



## BreathCare PAP Positive Airway Pressure Units

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# Content

## **Welcome**

The YH-480A is Yuwell's Auto Continuous Positive Airway Pressure devices (Auto CPAP).

## **Warning**

Read this entire user manual before using the device.

## **Caution**

This device is restricted to sale by or on the order of a physician.

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## 1. Warnings and cautions

### Warning

- Do not maintain the device while it is in use, otherwise it may lead to unacceptable risk.
- Do not modify this equipment without authorization of the manufacturer or open this device by yourself, contact your provider or Yuwell when the device need to be repaired.
- This device cannot be used for life support. It may be shut down by turning off the electricity, but no unacceptable risk will happen.
- The device can't be used in the environment where the air is mixed with flammable anesthetic gases or nitrous oxide gases. (Non-AP and Non-APG series PAP)
- The sources of oxygen must be located more than 1 m from the device to avoid the risk of fire and burns.
- Supplemental oxygen must not be used while smoking or in the presence of an open flame.
- Always make sure that the device is turned on and airflow generated before the oxygen supply is turned on. Always turn the oxygen supply off before the device is turned off, so that unused oxygen will not accumulate within the device enclosure or create a risk of fire.
- Make sure that you arrange the cables and heated tubing so that they will not twist around the head or neck. Otherwise it may result in strangulation.
- If you notice any unexplained change in the performance of the device, if it is making unusual sounds, if the device or the power supply are dropped or mishandled, or if the enclosure is broken, discontinue use and power off the equipment, then contact your provider or Yuwell.
- Do not place the device where it can be bumped or where someone is likely to trip over the power cord.
- Do not block the heated tubing and/or air inlet of the device while in operation otherwise it could cause overheating of the device.
- Keep the area around the device dry, clean and clear of anything (e.g. clothes, bedding, lint, dust or direct sunlight) that could block the air inlet, cover the power supply unit, affect patients' breathing or reduce the life of device.
- Place the device on the stable table. Placing device on the soft, out of flatness surface is forbidden.
- Keep the device far away from water.
- Make sure the power cord and plug are in good condition and the equipment is not damaged.
- Keep the power cord away from hot surfaces.
- Beware of electrocution. Do not immerse the device, power supply or power cord in water. If liquids are spilled into or onto the device. Unplug the device and let the parts dry naturally and contact your provider or Yuwell.
- Always unplug the device before cleaning and make sure that all parts are dry before plugging it back in.
- This device cannot be used for multiple patients.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Interconnection of this equipment to other equipment which is not the supply one is forbidden.
- 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 minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation.
- Keep device far away from the following environments, e.g. magnetic fields, electromagnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources and so on.
- Do not block the several holes in your mask, otherwise it will result in strangulation.
- Humidity performance of the device can be compromised when used outside the specified ambient temperature range or humidity range.
- The performance of the device can be compromised when exposed to environment, for example, electrocautery, electrosurgery, defibrillation, X-ray(gamma radiation), infrared radiation, conducted transient magnetic fields, magnetic resonance imaging (MRI), and radiofrequency interference.
- When the device is used near the children or disabled persons, the device must be supervised. Do not let the children or disabled persons inhale or swallow small parts. Otherwise, it may result in choking.
- Keep the area around the device dry, clean and clear of anything (eg, pets, pests or children) that could affect the device hygiene, drop the device, and so on.
- The device is intended for single patient use only. Do not let others use it.
- 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.
- Do not use the humidifier above an altitude of 3000 meters or outside a temperature of +5 °C ~ 35 °C . Using the humidifier outside of this temperature range or above this altitude can affect the humidifier performance.
- 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.

### Caution

- Using only Yuwell part and accessories with device. Non-Yuwell parts may reduce effectiveness of the treatment and/or damage the device.
- Use only vented masks recommended by Yuwell or by your doctor with this device. Fitting the mask without the device blowing air can result in rebreathing of exhaled air. Make sure that the mask vent holes are kept clear and unblocked to maintain the flow of the fresh air into the mask.

- If you use the humidifier, always place the device on a level surface lower than your head to prevent the mask and heated tubing from filling with water.
- Leave the water tank to cool for ten minutes before handling to allow the water to cool and to make sure that the water tank is not too hot to touch.
- Make sure that the water tank is empty before transporting the device.
- The proper placement and positioning of the mask on the face is critical to the consistent operation of this equipment.
- Not intended for use with patient whose upper airways have been bypassed.
- The time required for the device to warm from the minimum storage temperature between uses until the device is ready for its intended use when the ambient temperature is 20 °C is about 2 hours.
- The time required for the device to cool from the maximum storage temperature between uses until the device is ready for its intended use when the ambient temperature is 20 °C is about 2 hours.
- This device is not intended for children, and patients who are physically or mentally deficient can't use the device without assistance or supervision.
- The patient is an intended operator at home.

## 2. Introduction

The YH-480A self-adjusting device is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients weighing more than 66 lb(30 kg). It is intended for home and hospital/institutional use. The YH-480A consists of main device, water tank, power adapter and cable. Mask and heated tubing are purchased.

## 3. Scope of application

BreathCare PAP is a kind of the device which provides positive airway pressure to patient's airway. This therapy can make patient sleep better.

