

yuwell



BreathCare PAP Positive Airway Pressure Units User Manual



Suzhou Yuyue Medical Technology Co., Ltd.
No.9 Jinfeng Road, Suzhou Science & Technology Town, 215163
Suzhou, Jiangsu, PRC
TEL: (+86) 0512-67373001
Web address: www.yuyue.com.cn



Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse80, 20537 Hamburg, Germany

IFU-V-02 version: 04
Prepared date: 2022.06



Content



Welcome

The YH-560 and YH-580 are Yuwell's auto-adjusting pressure devices.
The YH-360 is Yuwell's Continuous Positive Airway Pressure (CPAP) device.



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.

- 1. Indications for use 01
- 2. Contraindications..... 01
- 3. Warnings 01
- 4. Precautions..... 03
- 5. Adverse reactions 04
- 6. Package table 05
- 7. Picture and explanation for product 05
- 8. Explanation of button 06
- 9. Installation..... 06
- 10. Therapy 07
- 11. Function 08
- 12. Caring for your device 13
- 13. Therapy data 17
- 14. Traveling 17
- 15. Trouble shooting 17
- 16. Specified of technology 20
- 17. Symbols 23
- 18. Limited warranty 24
- 19. Repairing 24
- 20. List of cables 25
- 21. Technical description 25
- 22. Warranty card 28



1. Indications for use

The YH-360 CPAP and YH-560 / YH-580 self-adjusting device are indicated for treatment of Obstructive Sleep Apnea (OSA) in patients weighing more than 66 lb (30 kg). It is intended both for home and hospital/institutional use. YH-360 CPAP and YH-560 / YH-580 consist of main device, water tank, power adapter and cable. Mask and air tube are purchased.

2. Contraindications

Positive airway pressure therapy may be contraindicated in some patients with the following pre-existing conditions:

Severe bullous lung disease, pneumothorax, pathologically low blood pressure, dehydration, cerebrospinal fluid leak, recent cranial surgery, or trauma

3. Warnings

- 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 air tube 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 air tube 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 the 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.

4. Precautions

- 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 air tube 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.

5. Adverse reactions

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.

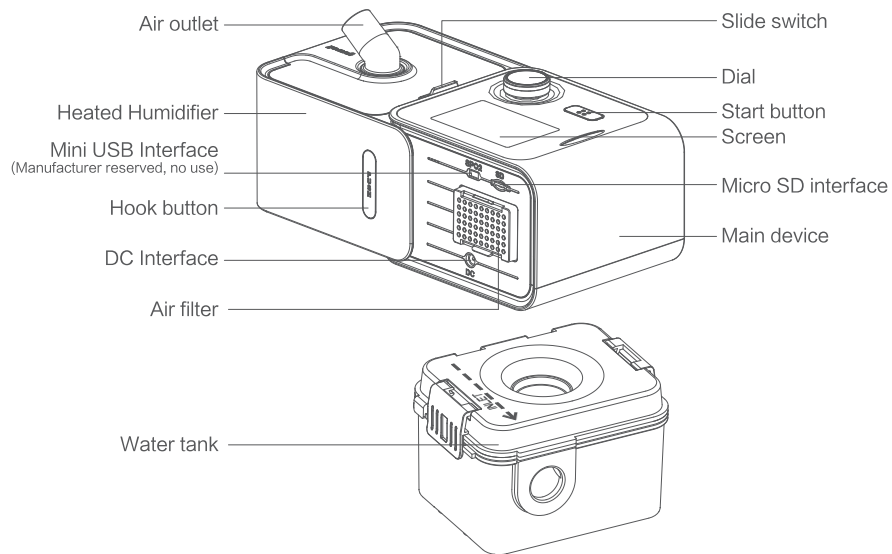
The following adverse reactions may arise during the course of therapy with the device:

- drying of the nose, mouth, or throat
- nosebleed
- bloating
- ear or sinus discomfort
- eye irritation
- skin rashes



