yuwell

User Manual

BreathCare PAP III

Model: YH-390N

Rx Only

Welcome

Thank you for choosing the BreathCare PAP III Continuous Positive Airway Pressure (CPAP) device, Model YH-390N. This user manual (Instructions for Use, IFU) is your comprehensive guide to setting up, operating, and maintaining your device to ensure optimal performance and comfort. We are committed to providing innovative healthcare solutions designed to support your well-being. Please read this user manual carefully before use to familiarize yourself with the device's features and functions, as well as important safety information. If you experience any difficulties or problems during use, please contact your healthcare provider or physician. If the package is damaged, contact your equipment provider. Thank you for the opportunity to serve you.

Caution

Federal law restricts this device to sale by or on the order of a physician.

Notice

For any serious incident that has occurred in relation to the device, please contact your device supplier.

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1. Introduction of the device

1.1. Intended use

YH-390N is indicated for the treatment of Obstructive Sleep Apnea (OSA) in adult patients weighing more than 66 lb.(30 kg). It is intended for home and hospital/institutional use.

1.2. Indications for use

YH-390N is indicated for the treatment of Obstructive Sleep Apnea (OSA) in adult patients weighing more than 66 lb.(30 kg). It is intended for home and hospital/institutional use.

1.3. Operating principle

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

1.4. Composition

YH-390N consists of a main device and a power adapter with a power cord.

2. Contraindications

Positive airway pressure therapy (such as YH-390N) may be contraindicated in patients with the following pre-existing conditions:

Severe bullous lung disease, pneumothorax, pathologically low blood pressure, dehydration, cerebrospinal fluid leak, recent cranial surgery, or trauma.

3. Warnings

(1) This device is not intended for use on patients weighing 66 lb (30 Kg) or less. Also, it is not for patients with physical or mental disabilities that could impair their ability to safely operate the device. Furthermore, this device is not intended for use with patients who have an upper airway bypass. Moreover, this device is not for life support or for patients who need a ventilator all the time.
(2) The device is provided non-sterile and does not require sterilization. It is intended for single patients, and multiple uses. Do not share the use of the device with others.
(3) Do not use this device in an oxygen-rich environment or in conjunction with an oxygen supply to avoid the risk of fire. Keep pure oxygen supply at least 3 ft away from the device.
(4) Do not serve or maintain the device during use.
(5) Do not use the device near flammable gases, such as oxygen or nitrous oxide, used in anesthetics to avoid the risk of fire or harm to patients or user.
(6) Keep this device away from a magnetic resonance (MR) environment. The device is MR unsafe and it could pose risk to the patient or damage the device or MR equipment.
(7) Do not use the device near electromagnetic equipment, such as CT scanners, diathermy machines, RFID systems, or electromagnetic security systems (e.g., metal detectors), as this may pose risks to the patient or damage the device. Some electromagnetic sources may not be obvious. If you notice unexplained changes in the device's performance or hear unusual or harsh sounds, immediately stop using the device, disconnect the power cord, and contact your healthcare provider.

(8) Do not use the device near equipment or conditions like electrocautery, electrosurgery, defibrillators, X-rays, strong magnets, or devices that release radio signals (e.g., portable Radio Frequency (RF) communication equipment with antenna cables or external antennas should be kept at least 12 inches (30cm)away. Avoid areas with electrical shocks, sudden changes in pressure, extreme heat, or static electricity. Exposure to these conditions can compromise the device’s performance or cause it to fail.

(9) Avoid placing this device next to or stacked with other equipment, as this may cause it to malfunction. If this setup is unavoidable, carefully monitor both devices to ensure they are working properly.

(10) Do not connect this device to any equipment and/or data transfer methods not listed in this user manual.

(11) Place the device on a stable, even surface where it will not be bumped or where someone could trip over the power cord. Avoid placing it on soft or uneven surfaces.

(12) Avoid the risk of electrocution. Keep the device away from water. Do not immerse the device, power adapter, or power cord in water. If liquid is spilled on the device, unplug it, let the parts dry naturally, and contact your equipment provider.

(13) Ensure the area around the device is clean and free from items like clothes, bedding, lint, or dust that could block the air inlet, cover the power adapter unit, affect patients' breathing, or shorten the device’s lifespan.

(14) Keep the device away from direct sunlight or anything that could block cooling airflow that can cause overheating, leading to burns, electrical hazards, toxic fumes/odors, or reducing device performance and lifespan.

(15) Check that the power cord and plug are in good condition, and ensure the main device is not damaged. Keep the power cord away from hot surfaces. If you notice any unexplained changes in the performance of the device (e.g., unusual noise), if the device or the power adapter is dropped or mishandled, or if the enclosure is damaged, turn off the device, unplug it from the power source, and contact your equipment provider.

(16) To ensure a safe and effective therapy, use only compatible accessories described in this user manual.