## 4. Contraindications and adverse effects

### ► 4.1 Contraindications:

Positive airway pressure therapy may be contraindicated in some patients with the following preexisting conditions:

- Severe bullous lung disease
- Pneumothorax
- pathologically low blood pressure
- Dehydration
- Cerebrospinal fluid leak
- Recent cranial surgery or trauma

### ► 4.2 Adverse effects:

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

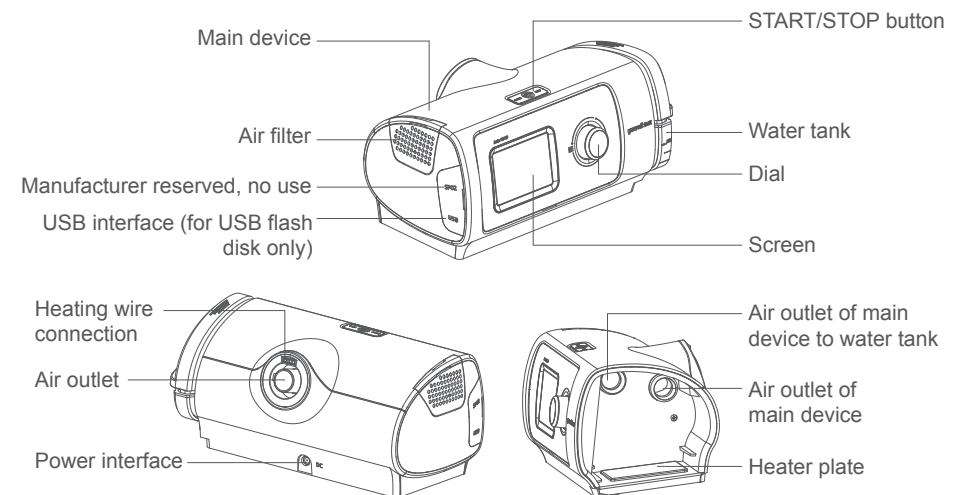
The following adverse reactions may arise during the course of therapy with the device:

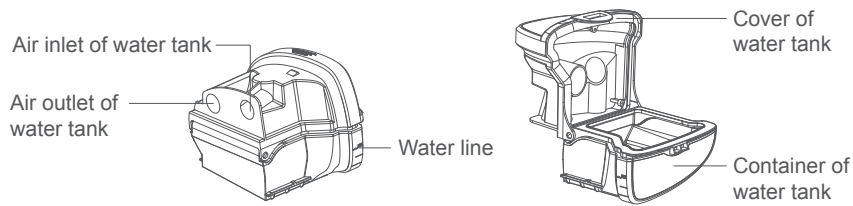
- Drying of mouth, nose, or throat
- Nosebleed
- Bloating
- Ear or sinus discomfort
- Eye irritation
- Skin rashes

## 5. Package table



Item	Quantity	Item	Quantity
Main device	1	Mask (with mask accessories)	1
Water tank	1	Air filter	2
Heated tubing	1	User manual	1
Power adapter and Cable(as part of the device)	1	Bag	1

## 6. Picture and explanation for product



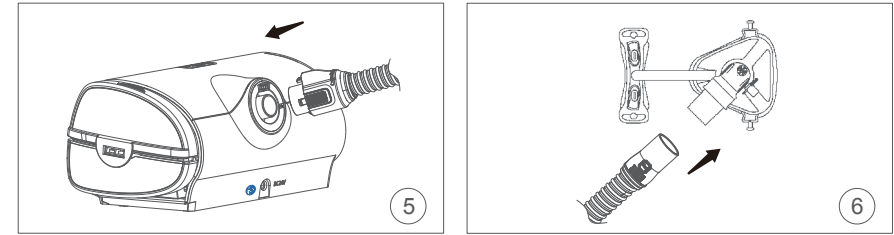
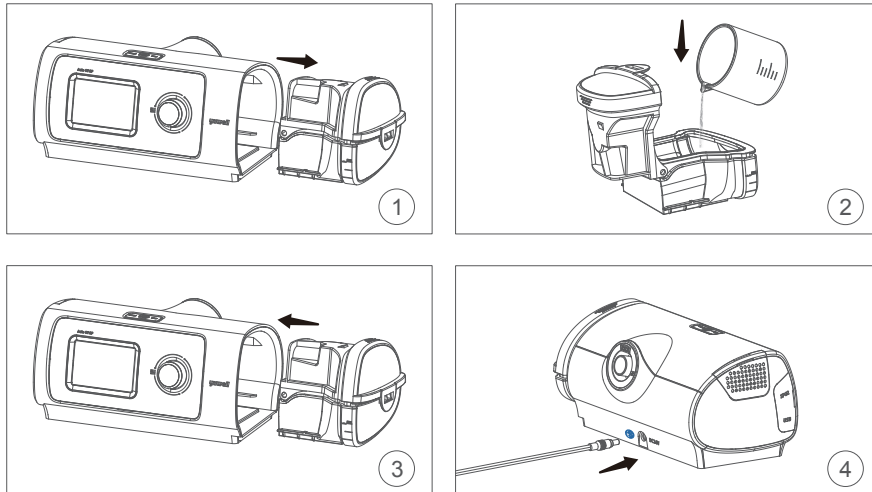


## 7. Explanation of button

	<p>START/ STOP button: press to start /stop therapy.</p>
	<p>Dial: turn to navigate the menu and press to select an option. Turn to adjust the options and press to save your choice.</p>

## 8. Installation

The following section will help you install your device by yourself



1. Place the device on a stable level surface; Hold the water tank at the top and bottom, press it gently and pull it away from the device;
2. Open the water tank and fill it with distilled water up to the maximum water level mark. Do not fill the water tank with hot water;
3. Close the water tank and insert it into the side of the device;
4. Plug the power connector into the rear of the device;
5. Connect the heated tubing firmly to the air outlet located on the rear of the device;
6. Fit your mask correctly (refer to the mask manual) and connect the free end of the heated tubing firmly onto the mask and press the start button to begin treatment.

