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BreathCare PAP Positive Airway Pressure Units

Content

Welcome

The YH-550 is YUWELL's auto-adjusting pressure device. The YH-350 is YUWELL's continuous positive airway pressure (CPAP) device.

Warning

Read this entire guide before using the device.

Caution

In the US, federal law restricts this device to sale by or on the order of a physician.

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1. Indications for use

The YH-550 self-adjusting device and YH-350 are indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients weighing more than 66 lb (30 kg). They are intended for home use only.

YH-550 and YH-350 consist of main device, water tank and power adapter. Mask and air tube are purchased. Mask and air tube are type BF applied part. The patient is an intended operator.

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 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 BreathCare PAP 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 Service Center.
 - 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 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 YUWELL Service Center.
 - 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 BreathCare PAP, 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 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.

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.
- Do not use bleach, chlorine, aromatic-based solutions, moisturizing or antibacterial soaps or scented oil to clean the device, water tank or air tube. Otherwise it may cause damage and reduce the life of these products.
- 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.
- This equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- 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.

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.

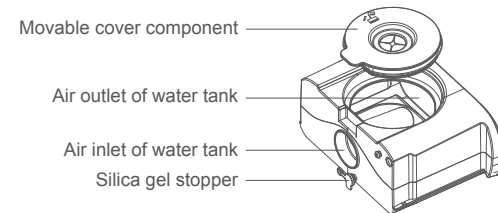
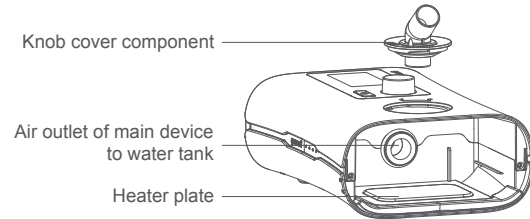
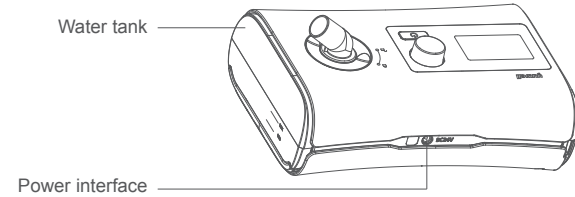
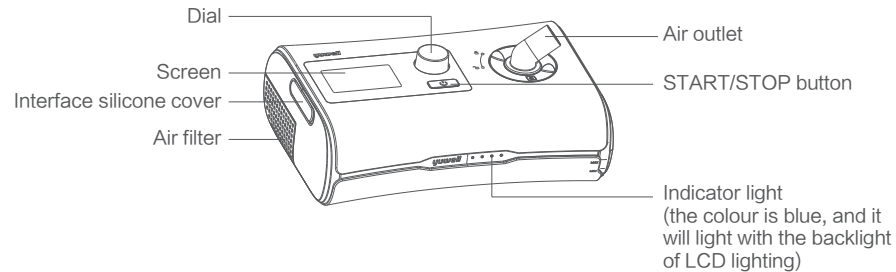
The following adverse reactions may arise during the course of therapy with the device:

- 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
Water tank	1	Air filter	2
Air tube	1	SD card	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.

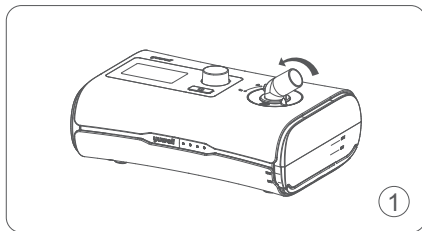
9. Installation



⚠ Caution:

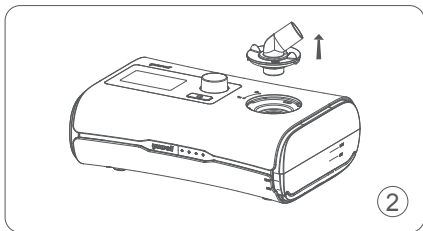
Do not overfill the water tank in case the water may enter the air tube and the device.

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.