(17) Using accessories, transducers and power cords not listed in this user manual or provided by the manufacturer could result in increased electromagnetic interference, and lead to improper operation.

(18) Do not use masks or accessories that prevent rebreathing of carbon dioxide or allow normal breathing can lead to suffocation.

(19) Make sure that the power cords and air tubing do not twist around the patient’s head or neck, as this could cause strangulation.

(20) Regular cleaning of the device and its accessories, as well as replacement of the air filter, is important to prevent respiratory infections.
(21) To avoid electric shock, always turn off and unplug the device before cleaning, and make sure that all parts are dry before plugging it back in.
(22) Do not open or modify the device. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorized service agent. Unauthorized service or attempted service/maintenance while the device is in use may lead to unacceptable risks, such as fire or electrical shock. Contact your equipment provider when the device needs repairing.

4. Precautions

(1) Federal law restricts this device to sale by or on the order of a physician.
(2) Properly placing and positioning the mask on the face is critical to the consistent operation of this device.
(3) The time required for the device to warm up from the minimum storage temperature to an intended use temperature of 68℉ (20℃) is about 2 hours.
(4) The time required for the device to cool down from the maximum storage temperature to the intended use temperature of 68℉ (20℃) is about 2 hours.
(5) Supervision is required for users with any type of disability.
(6) Therapeutic pressure should be set individually with the configuration of the device and accessories being used.
(7) Check device and accessories compatibility before use.
(8) Reassess therapy settings periodically for effectiveness.
(9) Do not use filters other than recommended.
(10) Contact your dealer for device maintenance and repair.
(11) Only use vented masks recommended by Yuyue Medical with this device. Using a mask without positive pressured air from the device can result in rebreathing of exhaled air. Ensure that the mask vent holes remain clear and unblocked to allow proper airflow from the device to the mask.
(12) Contact your physician if symptoms of obstructive sleep apnea reoccur. Contact your physician if you have any questions concerning your therapy.
(13) If you feel uncomfortable, experience unusual chest pain, severe headache, trouble breathing, or have an emergency, turn off the device or unplug the power cord immediately to stop the therapy. Then contact your healthcare professional right away.
(14) If you have an acute upper respiratory tract infection, you may need to stop using the device temporarily.

5. Adverse Effects

The following adverse effects may occur during treatment:

- Headache
- Dizziness
- Chest pain
- Dryness of the nose and mouth, and sore throat
- Nosebleed
- Bloating
- Ear or sinus discomfort
- Cough
- Eye irritation
- Skin irritation

6. Package Table

The following device and accessories are included in the YH-390N device package:

- Main Device （Qty:1）
- Power Adapter with Power Cord （Qty:1）
- User Manual （Qty:1）
- Carrying Bag （Qty:1）
- SD Card (not available in all devices)（Qty:1）
- Replacement Air Filters (Qty. 2)
- Mask (sample)（Qty:1）
- Air tube (sample)（Qty:1）

Notes：

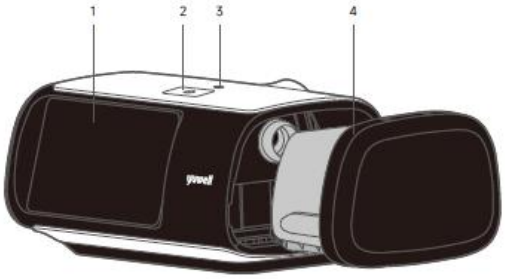
Compatible air tubes are standard 22 mm conical connectors (complies with ISO 5356-1:2015). An example of a compatible air tube is TRS22-19 manufactured by Guang Dong EDA Technology Co., Ltd.

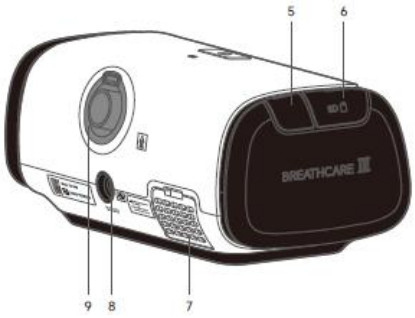
Compatible masks are 22 mm of the interface (complies with ISO5356-1:2015). An example of a compatible mask is the YN-02 mask manufactured by Suzhou Yuyue Medical Technology Co., Ltd.

Waring:

To ensure a safe and effective therapy, use only compatible accessories and parts.

7. System Features





Description		Purpose
1	Display touch screen	Navigates between functions and displays information on the operating status of the device.
2	Start/ Stop button	Press this button to start treatment when in stand by mode; press this button to stop treatment when in treatment mode; Press this button on other page store turn to the home page.
3	Light sensor	Automatically adjust the screen brightness based on the surrounding ambient light.
4	Side cover	The connecting adapter from the blower outlet to the exhaust pipe
5	Manufacturer reserved port	It is for use by the manufacturer only.
6	Side card cover	Removable cover the process the SD card slot.
7	Air inlet filter cover	Contains the air filter
8	Power inlet	Connects the power adapter
9	Outlet connector	Connects the air tube

⚠**Caution:**
Don’t use the manufacturer reserved port (Description 5), since it is reserved for the manufacturer for specific communication protocol. If non-manufacturer

designated personnel unintentionally plug a card into the interface, the device will not be recognized and will not affect the device operation.

