

Nanjing Superstar Medical Equipment Co., Ltd.

S1200 Ventilator

Operation Manual

Please read the manual carefully before operation.


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Remarks of the picture, sign, term and abbreviation in the machine and manual

“” indicates you should read the operation manual

“ warning “ and “ note” indicate if the instruction is not followed, there will be some emergencies, please read and keep to all the “ warning” and “note” items
















Warning: indicates that if the instruction is not followed, the machine may be damaged , you and your patient may be injured.



Note: indicates that if the instruction is not followed , the machine may be damaged, and can not work normally.

Hint: indicate you should pay attention to the explanation.

In the machine and manual, the picture, sign, term and abbreviation are used to replace the language remarks. However, all these picture, sign, term and abbreviation are not all involved in the machine and manual.

Table 1 Remarks of the picture, sign, term and abbreviation in the machine and manual

Picture, sign, term and abbreviation	Remarks
	Read the operation manual
	AC
	B Class
	Gas input
	Mute
	Lock
	Unlock
VT _H	Adult mode
VT _L	Child mode
	Main power supply indication
	Backup power battery
	Battery supply indication
	Indication for low voltage of battery
	Charging (main power supply) indication
	Indication for internal power failure
	Ground protection
	Check valve

Picture, sign, term and abbreviation	Remarks
	Nebulizer
	Trigger mark
IPPV	IPPV
A/C	AC
PCV	PCV
SIMV	SIMV
CPAP	CPAP
PSV	PSV
MANUAL	MANUAL
Standby	Standby surface
!!!	high priority alarm
!!	medium priority alarm
FiO ₂	Inspiratory O ₂ concentration
etCO ₂	End-expiratory CO ₂ concentration
MV	Minute Volume
V _T	Tidal Volume
Freq	Frequency
Ppeak	Airway peak pressure
PEEP	PEEP
C	Dynamic lung compliance
T _{insp}	Inspiration time
TiP	Holding time (Platform time、Inhalation platform)
Sigh	Sigh time
Pc	Pressure control
Ps	Pressure support
P _{tr}	Pressure trigger
F _{tr}	Flow trigger
Flow	Flow
Tapnea	Apnea time
Nebulizer	Nebulizer
Paw—t	Waveform of airway pressure and time

Picture, sign, term and abbreviation	Remarks
Flow—t	Waveform of flow and time
⊙	Off
⊙	On
O ₂ %	O ₂ concentration adjustment
O ₂	oxygen
Air	Air
Vmax	Maximum volume
BTPS	body temperature and pressure-saturated
/min	Beat per minute (Unit for frequency)
s	Second (Unit for time)
L	Liter (Unit for capability)
mL	Milliliter (Unit for capability)
L/min	Liter per minute (Unit for volume)
vol. %	Percent by volume
mL/cmH ₂ O	Millimeter / Centimeter water column (unit for compliance)
hPa	hPa (Unit for pressure)
kPa	kPa (Unit for pressure)
MPa	MPa (Unit for pressure)
cmH ₂ O	Centimeter water column (Unit for pressure)
mmHg	Millimeter of mercury (Unit for pressure)
AC	Alternating current
DC	Direct current
V	Voltage (Unit for voltage)
A	Ampere (Unit for current)
Hz	HZ (Unit for frequency)
VA	VA (Unit for power)
dB(A)	Decibel (Unit for noise)
℃	Celsius (Unit for temperature)

Safety item

Note:

- Please read the operation manual carefully before operation, assemble, operate, and maintain the machine in strict accordance with the manual.
- Please refer to the chapter of Installation and connection of expiratory flow sensor sampling tube and expiratory valve and O₂ sensor in this manual when install and connect the exhalation flow sensor sampling tube and exhalation valve and O₂ sensor.
- Please refer to the chapter of Clearance, Sterilization and Maintenance when do sterilization and clearance.
- The storage and working condition, power, and gas should comply with the requirement in this manual.
- All the power lines, tubes, and steeve should be disassembled before any transportation and move.
- Keep the ventilator stable and balance during operation, transportation or move.

Warning

- Check the safety performance of the machine before using to ensure that it is in good working conditions. Refer to the chapter of Check before use.
- If the alarm function is not working, do not use this machine. Otherwise, it may cause the injury or even death of the patient, or damage of the machine.
- If there is alarm during the operation, safeguard the patient firstly, then check immediately to fix the fault.
- This machine can only be operated by special qualified personnel after training.
- This machine can only be used under close observation. Though clinical safety has been fully considered in the design of this machine, the operator should not neglect the observation of the machine status and the patient. Only in this way can fault be detected and corrected in time.
- The gas for this machine is O₂ and Air.
- Never use the antistatic breathing tube and facemask. It may be cause inflammation if use this kind of breathing tube and face mask near the high frequency electric operation equipments
- Be careful when arranging the respiration circuit (screwed pipe) and cables to avoid tangle or suffocating the patient.
- Do not move, cover or repair the machine during the operation.
- Please keep the distance between the Back panel of the ventilator and wall or big barrier at least 0.5 meter to ensure the normal ventilation of the compressor. (if equipped with air compressor)
- Never use this machine in environment with inflammable or explosive gas.
- Never use this machine in environment of Nuclear Magnetic Resonance
- Never use this machine for newborn babies
- Do not add additional accessories, part or component to the breathing system, or the pressure grads between the breathing system and patient will go up, which will affect the safety of the patient.
- Do regular resection (Refer to the chapter for Maintenance) and replacement (Refer to the replacement of battery) of the battery.
- The medical equipment having similar or the same looks but different software and other

internal functions(including operation of alarm default and other alarm feature) may cause confusion between the operator.

- As using different warning settings and using the same or similar equipment at all the independent area, there may be potentially dangerous.
- Do not disassemble the ventilator without the authorization from our company. If the user needs to repair, This machine can only be operated by special qualified personnel after training. When necessary, our company can provide the necessary information.
- In order to avoid the risk of electric shock, the equipment should be connected only to a supply network with protect earth.

Claim

- Monitoring, alarm, and guard function for S1200 ventilator:

- Measurement and control for FiO_2
- Measurement and control for MV
- Measurement and control for Tidal volume
- Measurement and control for Frequency
- Measurement and control for ventilation pressure
- Measurement and control for PEEP
- Measurement for Dynamic lung compliance
- Measurement and control for continuous pressure
- Limitation for airway peak pressure
- Limitation for peak pressure of input gas
- Gas failure alarm
- Airway pressure alarm (Beyond the upper or low level)
- Minute ventilation alarm (Beyond the upper or low level)
- O_2 concentration alarm (Beyond the upper or low level)
- Continuous pressure alarm
- Apnea alarm
- Low oxygen or air supply pressure alarm
- AC failure alarm
- Low voltage of battery alarm
- Alarm when the temperature of compressor pump is too high (if equipped with air compressor) .

- According to the national standard IEC 60601-2-12, the humidifier, CO_2 monitor, oximeter and O_2 monitor should meet the following standards or be registered in national or provincial medical administration.

- Humidifier should meet the standard of ISO 8185;
- CO_2 monitor should meet the standard of ISO 9918
- Oximeter should meet the standard of ISO 9919
- O_2 monitor should meet the standard of ISO 7767

- According to the national standard IEC 60601-2-12, breathing circuit equipped on ventilator should meet the standards ISO 5367.

Function

Ventilation mode

- IPPV
- A/C
- SIMV
- PCV
- PSV
- CPAP
- SIGH
- MANUAL

Performance

- Electrical controlled and gas driven
- For VT_H and VT_L
- Color TFT screen
- Function of volume control and pressure limit
- More ventilation mode
- More ventilation function
- More alarm function
- Compliance compensated function
- More accurate and stable O_2 and Air blender
- Internal battery. The battery will work when the AC fails
- May be equipped with air compressor

Intended use

S1200 ventilator is applied to various medical institution and used for cardiopulmonary cerebral resuscitation respiratory support, acute respiratory insufficiency or oxygenation function disorder caused by various causes, others need ventilator treatment. It applies for 18 ~ 80 years old patients.

Adaption disease

- Cardiopulmonary cerebral resuscitation respiratory support
- Acute respiratory insufficiency or oxygenation function disorder caused by various causes
- Intraoperative and postoperative respiratory support
- Others need ventilator treatment

Contraindication

As to the ventilator there is no absolute contraindication. But the operator should pay attention to the relevant contraindication of mechanical ventilation. For example the patient with grave lung disease should not use or use ventilator with great caution.

EMC Information

Important Notice

- The S1200 Ventilator meets the requirement of electromagnetic compatibility in IEC60601-1-2.
- The user needs to install and use according to electromagnetism compatibility information which is attached with it.
- Portable and mobile RF communication devices may influence S1200 performance, so S1200 should be kept away from them during using.
- Guidance and manufacturer's declaration stated in the appendix.



Warning:

- S1200 Ventilator should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, S1200 should be observed to verify normal operation in the configuration in which it will be used.
- Class A equipment is intended for use in an industrial environment. S1200 may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances.

Table 1

Guidance and manufacturer's declaration –electromagnetic emissions		
The S1200 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the SECP-II should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The S1200 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The S1200 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The S1200 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the S1200 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 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 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 s	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the S1200 requires continued operation during power mains interruptions, it is recommended that the S1200 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 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 <i>UT</i> is the a.c. mains voltage prior to application of the test level.			

Table 3


Guidance and manufacture's declaration – electromagnetic immunity			
The S1200 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of S1200 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz outside ISM bands ^a 10 V _{rms} 150 kHz to 80MHz in ISM band ^a	3 V 3V	Portable and mobile RF communications equipment should be used no closer to any part of the S1200,, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 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 survey, ^c should be less than the compliance level in each frequency range. ^d Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 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 150kHz and 80MHz are 6.765 MHz to 6.795 MHz; 13.553MHz to 13.567MHz; 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 80MHz and in the frequency range 80MHz to 2.5GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.			
^c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the S1200 is used exceeds the applicable RF compliance level above, the S1200 Ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the S1200.			
^d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the S1200 Ventilator				
The S1200 Ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the S1200 Ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the S1200 Ventilator as recommended below, according to the maximum output power of the communications equipment.				
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM band $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.37	0.37	0.37	0.73
1	1.20	1.20	1.20	2.30
10	3.69	3.69	3.69	7.27
100	12.00	12.00	12.00	23.00
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66MHz to 40.70MHz.</p> <p>NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150kHz and 80MHz and in the frequency range 80MHz to 2.5GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.</p> <p>NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>				

The main structure and working principle for the ventilator

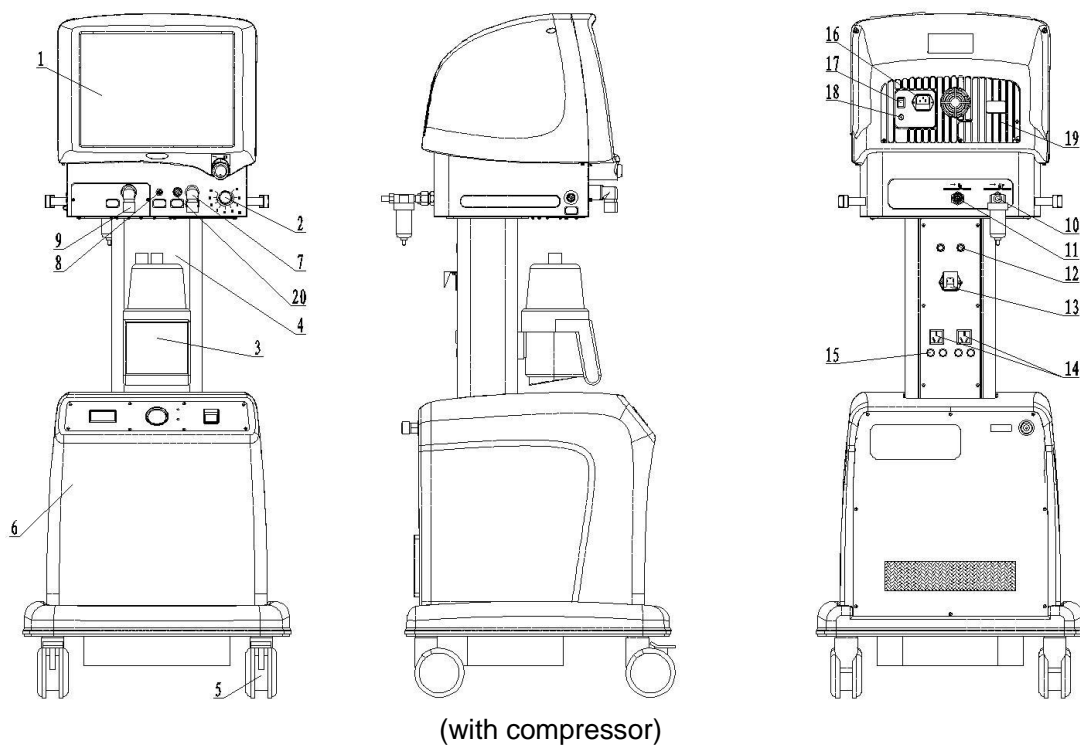


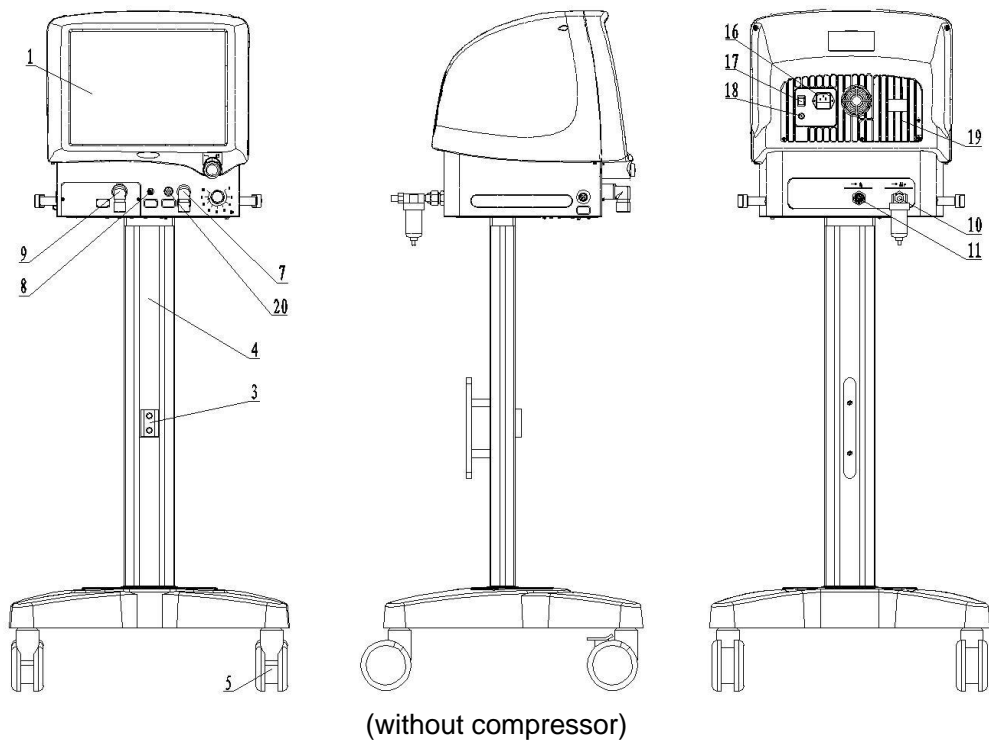
Note: Please refer to the manual of humidifier to learn the main structure and working principle of the humidifier.

Main unit

Structure

The S1200 ventilator is made up of main unit (including Ventilation parameters setting, monitoring, control and display system, Gas source input port, Patients connector, Oxygen concentration monitoring and O₂ and air blending system) and Air compressor (optional), rack (the overall appearance is shown in figure 1)





- | | | |
|---------------------------------------|---|------------------------|
| 1 Touch screen display window | 2 O ₂ and Air blender adjusting knob | 3 Humidifier holder |
| 4 Main frame | 5 Castor | 6 Air Compressor |
| 7 Inhalation port | 8 nebulization port | 9 Expiration port |
| 10 Air input port | 11 O ₂ input port | 12 compressor fuse box |
| 13 ~ 220V power input socket/Fuse box | | 14 Auxiliary socket |
| 15 Auxiliary socket fuse box | 16 Ventilator input power socket/Fuse box | |
| 17 Starting switch | 18 Earthing terminal | |
| 19 Backup battery cover | 20 CO ₂ signal input port | |

Fig 1 the structure of ventilator

Working Principle

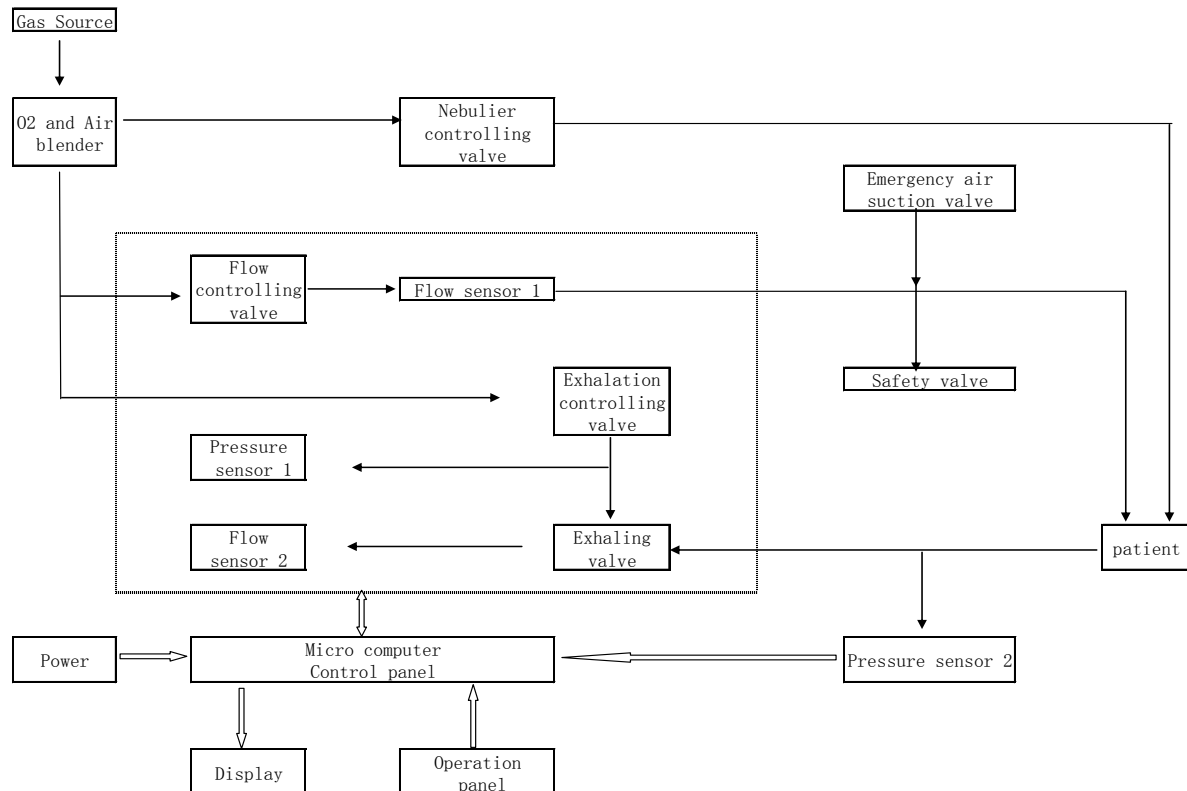


Fig 2 Graph for working principle

The gas source passes O₂ and air blender, then respectively enters nebulizer controlling valve, flow controlling valve and exhalation controlling valve.