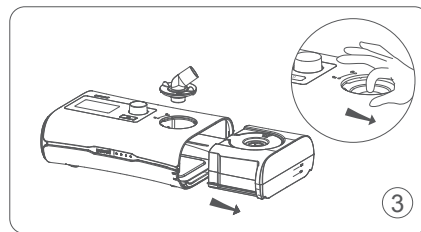
The following section will help you install your device by yourself.



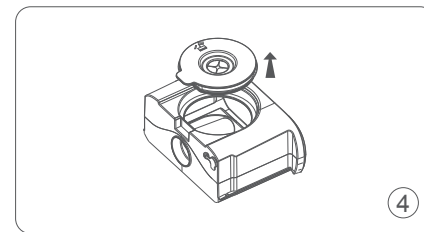
1. Place the device on a stable level surface; Rotate the knob cover component from the  to .



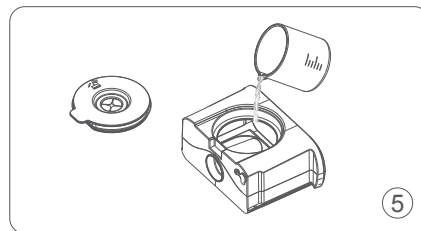
2. Pull the knob cover component out.



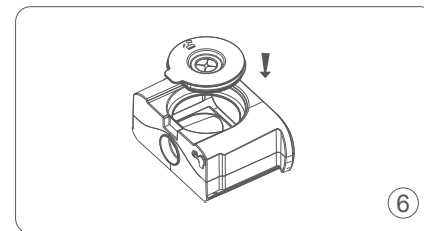
3. Press the water tank gently and pull it away from the device.



4. Open the movable cover component.

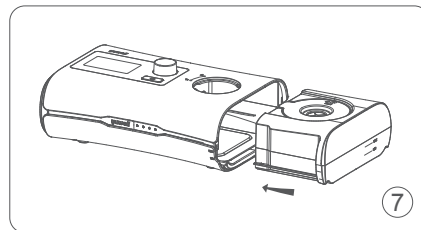


5. Fill the distilled water into the water tank, please notice that do not place the hot water into it.

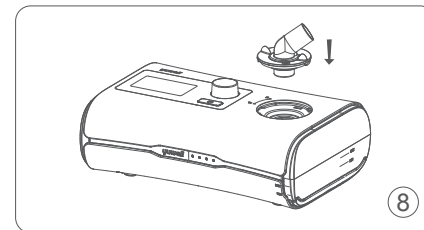


6. Close the movable cover component.

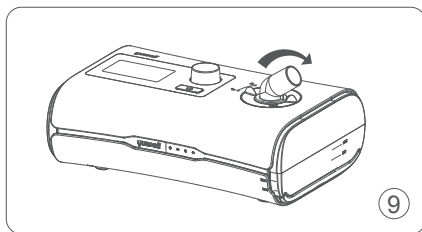
⚠ Caution: Please change the distilled water in the water tank every day.



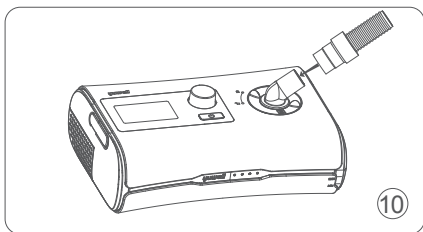
7. Insert it into the side of the device.



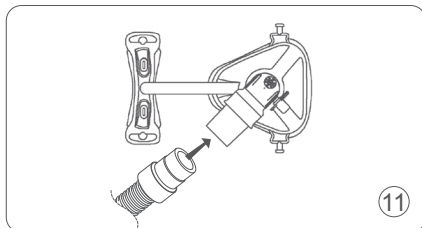
8. Close the knob cover component



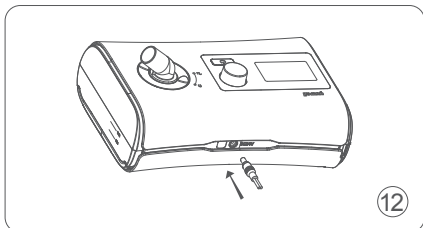
9. Rotate the knob cover component from the  to .



