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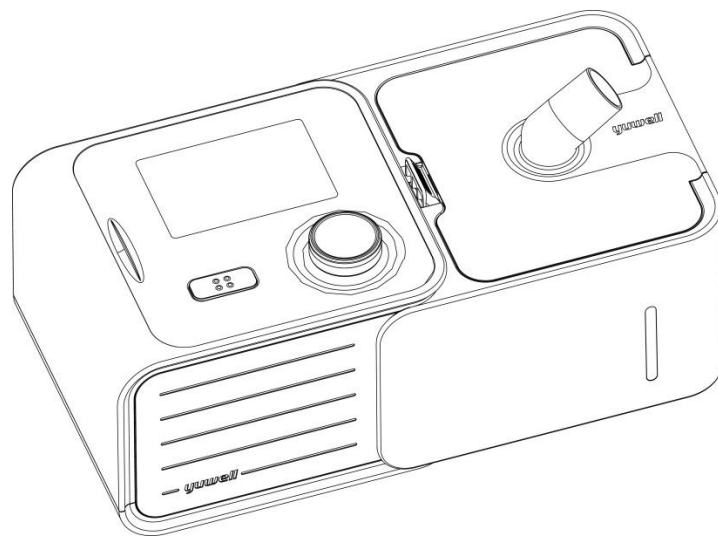
BreathCare PAP

This manual is suit for B-PAP

Model: YH-360/YH-560/YH-580-/YH-720/YH-725/YH-730/H-03

User manual

Version NO: **2016-08** English only



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Welcome

The YH-720, YH-725, YH730 are bi-level continuous positive airway pressure device (B-PAP).

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.

1. Introduction

B-PAP has 3 models: YH-720, and YH-725, YH-730. All these models of device consist of main device, humidifier and power adapter.

YH-720

The YH-720 B-PAP device is indicated for treatment of obstructive sleep apnea (OSA) in patients weighing more than 66lb (30kg). It is intended both for home use and hospital use. The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.

YH-725

The YH-725 B-PAP device is indicated for treatment of obstructive sleep apnea (OSA) in patients weighing more than 66lb (30kg). It is intended both for home use and hospital use. The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.

YH-730

The YH-730 B-PAP device is indicated for treatment of obstructive sleep apnea (OSA) in patients weighing more than 66lb (30kg). It is intended both for home use and hospital use. The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.

2. Scope of application

B-PAP 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

3.1 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

3.2 Adverse effects:

You should report unusual chest pain, severe headache, or increased breathlessness to your prescribing physician. And 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;

3.3 Precautions:

According to IEC60601-1-2:2007, BreathCare PAP (B-PAP) complies with all applicable electromagnetic compatibility requirements (EMC) .It may have harmful interference with other devices if you do not following the instructions.

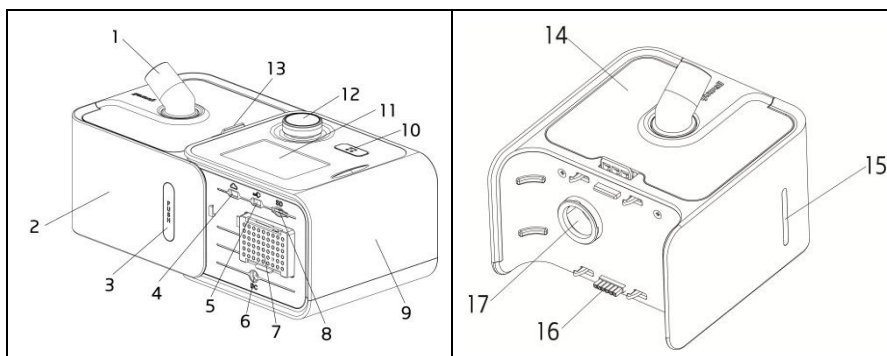
However, there is not certain it has not interference with other devices if you following the instructions. If it does have interference with other device, you can amend interference by the following methods.

