yuwell

User manual

Version NO: 2018-11 English only

Positive Airway Pressure Units
BreathCare PAP

Model: YH-820/YH-825/YH-830

Name of manufacturer：Suzhou Yuyue Medical Technology Co.,Ltd.
Add of manufacturer：No.9 Jinfeng Road, Suzhou Science & Technology Town,
215163 Suzhou, Jiangsu, PRC
TEL：0512-67373086
http://www.yuwell.com

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TWPP
Paper

Read this entire guide before using the device.

Welcome

The YH-820,YH-825,YH-830 are Yuwell’s bi-level continuous positive airway pressure device (Bi-level).

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.

Content

1.Introduction

Bi-level has 3 models: YH-820, YH-825 and YH-830. All these models of device consist of main device, water tank and power adapter. Mask and air tube are purchased.

YH-820

The YH-820 Bi-level device is indicated for treatment of sleep apnea hypopnea syndrome in patients weighing more than 66lb (30kg). It is intended both for home use and hospital use. The water tank is intended for single patient use in the home environment and re-use in a hospital/institutional environment.

YH-825

The YH-825 Bi-level device is indicated for treatment of sleep apnea hypopnea syndrome in patients weighing more than 66lb (30kg). It is intended both for home use and hospital use. The water tank is intended for single patient use in the home environment and re-use in a hospital/institutional environment.

YH-830

The YH-830 Bi-level device is indicated for treatment of sleep apnea hypopnea syndrome in patients weighing more than 66lb (30kg). It is intended both for home use and hospital use. The water tank is intended for single patient use in the home environment and re-use in a hospital/institutional environment.

2.Scope of application

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

3.Contraindications and adverse effect

▶ 1. Contraindications:

Positive airway pressure therapy may be contraindicated on some patients who has following disease:

> Severe bullous lung disease, pneumothorax, pathologically low blood pressure, dehydration, cerebrospinal fluid leak, recent cranial surgery, or trauma, severe lack of effective circulating blood volume with shock, coma or disturbance of consciousness, weak spontaneous breath.

▶ 2. Adverse effects:

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

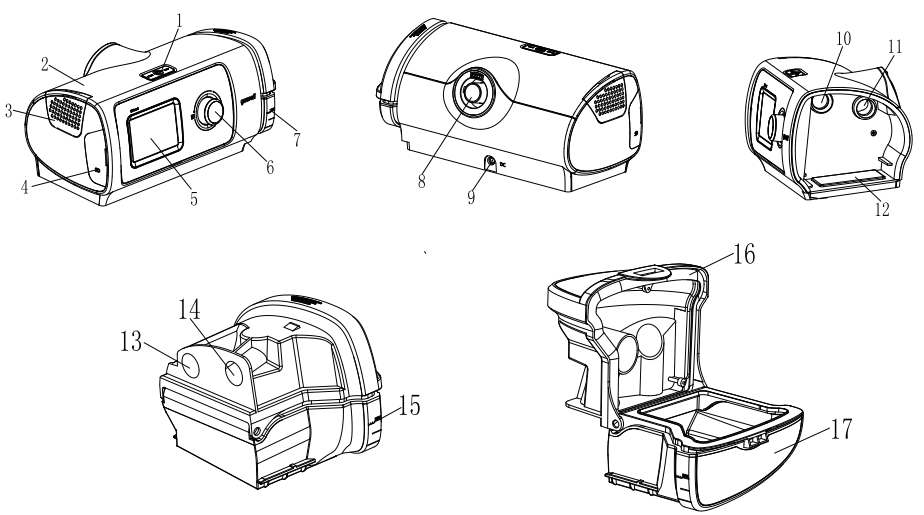
The following adverse effects may be shown during therapy:

> Dry of mouth、nose、throat, nosebleed, bloating, ear or sinus discomfort, eye irritation, skin rashes;

4.Package table

Name	Quantity	Name	Quantity
Main device	1	Mask (with mask accessories)	1
Water tank	1	Bag	1
Air tube	1	SD Card	1
Power adapter and Cable	1	Air filter	2
User manual	1		

