yuwell

User manual



BreathCare PAP
Positive Airway Pressure Units

Welcome

The YH-680A, and YH-680B are 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.

⚠ Notice

For any serious incident that has occurred in relation to the device, please contact Suzhou Yuyue Medical Technology Co., Ltd. or the competent authority of the member state in which the user or patient is established.

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1. Introduction of the device

▶ 1.1 Intended use

- YH-680A and YH-680B are indicated for the treatment of Obstructive Sleep Apnea (OSA) in adult patients weighing more than 66 lb (30 kg). They are intended for home and hospital/institutional use.

▶ 1.2 Operating principle

- The device uses electric power to generate positive airway pressure and delivers air to the patients within therapeutic range.

▶ 1.3 Composition

- YH-680A and YH-680B consist of main device, water tank, heated tubing (optional), power adapter and cable.

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 serve or maintain the device during use, otherwise it may lead to unacceptable risk.
- 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 the cables and air tube/heated tubing 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 position next to a curtain that blocks the flow of cooling air, thereby causing the equipment to overheat.
- 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.
- Use of this device 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.
- Do not add any attachments or accessories to the humidifier that contravene the instructions for use of the humidifier or accessory as the humidifier might not function correctly affecting the quality of the therapy or injuring the patient.
- 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 not described in the instructions for use is forbidden.
- 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.
- 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 at an altitude above 3000 meters or outside a temperature of +5℃~35℃. Using the humidifier outside of this temperature range or above this altitude can affect the quality of the therapy or injury the patient.
- To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used.
- This device is not intended for children, and patients who are physically or mentally

deficient can’t use the device without assistance or supervision.

- Failure to use a mask or accessory that permits spontaneous breathing in accordance with ISO 17510 can cause asphyxiation.
- Sleep apnoea breathing equipment are not suitable for patient's requiring continuous device support.
- 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.
- Do not modify this device without authorization of the manufacturer or open this device by yourself, contact YUWELL when the device needs repairing.
- Restrictions on the device connection to other equipment or network/data couplings, other than those forming part of an ME system.
- This device is not for life support. It may shut down without electricity, but no unacceptable risk will happen.
- The device can't be used in the presence of a flammable anesthetic mixture with air or with oxygen or with nitrous oxide gases. (Non-AP and Non-APG series PAP)
- Do not place the device where it can be bumped or where someone is likely to trip over the power cord.
- 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 device 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.
- Always power off the device before cleaning and make sure that all parts are dry before plugging it back in.
- 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.
- Do not use cleaning methods/products that are not recommended in this manual（e.g., bleach, chlorine, ozone, UV, alcohol, aromatic solution, moisturizer, antibacterial soap, fragrance oil）to clean the device and accessories, otherwise it may cause danger or affect the performance of the device or reduce the service life of the device.
- Basic safety and essential performance of the device should be maintained during the therapy.

4. Precautions

- Only using accessories, detachable parts, and materials described in the instructions for use. Non-specified parts may reduce effectiveness of the therapy and/or damage the device.
- The proper placement and positioning of the mask on the face is critical to the consistent operation of this equipment.
- 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 ℃ 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℃ 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.
- You should ensure that the therapeutic pressure settings are determined individually with the configuration of the device and accessories, being used.
- You should ensure the compatibility of the device and all of the parts and accessories used to connect to the patient before use.
- You should periodically reassess the settings of the therapy for effectiveness.
- Combinations with a humidifier, filter, or exhaust port other than recommended can alter the performance of the device.
- Under normal condition and single fault condition,exhaled air or body fluids do not pass through the water tank polluting the air pathway.
- The manufacturer will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel in parts repair.
- 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/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.
- Not intended for use with patient whose upper airways have been bypassed.
- If you feel uncomfortable or have any emergency, cut off the power immediately to stop therapy and contact your provider or seek medical attention if necessary.
- The intended position of the operator is where the operator can touch it.
- Before use, please check the packing to avoid being unintentionally open, damaged and exposed to unspecified environmental conditions.

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 therapy.

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	Air filter	2
Water tank	1	SD card (optional)	1
Power adapter and Cable (as part of the main device)	1	Clinical guide(optional)	1
User manual	1	Bag	1
Heated tubing(optional)	1		

All parts and accessories do not contain natural rubber latex.

The combined devices are mask(optional) and air tube(optianal).

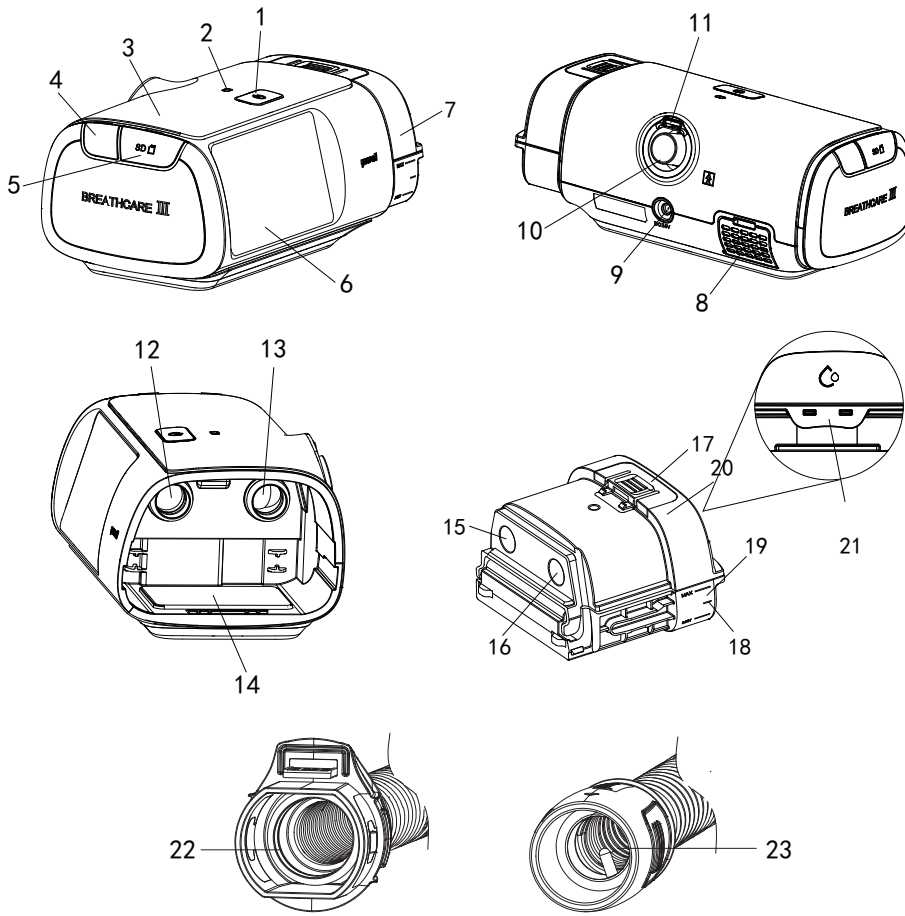
The air tube meeting the following conditions can be chosen to be used with the device.

