AS100C/AS100A

CPAP and Auto CPAP devices

User Manual

Xiaoniu health Co., Ltd.

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Table of Contents

1 Introduction

Review all information in this manual thoroughly before attempting to use the device.

The patient is an intended operator.

1.1 Manufacturer'sResponsibility

Xiaoniu is responsible for the safety, reliability and functions of the device, only when the following requirements are strictly adhered to:

- Only personnel authorized by Xiaoniu may perform installation, adjustments, repairs, and any replacement of safety components.
- Necessary electrical equipment and the working environment must be in accordance with the national standards, professional standards and the requirements listed in this manual.
- The device must be used as instructed in this manual.
- All the parts and accessories provided by Xiaoniu are compatible with the device for therapeutic

use.

1.2 Definitions

This manual uses three special indicators to convey information of a specific nature.

They include:

WARNING: Indicates the possibility of injury to the user or operator.

CAUTION: Indicates the possibility of damage to the device.

NOTE: Indicates points of particular emphasis that make operation of the device more efficient or convenient.

1.3 Warnings, Cautions and Notes

1.3.1 Warnings

- Read the entire manual before using the device.
- Use the device only as directed by your physician or healthcare provider.
- The instructions in this manual are not intended to supersede established medical protocols.

- Use the device only for the intended use as described in this manual. Advice contained in this manual should not supersede instructions given by the prescribing physician.
- This device is intended for adult use only.
- This device is not intended for life support.
- In the case of allergic skin reactions, contact your health care provider or prescription physician.
- Combinations with medical devices (e.g. humidifier, water tank, or filter) other than recommended can alter the performance of the device.
- If you notice any unexplained changes in the performance of the device, if it is making unusual or harsh sounds, if the device or the power supply are dropped or mishandled, if water is spilled into the device, or if the device is broken, discontinue use and contact your Xiaoniu Service Center.
- Beware of electrocution. Do not immerse the device, humidifier, power supply or power cord in water. In the event of a spill, disconnect the

device from the power supply and let the parts dry. Always unplug the device before cleaning and make sure that all parts are dry before plugging in the device.

- Explosion hazard—do not use in the vicinity of flammable anesthetics.
- Make sure the power cord and plug are in good condition and the equipment is not damaged.
- Keep the power cord away from hot surfaces. Do not put the device where it is difficult to unplug the cord to disconnect the device from power outlet.
- The device should only be used with masks recommended by Xiaoniu, or by a physician or respiratory therapist. A mask should not be used unless the device is turned on. Once the mask is fitted, ensure that the device is blowing air. The vent hole or holes associated with the mask should never be blocked.

  Explanation: The device is intended to be used with special masks (or connectors) which have vent holes to allow continuous flow of air out of

the mask. When the device is functioning properly, new air from the device flushes the exhaled air out through the mask vent holes. However, when the device is not operating, insufficient fresh air will be provided through the mask, and the exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can, in some circumstances, lead to suffocation. This applies to most models of CPAP or bilevel devices.

- Mask, tubing, and water tank are intended for single patients use.
- Do not use the air tubing if there are any visible signs of damage.
- Only air tubing, air filter and accessories recommended by Xiaoniu should be used with the device. A different type of air tubing or accessory may alter the pressure you actually receive, reducing the effectiveness of the treatment.
- Only use the Xiaoniu's power adapter.
- Blocking the air tubing and/or air inlet of the

device while in operation could lead to overheating of the device.

- this unit is not allowed to be used in an oxygen enriched environment.
- Sources of oxygen must be located more than1 m from the equipment to avoid the risk of fire and burns.
- Do not operate the H100 if it is not working properly or if any part of the device or H100 has been dropped or damaged.
- The room temperature must be kept below 95℉ (35° C) while the patient uses the device.If the room temperature is higher than 95℉ (35° C), the airflow produced by the device may exceed 109.4℉ (43° C).
- Humidity performance of the device can be affected when used outside the specified ambient temperature range or humidity range.
- This device should only be used with the mask and flexible tubing accessories manufactured or recommended by Xiaoniu or with those

recommended by your prescribing physician. The use of inappropriate masks and flexible tubing accessories may affect the performance of the device and impair the effectiveness of therapy. Failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation.

- If the device e is broken, or if water has entered the device, disconnect the power cord and discontinue use. Contact your home care provider immediately.
- The equipment cannot be exposed to, for example, electrocautery, electrosurgery, defibrillation, X-ray (gamma radiation), infrared radiation, conducted transient magnetic fields including magnetic resonance imaging (MRI).
- Keep the device and all accessories away from small children and pets , small parts may cause choking or serious injury if swallowed.
- Please don’t touch the DC24V Humidifier Connector described in the figure 2-2 of this

instruction.

1.3.2 Cautions

- Do not open the device body. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorised Xiaoniu service agent.
- Do not use bleach, chlorine, alcohol, or aromatic-based solutions, moisturising or antibacterial soaps or scented oils to clean the device, humidifier or air tubing. These solutions may cause damage and reduce the life of these products.
- Incorrect system setup may result in incorrect pressure reading. Ensure the system is correctly set up.
- Be careful not to place the device where it can be bumped or where someone is likely to trip over the power cord.
- Make sure the area around the device is dry and clean and clear of bedding, clothes or other objects that could block the air inlet or cover the

power adapter.

- Ensure that the device is protected against water if used outdoors. Enclose the device in the travel bag for transport.
- The H100 should only be used with tubing or accessories recommended by Xiaoniu. Connection of other delivery tubes or accessories could result in injury, or damage to the device.
- Do not open the H100 body. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorised Xiaoniu service agent.
- Do not overfill the water tank as water may enter the device and air tubing.
- Do not use any additives (eg, scented oils and perfumes). These may reduce the humidification output of the H100 and/or cause deterioration of the water tank materials.
- Take care when handling the H100 as the water/water tank may be hot. Leave the H100 for 10 minites to cool down before any operation The

H100 should only be connected or disconnected when the water tank is empty.

- Make sure that the water tank is empty before transporting the H100.
- Do not operate the H100 on an aircraft as water may enter the device and air tubing during turbulence.
- Always place the H100 on a level surface below the level of the user to prevent the mask and tubing from filling with water.
- The equipment must not be covered or positioned in such a way that the operation or performance of the equipment is adversely affected,
- Do not block the gas INTAKE PORT, thereby interfering with therapy.
- If liquids are inadvertently spilled into or on the H100, unplug the device from the power outlet And disconnect the H100 from the device and allow it to drain and dry before re-using.
- Keep the device in the protective case after using to prevent entry of dirt, dust, and insects.