5.Picture and explanation for product



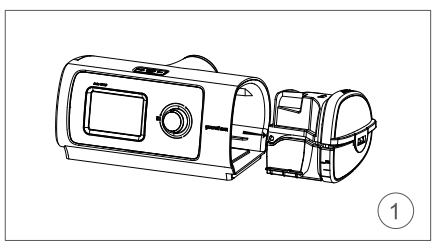
1.START/STOP button
2.Main device
3.Air filter
4.SD card interface
5.Screen
6.Dial
7.Water tank
8.Air outlet
9.Power interface
10.Air outlet of main device to water tank
11.Air outlet of main device
12.Heater plate
13.Air outlet of water tank
14.Air inlet of water tank
15.Water line
16.Cover of water tank
17.Container of water tank

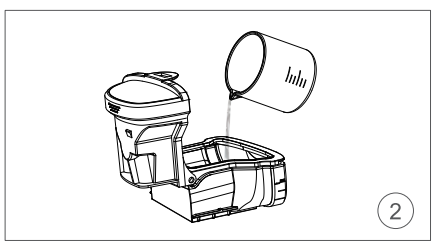
6.Explanation of button

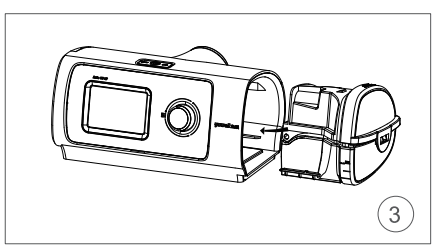
START/ STOP button: press to start /stop therapy.

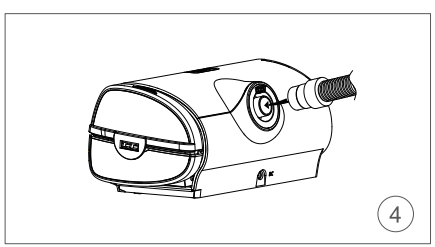
Dial: turn to navigate the menu and press to select an option. Turn to adjust the options and press to save your choice.

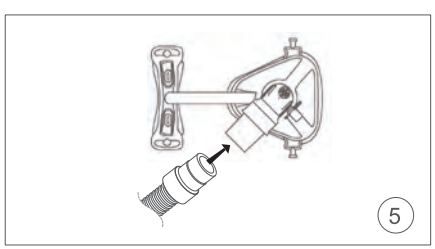
7.Installation

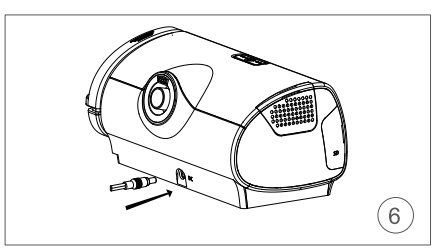












⚠ Caution

Do not overfill the water tank in case the water may enter the air tube and device.
The following section will help you install your device by yourself .

① Place the device on a stable level surface; Hold the water tank at the top and bottom, press it gently and pull it away from the device;

② Fill the distilled water into the water tank, please notice that do not place the hot water into it;

⚠ Caution

please change the distilled water in the water tank every day.

③ Place the water tank Back; The environmental temperature range for humidifier is +5℃~+35℃, the temperature for input environmental should not over 3℃ of environmental temperature;

④ Connect the air tube firmly to the air outlet located on the rear of the device;

⑤ Connect the free end of the air tubing firmly onto the mask; refer to mask instruction;

⑥ Plug the power connector into the rear of the device.

⚠ Caution

Please ensure the clinical parameter is set by your physician.

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.

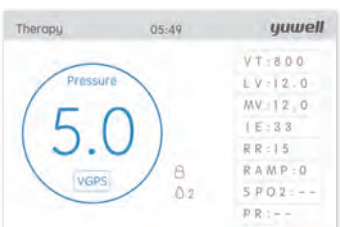
8.Therapy

▶1. Start therapy

1.Fit your mask;

2.Press the START /STOP button;

- The current treatment pressure will be shown on the screen;
- During the ramp time, the pressure increased gradually until the setting pressure has been reached.



