

RESmart® CPAP and Auto-CPAP

User Manual



3BTM

Solutions in Sleep Therapy ™ www.3Bproducts.com

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Symbols

CONTROL BUTTONS



Pressure Start / Stop



Ramp Start



Humidifier On I Off (iCode®)



User Button

—

User Button

DEVICE



Attention, Consult Accompanying Documents



Type BF Applied Part



Class II (Double Insulated)



AC Power

IPX1

Drip-Proof, Vertical

SN

Serial Number of the Product



Manufacturer

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.

CAUTION!

Federal law restricts this device to the sale by or on the order of a physician.

Indications for Use

The RESmart® CPAP and Auto-CPAP systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea. The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for single patient use by prescription in the home or hospital/ institutional environment on adult patients.

Contraindications

The RESmart® CPAP and Auto-CPAP device are NOT intended for life support. Studies have shown that the following pre-existing conditions may contrain dicate 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.

Warning!

Indicates the possibility for Injury to the user or the operator

- 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
- CPAP devices have the potential to allow rebreathing of exhaled air.
- Contact your health care professional if symptoms of sleep apnea recur.
- Using the RESmart® CPAP and Auto-CPAP at an incorrect elevation setting could result in airflow pressures higher than the prescribed setting. Always verify the elevation setting when traveling or relocating.

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 CPAP devices: At low CPAP pressures, some exhaled gas (CO₂) 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 anesthetic 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® CPAP and Auto-CPAP. 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. DO NOT immerse the device in any fluids.
- To remove AC power, disconnect the power cord from the electrical outlet.
- The use of accessories other than those specified or recommended by the manufacturer may adversely impact performance of the device.
- Inspect the power cord often for any signs of damage. Replace a damaged cord immediately.
- DO NOT use the RESmart® CPAP and Auto-CPAP if the display is erratic.
 Contact your home care provider for further instructions.

CAUTION!

Makesure the RESmart® CPAP and Auto-CPAP 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.

Indicates the possibility of damage to the device

 Tobacco smoke may cause tar build-up within the RESmart® CPAP and Auto-CPAP that may result in the device malfunctioning.

IMPORTANT!

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

WARNING!

DO NOT connect any equipment to the RESmart® CPAP and Auto-CPAP unless recommended by BMC or your health care provider.

CAUTION!

If the RESmart® CPAP and Auto-CPAP has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (approximately 2 hours) before beginning setup.

WARNING!

DO NOT use the RESmart® CPAP and Auto-CPAP if the display is erratic. Contact your home care provider for further instructions.

Specifications

Device Size

Dimensions: 8.66 × 7.6 × 4.4" (220 x 194 x 112mm),

12.3" (313 x 194 x 112mm) (with Integrated Heated Humidifier) Weight: 3.5 lbs. (1.6 kg), 5.3 lbs. (2.4 kg) (with Integrated Heated

Humidifier)

Product Use, Transport and Storage

Operation

Temperature: $41^{\circ}F$ to $95^{\circ}F$ (5 to $35^{\circ}C$) $-4^{\circ}F$ to 1 Humidity: $\leq 80\%$ Non-condensing $\leq 93\%$ Non-spheric Pressure: 860 to 1060 cmH₂O 500 to

Transport and Storage

-4°F to 131°F (-20 to 55°C)

≤ 93% Non-condensing

500 to 1060 cmH₂O

Mode of Operation

Continuous

Work Mode

CPAP. Auto

SD Card Capacity

2G bytes

AC Power Consumption

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

IPX1 -Drip-Proof, Vertical

Pressure Range

4 to 20 cmH₂O (in 0.5 cmH₂O increments)

Pressure Stability

4 to 20 cmH₂O (± 1 cmH₂O)

Altitude setting

Auto-CPAP: Manual setting: level 0 - 2 **CPAP:** Manual setting 0- 10000 ft.

Automatic altitude compensation for therapy pressure

Sound Pressure Level

<30 dB, when the device is working at the pressure of 10 cmH₂O

Maximum Flow

Test Pressure (cmH ₂ O)	4	8	12	16	20
Average flow at the patient connection port(L/min)	70.1	73.6	75.9	73.0	73.4

Accessories

The RESmart® CPAP and Auto-CPAP are not sold with mask, tubing or bacterial filters.

Accessories may be purchased separately. The RESmart® product line is designed to accommodate standard CPAP tubing (22mm) for easy interconnectibility of masks and air tubing.

