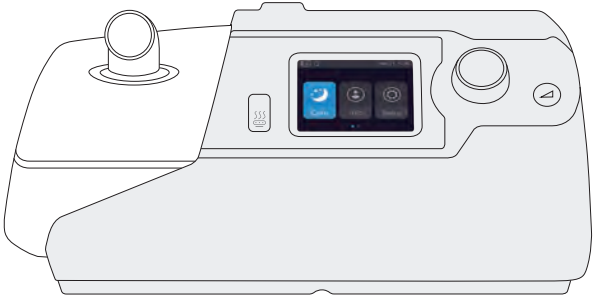
hypnus



Positive Airway Pressure Device

User Manual

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510530 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

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;
- Safekeep 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 supplier immediately.

The parts are as follows:
- Main Unit
- Humidifier
- Power Adapter
- Mask
- 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.

Warnings and Cautions

⚠Warning: This product should be used in conjunction with the Hypnus humidifier and mask, associated (or recommended) air tubing and other accessories. The accessories should have CE certification. The use of unauthorized accessories can weaken the therapy effect, or cause other potential safety hazards.

⚠Warning: 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.

⚠Warning:
- Do not use this device in a magnetic resonance environment.
- Do not use this device in a polluted environment.
- Do not use this device in an environment with flammable and explosive gases.
- Do not operate the device without enclosure, avoid personal injury and electric shock hazard.
- Do not place the device directly on carpets, fabrics or other flammable materials.

● Do not immerse the device in water. Do not let any fluids enter the device.
● 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.
● Do not perform any maintenance and disassembly when the device is running.
● Do not place the device in or on any container that can collect condensation.
● The device must not be covered or placed in a position where its operation or performance may be adversely affected.
● If the mask or accessory is not used to reduce CO_2 re-inhalation, or if there is spontaneous breathing, it may lead to suffocation.
● Sources of oxygen must be located more than 1m from the equipment to avoid the risk of fire and burns.
● 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.
● Failure to use a MASK or ACCESSORY that permits spontaneous breathing can cause asphyxiation.
● Not to position the medical device to make it difficult to operate the disconnection device.
● Filter air inlet shouldn't be blocked.

⚠Warning: 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 supplier.

⚠Caution:
● Prevent the tubing from twisting or knotting so that air output smoothly.
● To ensure safe operation, unplug the power cord from the home's power outlet before removing the power adapter.
● Periodically check the power adapter, power cord and interfaces. Replace immediately if damaged to ensure safe operation of the device.
● Keep the device away from pets, insects or children, children maybe strangulated due to cables and hoses.
● Trigger mode: Flow trigger.
● 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.
● When transporting the humidifier, drain all water within it. Do not move the humidifier when there is water inside.
● 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 supplier.
● 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.
● The last set parameters are stored in the device after the power failure is restored.
● The devices are not intended for use with patient whose upper airways have been bypassed.
● 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.
● The patient is an intended operator, patient can install, disassemble, maintain, clean and disinfect the medical device.
● 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 (MRL), Radiofrequency interference.

Table of Contents

Chapter 1 Overview

1.1 Product name

Positive airway pressure device

1.2 Model Introduction

Model	Mode	Max pressure (cmH_2O)	Functional module
CP720	CPAP	20	No
CA720W	CPAP, APAP	20	Humidifier heating module, heating tube module, WiFi module
CA720M	CPAP, APAP	20	Humidifier heating module, heating tube module, mobile communication module
CA720W-B	CPAP, APAP	20	Humidifier heating module, heating tube module, WiFi module
CA720	CPAP, APAP	20	Humidifier heating module, heating tube module
CA720W-HB	CPAP, APAP	20	Humidifier heating module, WiFi module
CA720-HB	CPAP, APAP	20	Humidifier heating module
CB725W	CPAP, BPBP-S	25	Humidifier heating module, heating tube module, WiFi module
CB725M	CPAP, BPAP-S	25	Humidifier heating module, heating tube module, mobile communication module
BA720W	CPAP, BPAP-S, Auto BPAP-S	20	Humidifier heating module, heating tube module, WiFi module
BA720M	CPAP, BPAP-S, Auto BPAP-S	20	Humidifier heating module, heating tube module, mobile communication module
BA720W-B	CPAP, BPAP-S, Auto BPAP-S	20	Humidifier heating module, heating tube module, WiFi module
BA725W	CPAP, BPAP-S, Auto BPAP-S	25	Humidifier heating module, heating tube module, WiFi module
BA725M	CPAP, BPAP-S, Auto BPAP-S	25	Humidifier heating module, heating tube module, mobile communication module
BA725W-B	CPAP, BPAP-S, Auto BPAP-S	25	Humidifier heating module, heating tube module, WiFi module
BA725	CPAP, BPAP-S, Auto BPAP-S	25	Humidifier heating module, heating tube module
ST720W	CPAP, BPAP-S, Auto BPAP-S BPAP-ST, BPAP-T	20	Humidifier heating module, heating tube module, WiFi module

