User Manual

for

8 Series Positive Airway Pressure Device

Version: A/0

DOC No.: UM-VEN8-02

hypnus

Table of Contents

Read Before Use

This manual describes the operating methods, technical parameters and maintenance instructions of the product. Please read this manual carefully for instructions of use.

Your particular attention is required to the following:

- Put the manual at a place within your easy reach for reference at any time;
- Safekeeping the manual when it is not needed.

This manual defines the following warning signs for the purpose of safe and correct operation:

⚠ **Warning: A warning indicates the possibility of injury to the user or the operator. Neglecting of the "Warning" information may result in potential safety hazard or product damage.**

⚠ **Caution: A Caution indicates the possibility of damage to the device.**

Check the Supplied Parts

After unpacking, please check whether all the parts mentioned are present and intact. If some of the parts are missing or damaged, please contact your provider immediately.

The parts are as follows:

- Main Unit
- Humidifier
- Power Adapter
- User Manual
- SD Card
- Air Filter
- Qualification Certificate
- Heating Tube (Optional)

⚠ **Caution: Please retain the packing material so that it can be reused when you transport the device.**

⚠ **Caution: This device is not equipped with a mask. Users need to buy a legally marketed mask by themselves. If you have any questions, please consult a doctor or manufacturer**

Chapter 1 Safety Guide

Please read the entire instruction manual before using Positive Airway Pressure Device. It will give you a better understanding of how the product works. If you are unsure whether a medical condition should preclude you from using the device, consult your medical practitioner.

1.1 Warning

1) This product consists of the main unit, humidifier, heating tube(optional) and the power adapter. The adapter HY90 should be used with Hypnus heating tube, and adapter HY52 should be used with the common air tubing without heating function. The use of unauthorized accessories such as the humidifier, adapter or heating tube can weaken the therapy effect, or cause other potential safety hazards.

2) If you are using a full-face mask, the mask must be equipped with a safety (anti-asphyxia) valve, to minimize CO_2 respiration when the device is not functioning.

3) Do not add any attachments or accessories to the humidifier that are not listed in the instruction for use of the humidifier or accessory or the humidifier might not function correctly affecting the quality of the therapy or injuring the patient.

4) Do not use the humidifier at an altitude above 2000m or outside a temperature of 5℃~35℃. Using the humidifier outside of this temperature range or above this altitude can affect the quality of the therapy or injure the patient.

5) To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used.

6) Covering breathing tubes with a blanket or heating them in an incubator or with an overhead heater can affect the quality of the therapy or injure the

patient.

7) Incompatible parts can result in degraded performance.

8) The responsible organization is accountable for the compatibility of the humidifier and all of the parts and accessories used to connect to the patient before use.

9) The conditions under which the HUMIDIFIER maintains the accuracy of controlled and displayed variables as disclosed in the instructions for use.

10) Do not use this device in a magnetic resonance environment.
11) Do not use this device in a polluted environment.
12) Do not use this device in an environment with flammable and explosive gases.
13) Do not operate the device without enclosure, avoid personal injury and electric shock hazard.
14) Do not place the device directly on carpets, fabrics or other flammable materials.
15) Do not immerse the device in water. Do not let any fluids enter the device.
16) Keep away from any heating or cooling appliances, such as radiators, air conditioners, indoor vents, etc., so as not to increase the temperature of the air coming out of the device.
17) Do not perform any maintenance and disassembly when the device is running.
18) Do not place the device in or on any container that can collect condensation.
19) The device must not be covered or placed in a position where its operation or performance may be adversely affected.
20) Failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation.
21) Sources of oxygen must be located more than 1m from the equipment to avoid the risk of fire and burns.
22) Nebulisation or humidification can increase the resistance of breathing system filters and the operator must monitor the breathing system filter frequently for increased resistance and blockage to ensure the delivery of the therapeutic pressure.
23) Not to position the medical device to make it difficult to operate the disconnection device.

24) Filter air inlet shouldn't be blocked.

25) 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 provider.

1.2 Caution

1) Federal law restricts this device to sale by or on the order of a physician.
2) Prevent the tubing from twisting or knotting so that air output smoothly.
3) To ensure safe operation, unplug the power cord from the home's power outlet before removing the power adapter.
4) Periodically check the power adapter, power cord and interfaces. Replace immediately if damaged to ensure safe operation of the device.
5) Keep the device away from pets, insects or children, children maybe strangulated due to cables and hoses.
6) Only use distilled water and purified water at room temperature in the humidifier. Do not add any chemicals or additives in the water, to avoid damaging the humidifier.
7) When transporting the humidifier, drain all water within it. Do not move the humidifier when there is water inside.
8) Periodically inspect the humidifier for signs of wear or damage. If the humidifier does not function properly or if there is any leakage, do not use the humidifier and promptly contact your provider.
9) When cleaning the humidifier, please use a mild detergent. Please follow all instructions provided in this manual when cleaning and disinfecting the device. Any operation that violates the operating instructions may affect the performance or durability of the product.
10) The last set parameters are stored in the device after the power failure is restored.

11) The humidifier is classified as category 2. Not intended for use in patients whose upper airway have been bypassed.

12) The proper placement and positioning of the mask on the face is critical to the

consistent operation of this equipment, if the mask doesn't place and position properly, the medical device will not achieve its intended use.

13) The patient is an intended operator, patient can install, disassemble, maintain, clean and disinfect the medical device.
14) The device shouldn't be exposed to environment, such as: Electrocautery, Electrosurgery, Defibrillation, X-Ray (Gamma radiation), Infrared radiation, Conducted transient magnetic fields, Magnetic resonance imaging (MRI), Radiofrequency interference.
15) The RESPONSIBLE ORGANIZATION should periodically reassess the setting(s) of the therapy for effectiveness.
16) The RESPONSIBLE ORGANIZATION should ensure that the therapeutic pressure settings were determined for the patient individually with the configuration of the equipment to be used, including accessories.
17) If you smell any odor during use, please stop using immediately.

1.3 Contraindications

This product is not a life support ventilator and may stop operation with power failure or in the unlikely event of certain fault conditions.

The use of this product may be contraindicated in patients with:

• acute sinusitis or otitis media

• epistaxis causing a risk of pulmonary aspiration

• conditions predisposing to a risk of aspiration of gastric contents

• impaired ability to clear secretions

• hypotension or significant intravascular volume depletion

• pneumothorax or pneumomediastinum

• recent cranial trauma or surgery.

⚠ **Warning: Physicians should assess individual patient risks before**

prescribing ASV and Auto ASV therapy for patients with chronic, symptomatic heart failure (NYHA II-IV) with left ventricular ejection fraction below 45% and moderate to severe predominant central sleep apnea.

⚠**Caution: This device is not suitable for patients with upper respiratory tract diversion (including tracheal intubation and tracheotomy). In addition, patients with upper respiratory tract infection, sinusitis or otitis media may need to temporarily discontinue CPAP therapy. Patients should report unusual chest pain, severe headache, or increased breathlessness to their prescribing physician. An acute upper respiratory tract infection may require temporary discontinuation of treatment.**

1.4 Adverse effects

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

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

• drying of the nose, mouth, or throat

• nosebleed

• bloating

• ear or sinus discomfort

• eye irritation

• skin rashes.

Chapter 2 Overview

2.1 Product name

Positive airway pressure device

2.2 Intended Use

The Positive Airway Pressure Device is indicated to provide CPAP and Bi-level therapy for the treatment of obstructive sleep apnea (OSA) in patients weighing more than 66 lb (30 kg). ASV and ASVAuto modes are also indicated for the treatment of central and/or mixed apneas, or periodic breathing. It is intended for home and hospital use.

