User Manual
RXiBreeze PAP System

Contents

1 Welcome

The RXiBreeze PAP Systems contains CPAP and APAP Modes. They are both continuous positive airway pressure devices.

The RXiBreeze PAP Systems include the following models:

RXiBreeze III CPAP, RXiBreeze III CPAP Pro, RXiBreeze III APAP and RXiBreeze III APAP Pro.

Responsibility on the Manufacturer Party

Resvent is responsible for the effects on safety, reliability and performance of this product, only if:

- All installation operations, expansions, changes, modifications and repairs of this product are conducted by Resvent authorized personnel.
- All spare parts for repair, accessories, consumable are conducted by Resvent or the authorized personnel.
- The electrical installation of the relevant room complies with the applicable national standard and the manual requirements.
- The product is used in accordance with the instruction for use.

IMPORTANT

Read this entire guide before using the device.

2 Intend Use

The RXiBreeze PAP Systems delivery positive airway pressure therapy for the treatment of Obstructive Sleep Apnea (OSA) in spontaneously breathing patients weighting over 30kg (66lbs), it is for use in the home, hospital, or institutional environment.

3 Contraindications

When assessing the relative risks and benefits of using this equipment, the clinician should understand that this device can deliver pressures up to 20 cmH2O. In the event of certain fault conditions, maximum pressure 30 cmH2O is possible. Studies have shown that the following pre-existing conditions may contraindicate the use of CPAP therapy for some patients:

- Severe coronary artery disease
- Bullous Lung Disease
- Pathologically Low Blood Pressure
- Bypassed Upper Airway
- Pneumothorax

Caution should be used when prescribing CPAP therapy for susceptible patients such as those with: cerebral spinal fluid (CSF) leaks, abnormalities of the cribriform plate, prior history of head trauma, and/or Pneumothorax.

The use of positive airway pressure therapy may be temporarily contraindicated if you exhibit signs of a sinus or middle ear.

Note: In either case above, it can only be determined by a competent physician whether to use CPAP device.

User qualifications

The person operating the device by the instruction in the user’s manual is referred as the “user”. In contrast, a “patient” is the person receiving the therapy. Always perform all the operating steps in accordance with the user’s manual.

Some lay person can receive specified professional training about how to use the device including all related to accessories from your dealer or the manufacturer.

4 Safety Information

 WARNING: Indicate the possibility of injury to the user or operator.

CAUTION: Indicate the possibility of damage to the device.

WARNINNG：

- This manual serves as a reference. The instructions in this manual are not intended to supersede the health care professional's instructions regarding the use of the device.
- The device is not suitable for patient's requiring continuous ventiator support..
- The person, who is responsible for connecting additional equipment to the input/output signal port, configure the medical system and is responsible for whether the system conforms to IEC60601-1 standard.
- Micro USB interface is used to connect with the calibration equipment provided by the manufacturer that meets the requirements of IEC62368-1.
- A mask should not be used unless the device is turned on, otherwise, there is danger of suffocation.
- The exhalation port(s) associated with the mask should never be blocked. The device is intended to be used with special masks or connectors that have exhalation ports to allow continuous flow of air out of the mask. When the device is turned on and functioning properly, new air from the device flushes the exhaled air out through the mask exhalation port. However, when the device is not operating, enough fresh air will not be provided through the mask.
- If you are using a full-face mask (a mask covering both your mouth and your nose), the mask must be equipped with a safety (entrainment) valve.
- Do not use the device near a source of toxic or harmful vapors.
- Do not use this device if the room temperature exceeds 35°C (95°F). If the device is used at room temperatures warmer than 35°C (95°F), the temperature of the airflow may exceed 43°C (109°F). This could cause irritation or injury to your airway.
- The device is not used beyond the specified temperature range.
- Do not operate the device in direct sunlight or near a heating appliance because these conditions can increase the temperature of the air coming out of the device.
- Contact your health care professional if symptoms of sleep apnea recur.
- If you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, disconnect the power cord and discontinue use. Contact your home care provider.
- Repairs and adjustments must be performed by Resvent-authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
- Do not use any accessories, detachable parts, and materials not recommended by Resvent. Incompatible parts or accessories can result in degraded performance.
- The Health Industry Manufacturers Association recommends that a minimum separation of 16cm be maintained between a wireless phone and a pacemaker to avoid potential interference with the pacemaker.
- Use only power cords supplied by Resvent for this device. Use of power cords not supplied by Resvent may cause overheating or damage to the device and may result in increased emissions or decreased immunity of the equipment or system.
- The device should not be used while stacked or in close approximation to other non-approved devices.
- Inspect the tubing for damage or wear. Discard and replace the tubing as necessary.
- Periodically inspect electrical cords and cables for damage or signs of wear. Discontinue use and replace if

damaged.

- To avoid electrical shock, always unplug the power cord from the wall outlet before cleaning the device. DO NOT immerse the device in any fluids.
- Be sure to route the power cord to the outlet in a way that will prevent the cord from being tripped over or interfered with by chairs or other furniture.
- This device is activated when the power cord is connected.
- For safe operation when using a humidifier, the humidifier must always be positioned below the breathing circuit connection at the mask. The humidifier must be level for proper operation.
- Please check whether there is water in the device before use. The maximum fill level is 350mL±20mL。
- Failure to use a mask or accessory that minimizes re-breathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation.
- Do not connect breathing tubes or accessories with any humidifier and ventilator that are not specified for use with these breathing tubes or accessories.
- Do not cover or heat the breathing tube with anything influent the patient end temperature.
- Do not use the humidifier at an altitude above 3000 meters or outside a temperature of 5℃~35℃. Using the the device outside of this temperature range or above this altitude can affect the quality of the therapy or injure the patient.
- No modification of this equipment is allowed.
- The PATIENT is an intended OPERATOR.The Patient can safely use therapy functions of the equipment and this equipment shall not be serviced or maintained while in use with the patient.
- Please first check the breathing tube is connected correctly to avoid strangulation risk due to breathing tube and hoses when used.
- Please do not use this equipment in places with high dust concentration, otherwise it may cause safety hazards or cause lung injury.
- Do not use the device in the presence of a flammable anaesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide.
- Do not use this equipment in an environment with flammable gas and rich oxygen. The equipment should be at least 1m away from the oxygen source when working.
- Do not pull or stretch the tubing. This could result in circuit leaks.
- If the device is used by multiple persons (such as rental devices), a low-resistance, main flow bacteria filter should be installed in-line between the device and the circuit tubing to prevent contamination.
- AHIflow are estimates provided by the device and not diagnostic parameters.
- Humidification can increase the resistance of breathing syetem filters and the operator must monitor the breathing system filter frequently for increased resistance and blockage to ensure the delivery of the therapeutic pressure.
- The proper palcement and positioning of the patient interface is critical to the consistent operation of this equipmant.

CAUTION：

- Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information, Contact your home care provider regarding EMC installation information.
- Mobile RF communications equipment can affect medical electrical equipment.
- Pins of connectors marked with the ESD warning symbol shall not be touched and connections shall not be made without special precautions. Precautionary procedures include methods to prevent build-up of

electrostatic charge (e.g., air conditioning, humidification, conductive floor coverings, non-synthetic clothing), discharging one's body to the frame of the equipment or system or to earth. It is recommended that all individuals that will handle this device understand these precautionary procedures at a minimum as part of their training.