8. Explanation of Button and Icons

8.1 Button

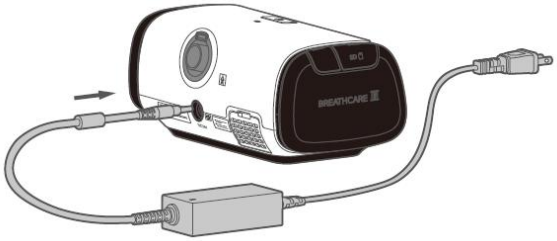
Button	Description
	Press this button to start treatment when in stand by mode; press this button to stop treatment when in treatment mode; Press this button on other page store turn to the home page.

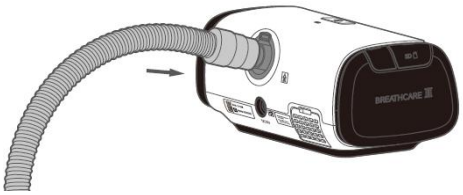
8.2 Icons

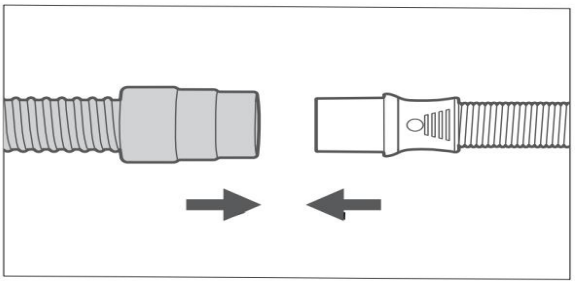
Icon	Description	Icon	Description
	No cellular connection		No Wi-Fi connection
	Weak cellular signal		Weak Wi-Fi signal
	Medium cellular signal		Medium Wi-Fi signal
	Strong cellular signal		Strong Wi-Fi signal
	Sleep Report		FPS
	Ramp		Mask-fit
	Settings		

9. Installation

The following section provides instructions for installing the device on your own.







(1) Place the device on a stable level surface.
(2) Connect the power cord to the power inlet at the rear of the device. Connect one end of the power cord to the power adapter and the other end into the power outlet. Ensure the device is set up and connected to power to enable settings to be applied to the device if required.
(3) Connect the air tube firmly to the outlet connector at the rear of the device.
(4) Connect the free end of the air tube firmly onto the mask.

See the mask and air tube user manual for detailed information.

Note:

- The indicator light of the power adapter will be green during normal operation.

10. Therapy

10.1 Using the touch screen

There are three actions to navigate through the touch screen:

Swipe: Swipe up or down the screen to view menu options.

Tap: Select a parameter setting to update.For other parameters(eg.Sound Reminder,Auto Start,Auto stop), tap the parameter to turn it on【 】 or tap to turn it off 【 】 .

Tap with two fingers : Tap two parameters simultaneously with two fingers to enter the 【Clinical Menu】.

10.2 Parameters settings

Prescription settings

The device can be set up according to the prescription parameters by your care provider.

Clinical Menu	Function	Description
Mode	Set Mode	CPAP (Continuous Positive Airway Pressure)
Pinit	Initial Pressure	The pressure at the start of treatment
Ptreat	Therapy Pressure	The pressure during treatment
FPS	Pressure Relief	When it is enabled,you may find it easier to breathe out.This setting can help you get used to therapy. FPS can be set 0 to 3 levels. The lager the number, the higher the FPS level and the more comfortable the patient.
Ramp	Ramp Time	Period during which the pressure increase from a low start pressure to the prescribed treatment pressure. Ramp Time can be set to 0 to 60 minutes(in 5 minutes increments) or Auto.
Erase Data	Erase Data	When it is enable,therapy data will be erased.

Personalizing your settings

The device can be set up for your needs by your care provider, but you may want to make adjustments to make your therapy more comfortable.

(1) Tap 【Ramp/Mask-Fit/FPS/Settings】 from the screen.
(2) Tap the parameter you wish to change.
(3) Tap the preferred setting.

Menu	Function	Description
Ramp	Ramp Time	Period during which the pressure increase from a low start pressure to the prescribed treatment pressure. Ramp Time can be set to 0 to 60 minutes(in 5 minutes increments) or Auto.