2.3 Device Description

The device mainly includes the main unit, heating tube, mask and the power adapter. The main unit is composed of humidifier, fans, control circuits and sensors, and should be used with the air tubing and mask. Based on the preset settings, the device outputs a certain level of positive airway pressure and air flow through the tubing and nasal mask, to the patient's upper respiratory tract. It keeps the patient's upper airway open and clear through the positive pressure airflow, thus eliminating snoring during sleep, low ventilation and sleep apnea. The 8 series has the following 12 models, please refer to the following table 1 for details

Table 1: Model Introduction

Model	Mode	Max pressure (cmH_2O)	Functional module
CA820M	CPAP, APAP	20	Bluetooth module and mobile communication

			module
CA820W	CPAP, APAP	20	Bluetooth module and WiFi module
CA820	CPAP, APAP	20	/
BA825M	CPAP,BPAP-S, Auto BPAP-S	25	Bluetooth module and mobile communication module
BA825W	CPAP,BPAP-S, Auto BPAP-S	25	Bluetooth module and WiFi module
BA825	CPAP,BPAP-S, Auto BPAP-S	25	/
ST830M	CPAP,BPAP-S, BPAP-ST, BPAP-T	30	Bluetooth module and mobile communication module
ST830W	CPAP,BPAP-S, BPAP-ST, BPAP-T	30	Bluetooth module and WiFi module
ST830	CPAP,BPAP-S, BPAP-ST, BPAP-T	30	/
SV825M	CPAP, ASV, Auto ASV	25	Bluetooth module and mobile communication module
SV825W	CPAP, ASV, Auto ASV	25	Bluetooth module and WiFi module
AU830Pro	CPAP,APAP, BPAP-S,Auto BPAP-S,BPAP-ST, BPAP-T, ASV, Auto ASV	30	Bluetooth module, WiFi module and mobile communication module

The model with WiFi module or mobile communication module can transmit data from the PAP device to support remote monitor the performance of device and patient compliance to therapy.

The collected including Equipment Identification like model, serial number, software version, Equipment Therapy Settings like mode of operation, treatment

pressure, Therapy Data like pressure, flow, detailed apnea event, detailed hypopnea event.

Any data collected is not involved with patient's personal information, it is carried out according to privacy and confidentiality legislation and ethical principles.

The following table 2 describes the therapy modes available.

Therapy mode	Description
CPAP	A fixed pressure is delivered.
APAP	Automatically adjust the CPAP pressure in response to snore, flow limited breaths and apneas.
BPAP-S	You may set two treatment pressures---one for inspiration (IPAP) and one for expiration (EPAP). The device senses when the patient in inhaling and exhaling and supplies the appropriate pressures accordingly.
Auto BPAP-S	Automatically adjusts pressure in response to flow limitation, snore and apneas. Pressure Support (PS) is fixed throughout the night and can be set by the clinician. Min EPAP and Max IPAP restrict the delivered pressure range.
BPAP-ST	The device augments any breath initiated by the patient, but will also supply additional breaths should the patient breath rate fall below the clinician's set "Backup" breath rate.
BPAP-T	The fixed breath rate and the fixed inspiration/expiration time set by the clinician is supplied regardless of patient effort.
ASV (Adaptive Servo-ventilation)	Treats central sleep apnea and/or mixed apneas and periodic breathing. In ASV mode, the expiratory positive airway pressure (EPAP) is adjusted by the clinician to maintain upper airway patency, while Min PS and Max PS restricts the range of automatically adjusted pressure support.
Auto ASV (Automatic	Treats central sleep apnea and/or mixed apneas and periodic breathing. In ASVAuto mode, the expiratory airway

Adaptive Servo-ventilation)	pressure (EPAP) is automatically adjusted to maintain upper airway patency between the limits set by Min EPAP and Max EPAP, while Min PS and Max PS restrict the range of automatically adjusted pressure support.

2.4 Structure and Components

The product consists of the main unit, humidifier, heating tube(optional) and the power adapter.

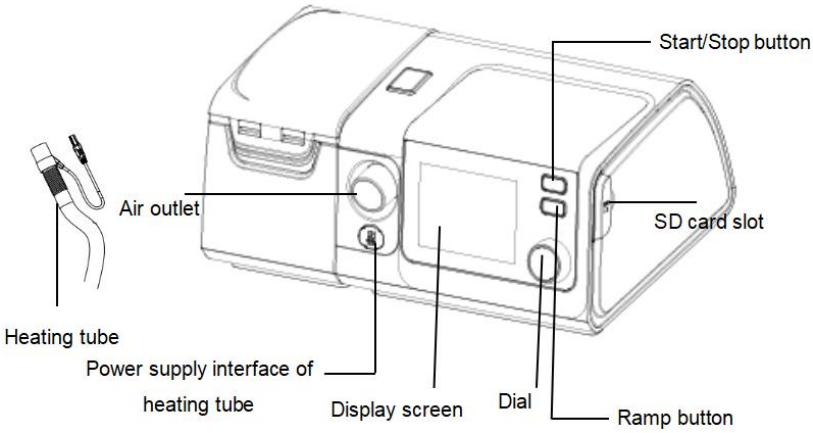


Figure 1 Font view

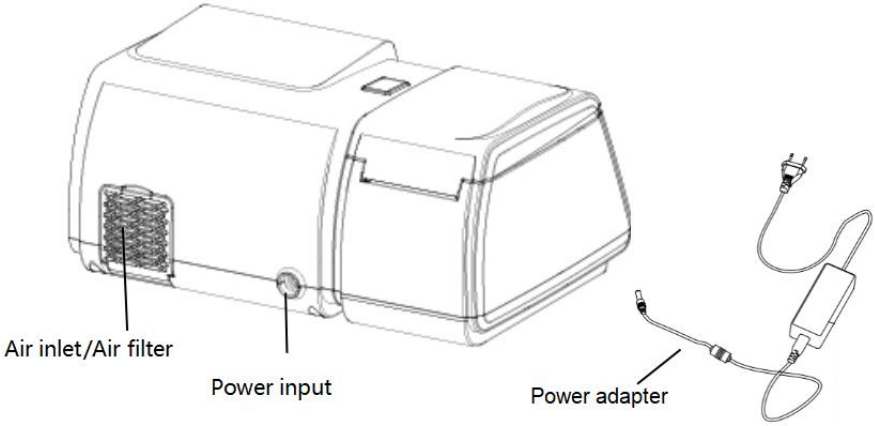
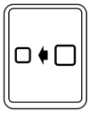


Figure 2 Rear view

⚠Caution: Not connect other medical devices which are not provided by Hypnus.

⚠Caution: Gas Intake (Air inlet) – Do not obstruct !

Button		Description
	Dial	Control to select parameters and settings
	Ramp button	1. In treatment mode, ramp time can be altered in five-minute increments (from OFF to a maximum ramp time set by your clinician) by pressing the ramp button. 2. If humidity level is between 1 and 5, in main interface, long press ramp button, device can preheat for 1 hour, when preheating, long press ramp button or disconnect humidifier again, device can stop preheating. 3. In other mode, device can back to previous operation interface
	Start/Stop button	Start or stop ventilation
	Separation button	Separate main unit and humidifier

2.5 Environment Requirements

	Operating Conditions	Storage and Transport Conditions
Temperature	5℃~35℃	-20℃~55℃
Relative Humidity	20%~93％	10%~93%, non-condensation
Atmospheric	79 kPa～106 kPa	79 kPa ~106 kPa

Pressure		
Altitude	-400m~2000m	-400m~2000m
Other Requirements	Do not use in an environment with corrosive, flammable or explosive gases	1) Long-term storage of the device should be in ventilated room without corrosive gases; 2) Severe shock, vibration, and snow or rain splash should be avoided during transportation.

