User Manual

Sleep Apnea Therapy Device and Accessories

RESmart BPAP System

20S/20A/25/25A Model (also sold as

BMC-720-S/BMC-720-A/BMC-770-25S/BMC-770-25A)

User Manual

InH2 Heated Humidifier

BMC-50

English

CE 0123

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User Manual

CE 0123

Table of Contents

1. Introduction

1.1 System Contents

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

No.	Item	Qty.	Notes
1	RESmart BPAP 20S/20A/25/25A	1	
2	InH2 Heated Humidifier	1	Optional
3	Power Cord	1	
4	Carrying Case	1	
5	User Manual	1	
6	SD Card	1	Optional

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.

IMPORTANT!

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

Note: If your system includes a humidifier, you will receive additional items with your package. See the instructions included with your humidifier for more information.

1.2 Intended Use

The RESmart BPAP System is a Bi-level Positive Airway Pressure device, which is intended to provide non-invasive ventilation for patients with obstructive sleep apnea (OSA), either in the hospital or at home.

The RESmart BPAP 20S/20A/25/25A 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 RESmart BPAP 20S/20A/25/25A as convenient and comfortable as possible. To ensure that you receive the safe, effective therapy prescribed for you, use only BMC accessories.

The RESmart BPAP 20S/20A/25/25A is only used for single patient and must not be re-used on another person. This is to avoid the risk of cross-infection.

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.

Adverse Effects

You should report unusual chest pain, severe headache or increased breathlessness to your physician. An acute upper respiratory tract infection may require temporary discontinuation of treatment.

The following side effects may arise during the course of therapy:

• drying of the nose, mouth or throat
• bloating
• ear or sinus discomfort

• eye irritation
• mask-related skin irritations
• chest discomfort

1.3 Warnings, Cautions and Contraindications

1.3.1 Warnings

A warning indicates the possibility for injury to the user or the operator.

WARNINGS!

• The instructions in this manual are not intended to supersede established medical protocols.
• This device is intended for adult use only.
• This device is not intended for life support.
• Images shown here are indicative only. If there is inconsistency between the image and actual product, the actual product shall govern.
• 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.
• BPAP devices have the potential to allow rebreathing of exhaled air.

To reduce this potential, observe the following:
- Use BMC circuit accessories.
- Do not wear the mask and headgear for more than a few minutes while the device is not operating.
- Do not block or try to seal the vent holes in the exhalation port.

As with most BPAP devices: At low BPAP pressures, some exhaled gas (CO_2) may remain in the mask and be rebreathed.
• If the room temperature is warmer than 95˚F (35°C), the airflow produced by the RESmart device may exceed 106˚F (41°C). The room temperature must be kept below 95˚F (35°C) while the patient uses the device.
• This equipment is not suitable for use in the presence of a flammable anaesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide.
• If you notice any unexplained changes in the performance of the RESmart BPAP 20S/20A/25/25A, 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, disconnect the power cord and discontinue use. Contact your home care provider.
• To avoid electrical shock, disconnect the power cord before cleaning and maintenance. DO NOT immerse the device in any fluids.
• Contact your health care professional if symptoms of sleep apnea recur.
• Using the RESmart BPAP 20S/20A/25/25A at an incorrect elevation setting could result in airflow pressures higher than the prescribed setting. Always verify the elevation setting when traveling or relocating.
• Please contact BMC to buy the SD card if you need it.

1.3.2 Cautions

Caution indicates the possibility of damage to the device.

CAUTIONS!

• Tobacco smoke may cause tar build-up within the RESmart BPAP 20S/20A/25/25A that may result in the RESmart BPAP 20S/20A/25/25A malfunctioning.
• This device is restricted to sale by or on the order of a physician.
• If you are using a SD card, make sure that the SD card is properly inserted into the device before it is powered on.
• In order to avoid impairing SD card or the data saved in it, please do not insert or pull out the SD card when the device is connected to a power source.
• The patient is an intended operator.
• Cleaning and disinfection can be performed by the patient.
• The device should not be placed in the place where it is difficult to disconnect the power cord.
• When the device reaches the end of its service life, dispose of the device and packaging in accordance with local laws and regulations.
• Unplug the power cord can be completely disconnected with the Reachctrl Power.
• 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.
• Please use the mask which meets ISO 17510:2015.

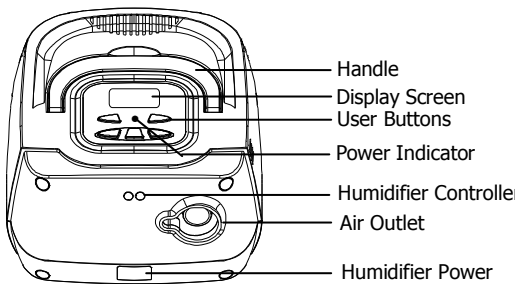
Additional warnings and cautions are located throughout this manual as they apply.

1.3.3 Contraindications

The BPAP should not be used if you have an insufficient respiratory drive to endure brief interruptions in non-invasive ventilation therapy. The BPAP is not a life support ventilator and may stop operating with power failure or in the unlikely event of certain fault conditions.
If you have any of the following conditions, tell your doctor before using the BPAP:

• acute sinusitis or otitis media.
• conditions predisposing to a risk of aspiration of gastric contents.
• epistaxis causing a risk of pulmonary aspiration.
• hypotension or significant intravascular volume depletion.
• Inability to maintain a patent airway or adequately clear secretions.
• pneumothorax or pneumomediastinum.
• recent cranial trauma or surgery.