Length	Inner diameter	The ends
6ft.(1.83m)	15mm/19mm	22mm Cone size comply with ISO 5356-1

The mask manufactured by Suzhou Yuyue Medical Technology Co., Ltd can be chosen to be used with the device.

The mask YN-02 manufactured by Suzhou Yuyue Medical Technology Co., Ltd and air tube HUE19018GT0SSGGK manufactured by PLASTIFLEX GROUP n.v. have been verified.

7. Picture and explanation for product



Number	Name of parts	Explain
1	Start/ Stop button	In standby mode, press this button to start therapy; In therapy mode, press this button to stop therapy
2	Light sensor	Adjusts the brightness of the screen by sensing the light of the environment around the device
3	Complete device	The PAP device

4	Manufacturer reserved port	It is for use by the manufacturer only, not by the user
5	SD card slot	For inserting SD card into the main device
6	Display touch screen	Navigates function and displays device operating status and other information
7	Water tank	Containing water for humidifying gases
8	Air inlet	Inhales fresh air and contains air filter inside to filter solid impurities in the air
9	Power interface	Connects the power adapter
10	Air outlet	Connects air tube/heated tubing to output air
11	Power connection of the heated tubing	Connects here to power heated tubing
12	Air outlet of main device to water tank	To connect water tank with main device
13	Host air adapter	The humidified air passes here and reaches the device outlet.
14	Heating plate	For heating the water in the water tank
15	Humidified air output port	The humidified air is output from here
16	Humidified air input port	Connect the device and air comes in from here
17	Water tank button	Press button to separate the water tank from the main device
18	Water level	Indicates the amount of water added to the humidifier
19	Humidifier base	Used to hold water
20	Humidifier top cover	Open this cover to add water to the humidifier
21	Water tank buckle	Lock or unlock the water tank
22	Device connection port	Connects to the main device
23	Mask connection port	Connects to the mask

8. Explanation of button and icons

▶ 8.1 Button

START/ STOP button: Press to start or stop

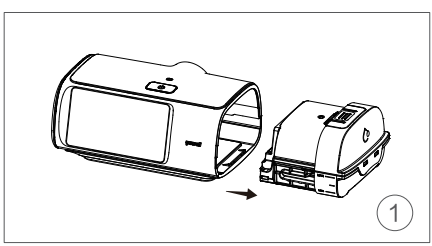
▶ 8.2 Icons

	Sleep Report		Weak signal
	Ramp		No signal
	Humidity		Please wait···
	Mask-fit		Heated tube connected
	Settings		Erase Data
	Strong signal		Data uploaded successfully
	Medium signal		Data upload failed

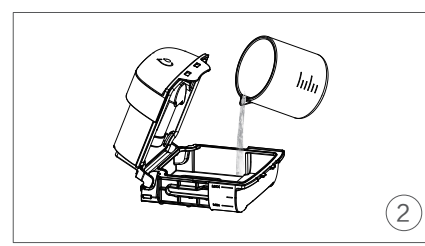
9. Installation

⚠ Caution:

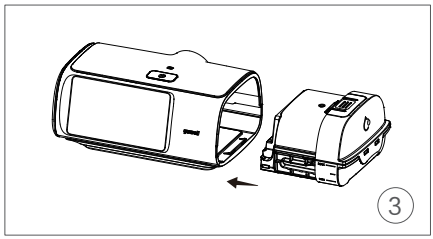
Do not overfill the water tank in case the water may leak into the air tube/heated tubing and the device.
Mains plug is used as the isolation means from mains supply, not to position the device so that it is difficult to operate the disconnection device.
The following section will help you install your device by yourself.



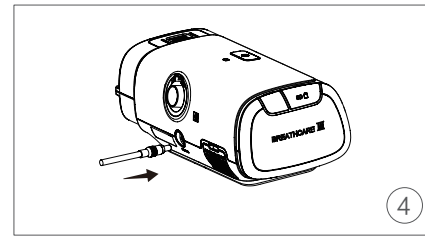
1.Press the water tank button to remove the water tank from the main device.



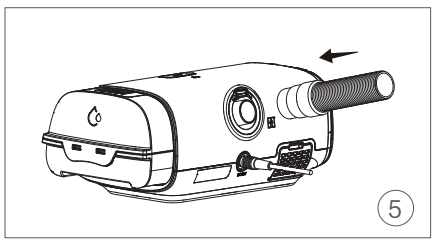
2.Open the water tank and add distilled water between the highest water level and the lowest water level.



