# RESmart® BPAP System 20T/25T/30T model

# **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 20T/25T/30T	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<sup>®</sup> BPAP 20T/25T/30T system is a BiPAP (Bi-level Positive Airway Pressure) device, which is intended to provide non-invasive ventilation for patients with respiratory insufficiency or obstructive sleep apnea (OSA), either in the hospital or at home.

The RESmart<sup>®</sup> BPAP 20T/25T/30T 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 treatment with the RESmart<sup>®</sup> BPAP 20T/25T/30T as convenient and comfortable as possible. To ensure that you receive the safe, effective therapy prescribed for you, use only BMC accessories.

The RESmart<sup>®</sup> BPAP 20T/25T/30T is only used for single patient and must not be re-used on another person. This is to avoid the risk of cross-infection.

#### IMPORTANT!

Read and understand the entire user manual before operating this system. If you have any questions concerning the use of this system, contact your home care provider or health care professional.

#### Adverse Effects

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

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

- drying of the nose, mouth or throat
- bloating
- · ear or sinus discomfort
- eye irritation
- mask-related skin irritations
- chest discomfort.

# 1.3 Warnings, Cautions and Contraindications

### 1.3.1 Warnings

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

#### 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 (CO<sub>2</sub>) may remain in the mask and be rebreathed.

- Do not use this device if the room temperature is warmer than  $86^{\circ}F$  ( $30^{\circ}C$ ). If this device is used at room temperatures warmer than  $86^{\circ}F$  ( $30^{\circ}C$ ), the temperature of the airflow may exceed  $106^{\circ}F$  ( $41^{\circ}C$ ). 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 20T/25T/30T, 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<sup>®</sup> BPAP 20T/25T/30T at an incorrect elevation setting could result in airflow pressures higher than the prescribed setting. Always verify the elevation setting when traveling or relocating.

#### 1.3.2 Cautions

Caution indicates the possibility of damage to the device.

#### **CAUTION!**

- $\bullet$  Tobacco smoke may cause tar build-up within the RESmart  $^{\! @}$  BPAP 20T/25T/30T that may result in the RESmart  $^{\! @}$  BPAP 20T/25T/30T 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.

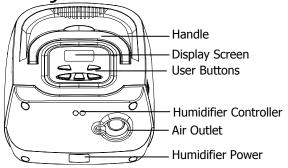
### 1.3.3 Contraindications

The device should not be used if you have severe respiratory failure without a spontaneous respiratory drive. If any of the following conditions applies to you, consult your physician before using the device:

If you have any of the following conditions, tell your doctor before using the BPAP:

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

### 1.4 System Overview



Handle: This handle is for lifting up the system.

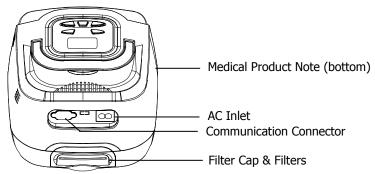
**Display Screen:** All system settings, total operating time, and therapy hours will appear here.

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

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

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

 $\textit{Humidifier Power:}\ \text{This socket provides the power to the }\ \text{InH2}^{\text{\$}}\ \text{heated humidifier.}$ 



*Medical Product Note:* For ease at airport security stations, there is a note on the bottom of the RESmart<sup>®</sup> BPAP 20T/25T/30T 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.

**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<sup>®</sup> BPAP 20T/25T/30T.

# 1.5 Glossary

The following terms appear throughout this manual:

Apnea: A condition marked by the cessation of spontaneous breathing

Backup RR: Backup Respiration Rate

**BPM:** Breaths Per Minute

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

EPAP: Expiratory Positive Airway Pressure

IPAP: Inspiratory Positive Airway Pressure

LED: Light Emitting Diode

OSA: Obstructive Sleep Apnea

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

**Rise Time:** The time it takes for the device to change from EPAP to IPAP. You can adjust this time for your comfort.

**RR:** Respiratory Rate. Number of breaths per minute.

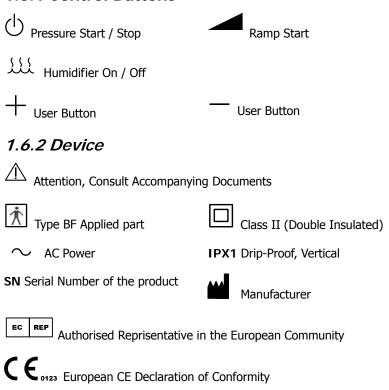
*S* (*Spontaneous*): A bi-level mode which responds to both your inhalation and exhalation by increasing pressure when you start to inhale and decreasing pressure when you start to exhale. There is no automatic delivery of a breath you do not inhale. IPAP (Inspiratory Positive Airway Pressure) and EPAP (Expiratory Positive Airway Pressure) are preset by home care provider. When the apnea is longer than 10 seconds, the device will start Backup Respiration Rate with a frequency of 10 times per minute to support respire.