6. Package table

| Name | Quantity | Name | Quantity |
|--|----------|------------------------------|----------|
| Main device | 1 | Mask (with mask accessories) | 1 |
| Humidifier (with water tank) | 1 | Air filter | 2 |
| Air tube | 1 | SD card (optional) | 1 |
| Power adapter and Cable (as part of the main device) | 1 | User manual | 1 |
| Bag | 1 | | |

7. Picture and explanation for product

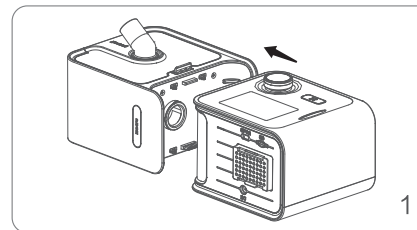


8. Explanation of button

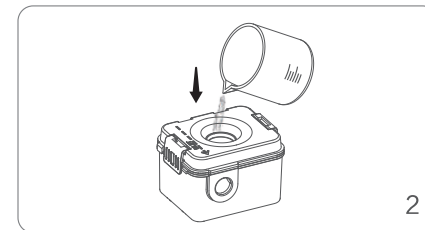
| | |
|---|--|
|  | START/ STOP button: Press to start /stop therapy. |
|  | Dial: Turn to navigate the menu and press to select an option. Turn to adjust the options and press to save your choice. |

9. Installation

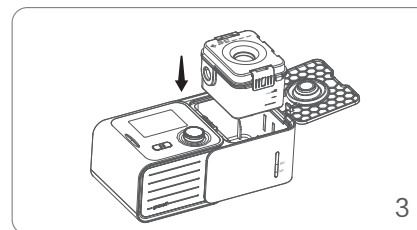
The following section will help you install your device by yourself.



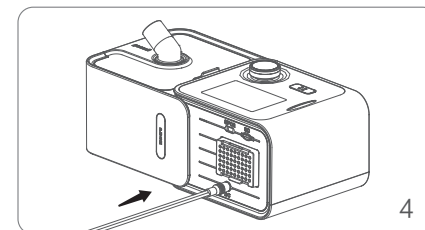
1. Connect the device with the humidifier;



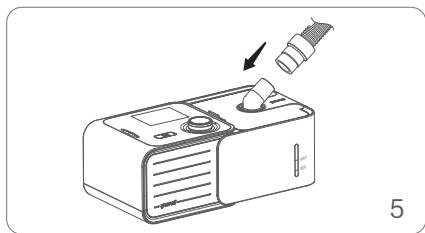
2. Fill the water tank with distilled water. please notice that do not pour the hot water into it;



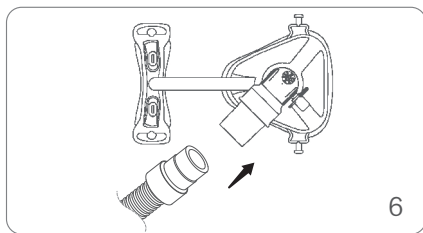
3. Put the water tank back to the heated humidifier.



4. Place the device on the floor, plug the power adapter into the rear of the device.



5. Connect the air tube firmly to the air outlet on the humidifier.



6. Fit your mask correctly (refer to the mask manual) and connect the free end of the air tubing firmly onto the mask and press the start button to begin treatment.

⚠ Caution:

- Do not add the distilled water above the maximum water level mark, in case the water may enter the air tube and the device.
- Please change the distilled water in the water tank every day.
- 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 cmH₂O, 8 hours is an expected duration of operation between refills.

10. Therapy

← 10.1 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;

- During the ramp time, the pressure increases gradually until the setting pressure has been reached;
- The screen backlight will turn off automatically after two minutes of no action. 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.