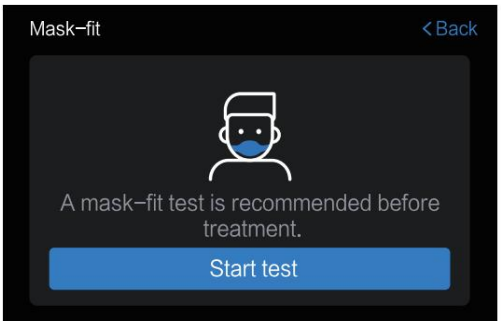
Mask-Fit	Mask-Fit	The function helps you assess and identify possible air leaks around your mask.
FPS	Pressure Relief	When it is enabled,you may find it easier to breathe out.This setting can help you get used to therapy. FPS can be set 0 to 3 levels. The higher the FPS level, the less pressure the patient will feel, and thus the more comfortable the patient will feel.
Settings	Auto Start	When it is enabled, therapy starts automatically when you breathe into your mask.
	Auto Stop	When it is enabled, therapy stops automatically after 8 seconds when you remove your mask.

10.3 Start therapy

Warning

The device is not intended to be operated by person (including children) with reduced physical, sensory or mental capabilities without adequate supervision by a person responsible for the patient's safety.

(1) Fit your mask.
(2) Press Start/Stop button or breathe normally if the 【Auto Start】 is enabled.



Notes:

- The screen will go black automatically after two minutes.Tap the screen to screen to turn it back on.

- The device has a light sensor that adjusts the screen brightness based on the light in the room.

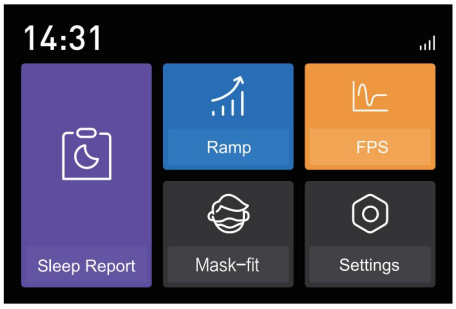
10.4 Stop therapy

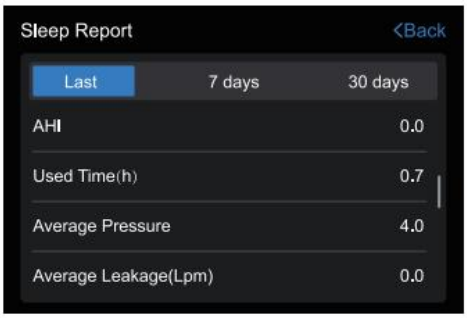
(1) Remove your mask；
(2) Press the start/stop button or wait until the device stops if 【Auto Stop】 is enabled.

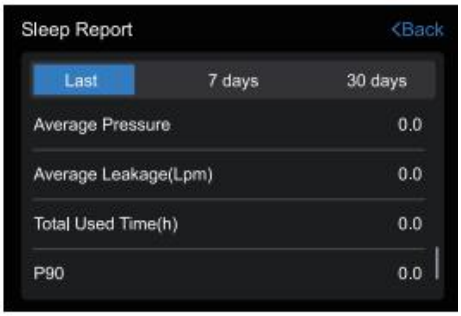
11. Function

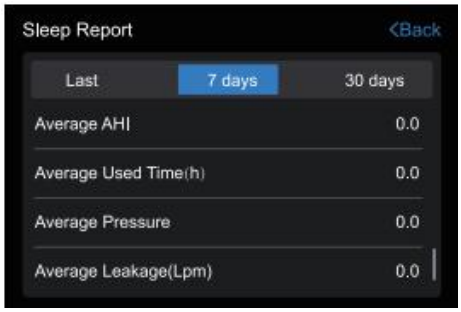
In addition to the functions described in Chapter 10, this device also offers information for the following functions.Please see below for details.

(1) Sleep Report









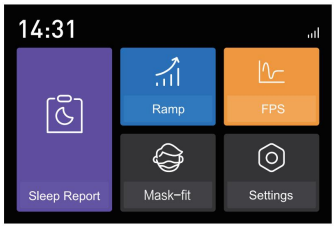
To track your sleep progress, tap 【Sleep Report】 to review more information.

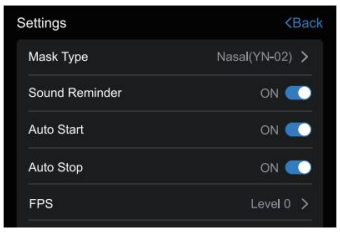
Sleep Report Menu	Description
AHI*[1]	The number of apneas and hypopneas per hour. AHI is an estimate and not diagnostic parameter.
Average AHI	The average number of apneas and hypopneas per hour within the selected time length(7 days/30 days)
Used Time(h)	The time duration of the last therapy
Average Used Time(h)	The average therapy duration within the selected time length (7 days/30 days)
Average Pressure	The average pressure of the last therapy
Average Leakage	The average air leakage within the selected time