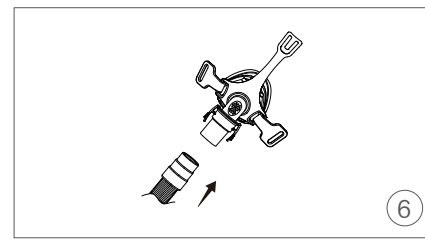
3.Insert the water tank back to the device following the direction shown. When you hear the sound of "da", the water tank is installed successfully.



4.Place the device on a stable level surface and plug the power cable in.



5.Properly connect the air tube/ heated tubing to the air outlet of the device.



6.Wear the mask correctly (refer to the mask user manual) and connect the air tube/ heated tubing to the mask.

⚠ **Caution:**

1. Please change the distilled water in the water tank every day.
2. When the humidity level is 6 and the therapy pressure is 20 cmH_2O/hPa, 8 hours is an expected duration of operation between refills.
3. Do not add any other substances like chemicals, drugs into the water tank, which may result in adverse effects.
4. The indicator light of the power adapter is green during normal operation.
5. Acceptable range of water level is between maximum water level and minimum water level.

10. Therapy

▶ 10.1 Start therapy

- Fit your mask;
- Press start/stop button or breathe normally if the Smart Start is enabled, therapy will start. During the therapy, the real-time average pressure, the initial pressure, the ramp time (min), and the humidity level will 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 start/stop button or tap the screen to turn it back on.

⚠ Caution:

When humidity level is between 1-6 and the device is delivering air pressure, the heating plate is heating (including the situations that the screen diaplays "Large Leakage" and the backlight of the screen is off). When humidity level is 0, the heating plate does not work.

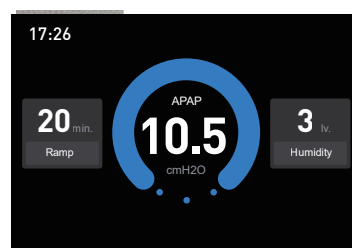


Figure 1: therapy

▶ 10.2 Stop therapy

- Remove your mask first;
- Press the start/stop button or if the Smart Stop function is enabled, therapy will stop automatically after about 8 seconds;
- To power off your device, please disconnect your power adapter from the mains supply.

11. Function

▶ 11.1 Function that patient can safely use

Sleep Report

You can track sleep health on report page after one therapy and read summary report of 7 days and 30 days after a period time of therapy. Following parameters will be displayed. Displayed parameters vary based on different device configuration.

AHI[1]: indicates the number of apneas and hypopneas per hour.

Average AHI: indicates the average number of apneas and hypopneas per hour within the selected time length.

Used Time(h): the time duration of the last therapy (h).

Average Used Time(h): the average therapy duration within the selected time length (h).

Average Pressure: the average pressure within the selected time length (cmH_2O/hPa).

Average Leakage(Lpm): average air leak volume per minute of the selected time length (L/min).

Total Used Time(h): accumulated therapy time of the device.

Uploaded/Total Data: number of data uploaded successfully/number of data stored in device.

P90: the pressure for the 90th percentile of the selected time length (cmH_2O/hPa).

*1: AHI provided by positive airway pressure units is an estimate and not diagnostic parameter.

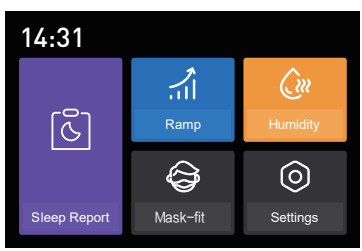


Figure 2-1: Home

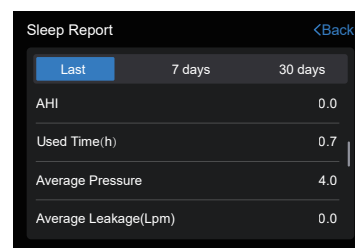


Figure 2-2: Sleep Report

Ramp

Ramp time is designed to make you feel more comfortable at the beginning of the therapy; you can adjust the ramp time from 0 to 60 min with an increment of 5min or automatic.

To adjust the Ramp time:

- Tap "Ramp" to enter the settings page;
- Tap time to adjust your setting;
- Tap "OK" to save your change.

You can change humidity level during therapy.

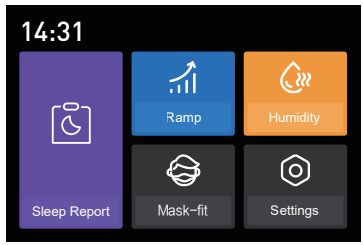


Figure 3-1: Home

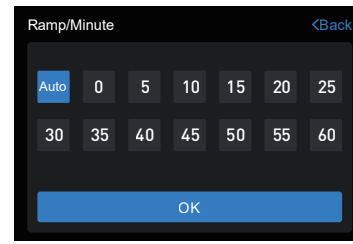


Figure 3-2: Ramp

Humidity Level

Humidifier is designed to moisten the air and to make therapy more comfortable. If you are getting a dry nose or mouth, turn up the humidity level. If there is any water droplets in your mask, turn down the humidity level. You can set humidity level between 0 to 6 or automatic, where 0 means this function is disabled, 1 is the lowest humidity level and 6 is the highest humidity level.

The temperature of each level on the heating plate does not exceed 68℃.

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

To adjust the humidity level:

- Tap "Humidity" to enter the settings page;
- Tap time to adjust your setting;
- Tap "OK" to save your change;

You can change humidity level during therapy.