*S/T (Spontaneous/Timed):* 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. If you do not start inhaling within a set time, the device automatically starts inhalation. When the device starts inhalation, it controls the time of inhalation and automatically decreases the pressure for exhalation within a set time. When the device starts inhalation, controls the time of inhalation and automatically decreases the pressure for exhalation within a set time.

*T (Timed):* A bi-level mode which the device automatically starts inhalation and exhalation, automatically controls the time of inhalation and that of exhalation according to the preset parameter.

# 1.6 Symbol Key

# 1.6.1 Control Buttons



# 2. Device Controls and Displays

Display Screen: All device settings will appear here.

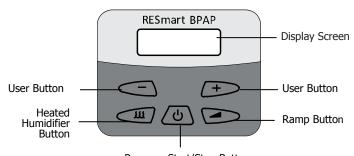
**Pressure Start/Stop Button:** Use this button to start/stop the airflow. DO NOT start the airflow until the circuit tubing is connected.

*Heated Humidifier Button:* Use this button when the optional InH2<sup>®</sup> 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, S mode or S/T 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<sup>®</sup> BPAP 20T/25T/30T settings.



Pressure Start/Stop Button

#### 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<sup>®</sup> BPAP 20T/25T/30T 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<sup>®</sup> BPAP 20T/25T/30T Home Care Provider Setup Instructions. Setup instructions are not provided in this manual.

#### WARNING!

DO NOT connect any equipment to the RESmart  $^{\otimes}$  BPAP 20T/25T/30T unless recommended by BMC or your health care provider.

#### **CAUTION!**

If the RESmart<sup>®</sup> BPAP 20T/25T/30T 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 20T/25T/30T is operating.

- a. Place the foam filter into the filter area on the back of the RESmart  $^{\! (\! g \!)}$  BPAP 20T/25T/30T.
- 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<sup>®</sup> BPAP 20T/25T/30T is powered on for use when the power cord is connected. The pressure start/stop button turns the blower on/off.

#### CAUTION!

Make sure the RESmart<sup>®</sup> BPAP 20T/25T/30T 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 20T/25T/30T 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<sup>®</sup> BPAP 20T/25T/30T (e.g., rental devices), a low-resistance, main flow bacteria filter should be installed in-line between the RESmart<sup>®</sup> BPAP 20T/25T/30T 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  $^{\!\otimes}\!$  BPAP 20T/25T/30T.
- 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<sup>®</sup> BPAP 20T/25T/30T is intended to be used with masks and circuits that have an exhalation port designed to exhaust  $CO_2$  from the circuit. When the RESmart<sup>®</sup> BPAP 20T/25T/30T is turned on and functioning properly, new air from the RESmart<sup>®</sup> BPAP 20T/25T/30T

flushes the exhaled air out through the exhalation port. When the RESmart® BPAP 20T/25T/30T 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 20T/25T/30T. 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<sup>®</sup> BPAP 20T/25T/30T. Plug the pronged end of the power cord into an electrical outlet. System status will appear on the RESmart<sup>®</sup> BPAP 20T/25T/30T screen.

# 4. Device operation

# 4.1 Starting the Device

#### Standby

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



**Work Mode:** The starting Mode. Default setting is S Mode. It may vary according to your home care provider's setup.

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<sup>®</sup> BPAP 20T/25T/30T. 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<sup>®</sup> BPAP 20T/25T/30T to stop the airflow. Or, if the Auto Off setting has been enabled, the airflow will automatically turn off.