### ⚠ Caution

- Please change the distilled water in the water tank every day.
- Do not add the distilled water above the maximum water level mark, in case the water may enter the heated tubing and the device.
- Appliance coupler or mains plug is used as the isolation means from mains supply, not to position the equipment so that it is difficult to operate the disconnection device.
- When the humidity level is 6 and the therapy pressure is 20 cmH<sub>2</sub>O, 8 hours is an expected duration of operation before refills.

## 9. Therapy

### ► 9.1 Start therapy

1. Power on your device;
2. Fit your mask;
3. Press Start / Stop button or breathe normally if Smart Start / Stop is enabled, therapy will start. During the therapy, the real-time average pressure, the set pressure, the ramp time (min), and the humidity level will all be displayed on the screen;
4. During the ramp time, the pressure increased gradually until the setting pressure has been reached;
5. The screen will go black automatically after about one minute. You can press any button to turn it back on.

### ⚠ Caution:

- When the level of the humidity is 1-6 and the device is delivering gas pressure, the heating plate will heat (including the situations that the screen shows "Large Leakage" and the backlight of the screen is off).

- When the level of the humidity is 0, the heating plate is not heating. Also if the device is not delivering gas pressure, the heating plate will not heat either.

## ▶ 9.2 Stop therapy

1. Remove your mask;
2. Press the Start / Stop button or the therapy will stop automatically after about one minute when the Smart Start / Stop is enabled;
3. To power off your device, please separate the plug from the electricity.

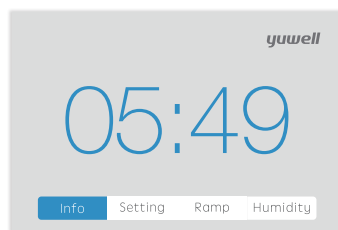
## 10. Function

### ▶ 10.1 Function that patient can safely use

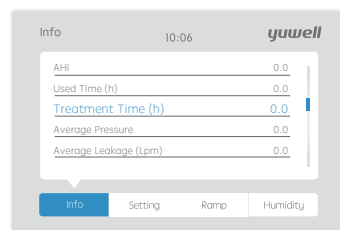
#### 10.1.1 Information:

You can read summary of sleep report on information page. Following parameters will be displayed.

- **AHI:** Indicates the number of apneas and hypopneas per hour.
- **Used Time (h):** The time duration for the last therapy (h).
- **Treatment Time (h):** The time of the patient wore the mask (h).
- **Average Pressure:** The average pressure for the last therapy (cmH<sub>2</sub>O/ hPa).
- **Average Leakage (Lpm):** Average air leak volume per minute for the last therapy (LPM).
- **Total Time (h):** The total time after the last therapy time (h).
- **P90:** The pressure for the 90 percent of the last therapy (cmH<sub>2</sub>O/hPa).
- **Version:** Software version number used for the device.
- **SN:** The serial number of device.



Picture 1-1: Home



Picture 1-2: Information


#### 10.1.2 Setting:

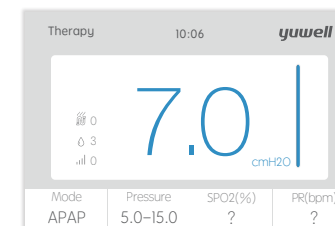
Your device has been set up for your needs by your care provider, but you may find you want to make small adjustments to make your therapy more comfortable. Highlight setting and press the dial to see your current settings. From here, you can personalize your options.

- **Wisdom Humidifying:** Enable this function, device can moistens the air automatically according to the environment condition.
- **Heated Tube:** You can set the heating level between 0 to 5, where 0 means this function is disabled, 1 is the lowest heating level, and 5 is the highest heating level. The heated tubing is used to heat the air, so that the treatment will become more comfortable. The heating level of the

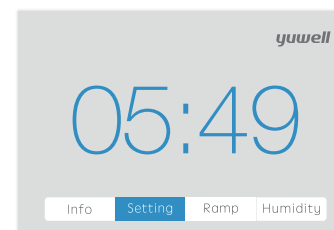
heated tubing (0-5 level) equivalent to the following temperature (accuracy  $\pm 2^{\circ}\text{C}$ ). (The following temperatures were measured with the humidification off and the wisdom humidification off)

0 : OFF      1 : 18°C      2 : 21°C      3 : 23°C      4 : 25°C      5 : 28°C

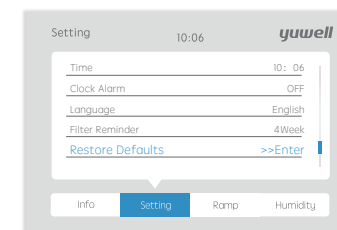
When the heated tubing is properly connected to the device, the therapy page will display the heating line icon , as shown in the figure:



- **Sound Reminder :** Enable this function, if abnormal air leakage occurs, the device will give a sound reminder.
- **Smart Start/Stop:** When this function is enabled, therapy starts automatically when you breathe into your mask. When you remove your mask, it will stop automatically after 1minute.
- **FPS Level:** When this function is enabled, you may find it easier to breathe out. This can help you get used to therapy. You can set the humidity level between 0 to 3, where 0 means this function is disabled, 1 is the lowest level of FPS, and 3 is the highest level of FPS. The higher FPS level means more comfortable expiration you will get.
- **Backlight (%) :** You can set the back light of the screen. The range of setting is 0-100%.
- **Date:** You can adjust time shown on the screen, include year, month and date.
- **Time:** You can adjust time shown on the screen, include hour and minute.
- **Clock Alarm:** Enable this function, you can setting time of clock as well.
- **Language:** You can choose English or Chinese.
- **Filter Remind:** Enable this function, this can notice you when to check and change filter.
- **Restore Defaults:** This function can restore the device parameters to the factory defaults.