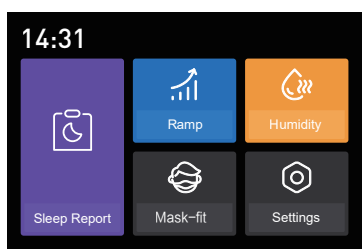


Figure 4-1: Home

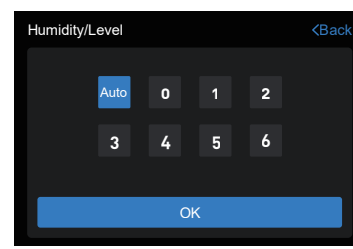


Figure 4-2: Humidity

Mask-fit

The mask test function can help you evaluate whether the mask is worn correctly and whether there is air leakage.

In the standby interface (Figure 5-1), click the "Mask Test" icon to enter the mask test page (Figure 5-2), where your mask fit can be tested. Put on the mask according to the mask wearing guide, click "Start Test", and the device will adjust according to your breathing conditions help you determine whether there is air leakage when wearing the mask.

After the mask test is completed, if is displayed , it means the mask is worn properly and there is no air leakage; if is displayed , it means the mask is not worn properly, it is recommended to read the mask wearing guide and then put the mask back on or adjust the mask and retest.

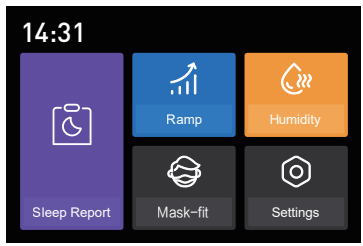


Figure 5-1: Home

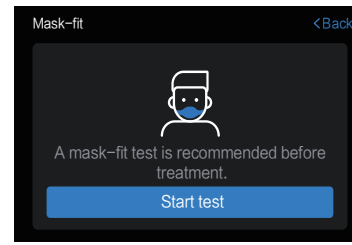


Figure 5-2: Mask-fit

Settings

You can set the following parameters:

- **Mask Type**: You can choose the mask type according to the actual mask worn, like full face and nasal mask, nasal pillow or others.
- **Tube Type**: You can choose the tube type according to the actual tube worn, like 15 mm（model：YHT-01） and 19 mm.
- **Heated Tubing**: You can choose the heated level (0-5 level) of the heated tubing or set auto mode to decrease the condensed water droplets.
- **Sound Reminder**: When this function is enabled, the device will give a sound reminder, if abnormal air leakage occurs.
- **Auto Start**: When this function is enabled, therapy starts automatically when you breathe into your mask.
- **Auto Stop**: After you remove your mask, it will stop automatically in 8 seconds.
- **FPS** : When this function is enabled, you may feel easier to breathe out; It helps you to get used to the therapy. FPS has 4 levels, 0 means this function is disabled, 1 is the lowest level of FPS, and 3 is the highest level of FPS. Higher FPS level means more comfortable expiration you will get.
- **Backlight**: Adjust the brightness of the screen manually or automatically.
- **Date and Time**: Adjust the date (year, month, day and time) displayed on the device.
- **Pressure Unit**: Adjust the unit of the pressure (cmH_2O/hPa).
- **Language**: You can choose English or other languages.
- **Upload Data**: You can choose to turn on or off this function.
- **Filter Reminder**: When this function is enabled, this can remind you to check and change the air filter.
- **Mask Reminder**: When this function is enabled, this can remind you to check and change the mask.

• **Tube reminder**: When this function is enabled, this can remind you to check and change the tube.
• **Reset**: When this function is enabled, parameters of the device will be reset to the factory defaults.
• **About**: You can refer release version/full version of the software, serial number (SN) of the device and motor running time.

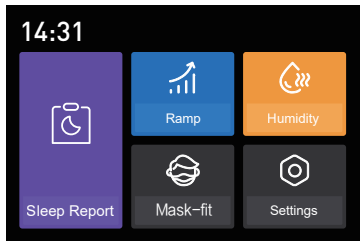


Figure 6-1: Home

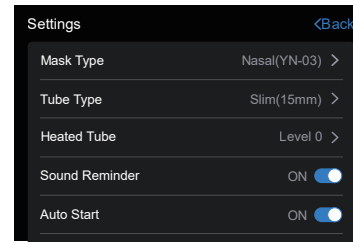


Figure 6-2: Settings

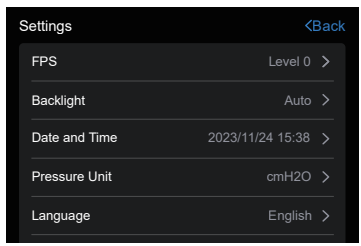


Figure 6-3: Settings

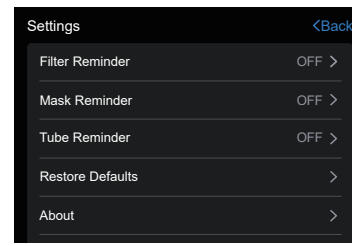
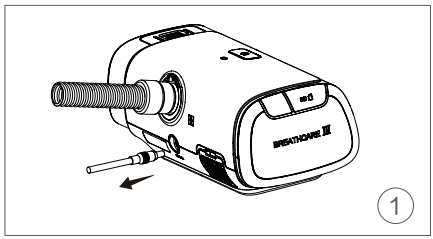


Figure 6-4: Settings

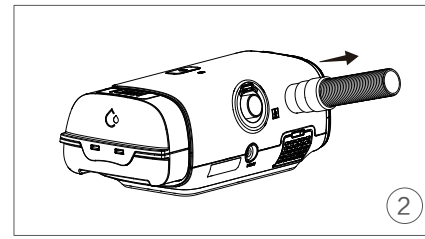
12. Caring for your device

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

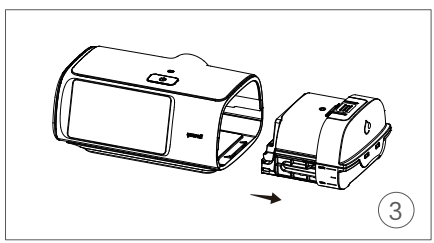
► **12.1 Disassembling**



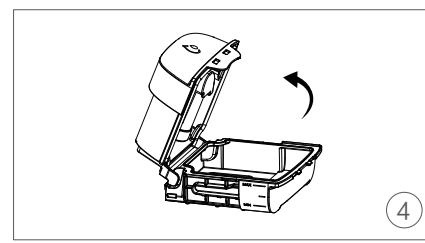
1.Disconnect the power adapter from the main device.