- Contact your health care professional if symptoms of sleep apnea recur. Contact your health care professional if you have any questions concerning your therapy.

1.3.3 Notes

- If any of the above parts are missing, contact your home care provider.
- Contact your home care provider for additional information on the available accessories of this device. When using optional accessories, always follow the instructions enclosed with the accessories.
- An irregular sleep schedule, alcohol consumption, obesity, sleeping pills, or sedatives may aggravate your symptoms.

1.4 Intended use

The AS100A/AS100C is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA) only in patients weighing more than 30 kg. The AS100A/AS100C is

intended for home or hospital/institutional environment use.

The device is to be used only on the instruction of a licensed health care professional who has received operation training from Xiaoniu or other authorized organzations. Pressure settings should be determined with the configuration of the device according to your health care professional's prescription.

WARNINGS

- This device is intended for adult use only.
- This device is not intended for life support.
- The instructions in this manual are not intended to supersede established medical protocols.

The H100 is indicated for the humidification of the air delivered from a CPAP or bilevel device. The H100 is for use only as recommended by a physician. The H100 is intended for single patient re-use in the home environment and re-use in a hospital/institutional environment.

1.5 Contraindications

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

Studies have shown that the following pre-existing conditions may contraindicate the use of positive airway pressure therapy for some patients:

Absolute Contraindications:

Pneumothorax, mediastinal emphysema; cerebrospinal fluid leak, traumatic brain injury, or pneumocephalus; shock caused by a variety of conditions before treatment; active epistaxis; upper gastrointestinal bleeding before treatment; coma or impaired consciousness making the use of mask during therapy impossible; giant vocal fold polyp, etc.

Relative Contraindications:

Severe coronary heart disease complicated with left

ventricular failure, acute otitis media, excessive respiratory secretions and weak cough, weak spontaneous breathing, nasal or oral tracheal intubation and tracheotomy, severe nasal congestion caused by a variety of conditions, lung bullae, and allergies to breathing masks, etc.

The following side effects may arise during the course of therapy with these devices:

- Drying of the mouth, nose and throat
- Abdominal bloating - Ear or sinus discomfort
- Eye irritation
- Skin irritation due to the use of a mask
- Chest discomfort

NOTE： An irregular sleep schedule, alcohol consumption, obesity, sleeping pills, or sedatives may aggravate your symptoms.

CAUTION： Contact your health care professional if symptoms of sleep apnea recur. Contact your health care professional if you have any questions concerning your therapy.

H100 contraindications

The H100 is contraindicated for use with patients whose upper (supraglottic) airway has been bypassed.

1.6 Symbols

1.6.1 Control Buttons

—	Previous or Down
+	Next or Up
OK	Confirm
⏻	Start/Stop

1.6.2 Symbols

Instead of illustrations, symbols may be utilized. Not all of these symbols may necessarily appear on the product, packaging, or in this User manual. The symbols include:

	Type BF Applied part	SD	SD Card
	Class II equipment	MAX	Max. water level line
IP22	Degree of Ingress Protection：≥12.5 mm Diameter, Dripping (15ºtilted)	1/2	1/2 water level line
	The waste of electrical and electronic facility must not be disposed as unsorted municipal waste and must be collected separately. Use the return and collection systems	MIN	Min. water level line

	according to local law.		
~	Alternating current		Water Inlet
SN	Serial Number		Do not fill in water
	Manufacturer	PRESS	Press the button
EC REP	**Authorised** Representative in the European Community	Max:30W	Max. input capacity
	Operating instruction/Consult instruction for use **instruction** for use		No Touching
CE 0123	CE Mark		Warning: Hot surface

	Insert SD card in this way		refer to instruction manual/booklet

1.6.3 Packing

	This side up		Temperature limitation
	Fragile, handle with care		Humidity limitation
	Keep dry		Atmospheric pressure limition
	Do not roll		Stacking limit by number

1.7 Glossary

Apnea

A condition marked by the cessation of spontaneous breathing.

AutoCPAP

Adjust CPAP pressure automatically to improve

patient comfort based on monitoring of apnea and snoring events.

Auto OFF

When this feature is enabled, the device automatically discontinues therapy whenever the mask is removed.

Auto ON

With this feature, the device automatically initiates therapy when you breathe into the mask. CPAP

Continuous Positive Airway Pressure.

LPM

Liters Per Minute.

OSA

Obstructive Sleep Apnea.

Ramp time

A feature that may increase patient comfort when therapy is started. During the Ramp time, Pressure

increases from Start Pressure to Therapy Pressure.

1.8 Package Contents

After unpacking the system, make sure you have everything shown here:

1. Main device		2. H100 Heated Humidifier (Optional)	
3. Power Adapter		4. Power Cord	
5. Mask (Recommended by Xiaoniu)		6. Air Filter	
7. Flexible tubing (Recommended by Xiaoniu)		8. SD Card	
9. Carrying Case		10. User Manual	

11. Warranty Cards		12. Certification	
13. PM2.5 Filter module (optional)			

All parts and accessories do not contain latex.

NOTE: If any of the above parts are missing, contact your home care provider.

NOTE: Contact your home care provider for additional information on the available accessories of this device. When using optional accessories, always follow the instructions enclosed with the accessories.

NOTE: The applied part of this product refers to the mask.

WARNING: This device should only be used with the mask and flexible tubing accessories manufactured or recommended by Xiaoniu or with those recommended by your prescribing physician.

The use of inappropriate masks and flexible tubing accessories may affect the performance of the device and impair the effectiveness of therapy.

WARNING: The use of accessories other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