Picture 2-1 : Home



Picture 2-2: Setting

#### 10.1.3 Ramp:

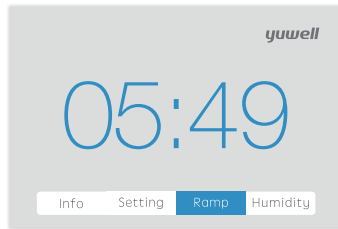
Ramp time designed to make you more comfortable at the beginning of the therapy; you can adjust the ramp time from 0 to 45 minute with an increment of 5min.

### To adjust the ramp:

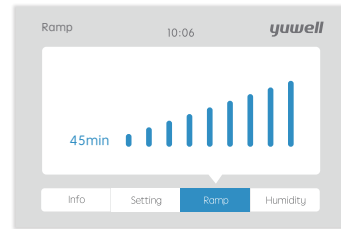
Highlight the ramp time, and press dial to see your current setting;

Press dial and rotate it to adjust your setting;

Press dial to save your change.



Picture 3-1: Home



Picture 3-2: Ramp

#### 10.1.4 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 between 0 to 6, where 0 means disable this function, 1 means the lowest level of the humidity and 6 represent the highest level of the humidity. If the humidity level is 1 to 6, it means that the heater plate is heating when the device is running.

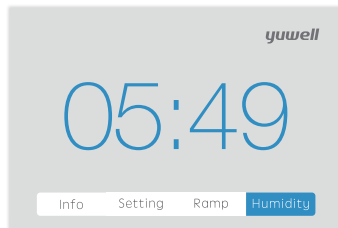
The temperature of each level on the heater plate is as following (accuracy is  $\pm 4^{\circ}\text{C}$ )

1 : 33 $^{\circ}\text{C}$     2 : 35 $^{\circ}\text{C}$     3 : 40 $^{\circ}\text{C}$     4 : 45 $^{\circ}\text{C}$     5 : 50 $^{\circ}\text{C}$     6 : 55 $^{\circ}\text{C}$

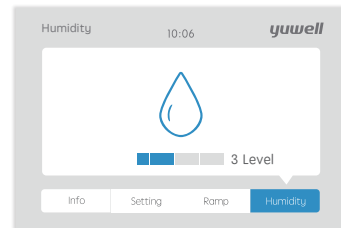
This temperature has been tested with empty water tank. The time required (warm-up time) to reach the set temperature from a starting temperature of (23 $^{\circ}\text{C} \pm 2^{\circ}\text{C}$ ) is 10 minutes.

#### To adjust the humidity level:

- Highlight the humidity level, press dial enter the humidity page;
- Press the dial and rotate it choose humidity level ,then press dial again to save your change and back to home page;
- You can change humidity level at any time during therapy.



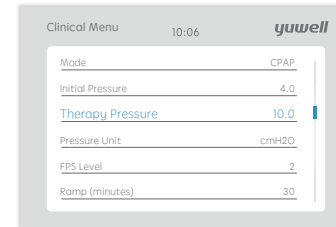
Picture 4-1: Home



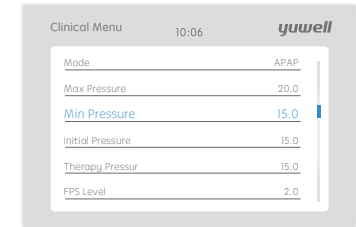
Picture 4-2: humidity

► 10.2 Function that patient must be used under the direction of doctor(Clinical menu):

The patient should use the device by the direction of physician.



Picture 5-1: Clinical menu (CPAP)



Picture 5-2: Clinical menu (APAP)

#### 10.2.1 Set Mode ( CPAP or APAP )

- At home page, press and hold START/STOP button and dial at the same time for three seconds, the clinical menu will be shown on screen (see picture 5-1).
- Rotate the dial, highlight the “Mode”, and then select CPAP or APAP.
- After mode setting, press dial to save your change.
- Highlight the “Back”, press dial to back to home page.

#### 10.2.2 Set Pressure

- At clinical page, choose “CPAP” mode, Highlight “Initial Pressure” or “Therapy Pressure”, press and rotate dial to set suitable value.
- You can rotate the dial to the right or to the left to rise or decrease therapy pressure (each step is 0.5 cmH<sub>2</sub>O / hPa).
- After setting therapy pressure, press dial to save your change.
- Highlight the “Back”, press dial to back to home page.
- You can set “Max Pressure”, “Min Pressure”, “Therapy Pressure” and “Initial Pressure” of APAP mode according to above method.

#### ⚠ Notice:

When you try to make the Max pressure lower than Min pressure, or Initial pressure, the device will let these three pressures at same value automatically.

#### 10.2.3 Set Pressure Unit

- At clinical page, highlight “Pressure Unit”.
- Rotate the dial to the right or left, set your pressure unit (cmH<sub>2</sub>O or hPa).
- After setting pressure unit, highlight the “Back”, press dial to back to home page.

#### 10.2.4 Set FPS Level:

- At clinical page, Highlight “FPS Level”.
- Rotate the dial to the right or left, set your level of FPS (0-3 level).
- After setting level of FPS, highlight the “Back”, press dial to back to home page.

#### 10.2.5 Set Ramp:

- At clinical page, Highlight “Ramp”.
- Rotate the dial to the right or left, set your ramp time (0-45minutes, step value is 5 minutes).
- After setting Ramp, highlight the “Back”, press dial to back to home page.