1.4 System Overview



Handle: This handle is for lifting up the system.

Display Screen: All system settings, total operating time, and therapy hours will appear here.

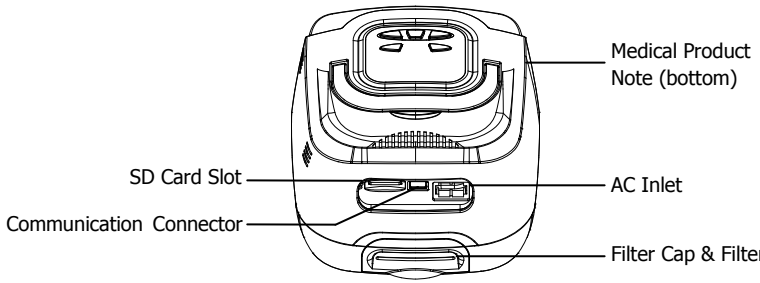
User Buttons + / -: These buttons can be used to turn on / off the system and change some of the system settings.

Power Indicator: When the device is connected to the power supply, the green indicator lights up.

Humidifier Controller: This controller turns the InH2 heated humidifier on / off and allows the heat setting to be adjusted. The humidifier is an optional accessory that may be purchased separately.

Air Outlet: Connect the flexible tubing (coaxial 22 mm) here.

Humidifier Power: This socket provides the power to the InH2 heated humidifier.



Medical Product Note: For ease at airport security stations, there is a note on the bottom of the RESmart BPAP 20S/20A/25/25A stating that it is medical equipment. It may help if you also take this manual with you when you travel.

AC Inlet: Connect / disconnect the AC power cord here.

SD Card Slot: Used to insert the SD card. As a memory medium, the SD card can record and save all patient treatment data.

Communication Connector: For clinical use with the Data Management Software. Connect the communications cable here (This port is for professional maintenance personnel only, and is not allowed to connect to other devices).

Filter Cap & Filters: The foam filter screens out normal household dust and pollens. The filter cap is designed to reduce the noise from the RESmart BPAP 20S/20A/25/25A.

1.5 Glossary

The following terms appear throughout this manual:

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

Auto S: 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.

Backup RR: Backup Respiration Rate.

BPM: Breaths Per Minute.

CPAP: A mode which the device output a constant positive pressure ignoring your inhalation or exhalation.

EPAP: Expiratory Positive Airway Pressure.

IPAP: Inspiratory Positive Airway Pressure.

LED: Light Emitting Diode.

OSA: Obstructive Sleep Apnea.

Ramp: A feature that may increase patient comfort when therapy is started. The ramp feature reduces the pressure and then gradually increases (ramps) the pressure to the prescription setting, so you 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.

RR: Respiratory Rate. Number of breaths per minute.

S (Spontaneous): 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. When the apnea is longer than 10 seconds, the device will start Backup Respiration Rate with a frequency of 10 times per minute to support respire.

1.6 Symbol Key

1.6.1 Control Buttons


Pressure Start / Stop Button


Ramp Button


Heated Humidifier Button


User Button

User Button

1.6.2 Device


Follow Instructions for Use


Type BF Applied Part (mask)


Class II (Double Insulated)


AC Power

IP21 ≥ 12.5 mm Diameter, Drip-Proof, Vertical

Serial Number of the Product


Manufacturer

Authorized Representative in the European Community

European CE Declaration of Conformity

2. Device Controls and Displays

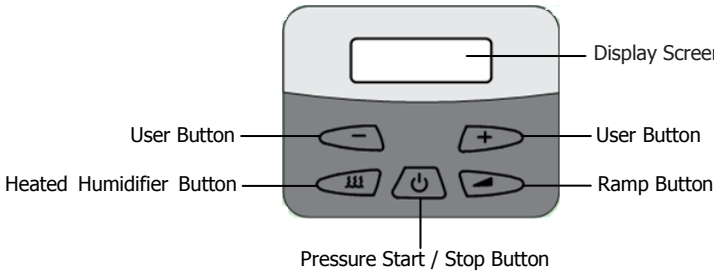
Display Screen: All device settings will appear here.

Pressure Start / Stop Button ⏻***:*** Use this button to start / stop the airflow. DO NOT start the airflow until the circuit tubing is connected.

Heated Humidifier Button ♨ ***:*** Use this button when the optional InH2 Heated Humidifier has been prescribed. This button will control the optional heated humidifier's output. Follow the instructions of the humidifier.

Ramp Button ◢***:*** When the device works under CPAP mode and the airflow is turned on, use this button to restart the ramp cycle (which lowers the airflow pressure and then gradually increases it). This will allow you to fall asleep more comfortably. When the airflow is turned off, use this button to access the patient menu. *Note: The ramp feature is not prescribed for all users.*

User Buttons + / -: These buttons can be used when entering various menus to change some of the RESmart BPAP 20S/20A/25/25A settings.



IMPORTANT!

• In the Setup Menu, the **User Buttons + / -** are used to go to the previous / next question or setting and operate as up and down keys to change the settings, the **Ramp Button** ◢ is used to confirm the setting change, and the **Pressure Start / Stop Button** ⏻ will allow you to exit the Setup Menu without saving.

3. First Time Setup

WARNING!

• Do not use the RESmart BPAP 20S/20A/25/25A until an appropriate professional adjusts the settings! To order any accessories not included with this system, contact your home care provider.

Note to home care provider: Before beginning setup, be sure that you have available the RESmart BPAP 20S/20A/25/25A Home Care Provider Setup Instructions. Setup instructions are not provided in this manual.