10. Connect the air tube firmly to the air outlet located on the top of the device.




11. Connect the free end of the air tube firmly onto the mask; See the mask user guide for detailed information.



12. Plug the power connector into the rear of the device.

10. Therapy

► 10.1 Start therapy

- ① Fit your mask;
- ② Press  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;
- ③ During the ramp time, the pressure increases gradually until the setting pressure has been reached;

- ④ 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 is heating (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 heat plate is not heating. Also if the device is not delivering gas pressure, the heat plate will not heat either.

Pressure 6.0	APAP
	6.0-15.0
	Ramp: 15
	Humidity: 6

Picture 1: therapy

► 10.2 Stop therapy

- ① Remove your mask first;
- ② Press the  or if Smart Start/Stop is enabled, therapy will stop automatically after about one minute;
- ③ To power off your device, please separate your 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:** the number of hours of the device working last session(h).
 - **Treatment Time:** the number of hours of therapy patient received last session(h).
 - **Average Pressure:** the average pressure of the last therapy (cmH₂O/hPa).

- **Average Leak volume:** average air leak volume per minute of the last therapy (L/min).
- **Total Time:** the number of hours of the device working.
- **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 device.

AHI	0.0
Used Time	0.4
Treatment Time	0.4
Average Pressure	20.0

Picture2-1: Info

Average Pressure	0.0
Average Leak Volume	0.0
Total Time	37.9
P90	20.0

Picture 2-2: Info

P90	20.0
Version	V1.00_AIC
SN	YH550A*940100001
Back<<	

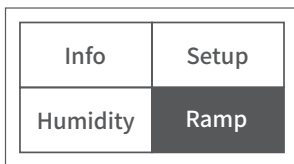
Picture 2-3: Info

② Ramp:

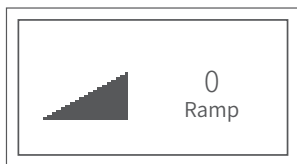
Ramp time is designed to make you more comfortable at the beginning of the therapy; you can adjust the ramp time from 0 to 45 minute with an increment of 5min.

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 3-1: Home



Picture 3-2: 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.

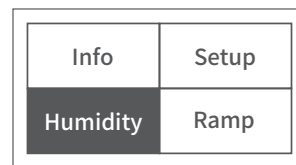
The temperature of each level on the heater plate is as following (accuracy is $\pm 4^{\circ}\text{C}$)

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.



Picture4-1: Home



Picture4-2: Humidity

④ Setting:

- **Sound Reminder:** When this function is enabled, the device will give a reminder, if 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.

- **Date:** Adjust the date (year, month, day) displayed on the device.
- **Time:** Adjust the time (hour, minute) displayed on the device.
- **Language:** You can choose English or Chinese.
- **Filter Cotton Reminder:** When this function is enabled, this can remind you to check and change the filter.
- **Reset:** When this function is enabled, parameters of the device will be reset to the factory defaults and data will be erased.

Info	Setup
Humidity	Ramp

Picture 5-1: Home

Sound Reminder	OFF
Smart Start/Stop	OFF
FPS Level	0
Date	2019-5-4

Picture 5-2: Setup

Date	2019-5-4
Time	9:27
Language	EN
Filter Cotton Reminder	OFF

Picture5-3: Setup

Language	EN
Filter Cotton Reminder	OFF
Reset	>>
Back<<	

Picture 5-4: 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 home page, press  and dial at the same time, 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" , "Initial Pressure" and "Therapy Pressure" of APAP mode according to above method.

⚠ Notice:

When you try to make the max pressure lower than min pressure,initial pressure or therapy pressure, these pressures will be equal to the max pressure.

③ Set Pressure Unit

- At clinical page, highlight "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 (0-45minutes, 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 (0–6level, step value is 1 level).
- After setting humidity level, highlight the "Back", press dial to back to home page.

