yuwell

BreathCare PAP

Positive Airway Pressure Device

User's Manual

Please read the user's manual closely before using!
Please check the certificate or the package for the production date.

Suzhou Yuyue Medical Technology Co.Ltd
No.9 Jinfeng Road,Suzhou Science & Technology
Town, Suzhou,Jiangsu,215163,PRC
http://www.yuwell.com

1030400-0A
Paper

Contents

Dear customers:

This user's manual covers the guidance for installation, use, routine maintenance and other aspects of YH-360CPAP/YH-380CPAP/YH-560APAP/YH-580APAP (hereinafter referred to as BreathCare PAP).

⚠ Warning

Please read the user's manual closely before using!

⚠ Note

The PAP device is sold only by professional doctors or based on the prescription.

I. Intended uses

BreathCare PAP is used for the therapy of OSAHS(obstructive sleep apnea-hypopnea syndrome). The device is used for homecare.

II. Use notes

Normally the device is not suitable for the patient with any of the following diseases. However, if its use is a "must", special attention must be taken. In any case, whether it can be used or not can be determined only by the physician in charge.

Heart function problems, severe hypotension, high risk barotrauma, severe lung, pneumothorax, dehydration cerebrospinal fluid leakage, recent intracranial surgery, intracranial trauma and etc

III. Side effects

It may cause following adverse reactions when the device is being used:

Dry mouth, nosebleeds, bloating, ear or sinus discomfort, eye irritation, rash and etc.

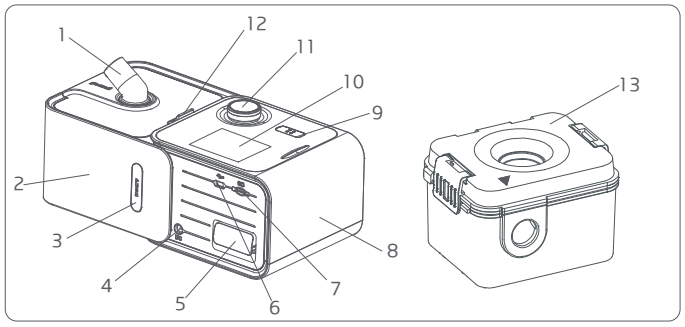
⚠ Note

Please contact the competent physician or the agent promptly; if the patient under treatment develops reactions such as chest pain, severe headache or breathing difficulty. Please stop the therapy immediately; if a viral infection is caused in the upper respiratory!

IV. Product packing list

Name	Quantity	Name	Quantity
Host machine	1 set	Heated Humidifier	1 set
Air hose	1 pc	Power adapter and line	1 set
User’s manual	1 pc	Mask and accessories (nose mask)	1 set
Kit	1 set	Micro SD card (YH-560/YH-580)	1 pc
Air filter	2 pcs		

V. Product instructions



1. Air outlet
2. Heated Humidifier
3. Hook button
4. Power connector
5. Air filter
6. Data connection port
7. Micro SD card slot
8. Breathing machine
9. Start/Stop button
10. Screen
11. Knob
12. Button
13. Humidifying tank

VI. Button instructions

START

“Start/Stop” button

Press this button to start or stop the therapy.

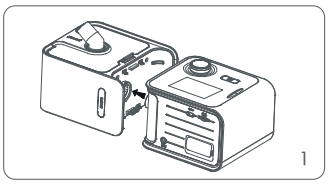
Knob

Press the knob to enter the selected interface, to select the items or to save the settings; also turn clockwise the knob to increase the selected setting parameters while turn counter clockwise to decrease.

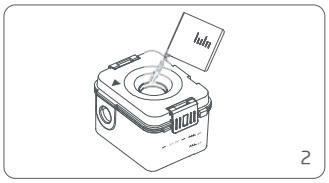
VII. Installation

⚠ Note

- Fill the humidifier with water which should not exceed the maximum level MAX ; otherwise the water may enter into the air hose and the device.
- Please fill it with the distilled water, or cool boiled water if no distilled water is available..