- Condensation may damage the device. If this device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (operating temperature) before starting therapy. Do not operate the device outside of the operating temperature range shown in the Specifications.
- Do not use extension cords with this device.
- Make sure the filter area on the side of the device is not blocked by bedding, curtains, lint or other items. Air must flow freely around the device for the system to work properly.
- If too much dust collects, The device inspiratory resistance increases.
- Make sure the gas intake port on the side of the device is not blocked by bedding, curtains, lint or other items. Air must flow freely around the device for the system to work properly.
- Do not place the device directly onto carpet, fabric, or other flammable materials.
- Do not place the device in or on any container that can collect or hold water.
- A properly installed, undamaged filter is required for proper operation.
- Tobacco smoke may cause tar build-up within the device, which may result in the device malfunctioning.
- Dirty inlet filters may cause high operating temperatures that may affect device performance. Regularly examine the inlet filters as needed for integrity and cleanliness.
- Always ensure that the DC power cord securely fits into your therapy device prior to use. Contact your home care provider or Resvent to determine if you have the appropriate DC cord for your specific therapy device.
- When DC power is obtained from a vehicle battery, the device should not be used while the vehicle's engine is running. Damage to the device may occur.
- Only use a Resvent DC Power Cord and Battery Adapter Cable. Use of any other system may cause damage to the device.
- When change the pressure setting, please consult your doctor.
- Do not position next to a curtain that blocks the flow of cooling air, thereby causing the equipment to overheat.
- Between the maintenance intervals of the equipment, Keep pressure stability indicators consistent with the product specifications.
- Please follow the local regulation when disposing of the device.
- The proper placement and positioning of the MASK on the face is critical to the consistent operation of this equipment.
- Please check that the compatibility of the equipment and all of the parts and accessories used to connect to the patient before use.
- Ensure that the therapeutic pressure settings were determined for the patient individually with the configuration of the equipment to be used, including accessories.
- For multiple patients use, please use personal breathing tube and mask, do not use other.
- You should position the device far away your pets, pests or children when you use the device in home environment.
- In case you feel comfortless when you contact the device. You shall stop to use the device and contact your supplier immediately. Because it may cause allergic reactions.
- Please periodically reassess the setting(s) of the therapy for effectiveness.
- Never install a wet filter into the device. You must ensure sufficient drying time for the cleaned filter.

- When rain, lightning, earthquake, fire and other accidents occur in the natural environment, resulting in the failure of network transmission data, save the the data by using the TF card.
- When accidental damage of physical media causes system failure, power failure, hardware failure and software failure, the protection of physical environment shall be strengthened and the use of equipment shall be controlled.
- If the environment or power supply exceeds the specification range, it may cause the machine to shut down automatically or the ventilation control cannot meet the specification.
- When the gas flow rate and setting exceed the recommended operating range, the humidification system output may be insufficient.
- The operator should operate the device directly in front of the device.
- For the useful service life of the accessories, please refer to the corresponding User manuals.
- The equipment shall not be exposed to electrocautery, electrosurgery, defibrillation, X-ray（γ X-ray) or infrared radiation, transient electromagnetic field, including magnetic resonance (MRI) environment, CT inspection environment and radio interference environment, because the equipment will not be able to operate normally in the environment, including humidifier performance can not meet the specifications.
- Tube and mask as applied parts.
- Under normal operating conditions, the maximum and minimum temperatures of the patient connection ports of the humidifier do not exceed 1 ℃(33 F°).

Empty the water tank before packing or moving the device!

FCC Caution:

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC RF Radiation Exposure Statement:

- This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
- This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.
- This equipment should be installed and operated with minimum distance 20cm between the radiator& your body.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

5 Symbol

The following symbols may appear on the device, power supply and accessories.

Symbol	Reference	Definition
	ISO 15223-1 symbol 5.1.1	Manufacturer.
	ISO 15223-1 symbol 5.1.3	Date of Manufacture(YYYY-MM-DD).
	ISO 15223-1 symbol 5.1.11	Country of manufacture:CN(China).
	ISO 15223-1 symbol 5.1.10	Model number
	ISO 15223-1 symbol 5.1.7	Serial number.
	ISO 15223-1 symbol 5.7.10	Unique device identifier
	IEC 60417 symbol 5031	DC Power.
	IEC 60878 symbol 5032	alternating current
	ISO 15223-1 symbol 5.3.7	Temperature limit
	ISO 15223-1 symbol 5.3.8	Humidity limitation
	ISO 15223-1 symbol 5.3.9	Atmospheric pressure limitation
	ISO 7010 Symbol M002	Follow instruction for use. This label on the device points the user to the operator's manual for complete information. In the operator's manual, this symbol cross-references the label.
	WEEE	Dispose according to Council Directive 2012/19/EU or WEEE (Waste Electrical and Electronic Equipment).
	IEC 60417 symbol 5172	Indicates the degree of protection against electric shock according to IEC 60601-1. Class II devices have double or reinforced insulation, as they have no provision for protective grounding.

Symbol	Reference	Definition
IP22	IEC 60529	Indicates the degree of protection provided by enclosure according to IEC 60529.
MD	ISO 15223-1 symbol 5.7.7	Medical device
	IEC 60417 Symbol 5333	Type BF Applied part (classification of medical electrical equipment, type B, as specified by IEC 60601-1).
	IEC 62570 Symbol P001	The device is not suitable for use in MRI environment.
	IEC 7010 symbol W017	Respiratory air humidifier is heated. Do not touch the element.
	resvent	Therapy On/Off Button (Starts and stops the airflow for therapy).
	resvent	Left button
	resvent	Right button
	resvent	Confirm button
	resvent	The air outlet adaptor is locked
	resvent	The air outlet adaptor is unlocked
	IEC 60878 symbol 5140	Nonionizing radiation
	ISO 7000 Symbol 0623	This way up at transport and storage.
	ISO 7000 symbol 2405	Do not roll.
	ISO 15223-1 symbol 5.3.1	Fragile, handle with care.
	ISO 15223-1 symbol 5.3.4	Keep dry at transport and storage.
	ISO 15223-1 symbol 5.3.2	Keep away from sunlight.
	ISO 7000 symbol 2403	Stacking limit by number.
	U+2672	Recyclable materials.

Symbol	Reference	Definition
Rx Only	21 CFR 801.109 (b)	U.S.Federal law restricts this device to sale by or on the order of a physician or any other practitioner licensed by state law.
FCC ID	47 CFR 15.19	Identifies unit has been registered as a radio device

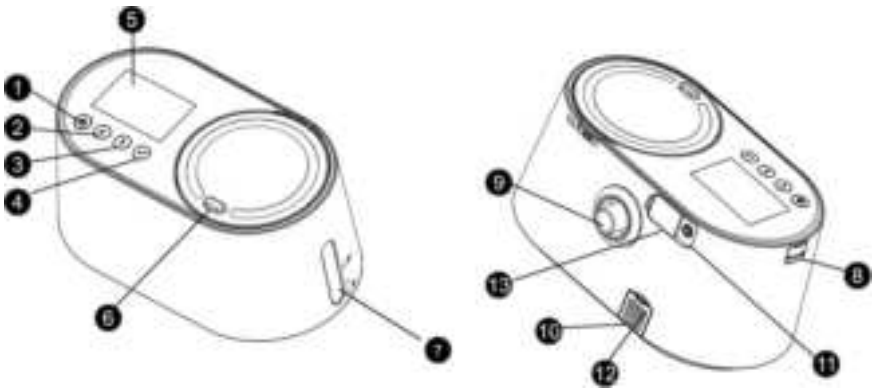
6 System Contents

RXiBreeze PAP Systems may include the following items:

- Device
- Power Adapter
- Humidifier

Note: If any of these items are missing, please contact your home care provider.