▶2.Stop therapy

- Remove your mask first;
- Press the START button, therapy will stop;
- To power off your device, please separate your plug from the electricity.

9.Function

▶9.1 Function that patient can safely use:

The therapy parameter (e.g. therapy pressure, model) will be set by your physician; however, you can make small adjustment to make your therapy more comfortable.

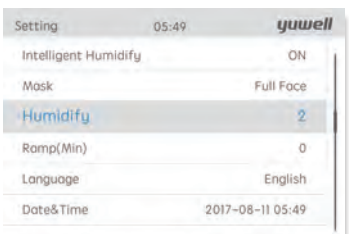
9.1.1. Setting:

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

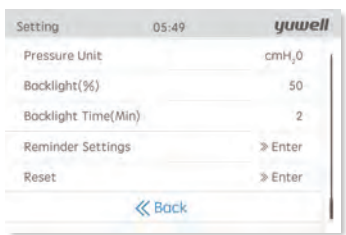
- **Intelligent humidify:** Enable this function, the output of humidify will be changed automatically according to the temperature of environment.
- **Mask:** Highlight this option, choose the mask type you use (full mask or nasal mask);
- **Humidity:** It is designed to moisten air and is designed to make therapy more comfortable. You can set Humidify between 0 to 6, where 0 means disable this function, 1 means the lowest level of the humidity and 6 represent the highest level of the humidity. This temperature has been tested with empty water tank. The time required (warm-up time) to reach the set temperature from a starting temperature of (23 ° C ± 2 ° C) is 10minutes.The temperature of each level on the heater plate is as following (accuracy is ±4℃)

  1=33℃ 2=35℃ 3=40℃ 4=45℃ 5=50℃ 6=55℃

- Highlight the humidify, press the dial and rotate it choose humidity level, then press dial again to save your change. You can change humidity level at any time during therapy.
- **Ramp(min)**: Ramp time designed to make you more comfortable at the beginning of the therapy; you can adjust the ramp time from 0 to 45 minute.
- **Language**: You can choose English or Chinese;
- **Date&Time**: You can adjust time shown on the screen;(year、month、date、hour、minute);
- **Pressure Unit:** You can choose cmH2O or hPa;
- **Back light(%):** You can set the back light of the screen of this PAP. The range of setting is 0-100%;
- **Backlight Time (Min):** You can set the backlight time of the screen of this PAP. The range of setting is from 1 minute to 30 minutes.
- **Reminder Settings:** Enable this function, this can notice you when to check and change accessories, e.g. filter, mask, and tube;
- **Reset:** This function can reset the machine parameters to the factory defaults.



Picture2−1：Setting page



Picture 2−2：Setting page

9.1.2 Reminder:

This option is designed to give notice information including sound and message when users come with some problems. There are following notice options:

- **High Pressure Reminder Sound**: When the user upper airway pressure is over 3.5cmH2O of the setting pressure, the PAP will beep with reminder message with reminder sound.
- **Low MV Reminder Sound:** The minute volume is lower than the setting value; the PAP will beep with reminder message with reminder sound. The range of the reminder value is 1 to 10 L.
- **Leak Reminder Sound:** When this option is enabled, the PAP beeps with reminder message with reminder sound if the mask leaks too much air or if you remove the mask during the therapy.
- **Outage Reminder Sound**: When the power is stopped suddenly, the PAP will beep with reminder message with reminder sound.
- **Asphyxiation Reminder Sound**: When the time of user asphyxia is over the set value, the PAP will beep with reminder message with reminder sound. The range of the reminder value is 10 to 40 second.
- **Low VT Reminder Sound:** The tidal volume is lower than the setting value; the PAP will beep with reminder message. The range of the reminder value is 50 to 500ml.