### 10.2.6 Set Humidity Level

- At clinical page, Highlight "Humidity Level".
- Rotate the dial to the right or left, set your humidity level (0-6level, step value is 1 level).
- After setting humidity level, highlight the "Back", press dial to back to home page.

### 10.2.7 Erase Data

- At clinical page, Highlight "Erase Data".
- Press the dial to the page where you can choose OK or Cancel about erase data.
- If you choose OK, your therapy data will all be erased.

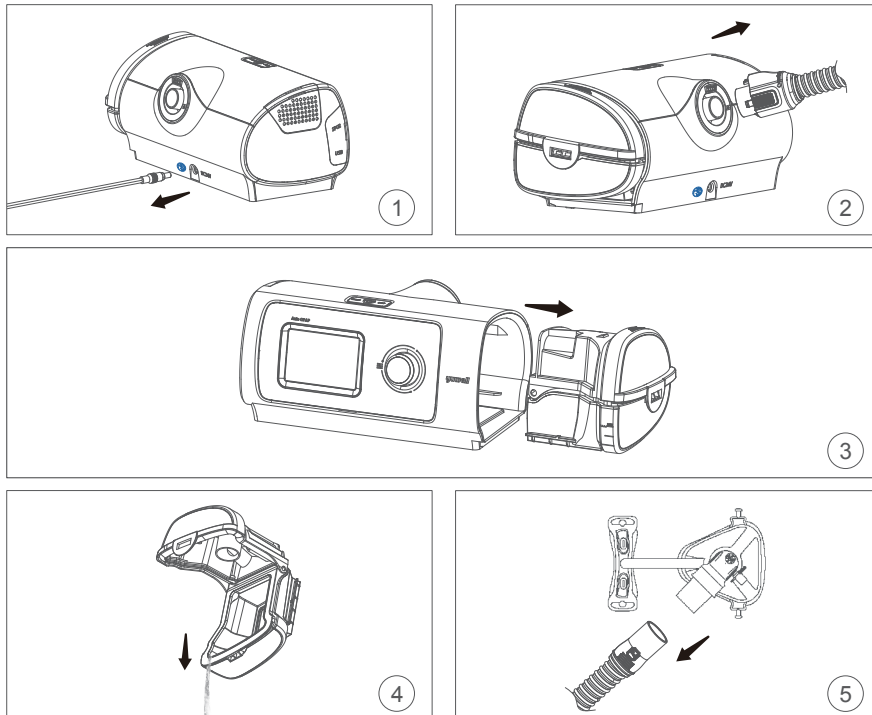
#### ⚠ Caution:

During your therapy, you can go to clinical menu by pressing and holding dial and START/STOP button at the same time for three seconds. Section 10.2 clinical menu tells the method to change all the parameters.

## 11. Caring for your device

It is important that you regularly clean your device to make sure you receive optimal therapy. The following sections will help you with disassembling, cleaning, checking, reassembling your device.

### ► 11.1 Disassembling



1. Pull the power connector out of device;
2. Press the snap on the heated tubing and gently pull it out of the machine;
3. Hold the water tank at the top and bottom, press it gently and pull it away from the device;
4. Open the water tank and pour out the left water;
5. Hold both the cuff of the heated tubing and the swivel of the mask, then gently pull apart.

⚠ **Notice:** Don't pull the threaded portion of the heated tubing.

### ► 11.2 Cleaning

#### ⚠ WARNINGS!

- Regular cleaning of the device and its accessories is very important for the prevention of respiratory infections.
- To avoid electric shock, always unplug the device before cleaning.
- Use mild soap that is nontoxic to humans.
- Before cleaning, check whether the device has been disconnected from the power supply, whether the power cord has been unplugged, and whether the water tank of the device has cooled down. Make sure the plate has cooled down to room temperature, so you do not get burned.
- Do not open or modify the device. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorized service agent.

#### ⚠ CAUTIONS!

- Overheating of the materials could lead to early fatigue of these materials.
- Do not clean the device with bleach, chlorine, ozone, UV light, aromatic solution, moisturizing factor, antibacterial soaps, sesame oil, or any other methods outside of this manual.
- Do not immerse the device in any fluids.

### 11.2.1 Cleaning the Water Tank

You can clean the water tank with a soft cloth which does not scratch the water tank (dip the soft cloth in liquid soap if necessary), rinse it thoroughly, and then wipe it dry with a soft cloth.

#### ⚠ WARNINGS!

- Emptying and cleaning the water tank daily will help prevent mold and bacteria growth.
- Allow the water in the chamber to cool down to room temperature before removing it from the device.

#### ⚠ CAUTIONS!

- Clean the water tank only after the water in it cools. Make sure that no water enters the device.
- After cleaning, rinse the water tank thoroughly in clean water to make sure that no soap residue is left; then wipe it dry with a lint-free cloth, so as to prevent calcareous accumulations.
- Inspect the water tank for any leak or damage. Replace the water tank if any damage is present.
- It is recommended to do daily cleaning of the water chamber.

### 11.2.2 Cleaning the Enclosure

Wipe the surface of the device with a soft, slightly damp cloth.

#### ⚠ CAUTIONS!

- The device can only be used after the enclosure is dry, so that no moisture enters the device.
- It is recommended to clean the enclosure once a week.

### ► 11.3 Checking:

You should check power adapter and cable, water tank, heated tubing and air filter regularly in case of any damage.

#### a. Check the power adapter and cable

- Wipe the power adapter and cable with the dry compress if it is dirty.
- Replace the power adapter and cable if it is broken.

#### b. Check the water tank

- Replace the water tank if it is broken or cracked.
- Replace the water tank if the seal is torn or cracked.