WARNINGS AND CAUTION

- 1. This device is restricted to sale by or on the order of a physician.
- 2. Ensure that the SD card is inserted into the device before you turn on RESmart® CPAP or Auto-CPAP device.
- 3. 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.

Unpacking the System

Included with your RESmart® unit:

No.	Item	Number
1	RESmart® CPAP or Auto-CPAP	1
2	Power Cord	1
3	Carrying Case with shoulder strap	1
4	User Manual	1
5	Provider Instructions	1
6	Extra Filter (M1020)	1
7	Humidifier Plug	1
8	SD Card	1

SN Record Serial Number	

IMPORTANT!

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

To order any accessories not included with this system, contact your home care provider.

Home Care Provider Contact Information

Available Therapies

The RESmart® is available in two models: CPAP (white) and Auto-CPAP (black). The two models deliver the following therapies:

Shown with humidifier



CPAP:

Delivers Continuous Positive Airway Pressure; CPAP maintains a constant level of pressure throughout the breathing cycle. If your health care professional prescribed ramp for you, you can press the Ramp button to reduce the pressure and then gradually increase the pressure to the therapeutic pressure setting so that you can fall asleep more comfortably.



Shown with humidifier

Auto-CPAP:

Automatically adjusts CPAP therapy pressure within the pressure range determined by your physician or healthcare provider.

System features



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 the system settings.

Humidifier Controller: This controller turns the Integrated Heated Humidifier on/off and allows the heat setting to be adjusted. This button allows access to iCode® data when the device is turned off.

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

Humidifier Power: This socket provides the power to the Integrated Heated Humidifier.

Handle: This handle is for lifting and carrying the device.

Medical Product Note: For ease at airport security stations, there is a note on the bottom of the RESmart® CPAP and Auto-CPAP 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.

Communications Connector: For clinical use with the Data Management Software. Connect the communications cable here.

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® CPAP and Auto-CPAP.

First Time Setup (Patient)

WARNING!

Do not use the RESmart® CPAP and Auto-CPAP system until an appropriate professional adjusts the settings.

Note to home care provider: Before beginning setup, be sure that you have available the RESmart® Setup Instructions. Clinician's (Provider's) Setup instructions are not included in this manual.

DO NOT connect any equipment to the RESmart® CPAP or Auto-CPAP unless recommended by BMC or your health care provider.

CAUTION!

If the RESmart® CPAP or Auto-CPAP has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (approximately 2 hours) before beginning setup.

Place the RESmart® CPAP or Auto-CPAP on a firm flat surface Install the Filter

Place the foam filter into the filter area on the back of the RESmart® CPAP and Auto-CPAP with the blue side facing out.

CAUTION! The foam filter must be in place at all times when the RESmart® CPAP and Auto-CPAP is operating.

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.

Attach the integrated Heated Humidifier

Please see the RESmart® Integrated Heated Humidifier User Manual enclosed with your device.

Connect Power Cord

Plug the socket end of the power cord into the AC inlet on the back of the RESmart® CPAP and Auto-CPAP. Plug the pronged end of the power cord into an electrical outlet. System status will appear on the

RESmart® CPAP and Auto-CPAP screen.

The RESmart® CPAP and Auto-CPAP is powered on for use when the power cord in connected. The **Pressure Start Stop Button** turns the blower on/off.

CAUTION!

Make sure the RESmart® CPAP and Auto-CPAP 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.

Standby

When you plug the device into a power source it will be in **Standby** mode. The blower will not engage unless you put your mask on or you press the start/stop button. After power on, system status will appear on display screen as described below.

Display Screen: LED screen where all device settings will appear as well as iCode® data and last night's sleep report.

User Buttons: These 4 buttons can be used when entering the Patient and Clinician's menus to change the RESmart® CPAP and Auto-CPAP settings.

+/- **User Buttons** are used to go to the previous/next option and operate as up and down keys to change the settings.

Ramp Button is used to confirm the setting change.

Start/Stop Button will allow you to exit the Setup Menu without saving, will turn on/off the blower.

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

Heated Humidifier Button: Use this button when the optional Integrated Heated Humidifier has been prescribed. This button will control the optional heated humidifier's output. This button will also provide iCode® data when the device is in the standby state.

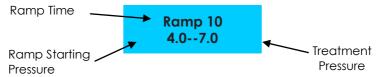
IMPORTANT!