⚠ Caution:

During your therapy, you can go to clinical menu by pressing dial and  at the same time. Section 11.2 clinical menu tells the method about how change all the parameters.

Mode	CPAP
Inital Pressure	4.0
Therapy Pressure	20.0
Unit	cmH20

Picture 6–1: Clinical menu (CPAP)

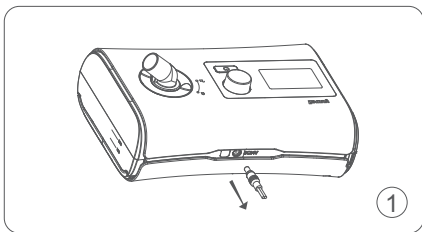
Mode	APAP
Max Pressure	15.0
Min Pressure	4.0
Initial Pressure	4.0

Picture 6–2: Clinical menu (APAP)

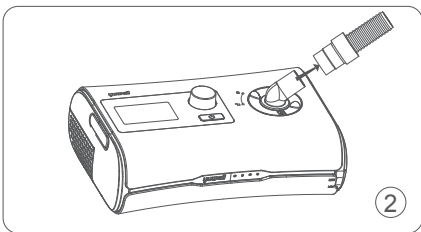
12. Caring for your device

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.

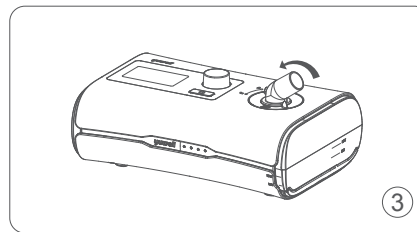
► 12.1 Disassembling





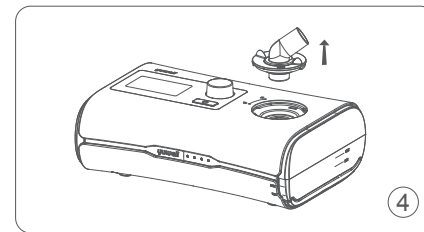
1. Pull the power connector out of device.



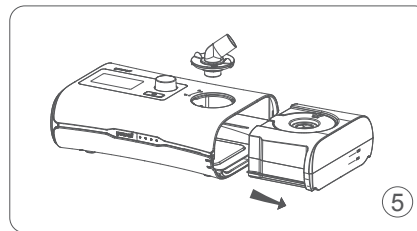
2. Hold the cuff of the air tubing and gently pull it away from device.



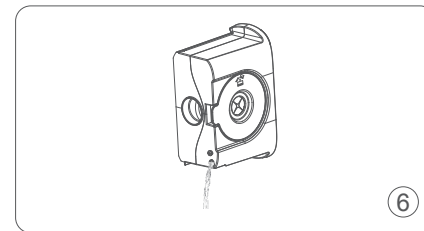
3. Rotate the knob cover component from the  to .



4. Pull the knob cover component out.

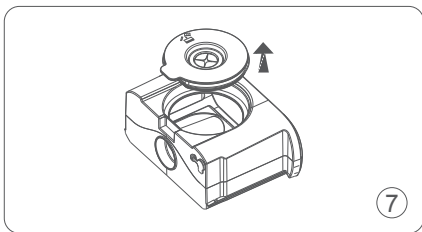


5. Press the water tank gently and pull it away from the device.

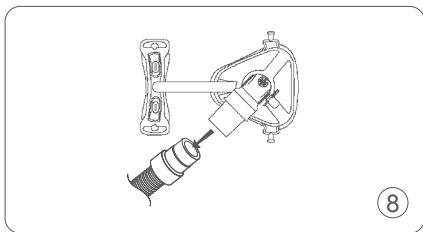


6. Open the silica gel stopper and discard the remaining water.

⚠ Notice: Close the silica gel stopper after the water has been poured out.



7. Open the movable cover component.



8. 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

Please clean your device under the service environment of this device. It may be influenced by dust, thus please following several steps to clean your device, and you should clean your device at least once a week. Refer to the mask and air tube user guides for detailed instructions on cleaning your mask and air tube.