2 System Overview

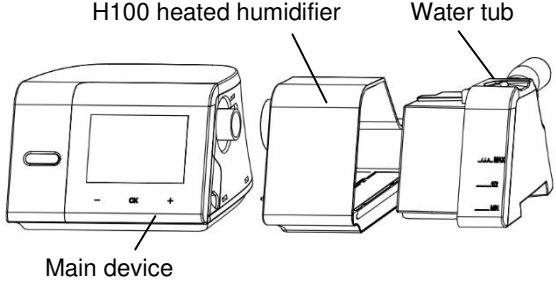


Figure 2-1 Front side of device

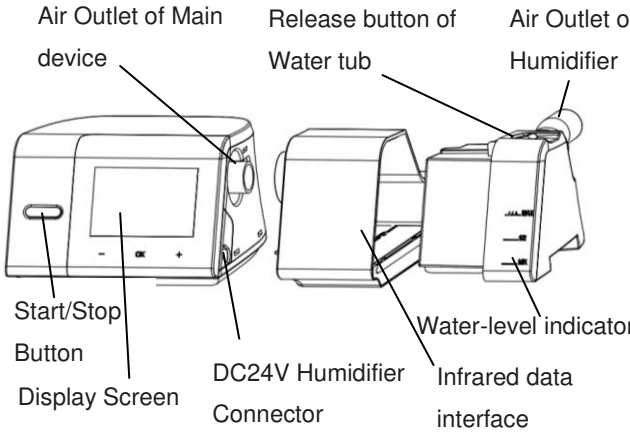


Figure 2-2 Front side of device

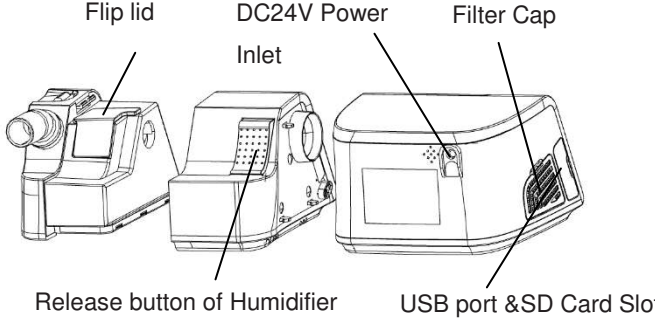


Figure 2-3 Rear side of device

Name	Function
Main device	Main device of AS100A or AS100C
Water tank	Water container, connected to the H100 Heated Humidifier
H100 Heated Humidifier	Control heating parts of humidifier, connected to the main device
Start/Stop Button	Start/Stop treatment
Display Screen	Display menus for operation, messages, monitoring data, etc.
Air Outlet of Main device	Deliver pressurized air; connected to the tube or the air inlet of the humidifier
DC24V Humidifier Connector	Provide power to the humidifier which is connected to the main device
Infrared data interface	Data transmission between main device and humidifier
Release button of Water tank	Press the button to remove the water tank from the humidifier.
Air Outlet of	Deliver pressurized air; connected

Name	Function
Humidifier	to the tube
Water-level indicator	Indicate the water level.
DC24V Power Inlet	An inlet for the DC24V power supply
USB port & SD Card Slot	Insert the SD card into this slot; USB port
Filter Cap	Place the cap on the air filter, which is used to filter dust and pollen in the air entering the device
Release button of Humidifier	Press the button and remove the humidifier from the main device.
Flip lid	Open the flip lid and fill the water tank with water. Close the flip lid and return the water tank to the H100 heated humidifier.

3 First Setup

WARNING: The device is only to be used on the instruction of an authorized physician.

WARNING: Pressure settings should be determined for the patient individually with the configuration of the equipment and accessories, periodically reassess the setting(s) of the therapy for effectiveness.
WARNING: The proper placement and positioning of the MASK on the face is critical to the consistent operation of this equipment.

3.1 Placing the Device

Place the device on a firm, flat surface.

WARNING: If the device has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, disconnect the power cord and discontinue use. Contact your home care provider immediately.

WARNING: The room temperature must be kept below 95℉ (35°C) while the patient uses the device.If the room temperature is warmer than 95℉ (35°C), the airflow produced by the device may exceed 109.4℉ (43°C).

WARNING: Please disconnect the power supply

before connecting the humidifier.

3.1.1 Filling the water tank

- Press the release button of water tank and remove the water tank.

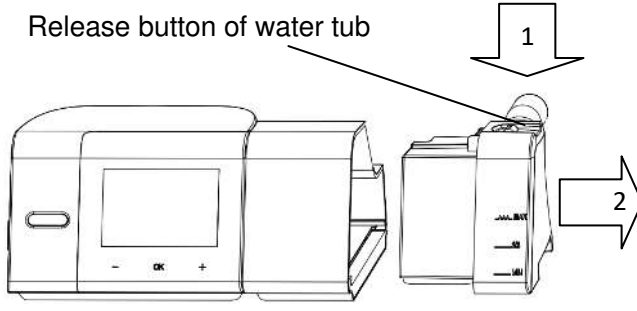


Figure 3-1 Removing water tank

- Lift open the flip lid.

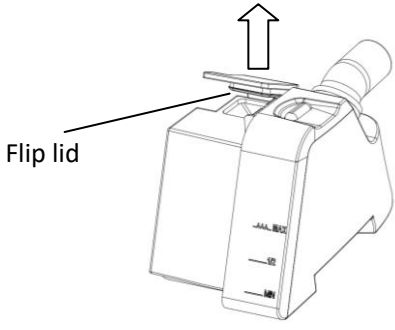


Figure 3-2 Opening flip lid

- Fill the water tank with water up to the maximum water level mark.

Figure 3-3 Filling water tank

- Close the flip lid and return the water tank to the

H100.

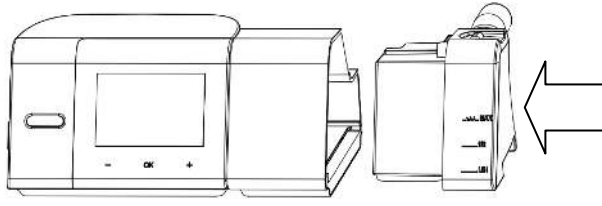


Figure 3-4 Reinstalling water tank

3.1.2 Installing the Air Filter and Filter Cap

- Attach the air filter to the filter cap, as shown in Figure 3-5.

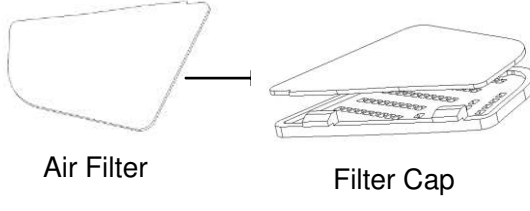


Figure 3-5 Attaching air filter to filter cap

- Install the filter cap containing the air filter to the

main device, as shown in Figure 3-6.

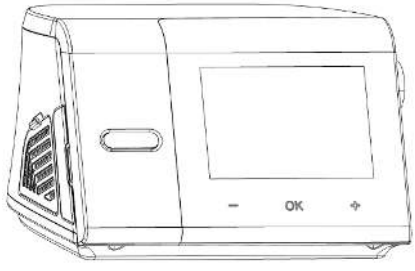


Figure 3-6 Filter cap with air filter installed

3.1.3 Inserting the SD Card

- Open the SD Card lid.
- Push the card into the device until it clicks.

