away from the device and avoid small objects being inhaled or swallowed.

• To avoid explosion, the 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.

11.3 Installing the Air Filter and Filter Cap

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

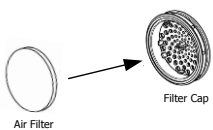

Fig. 11-1

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

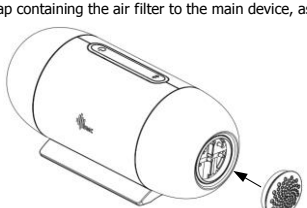

Fig. 11-2

CAUTION!

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

11.4 Connecting to Power

(1) Insert the plug of the power adapter into the DC Inlet of the device;

(2) Plug the other end of the power adapter into the power outlet.

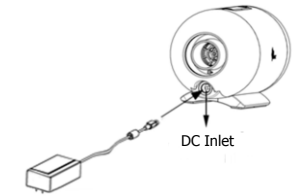

Fig. 11-3

WARNINGS!

• The device is powered on for use when the power adapter is connected. The Button ⏻ 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.

• Do not place the device where it is difficult to disconnect the power supply.

• Do not stack too long cables or tubing at the head of the bed, which may entangle the head or neck of the patient during sleeping.

CAUTION!

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

IMPORTANT!

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

11.5 Assembling the Tubing and Mask

(1) Connect one end of the tube to the air outlet of the main device, as shown in Fig. 11-4.

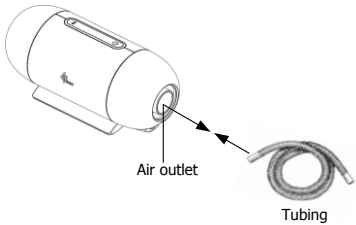

Fig. 11-4

(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 BMC.

- Do not wear the mask for more than a few minutes while the device is not operating.

- Use only masks with vent holes. Do not block or try to seal the vent holes in the exhalation port.

• Failure to use a mask or accessory that permits spontaneous breathing can cause asphyxiation.

• Failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation.

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 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 M1 Mini 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 Establish Bluetooth connection

Connect the device to a power supply. Press the Bluetooth button on the main device and the Bluetooth indicator light flashes. Then open the LightTrip App, click the Bluetooth icon, and start to search the device, select the device (name is device serial number, please check the device nameplate information) in the device list for Bluetooth connection. If the Bluetooth is connected successfully, the Bluetooth working status light of the main device will be kept on.

11.8 Setting

Click "Settings" and "Accessories" in the LightTrip App to enter the corresponding Settings interface respectively. See "13. Navigating the Patient Menu" in this manual for detailed of the interface.

11.9 Starting Treatment

Press the **Start/Stop Button** or click on the icon in the LightTrip App, 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 the device, contact your equipment supplier.

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

12. Routine Use

12.1 Connecting the Tubing

Connect the power adapter and tubing properly according to the instructions in the First Time Setup (Chapter 11). Connect the mask and headgear according to the user manual for the mask.

CAUTION!

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

12.2 Adjusting the Tubing

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

12.3 Turning on the Airflow

Press the **Start / Stop Button** or click on the icon in the LightTrip App to turn on the airflow. The LightTrip App will display treatment pressure and other information.

12.4 Using the Ramp Function

When the Ramp function is turned on, the pressure will gradually rise to the prescribed treatment pressure according to the preset ramp time from the initial pressure, so as to make the patient fall asleep easily. The LightTrip App displays a real-time countdown of the remaining ramp time in minutes.

CAUTION!

• The ramp feature is not prescribed for all users.

12.5 Turning the Device Off

Take off the mask and headgear, press the **Start / Stop Button** or click on the icon in the LightTrip App, and the device will stop delivering air. Disconnect the power adapter from the power outlet to power off the device.

13. Navigating the Patient Menu

13.1 Steps to Navigating the Patient Menu

13.1.1 Accessing the setup interface

Connect the power adapter properly. Turn on the device and LightTrip App for Bluetooth connection. After the Bluetooth connection is successful, click "Settings" and "Accessories" to enter the corresponding parameter setting interface.

