CPAP Clinical Guide

iBreeze 20C / 20C Pro
iBreeze 20A / 20A Pro

Contents

1 Welcome

The iBreeze™ CPAP System are Resvent's premium bilevel positive airway pressure devices.
The iBreeze™ CPAP System include the following models:
iBreeze 20C, iBreeze 20C Pro, iBreeze 20A, iBreeze 20A Pro.

IMPORTANT

Read this entire guide before using the device. Please keep the manual after reading, so that at any time you can read it when needed.
The device is to be used only on the instruction of a licensed physician. The home care provider will make the correct pressure settings and device configurations including accessories, according to the health care professional's prescription.
Refer to the User Manual for more information on using the Resvent therapy devices.

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.

2 Intended use

The iBreeze CPAP system 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 or hospital/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 40 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 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.

4 Symbol Key

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

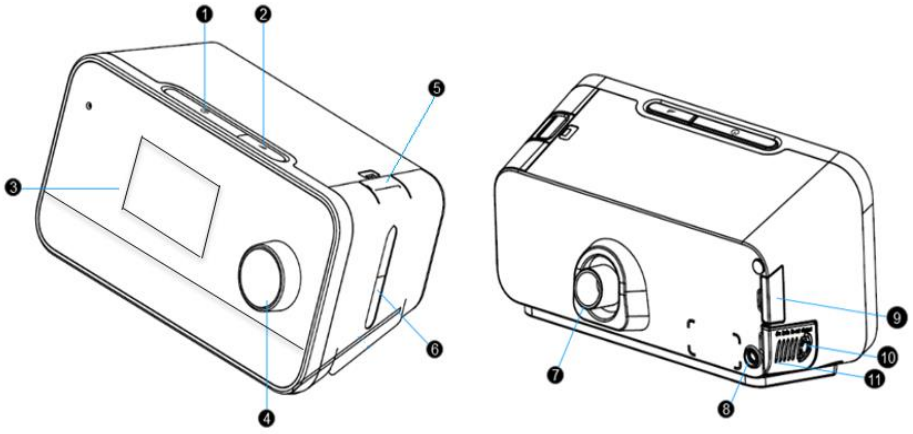
Symbol	Definition
	Manufacturer
	Date of Manufacture
	Serial number
	DC Power
	Temperature limitations at transport and storage
	Humidity limitations at transport and storage
	Atmospheric pressure at transport and storage
	Follow instruction for use. This label on the device points the user to the operator's manual for complete information. In the operator's manual, this symbol cross-references the label.
	The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive
	European Authorized Representative
	Dispose according to Council Directive 2012/19/EU or WEEE (Waste Electrical and Electronic Equipment)
	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.
IP22	Indicates the degree of protection provided by enclosure according to IEC 60601-1
	Type BF Applied part (classification of medical electrical equipment, type B, as specified by IEC 60601-1)
	The device is not suitable for use in MRI environment.
	Respiratory air humidifier is heated. Do not touch the element

	Therapy On/Off Button(Starts and stops the airflow for therapy)
	This way up at transport and storage
	Fragile, handle with care
	Keep dry at transport and storage
	Stacking limitations
	Recyclable materials

About the control panel

Symbol	Definition
	Press to start/stop therapy.
	Turn to navigate the menu and press to select an option. Turn to adjust a selected option and press to save your change.
	Press ramp to set ramp time quickly on standby interface.

5 System Overview



#	Device Feature	Description
1	Therapy On/Off Key	Starts and stops the airflow for therapy.
2	Ramp Key	Activate the ramp feature during therapy.
3	LCD Display screen	This is the User interface for the therapy device.
4	Control Dial	Turn the dial to scroll between options on the screen. Press the dial to choose the option.
5	Water Tank Lock	Press the water tank lock to remove the water tank.
6	Water Tank	This one piece removable water tank holds the water for humidification.
7	Air Outlet Port	Connect the tubing here.
8	Power Inlet	Connect the power cord here.
9	SD card Access Door	This door lifts open for access to SD card.
10	Air Inlet Port	Inlet for room air.
11	Filter Cotton Cover	Open the filter cotton cover to place or change the filter cotton.

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 control dial. Rotate the control dial in either direction to scroll through the menu options on the display screen. Note: The screen does not support touch operations. You must use the control dial to navigate the device menu.

To adjust a setting:

1. Rotate the control dial to your desired menu option.
2. Press the control dial to select that setting.
3. Rotate the control dial to change the setting.
4. Press the control dial again to save the change.

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

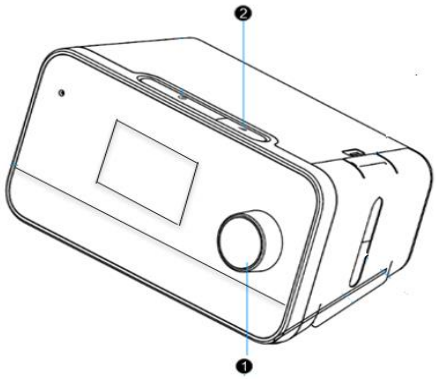
6 Operation

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

6.1 Accessing Clinical Mode

You can access, view and set parameters relating to a patient's therapy and device configuration in the Clinical Mode.

To access the Clinical Mode:



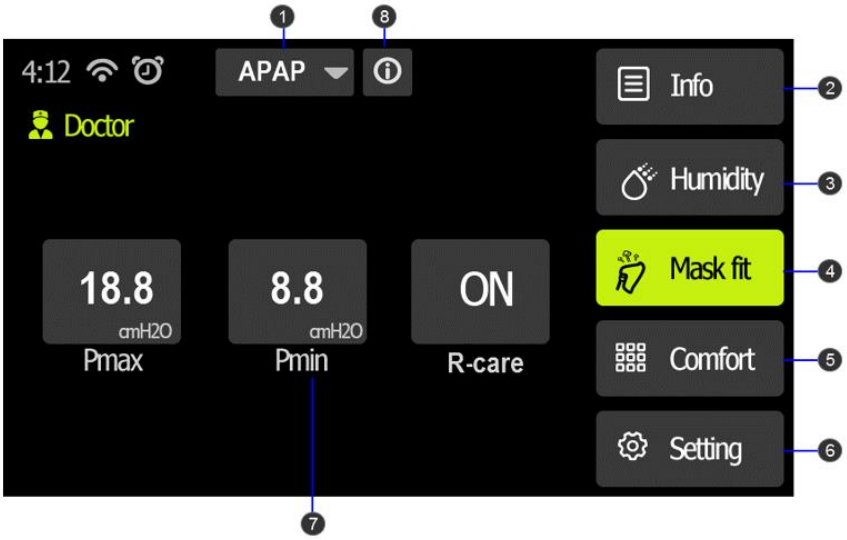
- Press and hold both the control dial and the Ramp button on the device for three seconds. The Home screen is displayed with an icon in the top right corner of the screen. You are now in the Clinical Mode.