Picture3−1：Reminder page

Picture 3−2：Reminder page

9.1.3 .Information:

You can read summary of sleep report on information page. Following parameter will been shown

- **AHI:** Indicated the number of apneas and hypopneas experienced per hour during latest therapy;
- **Total Time**: Indicated total time of therapy;
- **Once Time**: Indicated time of the latest therapy;
- **Average Leak Volume**: Indicated average leak volume of latest therapy;
- **Version:** Indicated the version of software inside the device;
- **SN**: Indicated serial number of the device.

Picture4−1: Information page

Picture 4−2：Information page

▶9.2Function that patient must be used under the direction of doctor (Clinical Parameter Setting):

The patient should use the device by the direction of physician. The clinical parameter should set by physician.

• At home page, press START/STOP and dial at the same time, the clinical menu will be shown on screen (see picture5-1).

• Or at home page, choose the therapy option and enter the therapy page, then press START/STOP and dial at the same time, the clinical menu will be shown on screen also (see picture5-2).

Picture5−1：Clinical setting

Picture 5−2：Clinical setting

9.2.1 Set the mode

• At clinical menu page, swirl the dial, highlight the “Mode” , and then select CPAP, S, ST, T or VGPS.

• After mode setting, press dial to save your change.

9.2.2 Choose the pressure(IPAP, EPAP, IPAP max, IPAP min, Initial Pressure, Pressure Setting)

• At clinical menu page, highlight “IPAP “, press and switch dial setting suitable value.

• You can swirl the dial to the right or to the left to rise or decrease IPAP (each step is 0.5cmH2O /hPa).

• After setting IPAP, press dial to save your change.

⚠ **Notice**:

The CPAP mode just has Initial Pressure and Pressure Setting.

The VGPS mode has IPAP max, IPAP min and EPAP.

9.2.3 Set respiratory rate (BPM)

• At clinical menu page, highlight “BPM “.

• Swirl the dial to the right or left, set respiratory rate (5-50bpm).

• After setting respiratory rate, press dial to save your change.

9.2.4 Set Trigger level:

• At clinical menu page, highlight “trigger “.

• Swirl the dial to the right or left, set your level of trigger (1-5 level).

• After setting level of trigger, press dial to save your change.

9.2.5 Set cycle level:

• At clinical menu page, highlight “cycle “.

• Swirl the dial to the right or left, set your cycle level (1-5 level).

• After setting cycle level, press dial to save your change.

9.2.6 Set the slope level

• At clinical menu page, highlight “slope “.

• Swirl the dial to the right or left, set your slope level (1-5level).

• After setting slope level, press dial to save your change.

9.2.7 Set the IE ratio (IE)

• At clinical menu page, highlight “IE “.

• Swirl the dial to the right or left, set your slope IE ratio (10%-70%).

• After setting IE ratio, press dial to save your change.

9.2.8 Set the tidal volume (VT)

• At clinical menu page, highlight “VT “.

• Swirl the dial to the right or left, set your VT (50-1500ml).

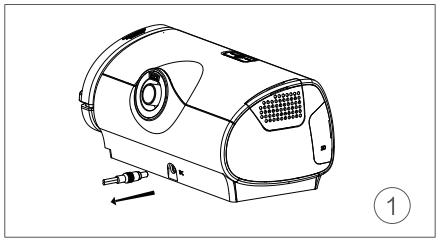
• After setting VT, press dial to save your change.

• This option only for VGPS mode

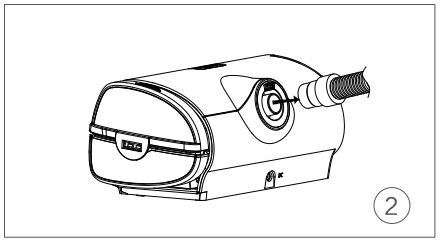
10.Caring your device

It is important for you to clean your device regularly to ensure your therapy effective. The following section will help you to disassembling、cleaning、checking、reassembling.