- If there is dust on your device, please wipe it with the dry compress;
- Wash the air tube and water tank in warm water using mild detergent. The temperature of the warm water should not be over 41°C .

⚠ Caution:

Do not use bleach, chlorine, aromatic solution, moisturizing factor, antibacterial soaps, and sesame oil to clean the device.

Do not wash in a dishwasher or washing machine.

Please wash the water tank every day.

- Rinse the water tank and air tube thoroughly and allow to dry out of direct sunlight and/or heat. (Temperature should not exceed 40°C).

⚠ Warning:

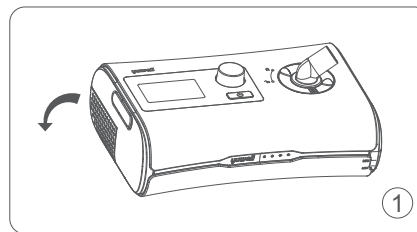
It is generally not necessary to sterilize your water tank if you are following the cleaning method. When the water tank is contaminated, it can be disinfected by immersing the water tank in a water which temperature is 75°C ± 2°C for 30 minutes.

► 12.3 Checking:

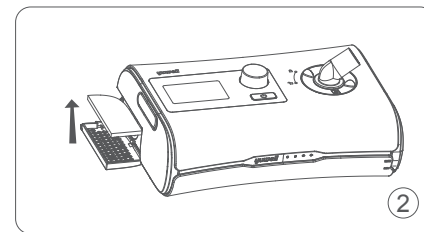
You should check power adapter and cable, water tank, air tube and air filter regularly in case of any damage.

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

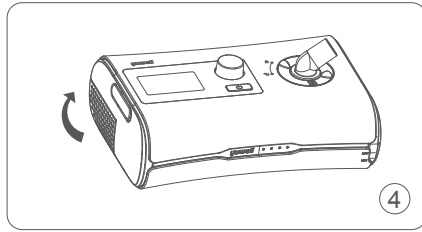
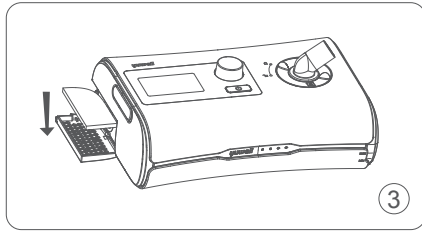
To replace the air filter



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.

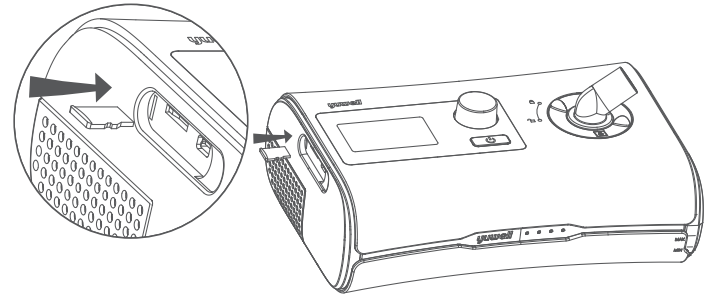
► 12.4 Reassembling:

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.

- Open the movable cover component and fill the distilled water into the water tank.
- Close the movable cover component, and insert it into the side of the device.
- Close the knob cover component and rotate it from  to .
- Connect the air tube firmly to the air outlet located on the top of the device.
- Connect the free end of the air tube firmly onto the assembled mask.

13. Therapy data

BreathCare PAP 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. Open the silica gel stopper at the left side of the device;
2. Push the SD card into the SD card connector;
3. Remove the SD card from the device after it wrote successfully.

⚠ Caution:

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

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.