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

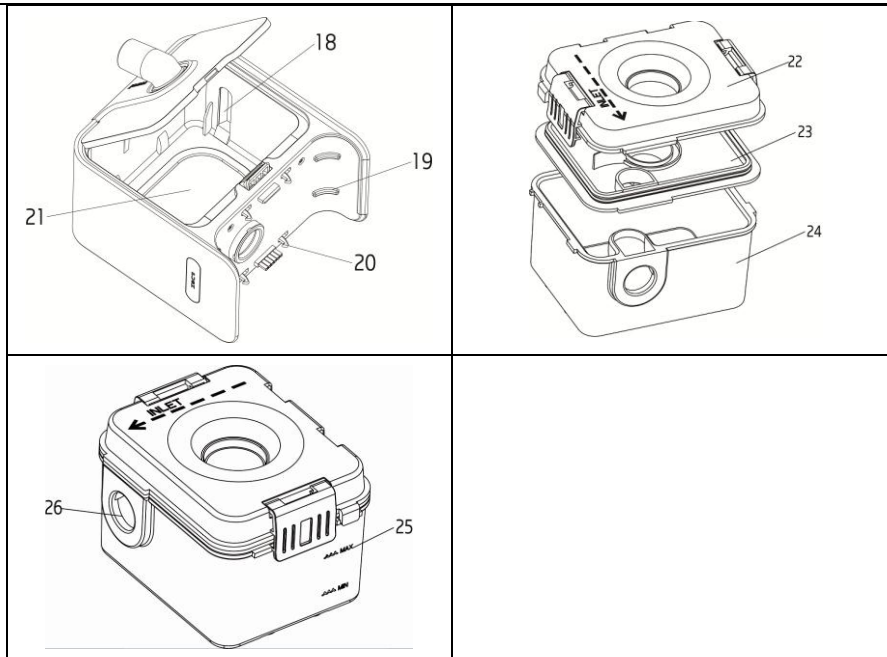
4. Package table

Name	Quantity
B-PAP Main Device	1
Humidifier(with water tank)	1
Air tube	1
power adapter	1
User manual	1
Mask (with mask accessories)	1
Bag	1
Micro SD Card	1
Air filter	2

5. Picture and explanation for product



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1. Air outlet	2. Humidifier	3. PUSH button	4. Mini USB Interface
5. Mini USB Interface	6. Power inlet	7. Air filter	8. Micro SD interface
9. B-PAP main device	10. Start button	11. Screen	12. Dial
13. Slide switch	14. Humidifier lid	15. Liquid level window	16. Humidifier power inlet
17. Humidifier air inlet	18. Indicator light	19. crash pad	20. Hook
21. Heat plant	22. Water tank lid	23. Water tank clapboard	24. Water tank
25. Water liner	26. Water tank air inlet		

6. Explanation of button

Start/ stop button: pressure to start /stop therapy.

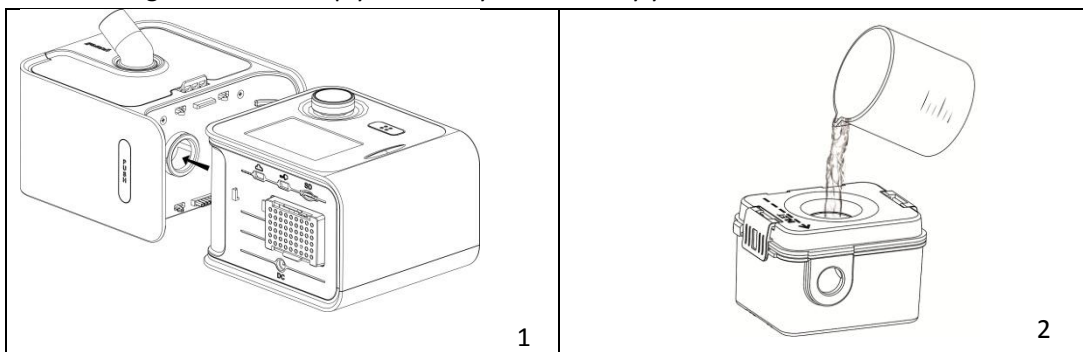


Dial: turn to navigate the menu and press to select an option. Turn to adjust the options and press to save your choice.

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

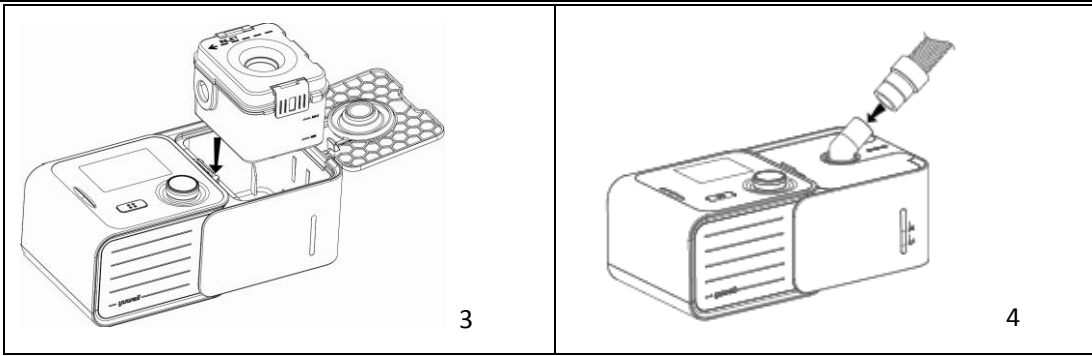


1. Connect the device with the humidifier;

⚠ Caution: please ensure the clinical parameter is set by your physician.