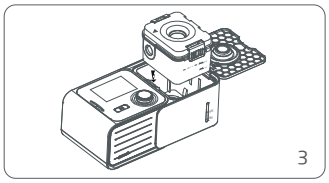


1. Connect the heated humidifier with the PAP device.

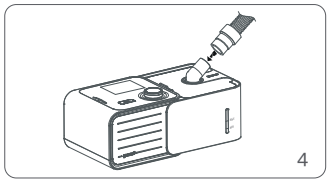


2. Take out the humidifying tank from the heated humidifier, and fill it with the distilled water through the hole on it to an appropriate level below the maximum level.

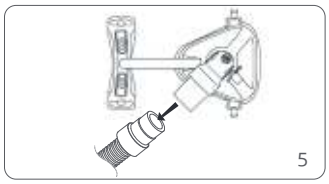
⚠ It is suggested to replace the water every day.



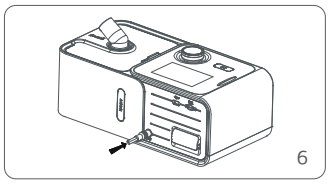
3. Place the humidifying tank back in the triangular arrow direction.



4. Connect the air hose to the outlet of the heated humidifier properly.



5. Connect the other end of the air hose to the matched nose mask. For more details, please consult the manual of the nose mask.



6. Place the PAP device on a level surface, and connect it with the power supply.

VIII. Start/stop the therapy

1. Wear the nose mask according to the requirements for the nose mask in user's manual.
2. Press "START" button to start the therapy. During the therapy, the real-time average pressure, the set pressure, the pressurize delay time (min), and the heated humidification level will all be displayed on the screen.

3. Press again "START" button to stop the therapy.
4. When the screen goes to sleep mode, press any button to wake it up and then press "START" again to stop the therapy.

Fig. 1: Therapy start interface

IX. Function instructions

1. Information inquiry:

A summary of the user sleep report will be shown when the information interface is entered into, which includes the following contents:

- **AHI:** indicates the number of apneas and hypopneas per hour.
- **Used time:** the time duration for the last therapy (h).
- **Average pressure:** the average pressure for the last therapy (cmH_2O/hPa).
- **Average leak volume:** average air leak volume per minute for the last therapy (LPM).
- **Total time:** the total time after the last therapy time (h).
- **Version:** software version number used for the PAP device.
- **SN:** the serial number of the PAP device.

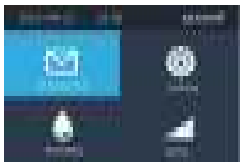


Fig. 2-1: Index information query

Fig. 2-2: Therapy query

2. RAMP

This function makes the therapy more comfortable. The Ramp refers to the time duration required by the pressure to increase from the initial to the minimum gradually or the time duration of the therapy pressure. The Ramp range is 0~45min, with an increment of 5min.

How to adjust the Ramp:

- Place the cursor on Ramp and press the knob to enter the setting interface.
- Turn the knob to select the pressurization delay.
- Press the knob again to save the settings and return to the standby interface.

Fig. 3-1: Pressurization delay setting

Fig. 3-2: Pressurization delay setting

3. Humidity level

The heated humidifier is used to heat and humidify the ambient air, making the therapy more comfortable. During the therapy, if the user feels thirsty, the heated humidifying function can be turned on. Reduce the Humidity level if the water vapor is felt inside the mask. There are 0-6 Humidity levels with Level 0 for turn off, Level 1 for the lowest level and Level 6 for the highest level. Levels 1-6 are equivalent to the following temperatures (with the accuracy of ±4℃) respectively. (Note: These temperatures are measured without the humidifier tank working):

Level 1 = about 33℃,	Level 2 = about 35℃,	Level 3 = about 40℃,
Level 4= about 45℃,	Level 5 = about 50℃,	Level 6 = about 55℃

How to adjust the Humidity level:

- Place the cursor on the Humidity option, press the knob to enter into the setting interface.
- Turn the knob to select the Humidity level, press the knob to save the settings and return to the stand by interface.
- Press and turn the knob to adjust the Humidity level, and press the knob again to save the settings during the therapy.