7 System Overview



#	Device Feature	Description
1	Therapy On/Off Button	Starts and stops the airflow for therapy
2	Left button	Select between options in the menu
3	Right button	Select between options in the menu
4	Confirm button	Confirm and activate the selected options in the menu
5	LCD Display screen	This is the User interface for the therapy device
6	Water Tank Lock	Press the water tank lock to remove the water tank
7	Water level observatory with light	To observe the water level
8	Access door to TF card slot/ nano-SIM card slot (optional)	This door lifts open for access to TF card and nano-SIM card
9	Air Outlet Port	Connect the tubing here.(22mm inner diameter)
10	Air Inlet Port	Inlet for room air
11	Power Inlet	Connect the power cord here
12	Filter Cotton Cover	Open the cover to place or change the filter cotton
13	USB debugging interface, heating tube interface	Open the protection cover to connect USB debugging (operated by professional engineers) and heated tube interface

7.1 Placing the Device

Place the device on a firm, flat surface somewhere within easy reach of where you will use it at a level lower than your sleeping position. Make sure the device is away from any heating or cooling equipment (e.g., forced air vents, radiators, air conditioners).

Note： When positioning the device, make sure that the power cable is accessible because removing power is the only way to turn off the device.

CAUTION：

- Make sure the filter area on the side of the device is not blocked by bedding, curtains, or other items. Air must flow freely around the device for the system to work properly.
- Do not place the device directly onto carpet, fabric, or other flammable materials.
- Do not place the device in or on any container that can collect or hold water.
- Do not contact the metal surface of the heater when pulling out the water tank.

7.2 Supplying AC Power

Complete the following steps to operate the device using AC power:

1. Plug the power supply cord's connector into the power inlet on the side of the device.

2. Plug the socket end of the AC power cord (included) into the power adaptor (also included).
3. Plug the pronged end of the AC power cord into an electrical outlet that is not controlled by a wall switch.

4. Verify that the plugs at the side of the device, at the power adaptor, and at the electrical outlet are fully inserted.
5. When turn off the device Press Therapy On/Off Button and the device will stop work.
6. Disconnecting Network power source.

WARNING：

- During use if the power cord is disconnected or a power failure, the device buzzer alert beeps. Please stop using it and check the power status.
- Please do not contact with the DC in connector when it was broken.
- Please avoid arcing, wiggling, or dropping the power supply on hard surfaces.
- Please periodically inspect electrical cords and cables for damage or signs of wear and to discontinue use and replace if damaged.
- Please first check the DC connector could be used normal and not breaking free.
- Never place the power cord around the neck.
- Do not use any small parts to fix power cord in position as they might be accidentally swallowed.

7.3 Connecting the Breathing Circuit

To use the system, you need the following accessories in order to assemble the recommended breathing circuit：

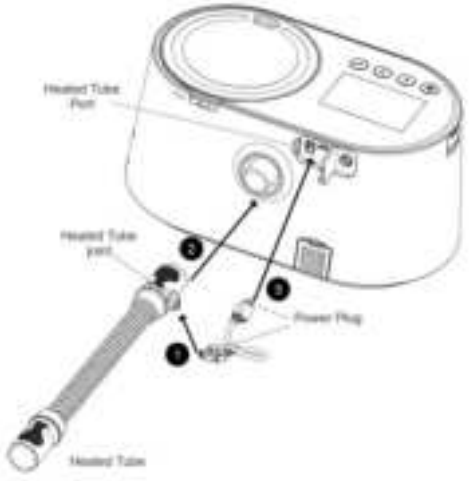
- Breathing interface （Full Face / Nasal / Pillow）with integrated exhalation port.
- Breathing flexible tube or Heated tube

To connect your breathing circuit to the device, please follow the below steps:

1. Ensure the connection adaptor is locked tightly to the back of the device, and connect one end of the tubing (22mm inner diameter) with the connection adaptor.

Note:

- If you are using a standard tube (not shown) instead of a heated tube, simply slide the tube over the air outlet port on the therapy device.
- If you are using a heate Tube,connect the heated tube joint to the air outlet of the device, and then insert the power plug into the heated tube port on the back of the device.As shown in the figure below:



- If the ambient temperature is too low, in order to avoid condensation, it is recommended to use the heated tube.

2. Connect the other end of the tubing to the mask. For specific parameters and the correct method of using the tubing, please refer to the breathing tubing manual.

WARNING: Do not pull or stretch the tubing, this could result in air circuit leakage

3. Attach the headgear to the mask. For specific parameters and the correct use of the method, please refer to the mask manual.

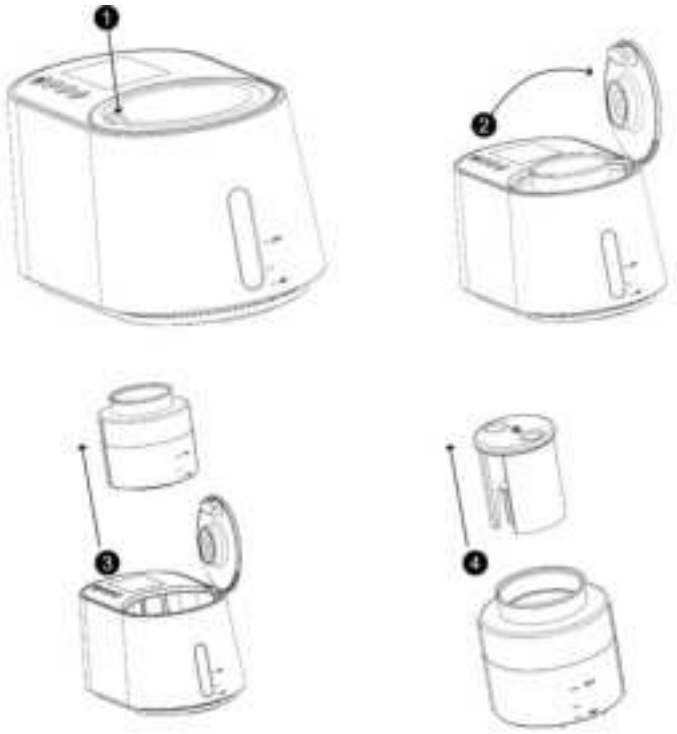
WARNING：

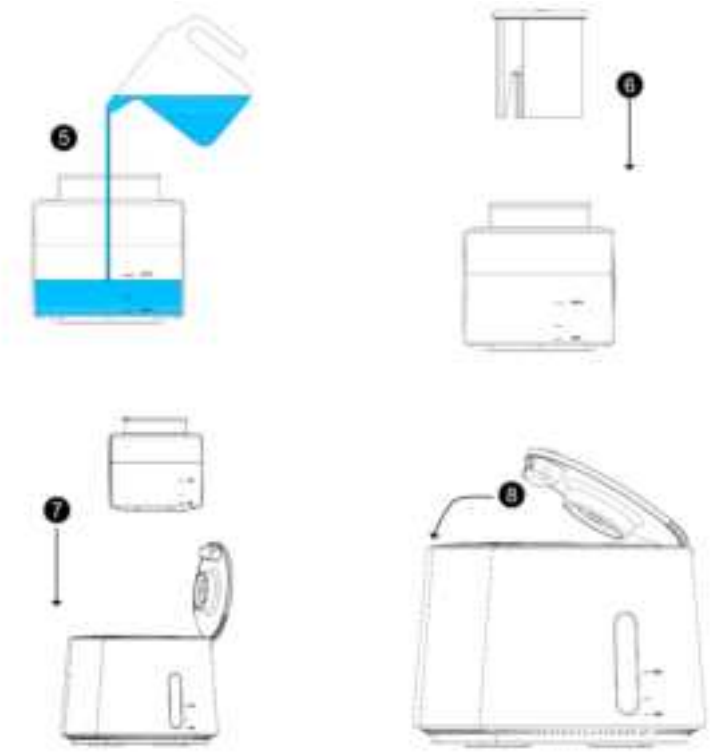
- If you are using a full face mask (a mask covering both your mouth and your nose), the mask must be equipped with an exhalation safety valve or vent holes to avoid asphyxia.
- If multiple users share the same equipment, use low-resistance and bacteria filter unit between the equipment and the tube.