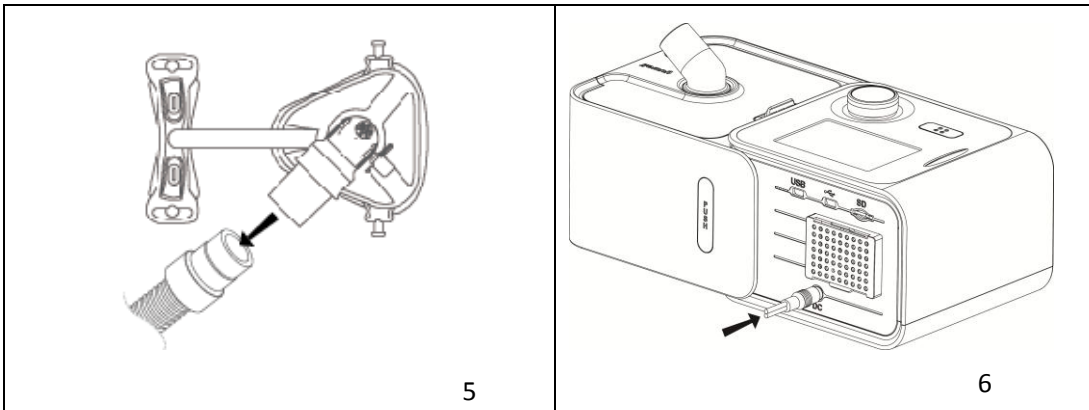
2. Fill the distilled water into the water tank, please notice that do not place the hot water into it 5 / 25

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



3. Place the water tank inset to the humidifier; The environmental temperature range for humidifier is +5°C~+35°C, the temperature for input environmental should not over 3°C of environmental temperature;

4. Connect the air tube on the humidifier;



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

6. Place the device on the floor, plug the power adapter;

8. Therapy

8.1 Start therapy

- 1) Fit your mask;
- 2) Press the START button;
- The current treatment pressure ,Mode ,VT ,MV ,LV ,RR ,IE and Humidity level will be shown on the screen;

* The screen will turn black after 2 minute of the therapy.

8.2 Stop therapy

- 1) Remove your mask first;
- 2) Press the START button, therapy will stop;
- 3) 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.

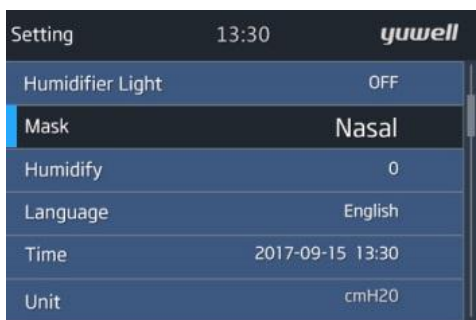
9.1.1 Setting:



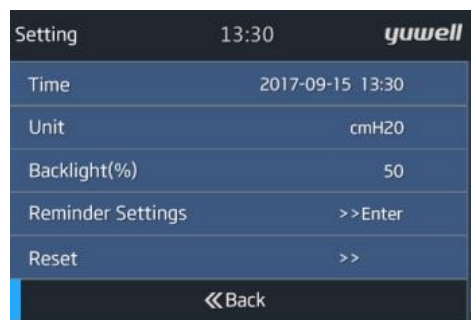
Picture 1: Therapy

Your B-PAP has been set up for your needs by your care provider, but you may find you 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.

- **Humidifier light:** Enable this function, you can see the surplus water inside water tank clearly;
- **Mask:** Highlight this option, choose the mask type you use(full mask or nasal mask);
- **Humidify:** Humidifier is designed to moisten air and is designed to make therapy more comfortable. You can set Humidity level 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 without water tank, preheating time is 10minutes.The temperature of each level on the heat planer is as following (accuracy is $\pm 4^{\circ}\text{C}$)
 0=close 1=33 $^{\circ}\text{C}$ 2=35 $^{\circ}\text{C}$ 3=40 $^{\circ}\text{C}$ 4=45 $^{\circ}\text{C}$ 5=50 $^{\circ}\text{C}$ 6=55 $^{\circ}\text{C}$
- **Language:** You can choose English or Chinese;
- **Time setting:** You can adjust time shown on the screen;(year、 month、 date、 hour、 minute);
- **Unit:** You can choose pressure unit cmH₂O or hPa;
- **Back light:** You can set the back light of the screen of this PAP. The range of setting is 0-100%;
- **Reminder Settings:** Enable this function, this can remind you when to check and change accessories, e.g. filers, mask, and air 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.

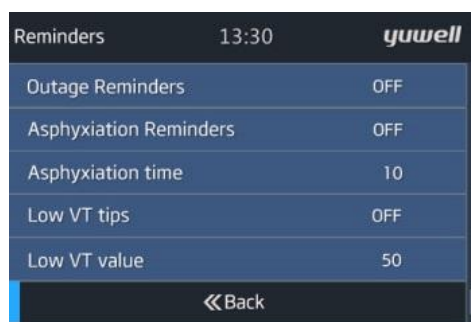
There are following notice options:

- **High Pressure Reminders:** When the user upper airway pressure is over 3.5cmH₂O of the setting pressure, the PAP will beep with reminder message.