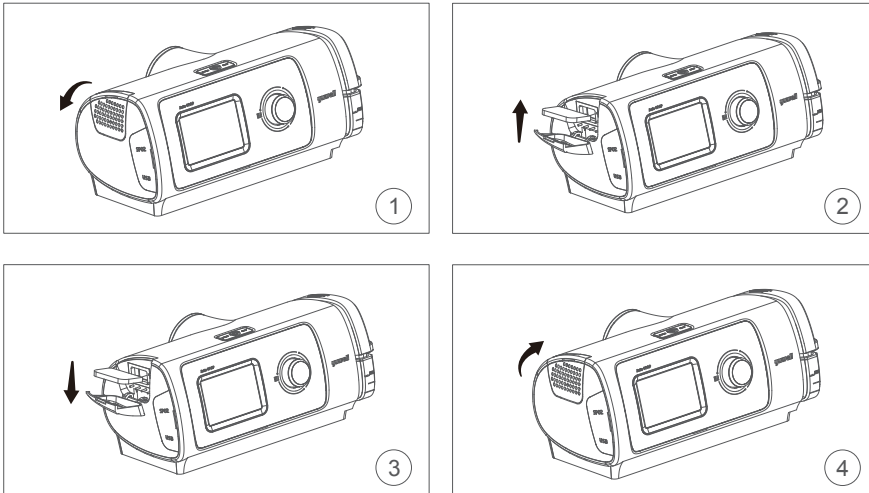
#### c. Check the heated tubing

- Replace the heated tubing if there are any holes, tears or cracks.

#### d. Check the air filter

- Please check the air filter every week and replace the air filter at least every four weeks.
- If you find some particle blocked in the air filter, replace it more often.

### To replace the air filter



1. Open the air filter cover;
2. Remove the dirty air filter;
3. Place a new air filter onto the air filter cover;
4. Close the air filter cover.

### ⚠ Caution:

Make sure the air filter is fitted at all times to prevent water and dust from entering the device.

### ► 11.4 Reassembling:

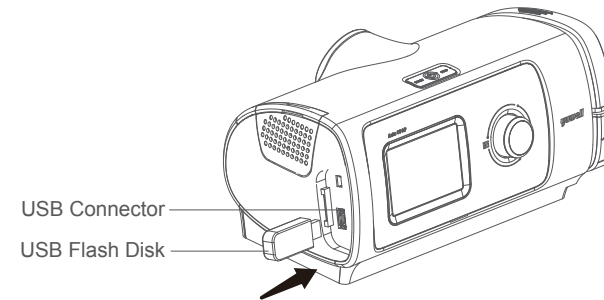
After finished all the cleaning steps, reassemble all these parts together. When the water tank and heated tubing are dry, you can reassemble the parts.

- Open the water tank and fill it with distilled room temperature water up to the maximum water level mark.
- Close the water tank and insert it into the side of the device.
- Connect the heated tubing firmly to the air outlet located on the rear of the device.
- Connect the free end of the heated tubing firmly onto the assembled mask.

## 12. Therapy data

The device records your therapy data for you and your care provider so they can view and make changes to your therapy if required.

The data is recorded in your therapy device and then transferred to your care provider via a USB Flash Disk.



1. Open the cover at the left side of the device;
2. After the machine page is transferred to the home page, push the USB Flash Disk into the USB Connector;
3. Remove the USB Flash Disk from the device after it wrote success.

## 13. Traveling

You can take your device with you wherever you go. Just keep the following in mind.


- Use the travel bag provided to prevent damage to the device.
- Empty the water tank and pack it separately in the travel bag.
- Make sure you have the appropriate power cord for the region you are traveling to. For information on purchasing, contact your provider or Yuwell.

## 14. Trouble shooting

When your device has trouble, look for the following table to find solution. Contact your physician, your provider or Yuwell if you cannot solve your problem. Do not try to open the device.

► 14.1 General troubleshooting:

Trouble	Cause	Solution
Air is leaking from around my mask.	Mask may be fitted incorrectly; The size of the mask is not suitable.	Ensure your mask is fitted correctly; See your mask user guide to check your mask fit and seal; Please refer to the nose measurement card to choose the appropriate mask size.
I am getting a dry or blocked nose.	Humidity level may set too low; For the blocked nose: History of nasal disease; The pressure parameter may be set improperly.	Adjust the humidity level; Use after treatment by a doctor; Adjust the pressure parameter.
I am getting droplets of water on my nose, in the mask and heated tubing.	The humidity level may be set too high; Condensation forms in the piping mask due to cold weather.	Adjust the humidity level; Open the heated tubing to solve condensation.
My mouth is very dry and uncomfortable.	Air may be escape from your mouth; The humidity level is not on or may be set too low.	You may need a chin strap to keep your mouth closed or a full face mask; Increase the humidity level.
Air pressure in my mask seems too high (it feels like I am getting too much air).	Ramp may be turned off; The pressure parameter may be set too high.	Enable your ramp option; Decrease the pressure.
Air pressure in my mask seems too low (it feels like I am not getting enough air).	Ramp may be in progress; The pressure parameter may be set too low.	Start your therapy after the setting pressure reached or turn ramp time off; Increase the pressure.
My screen is black.	After therapy start, the screen backlight went off; In other case, the power do not connect firmly.	Press dial to turn on the screen light; Check the connection of power, ensure it connect with device firmly.
My water tank is leaking.	Water tank assemble incorrectly or it is broken.	Check the water assemble correctly; Contact your provider or Yuwell if your water tank is broken.