#### IMPORTANT!

The humidifier button is active only when an  $InH2^{\$}$  Heated Humidifier is connected or when the RESmart<sup>\$</sup> BPAP 20T/25T/30T 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 20T/25T/30T 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<sup>®</sup> BPAP 20T/25T/30T. Air must flow freely around the RESmart<sup>®</sup> BPAP 20T/25T/30T for the system to work properly.
- If the airflow from the RESmart® BPAP 20T/25T/30T 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<sup>®</sup> BPAP 20T/25T/30T will resume with the working status before interruption automatically.

# 4.4 Change Device Settings

Verify/Change the RESmart<sup>®</sup> BPAP 20T/25T/30T 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<sup>®</sup> BPAP 20T/25T/30T 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<sup>®</sup> 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<sup>®</sup> is already with <u>automatic altitude compensation</u>. Even if without setting the altitude, RESmart<sup>®</sup> still can deliver proper pressure in any altitude worldwide.

#### Setting Auto ON

c. When the RESmart<sup>®</sup> BPAP 20T/25T/30T 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<sup>®</sup> BPAP 20T/25T/30T 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 Delay Off

f. When the optional InH2 $^{\otimes}$  Heated Humidifier is used, this setting allows the air flow continue for about 15 minutes at very low pressure (about 2hPa) after RESmart $^{\otimes}$  BPAP 20T/25T/30T is turned off. This will blow off the left vapor and protect the RESmart $^{\otimes}$  BPAP 20T/25T/30T. Default setting is Enable.

DelayOff Enable

#### Setting the RiseTime

g. 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

h. 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

i. The number of nights the RESmart<sup>®</sup> BPAP 20T/25T/30T 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

#### I Sense

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

I Sense 3

#### E Sense

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

E Sense

#### Setting BKP RR

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

BKP RR Disable

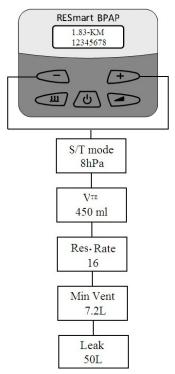
#### Exit the Settings

m. 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

# 4.5 Reading Therapy Information

Double-click the <+> or <-> button when device is working. Parameters of Therapy information such as Tidal volume can be read in turn from Vte (tidal volume), Res.Rate, Min Vent, Leak on the interface of the display screen.



Parameter (unit)	Definition	Range	Accuracy	Display Resolution
Tidal Volume (ml)	It gives the estimated value of exhaled tidal volume delivered last time. The value is updated following each breath. The value will keep the default "0" unless more that 3 breaths are given.	0-2000ml	±20% (Vte>100m  )	1
Respiratory . Rate	It gives the average frequency of previous 4 breaths. The value is updated following each breath. The value will keep the default set on the	3-40BPM	±1	1

	T-mode in the clinic menu unless more than 3 breaths are given.			
Minute ventilator (L)	It gives the average value of Exhaled Min Ventilator of the previous 4 breaths. The value will keep the default "0" unless more than 3 breaths are given.	0-801	±(1+20%)	0.1
leak (LPM)	It gives the real-time estimated value of air leakage in previous 10 seconds (without the exhaust volume delivered in normal condition).	0-100LP M	±(5+20%)	0.1

Note: Since there are leakage form mask, the parameters of tidal volume and minute ventilator are for reference only. It has an impact on the accuracy in some cases such as low tidal volume, instable respiration or rapidly changes in air leakage.

# 5. Alerts and Troubleshooting

The following table summarizes the device alerts.

ALERT	AUDIBLE INDICATOR	VISUAL INDICATOR	DEVICE ACTION	POSSIBLE CAUSE	PATIENT ACTION
System error	beep	LCD backlight flashes and "sys Err" displays	The device enters the "safe state" in which the device power remains on, but the airflow is disabled.	Device failure	Press any key to silence the alert. Remove the power supply cord from the device to remove power. Plug the cord back into the device's power inlet to restore power. If the alert continues to occur, contact your home care provider.
Mask leak	beep	LCD backlight flashes and "leak" displays	The device continue s to operate.	The breathing circuit is disconnect ed or there is a large air leak.	Check your breathing circuit connections and reconnect the tubing if it has come loose. Make sure your mask is on properly before you press the on/off button to restart the airflow.
Patient apnea	beep	LCD backlight flashes and "apnea" displays	The device continue s to operate.	An apnea occurred during therapy.	Continue using the device. Report the alarm to your home care provider.
Power off	beep	LCD backlight flashes and "power off" displays	The device stops operatin g.	The power is off or the power cord is not fixed well.	Check your power supply condition.