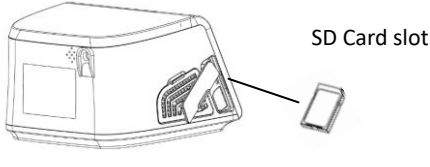


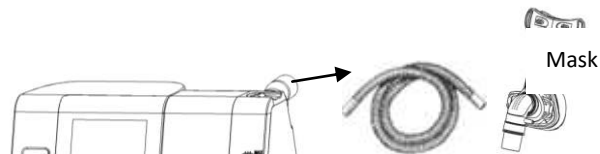
Figure 3-7 Inserting SD card

The following message is briefly displayed:

- Reading SD Card status：
- No SD Card status：

3.1.4 Connect the system

- Please confirm that there is no foreign matter in the tube before the connection.
- Connect one end of the tube to the air outlet of the main device. If the main device is used with a humidifier, connect one end of the tube to the air outlet of the humidifier.
- Connect the other end of the tube to the mask according to the user manual for the mask. Wear the mask.



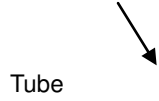


Figure3-8 Connect the tube and mask

Connecting the power cord：

- Insert the plug of the power adapter into the DC24V Inlet on the back of the device.
- Connect the power cord to the power adapter.
- Plug the other end of the power cord into the power outlet.

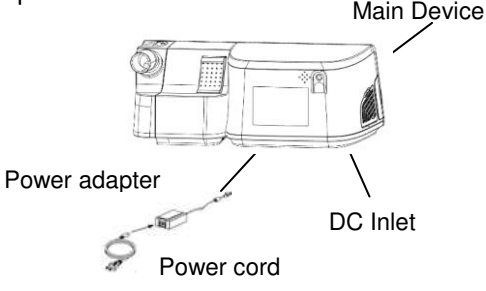


Figure 3-9 Connecting adapter and power cord

- Power on, the screen displays the standby interface.

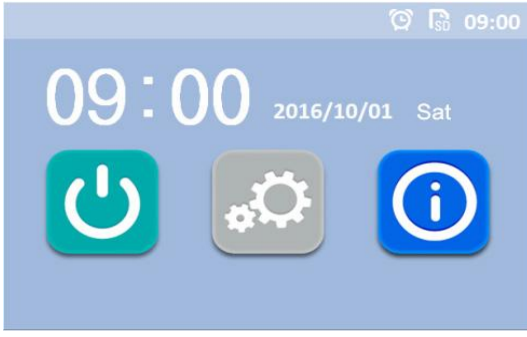


Figure 3-10 The standby interface

3.1.5 Starting Treatment

- Adjust humidity level: Humidity can be adjusted from 0-5 levels, the user can set the humidity through the user interface. Press the + or – user button in the therapy interface, you can quickly adjust the humidification level.
- Stop treatment: When the device is running, press the start/stop button, you can stop the device and back to the standby interface.
- Ramp time: Ramp time can be adjusted from 0 to 60 minutes. Ramp time is the period during which the pressure increases from an initial pressure to

the prescribed CPAP pressure or minimum AutoCPAP pressure. Ramp is available in both AutoCPAP and CPAP modes

- Auto ON and Auto OFF: When the Auto ON is set, the device will be triggered if patient is using the mask. When remove the mask, the device will automatically turn off.
- AS-Elex ON: Users can make therapy more comfortable with this function activated. The device will give a positive airway pressure at the end of exhalation according to the prescribed setting (level 0/1/2/3).
- Start therapy: After the previous steps completed, please wear the mask and press start/stop button or touch the  icon on the touchscreen to start the device. Now the device is running and the screen will display the therapy interface.

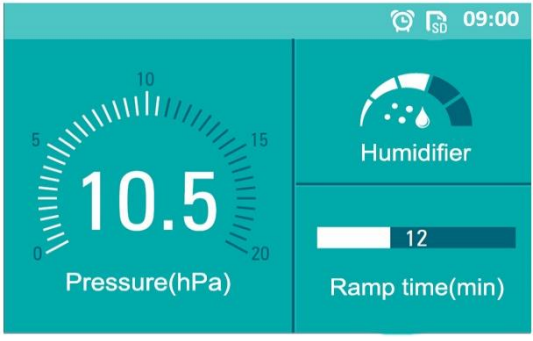


Figure 3-11 The therapy Interface

3.2 Navigating the setup Menu

Touch the +, - button to select the setup icon  in the standby interface, touch the OK to confirm and enter the setup interfacre.

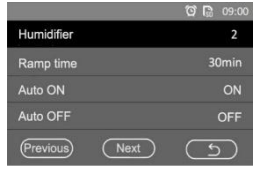


Figure 3-12 The setup interface A

Figure 3-13 The setup interface B

Ramp time, Auto ON, Auto OFF, Alert clock, Filter, About device, More settings can be select with the +, - user button, and check with the OK user button.

There are three touch setup icons.

Previous: Previous interface, touch it to backward the current interface.

Next Next interface; touch it to forward the current interface.

 : Back to the previous interface or the standby interface.

Ramp time: Ramp time can be adjusted from 0min to 60min. The default value is 30min.

Auto ON: Auto ON state can be set between ON and OFF. The default state is ON.

Auto OFF: Auto OFF state can be set between ON and OFF. The default state is OFF.

Alert clock:

Touch the  icon of Alert clock in the setup interface, the system will pop out the alert clock interface. There are 3 alert options can be set. Touch one of the three alerts, the system will pop out the alert clock setup interface. Label, On-Off, Repeat, Hour, Minute, a total of 5 options in the alert setup interface can be select with the +, - button, and check with the OK button. When all the three alerts are OFF, the  icon does not appear.

Label: Alert clock, Get up, Sleep, Take pills can be

set. The default option is alert clock.

On-Off: On-Off state can be set between ON and OFF. The default state is OFF.
Repeat: Every day/ Only once can be set. The default option is Every day.
Hour: Hour can be adjusted from 0 to 23. The default value is 8.
Minute: Minute can be adjusted from 0 to 59. The default value is 0.

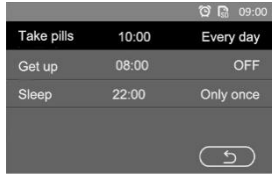


Figure 3-14 The alert clock interface

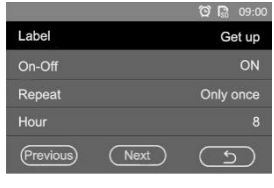


Figure 3-15 The alert clock setup interface A

Figure 3-16 The alert clock setup interface B

Iter:

Touch the >> icon of Filter in the setup interface, the system will pop out the Filter interface. There are Filter and Filter period can be viewed.