To exit the Clinical Mode:

- Press and hold the dial and the Ramp button for three seconds.

6.2 Clinical Standby Interface

After accessing the clinical mode, the clinical standby interface is displayed as below:

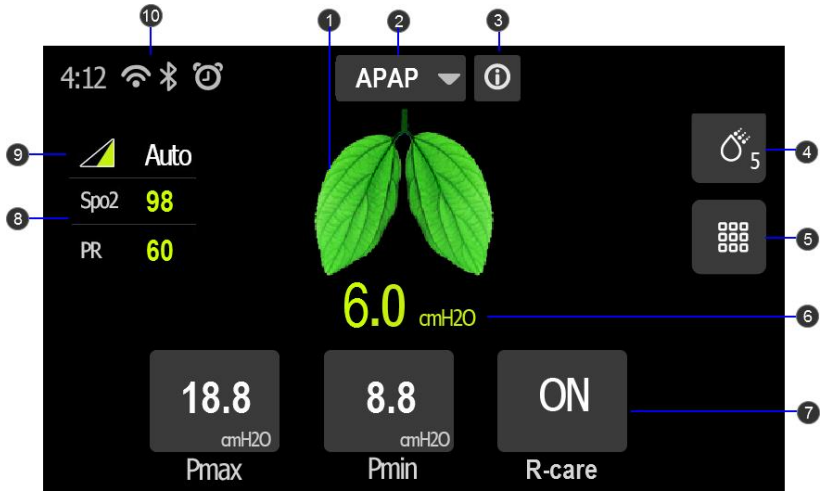


Clinical standby interface

#	Feature	Description
1	Therapy Mode	Displays the current mode and you can click here to set the Therapy Mode. Please refer Chapter7 “Therapy Information” for more details.
2	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.
3	Humidity	Humidity level setting, Enhance patient comfort of respiration. Option: Auto / OFF / 1 to 8 Default: 3 When auto humidity is enabled, the control algorithm adjusts the humidifier output to maintain a constant humidity level of 85% relative humidity while protecting against rainout. Note: The humidity only can be set when the water is higher than the limit level in the humidifier.
4	Mask fit	Mask fit test: In the selection of a new mask, need to test the face mask to wear whether the occurrence of leakage In standby or therapy mode, click on the mask fit test icon, display mask fit test in process with the animation interface
5	Comfort	Press Comfort key, enter Clinical comfort setting interface
6	Setting	Press Setting key, enter Clinical System Setting interface
7	Parameters Settings	Set the parameters of the current therapy mode Please refer Chapter7 “Therapy Information” for more details.
8	Alarm Message	Display the alarm messages.

6.3 Clinical Therapy Interface

When the therapy starts, the screen will switch to the Patient Therapy Interface, which displays the therapy parameters monitoring during therapy. The displayed parameters depend on the current therapy mode.

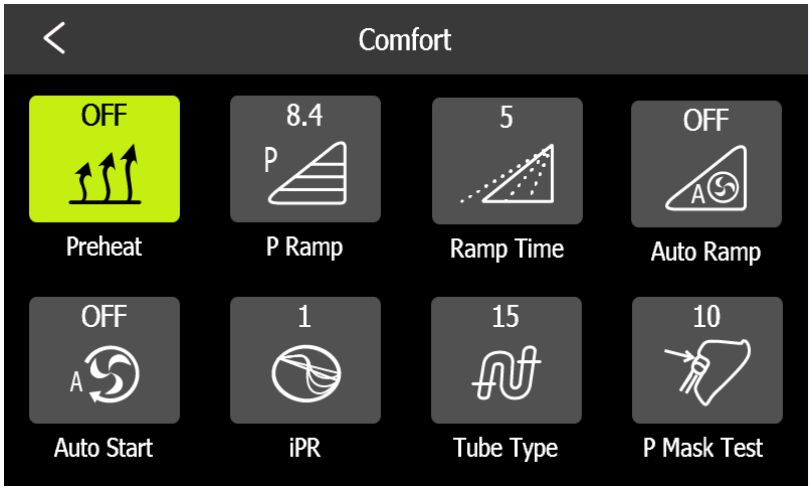


Clinical Therapy clean interface

#	Description
1	The background breathing dynamic diagram.
2	The current therapy mode.
3	Display the alarm messages. Please refer Chapter7 “Therapy Information” for more details.
4	Humidity adjustment shortcut key and Humidity level. Note：Only the humidity function is turned on for humidity level display
5	Comfort key, enter Clinical comfort setting interface.
6	The current therapy pressure.
7	The settings parameters of the corresponding mode. Please refer Chapter7 “Therapy Information” for more details.
8	If blood oxygen saturation is present and connected, the monitored blood oxygen saturation and pulse rate values are displayed in this area.
9	Ramp time dynamic diagram. Note：Only Ramp function is turned on for Ramp time dynamic diagram.
10	Work status icon bar.