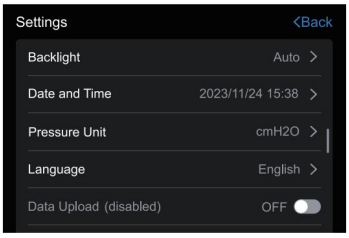
(Lpm)	length
Total Used Time(h)	The total used time
Uploaded/Total Data	Number of times data was uploaded successfully/ Number of times the patient received treatment
P90	The pressure for the 90 percent of the last therapy

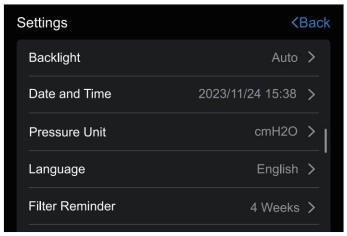
*1：AHI：Apnea-Hypopnea Index.

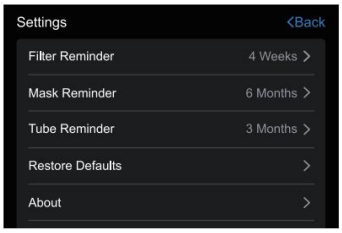
(2) Settings

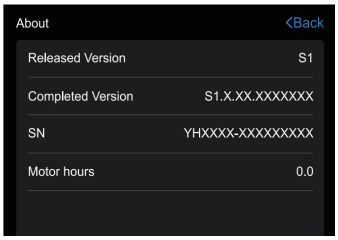












You can set the following parameters:

Settings Menu	Description
Mask type	choose the mask type including Nasal,Full Face,pillow and others
Sound Reminder	When it is enabled, the device will give a sound reminder, if abnormal air leakage occurs
Backlight	Adjust the brightness of the screen or automatic mode
Date and Time	Adjust the date (year, month, day and time)
Pressure Unit	Choose the unit of the pressure,cmH_2O or hPa
Language	Choose the different language
Data upload*1	When it is enabled, therapy data can auto upload after end of use
Filter Reminder	Filter Reminder can be set 4 to 10 weeks (in 2 weeks increments) or OFF.

	When it is enabled, this device can remind user to check and change the air filter
Mask Reminder	Mask Reminder can be set 6 to 9 months (in 3 months increments) or OFF. When it is enabled, this device can remind you to check and change the mask
Tube Reminder	Tube Reminder can be set 3 to 9 months (in 3 months increments) or OFF. When it is enabled, this can remind you to check and change the tube
Restore Defaults	Set parameters to the factory defaults
About	View the Released Version, Completed Version, SN, Motor Hour

*1：When the device has a transmission module, this function is displayed on the 【Settings】 menu.

12. Caring for your device

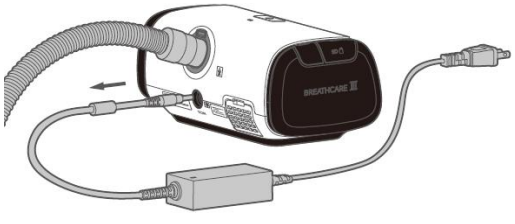
⚠Warning

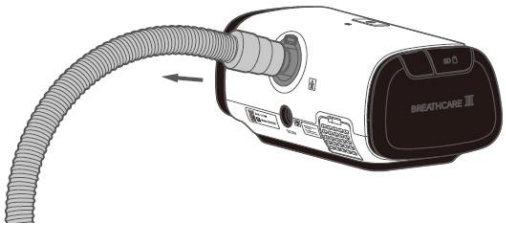
- Regular cleaning of the device is very important for the prevention of respiratory infections.
- To avoid electric shock, unplug the device before cleaning.
- Always unplug the device before cleaning and ensure that all parts are dry before plugging it back in.
- Do not open or modify the device. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorized service agent.
- Do not perform any maintenance tasks(eg, cleaning,changing the air filter) while the device is in operation.
- Discontinue use and contact your care provider or Yuwell if any of the following occur:
  - Device does not perform as usual.
  - Device is making unusual sounds.
  - Device is damaged.

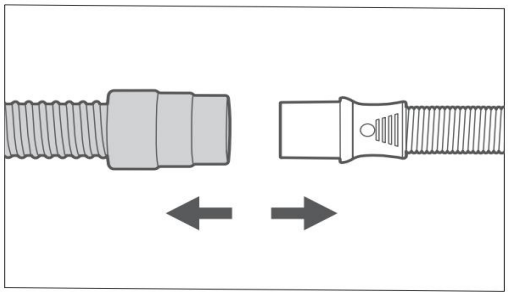
⚠Caution

- Overheating of the materials could lead to early fatigue of these materials.
- Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing moisturizing agents or antimicrobials should not be used either. These solutions may harden cleaned materials or reduce their lifespan.
- Do not immerse the device in any fluids.
- It is recommended to store the device and its components in the carrying bag after use and cleaning.
- If any visible deterioration of the component is apparent (cracking,discoloration,tears etc.), the component should be discarded and replaced.