15. Trouble shooting

When your device has trouble, look for the following table to find solution. Contact your physician or your provider 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.	Ensure your mask is fitted correctly. See your mask user guide to check your mask fit and seal.
I am getting a dry or blocked nose.	Humidity level may set too low.	Adjust the humidity level.
I am getting droplets of water on my nose, in the mask and air tube.	Humidity level may be set too high.	Adjust the humidity level.
My mouth is very dry and uncomfortable.	Air may be escape from your mouth.	Increase the humidity level. You may need a chin strap to keep your mouth closed or a full face mask.
Air pressure in my mask seems too high (it feels like I am getting too much air).	Ramp may be turned off.	Enable your ramp option.
Air pressure in my mask seems too low (it feels like I am not getting enough air).	Ramp may be in progress.	Start your therapy after the setting pressure reached or turn ramp time off.
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 if your water tank is broken.

► 15.2 Other trouble:

Message in LCD	Meaning of error	Solution
ERROR 1	There is a mistake of pressure sensor	Please contact your provider
ERROR 2	There is a mistake of flow sensor	Please contact your provider
ERROR 3	There is a mistake of temperature sensor	Please contact your provider
ERROR 5	There is a parameter exceed in parameter range	Please restart the device or contact your provider
ERROR 6	The pressure is exceed in pressure range	Please restart the device or contact your provider
ERROR 7	It is failed to supply power to the humidifier	Please contact your provider
ERROR 8	There is a mistake of blower	Please restart the device or contact your provider
ERROR 9	There is a mistake of RTC (loss power)	Please adjust the time of the device or contact your provider

16. Specified of technology

Items	Specifies	
Power	Powered by adapter (Model: BJE1M-0060-N600/DA-60I24) Input: 100~240VAC, 50~60Hz, 2A max Output: 24V DC, 2.5A	
Environment conditions	Temperature	Operate: +5°C ~35°C(+41°F ~95°F),Non-condensing Transport: -20°C ~70°C (-4°F ~158°F) Storage: -20°C ~70°C (-4°F ~158°F)
	Humidity	Operate: relative humidity 15%~90%, Non-condensing Transport: relative humidity 15%~90% Storage: relative humidity 15%~90%
	Atmospheric pressure range	700hPa~1060hPa
	Altitude	≤ 3000m
	Protection class	IP 21, Class II
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) BreathCare PAP ≤ 32dB (A)

	Sound power level	Sound power level measured according to ISO 80601-2-70:2015 (CPAP mode) BreathCare PAP ≤ 40dB (A)
Physical properties	Dimensions (length*width*height)	272.5mm * 181mm * 93mm or 10.73" * 7.13" * 3.7"
	Weight	About 1419 g
	Air tube	Plastic hose, about 1.8m
	Maximum volume of water tank	260 ± 10 mL
	Materials of water tank	PC, Injection molded plastic, stainless steel and silicone seal
	Air outlet	22 mm (complies with ISO 5356-1:2015)
Temperature	Maximum temperature of heater plate	55°C (131 °F)(± 4°C)
	Cut-out	110°C (if it is damaged, return to manufacturer)
	Maximum gas temperature	≤ 41°C
Air filter	Material: Polyester non-woven fiber Average arrestance: ≥ 85%for~2.5 micron dust	
Therapy pressure	4~20 hPa (adjustable, step is 0.5hPa) or 4~20 cmH ₂ O	
Initial pressure	4~20 hPa (adjustable, step is 0.5hPa) or 4~20 cmH ₂ O	

Maximum pressure	4~20 hPa (adjustable, step is 0.5hPa) or 4~20 cmH ₂ O																								
Minimum pressure	4~20 hPa (adjustable, step is 0.5hPa) or 4~20 cmH ₂ O																								
Ramp	0~45min (adjustable, step is 5minutes)																								
Maximum flowrate	The BreathCare PAP performance at set pressure is shown below: <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th colspan="5">Test pressures</th> </tr> <tr> <th>Measured pressure at the PATIENT-CONNECTION PORT (hPa)</th> <th>4</th> <th>8</th> <th>12</th> <th>16</th> <th>20</th> </tr> </thead> <tbody> <tr> <td></td> <td>2.97</td> <td>7.06</td> <td>11.25</td> <td>15.29</td> <td>19.34</td> </tr> <tr> <th>Average flow at the PATIENT-CONNECTION PORT (L/min)</th> <td>98.8</td> <td>107.8</td> <td>107.1</td> <td>111.1</td> <td>114</td> </tr> </tbody> </table>		Test pressures					Measured pressure at the PATIENT-CONNECTION PORT (hPa)	4	8	12	16	20		2.97	7.06	11.25	15.29	19.34	Average flow at the PATIENT-CONNECTION PORT (L/min)	98.8	107.8	107.1	111.1	114
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Average flow at the PATIENT-CONNECTION PORT (L/min)	98.8	107.8	107.1	111.1	114																				
Pneumatic flow path:	<pre> graph LR Atmosphere --> Filter Filter --> Blower Blower --> PS[Pressure sensor] PS --> Air_tube Air_tube --> Leak Leak --> Mask </pre>																								
Humidifier performance	Humidification system output: $\geq 12\text{mg/L}$ Relative humidity: $\geq 50\%$																								