- **Low Minute Volume (MV) Reminders:** The minute volume is lower than the setting value; the PAP will beep with reminder message. The range of the reminder value is 1 to 10lpm.
- **Leak Reminders:** When this option is enabled, the PAP beeps with reminder message if the mask leaks too much air or if you remove the mask during the therapy.
- **Outage Reminders:** When the power is stopped suddenly, the PAP will beep with reminder message.
- **Asphyxiation Reminders:** When the time of user asphyxia is over the set value, the PAP will beep with reminder message. The range of the reminder value is 10 to 40 second.
- **Low Tidal Volume (VT) tips:** 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

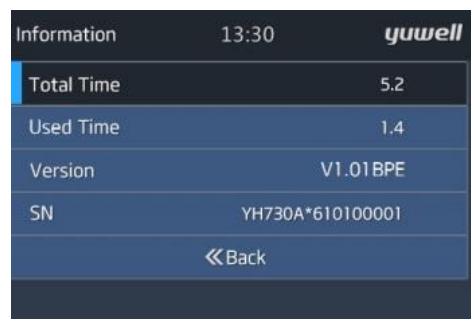
9.1.3 Information:

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

- **Total Time:** Indicated time of the total therapy;
- **Use Time:** Indicated time of the latest therapy;
- **Version Information:** Indicated the version of software inside the device;
- **SN:** Indicated serial number of BreathCare PAP;



Picture4-1: Information page

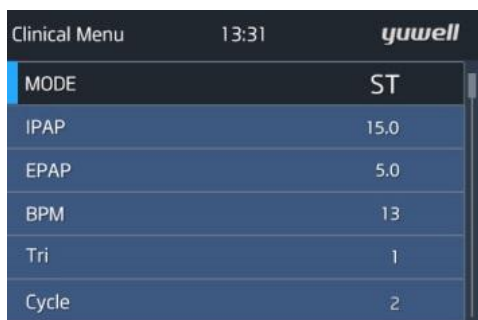


Picture 4-2: Information page

9.2 Function 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 button and dial at the same time, the clinical menu will be shown on screen (see picture5-1).
- At therapy page, press START button 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、 INITIAL PRESSURE、 THERAPY PRESSURE)

- 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 therapy pressure (each step is 0.5 cmH₂O /hPa).
- After setting therapy pressure, press dial to save your change.
- You can set IPAP、 EPAP、 INITIAL PRESSURE、 THERAPY PRESSURE 、 I_{max}、 I_{min} of PAP mode according to above method.

⚠ Notice: The CPAP mode just has initial pressure and therapy pressure. The VGPS mode has I_{max}、 I_{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 your 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 “tri”.
- 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.

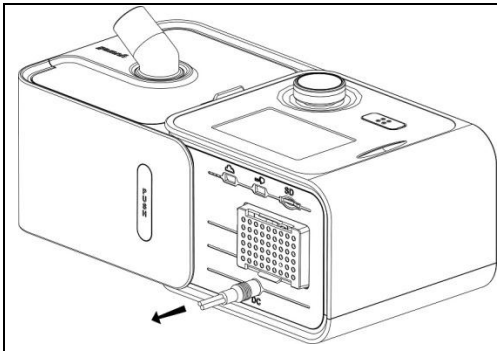
9.2.9 Set the Ramp

- At clinical menu page, highlight “RAMP”.
- Swirl the dial to the right or left, set your RAMP (0-45min).
- After setting RAMP, press dial to save your change.
- This option only for CPAP mode.

10. Caring your device

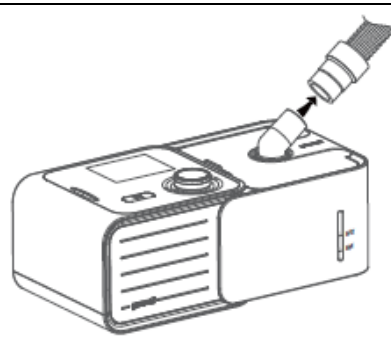
It is important for you to clean your device regularly to ensure your therapy effective. The following section will help you to disassembling、cleaning、checking、reassembling.