Filter displays total time of filter using.

Filter period recommended by Xiaoniu is 480h.

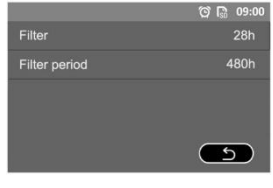


Figure 3-17 The filter interface

About device: Touch the >> icon of About device

in the setup interface, the system will pop up the device information interface. There are SN and Software Version can be see.

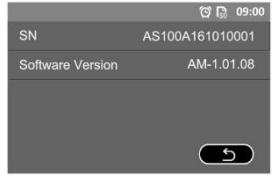


Figure 3-18 The device information interface

More settings: Touch the >> icon of More settings in the setup interface, the system will pop up the more setup interface. There are 10 options can be select with the +, - user button, and check with the OK user button.

Language: English and Chinese can be set. The default language is English

Mask test:

Touch the >> icon of More test in the More setup interface, the system will pop up the mask testing interface.

Every time a new mask manufactured by other company is used, you should have a mask test to make sure that the mask leakage.

- First covered the mask with hand, so that there's no leakage of mask.
- Secondly, touch the Start icon or press the OK user button to begin the test.
- Finally, after the test is over, the complete hint will pop up, and then touch the icon back to previous interface.

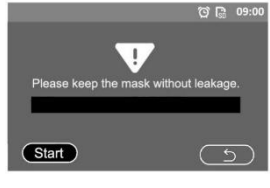


Figure 3-19 The mask testing interface A

Figure 3-20 The mask testing interface B

Mask wear:

- Touch the +, - button to select the setup icon  in the standby interface, touch the OK to confirm and enter the setup interfacre.

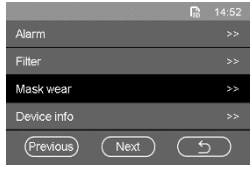


Figure 3-21 The Mask wear setup interface

- Touch the “Mask wear” option and touch the “OK” button to enter the mask wear interface.

Figure 3-22 The Mask wear interface

- Touch the Start icon to enter the test interface. After the test is successful, the “Mask wear succeed!” is displayed.

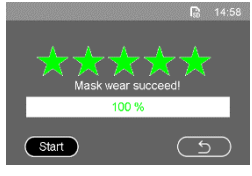


Figure 3-23 The Mask wear succeed interface

- If the test fails, the “Mask wear failed!” interface will be displayed. After adjusting the mask, you can touch “start” again to retest.

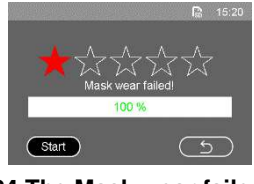


Figure 3-24 The Mask wear failed interface

Backlighting: Backlighting state can be set between

Auto and ON. The default state is Auto. When Auto is chosen, the backlight will be off if there is no any touch within 3 minutes in the standby interface or 30 seconds in the therapy interface.

Pressure unit: Pressure unit can be set between cmH2O and hPa. The default unit is hPa.

Time format: Time format can be set between 12Hour or 24Hour. The default Time format is 24Hour.

Year, Month, Day, Hour, Minute can be set.

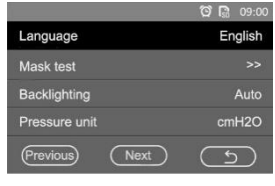


Figure 3-25 The more setup interface A

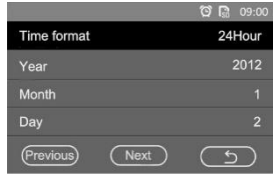


Figure 3-26 The more setup interface B

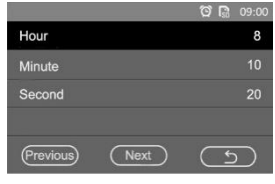


Figure 3-27 The more setup interface C

3.3 Navigating the Information Menu

Touch the +, - user button to select the information icon in the standby interface, touch the OK user button to confirm and enter the information interfacre. You can only change the period option, and look up the historical data within the last 1 year.

All information cannot be changed and only can be browsed in the information interface.

: Previous period, touch it you can select the previous period.

: Next period, touch it you can select the next period.

Period: Last night, One week, One month, Two months, Three months, Six months, One year, a total of 6 options in the information interface can be select with touching the , icon or pressing the OK user button.

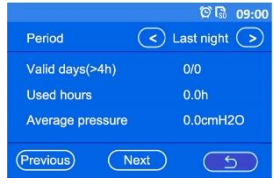


Figure 3-28 The information interface A

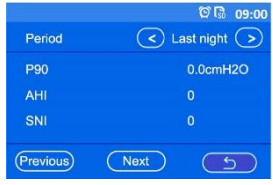


Figure 3-29 The information interface B

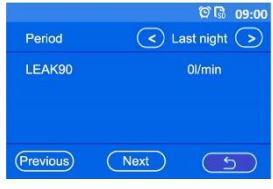


Figure 3-30 The information interface C

4 Cleaning and Disinfection

WARNING:

- Regular cleaning of the device and its accessories is very important for the prevention of respiratory infections.
- To avoid electric shock, always unplug the device

before cleaning.

- Use washing liquid that is nontoxic to humans and does not cause allergies in humans.
- Follow the manufacturer's instructions on cleaning the mask and tube and on determining the frequency of cleaning.
- Before cleaning, check whether the device has been disconnected from the power supply, whether the power cord has been unplugged, and whether the water tank of the humidifier has cooled down. Make sure the Humidifier plate has cooled down to room temperature, so you do not get burned.
- Do not perform any maintenance tasks while the device is in operation.

CAUTIONS:

- 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 the humidifying agent or antimicrobials should not be used either. These solutions may harden cleaned materials or reduce their life.

- Do not clean or dry the device and its accessories when the temperature is higher than 80°C (176℉). High temperatures could reduce product life.
- Do not immerse the device in any fluids.

4.1 Cleaning frequency

Regular cleaning machines and their accessories are very important to prevent respiratory infection， but it must be cleaned after dismantling:

- mask and tubing should be cleaned at least once every two weeks under normal.
- The treatment machine shell and humidifier are cleaned once a week.
- Water tank is recommended to be cleaned once every 2-3 weeks.

4.2 Cleaning the Mask and Headgear

For details, refer to the cleaning instructions in the user manual for the mask.

4.3 Cleaning the Water tank of the Humidifier

- Press the release button of kwater tank and remove the water tank.

