Non-invasive Ventilator

Shenzhen Viatom Technology Co., Ltd.

Contents

1. Introduction

Thank you for using Viatom Non-invasive Ventilator. This manual describes the purpose, function and safe use of the device. Before using this device, please read carefully and fully understand the contents of this manual to ensure the correct use of this device and the safety of patients and operators. Please keep this instruction manual after reading it so that you can refer to it at any time when you need it.

Release version of the software : V1

1.1 Security Information

Before using this device, please read this manual carefully and fully understand the relevant warnings and risks.

⚠ **Warning**：Indicates possible harm to the user or operator.

Notice: Indicates possible damage to the device.

⚠ **Warning**：

●This manual is for reference only, and it needs to be used under the guidance of a professional doctor.

●This device is non-life support device.

●Do not wear a mask when the device is not turned on, otherwise there is a risk of suffocation.

●When the device is not turned on and is not working properly, please do not wear a mask to avoid the danger of suffocation.

●This device should not be stacked or placed close to other unapproved device when in use.

●The device cannot be exposed to electrosurgery, defibrillation, X-ray (γ-ray) or infrared radiation. When the electromagnetic field includes magnetic resonance (MRI) or CT inspection environment and radio interference environment, the device will not operate normally in this environment.

●Portable and mobile radio frequency communication device may affect the use of this device. When using this device normally, it is recommended to stay away from such communication device.

●If there is a mixture of flammable anesthetics and air or oxygen or nitrous oxide around, do not use this device.

●Do not use this device in an environment with flammable gas and oxygen-rich environment. The device should be at least 1m away from the oxygen source during operation.

●Do not use the machine near the source of toxic gas or harmful gas.

●Do not use this device in a temperature exceeding the specified temperature range.

●Do not connect breathing tubes or accessories to unmarked humidifiers or device. Do not stretch the pipe, which may cause air leakage in the pipe.

●Do not cover or heat the breathing circuit to affect the temperature of the air flowing into the patient.

●Do not place this device directly on carpets, fabrics or other flammable materials.

●Do not place the device near curtains to obstruct the flow of cooling air, which may cause the device to

overheat.

●Do not use accessories or parts that are not recommended or configured. Incompatible accessories or accessories can cause performance degradation or affect the EMC performance of the device.

●Condensation may damage the device. If the device is exposed to extremely hot or cold temperatures, the device should be adjusted to room temperature (working temperature) before starting treatment. Do not use the device in a temperature environment outside the operating temperature range indicated in the parameters.

●Do not use this device when the room temperature exceeds 35°C (95°F). When the room temperature exceeds 35°C (95°F), the air temperature in the duct may exceed 43°C (109°F). Thereby causing irritation or injury to the respiratory tract.

●Do not use this device under direct sunlight or near heating device, as these conditions will increase the temperature of the output airflow of the device.

●If the environment or power supply exceeds the specification range, it may cause automatic shutdown or the ventilation control cannot meet the specifications.

●When you use this device in a home environment, you need to place this device away from pets and children.

●Please check if there is water in the device before use. The maximum water level limit of the water tank is 260ml.

●Before use, please confirm that the tubing is properly connected and avoid the risk of neck winding caused by the use of breathing tubing and hoses. Check the pipeline for damage or wear, and replace the pipeline if necessary.

●The patient is the intended operator. The patient can safely use the treatment function of the device. When the patient is using it, the parts of the device cannot be maintained or repaired.

●When using oxygen, the oxygen supply must comply with local standards for medical oxygen. It is forbidden to connect the device to an uncalibrated or high-pressure oxygen source. Please do not use oxygen when you smoke or have an open flame to avoid burning. The distance between the device and the oxygen source should be at least 1m to avoid fire and burns.

●When using oxygen, please turn on the machine before turning on the oxygen. Turn off the oxygen before turning off the machine. Prevent oxygen from accumulating in the machine. Warning explanation: When the machine is not working and the oxygen is still on, the oxygen transmitted to the hose can accumulate in the machine casing. The oxygen accumulated in the machine casing poses a fire hazard. Do not connect this device to an uncontrolled or high-pressure oxygen source.

●Incorrect use of masks or accessories may cause the CO2 concentration to increase to a critical value or allow unconscious breathing, which may cause breathing suffocation.

●Do not block the exhaust port of the mask. If you are using a full face mask (the mask covers your mouth and nose), the mask must be equipped with a safety (entrainment) valve.

● Repairs, services and maintenance should only be performed by the manufacturer or technicians expressly

authorized by the manufacturer. Repairing the machine without authorization may result in personal injury, invalidation of the warranty or damage to valuable parts.

●If apnea continues to occur after using this device, please contact a professional doctor.

●No modification to the device is allowed. If you want to dispose of this device, please follow local environmental regulations.

●When you need to measure blood oxygen and ECG, please refer to the user manual of the appropriate oximeter and ECG.

Other equipment connected to the signal port of the product must meet the requirements of relevant standards, such as IEC 60601-1 or IEC 62368-1, etc.

Do not place the device where it is difficult to disconnect the power supply.

Although the device has passed ISO10993 and ISO 18562 tests, the easily accessible materials of the device may cause allergic reactions.

Notice：

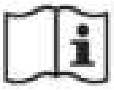
- Before use, make sure that the power cord is firmly installed to your treatment device.
- The correct wearing and position of the mask on the face is essential for the consistent operation of the device.
- When using, it must be ensured that the filter cotton is in good condition and installed in place.
- Cigarette smoke will cause the accumulation of smoke in the machine, which will cause the machine to fail to work normally.
- It is necessary to check the filter cotton regularly to ensure that it is completely clean. Dirty filter cotton may increase the working temperature and affect the performance of the device. Do not use wet filter cotton, you need to ensure that there is sufficient drying time.
- When the gas flow rate and setting exceed the recommended working range, the output of the humidification system may be insufficient, and the relative humidity of the output gas may be less than 70%.
- In order to be able to use the humidifier safely, the humidifier must be placed below the breathing circuit between the mask and the air outlet of the device.
- Please regularly check whether the power supply and various pipelines are normal. If there is any problem, please stop using the device and replace related accessories. Please disconnect the power before cleaning the device to avoid electric shock. Do not immerse the device in water or other liquids. Please pay attention to waterproofing.
- When the accidental damage of the physical media causes system failure, power failure, hardware failure, and software failure, the protection of the physical environment should be strengthened, and the use of device should be strengthened.
- When man-made threats cause accidental loss of backup data, network management policies should be carefully improved; effective management of network keys should be strengthened, and misoperations should be prevented.
- When the user’s personal information is unintentionally disclosed, the user’s identification and authentication mechanism should be adopted, and the password should be long enough; it should be changed frequently, and the password should be kept in a confidential place; at the same time, the security awareness of personnel should be strengthened and the scope of the spread of confidential information should be controlled , Encrypt the information transmitted in the network, etc.
- Please follow the doctor's advice and consider changing the treatment pressure. In order to make the treatment effect of the device more effective, please re-evaluate the treatment settings regularly.
- Ensure that the treatment pressure of the patient is individually set for the patient according to the configuration of the device used, including accessories.
- When the treatment device is used by multiple patients, each patient needs to be equipped with a separate

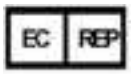
breathing circuit and mask, and other people's cannot be used.

