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- Equipment must be used as instructed in the operating instructions.

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Warranty valid for 18 months after ship date when cargo is picked-up at factory, the components and assemblies of this product is guaranteed to be free from defects manufacturing techniques and materials, provided that the equipment is properly operated under conditions of normal use and that the equipment is regularly maintained per requirements specified by our company. The warranty period for spare parts is three months from shipping date. Consumable parts are not included in this warranty. Our company's obligation under the above warranty is limited to repairing the equipment free of charge.

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- Any Aeonmed product from which Aeonmed 's original serial number tag or product identification markings have been altered or removed;
- Any product of any other manufacturer.

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- This product is not operated correctly in accordance with the manual instruction. The power supply used or operating environment does not follow the requirements in this manual.

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Follow the steps in case that the product needs to be returned to Aeonmed:

1. Obtain the rights of return

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2. Transportation charges

Transportation and insurance charges must be prepaid by the user for transporting the product to Aeonmed for repairing. (Customers charges is added with regard to the products sold to non-Chinese mainland users)

Warning for use

Thank you for purchasing an AEONMED Shangrila510s Ventilator.

In order to use this product correctly and effectively, please read these operating instructions carefully and completely before using the product for the first time.

When using the product, always proceed in accordance with the information provided in these operating instructions as detailed in this user manual.

This product is only for intended use as described in these operating instructions.

Only specially trained service professionals are authorized to perform the connection and service of this product.

For any situation in the use process, please contact with us. We will provide you with warm service.

Product specifications are subject to change without notification.

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Contents

1 Introduction

1.1 Product Description for Shangrila510S

The Shangrila510S ventilator is a pneumatically driven and electrically controlled machine. It can provide patients with mechanical ventilation, and also can monitor and display the ventilation parameters. The ventilator is controlled by microprocessor, equipped with model parameters and waveform monitor, capacity and other optional functions.

⚠**WARNING:** The user of Shangrila510S must be professional and trained.

⚠**WARNING:** Long-term use of the ventilator may become dependent.

⚠**WARNING:** Shangrila510S is unsuitable for use in a magnetic resonance imaging (MRI) environment.

1.1.1 Intended Use

Shangrila510S is intended to be used for adult, child and infant patients weighting over 3.5kg for ventilation assistance and respiratory support in general ward, recovery room and emergency department.

⚠**WARNING:** Shangrila510S is not used for newborn.

⚠**WARNING:** If the ventilator is used for infants, children, please replace the patient circuit for infants and children.

1.1.2 Contraindication

The Shangrila510S ventilator has no contraindications to its use at present.

1.2 Symbols

Instead of illustrations, other symbols may also be utilized. Not all of them may necessarily appear in the equipment and manual. The symbols include:

	Power supply switch		Type B applied part
	Power supply indication		Caution
	Dangerous voltage		Follow operating instructions
	Direct Current		Loudspeaker
	Alternating Current		Serial Number
	Date of manufacture		Manufacturer
	Battery		Alarm Silence Key
	Adult		Child
	Infant		Mode
	Inspiratory hold		Menu

	Manual		

1.3 Warnings and Cautions

⚠**WARNING** and ⚠**CAUTION** indicate all the possible dangers in case of violation of the stipulations in this manual. Refer to and follow them.

⚠**WARNING:** indicates potential hazards to operators or patients

⚠**CAUTION:** indicates potential damage to equipment

1.3.1 Warnings

⚠**WARNING:** Do not use the system until you have read and understood this manual including:

• All connections of the system

• All warnings and cautions

• Operation procedure of each and every component of the system

• Test procedure of each and every component of the system

⚠**WARNING:** Before using the ventilator, carry out pre-use inspection according to Chapter 4 of this manual and use it only after the function is confirmed to be normal. The user is responsible for the consequences of using the function without performing the function confirmation.

⚠**WARNING:** Every 6 months after use, the ventilator needs a comprehensive preventive maintenance.

⚠**WARNING:** To ensure proper servicing and avoid the possibility of physical injury, only qualified personnel should attempt to service or make authorized modifications to the ventilator.

⚠**WARNING:** 510S ventilator is not intended to be a comprehensive monitoring device and does not activate alarms for all types of dangerous conditions for patients on life-support equipment.

⚠**WARNING:** Patients on life-support equipment must be appropriately monitored by competent medical personnel and suitable monitoring devices at all times.

⚠**WARNING:** Patients on ventilator should be appropriately monitored by competent medical personnel and suitable monitoring devices.

⚠**WARNING:** Ensure that inspiratory and expiratory circuits are connected to the correct port before operation of equipment.

⚠**WARNING:** Disposable breathing hoses must not be reused. Reuse of the single use hoses can cause cross infection.

⚠**WARNING:** Ensure that all hosing equipment used with the device has the appropriate resistance and compliance to ensure proper therapy.

⚠**WARNING:** The ventilator must not be connected to any anti-static or electrically conductive hoses, tubing or conduit.

⚠**WARNING:** Make sure gas cylinders are connected with a sufficient amount of gas and the Battery module is functioning. Follow the hospital guidelines.

⚠**WARNING:** Use caution when handling flammable or fragile components.

⚠**WARNING:** Do not place containers of liquids (such as humidifier water reservoirs) on top of or above ventilator. Liquids getting into the ventilator can cause equipment malfunction with the risk of patient injury.

⚠**WARNING:** Using ventilator at an environment beyond the operating environment requirement may cause the tidal volume and airway pressure inaccurate so much as the ventilator cannot work.

⚠**WARNING:** Outside the environmental and supply conditions specified but within the limits declared, the ventilator cannot cause a safety hazard to the patient or operator.

1.3.2 Cautions

⚠**CAUTION:** If the system test fails, do not use the system. Attempt to troubleshoot and fix the failure. If you are unable to fix the device, ask an authorized service representative to repair the device.

⚠**CAUTION:** Check the ventilator periodically as outlined in this manual; do not use if defective. Immediately replace parts that are broken, missing, obviously worn, distorted, or contaminated.

⚠**CAUTION:** Do not put ventilator into service until the patient setup is complete.

⚠**CAUTION:** Measurements can be affected by mobile and RF communications equipment.

⚠**CAUTION:** Do not use oxygen hoses that are worn, frayed, or contaminated by combustible materials such as grease or oils. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen.

⚠**CAUTION:** Follow your hospital infection control guidelines for handling infectious material. Aeonmed recognizes that cleaning, sterilization, sanitation, and disinfection practices vary widely among health care institutions. It is not possible for Aeonmed to specify or require specific practices that will meet all needs, or to be responsible for the effectiveness of cleaning, sterilization, and other practices carried out in the patient care setting.

⚠**CAUTION:** Equipment not suitable for use in the presence of a Flammable Anesthetic mixture with Air or with Oxygen or Nitrous Oxide.

⚠**CAUTION:** To avoid an electrical shock hazard while servicing the ventilator, be sure to remove all power to the ventilator by disconnecting the power source and turning off all ventilator power switches.

⚠**CAUTION:** To avoid a fire hazard, keep matches, lighted cigarettes, and all other sources of ignition (e.g., flammable anesthetics and/or heaters) away from 510S ventilator and oxygen hoses.

⚠**CAUTION:** In case of fire or a burning odor, immediately disconnect the ventilator from the oxygen supply, facility power and backup power source.

⚠**CAUTION:** Do not use 510S ventilator in an MRI environment.

⚠**CAUTION:** Do not use sharp objects to make selections on the LCD touch screen or panel.

⚠**CAUTION:** Batteries should be removed if equipment will not be in service for more than 6 months. See Section 7.4 for maintaining battery.

⚠**CAUTION:** Do not immerse the oxygen sensor or the connector in any type of liquid.

⚠ **CAUTION:** When ventilator is exposed to conditions outside normal operating environments, allow 24 hours in normal environment before using.

⚠**CAUTION:** Do not connect items that are not specified as part of the system.

⚠**CAUTION:** The software development process complies with EN 62304.

⚠**CAUTION:** All volume, flow and ventilation specifications have been tested under ATPD.

1.4 Frequently Used Functions

(1) Power On / Off Switch
(2) Patient connection and hoses gas supply
(3) Settings
(4) Start Ventilation
(5) Monitoring data
(6) Alarms
(7) Calibration
(8) Cleaning and disinfection
(9) Breathing Circuit Components

(10) System interconnections for gas supply

1.5 Definitions, Acronyms, and Abbreviations

CPAP	Continuous Positive Airway Pressure (setting)
F	Respiratory rate, i.e. breaths per minute (setting)
f_{total}	Total respiratory rate, i.e. sum of and f_{spont} (monitored)
FiO_2	Delivered oxygen percentage (setting and monitored data)
I : E	Inspiration to expiration time, I to E ratio, (monitored)
MV	Exhaled minute volume (monitored)
Paw	Patient airway pressure
PEEP	Positive end expiratory pressure (setting and monitored data)
P_{INSP}	Inspiratory airway pressure in PCV (setting)
P_{peak}	Maximum patient airway pressure during a patient breath (monitored)
P_{sens}	Pressure sensitivity (setting)
P_{SUPP}	Pressure support (setting)
T_P	Inspiratory pause time; increase inspiration time to facilitate increased patient oxygenation (setting)
V_{sens}	Flow sensitivity (setting)
V_T	Tidal volume of mechanically delivered breaths (setting)

2 Structure

⚠**CAUTION:** The conditions of parameters monitoring in this system are as follows: the environment temperature: 23 ℃; gas temperature 25 ℃; humidity: 50%; Gas: oxygen.

⚠**WARNING:** Do not use antistatic or electrically-conductive breathing tubes and mask.

2.1 510S Profile

Figure 2-1

1	Main unit	2	Bag	3	Silicone threaded tube
4	Silica gel tube	5	Flow sampling pipe		

2.2 Front Panel

The front panel is composed of display area, function keys, free to define keys, knob, indicator light and power switch.

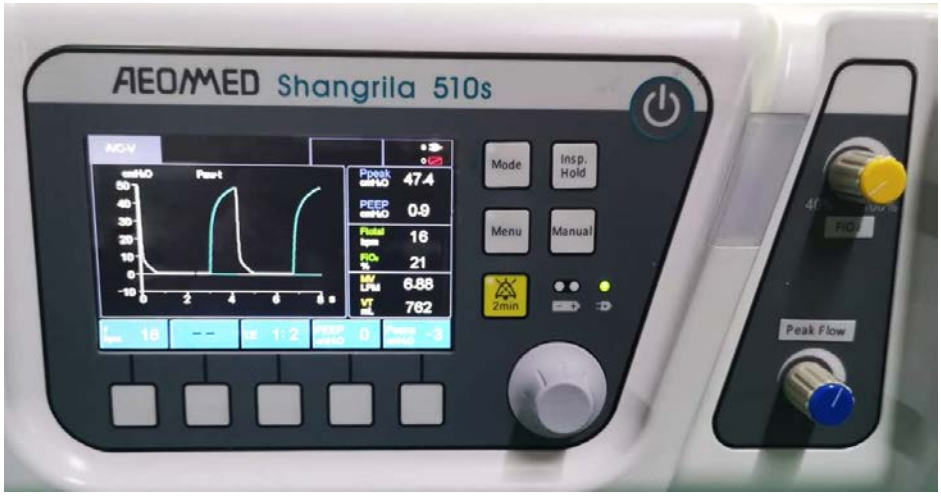


Figure 2-2

1. Display area

The windows of follow figure is display area, it contains: Patient Type, Patient Measured Parameters, Alarm Messages, AC and Battery indicators, Waveforms etc.

Figure 2-3

2. Function keys

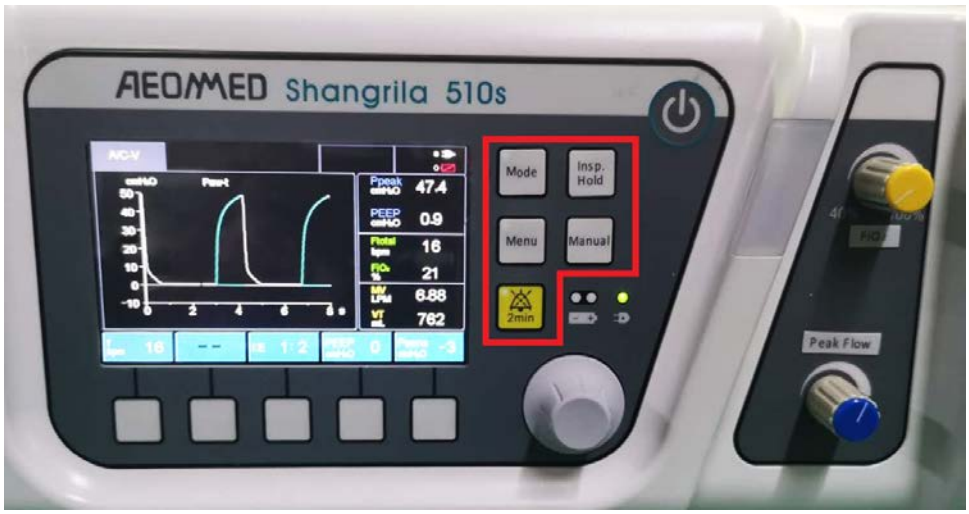


Figure 2-4

In Figure 2-4, the part of the rectangle is function keys, include:

	mode：	six ventilation modes，that is 【A/C-V】,【SIMV-V】,【SPONT/PSV】,【A/C-P】（optional）,【CPAP】（optional）,【SIMV-P】（optional）。
	Inspiratory Hold：	Press the Inspiratory Hold key during the Inspiratory phase, the expiratory phase will not start until the key is released or after 15 seconds.
	menu：	It can set parameters, alarm and system.
	Manual：	Manual Trigger is available in all ventilation modes. Press the manual trigger key to initiate a manual breath.
	Alarm silence key：	Turns off alarm sound for 2 minutes except Air & O_2 supply down alarm and Battery Exhausted.

