

RESmart® 25/25A BPAP System

User Manual



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1. Introduction

1.1 System Contents

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

No.	Item	Num.
1	RESmart® BPAP 25/25A	1
2	Power Cord	1
3	Carrying Case	1
4	User Manual	1

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 BiPAP (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 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 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 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.

Introduction (cont.)

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.

WARNING!

- 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.

 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 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 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. DO NOT immerse the device in any fluids.
- Contact your health care professional if symptoms of sleep apnea recur.
- Using the RESmart® BPAP 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.

Warnings, Cautions and Contraindications (cont.)

1.3.2 Cautions

Caution indicates the possibility of damage to the device.

CAUTION!

- Tobacco smoke may cause tar build-up within the RESmart® BPAP 25/25A that may result in the RESmart® BPAP 25/25A malfunctioning.
- The use of accessories other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.
- This device is restricted to sale by or on the order of a physician.

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

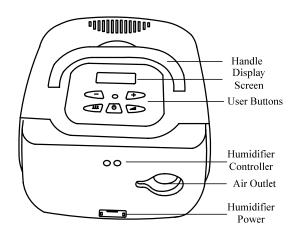
1.3.3 Contraindications

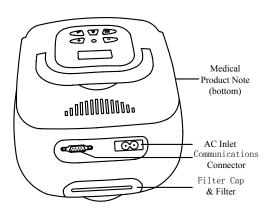
The BPAP should not be used if you have an insufficient respiratory drive to endure brief interruptions in non-invasive ventilation therapy. The BPAP is not a life support ventilator and may stop operating with power failure or in the unlikely event of certain fault conditions.

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





AC Inlet Connect/disconnect the AC power cord here.

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

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 ® BPAP 25/25A .

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.

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 25/25A stating that it is medical equipment. It may help if you also take this manual with you

when you travel.

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

Handle This handle is for lifting up the system.

1.5 Glossary

The following terms appear throughout this manual:

Apnea A condition marked by the cessation of spontaneous breathing.

Auto 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. 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.

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.

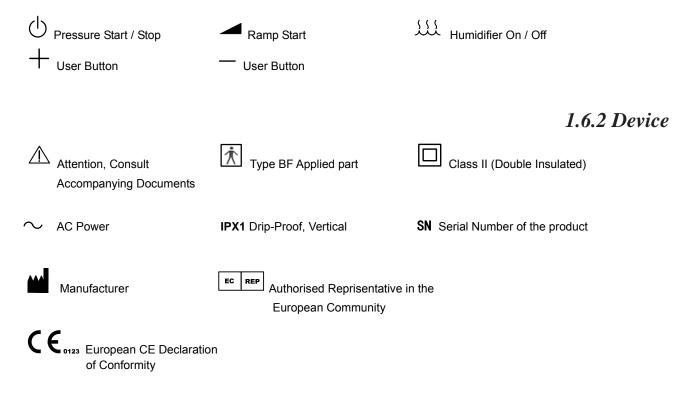
S(Spontaneous) A bi-level mode which responds to both your inhalation and

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.

1.6 Symbol Key

1.6.1 Control Buttons



2. Device Controls and Displays

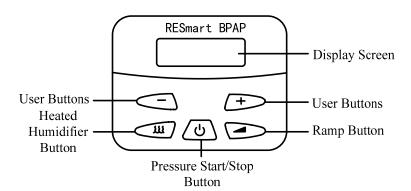
Display Screen: All device settings will appear here.

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 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 start/stop button will allow you to exit the Setup Menu without saving.

3. First Time Setup

WARNING!

Do not use the RESmart BPAP 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 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 25/25A unless recommended by BMC or your health care provider.

CAUTION!

If the RESmart® BPAP 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 $^{\otimes}$ BPAP 25/25A is operating.

- a. Place the foam filter into the filter area on the back of the RESmart $^{\otimes}$ BPAP 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 25/25A is powered on for use when the power cord is connected. The pressure start/stop button turns the blower on/off.

First Time Setup (cont.)

CAUTION!

Make sure the RESmart® BPAP 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 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 25/25A (e.g., rental devices), a low-resistance, main flow bacteria filter should be installed in-line between the RESmart BPAP 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 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 25/25A 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 25/25A is turned on and functioning properly, new air from the RESmart® BPAP 25/25A flushes the exhaled air out through the

First Time Setup (cont.)

exhalation port. When the RESmart® BPAP 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 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

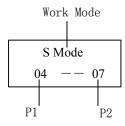
Plug the socket end of the power cord into the AC inlet on the back of the RESmart [®] BPAP 25/25A. Plug the pronged end of the power cord into an electrical outlet. System status will appear on the RESmart [®] BPAP 25/25A screen.

4. Device operation

4.1 Starting the Device

Standby

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



WorkMode: 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.;

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 $^{\text{®}}$ BPAP 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 25/25A 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 an InH2 Heated Humidifier is connected or when the RESmart® BPAP 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 any button on the RESmart [®] BPAP 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 25/25A . Air must flow freely around the RESmart [®] BPAP 25/25A for the system to work properly.
- If the airflow from the RESmart [®] BPAP 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 25/25A will resume with the working status before interruption automatically.

4.4 Change Device Settings

Verify/Change the RESmart [®] BPAP 25/25A settings. To start the setup menu, press and hold the ramp button until the setup menu appear (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 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.

Heater 3

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 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

IMPORTANT!

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

Setting Auto ON

c. When the RESmart [®] BPAP 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.

Auto On Enable

Setting Auto Off

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

Auto Off Enable

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.