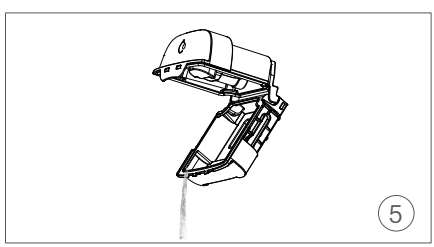
2.Rotate the air tube port (or hold the buckle of the heated tubing) and remove the tube from the device.



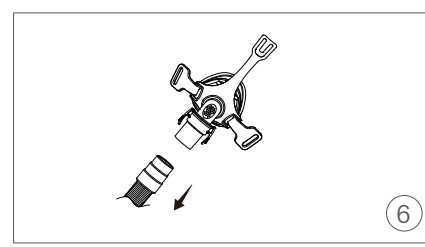
3.Separate the water tankt from the device following the direction shown



4.Release the water tank buckle and lift the top cover.



5.Pour out the remaining water.



6.Separate the mask from the air tube (or heated tubing).

⚠ **Notice:**

Don't pull the threaded portion of the air tube/heated tubing.

► **12.2 Cleaning**

⚠ **WARNINGS!**

Regular cleaning of the device and its accessories are 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 cable has been unplugged. Make sure the water tank and heating plate has cooled down to room temperature to avoid burn.
- 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 use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing moisturizing agents or antimicrobials should not be used either. These solutions may harden cleaned materials or reduce their lifespan.
- Do not immerse the device in any fluids.
- It is recommended to store the device and its components in a portable bag after use and cleaning.

12.2.1 Cleaning and drying the water tank

- Cleaning: 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.
- Drying: Allow the water tank to dry out of sunlight.

⚠ WARNINGS!

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

⚠ 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 tank.

12.2.2 Cleaning and drying the exterior

- Cleaning: Wipe the surface of the device with a soft, slightly damp cloth.
- Drying: Allow the device to dry for sufficient time.

⚠ **CAUTIONS!**

The device can only be used after the exterior is dry, so that no moisture enters the device.

- It is recommended to clean the exterior once a week.

12.2.3 Cleaning and drying the air tube

- Refer to the cleaning procedure in the user manual of the air tube.

⚠ **Note:**

Keep the electrode end of the heated tubing away from water or other fluids. When connecting the device, ensure that both the interior and the two connecting ports of the heated tubing are dry.

12.2.4 Cleaning and drying the mask and headgear

- Refer to the cleaning procedure in the user manual of the mask.

► 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 clean soft cloth 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/heated tubing

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

e. Check the mask

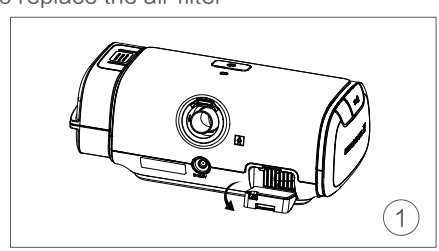
Replace the mask if there are any holes, tears or cracks.

f. Check the air filter

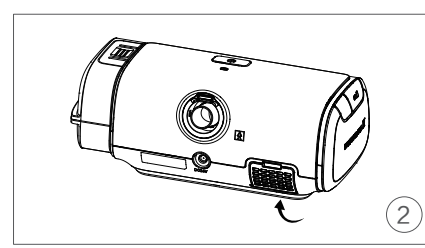
- Please check the air filter every week and prefer to replace the air filter every four weeks.

If you find some particle blocked in the air filter, replace it more often.

To replace the air filter



1.Open the filter cover and remove the old air filter.



2.Replace the air filter and close the 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/heated tubing are dry, you can reassemble the parts.

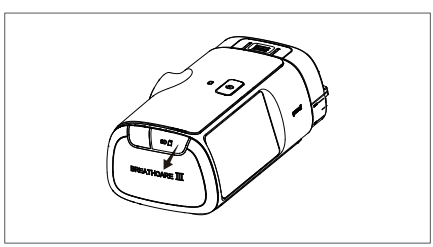
- Open the cover and fill the distilled water into the water tank.
- Close the cover, and insert it into the side of the device.
- Connect the air tube/heated tubing firmly to the air outlet located on the top of the device.
- Connect the free end of the air tube/heated tubing firmly onto the assembled mask.
- Plug the power adaptor into the rear of the device.

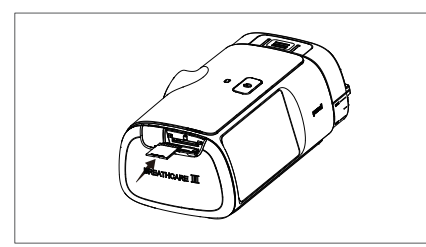
13. Therapy data

► 13.1 Export therapy data through SD card

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

- Before therapy, please open the silicone cover of the device SD card port;
- Insert the SD card into the SD card slot;
- Power on the device and start therapy. After therapy, the screen automatically displays "SD writing" , "Successfully" or "Write failed" .
- If you need to view the data on the SD card, remove the SD card from the device after successful copy.





⚠ Caution

Don' t use the Type-C interface, since it is reserved for the manufacturer.