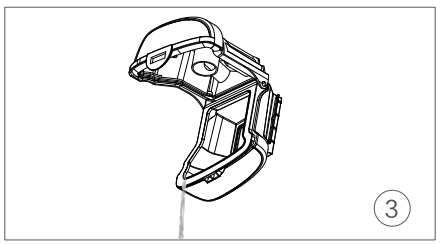
▶ **1.Disassembling**



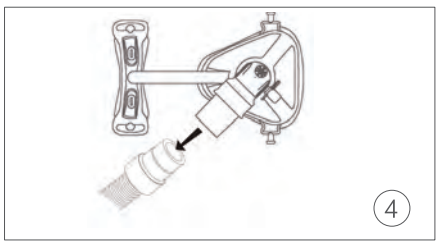
1. Pull the power connector out of device



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



3. Pull out the left water inside water tank



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

▶ **2.Cleaning**

Please clean your device under the service environment of this device. It may be influenced by dust, thus please following several steps cleans your device, and you must 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 your air tube, water tank and mask in warm water. The temperature of the warm water should not be over 41℃.

⚠ **Caution**

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

- Flushing air tube， water tank and mask totally, dry out of direct sunlight or heat.(Temperature should not beyond 40 degree);
- Wipe the air tube， water tank and mask with a dry cloth.

▶ **3.Checking:**

You should check water tank, air tube, air filter regularly in case any damage.

A.Check water tank:

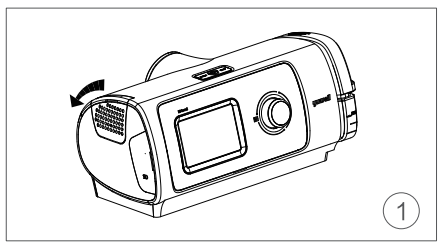
- Replace the water tank if it is broken or cracked;
- Replace the water tank if it is torn or cracked;
- Please check the water tank after use the PAP, please empty the water tank before put it inside the bag.

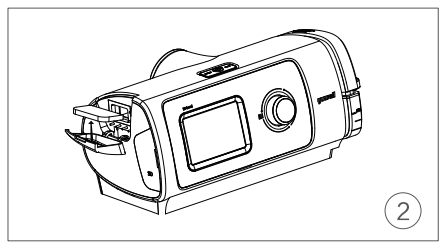
B.Check the air tube and mask

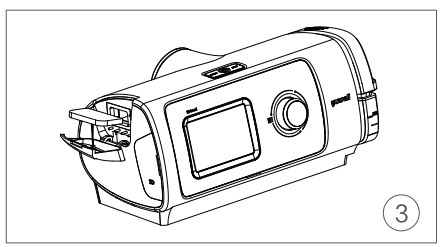
- Please check the mask and the air tube before use the PAP, clean the mask and air tube according to the instruction of mask and tube.
- Replace the air tube if it is any broken, holes or cracked;

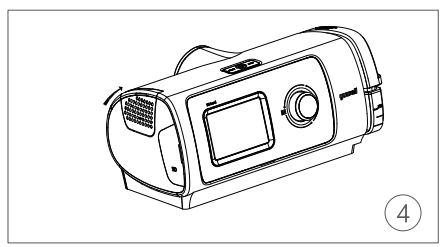
C.Check the air filter

- 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;









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.

▶ **4.Reassembling:**

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

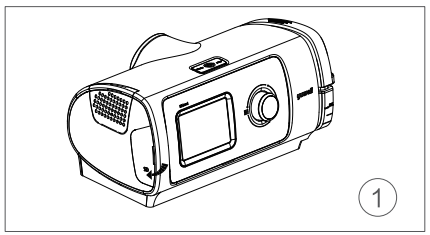
- Open the water tank and fill it with distilled room temperature water up to the maximum water level mark.
- Close the water tank and insert it into the side of the device.
- Connect the air tube firmly to the air outlet located on the rear of the device.
- Connect the free end of the air tube firmly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

11.Therapy data

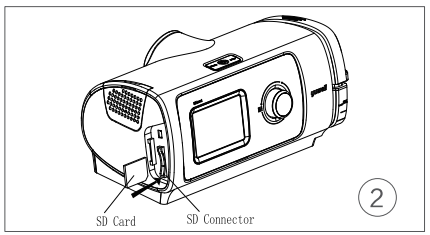
BreathCare PAP records your therapy data for you and your card provider so they can view and make change to your therapy if required. The data is recorded and then transferred to your care provider via a SD card.