3. Free to define keys

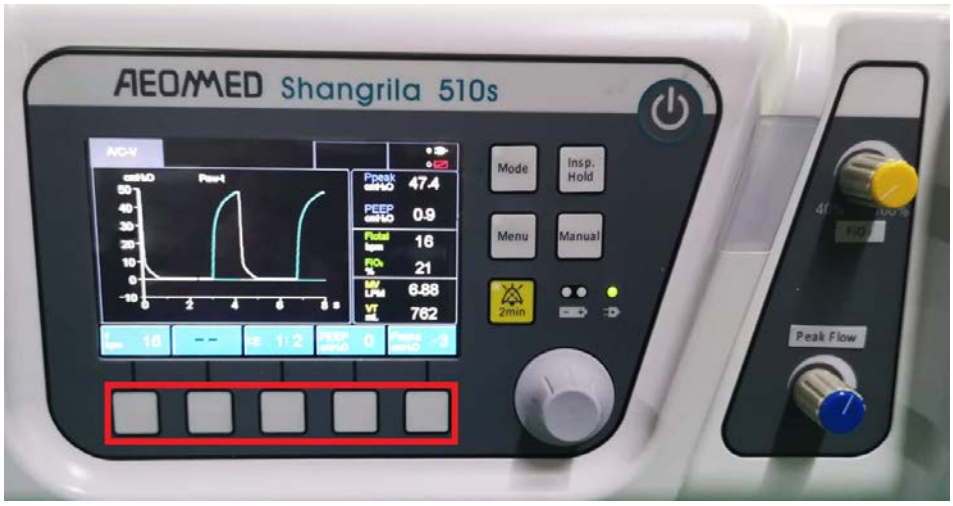


Figure 2-5

⚠**CAUTION:** If the [Psens] key is depressed the mode will change to [Vsens].

4. Knobs

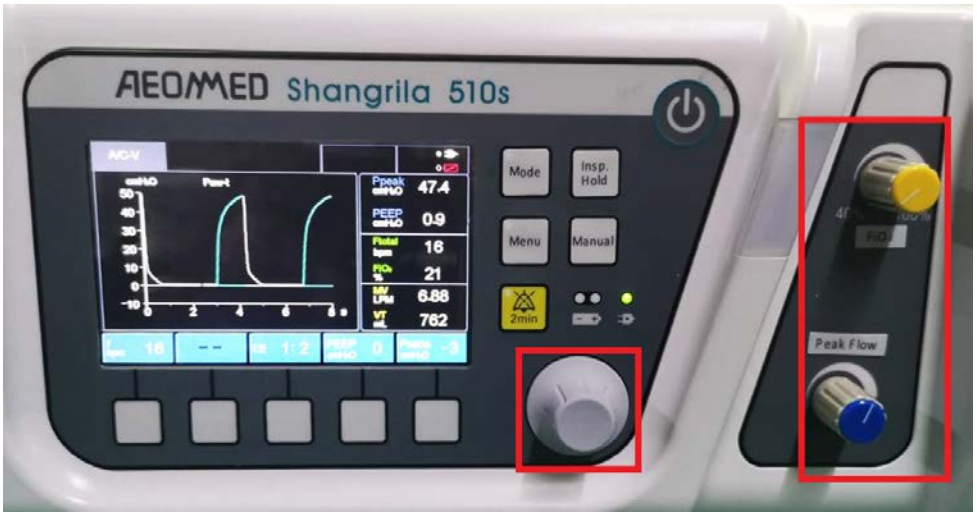


Figure 2-6

	knob：	Adjusts the value of a setting.

	FiO_2:	Adjust the oxygen concentration of the machine
	Peak Flow setting:	Adjust the flow rate to control the tidal volume of the machine

⚠**CAUTION:** Do not overexert when you adjust the knobs.

5. Indicator light and power switch

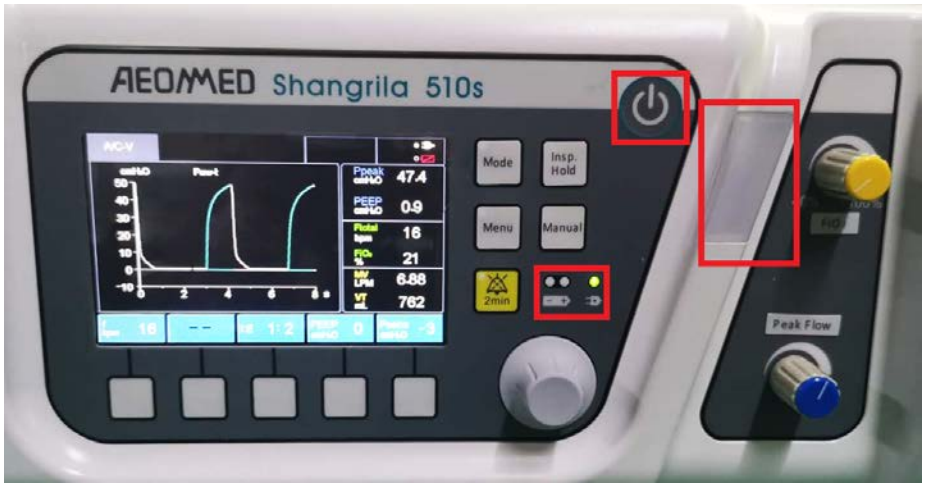


Figure 2-7

	Power switch:	Press power switch, the machine will enter starting up test.
	Battery indicator:	Indicate the work status of the battery
	Power indicator:	When the ventilator connected power, the lamp lights
	Alarm indicator:	When the alarm occurs, the lamp lights

2.3 Right Side Panel

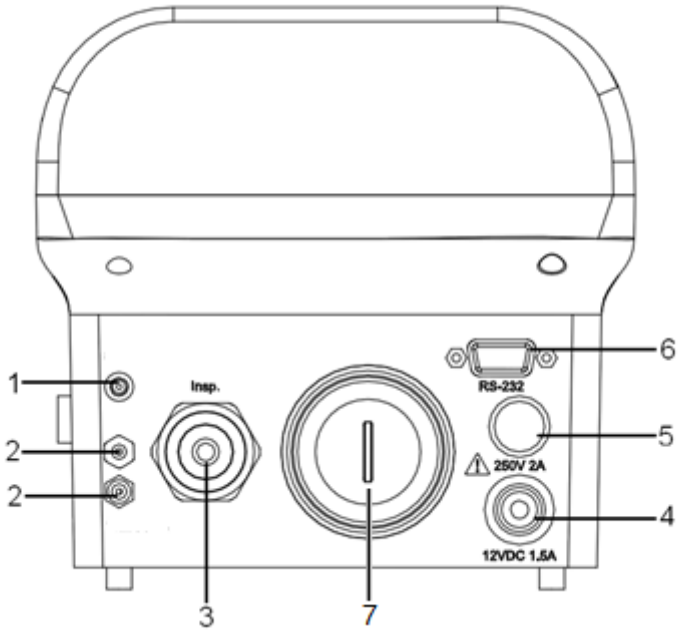


Figure 2-8

1	Control port	2	Flow sampling port （optional）	3	Inspiratory port
4	Power socket	5	Fuse	6	RS232 interface
7	O_2 sensor port				

Control port: It can control the open and close of the expiration valve.

Flow sampling port: is located at the closest position to the patient inspiration end, so it can provide accurate monitoring of VT and MV.

Inspiratory port：The gas from ventilator enters into inspiratory pipe through Inspiratory port.

Power socket：It is the power input port, and through the power adapter connected to 220 V AC power source. It can also be directly connected to the 12 V car power if used as a transport ventilator.

Fuse：Prevent excessive current damage equipment.

RS232 interface：The communications interface provides an RS-232 port for connection to patient data management system (PDMS), or other computer system. It can transmit data from the ventilator to a PDMS or other computer system through its RS-232 connector.

O_2 sensor port: Installing O_2 sensor, O_2 sensor is used to measure O_2 concentration.

⚠**CAUTION:** The equipment which connects the ventilator by RS232 port, must comply with IEC60601-1.

2.4 Left Side Panel

In the left-hand side panel of the ventilator, there is a window which can open. This is the internal battery replace window. Open this window to replace internal battery. The details will be displayed in Part 7.4.

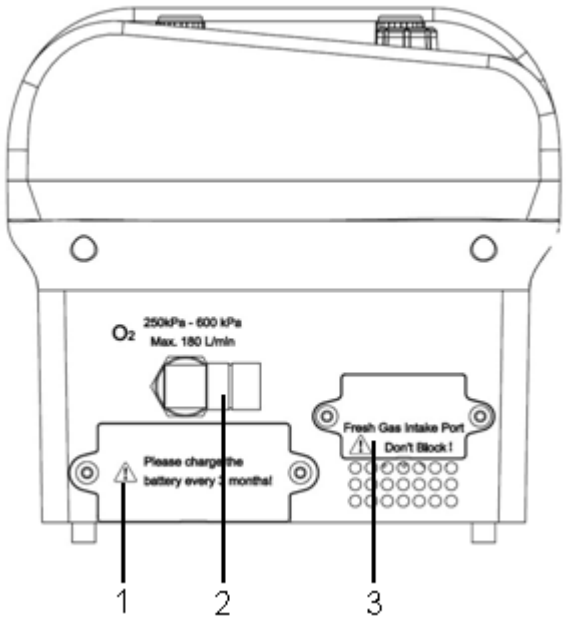


Figure 2-9

1. Internal battery replace window: Open this window to replace internal battery
2. Oxygen intake: Through the connection-peg, oxygen (after decompression) is transported.
3. Fresh Gas Intake: The intake of fresh gas, do not block.

2.5 Back Side Panel

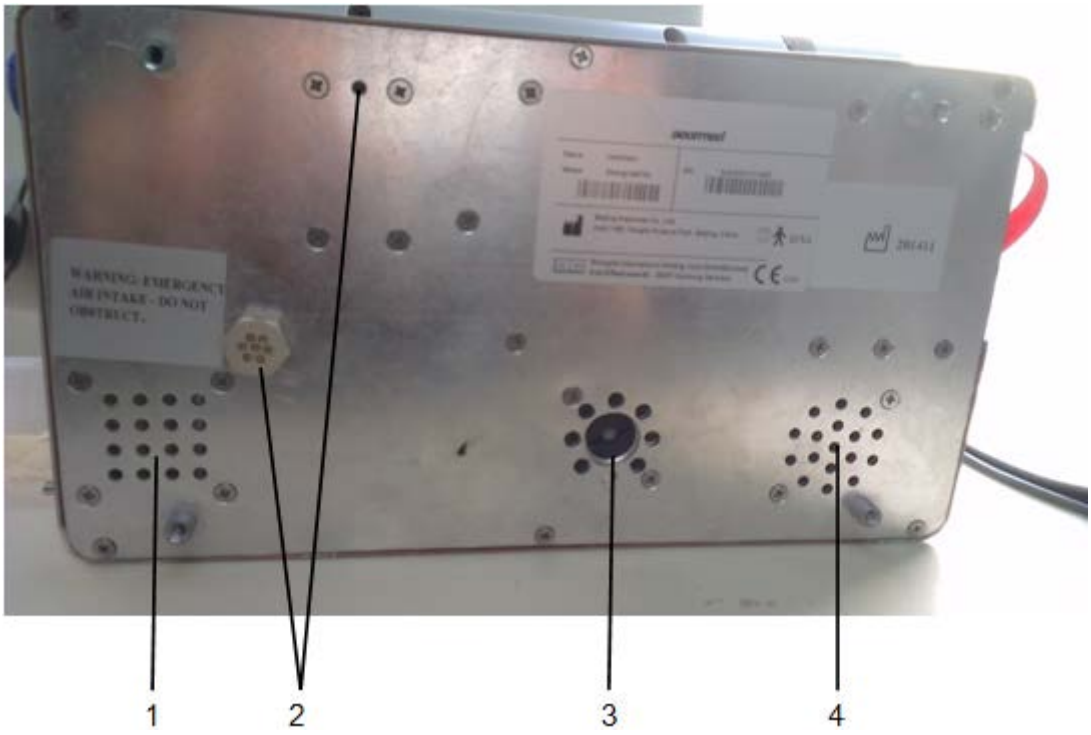


Figure 2-10

1. Emergency air intake：Do not obstruct.
2. Exhaust port：Do not obstruct.
3. Safety valve
4. Buzzer

3 Operating Guide

⚠WARNING:

- Do not connect to the patient before finish the patient setting.
- This ventilator was designed for patient safety and security, but always monitor the patient's clinical state in conjunction with the ventilator display and settings.

⚠CAUTION:

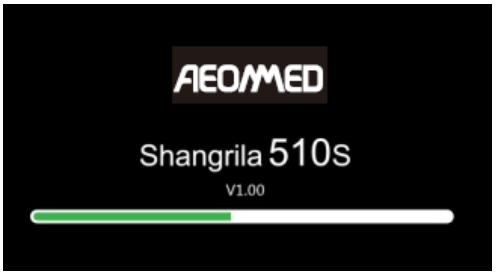
- Do not overexert when you adjust the knobs. If any knobs fail to work, stop using the ventilator immediately. Contact your service representative if necessary.
- If you find some monitor data is not accurate, firstly check your patient, then check the ventilator's function and work state.

3.1 Starting System

Connect power supply

Plug the power supply cable into power adapter. The power indicator light will turn green.

Press the power switch "  " on the front panel, the ventilator is started, then enter starting-up test, as shown in the right figure.



If starting-up mode fails then an error code will appear in red,as shown in the right figure.