⚠ **Caution: The user must check the device's safety function and see whether it meets proper operating conditions.**

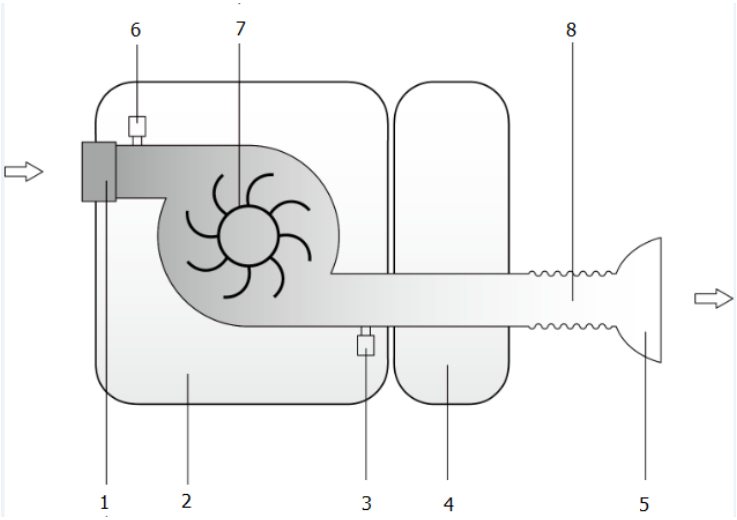
⚠ **Caution: Performance and lifetime of the device will be reduced when used outside the specified ambient temperature range or humidity range.**

Chapter 3 Product brief introduction

3.1 Work principle

The device mainly includes the main unit, heating tube (optional), mask (Customers need to buy legally sold products) and the power adapter. The main unit is composed of humidifier, fans, control circuits and sensors, and should be used with the air tubing and mask. Based on the preset settings, the device outputs a certain level of positive airway pressure and air flow through the tubing and nasal mask, to the patient's upper respiratory tract. It keeps the patient's upper airway open and clear through the positive pressure airflow, thus eliminating snoring during sleep, low ventilation and sleep apnea.

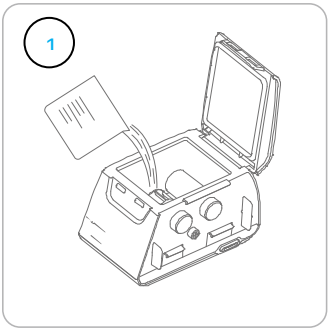
The pneumatic schematic diagram is shown below:

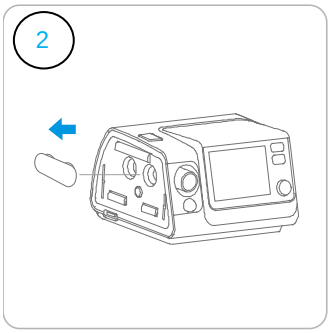


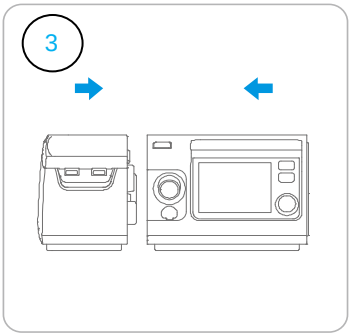
1	Air filter	5	Mask
2	Positive airway pressure device	6	Flow sensor

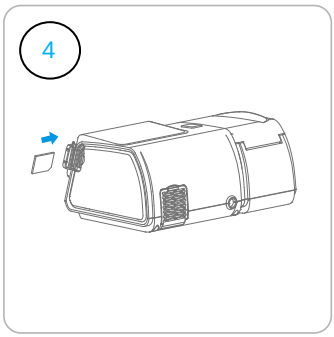
3	Pressure sensor	7	Blower
4	Humidifier	8	Air tubing

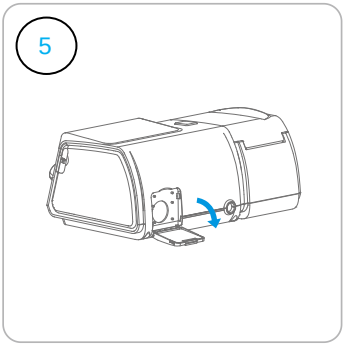
3.2 Install the medical device

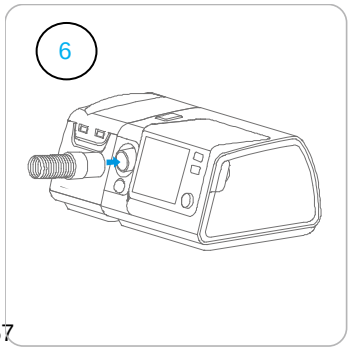


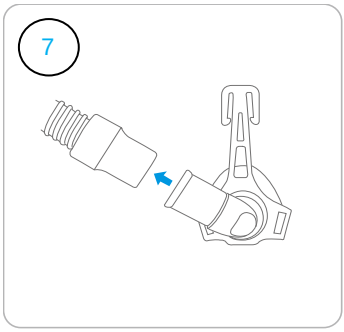


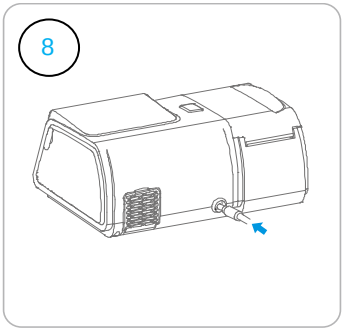












1. Open the upper cover of humidifier, fill the humidifier with distilled water or purified water (Please note that adding other substances can have adverse effects);
2. Remove the airway protection plug from the side of the main unit;
3. Place the device on a stable level surface, connect humidifier;
4. Insert SD card into the device;
5. Insert air filter into the device;
6. Connect air tubing to the air outlet of device;
7. Connect another side of air tubing to mask.
8. Connect the power adapter;

⚠**Caution:**

1. To avoid data to be destroyed or data lose, please remove the SD card after stopping the treatment.

2. When connecting the air tubing, do not use the brute force to pull the pipeline, avoid damaging the pipeline.

3. Do not exceed the maximum water level of the humidifier, avoid water enter the device and air tubing.

3.3 Starting therapy

1. After switching on the power supply, wear the mask.

2. Turn the dial to highlight **Cure**, and press the dial to starts therapy or breathe normally if SmartStart is enabled.

3. When the ramp time is enabled, the treatment pressure is gradually increasing from the lowest pressure to the treatment pressure.

You will know that therapy is on when treatment screen is displayed, progress bar shows the current treatment pressure in green.

Figure 3 Treatment Interface

⚠ **Caution: The treatment interface may vary depending on the treatment mode**.

⚠ **Caution: Regularly observe water level in the humidifier, when water level lower than the minimum water line, water should be added in time (please use distilled water or purified water, adding other substances can have adverse effects), but not exceed the highest water line. Excessive watering may cause damage to the humidifier or cause water to flow into the air inlet.**

⚠ **Caution: The humidifier with the maximum water capacity can run for 6 hours at the highest humidity setting until the next water addition.**

⚠ **Warning: Be sure to follow the doctor's established parameters and working conditions.**

⚠ **Caution: The patient should use the therapeutic pressure setting, as individually determined with the configuration of the equipment and accessories, being used.**

⚠ **Caution: The proper placement and positioning of the MASK on the face is critical to the consistent operation of this equipment**

3.4 Stopping therapy

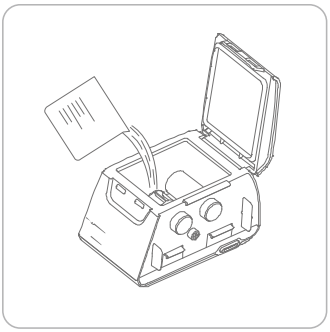
1. Remove the mask

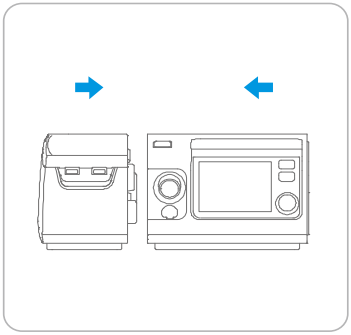
2. Press the dial to stop therapy, or if SmartStop is enabled, therapy will stop automatically after a few seconds. The treatment data is saved to the SD card.

⚠ **Caution: When the device reminds information, please stop using the device and check the device until the device returns to normal.**

3.5 Water the humidifier

Use fingers to hold the lower edge of the humidifier’s cover lock, and gently push up to open the humidifier cover. Put distilled water into the humidifier. Close the cover and press to lock it, and connect the humidifier to the main unit.



