S1100 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
- " Δ warning " and " Δ 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	
[]i	Read the operation manual	
~	AC	
*	B Class	
<u> </u>	Gas input	
	Audio paused	
	Lock	
	Unlock	
VTH	Adult mode	
VT∟	Child mode	
	Parameter setting	
	System setting	
\triangle	Alarm setting	
+-	Main power supply indication	
	Backup power battery	
+ -	Battery supply indication	
+ -	Indication for low voltage of battery	
	Charging (main power supply) indication	
Ø.	Indication for internal power failure	

Picture, sign, term and abbreviation	Remarks
\forall	Equipotential
	Ground protection
<u> </u>	Check valve
M	Trigger mark
IPPV	IPPV
A/C	AC
PCV	PCV
SIMV	SIMV
SPONT/ CPAP	SPONT/CPAP
PSV	PSV
€ or (MAUN)	MANU
Standby	Standby surface
च€	nebulizer
!!!	high priority alarm
!!	medium priority alarm
FiO2	O ₂ concentration of inhalation
MV (Minute Volume)	Minute Volume
V⊤ (Tidal Volume)	Tidal Volume
Freq (Frequency)	Frequency
Ppeak	Airway peak pressure
PEEP	PEEP
С	Dynamic lung compliance
Tinsp	Inspiration time
TiP	Holding time (Platform time、Inhalation platform)
Sigh	Sigh time
Pc	Pressure control
Ps	Pressure support
Ptr	Pressure trigger
Ftr	Flow trigger
Flow	Flow
Pcon	Alarm of Continuous airway pressure

Picture, sign, term and abbreviation	Remarks	
Tapn	Apnoea time	
Nebulizer	Nebulizer	
Paw—t	Waveform of airway pressure and time	
Flow—t	Waveform of flow and time	
Power	Power	
Ö	Off	
0	On	
O ₂ %	O ₂ concentration adjustment	
O ₂	oxygen	
Air	Air	
Vmax	Maximum volume	
BTPS	body temperature and pressure-saturated	
Bpm	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)	
DC	Direct current	
hPa	Hpa (Unit for pressure)	
kPa	kPa(Unit for pressure)	
MPa	MPa (Unit for pressure)	
cmH ₂ O	Centimeter water column (Unit for pressure)	
V	Voltage (Unit for voltage)	
А	Ampere (Unit for current)	
Hz	HZ (Unit for frequency)	
VA	VA (Unit for power)	
db(A)	Decibel (Unit for noise)	
°C	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.

- 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 Nanjing Super Star Medical Equipment Co., Ltd. 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.

C	aim en
•	Monitoring, alarm, and guard function for S1100 ventilator:
	——Measurement and control for FiO2
	——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
	——Apnoea 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
	npressor) .
•	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

entilation mode
IPPV
A/C
PCV
SIMV
SPONT/ CPAP
PSV
SIGH
MANU

Performance

- Electrical controlled and gas driven
- For Child and Adult
- 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 O₂ and Air blender
- Internal battery. The battery will work when the AC fails.
- May be equipped with air compressor.

Intended use

S1100 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 $18 \sim 80$ 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 S1100 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 S1100 performance, so S1100 should be kept away from them during using.
- Guidance and manufacturer's declaration stated in the appendix.

/ Warning:

- S1100 Ventilator should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, S1100 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. S1100 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 S1100 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 The S1100 uses RF energy only for its internal function. CISPR 11 Therefore, its RF emissions are very low and are not Group 1 likely to cause any interference in nearby electronic equipment. RF emissions The S1100 is suitable for use in all establishments other Class A CISPR 11 than domestic and those directly connected to the public low-voltage power supply network that supplies Harmonic emissions Class A buildings used for domestic purposes. IEC 61000-3-2 Voltage fluctuations / flicker emissions Complies

IEC 61000-3-3

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity

The S1100 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the S1100 should assure that it is used in such an environment.

	IEC 60601 test		Electromagnetic environment –	
Immunity test	level	Compliance level	guidance	
Electrostatic	₁ 6 kV contact	± 6 kV contact	Floors should be wood, concrete or	
discharge (ESD)	∄8 kV air	±8kV air	ceramic tile. If floors are covered with	
			synthetic material, the relative humidity	
IEC 61000-4-2			should be at least 30 %.	
Electrical fast	±2 kV for power	±2 kV for power	Mains power quality should be that of a	
transient/burst	supply lines	supply lines	typical commercial or hospital	
IEC 61000-4-4			environment.	
Surge	± 1 kV line(s) to	± 1 kV line(s) to	Mains power quality should be that of a	
	line(s)	line(s)	typical commercial or hospital	
IEC 61000-4-5	± 2 kV line(s) to	± 2 kV line(s) to	environment.	
	earth	earth		
Voltage dips, short	<5 % <i>U</i> T	<5 % <i>U</i> T	Mains power quality should be that of a	
interruptions and	(>95 % dip in <i>U</i> T)	(>95 % dip in <i>U</i> T)	typical commercial or hospital	
voltage variations	for 0,5 cycle	for 0,5 cycle	environment. If the user of the S1100	
on power supply	40 % <i>U</i> T	40 % <i>U</i> T	requires continued operation during	
input lines	(60 % dip in <i>U</i> T)	(60 % dip in <i>U</i> T)	power mains interruptions, it is	
	for 5 cycles	for 5 cycles	recommended that the S1100 be	
IEC 61000-4-11	70 % <i>U</i> T	70 % <i>U</i> T	powered from an uninterruptible power	
	(30 % dip in <i>U</i> T)	(30 % dip in <i>U</i> T)	supply or a battery.	
	for 25 cycles	for 25 cycles		
	<5 % <i>U</i> T	<5 % <i>U</i> T		
	(>95 % dip in <i>U</i> T) for 5 s	(>95 % dip in <i>U</i> T) for 5 s		
	101 5 8	101 5 8		
Power frequency	3 A/m	3 A/m	Power frequency magnetic fields	
(50/60 Hz)	3 FVIII		should be at levels characteristic of a	
magnetic field			typical location in a typical commercial	
IEC 61000-4-8			or hospital environment.	
NOTE UT is the a.c. mains voltage prior to application of the test level.				

