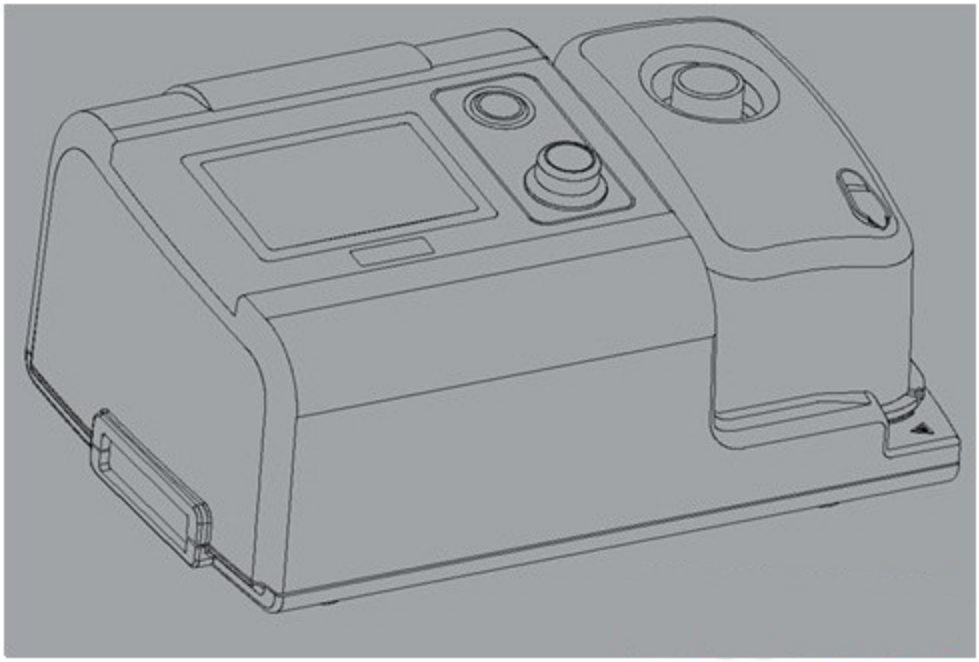
Sleep Apnea Therapeutic Device - BiPAP

User Manual
--- Colour Screen



Please read it carefully before using this product.

Dear Customer:

Thank you for choosing our BiPAP (Bi-level continuous positive airway pressure). This device could treat or alleviate respiratory disease by nasal continuous positive airway pressure therapy. We sincerely hope that this device bring you health and happiness. Please feel free to contact us if you have any suggestions or dissatisfaction about the device.

Read and understand the entire user manual before operating this device. If you have any questions concerning the use of this device, contact your home care provider or health care professional.

Contents

1. Introduction

1.1 Intended use

The BiPAP is bi-level continuous positive airway pressure device that mainly used for home care and clinical treatment of obstructive sleep apnea-hypopnea syndrome (OSAHS) or respiratory insufficiency.

This device is to be used only under the instruction of a licensed health care professional. Your home care provider will make the correct pressure settings according to your health care professional's prescription. You can set both the IPAP (inspiratory positive airway pressure) and the EPAP (expiratory positive airway pressure).

The humidifier cooperates with the host to provide the user with a air of suitable temperature and humidity to avoid drying of user's nasal mucosa and make comfort treatment. The host controls the humidifier's turning on/off, the principle of which is to heat the water in the chamber and make the air inhaled by the user with suitable temperature and humidity.

1.2 Application

BiPAP is applicable to the clinical treatment of adult OSAHS patients. It does not apply to children or the users that can not safely use on physical, sensory and intellectual without auxiliary and supervision.

1.3 Warnings & Cautions and Contraindications

1.3.1 Warnings

Warnings indicate the possibility of injury to the user or the operator.

- The Instructions is for reference. It cannot supersede the professional medical's guidance for the use of the device.
- This device is not intended for life support.
- This device may be influenced or disturbed under below environment:

  - The electromagnetic fields exceed 3V/m under the EN60601-1-2 test conditions.
  - Operation of high frequency device (diathermy).
  - (Electric shock) defibrillator, or short-wave therapeutic device.
  - Radiation (Such as x-ray, CT).

- Electromagnetic field (Such as MRI).

- Use Beyond circuit accessories or the accessories recommended by medical Professional.
- Do not wear the mask and headgear for more than a few minutes while the device is not operating.
- Keep the device dry, the tubing and mask smooth.
- If you notice any damager of the device or any unexplained performances such as unusual harsh sounds, please disconnect the power supply, empty the water in the chamber and stop using the device.Then you can contact your home care provider or the manufacturer.
- CPAP devices have the potential to allow rebreathing of exhaled air.
- To reduce this potential, observe the following:

  - Use Beyond circuit accessories.

  - Do not wear the mask and headgear for more than a few minutes while the device is not operating.

  - Do not block or try to seal the vent holes in the exhalation port.
- This device is not recommend to use with the oxygen to avoid fire hazard.
- Do not operate this devices in the presence of a flammable anaesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide.
- Keep away from toxic or hazardous steam.
- Do not use this device if the room temperature is higher than 35 ℃,otherwise the temperature of the air flow may exceed 41℃,this is could cause your airway damage.
- Do not use this device under direct sunlight or near to heating equipment, otherwise the temperature of the output will increase.
- To avoid electrical shock, disconnect the power cord before cleaning. DO NOT immerse the device in any fluids.
- Contact your health care professional if symptoms of sleep apnea recur.
- Check power cable and accessories regularly.
- Disconnect the power supply before checking the device.
- When using this device make sure the position of the mask is higher than the host, otherwise the condensed water in the tubing may flow into the user’s

nose which cause suffocation.