WARNING!

• Do not connect any equipment to the RESmart BPAP 20S/20A/25/25A unless recommended by BMC or your health care provider.

WARNING!

• 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.

CAUTION!

• If the RESmart BPAP 20S/20A/25/25A has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (approximately 2 hours) before beginning setup.

3.1 Installing the Filter

CAUTION!

• The foam filter must be in place at all times when the RESmart BPAP 20S/20A/25/25A is operating.

a. Place the foam filter into the filter area on the back of the RESmart BPAP 20S/20A/25/25A.

b. Attach the filter cap. Position the cap so that the small opening on the cap is facing down. Insert the cap's tabs into the filter area opening.

IMPORTANT!

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

WARNING!

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

WARNING!

• The RESmart BPAP 20S/20A/25/25A is powered on for use when the power cord is connected. The **Pressure Start / Stop Button** ⏻ turns the blower on / off.

CAUTION!

• Make sure the RESmart BPAP 20S/20A/25/25A is away from any heating or cooling equipment (e.g., forced air vents, radiators, air conditioners). Also make sure that bedding, curtains, or other items are not blocking the filter or vents of the device. Air must flow freely around the device for the system to work properly.

3.2 Connecting the Breathing Circuit

3.2.1 Assembling the Breathing Circuit

Place the RESmart BPAP 20S/20A/25/25A on a firm, flat surface. To use the system, you will need the following accessories in order to assemble the recommended circuit.

• Nasal Mask with integrated exhalation port
• 6 ft. (1.83 m) flexible Tubing
• Headgear (for the mask)

WARNING!

• If multiple persons are going to use the RESmart BPAP 20S/20A/25/25A (e.g., rental devices), a low-resistance, main flow bacteria filter should be installed in-line between the RESmart BPAP 20S/20A/25/25A and the circuit tubing. Pressures must be verified by your home care provider when alternate or optional accessories are in place.

a. Connect the flexible tubing to the air outlet on the front of the RESmart BPAP 20S/20A/25/25A.

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

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

WARNING!

• Do not block or otherwise try to seal the air openings (vent holes) on the exhalation port.

Explanation of the warning: The RESmart BPAP 20S/20A/25/25A is intended to be used with masks and circuits that have an exhalation port designed to exhaust CO_2 from the circuit. When the RESmart BPAP 20S/20A/25/25A is turned on and functioning properly, new air from the RESmart BPAP 20S/20A/25/25A flushes the exhaled air out through the exhalation port. When the RESmart BPAP 20S/20A/25/25A is turned off, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation. This warning applies to most BPAP devices.

WARNING!

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

IMPORTANT!

• Before each use, examine the flexible tubing for any damage or debris. If necessary, clean the tubing to remove the debris. Replace any damaged tubing.

c. Connect the mask to the headgear, following the instructions included with the headgear.

d. Put on the mask and headgear, and breathe normally through your nose. The airflow should automatically start when you begin breathing through the circuit. If the airflow does not start within four breaths, press the **Pressure Start / Stop Button** ⏻ on the top of the RESmart BPAP 20S/20A/25/25A. When operating the system with some mask types or some circuit configurations, the airflow may NOT automatically start.

3.2.2 Adjusting the Breathing Circuit

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

3.3 Connect the Power Cord

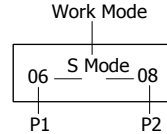
Plug the socket end of the power cord into the AC inlet on the back of the RESmart BPAP 20S/20A/25/25A. Plug the pronged end of the power cord into an electrical outlet. System status will appear on the RESmart BPAP 20S/20A/25/25A screen.

4. Device Operation

4.1 Starting the Device

Standby

After power on, system status will appear on display screen as below.



Work Mode: The starting Mode.

P1: EPAP when device work on Mode S, Default setting is 6 hPa.

P2: IPAP when device work on Mode S, Default setting is 8 hPa.

4.2 Using the Ramp Button

Pressing the **Ramp Button** will reduce the air pressure when you are trying to fall asleep. The air pressure will gradually increase until your prescription pressure is reached. If your physician prescribed ramp for you, pressing the button will reduce the pressure and then gradually increase (ramp) the pressure to the therapeutic pressure setting so that you can fall asleep more comfortably.

Note: The ramp feature is not prescribed for all users.

Press the **Ramp Button** on the top of the RESmart BPAP 20S/20A/25/25A. You can use the **Ramp Button** as often as you wish during the night.

4.3 Turning the System OFF

Remove the mask and headgear. Press the **Pressure Start / Stop Button** on the top of the RESmart BPAP 20S/20A/25/25A to stop the airflow. Or, if the Auto Off setting has been enable, the airflow will automatically turn off.

IMPORTANT!

• The **Heated Humidifier Button** is active only when an InH2 Heated Humidifier is connected or when the RESmart BPAP 20S/20A/25/25A is in the Setup Menu. Refer to the InH2 Heated Humidifier's instructions for additional information.

Helpful Hints

• If the alert tone sounds, press **Pressure Start / Stop Button** on the top of the RESmart BPAP 20S/20A/25/25A to silence the alert tone. Refer to the "Troubleshooting" Section of the manual for further instructions.

• Make sure that bedding, curtains, or other items are not blocking the filter or vents of the RESmart BPAP 20S/20A/25/25A. Air must flow freely around the RESmart BPAP 20S/20A/25/25A for the system to work properly.

• If the airflow from the RESmart BPAP 20S/20A/25/25A feels cold, reposition the circuit tubing so that it runs under your bed covers to reduce heat loss while you sleep.