12.1 Disassembling







(1) Disconnected the power adapter from the device.
(2) Pinch the cuff of the air tube,and gently put it away from the device.
(3) Hold both the cuff of the air tubing and the swivel of the mask, then gently pull apart.

12.2 Cleaning

You should clean enclosure of the device as described.For cleaning your mask and air tube,refer to their user guide for detailed instructions.

Weekly:
(1) Wipe the surface of the device with a soft, slightly damp cloth.
(2) Allow the device to dry for sufficient time.

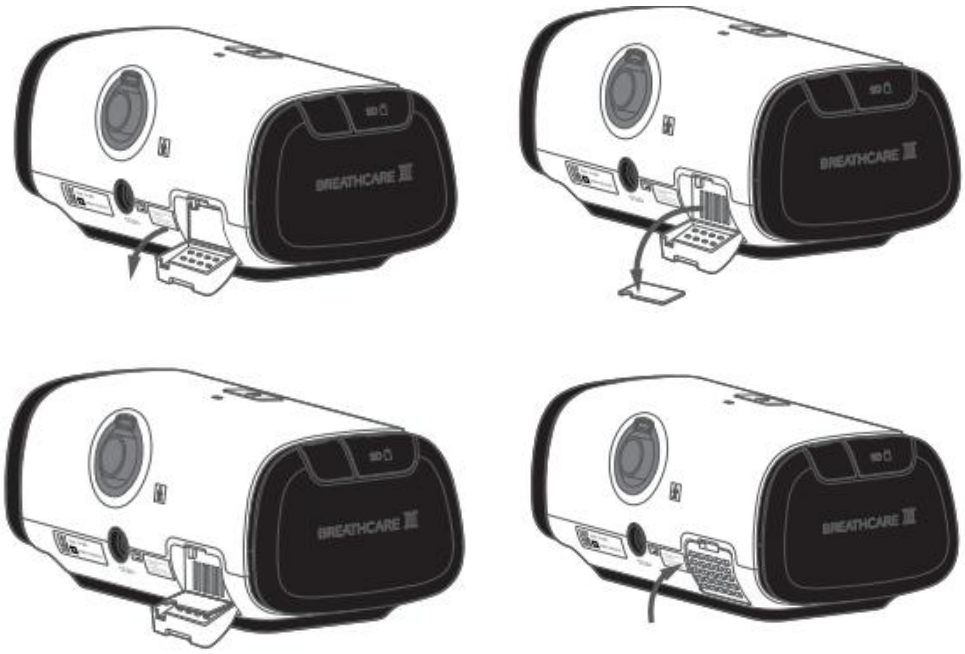
Note：
Clean this device only with a water-damped soft cloth. Do not use bleach, chlorine, ozone, UV light, alcohol, antibacterial soap, aromatic solution, moisturizer, or essential oil, as these can harden the materials and reduce the device’s service life.

12.3 Checking

You should check power adapter and power cord and air filter regularly in case of any damage.
(1) Check the power adapter and power cord
- Wipe the power adapter and power cord with the dry compress if it is dirty.
- Replace the power adapter and power cord if it is broken.

(2) Check the air filter
- Please check the air filter every week and prefer to replace the air filter every four weeks.
- If you find some particle blocked in the air filter, replace it more often.

12.4 To replace the air filter



(1) Open the air filter cover and remove the old air filter.
(2) Place a new filter onto the air filter cover and then close the cover.Make sure the air filter and air filter cover are fitted at all times to prevent water and dust from entering the device.

Note: The air filter is not washable or reusable.

13. Therapy data

The device can record your therapy data for up to 30 days. While the data can only be viewed on the device currently, the manufacturer is developing remote viewing features （i.e., SD card, WiFi, Bluetooth, or cellular) and thus has reserved relavant capabilities on the device for future upgrades post FDA approval.

14. Traveling

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

- Use the carrying bag provided to prevent damage to the device.
- Do not use the device in plane.

15. Troubleshooting

If you have any problems, have a look at the following troubleshooting topics.If you are not able to fix the problem, contact your care provider or yuyue.Do not try to open the device.