13.1.2 Setting and saving parameters

In the parameter setting interface, you can set the parameters as required. After setting the parameters, you need to save them, and the parameter setting is completed.

13.2 Options of the Patient Menu and Corresponding Descriptions

13.2.1 Treatment setting

Option	Range	Description
Ramp Time	0 ～ 60 minutes/ Auto	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. The numbering increases or decreases by five minutes. The LightTrip App displays a real-time countdown of the remaining ramp time in minutes.
Reslex	Off/1/2/3	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.
Auto on	On/Off	If this function is turned on, the device will automatically start delivering air under preset pressure after the patient puts on a breathing mask and takes several deep breaths. Click to select "On" or "Off".
Auto off	On/Off	If this function is turned on, the device will automatically stop delivering air and shut down after the patient takes off the breathing mask. Click to select "On" or "Off".
Tubing Type	22 mm/15 mm	There are two types of tubing available. Click to select "22 mm" or "15 mm".
Mask Type	Full Face/ Nasal/ Pillow/ Other	There are three mask types available, namely Full Face (full-face mask), Nasal (nasal mask), and Pillow (nasal pillow mask). But the patient can choose other suitable masks as well. When selecting masks other than the above three types of BMC masks, the patient can identify the masks as other.

Moisture Exchanger Type	None/ Ordinary edition/ Enhanced edition	It can be selected according to the moisture exchanger type of mask.

13.2.2 Accessories setting

Option	Range	Description
Air Filter	Off/7 days/14 days/ 21 days/30 days/60 days/ 90 days	Set the air filter remind cycle, it will remind the user once the cycle is over.
Mask	Off/30 days ～ 720 days	Set the mask remind cycle, it will remind the user once the cycle is over. The setting increment is 30 days.
Tubing	Off/30 days ～ 720 days	Set the tubing remind cycle, it will remind the user once the cycle is over. The setting increment is 30 days.
Moisture Exchanger	Off/7 days/14 days/ 21 days/28 days	Set the moisture exchanger remind cycle, it will remind the user once the cycle is over. The setting increment is 7 days
Days since last maintenance	Off/180 days/360 days	Set the cleaning and maintenance remind cycle, it will remind the user once the cycle is over.

14. Prompt

Prompt Message	Description
Power Failure!!!	If the device is accidentally disconnected from power when it is delivering air and the main device is connected with LightTrip App by Bluetooth, a prompt of "**Power Failure!!!**" will appear in LightTrip App. Note: The prompt will not appear if power failure occurs when the device is in standby state.
Device Fault!!!	If no airflow comes out of the machine when the device is started, the status light of device will flash. If the main device is connected with LightTrip App by Bluetooth, a prompt of "**Device Fault!!!**" will appear in LightTrip App.
Leak!!	If the Auto Off function of the device is off, when there is a large amount of air leakage in the device, the device status light flashes. If the main device is connected with LightTrip App by Bluetooth, a prompt of "**Leak!!**" will appear in LightTrip App.
Low Input Voltage!!	If the voltage supplied by the power adapter is too low,the status light of device will flash. If the main device is connected with LightTrip App by Bluetooth, a prompt of "**Low Input Voltage!!**" will appear in LightTrip App.
Please change the air filter!	When the remind cycle of air filter is set, the status light of device will flash if the preset remind cycle reaches but without replacing the air filter and reset remind cycle. If the main device is connected with LightTrip App by Bluetooth, a prompt of "**Please change the air filter!**" will appear in LightTrip App.
Please replace the tubing!	When the remind cycle of tubing is set, the status light of device will flash if the preset remind cycle reaches but without replacing the tubing and reset remind cycle. If the main device is connected with LightTrip App by Bluetooth, a prompt of "**Please replace the tubing!**" will appear in LightTrip App.
Please replace the mask!	When the remind cycle of Mask is set, the status light of device will flash if the preset remind cycle reaches but without replacing the mask and reset remind cycle. If the main device is connected with LightTrip App by Bluetooth, a prompt of "**Please replace the mask!**" will appear in LightTrip App.
Please replace the moisture exchanger!	When the remind cycle of moisture exchanger is set, the status light of device will flash if the preset remind cycle reaches but without replacing the moisture exchanger and reset remind cycle. If the main device is connected with LightTrip App by Bluetooth, a prompt of "**Please replace the moisture exchanger!**" will appear in LightTrip App.
Please perform cleaning and maintenance!	When the remind cycle of cleaning and maintenance is set, the status light of device will flash if the preset remind cycle reaches but without cleaning or maintaining and reset remind cycle. If the main device is connected with LightTrip App by Bluetooth, a prompt of "**Please perform cleaning and maintenance!**" will appear in LightTrip App.