← 10.2 Stop therapy

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

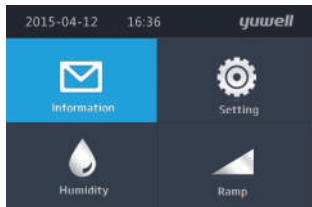
11. Function

← 11.1 Function that patient can safely use

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 of the last therapy (h).
- **Treatment Time(h):** The time of the patient wore the mask (h).
- **Average Pressure:** The average pressure of the last therapy (cmH₂O / hPa).
- **Average Leak Volume(Lpm):** Average air leak volume per minute of the last therapy (L/min).
- **Total Time (h):** Total time of therapy (h).
- **P90:** The Pressure for the 90 percent of the last therapy(cmH₂O / hPa).
- **Version:** The version of software used for the device.
- **SN:** The serial number of the device.



Picture 1-1: Home

| Information | 10:06 | yuwell |
|--------------------------|-------|--------|
| AHI | 6.2 | |
| Used Time(h) | 1.7 | |
| Treatment Time(h) | 8.1 | |
| Average Pressure | 0.0 | |
| Average Leak Volume(Lpm) | 0.0 | |
| Total Time(h) | 7.2 | |

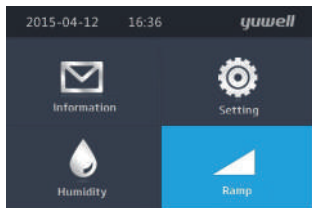
Picture 1-2: Information

② Ramp:

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

To adjust the Ramp:

- Highlight the "Ramp" and press dial to see your current setting;
- Press dial and rotate it to adjust your setting;
- Press dial to save your change.



Picture 2-1: Home



Picture 2-2: Ramp

③ Humidity level:

Humidifier is designed to moisten 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 Humidity level between 0 to 6, where 0 means this function is disabled, 1

is the lowest humidity setting and 6 is the highest humidity setting.

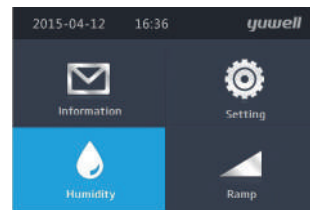
The temperature of each level on the heater plate is as following (accuracy is $\pm 4^{\circ}\text{C}$)

0: OFF 1: 33°C 2: 35°C 3: 40°C 4: 45°C 5: 50°C 6: 55°C

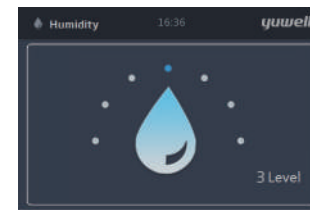
This temperature has been tested with empty water tank, with 10 minutes preheating time.

To adjust the humidity level:

- Highlight the "Humidity", press dial to enter the humidity page;
- Press the dial and rotate it to 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 3-1: Home

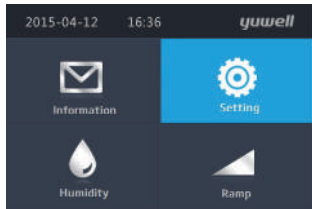


Picture 3-2: Humidity

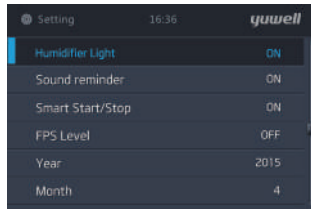
④ Setting:

- **Humidifier light:** When this function is enabled, you can see the remaining water inside the water tank clearly.
- **Sound Reminder:** When this function is enabled, the device will give a sound reminder when an abnormal air leakage occurs.
- **Smart Start/Stop:** When this function is enabled, therapy starts automatically when you breathe into your mask. After you remove your mask, it will stop automatically in one minute.
- **FPS Level:** When this function is enabled, you may feel easier to breathe out; It helps you get used to the therapy. It has 4 levels of FPS, 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.
- **Year:** Adjust the year displayed on the device.

- **Month:** Adjust the month displayed on the device.
- **Date:** Adjust the date displayed on the device.
- **Hour:** Adjust the hour displayed on the device.
- **Minute:** Adjust the minute displayed on the device.
- **Clock Alarm:** When this function is enabled, you can set time of clock as well.
- **Clock/Hour:** Set the hour of the clock.
- **Clock/Minute:** Set the minute of the clock.
- **Language:** You can choose English or Chinese.
- **Filter Reminder:** When this function is enabled, this can remind you to check and change the filter.
- **Restore Defaults:** When this function is enabled, parameters of the device will be reset to the factory defaults and data will be erased.