6.4 Clinical Comfort Settings

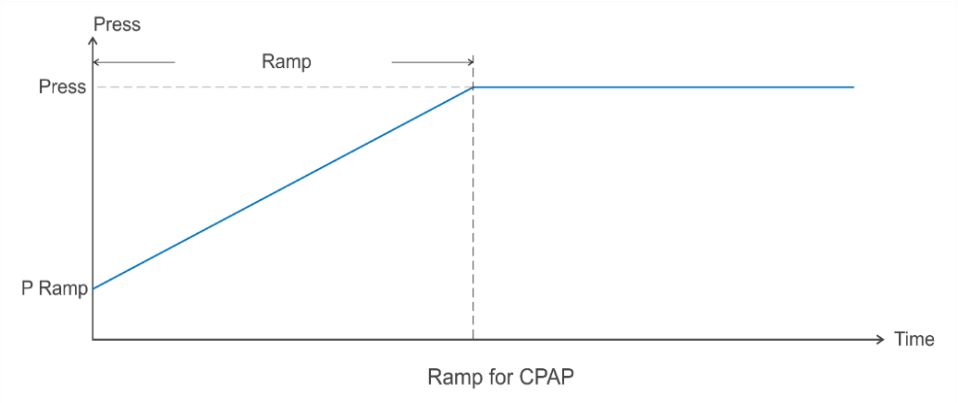
Press key in the clinical standby interface to enter clinical comfort settings interface.



Clinical Comfort Settings Interface

Ramp

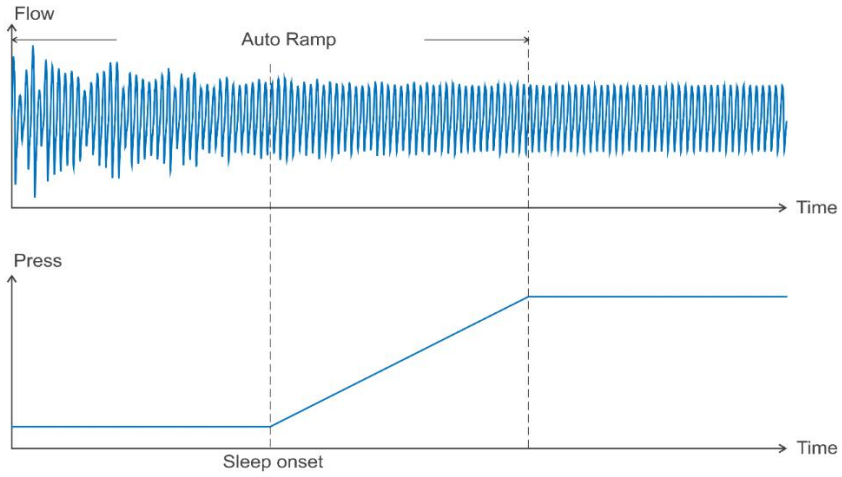
Ramp is designed to deliver the pressure in a gentle increasing manner at the beginning of therapy, affording enough time for the patient to adapt to the treatment pressure. The ramp process brings more comfortable and easier to get to sleep for the user, especially in cases when treatment pressure is high. Ramp is available for all therapy modes.
In Uni-Level mode, when ramp is enabled, the pressure delivered increases slowly from the initial ramp pressure to the target treatment pressure in the specified ramp time.



Ramp for CPAP

Auto Ramp

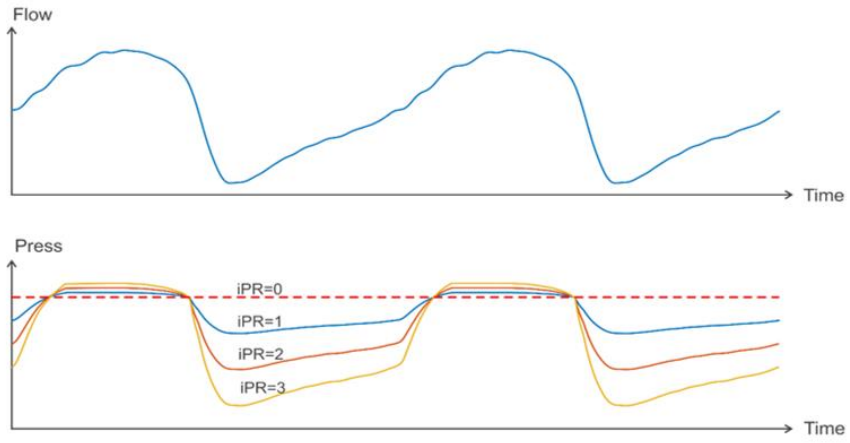
When auto ramp is enabled, the minimum treatment pressure (3cmH2O) is delivered before sleep onset of the patient. If sleep onset is detected, the pressure increases gradually from the minimum treatment pressure to the target treatment pressure in the specified ramp time.
The minimum ramp time in auto ramp is 5 minutes. However, if sleep onset is not detected within 60 minutes, the device will start to increase the pressure in the same manner still. Auto ramp is available for all therapy modes.



Auto Ramp for CPAP

iPR

Intelligent pressure release is designed to make the therapy more comfortable by reducing the treatment pressure in the cycle process and expiration. By applying iPR, the average treatment pressure is lower than its counterpart in normal operation.
The treatment pressure will not drop below 3cmH2O regardless of the iPR setting. iPR is available for all modes.
In Uni-Level modes, when iPR is enabled, the device senses the respirations of the patient and boosts pressure in inspiration. After the airflow reaches its peak and starts to decay, the pressure is released correspondingly. At the end of expiration, treatment pressure is kept below its prescribed value.