ST720M	CPAP, BPAP-S, Auto BPAP-S BPAP-ST, BPAP-T	20	Humidifier heating module, heating tube module, mobile communication module
ST720W-B	CPAP, BPAP-S, Auto BPAP-S BPAP-ST, BPAP-T	20	Humidifier heating module, heating tube module, WiFi module
ST725W	CPAP, BPAP-S, Auto BPAP-S BPAP-ST, BPAP-T	25	Humidifier heating module, heating tube module, WiFi module
ST725M	CPAP, BPAP-S, Auto BPAP-S BPAP-ST, BPAP-T	25	Humidifier heating module, heating tube module, mobile communication module
ST725W-B	CPAP, BPAP-S, Auto BPAP-S BPAP-ST, BPAP-T	25	Humidifier heating module, heating tube module, WiFi module
ST730	CPAP, BPAP-S, Auto BPAP-S BPAP-ST, BPAP-T	30	Humidifier heating module, heating tube module
ST730W	CPAP, BPAP-S, Auto BPAP-S BPAP-ST, BPAP-T	30	Humidifier heating module, heating tube module, WiFi module
ST730M	CPAP, BPAP-S, Auto BPAP-S BPAP-ST, BPAP-T	30	Humidifier heating module, heating tube module, mobile communication module

ST730W-B	CPAP, BPAP-S, Auto BPAP-S BPAP-ST, BPAP-T	30	Humidifier heating module, heating tube module, WiFi module
AU725W	CPAP, APAP, BPAP-S, Auto BPAP-S, BPAP-ST, BPAP-T	25	Humidifier heating module, heating tube module, WiFi module
AU725M	CPAP, APAP, BPAP-S, Auto BPAP-S, BPAP-ST, BPAP-T	25	Humidifier heating module, heating tube module, mobile communication module
AU730W	CPAP, APAP, BPAP-S, Auto BPAP-S, BPAP-ST, BPAP-T	30	Humidifier heating module, heating tube module, WiFi module
AU730M	CPAP, APAP, BPAP-S, Auto BPAP-S, BPAP-ST, BPAP-T	30	Humidifier heating module, heating tube module, mobile communication module

The main unit of each model has two colours, black and white.

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 describes the operation modes available.

Modes
CPAP A fixed pressure is delivered.
APAP Delivers CPAP therapy with optional Expiratory Pressure Relief. Automatically adjusts the CPAP pressure in response to snore, hypopneas and apneas.
BPAP-S (Spontaneous) 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 IPAP and EPAP in response to hypopneas, snore and apneas. Min EPAP and Max IPAP restrict the delivered pressure range.
BPAP-ST (Spontaneous/Timed) 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 (Timed) The fixed breath rate and the fixed inspiration/expiration time set by the clinician is supplied regardless of patient effort.

An apnea is scored when there is reduction in breathing by 75% of the flow baseline breathing for at least 10 seconds. A hypopnea is scored when there is a reduction in breathing by 50% of baseline breathing with partial upper airway obstruction for at least 10 seconds.

1.3 Structure and Components

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

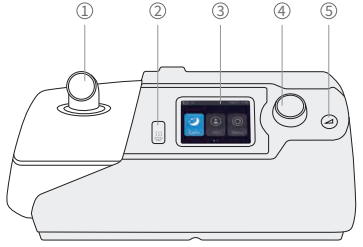


Figure 1 Font view

① Air outlet
② Power supply interface of heating tube
③ Display screen
④ Dial
⑤ Ramp button

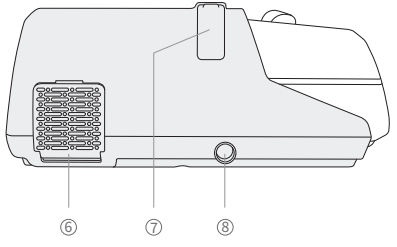


Figure 2 Rear view

⑥ Air inlet/Air filter
⑦ SD card slot
⑧ Power input

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

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.

1.4 Intended Use

The device is indicated to provide non-invasive ventilator support to treat patients weighing over 30kg with Obstructive Sleep Apnea (OSA). This device is intended for hospital and home use. It cannot be intended for those patients who are dependent on mechanical ventilation.

1.5 Contraindications

This product does not apply to the following contraindications:

(1) Absolute contraindications: pneumothorax, mediastinal emphysema; cerebrospinal fluid leakage, craniocerebral trauma or intracranial trauma or intracranial pneumatosis; shock caused by various causes and not treated; active phase of epistaxis; upper gastrointestinal bleeding that has not been effectively controlled; coma or associated with disturbance of consciousness that cannot receive or meet requirements for mask treatment; huge vocal cord polyps, etc.

(2) Relative contraindications: severe coronary heart disease with left-sided heart failure; acute otitis media; respiratory secretions accompanied with coughing and asthenia; weak spontaneous respiration (except for T mode); tracheal intubation (nasal or oral) and tracheotomy; severe nasal congestion caused due to different reasons; pulmonary bullae; respiratory mask allergy, etc.

⚠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.

1.6 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.

1.7 Environment Requirements

	Operating Conditions	Storage and Transport Conditions
Temperature	5°C~40°C	-20°C~55°C
Relative Humidity	20%~93%	10%~93%, non-condensation
Atmospheric Pressure	70 kPa~106 kPa	70 kPa ~106 kPa
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.