Fig. 4-1 Humidity setting

Fig. 4-2: Humidity setting

4. FPS level

There are 0-3 FPS levels; Level 0 is to turn off the function, Level 1 is the lowest level and Level 3 the highest. This function can help users to quickly adapt to the therapy of the PAP device.

5. Other functions

- **Humidifier light:** Turn on the humidifier light in order to see the remaining water quantity in the humidifying tank clearly.
- **Audible alarm:** When this function is turned on, an audio alarm will be sent incase of an air leak or motor failure occurred.
- **Smart start/stop:** With this function turned on, the PAP will start automatically when you put on the nose mask; and stop within 1 min after you remove the mask.
- **Time settings:** Adjust the time (minute, hour, day, month, year) displayed on the device.
- **Alarm clock:** Turn on this function and adjust the alarm time. (hour, minute)
- **Language:** English or Chinese can be selected.

Fig.5-1: Interface setting

Fig.5-2: Interface setting

X. Clinical menu

It is suggested to set the following parameters based on the physician's opinions.

1. MODE

- Starting from the standby interface, press the "START" button and the knob together to enter into the clinical menu. (Fig. 6-1)
- Turn the knob to locate the cursor on the mode option, press the knob to change the words color from white to blue, and then turn the knob to select CPAP or APAP mode (no A PAP mode on YH-360CPAP / YH-380CPAP).
- Press the knob to save the settings after selecting.
- Turn the knob to place the cursor on the return option and press the knob to return to the standby interface (Fig. 6-2).

2. Set the pressure

- On the clinical menu, select CPAP mode, locate the cursor on the Initial Pressure or the Therapy Pressure option, press the knob to change the words color from white to blue, and then turn the knob to select the pressure desired .
- Turn the knob left or right to adjust the desired pressure, with each section of the pressure rise/drop level of 0.5cm H_2O/hPa.
- Press the knob to save the settings.

- Turn the knob to the return option and press the knob to return to the standby interface. (Fig. 6-2)

In the APAP mode, set the maximum pressure, minimum pressure, therapy pressure and initial pressure by the same operational order. (Remark: No therapy pressure option is available in the network APAP mode)

⚠ Description

In the APAP mode, if the maximum pressure is set lower than the initial pressure, the therapy pressure and the minimum pressure, the initial pressure all the three will be automatically set equal to the maximum pressure.

Fig. 6-1: CPAP setting in the clinical menu

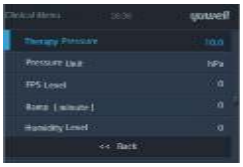


Fig. 6-2: CPAP setting in the clinical menu

3. Select the Pressure Unit

- In the clinical menu, turn the knob to locate the cursor on Pressure Unit option, press the knob to change the words color from white to blue, and then turn the knob to select cmH_2O or hPa.
- Press the knob to save the setting.
- Turn the knob to the return option and press the knob to return to the standby interface. (Fig. 6-2)

4. Select the FPS Level

- In the clinical menu, turn the knob to place the cursor on FPS Level option, press the knob to change the words color from white to blue, and then turn the knob to select the FPS Level. (Among Level 0-3)
- Press the knob to save the setting.

● Turn the knob to the return option and press the knob to return to the standby interface. (Fig. 6-2)

5. Select the Ramp(min)

● In the clinical menu, turn the knob to place the cursor on the Ramp option, press the knob to change the words from white color to blue, and then turn the knob to select the Ramp time (0-45min,
● 5min/level);
● Press the knob to save the setting;
Turn the knob to the return option and press the knob to return to the standby interface. (Fig. 6-2)

6. Select the Humidity

● In the clinical menu, turn the knob to place the cursor on the Humidity option, press the knob to change the words from white color to blue, and then turn the knob to select the heated humidification level. (Among Level 0-6)
● Press the knob to save the setting.
● Turn the knob to the return option and press the knob to return to the standby interface. (Fig. 6-2).