If starting-up is passed, display shows the patient type [adult], [children], [infant]. According to the situation of the patient choose patient type. See right figure

3.2 Setup Ventilation Mode

Step 1：

Press the MODE key, enter **[mode]** interface, as shown in the right figure.

Step 2：

Turn the knob, move to 【A/C-P】 key of interface, press knob, enter into 【A/C-P】mode interface, as shown in the right figure.

Step 3：

Turn the knob and select “Yes”, then press knob. The setting of 【A/C-P】 mode is finished now.

⚠**CAUTION:** If the knob is not pressed at the end, the system will go back to the original after 10 seconds, the new setting will have no effect.

Setting method about other ventilation mode is similar to above.

3.3 Ventilation Mode Introduction

3.3.1 A/C

In A/C mode, the ventilator delivers only mandatory breaths. When the ventilator detects patient inspiratory effort, it delivers a patient-initiated mandatory (PIM) breathe (also called an assisted breath). If the ventilator does not detect inspiratory effort, it delivers a ventilator-initiated mandatory (VIM) breath (also called a control breath) at an interval based on the set respiratory rate. Breaths can be pressure- or flow-triggered in A/C mode.

Figure 3-1 shows A/C breath delivery when no patient inspiratory effort is detected and all inspirations are VIMs. And Tb is the breath period in seconds.

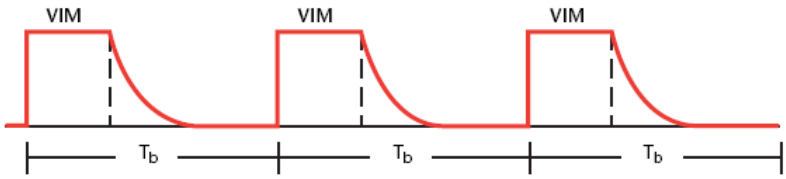


Figure 3-1 A/C mode, no patient effort detected

Figure 3-2 shows A/C breath delivery when patient inspiratory effort is detected. The ventilator delivers PIM breath at a rate more than the set respiratory rate. And Tb is the breath period in seconds.

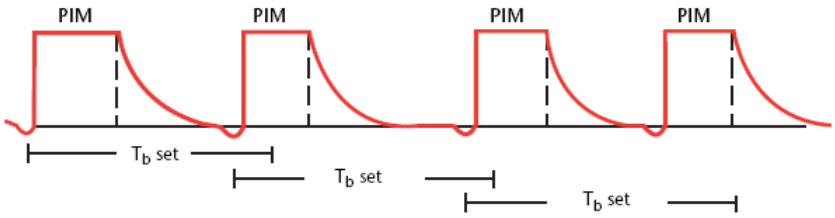


Figure 3-2 A/C mode, patient effort detected

Figure 3-3 shows A/C breath delivery when there is a combination of VIM and PIM breaths. And Tb is the breath period in seconds.

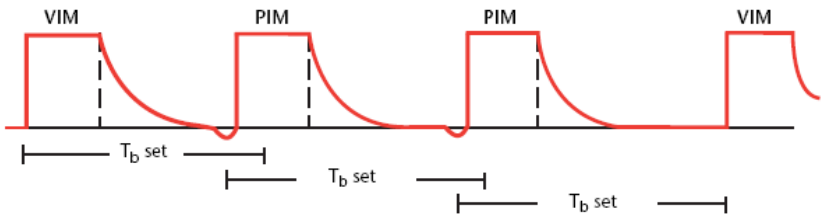


Figure 3-3 A/C mode VIM and PIM breaths

⚠**CAUTION:** Setting of trigger pressure' false or ability for breath of patient intensify may lead to A/C mode delivers too much.

3.3.2 A/C-V

A/C-V (Volume Control Ventilation) is mandatory ventilation with preset respiratory frequency and tidal volume. When ventilator detects patient's spontaneous breath, it will work according to the above settings.
Tidal volume adjustment: according to the frequency and I:E set by the ventilator , observe the VT monitoring value on the screen, and adjust the VT to the expected value by adjusting the peak flow.

⚠**CAUTION:** When the flow rate is constant,changing the frequency or I:E will affect the tidal volume.

⚠**CAUTION:** When the flow rate is constant,adjusting PEEP will affect the tidal volume.

⚠**CAUTION:** When the flow rate is constant,changing the compliance and resistance will affect the tidal volume.

3.3.3 A/C-P

PCV (Pressure Control Ventilation) is mandatory ventilation with preset respiratory frequency and pressure limit. When ventilator detects patient's spontaneous breath, it will work according to the above settings.

3.3.4 A/C+SIGH

A/C+SIGH, base on A/C mode. The difference is a high tidal volume (1.5 times as set) delivers every 100 breaths. It is suitable for patients who need mechanical ventilation for a long time, and can also be used for "lung expansion" of thoracic surgery.During "lung expansion", due to the continuous sighing several times, medical staff need to switch back and forth between the A/C and A/C+SIGH ventilation modes several times. When sighing, due to the doubling of tidal volume and the increase of the peak value of airway pressure, the upper limit setting value of airway pressure should be increased, that is, 1kPa higher than the peak pressure when sighing, and other parameter settings are the same as A/C.

3.3.5 SIMV

SIMV (Synchronized Intermittent Mandatory Ventilation) is a mixed ventilator mode that allows both mandatory and spontaneous breaths. The mandatory breaths can be volume or pressure-based, and the spontaneous breaths can be pressure-assisted (for example, when pressure support is in effect.) You can select pressure- or flow-triggering in SIMV.

The SIMV algorithm is designed to guarantee one mandatory breath each SIMV breath cycle. This mandatory breath is either a patient-initiated mandatory (PIM) breath (also called an

assisted breath) or a ventilator-initiated mandatory (VIM) breath (in case the patient's inspiratory effort is not sensed within the breath cycle).

As shown in Figure 3-4, each SIMV breath cycle (Tb) has two parts: the first part of the cycle is the mandatory interval (Tm) and is reserved for a PIM. If a PIM is delivered, the Tm interval ends and the ventilator switches to the second part of the cycle, the spontaneous interval (Ts), which is reserved for spontaneous breathing throughout the remainder of the breath cycle. At the end of an SIMV breath cycle, the cycle repeats. If a PIM is not delivered, the ventilator delivers a VIM at the mandatory interval, then switches to the spontaneous interval.

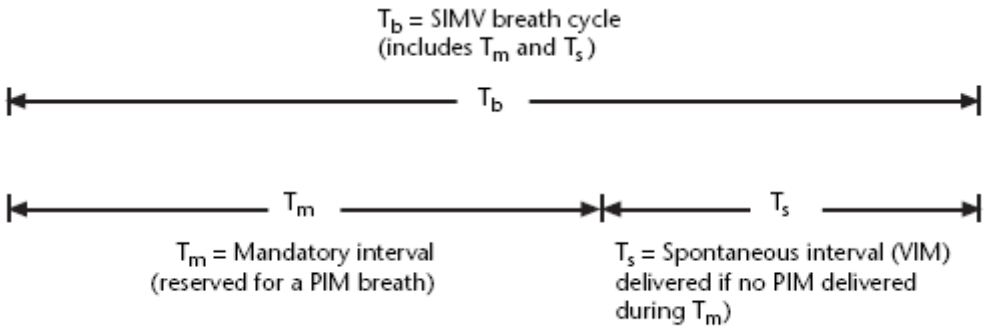


Figure 3-4 SIMV breath cycle (mandatory and spontaneous intervals)

⚠**WARNING:** This mode may cause insufficient ventilation or and cause the patient to become hypoxic.

3.3.6 CPAP

CPAP (Continuous Positive Airway Pressure), the ventilator delivers a continuous flow that always maintains positive pressure flow, throughout inspiration phase of ventilation.

3.3.7 SPONT

In SPONT (spontaneous) mode, inspiration is usually initiated by patient effort. Breaths are initiated via pressure or flow triggering, whichever is currently active. An operator can also initiate a manual inspiration during SPONT.

3.4 Parameter Settings

Press the menu key " 

" on the front panel, Turn the knob, move to 【Parameter settings】 key, press knob, enter into 【Parameter settings】 interface.

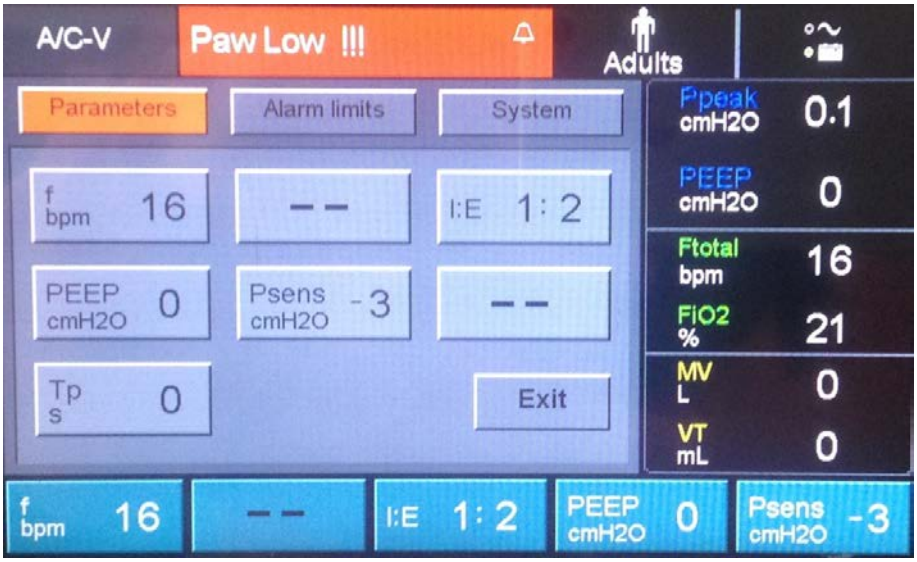


Figure 3-5

Press the free to define key of【f】,【f】turns yellow，as shown in the below figure.

Figure 3-6

Rotate the knob to adjust value until the wanted, and then press it again to confirm.

Figure 3-7

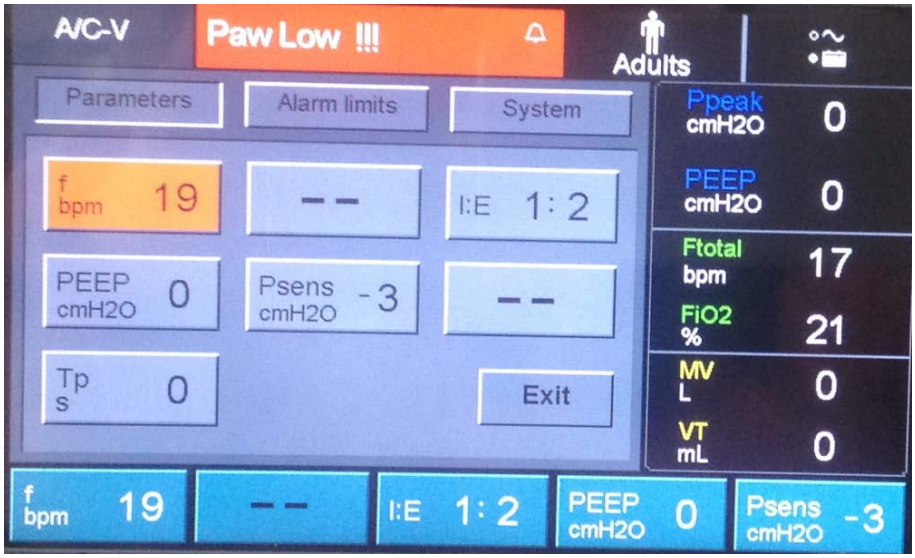


Figure 3-8

Setting procedure about other parameters is similar to one above. When ventilation mode is changed, the values of the parameter keys displayed will change to correspond to the new ventilation mode.

⚠**CAUTION:** If the knob is not pressed for confirmation, the previous value will be displayed.

The following conditions should be noticed in parameter setting:

a) Pressure parameter setting is subject to high pressure limit.

b) When setting up the P_{SUPP} and P_{INSP} parameters need peak flow knob adjustment.

c) P_{SUPP} and P_{INSP} are relative pressure to PEEP.

3.5 Alarm Settings

There are the following parameters can be set:

Alarm parameter	Meaning	unit
MV	Minute volume upper limit and lower limit	L
Paw	Airway pressure upper limit and lower limit	0.1kPa
FiO_2	Oxygen concentration upper limit and lower limit	——

Setting method as shown in the following:

Press the menu key " 

" on the front panel, Turn the knob, move to 【Alarm limits】 key, press knob, enter into 【Alarm limits】 interface.

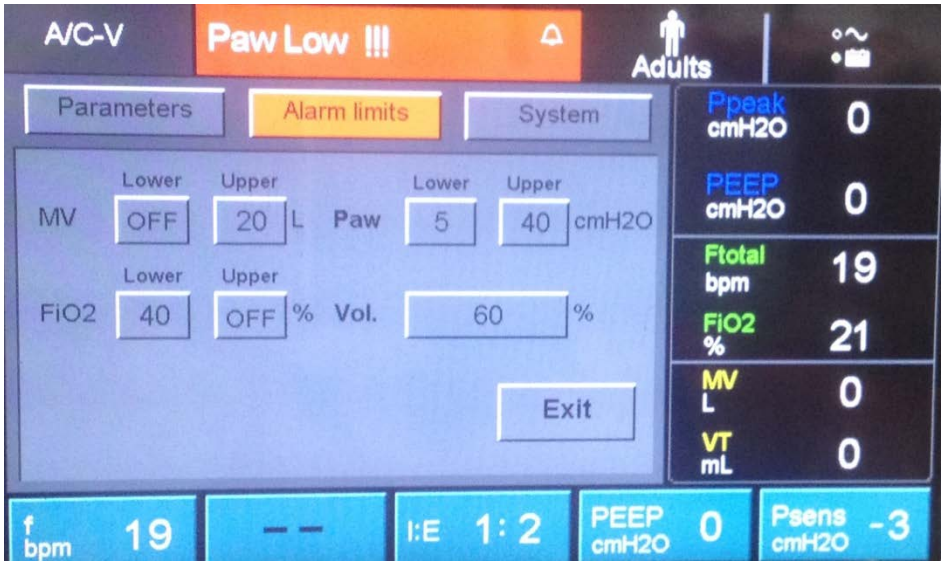


Figure 3-9

Rotate the knob to adjust alarm parameter until the wanted, and then press it again to confirm.