Picture 4-1: Home



Picture 4-2: Setup

← 11.2 Function that patient must use under the direction of doctor (Clinical menu)

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

① Set Mode (CPAP or APAP)

- At the 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.
- 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.

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 cmH₂O / 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" 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, these pressures will be equal to the Max pressure.

③ Set Pressure Unit

- At clinical page, highlight "Pressure Unit".
- Rotate the dial to the right or left, set your pressure unit (cmH₂O or hPa).
- After setting pressure unit, highlight the "Back", press dial to back to home page.

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.

⑤ Set Ramp

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

⑥ Set Humidity Level

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

⑦ Erase Data

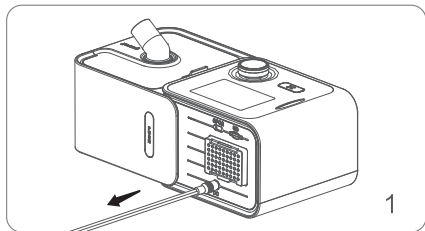
- At clinical page, Highlight "Erase Data".
- Press the dial to the page where you can choose OK or Cancel about erase data.
- If you choose OK, your therapy data will all be erased.

⚠ Caution:
During your therapy, you can go to the clinical menu by Pressing and holding START/STOP button and dial at the same time for three seconds. Section 11.2 clinical menu tells the method to change all the parameters.

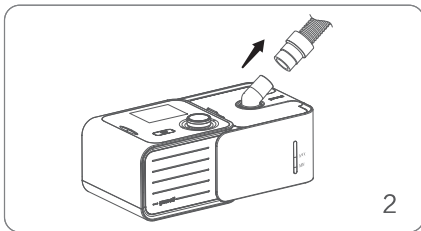
12. Caring for your device

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.

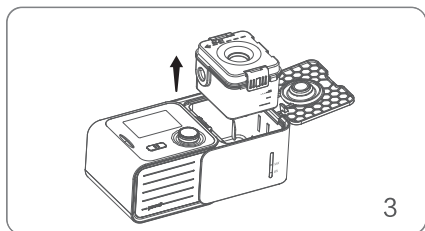
← 12.1 Disassembling



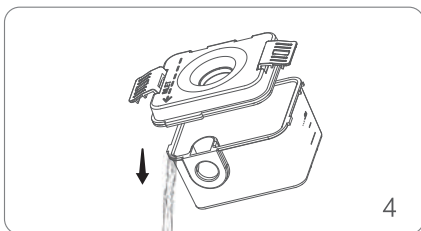
1. Pull the power connector out of device



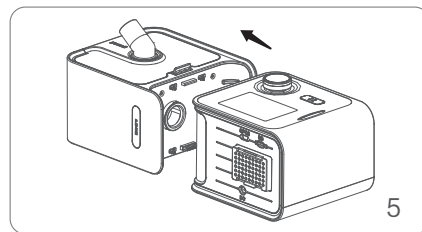
2. Hold the cuff of the air tubing and gently pull it away from device



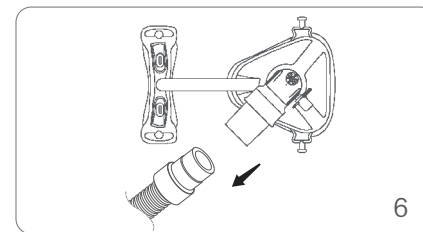
3. Press the Slide switch, and take out the water tank.



4. Pour out the left water in the water tank.



5. Press the water tank gently and pull it away from the device.



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

⚠ Notice: Don't pull the threaded portion of the air tubing

← 12.2 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.

12.2.1 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.

12.2.2 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.

12.3 Checking:

You should check power adapter and cable, water tank, air tube 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.