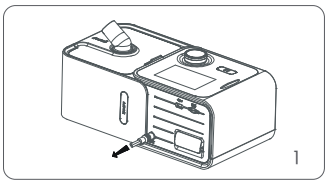
⚠ Note

Press the "START" button and the knob at the same to enter into the clinical menu during the therapy; Perform Steps 1-6 above to adjust the therapy parameters, and then press the button on the back option to return to the therapy interface.

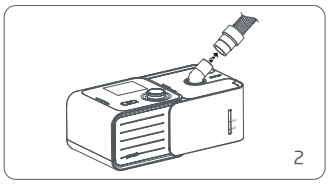
XI. Maintenance and Service

Daily maintenance is needed for the PAP device in order to ensure better therapy quality for users. The Maintenance and service include disassembly, cleaning, inspection, reassembly and etc.

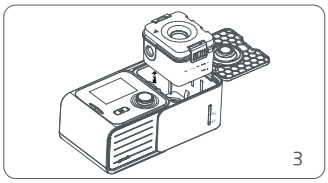
1. Disassembly



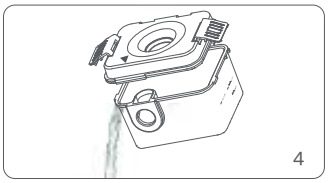
1. Disconnect the power supply for the device.



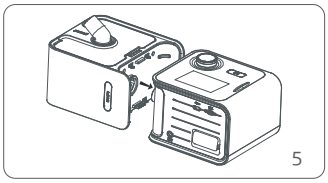
2. Turn the port of the air hose and then remove the hose from the device.



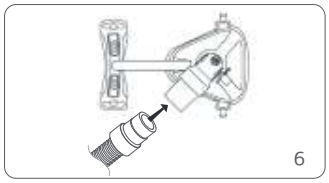
3. Press the split button on the heated humidifier to open it and remove the humidifying tank.



4. Open the humidifying tank's top cover and drain the remaining water in it.



5. Hold both the PAP device and the heated humidifier tightly, and press the hook button to separate the two.



6. Separate the air hose from the nose mask.

2. Cleaning

The PAP device should be cleaned at least once a week with the following steps. Please refer to the relevant details for mask cleaning in the manual.

- Any dust on the exterior of the PAP device and the heated humidifier should be cleaned gently with clean and wet cloth.
- Clean the interior of the humidifier tank and the air hose by filling them with the warm water (the
- temperature of which should be less than 41℃).
- Rinse the humidifier tank and the air hose completely, and dry then in the air.
  Wipe the device with a dry and clean cloth.

⚠ Note
Do not use a dishwasher or a cleaning machine nor any cleaner containing fragrance or adjusting agent for cleaning.

3. Inspection

The humidifier tank, air hoses, air filters should be inspected regularly.

A. Humidifier tank inspection:

- If there is any break or crack in the humidifier tank, the tankit should be replaced with a new one.
- If its separator's seal is damaged or cracked, the seal should be replaced with a new one.

B. Air hose inspection:

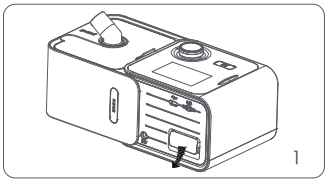
Inspect the air hose for any damage and crack. Or replace it with a new one.

C. Air filter inspection:

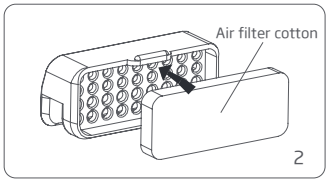
Inspect the air filter cotton once a week, and it is recommended to replace the air filter once every 4 weeks.