• If interruption of the power supply occurs during system working, the audible alert (a beeping sound) will start and continue. Restoration of the power supply will stop the audible alert.

• After interruption and restoration of the power supply, the RESmart BPAP 20S/20A/25/25A will resume with the working status before interruption automatically.

4.4 Change Device Settings

Verify / Change the RESmart BPAP 20S/20A/25/25A settings. To start the setup menu, press and hold the **Ramp Button** until the setup menu appears (about 5 seconds) when system standby (The airflow must be turned OFF).

IMPORTANT!

• Pressing the **Ramp Button** (when the airflow is turned on) will lower the airflow pressure, if prescribed, and then will gradually increase it.

WARNING!

• DO NOT use the RESmart BPAP 20S/20A/25/25A if the display is erratic. Contact your home care provider for further instructions.

IMPORTANT!

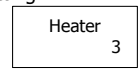
• If at any time you wish to exit the setup menu, press the **Pressure Start / Stop Button** ⏻ and the display will go back to the system standby screen.

Setting the Humidifier

a. When the optional InH2 Heated Humidifier is used, this setting can change the temperature and humidity of airflow between level 0 to 5. Default setting is 3.

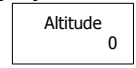
IMPORTANT!

• Press the **Ramp Button** to enter change status and press **User Buttons + / -** to change the setting. Press **Ramp Button** again to confirm the setting. Press **User Buttons + / -** to access the next setting.



Setting the Altitude

b. The altitude setting can be changed between level 0 to 2. Default setting is 0.
0 = less than 2,460 ft. (< 750 m)
1 = 2,460 to 4,921 ft. (750 to 1500 m)
2 = 4,924 to 8,202 ft. (1501 to 2500 m)
*over 8,202 ft. = The airflow pressure may not be accurate. Contact your home care provider to have your pressure setting adjusted.

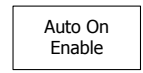


IMPORTANT!

RESmart is already with automatic altitude compensation. Even if without setting the altitude, RESmart still can deliver proper pressure in any altitude worldwide.

Setting Auto ON

c. When the RESmart BPAP 20S/20A/25/25A is standby and wearing mask, your deep breath will start airflow automatically *(This function is **NOT** available on certain model).* Default setting is Enable.



Setting Auto Off

d. When the mask is removed, the RESmart BPAP 20S/20A/25/25A will stop airflow automatically *(This function is **NOT** available on certain model).* Default setting is Disable.

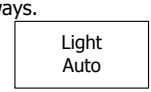
Setting the LCD Light

e. This setting allows you to adjust the LCD light among Auto, On and Off. Default setting is Auto.

Auto: LCD light will be turned on when any button pressing and turned off after few seconds.

On: LCD light will be turned ON always.

Off: LCD light will be turned OFF always.

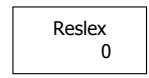


Setting the Alert

f. This setting allows you to turn on / off the patient disconnect alert. When a large, continuous air leak (such as mask removal) has been detected in the circuit, this setting enables / disables the audible alert (a beeping sound). This setting is only effective when the Auto Off setting is disabled *(This function is **NOT** available on certain model).* Default setting is Disable.

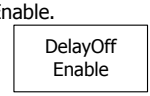
Setting Reslex

g. This setting monitors the inhale and exhale timing in therapy. the pressure will be lower when exhale so the patient will feel more comfortable. The pressure setting can be changed between level 0 to 3. 0 means disabled and the default setting is 0 (this setting only available on 20A/25A model).



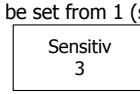
Setting the Delay Off

h. When the optional InH2 Heated Humidifier is used, this setting allows the air flow continue for about 15 minutes at very low pressure (about 2 hPa) after RESmart BPAP 20S/20A/25/25A is turned off. This will blow off the left vapor and protect the RESmart BPAP 20S/20A/25/25A. Default setting is Enable.



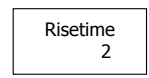
Setting the Sensitive

i. The Sensitive Setting is only effective when Auto Feature opened. The sensitivity of automatically pressure adjusting can be set from 1 (soft) to 5 (hard). Default setting is 3.



Setting the RiseTime

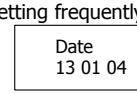
j. Rise time settings are adjustable by the patient and the provider from 0 to 3. Rise time varies from 150 to 400 msec dependent on patient setting and the pressure differential from IPAP to EPAP. The rise time setting should be adjusted according to the patient comfort level. Default setting is 2.



Setting the Date

k. The current date is displayed and can be modified if needed.

Note: Check and confirm this Date Setting frequently to ensure the usage log is correct.

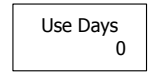


iCode

l. The "iCode" consists of six separate codes displayed in the patient menu. These codes include "Last Day", "Last 7 Days", "Last 30 Days", "Last 90 Days", "Last 182 Days" and "Last 365 Days". Patient should send these code numbers to your physician when needed. When the system standbys after power on, or after exit the setup menu, click the **Heated Humidifier Button** , the iCode number will appear. To exit the screen, please click any other button. Default setting is Disable.

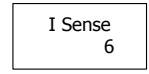
Use Days

m. The number of nights the RESmart BPAP 20S/20A/25/25A was used for therapy for more than 4 hours will appear. The number is automatically generated and users can not change it. This screen is only for reference. Your home care provider may periodically ask you for this information.