1.8 Symbol Instructions

	Humidifier is cooling		Caution, consult accompanying documents
	Humidifier has connected	IP21	Protect against solid foreign objects of 12,5 mm ∅ and greater, protect against vertically falling water drops
	Humidifier is preheating		Separately dispose electrical and electronic equipment as per EC Directive 2002/96/EC.
	Heating tube has connected	CE 0123	Separately dispose electrical and electronic equipment as per EC Directive 2002/96/EC.
	Type BF Applied Part	EC REP	Authorized Representative in the European Community
	Recyclable		Refer to instruction manual / booklet
	Class II equipment		Short-circuit proof safety isolating transformer
	Only for indoor use		Manufacturer

SN	Serial number	LOT	Batch code
	Keep dry		Fragile, handle with care
	This way up		Keep away from sunlight
	Temperature limit		Atmospheric pressure limitation
	Humidity limitation		

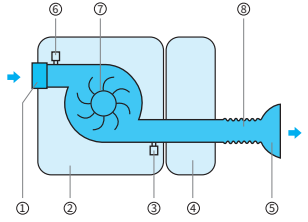
Chapter 2 Product brief introduction

2.1 Work principle

The device mainly includes the main unit, humidifier, heating tube(optional) mask and the power adapter. The main unit is composed of fans, control circuits and sensors, and should be used with the air tubing and mask. Based on the preset settings, the device

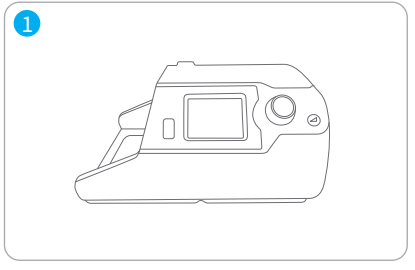
outputs a certain level of positive airway pressure and air flow through the tubing and nasal mask, to the patient's upper respiratory tract. It keeps the patient's upper airway open and clear through the positive pressure airflow, thus eliminating snoring during sleep, low ventilation and sleep apnea.

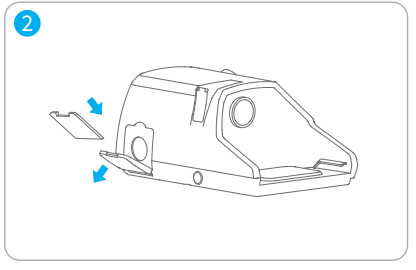
The pneumatic schematic diagram is shown below:

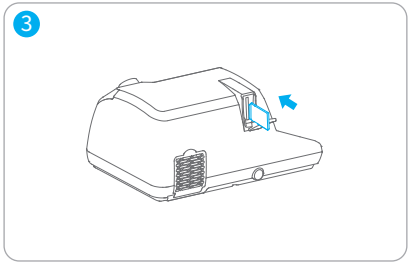


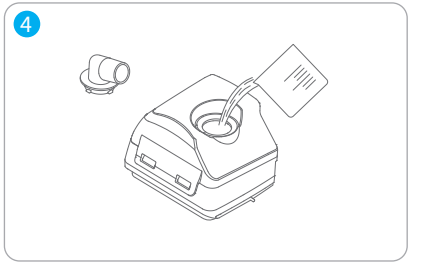
① Air filter	⑤ Mask
② Positive airway pressure device	⑥ Flow sensor
③ Pressure sensor	⑦ Blower
④ Humidifier	⑧ Air tubing

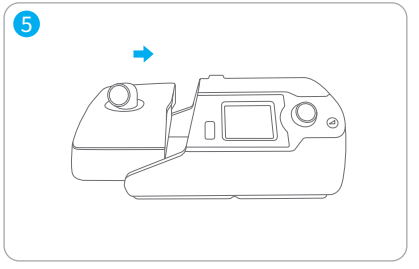
2.2 Install the medical device

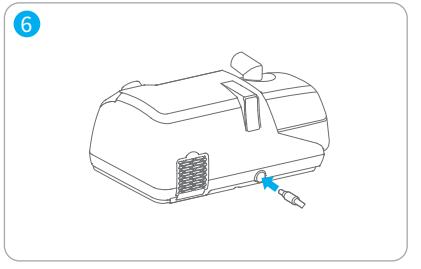


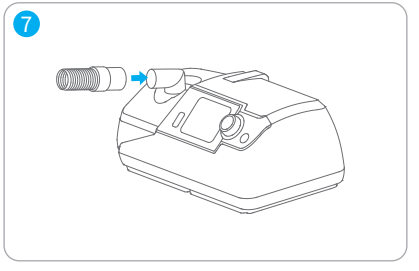


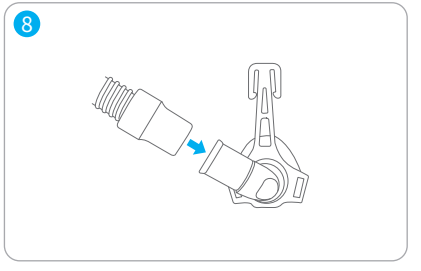












1.Place the device on a stable level surface;
2.Insert air filter into the device;
3.Insert SD card into the device;
4.Fill the humidifier with distilled water or purified water;
5.Insert the humidifier into the side of the device;
6.Connect the power adapter;
7.Connect air tubing to the air outlet of device;
8.Connect another side of air tubing to mask.

⚠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.

2.3 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.