- If the air filter is damaged or clogged by particulate dusts, replace it with a new one immediately.

D. Replacement steps of Air filter :



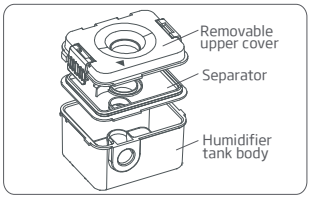
1. Open the filter cover, and remove the old filter cotton.



2. Place the new air filter cotton on the filter cover, and then install them onto the PAP device.

⚠ Note
Ensure that the size of the air filter cotton is proper, so as to prevent water or dust from going into the PAP device.

4. Reassembly



After the humidifier tank and the air hose are cleaned and dried, re-assemble them together.

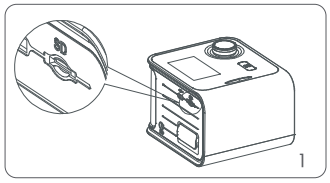
- The humidifier tank should be reassembled as shown in the figure. The removable cover, the partition and the humidifier tank body should be properly installed with their embossing positions aligned.
- Hold tight the humidifier body , aligning the PAP device with the port and connect them together properly.
- Place the humidifier tank into the humidifier body and close the top cover.
- Connect one end of the air hose to the outlet and the other end to the nose mask.

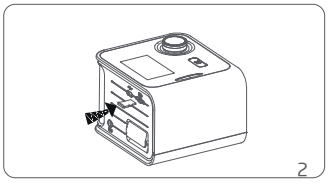
XII. Therapy parameter storage

BreathCare PAP can automatically store user's therapy data to reference for physician, and these therapy data can be used as a basis for adjusting the therapy parameters.

1. Micro-SD card

Turn on the PAP device and insert Micro-SD card into the slot to read and write data. Remove it from the PAP after reading or writing is prompted to have finished.





1. The Micro-SD card slot is on the back of the PAP device.
2. Insert Micro-SD card into the slot, and press SD card to remove it.

⚠ Note

This Micro-SD card can not be used for other purposes.

XIII. Carrying

BreathCare PAP can be carried on with. However, please pay attention to the following:

- The PAP device should be placed in the portable package, to avoid any damage to the device.
- Pour away the water of humidifier tank, and put the PAP device and humidifier separated into the bag.

XIV. Troubleshooting

Check the following table to see if the problem can be solved when any problem hashappened to the device. Please contact yuwell company or the dealers if the table does not work. Do not disassemble the device privately.

- General failures

Symptom	Possible reasons	Solution
Nose mask leaks	● The nose mask is not installed properly ● The nose mask size is unqualified ● The nose mask type is unqualified	● Install it in accordance with the user's manual of the nose mask ● Replace the nose mask with one of the proper size ● Change the nose mask type
The nose has dry and obstruction symptoms	● The humidify level is low ● The nose has other disorders	● Increase the humidify level ● Consult a doctor
There is moisture in the nose, the nose mask or the air hose	● The humidify level is too high ● The temperature difference between inside and outside of the hose is high	● Decrease the humidify level ● Mount a heat shield around the exterior of the hose or replace the hose with the heating wire
The mouth feels dry and uncomfortable	● The air is exhaled through the mouth	● Use the full face mask or contact your physician
The pressure inside the nose mask is too high (the user receives excess air)	● The FPS level function is not turned on	● Turn on the FPS level function
The pressure in the nose mask is too low (the user inhales less air)	● The FPS level function is turned on	● Start the therapy until the pressure rises to the minimum pressure or the therapy pressure ● Turn off the FPS level function

Blank screen	● The screen backlight will automatically turn off in 2 minutes, to enter into the sleeping mode ● The power supply is not connected	● Press any key to light up the screen again ● Connect the power supply and make sure of good contacts
Humidifier tank leak	● The humidifier tank is assembled incorrectly ● The humidifier tank is damaged	● Check if the humidifier tank is assembled correctly, and reassemble it according to the user's manual; ● Check if the humidifier tank is damaged, and replace it with a new one if it is

