



RESmart[®] BPAP 25A System
User Manual



3BTM

Solutions in Sleep TherapyTM

www.3Bproducts.com

Table of Contents

Symbols	1
Indications for Use	2
Warning & Cautions	3
Specifications	5
Unpacking the System	7
Available Therapies	8
System Features	9
First Time Setup	10
Installing the Filter	10
Device Settings	13
Assembling the Circuit	17
Adding a Humidifier	18
Adding Oxygen	19
Routine Use	20
Connecting the Circuit	20
Adjusting the Circuit	20
Using the Ramp Button	20
Turning the System OFF	20
Helpful Hints	21
Routine Maintenance	22
Cleaning the Filter	22
Cleaning the System	22
Reordering	23
Service	23
Traveling with RESmart®	24
Troubleshooting	25
EMC Requirements	26
Glossary	32
Limited Warranty	35

Symbols

Control Buttons



Pressure Start / Stop



Ramp Start



Humidifier On / 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 sale by or on the order of a physician.

Indications for Use

The 3B and BMC RESmart® BPAP system is a Bi-level PAP (Bi-level Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA). 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. It is to be used on patients >66lbs/30kg for whom positive airway pressure therapy has been prescribed. The system can deliver bilevel therapy or auto-bilevel therapy.

Contraindications

The RESmart®BPAP device 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 inner ear infection
- Conditions predisposing to a risk of aspiration of gastric contents
- Epitaxis 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.

Caution should be used when prescribing BPAP 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).

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

WARNING!

Indicates the possibility for injury to the user or 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
- BPAP devices have the potential to allow rebreathing of exhaled air.
- Contact your health care professional if symptoms of sleep apnea recur.
- Using the RESmart® BPAP 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 BPAP devices: At low BPAP pressures, some exhaled gas (CO₂) may remain in the mask and be rebreathed.
- Do not use this device if the room temperature is warmer than 86°F (30°C). If this device is used at room temperatures warmer than 86°F (30°C), the temperature of the airflow may exceed 106°F (41°C). This could cause irritation to your airway.
- 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® BPAP, 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® BPAP if the display is erratic. Contact your homecare provider for further instructions.

CAUTION!

Indicates the possibility of damage to the device.

- Make sure the RESmart®BPAP is kept 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.
- Tobacco smoke may cause tar build-up within the RESmart®BPAP 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®BPAP unless recommended by BMC or your health care provider.

CAUTION!

If the RESmart®BPAP 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®BPAP 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) with Integrated Heated Humidifier

Weight: 3.5 lbs. (2.2 kg), 4.8 lbs. (3 kg) 6.6 lbs. (with Integrated Heated Humidifier)

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	41°F to 86°F (5 to 30°C)	-4°F to 131°F (-20 to 55°C)
Humidity:	≤ 80% Non-condensing	≤ 93%
Non-condensing Atmospheric Pressure:	860 to 1060 cmH ₂ O	500 to 1060 cmH ₂ O

Mode of Operation

Continuous

Work Mode

CPAP, Auto-BPAP, BPAP

SD Card Capacity

2G bytes

AC Power Consumption

100 – 240V AC, 50/60Hz, 95VA 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 25 cmH₂O *(in 0.5 cmH₂O increments)

Pressure Stability

4 to 25 cmH₂O (±1 cmH₂O)

Altitude setting

Manual setting: level 0-2

Automatic altitude compensation for therapy pressure

Sound Pressure Level

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

Maximum Flow

Test Pressure (cmH ₂ O)	4	10	15	20	25
Average flow at the patient connection port(L/min)	70.1	73	64	73.4	74.6

Accessories

The RESmart® BPAP 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 interconnectivity 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® BPAP 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®BPAP	
2	Power cord	
3	Carrying Case with shoulder strap	
4	User Manual	
5	Provider Instructions	
6	Flexible tubing	
7	Extra Filter (M1020)	
8	Humidifier Plug	
9	SD Card	

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® BPAP is available in the model 25A, which delivers the following therapies:

CPAP: Delivers Continuous Positive Airway Pressure; CPAP maintains a constant level of pressure throughout the breathing cycle. If your health care professional 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.

BPAP: Delivers dual Continuous Positive Airway Pressures at set levels for inhalation and exhalation, which affords added comfort during treatment.



Shown With Humidifier

Auto-BPAP: Automatically adjusts dual therapy pressures for inhalation and exhalation within prescribed pressure ranges 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.

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® BPAP 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. (RS232 Cable)

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

First Time Setup (Patient)

WARNING!

Do not use the RESmart® BPAP 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® BPAP unless recommended in this manual or by your health care provider.

CAUTION

If the RESmart® BPAP 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® BPAP on a firm flat surface

I. Install the Filter

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

CAUTION! The foam filter must be in place at all times when the RESmart® BPAP is operating.

IMPORTANT! Remove power to the device by disconnecting the power cord from the electrical outlet.

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

II. Attach the Integrated Heated Humidifier

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

III. Connect Power Cord

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

The RESmart® BPAP is powered on for use when the power cord is connected.

Pressing the Start/Stop Button  turns the blower on/off.