During inhalation, flow controlling valve and exhalation controlling valve open, while the exhaling valve closes. O₂ and Air mixture will be supplied to patient by passing flow controlling valve and flow sensor 1, and flow controlling valve will adjust the tidal volume delivered to patient.

During exhalation, flow controlling valve and exhalation controlling valve close, while the exhaling valve opens. The exhaling gas will be delivered to atmosphere by passing exhaling valve and flow sensor 2.

Nebulization function start up, nebulizer controlling valve opens during inhalation and it closes during exhalation.

The micro computer panel will work under the ventilation mode and parameters set on the operation panel, and process airway pressure and tidal volume sampled from flow and pressure sensor, then control inhaling time, exhaling time, breathing rate, and tidal volume, and display the monitored ventilation parameters on the screen.

When the monitored ventilation parameters are beyond the set alarm limit, the micro computer panel will activate the sound and visible alarm.

When the airway pressure reaches to the set pressure of safety valve (Under 12.5kPa), the safety valve will be open to release the pressure to avoid excessive airway pressure.

Under the fault condition, patients breathe spontaneously, emergency air suction valve will be open for inhalation, so that the patient can breathe the air from atmosphere.

Air compressor(if equipped with air compressor)

Structure

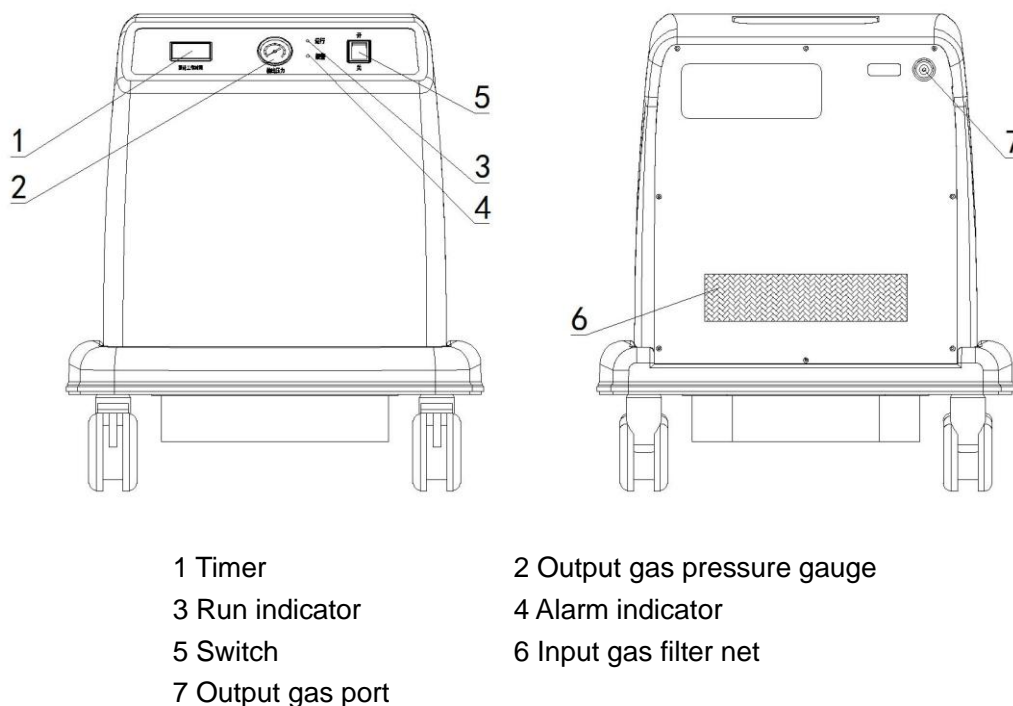


Fig 3 air compressor structure

Working Principle

The gas enter the compressor through filter and muffler, and is compressed into the high temperature gas of 400kPa. Then the gas will pass the cooler, filter and oil and mist separator for first water and impurity elimination. The second water elimination will be done by membrane drier, then the gas will enter the ventilator.

O₂ and Air blender

Working principle

The O₂ and Air blender is consist of balance device, O₂ concentration adjusting device. The balance device will balance the pressure of air and O₂ whose differential pressure is less than 100kPa, then sent them to O₂ concentration adjusting device. In O₂ concentration adjusting device, the change of two-way valve position can adjust ratio of air and O₂ mixture.

Preparation

Gas supply connection



Note:

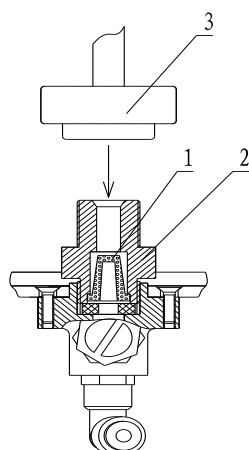
- 1 The rated working pressure of ventilator is $400\text{kPa}\pm 20\text{kPa}$, and the maximum flow is 70L/min .
- 2 The gas source should be specialized for medical usage.
- 3 Be aware the impurity from the central gas pipe when use the central gas supply as gas source.
- 4 Make sure that gas has no oil, water, or impurity when use compressor (if equipped with air compressor) as gas source.
- 5 The fresh gas can not be used as gas source.
- 6 Please use pressure regulator when use cylinder gas, the pressure regulator should meet the standard of ISO 10524..
- 7 As to the installation and use of pressure regulator, please refer to the Chapter of Pressure regulator installation and use.

Hint:

The connector to the central gas supply should be supplied by the manufacturer of the central gas system. If the purchaser need the connector manufactured by our company, the detailed technical information of the connector should be provided in the PO.

O₂ connection

- This machine can use central gas supply or high-pressure O₂ cylinder as gas source.
- If take the center gas supply system as the gas source, it is only to connect the oxygen input port(Fig 4-2) with the central gas supply system by high pressure oxygen hose, but the supply pressure must accord with requirement of this machine.
- If take the high-pressure oxygen cylinder as the gas source, pressure regulator must be used. Check and adjust pressure regulator to ensure the output pressure within the range of $400\text{kPa}\pm 20\text{kPa}$, then connecting cylinder with the oxygen input port (fig 4-2) by high pressure oxygen hose.



- 1 Filter
- 2 O₂ port
- 3 Connector of high pressure O₂ hose

Fig 4 O₂ connection

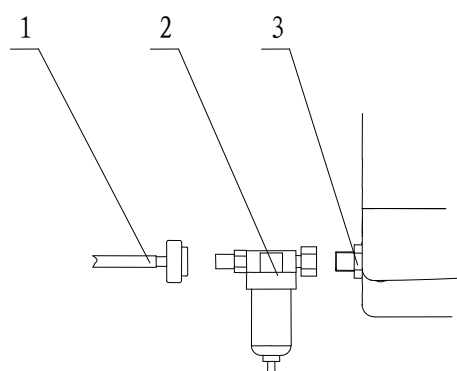
Air connection

- This machine can use central gas supply or high-pressure O₂ cylinder (if equipped with air compressor) as gas source;
- Check that the pressure of gas source from air compressor or central gas supply must accord with requirement of this machine;
- See Fig 5, connect filter 2 and Connector 3 (the flow direction of filter face the machine);
- Connect one end of high pressure air hose 1 and input port of filter 2;
- Connect one end of high pressure air hose 1 and the output port of air compressor or central gas supply.



notice:

- 1) the flow direction of filter face the machine;
- 2) the gasket between filter and air input port can not be dropped;



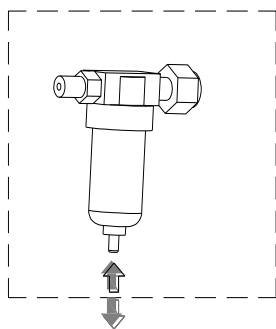
- 1 high pressure air hose
2 Filter
3 Connector of high pressure air hose

Fig 5 Air source connection

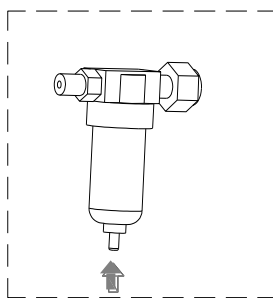
Filter drain

The way of filter drain:

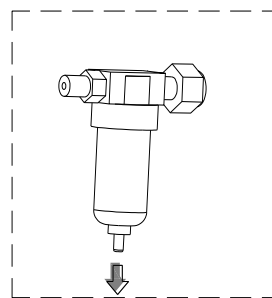
- 1) there is a semi-automatic button at the bottom of filter, when no pressure in filter ,water drains out automatically , otherwise the button closes automatically. See Fig 6-a;
- 2) if need draining the water off when having pressure, push the semi-automatic button to release the water. See Fig 6-b;
- 3) if need closing the button when having no closing pressure, pull down the semi-automatic button in place manually .See Fig 6-c.



a



b



c

Fig 6 The way of filter drain

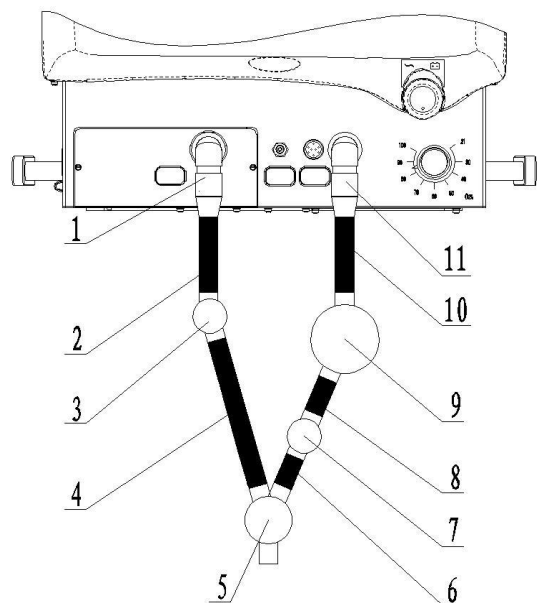
Connection of breathing tubes



Note:

1. Never use the antistatic breathing tube and facemask. It may cause inflammation if used near high frequency electric operation equipment.
2. Breathing circuit equipped on ventilator should meet the standards ISO 5367.

Refer Fig 7 for breathing tubes connection



- | | |
|--------------------|-------------------------------|
| 1 Exhalation port | 2 Breathing tube 1 (400mm) |
| 3 Water trap 1 | 4 Breathing tube 2(800mm) |
| 5 Y connector | 6 Breathing tube 3(800mm) |
| 7 Water trap 2 | 8 Breathing tube 4 (400mm) |
| 9 Humidifier | 10 Breathing tube 5 (400mm) |
| 11 Inhalation port | |

Fig 7 Connection of breathing tubes

- 1) Connect Exhalation port and other end of water trap (1) by breathing tube (1) .
- 3) Connect water trap (1) and other end of Y connector by breathing tube (2) .
- 4) Connect the end of Y connector and other end of water trap (2) by breathing tube (3) .
- 5) Connect water trap (2) and humidifier by breathing tube (4) .
- 6) Connect humidifier and other end of the Inhalation port by breathing tube (5) .



Note: When a patient uses the ventilator for more than 4 hours, humidifier should be used.

The installation and connection of exhalation valve

The exhalation valve is installed already on the machine before leaving factory. If you need to re-install them, please follow the following steps and refer to Fig 8.

Install the exhalation valve, cover, and exhalation connector in turn from Direction. Do not leak the gas.

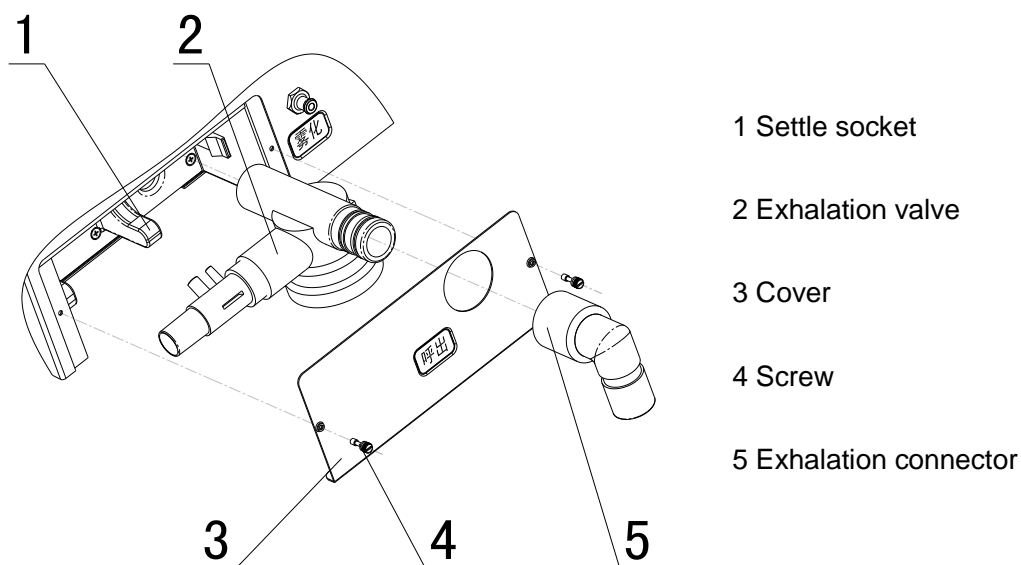


Fig 8 The installation and connection of exhalation valve

Installation and connection of O₂ sensor

The O₂ sensor is installed already on the machine before leaving factory. If you need to re-install it, please follow the following steps and refer to Fig 9.

- 1) Turn clockwise the O₂ sensor (Item 1 in Fig 9). Do not leak the gas or turn with excess force.
- 2) Plug the plug of O₂ sensor (Item 1 in Fig 9) into the port of O₂ sensor.
- 3) Fix the cover board (Item 2 in Fig 9).

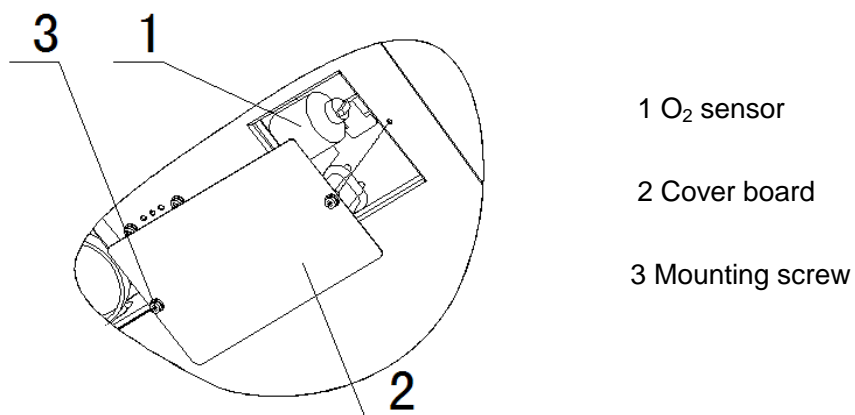
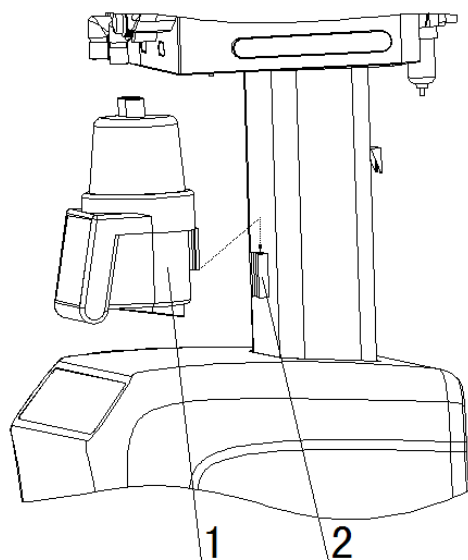


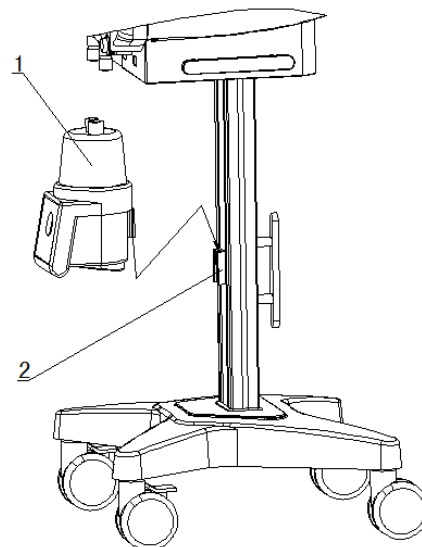
Fig 9 The installation and connection of O₂ sensor

Installation of humidifier

Refer Fig 10 for installation and connection of humidifier.