⚠ Caution

this card is only used for record therapy data.



1.Find the SD interface at the left side of main device



2. Inset SD card and wait until the screen shown “SD card write successful.”

12.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 before packing it.
- Make sure you have the appropriate power cord for the region you are traveling to. For information on purchasing, contact your provider.

13.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. Please do not take your device apart by yourself.

▶ **1.General trouble**

Trouble	Cause	Solution
Air is leaking from may 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 dry or blocked nose.	Humidify may set too low	Adjust humidify.
I am getting droplet in my mask and air tube.	Humidify level may set too high	Adjust humidify
My mouth is very dry and uncomfortable	Air may be escape from your mouth	Adjust humidify Use the full mask.
Air pressure in my mask seems too high	Ramp may be turned off	Enable your ramp option.
Air pressure in my mask seems too low	Ramp may be enabled	Start your therapy after the setting pressure reached or turn ramp time off.
My screen is black	After therapy start, the screen turn black; 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 air is leak from water tank.	Water tank assemble incorrectly or it is broken	Check the water tank assemble correctly; Contact your provider if your water tank is broken.

▶ **2.Other trouble**:

Message in LCD	Meaning of error	Solution
High pressure Reminder	There is a mistake of pressure	Please check the pressure sensor or restart the device
Low MV Reminders	The volume of breath per minute is too small	Check the situation of breath or lower the set Low MV reminder value
Leakage Reminders	There is a large leak of mask	Please check the mask fit
Asphyxiation Reminders	The user do not has autonomous respiration	Please check the mode if it is suit for the patient
Low VT Reminders	The mode patient used is not suitable	Please check the mode if it is suit for the patient

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

14.Warning and cautions

▶ **1.Warning:**

- Do not maintain the device while it is in use, otherwise it may leads to unaccepted risk.
- Do not modify this equipment without authorization of the manufacturer or open this device by yourself, contact yuwell when you need repair the device.
- This device cannot be used for life support. It may be shut down by turn off the electricity, but no unaccepted risk will happen.
- The parameters of the device can be only adjusted by your physician; the patient cannot operate this device without the instruction of physician.
- Using only yuwell part and accessories with device. Non-YUWELL parts may reduce effectiveness of yuwell device and may damage the device.
- According to IEC60601-1, this device is belonging to neither AP nor class APG, so using it in environment has Flammable anesthetic agents with oxygen is forbidden.
- Please use the yuwell mask with several holes. Keep outlet clean, smooth ensure fresh air can get in your mask.
- Do not block the several holes in your mask, otherwise it will result strangulation.
- Do not place the device where it can be crashed or somewhere children may be tripped by the power.
- Do not block the air tube and/or air inlet of the device while in operation could lead to overheating of the device.

- Place the device on the stable table. Placing device on the soft, out of flatness surface is forbidden.
- Keep the environment around the device clean and tidy; be apart from anything that can block outlet.
- Keep device far away from water.
- Do not use bleach, chlorine, alcohol, 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.
- Power is a mean to isolate it circuits electrically from the supply mains may on all poles simultaneously
- Place the device beyond the surface of your head to prevent water flow backward patient’ s mask and air tube.
- Pour out the water in the water tank before you move it.
- This device cannot be used for multiple patient
- Interconnection of this equipment to other equipment which is not the supply one is forbidden.
- The sources of oxygen should be located more than 1 m from the BreathCare PAP to avoid the risk of fire and burns.
- The duration of contact should not over 24 hours.
- 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.
- 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.
- The device may be disturbed or affected when exposed to the following environments, e.g. magnetic fields, electromagnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources.
- 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, Infrared radiation, Conducted transient magnetic fields, Magnetic resonance imaging (MRL), Radiofrequency interference.