- If you feel uncomfortable when using the device, please stop using the device and contact the device provider immediately. Because it may cause allergies.
- If the machine has abnormal working conditions, such as abnormal noise, falling, water entering the machine, or breaking of the machine shell, please disconnect the power supply, stop using the machine, and contact the device provider immediately.

1.2 Graphics and symbols

This device uses the following symbol identification, and its meaning is explained in the table below.

Symbol	Description
	Indicates the item is a medical device
	Follow Instructions for Use.
	Indicates the need for the user to consult the instructions for use
	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Indicate separate collection for electrical and electronic device (WEEE).
	Indicates the medical device manufacturer
	Indicates the date when the medical device was manufactured
	Serial Number
	Indicates the date after which the medical device is not to be used
	Class II (Double Insulated)
IP22	≥ 12.5 mm Diameter, Dripping (15ºtilted)
	Type BF Applied Part
	AC Power
	DC Power
	Non-Ionizing Radiation

Symbol	Description
	Ramp Button
	Start/stop therapy button
	This product complies with the Europea Council EU 2017/745 (MDR)
	Authorized representative in the European Community
	Indicates a carrier that contains unique device identifier information
	The product has passed FCC certification

1.3 Terms and definitions

Terms	Description
CPAP mode	Continuous positive airway pressure The device performs continuous positive pressure ventilation according to the set treatment pressure, and the treatment pressure is the same in the inspiratory and expiratory phases.
APAP mode	Automatic continuous positive airway pressure mode APAP can be called Auto CPAP mode. When the device is ventilating, when a respiratory event is detected, the treatment pressure is automatically increased, and when the respiratory event disappears, the treatment pressure is automatically reduced, that is, the pressure is automatically adjusted by judging that the respiratory event is within the set pressure range.
S mode	Autonomous trigger mode. When the device is ventilated, the patient's own breathing is used to control the operation of the device (the device provides inspiratory pressure when inhaling, and the device provides expiratory pressure when exhaling), and the breathing rate of the device is fully synchronized with that of the patient.
S/T mode	Autonomous trigger/time mode. When the device is ventilated, if the patient breathes well on their own, the device and the patient's breathing rate are kept fully synchronized; if the patient's breathing is unstable or stops, the device will ventilate the patient according to the preset pressure and breathing rate.
T mode	Time control mode. When the device ventilates, the patient is ventilated according to the set pressure and respiratory rate and other parameters. This mode is mainly suitable for patients with weak breathing trigger ability.

2. Product introduction

2.1 Product name and model

Product name： Non-invasive Ventilator

Model： LeRes-C, R10, LeRes-A, R20, LeRes-C1, R11, LeRes-A1, R21, LeRes-S, R100, LeRes-B, R200, LeRes-S1, R101, LeRes-B1, R201.

Product models are divided according to different product configurations, see the table below for details:

Model / configurations	LeRes-B	R100	LeRes-S	R200	LeRes-B1	R101	LeRes-S1	R201	LeRes-C	R10	LeRes-A	R20	LeRes-C1	R11	LeRes-A1	R21
Colour	Black	Black+ Blue	Black	Black+ Blue	Black	Black+ Blue	Black	Black+ Blue	White	White +Blue	White	White +Blue	White	White +Blue	White	White +Blue
CPAP mode	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
APAP mode	○	○	●	●	○	○	●	●	○	○	●	●	○	○	●	●
S mode	●	●	●	●	●	●	●	●	×	×	×	×	×	×	×	×
S/T mode	●	●	●	●	●	●	●	●	×	×	×	×	×	×	×	×
T mode	●	●	●	●	●	●	●	●	×	×	×	×	×	×	×	×

WIFI	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Bluetooth	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
Turbo code	B	B	B	B	C	C	C	C	A	A	A	A	C	C	C	C
Note: 1. "●" stands for standard configuration; "○" stands for optional configuration; "×" stands for none. Turbine information is disclosed in technical documents.																

2.2 Intended Use

It is intended for relieve obstructive sleep apnea(OSA)and Chronic obstructive pulmonary disease(COPD) in patients weighing more than 30Kg, So as to achieve the purpose of adjuvant therapy. It cannot be used for life support and treatment central sleep apnea. It needs to be used under the guidance of a professional doctor.

2.3 Product structure and composition

It consists of host, power adapter and humidifier.

2.4 Contraindication

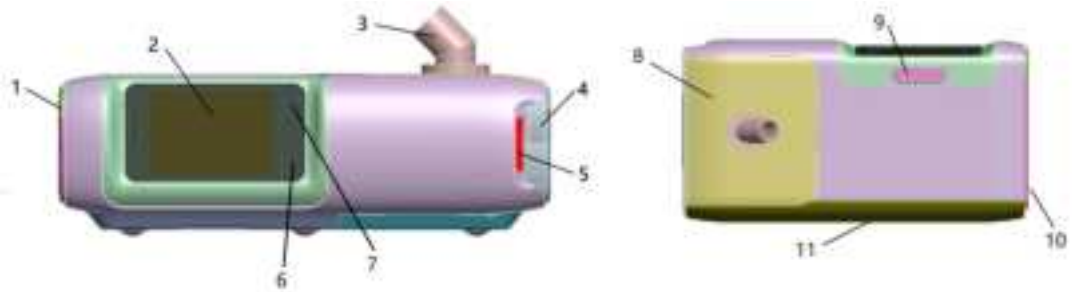
When patients with the following conditions may not be suitable for treatment with a positive pressure ventilation therapy machine, please inform your doctor before using this device. Only after a doctor's examination and diagnosis, can this device be used for treatment:

Absolute contraindications: pneumothorax; pneumomediastinum; cerebrospinal fluid leakage, craniocerebral trauma or intracranial trauma or intracranial pneumoconiosis; shock caused by various causes and has not been corrected; epistaxis is active; epistaxis has not been effectively controlled Gastrointestinal bleeding; coma or unconsciousness that cannot cooperate or receive mask treatment; huge vocal cord polyps; severe insufficiency of effective circulating blood volume with shock.

Relative contraindications: severe coronary heart disease with left heart failure; acute otitis media; excessive respiratory secretions and weak cough;

Spontaneous breathing is weak; tracheal intubation (through the nose or mouth) and tracheotomy; severe nasal congestion caused by various reasons; pulmonary bullae; respiratory mask allergy.

2.5 Host appearance



No.	Component	Description
1	USB interface	USB data interface, connect external device
2	Display screen	Display system menu, support touch operation
3	Air outlet	Connect breathing circuit here
4	Water tank	Place the water needed for the humidifier
5	Indicator light	Indicating effect
6	Home button	Click to return to the main interface of the system
7	Delay boost button	Click to set the delay boost time
8	Radiator cap	Open the water tank cover to extract the water tank
9	Start/stop button	Start and stop device ventilation
10	Air inlet	The air inlet of the device, the installation position of the filter cotton
11	Power socket	Connect the power cord here

2.6 Humidifier use

During the use of the device, turning on the humidifier to heat and humidify can increase the humidity of the inhaled air, prevent the nasal mucosa from drying out, and improve the comfort of use. If you need to enable the humidification function, you need to add water to the water tank so that the humidifier can work normally. Please follow the steps below:

1. Open the water tank cover and take the water tank out of the humidifier.

2. Pour water into the water tank, the water volume does not exceed the highest water level line of the water tank.

3. Put the water tank back into the humidifier and buckle the water tank cover.

Notice ：

- Only distilled water or purified water can be filled, and the amount of water added each time should not exceed the highest water level line of the water tank.
- When the water volume of the water tank reaches the highest water level, do not tilt the water tank.
- When the device is not in use, please pour out the remaining water in the water tank.
- Do not touch the metal surface of the heater when pulling out the water tank.