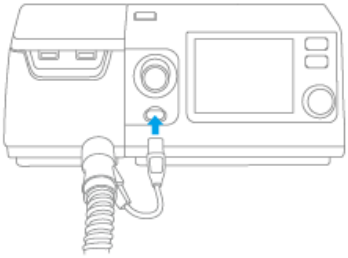


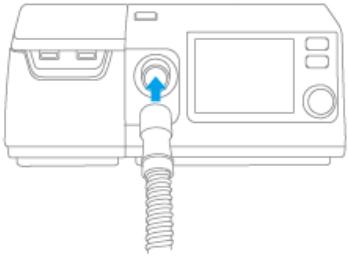
⚠ **Warning: Before filling humidifier with water, please disconnect humidifier and main unit first, to avoid pouring water into the equipment.**

⚠ **Caution: Distilled water and purified water are recommended for use in the humidifier. Do not use normal saline. Water line should not over maximum water level mark.**

3.6 Connect the heating tube

Plug the power connector of heating tube to the power output port in main unit, and connect heating tube to the air outlet of main unit.





Chapter 4 Menu parameter settings

4.1 User Settings

4.1.1 Ramp time feature

Designed to make the beginning of therapy more comfortable. Ramp Time is the period during which the pressure increases from a low start pressure to the treatment pressure. You can set your Ramp Time to OFF, 5 to 45 minutes.

To adjust Ramp Time:

1. On the **main interface**, turn the dial to highlight **Ramp** and press the dial.

2. Turn the dial to adjust ramp time and press the dial to save the ramp time.

3. Or on **treatment interface**, press ramp button, ramp time can be added 5 minutes each time.

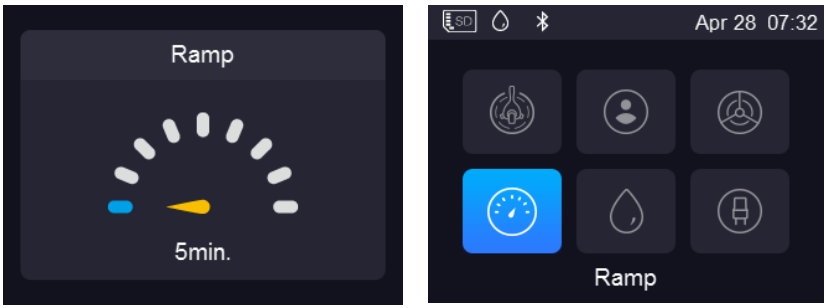


Figure 4 Ramp Time

4.1.2 Humidity level

The humidifier moistens the air and is designed to make therapy more comfortable. If you are getting a dry nose or mouth, turn up the humidity. If you are getting any moisture in your mask, turn down the humidity.

You can set the Humidity Level to Off or between 1 and 5, where 1 is the lowest

humidity setting and 5 is the highest humidity setting.

To adjust humidity level:

1. On the **main interface**, turn the dial to highlight **Humidity Level** and press the dial to enter **humidity level interface**.

2. Turn the dial to adjust humidity level and press the dial to save the humidity level.

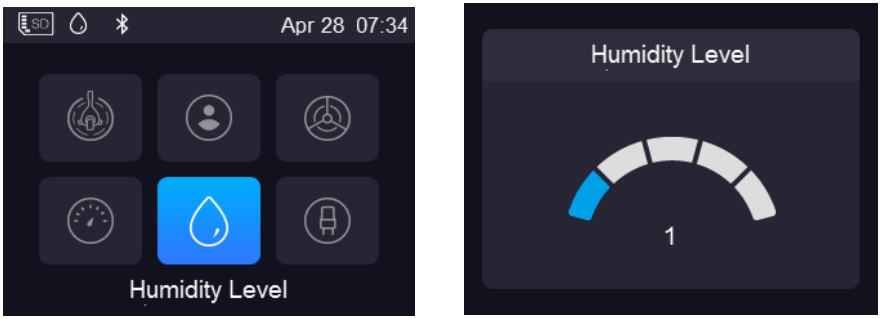


Figure 5 Humidity Level

4.1.3 Heating tube temperature

Heating tube can keep the air moist and prevent condensation water, and ensure the comfort of the treatment.

To adjust heating tube temperature:

1. On the **main interface**, turn the dial to highlight **Heat** and press the dial to enter **heating tube temperature interface**.

2. Turn the dial to adjust temperature and press the dial to save the heating tube temperature. The temperature can be set to OFF or 16-30℃.

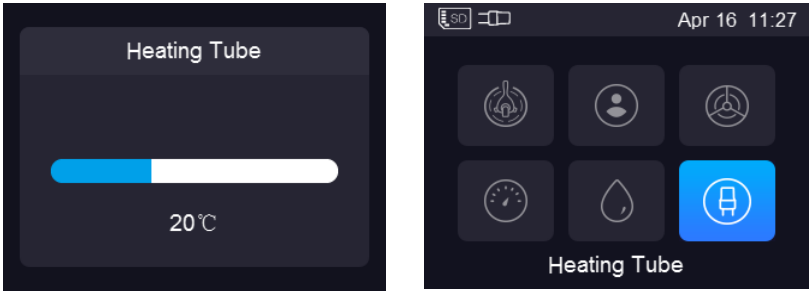


Figure 6 Heating tube temperature

4.1.4 Preheat humidifier

If humidity level is between 1 and 5, in main interface, long press ramp button, device can preheat for 1 hour, when preheating, long press ramp button or disconnect humidifier again, device can stop preheating.

4.1.5 More parameters

On the **main interface**, turn the dial to highlight **Setup** and press the dial to enter **configuration interface**.

You can select **user settings** and **device information**, in **user settings** menu, you can set language, LEDs, backlight, screensaver, tube options, make, smart start, smart stop, start pressure, temperature unit, airplane mode and time, detail information about these functions are listed in the following table.

Functions	Description
BackLight	Sets the time of screen backlight. It can be set as ON, 15 seconds, 30 seconds and 60 seconds. The screen will be always on if sets as ON.
Screensaver	Sets the screensaver mode ON or OFF, the time changes to screensaver mode is 30 seconds.

Tube options	Sets the type of air tubing used by the patient. The tube can be set as 22mm diameter or 15mm diameter.
Mask	Sets the type of mask used by the patient. It can be set as Nasal, Full Face or Pillows.
Smart Start	When Smart Start is enabled, therapy starts automatically when you breathe into your masks.
Smart Stop	When Smart Stop is enabled, therapy stops automatically after few second when you remove your mask.
Start Pressure	Sets the pressure at the start of ramp, up to minimum treatment pressure.
Temperature Unit	Sets temperature unit. It can be set as °F or °C.
Airplane Mode	When Airplane Mode is ON, the wireless connection will be disabled.
Time Setting	Sets the time in the machine.

In **device information** menu, you can view device information, such as: model, device time, motor time, version, ID and SN.

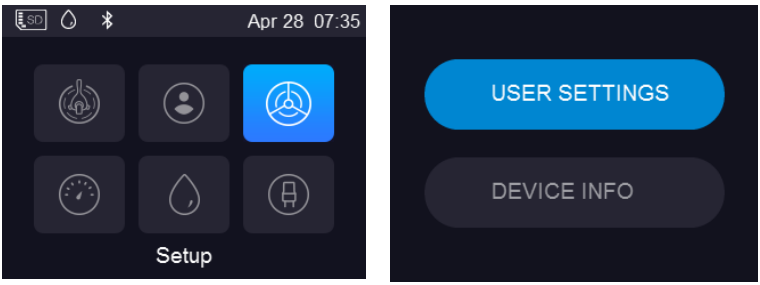


Figure 7 More parameters

4.1.6 Sleep report

On the **main interface**, turn the dial to highlight **Info** and press the dial to enter **sleep report interface**, then you can view your sleep report of the last one day, one week, two weeks, one month, three months, six months or one year. The data is recorded via an SD card.