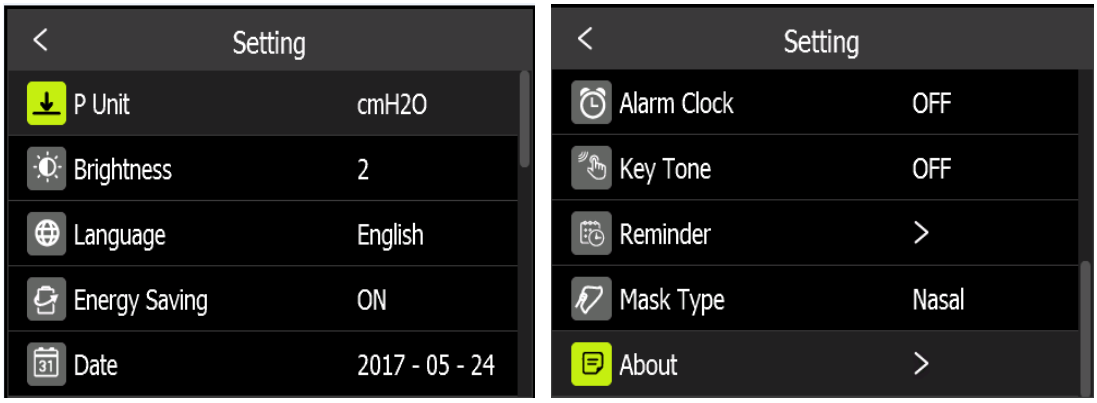
iPR for CPAP

Icon	Text	Description
	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. 3. Preheat function is not available in the iBreeze 20C.
	Auto Ramp	Turn Auto Ramp function on or off. When Auto Ramp is on, Sleep state can be identified automatically, sleep begins to start Ramp function, awake do not start ramp function. Option: On / OFF Default: OFF
	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 cmH_2O-Setting pressure, 0.5 cmH_2O increments. Default: 4 cmH_2O
	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. During therapy, if the mask is removed more than 5 seconds, the therapy mode will stop. Option: ON / OFF Default: ON
	IPR	Set IPR (Intelligence Pressure Release) level. Option: OFF / 1-3 Default: 2
	Tube Type	Set the Tube type. Option: 15 mm / 19 mm Default: 15 mm

Icon	Text	Description
	P Mask Test	Setting the mask fit testing pressure Setting Range: 6cmH2O-18, 2cmH2O increment Default: 10 cmH2O

6.5 Clinical System Settings

Select key in the clinical standby interface to enter the clinical system settings interface.



Clinical Settings Interface

Icon	Text	Description
	Pressure Unit	Set the pressure unit. Option: hPa / cmH_2O Default: cmH_2O
	Screen Brightness	Adjust the Screen Brightness. Option: Auto / 1-3 Default: 2
	Language	Set the system interface language. Default: English / Chinese Default: English.
	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
	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.
	Date Format	Set the system date format. Option: YYYY-MM-DD / MM-DD-YYYY / DD-MM-YYYY Default: YYYY-MM-DD

Icon	Text	Description
	Time	Set the system time. Note: time setting can't be earlier than the latest time of the report in the device.
	Key Tone	Set the switch key tone volume on or off. Option: ON / OFF Default: OFF
	WiFi	Set the WiFi function on or off. Option: ON / OFF Default: OFF
	GPRS	Set the GPRS function on or off. Option: ON / OFF Default: OFF
	Reminder	Set the Reminder type and time. You can turn on or off the different type of reminders, including: Mask, Filter, Water tank, Tube, Clinic, Maintenance interval. Option: ON / OFF Default: OFF Note: 1. Set the date of reminder, will pop-up reminder box first time to enter standby mode in the day of setting reminder day. 2. Click OK to change the relevant accessories, and then no longer remind. 3. Click Ignore, the next day and next starting time will pop-up reminder box.
	Mask Type	Set the Mask type. Option: Full Face / Nasal / Pillow Default: Nasal
	Info Menu	When you set the info menu on, the Clinical Information Interface is displayed in patient mode. Option: On / OFF Default: OFF
	Factory Reset	Restores the settings to the factory defaults.
	Erase Data	Erase the therapy data on the device.
	Service	Display the factory maintain function.
	About	Display the device informaiton including system version, serial number, blower running time etc..

6.6 Clinical Alert Settings

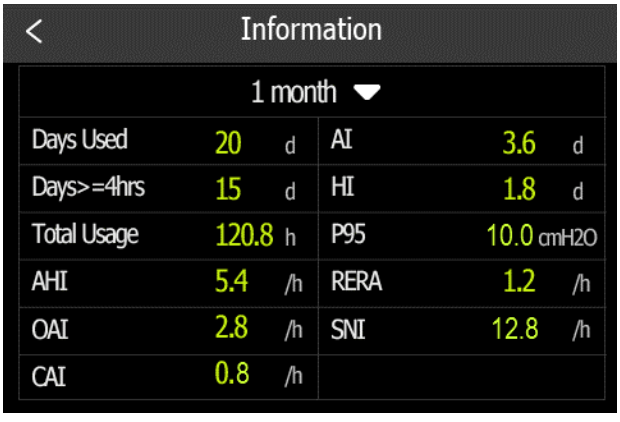
Select **Alert** menu in the system settings screen to enter the alert settings menu.

Clinical Alert Settings Interface

#	Feature	Description
1	Leakage high	Alert level: Alert1 Setting leakage high alert Option: OFF / 15S / 30S / 45S / 60S Default: OFF Alert limit: Total velocity-base velocity>100L/min, trigger time is the set time.
2	Mask vent holds blocked	Alert level: Alert1 Setting Mask vent holds blocked alert Option: ON / OFF Default: OFF Alert limit: the actual leak flow is less than 10lpm or 30% of the expected leak flow at present mask pressure and lasts longer than 60s.

6.7 Clinical Information Interface

Press information key in clinical standby interface to enter clinical information interface. The Information Screen provides a summary of the therapy session.