3. Preparation before use

Before using the device, please read this chapter carefully and follow the instructions in this chapter to install, connect and check the device.

For accessories used with this device, please check in accordance with the instruction manual of each accessory.

3.1 Place

Please place the device horizontally on a safe and reliable platform. Do not place the positive pressure ventilation therapy machine around any heating or cooling device (fans, radiators, air conditioners).

Notice:

●When placing the machine, make sure that the power cord is accessible, because cutting off the power is the only way to turn off the device.

● Make sure that the air inlets of the device are not blocked by sheets, curtains and other things.

●Do not place it directly on carpets, fabrics or other flammable materials.

●Do not place it directly on a container with water.

3.2 Install the filter

The air inlet of the device is equipped with reusable filter cotton, and the device can only be used after the filter cotton is installed. Please check the filter every 1-3 months. If there is any foreign matter or dust blocking the air inlet, please clean or replace the filter cotton.

Please follow the steps below to install the filter:

1. Open the side cover of the device.

2. Place the cotton filter in the filter of the air inlet and replace it on the side panel.

If it is to replace the filter cotton, take out the old filter cotton and put in a new one.

Note: After receiving the device, please confirm whether the filter is installed in the air inlet. If the filter is not installed, please install the filter before using the device.

3.3Connect the power supply

Please follow the steps below to connect the power supply:

1. Connect one end of the power cord to the power adapter, and plug the other end into the power socket;

2. Connect the power adapter to the power socket of the device;

3. Make sure that the plugs of the device end, power adapter and socket have been inserted firmly.

Warning：

- If the power supply is disconnected during the use of the device, the device buzzer will emit a "di di..." prompt sound, please stop using it and check the power connection.
- When the device is damaged, please do not connect to the power supply.
- If the surface of the power adapter or power cord is damaged, please stop using the device and replace the adapter or power cord.

3.4 Connect tubing and mask

Please follow the steps below to connect the tubing or mask:

1. Connect one end of the pipe to the air outlet on the top of the device.

2. Connect the other end of the tubing to the mask.

3. Wear the face mask, adjust the tightness of the headband of the face mask, so that the face mask fits the face and does not leak air.

Notice:

●Do not pull the pipeline to avoid air leakage.

●If the mask and pipeline are damaged, please stop using it and replace it in time.

3.5Device Operation Guide

The user interface of this device allows you to adjust device settings and check your treatment information. The user interface includes a display screen and a touch screen and buttons. Touch the screen to select various options or settings on the screen.

Ventilation button-press it to start ventilation, press and hold for 5 seconds to stop ventilation.

Ramp function touch button: press it to quickly enter the Ramp menu page

Home function touch button: press to return to the first page

Note: The screen examples shown in this manual are for reference only, and the actual screens may vary according to different machine models and vendor settings.

4. Instructions for use

This chapter introduces the basic operations and precautions related to the device.

4.1 Power on/off

Turn on: The device will automatically turn on after it is connected to the power source. After a few seconds, the device will enter the standby state.

Shutdown: When the device is in a non-ventilated state, disconnect the power supply to automatically shut down. Shutting down under ventilation will trigger a power-down alarm.

4.2 Initiate ventilation

Start ventilation: After connecting the pipe pavement cover, press the "Start/Stop" button, the device will begin to ventilate, and the display will show parameter information such as treatment pressure.

Stop ventilation: During ventilation, press the "Start/Stop" button, and the device will stop ventilation.

Notice:

1. During the ventilation process, when the device has a power interruption (such as a power failure), if the power supply is restored within 60 minutes, the device will automatically return to the ventilation state before the power failure.

2. Under normal conditions: there is a leak hole on the full face mask. When the patient exhales, the exhaled carbon dioxide is squeezed out from the leak hole through the patient's exhaled pressure and the pressure output by the ventilator.

3. In a single fault state: when the power is off, when the patient exhales, the exhaled carbon dioxide is simultaneously squeezed out from the leak hole and breathing tube on the mask, and fresh gas is inhaled from the leak hole and breathing tube when inhaling.

4.3 Humidification function

When using the device, you can turn on the humidification function to heat and humidify the gas output by the device. Select the [Humidification] menu and set the humidification level. After opening the ventilation, the device will automatically start the humidification function.

Note: When turning on the humidification function, please make sure that there is enough water in the water tank to avoid dry-burning the humidifier.

4.4 Delay boost function

The delayed pressure boost function can make the pressure output by the device gradually rise

from the initial pressure and reach the set treatment pressure after a preset time, making it easier for the user to fall asleep. Select the [Comfort] menu, set [Delay Boost Pressure] and [Delay Boost Time] to enable the delay boost function.

4.5 View report

When the device is in standby mode, you can view the usage of the device in the report menu interface, and the duration of this ventilation, average usage time, etc. will be displayed. Select the [Report] menu, the day's usage data will be displayed by default, and you can select other usage times for query.

4.6 Function menu description

The system will display different menu items according to different user types, including three modes of menus: normal mode, advanced mode, and maintenance mode. After the device is started, it enters the normal mode by default.

Standby interface

Ventilation interface

4.6.1Normal mode menu

This mode is mainly operated by the patient, and the device can be set. The normal mode menu mainly includes humidification setting, comfort setting, system setting, view report, etc. For detailed menu description, please refer to the following table.

Menu interface

Comfort setting interface

Menu		Function Description
Humidify	Humidification grade	Set the humidification level of the humidifier, optional values: automatic, 0-5 gears; Level 0 is to turn off the humidification function. The greater the number of levels, the greater the humidification capacity. The default is 0 level.
Comfort	Expiratory hypotension	Set the level of expiratory pressure reduction, and automatically reduce the pressure in the mask according to the breathing rhythm during the expiration phase to improve comfort. Optional values: 0-3 gears, 0 gear is to turn off this function, default value: 2 gears.
	Automatic start	Turn on/off the automatic ventilation function; when turned on, the device will automatically start ventilation after the user wears the mask and breathes; Optional value: on/off, the default value is on.
	Automatic stop	Turn on/off the automatic stop ventilation function; when turned on, the device will automatically stop the ventilation after detecting that the user takes off the mask; Optional value: on/off, the default value is on.
	Delay start pressure	Set the starting pressure of the delay boost function. Optional value 3-20cmH2O, Default value: 4 cmH2O. Note: The initial pressure value must be less than the set pressure value.
	Delay boost time	Set the delay time of the delay boost function, optional value: 0-60 minutes, when set to 0, the delay boost function will be closed, default value: 15 minutes.
	Preheat	Turn on/off the pre-heating function. After turning on, the humidifier will start to work for 30 minutes before being ventilated to pre-heat.
Report	View usage information	Display the usage of the device, including usage time, sleep quality information, etc.