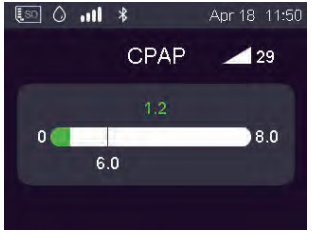


Figure 3 Treatment Interface

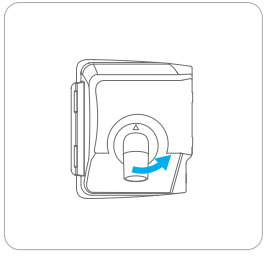
⚠Caution: The treatment interface may vary depending on the treatment mode.
⚠Caution: Regularly observe water level in the humidifier, when water level lower than the minimum water line, water should be added in time (please use distilled water or purified water), but not exceed the highest water line. Excessive watering may cause damage to the humidifier or cause water to flow into the air inlet.
⚠Warning: Be sure to follow the doctor's established parameters and working conditions.

2.4 Stopping therapy

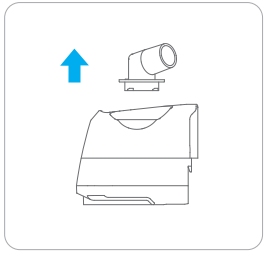
1. Remove the mask.
2. Press the dial to stop therapy, or if SmartStop is enabled, therapy will stop automatically after a few seconds. The treatment data is saved to the SD card.

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

2.5 Water the humidifier



1



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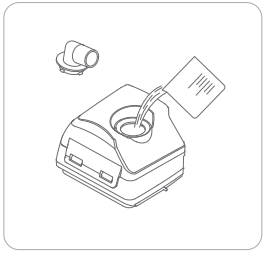


3

1. Pull off air tubing, then remove humidifier from the device.
2. Rotate the air outlet of the humidifier and remove it, fill humidifier with water.
3. Close the air outlet of humidifier and insert humidifier into the side of the device.

⚠**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.

Chapter 3 Menu parameter settings

3.1 User Settings

3.1.1 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.

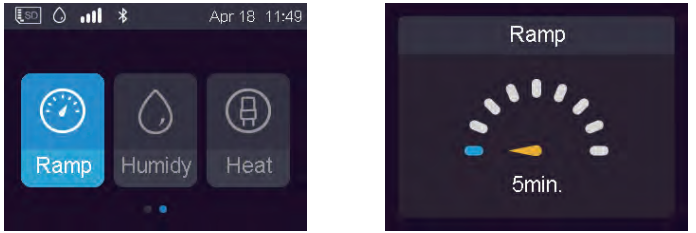


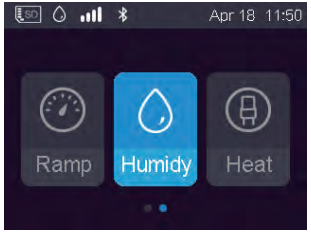
Figure 4 Ramp Time

3.1.2 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 Humidy 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.



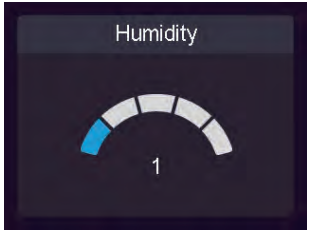


Figure 5 Humidity Level

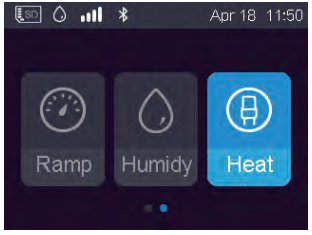
⚠**Caution:** CP720 cannot set humidity level.

3.1.3 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°C.



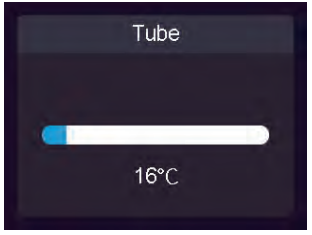


Figure 6 Heating tube temperature

⚠**Caution:** CP720, CA720W-HB, CA720-HB cannot set heating tube temperature.

3.1.4 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.

3.1.5 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, Mask, Smart Start, Smart Stop, Start Pressure, Temperature Unit, Airplane Mode, and Time Setting, detail information about these functions are listed in the following table.

Functions	Description
LEDs	Sets the indicator lights ON or OFF. The indicator lights including the LED around the Dial and humidifier indicator.
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.

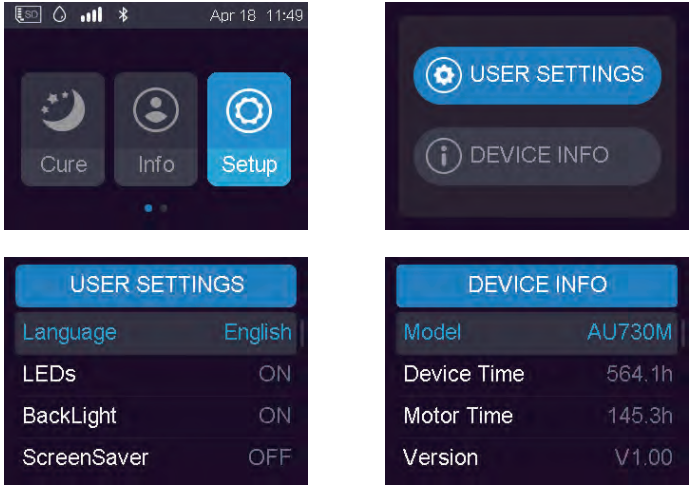


Figure 7 More parameters

3.1.6 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.