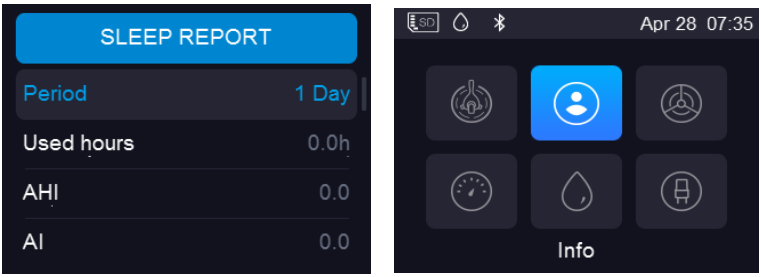


Figure 8 Sleep report

Chapter 5 Cleaning and Maintenance

⚠WARNING

- **Beware of electrocution:**

1) **Do not immerse the device, AC Adapter power cord in water.**
2) **Do not connect to power while the device is wet. Make sure that all parts are dry before plugging it in.**
3) **If liquids are spilled into or onto the device, unplug the device and let the parts dry.**

- **Always unplug the device before cleaning and ensure that all parts are dry before plugging it back in.**
- **Do not perform any maintenance tasks (eg, cleaning, changing the air filter) while the device is in operation.**
- **Clean the device and its components according to the guide shown in this guide, to maintain the quality of the device and to prevent the growth of germs that can adversely affect your health.**
- **Regularly inspect power cords, cables, and power supply for damage or signs of wear. Discontinue use and replace if damaged.**
- **Do not open or modify the device. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorized HYPNUS service agent.**

⚠CAUTION

- **Do not use bleach, chlorine, or aromatic-based solutions, moisturizing or antibacterial soaps or scented oils to clean the**

device, the humidifier tub or air tubing. These solutions may cause damage or affect the humidifier performance and reduce the life of the products. Exposure to smoke, including cigarette, cigar or pipe smoke, as well as ozone or other gases, may damage the device. Damage caused by any of the foregoing, will not be covered by Hypnus's limited warranty.

- **Leave the humidifier tub to cool for ten minutes before handling to allow the water to cool and to make sure that the humidifier tub is not too hot to touch.**
- **It is important that the device is cleaned regularly to ensure optimal therapy. The following sections will help with disassembling, cleaning, checking and reassembling the device.**

The following sections will help you with:

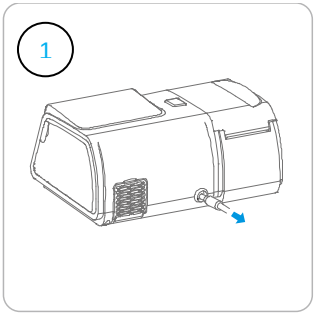
• Disassembling

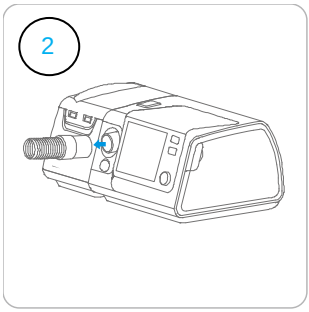
• Cleaning

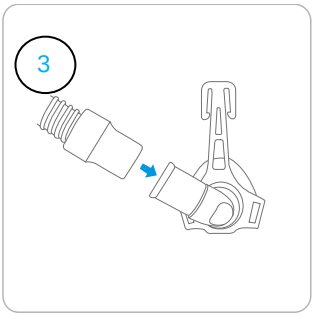
• Checking

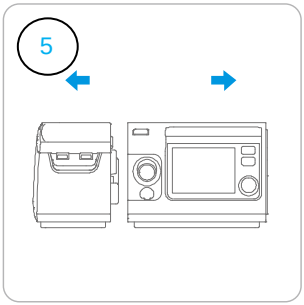
• Reassembling

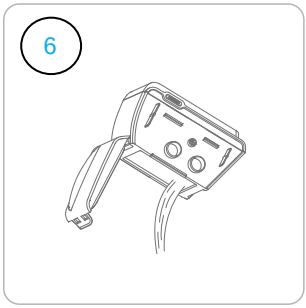
5.1 Disassembly











1. Unplug the power cord from the power outlet and the rear panel of the device;

2. Hold the cuff of the air tubing and gently pull it away from the device;

3. Hold both the cuff of the air tubing and the swivel of the mask, then gently pull apart;

4. Open SD card cover, gently press the SD card, the SD card will pop-out, remove the SD card from the device;

5. Press the separation button on the main unit, pull the humidifier away from the main unit;

6. Open two clasps of the humidifier, pour out the rest of water and clean the humidifier.

5.1.2 Cleaning

The following instructions are for home cleaning. You should clean the device, humidifier and heated tube as described.

- **Device enclosure and air outlet**

Cleaning（Weekly）

Clean the device enclosure and air outlet using an alcohol based cleaning wipe or wiping with 70%-75% Ethyl alcohol solution, swipe 10 times in the same place, do not let any liquids enter the device.

1) Use a minimum of two wipes.;
2) If visual debris is still present, perform the following: Clean with a dry, soft bristle brush and using a new cleaning wipe for cleaning.

Drying

Allow sufficient time for the device to air dry completely.

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 your HYPNUS Service Center.

- **Humidifier, heated tube**

Cleaning

Daily use:

1. Empty the humidifier and wipe it thoroughly with a clean disposable cloth. Allow it to dry out of direct sunlight.

2. Refill the humidifier, use distilled water or purified water only.

Weekly:

Note: For all cleaning, rinsing steps use drinking quality water.

1. Make a solution of a Cleaning detergent and drinking water as directed by the manufacturer's instructions.

Cleaning detergent: 3M 70508 Natural multienzyme cleaning

Dilution ratio 1:100~1:200

2. Soak all components for 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.

- Humidifier: 5 minutes of brushing
- heated tube :5 minutes of brushing

Note: A soft bristle tube/bottle brush is required to clean the inside of the tubing. Remove tubes from the detergent solution to assist brushing.

4. Thoroughly rinse each component as follows:

1) in 5 liters of water at ≤113℉ (≤45℃) for each component by immersing it for 1-2minutes. Agitate the component in the rinsing water to ensure there are no air bubbles.

2) Rinse tube for 1-2minutes in running water.

5. Repeat the rinse procedure two additional times using fresh water for a total of three rinses.

Inspection

Inspect and if required, repeat the cleaning steps until visually clean. Shake air tubing to remove excess water.

Drying

Wipe the exterior of the Humidifier with a dry cloth.

Allow the components to dry out of direct sunlight.

Notes:

• Do not wash the Humidifier, heated tube in a dishwasher or washing machine.

• The air filter is not washable.

The frequency and Max number of cycles for cleaning are following:

Components	Frequency of cleaning	Service life	Maximum number of cycles for cleaning in the service life
Humidifier	Weekly	2.5 years	130
heated tube	Weekly	12 months	52

5.1.3 Checking

⚠**WARNING**

- **Discontinue use and contact your care provider or Hypnus Service Center if any of the following occur:**

➢ **device does not perform as usual**

- **device is making unusual sounds**
- **device is damaged**

⚠**CAUTION**

If any visible deterioration of a system component is apparent (cracking, discoloration, tears etc.), the component should be discarded and replaced.

Regularly check the Humidifier, heated tube, and air filter for any damage.

1. Check the humidifier:

• Replace it if it is leaking or has become cracked, cloudy, or pitted.

• Replace it if the seal is cracked or torn.

2. Check the heated tube and replace it if there are any holes, tears, or cracks.

3. Check the air filter and replace it every three months. Replace it more often if there are any holes or blockages by dirt or dust.

Replace the air filter :

1) Remove the air filter cover at the back of the device.

2) Remove and discard the old air filter.

3) Insert a new filter.

4) Reinsert the air filter cover.

Note: The air filter is not washable or reusable.

5.1.4 Reassembling

When the components are dry, you can reassemble the parts. To reassemble the PAP Device:

1. Fill the humidifier with distilled water or purified water up to the maximum water level mark.
2. Close the humidifier and insert it into the side of the device.
3. Connect air tubing to the air outlet of device.
4. Connect another side of air tubing to mask.

5.1.5 Device maintenance

- The device should be switched on, checked once a quarter, and its functions should be tested to ensure it works properly.
- When you don't use the device for a long time, unplug the power adapter from the power outlet, clean the device and then store it in a dry and well-ventilated environment.
- When users don't use the device for a long time, clean the device and put it back to original package box.

5.1.6 Replace the SD card

1) Open the SD card cove, push in the SD card to release it, remove the SD card from the device.
2) Insert the SD card in SD card slot and then push in the SD card.

5.2 Troubleshooting

If you have any problems, have a look at the following troubleshooting topics. If the problem cannot be solved, contact your provider or Hypnus.