- Stop using this device if the humidifier is damaged.
- Do not touch the heater plate before it cools down after disconnecting the power supply.
- Do not add water with a temperature above 35℃.
- Do not splash the water into the device when installing the water chamber

1.3.2 Cautions

Cautions indicate it may damage the device,please read it carefully.

- Do not wear the mask until the device is running normally.
- Do not operate the device beyond the range of non-operating temperature. If the device was exposed at a too-high or too-low temperature previously, make it return to the room temperature before use.
- Do not immerse the device in any liquid, or let any liquid enter into the device or the filter at the air inlet.
- The condensated water may damage the device. Make sure the device reach the room temperature before use.
- A properly good fitted filter is required during the normal running.
- The tar generated by smoking gathering on the device shell will lead to device failure.
- If any liquid splashes on the heater plate, disconnect the power supply,use it until it get completely dry.
- Take preventive measures to avoid device damages due to water.
- Only the distilled or pure water can be used in the water chamber. Other liquid may damage the humidifier and device, even endanger the user.
- Do not exceed the maximum water level marked on the water chamber.
- Do not splash the water into the device when installing the water chamber.
- Do not tilt the device to avoid the water flowing back into the device.If it happens, please disconnect the power and stop using it.

1.3.3 Contraindications

Clinicians should know the device can provide a pressure up to 20cm H_20,when evaluating relative risks and benefits of using the device. In case of any single fault, the max pressure should not be more than 30cm H_20. Studies have shown that some patients with the following circumstances may not be suitable for the treatment of this

device.

- Bullous lung disease
- Pneumothorax
- Pneumomediastinum
- Serious lack of effective circulating blood volume with shock
- The one in a coma or disturbance of consciousness and unable to cooperate with or accept the mask treatment
- Lots of respiratory secretions and coughing, weak breathing independently
- Pathological hypotension
- Pneumothorax when using nasal continuous positive airway pressure.

Be careful when making prescriptions for the following susceptible patients with the treatment of the sleep apnea therapeutic device: cerebrospinal fluid (CSF) leakage, cribriform plate malformation, brain trauma history and / or pneumothorax. (Chest 1989;96:1425-1426)

Those with symptoms of sinusitis or otitis media is not suitable to adopt the positive airway pressure therapy. The patient with upper airway obstruction and the alcoholics is also not suitable to adopt the positive airway pressure therapy. In case of any questions about the treatment, please contact your doctor.