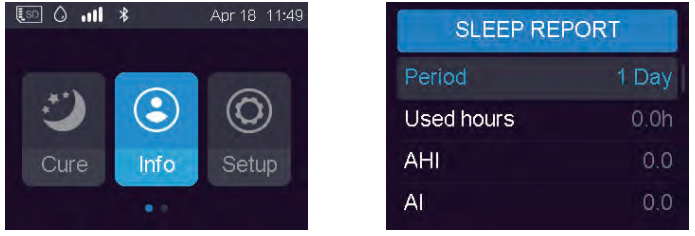


Figure 8 Sleep report

3.2 Clinical settings

⚠**Warning:** Only medical professionals can enter the clinical parameter interface to set the clinical parameters.

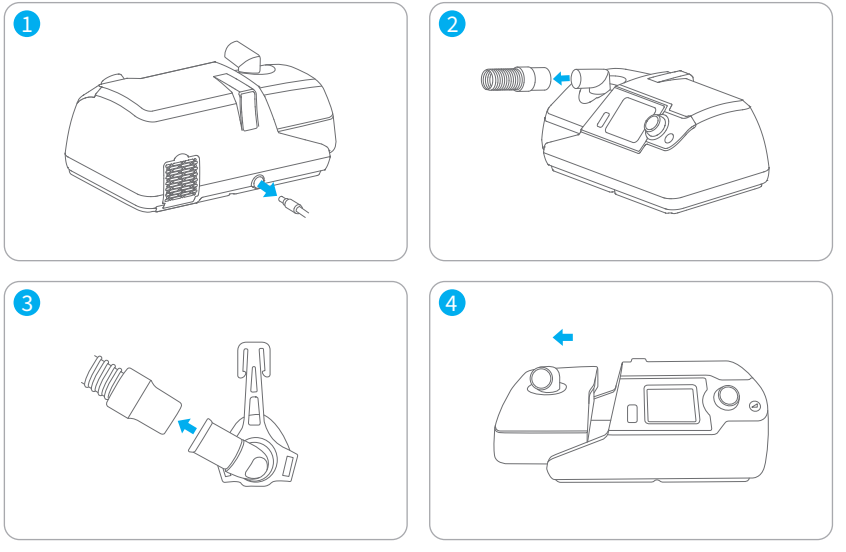
- Rotate the dial the highlight Setup, then press the dial and ramp button at the same time to enter the clinical settings interface, if users want to modify the parameter values, turn the dial to highlight clinical parameter and then press the dial, turn the dial to adjust the clinical parameter and press the dial to save the change.

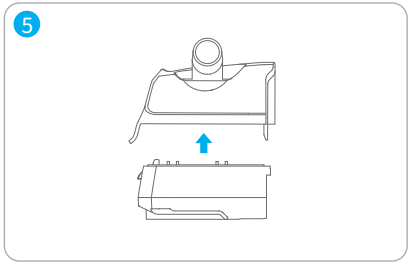
- Turn the dial to scroll down to view more detailed usage data.

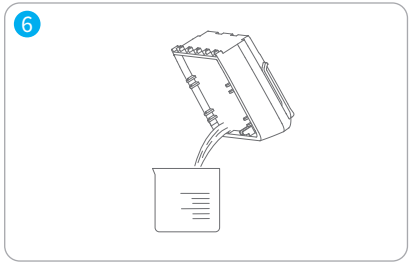
⚠**Caution:** Pressing ramp button can return to previous menu.

Chapter 4 Cleaning and Maintenance

4.1 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. Press the device, pull the humidifier away from the device;
5. Open two clasps of the humidifier;
6. Pour the rest of water and clean the humidifier.

4.2 Maintenance

- The device should be switched on, checked once a quarter, and its functions should be tested to ensure it works properly.
- The air tubing of should be fixed firmly, avoid being rough movements, excessive pulling, eventually crack and leakage.
- Inspect the mask and air tubing before use to ensure there are not holes, tears or cracks.
- The air filter needs to be replaced at least every three months. If air filter contains holes or is blocked by dirt, please replace the air filter immediately. To 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 Replace the air filter cover.

- After operating for 1,000 hours, the device should have complete maintenance, all consumables should be replaced.
- 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.
- 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.

4.3 Cleaning and disinfection

Cleaning

- Gently wipe the exterior of the device with a soft wet towel, if necessary, wipe the front panel with 75% alcohol, swipe 10 times in the same place, do not let any liquids enter the device.
- Clean the humidifier with mild detergent and rinse in clean water, then wipe the inside and outside of the humidifier with dry towel every day.
- Clean the heating tube with mild detergent in clean water, then rinse thoroughly and hung it to dry every week. The maximum number of repeatable cleanings is 52. Heating tube doesn't need to be disinfected and sterilized.

Disinfecting

- The device should be disinfected every 3-6 months if it is used by the same patient, the device must be disinfected before transfer another patient.