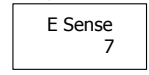
I Sense

n. This Setting can adjust the trigger sensitivity when patient's breath switch into inhaling phase. It makes device work synchronically to patient breath and to make patients feel more comfortable. Press **Ramp Button** to end the setup menu. The I sense can be adjusted from 1 (soft) to 8 (hard) by pressing **User Buttons + / -**. Press **Ramp Button** to confirm the change. Default setting is 6.



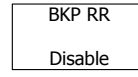
E Sense

o. This Setting can adjust the trigger sensitivity when patient's breath switch into exhaling phase. It makes device work synchronically to patient breath and to make patients feel more comfortable. Press **Ramp Button** to end the setup menu. The sensitivity can be adjusted from 1 (soft) to 8 (hard) by pressing **User Buttons + / -**. Press **Ramp Button** to confirm the change. Default setting is 7.



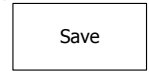
Setting BKP RR

p. This setting allows you to turn on / off the BKP RR. When turn on this setting, the device can output an airflow with frequency of 10 and breathing time ration of 1:2 to patient who can not breath automatically. Press the **Ramp Button** to enter change status in which a cursor is blinking and press **User Buttons + / -** to change the setting. Default setting is Disable. Press **Ramp Button** again to confirm the setting (this setting only available under S mode).



Exit the Settings

q. The settings are complete. Press the **User Button + / -** to access the SAVE setting and **Ramp Button** to save all changes and exit the settings menu.



5. Troubleshooting

The table below lists common problems you may have with the RESmart BPAP 20S/20A/25/25A and possible solutions to those problems. If none of the corrective actions solve the problem, contact your home care provider.

Problem	Solution (s)
The pressure being delivered feels different	Check the altitude setting to be sure it is set to your altitude. Change the altitude setting if necessary. If the altitude setting is correct, contact your home care provider for directions on having the RESmart BPAP devices serviced. Please have the device's serial number ready when you call
The airflow from the RESmart BPAP 20S/20A/25/25A seems warm	Replace or clean the filter. Make sure the RESmart BPAP 20S/20A/25/25A is away from bedding or curtains that could block the flow of air around the RESmart BPAP 20S/20A/25/25A. Make sure the RESmart BPAP 20S/20A/25/25A is away from heating equipment. (e.g., forced air vents, radiators)
The noise level of the RESmart BPAP 20S/20A/25/25A has changed to include unusual or harsh sounds during operation	Contact your home care provider for directions on having the RESmart devices serviced. Please have the device's serial number ready when you call
The RESmart BPAP 20S/20A/25/25A will not turn on	Make sure that the RESmart BPAP 20S/20A/25/25A is plugged into a working outlet. Contact your home care provider for directions on having the RESmart BPAP devices serviced. Please have the device's serial number ready when you call
Pressing the **Ramp Button** ◢ does not reduce the air pressure	Contact your home care provider. Ramp may not have been prescribed for you
The RESmart BPAP 20S/20A/25/25A has been dropped into water or fluids have gotten into the enclosure	Discontinue use. Disconnect the power cord from the AC wall outlet. Contact your home care provider for directions on having the RESmart BPAP devices serviced. Please have the device's serial number ready when you call

6. Accessories

6.1 Adding a Humidifier

The InH2 Heated 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.

WARNING!

• The RESmart unit should only be connected to the humidifiers or accessories specified in this Manual. Connection of other Items may result in injury or damage to the RESmart unit.

6.2 Adding Oxygen

Oxygen may be added at the mask connection. Please note the warnings listed below when using oxygen with the RESmart BPAP 20S/20A/25/25A.

WARNING!

• The oxygen supply must comply with the local regulations for medical oxygen.

WARNING!

• Turn the RESmart BPAP 20S/20A/25/25A on before turning the oxygen on. Turn the oxygen off before turning the RESmart BPAP 20S/20A/25/25A off.

Explanation of Warning: When the RESmart BPAP 20S/20A/25/25A is turned off, but the oxygen flow is still turned on, oxygen may accumulate within the RESmart BPAP 20S/20A/25/25A enclosure and create a fire risk. Turning the oxygen off before turning the RESmart BPAP 20S/20A/25/25A off will prevent oxygen accumulation in the RESmart BPAP 20S/20A/25/25A and will reduce the risk of fire. This warning applies to most BPAP devices.

WARNINGS!

• Oxygen accelerates fires. Keep the RESmart BPAP 20S/20A/25/25A and the oxygen container away from heat, open flames, any oily substance, or other sources of ignition. Do not smoke in the area near the RESmart BPAP 20S/20A/25/25A or the oxygen container.

• Contact your home care provider for additional information on the accessories available for the RESmart BPAP 20S/20A/25/25A. When using optional accessories, always follow the instructions enclosed with the accessories.

7. Routine Maintenance

7.1 Cleaning the Filter

The foam filter should be cleaned at least once every two weeks under normal usage and replaced with a new one every six months.

CAUTION!

• Operating the RESmart BPAP 20S/20A/25/25A with a dirty filter may keep the system from working properly and may cause damage to the device.

(1) Remove the filter cap by gently pressing on its bottom.

(2) Change the filter.

a. Remove the foam filter by gently pulling around the edges of the filter. Rinse the filter in a steady stream of running water. Squeeze out the water and repeat. Air dries the filter on a rack for 8 to 12 hours or in a clothes dryer for 15 to 20 minutes.

b. Insert the filter into the filter area on the back of the RESmart BPAP 20S/20A/25/25A. Replace the filter cap.

CAUTION!