10.1 Disassembling:



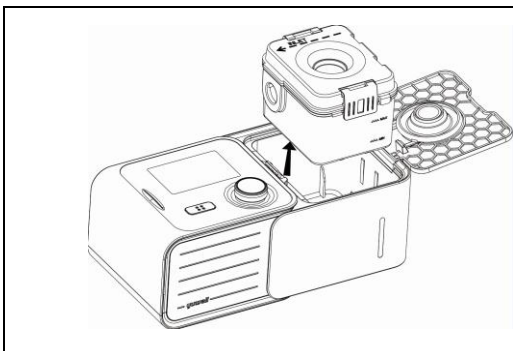
1

1. Pull the power connector out of device



2

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



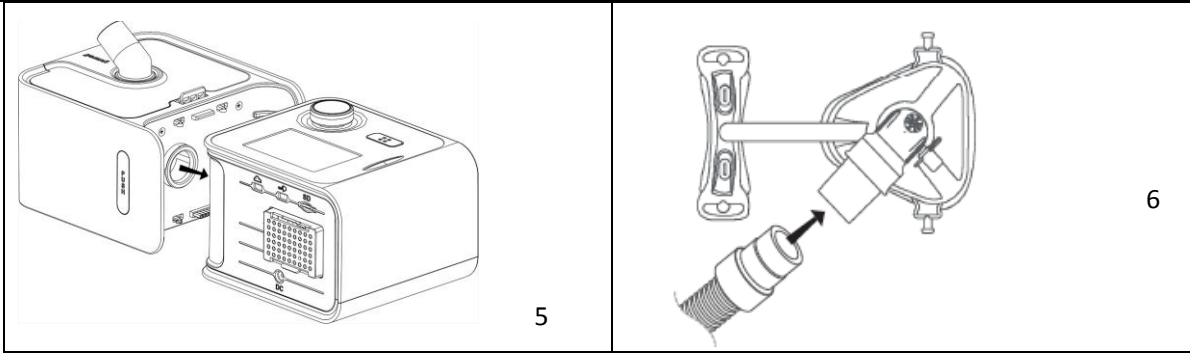
3

3. Press Slide switch, take out water tank



4

4. Pull out the left water inside water tank



5. Hold humidifier and main device; separate them by pressing PUSH button

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

10.2 Cleaning

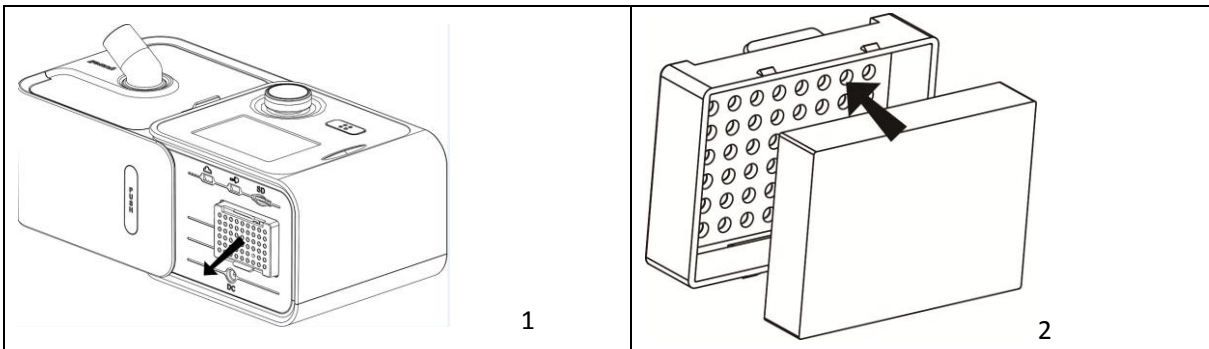
Please clean your device under the service environment of this device. It may be influenced by dust, thus please following several steps cleans your device, and you must clean your device at least once a week.

- 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°C.
- ⚠ **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.

10.3 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;
 - Using a solution of one part household vinegar to 10 parts water to remove scale;
- b) Check the air tube
 - Replace the air tube if it is any broken, holes or cracked;
- c) Check the air filter
 - Replace the air filter at least every six week;
 - If you find some particle blocked in the air filter, replace it more often;



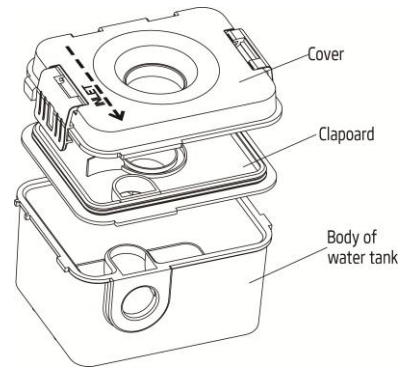
1. Open the air filter cover and remove the dirty filter

2. Place a new air filter onto the air filter cover and then close it. Make sure the air filter is fitted at all times to prevent water and dust from entering the device

10.4 Reassembling:

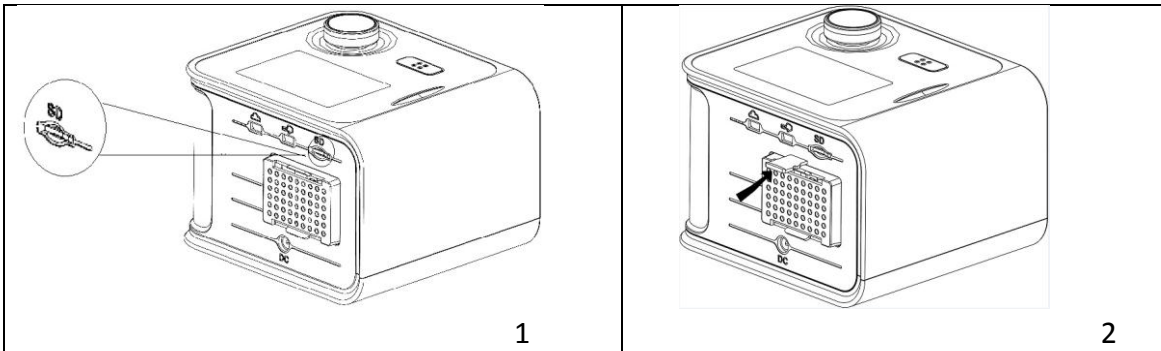
After finished all the cleaning steps, reassemble all these parts together. When the water tank and air tubing are dry, you can reassemble the parts.