1.4 Device Components

- **Device Components**

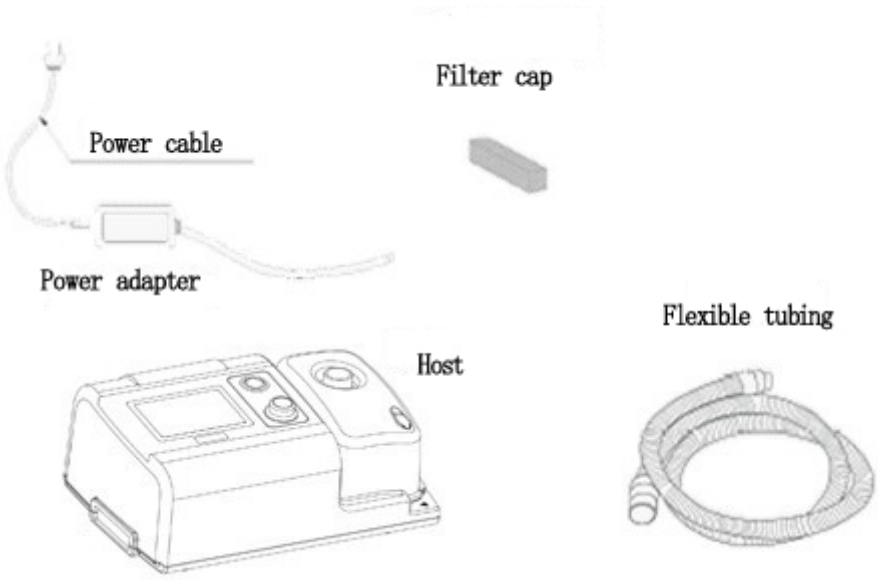


Fig.1-1 Device Components

- **Host Composition**

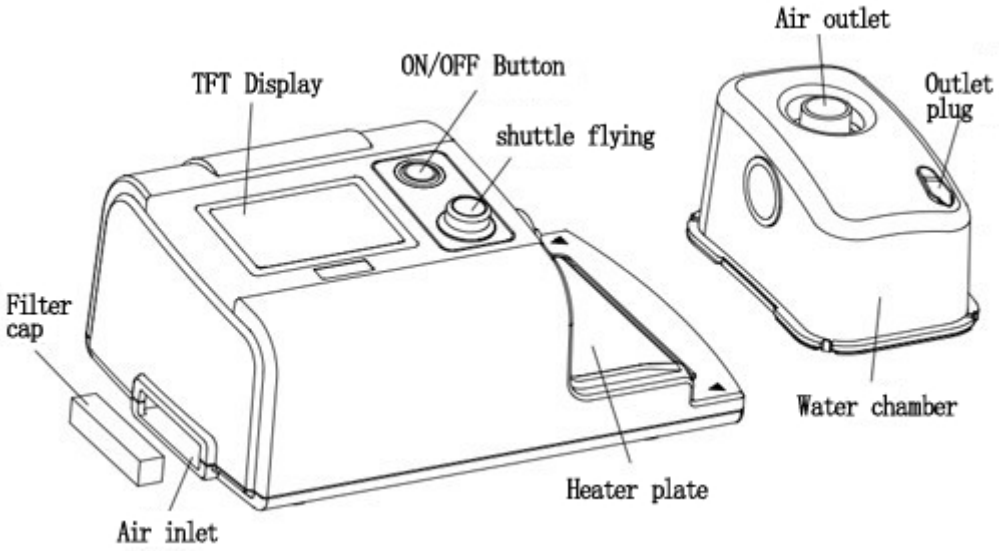


Fig.1-2 Front Panel of Host

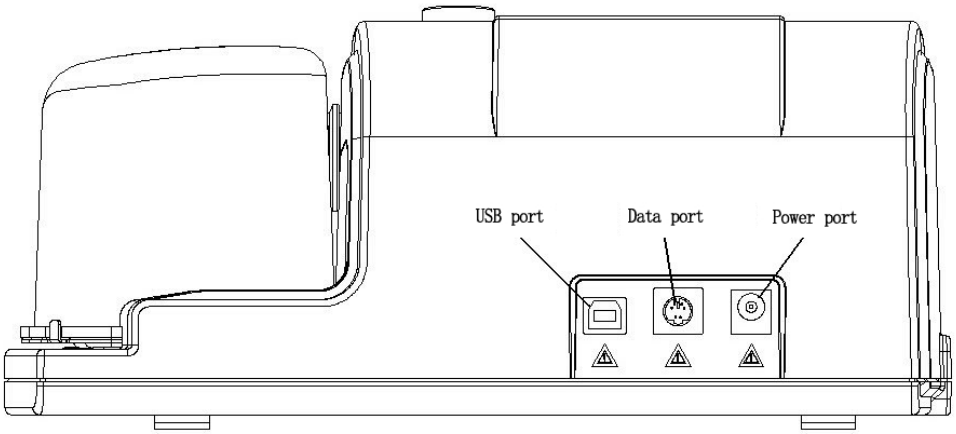


Fig.1-3 Back Panel of Host

1.5 List of Terms

Terms and abbreviations in the Instructions are as follows:

Term/Abbreviation	Definition
Shuttle flying	Able to be rotated clockwise or counterclockwise and be pressed.
ON/OFF button	Enable the device in a booting or standby state.
Booting state	The host motor works; the humidifier works as set by the user. The device turns to the state of providing fresh air for the user.
Standby state	The host motor stops working. If the humidifier is on, turn it off.

1.6 List of Symbols

The symbols on the device as follows:

Symbol	Definition
	Type BF applied part
	Class II (double insulation)
	Caution
IPX1	Degree of Protection Against Ingress of Water
	Conform to the Waste Electrical and Electronic Equipment /the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment
	Warning for hot

The symbol in the Instructions as follows:

Symbol	Definition
	Warnings, cautions

2. Features

2.1 Buttons

1. ON/OFF button: It may turn on or off the device and close alarms. If the device is connected to the power, the ON/OFF button indicator will be on.

2. Shuttle flying: It can be rotated clockwise/counterclockwise or be pressed. When it is rotated clockwise, it may move to the next settings on the current interface or enlarge the parameter or come to the next parameter. When it is rotated counterclockwise, it may move to the previous focus on the current interface or diminish the parameter or come to the previous parameter. Press the shuttle flying, it may perform the functions indicated by the current focus, or enter / edit the interface/confirm.

⚠ Do not remove the shuttle cap. The metal rod in the shuttle may contact the external current, resulting in the damage of the host. If the shuttle cap falls off, you may contact the dealer or us to purchase a new shuttle cap.

⚠ In case of the button failure, you may contact the dealer or us for help.

⚠ Press any button to activate the screen backlight, if screen backlight is turned off . This press will not cause any operation.

2.2 TFT Display

A 3.5-inch TFT display is adopted to mainly display the current parameters and states for the user and operator. Please refer to Chapter 3 Device Operation for more interface operation.

⚠ If the display does not work normally, please contact us or the dealer for maintenance.

2.3 Power Adapter, Power Port, Data Port, USB Port and USB Cable

1. The power adapter is mainly to transfer the external power supply into the voltage and current required for the device operation.

⚠ Please use the power safely at the power connection part.

⚠ Please adopt an appropriate power adapter socket when using the device in other countries.

⚠ Do not block the power port or splash any liquid, shorten the circuit and touch the power port or placed in any metal,liquid,flammable gas and other items that may cause danger during the running.

⚠ Please disconnect the power supply and put it at a safe place when the device is not used.

2. The data port is mainly for software updating and maintenance by the manufacturer.

⚠ Do not block, short the circuit or splash the liquid.

3. USB port and cable. The operator may connect the device via a USB cable to get the data of the user.

⚠ Do not block, short the circuit or splash the liquid.

2.4 Humidifier

The humidifier is to provide users with comfort airflow by heating the water in the water room . Please turn off the humidifier when you need not it. Better use the recommended accessories by manufacturer otherwise it may cause air leakage.

2.5 Power Outage Alarm

During the running state, the exhaled air may be re-inhaled by the user in case of any power outage happens. To avoid this phenomenon,when power outage happened the system will provide a buzzing alarm and it will last for 30 seconds. During the

alarm, press the ON/OFF button, or connect the device with power again, the alarm will stop. After connect the device with power, the system will enter into the normal working state.

2.6 Interface

2.6.1 Main Interface and Sub-interface

The device has one main interface and five sub-interfaces as shown in Fig.2-1 to 2-10.