► 13.2 Transferring therapy data through WiFi (Optional)

The device is equipped with a WiFi module that can transfer therapy data to the designated server.
For more information on how to connect the device to a wireless network and check the wireless network signal, therapy data. Refer to the “wireless connection operation guide”.

► 13.3 Transferring therapy data through cellular communication (Optional)

The device is equipped with a cellular module that can transfer therapy data to the designated server.
• Power on the device, enter the “Setting” page, confirm the “Upload data” displays ON, and then back to the home page.
• On the home page, confirm the net signal according to the signal icon in the upper right corner of the main page. Otherwise, the data cannot be uploaded.
• When the signal strength of the device is different, the signal icon will have different display, which are “no signal”, “weak”, “ medium” or “strong”.

► 13.4 Wireless Electronic interface information(Optional)

13.4.1 Characteristics of the wireless technology

Module	WiFi&Bluetooth module
Frequency	WiFi: 2400-2483.5MHz ; Bluetooth: 2400-2483.5MHz ;
RF Modulation	WiFi: IEEE802.11b/g/n : 11b: DBPSK, DQPSK, CCK for DSSS; 11g:BPSK, QPSK, 16QAM, 64QAM for OFDM; 11n:BPSK, QPSK, 16QAM, 64QAM for OFDM; Bluetooth: BLE4.2

Modulation mode Data rates	WiFi: IEEE802.11b/g/n : 11b：1,2,5.5 ,11Mbps; 11g:6,9,12,18,24,36,48,54Mbps; 11n_HT20: MCS0~7, 65Mbps max; Bluetooth: BLE4.2 : 1Mbps max;
Bandwidth	20MHz bandwidth transmission
Rated Output Power	WiFi: IEEE802.11b/g/n : 11b: 16dBm; 11g: 15dBm; 11n: 13dBm ; Bluetooth: BLE4.2: 5dBm

Cellular Module	Cat. 1
LTE-FDD/Frequency	B1,B3,B7,B8,B20,B28
Transmission power	23dBm ± 2.7dB

*Bands may not be available in all regions.

13.4.2 QoS needs

The wireless function (including WiFi and cellular networks) requires a throughput of more than 100kbps. Transmission of a data package should have a latency of less than about 2s. The wireless function should not exceed 5% packet error rate (PER). Otherwise, it may fail to upload the therapy data to the server.

13.4.3 Information addressing wireless issues and wireless coexistence

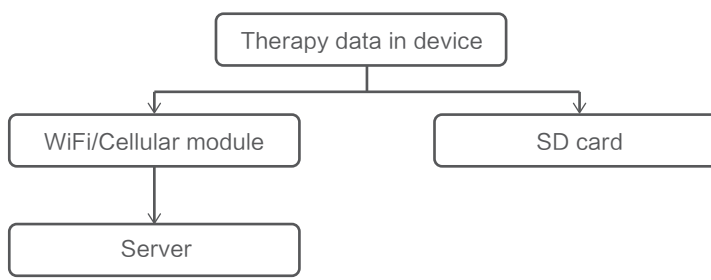
Problem	Possible Cause	Solution(s)
Fail to configure network	Incorrect account password or incorrect format.	Check the account password and format, try to configure again referring to the instructions.
	Too far away from the router or access point.	Reduce the distance from the router or access point.
	The influence of other RF transmitters.	Increase separation distances from other RF transmitters.
Fail to upload data	Fail to connect to the access point.	Check the network and reduce the distance from the router or access point.
	The influence of other RF transmitters.	Increase separation distances from other RF transmitters.

▶ 13.5 IT Security

• The intended operating environment: The WiFi data transmission function is expected to be used in the home/hospital wireless network environment. The cellular data transmission function is expected to be used in the 4G network environments.

• User requirements in terms of training / required skills：Refer to the user manual and operation guide to connect to the network. Refer to the user manual to operate the device and transmit therapy data.

• Network diagrams: Network diagram is as shown in the figure below：



Matrix of the network data streams:

Protocol types	Origin of data streams	Destination of data streams	Addressing scheme
private protocol	Positive Airway Pressure Units	WiFi module/Cellular modulel	serial port communication
MQTT	WiFi module	server	IP addressing
MQTT	Cellular module	server	IP addressing

List of network ports:

Network ports	Attribute	Function
SD	Incoming/outgoing	data copy; SD drive distribution network (For connecting WiFi)
WiFi module	outgoing	data transmission
Cellular module	outgoing	data transmission
Type-C	Incoming/outgoing	Manufacture reserved

- The procedures of backup and restore：Server automatically backs up data.
- Security update:The data storage service is deployed on the Amazon cloud service provider. Amazon provides corresponding security services, including server network security trends and patch vulnerabilities.
- Logs：Server operation logs record device login records, data transmission records, and operation records.

14. Traveling

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

- 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 troubles, 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 around my mask	Mask may be fitted incor-rectly; The size of the mask is not suitable	Ensure your mask is fitted correctly; See your mask user man-ual 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 consulting a doctor; Adjust the pressure parameter
I am getting water droplets 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 tubing to solve condensation
My mouth is very dry and uncomfortable	Air may be escape from your mouth; The humidity level is not enabled 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.	Click the screen 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
Humidifier leaking	The humidifier is broken	Check whether the humid-ifier is damaged. If dam-aged, please replace the humidifier.
There is no air in the mask	Device does not turn on or malfunctions The breathing circuit (or heated breathing circuit) is not connected correctly The breathing circuit (or heated breathing circuit) is blocked	Refer to the device instruction manual to use the device correctly. Reconnect the breathing tube (or heated breathing tube) correctly Clear the obstruction in the breathing tube (or heated breathing tube)

▶ 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 4	The protection circuit fail	Please contact your provider
ERROR 5	There is a parameter exceed in parameter range	Please repower the device or contact your provider
ERROR 6	The pressure exceeds in pressure range	Replace the filter with a new one or repower 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. Specification of technology