(with compressor)



(without compressor)

1 Humidifier 2 Bracket

Fig 10 Installation of humidifier

Installation of nebulizer



Warning:

nebulizer should be registered in national or provincial medical administration.

- connection of nebulizer port and nebulization port (Item 8 Fig1) .
- according to the instructions of nebulizer, put the drug into the cup of nebulizer by the doctor's means.

The installation and connection of O₂ monitor, CO₂ monitor and Oximeter

If equipped with O₂ monitor、CO₂ monitor and Oximeter, please refer to the operation manual to install and connect them.

Installation and use of pressure regulator

Installation and use



Warning:

- 1) Please make sure that O₂ pressure regulator is only compatible with O₂ cylinder,.
- 2) If there is any grease on the O₂ pressure regulator or the O₂ cylinder output port, the explosion will be caused.



Note:

- 1 The pressure regulator should meet the requirement of Standard of ISO10524.
- 2 Before turning on the cylinder valve, the adjusting valve of pressure regulator should be unscrewed anticlockwise fully. If not, the sudden pressure from the cylinder will break the membrane of the pressure regulator, which will damage the pressure regulator and the operator.
- 3 When turning on the cylinder valve, the operator should not stand front or behind of the cylinder port or pressure regulator.
- 4 Turn on the cylinder valve quickly, otherwise, the reverse pressure of discharged gas will turn the cylinder down.

- Place the cylinder upright steadily;
- Stand at the side of cylinder. Turn on or off the cylinder valve quickly so as to clean the valve port;
- Confirm that the pressure regulator is in conformity with cylinder gas;
- Clean up any oil stain and impurity at inlet port of pressure regulator and the cylinder valve port.
- Turn the pressure adjusting valve of pressure regulator anticlockwise fully to release pressure adjusting spring;
- Install the pressure regulator onto the relevant cylinder and tighten up with a wrench;
- Connect the relevant high-pressure hose and tighten with wrench
- The other end of high-pressure hose is connected to the relevant gas input port at rear panel of the ventilator;
- Turn on the cylinder valve slowly and adjust pressure regulator so that the output pressure is in 400 kPa range.

On completion of operation

- Turn off the cylinder valve;
- Turn the pressure adjusting valve of pressure regulator anticlockwise fully to release pressure adjusting spring;
- Check to see if the manometer of pressure reducer indicates to zero so as to check if the cylinder valve is fully closed;
- If the pressure regulator is not used for prolonged period, remove the regulator from cylinder and have it protected with protection sleeves at inlet and outlet. Put it indoors with good ventilation and free from corrosive gases.

Power supply



Warning:

1 IEC 60601-1-1 is applicable to connection of all medical devices and the connection between least one medical device with one or more nonmedical devices. The nonfunctional connection on an auxiliary net power socket between the separate parts of the device will come into the medical electronic system.. The operator should be aware that the risk of leakage current will be escalating when the device is connected to auxiliary net power socket.

2 If equipped with air compressor ,the back-up battery cannot supply power to air compressor, so when the AC fails, the high pressure air input port should connect with central gas supply system or high pressure air cylinder.



Note:

The main power is $\sim 220\text{ V}\pm 10\%$, and frequency is $50\text{ Hz}\pm 2\%$.

Main power—AC

——If equipped with air compressor

- Insert the power plug into the power input socket (item 13 in fig 1) at the rear panel of the ventilator and the AC socket;
- Connect the power input socket(item 16 in Fig 1) at the rear panel with the auxiliary socket (Item 14 in Fig 1) by the power cord.



——Without air compressor

- Insert the power plug into the power input socket (item 16 in fig 1) at the rear panel of the ventilator and the AC socket;

——Access to AC power:

- After inserting the power plug into the mains socket, the power indicator light at the panel is on(Item 13 in Fig 12)

——When the power is supplied by AC:

- The power state indication place will display the signal of “” or “”

Back-up battery


- Back-up battery:

Model: BT-12M4.0AC


Capacity: 4Ah

Voltage: DC12V


Current: 1.5A

- When the back-up battery is fully charged, the battery will supply power for the ventilator about 2 hours.
- If the machine is powered by battery, the power state indication place will display the signal of “”.
- When the power is changed from AC to back-up battery, the ventilator will keep same functions as working under AC.

Main power supply -----Backup battery transition

- It will switch over to backup battery automatically when the main power supply fails during operation
- When the back-up battery power the ventilator, there is sound indication from the machine, and the power state indication place will display the signal of “”.

Low voltage of back-up battery



- When the voltage of back-up battery is low (11.3V), the power state indication place will display the signal of “”, and there will be sound alarm.
- At this time, power supply should transit to AC or switch off the starting switch of ventilator, and charge the battery.




Warning:

Power supply should transit to AC when the battery is low voltage. If not, the ventilator should be timely closed , and manual ventilator should be used immediately to manual ventilation.

Charge of back-up battery

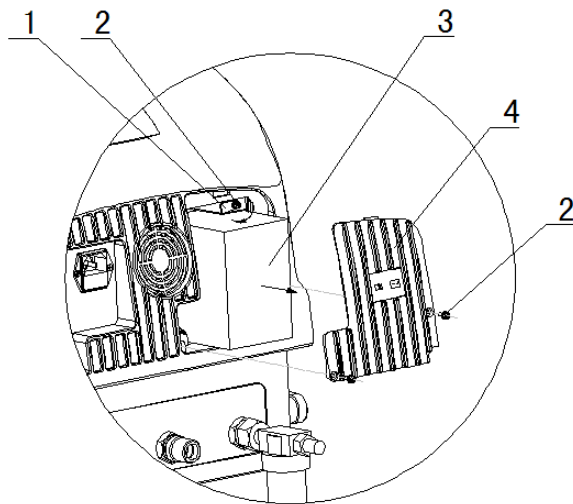
- When the ventilator is supply by AC power, the battery will be charged automatically, the power state indication place will display the signal of “”. And the power state indication place will display the signal of “”after charging fully.
- Charge can be carried out continually, or intermittently.
- The backup battery should be charged in time after using, generally it should be charged for more than 3 hours after using for one hour.

Discharge of back-up battery

- It should be discharged in regular time when no using for a long time.
- Discharge method: Do not connect the AC power, and supply the ventilator by backup battery till the power state indication place display the signal of “”.
- It should be charged in time after discharging.
- Intervals of discharge do not beyond 3 months.

Replacing of the back-up battery

- Usually, the battery can be used for 3- 6 years, if it is often used in over voltage state, or often power cut or the environment temperature is excessive high, efficiency will become lower the and life will be shorten.
- The battery should be replaced when the efficiency receded or shattered. Battery replacing should be managed by special technical personal. When in replacing the battery, firstly switch off the AC, and then open the cover to get the battery out. Pay attention to the specification of the battery and do not overturn the polarity.



1 Battery shrapnel

2 Screw

3 Back-up battery

4 Back-up battery cover

After unloading back-up battery cover, unscrew the shrapnel screw, rotate shrapnel to level, the back-up battery can be taken out.

Fig 11 Replacing of the back-up battery



Warning:

Do not throw the battery into the fire in case of explosive; Do not open or destroy the battery, because it contains injurant which may injure skin and eyes. Please dispose the battery under the local environment law.

Fuse replacing

- Fuse replacing for machine power

——When the input AC power is normal, switch on the ventilator (Item 17 in Fig 1), there is no display on the screen, the compressor doesn't work after starting the switch(Item 3 in Fig 5), you should check the fuse(Model: T10AL 250V)of 220V power input socket/Fuse box(Item 13 in Fig 1);

——Cut off the main power supply and open the fuse box by screwdriver to replace the fuse if it is damaged.

——When you replace the fuse you should care the specification and type of the fuse.

- Fuse replacing for mainframe power

——When the input AC power is normal, power indicator(Item 13 in Fig 12) isn't on, switch on the ventilator (Item 17 in Fig 1), the power is supplied by charged back-up battery(if equipped with compressor, the compressor is normal) you should check the fuse(Model:T1AL 250V) of the ventilator power connection socket/fuse box(Item 16 in Fig 1).

——Cut off the main power supply and open the fuse box by screwdriver to replace the fuse if it is damaged.

——When you replace the fuse you should care the specification and type of the fuse.

- Fuse replacing for compressor power (If equipped with compressor)

——When the input AC power is normal, open the switch(Item 5 in Fig 3),the compressor doesn't work while the mainframe is normal, you should check the fuse (Model: T6.3AL250V) of compressor fuse box(Item 12 in Fig 1);

——Cut off the main power supply and open the fuse box by screwdriver to replace the fuse if it is damaged.

——When you replace the fuse you should care the specification and type of the fuse.

- Fuse replacing for auxiliary mains

——When the input AC power is normal, the compressor works while the mainframe or humidifier isn't normal, you should check the fuse(Model: T1AL 250V)of auxiliary mains fuse box.

——Cut off the main power supply and open the fuse box by screwdriver to replace the fuse if it is damaged.

——When you replace the fuse you should care the specification and type of the fuse.

- Fuse replacing for back-up battery

——When the power is supplied by charged back-up battery, switch on the ventilator (Item 17 in Fig 1), but there is no display on the screen, you should check the fuse of back-up battery (the fuse box connects back-up battery)(Model: T2AL250V).

——Open the back panel of the ventilator and the fuse box by screwdriver to replace the fuse if it is damaged.

——When you replace the fuse you should care the specification and type of the fuse.

- Specification of the fuse

——Machine power	T10AL 250V;
——Mainframe power	T1AL 250V;
——Compressor power	T6.3AL 250V;
——Auxiliary mains	T1AL 250V;
——Back-up battery	T2AL250V.



Warning:

- 1) Cut off the main power supply when you check or replace the fuse.
- 2) When you replace the fuse you should care the specification and type of the fuse.

Check before operation



Warning:

- 1) In order to ensure the excellent performance in operation, the safety feature and ventilation function must be checked before operation.
- 2) Do not use machine with problem. If there is alarm from the machine, do not use it, for machine may be damaged, or the patient may be injured.
- 3) As to the check before operation of humidifier, please refer to the operation manual of humidifier.

Check interval






Please do check before operation under the following situation;

- Before usage of first patient every day;
- Before usage of every patient;
- After maintenance and sterilization;
- After servicing .

System check

- Check all connection part is stable and correct;
- Check the breathing tubes is in good condition and are connected stable and correct;
- Gas supply connection is good and correct;
- The connection of the power lines are stable switch on the ventilator, the ventilator will work normally.

Check for power supply alarm

- Connect the machine with AC, switch on the ventilator, the power state indication place will display the signal of “ ” or “ ”.
- Cut off the main power, then the machine will be powered by back-up battery automatically, and there is sound indication from the machine, the power state indication place will display the signal of “ ”.
- Connect the AC to the machine, then the sound indication will mute, and the power state indication place will display the signal of “ ” or “ ”.

Gas supply check

- The gas pressure of central gas supply should be 440 kPa±160 kPa (280 kPa ~ 600 kPa)
- If take air cylinder as gas source, the gas in the air cylinder should be full or enough for operation and the output pressure of the pressure regulator should be 400kPa.
- If the compressor is equipped, switch on the compressor (Item 5 in Fig 3), pressure gauge on the compressor panel should be 400kPa when the compressor is working stably.

Ventilation function check

Check the ventilation function as the following steps;

- 1) Connect the machine with power and gas source, and connect the Y connect with breathing bag.
- 2) Switch on the ventilator, and check if tidal volume, frequency, MV, O₂ concentration, and airway pressure are normal under various ventilation mode.
- 3) Breath at the Y connector under A/C mode to check if the trigger function is good or not.
- 4) Open the atomization function, check if the atomization function is good or not.

Check for Alarm function

- Connect the Y connector with artificial lung;
- Switch on the ventilator;
- Set the ventilation parameters to the following value under ventilation mode IPPV (Adult);
Tidal volume: 0.50 L Frequency: 10 /min;
Inspiratory time: 2S PEEP: 0
- Press start key
- The monitoring parameters displayed on the screen is correct;
- PEEP is 0kPa.
- Check for high MV alarm:
 - Set the upper limit of MV to 8.0 L/min;
 - Reset tidal volume and frequency to make the MV over upper limit of MV;
 - When the MV overpass 8.0 L/min, there will be an alarm for High MV alarm.
- Check for Low MV alarm:
 - Set the low limit of MV to 6.0 L/min;
 - Reset tidal volume and frequency to make MV under the low limit of MV;
 - When the MV is lower than 6.0 L/min, there will be an alarm for low MV alarm.
- Check for High Ppeak alarm:
 - Set the upper limit of Ppeak to 20 cmH₂O;
 - Reset the tidal volume to make the Ppeak over the high Ppeak limit;
 - When the Ppeak overpass 2.0 L/min, there will be an alarm for High Ppeak alarm. When there is an alarm for High Ppeak, the pressure should be limited under 20 cmH₂O.
- Check for low Ppeak alarm:
 - Set the low limit of Ppeak alarm to 10 cmH₂O;
 - Reset the tidal volume to make Ppeak under the low limit;
 - When the Ppeak is under the low limit, there will be an alarm for low Ppeak alarm.
- Gas failure alarm
 - Pull out the breathing tubes;
 - There will be an alarm for gas failure lasting for 6 seconds.

- Check for continuous pressure alarm:
 - Block up the exhaust port of Exhaling valve, when the airway pressure is greater than 15 cmH₂O, delay 16 seconds, there should be a continuous pressure alarm.
- Check for High O₂ concentration alarm:
 - Set the upper limit of O₂ concentration to 80%
 - Adjust the O₂ and air blender adjusting valve, and set the O₂ concentration over 80%;
 - There will be an alarm for high O₂ concentration.
- Check for low O₂ concentration alarm:
 - Set the low limit of O₂ concentration to 40%;
 - Adjust the O₂ and air blender adjusting valve, and set the O₂ concentration under 40%;
 - There will be an alarm for low O₂ concentration.
- Set the Apnea time under the SIMV mode, check if the Apnea alarm is correct when there is no spontaneous or Mechanical ventilation, and check if the mode can be changed to A/C mode; After the change to A/C mode, when there is trigger ventilation, check if the mode can be changed to the former ventilation mode.



Warning:

In order to ensure the excellent performance in operation, the safety feature and ventilation function must be checked before operation.

Operation



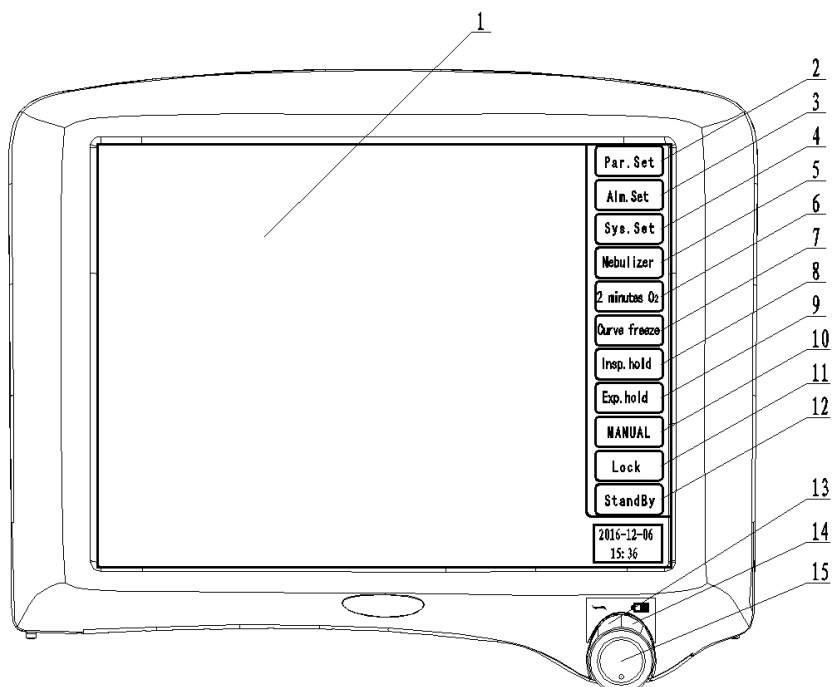
Warning:

- 1) This machine can only be operated by special qualified personnel after training.
- 2) Please read the operation manual carefully before operation. And operate the machine in strict accordance with the manual.
- 3) This machine can only be used under close observation. Though clinical safety has been fully considered in the design of this machine, the operator should not neglect the observation of the machine status and the patient. Only in this way can fault be detected and corrected in time.
- 4) Set the ventilation parameters and alarm value according to the patient status.
- 5) Be careful when arranging the respiration circuit (screwed pipe) and cables to avoid tangle or suffocating the patient.
- 6) Do not move, cover or repair the machine during the operation.
- 7) If there is alarm during operation, safeguard the patient firstly, then check immediately to fix the fault.
- 8) Any liquid into the machine may damage the machine or lead to electric shock.
- 9) Never use this machine in environment with inflammable or explosive gas.
- 10) Never use this machine in environment of Nuclear Magnetic Resonance
- 11) Keep the ventilator stable and balance during operation.
- 12) Please refer to the manual of humidifier about the operation of the humidifier.

Operation of ventilator

Ventilator panel and operation key

Refer to Fig 12 of the ventilator panel and operation key



- | | | | |
|---|--|-----------------|--------------------|
| 1 Touch screen display window | 2 parameters setting | 3 Alarm setting | 4 system setting |
| 5 Nebulizer | 6 2 minutes O ₂ supply | 7 Curve freeze | 8 Inspiration hold |
| 9 Expiration hold | 10 Manual ventilation | 11 Screen lock | 12 Standby |
| 13 Power supply indicator | 14 Charging indicator for backup battery | | |
| 15 Adjusting shuttle /confirmation knob | | | |

Fig12 Panel of ventilator

Start-up

- Connect the power and gas source.
- Switch on the ventilator switch, then the machine will enter the self-check surface.
- When self-check is finished, the machine will enter VT_L/VT_H ventilation mode selection surface.