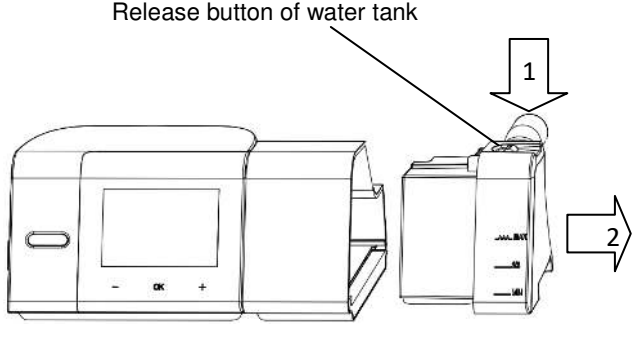


Figure 4-1 Removing water tank

- Remove the heated metal plate from the water tank.
- Clean the water tank and the heated meatal plate in warm water using mild detergent.
  Do not wash in a dishwasher or washing machine, and then rinse it in clean water thoroughly.
- After cleaning, wipes the surface of the water tank and the heated meatal plate dry with the soft cloth, or air-dry it in a cool, well-ventilated area, and avoid direct sunlight. Check whether the surface is completely dry before reuse.

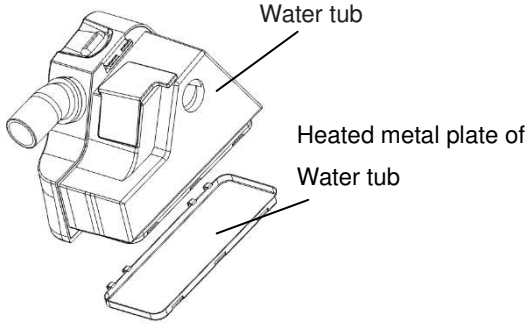


Figure 4-2 Water tub and metal plate

4.4 Replacing the Air Filter

CAUTIONS: To avoid material damage, do not place the spare air filter in direct sunlight, humid environments, or temperatures below the freezing point. The air filter should be replaced every 3 months (It may be replaced more frequently based on actual sanitary conditions).

CAUTIONS: Operating the device with a dirty air filter may stop it from working properly and may cause damage to the device.

WARNING: Nebulisation or humidification can increase the resistance of breathing system filters, and the operator must monitor the breathing system filter frequently for increased resistance and blockage to ensure the delivery of the therapeutic pressure.

Note: The most penetrating particle size through the filter is 10μ m.

Refer to 3.1.2 to replace the filter.

4.5 Cleaning the Device

Wipe the surface of the device with a soft, slightly damp cloth.

CAUTION: The device can only be used after the enclosure is dry, so that no moisture enters the device.

4.6 Cleaning the Tube

- Remove the tube from the device and mask before cleaning.
- Clean the tube in warm water which contains mild washing liquid, and then rinse it in clean water thoroughly.
- After cleaning, air-dry the tube in a cool, well-ventilated area, and avoid direct sunlight. It takes approximately 30 minutes to completely air-dry the tube. Check whether the tube is completely dry before re-use.
- Please cleanthe tube under the environment

conditions specified by 1.6.2 of this instruction. We recommend cleaning the tube once every two weeks in the life cycle of tube.

4.7 Disinfection

Generally speaking, if you have strictly followed the above cleaning instructions, you do not have to disinfect the device and / or humidifier. If the device is contaminated or used in clinical trials, you may purchase disinfectants from a pharmacist to disinfect the water tank.

Disinfection of the Humidifier Water tank:

Clean the water tank in warm water which contains neutral disinfectants, and then rinse it in clean water thoroughly.

CAUTIONS: Disinfectants tend to damage materials and reduce the life of components. Try to select the appropriate disinfectant, and follow the disinfectant manufacturer's instructions and recommendations.

CAUTIONS: After disinfection, check the disinfected

component for any signs of damage. Replace any damaged component immediately.

WARNINGS: After disinfection, rinse any disinfected component in clean water thoroughly, especially components in close contact with the patient such as the mask, headgear and tube, so as to prevent disinfectant residuals from damaging the skin or respiratory tract or causing allergies.

WARNINGS: The device shall not be serviced or maintained while in use with a patient.

WARNINGS: Sterilization of this device and its components other than recommended is not permitted.

5 Traveling with the Device

CAUTIONS: Empty the water tank of the humidifier before packing the device for your trip; in order to prevent any remaining water from entering the device.

- FUse the Xiaoniu carrying case to carry the device and accessories along with you. This device operates on power supplies of 100-240 VAC and 50 / 60 Hz, and is suitable for use in any country in the world.
- Remember to bring a spare air filter and the emergency documents (filled and signed by your physician) about this device. If you plan to travel by air, remember to bring the multi-language emergency documents about respiratory therapy, in case that the border and customs officers in your destination country inspect the device. With the emergency documents, you can prove to them that it is a medical device.
- Security Stations：For convenience at security stations, there is a note on the lable of the device stating that it is medical equipment. It may be helpful to bring this manual along with you to help security personnel understand the device.

6 Troubleshooting

The table below lists common problems you may have with the device and possible solutions to those problems. If none of the corrective actions solve the problem, contact your home care provider.

6.1 Common Problems in Patients and Corresponding Solutions

Problem	Possible Cause	Solution(s)
Dry, cold, runny, and blocked nose	The nose reacts to the airflow and cold. Due to fast airflow, the air becomes cold, leading to nasal mucosa irritation and subsequent dryness and swelling.	Increase the humidity setting of the humidifier. Contact your physician, and continue treatment unless the physician suggests the opposite.
Dry mouth and throat	Probably because the patient sleeps	Use a chin strap to prevent the mouth

Problem	Possible Cause	Solution(s)
	with his or her mouth open, and the pressurized air goes out via the mouth, leading to nasal and throat dryness.	from opening during sleep, or use a full-face mask. Contact your physician for details.
Water in mask	When the humidifier is used, the humidified air tends to condense in the cold tube and mask if the room temperature is low.	Turn the humidity setting down, or raise the room temperature. Place the tube under the quilt, or use the tube cover. Hang the tube loosely, and the lowest part of the tube should be lower than the patient's head.
Air delivered from the	The air inlet of the device may be partially	Replace the air filter, and clean the

Problem	Possible Cause	Solution(s)
device is abnormally hot.	blocked, leading to insufficient airflow into the device.	air inlet. Place the device in an area where air flows freely, and make sure the device is at least 20 centimeters away from the wall, curtain, or other things.
The device is too noisy.	The tube is not connected properly.	Reconnect the tube properly.