Fig.2-1 CPAP Main Interface

Fig.2-2 ST Main Interface

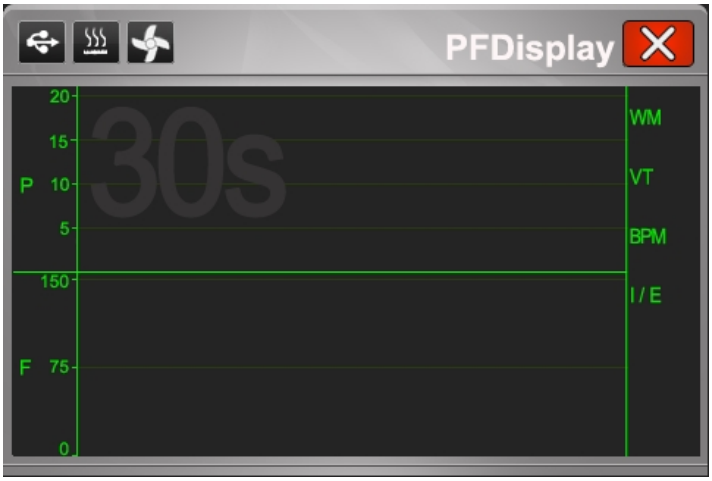


Fig.2-3 PFDisplay

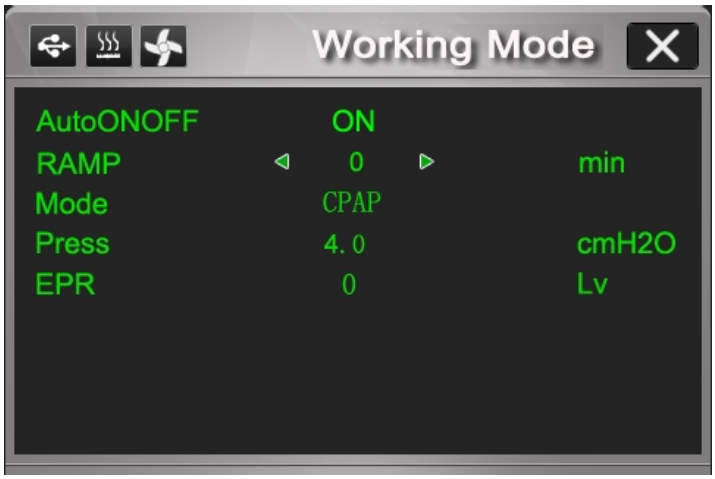


Fig.2-4 CPAP Working Mode

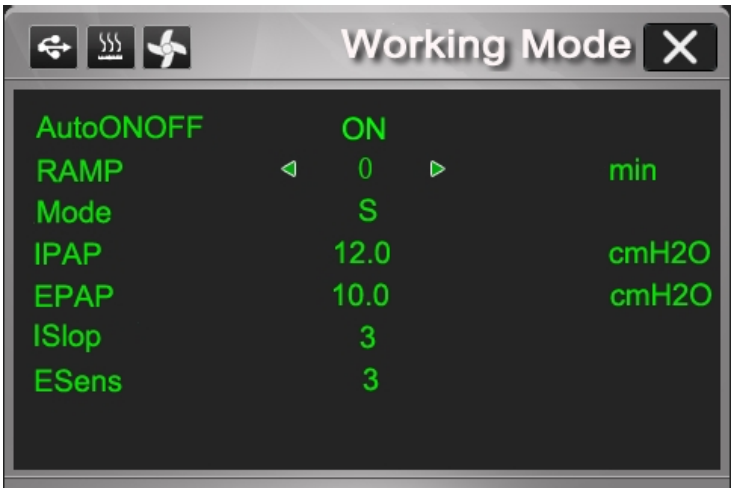


Fig. 2-5 S Mode Parameters Setting Interface

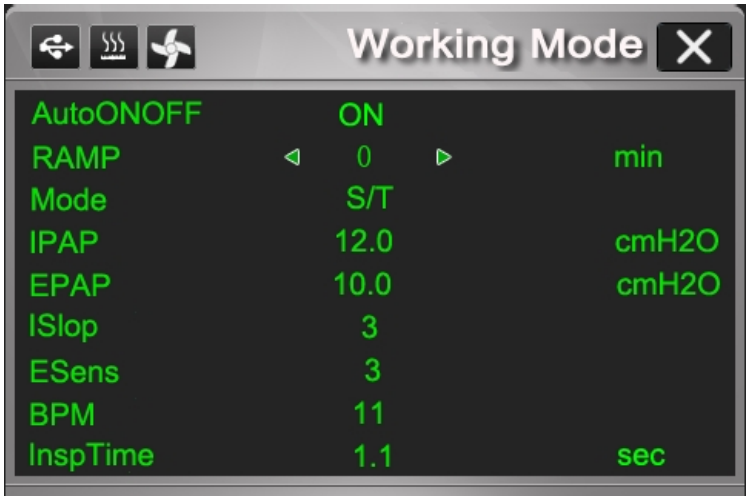


Fig. 2-6 S,T S/T Mode Parameters Setting Interface

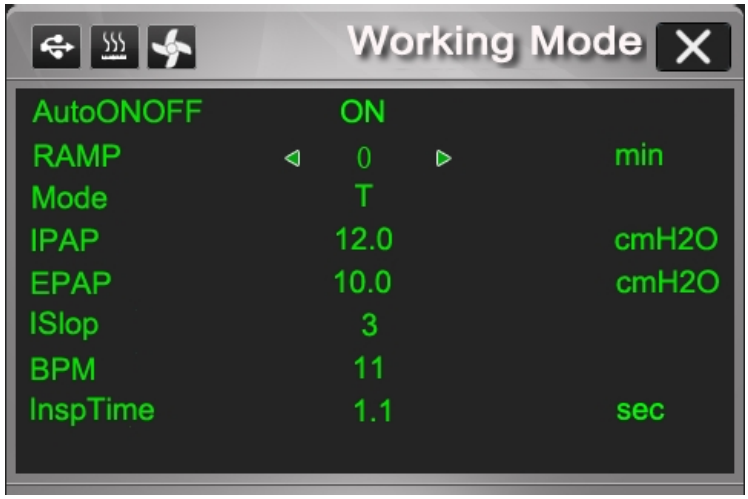


Fig.2-7 T Mode Parameters Setting Interface

Fig.2-8 Humidifier Setting Interface

Fig.2-9 System Setting

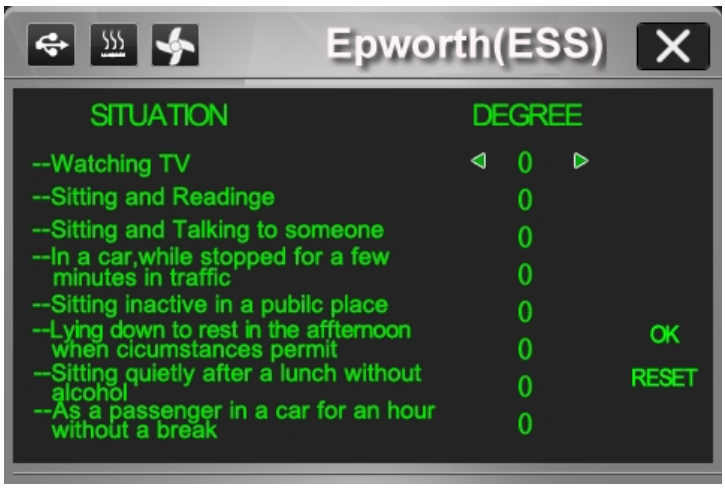


Fig.2-10 Epworth

2.6.2 Interface Icon

The small icons on the interface as follows,

Icon	Description
	Indicating USB has been connected with the device
	Indicating that the humidifier is working
	Indicating the motor is working
	Indicating that the Ramp has been set
	Indicating that the parameter setting interface is locked, and some parameters can not be modified. In case of it go back to the main interface move cursor to the parameter setting icon, and press shuttle button until you hear a buzzing alarm

2.6.3 Parameter Instruction

Auto ON/OFF: When the Auto ON/OFF is set to “ON”, user wears the mask and takes 3 breaths under the standby state, then the device will enter into working state; User takes off the mask under the working state,then within 15 seconds the device will enter into the standby state.When such function is set, the device will automatically enter into the standby state in case of the mask or tube falls off during the sleep.

RAMP: Setting pressure ramp duration function,the device works at a 4cmH_2O output pressure at the beginning and increase stably to the setting pressure within the setting time. After this function is set, pressing the on/off button for the first time the device will start running with ramp function; and with the second pressing, the device will jump the ramp function and run at the setting pressure directly.

Working mode: There are four working modes(CPAP,S,T,S/T)

CPAP mode: The device outputs a constant pressure.

S(Spontaneous) mode: Trigger by spontaneous respiration of patient, automatically conversion between inspiration pressure and expiration pressure.

T(timed) mode: After setting the BPM(breath frequency per minute) and inspiration time, the device will automatically convert between inspiration pressure and expiration pressure according to the setting parameter.