15. Introduction of "Report"

Users can select to view the usage reports generated in a certain day or a certain period of time according to your needs. Users can use shortcut keys to quickly query or customize the time period query.

Statistical information	Range	Description
Score	0 ～ 100	According to the usage data of the selected time period, the usage effect is calculated with different weights.
Using effect:		
Used time	0 ～ 60/60	The score is calculated according to the user's usage in the selected time period. The "0 ～ 60" part represents the score of usage time, with the full score of 60.
Leak	0 ～ 20/20	The score is calculated according to the air leakage in the selected period time. The "0 ～ 20" part represents the score of air leakage, with a full score of 20.
AHI	0 ～ 10/10	The score is calculated according to the number of AHI occurrences in the selected period. The "0 ～ 10" part represents the score of AHI index, with a full score of 10.
Compliance	0 ～ 10/10	The compliance of a single day is calculated according to the proportion of effective days used in the past week, while the compliance of multiple days is calculated according to the proportion of effective days used in the selected period. The "0 ～ 10" part represents the compliance score, with a full score of 10.

For the above data, you can also click to view the column chart of each item to analyze the trend of single use effect.

In addition to the above data, the report also contains detailed statistics on usage, pressure, respiratory index and air leakage.

16. Introduction of "More"

Option	Description
Pressure Unit	Users can choose a pressure measurement unit, "hPa" or "cmH_2O". The default setting is "**cmH_2O**".
Upload Sleep Data	Users can choose whether or not to upload sleep data to the cloud platform. If the upload sleep data is selected, the device will automatically upload sleep data to the cloud platform.
Erase Data	Users can choose to erase the data stored in the APP or the main device.

In addition to the above functions, users can also view more information. Refer to the LightTrip App manual for details.

17. Software upgrading

When there is a new version of LightTrip App or device firmware, there will be a prompt when opening LightTrip App. According to the prompt, the software and firmware can be upgraded.

CAUTIONS!

• Please maintain Bluetooth connection between APP and main device during firmware upgrade.

• In order to ensure the best performance, it is recommended to keep the latest version of LightTrip App and device firmware.

18. Cleaning and Maintenance

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 washing liquid that is nontoxic to humans and does not cause allergies in humans.

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

• 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.

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

(1) Different patients need to replace a new BSF before using this equipment.

(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 fatigue of these materials.

• Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device

and its accessories. Liquid soap containing the humidifying agent or antimicrobials should not be used either. These solutions may harden cleaned materials or reduce their life.

• Do not clean or dry the device and its accessories when the temperature is higher than 80°C (176°F). High temperatures could reduce product life.

• Do not immerse the device in any fluids.

18.1 Cleaning the Mask and Headgear

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

18.2 Cleaning the 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.

18.3 Cleaning the Tubing

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

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

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

18.4 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, as shown in Fig. 18-1.

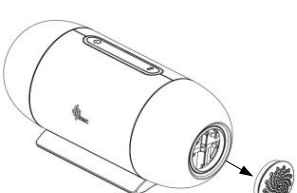

Fig. 18-1

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 at least every 6 months (the replacement cycle can be shortened according to local air quality, please replace it in case of damage and crack).

• Operating the device with a dirty air filter may stop it from working properly and may cause damage to the device.