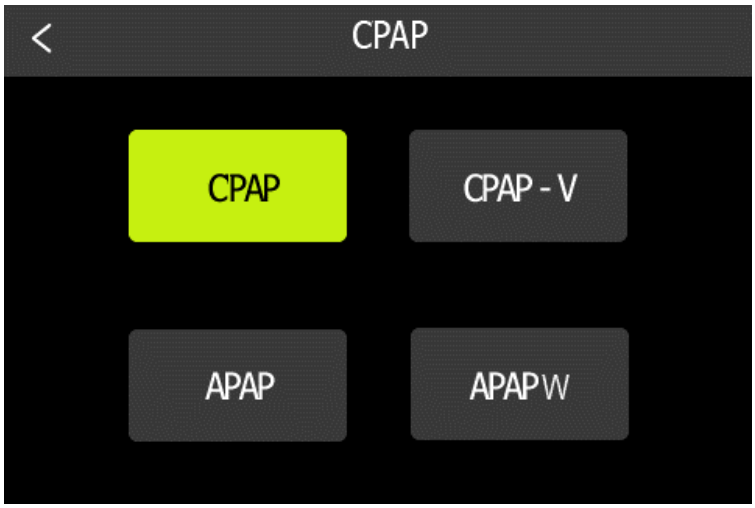


Clinical Information Interface

#	Parameter	Description
1	Time and date selection	Users can choose the date of the last 6 days to review the corresponding date of the device use, also can choose 7 days, 14 days, 1 month, 3 months, 6 months, 1 year to review.
2	AHI	Apnea-Hypopnea Index—average AHI during the selected period.
3	OAI	Obstructive AI—average OAI during the selected period.
4	CAI	Central Apnea Index—average CAI during the selected period
5	AI	Apnea Index—average total AI during the selected period.
6	HI	Hypopnea Index—average HI the selected period.
7	P95	Average inspiratory pressure during the selected period (95th percentile for each day; average of 95th percentile values for periods >1 day) pressure 95% The 95th percentile says that 95% of the time, the variable (eg, pressure) is at or below this amount. Just the same, during the remaining 5% of the time, the variable is above that amount.
8	Avg. leak	Avg. Leakage Average of the 95th percentile values of leak during the selected period
9	RERA	Respiratory Effort Related Arousals One day: the average number of RERA events occurred in an hour of the day used >= One day: the average of RERA every day
10	SNI	Snore Index One day: the average number of Snore events occurred in an hour of the day used >= One day: the average of SNI every day
11	Total Usage	Total therapy time
12	Days Used	Number of days the device has been used during the selected period
13	Days>=4hrs	Number of days the device has been used for more than 4 hours during the selected period
14	Avg.Usage	Average number of hours per day the device has been used during the selected period.

7 Therapy Information

To set the therapy mode, click the Therapy Mode button on the clinical standby interface to enter the therapy mode menu.



Therapy Mode Setting Interface

Uni-Level therapy mode

In Uni-Level therapy mode, the treatment pressures in inspiration and expiration are equal. The following modes are Uni-level therapy mode: CPAP, CPAP-V, APAP and APAPW.

7.1 CPAP Mode

In CPAP mode, a constant pressure is delivered to the patient throughout the whole therapy. When E-COMP is enabled, the treatment pressure delivered at the first day is reduced to the maximum value of 50% of the prescribed pressure and 4 cmH2O, then treatment pressure increases 1 cmH2O per day, until the prescribed pressure is reached.

CPAP Mode Parameters Setting

#	Parameter	Description
1	Pressure	Set the prescribed pressure throughout the therapy. You can adjust this setting from 4 to 20 cmH2O. The increment is 0.1/0.5 cmH2O.
2	E-COMP	This feature reduces the therapy pressure setting for the first few days of operation and gradually increases this setting until the prescription therapy pressure is reached. OFF: E-COMP is deactivated. ON: E-COMP is activated. The initial treatment pressure delivered at the first day is reduced to the maximum value of 50% of the prescription pressure, but no lower than 4 cmH2O. After each day of successful use, the therapy pressure will increase by 1 cmH2O until the prescription pressure is reached. From that point forward, the therapy device would operate in normal CPAP mode.

7.2 CPAP-V Mode

The CPAP-V mode is a combination of CPAP mode and APAP mode with limited trial days, which is used to titrate the patient. The device operates in APAP mode with R-Care off in the preset titration time, during which a P95 pressure is generated, when the titration time expires, the device operates in CPAP mode, with P95 as suggested prescribed pressure.

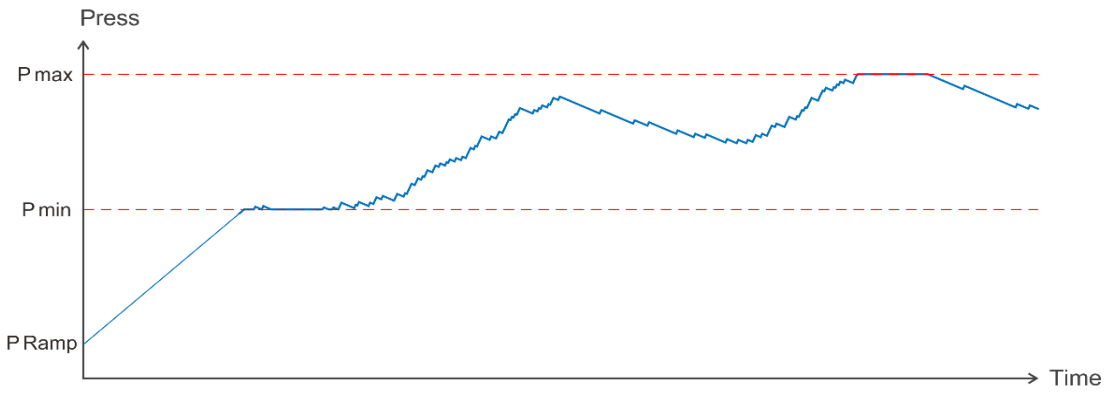
CPAP-V Mode Parameters Setting

#	Parameter	Description
1	Pmax	This feature sets upper limit of the treatment pressure in titration session. The device operates in APAP mode during the titration session, thus treatment pressure is adapted automatically according to the patient's conditions. The initial default setting is 12 cmH2O. You can adjust the setting from the P min setting to 20 cmH2O. The increment is 0.1/0.5cmH2O.
2	Pmin	This feature sets lower limit of the treatment pressure in titration session. The device operates in APAP mode during the titration session, thus treatment pressure is adapted automatically according to the patient's conditions. The initial default setting is 6 cmH2O. You can adjust the setting from 4 cmH2O to the P max setting. The increment is 0.1/0.5cmH2O.
3	Titra time	Set the days that the device operates in APAP mode. When the titra time expires, the device operates in CPAP mode and P95 is applied as the prescribed pressure. This screen allows you to adjust the duration of the Auto-Trial feature in number of days. You can set this from 7 to 28 days. The default is 7 days. Note: The CPAP-V mode can't be used more than 28 days.

7.3 APAP Mode

In APAP mode, the pressures delivered to the patient in both inspiration and expiration are equal. The treatment pressure is adapted automatically according to the patient's status, to maintain an average lower pressure while keeping the upper airway open. A fuzzy adaptive algorithm is applied to regulate the pressure by detecting four types of sleep disorders, obstructive Apnea, Hypopnea, Snore and Flow Limitation (refer to chapter 7.5 Events). Within the upper and lower limitations specified by Pmax and Pmin, the pressure increases and decreases accordingly with the occurrence and cessation of those events. Refer to Automatically pressure regulation rules for more information.