S/T(Spontaneous/Timed) mode: the device works at S mode if the patient breath normally; the device will switch to T mode if the spontaneous respiration interval of patient exceeds the set respiratory frequency.

Pressure: Under Mode CPAP, the device outputs the setting pressure.

EPR: Setting the EPR function under the CPAP Mode,the device will automatically detect respiratory rhythm of the user and lower pressure in the mask during the expiration to make the user feel more comfortable.

IPAP: Inspiratory Positive Airway Pressure under S, T and S/T Mode

EPAP: Expiratory Positive Airway Pressure under S, T and S/T Mode

Islop: It depends the time of the pressure rising from expiration phase to inspiration phase under S, T and S/T Mode.The time for 1-6 gear are 600ms, 500ms, 400ms, 300ms, 200ms and 100ms; the larger the gear is, the short the time is.

Esens: It depends the trigger time of the switching from inspiration phase to expiration phase under S, T and S/T Mode.

Inspiration time: Under Mode T and S/T, length of inspiration time within one

respiratory cycle is set based on the inspiration time.

BPM: Under Mode T and S/T, the BPM(respiratory frequency) for the device to convert between inspiration pressure and expiration pressure

Humidifier: This controller turns the InH2 heated humidifier on/off and allows the heat setting to be adjusted

Date and time of the system: The device will take the record of patient information

Therapy Time: Total therapy time which can be reset

Use Time: Total use time which can't be reset.

Use Days: The device continuously work for more than 4hours is one day, and this time can't be reset.

2.6.4 Parameter Setting

Refer to 2.6.1, you can find the position of the parameter that you want to set.

E.g.: Modifying pressure 4cmH_2O as 5cmH_2O (if you are on the main interface). Rotate the shuttle flying clockwise once to move the cursor the parameter setting icon -> press the shuttle flying -> rotate the shuttle clockwise twice (the clockwise rotation increases pressure while the counterclockwise decreases pressure. The max pressure is 20cmH_2O while the min pressure is 4cmH_2O with a 0.5 cmH_2O increment) -> press the shuttle flying (save and exit parameter settings).