▶ **2.Caution:**

- Ensure the air tube connect smoothly. Do not warping the air tube.
- Ensure the power adapter and plug is not broken.
- Do not lay the power adapter near to the heat source.
- If device has any strange, e.g. strange nosy, falling from the table, broken device shell, please stop using this device and power off the equipment, then contact with your provider.
- Be care of your power supply. Do not put device, power, and power adapter into the water. Cut down the electricity and separate the device and water tank if you spill some water on the device.
- Separate the device and water tank before your cleaning and combine them after cleaning.
- Do not cleaning the device during the time of device active.
- 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 humidification system output and relative humidity over the recommended operating range of gas flowrates and settings are not more than 50%.

15.Specified of technology

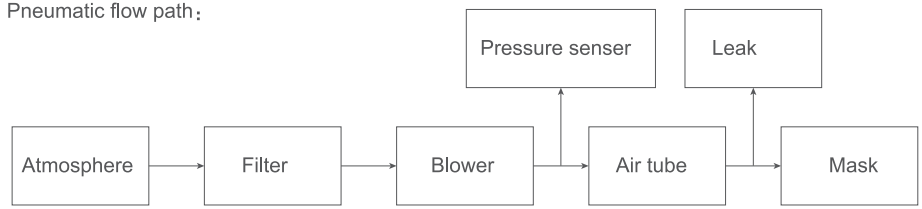
Items	Specifies	
Power	Powered by adapter（Model: BJE1M-0080-N608） Input :100-240VAC(±10%), , 50/60Hz,1.8Amax Output:24V DC,3.33A	
Environment conditions	Operating Temperature	Operate:+5℃~35℃(+41℉~95℉), （non-condensation） Transport :-20℃~70℃(-4℉~158℉), Storage:-20℃~70℃(-4℉~158℉), Deliver:-20℃~70℃(-4℉~158℉), Atmospheric pressure range:700hPa ～ 1060 hPa Altitude: ≤3000m
	Operating Humidity	Operate: relative humidity 15%-90% Transport : relative humidity 15%-90% Storage: relative humidity 15%-90%
Protection class	IP21， Class II, type BF applied part (mask)	
Mode 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_2O	
Sound	Sound Pressure Level	Sound pressure level measured according to ISO 80601-2-70:2015 (CPAP mode) BreathCare PAP ≤35dB（A）.
	Sound Power Level	Sound power level measured according to ISO 80601-2-70:2015 (CPAP mode) BreathCare PAP ≤43dB（A）.
Physical properties	Dimensions (length*width*height)	285mm*155mm*125mm or 11.2" *6.1" *4.9"
	Weight	About 1500 g
	Air tube	Plastic hose，1.8m
	Maximum volume of water tank	260±10mL
	Material 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℃(131℉)(±4℃)
	Cut-out	110℃(if it damage, return To manufacturer)
	Maximum gas temperature	≤41℃
Air filter	Material: Polyester non-woven fiber Average arrestance: ≥85%for ～ 2.5 micron dust	
IPAP (S,T,ST,VGPS)	4-20 cmH_2O（suit for YH-820）, ± (2% of the full scale reading+4% of the actual reading) 4-25cmH_2O（suit for YH-825）, ± (2% of the full scale reading+4% of the actual reading) 4-30cmH_2O（suit for YH-830）, ± (2% of the full scale reading+4% of the actual reading)	
EPAP (S,T,ST,VGPS)	4-20 cmH_2O（suit for YH-820）, ± (2% of the full scale reading+4% of the actual reading) 4-25cmH_2O（suit for YH-825）, ± (2% of the full scale reading+4% of the actual reading) 4-30cmH_2O（suit for YH-830）, ± (2% of the full scale reading+4% of the actual reading)	
Therapy setting (CPAP)	4-20cmH2O（suit for YH-820, YH-825, YH-830）, ± (2% of the full scale reading+4% of the actual reading)	
Mode	CPAP、S、ST、T、VGPS（suit for YH-820、YH-825、YH-830）	
BPM	5-50bpm adjustable，step is 1 bpm	
Slope	1-5 level adjustable	
Trigger	1-5 level adjustable	
Cycle	1-5 level adjustable	
IE ratio	10-70% adjustable	
Ramp	0-45min	
Tidal volume	50-1500ml（only for VGPS mode）	
Maximum flow	150 LPM	
Output flow	The BreathCare PAP performance at set pressure is shown below：	