Note： The selected mask, breathing tube shall meet the performance requirements with good stability. The user should check the mask and tube for damage before each use.

- If necessary, place a bacterial filter unit in the air outlet of the unit and connect the tube. The use of bacterial filter unit may affect the equipment work. However, the device can remain functional.

7.4 Water-filling Operation





(1) Press the water tank lock.

(2) Open the device lid.

(3) Remove the water tank from the device.

(4) Remove the water tank cover.

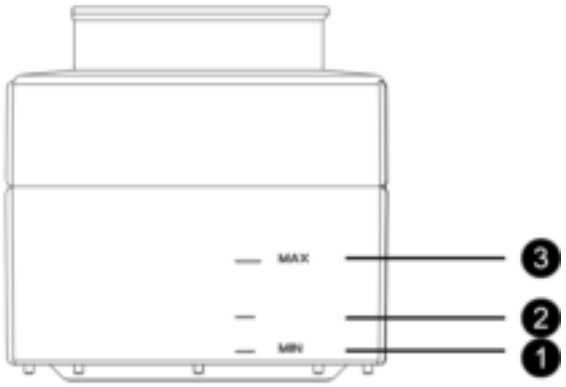
(5) Fill in only distilled or purified water up to the maximum water level.

(6) Insert the water tank cover back to the water tank.

(7) Install the water tank into the device.

(8) Close the water tank lid.

Note: Please each time do not add more water than the maximum water level of the water tank. Please refer to the following figure:



1. The fill line indicates the minimum water level for safe operation.
2. The fill line indicates 1/2 water level for safe operation.
3. The fill line indicates the maximum water level for safe operation.

CAUTION：

- If you are using the device every night, always refill the water tank to the maximum water level before use.
- Use only room temperature distilled water or purified water.
- When the water volume of the water tank reaches the highest water level, do not tilt the water tank.
- When the equipment is not in use, please pour out the remaining water in the water tank and clean the water tank.
- The water tank must be used with the inserted air circuit board. Do not use the equipment without inserting the air circuit board.
- Empty the water tank after each use or when the device is not in use.
- After starting the equipment, the liquid level indicator is always on during the standby period. If it enters the treatment period, the liquid level indicator is off.

8 Navigating the Device Screens

The User Interface (UI) on this device allows you to adjust the device settings and view information about your therapy. The UI is comprised of the display screen and the pressing buttons. Press the Left / Right / Confirm buttons to select between the menu options on the display screen.

Note: The screen does not support touch operations. You must use the pressing buttons to navigate the device menu.

To adjust a setting:

1. Press the Left / Right button to locate your desired menu option.
2. Press the Confirm button to select that setting.
3. Press the Left / Right button to change between the setting parameters.
4. Press the Confirm button again to save the change.

Note: The screens shown throughout this manual are examples for reference only.Actual screens may vary based on device model and provider settings.

9 Operation

This chapter describes basic operation and precautions associated with this device.

Each time you turn on the device, it will automatically run set by the user.

9.1 Starting the Device

1. Ensure power is supplied to the device. The first screen to display will be the Resvent logo, within 5 second followed by the patient standby screen (See Figure 4-1).

Note：

- The language setting interface and time setting interface will pop up automatically after the startup waiting interface for the first time. You can enter the patient standby interface only after completing the settings.
- Boot buzzer should be “beep”. If not, you can’t use the equipment and then contact the supplier for inspection.

2. Put on your mask assembly. Refer to the user instructions supplied with the mask.
3. Press the Therapy On/Off key on top of the device to turn on airflow and begin therapy. The screen will display to patient therapy interface (see Figure 4-2)
4. Make sure that no air is leaking from your mask around the face contacting area. If necessary, adjust the mask and headgear until there is no air leakage around the face contacting area.
5. If you are using the device in a bed with a headboard, try placing the tubing over the headboard. This may reduce tension on the mask.

6. Press the Therapy On/Off key again to turn off therapy.

Note:

- When any power interruption (e.g., blackout) happens during therapy, the device will resume therapy mode if the power is restored within 60 minutes.
- Please keep away from incense and candles avoiding catching fire during use.
- Under normal conditions: there is a leak hole on the full face mask. When the patient exhales, the exhaled carbon dioxide will be squeezed out of the leak hole through the patient's exhalation pressure and the pressure output by the positive pressure ventilation treatment machine.
- Under a single fault state: when the power is off, when the patient exhales, the exhaled carbon dioxide is discharged from the air leakage hole and breathing pipe on the mask at the same time, and the fresh gas is inhaled from the air leakage hole and breathing pipe at the same time.

9.2 Patient Menu Navigation Settings

Patient menu navigation setting includes therapy interface shortcut operation, therapy report interface, mask fitting interface, comfort parameters setting interface, system setting interface.

9.2.1 Patient Standby Interface

The Patient Standby Interface displays setup menus for the system main features, and the icons to indicate the current enabled features.

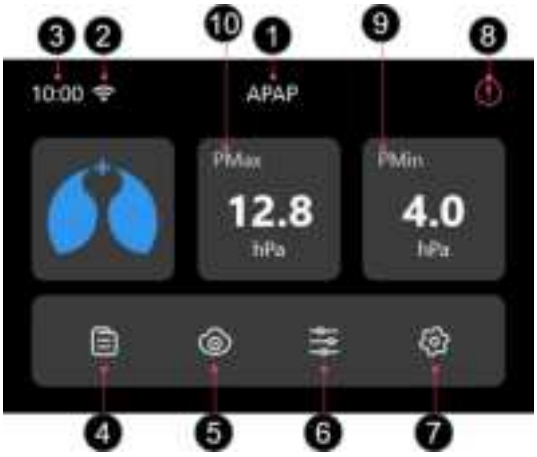


Figure 4-1 Patient Standby Interface

#	Feature	Description
1	Mode	Display the current mode.
2	Enabled features	Depending on setup, certain enabled therapy features will display here.
3	Time	Display the current time.
4	Patient Sleep Quality Report	Displays the patient sleep quality report and the options for period of the report are: daily (recent 6 days) / 7 days / 14 days / 1 month / 3 months / 6 months / 1 year.
5	Mask fit	Mask fit feature allows you to check the fitness of your mask prior to starting therapy. This is done by measuring the amount of air leakage.

6	Comfort	Press to enter Comfort setting interface.
7	Setting	Press to enter Patient System Setting interface.
8	Alert Message	Display the alert messages. Press confirm button to get more detail alert information. Refer to the Device Alert section to manage the alerts.
9、10	Therapy parameters	Displays treatment parameters in the current breathing mode

9.2.2 Patient Therapy Interface

When the therapy starts, the screen will switch to the Patient Therapy Interface, which displays the therapy parameters monitoring during therapy (See Figure 4-2). The displayed parameters depend on the current therapy mode.

Note: The screen displays the treatment pressure.