● Ultraviolet irradiation with intensity of 70 uW/cm2 for 30 minutes or connecting ozone to the pipe of device for 1 hour to disinfect the exterior of the device.
● Before air outlet disinfection, please wash the humidifier thoroughly.
● The disinfection procedures of air outlet is showed below, only one disinfection process needs to be performed:

High level thermal	Hot water: 90°C for 1 minute OR 75°C for 30 minutes
High level chemical	CIDES OPA Ortho-phthalaldehyde for 12 minutes Gigasept FF 5% for 15 minutes

⚠**Warning:** Please unplug the power cord from the power outlet during cleaning or routine maintenance.
⚠**Caution:** Please use the air filters only provided by the Hypnus.
⚠**Caution:** The humidifier's electrical heating section and the interface are wiped clean with a clean soft damp cloth, cannot be immersed in disinfectant solution, so as not to affect heating function.
⚠**Caution:** The device doesn't need to be calibrated.

4.4 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 not connected	Connect power supply again. Ensure the power cable is connected
Insufficient air delivered from the device	Ramp Time is in use	Wait for air pressure to build up
	Air filter is dirty	Replace air filter
	Air tubing is kinked or punctured	Avoid extruding air tubing, remove the blocking material or replace tubing
	The set pressure is too low	Appropriate increase pressure
	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
	Mask bottom is pressing tightly against the skin	Adjust the headgear

Excessive noise	Connect air tubing wrongly	Connect air tubing properly
Humidifier doesn't work	Device cannot detect humidifier	Reconnect humidifier
	There isn't water in humidifier	Add water to the humidifier
	The set temperature is high than environment temperature	Reset the heating temperature
Heating tube doesn't work	Device cannot detect heating tube	Reconnect heating tube, ensure the power supply of the device is normal
System malfunction reminder	Electrical wiring loose or component malfunction	Please contact your provider or Hypnus
Excessive pressure reminder	Electrical wiring loose or component malfunction	Please contact your provider or Hypnus
Severe air leakage reminder	Leak of air tubing, mask, humidifier	Check whether air tubing, mask and humidifier connect reliably.
	Humidifier and main unit didn't connect properly	Reconnect humidifier
There is condensate water in air tubing	Humidified level is too high	Decrease humidified level

Chapter 5 Product Service Life

5.1 Lifetime

The service life of this device is 5 years. Heating tube isn't single-use device, the maximum number of reuse is 365 times, the maximum period of reuse is 12 months, the shelf-life is 36 months if heating tube is unpacked in storage conditions. 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).

5.2 Waste Disposal

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

5.3 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 6 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. Hypnus will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel in parts repair.

⚠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.

Annex A Technical Specifications

IEC 60601-1 classifications	Class II, type BF		
Ingress protection	IP21		
Continues working time	Continues working time isn't less than 8 hours		
Power supply	Adapter: input: 100-240VAC, 50/60Hz, 1.5A Output: 24VDC		
Power input of heating plate	24VDC, 1.2A		
Power input of heating tube	24VDC, 1.2A		
Pressure display accuracy	±(2% full scale (40cmH_2O) + 4% actual pressure)		
Operating pressure range	Model	Mode	Operating pressure range
	CP720	CPAP	4~20cmH_2O
	CA720W CA720M CA720W-B CA720W-HB CA720 CA720-HB	CPAP, APAP	4~20cmH_2O

Operating pressure range	CB725W CB725M	CPAP	4~20cmH₂O
		BPAP-S	IPAP: 4~25cmH₂O EPAP: 4~25cmH₂O
	BA720W BA720M BA720W-B	CPAP	4~20cmH₂O
		BPAP-S, Auto BPAP-S	IPAP: 4~20cmH₂O EPAP: 4~20cmH₂O
	BA725W BA725M BA725W-B BA725	CPAP	4~20cmH₂O
		BPAP-S, Auto BPAP-S	IPAP: 4~25cmH₂O EPAP: 4~25cmH₂O
	ST720W ST720M ST720W-B	CPAP	4~20cmH₂O
		BPAP-S, Auto BPAP-S, BPAP-ST, BPAP-T	IPAP: 4~20cmH₂O EPAP: 4~20cmH₂O
	ST725W ST725M ST725W-B	CPAP	4~20cmH₂O
		BPAP-S, Auto BPAP-S, BPAP-ST, BPAP-T	IPAP: 4~25cmH₂O EPAP: 4~25cmH₂O
	ST730 ST730W ST730M ST730W-B	CPAP	4~20cmH₂O
		BPAP-S, Auto BPAP-S	IPAP: 4~25cmH₂O EPAP: 4~25cmH₂O
		BPAP-ST, BPAP-T	IPAP: 4~30cmH₂O, EPAP: 4~25cmH₂O

Operating pressure range	AU725W AU725M	CPAP	4~20cmH₂O
		BPAP-S, Auto BPAP-S, BPAP-ST, BPAP-T	IPAP: 4~25cmH₂O EPAP: 4~25cmH₂O
	AU730W AU730M	CPAP	4~20cmH₂O
		BPAP-S, Auto BPAP-S	IPAP: 4~25cmH₂O EPAP: 4~25cmH₂O
		BPAP-ST, BPAP-T	IPAP: 4~30cmH₂O, EPAP: 4~25cmH₂O
Air outlet	22 mm conical, compatible with ISO 5356-1:2015 Anaesthetic & Respiratory Equipment – Conical Connectors		
I:E Ratio	Only applicable for BPAP-ST and BPAP-T mode, options: 1:1~1:6, error is ±10%		
Respiratory rate	Only applicable for BPAP-ST and BPAP-T mode, options: 5-40 bpm, error is±1 bpm		
Noise	Noise ≤29dB(A) in the operating pressure of 10 cmH₂O		
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 ± 0.2cmH₂O.		