The heated tubing does not work.	The heated tubing is not properly connected; The function of the heated tubing is not enabled; The heated tubing is broken.	Checking the connection of the heated tubing, when the connection is successful, the icon  will be shown in the therapy page; Enable the heated tubing function in the setting page; Or contact your provider or Yuwell.
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► 14.2 Other trouble:

Message in LCD	Meaning of error	Solution
ERROR 1	There is a mistake of pressure sensor	Please contact your provider or Yuwell
ERROR 2	There is a mistake of flow sensor	Please repower your device or contact your provider or Yuwell
ERROR 3	There is a mistake of temperature sensor	Please contact your provider or Yuwell
ERROR 4	Functional safety detection is abnormal	Please contact your provider or Yuwell
ERROR 5	There is a parameter out of the corresponding range	Please repower the device or contact your provider or Yuwell
ERROR 6	The pressure is out of range	Replace the filter with a new one or repower the device or contact your provider or Yuwell
ERROR 7	It is failed to supply power to the humidifier	Please contact your provider or Yuwell
ERROR 8	There is a mistake of blower	Please contact your provider or Yuwell
ERROR 9	There is a mistake of RTC ( loss power )	Please adjust the time of the device or contact your provider or Yuwell

## 15. Specification of technology

Items	Specifies
Power	Input :100-240VAC, 50-60Hz, 2Amax Output:24V DC, 5A
Heated tubing	Power supply connection: 0-24VDC, 2A (max) Connection port output: 0-24VDC, 2A (max)









Environment conditions	Temperature	Operate: +5°C ~ 35°C (+41°F ~ 95°F) Non-condensing Transport and storage: -20°C ~ 70°C (-4°F ~ 158°F) Non-condensing
	Humidity	Operate: relative humidity 15%-90% Non-condensing Transport and storage: relative humidity 15%-90% Non-condensing
	Atmospheric pressure range	700 hPa~1060 hPa
	Altitude	≤3000 m
Protection class	Type of Protection Against Electric Shock: Class II Degree of Protection Against Ingress of Water: IP21 (the device) IP22 (the Power adapter) Degree of Protection Against Electric Shock: Type BF Applied Part	
Mode of operation	Continuous operation	
Maximum single fault steady pressure	Device will shut down in the presence of a single fault if the steady state pressure exceeds: 40 cmH <sub>2</sub> O	
Sound	Sound pressure level	Sound pressure level measured according to ISO 80601-2-70:2015 (CPAP mode) : 28±2 dB (A)
	Sound power level	Sound power level measured according to ISO 80601-2-70:2015 (CPAP mode) : 36±2 dB (A)
Physical properties	Dimensions (length*width*height)	285 mm*155 mm*125 mm or 11.2" * 6.1" * 4.9"
	Weight	About 1500 g
	Heated tubing	Plastic hose, about 1.8 m
	Maximum volume of water tank	260 ± 10 mL
	Air outlet	22 mm (complies with ISO 5356-1:2015)











Temperature	Maximum temperature of heater plate	55°C ±4°C ( 131°F ±14.4°F )				
	Cut-out	110°C (if it is damaged, return to manufacturer)				
	Maximum gas temperature	43°C				
Air filter	Material: Polyester non-woven fiber Average arrestance: ≥ 85% for~2.5 micron dust					
Therapy pressure	4~20 hPa (adjustable, step is 0.5 hPa) or 4~20 cmH <sub>2</sub> O					
Initial pressure	4~20 hPa (adjustable, step is 0.5 hPa) or 4~20 cmH <sub>2</sub> O					
Maximum pressure	4~20 hPa (adjustable, step is 0.5 hPa) or 4~20 cmH <sub>2</sub> O					
Minimum pressure	4~20 hPa (≤ maximum pressure, adjustable, step is 0.5 hPa) or 4~20 cmH <sub>2</sub> O					
Ramp	0~45 minutes (adjustable, step is 5 minutes)					
Gas leakage	2 L/min at the maximum rated pressure					
Maximum flowrate	The performance of the device at set pressure according to ISO 80601-2-70:2015 is shown below					
	Test pressures(hPa)	4	8	12	16	20
	Average flow at the PATIENT-CONNECTION PORT (L/min)	≥100	≥100	≥100	≥100	≥100
Pneumatic flow path:						
<pre> graph LR     Atmosphere --&gt; Filter     Filter --&gt; Blower     Blower --&gt; Air_tube[Air tube]     Air_tube --&gt; Mask     Blower --- Flow_sensor[Flow sensor]     Blower --- Pressure_sensor[Pressure sensor]     Air_tube --- Leak     </pre>						
Humidifier performance	Humidification system output: ≥ 12 mg/L (The humidifier belongs to Category 2 according to the standard ISO 80601-2-74:2017) Relative humidity: ≥ 50%					

Pressure accuracy	Maximum static pressure variation according to ISO 80601-2- 70:2015 ± [2% of the full scale +4% of the set value]		
	Maximum dynamic pressure variation according to ISO 80601-2-70:2015		
	Pressure(cmH <sub>2</sub> O)	10 bpm	15 bpm
	4	± [2% of the full scale +4% of the set value]	
	8	± [2% of the full scale +4% of the set value]	
	12	± [2% of the full scale +4% of the set value]	
	16	± [2% of the full scale +4% of the set value]	
20	± [2% of the full scale +4% of the set value]		
Maximum limited pressure	The maximum limited pressure 20 cmH <sub>2</sub> O in normal condition 40 cmH <sub>2</sub> O under single fault Condition		
The Uncertainty of measurement:	For measures of pressure: ± 0.2 hPa For measures of flow: ± 2 L/min or ± 3% (whichever is greater)		
Expected service life	Device (excluding accessories)	5 years	
	Water tank	90 days	
	Heated tubing and mask	Refer to the label of the heated tubing and user manual of the mask	