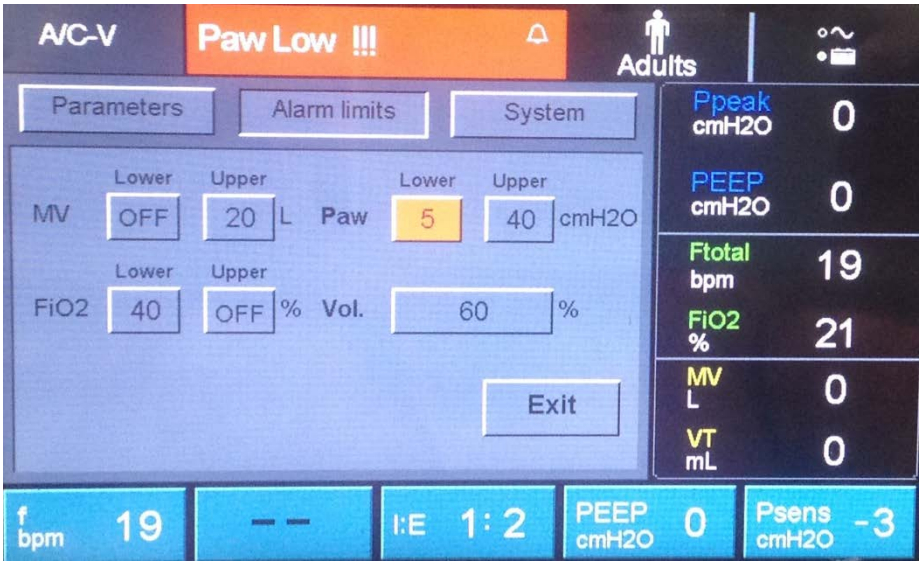


Figure 3-10

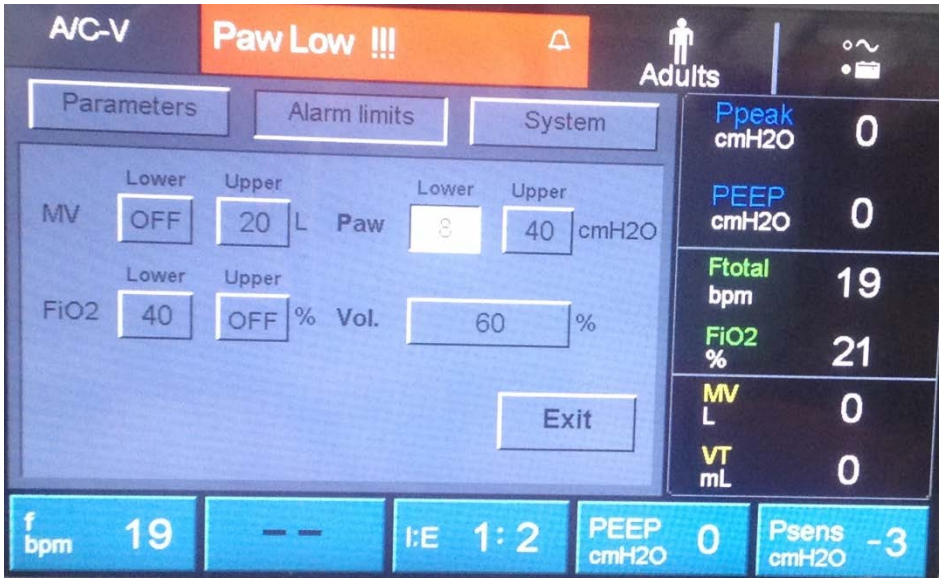


Figure 3-11

Turn the knob to select appropriate value and depress the knob..

Figure 3-12

⚠**CAUTION:** If “Accept” is not clicked, the screen will return to the main menu after 10 seconds, and the last setup changes made will have no effect.

⚠**CAUTION:** In the case of an alarm during operation, the following scenarios may have occurred:

Improper breathing parameter setting or alarm limit setting;

1. Leakage in patient circuit; turn off the machine first and then check. In case of no resolution, contact service representative.
2. Problems with patient;
3. Power supply failure or ventilator failure.

If the alarm and fault is not obvious, diagnose the patient first, then if no abnormal reaction, proceed to review and eliminate the alarm cause on the ventilator at the same time.

⚠**CAUTION:** Do not set alarm limit parameter to extreme values that can render the alarm system useless.

⚠**WARNING:** A potential hazard can exist if different ALARM PRESETS are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theatre.

⚠**CAUTION:** All alarm limit setting parameters are retained during power interruption and can be restored when power returns.

3.6 System

Press the menu key “ 

” on the front panel, Turn the knob, move to 【System】 key, press knob, enter into 【System】 interface.

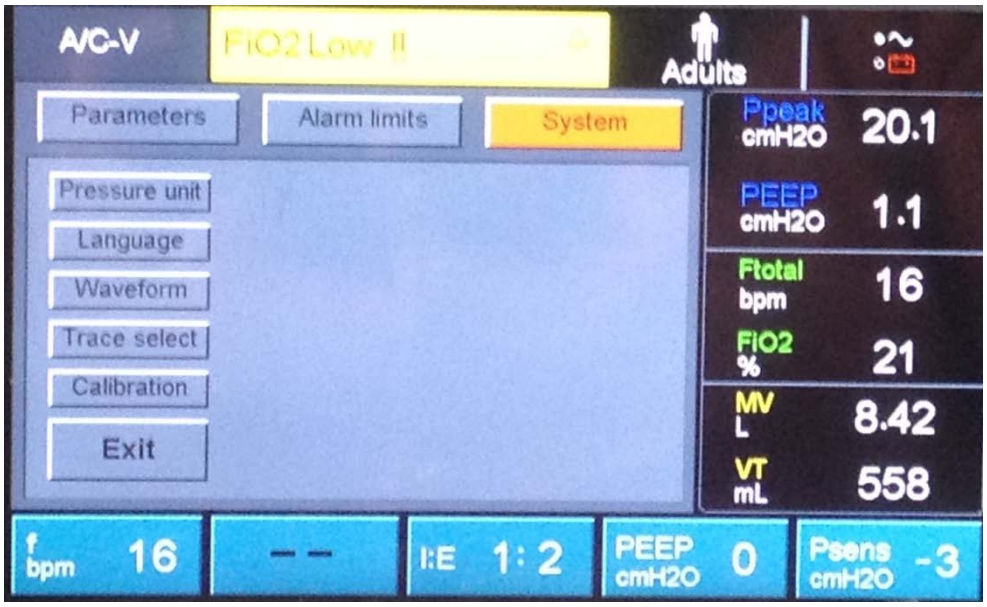


Figure 3-13

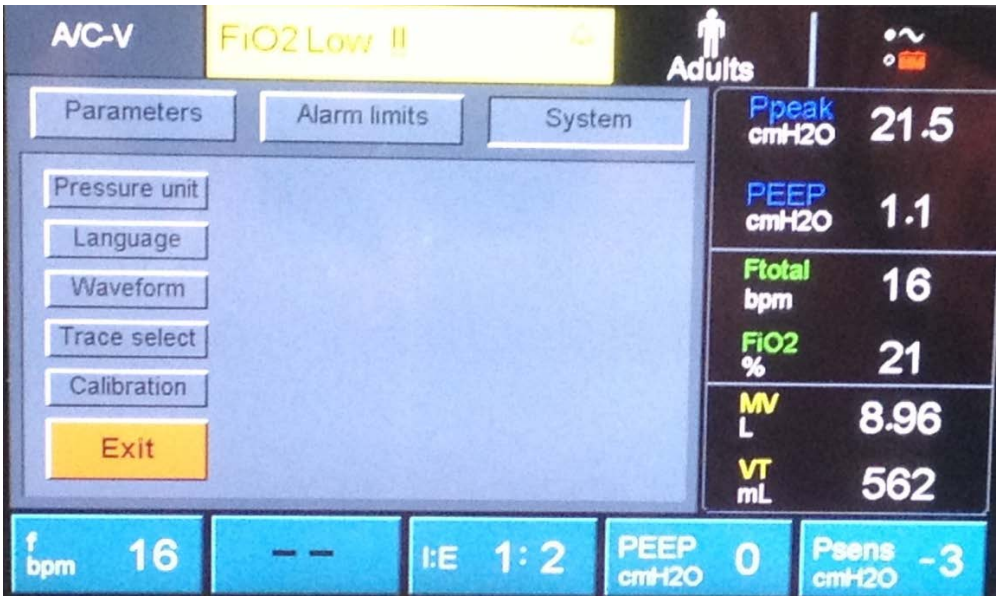


Figure 3-14

3.6.1 Unit

Turn the knob, move to 【Unit】 key, press knob, enter into 【Unit】 interface.

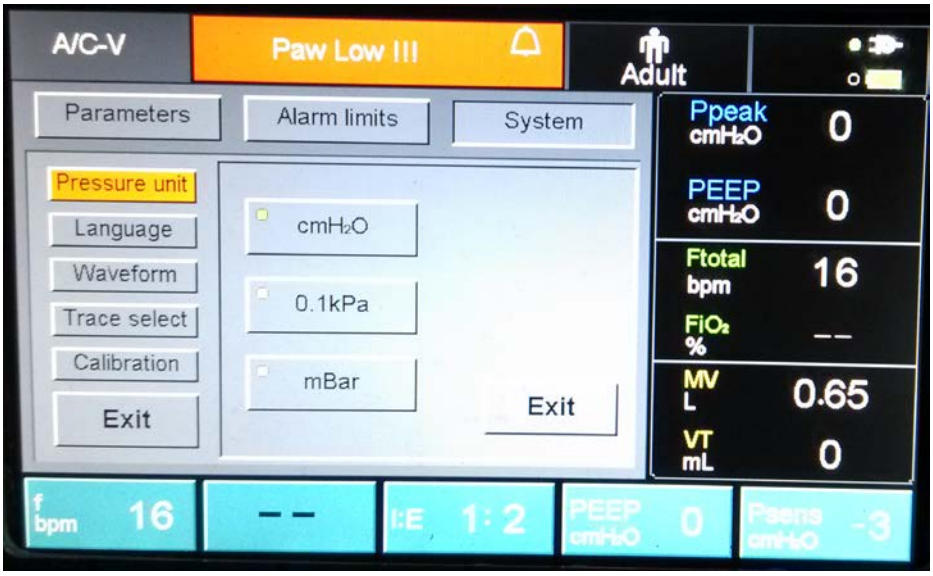


Figure 3-15

Unit: cmH_2O、0.1kPa、mBar.

When pressure unit changed, the Y-axis unit of waveforms changed in-phase and keep identical.

3.6.2 Language

Turn the knob, move to 【Language】 key, press knob, enter into 【Language】 interface.

Figure 3-16

Language：Chinese, English, Spanish, and so on.

3.6.3 Waveform

Turn the knob, move to 【Waveform】 key and press knob, enter into 【Waveform】 interface.

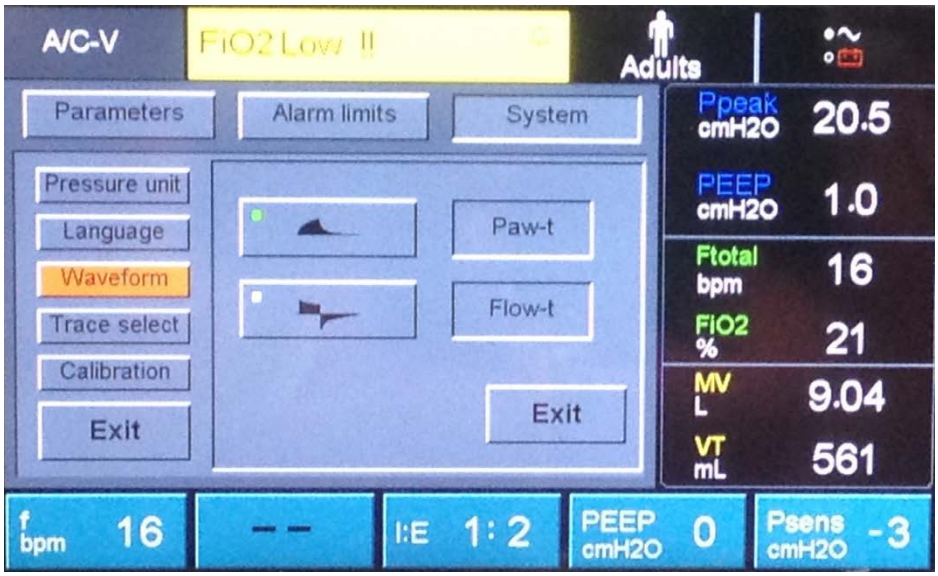


Figure 3-17

Waveform style: Paw-t and Flow-t.

3.6.4 Trace Select

Turn the knob, move to 【Trace select】 key and press knob, enter into 【Trace select】 interface.