15.1 General Troubleshooting

Problem/possible cause	Solution
Air is leaking from around my mask Mask may be fitted incorrectly.	Ensure your mask is fitted correctly.See your mask user guide for fitting instructions .
I am getting too much air. Ramp may be turned off. The 【Ptreat】 parameter may be set too high.	Enable your 【Ramp】 option; Decrease the pressure.
I am not getting enough air. Ramp may be in progress. The pressure parameter may be set too low.	Start your therapy after the setting pressure reached or turn ramp time off. Increase the pressure.
My device screen is black. After therapy start, the screen backlight go off. In other case, the power do not connect firmly.	Click the screen to turn on the【Backlight】. Check the connection of power.ensure it connect with device firmly

15.2 Error Codes

Error Code/Description	Solution
ERROR 1 Pressure sensor error.	Contact your care provider or supplier.
ERROR 2 Flow sensor error.	Contact your care provider or supplier.
ERROR 4 Failure of the protection circuit.	Contact your care provider or supplier.
ERROR 5 The parameter value is outside the allowed range.	Restart the device. If the problem continues, contact your care provider or supplier.
ERROR 6 The pressure is outside of allowed range.	Replace the filter with a new one or restart the device. If the problem continues, contact your care provider or supplier.
ERROR 8 There is a problem with the blower.	Restart the device. If the problem continues, contact your care provider.
ERROR 9 There is a problem with the RTC (loss of power).	Adjust the device time. If the problem continues, contact your care provider or supplier.

16. Product Specification

Model	Configuration
YH-390N	No wireless communication
	WIFI&Bluetooth communication
	Cellular communication

Specification	
80W power adapter	
Input: 100-240VAC, 50 Hz-60 Hz, 1.8 A max	
Output: 24V DC, 3.33A	
Environment conditions	
Temperature	Operate: +41℉ to + 95℉ (+5℃ to +35℃)
	Transport: -4℉ to +140℉ (-20℃ to + 60℃)
	Storage: -4℉ to + 140℉ (-20℃ to + 60℃)
Humidity	Operate: Relative humidity 15% to 90%, Non-condensing
	Transport: Relative humidity 15% to 90%, Non-condensing
	Storage: Relative humidity 15% to 90%, Non-condensing
Altitude	Sea level to 9842 ft(3000m)
	air pressure range 700hPa to 1060hPa
IEC 60601-1 classification	
Type of Protection Against Electric Shock	Class Ⅱ
Degree of Protection Against Ingress of Water	IP22
Degree of Protection Against Electric Shock	Type BF Applied Part
Applied Parts	
Mask and air tube, both are not included with this device	
Mode of operation	
Continuous mode	
Sound	
Sound pressure level measured according to ISO 80601-2-70:2020	
<30 dB(A)	
Sound power level measured according to ISO 80601-2-70:2020	
<38dB(A)	
Physical properties	
Dimensions (length x width x height)	9.84” x 5.31” x 4.13”
	(250 mm x 135 mm x 105 mm)

Weight	3.09 lb (1400g)
Air out	22 mm (complies with ISO5356-1:2015)

Operating pressure range

4 to 20 cmH_2O (4 to 20 hPa)

Maximum limited pressure

20 cmH_2O (20 hPa) in normal condition

40 cmH_2O (40 hPa) under single fault pressure

Mode pressure range:

CPAP:

Therapy pressure:4 to 20 cmH_2O(4 to 20 hPa),step is 0.5 cmH_2O (0.5 hPa)

Initial pressure:4 to 20 cmH_2O(4 to 20 hPa),step is 0.5 cmH_2O (0.5 hPa)

Pressure accuracy

The maximum static pressure variation at 10 cmH_2O (10 hPa) according to ISO 80601-2-70:2020 is ±0.5 cmH_2O (0.5 hPa)

The maximum dynamic pressure variation according to ISO 80601-2-70:2020 are as follows:

Pressure (cmH_2O/hpa)	10bpm	15bpm	20bpm
4	±0.5	±0.5	±0.5
8	±0.5	±0.5	±0.5
12	±1	±1	±1
16	±1	±1	±1
20	±1	±1	±1

Maximum flowrate

The device performance at set pressure according to ISO 80601-2-70:2020 is shown below：

Test pressures(cmH_2O/hpa)	4	8	12	16	20
Average flow at the Patient-Connection Port (L/min)	≥110	≥110	≥110	≥110	≥110

Ramp

0 to 60 minutes (in 5 minutes increments) or Auto

Pressure measurement tolerance

±0.5 cmH_2O(0.5hPa)

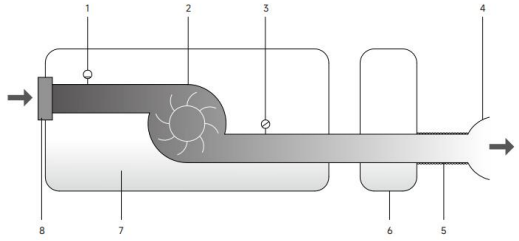
The uncertainty of measurement

Pressure: ±0.2 cmH_2O(0.2hPa)

Flow: ±2 L/min or ±3% (whichever is greater)

Pneumatic diagram

1.Flow sensor



2.Blower
3.Pressure sensor
4.Mask
5.Air tube
6.Side cover
7.Device
8.Air filter

Maximum delivered gas temperature

≤43℃(109.4℉)

Service life

Main device 5 years

Air filter

Average arrestance: ≥75% for 2-micron dust

SD card

16GB. Each use creates about 15KB of data. Based on calculations, The SD card has enough memory space to store data for the entire device service life.