CAUTION! Make sure the RESmart® BPAP 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 powering on, the 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 buttons can be used when entering the Patient and Clinician's menus to change the RESmart® BPAP 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. DO NOT 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 humidifier is off. See iCode®.

IMPORTANT: The humidifier button is active only when an Integrated Heated Humidifier is connected or when the RESmart® BPAP is in the Setup Menu. 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 the 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 cmH₂O.

Treatment Pressure (Min APAP): The Physician prescribed pressure which is the baseline for system automatic adjustment after ramp time. Default setting is 4 cmH₂O.

Ramp Timer: The ramp time from starting pressure to system automatic adjustment. 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!

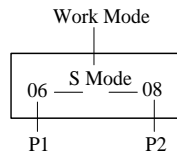
Pressing the ramp button (when the airflow is turned on) will lower the airflow pressure, if prescribed, and then will gradually increase it.

IV. Patient Menu Set-Up

Starting the Device

Standby

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



Work Mode: The starting Mode. Default setting is S Mode.

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

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

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. You can use the Ramp button as often as you wish during the night.

Turning the System OFF

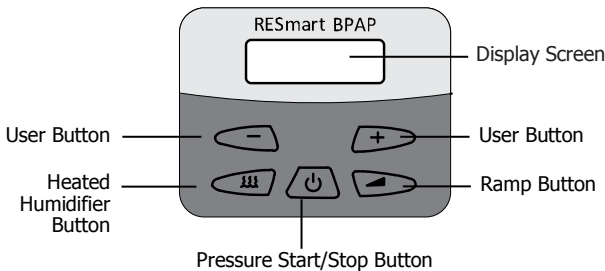
Remove the mask and headgear. Press the pressure start/stop button on the top of the RESmart® BPAP to stop the airflow. Or, if the Auto Off setting has been enable, the airflow will automatically turn off.

IMPORTANT!

The humidifier button is active only when a RESmart® Heated Humidifier is connected or when the RESmart® BPAP is in the Setup Menu. Refer to the RESmart® Heated Humidifier's instructions for additional information.

Helpful Hints

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

Selecting Patient Device Settings**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 go through each option by pushing 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. Setting changes are not finalized until they are saved by pressing the ramp button on the Save screen at the end of the menu option cycle.

Press +/- user buttons to access the menu settings. Proceed through the following settings: (1) Heater, (2) Altitude, (3) Auto On, (4) Auto Off, (5) Light, (6) Alert, (7) Reslex, (8) Delay Off, (9) Date, (10) Use Days, (11) Save

WARNING!

DO NOT use the RESmart® BPAP 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

When the optional RESmart® 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

Setting the Altitude

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. = The airflow pressure may not be accurate. Contact your home care provider to have your pressure setting adjusted.

Altitude 0

Setting Auto ON

When the RESmart® BPAP is standby and wearing mask, your deep breath will start airflow automatically. Default setting is Enable.

Auto On Enable

Setting Auto Off

When the mask is removed, the RESmart® BPAP will stop airflow automatically. Default setting is Disabled.

Auto Off Disable

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 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.

Light Auto

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 disabled. Default setting is Disable.

Alert Disable

Setting Reslex

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. The default setting, 0, indicates that the feature is disabled.

Reslex
0

Setting the Delay Off

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

DelayOff
Enable

Setting the RiseTime

Rise time settings are adjustable by the patient and the provider from 0 (off) to 3. Rise time varies from 150 msec to 400msec 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.

Risetime
2

Setting the Date

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.

Date

Use Days

The number of nights the RESmart® BPAP 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.

Use Days
0

Exit the Settings

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.

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 stop/start 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), AHI (apnea-hypopnea index), and SNI (snore index).

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, 7 day, 30 day, 60 days, etc.).

Step 2: To generate a report, go to www.bmc-iCode.com. There are three mandatory fields required to generate a report: the device serial number, retrieval date, and iCode® string. All other fields are optional and may be entered depending on the requirements 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® BPAP models. As simple as taking a picture. Absolutely free of charge. Take a photo of the display and generate a sleep report. Automatically email physician or provider.



VI. Assembling the Circuit (interface "Mask")

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

- (11) Mask with integrated exhalation port
- (12) 6ft. (1.83 m) flexible Tubing (included)
- (13) Headgear (for the mask)

a. Connect the flexible tubing to the air outlet on the front of the RESmart® BPAP.

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 is intended to be used with masks and circuits that have an exhalation port designed to exhaust CO₂ from the circuit. When the RESmart® BPAP is turned on and functioning properly, new air from the RESmart® BPAP flushes the exhaled air out through the exhalation port. When the RESmart® BPAP is turned off, there will not be enough fresh air 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 PAP 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 anti-asphyxia valve.

Accessories

Contact your home care provider for additional information on the accessories available for the RESmart® BPAP. 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 below when using oxygen with the RESmart® BPAP.

WARNING!

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

Turn the RESmart® BPAP on before turning the oxygen on. Turn the oxygen off before turning the RESmart® BPAP off.

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

Oxygen accelerates fires. Keep the RESmart® BPAP 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 or the oxygen container.