Refer to Fig 13.

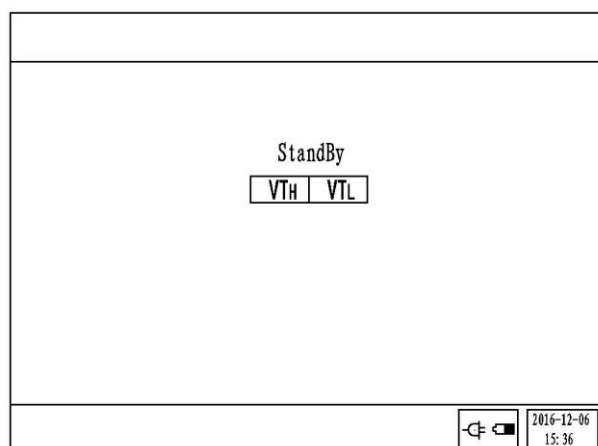


Fig 13 VT_L/VT_H ventilation mode selection surface

Selection of VT_L/VT_H ventilation mode

- Enter the surface of VT_L/VT_H ventilation mode selection
 - Switch on the ventilator, then the self-test is performed automatically;
 - Touch standby key (Item 12 in Fig 12) on the operation panel, and the machine will enter the surface of VT_L/VT_H mode selection.
- choose VT_L/VT_H mode
 - Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) to choose VT_L or VT_H mode, press adjusting shuttle /confirmation knob to confirm, then machine will work under chosen mode.
- The above operation steps are also performed by touching relevant keys on the touch screen display window.

Hint:

The item selected is opposite color, the same bellow.

Setting of ventilation mode and parameters

- Enter the surface of setting of ventilation mode and parameters
 - Choose VT_L or VT_H mode, and press confirmation key;
 - Touch parameters setting key (Item 2 in Fig 12) in working surface, you can reset ventilation mode and parameters.
 - Fig . 14.15.16.17.18.19 are the ventilation mode and parameters setting surface under IPPV, A/C、SIMV、PCV、PSV and CPAP mode.
- Ventilation mode selection:
 - Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to required mode, and press it for confirmation.
- Setting of parameters:
 - Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to the required parameter, and press it for confirmation;
 - Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) for setting (Turning clockwise will max the parameter; Turning anticlockwise will minimum the parameter). Press adjusting shuttle/Confirmation knob (Item 15 in Fig 12) for confirmation when the required parameter is set already.
 - When confirmation is done, turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to“confirm”, press adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to exit the setting surface.
 - The machine will work under the set mode and parameters.
- The above operation steps are also performed by touching relevant keys on the touch screen display window.

Note: The machine will work under the former ventilation mode and parameters when do the settings.

IPPV	A/C	SIMV	PCV	PSV	CPAP
VT [mL]	500	Freq [/min]	12	Tinsp [s]	1.7
Tip [S]	0.0	Sigh [/100]	OFF	PEEP [cmH ₂ O]	0
					Confirm Cancel

Fig 14 Setting of mode and parameter under IPPV

IPPV	A/C	SIMV	PCV	PSV	CPAP
VT [mL]	500	Freq [/min]	12	Tinsp [s]	1.7
Ptr [cmH ₂ O]	-5	Ftr [L/min]	OFF	PEEP [cmH ₂ O]	0
					Confirm Cancel

Fig 15 Setting of mode and parameter under A/C

IPPV	A/C	SIMV	PCV	PSV	CPAP
VT [mL]	500	Freq [/min]	12	Tinsp [s]	1.7
Ptr [cmH ₂ O]	-5	Ftr [L/min]	OFF	PEEP [cmH ₂ O]	0
Tapnea [S]	OFF				Confirm Cancel

Fig 16 Setting of mode and parameter under SIMV

IPPV	A/C	SIMV	PCV	PSV	CPAP
Ramp [S]	0.5	Freq [/min]	12	Tinsp [s]	1.7
Pc [cmH ₂ O]	15	PEEP [cmH ₂ O]	0		
					Confirm Cancel

Fig 17 Setting of mode and parameter under PCV

IPPV	A/C	SIMV	PCV	PSV	CPAP
Tramp [S]	0.5	Ptr [cmH ₂ O]	-5	Ftr [L/min]	OFF
Ps [cmH ₂ O]	15	PEEP [cmH ₂ O]	0	Tapnea [S]	OFF
					Confirm Cancel

Fig 18 Setting of mode and parameter under PSV

IPPV	A/C	SIMV	PCV	PSV	CPAP
Flow [L/min]	30	PEEP [cmH ₂ O]	0	Tapnea [S]	OFF
					Confirm Cancel

Fig 19 Setting of mode and parameter under CPAP

Reset of alarm parameter

- Reset of alarm parameter:

——Touch alarm setting key (Item 3 in Fig 12), the machine will enter reset of alarm parameter surface. Refer to Fig 20.

- Reset of the alarm parameter value:

——Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to the parameter to be adjusted;

——Press it for confirmation;

——Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) for setting (Turning clockwise will max the parameter; Turning anticlockwise will minimum the parameter). Press it for confirmation when the required parameter is set already;

——Repeat the previous step if there is a next alarm value to be adjusted;

——Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to “Confirm”, press it to exit the setting surface, and the machine will work under set values.

- Alarm clearance

——Touch alarm setting key (Item 3 in Fig 12) to enter the alarm setting surface. Refer to Fig.20.

——Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to “info”, press it for confirmation and enter the “info” surface. Refer to Fig 21.

——Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to “alarm reset”, press it for confirmation

——Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to “Exit”, press it to exit the setting surface.

- The above operation steps are also performed by touching relevant keys on the touch screen display window.

O ₂	MV	P _{peak}	etCO ₂	
100	10	12	7.0	Confirm Cancel
18	0.0	0	0	
vol. %	L/min	cmH ₂ O	vol. %	

Fig 20 Reset of alarm parameter surface (one)

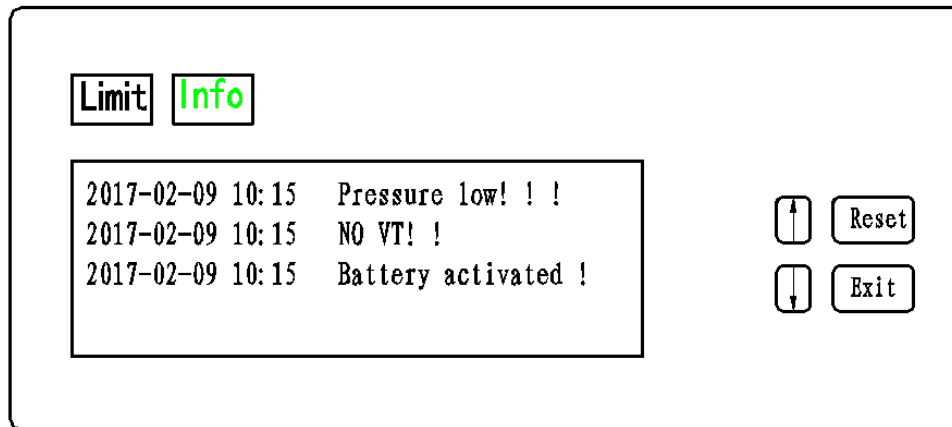


Fig 21 Reset of alarm parameter surface(two)

Hint:

Only under the modes of SIMV、CPAP、PSV, apnea time can be set.

Reset of system setting

- Reset of system setting:

——Enter the relevant surface of ventilation mode, if do not use previous mode or default system setting, can do reset of system setting;

——If need to change system setting, touch “Sys. set” key (Item 4 in Fig12);

——See Fig 22 “Sys. set” surface.

- System parameter adjustment:

——Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to the parameter to be adjusted;

——Press it, parameter setting value become opposite color;

——Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to the parameter to be adjusted;

——Press it for confirmation;

——Repeat the previous step if there is a next parameter to be adjusted;

——Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to “Exit”, press it to exit the setting surface, and the machine will work under set values.

- The above operation steps are also performed by touching relevant keys on the touch screen display window.

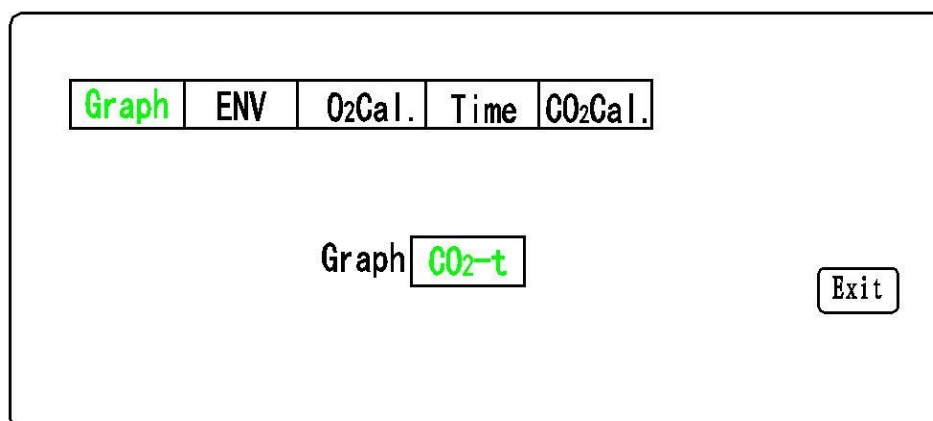


Fig 22 system setting surface

Start up for operation——IPPV ventilation mode

- Enter IPPV mode:
 ——Choose IPPV mode under the surface of ventilation mode and parameter setting (Fig.14) ;
 ——Press adjusting shuttle/Confirmation knob (Item 15 in Fig 12) for confirmation and machine will enter standby status;
 ——Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to “Exit”, and press it for exit, and the machine will work under mode of IPPV.
- The above operation steps are also performed by touching relevant keys on the touch screen display window.
- Working surface of IPPV mode:
 Please refer to Fig 23.

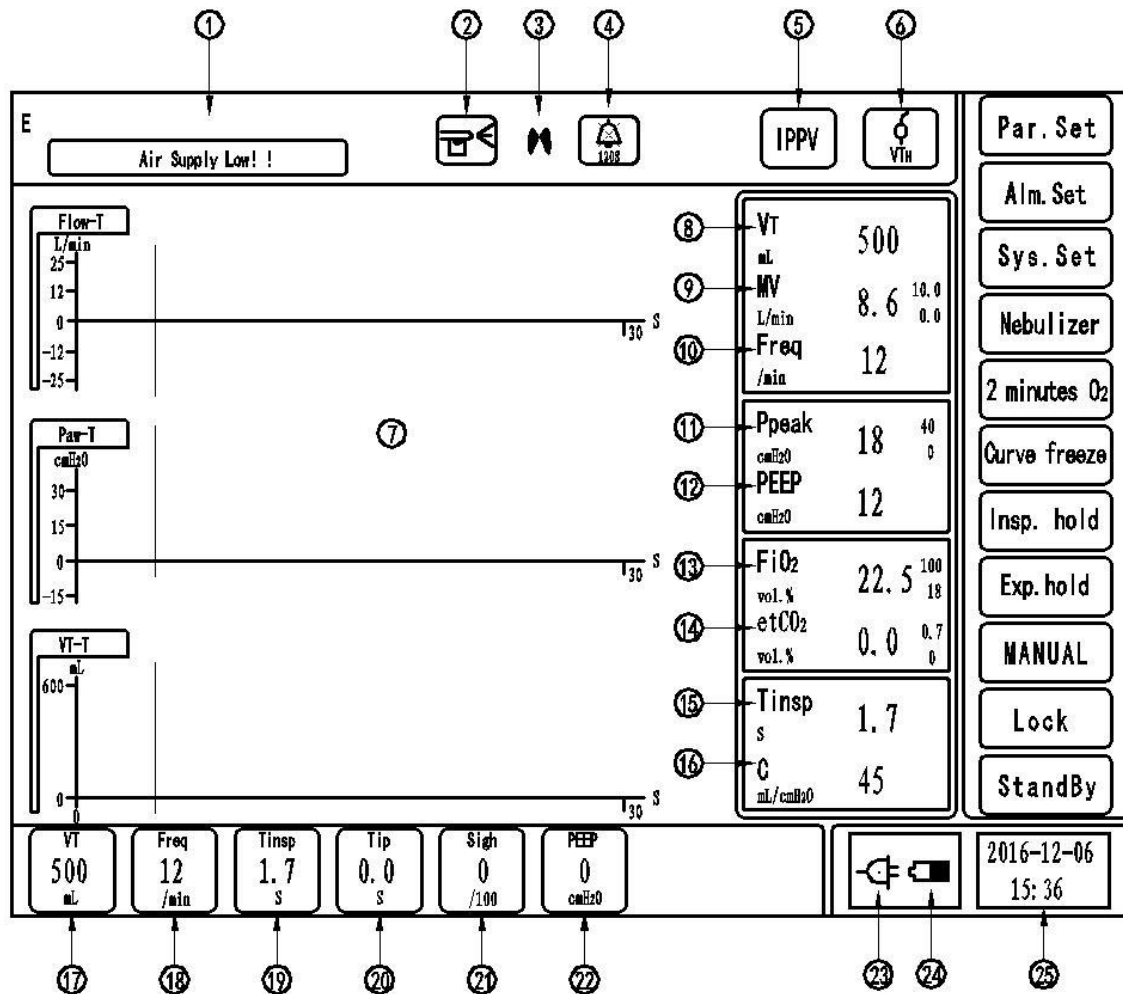


Fig 23 Working surface of IPPV mode

Illustration for the surface:

- (1) is respectively indication place for alarms.
- (2) is indication for working status of nebulizer.
- (3) is indication for the trigger condition (this mode is no trigger).
- (4) is Alarm mute indication place.
- (5) is indication place for ventilation mode
- (6) is indication place for VT_H/VT_L mode.
- (7) is indication place for waveform.
- (8) is the monitoring value of tidal volume.
- (9) are the monitoring values of MV, the presetting values of upper and low limit for MV alarm .
- (10) is the monitoring values of frequency.
- (11) are the monitoring values of Ppeak, the presetting values of upper and low limit for Ppeak alarm .
- (12) is the monitoring values of PEEP.
- (13) are the monitoring values of O_2 concentration, the presetting values of upper and low limit for O_2 concentration alarm .
- (14) is the monitoring value of CO_2 .
- (15) is the monitoring value of inspiration time.
- (16) is the monitoring values of dynamic lung compliance.
- (17) ~ (22) are respectively indication place of the presetting values for tidal volume, frequency, inspiration time, inspiration platform., sigh time and PEEP.
- (23) is indication for working by main power.
- (24) is indication for working status of backup battery.
- (25) is indication for date.

Start up for operation——A/C ventilation mode

- Enter A/C mode:
 ——Choose A/C mode under the surface of ventilation mode and parameter setting (Fig.15) ;
 ——Press adjusting shuttle/Confirmation knob (Item 15 in Fig 12) for confirmation and machine will enter standby status;
 ——Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to “Exit”, and press it for exit, and the machine will work under mode of A/C.

- The above operation steps are also performed by touching relevant keys on the touch screen display window.

- Working surface of A/C mode:

Please refer to Fig 24.

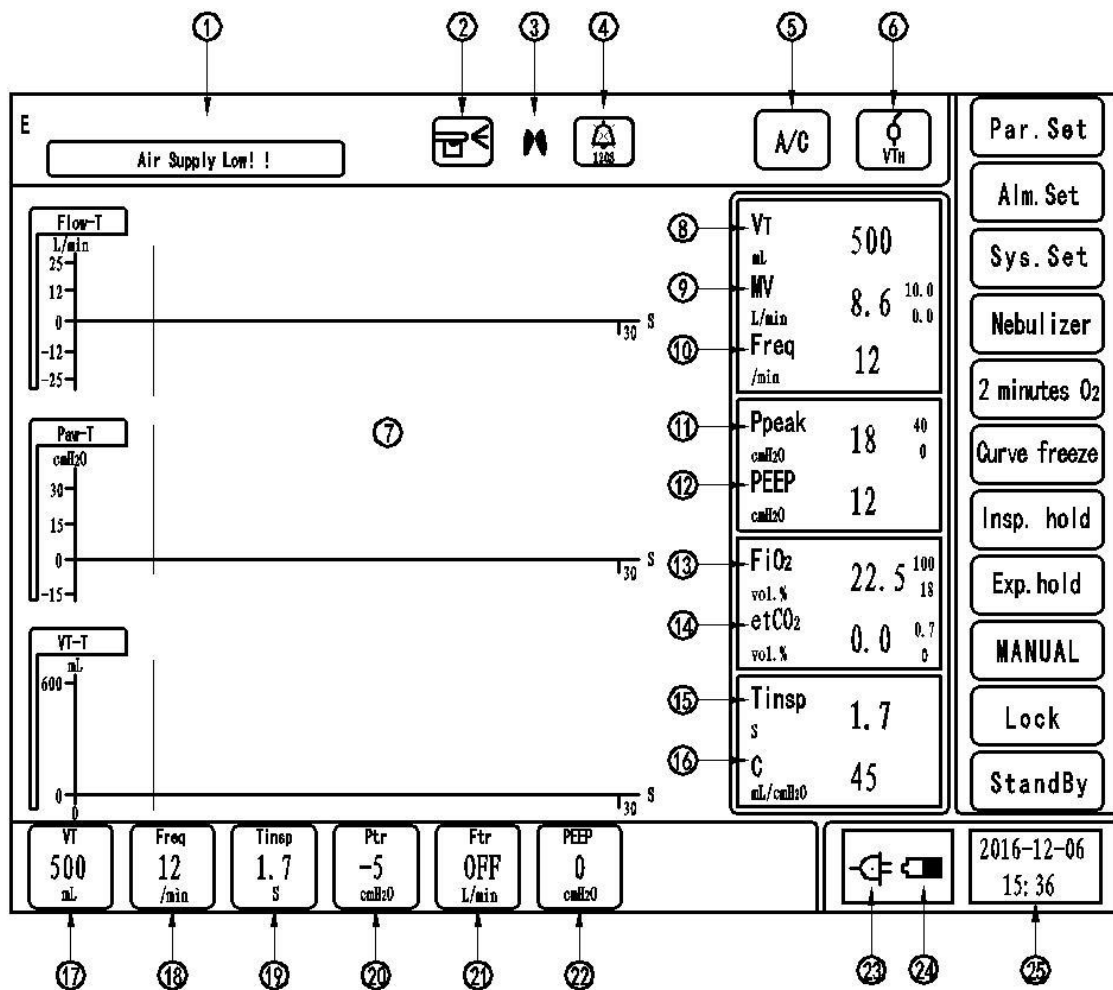


Fig 24 Working surface of A/C mode

Illustration for the surface:

- (1) is respectively indication place for alarms.
- (2) is indication for working status of nebulizer.
- (3) is indication for the trigger condition (this mode is no trigger).
- (4) is Alarm mute indication place.
- (5) is indication place for ventilation mode
- (6) is indication place for VT_H/VT_L mode.
- (7) is indication place for waveform.
- (8) is the monitoring value of tidal volume.
- (9) are the monitoring values of MV, the presetting values of upper and low limit for MV alarm .
- (10) is the monitoring values of frequency.
- (11) are the monitoring values of Ppeak, the presetting values of upper and low limit for Ppeak alarm .
- (12) is the monitoring values of PEEP.
- (13) are the monitoring values of O_2 concentration, the presetting values of upper and low limit for O_2 concentration alarm .
- (14) is the monitoring value of CO_2 .
- (15) is the monitoring value of inspiration time.
- (16) is the monitoring values of dynamic lung compliance.
- (17) ~ (22) are respectively indication place of the presetting values for tidal volume, frequency, inspiration time, inspiration platform., sigh time and PEEP.
- (23) is indication for working by main power.
- (24) is indication for working status of backup battery.
- (25) is indication for date.