> Light Auto

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.

> Alert Disable

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

> DelayOff Enable

Setting the Sensitive h. 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.

Sensitiv 3

Setting the RiseTime i. 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 0 (disable).

Risetime 1

Setting the Date

j. 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

k. The number of nights the RESmart [®] BPAP 25/25A was used for therapy for more than 4 hours will appear. 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

5. Troubleshooting

The table below lists common problems you may have with the RESmart® BPAP 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 25/25A serviced. Please have the device's serial number ready when you call.
The airflow from the RESmart [®] BPAP 25/25A seems warm.	Replace or clean the filter. Make sure the RESmart [®] BPAP 25/25A is away from bedding or curtains that could block the flow of air around the RESmart [®] BPAP 25/25A . Make sure the RESmart [®] BPAP 25/25A is away from heating equipment (e.g., forced air vents, radiators).
The noise level of the RESmart ® BPAP 25/25A has changed to include unusual or harsh sounds during operation.	Contact your home care provider for directions on having the RESmart ® BPAP 25/25A serviced. Please have the device's serial number ready when you call.
The RESmart ® BPAP 25/25A will not turn on.	Make sure that the RESmart [®] BPAP 25/25A is plugged into a working outlet. Contact your home care provider for directions on having the RESmart [®] BPAP 25/25A 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 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 25/25A 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 25/25A.

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

WARNING! Turn the RESmart® BPAP 25/25A on before turning the oxygen on. Turn the oxygen off before turning the RESmart® BPAP 25/25A off.

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

WARNING!

Oxygen accelerates fires. Keep the RESmart® BPAP 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 25/25A or the oxygen container.

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

7. Cleaning and 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 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 25/25A. Replace the filter cap.

CAUTION!

Never install a wet filter into the RESmart® BPAP 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 25/25A before cleaning. Do not immerse the RESmart® BPAP 25/25A in any fluids.

- 1. Disconnect the flexible tubing from the RESmart [®] BPAP 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 25/25A with a cloth slightly dampened with water and a mild detergent. Let the RESmart [®] BPAP 25/25A dry before plugging in the power cord.
- 3. Inspect the RESmart® BPAP 25/25A and all circuit parts for any damage after

Cleaning and Maintenance (cont.)

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 Reordering

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

Service The RESmart ® BPAP 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

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 25/25A malfunctions, contact your home care provider

immediately. Never attempt to open the RESmart® BPAP 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.

7.4 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.

7.5 Security Stations

For convenience at security stations, there is a note on the bottom of the RESmart[®] BPAP 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 25/25A.

Cleaning and Maintenance (cont.)

7.6 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: $220 \times 194 \times 112 \text{ mm}$, $313 \times 194 \times 112 \text{ mm}$ (with InH2TM heated humidifier)

Weight: 2.2kg, 3 kg(with InH2TM heated humidifier)

Product Use, Transport and Storage

Operation Transport and Storage

Temperature: $5 \text{ to } 30^{\circ}\text{C}$ $-20 \text{ to } 55^{\circ}\text{C}$

Humidity: $\leq 80\%$ Non-condensing $\leq 93\%$ Non-condensing

Atmospheric Pressure: 860 to 1060 hPa 500 to 1060 hPa

Mode of Operation:

Continuous

Work Mode:

BPAP 25: "CPAP", "S Mode"

BPAP 25A: "CPAP" "S Mode", "Auto S"

AC Power Consumption

100 - 240V AC, 50/60Hz, max 95VA

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

IPAP: 4 hPa to 25 hPa(in 0.5 hPa increments)

EPAP: 4 hPa to 25 hPa (in 0.5 hPa increments)

Pressure Stability

Static Pressure Stability: 4 to 25 hPa (±0.5 hPa)

Dynamic Pressure Stability: 4 to 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

Specifications (cont.)

Maximum Flow

Test Pressure(hPa)	4	10	15	20	25
Average flow at the patient connection port(L/min)	56	62	64	66	63

Appendix A: 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		
Harmonic emissions IEC 61000-3-2	Class A	The RESmart® is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Class D	that supplies buildings used for domestic purposes.	

Appendix A: EMC Requirements (cont.) Guidance and manufacturer's declaration - electromagnetic

<u>immunity</u>

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	Compliance	Electromagnetic environment -
	level	level	guidance
Electrostatic discharge (ESD)	±6 kV contact	±6 kV contact	Floor should be wood, concrete or ceramic tile. If floors are covered with
IEC 61000-4-2	±8 kV air	±8 kV air	synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical home or hospital.
IEC 61000-4-4	±1 kV for input/output lines	±1 kV for input/output lines	typical nome of neophan
Surge	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a
IEC 61000-4-5	±2 kV common mode	±2 kV common mode	typical home or hospital.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$<5\% U_T$ $(>95\% \text{ dip in } U_T)$ for 0.5 cycle $40\% U_T$ $(60\% \text{ dip in } U_T)$ for 5 cycles $70\% U_T$ $(30\% \text{ dip in } U_T)$ for 25 cycles $<5\% U_T$ $(>95\% \text{ dip in } U_T)$ 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 AC mains voltage pi	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.

Appendix A: EMC Requirements (cont.)

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	
			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 $d=1.2\sqrt{P}$	
Conducted RF	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms	d=1.2 $√P$ 80 MHz to 800 MHz d =2.3 $√P$ 800 MHz to 2.5 GHz	
IEC 61000-4-6			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> is the	
Radiated RF			recommended separation distance in meters (m).	
61000-4-3			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 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 [®]

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

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:

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