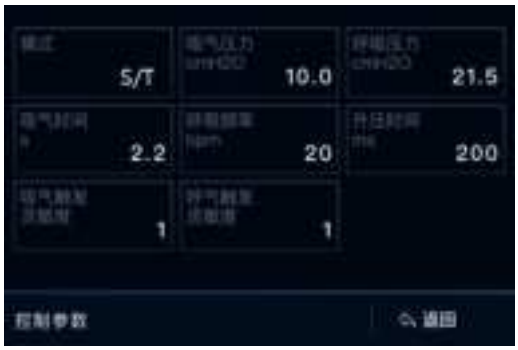
Menu		Function Description
		You can choose to view the usage for one or more days.
Hint	Pipe disconnected	Turn on/off the "pipeline disconnected" prompt. After opening, when the pipeline is disconnected from the device, the screen will display a prompt message.
	Blocked pipe	Turn on/off the "piping blocked" prompt. After opening, when the pipeline is blocked, the screen will display a prompt message.
	High air leakage	Turn on/off the "high air leakage" prompt. After it is turned on, the screen will display a prompt message when an air leak occurs.
Appendix	Pipeline type	Select the type of pipeline to be used, optional value: 15mm/22mm, default value: 22mm.
	Mask type	Select the type of mask to use, optional values: oronasal mask/nasal mask/nasal pillow, default value: nasal mask.
	Mask test	Test whether the mask is worn correctly. If the test fails, the position of the mask needs to be re-adjusted.
	Remind	Set the reminder of the service life of accessories and consumables, including filters, masks, pipes and other accessories, optional values: off, 1-12 months, default value: off.
Bluetooth	Bluetooth settings	Turn on/off the Bluetooth function and choose to connect to a Bluetooth device.
Wi-Fi	Wi-Fi settings	Turn on/off the Wi-Fi function and choose to connect to a Wi-Fi network.
System	Pressure unit	Set the pressure unit displayed on the screen, optional value: cmH2O/hPa, default value: cmH2O.
	Screen brightness	Set screen brightness, optional value: 0-100%, default value: 60%.
	Language	Set the language of the system, optional values: Chinese/English, default value: Chinese.
	Date	Set the system date.

Menu		Function Description
	Date format	Set the system date format, optional values: year, month, day/month, day, year/day, month, year, default value: year, month, day.
	Time	Set the system time.
	Time format	Set the system time format, optional values: 24 hours/12 hours, default value: 24 hours.
	Alarm clock	Set an alarm reminder.
	Volume	Set the alarm volume of the device, optional value: 0-100%, default value: 30%.
	Clear data	Clear device usage information, including ventilation usage time, report information, etc.
	About	Display device information, including model, software version, SN, etc.

4.6.2 Advanced mode menu

The advanced mode menu is only for clinicians to operate and set, or set according to doctors' opinions. In order to prevent patients from misoperation, it is necessary to manually enter the password to switch to the advanced mode. Click the "More Parameters" button to select the current ventilation mode and set the ventilation parameter values.

Ventilation interface



Parameter setting interface

Menu		Function Description
Model	Ventilation mode	Set the ventilation mode, optional values: CPAP, APAP, S, S/T, T. Note: Different types of device support different ventilation

Menu		Function Description
		modes.
Parameter	Pressure	Set the treatment pressure of the device in CPAP mode, optional values: 4.0-20.0 cmH_2O, and the default value is 6.0 cmH_2O.
	Maximum pressure	Set the maximum treatment pressure of the device in APAP mode, optional values: 4.0-20.0 cmH_2O, and the default value is 12.0 cmH_2O. Note: The pressure value must be greater than the current minimum pressure value.
	Minimum pressure	Set the minimum treatment pressure of the device in APAP mode, optional values: 4.0-20.0 cmH_2O, and the default value is 4.0 cmH_2O.
	Suction pressure	Set the suction pressure of the device in S, S/T, and T modes. The optional values are 6.0-25.0 cmH_2O, and the default value is 10.0 cmH_2O. Note: The pressure value must be greater than the current expiratory pressure value.
	Expiratory pressure	Set the expiratory pressure of the device in S, S/T, and T modes. The available values are 4.0-25.0 cmH_2O, and the default value is 6.0 cmH_2O.
	Inspiration time	Set the inspiratory time of the device in S/T and T mode, optional value: 0.3-4.0 seconds, the default value is 1.0 second.
	Respiratory rate	Set the inspiratory time of the device in S/T and T modes, optional values: 5-30 bpm, and the default value is 12 bpm.
	Pressure rise time	Set the pressure rise time of the device in S, S/T, and T modes, optional values: 100--900 ms, and the default value is 200 ms.
	Inspiratory trigger sensitivity	Set the inspiratory trigger sensitivity of the device in S, S/T mode, optional values: automatic, 1-5 gears, and the default value is 3 gears.
	Exhalation trigger	Set the exhalation trigger sensitivity of the device in S, S/T mode, optional values: automatic, 1-5 gears, and the default value is 3

Menu		Function Description
	sensitivity	gears.

4.6.3Maintenance mode menu

The maintenance mode menu is only used by the customer service personnel of the manufacturer, and can be used to upgrade the software of the device and restore the factory settings. Switching to advanced mode requires manual input of the password.

Menu	Function Description
Pressure calibration	Perform pressure calibration on the device.
Flow rate calibration	Calibrate the flow rate of the device.
Software upgrade	Upgrade the software of the device.
Reset	Restore the factory settings of the device.

4.7Device tips

During the use of the device, the system will display prompt information on the screen according to the current status. For details, refer to the following table:

Tips	Function Description
High air leakage	In the process of using the device, if the mask and breathing tube are not properly connected, or the water tank is not installed properly, the screen will display a prompt message.
Asphyxia	When apnea is detected during the use of the device, and the set time is exceeded, a prompt message will be displayed on the screen.
Pipe disconnected	During the use of the device, if the connection between the pipeline and the device outlet is interrupted, or the connection between the mask and the pipeline is interrupted, a prompt message will be displayed on the screen.
Blocked pipe	In the process of using the device, if the pipeline or the air inlet of the device is blocked, the screen will display a prompt message.
Power down	During the ventilation process of the device, the power supply is accidentally disconnected. After the power supply is restored and the

	power is turned on, the screen will display a prompt.
The input voltage is abnormal, please check!	The power adapter is incorrectly matched, causing the voltage to be too high or too low, and a prompt message will be displayed on the screen. Please use the supplied power adapter.
The service life of the pipeline is up, please replace it.	If the pipeline reminder in the "Consumables reminder" function is turned on, when the scheduled pipeline replacement time is reached, the device will issue a reminder to remind you to replace the pipeline.
The expiration date of the water tank is up, please replace it.	If the water tank reminder in the "Consumables Reminder" function is turned on, when the scheduled water tank replacement time is reached, the device will give a reminder to remind you to replace the water tank.
The filter expiration date is up, please replace it.	If the filter reminder in the "Consumables reminder" function is turned on, when the predetermined filter replacement time is reached, the device will issue a reminder to remind you to replace the filter.
The expiration date of the mask is up, please replace it.	If the mask reminder in the "Consumables reminder" function is turned on, the device will send out a reminder to remind you to replace the mask when the scheduled time for mask replacement is reached.