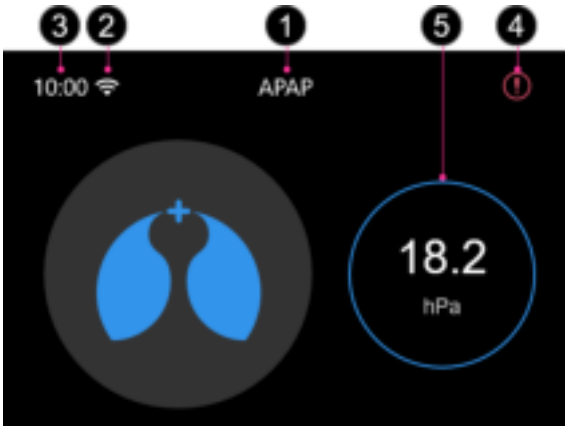


Figure 4-2 Patient Therapy Interface

#	**Description**
1	The current therapy mode.
2	Depending on setup, certain enabled therapy features will display here.
3	Display the current time.
4	Display the alert messages.
5	The current therapy pressure.

9.2.3 Patient Report Menu

Press info key  in Patient Standby Interface to enter Patient Report Interface.

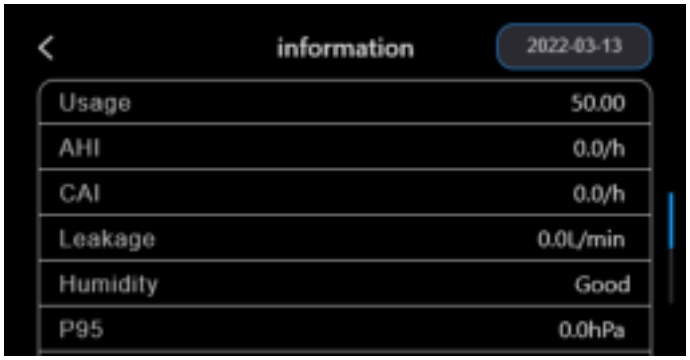


Figure 4-3 Patient Report Interface

Item	Description
Period	Set the time interval covered by the report. Options: daily (for recent 6 days) / 7 days / 14 days / 1 month / 3 months / 6 months / 1 year.
Usage	Number of hours the device has been used in the selected period.
AHI	The average Apnea-hypopnea index in the selected period.
CAI	The average Central-apnea index in the selected period.
Leakage	Shows that 95% of the time during the reported statistical period, the air leakage was less than this value
Humidify	Display the humidifier usage during the reporting statistical period to evaluate the humidification effect. Good, indicating that the humidifier service time accounts for 60~100% of the total service time. Medium,In which the humidifier service time accounts for 30~59% of the total service time bad, indicating that the humidifier service time accounts for 5~29% of the total service time. --, indicating that the service time of humidifier is less than 5% of the total service time.
P95	Display the 95% weighted treatment pressure of the statistical series in the therapy period

9.2.4 Mask Fit

Click the button on the patient standby interface to enter the mask matching interface.

Figure 4-4 Mask Fit

Start the test immediately after entering the mask matching interface. Users can click  to pause the test or click  to start the test.

Item	Description
Test Pressure	Set the gear for Intelligent Pressure release. Option:6~18hPa Default: 10hPa Note: 1. It cannot be adjusted during the test.

9.2.5 Patient Comfort Setting

Press  key in the Patient Standby interface to enter Patient Comfort Setting Interface.

Figure 4-5 Patient Comfort Setting

Item	Description
iPR	Set IPR (Intelligence Pressure Release) level. Option: OFF / 1-3 Default: 2
Humidity	Set humidifier level to enhance patient comfort of respiration. Option: OFF / 1-3 Default: 1 Note: The humidity level only can be set when the water in humidifier exceeds the minimum water level for safe operation.
Preheat	Turn Preheat function on or off. When the Preheat is on, the humidifier starts preheating in the standby mode and the maximum preheating time is 30 minutes. In the therapy mode, the preheating stops. Option: ON / OFF Default: OFF Note: 1. If the humidifier water level below the limit, Preheat function will be turned off automatically. 2. If humidifier function is turned off, Preheat function will be disable.
Auto Start	Turn Auto Start function on or off. When the Auto Start function is on, the system will start therapy automatically if a breath with mask is detected. Option: On / OFF Default: ON
Auto Stop	Turn Auto Stop function on or off. When the Auto Stop function is on, if the mask is removed more than 5 seconds, the therapy will automatically stop. Option: On / OFF Default: ON
Ramp Time	Set the increase time from Ramp pressure to the setting therapy pressure. Option: 0-60 mins, 5 mins increments Default: 15 mins Note: if Ramp Time sets to 0 min, Ramp function will be off.
P Ramp	Set the starting pressure of Ramp. Setting Range: 3 cmH2O-Setting pressure. Default: 4 cmH2O
Mask Type	Set the Mask type. Option: Full Face / Nasal / Pillow Default: Nasal
Heat Tube(optional)	Set whether the heating tube function is enabled. Option: On / OFF Default: ON Note: 1. This setting item is displayed only when the heating tube is connected.

9.2.6 Patient System Setting

Press  key in the Patient Standby interface to enter Patient Setting interface.

Figure 4-6 Patient System Setting

Item	Description
P Unit	Set the pressure unit. Option: hPa / cmH_2O Default: cmH_2O
Language	Set the interface language of the system. Option:English/Spanish/Deutsch/Portuguese/French/Italiano Default: English
WiFi (optional)	Set the WiFi function on or off. Option: ON / OFF Default: ON
Mobile Network (optional)	Set the Mobile Network function on or off. Option: ON / OFF Default: OFF
Date Format	Set the system date format. Option: YYYYMMDD / MMDDYYYY / DDMMYYYY Default: DDMMYYYY
Date	Set the system date. Note: 1. Date setting can't be earlier than the latest time of the report in the device. 2. The system date is required to reset on the first time start up when the device is restored the factory default settings.
Time	Set the system time. Note: time setting can't be earlier than the latest time of the report in the device.

Energy Saving	Set the Energy Saving function on or off. When Energy Saving is on, the screen will be turned off automatically if there is no operation within 3 minutes in standby mode, or 30 seconds in therapy mode. If Energy Saving is off, the screen is always on. Option: ON / OFF Default: ON
Software update (optional)	Download and update the software version when connected to the Internet.
About	Display the device information including system version, serial number, blower running time etc..

9.2.7 TF Card

The RXiBreeze PAP Systems comes with an TF card already inserted in the device to store therapy information for the home care provider.

Your home care provider may ask you to send the TF card to them for evaluation.

To remove the TF card

1. Stop the therapy and open the TF card cover.
2. Press the TF card to release it from the slot. Remove the TF card from the device.
3. Place the TF card in the protective folder and send it to your care provider.

Note：

- Do not remove the TF card from the device during therapy.
- Do not use the TF card for any other purpose.
- This device can use only manufacturer TF card. Please contact your supplier for purchasing.

9.3 Wireless transmission module (Optional)

9.3.1 WiFi module connection

Connect to the network through the device

1. Power on and start up the device，enter the setting interface—WiFi—set to On.

2. WiFi interface on the device, click “search”—search for the WiFi signals nearby—enter the WiFi list interface.
3. Click on an available WiFi—enter the WiFi password input interface， enter the correct password -- until WiFi connected successfully.
4. Sign of connection successful：WiFi status is connected， WiFi status icon is  .

9.3.2 WiFi Status Sign

WiFi Off	No WiFi sign
WiFi On, WLAN hot spots unconnected	
WiFi connect normally	
WiFi upload data	

9.3.3 Mobile NetWork Module

1. Enter Setting - press “On” or “Off” to enable or disable Mobile Network function
2. Connection success Sign: the mobile network connection status is connected, and the mobile network status icon is. 