• Never install a wet filter into the RESmart BPAP 20S/20A/25/25A. We recommend that you clean the filter in the morning and alternate using the filter provided with the system to ensure enough drying time for the cleaned filter.

7.2 Cleaning the System

Clean the mask and tubing daily.

WARNING!

• To avoid electrical shock, unplug the RESmart BPAP 20S/20A/25/25A before cleaning. Do not immerse the RESmart BPAP 20S/20A/25/25A in any fluids.

(1) Disconnect the flexible tubing from the RESmart BPAP 20S/20A/25/25A. Gently wash the flexible tubing in a solution of warm water and a mild detergent. Rinse the tubing thoroughly and air dry.

(2) Wipe the outside of the RESmart BPAP 20S/20A/25/25A with a cloth slightly dampened with water and a mild detergent. Let the RESmart BPAP 20S/20A/25/25A dry before plugging in the power cord.

(3) Inspect the RESmart BPAP 20S/20A/25/25A and all circuit parts for any damage after cleaning. Replace any damaged parts.

(4) For details on cleaning your mask and accessories, refer to the cleaning instructions packaged with the accessories.

7.3 Disinfection of the Humidifier Water Chamber

See the Disinfection section of the humidifier user manual for more information on the disinfection of the water chamber.

7.4 Reordering

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

Service

The RESmart BPAP 20S/20A/25/25A does not require routine servicing.
The RESmart unit contains electrical and / or electronic equipment. When necessary, dispose of the RESmart and accessories in accordance with local regulations.

WARNING!

• If you notice any unexplained changes in the performance of the RESmart BPAP 20S/20A/25/25A, 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.

WARNING!

• If the RESmart BPAP 20S/20A/25/25A malfunctions, contact your home care provider immediately. Never attempt to open the RESmart BPAP 20S/20A/25/25A's enclosure. 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.

7.5 Traveling with RESmart

When you are traveling, the carrying case is for carry-on luggage only. The carrying case will not protect the system if it is stored as checked baggage.

7.6 Security Stations

For convenience at security stations, there is a note on the bottom of the RESmart BPAP 20S/20A/25/25A stating that it is medical equipment. It may be helpful to bring this manual along with you to help security personnel understand the RESmart BPAP 20S/20A/25/25A.

7.7 Checking the Power Cord

If you are traveling to a country with a line voltage different than the one you are currently using, a different power cord or an international plug adapter may be required to make your power cord compatible with the power outlets of the country to which you are traveling. Contact your home care provider for additional information.

8. Specifications

Device Size

Dimensions: 220 mm × 194 mm × 112 mm, 313 mm × 194 mm × 112 mm (with InH2 heated humidifier)
Weight: 2.2 kg, 3 kg (with InH2 heated humidifier)

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	5°C to 35°C	-20°C to 55°C
Humidity:	≤ 80% Non-condensing	≤ 93% Non-condensing
Atmospheric Pressure:	700 to 1060 hPa	500 to 1060 hPa

Mode of Operation

Continuous

Work Mode

Product Model	Pressure (hPa)	Work Mode	
20S	4 ～ 20	S, CPAP	No *Auto* Feature
20A	4 ～ 20	S, CPAP	Auto S (*Auto* Feature available)
25	4 ～ 25	S, CPAP	No *Auto* Feature
25A	4 ～ 25	S, CPAP	Auto S (*Auto* Feature available)

SD Card

The SD card can record patient data and fault information.

AC Power Consumption

100 - 240 V ～ 2 - 1 A, 50 / 60 Hz

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

IP21 – ≥ 12.5 mm Diameter, Drip-Proof, Vertical

Pressure Range

For 20S/20A:
IPAP: 4 to 20 hPa (in 0.5 hPa increments)
EPAP: 4 to 20 hPa (in 0.5 hPa increments)

For 25/25A:
IPAP: 4 to 25 hPa (in 0.5 hPa increments)
EPAP: 4 to 25 hPa (in 0.5 hPa increments)

≤ 40 hPa under single fault conditions.

Pressure Stability

Static Pressure Stability: 4 to 20 / 25 hPa (±0.5 hPa)
Dynamic Pressure Stability: 4 to 20 / 25 hPa (±1.0 hPa)

Altitude Compensation

Manually setting, level 0, 1, 2
Automatic altitude compensation

Sound Pressure Level

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

Maximum Flow

For 20S/20A:

Test Pressure (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)	70.1	72.1	72.3	70.1	73.4

For 25/25A:

Test Pressure (hPa)	4	10	15	20	25
Measured Pressure at the Patient Connection Port (hPa)	3	9	14	19	24
Average flow at the patient connection port (L/min)	70.1	73.0	64	73.4	74.6

Appendix A: EMC Requirements

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

WARNINGS!

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.

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle 70% U_T; 25 / 30 cycle At 0° 0% U_T; 250 / 300 cycle	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle 70% U_T; 25 / 30 cycle At 0° 0% U_T; 250 / 300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Note: U_T is the 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 Radiated RF IEC 61000-4-3	3 V 0.15 MHz ～ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 10 V/m 80 MHz to 2.7 GHz	3 V 0.15 MHz ～ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 10 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{p}$ $d = 0.35\sqrt{p}$ 80 MHz to 800 MHz $d = 0.70\sqrt{p}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

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

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

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

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

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

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

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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: 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.