E.g.: Setting the time 09:37:15 as 09:37:20 (if you are on the main interface). Rotate the shuttle flying clockwise three times to move the cursor to the system setting icon-> press the shuttle flying -> rotate the shuttle flying counterclockwise once -> press the shuttle flying -> rotate the shuttle flying twice to move the cursor to 15 -> press the shuttle flying and rotate the shuttle clockwise for five times -> press the shuttle flying and exit the edit mode.

Environmental Specifications

	Working Environment	Storage Environment
Temperature	5℃ to 35℃	-20℃ to 60℃
Humidity	15% to 95% (no condensation)	15% to 95% (no condensation)
Atmosphere pressure	77 to 101kPa	Inapplicable

Physical Specifications

Dimension	255mm*170mm*112mm
Weight	1.8Kg
Water capacity	MAX 200ml

Parameter Scope

Pressure	4~ 20cmH_2O (±1cmH_2O) with a 0.5cmH_2O increment
IPAP	4~ 20cmH_2O (±1cmH_2O) with a 0.5cmH_2O increment
EPAP	4~ 20cmH_2O (±1cmH_2O) with a 0.5cmH_2O increment
ISlop	1-6 level
Esens	1-6 level
BPM	4-40BPM
Insp Time	0.5-3.0s
Ramp	0 -60 min
EPR	0 level Close EPR 1 level setting pressure -2cmH_2O 2 level setting pressure -3cmH_2O 3 level setting pressure -4cmH_2O
Humidifier	0 gear close the humidifier 1 level 45℃ 2 level 50℃ 3 level 55℃ 4 level 60℃ 5 level 65℃
System time	24-hour
Backlight	30seconds,60seconds,90seconds,120seconds,150seconds,240seconds,330seconds,420seconds,510seconds,600seconds

Electrical Specifications

Power adapter	Model: DSS-240250 60VA Input: 100-240V,50-60Hz Output: +24V,2.5A
Type of protection Against Electric Shock	Class II Equipment
Degree of protection Against Electric Shock	Type BF applied part
Degree of protection Against Ingress of Water	IPX1
Noise level	<30dB,when the device is working at the pressure of 10cmH_2O

Humidifier

Do the test according to YY 0786-2010 standard or equivalent methods.

Output air flow temperature:	＜40℃
Humidity scope:	10-40mg/L
Pressure drop caused by humidifier:	＜0.5cmH_2O (with the flow rate of 60LPM)
Leaking under maximum working pressure:	<25mL/min (Together with the tubing)
Adaptability:	＜20mL/kPa(Together with the tubing)
Preheating time:	30 minutes

Pressure Accuracy

According to the maximum dynamic pressure changes of ISO 17510-2007 standard.

Pressure (cmH_2O)	10 BPM	15 BPM	20 BPM
4	0.21	0.5	0.71
8	0.3	0.54	0.75
12	0.39	0.58	0.85
16	0.40	0.65	0.87
20	0.40	0.70	0.97
25	0.53	0.78	1.09

Maximum Flow

According to the maximum flow of ISO 17510-2007 Standard

Set pressure (cmH_2O)	Measured pressure (cmH_2O)	Maximum flow (L/min)
4	3	38.2
8	7	38.6
12	12	39.5
16	16	41.1
20	19	41.9
25	24	44.1

Note: The design of the device as a whole include the host and the humidifier, all test data were carried out under conditions with the humidifier.

3. Operation

3.1 Device Inspection and Connection

When connecting the device, check it according to the following sequence before using it.

1. Check the power supply, if it is damaged or may cause the power leakage.

2. Check the air filter,if there is obvious dust on it,please replace it

3. In case of any damage to the tubing, mask and headgear, or beyond its validity, please replace them immediately.

4. If the water chamber cracks, leaks or deforms, please replace it.

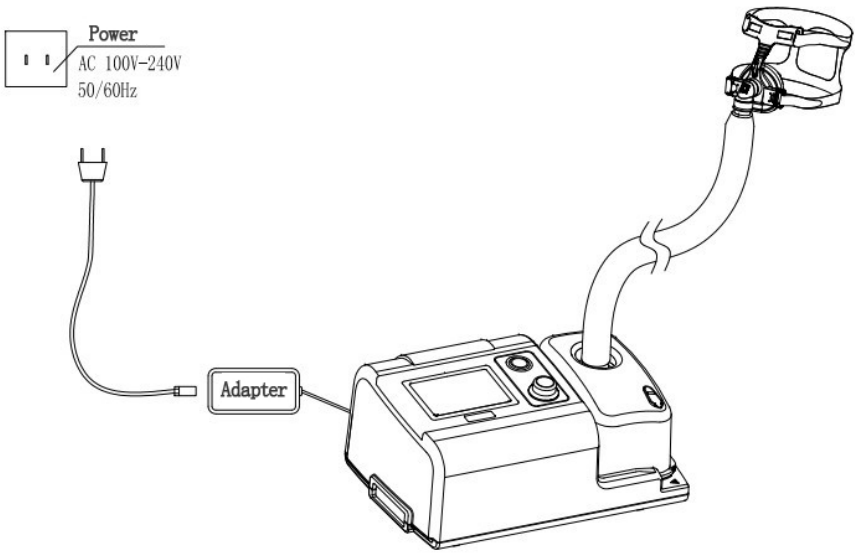
5. Check the power port, data port or USB port whether it is blocked or shorted.

6. Check whether there is a shuttle flying cap.

7.Check the host,if damaged it may cause the user inhaling the unfiltered air.