9.3.4 Mobile NetWork Status Sign

Mobile Network module icon in Off status	No Mobile Network sign
Mobile network is on, but not connected to the network	
Mobile Network module icon in On status	
Mobile Network module icon when uploading data	

10 Device Alert

There are 4 types of alerts described here:

- Alert 0: Gray background white tips, no light, no sound, always display, disappear until the prompt condition not met.
- Alert 1: Orange background white tips, blue-ray flashing, with sound, always display, disappear until the prompt condition not met.
- Alert 2: Red background white tips, blue-ray flashing, with sound, exclusive alert until the user opens the alert to confirm or press the Therapy On/Off key.
- Notification: White reminder message, no light, no sound, after the corresponding process, the message automatically disappears.

Alert Summary Table: The following table summarizes the alerts：

Alert	Type	Possible Cause	Action
High Leakage Volume.	Alert 1	1. Inappropriate connection of mask and respiration tube. 2. The water tank is not plugged in.	Check the connection of the mask or respiration tube, and the connection of the water tank.
Apnea.	Alert 1	An apnea is detected and exceeds the setting duration.	Check the respiration tube or adjust therapy parameter setting.
Mask vent holes blocked.	Alert 1	Mask vent holes is blocked.	Check the mask.
Input voltage is abnormal, please check!	Alert 2	Power Adapter with the wrong type, resulting in voltage is too high or too low	Use the Power Adapter provided by Resvent.
The temperature of the heating module is too high. Contact the supplier	Alert 0	Heating module temperature exceeding 75℃	Turn off humidifier and stop using device, wait for heating module cool down.
RTC clock failure. Reports may not be saved.	Alert1	RTC clock failure.	Please contact the supplier if you want reports be

			saved.
TF card write/read underway, do not remove the TF card, do not cut off the power.	Notification	1. Insert TF card during data synchronization; 2. Input the configuration on the TF card.	No action.
TF Card Full, Please replace the TF Card.	Notification	In Standby mode, TF card storage space only 200M	Replace the TF card or clean the data after export the data in the TF card.
TF card error, please remove and insert again.	Notification	TF card failure, may be: 1.TF card can't read and write. 2.TF card read and write data errors.	Remove TF Card, Reinsert or replace with a new card.
System error code: XXXX Please try to restart, please contact the supplier if repeat.	Alert 2	1. Pressure sensor failure, flow sensor failure, blower failure in therapy state; 2. Power board short-circuit 3. Humidifier heating circuit short-circuit	Please try to restart, please contact the supplier if repeat.
No Calibration	Notification	Device calibration self-checking error	Please contact the supplier.
Low battery charge, reports may not be saved.	Notification	Low button battery power.	Please contact the supplier if you want reports be saved.
System Drying	Notification	The device generates a small flow to dry the system when it is the standby mode after 30 minutes usage with humidification.	No action.

Note: Some alert messages depend on the device model.

11 Troubleshooting

If your device has the following problems in the usage, please try the following measures. If it can't be resolved, please contact the maintenance provider.

Problem	Possible Cause	Action
Nothing happens when you apply power to the device. The backlights on the keys do not light.	There's no power at the outlet or the device is unplugged.	Check the outlet and verify that the device is properly plugged in. Make sure there is power available at the outlet. Make sure the AC power cord is connected correctly to the power supply and the power supply cord is securely connected to the device's power inlet. If the problem continues to occur, contact your home care provider. Return both the device and power supply to your provider, so they can determine if the problem is with the device or power supply.
Air is leaking from around my mask	Mask may be fitted incorrectly.	Make sure your mask is fitted correctly. See your mask user guide for fitting instructions or use the Mask Fit function to check your mask fit and seal.
I am getting a dry or blocked nose	Humidity level may be set too low.	Adjust the Humidity Level.
I am getting droplets of water on my nose, in the mask and air tubing	Humidity level may be set too high.	Adjust the Humidity Level.
My mouth is very dry and uncomfortable	Air may be escaping through your mouth.	Increase the Humidity Level. You may need a chin strap to keep your mouth closed or a full face mask.
Air pressure in my mask	Ramp may be turned	Use the Ramp Time option.

seems too high (it feels like I am getting too much air).	off.	
Air pressure in my mask seems too low (it feels like I am not getting enough air).	Ramp may be in progress.	Wait for air pressure to build up or turn Ramp Time off.
I have stopped therapy, but the device is still blowing air.	Device is cooling down.	Device blows a small amount of air in order to avoid condensation in the air tubing. It will stop automatically after a few minutes.
The device's display is erratic (crash blank or blue screen).	The device has been dropped or mishandled.	Unplug the device. Reapply power to the device. If the problem continues, contact your home care provider.
My water tank is leaking.	Water tank may not be assembled correctly. Water tank may be damaged or cracked.	Check for damage and reassemble the water tank correctly. Contact your care provider for a replacement.
Key exception (non-responsive or insensitive).	Program crashes or key misalignment.	Unplug the device. Reapply power to the device. If the problem continues, contact your home care provider.

12 Reprocessing

NOTE:

This device comply with cleaning and disinfection requirements of the ISO 17664:2017 standard.

The machine needs to be cleaned and disinfected regularly so that these germs and contaminants do not grow inside of your equipment and make you sick. Dust and dirt can also cause problems with the machine, making it more likely to break or need replacement. Please strictly follow the cleaning and disinfection process below:

12.1 Cleaning Schedule

To avoid prolonged exposure to dusty and humid environment, resulting in impaired performance and reliability, the user must clean the device regularly. The clean interval of the device and accessories, please refer the below table:

Interval	Action
Weekly	Clean the device casing. Clean the water tank

Note 1: the cleaning schedule is only applicable to the device casing, water tank. For others like the mask and air tube, please refer to their specific user manuals.

Note 2: the device casing, water tank can not withstand automated cleaning.

12.2 Disinfection Schedule

To avoid germs and allergens growing inside of your equipment and making you sick, the user must disinfect the device regularly. The disinfection interval of the device and accessories, please refer the below table:

Interval	Action
Monthly	Disinfect the device casing Disinfect the water tank, air outlet adaptor, air outlet of water tank

Note 1: the disinfection schedule is only applicable to the device surface, water tank. For others like the mask and air tube, please refer to their specific user manuals.

Note 2: the device casing, water tank, air outlet adaptor, air outlet of water tank can not withstand automated disinfection.

12.3 Cleaning and Disinfection Process for Device Surface

12.3.1 Cleaning (Weekly)

WARNING: To avoid electrical shock, always unplug the power cord from the wall outlet before cleaning the device. Do not immerse the device in any fluids. Wait until the device cool down the room temperature.

1. Please power off and unplug of the device, and throughout cleaning the casing of the device to removal of soil, stain or oil by using a soft cloth slightly dampened with neutral detergent (such as, 5% soapsuds)
2. Use a soft cloth slightly dipped in water to wipe and rinse the surface that was cleaned with soapy water in the previous step for 5 minutes, and repeat the above steps at least additional 2 times, three times in total.
3. Visual inspection the casing of the device, ensure there is no soil, stain or oil is seen. If there is determined not to

be visually cleaned at the end of the cleaning steps. You should either repeat the relevant previous cleaning steps, so that a visible soiled device is not used again. Wait about at least 1 minutes for drying completely before plugging in the power cord.