The humidifier button is active only when an Integrated Heated Humidifier is connected. Refer to the Integrated Heated Humidifier's instruction for additional information.

Ramp Button: When 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 and to retrieve previous night's sleep data.

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



Ramp Starting Pressure (Ramp P): The starting pressure after blower is turned on. Default setting is $4 \text{ cmH}_2\text{O}$.

Treatment Pressure: This setting (Min APAP) is the minimum pressure of the therapy pressure range in Auto mode. This setting (Treat P) is the designated fixed prescription pressure setting in CPAP mode. Default setting is $7 \text{ cmH}_2\text{O}$.

RampTime: The ramp time from starting pressure to prescription pressure. This enables the patient to comfortably move from wakefulness to sleep and can be adjusted in 5 minute increments. Default setting is 10 minutes.

IMPORTANT!

Pressing the ramp button (when the airflow is turned on) will lower the airflow pressure, if prescribed, and then will gradually increase it.

Patient Menu Set-Up

Depress the Ramp — button for 3 seconds

(The airflow must be turned OFF)

You are now in the Patient Menu Set-up. You will need to press the Ramp Button to enter change status and go through each option by pressing the + or - Button. The cursor will blink, and values may be changed using the User Buttons (+/-). Confirm the setting by pressing the ramp again and the cursor will stop blinking.

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.

Selecting Patient Device Settings



Pressure Start/Stop Button

IMPORTANT!

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

Press +/-User Buttons to access the next setting. Proceed through the following settings:

- (1) Heater, (2) Altitude, (3) Auto On, (4) Auto Off, (5) Light, (6) Alert,
- (7) Reslex, (8) RampTime, (9) Delay, (10) Date, (11) Time, (12) Save
- (1) Setting the Humidifier (Heater)

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

Heater 3

Altitude

(2) Setting the Altitude

For Auto-CPAP: 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 m to 1500 m)

2 = 4,924 to 8,202 ft. (1501 m to 2500 m)

*over 8,202 ft. = Measurement of air leakage may not be accurate.

For CPAP: The altitude setting can be changed between 0000ft and

10000ft manually. The increment is 1,000 ft. **Default setting is 0000ft**. *over 10,000 ft. = Measurement of air leakage may not be accurate.

IMPORTANT!

The RES mart® device is equipped to function with automatic adjustment of the rapy pressure to compensate for changes in altitude. Even without setting the altitude, the RESmart® device can still deliver proper pressure in any altitude worldwide. However, the correctsetup of altitude will prevent the device giving out a false alert. Generally, a false alert is caused by calculation of leakage at the wrong range of altitude settings.

(3) Setting Auto On

When the RESmart® CPAP and Auto-CPAP is instandby mode and you are wearing your mask. Your deep breath will start airflow automatically.

Auto On

On

Off

Light

Auto

Off

Default setting is On.

(4) Setting Auto Off

When the mask is removed, the RESmart® CPAP and Auto-CPAP will stop airflow automatically. **Auto Off**

Default setting is Off.

(5) Setting the LCD Light

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

Auto: LCD light will turn on when any button is pressed and dim after few seconds.

On: LCD light will always be turned ON.

Off: LCD light will always be dimmed.

(6) Setting the Alert

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 off. **Alert**

Defaultsetting is Off.

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(7) Setting the Reslex

The Reslex setting displays the Reslex level set by your home care provider. This setting allows you to adjust the level of air pressure relief that you feel when you exhale during therapy. Your home care provider will have already set a Reslex level. If this is not comfortable for you, you can increase or decrease the setting. The setting of "1" provides a small amount of pressure relief. Use the + and – keys to increase or decrease the pressure relief provided on exhalation.

Default setting is 0 (disable).

Reslex 0

(8) RampTime

This setting is the ramp time from starting pressure to prescription pressure. The device gives airflow at the relative lower pressure of Ramp P from start point of ramp time, and increases the output pressure to the prescription pressure gradually during ramp. Setting range is 0-60mins with the adjustment step of 5mins. **Default setting is 10mins.** The device reduces the output pressure and counts down to zero every time the Ramp key is pressed.

RampTime 10

(9) Setting the Delay

When the optional Integrated Heated Humidifier is used, this setting allows the air flow to continue for about 15 minutes at very low pressure (about 2 cmH₂O) after RESmart® CPAP and Auto-CPAP is turned off. This will blow off the residual vapor and protect the RESmart® CPAP and Auto-CPAP.