	Test pressures				
	4	10	17	24	30
Measured pressure at the PATIENT -CONNECTION PORT（hPa）	2.76	8.81	16.05	23.20	29.25
Average flow at the PATIENT -CONNECTION PORT (l/min)	70	80	85	85	80

Humidification system	Pressure drop	Flowrate (l/min)	Pressure drop (cmH2O)
		30	0.18
		60	1.02
		90	2.34
	Gas leakage at the maximum operating pressure	＜1 l/min	

Pneumatic flow path：



General	The patient is an intended operator. The operator needs to be adult who have basic education to operate this PAP.		
Displayed values	**Value**	**Range**	**Accuracy**
	Tidal volume（VT）	50-1500ml	±50ml or ±25% of reading whichever is greater
	Leak volume	20~99.9l/min	±50ml or ±25% of reading whichever is greater
	Minute Volume(MV)	0~50 l/min	±20%
	Respiratory Ratio(I/E)	10%~70%	±20%
	Respiratory Rate(BPM)	5-50bpm	±2bpm
Pressure accuracy	Maximum static pressure variation at 10 cmH2O according to ISO80601-2-70:2015 ± (2% of the full scale reading+4% of the actual reading)		
	Maximum dynamic pressure variation according to ISO80601-2-70:2015 (CPAP mode)		

Pressure(cmH2O)	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 dynamic pressure variation according to ISO80601-2-70:2015 (S mode) ± (2% of the full scale reading+4% of the actual reading)

Maximum limited pressure	The maximum limited pressure 30 cmH2O under normal use 40 cmH2O under single fault Condition	
Expected service life	Device (excluding accessories)	5 years
	Water tank	90 days
	Air tube	90 days
Number of Cycles	2000	

16.Symbols

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

Symbol	Meaning	Symbol	Meaning
	Follow instructions for use	START STOP	Press to start /stop therapy
	Caution	70°C 158°F -20°C -4°F	temperature limitation for storage and transport
	Manufacturer		type BF applied part
	Date of manufacture		class II equipment
SN	serial number	MAX	maximum water level
Rx Only	prescription only	MIN	minimum water level
	Warning: hot surface	EC REP	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		

▶ **2. Disposal statement:**

⚠ **Warning:**

Please contact local authorities to determine the proper method of disposal of this device.

17.Limited warranty

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

Product	Quality warranty
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.**

18.Repairing

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

19.List of cables

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

20.Technical description

▶ **1. Disposal statement:**

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

▶ **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	<5%UT (>95 dip in UT) for 0.5 cycle 40%UT (60 dip in UT) for 5 cycles 70%UT (30 dip in UT) for 25 cycles <5%UT (>95 dip in UT) for 5 sec
Power frequency(50Hz) magnetic field IEC61000−4−8	30A/m
Radiated RF EM fields	10 V/m 80 MHz −2,7 GHz 80 % AM at 1 kHz
Conducted disturbances induced by RF fields	3 V 0, 15 MHz −80 MHz 6 V in ISM and amateur radio bands between 0, 15 MHz and 80 MHz 80 % AM at 1 kHz
NOTE U_T is the a.c mains voltage prior to application of the test level.	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380– 390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ■ 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

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

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

▶ 3.Precautions

According to IEC60601-1-2:2014, BreathCare PAP（Bi-level）complies with all applicable electromagnetic compatibility requirements (EMC) .It may have harmful interference with other devices if you do not following the instructions. However, there is not certain it has not interference with other devices if you following the instructions. If it does have interference with other device, you can amend interference by the following methods.

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

The pressure and flow should be calibrated every two years. If you need calibrate your PAP, please contact yuwell. This is device is only can be calibrated by the agency who has be authorized.

21. Warranty card

yuwell

BreathCare PAP Warranty card

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 does not involved in Quality warranty sheet.

User sign _____

Date _____

yuwell

BreathCare PAP Warranty card

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 does not involved in Quality warranty sheet.

User sign _____

Date _____