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



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

2. Inset Micro SD card and wait until the screen shown "SD card write success."

⚠ Caution: this card is only used for record therapy data.

12. Traveling

You can take your BreathCare PAP 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 and pack it separately in the travel bag.
- 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.

13.1 General trouble:

Trouble	Cause	Solution
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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.	Humidifier level may set too low	Adjust your humidifier level.
I am getting droplet in my mask and air tube.	Humidifier level may set too high	Adjust your humidifier level
My mouth is very dry and uncomfortable	Air may be escape from your mouth	Adjust your humidifier level 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 humidifier	Water tank assemble incorrectly or it is broken.	Check the water assemble correctly; Contact your provider if your water tank is broken.

13.2 Other trouble:

Message in LCD	Meaning of error	Solution
High pressure Reminder	There is a mistake of pressure sensor	Please check the pressure sensor
Low minute volume Reminder	There is a mistake of flow sensor	Please check the mask fit
Large leak volume Reminder	There is a large leak of mask	Please check the mask fit
Asphyxia Reminder	The user do not has autonomous respiration	Please check the mode if it is suit for the patient
Low Tidal volume Reminder	The mode patient used is not suitable	Please check the mode if it is suit for the patient

14. Warning and cautions

14.1 Warning:

- a) Do not maintain the device while it is in use, otherwise it may leads to unaccepted risk.
- b) Do not modify this equipment without authorization of the manufacturer or open this device by yourself, contact yuwell when you need repair the device.
- c) This device cannot be used for life support. It may be shut down by turn off the electricity, but no unaccepted risk will happen.

- d) The parameters of the device can be only adjusted by your physician; the patient cannot operate this device without the instruction of physician.
- e) Using only yuwell part and accessories with device. Non-YUWELL parts may reduce effectiveness of yuwell device and may damage the device.
- f) 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.
- g) Please use the yuwell mask with several holes. Keep outlet clean, smooth ensure fresh air can get in your mask.
- h) Do not block the several holes in your mask, otherwise it will result strangulation.
- i) Do not place the device where it can be crashed or somewhere children may be tripped by the power.
- j) Do not block the air tube and outlet, in case the device turns too hot.
- k) Place the device on the stable table. Placing device on the soft, out of flatness surface is forbidden. Please place device where can be separated the plug easily.
- l) Keep the environment around the device clean and tidy; be apart from anything that can block outlet.
- m) Keep device far away from water.
- n) Do not use bleach, chlorine, alcohol, aromatic-based solutions, moisturizing or antibacterial soaps or scented oil to clean the device, humidifier or air tube. Otherwise it may cause damage and reduce the life of these products.
- o) Power is a mean to isolate it circuits electrically from the supply mains may on all poles simultaneously
- p) Place the humidifier beyond the surface of your head to prevent water flow backward patient's mask and air tube.
- q) Pour out the water in the water tank before you move it.
- r) This device cannot be used for multiple patient
- s) Interconnection of this equipment to other equipment which is not the supply one is forbidden.
- t) The maximum temperature of applied part may not over 41 °C.
- u) The sources of oxygen should be located more than 1 m from the BreathCare PAP otherwise it may invite danger.
- v) The duration of contact should not over 24 hours.

14.2 Caution:

- w) Ensure the air tube connect smoothly. Do not warping the air tube.
- x) Ensure the power adapter and plug is not broken.
- y) Do not lay the power adapter near to the heat source.
- z) If device has any strange, e.g. strange nosy, falling from the table, broken device shell, please stop using this device and contact with your provider.
- aa) 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 humidifier if you spill some water on the device.
- bb) Separate the device and humidifier before your cleaning and combine them after cleaning.
- cc) Do not cleaning the device during the time of device active.