The table below lists common problems you may have with the RESmart® BPAP 20T/25T/30T 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	Check the altitude setting to be sure it is set
feels different.	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
	20T/25T/30T serviced. Please have the
	device's serial number ready when you call.
The airflow from the RESmart®	Replace or clean the filter. Make sure the
BPAP 20T/25T/30T seems	RESmart <sup>®</sup> BPAP 20T/25T/30T is away from
warm.	bedding or curtains that could block the
	flow of air around the RESmart® BPAP
	20T/25T/30T. Make sure the RESmart®
	BPAP 20T/25T/30T is away from heating
	equipment (e.g., forced air vents,
	radiators).
The noise level of the	Contact your home care provider for
RESmart® BPAP 20T/25T/30T	directions on having the RESmart® BPAP
has changed to include	20T/25T/30T serviced. Please have the
unusual or harsh sounds	device's serial number ready when you call.
during operation.	M.I. J. J. DEC. J. R. DEAD
The RESmart® BPAP	Make sure that the RESmart® BPAP
20T/25T/30T will not turn on.	20T/25T/30T is plugged into a working
	outlet. Contact your home care provider for
	directions on having the RESmart® BPAP
	20T/25T/30T serviced. Please have the
Drossing the ramp butter does	device's serial number ready when you call.
Pressing the ramp button does	Contact your home care provider. Ramp
not reduce the air pressure.  The RESmart® BPAP	may not have been prescribed for you.  Discontinue use. Disconnect the power cord
20T/25T/30T has been	from the AC wall outlet. Contact your home
dropped into water or fluids	care provider for directions on having the
have gotten into the enclosure.	RESmart <sup>®</sup> BPAP 20T/25T/30T serviced.
have gotten into the enclosure.	Please have the device's serial number
	ready when you call.

### 6. Accessories

# 6.1 Adding a Humidifier

The InH2<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> BPAP 20T/25T/30T.

#### **WARNING!**

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

#### WARNING!

Turn the RESmart<sup>®</sup> BPAP 20T/25T/30T on before turning the oxygen on. Turn the oxygen off before turning the RESmart<sup>®</sup> BPAP 20T/25T/30T off. Explanation of Warning: When the RESmart<sup>®</sup> BPAP 20T/25T/30T is turned off, but the oxygen flow is still turned on, oxygen may accumulate within the RESmart<sup>®</sup> BPAP 20T/25T/30T enclosure and create a fire risk. Turning the oxygen off before turning the RESmart<sup>®</sup> BPAP 20T/25T/30T off will prevent oxygen accumulation in the RESmart<sup>®</sup> BPAP 20T/25T/30T and will reduce the risk of fire. This warning applies to most BPAP devices.

#### WARNING!

Oxygen accelerates fires. Keep the RESmart  $^{\otimes}$  BPAP 20T/25T/30T 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  $^{\otimes}$  BPAP 20T/25T/30T or the oxygen container.

Contact your home care provider for additional information on the accessories available for the RESmart<sup>®</sup> BPAP 20T/25T/30T. 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<sup>®</sup> BPAP 20T/25T/30T 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<sup>®</sup> BPAP 20T/25T/30T. Replace the filter cap.

#### CAUTION!

Never install a wet filter into the RESmart<sup>®</sup> BPAP 20T/25T/30T. 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<sup>®</sup> BPAP 20T/25T/30T before cleaning. Do not immerse the RESmart<sup>®</sup> BPAP 20T/25T/30T in any fluids.

- 1. Disconnect the flexible tubing from the RESmart<sup>®</sup> BPAP 20T/25T/30T. 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<sup>®</sup> BPAP 20T/25T/30T with a cloth slightly dampened with water and a mild detergent. Let the RESmart<sup>®</sup> BPAP 20T/25T/30T dry before plugging in the power cord.

- 3. Inspect the RESmart<sup>®</sup> BPAP 20T/25T/30T and all circuit parts for any damage after cleaning. Replace any damaged parts.
- 4. For details on cleaning your mask and accessories, refer to the cleaning instructions packaged with the accessories.

# 7.3 Reordering

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

#### Service

The RESmart® BPAP 20T/25T/30T does not require routine servicing.

The RESmart<sup>®</sup> unit contains electrical and/or electronic equipment. When necessary, dispose of the RESmart<sup>®</sup> and accessories in accordance with local regulations.