Problem/ Possible Cause	**Solution**
No display	
Power adapter is not connected	Ensure the power cable is connected, and the power socket (if has) is in the ON position

DC plug is partially inserted into the device	Insert the DC plug totally
Insufficient air delivered from the device	
Ramp Time is in use	Wait for air pressure to build up or modify ramp time
Air filter is dirty.	Replace air filter
Improper connection of air tube	Check the connection of air tube
Air tube is blocked, squashed or punctured.	Remove the blocking material or avoid air tube from squashing, check if air tube is punctured
The set pressure is too low	Please consult your clinician
Mask and headgear not positioned correctly	Adjust the position of mask and headgear.
Abnormal pressure increase	
Talk, cough or breathe in unusual ways	Avoid talking when wearing mask, keep normal breathing
Air leakage around the mask	
Improper fitting of mask	Please refer to the user manual of mask, fit mask correctly
Nose is dry or stuffy nose	
Humidity level is too low	Adjust humidity level
There is condensate water on mask and air tube	
Humidity level is too high	Adjust humidity level
Air leakage of humidifier	
Improper connection of humidifier	Ensure humidifier and main unit assemble correctly, and check if there is damage, if there is damage, please contact your provider
Humidifier damage	
Device prompt: device air leakage, please check	

Improper connection of air tube	Please ensure air tube, mask connect correctly, humidifier and main unit assemble correctly
Improper fitting of mask	
Improper assembly of humidifier	
Device prompt: Airway obstruction, please check	
Air tube obstruction	Please check air tube, clean the obstructions in the air tube or avoid air tube from being squeezed
Device prompt: SD card is not recognized, please replace the SD card	
SD card is not inserted correctly	Remove SD card and reinsert
SD card is damaged	Replace SD card
Device prompt: System error, please refer to user manual, error 006	
Device is placed in an overheated environment	Please use the device in the specified environment
Heating tube malfunction	Please contact your provider to change heating tube
Other error information, such as: system error, please refer to user manual, error 0XX	
An unrecoverable error may happen on the device	Please contact your provider, don’t spate the device

Chapter 6 Product Service Life

6.1 Lifetime (Service life)

Device	5 years
Humidifier	2.5 years
heated tube	12 months（shelf-life is 36 months in storage conditions）
Air filter	3 months

If the product quality fails to meet the technical specifications as stipulated in the User's Manual, you can use the warranty card to request the manufacturer for free repair and replacement (except for consumables).

6.2 Waste Disposal

After the product exceeds its service life, it should be disposed according to local and national laws and regulations.

6.3 Transportation and Storage

The device should be kept away from heat source, severe impacts and vibration during transportation and unpacking. Do not place the device in direct sunlight.

When the device is not used for a long time, the device should be stored in a dry and well-ventilated environment. There shouldn't be corrosive gases in the air and avoid storing in an environment with strong electromagnetic interference.

Chapter 7 After-sales Service

Under the following conditions, the warranty period of the device is 2 years, the warranty period of humidifier is 1 year from the date of purchase:

1. Storage and working environments meet the national standards, professional standards and requirements specification;

2. Device is installed, commissioned and maintained by person who is authorized by our company;

3. Use the device in accordance with the operating instructions.

If the product fails under conditions of normal use within the warranty period, Hypnus will repair or replace.

⚠ **Caution:**

- **Heating tube belongs to vulnerable part, the warranty period is 6 months from the date of purchase;**
- **For the mask recommended by Hypnus, please check the instruction provided by the original factory for its warranty period;**
- **Air filter belongs to consumable and is not within the warranty scope.**

Product failure or damage caused by the following circumstances, is not within the scope of free warranty:

1. Breakdown or damage caused by improper operation or failure to follow the instructions (any application beyond the usage scope of the device).

2. Breakdown or damage caused by the repair, modification or inspection performed by an unauthorized service personnel.

3. Breakdown or damage caused by natural disasters such as fire, flood, earthquake or lightning.

4. Can’t show warranty card or voucher to buy the device.

⚠ **Caution: Do not disassemble the product, otherwise it will not be guaranteed.**

⚠ **Caution: Please keep warranty card carefully, show the warranty card if the device need to be repaired.**

Chapter 8 Symbol Instructions

Symbol	Instructions
	Humidifier is cooling
	Humidifier has connected
	Humidifier is preheating
	Heating tube has connected
	Class II equipment
	Type BF Applied Part
	Caution, consult accompanying documents
	Separately dispose electrical and electronic equipment as per EC Directive 2002/96/EC.
	Refer to instruction manual / booklet
	Recyclable
	Only for indoor use
	Short-circuit proof safety isolating transformer
EC REP	Authorized Representative in the European Community
CE 0123	CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.

	Manufacturer
	Serial number
	Batch code
IP21	Protect against solid foreign objects of 12,5 mm ø and greater, protect against vertically falling water drops
	Keep dry
	This way up
	Fragile, handle with care
	Keep away from sunlight
	Temperature limit
	Atmospheric pressure limitation
	Humidity limitation

Annex A Technical Specifications

Table 1 Specifications:

<table>
<tr><td>IEC 60601-1 classifications</td><td colspan="3">Class II, type BF</td></tr>
<tr><td>Ingress protection</td><td colspan="3">IP21</td></tr>
<tr><td>Water/dust proof level</td><td colspan="3">Adapter:
Model: HY52, input: 100-240VAC, 50/60Hz, 1.5A Output: 24VDC, 2.2A
Model: HY90, input: 100-240VAC, 50/60Hz, 1.5A Output: 24VDC, 3.75A</td></tr>
<tr><td>Pressure display accuracy</td><td colspan="3">±(2% full scale (40cmH_2O)＋4% actual pressure)</td></tr>
<tr><td rowspan="8">Operating pressure range</td><td>Model</td><td>Mode</td><td>Operating pressure range</td></tr>
<tr><td>CA820M
CA820W
CA820</td><td>CPAP, APAP</td><td>4~20cmH_2O</td></tr>
<tr><td rowspan="2">BA825W
BA825M
BA825</td><td>CPAP</td><td>4~20cmH_2O</td></tr>
<tr><td>BPAP-S, Auto
BPAP-S</td><td>IPAP: 4~25cmH_2O
EPAP:4~25cmH_2O</td></tr>
<tr><td rowspan="2">ST830W
ST830M
ST830</td><td>CPAP</td><td>4~20cmH_2O</td></tr>
<tr><td>BPAP-S,
BPAP-ST, BPAP-T</td><td>IPAP: 4~30cmH_2O
EPAP: 2~25cmH_2O</td></tr>
<tr><td rowspan="2">SV825M
SV825W</td><td>CPAP</td><td>4~20cmH_2O</td></tr>
<tr><td>ASV, Auto ASV</td><td>4~25cmH_2O,
EPAP: 4~15cmH_2O,
Min PS: 0-6cmH_2O,</td></tr>
</table>

			Max PS:5-20cmH_2O
	AU830Pro	CPAP, APAP	4~20cmH_2O
		Auto BPAP-S	IPAP: 4~25cmH_2O EPAP: 4~25cmH_2O
		BPAP-S,BPAP-ST, BPAP-T	IPAP: 4~30cmH_2O EPAP: 2~25cmH_2O
		ASV, Auto ASV	4~25cmH_2O, EPAP: 4~15cmH_2O, Min PS: 0-6cmH_2O, Max PS:5-20cmH_2O
Air outlet	22 mm conical, compatible with ISO 5356-1:2015 Anaesthetic & Respiratory Equipment – Conical Connectors		
Duration of inspiration	For BPAP-ST mode: Ti Min: 0.1-4.0 sec, Ti Max: 0.3-4.0 sec. For BPAP-T mode: Ti: 0.1-4.0 sec		
Respiratory rate	Only applicable for BPAP-ST and BPAP-T mode, **options**: 5-40 bpm, error is±1 bpm		
Noise	27±2 dB(A) in the operating pressure of 10 cmH_2O		
Water capacity	280±20ml		
Gas temperature of patient connection	≤ 43°C		
Inspiratory and expiratory pressure drop	At a flow rate of 60L/min, the humidifier pressure drop is 0.6 ± 0.2cmH_2O.		
Gas leakage	Less than 5L/min		
Temperature of heating tube	**Options**: OFF, 16~30℃, error is ±1℃		