If R-Care is enabled, the initial treatment pressure is the P95 pressure of the last 7 days (if the actual used days are less than seven, P95 of the actual available days are used), otherwise, Pmin is used as the initial treatment pressure.



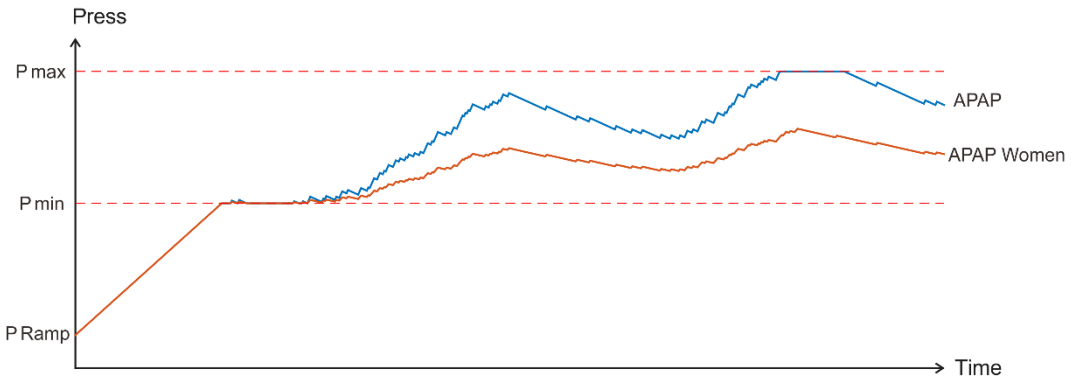
APAP

APAP Mode Parameters Setting

#	Parameter	Description
1	Pmax	This feature sets upper limit of the treatment pressure. The treatment pressure is adapted automatically according to the patient's conditions. The initial default setting is 12 cmH2O. You can adjust the setting from the P min setting to 20 cmH2O. The increment is 0.1/0.5cmH2O.
2	Pmin	This feature sets lower limit of the treatment pressure. The treatment pressure is adapted automatically according to the patient's conditions. The initial default setting is 6 cmH2O. You can adjust the setting from 4 cmH2O to the P max setting. The increment is 0.1/0.5cmH2O.
3	R-care	ON: R-Care is activated, the initial treatment pressure is the P95 pressure of the last 7 days (if the actual used days are less than seven, P95 of the actual available days are used). OFF: R-Care is deactivated. The initial treatment pressure is P Min.

7.4 APAPW Mode

The APAPW (APAP Women) mode is an APAP mode specified for female patients, with increased sensitivity on sleep disorders detection and moderate pressure regulations compared with the APAP mode.
The APAPW mode treats apnea and hypopnea up to 15 cmH2O and continues to respond to snore and flow limitation up to 20 cmH2O.



APAP&APAP Women

APAPW Mode Parameters Setting

#	Parameter	Description
1	Pmax	This feature sets upper limit of the treatment pressure. The treatment pressure is adapted automatically according to the patient's conditions. The initial default setting is 12 cmH2O. You can adjust the setting from the P min setting to 20 cmH2O. The increment is 0.1/0.5cmH2O.
2	Pmin	This feature sets lower limit of the treatment pressure. The treatment pressure is adapted automatically according to the patient's conditions. The initial default setting is 6 cmH2O. You can adjust the setting from 4 cmH2O to the P max setting. The increment is 0.1/0.5cmH2O.
3	R-care	ON: R-Care is activated, the initial treatment pressure is the P95 pressure of the last 7 days (if the actual used days are less than seven, P95 of the actual available days are used). OFF: R-Care is deactivated. The initial treatment pressure is P Min.

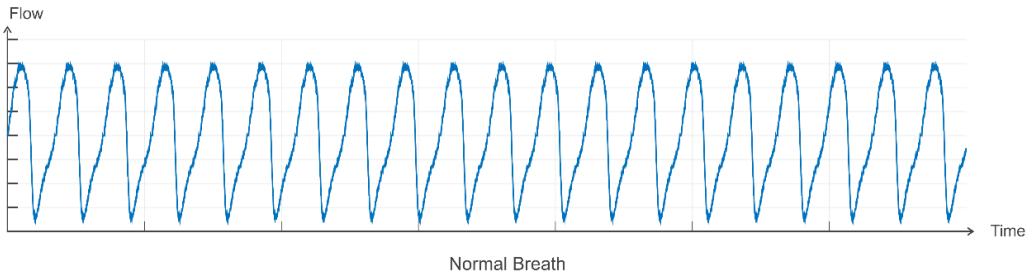
7.5 Events

Automatically pressure regulation rules

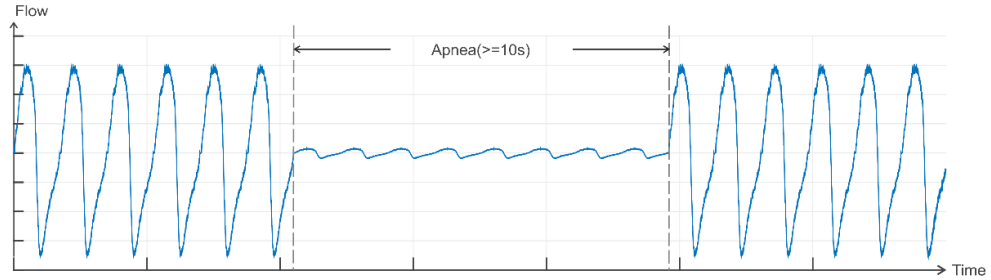
The treatment pressure required for the patient to keep the upper airway clear may vary with body position and sleep state of the patient throughout the night. To avoid uncomfortable feelings resulting from high-level mask pressure, the adequate treatment pressure is expected to be the lowest pressure that is enough to keep patency of the upper airway. The device adjusts the treatment pressure according to the detection of the following several types of sleep events, apnea, hypopnea, snoring, flow limitation, RERA and periodic breathing. A fuzzy adaptive algorithm is applied to detect the events mentioned above. Treatment pressure is adjusted based on the detecting results, as obstructive apnea, hypopnea, snoring and flow limitation lead to pressure increasing, but the increasing amplitudes get more and more moderate sequentially. No therapy adjustments are made in response to the other events. Once in normal breathing again, the treatment pressure reduces gradually.
By the automatic pressure adjustment method mentioned above, the average treatment pressure resides in a relative lower level, which offers a better therapy compliance. This function is enabled in APAP, APAPW Mode.