6.2 Common Problems in the Device and Corresponding Solutions

Problem	Possible Cause	Solution(s)
The device does not work when	The Auto ON / Auto OFF feature is enabled.	Take a few deep breaths with the mask on, and the

Problem	Possible Cause	Solution(s)
it is turned on.		device will start automatically.
	Power is not connected properly.	Ensure that the power cord, power adapter, and the device are connected properly.
	There is no voltage.	Check whether a power outage occurs by turning on a light or other means. If you are sure the fuse in the device is broken, contact your equipment supplier for repair.
	Cannot find any cause.	Contact your equipment supplier.
The device is too noisy.	The tube is not connected properly.	Reconnect the tube properly.

Problem	Possible Cause	Solution(s)
The device produces very low pressures.	The air inlet of the device may be blocked.	Replace the air filter, and clean the air inlet. Make sure the air inlet is unblocked.
	The treatment pressure has been changed accidentally.	Contact your physician.
	When the Ramp feature is enabled, it takes some time for the initial pressure to rise to the treatment pressure. This is normal.	If necessary, disable the Ramp feature, or set the ramp time shorter.

6.3 Alert Information

Alert	Alert conditions	Remarks
NULL	System power off at work	Abnormal power loss of equipment

Alert	Alert conditions	Remarks
Reinsert SD card!	SD card read and write data is incorrect	SD card reading and writing errors
SD card full!	SD card data is full	SD card without storage space
Change Filter !	The use of filter core is too long	Use time beyond the set filter core
Reset the time !	Device time and date have not been set	Ununifying time of equipment
Leak!	The leakage of the equipment is prompted, and there is a large leakage event in the working condition.	A large leakage event in the working state of the device

7 Specifications

7.1 Main device Specifications

Device Size
Dimensions: 160 mm × 148 mm × 99.5 mm, or 247 mm × 148mm × 99.5 mm (with the humidifier)
Weight: 0.82 kg, or 1.26 kg (with the humidifier)

Operation, Transport and Storage

	Operation	Transport and Storage
Temperature	5℃ to 35℃	-20℃ to +60℃
Humidity	10% to 93% Non-condensing	10% to 93% Non-condensing
Atmospheric Pressure	760 to 1060 hPa	500 to 1060 hPa

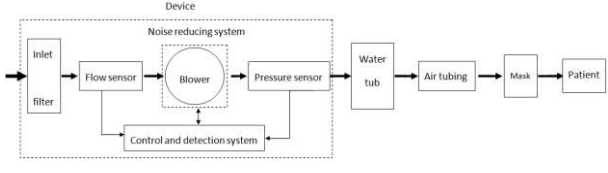
Mode of Operation

Continuous

The following table describes the operating modes available on the AS100C and AS100A.

Mode	AS100C	AS100A
CPAP mode A fixed Continuous Positive Airway Pressure is delivered. CPAP maintains a constant level of pressure throughout the breathing cycle.	√	√
AutoCPAP mode The AutoCPAP algorithm automatically adjusts pressure in response to inspiratory flow limitation, snore and apnoea. You can set the minimum and maximum allowable treatment pressures.	-	√

Pneumatic flow path as shown in the diagram below:



SD Card

With a capacity≥8 G, the SD card can record patient data and fault information.

AC Power Consumption

100-240VAC, 50/60 Hz, 2.0 A max

Type of Protection Against Electric Shock

Class II Equipment

Degree of Protection Against Electric Shock

Type BF Applied Part

Degree of Ingress Protection

IP22

Pressure Unit

Units are expressed in cm H2O and hPa,1 cm H2O is equal to 0.98 hPa.

Pressure Range

4 to 20 hPa (in 0.5 hPa increments), ≤30 hPa under single fault conditions.

Pressure Display Accuracy

±0.5 hPa

Pressure Stability

4 to 20 hPa (±1 hPa)

Ramp time

The ramp time ranges from 0 to 60 minutes.

Sound Pressure Level

＜30 dBA with uncertainty of 2 dBA, when the device is working at the pressure of 10 hPa.

Sound Power Level

＜38 dBA with uncertainty of 2 dBA,, when the device is working at the pressure of 10 hPa.

Measurement system uncertainties

In accordance with ISO 80601-2-70:2015 the measurement uncertainty of the manufacturer's test

equipment is:

For measures of flow[1]	±2% of reading or 0.05 Std L/min, whichever is greater
For measures of pressure[1]	±（0.1hPa+1.5% of reading）

[1]Results are expressed at STPD (Standard Temperature and Pressure, Dry).

Pressure accuracy

Maximum static pressure variation at 10 cm H2O (10 hPa) according toISO 80601-2-70:2015

Without humidification ± 0.5 hPa

With humidification ± 0.5 hPa

Maximum Flow

The following are measured accordingly to ISO 80601-2-70:2015 at the end of the specified air tubing:

Test Pressure（hPa）	4	8	12	16	20
Average Flow at the Patient Connection Port（l/min）	129	136	128	110	90

Maximum dynamic pressure variation according to ISO80601-2-70:2015

Pressure (cmH2O)	10BPM	15BPM	20BPM
Standard air tubing. Device without humidification/Device with humidification			
4	0.40/0.49	0.54/0.53	0.60/0.58
8	0.77/0.80	0.80/0.82	0.83/0.82
12	0.90/0.92	0.93/0.92	0.96/0.95
16	0.92/0.90	0.95/0.93	0.98/0.96
20	0.96/0.97	0.97/0.97	0.98/0.97

Tube

Length: 1.8m

Inner diameter: 19mm

The Form and the Dimensions of the Patient Connection Port

The 22mm conical air outlet complies with ISO 5356-1.

7.2 H100 Specifications

Operation, Transport and Storage

	Operation	Transport and Storage
Temperature	5℃ to 35℃	-20℃ to +60℃
Humidity	10% to 93% Non-condensing	10% to 93% Non-condensing
Atmospheric Pressure	760 to 1060 hPa	500 to 1060 hPa

Maximum temperature of delivered gas 43°C（109℉）

Humidity level

At room temperature 23±2℃，the humidity level corresponds to the gas temperature of the tube.

Humidity evel	0	1	2	3	4	5
Gas emperature at 10hpa（℃）	29.7	31.1	31.2	32.3	32.5	32.7

OFF ,1-5 levels

Water capacity

≤300mL

CAUTIONS: Check that water flows into the chamber and is maintained below the fill line ,if the water level rise above the fill line ,replace the chamber immediately .