XV. Warnings and notes

⚠ Warning

- The PAP device can not be used for a life-support. It may stop working due to a power outage, but it will not endanger the user.
- The PAP device can be used together with only the supporting mask produced by its original manufacturer or recommended by the physician. Do not block the air vents on the nose mask, so as to protect the normal breathing.
- Ensure that the air hose is smoothly connected and not twisted.
- Ensure that there is no damage in the power line and the plug.
- Do not place the power line nearby any hot objects.
- For any unusual noise, or the PAP device or power supply drop from desktop and caused damage and etc, please stop use and contact yuwell company or local dealers immediately.
- Do not disassemble the PAP device by yourself so as to avoid electric shocks.

- Do not dip the device, the power supply unit and the power line into water. If any water is splashed onto the device inadvertently,cut off the power supply immediately, separate the humidifier from the PAP device, let the device dry in the air, and at the same time contact the Yuwell's Customer Service.
- Separate the humidifier from the PAP device before cleaning and ensure that all parts are completely dried before reassembly.
- Do not do any maintenance when the device's running.
- The device can not be used in the environment where the air is mixed with flammable anesthetic gases or nitrous oxide gases. (Non-AG and Non-APG series PAP).

⚠ Note

- The product should be used on a horizontal platform, and be kept away from water.
- All the parts of the device must use the products supplied by yuwell company, or the therapy efficiency may be mitigated and damage caused to the device.
- Please use the nose mask with the air outlet produced by yuwell company. Ensure that the mask outlet is clean and smooth.
- Do not place the device where it may get crashed easily or its power cord may be tripped.
- Do not block the air hose and the air outlet, so as to avoid overheating the device.
  Keep the device away from anything that may block the outlet, and placed it in a clean and tidy environment.
- Do not use bleach, chlorine, alcohol, aromatic solution, moisturizer, antibacterial soap, sesame oil and other solutions to clean the device, which may cause danger to the device, affect the humidification effect and even reduce the service life of the product.
- When the heated humidifier is used, please place the device in a height below the user's head, to prevent any water from backflowing into the air hose and the nose mask.
- Please drain the remaining water in the humidifier tank before moving the device. Do not tilt, flip or shake the device if there is any water in the humidifier tank to prevent the water from flowings back into the device.
- Refer to the user's manual for details in regard of the heated humidifier operation.(P06).

- The power adapter and line which are notsupplied by yuwell company may increase the emission or reduce the anti-interferenceability of the device.
- Do not close to other devices or stack upwith them when using. If it has to, please observe and check if the PAP device isnormally working in this environment.

XVI. Technical specifications

Item		Specification
Power supply		Input voltage: AC100V-240V, Allowable tolerance: ±10%, 1.4A; Frequency: 50HZ-60HZ, Allowable tolerance: ±1%
Environmental conditions	Temperature	Operation: +5℃ ~ +35℃ (+41℉ ~ + 95℉), (No condensation) Storage: -20℃~ +70℃ (-4℉ ~ +158℉) Transportation: -20℃~ +70℃ (-4℉ ~ +158℉)
	Humidity	Operation: RH 10% ~ 90% (No condensation) Storage: RH 10% ~ 90% Transportation: RH 10% ~ 90% Atmospheric pressure range: 600hPa ~ 1060hPa
EMC		BreathCare PAP meets EMC requirements of GB9706.1: 2007. This device can provide a reasonable protection against harmful interferences. This device generates, uses, or radiates a radio frequency energy. If it is not installed and used in accordance with the instructions, it may cause harmful interference to other devices around. Even if it is properly installated, it may still produce the risk to interfere. It is recommended to try the following ways to solve the problem :