8. Check whether there are foreign objects in the water chamber.

Refer to the following figure for the connection method.



1. Put the water chamber into the host. Please refer to 3.2 Use of Water Chamber.

2. Connect one end of the tubing to the water chamber outlet while the other end to the mask inlet.

3. Put the filter into the host inlet.

4. Connect the adapter to power supply.

5. Start up the device and wait for more than 10 seconds to exclude the exhaust gas in the dead space of the host and pipes.

6. Put on the mask to use the device.

⚠ Put the device on a solid and flat surface place where it is easy to approach but not easy to fall off and keep it lower than the sleep place.

⚠ Ensure that the device inlet is not blocked by beddings, curtains or other objects.

⚠ Ensure that the air surrounding the device can flow freely,so that the system can provide better fresh air to the user.

⚠ Ensure that the device is far away from any heating or cooling equipment (such as mandatory vent, radiator and air conditioning, etc.).

⚠ Do not place the device directly on a carpet, fabrics or other flammable materials.

⚠ Do not place the device in or on a container where the water may retain.

⚠ Take preventive measures to avoid device damage due to water.

⚠ Do not start up the device before installing the water chamber.

⚠ Do not move the device when there is water in the water chamber, to avoid the water splashing into the host or the tube.

3.2 Humidifier Installation

1.Refer to 4.2 for Water Chamber Cleaning and Maintenance before use

2.Adding distilled or pure water into the water chamber if need cooperation with humidifier

⚠ It is recommended adding suitable warm water in the winter. The water temperature should not exceed 35℃.

⚠ The water added should not exceed the maximum water level.

⚠ If water runs out during the working state,please turn off the humidifier or turn off the device and add water when the humidifier cools down to the room temperature. Do not add water when the humidifier is running.

⚠ Do not splash the water in the host when adding water.

3. It is recommended to directly push the water chamber into the host with the host facing up.

⚠ Please push in the water chamber completely to meet the host outlet.

⚠ Do not touch the heater plate.

⚠ Do not tilt the water chamber.

4.Un-installation: refer to above method to take out the water chamber.

3.3 Turn on/of Device

Press the on/off button to start up the device after properly installing the device. Press the on/off button to turn off the device in the operation.

⚠ Please refer to 3.1 and 3.2 before starting up the device.

⚠ Please disconnect the power supply after turning off the device.

⚠ Turn off the device, uninstall the water chamber and empty the water in the water chamber.

4. Cleaning and Maintenance

4.1 Host Cleaning

1. Disconnect power supply of the device

2. Immerse a cloth with clean water or neutral detergent to wipe the front panel and the outer shell.

3. Dry the device.

⚠ Please avoid the liquid flowing into the device during cleaning.

4.2 Water Chamber Cleaning

1.Disconnect power supply of the device.

2. Remove the water chamber.

3. Empty the water in the water chamber if any.

4. Clean the water chamber with detergent or neutral detergent.

5. Rinse it with clean water.

6. Dry it.

Please clean it at least once per day if it is used often.

⚠ If the water chamber cracks, leaks or deforms, please replace it.

⚠ Empty the water in the water chamber everyday to prevent breeding mold and bacteria into water chamber

4.3 Tubing Cleaning

1. Disconnect power supply of the device

2. Disconnect the tube form the water chamber and mask.

3. Clean the tube with the detergent or neutral detergent gently.

4. Rinse it with water.

5. Dry it.

⚠ Replace the tube immediately if it is damaged.

4.4 Mask Cleaning

1.Clean the mask carefully with the neutral detergent, especially the silicon pad close the skin.

2.Rinse all the components with the water.

3.Dry it with the soft cloth.

⚠ Do not place it under the directly sunshine or on the central heating.

4.5 Filter Cleaning

Filter should be used for short time, usually one to two weeks.

⚠ Please replace the filter if it is damaged.

⚠ It is prohibited installing a wet air filter into the host.

⚠ The air filter must be installed before running the device.

4.6 Disinfection

Generally, if you follow the cleaning instruction correctly, you do not have to sterilize the device and its components. When water chamber and other components are contaminated or used for the clinic, the standard sanitizer get from pharmacist can be used to do the sterilizing.

⚠ Please note that sanitizer will damage the material surface and shorten their service life. Therefore, you shall follow suggestions given by sanitizer supplier on the applicable specific material and application instruction.

⚠ At last, using water to completely clean the components which have close contact with patient, such as mask, headgear and tube, etc., to prevent skin and respiratory tract infection caused by residual solution.

4.7 Transferring to another patient

⚠ If device is to be delivered to another patient, for sanitation purpose, the component which have close contact with this patient, such as mask, headgear, tube and air filter shall be replaced with new ones. Or referring to the description in 4.5 “Disinfection”