Default setting is Off.

(10) Setting the Date

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

Note: Check and confirm this Date Setting frequently to ensure that compliance data reporting is accurate.

Date

Delay

Off

13 01 04

(11) Setting the Time

The current Time is displayed and can be modified if needed.

Note: Check and confirm this Time Setting frequently to ensure that compliance data reporting is accurate.

Time 15:26

(12) Save and Exit the Settings

All changes to settings must be saved. Confirm the saved settings by hitting the ramp button once. This will exit the patient menu.

Save

Reviewing Sleep Data

The RESmart® allows review of the prior night's sleep data. To access your data, make sure that the blower is not running by pressing the start / stop button.

Press the Ramp Start button and scroll through the display using the +/- buttons. The data displayed consists of completion time(Compl), P95(95th percentile of the airway pressure over time), Mean P, AHI(apnea-hypopnea index), and SNI(snore index).

Quit reviewing the sleep data by pressing the start / stop button.

View Your Sleep Report with iCode®

Step 1: Press the humidifier button to retrieve your iCode® string. Continuously pressing the humidifier button steps through all iCode® values (iCode® 1 day, iCode® 7 day, iCode® 30 day, iCode® 60 day,etc.)

Step 2: To generate a report, go to www.bmc-iCode.com. There are three mandatory fields required to generate a report: device serial number, retrieval date, and iCode® string. All other fields are optional and may be entered depending on the requirement for the report.

For instructions on viewing your sleep report go to the Patient Portal at WWW.3bproducts.com.

Ability to Use Smartphone Apps





For use with all RESmart[®] CPAP and Auto-CPAP models. As simple as taking a picture. Absolutely free of charge. Take a photo of the display and generate a sleep report. Auto email physician or provider.





Assembling the Circuit (interface "Mask")

To use the system, you will need the following accessories in order to assemble the recommended circuit.

- (1) Mask with integrated exhalation port
- (2) 6ft. (1.83 m) flexible Tubing (included)
- (3) Headgear (for the mask)

WARNING!

Ifmultiplepersons are going to use the RESmart [®]CPAP and Auto-CPAP (e.g., rental devices), a low-resistance, main flow bacteria filter should be installed in-line between the RESmart [®]CPAP and Auto-CPAP and the circuit tubing. <u>Pressures must be verified by your home healthcare provider when alternate or optional accessories are in place.</u>

- a. Connect the flexible tubing to the air outlet on the front of the RESmart[®] CPAP and Auto-CPAP.
- 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[®] CPAP and Auto-CPAP is intended to be used with masks and circuits that have an exhalation port designed to exhaust CO₂ from the circuit. When the RESmart[®] CPAP and Auto-CPAP is turned on and functioning properly, new air from the RESmart[®] CPAP and Auto-CPAP flushes the exhaled air out through the exhalation port. When the RESmart[®] CPAP and Auto-CPAP 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 CPAP 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 an antiasphyxia valve.

Accessories

Contact your home care provider for additional information on the accessories available for the RESmart[®] CPAP and Auto-CPAP system. When using optional accessories, always follow the instructions enclosed with the accessories.

Adding a Humidifier

The Integrated 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.

Using Oxygen with Device

Oxygen may be added at the mask connection. Please note the warnings listed belowwhen using oxygen with the RESmart $^{\rm B}$ CPAP and Auto-CPAP.

WARNING!

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

Turn the RESmart[®] CPAP and Auto-CPAP on before turning the oxygen on. Turn the oxygen off before turning the RESmart[®] CPAP and Auto-CPAP off.

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

Oxygen accelerates fires. Keep the RESmart® CPAP and Auto-CPAP and the oxygen container away from heat, open flames, any oily substance, or other sources of ignition. DO NOTsmoke in the area near the RESmart® CPAP and Auto-CPAP or the oxygen container.

Routine use (Patient)

Connecting the Circuit (Interface-Mask and tubing)

1. Connect the circuit by attaching tubing to air outlet on device or on the integrated humidifier air outlet.

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.

- a. Connect the mask to the headgear, following the instructions included with the headgear.
- b. 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® CPAP and Auto-CPAP. When operating the system with some mask types or some circuit configurations, the airflow may NOT automatically start.

Adjusting the Circuit

2. Adjust the 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.

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.

3. Press the Ramp button on the top of the RESmart® CPAP and Auto-CPAP. You can use the Ramp button as often as you wish during the night.