Start up for operation——SIMV ventilation mode

- Enter SIMV mode:
 ——Choose SIMV mode under the surface of ventilation mode and parameter setting (Fig.16) ;
 ——Press adjusting shuttle/Confirmation knob (Item 15 in Fig 12) for confirmation and machine will enter standby status;
 ——Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to “Exit”, and press it for exit, and the machine will work under mode of SIMV.

- The above operation steps are also performed by touching relevant keys on the touch screen display window.

- Working surface of SIMV mode:

Please refer to Fig 25.

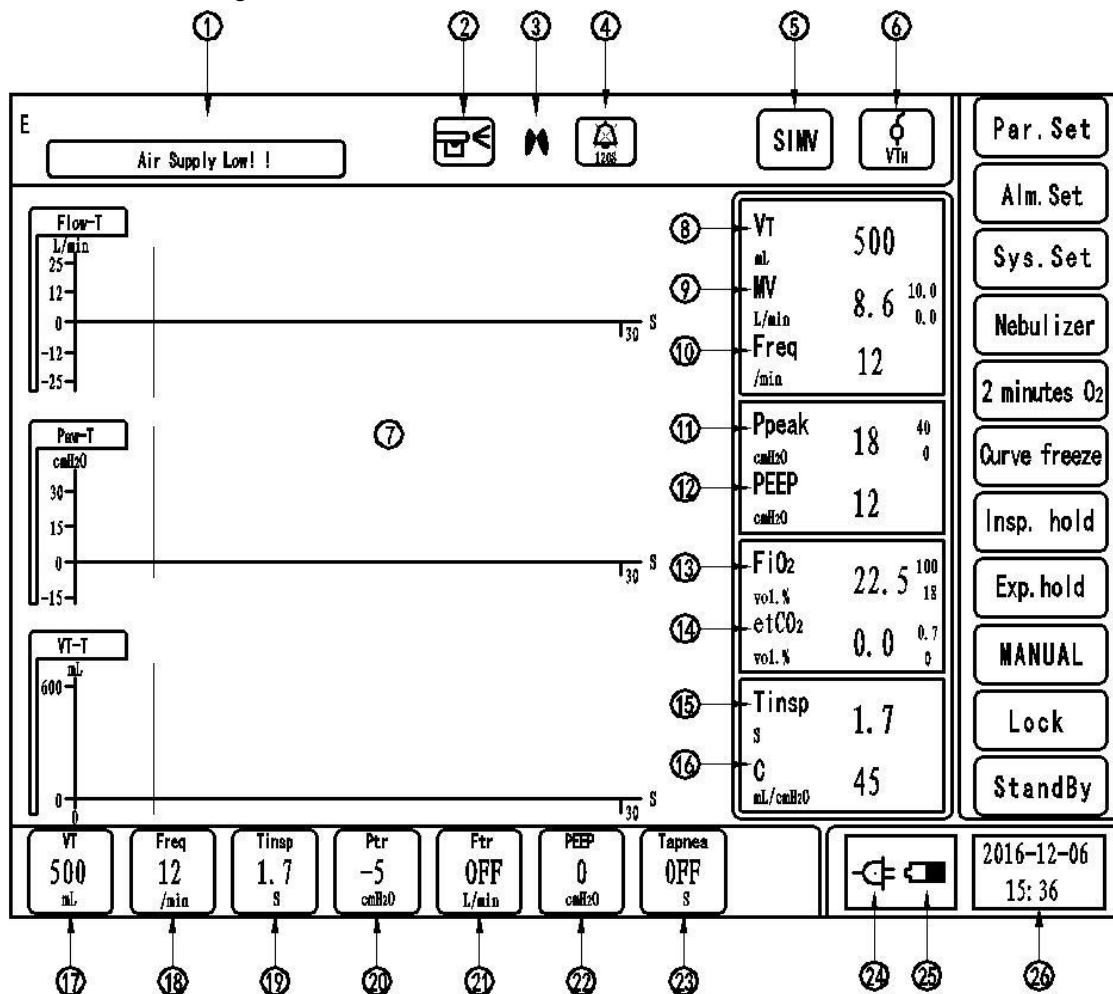


Fig 25 Working surface of SIMV mode

Illustration for the surface:

- (1) is respectively indication place for alarms.
- (2) is indication for working status of nebulizer.
- (3) is indication for the trigger condition (this mode is no trigger).
- (4) is Alarm mute indication place.
- (5) is indication place for ventilation mode
- (6) is indication place for VT_H/VT_L mode.
- (7) is indication place for waveform.
- (8) is the monitoring value of tidal volume.
- (9) are the monitoring values of MV, the presetting values of upper and low limit for MV alarm .
- (10) is the monitoring values of frequency.
- (11) are the monitoring values of Ppeak, the presetting values of upper and low limit for Ppeak alarm .
- (12) is the monitoring values of PEEP.
- (13) are the monitoring values of O_2 concentration, the presetting values of upper and low limit for O_2 concentration alarm .
- (14) is the monitoring value of CO_2 .
- (15) is the monitoring value of inspiration time.
- (16) is the monitoring values of dynamic lung compliance.
- (17) ~ (22) are respectively indication place of the presetting values for tidal volume, frequency, inspiration time, inspiration platform., sigh time and PEEP.
- (23) is indication for working by main power.
- (24) is indication for working status of backup battery.
- (25) is indication for date.

Start up for operation——PCV ventilation mode

- Enter PCV mode:
 - Choose PCV mode under the surface of ventilation mode and parameter setting (Fig.17) ;
 - Press adjusting shuttle/Confirmation knob (Item 15 in Fig 12) for confirmation and machine will enter standby status;
 - Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to “Exit”, and press it for exit, and the machine will work under mode of PCV;
- The above operation steps are also performed by touching relevant keys on the touch screen display window.
- Working surface of PCV mode:
 - Please refer to Fig 26.

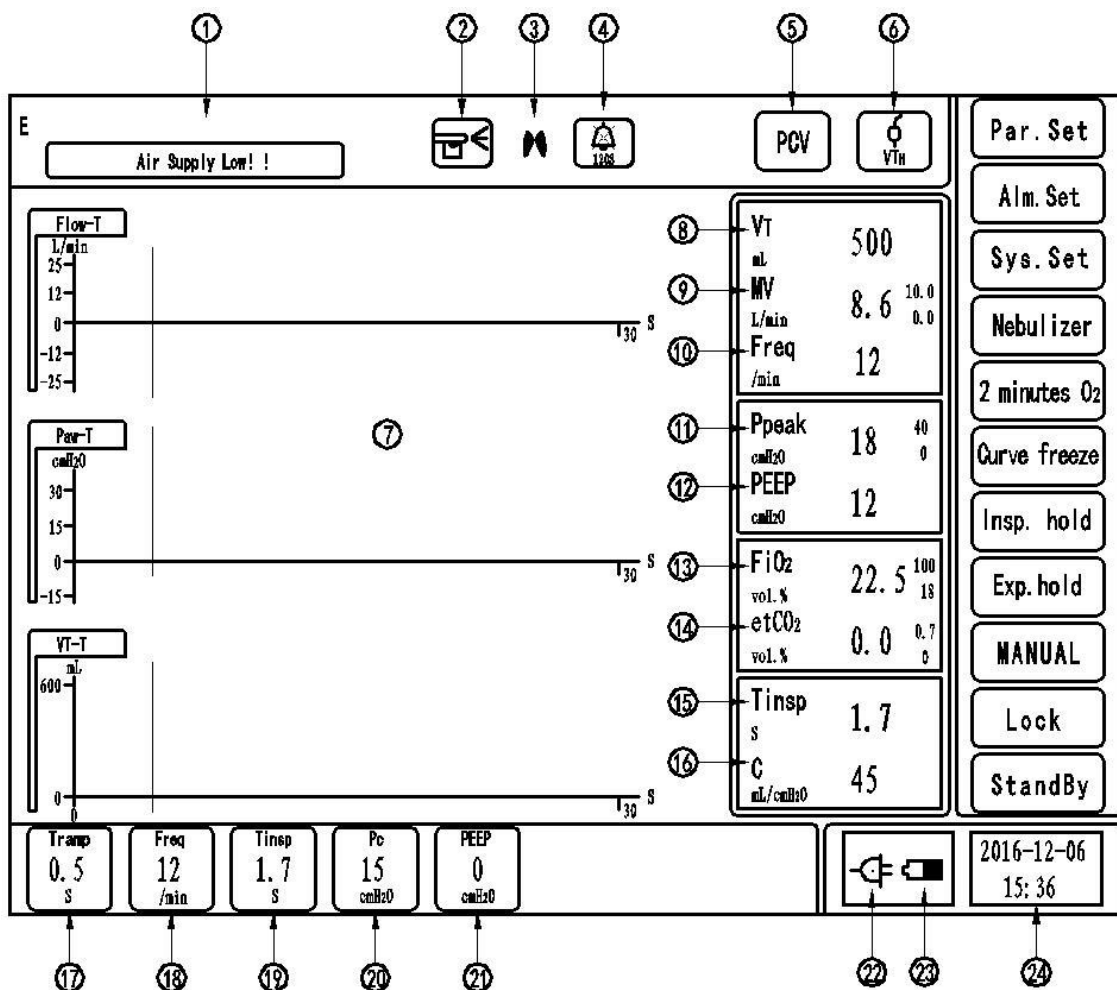


Fig 26 Working surface of PCV mode

Illustration for the surface:

- (1) is respectively indication place for alarms.
- (2) is indication for working status of nebulizer.
- (3) is indication for the trigger condition (this mode is no trigger).
- (4) is Alarm mute indication place.
- (5) is indication place for ventilation mode
- (6) is indication place for VT_H/VT_L mode.
- (7) is indication place for waveform.
- (8) is the monitoring value of tidal volume.
- (9) are the monitoring values of MV, the presetting values of upper and low limit for MV alarm .
- (10) is the monitoring values of frequency.
- (11) are the monitoring values of Ppeak, the presetting values of upper and low limit for Ppeak alarm .
- (12) is the monitoring values of PEEP.
- (13) are the monitoring values of O_2 concentration, the presetting values of upper and low limit for O_2 concentration alarm .
- (14) is the monitoring value of CO_2 .
- (15) is the monitoring value of inspiration time.
- (16) is the monitoring values of dynamic lung compliance.
- (17) ~ (22) are respectively indication place of the presetting values for tidal volume, frequency, inspiration time, inspiration platform, sigh time and PEEP.
- (23) is indication for working by main power.
- (24) is indication for working status of backup battery.
- (25) is indication for date.

Start up for operation——PSV ventilation mode

- Enter PSV mode:
 ——Choose PSV mode under the surface of ventilation mode and parameter setting (Fig.18) ;
 ——Press adjusting shuttle/Confirmation knob (Item 15 in Fig 12) for confirmation and machine will enter standby status;
 ——Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to “Exit”, and press it for exit, and the machine will work under mode of PSV.
- The above operation steps are also performed by touching relevant keys on the touch screen display window.
- Working surface of PSV mode:
 Please refer to Fig 27.

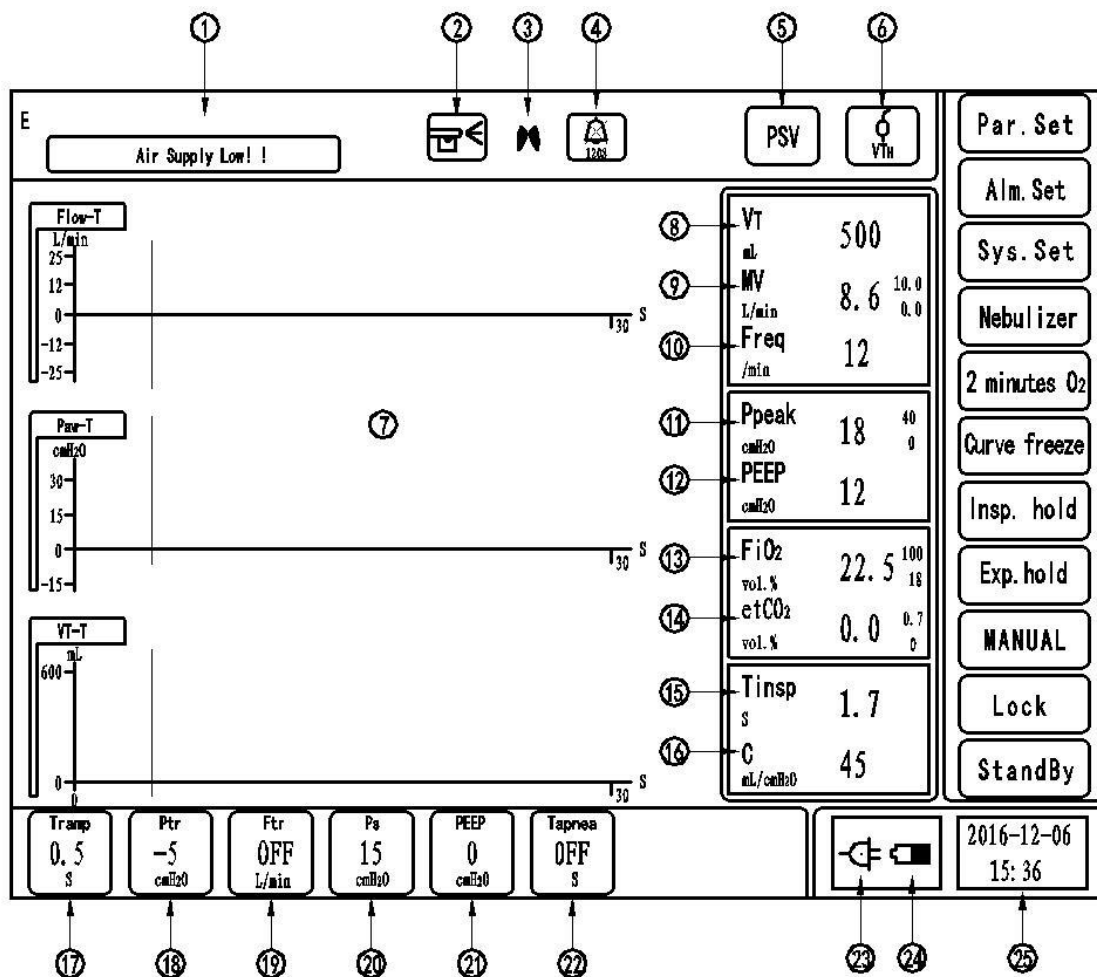


Fig 27 Working surface of PSV mode

Illustration for the surface:

- (1) is respectively indication place for alarms.
- (2) is indication for working status of nebulizer.
- (3) is indication for the trigger condition (this mode is no trigger).
- (4) is Alarm mute indication place.
- (5) is indication place for ventilation mode
- (6) is indication place for VT_H/VT_L mode.
- (7) is indication place for waveform.
- (8) is the monitoring value of tidal volume.
- (9) are the monitoring values of MV, the presetting values of upper and low limit for MV alarm .
- (10) is the monitoring values of frequency.
- (11) are the monitoring values of Ppeak, the presetting values of upper and low limit for Ppeak alarm .
- (12) is the monitoring values of PEEP.
- (13) are the monitoring values of O_2 concentration, the presetting values of upper and low limit for O_2 concentration alarm .
- (14) is the monitoring value of CO_2 .
- (15) is the monitoring value of inspiration time.
- (16) is the monitoring values of dynamic lung compliance.
- (17) ~ (22) are respectively indication place of the presetting values for tidal volume, frequency, inspiration time, inspiration platform., sigh time and PEEP.
- (23) is indication for working by main power.
- (24) is indication for working status of backup battery.
- (25) is indication for date.