12.3.2 Disinfection (Monthly)

WARNING: If it has not yet reached the disinfection schedule time, please skip this step.The cleaning process before disinfection is one of the scheduled weekly cleaning process instead of an additional cleaning operation. The disinfection process must be carried out after cleaning process.

1. After the cleaning procedure, use an 75% ethyl alcohol swab or cotton swab moistened with 75% ethyl alcohol to disinfect the device surface for about 5 minutes.
2. Repeat the above steps at least 3 times, then wipe surface dry with a clean cloth, and wait about 1 minute for drying after disinfection process.

12.3.3 Drying

Air dry the device completely lest the residual may interfere with the subsequent reprocessing process.

12.3.4 Inspection

Perform a visual inspection of the device casing. If any visible deterioration is apparent (cracking, crazing etc) discontinue use and contact your care provider or Resvent.

12.4 Cleaning and Disinfection Process for (water tank, air outlet adaptor, air outlet of water tank)

12.4.1 Cleaning (Weekly)

WARNING: Before cleaning, power off and unplug of the device, wait until the device cool down the room temperature.

1. Remove all detachable parts(water tank, air outlet adaptor, air outlet of water tank) from the device. Make a solution of a neutral detergent (such as, 5% soapsuds) and water.
2. Soaked all components(water tank, air outlet adaptor, air outlet of water tank) for about 5-10 minutes. Agitate the component in the cleaning solution to ensure there are no air bubbles
3. Clean the inside and outside of all components with a soft bristle brush while soaking in a detergent solution. Pay particular attention to all crevices and cavities
4. Soaking all the components in the solution,and through rinse each component in the rinsing water to ensure there are no air bubbles. Repeat the rinse procedure two additional times using fresh water for a total of three rinses.
5. Visual inspection to ensure there is no soil, stain or oil is seen. If there is determined not to be visually cleaned at the end of the cleaning steps. You should either repeat the relevant previous cleaning steps, so that a visible soiled device is not used again.
6. Shake the component to remove excess water, and allow the component to air dry rather out of direct sunlight.

Note: Failure to clean the component as indicated may result in inadequate disinfection.

12.4.2 Disinfection (Monthly)

WARNING: If it has not yet reached the disinfection schedule time, please skip this step.The cleaning process

before disinfection is one of the scheduled weekly cleaning process instead of an additional cleaning operation. The disinfection process must be carried out after cleaning process.

1. After the cleaning procedure, immerse all components(water tank, air outlet adaptor, air outlet of water tank) in a water bath, and make a solution of a 3% hydrogen peroxide, Soak all components in the solution at room temperature for at least 30 minuets. Rinse and agitate all components in the solution for 1 minutes.
2. Soaking all components in the solution,and rinse and agitate the component in a fresh water thoroughly for at least 3 times, 10 minutes per time and

12.4.3 Drying

Air dry the components(water tank, air outlet adaptor, air outlet of water tank) completely. Do not dry the components under direct sunlight or heat sources.

12.4.4 Inspection

1. Perform a visual inspection of the device components. If any visible deterioration is apparent (cracking, crazing etc) discontinue use and contact your care provider or Resvent.
2. After Inspection if no visible deterioration found, install all the component (water tank, air outlet adaptor, air outlet of water tank) to the device, do not leave the components uninstalled.

12.5 Maximum reprocessing times

The maximum number of cleaning for the device surface, water tank, air outlet adaptor, air outlet of water tank is 260 times and the maximum number of disinfection is 60 times. Please limit your reprocessing times within the range.
Note: the maximum reprocessing times are only applicable to the device surface, water tank, air outlet adaptor, air outlet of water tank. For others like the mask and air tube, please refer to their specific user manuals.

13 Maintenance

RESVENT CPAP therapy device is designed to have useful service life and shelf life of 5 years. If the therapy device is used as intended in accordance with the instructions for use, it does not require any maintenance within this period. If the therapy device is used beyond this period, we recommend having it checked by an authorized dealer. If the respiratory air humidifier is used as intended in accordance with these instructions for use, it does not require any maintenance. If you identify faulty parts during the function check, please contact your authorized dealer immediately.

13.1 Maintenance Schedule

Interval	Action
Every 4 weeks	Replace the air filter
Every 6 months	Replace the water tank

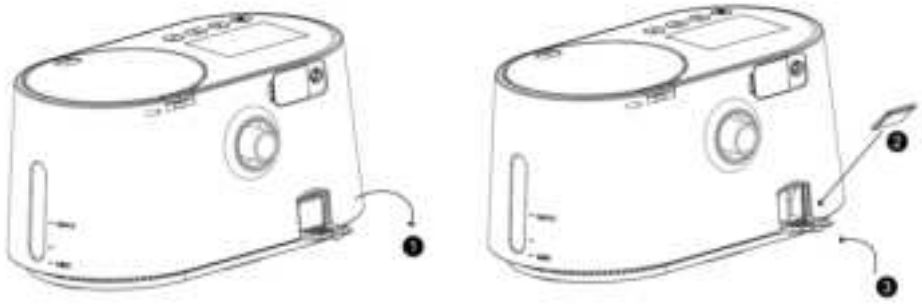
Interval	Action
When changing patients	If the device has been used without a bacteria filter: Have professional hygienic preparation performed before using the device again.

13.2 Installing/Replacing the Air Filter

The device comes with a reusable air filter, it must be in place at all times when the device is operating. Please check the air filter every 4 weeks, clean or replace it if there are any holes or blockages by dirt or dust.

Note: When you receive your device, if the filter cotton is not installed, you must install the filter cotton before using the device.

To install or replace the air filter, please follow the below steps：



1. Open the air filter cover.
2. Place a filter cotton onto the air filter cover and then close it.

If the filter cotton is replaced, take out the old filter cotton and put in the new filter cotton.

If you need to purchase new filter cotton, please contact your dealer.

13.3 Traveling with the Device

Use the Resvent travel bag to carry the device and accessories when traveling.

Please follow the below steps for packing:

1. Remove the water tank from the device and pour out all water.
2. Install the water tank back on the device.
3. Put the device and accessories in the travel bag.

13.4 Device Maintenance

No regular maintenance is required. If you notice abnormal running of the device, abnormal sounds, device or power supply drops from the tabletop, or have mistakenly operated, liquid has entered the device and the cover has ruptured, disconnect the power and contact your supplier.

14 Storage and Disposal

14.1 Storage

14.1.1 Storage Information

Store the device under the prescribed ambient conditions.

14.1.2 Storage the therapy device

- Switch off the therapy device.
- Disconnect the therapy device from the power supply.
- Clean the therapy device, components, and accessories.
- Store the therapy device, components, and accessories in a dry place.

14.2 Disposal

Electronic waste 

Do not dispose of the product in the household waste. Consult an authorized, certified electronic waste recycling company for proper disposal. You can find out their address from your environmental officer or from your local council.

The device packaging (cardboard box and inserts) can be disposed of as waste paper.

Risk of injury if disposable items are reused!

Disposable items are only intended to be used once. Reused disposable items may be contaminated and/or not functions correctly and thus cause patient injury.

15 Specification

Physical

Dimension (L*W*H): 282*172.5*141.5mm

Weight: Approximately 1.9kg

Operating Environmental

Temperature: 5℃~35℃

Relative Humidity: 10%~95% (non-condensing)

Atmospheric Pressure: 70 kPa~106 kPa

Transportation and Storage Environmental

Temperature: -20℃~60℃

Relative Humidity: 10%~95% (non-condensing)

Atmospheric Pressure: 70 kPa~106 kPa

Noise Value

Sound pressure level	Uncertainty	Sound power level	Uncertainty
30 dB(A)	2 dB(A)	38 dB(A)	2 dB(A)

Standards compliance

IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1:

General requirements for basic safety and essential performance.

IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

ISO 80601-2-70 Second edition 2020-11 Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment.

ISO 80601-2-74 First edition 2017-05 Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment.

Electrical

Specified power supply: Shenzhen Longxc Power Supply Co.，Ltd

Model: LXCP61（II）-024300

AC Input: 100-240V～ 50/60 Hz 1.5A Max

DC Output: 24.0 V ⎓ 3.0 A

Specified power supply: Enargy Power(Shenzhen)Co.,Ltd.

Model: MDA60F-220S24-02

AC Input: 100-240V～ 50/60Hz 2A Max

DC Output: 24 V ⎓ 2.5 A

NOTE： The adapter conforms to IEC 60601-1 and is part of the device.

Pressure

Setting Range: 4.0-20.0 cmH_2O

Max Single Fault Steady Pressure: 30.0 cmH_2O

Static Pressure Accuracy: ±0.5 cmH_2O (Measurement uncertainty:1.87%)

Dynamic Pressure Accuracy: ±1cmH_2O (Measurement uncertainty:2.55%)

Flow

		Test pressure (cmH2O)				
		4	8	12	16	20
19mm breathing tubing	Measured pressure at the patient connection port (cmH_2O)	2.9	7.1	11.0	15.1	19.1
	Average flow at the patient connection port (L/min)	≥80	≥90	≥100	≥100	≥105

Humidifier

Water capacity: 350mL±20mL(MAX Water Level)

Humidity: >12 mg/L BTPS (In the temperature range of 16-35°C and within the set pressure range)

Air Filter

Dimension: 27 × 27 mm

Air Filter filtration effect: filter atmosphere ≥ 5um particles of dust and suspended particles.

16 EMC

Essential Performance：

CPAP mode: work pressure 10 cmH2O.

The RXiBreeze PAP Systems is intended for use in the specified electromagnetic environment listed in form A-1, A-2 and A-3. The customer or the user of RXiBreeze PAP Systems should assure that it is used in such an environment as described below.

The RXiBreeze PAP Systems is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of RXiBreeze PAP Systems can help prevent electromagnetic interference by maintaining a minimum distance between portable/mobile RF communications equipment (transmitters) and the RXiBreeze PAP Systems (as recommended in form A-3) , according to the maximum output power of the communications equipment.

Form A-1 Guidance and Declaration - Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment - guidance
Radiated emissions CISPR11	Group 1	The RXiBreeze PAP Systems 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.
Conducted emissions CISPR11	Class B	The RXiBreeze PAP Systems 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

Form A-2 Guidance and Declaration - Electromagnetic Immunity

Immunity test	IEC60601test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge（ESD） IEC61000-4-2	Contact：±8kV Air：±15 kV	Contact：±8 kV Air：±15V	Floors 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 IEC61000-4-4	Power supply lines：±2 kV input/output lines：±1 kV	Power supply lines：±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	line(s) to line(s)：±1 kV line(s) to earth：±2 kV	line(s) to line(s)：±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	0%, 70%, 0% of UT	0% for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment.
		0% for 1 cycle	
		70% for 25 cycles	
		0% for 250 cycles	
Power frequency（50/60Hz）magnetic field IEC61000-4-8	50Hz,60Hz 30A/m	50Hz:30A/m 60Hz:30A/m	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC60601test level	Compliance level	Electromagnetic environment - guidance
Conduced RF IEC61000-4-6	150KHz to 80MHz 3Vrms ISM and amateur radio bands between 150KHz to 80MHz 6Vrms	3Vrms 6Vrms (in ISM and amateur radio bands) 80% AM at 1kHz.	Portable and mobile RF communications equipment should be used no closer to any part of the RXiBreeze PAP Systems, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: $d=0.35\sqrt{P}$ $d=1.2\sqrt{P}$
Radiated RF IEC61000-4-3	80MHz to 2700MHz 10V/m (rms) 385MHz 27V/m (rms) 450MHz 28V/m (rms) 710MHz, 745MHz, 780MHz 9V/m (rms) 810MHz, 870MHz, 930MHz 28V/m (rms) 1720MHz, 1845MHz, 1970MHz 28V/m (rms)	10V/m, 80% AM at 1kHz 27V/m PM at 18Hz 28V/m FM ± 5 kHz deviation at 1kHz sine 9V/m PM at 217 Hz 28V/m PM at 18Hz 28V/m PM at 217 Hz 28V/m PM at 217 Hz	80MHz to 800MHz： $d=1.2\sqrt{P}$ 800MHz to 2.5GHz： $d=2.3\sqrt{P}$ Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of

Immunity test	IEC60601test level	Compliance level	Electromagnetic environment - guidance
	2450MHz 28V/m (rms) 5240MHz, 5500MHz, 5785MHz 9V/m (rms)	9V/m PM at 217 Hz	equipment marked with the following symbol: 

Form A-3.Recommended Separation Distance between Portable/Mobile RF Communications Equipment and the RXiBreeze PAP Systems.

Rated maximum output power of transmitter(W)	Separation distance in meters (m) according to frequency of the transmitter		
	150kHz~80MHz $d=1.2\sqrt{P}$	80MHz-800MHz $d=1.2\sqrt{P}$	800MHz-2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Statement

Resvent Medical Technology Co., Ltd.（hereinafter called "Resvent") owns the intellectual property rights to this manual. Resvent intends to maintain the contents of this manual and confidential information.

This manual serves as a reference. The instruction in this manual is not intended to supersede the health care professional's instructions regarding the use of the device.

Disclosure of the information in this manual in any manner whatsoever without the written permission of Resvent. Release, amendment, reproduction, distribution, rental, adaptation or any other derivative work of this manual in any manner whatsoever without the written permission of Resvent is strictly forbidden.

All information contained in this manual is believed to be correct. Resvent shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this manual. Contents of this manual are subject to change without prior notice.

Limited Warranty

Resvent warrants that the system shall be free from defects of workmanship and materials and will perform in accordance with the product specifications within the warranty period. During the warranty time, If the product fails to perform in accordance with the product specifications, Resvent will repair or replace – at its option – the defective material or part. Resvent will pay customary freight charges from Resvent to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration, water ingress, and other defects not related to material or workmanship.

To exercise your rights under this warranty, contact your local authorized dealer or Resvent.

Contact information

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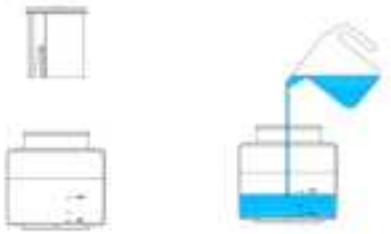
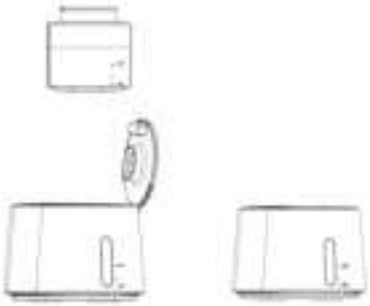
Quick Operation Guide

1.Remove the water tank from the device.



2.Remove the water tank cover and Fill in only distilled or purified water up to the maximum water level.



3.Install the water tank into the device and Close the water tank lid.

4.Connect one side of the tube to the air outlet and mask at the other end.

5.Plug the socket end of the AC power cord (included) into the power adaptor (also included).

6. Plug the pronged end of the AC power cord into an electrical outlet that is not controlled by a wall switch.