4.8 Connect the pulse oximeter

This device can be used with a pulse oximeter, and the screen will display the measurement parameters of the oximeter. The connection method of the device and the pulse oximeter is as follows:

1. Wear a pulse oximeter and keep the pulse oximeter in a normal working condition.

2. Select the [Bluetooth] menu in the device's menu, turn on the Bluetooth function, and wait for the device to search for the pulse oximeter.

3. Select the name of the searched pulse oximeter and wait for the connection to be completed to see the measurement parameters of the pulse oximeter on the device.

Note: The device only supports the pulse oximeter in the list of accessories. Please refer to Chapter 9 for specific models.

4.9 Connect Dynamic ECG Recorder

This device can be used with Dynamic ECG Recorder, and the screen will display the measurement parameters of Dynamic ECG Recorder. The connection method of the device and Dynamic ECG Recorder is as follows:

1. Wear the Dynamic ECG Recorder and keep the Dynamic ECG Recorder in normal working condition.

2. Select the [Bluetooth] menu in the device's menu, turn on the Bluetooth function, and wait for the device to search for Dynamic ECG Recorder.

3. Select the name of the Dynamic ECG Recorder found and wait for the connection to be completed to see the measurement parameters of the Dynamic ECG Recorder on the device.

Note: The device only supports the Dynamic ECG Recorder in the list of accessories. Please refer to Chapter 9 for specific models.

5. Common problem

If there is a problem with your device during use, please try the measures listed in the table below, if it still does not solve

For questions, please contact your device maintainer.

Problem	Possible Causes	Measure
No response after the device is powered on	There is no power at the power outlet or the device is not plugged into a power source	Please check the power socket and make sure that the device is correctly plugged into the power source. Make sure that the power outlet has power. Make sure that the power cord is properly connected to the power supply and the device socket. If the fault still occurs, please contact customer service.
Mask leaks	Mask size is not suitable	Make sure your mask is of the right size, please refer to the mask user manual for specific information, or use the mask test function to check whether the mask is leaking.
Dry or blocked nose	The humidification gear is set too low	Upgrading grade
Water in the mask	The humidification gear is set too high	Lower the gear level or increase the indoor ambient temperature.
Dry mouth	The mouth opens during sleep, causing air leakage	Increase the humidification level. Wear the headband to fix the jaw, or change the full face mask
Excessive pressure in the mask	Delay boost function is turned off	Turn on the delayed boost function
After stopping ventilation, the device is still ventilating	The device is cooling	The device is cooling the pipeline, and the ventilation will automatically stop after a few minutes

Problem	Possible Causes	Measure
Screen display is abnormal	Device dropped or bumped	The device is cooling the pipeline, and the ventilation will automatically stop after a few minutes
During use, the treatment pressure set by the device is different from the pressure output to the mask end	Improper pipe connection or leakage	Recheck the connection of the pipeline, if the problem still exists, please contact customer service
The output pressure of the device is too low	The air inlet of the device may be blocked. Delay boost function is turned on	Clean or replace the filter cotton in the air inlet. Turn off the delay boost function, or shorten the delay boost time
Leaking water tank	The water tank is not installed correctly. Damaged water tank	Check if the water tank is installed correctly. Check whether the water tank is damaged. Contact customer service staff to replace the new water tank
The touch screen is not responding	Touch screen failure	Restart, if the problem persists, please contact customer service
Unable to connect to pulse oximeter	The Bluetooth function is not turned on or the pulse oximeter is not turned on	Turn on the Bluetooth function of the device. Wear a pulse oximeter and keep it in normal working condition
Cannot connect to Dynamic ECG Recorder	The Bluetooth function is not turned on or the Holter recorder is not turned on	Turn on the Bluetooth function of the device. Wear the Dynamic ECG Recorder and keep it in normal working condition

6. Cleaning and maintenance

Regular cleaning of device and accessories is very important to prevent respiratory infections. Please refer to the following instructions to clean and maintain device and accessories.

6.1 device cleaning

Warning: Please unplug the device before cleaning, and make sure that the heating chassis of the humidifier has cooled down to avoid burns.

Note: Do not use solutions containing bleach, chlorine or fragrances and wetting agents to clean device and accessories.

Please use a soft and clean cloth slightly dipped in mild detergent to clean the outside of the device, and then connect it to the power supply after it is thoroughly dried. It is recommended to clean the device housing once a month.

6.2 Water tank cleaning

Please use tap water to rinse and clean the water tank, and scrub with a soft clean cloth (if necessary, dip in 75% ethanol). After cleaning, wait for the water tank to dry before installing the water tank back on the device. It is recommended to clean the water tank once a week.

6.3 Cleaning the mask and pipeline

For the cleaning of the mask and pipeline, please refer to the instructions in the cleaning section of the instructions attached to the mask and pipeline, or consult customer service personnel. After cleaning, please dry the mask and tubing before using it. It is recommended to clean the mask and tubing once a week.

6.4 Traveling with device

If you need to use the device when traveling, please use the travel backpack in the accessories, and pack the device and accessories into the travel bag to carry at any time.

Notice:

- Before putting the device in the travel bag, please pour out the water in the water tank to prevent the water in the water tank from pouring into the inside of the device.
- Determine the type of power outlet at the travel destination, and bring a power outlet adapter if necessary.
- It is recommended to bring a spare filter cotton.

7. Maintain

The warranty period of the Non-invasive Ventilator is 1 year and the service life is 8 years. If the treatment device is used in accordance with the instructions for use, no maintenance is required during this period. If the treatment device is used beyond this period, we recommend that an authorized dealer inspect the device.

If the humidifier of the positive pressure ventilation treatment machine is used in accordance with the requirements of the instructions for use, no maintenance is required. If faulty parts are found during the functional inspection, please contact an authorized dealer.

8. Storage and disposal

8.1 Storage

8.1.1 Store information

Store the device under specified environmental conditions (see "Appendix A).

8.1.2 Storage of treatment device

●Turn off the treatment machine

●Disconnect the treatment machine from the power supply

●Clean treatment machine, parts and accessories

●Store the treatment machine, parts and accessories in a dry place

8.2Discard

8.2.1E-waste

Do not throw the product into household garbage. Consult an authorized and certified e-waste recycling company on how to properly dispose of these wastes. You can obtain their addresses from environmental protection officials or local governments.

The device packaging (carton and filler) can be disposed of as waste paper.

Risks and hazards of reusing disposable products

Disposable items can only be used once. Reuse of disposable products may be infected and/or damage the functionality of the product, resulting in damage to the patient.