15. Specified of technology

Items	Specifies	
Power	Powered by adapter Input :100-240VAC(±10%), , 50/60Hz,1.8Amax Output:24V DC,3.33A	
Environment conditions	Operating Temperature	Operate:+5°C~35°C (+41°F~95°F) , (non-condensation) Transport :-20°C~70°C (-4°F~158°F) , Storage:-20°C~70°C (-4°F~158°F) ,

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		Deliver:-20℃~70℃ (-4°F~158°F) , 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% Deliver: 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 ₂ O	
Sound	Sound pressure level measured according to ISO 17510-1(CPAP mode, Pressure @10cmH ₂ O) BreathCare PAP (B-PAP) (with humidifier) ≤31dB (A) .	
Physical properties	Dimensions (length*width*height)	270mm*135mm*100mm or 0.63''*5.31''*3.94''
	Weight	About 1600 g (With humidifier)
	Air tube	Plastic hose, 1.8m
	Maximum volume of water tank	260ml
	Texture of water tank	PC
	Gas output port connectors	22 mm conical connector complying with ISO 5356-1 or ISO 5356-2
Temperature	Maximum temperature of heater plate	55℃(131°F)
	Cut-out	Type: E7F51110C, 250VAC, 5A, 110℃ (if it damage, return To Depot)
	Maximum gas temperature	≤41℃
Air filter	Material: Polyester non-woven fiber	
IPAP	4-20 cmH ₂ O (suit for YH-720) ,±[2%of full scale+4% of measured value]	
	4-25cmH ₂ O (suit for YH-725) ,±[2%of full scale+4% of measured value]	
	4-30cmH ₂ O (suit for YH-730) ,±[2%of full scale+4% of measured value]	
EPAP	4-20 cmH ₂ O (suit for YH-720) ,±[2%of full scale+4% of measured value]	
	4-25cmH ₂ O (suit for YH-725) ,±[2%of full scale+4% of measured value]	
	4-30cmH ₂ O (suit for YH-730) ,±[2%of full scale+4% of measured value]	
Mode	CPAP、S、ST、T、VGPS (suit for YH-720、YH-725、YH-730)	
BPM	5-50bpm adjustable, step is 1 bpm	
Slope	1-5 level adjustable	
Trigger	1-5 level adjustable	

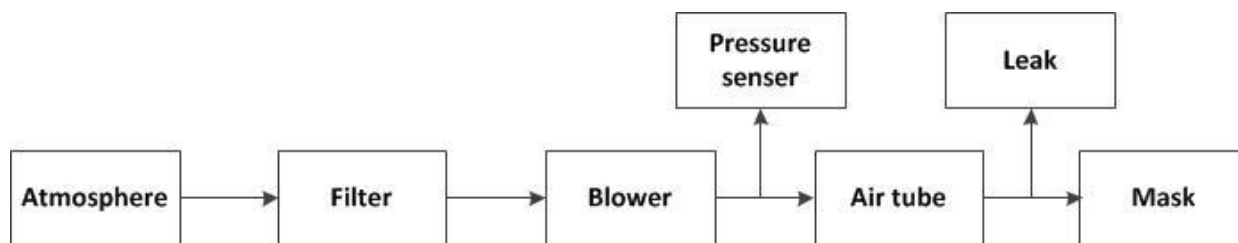
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Cycle	1-5 level adjustable
IE ratio	10-70% adjustable
Ramp	0-45min
Tidal volume	50-1500ml (only for VGPS mode)

The BreathCare PAP performance at set pressure is shown below:

	Test pressure		
	10	20	30
Measured pressure at the connection port (cmH ₂ O)	9.98	20.05	32.8
Average flow at the patient connection port (l/m)	99.2	141.8	175.2

Pneumatic flow path:



General The patient is an intended operator.

Displayed values	<i>Value</i>	<i>Range</i>	<i>Accuracy</i>
	Tidal volume (VT)	50-1500ml	±50ml or ±25% of reading whichever is greater
	Leak volume	20~99.9l/min	±2l/min or ±20% 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 ISO17510-1:2007			
	Standard air tube			
	Without humidifier	±[2%of full scale+4% of measured value]		
	With humidifier	±[2%of full scale+4% of measured value]		
	Maximum dynamic pressure variation according to ISO17510-1:2007			
	Device without humidifier/Device with humidifier (CPAP mode)			
	Pressure(cmH₂O)	10bpm	15bpm	20bpm
	4	0.6/0.6	1.0/1.0	1.4/1.4

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	8	0.7/0.7	1.1/1.1	1.5/1.5
	12	0.8/0.8	1.2/1.2	1.6/1.6
	16	0.9/0.9	1.3/1.3	1.7/1.7
	20	1.0/1.0	1.4/1.4	1.8/1.8
pressure at the patient connection port	<i>The maximum steady limiting pressure at patient connection port</i> 30±0.5 cmH2O under normal use 40±0.5 cmH2O under single fault Condition			
Expected service life	Device with humidifier (excluding accessories)	5 years		

16. Symbols

16.1 The following symbols may appear on the product or packaging

Symbol	Meaning	Symbol	Meaning
	Consult instructions for use		Start/ stop
	Caution.		temperature limitation
	Manufacture		type BF applied part;
	Date of manufacture		class II equipment
	serial number		maximum water level
	prescription only		minimum water level
	Warning: hot surface		EC-Representative
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC		
	protected against finger sized objects and against dripping water on the surface of the device		

16.2 Disposal statement:

Warning: please contact local authorities to determine the proper method of disposal of this device.