Start up for operation——CPAP ventilation mode

- Enter CPAP mode:
 ——Choose CPAP mode under the surface of ventilation mode and parameter setting (Fig.19) ;
 ——Press adjusting shuttle/Confirmation knob (Item 15 in Fig 12) for confirmation and machine will enter standby status;
 ——Turn adjusting shuttle/Confirmation knob (Item 15 in Fig 12) to “Exit”, and press it for exit, and the machine will work under mode of CPAP.
- The above operation steps are also performed by touching relevant keys on the touch screen display window.
- Working surface of CPAP mode:
 Please refer to Fig 28.

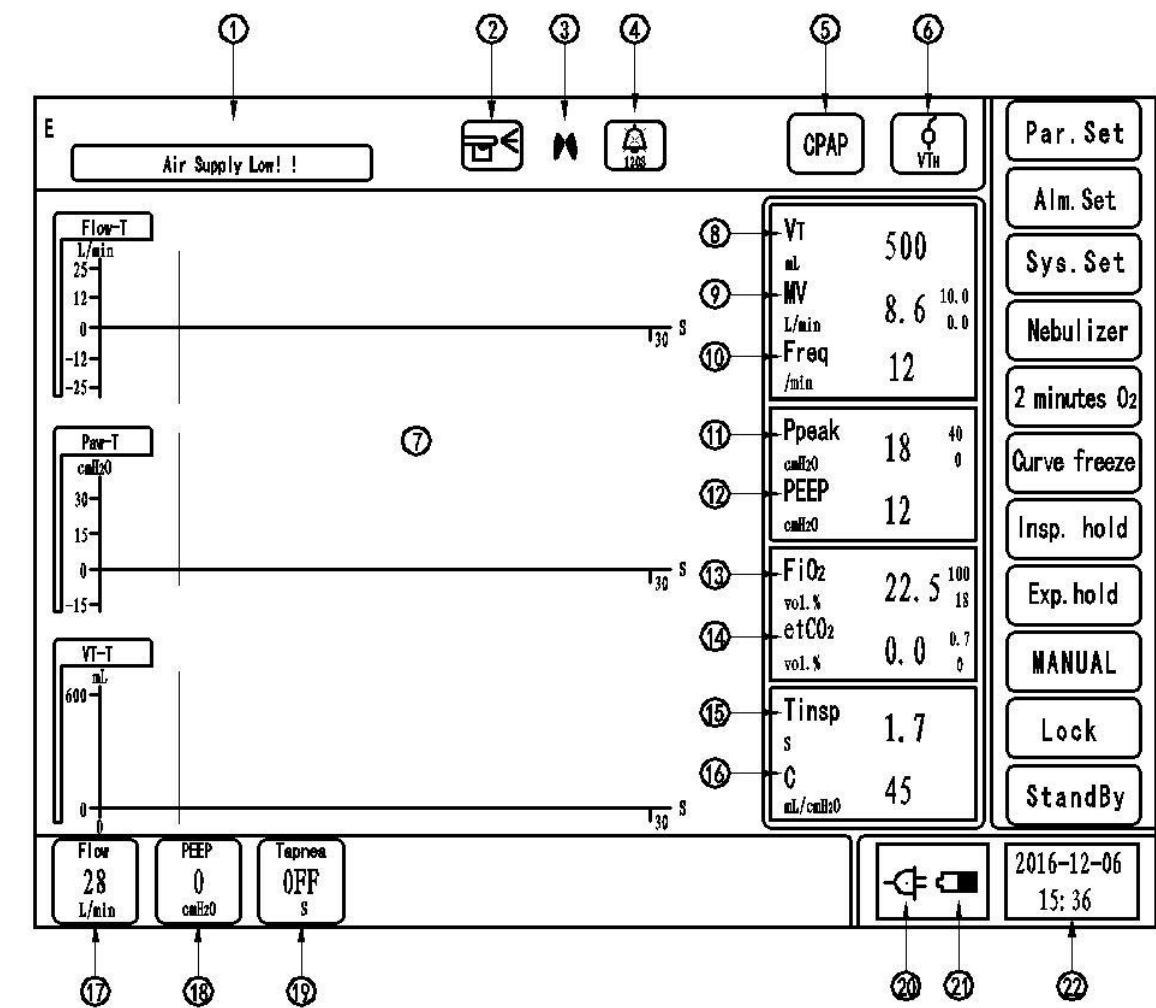


Fig 28 Working surface of CPAP mode

Illustration for the surface:

- (1) is respectively indication place for alarms.
- (2) is indication for working status of nebulizer.
- (3) is indication for the trigger condition (this mode is no trigger).
- (4) is Alarm mute indication place.
- (5) is indication place for ventilation mode
- (6) is indication place for VT_H/VT_L mode.
- (7) is indication place for waveform.
- (8) is the monitoring value of tidal volume.
- (9) are the monitoring values of MV, the presetting values of upper and low limit for MV alarm .
- (10) is the monitoring values of frequency.
- (11) are the monitoring values of Ppeak, the presetting values of upper and low limit for Ppeak alarm .
- (12) is the monitoring values of PEEP.
- (13) are the monitoring values of O_2 concentration, the presetting values of upper and low limit for O_2 concentration alarm .
- (14) is the monitoring value of CO_2 .
- (15) is the monitoring value of inspiration time.
- (16) is the monitoring values of dynamic lung compliance.
- (17) ~ (22) are respectively indication place of the presetting values for tidal volume, frequency, inspiration time, inspiration platform., sigh time and PEEP.
- (23) is indication for working by main power.
- (24) is indication for working status of backup battery.
- (25) is indication for date.

Start up for operation——MANUAL ventilation mode

——Touch MANUAL key (Item 10 in Fig12), the machine will supply the gas to the patient. The machine will stop gas supply if you do not press the MANUAL key.

Start up for operation——Apnea function

hint: Only under the ventilation mode of SIMV、CPAP and PSV, apnea time can be set.

——Before Choose of apnea mode, please set the proper ventilation parameters under the mode of A/C.

——Choose apnea ventilation under mode of SIMV、SPONT/CPAP、PSV and set the apnea time.

——If there is no spontaneous or assisted ventilation during Apnea time, the mode will change to AC, and there is alarm indication of Apnea (Red color).

——If there are 4 times of Spontaneous ventilation after change mode to A/C, the mode will change to the former ventilation mode, and there is alarm indication of Apnea (Green color).


Note: When the sigh time is set to OFF, there will be no apnea ventilation or apnea alarm indication.

Start up for operation——SIGH function

——Under the mode of IPPV, choose sigh function and set sigh time.

Start up for operation——Nebulization function

——Under the every ventilation mode, touch “Nebulizer” key (item 5 in Fig. 12), ventilator starts

nebulization function and its touch screen displays “” ;

——Touch nebulizer key (item 5 in Fig. 12) again, ventilator switches off nebulizer.

Start up for operation——2 minutes O₂ supply function

——Under the every ventilation mode, touch “2 minutes O₂” key (item 6 in Fig. 12), ventilator starts 2 minutes 100% O₂ supply function ;

——After 2 minutes O₂ supply, ventilator return to the former ventilation mode.

Start up for operation——Curve freeze function

——Under the every ventilation mode, touch “curve freeze” key (item 7 in Fig. 12), ventilator starts curve freeze function, the display waveforms are freezed;

——Touch “curve freeze” key (item 7 in Fig. 12) again, curve freeze function disappears.


Start up for operation——Inspiration and expiration hold function


- Under the every ventilation mode, touch "Insp. hold" key (item 8 in Fig.12) or "Exp. hold" key (item 9 in Fig. 12) for a long time, ventilator starts inspiration hold or expiration hold function;
- These functions will disappear after 30s or loosening finger.

Start up for operation——Standby function

- Under the every ventilation mode, touch "StandBy" key (item 12 in Fig.12) and last about 5s, ventilator enter to standby surface.

Start up for operation——Mute function

- When an alarm occurs, the alarm will resume within 2 minutes by touching mute key "", (item 4 in Fig. 23). after mute time (2 minutes), alarm will remain unless the problem is solved properly.

- When the sound alarm is muted, the alarm indication " " on the screen will remain unless the problem is solved properly.

Start up for operation——Key lock function

- Under the every ventilation mode, touch "Lock" key (item 11 in Fig.12), this key turns into "Unlock", at the same time colour of "Par. set", "Alm. set", "Sys. set" and "StandBy" keys become gray, these keys can not be operated;
- Touch "Unlock" key (item 11 in Fig.12), this key turns into "Lock", setting function resume.

Waveform

——Under the every ventilation mode, touch “Sys. set” key (item 4 in Fig.12), enter system setting surface;

——Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) and choose “Graph”;

——Press adjusting shuttle /confirmation knob (Item 15 in Fig 12) to enter “Graph” surface, refer to Fig 29;

——Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) to choose required waveform;

——Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) to “Exit” and press it to exit this surface.

——The above operation steps are also performed by touching relevant keys on the touch screen display window.

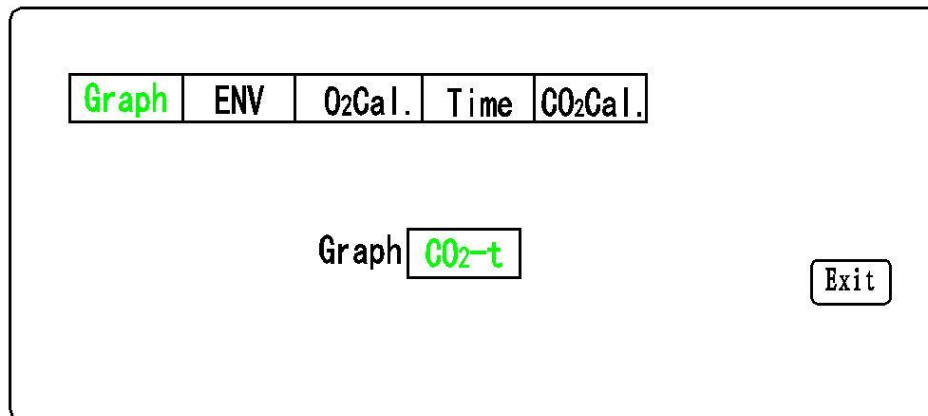


Fig 29 Waveform

Language and pressure zero calibration

——Under the every ventilation mode, touch “Sys. set” key (item 4 in Fig.12), enter system setting surface;

——Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) and choose “ENV”;

——Press adjusting shuttle /confirmation knob (Item 15 in Fig 12) to enter “ENV” surface, refer to Fig 30;

——Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) to choose required language or do pressure zero calibration ;

——Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) to “Exit” and press it to exit this surface.

——The above operation steps are also performed by touching relevant keys on the touch screen display window.

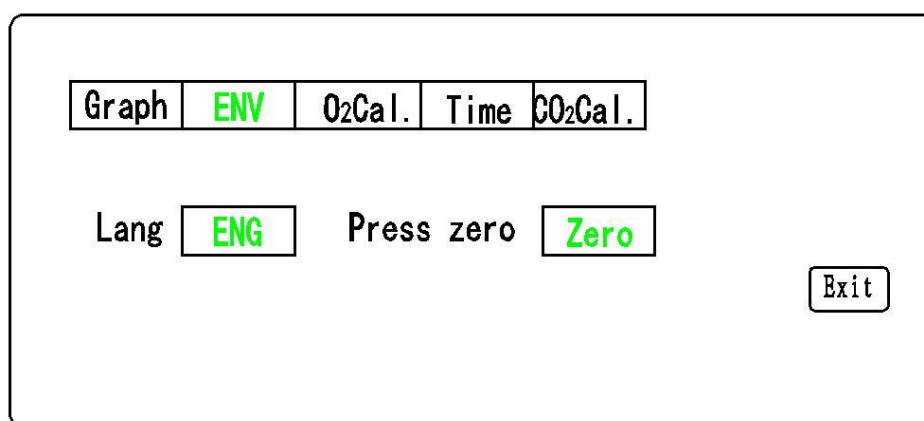


Fig 30 Language and pressure zero calibration

Oxygen concentration calibration

—Under the every ventilation mode, touch “Sys. set” key (item 4 in Fig.12), enter system setting surface;

—Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) and choose “O₂ Cal.”;

—press adjusting shuttle /confirmation knob (Item 15 in Fig 12) to enter “O₂ Cal.”surface, refer to Fig 31;

—Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) to “21%”and press it till the indication “Complete ”will be on the screen;

—Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) to “100%”and press it till the indication “Complete ”will be on the screen;

—After Completing O₂ calibration, turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) to “Exit” and press it to exit O₂ calibration surface.

—The above operation steps are also performed by touching relevant keys on the touch screen display window.

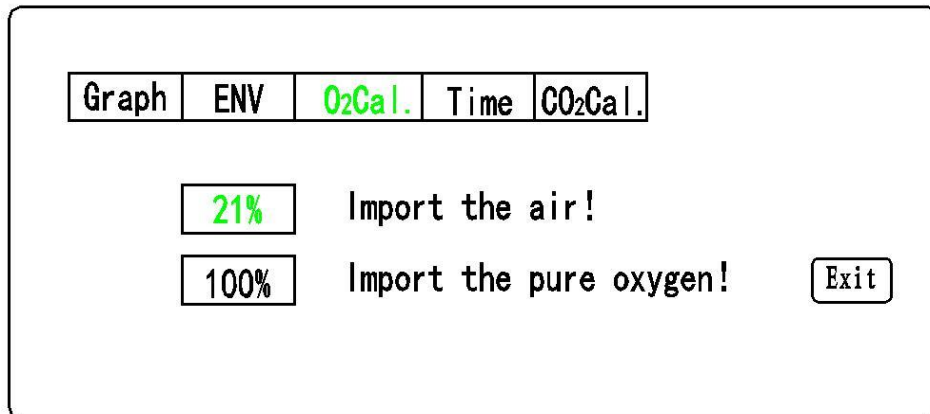


Fig 31 Oxygen concentration calibration

Hint: Calibrate the oxygen concentration before each use.

Date setting

- Under the every ventilation mode, touch “Sys. set” key (item 4 in Fig.12), enter system setting surface;
- Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) and choose “Time”;
- Press adjusting shuttle /confirmation knob (Item 15 in Fig 12) to enter “Time” surface, refer to Fig 32;
- Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) to set the date;
- Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) to “Exit” and press it to exit this surface.
- The above operation steps are also performed by touching relevant keys on the touch screen display window.

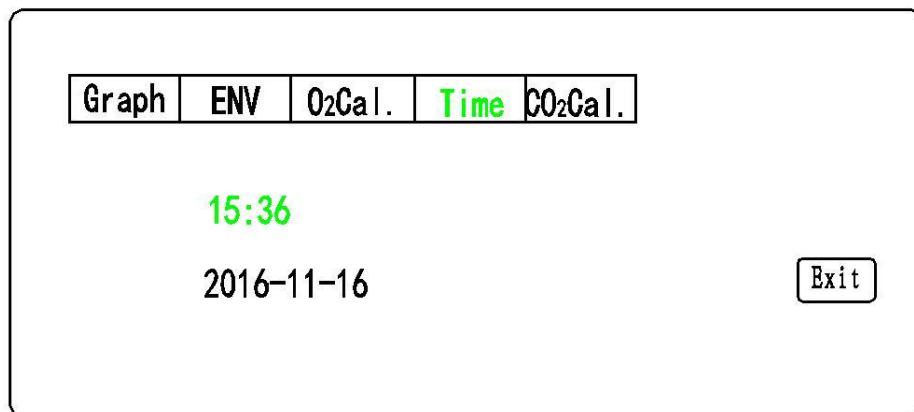


Fig 32 Date setting

CO₂ zero

——Under the every ventilation mode, touch “Sys. set” key (item 4 in Fig.12), enter system setting surface;

——Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) and choose “CO₂ Cal.” refer to Fig 33;

——Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) to enter “CO₂ zero” and press it for CO₂ zero;

——Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) to enter “CO₂ Unit” and press it for confirmation;

——Turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) to required CO₂ Unit;

——After Completing CO₂ calibration, turn adjusting shuttle /confirmation knob (Item 15 in Fig 12) to “Exit” and press it to exit CO₂ calibration surface.

——The above operation steps are also performed by touching relevant keys on the touch screen display window.

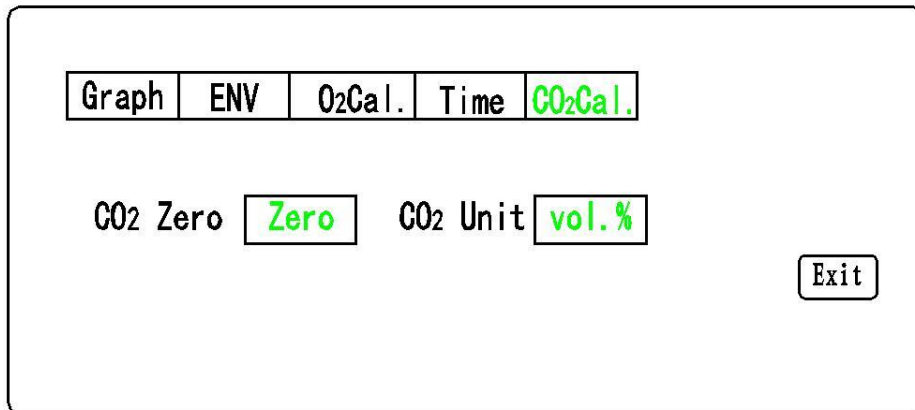


Fig 33 CO₂ zero

Operation of Air and O₂ blender

Turn O₂ and Air blender adjusting knob(Item 2 Fig 1) of the blender to the required scale.

Operation of air compressor (if equipped with air compressor)

When the machine is connected to the main power, press the switch of air compressor (Item 5 Fig 3), and it will start working, pressure gauge on the compressor panel should be 0.4MPa when the compressor is working stably.