8. 3 FCC Statement

FCC ID: 2ADXK-9001
FCC Warning

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.
Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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

9. Attachment list

Non-invasive Ventilator should be used with the following accessories:

Name	Model	Manufacturer	Remark
Masks	804	HSINER Co., Ltd	CE 2460
Tubes	AT001-70243	HSINER Co., Ltd	CE 2460
Adapter	MDA90B-220S24 -18	Enargy Power (Shenzhen) Co., Ltd	TUV SUD Report No.: 68.270.15.017.01
Power line	E-JUN EJ-601 10A 250V-	Dongguan E-jun Wire Co., Ltd（China）	/

The Useful life of these accessories is detailed in their instructions.

Appendix A Technical Specifications

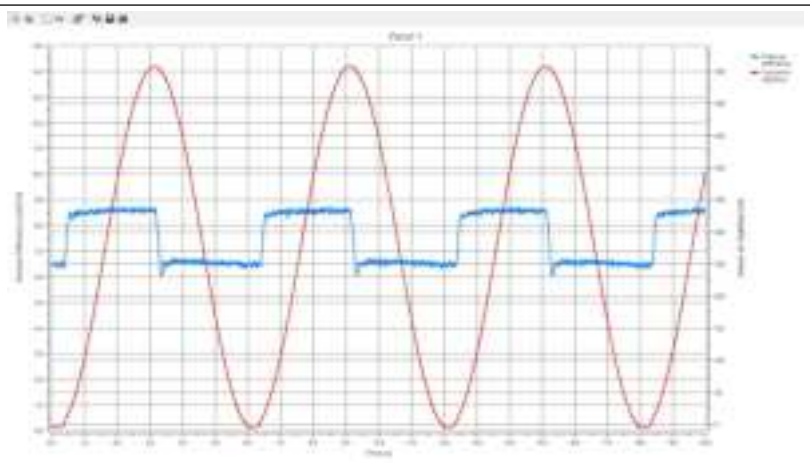
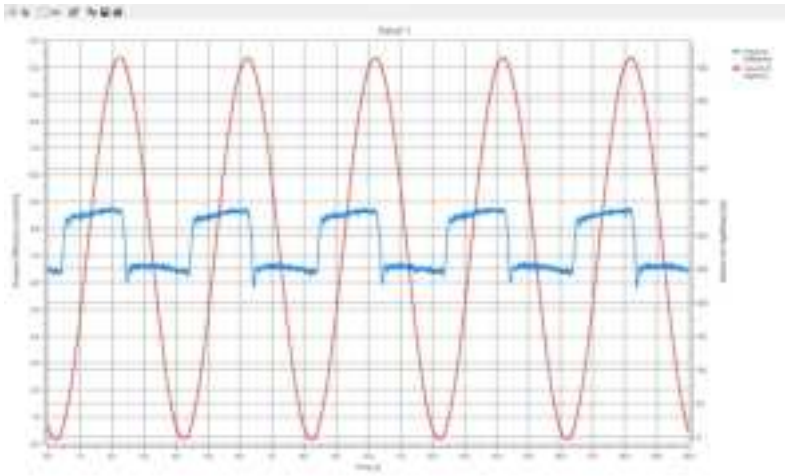
The technical specifications of A1 device are as follows:

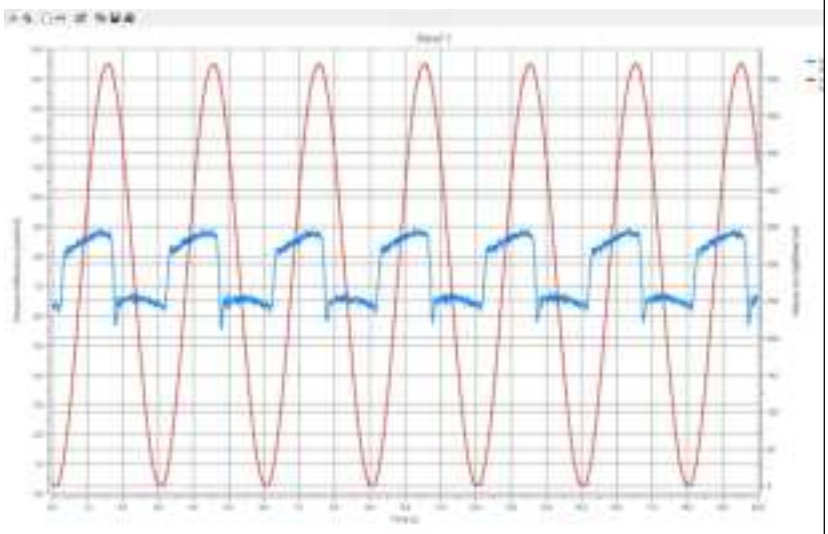
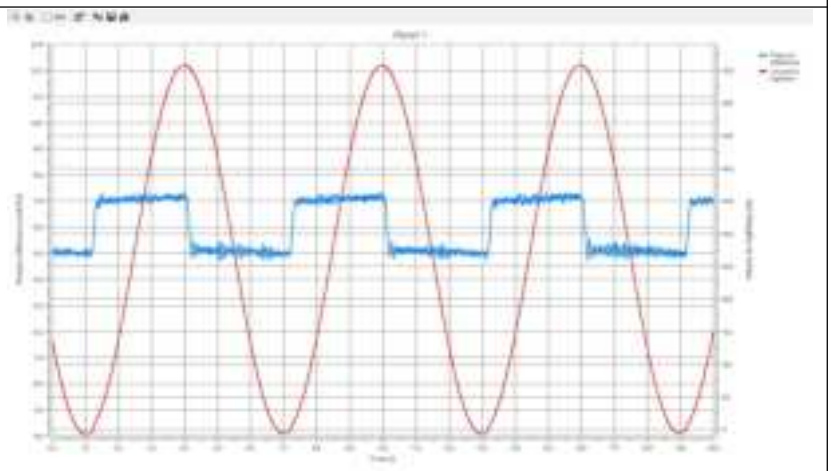
Parameter item		Specifications
Physical properties	Size (length*width*height) mm	270*168*91mm
	Weight	1.6kg
Working environment	Temperature	5ºC ~ 35 ºC
	Relative humidity	10% ~ 95%（Non-condensing）
	Atmospheric pressure	70kPa ~ 106kPa
Storage environment	Temperature	-25ºC ~ 60ºC
	Relative humidity	10% ~ 95%（Non-condensing）
	Atmospheric pressure	70kPa ~ 106kPa
Running noise	A-weighted sound pressure level	≤30 dB(A)
	A-weighted sound power level	≤38 dB(A)
Electromagnetic compatibility	RF emission level	1 group, B grade
Electrical Specifications	AC input	100 -240 V ~ 50/60Hz 2.0A Max
	DC output	3.75A，90W