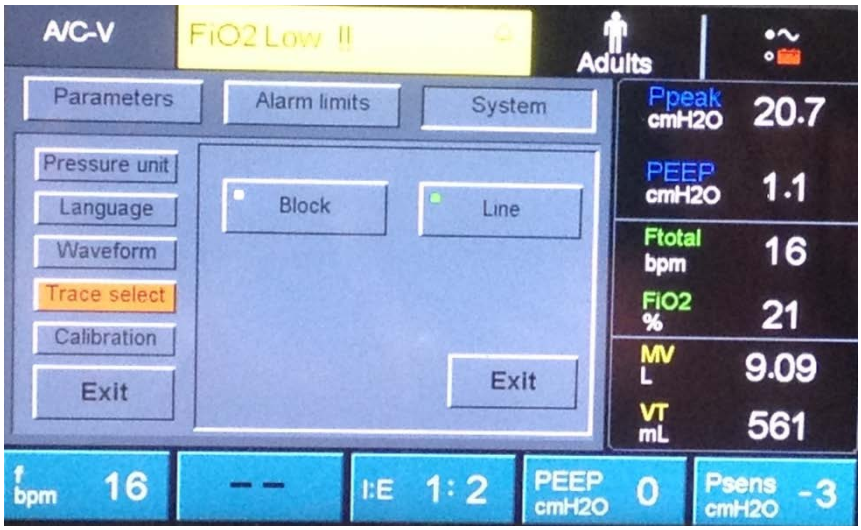


Figure 3-18

Waveforms two types: Block and Line.

3.6.5 Calibration

Turn the knob, move to【Calibration】key and press knob, enter into【Calibration】interface.

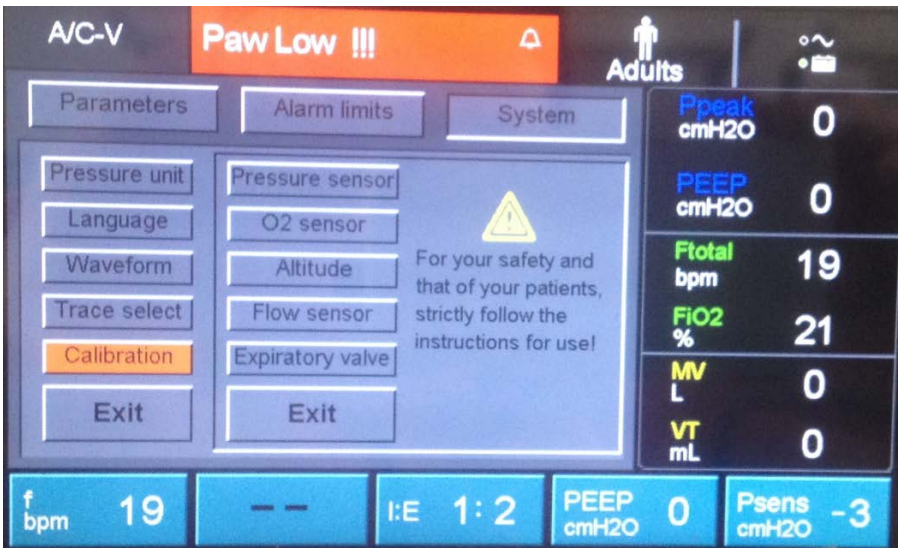


Figure 3-19

The calibration choices include: Pressure Sensor Calibration, O_2 Sensor Calibration, elevation compensation, Flow Sensor Calibration, Expiratory Valve Calibration.

3.6.5.1 Pressure Sensor Calibration

Press “Pressure Sensor” to enter the calibration interface. A message is displayed: “To offset zero of pressure sensor, please remove the circuit from the ventilator.”

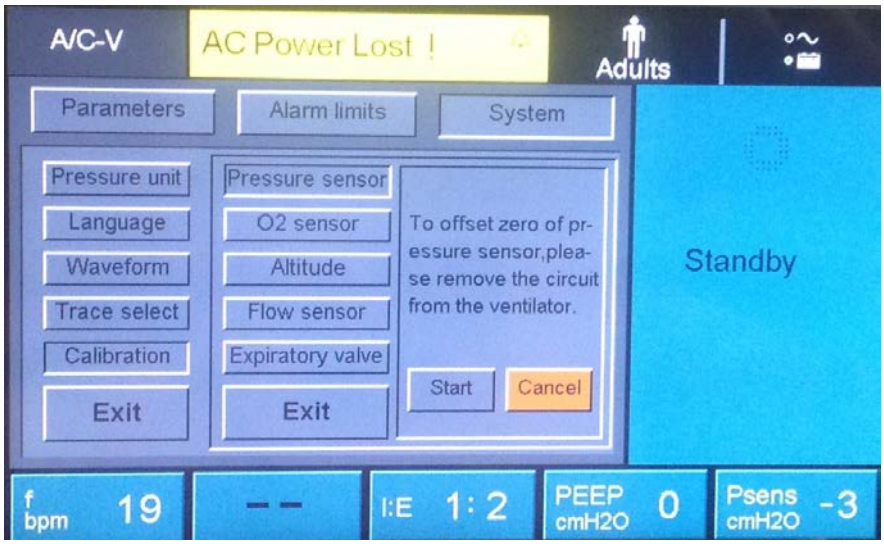


Figure 3-20

Press “Start” to start pressure sensor calibration. A progress bar will be displayed. After calibration, the result will appear: Calibration succeeded or Calibration failed. If failed, restart the calibration.

⚠**NOTE:** During this period no, other operation can be performed. Clicking other areas will have no response.

Calibration succeeded，appear “Calibration completed”, as shown in the below figure.

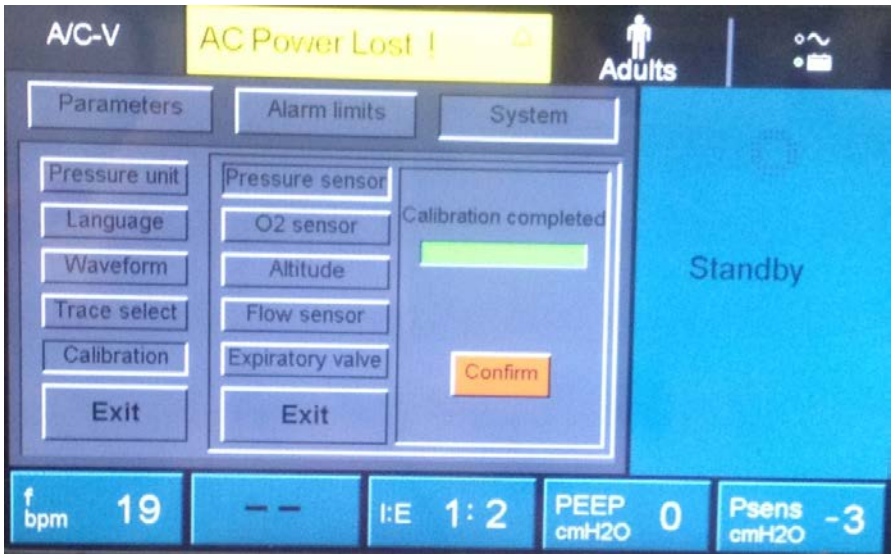


Figure 3-21

3.6.5.2 O_2 Sensor Calibration

Press “O_2 Sensor” to enter the interface. There are two keys below the legend: “21%” and “100%”. Choose the needed one and press, as shown in Figure 3-22. The remaining procedure is the same as described above.

⚠**NOTE:** When calibrating 21% oxygen concentration, please put the oxygen sensor in the air for at least 3 minutes. When calibrating 100% oxygen concentration, please set the oxygen concentration knob of the ventilator to 100% scale.

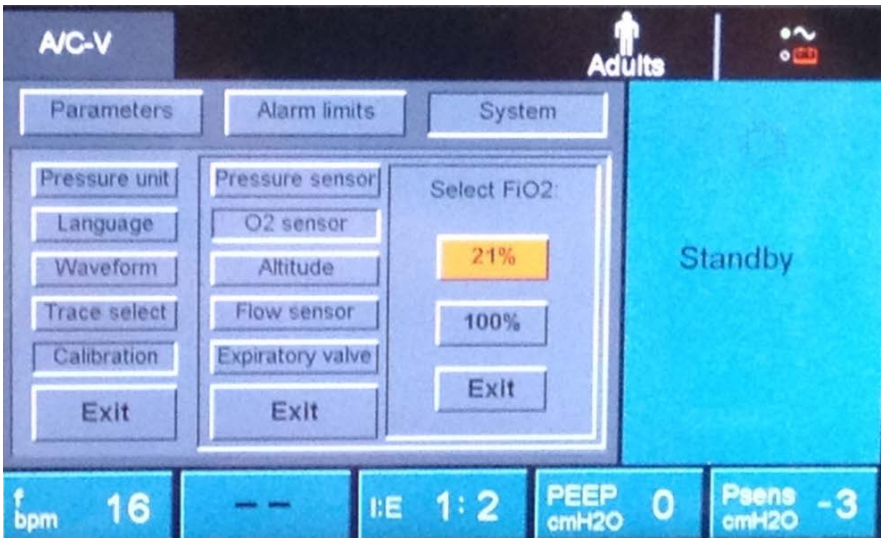


Figure 3-22

"21%" calibration: remove the oxygen battery from the gas circuit of the ventilator, put it in the air for at least 3 minutes, press the “shuttle button” to confirm, and the ventilator will perform the calibration.

"100%" calibration:

1. After 21% calibration, return the oxygen sensor back to the ventilator.
2. In A/C-V mode, use the test lung or white air resistance connector of the ventilator self-contained.
3. Adjust the oxygen concentration knob to 100%.
4. Adjust the flow rate knob to adjust the tidal volume value to 600-700mL .
5. Keep the relevant settings, and enter into the "100%" calibration interface.
6. Press the “shuttle button” for confirmation.
7. Connect the gas resistance of the ventilator self-contained to the suction port of the ventilator after 3 seconds of ventilation.
8. Perform the calibration, as shown in Figure 3-23.

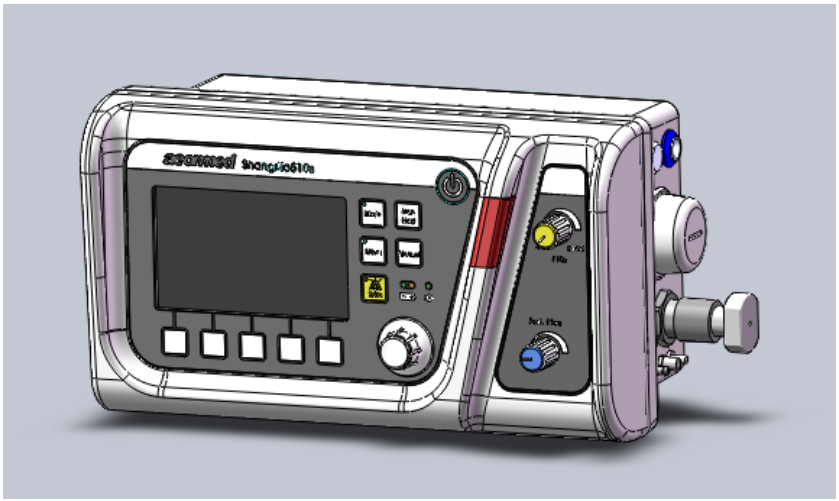


Figure 3-23

⚠**NOTE:** Please disconnect the wiring plug when disassembling the oxygen concentration sensor and be careful not to damage the wiring.

3.6.5.3 Flow Sensor

Press “Flow Sensor” to enter the interface. A message is displayed: “To offset zero of flow sensor, please remove the circuit from the ventilator.” as shown in Figure 3-24.

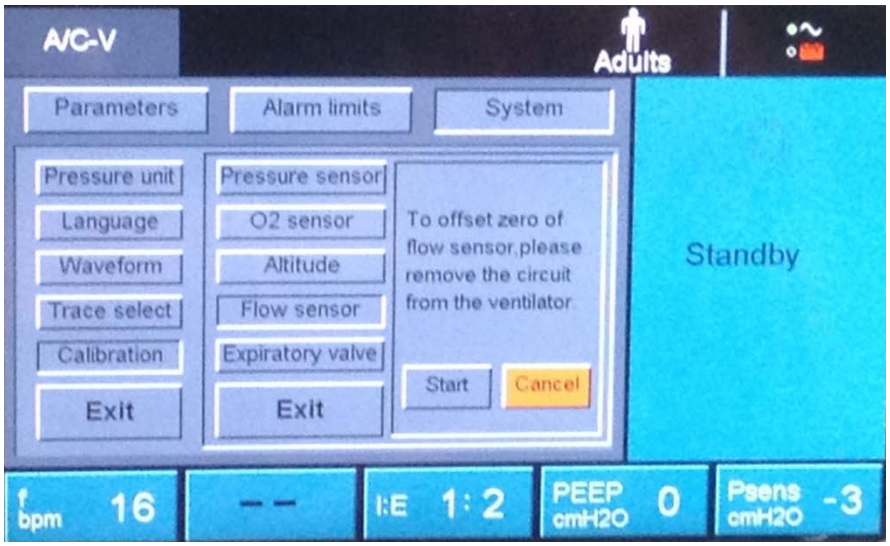


Figure 3-24

Press the “Start” button to start flow sensor calibration, the remainder of procedure should be the same as the pressure sensor calibration.

3.6.5.4 Expiratory Valve

Press “Expiratory Valve” to enter the interface. A message is displayed: “Please connect the circuit before calibration” as shown in Figure 3-25.