Turning the System OFF

4. Remove the mask and headgear. Press the pressure start/stop button on the top of the RESmart® CPAP and Auto-CPAP to stop the airflow. Or, if the Auto Off setting has been enable, the airflow will automatically turn off.

Helpful Hints

- If the alert tone sounds, press any button on the RESmart® CPAP and Auto-CPAP 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® CPAP and Auto-CPAP. Air must flow freely around the RESmart® device for the system to work properly.
- If the airflow from the RESmart® CPAP and Auto-CPAP 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 function, 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® CPAP and Auto-CPAP will automatically resume the working status before interruption.

Routine Maintenance

Replacing the Filter

It is recommended that the air filter be changed every 30 days.

- 1. Remove the filter cap by gently pressing on its bottom.
- 2. Remove the foam filter by gently pulling around the edges of the filter. Remove and replace with blue side facing out.
- 3. Replace filter cap so that the small opening on the cap is facing down. Insert the cap's tabs into the filter area opening.

CAUTION!

Operating the RESmart® CPAP and Auto-CPAP with a dirty filter may keep the system from working properly and may cause damage to the device.

Never install a wet filter into the device. 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.

Cleaning the System

Clean the mask and tubing daily.

WARNING!

To avoid electrical shock, unplug the RESmart® CPAP and Auto-CPAP before cleaning. Do not immerse the RESmart® CPAP and Auto-CPAP in any fluids.

- 1. Disconnect the flexible tubing from the RESmart® CPAP and Auto-CPAP. 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® CPAP and Auto-CPAP with a cloth slightly dampened with water and a mild detergent. Let the RESmart® CPAP and Auto-CPAP dry before plugging in the power cord.
- 3. Inspect the RESmart® device 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.

Reordering

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

Service

The RESmart® CPAP and Auto-CPAP system 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 the RESmart® device malfunctions, contact your home care provider immediately. Never attempt to open the RESmart® CPAP or Auto-CPAP's enclosure. Repairs and adjustments must be performed by 3B Medical, Inc. 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 3B Medical, Inc. for technical support and documents.

If you notice any unexplained changes in the performance of the RESmart® CPAP and Auto-CPAP, 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.

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.

Security Stations

For convenience at security stations, there is a note on the bottom of the RESmart® device stating that it is medical equipment.

It may be helpful to bring this manual along with you to help security personnel understand the RESmart® CPAP and Auto-CPAP.

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.

Troubleshooting

The table below lists common problems you may have with the RESmart® CPAP and Auto-CPAP system 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® CPAPandAuto-CPAP serviced. Please have the device's serial number ready when you call.
The airflow from the RESmart® CPAPandAuto-CPAP seems warm.	Replace or clean the filter. Make sure the RESmart® CPAPandAuto-CPAP is away from bedding or curtains that could block the flow of air around the RESmart® CPAPandAuto-CPAP. Make sure the RESmart® CPAPandAuto-CPAP is away from heating equipment (e.g., forced air vents, radiators).
The noise level of the RESmart® CPAPandAuto-CPAP has changed to include unusual or harsh sounds during operation.	Contact your home care provider for directions on having the RESmart® CPAP and Auto-CPAP serviced. Please have the device's serial number ready when you call.
The RESmart® CPAP and Auto-CPAP will not turn on.	Make sure that the RESmart® CPAPandAuto-CPAP is plugged into a working outlet. Contact your home care provider for directions on having the RESmart® CPAPandAuto-CPAP 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® CPAP and Auto-CPAP 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® CPAP and Auto-CPAP serviced. Please have the device's serial number ready when you call.

EMC Requirements

Guidance and manufacturer's declaration - electromagnetic emissions

The RESmart® is intended for use in the electromagnetic environment specified below. The user of the RESmart® should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1, Class B	The RESmart® uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Group 1, Class B	The RESmart® is suitable for use in all establishments including
Harmonic emissions IEC 61000-3-2	Class A	domestic establishments and those directly connected to the
Voltage fluctuations /flicker emissions IEC 61000-3-3	Class D	public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity

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

environment.					
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance		
Electrostatic discharge (ESD)	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.		
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical home or hospital.		
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical home or hospital.		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4- 11	<5 % U _T (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 s	<5% U _T (>95 % dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles <5% U _T (>95% dip in U _T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RESmart® requires continued operation during power mains interruptions, it is recommended that the RESmart® be powered from an uninterruptible power supply or from a battery.		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	0.3 A/m	If the pressure deviates more than is indicated in the device specification, it may be necessary to position the RESmart® further from sources of power frequency magnetic fields. The power frequency magnetic field should be measured in the		

	intended installation location to ensure that it is sufficiently low.	
NOTE: U_7 is the AC mains voltage prior to application of the test level.		