Gas leakage	Less than 5L/min
Temperature of heating tube	Options: OFF, 16~30°C, error is ±1°C
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
Relative humidity	75.8%RH-96.5%RH

Flowrate performance at set pressures

	P_{min}	$P_{min}+1/3(P_{max}-P_{min})$	$P_{min}+2/3(P_{max}-P_{min})$	P_{max}
Set pressure (cmH_2O)	4	13	21	30
Average flow(L/min)	65±5	75±5	93±5	75±5

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

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

Pressure(cmH_2O)	The stability of the dynamic airway pressure accuracy(cmH_2O)
4	≤0.9
8	≤0.9
12	≤0.6
16	≤0.6
20	≤0.5

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

Inspiratory (cmH_2O)	Expiratory (cmH_2O)	The stability of the dynamic airway pressure accuracy for inspiratory pressure (cmH_2O)	The stability of the dynamic airway pressure accuracy for expiratory pressure (cmH_2O)
8	4	≤0.7	≤0.6
13	9	≤0.3	≤1.3
19	15	≤0.2	≤1
26	22	≤1	≤0.9
30	25	≤0.7	≤1.54

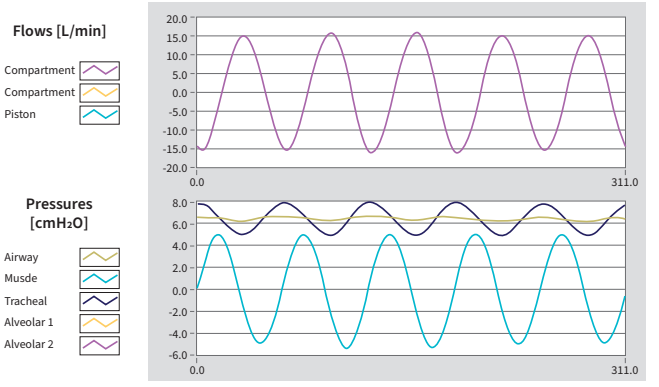
The time required to reach the set temperature of heating tube from a starting temperature of (23°C ± 2°C) when the medial device works in CPAP mode, the pressure is 10cmH_2O and the ambient temperature is 23 degrees

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

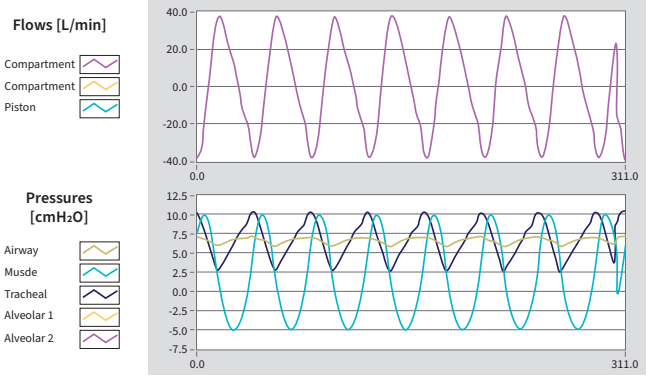
Maximum pressure at the patient connector in normal state and single fault state is shown below:

Model	Maximum pressure in normal state	Maximum pressure in single fault state
CP720, CA720W, CA720M, CA720W-B, CA720, CA720W-HB, CA720-HB, BA720W, BA720M, BA720W-B, ST720W, ST720M, ST720W-B	20cmH_2O	30cmH_2O
CB725W, CB725M, BA725W, BA725M, BA725W-B, BA725, ST725W, ST725M, ST725W-B, AU725W, AU725M	25cmH_2O	40cmH_2O
ST730, ST730W, ST730M, ST730W-B, AU730W, AU730M	30cmH_2O	40cmH_2O

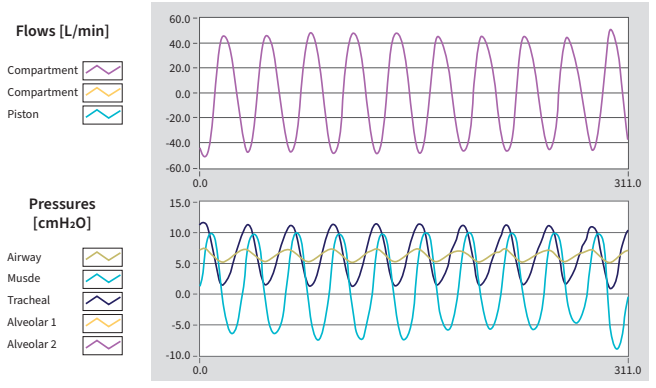
⚠**Caution:** Before the device is used for any patient, the user should ensure compatibility and connection of all parts and accessories in use.
⚠**Caution:** You should ensure that the patient's treatment pressure is set correctly, and the therapeutic effect of the set should be regularly assessed.
⚠**Caution:** The filtering level of the air filter is greater than or equal to 5μm.
⚠**Caution:** The pressure / capacity curve for the device is:



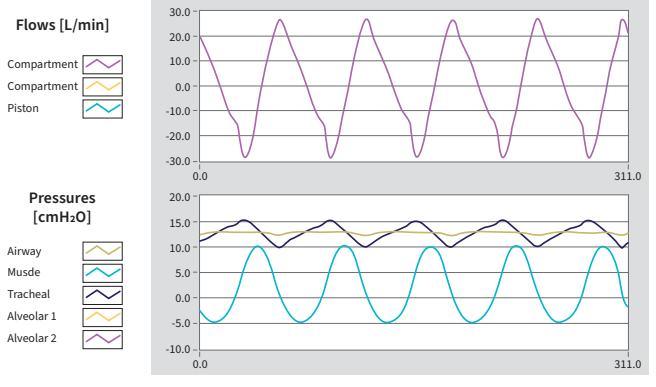
7cmH_2O 10BPM



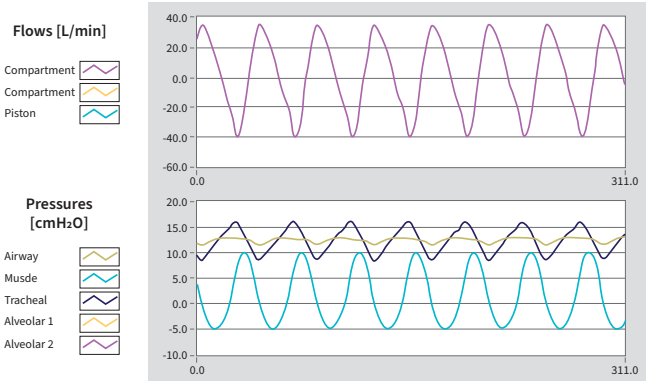
7cmH_2O 15BPM



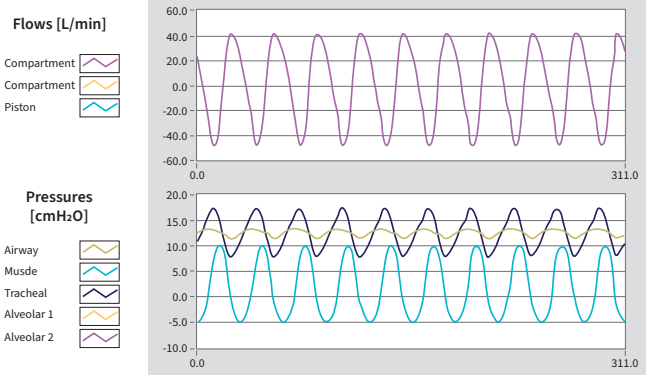
7cmH₂O 20BPM



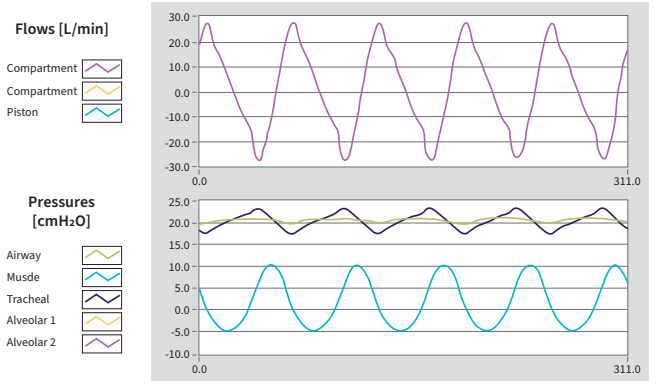
13cmH₂O 10BPM



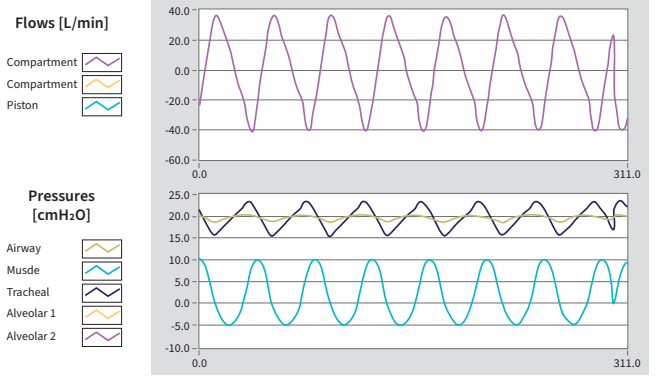
13cmH₂O 15BPM



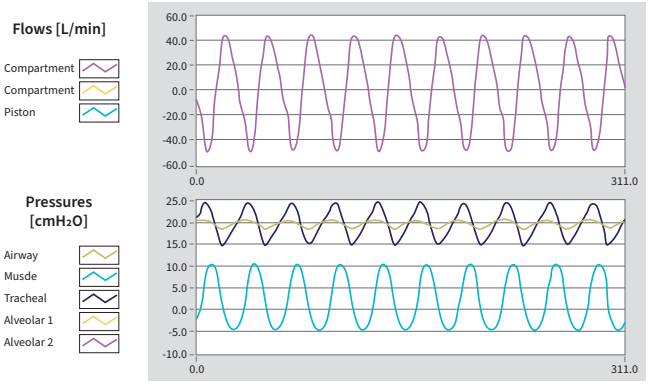
13cmH₂O 20BPM



20cmH₂O 10BPM



20cmH₂O 15BPM



20cmH₂O 20BPM

Annex B EMC Information

⚠Caution: The Continuous 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.			