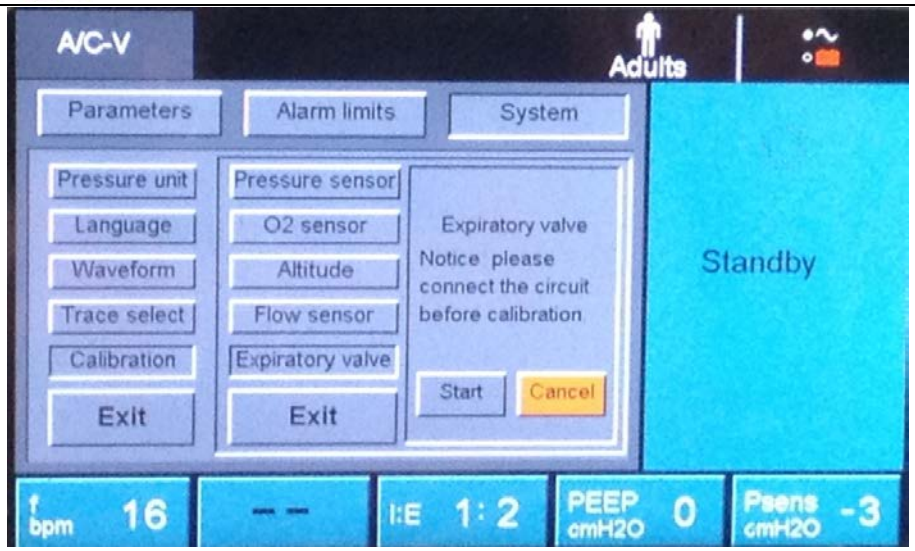


Figure 3-25

Connect the breathing circuit, connect the gas resistance connector of the ventilator self-contained to the test lung, and adjust the flow rate knob to about 3/4 of the full range.

Press the “Start” button to start Expiratory Valve Calibration, the remaining procedure is the same as the pressure sensor calibration.

⚠**NOTE:** The use of the ventilator self-contained test lung calibration must be equipped with self-contained gas resistance connector.

3.6.5.5 Altitude

Press “Altitude” to enter the interface, as shown in Figure 3-26.

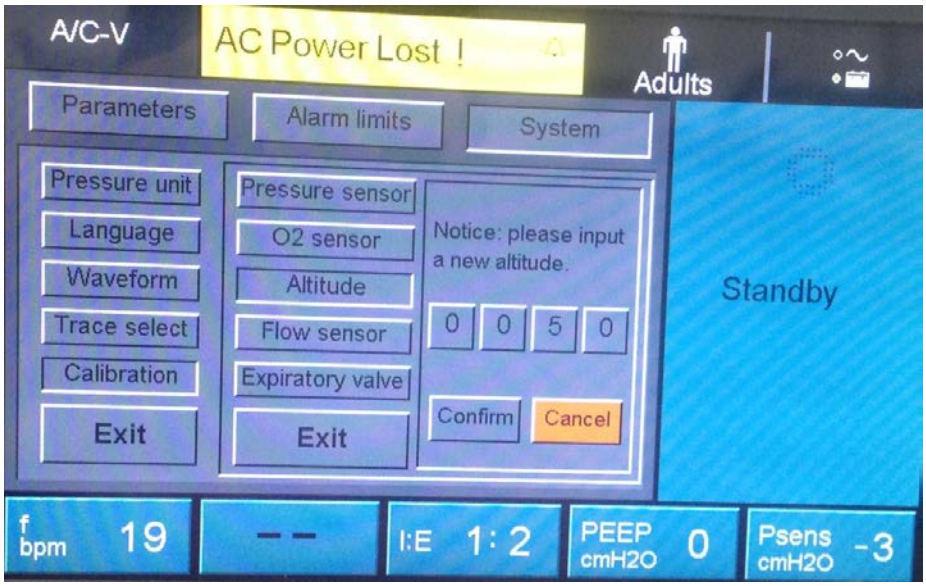


Figure 3-26

A message box appears. Input desired new altitude in the message box then press knob to confirm it.

Figure 3-27

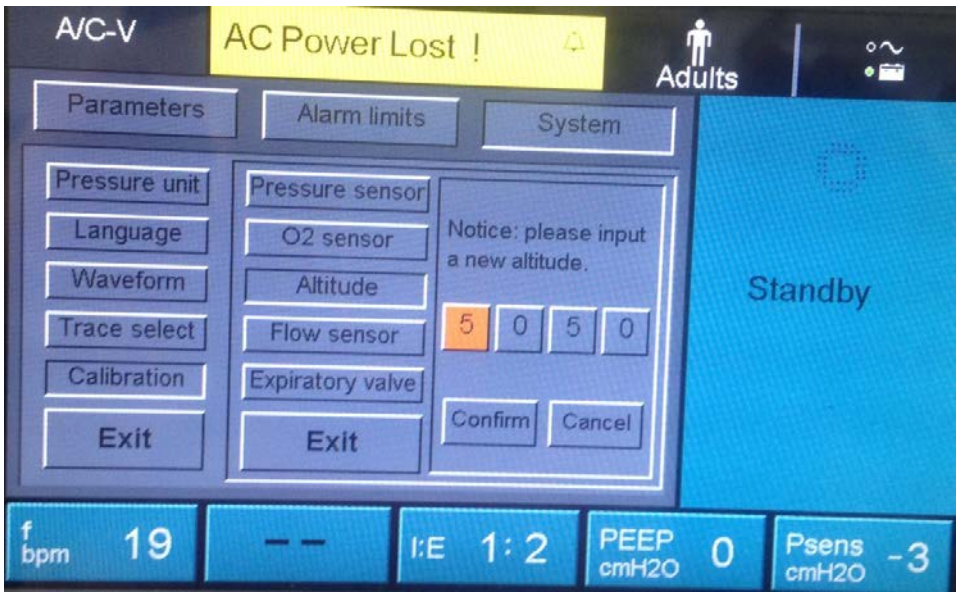


Figure 3-28

⚠**NOTE:** The altitude measurement is meters.

3.7 Patient Data Menu

This area displays all of the monitored patient parameters including VT, MV, PEEP, Ppeak, Ftotal, FiO_2.

Figure 3-29

3.8 Turn off the Ventilator

(1) Disconnect the breathing hoses from the patient.

(2) Turn off the power switch.

(3) Disconnect the gas supply.

(4) Disconnect the power adapter from the power supply.

⚠**NOTE:** The detachable power supply cable is used to isolate its circuits electrically from the AC supply on all poles simultaneously.

4 Pre-use Test

4.1 AC Failure Alarm Test

1. Turn on power switch “  ” on the front panel, the ventilator is started,enters into A/C ventilation mode interface after self-test.
2. After the ventilator operates for five minutes, pull out power cord.
3. Make sure that power failure alarm occurs(alarm bell sounds; the yellow alarm indicator light is on; “AC Failure!” message displays on the top screen).
4. Reconnect power cord.
5. Make sure the alarm is eliminated.

4.2 Alarm Test

1. Apnea alarm test

Set ventilation mode to SPONT, the sound and light alarm occurs after 12s~18s, and the ventilator turns to A/C mode automatically.

2. External power failure alarm test

External Power failure and alarm test steps below:

a. Turn on the power switch
b. The ventilator is started and enters the ventilation mode interface. The ventilator works in the standard state, after operating 5 minutes, pull out power cord to ensure that power failure alarm occurs
c. Reconnect the power cord to ensure that the alarm is eliminated.

3. Airway pressure upper alarm function test

The ventilator works in the standard state,adjust the tidal volume to make the peak value of airway pressure indication about 2.5kPa,adjust the upper pressure limit value in the alarm setting area,when the pressure upper limit value is slightly lower than 2.5kPa, there should be a sound and light alarm, at this time, the ventilator switches to expiration phase immediately, the airway pressure drops accordingly.

4. Airway pressure lower alarm function test

The ventilator works in the standard state,adjust the tidal volume to make the peak value of airway pressure indication about 2.5kPa,adjust the lower pressure limit value in the alarm setting area, when the pressure lower limit value is slightly higher than 2.5kPa, there should be a sound and light alarm.

5. Low Oxygen Concentration Alarm FunctionTest

The ventilator works in the standard state, Ventilation for more than 2 minutes,after the oxygen concentration monitoring is stable, adjust the oxygen concentration lower limit value in the alarm setting area,the oxygen concentration lower limit value is slightly higher than the monitoring value of the ventilator, and there should be a sound and light alarm.

4.3 Breathing System Test

⚠**WARNING:** Failure to ensure correct setup and operation before use can result in patient injury.

1. Check the work state of the ventilator

Standard adult work state of the ventilator settings below:

Ventilation mode	A/C-V
Rates of breath:	16bmp
I:E	1:2
V_T	600mL
Psens	-0.3kPa
FiO_2	40%

2. Tidal volume test

After starting the ventilator, connect the test lung, observe the tidal volume display in the parameter monitoring area of the front panel, where the tidal volume display should be consistent with the value measured by the ventilation meter.

3. Trigger pressure function test

Let the ventilator work at a standard work state,set the PEEP value at 3cmH_2O,set the trigger pressure value at -0.1cmH_2O,disconnect the test lung,then the ventilator ventilation will be triggered,meanwhile the “trigger indicator light” on the front panel flashes.

4. SIMV

Set ventilation mode to SIMV, change the breathing rates, see the display of “ftotal” for 1 minute this should reflect setting made by user.

5. SIGH

Let the ventilator work at a standard work state, record the tidal volume. Then change ventilation mode to SIGH, adjust the airway upper limit pressure to maximum, see the display of the tidal volume data, it should 1.5 time as normal the second time respiration takes place. This happens every 100 times, during this ventilation mode.

6. System Test

Enter into the system setting interface, select system calibration, and then carry out system calibration for the ventilator according to chapter 3.6.5 of this manual,all system calibration can be completed.

5 Connection

⚠**WARNING:** To prevent generating wrong data and malfunction, please use the cables, hoses, and tubes from Aeonmed.

⚠**WARNING:** The operator will have to ensure that the inspiratory and expiratory resistances are not exceeded when adding attachments or other components or sub-assemblies to the breathing system.

⚠**CAUTION:** To avoid equipment false alarm caused by high strength electric field:

- Put the electricity surgical conducting wire far from the breathing system.
- Do not put the electricity surgical conducting wire on any parts of the anesthetic system.

⚠**CAUTION:** Please pay attention to the flow label of the expiration valve.

⚠**CAUTION:** To protect the patient, as the electricity surgical equipment is being used:

- Monitor and ensure that all the life supporting and monitoring equipment are operated correctly.
- Never use electrical conduction masks or hoses.

5.1 Connect Power Supply

⚠**WARNING:**

- Put the power supply cable and screwed tube in a safe place, to avoid in the patient.
- Only connect the specified external power adapter (Model: SNP-A047-M or MENB1040A1203N01). Pay attention to polarity if necessary.
- For two-phase alternating current circuit user, do not attempt to switch earth line and zero line.
- Low battery alarm may be occur, if the ventilator does not external power supply for a long time. If this happens, connect the ventilator to an external power supply (use the exclusive power adapter) to charge for 10 hours at least. If the alarm persists the internal battery must be replaced. (Please contact a qualified technician).

⚠**CAUTION:** The power supply is specified as a part of the ventilator. The user must use the cable provided with the ventilator.

⚠**CAUTION:** The power supply plug is used as isolation means. Do not to position the

ventilator to make it difficult to operate and risk device disconnection.

⚠**CAUTION:** If voltage fluctuation exceeds 10%, Aeonmed recommends using an AC stabilizer.

A new fully charged battery can provide ventilator work at least four hours with good working condition. The unit can be used without external power supply in special circumstances. This is not recommended.

External power socket is located in right side panel of ventilator, it is the power input port, and is connected to the AC power socket through the power adapter. If any faults are noted, stop using the ventilator immediately, and contact the manufacturer for maintenance.

5.2 Connect Oxygen Supply and Patient Circuit

Shangrila510S can work with oxygen bottle gas supply in the ambulance or on the wall. When the ventilator is working, make sure the gas supply has been connected without any false, no break, no leak or wrong connecting, and check the pressure monitor is right. If something wrong happens, stop using the ventilator immediately then check connectors. Please connect the oxygen supplies, patient circuit, and accessories fellow these steps:

⚠**CAUTION：**

- Ensure the gas supply is always between 0.25MPa and 0.6MPa.
- Connect gas supply to inlet on the left side of ventilator.
- The high-pressure input ports of the ventilator will be used as Fresh Gas and will be supplied to the patient.

⚠**CAUTION：** The silicone threaded tube shown in the figure below is schematic figure. If there are inconsistency between the figure and the actual product, the actual product shall govern.

Step 1 Connect silicone threaded tube to the right hand side panel suction port of the ventilator.	

Step 2

Connect pressure controlling pipe

Step 3

Connect the O_2 inlet pipe

Step 4

Connect flow sampling pipe

Step 5

Connect gas outlet pipe to breath valve

Step 6

Connect pressure controlling pipe

Step 7

Connect flow sampling probe

Step 8

Connect flow sampling pipe

Step 9

Connect elbow

Step 10

Connect the test lung

⚠**WARNING:**

- Connect only oxygen to the oxygen inlet. Do not attempt to connect any other gas.
- To minimize the risk of patient injury, use only patient circuits qualified for use in oxygen-enriched environments with the Shangrila510S ventilator. To avoid an electrical shock hazard, do not use antistatic or electrically conductive tubing. To ensure a leak-tight connection, only use connectors and tubes with ISO-standard cone and socket.
- Aeonmed recommends that you use one of the patient circuits identified by Aeonmed, or their equivalents to ensure that the maximum pressure/flow values specified by EN794-1 are not exceeded (see related content in part 9 specifications). Using a circuit with a higher resistance does not prevent ventilation but can cause compromise the patient's ability to breathe through the circuit.
- Only use the ventilator to patient whose tidal volume over 20ml and avoirdupois over 3.5kg. This machine is not suitable with newborn. Only use this ventilator for patient whose tidal volume over 20ml and body weight is over 3.5kg. This machine is not suitable for use on newborns.
- The distance between breathing valve and patient is as short as possible, or it can increase the concentration of CO_2.