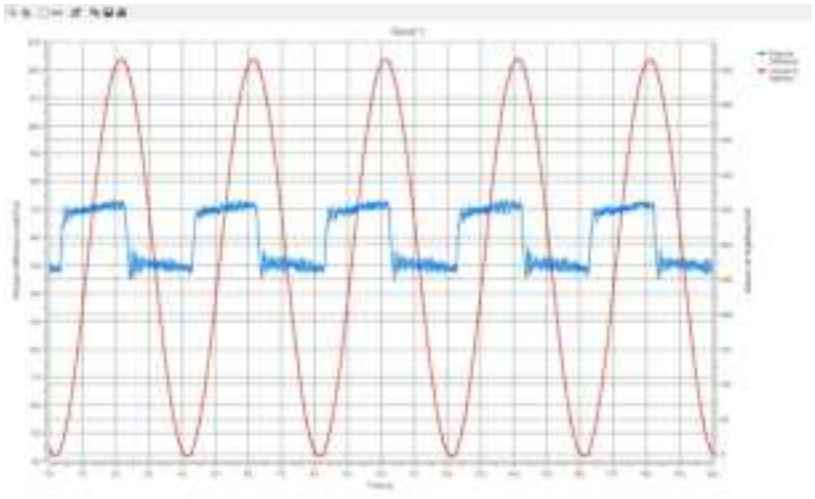
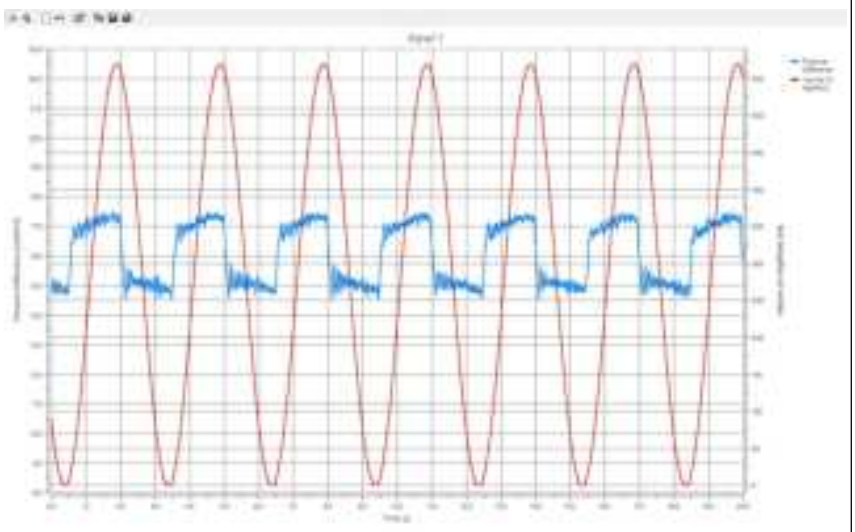
Parameter item		Specifications
Safety features	Electric shock protection type	Class II device
	Electric shock protection level	Type BF
	Operating mode	continuously working
	Waterproof protection level	IP22
	Safety to flammable anesthetic gas	Can not be used in the presence of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide
	Installation and use classification	Portable device
	Power connection	Adapter detachable power cord
Pressure	Setting range	4.0-25cmH_2O (EPAP)
	Maximum ultimate pressure	40cmH_2O(Single failure) 25cmH_2O (Normal status)
	Static pressure control accuracy	±0.5 cmH_2O
	Dynamic pressure control accuracy	±1 cmH_2O
Flow	Maximum flow rate (1/3, 2/3 and maximum value of the maximum adjustable pressure)	8 .5cmH_2O:≥120 L/min; 17 cmH_2O: ≥120L/min 25 cmH_2O: ≥120 L/min
Tidal volume (BTPS)	Tidal volume measurement range	0-3000 mL:±(20% of actual reading) Other scope: no definition
	Tidal volume control	±(50 mL+20% of setting value)

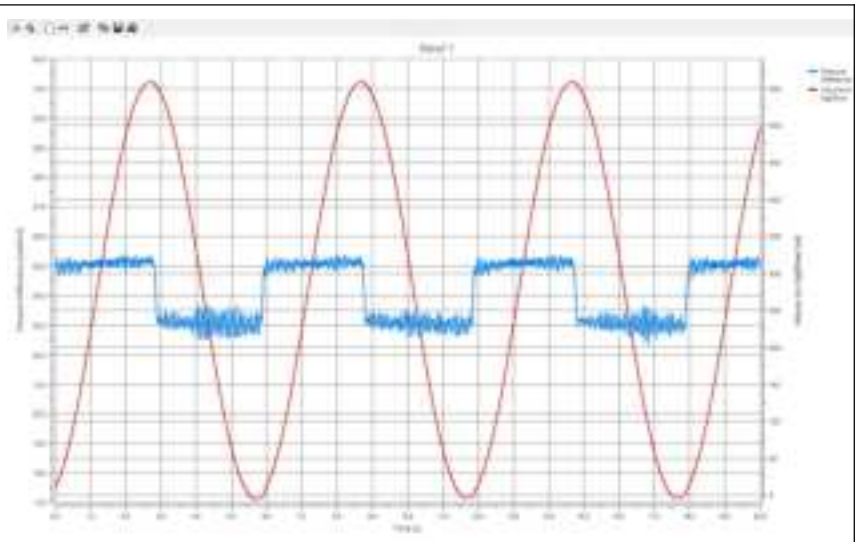
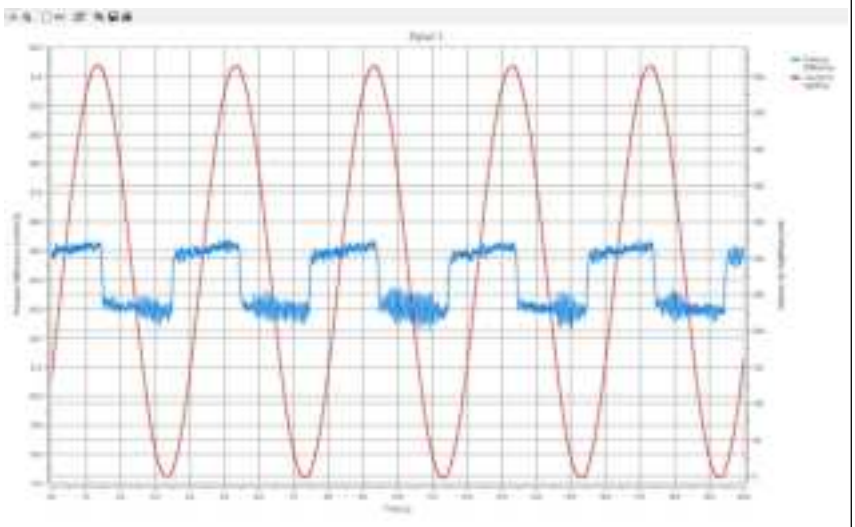
Parameter item		Specifications
	accuracy	
	Minute ventilation measurement range	0-60L/min: ±(20% of actual reading) Other scope: no definition
Humidification system output	Wetting ability	Not less than 10mg/L
	Water storage	260±5ml
	Gas temperature at patient connection	< 43℃
Wireless		Support Bluetooth 4.0BLE
		Support WIFI connection Transmitting frequency or frequency band (MHz): 2412 ~ 2472 Modulation type: DSSS; OFDM Effective radiated power (dBm): 16.49 (IEEE 802.11b), 15.13 (IEEE 802.11g), 14.96 (IEEE 802.11n)
Connect to devices with blood oxygen module via Bluetooth.		Pulse oximeter (Model:Oxiband,Oxiband01), manufactured by Viatom, CE 0197.
Connect to devices with ECG module via Bluetooth.		Dynamic ECG Recorder (Model:ER1), manufactured by Viatom, CE 0197.
Useful life		8 years
Production Date		See the label for details