Connecting the Circuit (Interface-Mask and Tubing)

1. Connect the circuit by attaching tubing to air outlet on the 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® BPAP. 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® BPAP. 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® BPAP 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® BPAP 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. Air must flow freely around the RESmart® device for the system to work properly.
- If the airflow from the RESmart® BPAP 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® BPAP 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® BPAP with a dirty filter may keep the system from working properly and may cause damage to the device.

Never install a wet filter in 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® BPAP before cleaning. Do not immerse the RESmart® BPAP in any fluids.

1. Disconnect the flexible tubing from the RESmart® BPAP. 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 with a cloth slightly dampened with water and a mild detergent. Let the RESmart® BPAP 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® BPAP 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® BPAP'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® BPAP, 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® BPAP.

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® BPAP and possible solutions to those problems. If none of the corrective actions solve the problem, contact your homecare 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 serviced. Please have the device's serial number ready when you call.
The airflow from the RESmart® BPAP seems warm.	Replace or clean the filter. Make sure the RESmart® BPAP is away from bedding or curtains that could block the flow of air around the RESmart® BPAP. Make sure the RESmart® BPAP is away from heating equipment (e.g. forced air vents, radiators).
The noise level of the RESmart® BPAP has changed to include unusual or harsh sounds during operation.	Contact your home care provider for directions on having the RESmart® BPAP serviced. Please have the device's serial number ready when you call.
The RESmart® BPAP will not turn on	Make sure that the RESmart® BPAP is plugged into a working outlet. Contact your home care provider for directions on having the RESmart® BPAP 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 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 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 RESmart® user 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 domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmoni c emissions IEC 61000-3-2	Class A	
Voltage fluctuation s /flicker emissions IEC 61000-3-3	Class D	

Guidance and manufacturer's declaration -electromagnetic immunity


The RESmart® is intended for use in the electromagnetic environment specified below. The RESmart® user 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	±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	Main 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	Main power quality should be that of a typical home or hospital.

<p>Voltage dips, short interruptions and voltage variations on power supply input lines</p> <p>IEC 61000-4-11</p>	<p><5% U_T (>95% dip in U_T) for 0.5 cycle</p> <p>40% U_T (60% dip in U_T) for 5 cycles</p> <p>70% U_T (30% dip in U_T) for 25 cycles</p> <p><5% U_T (>95% dip in U_T) for 5 s</p>	<p><5% U_T (>95% dip in U_T) for 0.5 cycle</p> <p>40% U_T (60% dip in U_T) for 5 cycles</p> <p>70% U_T (30% dip in U_T) for 25 cycles</p> <p><5% U_T (>95% dip in U_T) for 5 s</p>	<p>Main power quality should be that of a typical commercial or hospital environment. If the user of the RESmart® requires continued operation during power main interruptions, it is recommended that the RESmart® be powered from an uninterruptible power supply or from battery.</p>
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<p>Power frequency (50/60Hz) magnetic field</p> <p>IEC 61000-4-8</p>	<p>3A/m</p>	<p>0.3 A/m</p>	<p>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.</p>
<p>NOTE: U_T is the AC main voltage prior to application of the test level.</p>			

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.			
Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic Environment · Guidance
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz	3Vrms	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 $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 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

			<p>fixed RF transmitter, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applied.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^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®.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.</p>			

Glossary

AHI	Apnea/Hypopnea Index
Apnea	
Auto-BPAP	A bi-level mode which responds to both your inhalation and exhalation. The differential pressure of IPAP and EPAP are preset by your homecare provider. While in Auto mode, the device will automatically adjust the IPAP and EPAP when it detects an apnea event.
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. This feature is always enabled.
Backup RR	Backup Respiration Rate
BPAP Mode	A bi-level mode that responds to 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 and EPAP are preset by your homecare 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 respiration.
BPM	Breaths per Minute
CPAP	Continuous Positive Airway Pressure
Compliance	(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 90 day time frame.

EPAP	Expiratory Positive Airway Pressure
IPAP	Inspiratory Positive Airway Pressure
iCode®	A feature that gives access to compliance and therapy management information using encrypted codes. The iCode consists of six separate codes (1 day, 7 day, 30 day, 60 day, 90 day, 180 day) displayed in the patient menu and retrieved by pressing the humidifier button when the device is not being used.
LPM	Liters per minute
OSA	Obstructive Sleep Apnea
P95	The 95 th 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 such as the ramp starting pressure.

Pressure Settings

Treat P	In CPAP mode, Treat P is the designated fixed prescription pressure setting.
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.
Ramp T	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.
Rise Time	The time it takes for the device to change from EPAP to IPAP. You can adjust this time for your comfort.

SNI	Snore Index
Standby	The state of the device when power is applied but flow is turned off.
Units	cmH ₂ O or hPa
Use Days	Total days where use exceeds 4 hours
Use Time	Total hours this device been used

Limited Warranty

3B Medical, Inc. warrants that the RESmart® BPAP will be free of all defects in workmanship and materials, and will perform according to specifications, for a period of two (2) years of sale from the 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 27 N
Lake Wales, FL 33859
T: (863) 226-6285
F: (863) 226-6284

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