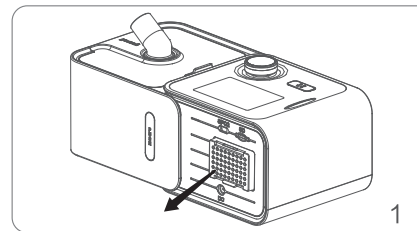
c. Check the air tube

- Replace the air tube if there are any holes, tears or cracks.

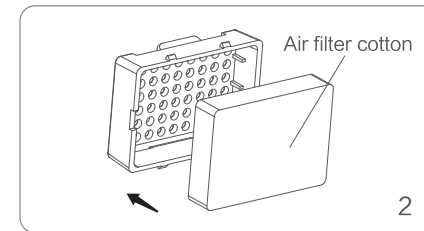
d. Check the air filter

- 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 and remove the old air filter cotton;



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

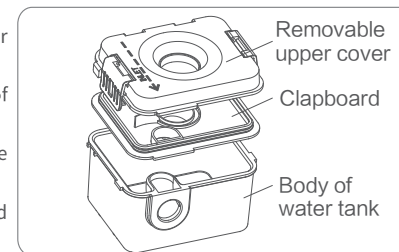
⚠ Caution:

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

← 12.4 Reassembling:

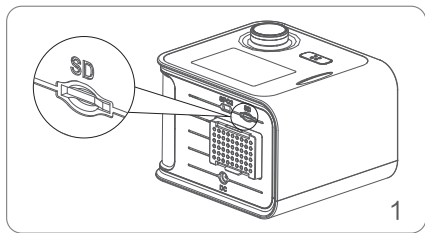
After finishing all the cleaning steps, reassemble all these parts together. When the water tank and air tube are dry, you can reassemble the parts.

- Please reassemble cover, clapboard, body of water tank according to the picture.
- Hold the humidifier and main device, connect two of them.
- Connect the air tube to the air outlet located on the upper of the humidifier.
- Connect the free end of the air tube with assembled mask.

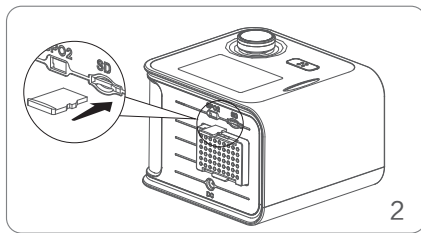


13. Therapy data

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 and then transferred to your care provider via a SD card.



1. Look for the SD interface at the reverse side of main device.



2. After the device page is transferred to the home page, inset Micro SD card and wait until the screen displays “SD card write success” .

⚠ Caution:

Don't use the interface of the mini USB, since it is reserved for the manufacturer.

14. 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.
- Make sure you have the appropriate power cord for the region you are traveling to. For information on purchasing, contact your provider or Yuwell.

15. 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.

← 15.1 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 air tube. | Humidity level may be set too high; Condensation forms in the piping mask due to cold weather. | Adjust the humidity level; Buy heated tube 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. |

← 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 | Check the main device and humidifier to make sure the correct connection or 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 |

16. Specified of technology

| Items | Specifies | |
|---|---|--|
| Power | Input :100-240 VAC, 50-60 Hz, 1.8 A max Output:24 V DC, 3.33 A | |
| 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 ₂ 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) | 270mm * 138mm * 100mm or 10.63" * 5.43" * 3.94" |
| | Weight | About 1560 g or 3.44 lb (With the humidifier) |
| | Air tube | 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: Polyurethane Average arrestance: 80% for~10 micron dust | |
| Therapy pressure | 4~20 hPa (adjustable, step is 0.5 hPa) or 4~20 cmH ₂ O | |
| Initial pressure | 4~20 hPa (adjustable, step is 0.5 hPa) or 4~20 cmH ₂ O | |
| Maximum pressure | 4~20 hPa (adjustable, step is 0.5 hPa) or 4~20 cmH ₂ O | |
| Minimum pressure | 4~20 hPa (≤ maximum pressure, adjustable, step is 0.5 hPa) or 4~20 cmH ₂ O | |
| Ramp | 0~45 minutes (adjustable, step is 5 minutes) | |
| Pneumatic flow path: | | |
| <pre> graph LR Atmosphere --> Filter Filter --> Blower Blower --> Water_tank[Water tank] Water_tank --> Air_tube[Air tube] Air_tube --> Mask Blower --> Flow_sensor[Flow sensor] Water_tank --> Pressure_sensor[Pressure sensor] Air_tube --> Leak </pre> | | |