Guidance and manufacturer's declaration - electromagnetic immunity

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

environment.	IEC 60601	Compliance	Electromagnetic environment -
Immunity test	test level	level	guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the RESmart®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ $80 \text{ MHz to } 800 \text{ MHz}$ $d=2.3\sqrt{P}$ $800 \text{ MHz to } 2.5 \text{ GHz}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	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:
			((c))

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.

RESmart® CPAP and Auto-CPAP User Manual

^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 RESmart[®] is used exceeds the applicable RF compliance level above, the RESmart[®] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RESmart[®].

 $^{\rm b}$ Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Glossary

AHI Apnea/Hypopnea Index

Apnea A condition marked by the cessation of spontaneous

breathing.

Auto-CPAP Type of device that adjusts 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 begin breathing on the device.

CPAP Continuous Positive Airway Pressure

Best 30 day Adherence Score

A percentage of the best consecutive 30 days of usage that meets the CPAP LCD. Using an adherence threshold of 4 hours or more of continuous use each night, the Best 30 Day Adherence Score will show the best adherence percentage achieved for any rolling period of 30 consecutive days of use within a

60 day time frame or a 90 day time frame.

iCode® A feature that gives access to compliance and

therapy management information using encrypted codes. The iCode consists of six separate codes (1day, 7 day, 30 day, 60 day, 90 day, 180 day) displayed in the patient menu and retrieved by pressing the humidifier buttonwhen the device is

not being used.

LPM Lifers per minute

OSA Obstructive Sleep Apnea

P95 The 95th percentile pressure (P95) is the level of

pressure exceeded only 5% of the time.

Patient Setup Menu

The display mode in which you can change patient-adjustable device settings.

Pressure Settings

Treat P

In CPAP mode, Treat P is the designated fixed prescription pressure setting.

Min APAP

This setting is the minimum pressure of the therapy pressure range in Auto mode. It may be adjusted from $4 \text{ cmH}_20 \text{ to } 20 \text{ cmH}_20 \text{ in } 0.5 \text{ cmH}_20 \text{ increments}$.

Max APAP

The setting is the maximum pressure of the therapy pressure range in Auto Mode. It may be adjusted from $4 \text{ cmH}_20 \text{ to } 20 \text{ cmH}_20 \text{ in } 0.5 \text{ cmH}_20 \text{ in crements}$.

Ramp P

The designated starting pressure for ramp

Ramp

A feature that may increase patient comfort when therapy is started. The ramp feature reduces pressure and then gradually increases the pressure to the prescription setting so you can fall asleep more comfortably.

RampTime

This setting is the time at which the pressure ramp begins.

Reslex

A therapy feature that provides pressure relief during exhalation, if enabled by your home care provider

SNI Snore Index

Standby

The state of the device when power is applied but their flow is turned off.

Units

cmH₂O or hPa, default setting is cmH₂O.

Use time

Total hours this device been used.

Limited Warranty

3B Medical, Inc. warrants that the RESmart® CPAP and Auto-CPAP devices will be free of all defects in workmanship and materials, and will perform according to specifications, for a period of two (2) years from the date of sale of the device, and 90 days on any accessories.

If the product fails to perform in accordance with the product specifications, 3B Medical, Inc. will repair or replace, at its option, the defective material or part. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

- 3B will issue an RMA (Return Merchandise Authorization) within 24 hours of receipt of written notification of a failed or defective unit. Failed/defective units must be returned within 30 days of the RMA date.
- This warranty coverage is applicable to all 3B/BMC CPAP, Auto-CPAP and Auto Bi-level devices.
- The warranty policy does not cover any damages caused as a result of alteration, intentional damage, modification, or unauthorized repair of the device.
- 3B reserves the right to amend this policy at any time.

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

3B Medical, Inc. 21301 US Highway 27N Lake Wales, FL 33859 T: (863) 226-6285 F: (863) 226-6284 www.3bproducts.com

For additional information, please visit our Patient Portal at: www.3Bproducts.com

icodeconnect.com – Web-based cloud for report generation and storage

www.bmc-icode.com-Website for iCode data report retrieval

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