EMC	● Re-locate or re-set the receiving device. ● Increase the distance to this product. ● Connect the device to a socket that located on another power line that does not supply power to the units being interfered with. ● Consult with the manufacturer or the service technician for help.	
Safety type	PAP: Class II, type BF	
Noise	Noise level	According to the requirements of ISO-17510-1: 2007 (CPAP mode), under the pressure of 10cmH_2O, at the distance of 1m, when the PAP (with heated humidifier) is under normal operation, the noise should be ⩽32dB (A), and when the PAP (without heated humidifier) is under normal operation, the noise should be ⩽30dB (A).
Physical properties (PAP device, humidifier with tank)	Size	270mm *135mm *100mm or 10.63"*5.31"*3.94" (L * W * H)
	Weight	About 1560g or 3.44lb (including the heated humidifier)
	Air hose	Plastic hose, 1.8m (approx.)
	Humidifier tank material	PC, injection molding, stainless steel bottom, TPE, seal strip
Theraphy pressure	4-20cm H_2O/hPa (adjustable , increment: 0.5cm H_2O/hPa)	
Initial pressure	4-20cm H_2O/hPa (adjustable , increment: 0.5cm H_2O/hPa)	
Maximum pressure	4-20cm H_2O/hPa (adjustable , increment: 0.5cm H_2O/hPa)	
Minimum pressure	4-20cm H_2O/hPa (adjustable , increment: 0.5cm H_2O/hPa)	

Ramp (min)	0-45min (adjustable , increment: 5 min)
Maximum air leak compensation	0-130LPM, Allowable tolerance ±5LPM

XVII. Symbols

The following symbols may be used on the product and its package.

	Please consult the user's manual before use		Warning or Caution
	Type BF		Class II products
	Maximum water level		Minimum water level
	Start/Stop therapy		Air flow direction
	Product serial number		Protection class
	Electrical and electronic waste disposal (WEEE)		Risk for Burn

This product should be recycled by the appropriate electrical and electronic device recycling center. For more details about this product recycling, please contact with the local household waste disposal unit or the product dealer.

The instrument conforms to the requirements of electromagnetic compatibility of GB9706.1: 2007/YY0505-2012. The instrument doesn't require any installation. Please use and operate this instrument according to the Guidance and Manufacturer's Declaration in below table.

Guidance and manufacturer's declaration – electromagnetic emissions – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer’s declaration – electromagnetic emission		
The BreathCare PAP device is intended for use in the electromagnetic environment specified below. The customer or the user of the PAP device should assure the instrument is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions GB4824	Group 1	The the BreathCare PAP device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions GB4824	Group B	The BreathCare PAP device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions GB17625.1	Class A	
Voltage fluctuations/ flicker emissions GB17625.2	Compliant	

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer’s declaration – electromagnetic immunity			
The BreathCare PAP decice is intended for use in the electromagnetic environment specified below. The customer or the user of the PAP device should assure the instrument is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) GB/T17626.2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst GB/T17626.4	± 2 kV to power supply lines ± 1 kV to input/ output lines	± 2 kV to power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge GB/T17626.5	± 1 kV lines to lines ± 2 kV lines to ground	± 1 kV lines to lines ± 2 kV lines to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines GB/T17626.11	<5% U_T, (>95% dip in U_T) for 0.5 cycle 40% U_T, (60% dip in U_T) for 5 cycle 70% U_T,(30% dip in U_T) for 25 cycle <5% U_T,(>95% dip in U_T) for 5 seconds	<5% U_T, (>95% dip in U_T) for 0.5 cycle 40% U_T, (60% dip in U_T) for 5 cycle 70% U_T,(30% dip in U_T) for 25 cycle <5% U_T,(>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment.if the user of the BreathCare PAP device requires continued operation during power mains interruptions, it is recommended that the BreathCare PAP device be powered from an uninterruptible power supply.