Limited Warranty

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

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

To exercise your rights under this warranty, contact your 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
URL: en.bmc-medical.com
E-mail: intl@bmc-medical.com
Tel: +86-10-51663880
Fax: +86-10-51663880 Ext. 810

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

Manufacturing Site:
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Tel: +86-22-82939881

Issue date: 26 November, 2020

InH2 Heated Humidifier

User Manual

CE 0123

The model of the InH2 Heated Humidifier is BMC-50. The InH2 Heated Humidifier is designed only for use with specific BMC RESmart CPAP / Auto CPAP or BPAP devices. Do not use InH2 with any other devices.

The humidifier moistens the air delivered by the BMC RESmart CPAP / BPAP devices.

The InH2 Heated Humidifier is only used for single patient and must not be re-used on another person. This is to avoid the risk of cross-infection.

The InH2 Heated Humidifier is not intended for use with a patient whose upper airways have been bypassed.

Table of Contents

Intended Use

InH2 Heated Humidifier is designed for specific BMC CPAP / Auto CPAP or BPAP devices and is used to increase the outlet air humidity. These devices are intended to deliver positive pressure for the treatment of adult Obstructive Sleep Apnea (OSA) only, either in the hospital or at home.

Contraindications

1. When InH2 Heated Humidifier is used along with the RESmart CPAP / Auto CPAP System, the contraindications are as follows:

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

- Bullous Lung Disease
- Bypassed Upper Airway
- Pneumothorax
- Pathologically Low Blood Pressure
- Pneumocephalus has been reported in a patient using nasal Continuous Positive Airway Pressure. Caution should be used when prescribing CPAP for susceptible patients such as those with: cerebral spinal fluid leaks, abnormalities of the cribriform plate, prior history of head trauma, and / or pneumocephalus.
(Chest 1989; 96:1425-1426)
- The use of positive airway pressure therapy may be temporarily contraindicated if you exhibit signs of a sinus or middle ear infection.

Contact your health care professional if you have any questions concerning your therapy.

2. When InH2 Heated Humidifier is used along with the RESmart BPAP System, the contraindications are as follows:

The BPAP should not be used if you have an insufficient respiratory drive to endure brief interruptions in non-invasive ventilation therapy. The BPAP is not a life support ventilator and may stop operating with power failure or in the unlikely event of certain fault conditions.
If you have any of the following conditions, tell your doctor before using the BPAP:

- acute sinusitis or otitis media.
- conditions predisposing to a risk of aspiration of gastric contents.
- epistaxis causing a risk of pulmonary aspiration.
- hypotension or significant intravascular volume depletion.
- Inability to maintain a patent airway or adequately clear secretions.
- pneumothorax or pneumomediastinum.
- recent cranial trauma or surgery.

Warnings & Cautions

IMPORTANT!

• Read all instructions before using the humidifier.
• Use only with BMC RESmart devices whose instructions specify the use of this humidifier.
• Please use the mask which meets ISO 17510:2015.

CAUTIONS!

• Indicates the possibility of damage to the device.
• US federal law restricts this device to sale by or on the order of a physician.
• If fluids are spilled onto the humidifier platform, unplug the power cord from the AC wall outlet and allow the humidifier platform to drain and dry before using.
• Take precautions to protect furniture from water damage.

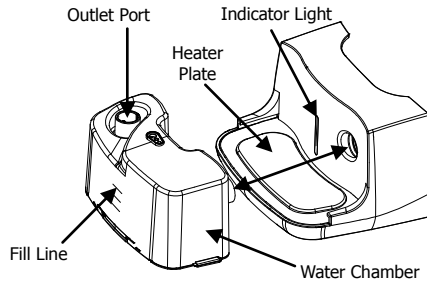
WARNINGS!

• Indicates the possibility for injury to the user or the operator.
• Use the humidifier only for its intended use as described in this manual.
• Use only accessories recommended by BMC.
• Images shown here are indicative only. If there is inconsistency between the image and actual product, the actual product shall govern.
• Never operate the humidifier if any of the parts are damaged, if it is not working properly, or if the humidifier has been dropped or mishandled. Do not use the humidifier if the water chamber is leaking or damaged in any way. Have any damaged parts replaced before continuing use.
• Never touch the heater plate unless the humidifier is unplugged and the plate has cooled down.
• This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
• Periodically inspect the power cord for signs of wear or damage. Replace if necessary.
• Do not operate the device in direct sunlight or near a heating appliance because these conditions can increase the temperature of the air coming out of the device.
• When humidifier is used outside the specified ambient temperature range or humidity range, the performance of humidifier will be compromised.
• 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.

Symbols

	Follow Instructions for Use
	Type BF Applied Part (mask)
	Class II (Double Insulated)
	DC Power
IP21	≥ 12.5 mm Diameter, Drip-Proof, Vertical
	Serial Number of the Product
	Manufacturer
	Authorized Representative in the European Community
	European CE Declaration of Conformity

Features



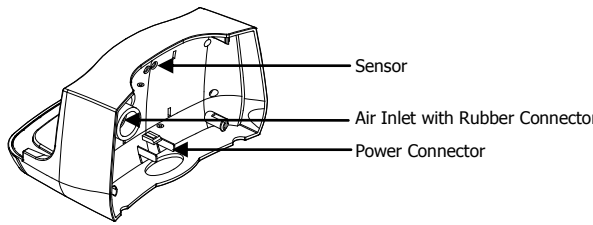
Fill Line: This indicates the maximum water level for safe operation.

Outlet Port: Connect the flexible tubing (coaxial 22 mm) here.

Water Chamber: The removable water chamber holds the water for humidification. It has a silica gel cover to outflow the water in cleaning.

Heater Plate: Warms the water in the water chamber.

Indicator Light: When lit, this indicates that the heater plate has been turned on.