Specification of heating tube	Inside diameter: 15mm, Length: 1.8±0.1m
Resistance to flow and test flow of heating tube	R@30 L/min: 0.05hPa/l/min
Total compliance and the test pressure of heating tube	C @60hPa: 0.37ml/hPa
Humidification system output	≥12mg/L (Flow measurement tolerance ±6 L/min or 10% of reading, whichever is greater)
Relative humidity	75.8%RH-96.5%RH

Table 2: Maximum flowrate (Flow measurement tolerance ±6 L/min or 10% of reading, whichever is greater)

Test Pressures[a] (cmH_2O)	P_{min}	P_{min} + ¼ (P_{max} - P_{min})	P_{min} + ½ (P_{max} - P_{min})	P_{min} + ¾ (P_{max} - P_{min})	P_{max}
	2	**9**	**16**	**23**	**30**
Measured pressure at the PATIENT-CONNECTION PORT(cmH_2O)	**1.8**	**9.0**	**16.0**	**23.2**	**30.2**
Average flow at the PATIENT-CONNECTION PORT (L/min)	**59.6**	**74.2**	**77.2**	**73.3**	**74.5**

Note: [a] Set pressure rounded to the nearest whole integer **Where** ***P*min is the minimum pressure setting.** ***P*max is the maximum pressure setting.**
Supplementary information: Mode BPAP-ST measured

Table 3: The stability of the static airway pressure accuracy

Pressure(cmH_2O)	**The stability of the static airway pressure accuracy(cmH_2O)**
4	≤0.5
10	≤0.5
20	≤0.5
30	≤0.5

Table 4: The stability of the dynamic airway pressure accuracy, with the medical device operating in CPAP mode in normal condition

Pressure (cmH2O)	The stability of the dynamic airway pressure accuracy(cmH2O)		
	10BPM	15BPM	20BPM
4	≤±1.0	≤±1.0	≤±1.0
8	≤±1.0	≤±1.0	≤±1.0
12	≤±1.0	≤±1.0	≤±1.0
16	≤±1.0	≤±1.0	≤±1.0
20	≤±1.0	≤±1.0	≤±1.0

Table 5: The stability of the dynamic airway pressure accuracy for both the inspiratory and expiratory pressure, with the medical device operating in Bi-level mode in normal condition (Means, Standard Deviations)

Inspiratory (cmH_2O)	10BPM	15BPM	20BPM
6	0.2, 0.106	0.1, 0.104	0.2, 0.080
11	0.2, 0.114	0.2, 0.101	0.4, 0.079
18	0.2, 0.463	0.2, 0.176	0.3, 0.441
25	0.1, 0.429	0, 0.474	0.2, 0.394

30	1.3, 1.001	1.3, 0.822	1.0, 0.526

Expiratory (cmH_2O)	10BPM	15BPM	20BPM
2	0.5, 0.007	0.6, 0.023	0.7, 0.066
7	0.6, 0.026	0.6, 0.018	0.7, 0.040
14	0.9, 0.078	0.9, 0.104	0.9, 0.022
21	1.0, 0.034	1.1, 0.040	1.1, 0.359
25	0.3, 0.203	0.4, 0.080	0.3, 0.034

Note: The figures in the above table are calculated for 60% to 85%of the inspiratory phase and 50% to 80% percent of the expiratory phase.

Table 6: The time required to reach the set temperature of heating tube from a starting temperature of (23°C ± 2°C) when the medial device works in CPAP mode, the pressure is 10cmH_2O and the ambient temperature is 23 degrees

Set temperature (°C)	Time required (s)
24	10-15
25	15-20
26	20-27
27	27-35
28	35-45
29	45-55
30	55-70

.

Table 7: Maximum pressure at the patient connector in normal state and single fault state is shown below:

Model	Maximum pressure in normal state	Maximum pressure in single fault state
CA820M, CA820W, CA820	20cmH_2O	30cmH_2O

BA825W, BA825M, BA825, SV825M SV825W	25cmH_2O	40cmH_2O
SV825W,SV825M	25cmH_2O	40cmH_2O
ST830W, ST830M, ST830, AU830Pro	30cmH_2O	40cmH_2O

⚠ **Caution: The portions of the GAS PATHWAYS through the HUMIDIFIER that can become contaminated with body fluids or expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION.**

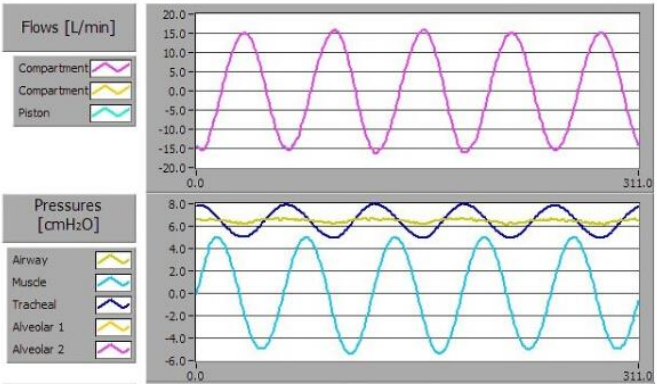
⚠ **Caution: Before the device is used for any patient, the user should ensure compatibility and connection of all parts and accessories in use.**

⚠ **Caution: You should ensure that the patient's treatment pressure is set correctly, and the therapeutic effect of the set should be regularly assessed.**

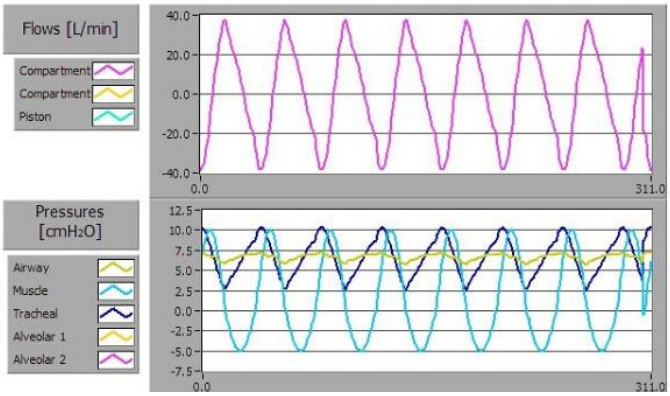
⚠ **Caution: The filtering level of the air filter is greater than or equal to 5μm.**