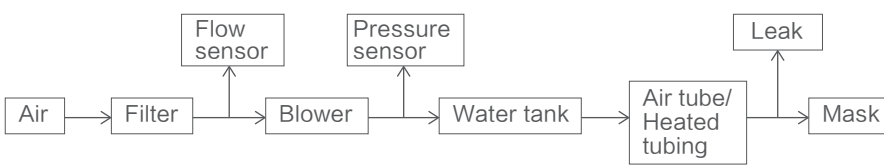
► 16.1 Model

Model	Transmission module
YH-680A	/
YH-680B	WiFi+BLE/Cellular module

► 16.2 Specification of technology

Items	Specification	
Power	Input :100-240VAC, 50 Hz-60 Hz,1.8 A max Output:24V DC, 3.33A	
Environment conditions	Temperature	Operate:+5℃~35℃（+41°F~95°F） Transport :-20℃~60℃（-4°F~140°F） Storage:-20℃~60℃（-4°F~140°F）
	Humidity	Operate: relative humidity 15%-90%, Non-condensing Transport: relative humidity 15%-90%, Non-condensing Storage: relative humidity 15%-90%, Non-condensing
	Atmospheric pressure range	700hPa～1060hPa
	Altitude	≤3000m
Protection class	Type of Protection Against Electric Shock: Class Ⅱ Degree of Protection Against Ingress of Water: IP 22 Degree of Protection Against Electric Shock: Type BF Applied Part	
Applied Parts	Patient interface (mask) and air tube/heated tubing	
Mode of operation	Continuous operation	

Sound	Sound pressure level	Sound pressure level measured according to ISO 80601-2-70:2020 (CPAP mode) 27 ± 2 dB (A)
	Sound power level	Sound power level measured according to ISO 80601-2-70:2020 (CPAP mode) 35 ± 2 dB (A)
Physical properties	Dimensions (length*width*height)	265 mm * 135 mm * 105 mm
	Weight	About 1500 g
	Air tube	Plastic hose，1.80 m ± 0.18 m
	Maximum volume of water tank	300 mL ± 30 mL
	Air outlet	22 mm (complies with ISO5356-1:2015)
Temperature	Maximum temperature of heating plate	68℃ (154.4 °F)
	Cut-out	110℃ (if it is damaged, return to manufacturer)
	Maximum delivered air temperature	⩽ 43℃
Heated tubing	Can be connected to 22 mm standard connectors specified in ISO 5356-1:2015 Pipe length: 1.80 m ± 0.18 m Air flow resistance of threaded pipe: 30 L/min, ⩽0.06 hPa/L/min Leakage rate: ⩽10 mL/min per meter of threaded pipe length Compliance: At a pressure of 6 kPa, the compliance of the threaded tube of the heated breathing tube should not exceed 10 mL/kPa per meter of tube length Power connection: 0-24VDC, 2A (max) Connector output: 0-24VDC, 2A (max)	
Air filter	Average arrestance: ⩾ 75% for 2 micron	
Operating pressure	4~20 cmH_2O/hPa	

<table>
<tr><td>Therapy pressure</td><td>4~20 cmH_2O/hPa (adjustable, step is 0.5 cmH_2O/hPa)</td></tr>
<tr><td>Initial pressure</td><td>4~20 cmH_2O/hPa (adjustable, step is 0.5 cmH_2O/hPa)</td></tr>
<tr><td>Maximum pressure</td><td>4~20 cmH_2O/hPa (adjustable, step is 0.5 cmH_2O/hPa)</td></tr>
<tr><td>Minimum pressure</td><td>4~20 cmH_2O/hPa (adjustable, step is 0.5 cmH_2O/hPa)</td></tr>
<tr><td>Ramp</td><td>0~60min (adjustable, step is 5min) or automatic</td></tr>
<tr><td>Air leakage</td><td>2 L/min at the maximum rated pressure</td></tr>
<tr><td>Maximum flowrate</td><td>The BreathCare PAP performance at set pressure according to ISO 80601-2-70:2020 is shown below：
<table>
<tr><td>Test pressures (cmH_2O/hPa)</td><td>4</td><td>8</td><td>12</td><td>16</td><td>20</td></tr>
<tr><td>Average flow at the PATIENT-CONNECTION PORT (L/min)</td><td>⩾100</td><td>⩾100</td><td>⩾100</td><td>⩾100</td><td>⩾100</td></tr>
</table></td></tr>
<tr><td colspan="2">Pneumatic flow path：
 
</td></tr>
<tr><td>Humidifier performance</td><td>Humidification system output: ⩾ 10 mg/L（BTPS）
Note1: Tested at 15℃-35℃and the humidity level is set at 6
Note2: The humidifier belongs to Category 2 according to the standard ISO 80601-2-74:2021</td></tr>
<tr><td rowspan="2"></td><td>Maximum static pressure variation at 10 cmH_2O/hPa according to ISO 80601-2-70:2020
±0.5 cmH_2O/hPa</td></tr>
<tr><td>Maximum dynamic pressure variation according to ISO 80601-2-70:2020</td></tr>
</table>