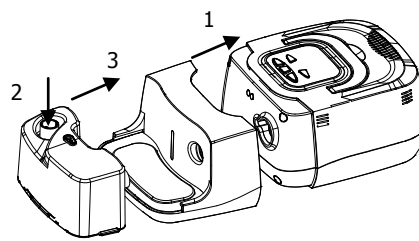


Sensor: Do not block this sensor. The humidifier will not operate unless it can detect that the RESmart device is connected correctly.

Air Inlet with Rubber Connector: Connect to the outlet port on the RESmart device.

Power Connector: Plug this connector into the power outlet on the BMC RESmart device.

Set Up



1. Connect the humidifier to the RESmart device. Make sure they are connected completely.

2. Place the RESmart device and humidifier on a firm, flat surface at a level lower than your sleeping position.

CAUTIONS!

• Do not turn the humidifier on without the water chamber installed.

• Do not touch the metal parts of the water chamber during device operation, otherwise it may cause burns.

• Take precautions to protect furniture from water damage.

Daily Use

1. Fill the chamber to the fill line with water (approx. 350 ml) from the outlet port. Distilled water is recommended. Do not overfill the water chamber.

CAUTION!

• Always remove the chamber from the humidifier before filling with water.

2. Press down the spring loaded heater plate with the water chamber and slide the chamber into place. Make sure the rubber connector on the inlet port fits securely over the RESmart device's air outlet.

3. Connect the flexible tubing to the outlet port on the water chamber.

CAUTION!

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

4. When the RESmart device begins blowing, the humidifier will work automatically. The yellow indicator light on the humidifier will turn on. Press the humidifier button can turn off or restart the humidifier.

5. The ideal humidity setting depends on room temperature and humidity. Initially, a setting of 3 is recommended. You can adjust this setting at any time. Please adjust the humidifier setting according to the CPAP User Manual.

IMPORTANT!

• When the air flow is turned off, the humidifier will automatically shut off.

Cleaning

The water chamber should be cleaned daily or after each use.

WARNING!

• Emptying and cleaning the water chamber daily will help to prevent mold and bacteria growth.

WARNING!

• Allow the water in the chamber to cool down to room temperature before removing it from the humidifier.

WARNING!

• To avoid electrical shock, disconnect the power cord of RESmart device before cleaning the humidifier. DO NOT immerse the humidifier into any fluids.

Water Chamber

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

2. Disconnect the tubing from the water chamber. Press down on the water chamber and slide it out of the humidifier platform.

3. Open the silica gel cover of water chamber and discard any remaining water. Fill a solution

of warm water and a mild dishwashing detergent into the chamber, cover the silica gel cover, rock the chamber a few minutes, and then outflow the solution. Rinse the chamber several times with clean water and allow to air dry.

4. Fill the water chamber and close the silica gel cover. Inspect the water chamber for any leak or damage. Replace the water chamber if any damage is present.

Humidifier Platform

1. Clean the humidifier platform by wiping with a damp cloth. Allow to air dry.

2. Inspect the humidifier platform for any damage and replace if necessary.

Silicone Tubing of Humidifier

Clean the Silicone Tubing by wiping with an alcohol cotton stick. Allow to air dry.

Disinfection

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

Disinfection of Humidifier Water Chamber

Prior to disinfection, clean the water chamber according to Section "Cleaning". 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.

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.

Service

The humidifier does not require routine servicing.
If the humidifier malfunctions, contact your home care provider immediately. Never attempt to open the humidifier's enclosure. If necessary, contact your local authorized dealer or BMC Medical Co., Ltd. for technical support and documents.

Specifications

Size

Dimensions: 120 mm × 194 mm × 112 mm
Weight: 0.8 kg
Water Capacity: 350 ml at recommended water level

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	5°C to 35°C	-20°C to 55°C
Humidity:	≤ 80% Non-condensing	≤ 93% Non-condensing
Atmospheric Pressure:	700 to 1060 hPa	500 to 1060 hPa

Power Requirements

24 V DC 1.0 A max

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

IP21 – ≥ 12.5 mm Diameter, Drip-Proof, Vertical

Heater Settings

1 to 5 (104˚F to 149˚F / 40°C to 65°C)

Maximum Operating Pressure

40 hPa

Pressure Drop with Humidifier

< 0.5 hPa at 60 LPM flow

Maximum Delivered Gas Temperature

< 40°C

Humidity Range

10 to 45 mg H_2O/L

Disposal

When necessary, dispose of the device and accessories in accordance with local regulations.

Traveling with the System

Packing the System

When traveling, the optional CPAP carrying case is for carry-on luggage only. The carrying case will not protect the humidifier if it is put through checked baggage.

Security Stations

For ease at security stations, there is a note on the bottom of the humidifier stating that it is medical equipment. It may be helpful to bring this manual along with you for security personnel.

EMC Requirements

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

WARNINGS!

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.

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle 70% U_T; 25 / 30 cycle At 0° 0% U_T; 250 / 300 cycle	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle 70% U_T; 25 / 30 cycle At 0° 0% U_T; 250 / 300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Note: U_T is the 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 Radiated RF IEC 61000-4-3	3 V 0.15 MHz ~ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 10 V/m 80 MHz to 2.7 GHz	3 V 0.15 MHz ~ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 10 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{p}$ $d = 0.35\sqrt{p}$ 80 MHz to 800 MHz $d = 0.70\sqrt{p}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applied. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. [b] Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 10 V/m.			

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

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

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

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

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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: 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.

Warranty

BMC Medical Co., Ltd. warrants that this humidifier 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 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.

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

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