Power frequency magnetic field (50Hz/60Hz) GB/T17626.8	3A/m	3A/m	If image distortion occurs, it may be necessary to position the BreathCare PAP device further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic filed should be measured in the intended installation location to assure that it is sufficiently low.
Note: U_T is the a.c. Mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The BreathCare PAP device is intended for use in the electromagnetic environment specified below. The customer or the user of the PAP device should assure the instrument is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiation conduction GB/T17626.6	3 V (Effective value) 150 kHz ~ 80 MHz	3 V (Effective value)	Portable and mobile RF communications equipment should be used no closer to any part of the BreathCare PAP device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
RF Radiation GB/T17626.3	3V/mc 26MHz ~ 1GHz 10V/md 26MHz ~ 1GHz	3V/mc 10V/md	

Radiation conduction GB/T17626.6	3 V (Effective value) 150 kHz ~ 80 MHz	3 V (Effective value)	Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 26MHz ~ 800MHz $d=1.2\sqrt{P}$ 800MHz ~ 2.5GHz
RF Radiation GB/T17626.3	3V/mc 26MHz ~ 1GHz 10V/md 26MHz ~ 1GHz	3V/mc 10V/md	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BreathCare PAP is used exceeds the applicable RF compliance level above, the BreathCare PAP device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BreathCare PAP device.

XVIII. Warranty

Generally, Suzhou Yuyue Medical Technology Co., Ltd. provides the warranty periods for the product and its accessories as follows:

Parts	Warranty
Oxygen mask (nose mask)	90 days
Air hose	90 days
Humidifier tank	90 days
Micro-SD card	1 year
BreathCare PAP(including heated humidifier)	2 years
Power adapter	1 year

The warranty for this product applies only for the first time buyer, and can not be transferred to surrenderee.

The product warranty excludes the following cases:

- Any problem caused by error use, disassembly, or modification.
- Any problem caused by maintenance without permission of yuwell.
- Any damage or contamination caused by cigarette, the cigarette pipe, cigar or other tobacco goods.
- Any damage caused by splashed water.

Yuwell Company has the final right to explain the warranty for this product.

Cut along the dotted line

yuwell

Warranty Card for BreathCare Positive Airway Pressure Device

Manufacturer copy

Manufacturer contact _____ Department _____ User _____

Address _____

Diagnosis _____ Phone _____

Product Model _____ Product No _____

Invoice Number _____ Purchase Date _____

Dealer _____

The following cases are not included in the warranty scope:

1. Failure or damage caused by any unauthorized modification and repair by non-authorized technicians from yuwell company.
2. Malfunction or damage caused by any improper use or maintenance.
3. Failure or damage caused by any accident, natural or man-made disaster.
4. Parts excluded from the manufacturer warranty scope.

User: _____

Date: _____

Cut along the dotted line

yuwell

Warranty Card for BreathCare Positive Airway Pressure Device

User copy

Manufacturer contact _____ Department _____ User _____

Address _____

Diagnosis _____ Phone _____

Product Model _____ Product No _____

Invoice Number _____ Purchase Date _____

Dealer _____

The following cases are not included in the warranty scope:

1. Failure or damage caused by any unauthorized modification and repair by non-authorized technicians from yuwell company.
2. Malfunction or damage caused by any improper use or maintenance.
3. Failure or damage caused by any accident, natural or man-made disaster.
4. Parts excluded from the manufacturer warranty scope.

User: _____

Date: _____

b. Over the frequency range 150 kHz ~ 80 MHz, field strengths should be less than 3 V/m.
c. Over the frequency range 26MHz ~ 1GHz, and immunity test level less than 3V/m, continuously
d. perform the expected function required by the manufacturer.
Over the frequency range 26MHz ~ 1GHz, and immunity test level range 3V/m ~ 10V/m, continuously perform the expected function required by the manufacturer. Or it fails but no safety risk happens.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the BreathCare PAP device

The BreathCare PAP device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BreathCare PAP device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter(W)	Separation distance according to frequency of transmitter/m		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 kHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.