For optimal ventilator performance, let the unit run for at least 3 minutes before using on a patient to allow system to warm up if necessary.

⚠**NOTE**：Alarm functionality is tested and verified as part of ventilator test before using. Details about Alarms will be displayed in part 4.

5.3 Power on

Press the power button, all indicator lights on the front panel are ON together with a short buzz. If something abnormal happened, stop using the ventilator immediately, and connect the manufacturer for some repairing. Details about it will be displayed in the section 8 Alarm and Troubleshooting.

⚠**CAUTION**：If the ventilator can power on with LCD displays normally but without any buzz, this is considered an alarm failure. You should pay attention to this case. Contact the manufacturer for repairing if necessary.

6 Clean, disinfect and sterilize

⚠**WARNING:** Use a cleaning, disinfection and sterilizing schedule that conforms to your institution's sterilization and risk-management policies.

- Refer to the material safety data policy of each agent.
- Refer to the operating and maintaining manual of all the sterilizing equipment's.
- Wear safety gloves and safety goggles.

⚠**CAUTION:** To prevent damage:

- Refer to the data supplied by the manufacturer if there are any questions about the agent.
- Never use any organic, halogenate or oil base solvent, anesthetic, glass agent, acetone or other irritant agents.
- Never use any abrasive agent to clean any of the components (i.e. Steel wool, silver polish or agent).
- Keep liquids far from the electrical components.
- Prevent liquid from entering the equipment.
- Do not immerse the synthetic rubber components for more than 15 minutes: any longer will cause degradation, or accelerating aging.
- The PH value of the cleaning solution must be from 7.0 to 10.5.

⚠**WARNING:** Talc, zinc stearate, calcium carbonate, or corn starch that has been used to prevent tackiness could contaminate a patient's lung or oesophagus, causing injury.

⚠**WARNING:** Check if there is damage in the components. Replace if necessary.

Table 6-1 Cleaning, disinfecting and sterilizing

<table>
<tr><th>Part</th><th>Procedure</th><th>Comments</th></tr>
<tr><td rowspan="2">Ventilator exterior (including LCD Screen)</td><td>Wipe clean with a damp cloth and mild soap solution or with one of these chemicals or their equivalents. Use water to wipe off chemical residue as necessary.</td><td>Do not allow liquid or sprays to penetrate the ventilator or cable connections. Do not use pressurized air to clean or dry the ventilator.</td></tr>
<tr><td colspan="2">⚠WARNING:
● Do not use organic impregnate to clean the ventilator surface.
● If use ultraviolet radiation to disinfect, do not let the time over 1 hour.</td></tr>
<tr><td rowspan="2">Patient circuit tubing</td><td>Disassemble and clean, then autoclave, pasteurize, or chemically disinfect.
Single-patient use: Discard.</td><td>If submerged in liquid, use pressurized air to blow moisture from inside the tubing before use. Inspect for nicks and cuts, and replace if damaged.</td></tr>
<tr><td colspan="2">⚠CAUTION:
● Steam disinfection is a viable disinfecting method of Shangrila510S patient circuits supplied by Aeonmed, but it may shorten the tubing’s life span. Discoloration (yellowing) and decreased tubing flexibility are expected side effects of steam disinfecting this tubing. These effects are cumulative and irreversible.
● Disposable patient circuit tubing shall not be reused,throw away disposable patient circuit tubing when used up.</td></tr>
<tr><td>Air inlet filter sponge</td><td>Clean and disinfect every 2 to 3 weeks.</td><td>Replace a new sponge at least half a year.</td></tr>
<tr><td>Expiration valve</td><td colspan="2">Cleaning
Disassemble the valve and rinse all parts with warm water prior to disinfecting to remove dried organic matter from surfaces.Thoroughly clean all components,grooves and orifices.
High Level Disinfection
Perform high level disinfection of the valve using Cidex Plus ® or equivalent.Follow manufacturer’s instructions.Allow to soak for 20 minutes.
Sterilization
The valve can be autoclaved using the following vacuum steam sterilization cycle:
Temperature: 134℃(273℉)
Time: 5minutes</td></tr>
</table>

	Vacuum Pressure: 20psig(138kPa) Drying Time: 20minutes

⚠**CAUTION:** Disposable breathing hoses must not be reused. Reuse of the single use hoses can cause cross infection and patient harm.

7 User Maintenance

⚠**WARNING:** Movable components and detachable parts can cause injury. Use caution when system components and parts are being moved or replaced.

⚠**WARNING:** Disposal of waste or invalidated apparatus must be in accordance with the relevant policies in local government.

7.1 Repair Policy

Do not use malfunctioning equipment. Make all necessary repairs or ask an authorized Aeonmed Service Representative for servicing. After repair, test the equipment to ensure that it is functioning properly, in accordance with the manufacturer's published specifications.

To ensure full reliability, have all repairs and service done by an authorized Aeonmed Representative. If this is not possible, replacement and maintenance of parts in this manual should be performed by a competent, trained individual with experience in Anesthesia Systems repair, and appropriate testing and calibration equipment.

⚠**CAUTION:** No repair should ever be undertaken or attempted by anyone without proper qualifications and equipment.

⚠**WARNING:** The power adapter is not field-repairable. If it is damaged then timely replacement should occur.

It is recommended that you replace damaged parts with components manufactured or sold by Aeonmed. After any repair work, test the unit to ensure it complies with the manufacturer's published specifications.

Contact the nearest Aeonmed Service Center for service assistance. In all cases, other than where Aeonmed's warranty is applicable, repairs will be made at Aeonmed's current list price for the replacement part(s) plus a reasonable labour charge.

7.2 Maintaining Outline and Schedule

The schedule is designed based on the typical condition, that is to say, the least maintenance times is 2000h operating per year. In case the actual operating time is longer than 2000h per year, the maintenance times should be more.

7.2.1 User Maintenance

Minimum maintenance interval	**Task**
Daily	Clean the outer surface, Clean and keep dryness of Patient circuit.
2~3(works)	Clean air inlet filter sponge.
Every 3 months or shorter	Do a discharge and recharge process for internal battery.
Every 6 months	Entire ventilator and components, preventive maintenance is carried out by professional service personnel according to the relevant chapters of the service manual.
After cleaning and connecting	Check if any components are broken and replace or repair them if necessary.
As required	Replace invalid fuse with new one.

7.2.2 Useful Life Estimation

⚠**CAUTION:** The useful life of the following parts should be considered in normal environment and operating requirements.

Flow sampling pipe	1500 times
Corrugated tubing used repetitious	Not less than 1 year
Power line	8 years
Ni-MH battery	1 years
Gas piping	8 years
Main unit	6 years

⚠**WARNING:** Face mask and breathing valve are single use only. Avoided using repeatedly, because this can result in cross infection and patient harm.

7.3 Replacing Fuses

⚠**WARNING:**

- Disconnect from power supply before replacing fuses. This may injure or cause death of the operator.
- Replace fuses with only those of the specified type and current rating, otherwise this can damage the equipment.

⚠**CAUTION:** The fuse is fragile, so replacement should be performed carefully. Do not use excessive force.

The location of fuse is in the right-side panel of the ventilator, see Chapter 2.3.

Replacing steps:

1 Plug the screwdriver to groove on the end of fuse box.
2 Turn counterclockwise 3~5 circles then pull out fuse tubes lightly.
3 Take off fuse tubes.
4 Enclose the new ones.
5 Push fuse tubes to original place gently.
6 Turn clockwise 3~5 circles with screwdriver to tighten.

Connect mains supply.

7.4 Maintaining Battery

1. Specification

DC12V 1800mAh; KAN Ni-MH battery

Charge: 264 minutes typically

2. Cautions

Charge: The battery will be charged automatically if AC power connected. It is recommended that charging time is greater than 264 minutes.

Discharge: It will last 4.5 hours without mains supply.

The alarm “Battery Low!!!” should be displayed on the screen when the capacity of battery is insufficient to prevent the system from automatically shutting-down. The user/operator should connect mains supply to charge battery in time and avoid system shut-off prematurely.

Do not disassemble battery device without valid authorization.

Do not short-circuit between positive plate and negative plate of battery.

3. Storage

The maintenance of charging should be carried out with interval of 3 months at least if storage of battery exceeds 3 months.

Stored environment should avoid dampness, high temperature.

If improper maintenance makes battery damaged, replace it in time to avoid liquification causing corrosion of the apparatus. Replace the battery, please contact Aeonmed service representatives.

4. Replacement

Same model battery with CE certification is suggested.

⚠**CAUTION:** An authorized Aeonmed services representative can replace battery. If the battery is not used for a long-time, please contact Aeonmed service representatives to disconnect the battery. The waste battery should be disposed in accordance with the local regulations.

⚠**CAUTION:** When 'battery low' alarm occurs, charging should be done immediately. Or else, the Shangrila510S ventilator system will shut off in several minutes automatically.

⚠**WARNING:** Please ensure that the battery cover is closed when using the ventilator.

5. Disposal

Correct Disposal of Batteries and O_2 Sensors

⚠**WARNING:** Treatment of batteries and O_2-sensor capsules:

- Do not throw into fire! Risk of explosion.
- Do not force open! Danger of bodily injury.
- Follow all local regulations with respect to environmental protection when disposing of batteries and O_2-sensor capsules.

This product must not be disposed of with your other waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment, or by returning it to Medical Illumination

International, Inc for reprocessing. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local city office, your waste disposal service, or your product distributor or retailer.

8 Alarm and Troubleshooting

⚠**WARNING:** No repair should ever be undertaken or attempted by anyone without proper qualifications and equipment.

8.1 About Alarm

The operator may be positioned anywhere around the unit to view the alarm light. The alarm light is visible from a distance of 3 meters. To observe the alarm messages the operator position must be in front of the display and within a distance of 1 meter.

⚠**CAUTION:** If an alarm occurs, protect patient safe in the first instance, and then proceed to diagnose fault or service it if necessary.

⚠**CAUTION:** Except for the normal alarm settings, other default alarm settings are changed only by changing the control program and restricted access to changing or to the storage of changes.

⚠**CAUTION:** The alarm signal conforms to Table 3 and Table 4 of IEC60601-1-8.

The high priority alarms must be disposed immediately.

Priority	**Sound**	**Silence**	**Prompt**	**Alarm lamps**
High	5 tones, 2 hurry; Periods: 10 seconds	120 seconds	Red background, “!!!”	Red, blinking
Medium	3 tones Periods: 25 seconds	120 seconds	Yellow background, “!!”	Yellow, blinking
Low	1 tone Once only.	---	Yellow background, “!”	Yellow

Alarm messages (1) displays on the top area of display screen, see Figure 8-1.

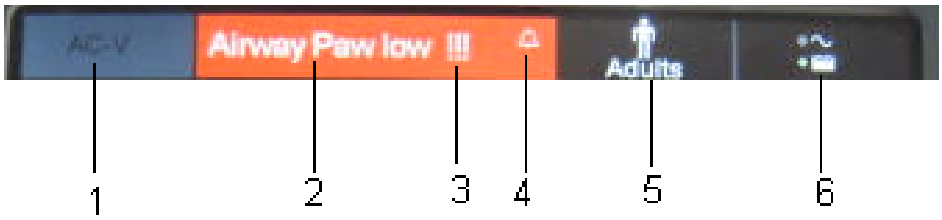


Figure 8-1 Alarm message area

1	Ventilation mode	4	Alarm mute time
2	Alarm messages	5	Patient type
3	Alarm level	6	Power supply and battery indicator

⚠**NOTE:** If a high-priority alarm goes away spontaneously (autoresets), its message remains lit with blue background (not flashing) until you press the alarm reset key.

⚠**NOTE:** When alarm silencing, the alarm bell has dashed “X” in itself and the countdown of 120 seconds present underside. At the same time, alarm sound disappears. After 120 seconds, alarm bell turns to original shape and alarm sound reappears.

8.2 Alarm Message List

Message	Priority	Type	Alarm definition	Operator action
Ex. Power Lost!	low	Technical	During ventilator operation, when an AC power failure occurs and there is no battery power, the power board will alarm for 120 seconds minimum. When powered from batteries, an “AC Failure” alarm would occur.	Restoration of AC.
Gas supply down!!	Medium	Physiological	Standby, or gas supply pressure less than 0.25MPa	Check patient and gas source. Obtain alternative ventilation if necessary.
O_2 Deficiency!!	Medium	Physiological	MV less than low limit.	Check patient and settings.

Message	Priority	Type	Alarm definition	Operator action
MV High!!	Medium	Physiological	MV greater than high limit.	Check patient and settings.
Battery Low!!!	High	Technical	Under the battery operation, the remaining battery run time is less than 10min.	Charge the battery quickly. Obtain alternative ventilation if necessary.
FiO_2 Low!!!	High	Physiological	FiO_2 less than low limit.	Check patient, air and oxygen supplies, oxygen analyzer, and ventilator.
FiO_2 High!!!	High	Physiological	FiO_2 greater than high limit.	Check patient, air and oxygen supplies, oxygen analyzer, and ventilator.
Paw Low!!!	High	Physiological	Paw monitored less than low limit, and last more than 7 seconds.	Check patient and settings.
No V_T!!!	High	Physiological	No tidal volume	Check patient and settings.
Apnea!!!	High	Physiological	The set apnea interval has elapsed without the ventilator, patient, or operator triggering a breath. The ventilator has entered apnea ventilation.	Check patient and settings.
Paw High!!!	High	Physiological	The measured airway pressure is equal to or greater than the set limit. Reduced tidal volume likely.	Check patient, patient circuit, and endotracheal tube.
CP High!!!	High	Physiological	Paw monitored more than high limit last for 15 seconds in ventilating process.	Airway pressure is lower than PEEP+15cmH_2O continuously for 5sec

8.3 Troubleshooting

Symptom	Possible Cause	Recommended Action
Ventilator does not work	Power supply cable is unplugged Power switch is off Fuse is burned	Plug in power supply cable Turn on power switch Replace with a new fuse
Ventilator stops operating suddenly, indicator light turns off, and sounds alarm	Power supply is interrupted	Use manual ventilation, and check the power supply
The external power supply indicator light flicker sometimes	Power supply cable is not connect so fastness	Fasten the cable

9 Specifications

9.1 General

This device complies with requirements of Medical Device Directive 93/42/EEC.