19. Traveling with the Device

19.1 Traveling

(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 - 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 bought in electronics stores.

(3) Remember to bring a spare air filter and the emergency documents (filled and signed by your physician) about the 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.

CAUTIONS!

• 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.

19.2 Traveling by airplane

For some airlines, medical devices do not count toward carry-on luggage limits. Please check with your airline for their policy regarding medical equipment.

You can use your M1 Mini on a plane as it meets the Federal Aviation Administration (FAA) requirements.

WARNINGS!

• When connected to power, disable Bluetooth (enter airplane mode) by double clicking the Bluetooth button on the device to turn off the Bluetooth function.

• Do not use the LightTrip App. Use the Start/Stop button on the device to start or stop therapy.

• To reconnect Bluetooth (exit airplane mode), press the Bluetooth button on the device.

20. Transferring the Device to Another Patient

The air filter must be discarded and replaced, as it cannot be disinfected and cannot be used between other patients.

For instructions of other accessories, refer to their user manuals.

21. Reordering

Contact your home care provider to order accessories or replacement filters.

The device does not require routine servicing.

WARNINGS!

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

• If the device malfunctions, contact your home care provider immediately. Never attempt to open the enclosure of the device. Repairs and adjustments must be performed by BMC -authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.

• If necessary, contact your local authorized dealer or BMC Medical Co., Ltd., for technical support and documents.

22. Technical Support

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

23. Disposal

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

24. Troubleshooting

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

24.1 Common Problems in Patients and Corresponding Solutions

Problem	Possible Cause	Solution (s)
Dry, cold, runny, and blocked nose; having a cold	The nose reacts to the airflow and cold. Due to fast airflow, the air becomes cold, leading to nasal mucosa irritation and subsequent dryness and swelling	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
Facial reddening	Wrong mask size	Contract your equipment supplier for a correct-size mask
	The patient is allergic to the materials of the mask	Contact your physician and equipment supplier. Use a mask which is not made with natural rubber latex. Place a lining between the skin and mask
Nasal, sinus, or ear pain	Sinus or middle ear inflammation	Contact your physician immediately

Problem	Possible Cause	Solution (s)
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 18.4 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

24.2 Common Problems in the Device and Corresponding Solutions

Problem	Possible Cause	Solution(s)
The device does not work when it is turned on	The Auto On / Off feature is enabled	Take a few deep breaths with the mask on, and the device will start automatically
	Power is not connected properly	Ensure that the power 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 effects of degraded sensors and electrodes, or loosened electrodes	Contact your equipment supplier
The device produces very low pressure	The air inlet of the device may be blocked	Replace the air filter (see 18.4 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
The device is in standby, and will not start	The operating system of the device needs to be readjusted or restarted	Unplug the power cord of the device, and re-plug it 20 seconds later

25. EMC Requirements

The cables must be provided by BMC. The information of each cable is as follows:

(1) Power adapter: 1800 mm ± 45 mm, unshielded

(2) Tubing: 1800 mm ±10%, unshielded

Guidance and manufacturer's declaration - electromagnetic emissions	
The device is intended for use in the electromagnetic environment specified below. The customer or 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

Guidance and manufacturer's declaration - electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure 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 ±15 kV air	±8 kV contact ±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 cycles At 0° 0% U_T; 250 / 300 cycle
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: U_T is the a.c. mians 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 customer or the user of the device should assure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**
Conducted RF IEC 61000-4-6	3 V 0.15 MHz ~ 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz ~ 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz
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
385	1.8	0.3	27	27
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: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARNINGS!

• Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the M1 Mini, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. If you have to do so, the device should be observed to verify normal operation.

• The use of accessories and power adapter 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.

• The device may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

• During operation of the device, due to electrostatic interference, the following phenomena may occur: (1) Temporary loss of function or degradation of performance, such as abnormal screen display, etc. The device will recover to normal after being restarted; (2) Automatic restart of the device. These phenomena will not affect the normal use of the device, and will not cause permanent performance degradation or function loss of the device.

26. Limited Warranty

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

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

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

MANUFACTURER:

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