<table>
<tr><td></td><td>
<table>
<tr><td>Pressure (cmH_2O/hPa)</td><td>10bpm</td><td>15bpm</td><td>20bpm</td></tr>
<tr><td>4</td><td colspan="3">± [2% of the full scale +4% of the set value]</td></tr>
<tr><td>8</td><td colspan="3">± [2% of the full scale +4% of the set value]</td></tr>
<tr><td>10</td><td colspan="3">± [2% of the full scale +4% of the set value]</td></tr>
<tr><td>12</td><td colspan="3">± [2% of the full scale +4% of the set value]</td></tr>
<tr><td>16</td><td colspan="3">± [2% of the full scale +4% of the set value]</td></tr>
</table>
</td></tr>
<tr><td>Maximum limited pressure</td><td>The maximum limited pressure (main device/ humidifier and accessories)
20 cmH_2O/hPa in normal condition
40 cmH_2O/hPa under single fault condition</td></tr>
<tr><td>The uncertainty of measurement:</td><td>For measurement of pressure: ±0.2 cmH_2O/hPa
For measurement of flow: ±2 L/min or ±3% (whichever is greater)
For measurement of humidification output: ±0.5 mg/mL (BTPS)</td></tr>
<tr><td>SD card</td><td>16 GB
The amount of data in a single use is about 15kB. After calculation, the capacity of the SD card can meet the memory requirements during the service life.</td></tr>
<tr><td>Expected service life</td><td>
<table>
<tr><td>Device (excluding accessories)</td><td>5 years</td></tr>
<tr><td>Water tank</td><td>90 days</td></tr>
<tr><td>Air tube</td><td>Refer to user manual of the air tube</td></tr>
<tr><td>Heated tubing</td><td>90 days</td></tr>
<tr><td>Mask</td><td>Refer to user manual of the mask</td></tr>
</table>
</td></tr>
<tr><td colspan="2">All air volume, flow and leakage specifications shall be expressed at STPD</td></tr>
</table>

17. Symbols

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

Symbol	Meaning	Symbol	Meaning
	Follow instructions for use		A warning/caution
	Type BF applied part		Class II equipment
	Minimum water level		Maximum water level
	Press to start /stop therapy		Warning: hot surface
MD	Medical device		Alternating current
SN	Serial number		Direct current
	Manufacturer		MR unsafe
	General warning sign		Temperature limitation for storage and transport
	Humidity limitation		Atmospheric pressure limitation
Rx Only	Prescription only	#	Model number
UDI	Unique device identifier	REF	Catalogue number
CE 0123	Conforms with medical device regulations 2017/745/EU		
EC REP	Authorized representative in the European Community/ European Union		
	Country of manufacture (China) Date of manufacture is on the right side of the symol or below it.		
	Environmental information (EU directive 2012/19/EE Waste Electrical and Electronic Equipment (WEEE))		
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 titled up to 15 degrees.		

▶ **17.2 The following symbols may appear on the product or packaging:**

⚠ **Warning:**

- The device should be disposed separately, not as unsorted municipal waste.
- You should use appropriate return and collection systems available in your region. The use of these collection, reuse and recycling systems is designed to reduce pressure on natural resources and prevent hazardous substances from damaging the environment.
- The device contains electronic compotents, please do not throw away with common waste. Please dispose of the electronic devices in accordance with the local authorities.
- After usage, please dispose mask, air tube/heated tubing, water tank into garbage bags. In hospital/institution, related personnel shall carry out the terminal treatment in accordance with its own standard sewage treatment process.

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. EMC information

Essential performance: N/A
Pass and fail criteria:
1.static pressure deviation not more than twice the airway pressure accuracy (the airway pressure accuracy is ±0.5cmH_2O)
2.The temperature at the patient-connection port does not exceed 43℃.
Intended use environment: Home healthcare environment & Professional healthcare facility environment.

► 21.1 Compliance information for Emission test

Guidance and manufacturer's declaration – electromagnetic emissions	
The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.	
Phenomenon	Compliance
Conducted emissions CISPR 11	Group 1 Class B
Radiated RF emissions CISPR 11	Group 1 Class B
Harmonic distortion IEC 61000-3-2	Class A
Voltage fluctuations and flicker IEC 61000-3-3	Compliance

► 21.2 Compliance information for Immunity test

Guidance and manufacturer's declaration − electromagnetic immunity	
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.	
Phenomenon	Compliance Level
Electrostatic discharge (ESD) IEC 61000−4−2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields IEC 61000−4−3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Rated power frequency magnetic fields IEC 61000−4−8	30 A/m 50 Hz or 60 Hz
Electrical fast transients/bursts IEC 61000−4−4	± 2 kV 100 kHz repetition frequency
Surges IEC 61000−4−5	± 0,5 kV, ± 1 kV (line to line)
Conducted disturbances induced by RF fields IEC 61000−4−6	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
Voltage dips 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°
Voltage interruptions IEC 61000−4−11	0 % U_T; 250/300 cycles

Test specifications for ENCLOSE PORT IMMUNITY to RF wireless communications equipment (According to IEC61000-4-3)

Test Frequency (MHz)	Band (MHz)	Service	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 − 390	TETRA 400	Pulse modulation 18Hz	27
450	430 − 470	GMRS 460, FRS 460	FM ±5 kHz deviation 1kHz sine	28
710	704 − 787	LTE Band 13, 17	Pulse modulation 217 Hz	9217 Hz
745				
780				
810	800 − 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1700 − 1990	GSM 1800, CDMA 1900, GSM 1900, DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2400 − 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240	5100 − 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

Test specifications for ENCLOSE PORT IMMUNITY to proximity magnetic fields (According to IEC 61000-4-39)

Test frequency	Modulation	Immunity test level (A/m)
30 kHz [a)]	CW	8
134,2 kHz	Pulse modulation [b)] 2,1 kHz	65 [c)]
13,56 MHz	Pulse modulation [b)] 50 kHz	7,5 [c)]
a)This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEATHCARE ENVIRONMENT. b)The carrier shall be modulated using a 50% duty cycle square wave signal. c)r.m.s., before modulation is applied.		

▶ 21.3 Precautions According to IEC60601

According to IEC60601-1-2:2020, BreathCare PAP complies with all applicable electro-magnetic 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 inter-ference 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.
- Stop therapy and 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 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 _____

yuwell

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 _____

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