Apnea

Apnea is defined as amplitude of the patient flow reduces to 10% of its corresponding value when in normal breathing and lasts for over 10 seconds.



Normal Breath

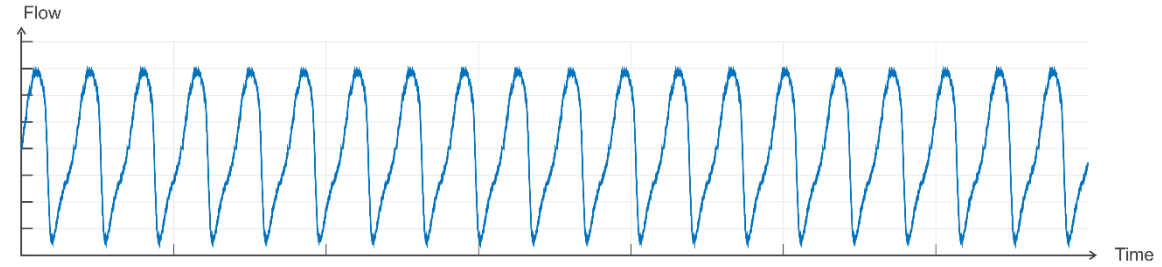


Apnea Breath

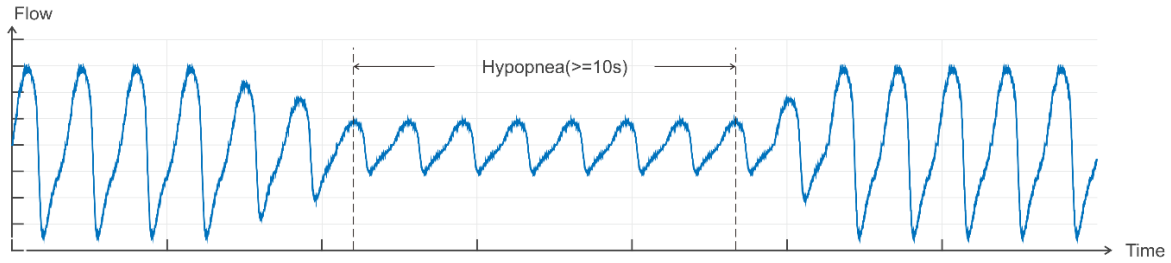
Once the device senses a latent apnea, the device delivers a test pulse to identity patency of the upper airway. If the apnea is confirmed and the airway is clear, then central apnea is reported and no action is taken. If the airway is obstructed, obstructive apnea is reported and treatment pressure increases in an adaptive way as soon as breathing efforts detected. The treatment pressure reduces gradually when in continuous normal breathing.

Hypopnea

Hypopnea is defined as amplitude of the patient flow reduces to 50% of its corresponding value when in normal breathing and lasts for over 10 seconds.



Normal Breath



Hypopnea Breath

Once the device identifies a hypopnea, the treatment pressure increases in an adaptive way. When the breathing becomes normal again, pressure reduces gradually.

Snore

In cases the upper airway has collapsed to certain extent, vibration of the walls of the airway may appear along with the inspiration, accompanied by unpleasant sound. Once the device identifies the occurrence of snoring, treatment pressure increases until snoring stops. When the breathing becomes normal again, pressure reduces gradually.

Flow Limitation

As the upper airway starts to collapse, the inspiratory portion of the airway waveform becomes flat, which is a presymptom of snoring, hypopnea and apnea. The device recognizes this pattern and increases the treatment pressure accordingly. When the breathing becomes normal again, pressure reduces gradually.

RERA

Respiratory effort-related arousal is defined as an arousal resulting from increasing respiratory efforts. In such cases, there is a subtle reduction then followed by a sudden increase in airflow or tidal volume. When the device recognizes this pattern, a RERA event is reported. No pressure adjustments are made in response to RERA.

8 Device Alert

There are 4 types of alerts described here:

- **Alert 0**: Gray bottom white tips, no light, no sound, always display, disappear until the prompt condition not met.
- **Alert 1**: Orange bottom white tips, blue-ray flashing, with sound, always display, disappear until the prompt condition not met.
- **Alert 2**: Red bottom white tips, blue-ray flashing, with sound, exclusive alarm 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
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.
SD card write/read underway, do not remove the SD card, do not cut off the power.	Notification	1. Insert SD card during data synchronization; 2. Input the configuration on the SD card.	No action.
SD Card Removed.	Notification	1. No SD card in the device. 2. SD card has been removed.	Reinsert functional SD card.
SD Card Full, Please replace the SD Card.	Notification	In Standby mode, SD card storage space only 200M	Replace the SD card or clean the data after export the data in the SD card.
SD card can't be written, please unlock and insert again.	Notification	The SD card is read-only and can't be written.	Remove the SD card, unlock and insert it again.
SD card error, please remove and insert again.	Notification	SD card failure, may be: 1.SD card can't read and write. 2.SD card read and write data errors.	Remove SD Card, Reinsert or replace with a new card.
Software update underway, Do not cut off the power!	Notification	Software update.	No action.
Water level is too low, please add to the appropriate water level.	Alert 0	During the heating process, the water level is below the defined threshold.	Remove the water tank and add to the appropriate water level.
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.