#### WARNING!

If you notice any unexplained changes in the performance of the RESmart<sup>®</sup> BPAP 20T/25T/30T, 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 20T/25T/30T malfunctions, contact your home care provider immediately. Never attempt to open the RESmart® BPAP 20T/25T/30T'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<sup>®</sup> BPAP 20T/25T/30T stating that it is medical equipment. It may be helpful to bring this manual along with you to help security personnel understand the RESmart<sup>®</sup> BPAP 20T/25T/30T.

# 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 mm, 313  $\times$  194  $\times$  112 mm (with InH2<sup>®</sup> heated

humidifier)

Weight: 2.2kg, 3 kg (with InH2® heated humidifier)

#### Product Use, Transport and Storage

Operation Transport and Storage

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

CPAP, S, T, S/T

Product Model	Pressure	Work Mode
20T	4-20hPa	S, CPAP,T, S/T
25T	4-25hPa	S, CPAP,T,S/T
30T	4-30hPa	S, CPAP,T,S/T

#### **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

For 20T:

IPAP: 4hPa to 20hPa (in 0.5hPa increments) EPAP: 4hPa to 20hPa (in 0.5hPa increments)

For 25T:

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

For 30T:

IPAP: 4hPa to 30hPa (in 0.5hPa increments) EPAP: 4hPa to 25hPa (in 0.5hPa increments)

#### Pressure Stability

For 20T:

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

For 25T:

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

For 30T:

Static Pressure Stability: 4 to 30hPa (±0.5hPa) Dynamic Pressure Stability: 4 to 30hPa (±1.0hPa)

#### Altitude Compensation

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

#### Sound Pressure Level

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

#### Maximum Flow

#### For 20T:

Test Pressure(hPa)	4	8	12	16	20
Average flow at the patient connection port(L/min)	70.1	72.1	72.3	70.1	73.4

#### For 25T:

Test Pressure(hPa)	4	10	15	20	25
Average flow at the patient connection port(L/min)	70.1	73.0	64	73.4	74.6

#### For 30T:

Test Pressure(hPa)	4	10.5	17	23.5	30
Average flow at the patient connection port(L/min)	70.1	73.0	70.5	71.7	72.8

# 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 <sup>®</sup> should ensure that it is used in such an environment.

The user of the RESmar	t® should ensure tl	hat it is used in such an environment.
Emissions Test Compliance		Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1, Class B	The RESmart <sup>®</sup> 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
Harmonic emissions IEC 61000-3-2	Class A	establishments including domestic establishments and those directly connected to the public low-voltage
Voltage fluctuations /flicker emissions IEC 61000-3-3	Class D	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.

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	
	±2 kV for	±2 kV for	least 30%.	
Electrical fast transient/burst	power supply lines	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		
Surge	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical home or	
IEC 61000-4-5	±2 kV common mode	±2 kV common mode	hospital.	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % $U_{7}$ (>95% dip in $U_{7}$ ) for 0.5 cycle 40% $U_{7}$ (60% dip in $U_{7}$ ) for 5 cycles 70% $U_{7}$ (30% dip in $U_{7}$ ) for 25 cycles <5% $U_{7}$ (>95% dip in $U_{7}$ ) for 5 s	<5% $U_{7}$ (>95 % dip in $U_{7}$ ) for 0.5 cycle  40% $U_{7}$ (60% dip in $U_{7}$ ) for 5 cycles  70% $U_{7}$ (30% dip in $U_{7}$ ) for 25 cycles  <5% $U_{7}$ (>95% dip in $U_{7}$ ) 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 3 A/m 0.3 A/m IEC 61000-4-8	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.
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NOTE:  $U_T$  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.

The user of	HE RESINA	rt snould make sure u	nat it is used in such an environment.
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms	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√P 80 MHz to 800 MHz d=2.3√P 800 MHz to 2.5 GHz  where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).  Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> 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.

<sup>a</sup> 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<sup>®</sup> is used exceeds the applicable RF compliance level above, the RESmart<sup>®</sup> 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<sup>®</sup>.

 $^{\mathrm{b}}$  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:

#### MANUFACTURER:

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Beijing 100043, P.R.China

Tel: 86-10-51663880

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#### **EU AUTHORISED REPRESENTATIVE:**

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