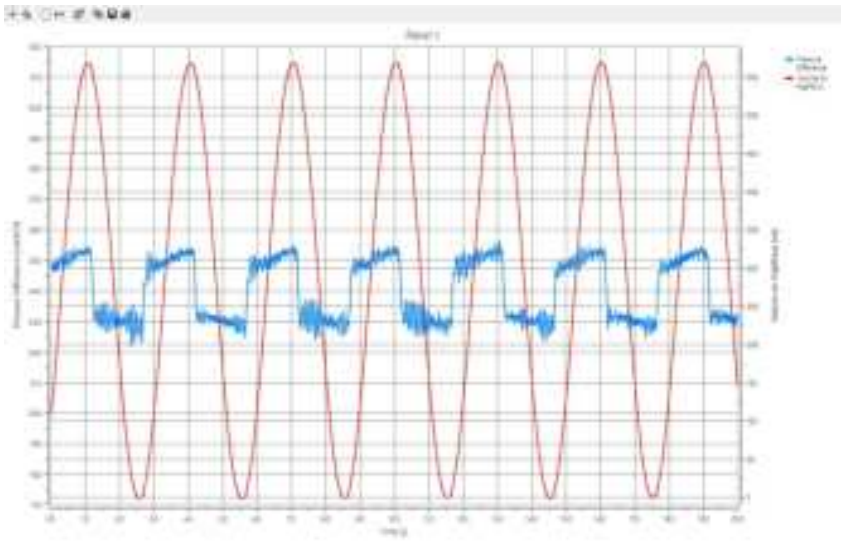
A2 pressure/volume curve and breathing pressure change graph：

	Fractional ratio of maximum adjustable pressure
	1/3 (IPAP：8.5 cmH_2O ； EPAP：6.5 cmH_2O)
f Respiration rate/(number of breaths/min)	10
V_T Tidal volume/ml	500
Pressure/volume curve and breathing pressure Change graph	
	Fractional ratio of maximum adjustable pressure
	1/3 (IPAP：8.5 cmH_2O ； EPAP：6.5 cmH_2O)
f Respiration rate/(number of breaths/min)	15
V_T Tidal volume/ml	500
Pressure/volume curve and breathing pressure	
	Fractional ratio of maximum adjustable pressure
	1/3 (IPAP：8.5 cmH_2O ； EPAP：6.5 cmH_2O)

f Respiration rate/(number of breaths/min)	20
V_T Tidal volume/ml	500
Pressure/volume curve and breathing pressure	
	Fractional ratio of maximum adjustable pressure
	2/3 (IPAP：17 cmH_2O ； EPAP：15 cmH_2O)
f Respiration rate/(number of breaths/min)	10
V_T Tidal volume/ml	500
Pressure/volume curve and breathing pressure	
	Fractional ratio of maximum adjustable pressure
	2/3 (IPAP：17 cmH_2O ； EPAP：15 cmH_2O)
f Respiration rate/(number of breaths/min)	15

V_T Tidal volume/ml	500
Pressure/volume curve and breathing pressure	
	Fractional ratio of maximum adjustable pressure
	2/3 (IPAP：17 cmH_2O ； EPAP：15 cmH_2O)
f Respiration rate/(number of breaths/min)	20
V_T Tidal volume/ml	500
Pressure/volume curve and breathing pressure	
	Fractional ratio of maximum adjustable pressure
	3/3 (IPAP：25 cmH_2O ； EPAP：23 cmH_2O)
f Respiration rate/(number of breaths/min)	10
V_T Tidal volume/ml	500

Pressure/volume curve and breathing pressure	
	Fractional ratio of maximum adjustable pressure
	3/3 (IPAP：25 cmH2O ； EPAP：23 cmH2O)
f Respiration rate/(number of breaths/min)	15
V_T Tidal volume/ml	500
Pressure/volume curve and breathing pressure	
	Fractional ratio of maximum adjustable pressure
	3/3 (IPAP：25 cmH2O ； EPAP：23 cmH2O)
f Respiration rate/(number of breaths/min)	20
V_T Tidal volume/ml	500

Pressure/volume curve and breathing pressure	

Appendix B Electromagnetic compatibility

Guidance and Manufacturer's Declaration - Electromagnetic Emissions: This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The 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 device.
RF emissions CISPR 11	Class B	The 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 IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comples	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity: This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity test	IEC/EN 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic discharge(ESD) IEC/EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 / EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	AC power ("mains") quality should be that of a typical commercial or hospital environment.
Surge IEC / EN 61000-4-5	± 1 kV lines/lines ± 2 kV lines/earth	± 1 kV lines/lines ± 2 kV lines/earth	AC power ("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 / EN 61000-4-11	< 5% U_T (> 95% dip in U_T for 0.5 cycle) 40% UT (60% dip in UT for 5 cycles) 70% UT (30% dip in UT for 25 cycles) < 5% UT (> 95% dip in UT for 5 s)	< 5% UT (> 95% dip in UT for 0.5 cycle) 40% UT (60% dip in UT for 5 cycles) 70% UT (30% dip in UT for 25 cycles) < 5% UT (> 95% dip in UT for 5 s)	AC power (“mains”) power quality should be that of a typical commercial or hospital environment. If the user of the ventilator requires continued operation during power mains interruptions, it is recommended that the ventilator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC/ EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT 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 this device should make sure it is used in such an environment.

Immunity Test	**IEC / EN 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment–Guidance**
Conducted RF IEC / EN 61000-4-6 Radiated RF IEC / EN 61000-4-3	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 10 Vrms inside ISM bands[a] 10 V/m 80 MHz to 2.5 GHz	3 Vrms 150 kHz to 80 MHz outside ISM bands 10 Vrms inside ISM bands 10 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications device should be used no closer to any part of the ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**

			d =0.35 $\sqrt{P}$ d=d=1.2 $\sqrt{P}$ d=1.2 $\sqrt{P}$ 80 MHz to 800 MHz d =2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveyc, should be less than the compliance level in each frequency range[d]. Interference may occur in the vicinity of device marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

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

a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz;
26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz and 2.5 GHz are
intended to decrease the likelihood that mobile/portable communications device could cause interference if it is inadvertently brought
into patient areas. For this reason, an individual factor of 10/3 is used in calculating the recommended separation distance for transmitters in
these frequency ranges.

c Field strength 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 Device is
used exceeds the applicable RF compliance level above, the 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 Device.
d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications device and This Device: The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications device (transmitters) and this device as recommended below, according to the maximum output power of the communications device.

Rated Maximum Output Power of Transmitter (W)	**Separation Distance According to Frequency of Transmitter**			
	150 kHz to 80 MHz (outside ISM bands) $d=0.35\sqrt{P}$	150 kHz to 80 MHz (in ISM bands) $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.035m	0.12m	0.12m	0.23m
0.1	0.11m	0.38m	0.38m	0.73m
1	0.35m	1.2m	1.2m	2.3m
10	1.1m	3.8m	3.8m	7.3m
100	3.5m	12m	12m	23m
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres(m) can be determined 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:

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

• The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz;
13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

• An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications device could cause interference if it is inadvertently brought into patient areas.

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

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PN：92-01650-00 Version: A

Non-invasive Ventilator

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