DC Power Consumption

30W, 24VDC

Humidification capacity：

The humidification system output is about 12.5 mg/L and the relative humidity is 74% when the device set for maximum gas flowrate(maximum presure setting) and the humidity level 5 under the environment conditions of temperature at 22 ℃ and the humidity at 10%.

8 Disposal

When the device reaches the end of its service life, dispose of the device and packaging in accordance with local laws and regulations.

Environmental information

WEEE 2002/96/EC is a European Directive that requires the proper disposal of electrical and electronic equipment. This device should be disposed of separately, not as unsorted municipal waste. To dispose of your device, you should use appropriate collection, reuse and recycling systems available in your region. The use of these collection, reuse and recycling systems is designed to reduce pressure on natural resources and prevent hazardous substances from damaging the environment. If you need information on these disposal systems, please contact your local waste administration. The crossed-bin symbol invites you to use these disposal systems. If you require information on collection and disposal of your device please contact your Xiaoniu office, local distributor.

9 Statement of manufacturer for EMC

The essential performance of CPAP or Auto CPAP device is to provide user the continuous positive

airway pressure.

The customer or the user of the CPAP or Auto CPAP device should assure that it is used in such an environment specified by table 1, table 2, table4 and table6, otherwise, could result in the CPAP or Auto CPAP device improper operation

“WARNING: Use of The CPAP or Auto CPAP device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, CPAP or Auto CPAP device and the other equipment should be observed to verify that they are operating normally

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the CPAP or Auto CPAP device could result in increased electromagnetic emissions or decreased electromagnetic immunity of the CPAP or Auto CPAP device and result in improper operation

WARNING: Portable RF communications equipment (including peripherals such as antenna

cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CPAP or Auto CPAP device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 1

Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS		
The CPAP or Auto CPAP device is intended for use in the electromagnetic environment specified below. The customer or the user of the CPAP or Auto CPAP device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The CPAP or Auto CPAP device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not

		likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CPAP or Auto CPAP device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The CPAP or Auto CPAP device is intended for use in the electromagnetic environment specified below. The customer or the user of the CPAP or Auto CPAP device should assure that it is used in such an environment.			
IMMUNITY	**IEC 60601**	**Complian**	**Electromag**

test	**test level**	**ce level**	**netic environment –guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors 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/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines not comply	Mains power quality should be that of a typical commercial or hospital

			environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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 IEC 61000-4-11	<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	<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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CPAP or Auto CPAP device requires continued

	UT) for 5 s	<5 % UT (>95 % dip in UT) for 5 s	operation during power mains interruptions, it is recommended that the CPAP or Auto CPAP device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 0A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical

			location in a typical commercial or hospital environment.

Table 4

Guidance and manufacturer's declaration – electromagnetic immunity			
The CPAP or Auto CPAP device is intended for use in the electromagnetic environment specified below. The customer or the user of the CPAP or Auto CPAP device should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 6 Vrms 150 kHz to 80 MHz ISM bands between 150 kHz to 80 MHz	3 Vrms 6 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the CPAP or Auto CPAP

Radiated RF IEC 61000-4-3	3 V/m, 80 MHz to 2700MHz; 27 V/m,385MHz; 28 V/m,400MHz; 9V/m,710MHz; 9V/m,745MHz; 9V/m,780MHz; 28V/m,810MHz; 28V/m,870MHz; 28V/m,930MHz; 28V/m,1720	3V/m 9V/m 27 V/m 28 V/m	device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts(W)according to the

	MHz; 28V/m,1845 MHz; 28V/m,1970 MHz; 28V/m,2450 MHz; 9V/m,5240M Hz; 9V/m,5500M Hz; 9V/m,5785M Hz;		transmitter manufacturer and *d* is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters,as determined by an electromagnetic site survey,[a]should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment

			marked with the following symbol: 

NOTE 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 [ME EQUIPMENT or ME SYSTEM] is used exceeds the applicable RF compliance level above, the CPAP or Auto CPAP device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CPAP or Auto CPAP device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Table 6

Recommended separation distances between portable and mobile RF communications equipment and the CPAP or Auto CPAP device

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz～80 MHz $d = 1.2\sqrt{P}$	80 MHz～800 MHz $d = 1.2\sqrt{P}$	800 MHz～2.5 GHz $d = 2.3\sqrt{P}$

0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

10 Limited Warranty

The service life of the device, components and accessories:

Main body: 5 years;

Water tank: 2.5 years;

Air tubing and mask: 6 months.

Xiaoniu health Co., Ltd. (hereafter 'Xiaoniu') warrants that your Xiaoniu product shall be free from defects in material and workmanship from the date of purchase for the period specified below.

Product	Warranty period
Mask	90 days
Flexible tubing	90 days
Water tank	90 days
SD Card	1 year
Power Adapter	1 year
Main device	2 years
H100 Heated humidifier	2 years

This warranty is only available to the initial consumer. It is not transferable.

If the product fails under conditions of normal use, Xiaoniu will repair or replace, at its option, the

defective product or any of its components.

This Limited Warranty does not cover:

Warranty is void on product sold, or resold, outside the region of original purchase.

Warranty claims on defective product must be made by the initial consumer at the point of purchase.

This warranty replaces all other expressed or implied warranties, including any implied warranty of merchantability or fitness for a particular purpose. Some regions or states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

Xiaoniu shall not be responsible for any incidental or consequential damages claimed to have resulted from the sale, installation or use of any Xiaoniu product. Some regions or states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

This warranty gives you specific legal rights, and

you may also have other rights which vary from region to region. For further information on your warranty rights, contact your local Xiaoniu dealer or Xiaoniu office.

11 Reordering

Contact your home care provider to order accessories or replacement filters. The device does not require routine servicing.

WARNINGS: If you notice any unexplained changes in the performance of the device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, discontinue use. Contact your home care provider.

WARNINGS: If the device malfunctions, contact your home care provider immediately. Never attempt to open the enclosure of the device. Repairs and adjustments must be performed by Xiaoniu-authorized service personnel only. Unauthorized service could cause injury, invalidate

the warranty, or result in costly damage.

WARNINGS: If necessary, contact your local authorized dealer or Xiaoniu for technical support and documents.

12 Technical Support

Please contact Xiaoniu directly if you need the circuit diagram of the device and the list of components for certain purposes such as maintenance or connection to other equipment. Xiaoniu will provide the circuit diagram and/or other technical documents in whole or in part according to your needs.

Manufacturer:

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CPAP and Auto CPAP devices User Manual

V1.3

Sep. 2018

Xiaoniu health Co., Ltd.

This manual No.：3000071 Version: V1.3

Directive 93/42/EEC
concerning Medical Devices