| | | | | | | |
|---|---|---|--------|--------|-------|-------|
| 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 |
| 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 ₂ O) | 10 bpm | 15 bpm | 20 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 ₂ O in normal condition 40 cmH ₂ 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 |
| | Air tube and mask | Refer to user manual of the air tube or the mask |

17. Symbols

← 17.1 The following symbols may appear on the product or packaging:

| Symbol | Meaning | Symbol | Meaning |
|---|---|---|--|
|  | Follow instructions for use |  | Start therapy / stand-by |
|  | Caution |  | Temperature limitation for storage and transport |
|  | Manufacturer |  | Type BF applied part |
|  | Medical device |  | Model number |
|  | Serial number |  | Maximum water level |
|  | Prescription only |  | General warning sign |
|  | Warning: hot surface |  | European Authorized Representative |
|  | Class II equipment | | |
|  | 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 | | |
|  | 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. | | |

| | |
|-------------|--|
| IP22 | 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. |
|-------------|--|

← 17.2 Disposal statement:

 Warning:

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

18. 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 and Heated Humidifier | 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.

19. Repairing

- If your device is in trouble, please contact your provider or Yuwell. This device only can be repaired by the provider who has been authorized.
- The user should follow the instruction of cleaning and safety to guarantee that the device can be used for a long time.
- 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.yuwell.com.cn

20. List of cables

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

21. Technical description

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

← 21.1 Compliance information for Emission test

| Emissions 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 |

← 21.2 Compliance information for Immunity test

| Immunity Test | Compliance Level |
|---|--|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact, ±15 kV air |
| Electrical fast transient / burst IEC 61000-4-4 | ±2 kV for power supply lines |
| Surge IEC 61000-4-5 | ±1 kV line (s) to line (s) |
| 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 70% U _T ; 25 / 30 cycle At 0° 0% U _T ; 250 / 300 cycle |

| | |
|--|--|
| Power frequency (50Hz) magnetic field IEC 61000-4-8 | 30 A/m |
| Radiated RF EM fields | 10V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz |
| Conducted disturbances induced by RF fields | 3V 0, 15 MHz - 80 MHz 6V 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 ^{a)} (MHz) | Service ^{a)} | Modulation ^{b)} | Maximum power (W) | Distance (m) | IMMUNITY TEST LEVEL (V/m) |
|----------------------|--------------------------|--|--|-------------------|--------------|---------------------------|
| 385 | 380 – 390 | TETRA 400 | Pulse modulation ^{b)} 18 Hz | 1,8 | 0,3 | 27 |
| 450 | 430 – 470 | GMRS 460, FRS 460 | FM ^{c)} ±5 kHz deviation 1 kHz sine | 2 | 0,3 | 28 |
| 710 | 704 – 787 | LTE Band 13, 17 | Pulse modulation ^{b)} 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 ^{b)} 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 ^{b)} 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 ^{b)} 217 Hz | 2 | 0,3 | 28 |
| 5 240 | 5 100 – 5 800 | WLAN 802.11 a/n | Pulse modulation ^{b)} 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.

← 21.3 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 follow the instructions. However, there is not certain it has not interference with other devices if you follow 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 been authorized.

Cut along the dotted line

22. Warranty card



BreathCare PAP Warranty Card

Feedback Couple

| | | |
|----------------|------------------|------------|
| 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 organizations that have 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: _____

Cut along the dotted line



BreathCare PAP Warranty Card

Feedback Couple

| | | |
|----------------|------------------|------------|
| 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 organizations that have 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: _____