Humidification system	Pressure drop (ISO 5367:2014)	Flowrate (L/min)	Pressure drop (cmH ₂ O)	
		30	0.18	
		60	0.6	
		90	1.2	
	Gas leakage at the maximum operating pressure (ISO 5367:2014)	< 2 L/min		
Displayed values	Value	Range	Display resolution	
	Pressure measurement: Mask pressure	4~20 cmH ₂ O	0.1 cmH ₂ O	
	Value	Accuracy		
	Pressure measurement: Mask pressure	$\pm [2\% \text{ of the full scale} + 4\% \text{ of the set value}]$		
Pressure accuracy	Maximum static pressure variation at 10 cmH ₂ O according to ISO80601-2-70:2015 $\pm [2\% \text{ of the full scale} + 4\% \text{ of the set value}]$			
	Maximum dynamic pressure variation according to ISO80601-2-70:2015			
	Pressure(cmH ₂ O)	10bpm	15bpm	20bpm
	4	0.6	0.9	1.1
	8	1.0	1.2	1.4
	12	1.2	1.4	1.6
	16	1.4	1.6	1.8
	20	1.6	2.0	2.3

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: ± 0.25 hPa For measures of flow: ± 2.5 L/min	
Expected service life	Device (excluding accessories)	5 years
	Water tank	90 days

17. Symbols

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

Symbol	Meaning	Symbol	Meaning
	Follow instructions for use		Press to start /stop therapy
	Caution		Temperature limitation for storage and transport
	Manufacturer		Type BF applied part
	Date of manufacture		Class II equipment
	Serial number	___ MAX	Maximum water level

Rx Only	Prescription only	___ MIN	Minimum water level
	Warning: hot surface		European Authorized Representative
	Environmental information (EU directive 2012/19/EE Waste Electrical and Electronic Equipment (WEEE))		
IP21	Protected against finger sized objects and against dripping water on the surface of the device		

► 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	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.

YUWELL has the interpretation about the device's warranty.

19. Repairing

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

20. List of cables

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

21. Technical description

► 21.1 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 IEC61000-3-3	Complies

► 21.2 Compliance information for Immunity test

Immunity test	Compliance level
Electrostatic discharge(ESD) IEC61000-4-2	± 8kV contact ± 15kV air
Electrical fast transient/burst IEC61000-4-4	± 2kV for power supply lines
Surge IEC61000-4-5	± 1kV differential mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	0 % UT; 0, 5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle
Power frequency(50Hz) magnetic field IEC61000-4-8	30A/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)} 18Hz	1,8	0,3	27
450	430–470	GMRS 460 FRS 460	FM ^{c)} ± 5kHz deviation 1 kHz sine	2	0,3	28
710	704–787	LTE Band 13,17	Pulse modulation ^{b)} 217Hz	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						
1 845	1 700–1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25;UMTS	Pulse modulation ^{b)} 217Hz	2	0,3	28
1 970						
2 450	2 400–2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217Hz	2	0,3	28
5 240	5 100–5 800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217Hz	0,2	0,3	9
5 500						
5 785						

NOTE

If it's 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 IEC60601–1–2:2014, BreathCare PAP (Auto CPAP) 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.

22. 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 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 _____



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.
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User sign _____

Date _____