Alert	Type	Possible Cause	Action
The respiration tube expired, please replace.	Notification	In standby state, the usage time exceed the respiration tube setting service life.	Click “Confirm”, replace the respiration tube.
The water tank expired, please replace.	Notification	In standby state, the usage time exceed the water tank setting service life.	Click “Confirm”, replace the water tank.
The filter expired, please replace .	Notification	In standby state, the usage time exceed the filter setting service life.	Click “Confirm”, replace the filter
The mask expired, please replace.	Notification	In standby state, the usage time exceed the mask setting service life.	Click “Confirm”, replace the mask
It is time for device maintenance ,Please contact the service provider for device maintenance.	Notification	In standby state, the usage time exceed the setting device maintenance time.	Click “Confirm”, contact the service provider for device maintenance.
Low Minute Volume (MV).	Alert 0	Minute volume less than the setting threshold value.	Check the respiration tube or adjust therapy parameter setting.
High Respiratory Rate (RR).	Alert 0	Respiratory Rate exceed the setting threshold value.	Check the respiration tube or adjust therapy parameter setting.
Low Respiratory Rate (RR).	Alert 0	None.	Check the respiration tube or adjust therapy parameter setting.
Apnea.	Alert 1	An apnea is detected and exceeds the setting duration.	Check the respiration tube or adjust therapy parameter setting.
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.
High Inspiration Pressure.	Alert 0	During breath cycle monitored pressure is higher than the set pressure threshold.	Check the respiration tube or adjust therapy parameter setting.
Low Expiratory Pressure.	Alert 0	During breath cycle monitored pressure is lower than the set pressure threshold.	Check the respiration tube or adjust therapy parameter setting.
Mask vent holes blocked.	Alert 1	Mask vent holes is blocked.	Check the mask.
Low Tidal Volume (Vt).	Alert 0	During breath cycle, Average Vt less than 0.6*Setting Value.	Check the respiration tube or adjust therapy parameter setting.

9 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 seems too high (it feels like I am getting too much air).	Ramp may be turned off.	Use the Ramp Time option.
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.
The knob is insensitive.	Encoder is damaged	Unplug the device. Reapply power to the device. If the problem continues, contact your home care provider.
The touchscreen is not working.	Touchscreen is damaged	Unplug the device. Reapply power to the device. If the problem continues, contact your home care provider.

10 Cleaning and Maintaining

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. Clean the tube. Clean the water tank.
Monthly	Clean the air filter.
Every 6 months	Replace the air filter.
Annually	Replace the tube.
As necessary	Descale the water tank. In clinical areas: Disinfect the tube. For reasons of hygiene: Replace the water tank if it is in poor condition (e.g., if cracks appear).
When changing patients	If the device has been used without a bacteria filter: Have professional hygienic preparation performed before using the device again. Send the device to the authorized dealer.

10.1 Cleaning the Device

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.

1. Unplug the device, Wipe the outside of the device using a cloth slightly dampened with water and a mild detergent. Let the device dry completely before plugging in the power cord.
2. Inspect the device and all circuit parts for damage after cleaning. Replace any damaged parts.

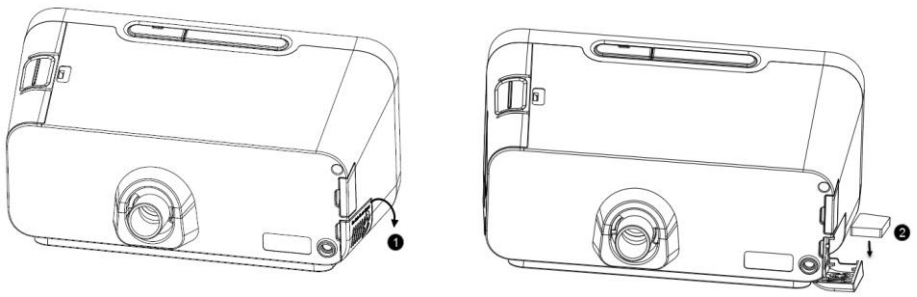
10.2 Cleaning the Tube/Water Tank

Clean the flexible tube and water tank before first use. Remove the flexible tube and water tank from the device. Gently wash the tube and water tank in a solution of warm water and a mild detergent. Rinse thoroughly and allow to dry out of direct sunlight or heat.

10.3 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 1-3 months, 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 replacing, remove the old filter cotton and then place a new one.

10.4 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.

10.5 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.

11 Maintenance

RESVENT CPAP therapy device is designed to have a useful service life of 10 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.

12 Storage and disposal

12.1 Storage

12.1.1 Storage Information

Store the device under the prescribed ambient conditions.

12.1.2 Storing 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.

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

13 Specification

Physical

Dimension (L*W*H): 235*148*125 mm
Weight: Approximately 1.55 kg

Operating Environmental

Temperature: 5℃~35 ℃
Relative Humidity: 10%~95% (non-condensing)
Atmospheric Pressure: 70 kPa~106 kPa

Storage Environmental

Temperature: -25℃~70℃
Relative Humidity: 5%~95% (non-condensing)
Atmospheric Pressure: 70 kPa~106 kPa

Noise Value

A-weighted sound pressure level: ≤ 28 dBA (uncertainty of 2 dBA).
A-weighted sound power level: ≤ 36 dBA (uncertainty of 2 dBA).

Standards compliance

IEC 60601-1:2005Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

IEC 60601-1-2:2014Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests.

ISO 80601-2-70:2015 Medical electrical equipment - Part 2-70: Particular requirements for basic safety and essential performance of Sleep apnea breathing therapy equipment.

ISO 8185:2009 Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems.

IEC 60601-1-11:2015 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.

Electrical

AC Power Input: 100~240 V～ 50/60 Hz 2.0 A Max
DC Power Input: 24 V, ≤2.5 A

Safety Specifications

Class II
Type BF
Ingress Protection: IP22

Air filter

Air filter: Filter Efficiency: >75% (7 micron dust)

Pressure

Setting Range: 4-20 cmH_2O
Max Single Fault Steady Pressure: 40 cmH_2O
Pressure Control Accuracy: ±0.5 cmH_2O
Dynamic Pressure Variation: < 1 cmH_2O
Pressure monitoring Accuracy: ± (2%*full scale reading + 4%*actual reading)

Flow

Flow: >120 L/min

Humidifier

Water capacity: 290 ml (MAX Water Level)
Humidity: >10 mg/L BTPS (Within the set pressure range)

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 ad confidential information.

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

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Limited Warranty

Resvent, Inc. 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, Inc.will repair or replace – at its option – the defective material or part. Resvent, Inc. will pay customary freight charges from Resvent, Inc. 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, Inc.

Contact information

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Issue date：Sept., 2017

4000-000040-00-V1.1