On completion

When the operation is completed:

- Switch off the starting switch of ventilator (Item 17 in Fig 1);
- Switch off the power of humidifier;
- If equipped with air compressor ,Switch off the switch of the air compressor (Item 5 in Fig 3);
- If take central gas supply as gas source, cut off the central gas supply;
- If take cylinder gas as the gas source, please refer to the chapter of on completion of operation under Installation and use of pressure regulator;
- For there is interval between cut off O₂ and Air, so there is alarm during the process of gas cut off, which is normal.
- If there is a long interval to next use of the ventilator, pull out the power line from the main power supply socket.

Alarm, warning and hint information






Warning:

- 1) If there is alarm during operation, safeguard the patient firstly, then check immediately to fix the fault.
- 2) As to the alarm of humidifier, please refer to the operation manual of humidifier.

Please refer to table 2 of the alarm and warning information.




Table 2 Alarm and warning information

Alarm and warning information	Cause of alarm and warning
"No VT"	Gas failure in 6 second
"MV high"	MV over the set upper alarm limit of MV
"MV low"	MV under the set low alarm limit of MV
"PAW high"	Ppeak over the set upper alarm limit of Ppeak
"PAW low"	Ppeak under the set low alarm limit of Ppeak in 5 to 20 seconds
"FiO ₂ high"	Concentration over set upper alarm limit of O ₂ concentration
"FiO ₂ low"	Concentration under set low alarm limit of O ₂ concentration
"etCO ₂ high"	Concentration over set upper alarm limit of CO ₂ concentration
"etCO ₂ low"	Concentration under set low alarm limit of CO ₂ concentration
"Pcon high"	Continuous pressure over the set upper alarm limit of continuous pressure in 16 second (PEEP+1.5kPa)
"Air supply low"	Air supply pressure is lower than 280 kPa
"O ₂ supply low"	O ₂ supply pressure is lower than 280 kPa
"Fan failure"	Fan doesn't work
"Apnea" (Red)	There is no spontaneous or assisted ventilation during SIGH time, the mode will change to AC, and there is alarm indication of Apnea (Red color).
"Apnea" (Black)	There are 3 times of Spontaneous ventilation after change mode to A/C, the mode will change to the former ventilation mode, and there is alarm indication of Apnea (Black color).
"  "	Main power disconnection or problem, and the power is supplied by Battery.

	Power supplied by Battery and the battery low voltage (Lower than 11.3V)
	Internal power failure
Alarm light of the compressor (Item 4 in Fig 3) is on (if equipped with air compressor)	Temperature of compressor pump over 85 °C ± 10°C

Please refer to table 3 of the hint information.

Table 3 Hint information

Hint information	Meaning of hint information
	Power supply by main power
	Mute
Lock	Lock
Unlock	Unlock
VT _H	High V _T mode
VT _L	Low V _T mode
	Trigger mark
MANUAL	Manual ventilation

Clearance and disinfection



Warning:

- 1) Do not use talc, zinc stearate, CaCO₃, cornstarch or similar material, which will enter the lung or Respiratory tract of the patient.
- 2) Any liquid into the machine may lead to electric shock or damage to the machine.



Note:

- 1) Read the operation manual of the clearing agent.
- 2) Read the operation of the disinfections equipment
- 3) Do not use irritation clearing agent of organic, halogenated, or petroleum Solvent, anesthesia agent, detergent for glass, acetone.
- 4) Do not use abrasive clearing agent of steel wool, or sliver cleaner.
- 5) Put the liquid from the electronic parts.
- 6) No liquid into the inner of machine.
- 7) After clearance and disinfection, check the machine according to the Chapter of "Check before operation".
- 8) As to the clearance and disinfection of humidifier, please refer to the operation manual of humidifier.

- After being used by infectious patients, remove the breathing pipe (breathing tube), Y connector, inhalation port, exhalation port, exhalation valve, exhalation tidal volume sampling tube and water trap, wash the parts with soapsuds at first, and then use clean water to rinse, blow dry, put the parts in the disinfection cabinet or immerse them in 70% alcohol for 30 minutes, then rinse with clean water and dry, or refer to the disinfection norm.
- After being used by general patients, remove the breathing pipe (breathing tube), Y connector, inhalation port, exhalation port, exhalation valve, exhalation tidal volume sampling tube and water trap, wash the parts with clean water and dry, or refer to the disinfection norm.
- Clean the surface of the machine with soft cloth soaked with water-soluble disinfectant, and also can use organic solvent to clean the surface.

Clearance and disinfection of the contact part with patient

Clearance and disinfection before first use

- Clean the surface of the machine with soft cloth soaked with water-soluble disinfectant.
- Wash and dry the high-pressure hoses.
- Wash breathing tubes, Y connector, inhalation port, exhalation port, exhalation valve, tidal volume sampling tube, water trap by water, and dry them by air, or refer to the Code of disinfection.

Clearance and disinfection of reusable part

The reusable parts of this machine include Breathing tubes with Y connector, inhalation port, exhalation port, exhalation valve, tidal volume sampling tube and water trap.

Process for clearance and disinfection after operation:

- Remove the parts from the machine;
- Wash the parts by soapsuds;
- Wash the parts by clean water
- Put the parts in the sterilizing cabinet or immerse them in 70% alcohol for 30 minutes. Or refer to the Code of disinfection.
- Wash the parts by clear water.

Using times for the reusable part

Under normal condition, inhalation port, exhalation port, exhalation valve (Except gasket and O type circle), tidal volume sampling tube and water trap can be used with unlimited times.

- gasket and O type circle (exhalation valve) should be changed every year or after 2500 hours operation.
- As to the using times of breathing tubes with Y connector, please refer to its operation manual.

Surface of the machine

Clean the surface of the machine with soft cloth soaked with water-soluble disinfectant. Never use organic solvent.

Maintenance



Warning:

- 1) Do not use machine with problem.
- 2) The machine can only be repaired by authorized personnel. If the user needs to repair, This machine can only be operated by special qualified personnel after training. When necessary, our company can provide the necessary information
- 3) Only authorized and qualified personnel can do calibration of the machine, or special qualified personnel after training.
- 4) Do not throw the battery into fire in case of explosive; Do not open or destroy the battery, for it contains injurant which may injure skin and eyes. Please dispose the battery under the local environment law.
- 5) Do not discard the replaced electronic and plastic parts, which will cause environment pollution. Please dispose the battery under the local environment law.
- 6) As to the maintenance of humidifier, please refer to the operation manual of humidifier.



Note:

After maintenance, check the machine according to the Chapter of "Check before operation".

Before everyday operation

Before first operation, clean the surface of the machine everyday.

After operation of every patient

Do disinfection after operation of every patient.

Assemble after disinfection

Check the gasket of exhalation valve and O type circle and other part when doing assemble after disinfection. If any part is broken, replace it immediately.

Every day or in case of needed

- Water drain of water trap (Item 3 in Fig7). Turn clockwise the water trap, drain the water and turn counterclockwise to install the water trap.
- Filter drain (see Fig 6.

Every month or incase of needed

- If equipped with air compressor, clean input gas filter net of air compressor every month or every use 300 hours, firstly take down the filter net at bottom of machine (Item 3 figure 7) , clean it with detergent, then rinse and dry(not use heater to dry the sponges), Install filter net in the original position after drying, otherwise do not turn on the machine.

Every three months or over 1000 hours

If equipped with air compressor

- Every three months or over 1000 hours, wash the sponge in the round filter(Item 1 Fig 32) by one time.
- Take off the back panel by cross screwdriver.
- Take off the round filter and remove the cover.
- Get out the sponge and wash it by cleaner.
- Wash it by clear water (do not dry it by the heater), assemble it after it is dry. Refer to Fig 34.

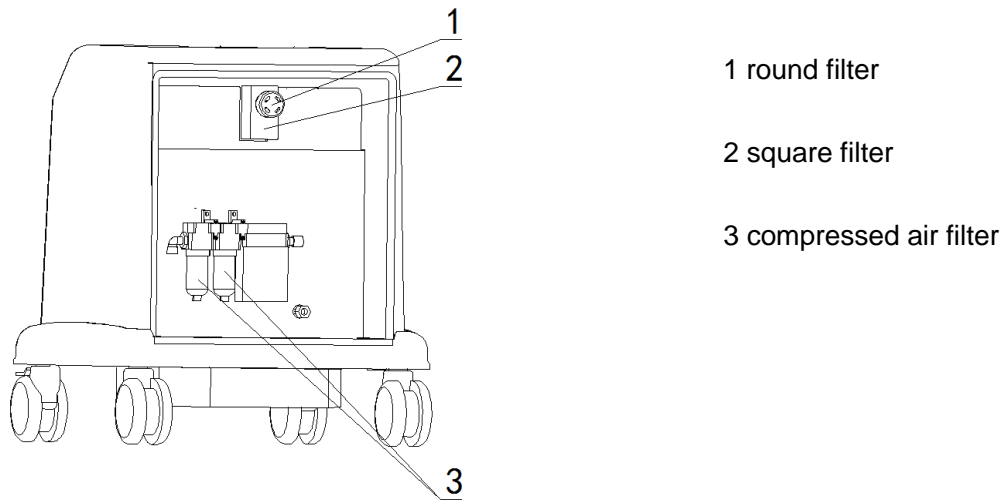


Fig 34 Clearance and replacement of input gas filter net

Operation over 1500 hours or 6 months

- If equipped with air compressor, every 6 months or over 1500 hours, replace the square filter(Item 2 Fig 31). According to the aforementioned method to get out the square filter, assemble it after replacing. Refer to Fig 34.
- Test of battery
 - 1) Discharge the battery. Please refer to the Chapter of Discharge of battery
 - 2) Charge over 12 hours. Refer to Chapter Charge of battery.
 - 3) Switch on the machine and work under power supply by battery, if the power state indication place display the signal of "■", or the battery can not supply power for 30 minutes, the battery is broken, so you have to replace the battery. Please refer to Chapter Replacing of the back-up battery

Every year or operation over 2500 hours

- Maintain, and check the machine completely;
- Replace the gasket and O type circle;
- Replace the input gas filter net (Item 6 Fig 3)of the compressor (if equipped with air compressor)
- Check and calibrate:
 - Monitoring value of tidal volume and minute ventilation;
 - Monitoring value of frequency;
 - Monitoring value of inhalation time;
 - Monitoring value of pressure;
 - Monitoring value of O₂ concentration.

Every two years or operation over 5000 hours

- Ventilator:
 - Replace the O₂ sensor (or replace as needed) Refer to Fig 9
 - Replace of battery (or replace as needed)
- Compressor (if equipped with air compressor):
 - Replace the compressed air filter core (Item 3 Fig 34).

Waste disposal

Disposal of battery and O₂ sensor



Warning

Do not throw the battery or O₂ sensor into the fire in case of explosive; Do not open or destroy the them, because it contains injurant which may injure skin and eyes. Please dispose the battery under the local environment law.

- For there is polluting material in battery, please dispose battery according local environment law.
- O₂ sensor is special waste, do dispose it according local environment law.
- Please refer to Environmental Protection Agency or government or waste disposal company for relevant environment law.

Disposal of electronic and plastic parts



Warning

Do not discard the broken electronic and plastic parts ignorantly for environment protection.

- Do not discard the broken electronic and plastic parts ignorantly for environment protection. Please dispose them under the environment law.

Scrap disposal of medical equipment

When service life is over, do not dispose it as household waste, and dispose it separately.

- Please abide the local environment law for waste disposal.
- Please refer to Environmental Protection Agency or government or waste disposal company for waste disposal.

Alarm and disposal system



Warning:



- 1) If there is alarm during the operation, safeguard the patient firstly, then check immediately to fix the fault.
- 2) If there's failure during operation, and the machine stop working, please do manual ventilation to the patient.

- If there is alarm during the operation, safeguard the patient firstly, then check immediately to fix the fault.
- When reach the alarm conditions, there's the alarm immediately.
- When there are two or more alarm occur at the same time, the alarm is the high priority alarm.
- The position of the operators:
 - Visual alarm: The operator is 1 m from the display screen, at any position (in the cone which is 30 ° angle with the center of the screen plane level);
 - Auditory alarm: The operator is at any position(1 m from equipment)
- Before and after the interruption of power supply, alarm default values will not change.
- Alarm default values must do with access change or storage change by a special tool.
- The volume of the auditory alarm signal: high priority: 68 dB middle priority: 68 dB
- The alarm priority is classified by the risk level to the patient.
- The high priority alarm should be disposed immediately.
- Alarm priority:

Priority	Alarm way
High	Continuous and repeated ten tones and with 7 second interval
Medium	Continuous and repeated three tones and with 23 second interval
Low	Odd tune

● Alarm information:

Alarm	Priority	Setting range	Default value	Alarming way
High Ppeak alarm	High	20 ~ 100 cmH ₂ O	40 cmH ₂ O	When the monitoring value over the upper limit of Ppeak, there will be a sound alarm and display "PAW high !!!".
Low Ppeak alarm	High	0 ~ 20 cmH ₂ O	4 cmH ₂ O	When the monitoring value under low limit of Ppeak, there will be a sound alarm and display "PAW low !!!".
High MV alarm	Medium	adult 5 ~ 99 L/min child 1 ~ 30 L/min	10 L/min	When the monitoring value over upper limit of MV, there will be a sound alarm and display "MV high !!!".
Low MV alarm	Medium	0 ~ 20 L/min	0 L/min	When the monitoring value under low limit of MV, there will sound alarm and display "MV low !!!".
Gas failure alarm	Medium	--	--	If there is no tidal volume in 6 seconds, there will be a sound alarm and display "No VT !!!".
High O ₂ alarm	High	19% ~ 100%	99%	When the monitoring value of O ₂ concentration over the upper limit of O ₂ , there will be a sound alarm and display "FiO ₂ high !!!".
Low O ₂ alarm	High	18% ~ 99%	18%	When the monitoring value of O ₂ concentration under low limit of O ₂ concentration, there will be a sound alarm and display "FiO ₂ low !!!".

Alarm	Priority	Setting range	Default value	Alarming way
Continuous pressure alarm	High			If the airway pressure (PEEP+15 cmH ₂ O) over or under the set upper or low limit of continuous pressure alarm in 16 seconds, there will be a sound alarm and display "Pcon high !!!".
Apnea alarm	Medium	OFF , 5s ~ 60s	OFF	If there is no spontaneous or assisted ventilation during SIGH time, the mode will change to AC mode, and there will be a sound alarm and display " Apnea "(Red color). If there are 3 times of Spontaneous ventilation after change mode to A/C, the mode will change to the former ventilation mode, and there will be a sound alarm and display "Apnea !! "(Green color).
Power failure alarm	Low	--	--	Main power disconnection or problem, the machine power supply will be battery, there will be a sound alarm and display of "  ".
Low voltage alarm	Medium	--	--	When the voltage of back-up battery is low (11.3V), the power state indication place will display the signal of "  ", and there will be a sound alarm.

Alarm	Priority	Setting range	Default value	Alarming way
Air supply pressure low	Medium	--	--	When the air supply pressure is lower than 280 kPa, the screen will display the signal of "Air supply low !!", and there will be a sound alarm.
O ₂ supply pressure low	Medium	--	--	When the O ₂ supply pressure is lower than 280 kPa, the screen will display the signal of "O ₂ supply low !!", and there will be a sound alarm.
Fan failure	Medium	--	--	When the fan doesn't work, the screen will display the signal of "Fan fault !!", and there will be a sound alarm.
High temperature of compressor pump alarm (if equipped with air compressor)	--	--	--	Sound alarm and alarm indication light will be on

● Cause of alarm and solution of the alarm:

Alarm	Cause	Solution of alarm
High Ppeak alarm	1 Block of breathing tubes 2 Block of patient airway. 3 Upper limit of alarm is too low. 4 Ventilation parameters are set improperly.	1 Check the breathing tubes 2 Check the patient status 3 Re-set the upper limit of alarm. 4 Reset ventilation parameters.
Low Ppeak alarm	1 Leakage or disconnection of breathing circuit pipe 2 Low limit of alarm is too high. 3 The compliance of patient changes.	1 Check and reconnect the pipe. 2 Reset the low limit of alarm 3 Check the patient status.
High MV alarm	1 Upper limit of MV alarm is too low. 2 High frequency or High tidal volume	1 Reset the upper limit of MV alarm. 2 Reset frequency or tidal volume
Low MV alarm	1 Low limit of MV is too high. 2 Leakage or disconnection of breathing tube 3 Low frequency or tidal volume 4 No input gas 5 Problem with flow sensor	1 Reset the low limit of MV. 2 Check and reconnect the tube. 3 Reset frequency or tidal volume 4 Check the input gas supply 5 Check the flow sensor
High O ₂ concentration alarm	1 Upper limit of alarm is too low. 2 Problem with Air and O ₂ blender adjustment	1 Reset the upper limit of O ₂ . 2 Re-adjust the air and O ₂ blender.
Low O ₂ concentration alarm	1 Low limit of alarm is too high. 2 problem of O ₂ sensor. 3 Problem with Air and O ₂ blender adjustment	1 Reset the low limit of O ₂ alarm. 2 Calibrate the O ₂ sensor. 3 Re-adjust the air and O ₂ blender
Gas failure alarm	1 With upper limit of Ppeak alarm a. Block of pipe b. Block of patient airway 2 With low limit of Ppeak alarm a. Leakage and disconnection of breathing tubes. b. No input gas. c. No tidal volume 3 Problem with flow sensor	1 a. Check the breathing tubes b. Check the patient status 2 a. Check and reconnect the pipe b. Check input gas supply c. Check the patient status. 3 Check the flow sensor.
Apnea alarm	1 Problem with breathing circuit pipe 2 Block of patient airway 3 Leakage and disconnection of breathing circuit pipe. 4 No input gas 5 No tidal volume 6 Problem with flow sensor	1 Check the pipe 2 Check patient status 3 Check and reconnect the pipe 4 Check the input gas supply 5 Check patient status 6 Check the flow sensor

Alarm	Cause	Solution of alarm
Continuous pressure alarm	1 Problem with breathing tubes 2 Block of patient airway 3 Alarm limit of is too low 4 Ventilation parameters are set improperly.	1 Check and reconnect the pipe 2 Check the patient status 3 Reset the alarm limit 4 Reset the ventilation parameters
Power failure alarm	1 Main power disconnection or problem 2 Problem with fuse	1 Check the main power supply 2 Replace the fuse
Alarm of low voltage of battery	1 Low voltage of battery	1 Change the power supply to main power
Air supply pressure low	1 Air supply pressure is low	1 Check gas source
O ₂ supply pressure low	1 O ₂ supply pressure is low.	1 Check gas source
Fan failure	1 Fan doesn't work.	1 Change the fan.
Alarm of high temperature of compressor pump (if equipped with air compressor)	1 Ventilation of working place is not good, and temperature of working place is too high. 2 Block of ventilation port. 3 Problem with fan	1 Improve the condition of working place 2 Clean the port. 3 Change the fan

Fault and solution way

- Cause to the fault and solution way:

Fault	Cause	Solution way
There is no display on screen and ventilator do not work.	1 The main power is off 2 Power line disconnection 3 The starting switch is off. 4 Fuse is broken	1 Check the power supply in the working place 2 Connect the power line 3 Switch on the ventilator 4 Change the fuse
Abnormal display of tidal volume	1 Loose connection of flow sensor sampling tube 2 Leakage of breathing circuit pipe 3 Leakage of exhalation valve	1 Re-connect the flow sensor sampling tube 2 Re-connect or change pipe 3 Check exhalation valve
Leakage of breathing tubes	1 Pipe broken or connector loose 2 Leakage of exhalation valve	1 Re-connect or change pipe 2 Check exhalation valve
The output pressure of compressor is low (if equipped with air compressor)	1 Leakage of the compressor 2 Block of air filter	1 Check the airway of compressor 2 Change new air filter
Compressor do not work (if equipped with air compressor)	1 Power supply disconnection 2 Low voltage of main power	1 Connect machine to main power 2 Check voltage of main power

Main technical specification

Environment conditions

- Working environment:
 - Ambient temperature 5 °C ~ 40 °C
 - Relative humidity ≤80 %
 - Atmospheric pressure 700 hPa ~ 1060 hPa
- Storage environment:
 - Ambient temperature - 20 °C ~ + 50 °C
 - Relative humidity ≤93 %
 - Atmospheric pressure 500 hPa ~ 1060 hPa

Classification

Classified according to IEC60601-1, S1200 belong to:

- Class I equipment, internally powered equipment;
- Category B equipment;
- Common equipment;
- Continuous operation;
- please refer to the Chapter “clearance and disinfection”.