5. Troubleshooting

Phenomenon	Possible cause analysis	Troubleshooting
Nothing display on the screen or the main interface not come after turn on.	The power supply is not connected well.	Disconnect the power plugs and re-connect
The device beeps after turn on.	The power supply is not connected well.	Disconnect the power plugs and re-connect
The device fails to stop automatically after remove the mask	"Auto on/off" function is off	Set the "Auto on/off" function as "On"
Nose and throat are dry with irritation symptoms	Dry air	Increase the temperature of the humidifier or consult the doctor
Nose turns cold	Room temperature is too low	Increase the room temperature
Nose and throat are dry	Nose and throat are dry when breathing through mouth	Probably because the setting pressure of the device is insufficient. Please consult the doctor.
Eyes are irritated or dry.	Air leakage of the mask or mask size improper	Adjust the mask and its headgear,consult the doctor whether should be replaced. Please replace the mask beyond its validity.Try other size mask.
Face gets inflamed	The headgear is too tight. The mask model is not suitable. Allergic to the mask material	Adjust the headgear appropriately Consult the doctor Consult the doctor
There is water in the mask	The room temperature is too low, resulting in the water condensation in the mask.	Reduce the temperature of the humidifier or increase the room temperature. Cover the tube with a towel or similar heat preservation soft cloth
The device has a high pressure that has not been set or the pressure fluctuation is too large.	Pressure sampling tube is blocked or there is water in it. Pressure sampling tube is not connected with the host	Dry the pressure sampling tube completely or remove the block Connect the pressure sampling tube with the host
The nose, paranasal sinus or ear hurts	Inflammation	Stop using and consult the doctor
OSAHS relapse (e.g.: drowsiness in daytime)	The treatment pressure that you require may be changed due to your weight, nasal obstruction, drinking or other reasons.	Consult the doctor
The temperature of the air inhaled is too high	The is blocked by the dirty air filter. The device is too close to the wall, curtain or other objects, resulting in the non-smoothness air flow	Replace the air filter Check the air inlet Move the device to a place with a smooth air flow, at least 20cm from the wall, curtain or other objects
No airflow output	Device fault There is water in the sampling pressure tube	Contact with the manufacturer Dry the sampling pressure tube

The output air flow is too small.	The air inlet is blocked under Ramp working state	Shorten the time of Ramp Check the air inlet
The blower is at a high speed always	Pressure sampling tube is not connected or blocked The device leaks.	Inspect the pressure sampling tube Contact the manufacturer for maintenance
The device is not working after turn on	The device has failure.	Contact with the manufacturer
The device is working while the mask pressure is obviously different with the setting pressure	The tube leaks. Sampling pressure tube is connected incorrectly or blocked.	Ensure the tube is correctly connected Contact the manufacturer for maintenance
The device can only generate low pressure.	The air inlet is blocked The treatment pressure has been re-adjusted. The Ramp is set	Replace the air filter, clean the inlet Consult with the doctor If necessary, you may cancel the Ramp or reset the Ramp time.
The device is too noisy	The tube is not connected or is not connected correctly. The mask or the tube leaks.	Ensure the connection is correct. Ensure there is not leakage of the tube and mask
The pressure cannot be set	In a Ramp state	Please exit from the Ramp state and re-set it.
Ramp cannot be set	In a Ramp state	Please exit from the Ramp state and re-set it.

6.Waste Disposal

Except for designated specifically the device components and packaging boxes , please follow the following user manual: Please dispose them according to relevant national laws and regulation.

7. Warranty

From the date of purchase, we provide a one year warranty for the host, 3 months warranty for the tubing, mask and humidifier.

We,the manufacturer do not undertake the losses caused due to user misuse, abuse or accidents.

Device damage due to the water by user’s misuse is not covered under warranty.

Disassembling the host without the manufacture’s permission is deemed to give up the warranty.

8. Packing List

Host ×1, water chamber ×1, power adapter ×1, filter ×2, tubing ×1, mask ×1, user manual ×1, traveling bag ×1.

9. EMC Requirements

Guidance and manufacturer's declaration - electromagnetic emissions– this device is intended for use in the electromagnetic environment specified below.

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR11	Group 1 Class B	The internal function of the device only use the RF energy. Therefore its RF emissions is very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11	Group 1 Class B	This 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 IEC61000-3-2	Class A	
Voltage fluctuation /flicker emissions IEC61000-3-3	Class D	

Guidance and manufacturer's declaration - electromagnetic immunity – this 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.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC61000-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient /pulse IEC61000-4-4	±2KV for power line ±1KV for input/output line	±2KV for Main power line ±1KV for input/output lines	Mains power supply should be typical home or hospital power supply
Surge IEC61000-4-5	±1K differential mode ±2KV common mode	±1KV differential mode ±2KV common mode	Mains power should be typical home or hospital power supply
Voltage dips, short interruptions and voltage variations of the input power IEC61000-4-11	<5% U_T (>95% dip in U_T), for 0.5 cycle 40% U_T (60% dip in U_T), for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T), for 0.5 cycle 40% U_T (60% dip in U_T), for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power should be typical home or hospital power supply If the main supply interrupt,it is recommended to choose a uninterruptible power supply or the battery to support the device
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic field shall be typical level of power frequency magnetic fields in hospital or home environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity – this 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.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3Vrms 3V/m	Portable and mobile RF communications equipment should be not less than the recommended distance to any part of the device, including cables, which is calculated from the equation application to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{p}$ $d=1.2\sqrt{p}$ 80MHz to 800MHz $d=2.3\sqrt{p}$ 800MHz to 2.5GHz $\sqrt{p}$ is the maximum normal output power of the transmitter,its unit is Watt (W) and *d* is the recommended separation distance,its unit is meter (m). Measured magnetic field strengths [a] from fixed RF transmitter 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 applied. Note 2: These guidelines may not be apply in all situations. Electromagnetic propagation is affected by absorption and reflection of the building , objects and human body. a. Magnetic 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 of the fixed RF transmitters, an electromagnetic site survey should be considered. If the measured magnetic field strength in the location in which the device is used exceeds the applicable RF compliance level above, check the device whether it can under normal operation. If abnormal performance is observed , additional measures should be taken. b. The field strengths should be less than 3 V/m,when the frequency range is from 150kHz to 80MHz.			

Version No.: BiPAP/20140526/002