All gas volume, flow, pressure and leakage specifications shall be expressed at Standard Temperature and Pressure, Dry (STPD).

This device is not made with natural rubber latex.

17. Symbols

17.1 Symbol

Symbol	Meaning	Symbol	Meaning
	Refer to instruction		Medical device
	General warning sign		Caution
	Manufacturer		Type BF applied part
	Serial number		Batch code
	Direct current		Alternating current
	MR unsafe		Stack limit:8 Layers
	Keep dry		Fragile
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a physician		
	Environmental information (EU directive 2012/19/EE Waste Electrical and Electronic Equipment (WEEE))		
	Country of manufacture (China) Date of manufacture is on the right side of the symbol or below it.		
IP22	Protected against access to hazardous parts with a finger and solid foreign objects of 12.5 mm in diameter and greater, protected against vertically falling water drops when enclosure titled up to 15 degrees.		

17.2 Disposal statement:

 **Warning:**

- The device contains electronic components, please do not throw away with common waste. Please dispose of the electronic devices in accordance with the local authorities.
- After usage, please dispose mask, air tube into garbage bags. In hospital/institution, related personnel shall carry out the terminal treatment in accordance with its own standard sewage treatment process.

18. Limited warranty

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

Product	Warranty period
Power adapter	1 year
Device	2 years

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

19. Repairing

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

20. List of power cords

Name	**Lengths(m)**
Power cord (AC)	1.5
Power cord (DC)	1.2

21. Electromagnetic Compatibility (EMC) information

The device is considered to not have essential performance. Notwithstanding this fact, when evaluating essential performance as acceptance criteria: static pressure deviation is not more than twice the airway pressure accuracy (the airway pressure accuracy is ±0.5cmH_2O).

21.1 Compliance information for Emission test

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

21.2 Compliance information for Immunity test

Guidance and manufacturer's declaration - electromagnetic immunity
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.

Phenomenon	**Compliance Level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ±15 kV air
Radiated RF EM fields IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Electrical fast transients/bursts IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges IEC 61000-4-5	± 0.5 kV, ± 1 kV (line to line)
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips IEC 61000-4-11	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
	0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°

Voltage interruptions IEC 61000-4-11	0 % U_T; 250/300 cycles

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

Test Frequency (MHz)	Band (MHz)	Service	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18Hz	27
450	430 - 470	GMRS 460, FRS 460	FM ±5 kHz deviation 1kHz sine	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900,	Pulse modulation 217 Hz	28
1845				
1970				

		DECT; LTE Band 1, 3, 4, 25; UMTS		
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

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

Test frequency	Modulation	Immunity test level (A/m)
30 kHz [a)]	CW	8
134.2 kHz	Pulse modulation [b)] 2.1 kHz	65 [c)]
13.56 MHz	Pulse modulation [b)] 50 kHz	7.5 [c)]

[a)] This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEATHCARE ENVIRONMENT.

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

[c)] r.m.s., before modulation is applied.

21.3 Precautions According to IEC60601

According to IEC60601-1-2:2020, YH-390N complies with all applicable electromagnetic compatibility requirements (EMC) . It may have harmful interference with other devices if you do not follow the instructions. However, there is not certain it has not interference with other devices if you follow the instructions. If it does have interference with other device, you can amend interference by the following methods.

- Enlarge the distance between this device and other device.
- Connect the two devices with different power socket.
- Stop therapy and ask YUWELL engineer for help.

FCC additional information

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
—Reorient or relocate the receiving antenna.
—Increase the separation between the equipment and receiver.
—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
—Consult the dealer or an experienced radio/TV technician for help.

FCC RF Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20cm between the radiator and any part of your body.

FCC Compliance Statement
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

yuwell

BreathCare PAP III Warranty Card

Feedback Couple

Contact_____Department_____User_____

Add. _____

Diagnose_____Tel. _____

Model_____SN_____

Invoice number_____purchasing date_____

Dealer_____

This limited warranty does not cover:
Any damage caused as a result of improper use, abuse, modification or alteration of the product.
Repairs carried out by any service organizations that have not been expressly authorized by Yuwell to perform such repairs.
Any damage caused as accident, act of god or human factor.
Product which is not involved in quality warranty sheet.

User sign_____
Date _____

yuwell

BreathCare PAP III Warranty Card

Feedback Couple

Contact_____Department_____User_____

Add. _____

Diagnose_____Tel. _____

Model_____SN_____

Invoice number_____purchasing date_____

Dealer_____

This limited warranty does not cover:
Any damage caused as a result of improper use, abuse, modification or alteration of the product.
Repairs carried out by any service organizations that have not been expressly authorized by Yuwell to perform such repairs.
Any damage caused as accident, act of god or human factor.
Product which is not involved in quality warranty sheet.

User sign_____
Date _____

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