Standards

IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007+A1:2012 The device classification is: Class II, Type B applied part (ventilator breathing tube and mask), ordinary enclosed equipment without protection against ingress of liquids, continuous operation

IEC 60601-1-8: 2006 +Am.1:2012
EN 794-3:1998+A2:2009
IEC 62304:2006+A1:2015
Electromagnetic Compatibility (EMC): According to IEC 60601-1-2:2014

9.2 Physical Specification

All specifications are approximately, maybe changed at any moment without notice.

⚠**CAUTION:** Do not put Shangrila510S into the shock environment.

⚠**CAUTION:** Do not lay the heavy on the top.

Size	300mm(H)×168mm(W)×156mm(D)
Weight	Total:8kg Accessories:3kg
Power cord	Rating voltage: 90 to 264VAC; Capacity of current: 220 to 240VAC 10A; Type: Two-core cable (Medical level)
Fuse	Φ5×20 T2AL250V
Screen	5.0 inches LCD

9.3 Environment Requirements

Temperature	Operation:	-18℃～+50℃
	Storage:	-20℃-60℃
	Transport:	-40℃～+70℃
Relative humidity	Operation:	15%～95%, non-condensing
	Storage:	10%～95 %
	Transport:	10%～100%
Atmospheric Pressure	Operation:	70～110kPa
	Storage:	50～110kPa
	Transport:	50～110kPa

⚠**CAUTION:** The device should be stored in a room with good ventilation in which there are no corrosive gas.

⚠**CAUTION:** When the storage conditions are beyond the requirements of the operational environment, and the storage state is transferred into operation state, the product can only be used after being stored in the environment for over 24 hours.

⚠**CAUTION:** The temperature of the applied part is less than 51℃.

9.4 System Technical Specification

9.4.1 Technical Parameters

Compliance C	≤3mL/100Pa
The resistance at patient connection port	Combined with breath valve and 1.2m screw tubing. Compliance: 10ml/kPa, and expiration resistance: ≤0.6kPa/L/s, (For adult use a velocity of flow at 60L/min, for children at 30L/min, for infant at 5L/min) the cavum is 12mL

9.4.2 Gas Supply

Gas supply

Composition:	Compress O_2
Pressure:	0.25MPa～0.6MPa
Flow	Max 180L/min

⚠**CAUTION:** All gas must be medical grade.

⚠**CAUTION:** If gas supply pressure less than 0.25MPa, there will be Gas supply down alarm, Thia may affect tidal volume.

9.4.3 Power Supply

Voltage	AC100V～240V, 50Hz/60Hz or DC12V; Internal Battery DC12V
Input current	1.5A

⚠ **WARNING:** Stop using if the power is abnormal and contact manufacturer for maintenance.

9.5 Alarms Miscellaneous

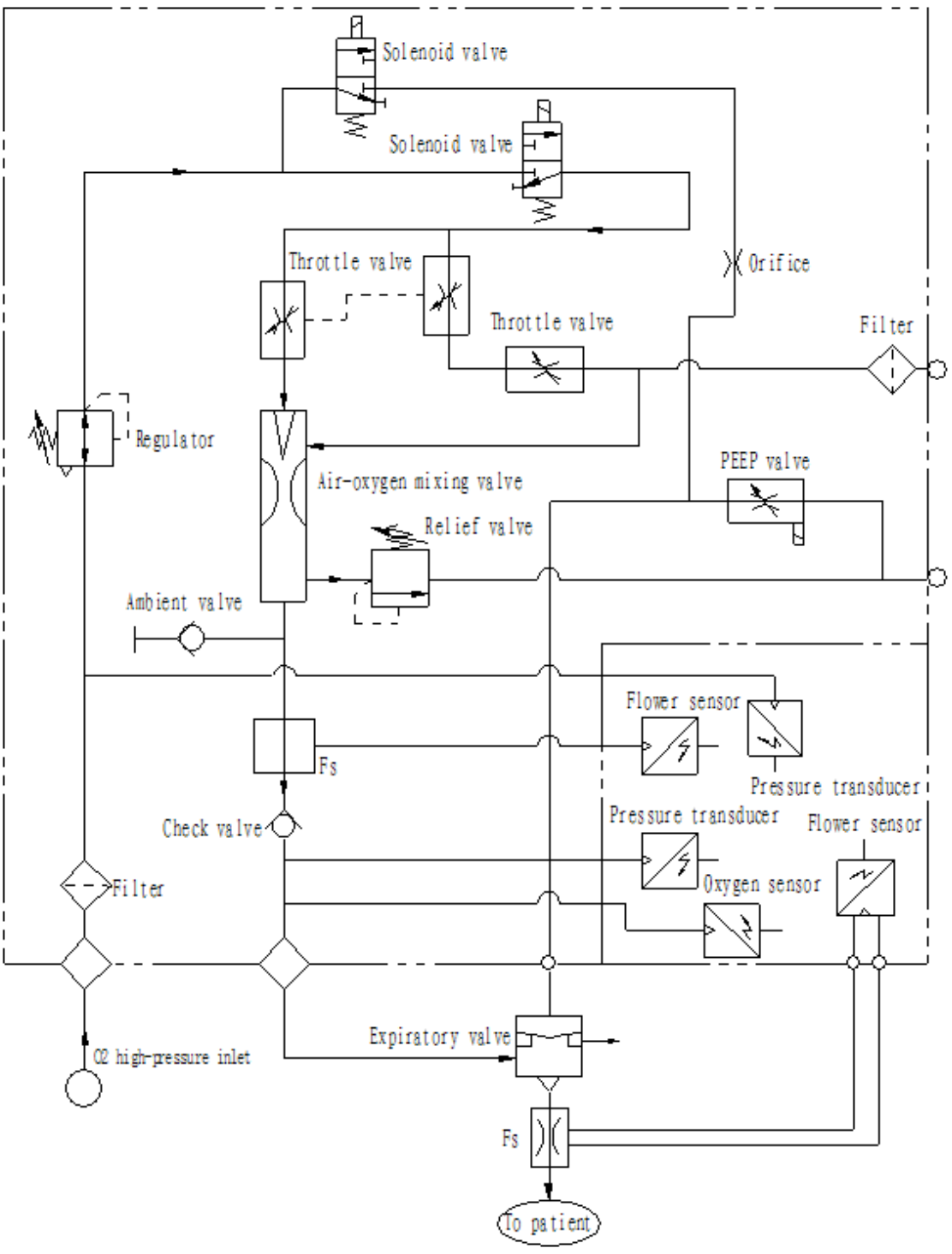
Alarm Silence/reset

Press this key to silence alarms for two minutes. This key also resets latched alarms.

Alarm Sound Pressure

The alarm sound pressure is above 60 dB at lowest volume setting at a distance of 1 meter from the front of the ventilator.

9.6 Operation Principle



9.7 Performance Parameters

9.7.1 System Performance

Maximum security pressure	≤ 8kPa
Maximum working pressure	≤ 6.6 kPa
Compliance	≤ 4mL/100Pa
Electrical safety	Meet requirements for Class II, type B equipment specified in EN60601-1 *Medical Electrical equipment: Part one: General requirement for safety*.
Classification	According to EN 60601-1, Shangrila510S belongs to the following classifications: Class II, Type B, General, portable equipment.
Noise:	≤ 65dB(A)
FiO_2	Response time ≤ 15s

9.7.2 Ventilation Mode

Ventilation mode
A/C mode A/C-V mode A/C-P mode
SIGH mode
SIMV mode
SPONT mode
CPAP mode
Manual mode

9.7.3 Setting Ventilating Parameters

Based on the principle of ventilator, the value of oxygen concentration can be satisfied under standard conditions, but the accuracy of oxygen concentration will deviate under some boundary conditions.

Item	Range	Resolution	Accuracy	Remark
V_T	0～2000mL	----	±40mL（≤200mL）; ±20％（other）	Peak flow = V_T * f / T_I
f	1～120bpm	1 bpm	±2 bpm（≤20 bpm）; ±10%（other）	In SIMV mode 1～40 bpm
FiO_2	40%～100%	----	±20％	----
I：E	4:1—1:10	----	±15%	----
Psens	-2kPa～0	0.1kPa	±100Pa（-1.0～0kPa）; ±10%（other）	----
Vsens	2L/min—30L/min	0.5 L/min	±1 L/min or ±20%	optional
PEEP	0kPa～3kPa	----	±0.2kPa or ±20%	
Psupp	0～50cmH_2O	1cmH_2O	±2cmH_2O or ±20%, select the maximum of the two values	----

9.7.4 Monitoring Performance

Item	Range	Resolution	Accuracy
VT	0～2500 mL	1 mL	±40mL (＜200 mL); ±20% (other)
f_{total}	0～120 bpm	1 bpm	±2 bpm (＜20 bpm); ±10% (other)
P_{peak}	0kPa～+8kPa	0.1kPa	±300Pa (＜3kPa); ±10% (other)

9.7.5 Setting Alarm Parameters

Item	Range	Accuracy
MV-upper limit	OFF，1～25L, default 25L	±1L(1-3L); ±10%(other)
MV-lower limit	OFF，0～24L, default OFF	±1L(1-3L); ±10%(other)

Item	Range	Accuracy
FiO_2- upper limit	OFF，50%～100%, default OFF	±10%
FiO_2- lower limit	OFF，35%～99%, default 40%	±10%
P_{aw}-upper limit	6 cmH_2O～80 cmH_2O, default 40 cmH_2O	±2cmH_2O or ±10%
P_{aw}-lower limit	0 cmH_2O～40 cmH_2O, default 5 cmH_2O	±2cmH_2O or ±10%

⚠**CAUTION:** All low limits of parameters in above table may not be set up the high limits, nor may the high limits be set below the low limits.

9.8 The effect of Tidal Volume and FiO_2 on Pressure Changing

Standard working state, to maintain a certain velocity, changing the patient compliance, make pressure at the patient connection port changes as follow.

Pressure	Tidal volume	FiO_2
P1=0.5kPa	973mL	37%
P2=1.5kPa	848mL	40%
P3=3.0kPa	380mL	54%
P4=6.0kPa	40mL	70%

⚠**NOTE:** When changing the mean pressures, volume and FiO_2 will change, please notice the value of monitoring.

9.9 Accessories

AC adapter, Power Cord, Battery, Face Mask, O_2 Pipeline, Fillet, Exhalation Valve, 2L Breathing bag, Flow sampling pipe(Optional), Silicone threaded tube, Silica gel tube, Frame(Optional), Bag(Optional), Flow sampling probe(Optional), Fuse etc.

9.10 EMC Guidelines

Important information regarding Electro Magnetic Compatibility (EMC):

Shangrila510S VENTILATOR needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; Shangrila510S conforms to this IEC 60601-1-2:2014 standard for both immunity and emissions. Nevertheless, special precautions need to be observed.

- Shangrila510S VENTILATOR with Following ESSENTIAL PERFORMANCE is intended used in Professional healthcare facility environment.

  PERFORMANCE: A/C mode, the parameter by default, control is correct.

- WARNING: Use of Shangrila510S VENTILATOR adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

Below cables information are provided for EMC reference.

Cable	Max. cable length, Shielded/unshielded		Number	Cable classification
AC cable	5.0m	Unshielded	1 Set	AC Power

- WARNING: The Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the Shangrila510S VENTILATOR could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment 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 Shangrila510S VENTILATOR, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

EMI Compliance Table

Table 1 - Emission

Phenomenon	Compliance	Electromagnetic environment
RF emissions	CISPR 11 Group 1, Class A	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Professional healthcare facility environment

EMS Compliance Table

Table 2 - Enclosure Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Radiated RF EM field	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80% AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m 50Hz or 60Hz

Table 3 – Proximity fields from RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Immunity test levels
		Professional healthcare facility environment
385	380-390	Pulse modulation 18Hz, 27V/m
450	430-470	FM, ±5kHz deviation, 1kHz sine, 28V/m
710	704-787	Pulse modulation 217Hz, 9V/m
745		
780		
810	800-960	Pulse modulation 18Hz, 28V/m
870		
930		
1720	1700-1990	Pulse modulation 217Hz, 28V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217Hz, 28V/m
5240	5100-5800	Pulse modulation 217Hz, 9V/m
5500		
5785		

Table 4 – Input a.c. power Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrical fast transients/burst	IEC 61000-4-4	±2 kV 100kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5 kV, ±1 kV
Surges Line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz
Voltage dips	IEC 61000-4-11	0% U_T; 0.5 cycle At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º
		0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0º
Voltage interruptions	IEC 61000-4-11	0% U_T; 250/300 cycles

Table 5 – Signal input/output parts Port

Phenomenon	Basic EMC standard	Immunity test levels
		Professional healthcare facility environment
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Electrical fast transients / bursts	IEC 61000-4-4	±1 kV 100 kHz repetition frequency
Conducted disturbances induced by RF fields	IEC 61000-4-6	3V, 0.15MHz-80MHz 6V in ISM bands between 0.15MHz and 80MHz 80%AM at 1kHz

This manual No.: 130015824

CE mark in this manual applies only to product with CE mark.

Directive 93/42/EEC
concerning Medical Devices

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Edition: V00.10
June 2021