17. Quality 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
BreathCare PAP with humidifier	2 years

The quality warranty is only available to the initial customer. It is not transferable. Warranty is void on product sold, or resold, outside the original purchase, repaired by the company without accredited, and pollution caused by smoking **Yuwell has the interpretation about the device's warranty.**

18. Repairing

18.1 If your device is in trouble, please contract yuwell. This device is only can be repaired by the service man who has be authorized. Our company will provide circuit diagrams, component part list, descriptions, and calibration instructions to assist to service personnel in parts repair

18.2 The user should follow the instruction of cleaning and safety to guarantee the device can be used for a long time.

18.3 If you 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

18.4 Manufacturer’s optional requirements for minimum qualifications of service personnel are as following: Service person must be engineer and must be trained before repaired this device.

19. EMC declaration

**Guidance and manufacturer’s declaration- electromagnetic emissions-
for all Equipment and Systems**

Guidance and manufacture’s declaration –electromagnetic emission		
The BreathCare PAP is intended for use in the electromagnetic environment specified below. The customer or the user of the BreathCare PA should assure that it is used in such and environment.		
Emission test	compliance	Electromagnetic environment -guidance
RF emissions CISPR 11	Group 1	The BreathCare PAP USES RF energy only for its internal function. Therefore, it RF emission are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The BreathCare PAP is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

**Guidance and manufacturer’s declaration- electromagnetic immunity-
for all Equipment and Systems**

Guidance and manufacture’s declaration-electromagnetic immunity			
The BreathCare PAP is intended for use in the electromagnetic environment specified below. The customer or the user of BreathCare PAP should assure that it is used in such an environment			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic	±6kV contact	±6kV contact	Floors should be wood, concrete or ceramic

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discharge(ESD) IEC61000-4-2	±8kV air	±8kV air	tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV differential mode	±1kV differential mode	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 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	<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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BreathCare PAP requires continued operation during power mains interruptions, it is recommended that the BreathCare PAP be powered from an uninterruptible power supply.
Power frequency(50Hz) magnetic field	3A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.

IEC61000-4-8

NOTE U_T is the a.c mains voltage prior to application of the test level.

**Guidance and manufacturer’s declaration- electromagnetic immunity-
for all Equipment and Systems that are not LIFE-SUPPORTING**

Guidance and manufacture’s declaration-electromagnetic immunity

The BreathCare PAP is intended for use in the electromagnetic environment specified below. The customer or the user of BreathCare PAP should assure that it is used in such an environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC61000-4-6	3vrms 15kHz to 80 kHz	3vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the BreathCare PAP, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$
Radiated RF IEC61000-4-3	3V/m	3V/m	<p>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 meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked</p>

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with the following symbol:



NOTE 1 At 80MHz and 800MHz, 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 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.

b over the frequency range 150kHz to 80kHz, field strengths should be less than 3V/m.

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

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

The BreathCare PAP is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of BreathCare PAP can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications equipment (TRANSMITTERS) and the BreathCare PAP 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 ransmitter(m)		
	150kHz to 80MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80MHz to 800MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800MHz to 2.5GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33

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10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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 80MHz and 800MHz, 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.

20. Warranty card



BreathCare PAP Warranty card

Contact _____	Department _____	User _____
Add. _____		
Diagnose _____	Tel. _____	
Model _____	SN _____	
Invoice number _____	purchasing date _____	
Dealer _____		

This limited warranty does not cover:

- a) Any damage caused as a result of improper use, abuse, modification or alteration of the product.
- b) Repairs carried out by any service organization that has not been expressly authorized by Yuwell to perform such repairs
- c) Any damage caused as accident, Act of God or human factor.
- d) Product which does not involved in Quality warranty sheet.

User sign _____

Date _____



BreathCare PAP Warranty card

Contact _____ Department _____ User _____
Add. _____
Diagnose _____ Tel. _____

Model _____ SN _____
Invoice number _____ purchasing date _____
Dealer _____

This limited warranty does not cover:

- a) Any damage caused as a result of improper use, abuse, modification or alteration of the product.
- b) Repairs carried out by any service organization that has not been expressly authorized by Yuwell to perform such repairs
- c) Any damage caused as accident, Act of God or human factor.
- d) Product which does not involved in Quality warranty sheet.

User sign _____
Date _____

CE SERTİFİKA NUMARASI NO.: G2150992486002



ÜRETİCİ FİRMA: JIANGSU YUYUE MEDICAL EQUIPMENT&SUPPLY CO.,LTD
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İTHALATÇI FİRMA: ECE TIBBİ CİHAZLAR VE MEDİKAL SAN. TİC.A.Ş.
www.ecemedikal.net
www.respirox.com.tr

İSTANBUL

Merkez / Teknik Servis – ZEYTİNBURNU

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ANKARA

Şube 3 - BAHÇELİEVLER

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