⚠ **Caution: The pressure / capacity curve for the device is:**

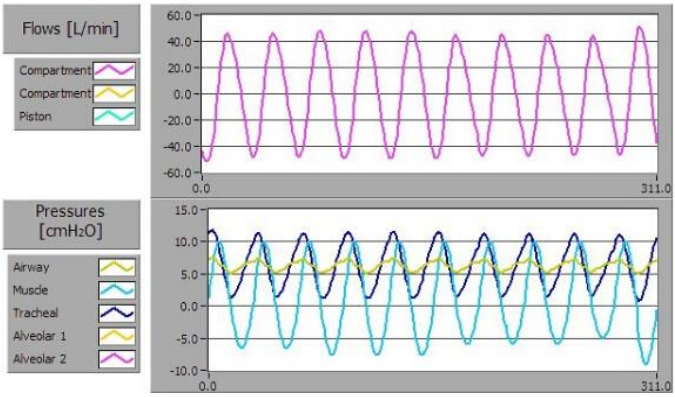
7cmH_2O 10BPM



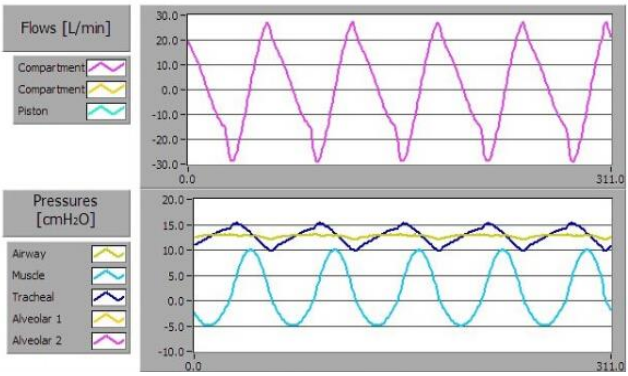
7cmH_2O 15BPM



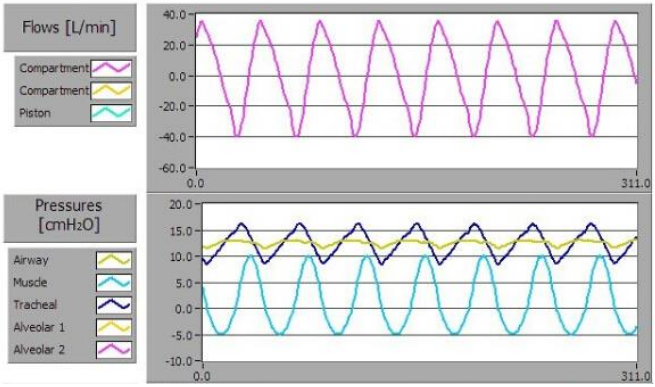
7cmH_2O 20BPM



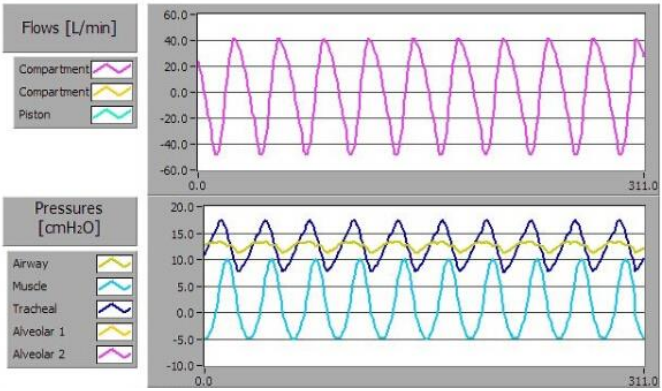
13cmH_20 10BPM



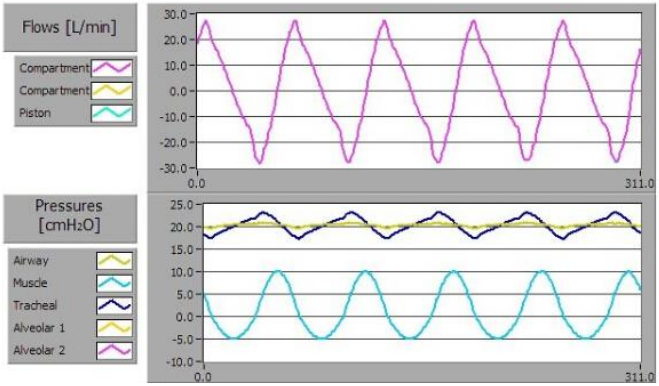
13cmH_20 15BPM



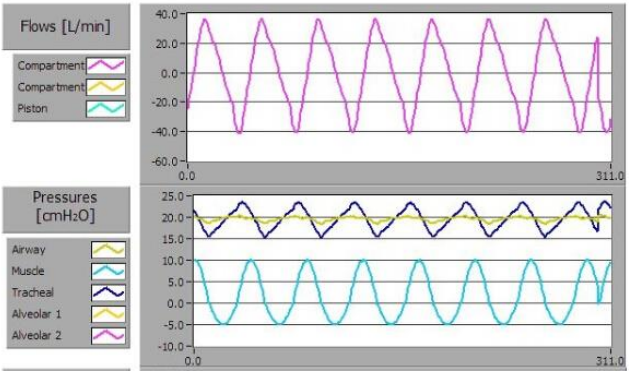
13cmH_20 20BPM



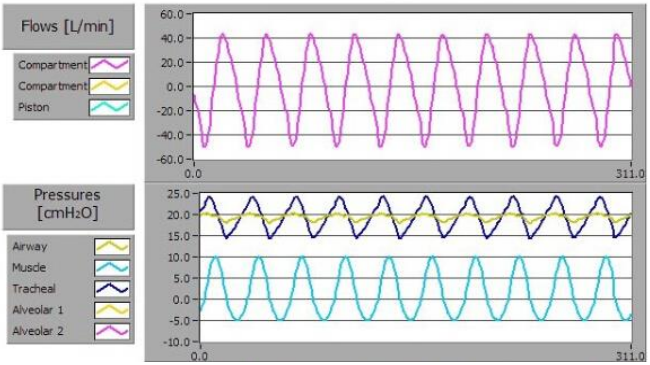
20cmH_20 10BPM



20cmH_20 15BPM



20cmH_20 20BPM



Annex B EMC Information

⚠ **Caution： The Positive Airway Pressure Device fulfills the requirements of EN 60601-1-2:2015, IEC 60601-1-2:2014, IEC 60601-1-11:2015, ISO 80601-2-70:2015, EN ISO 8185:2009.**

⚠ **Caution: Installing and using the device should be according to the random file for electromagnetic compatibility.**

⚠ **Caution: It could cause emission-increase or immunity-reduction of the device when used with unoriginal component or accessories beyond authorized**

⚠ **Warning: Do not use the device with another equipment together or nearby, which has the same work frequency. Ensure the headlight performance to be well if need use it with the-same-working-frequency device together.**

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its function. Therefore, its RF emissions are very low and are not likely to causes any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	Class A	

Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies		
Guidance and manufacturer's declaration – electromagnetic immunity **Guidance and manufacturer's declaration – electromagnetic immunity**			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV air, ± 15kV	Contact: ± 8 kV Air: ± 15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

Radiated Immunity (IEC 610004-4-3)	80 MHz to 2700 MHz 10V/m (rms) 385 MHz 27V/m (rms) 450 MHz 28V/m (rms) 710 MHz, 745 MHz, 780 MHz 9V/m (rms) 810 MHz, 870 MHz, 930 MHz 28V/m (rms) 1720 MHz,1845 MHz, 1970 MHz 28V/m(rms) 2450 MHz 28V/m(rms) 5240 MHz, 5500 MHz, 5785 MHz 9V/m (rms)	10V/m, 80%, Am at 1kHz 27V/m PM at 18Hz 28V/m FM ± 5 kHz deviation at 1 kHz sine 9V/m Pm at 217 Hz 28V/m PM at 18Hz 28V/m PM at 217Hz 28V/m PM at 217Hz 9V/m PM at 217Hz	
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Power supply lines: ± 2 kV	Mains power quality should be that of a typical home or hospital environment.

Surge IEC 61000-4-5	±0.5kV, ± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Line to line: ± 1 kV	Mains power quality should be that of a typical home or hospital environment.
Conducted Immunity (IEC 61000-4-6)	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	
Voltage dips, and Interruption IEC 61000-4-11	0%, 70%, 0% of U_T	0% for 0.5 cycle 0% for 1 cycle 70% for 25 cycles 0% for 250 cycles	Mains power quality should be that of a typical home or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field IEC 61000-4-8	50Hz, 60 Hz 30A/m	50Hz: 30A/m, 60Hz: 30A/m,	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital or home environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

FCC Warning

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.

NOTE 1: 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 andon, 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.
This equipment should be installed and operated with minimum distance 20cm bet ween the radiator & your body.

NOTE 2: Any changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

Operational Description

The model with WiFi module or mobile communication module,also integrated with a Bluetooth chipset, can transmit data from the PAP device to support remote monitor the performance of device and patient compliance to therapy.

Wireless transmitter information

WiFi:

Vcc: 5.0Vdc，IEEE 802.11b/g/n，Transmitting frequency：2.412~2.484GHz, Modulation type: BPSK/QPSK/16-QAM/64-QAM, Gain: 1.5 Dbi

Bluetooth:

Vcc:3.3Vdc, Transmitting frequency: 2.402GHz-2.480GHz ISM, Modulation Type: GFSK; Gain：1.5 Dbi

LTE:

Vcc:5.0Vdc, LTE Bandwidths of 1.4/3/5/10 MHz in Band 12 (Part 27），1.4/3/5/10/15/20 MHz in Band 2 and Band 4(Part 24 and 27). The maximum antenna gain is 1.0 dBi.

EC REP

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