Gas supply

- Gas source O₂ (For medical use)
Air (For medical use) or compressed air
- Rated working pressure 400 kPa
- Input pressure range 280 kPa ~ 600 kPa
- Output pressure of regulator (gas cylinder supply) 400 kPa
- Safety valve 750kPa

Power supply

- Voltage ~ 220 V \pm 22 V
- Frequency 50 Hz \pm 1 Hz
- Input power 900VA (if equipped with air compressor)
80 VA (if not equipped with air compressor)
- Internal power DC12V 4Ah
- Fuse
 - Main power T1AL250V
T10AL250V (if equipped with air compressor)
T6.3AL250V (if equipped with air compressor)
 - Internal power T2AL250V

Electromagnetism compatibility



Warning:

- 1) Cell phone and other radiation equipment used near the machine will cause unexpected problem to the ventilator. If there is radio frequency radiation source nearby, working status of the equipment should be monitored.
- 2) The other equipment added to ventilator will lead to disturbance to the machine. Before used to the patient, check if the machine work normally under the set values.

Breathing system performance

- Connect breathing system according to Fig 7, when main power failure or damaged electronic component endanger the normal ventilation, under the follow flow, pressure drop value of inhalation and exhalation measured at the patient connection port.

	60 L/min	30 L/min	5 L/min
Inhalation pressure drop value	≤ 0.6kPa	≤ 0.4kPa	≤ 0.15kPa
exhalation pressure drop value	≤ 0.5kPa	≤ 0.2kPa	≤ 0.05kPa

Breathing tubes

- Pressure and flow table

Flow (L/min)	Pressure (kPa)
2	0.02
10	0.03
20	0.07
30	0.11
40	0.18
50	0.25
60	0.3

- Compliance: ≤ 0.01L/ kPa
- Internal capacity: ≤ 0.9L

Humidifier

- Pressure and flow table

Flow (L/ min)	Pressure (kPa)
2	0.02
10	0.03
20	0.04
30	0.05
40	0.07
50	0.1
60	0.12

- Compliance: $\leq 0.01\text{L/ kPa}$
- Internal capacity: $\leq 0.6\text{L}$

Remarks: The above mentioned data are based on the humidifier of Infinium.

Ventilation mode

- IPPV
- A/C
- SIMV
- PSV
- PCV
- CPAP
- SIGH
- MANUAL

Ventilation parameter adjustment

- Frequency
 - Adjusting range
 - 1 /min ~ 100 /min
 - (Under SIMV: 1 /min ~ 40 /min
 - All mode except SIMV: Child 4 /min ~ 40 /min
 - Adult 20/min ~ 100 /min)
 - Allowable error
 - $\pm 15 \%$
- Inhalation time (I:E) (T_{insp})
 - Adjusting range
 - 0s ~ 12s(4:1 ~ 1:8)
 - Allowable error
 - $\pm 15 \%$
- Tidal volume (V_T)
 - Adjusting range
 - 0 mL ~ 1500 mL
 - And:
 - Child: 250 mL ~ 1500 mL
 - Adult: 0 mL ~ 300 mL

- Minute ventilation (MV)
 - Max MV
 - Child: ≥ 18 L/min
 - Adult: ≥ 10 L/min
- PEEP
 - Adjusting range 0 cmH₂O ~ 20 cmH₂O
- CPAP
 - Adjusting range 0 cmH₂O ~ 20 cmH₂O
- Continuous flow
 - Adjusting range
 - Child: 7 L/min ~ 60 L/min
 - Adult: 2 L/min ~ 30 L/min
- Pressure trigger (PTr)
 - Adjusting range - 20 cmH₂O ~ 0 cmH₂O (Under PEEP)
 - Allowable error $\pm (1 \text{ cmH}_2\text{O} + 10 \% \text{ setting valve})$
- Pressure control (Pc)
 - Adjusting range 5 cmH₂O ~ 60 cmH₂O
- Pressure support (Ps)
 - Adjusting range 0 cmH₂O ~ 60 cmH₂O
- Flow trigger (FTr)
 - Adjusting range Off, 1 L/min ~ 30 L/min
 - Allowable error
 - $> 3\text{L/min}$: $\pm 15\%$
 - $\leq 3\text{L/min}$: $\pm 0.5 \text{ L/min}$
- O₂ concentration
 - Adjusting range 21 % ~ 100 %
 - Allowable error $\pm 15 \%$
- Holding time (Inhalation platform) (TIP)
 - Adjusting range 0 ~ 6s(0% ~ 50% inhalation time)
- Apnea ventilation
 - Adjusting range OFF, 5 s ~ 60 s
- Maximal Inspiratory Flow Rate
 - Maximal Inspiratory Flow Rate: $\geq 60 \text{ L/min}$
- Max set working pressure
 - (pressure limit range) 20 cmH₂O ~ 100 cmH₂O
- Max pressure $\leq 125 \text{ cmH}_2\text{O}$
- Output MV under manual ventilation $\geq 25\text{L/min}$
- Nebulizer gas
 - maximum output pressure $\leq 0.2 \text{ MPa}$
 - maximum output flow $\geq 8 \text{ L/min}$

explanation:

- 1) set pressure limit value to produce maximum working pressure(the upper limit of high airway pressure alarm).
- 2) do not use negative pressure at exhalation.
- 3) maximum limit pressure is pressure of the safety valve.

Ventilation parameter Monitoring range

- The following are monitoring parameters under the environment of body temperature and pressure-saturated.
- Fig display:

Parameter	Range	Resolving power	Accuracy
Frequency (Freq)	0 /min ~ 100 /min	1 /min	±15 %
Tidal volume (VT)	0 mL ~ 2000 mL	10 mL	> 100 mL: ±15% ≤ 100 mL: ±20 mL
Minute ventilation (MV)	0 L/min ~ 99 L/min	0.1 L/min	> 3 L/min: ±15% ≤ 3 L/min: ±0.5 L/min
(Ppeak)	0 cmH ₂ O ~ 100 cmH ₂ O	1 cmH ₂ O	± (2% full scale + 4% actual reading)
O ₂ concentration	15 % ~ 100 %	0.1 %	±[2.5 % (v/v) + 2.5 % (concentration level)]
Compliance	1 ~ 1000 mL / cmH ₂ O	1 mL / cmH ₂ O	

- Waveform display:
 - Time- airway pressure (under all modes)
 - Time—flow (under all modes)
 - pressure volume loop (all modes)

Remarks: The machine cannot record all the adjusting and monitoring values.

- the purpose、sensor position、type and sampling method of control、measurement and display device

the purpose	sensor position	type	sampling method
Airway pressure	Exhaling end	pressure- voltage、 Simulated data	Choose average value from multiple sampling
PEEP	Exhaling end	pressure- voltage、 Simulated data	Choose average value from multiple sampling
Continuous pressure	Exhaling end	pressure- voltage、 Simulated data	Choose average value from multiple sampling
freq	built-in	time、 simulated data	Choose average value from multiple sampling
Inhalation time	built-in	time、 simulated data	Choose average value from multiple sampling
Holding time	built-in	time、 simulated data	Choose average value from multiple sampling
tidal volume	Exhaling end	flow- voltage、 Simulated data	Choose average value from multiple sampling
flow	Exhaling end、 inhaling end	flow-voltage、 simulated data	Choose average value from multiple sampling
O ₂ concentration	Inhaling end	O ₂ concentration-voltage、 simulated data	Choose average value from multiple sampling

Technical specification of air compressor

- Rated output pressure: 0.35MPa±0.05MPa
- Continuous output flow: When the output pressure is 0.35MPa, continuous output flow is ≥ 45L/min
- Peak flow: When duration is 1 second, the peak flow is ≥120L/min
- Dew point temperature: ≤ 5℃
- Alarm temperature: temperature in compressor cabinets ≥ 85℃±10℃

Noise

- Noise under normal working condition ≤ 65dB(A).

Additional part to ventilator

Monitoring equipment



In accordance with the standard of IEC 60601-2-12, CO₂ monitor and oximeter equipped on ventilator should meet the standards of ISO 9918 and ISO 9919 separately.

Humidifier


In accordance with the standard of IEC 60601-2-12, humidifier equipped on ventilator should meet the standards of ISO 8185.

Alarm hint and protection

- Main power failure alarm

When the power is supplied by AC, the power state indication place will display the signal of “”. When the power is changed from AC to back-up battery, there will be a sound alarm, and the power state indication place will display the signal of “”.

- Alarm of low voltage of back-up battery

When the voltage of back-up battery is low (11.3V), the power state indication place will display the signal of “”, and there will be a sound alarm.

Alarm lasting time: > 120 s



Warning:

If main power fails or the voltage of back-up battery is low during operation, and the machine stop working, please do manual ventilation to the patient.

- Gas failure (No tidal volume) alarm

If there is no tidal volume in 6 seconds, there will be a sound alarm and display of No tidal volume.

Alarm lasting time > 120 s

- High or low MV alarm

When the monitoring value over upper limit of MV or under low limit of MV, there will be a sound alarm and display of alarm hint.

——Setting range of upper limit	Child: 5 L/min ~ 99 L/min
	Adult: 1 L/min ~ 30 L/min
——Setting range of lower limit	0 L/min ~ 20 L/min

- High or low Ppeak alarm

When the monitoring value of Ppeak over the upper limit or under the low limit in 5-20 seconds, there will be a sound alarm and display of alarm hint.

——Setting range of upper limit	20 cmH ₂ O ~ 100 cmH ₂ O
——Setting range of low limit	0 cmH ₂ O ~ 20 cmH ₂ O

- Pressure limit

When the Ppeak value is higher than the upper limit preset value, the airway pressure alarm sounds, the airway peak pressure is limited in upper limit preset value level.

- Continuous pressure alarm

If the airway pressure (PEEP+15 cmH₂O) over the upper limit or under low limit of continuous pressure alarm in 16 seconds, there will be a sound alarm and display “Pcon high!!!”

- High or low O₂ concentration alarm

When the monitoring value of O_2 concentration over the upper limit of O_2 , or under the low limit, there will be a sound alarm and display of alarm hint.

—Setting range of upper limit 19% ~ 100 %

—Setting range of low limit 18 % ~ 99 %

- Apnea alarm

Choose Sigh ventilation under mode of SIMV and set the SIGH time. If there is no spontaneous or assisted ventilation during SIGH time, the mode will change to AC, and there is alarm indication of Apnea (Red color).

If there are 5 times of Spontaneous ventilation after change mode to A/C, the mode will change to the former ventilation mode, and there is alarm indication of Apnea (Green color).

—Apnea time setting range OFF, 5 s ~ 60 s



Note:

When there is Apnea alarm, the mode will change to A/C. So if set Apnea alarm under SIMV, proper parameters should be set under A/C.

Note: When the sigh time is set to OFF, there will be no Sigh ventilation or Apnea alarm indication.

- Mute

When an alarm occurs, the alarm sound may be muted for 2 minutes by pressing muting key but the alarm indication will display on the screen, unless the problem is solved.

—Muting time < 120 s

- Safety valve

When the airway press over the safety valve pressure, the safety valve will release the excess gas.

—safety valve pressure ≤ 125 cmH₂O

Move, storage and transportation

Move



Note:

Keep the balance and stable of the machine when move the ventilator.

- Before the move, all the power line and breathing tubes should be pull out from the machine.
- Keep the balance and stable of the machine when move the ventilator.

Storage

- The anesthesia apparatus shall be stored indoors with ambient temperature of $-20^{\circ}\text{C} \sim 50^{\circ}\text{C}$, relative humidity not exceeding 93% and atmospheric pressure at 500 hPa \sim 1060 hPa, free of corrosive gases and not affected by strong magnetic field, and with good ventilation.

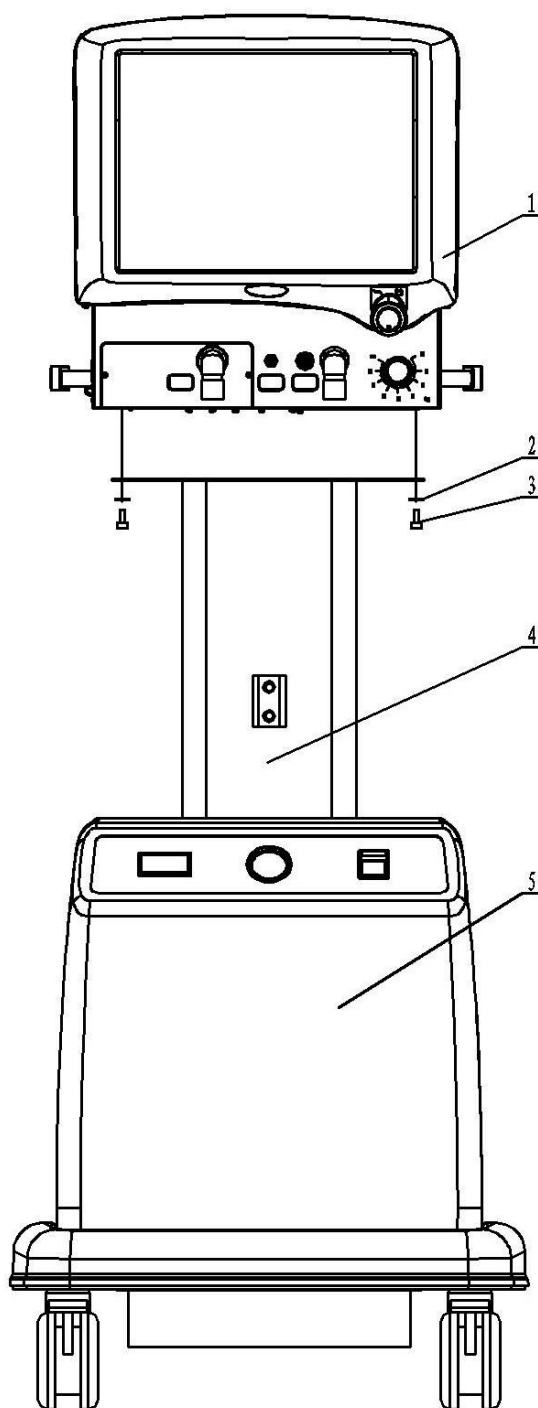
Transportation

- Ventilator to be transported shall be packed in package. Each set of machine shall be secured in its package and soft material of adequate thickness shall be inserted in between the package and product to protect against movement and rubbing against each other during transportation. The package shall be protected from damp and rain to ensure that the product will not be damaged in natural condition.
- The packed ventilator can be transported by general means. The product shall be protected from rain, damp, corrosion and against strong vibration, turn over at handling is forbidden.

Others

- If complying with the rules of storage、transport and use, and the equipment can work normally ,our company will repair it freely within one year from leaving factory.

Appendix: Installation diagram



NO.	Name	Specification	Remark
1	Ventilator	2.782.074A	Packing box 1
2	Serrated saddle	$\phi 5$	
3	Screw	M5x12	
4	Bracket base	4.142.013A	packing box2(they have already assembled together)
5	Air Compressor	2.782.076A	

Fig.1 Installation of main machine

Thank you for choosing S1200 ventilators

Please read this manual before operation, and keep it for inspection.

Manufacturer: Nanjing Superstar Medical Equipment Co., Ltd.

Address: The 2nd and 3rd Floors, No. 6 Building, No. 9 Bofu Road,

Yanjiang Industrial Development Zone, Liuhe District,

Nanjing, P. R. China

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