## 16. Symbols

► 16.1 The following symbols may appear on the product or packaging:

Symbol	Meaning	Symbol	Meaning
	Follow instructions for use		Start therapy / stand-by
	Caution		Date of manufacture
	Manufacturer		Type BF applied part
	Medical device		Model number

	Serial number		Maximum water level
Rx Only	Prescription only		General warning sign
	Warning: hot surface		Class II equipment
	Use-by date		Batch code
	Temperature limitation for storage and transport		
	Country of manufacture (china) Date of manufacture is on the right side of the symbol or below it.		
	Symbol for the marking of electrical and electronics devices according to directive 2012/19/EU		
<b>IP21</b>	Protected against access to hazardous parts with a finger and solid foreign objects of 12.5 mm in diameter and greater, protected against vertically falling water drops.		
<b>IP22</b>	Protected against access to hazardous parts with a finger and solid foreign objects of 12.5 mm in diameter and greater, protected against vertically falling water drops when enclosure tilted up to 15 degrees.		

► 16.2 Disposal statement:

 **Warning:**

Please contact local authorities, your provider or Yuwell to determine the proper method of disposal of this device.

## 17. Limited warranty

Yuwell warrants that your device shall be free from defects in material and workmanship from date of purchase for the period specified below:

Product	Warranty period
Water tank	90 days
Power adapter	1 year
Device	2 years

The quality warranty is only available to the initial customer. It is not transferable. Warranty is void on product sold, or resold, outside the original purchase, repaired by the company without accredited, and pollution caused by smoking

Your provider or Yuwell has the interpretation about the device's warranty.

## 18. Repairing

- 18.1. If your device is in trouble, please contact your provider or Yuwell. This device only can be repaired by the provider who has be authorized.
- 18.2. The user should follow the instruction of cleaning and safety to guarantee the device can be used for a long time.
- 18.3. If you have troubles in setting up, using or maintaining the equipment or meet some unexpected operation or events, please contact your provider or Yuwell as well. If you want to know more information about your device, you can visit the website of YUWELL: [www.yuyue.com.cn](http://www.yuyue.com.cn)

## 19. List of cables

Name	Lengths(m)
Cable(AC)	1.5
Cable(DC)	1.2

## 20. Technical description

The device is intended both for home healthcare environment and professional healthcare facility environment.

### ► 20.1 Compliance information for Emission test

Emission test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies

### ► 20.2 Compliance information for Immunity test

Immunity test	Compliance level
Electrostatic discharge(ESD) IEC 61000-4-2	±8kV contact ±15kV air
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines

Surge IEC 61000-4-5	±1kV differential mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % $U_T$ ; 0, 5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % $U_T$ ; 1 cycle and 70 % $U_T$ ; 25/30 cycles Single phase: at 0° 0 % $U_T$ ; 250/300 cycle
Power frequency(50Hz) magnetic field IEC 61000-4-8	30A/m
Radiated RF EM fields	10 V/m 80 MHz -2,7 GHz 80 % AM at 1 kHz
Conducted disturbances induced by RF fields	3 V 0, 15 MHz -80 MHz 6 V in ISM and amateur radio bands between 0, 15 MHz and 80 MHz 80 % AM at 1 kHz
NOTE $U_T$ is the a.c mains voltage prior to application of the test level.	

### Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation <sup>b)</sup> 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM <sup>c)</sup> ±5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation <sup>b)</sup> 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation <sup>b)</sup> 18Hz	2	0,3	28
870						
930						

1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation <sup>b)</sup> 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

- a) For some services, only the uplink frequencies are included.
- b) The carrier shall be modulated using a 50% duty cycle square wave signal.
- c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

#### ► 20.3 Precautions According to IEC 60601

According to IEC 60601-1-2:2014, the device complies with all applicable electromagnetic compatibility requirements (EMC) .It may have harmful interference with other devices if you do not following the instructions. However, there is not certain it has not interference with other devices if you following the instructions. If it does have interference with other device, you can amend interference by the following methods.

- Enlarge the distance between this device and other device.
- Connect the two devices with different power socket.
- Ask Yuwell engineer for help.

Essential performance and basic safety testing should be done every two years. If your device needs to be done, please contact your provider or Yuwell. This device only can be tested by the provider who has be authorized.

## 21. Warranty card

**yuwell**

### BreathCare PAP Warranty card

Feedback Couplet

Contact _____	Department _____	User _____
Add. _____		
Diagnose _____	Tel. _____	

Model _____	SN _____
Invoice number _____	purchasing date _____
Dealer _____	

#### This limited warranty does not cover:

- Any damage caused as a result of improper use, abuse, modification or alteration of the product.
- Repairs carried out by any service organization that has not been expressly authorized by Yuwell to perform such repairs
- Any damage caused as accident, Act of God or human factor.
- Product which is not involved in Quality warranty sheet.

User sign \_\_\_\_\_

Date \_\_\_\_\_



## BreathCare PAP Warranty card

Customer Couplet

Contact _____	Department _____	User _____
Add. _____		
Diagnose _____	Tel. _____	

Model _____	SN _____
Invoice number _____	purchasing date _____
Dealer _____	

**This limited warranty does not cover:**

- Any damage caused as a result of improper use, abuse, modification or alteration of the product.
- Repairs carried out by any service organization that has not been expressly authorized by Yuwell to perform such repairs
- Any damage caused as accident, Act of God or human factor.
- Product which is not involved in Quality warranty sheet.

User sign \_\_\_\_\_

Date \_\_\_\_\_