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Table 3

Guidance and manufacture's declaration - electromagnetic immunity

The S1100 Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of S1100 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Complianc e level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V _{ms} 150 kHz to 80 MHz outside ISM bands ^a 10 V _{ms} 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 S1100,, 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 S1100 is used exceeds the applicable RF compliance level above, the S1100 Ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the S1100.
- 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 S1100 Ventilator

The S1100 Ventilator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the S1100 Ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the S1100 Ventilator as recommended below, according to the maximum output power of the communications equipment.

Rated	Separation distance according to frequency of transmitter (m)			
maximum output power of transmitter (W)	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

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

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

NOTE 2 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.

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.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

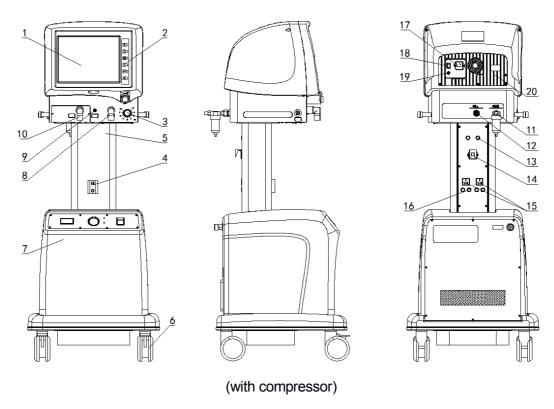
The main structure and working principle for the ventilator

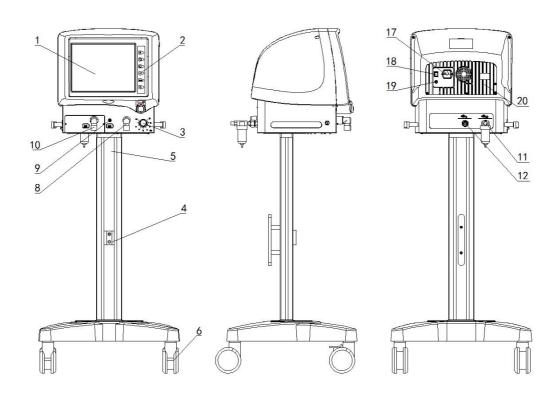
⚠ Note: Please refer to the manual of humidifier to learn the main structure and working principle of the humidifier.

Main unit

Structure

The S1100 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 O_2 and air blending system) and Air compressor (optional), rack (the overall appearance is shown in figure 1)





(without compressor)

1Parameter display screen	2 panel	3 O ₂ and Air blender adjusting knob
4 Humidifier Bracket	5 Main frame	6 Castor
7 Air Compressor	8 Inhalation port	9 nebulization port
10 Exhalation port	11 Air input port	12 O ₂ input port
13 compressor fuse box	14 ~220V power input socket/Fuse box	
15 Auxiliary socket	16 Auxiliary socket fuse box	
17 Ventilator input power socket/Fuse box		18 Starting switch

Fig 1 the structure of ventilator

20 Backup battery cover

19 Earthing terminal

Working Principle

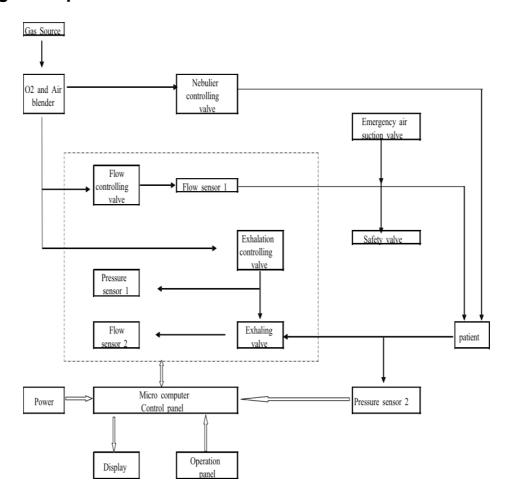


Fig 2 Graph for working principle

The gas source passes O₂ and air blender, then respectively enters nebulier 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 breath the air from atmosphere.

Air compressor (if equipped with air compressor)

Structure

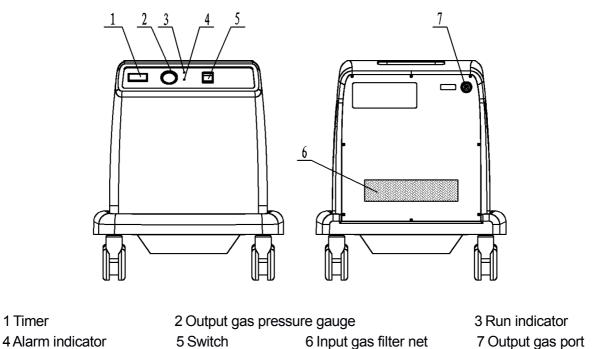


Fig 3 air compressor structure

Working Principle

1 Timer

The gas enter the compressor thought 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 value position can adjust ratio of air and O₂ mixture.

Preparation

Gas supply connection

∧ Note:

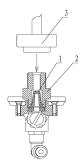
- 1 The rated working pressure of ventilator is 400kPa±20kPa, and the maximum flow is 70L/min.
- 2 The gas source should be specialized for medical usage.
- 3 Be aware the impurity from the central gas pipe when use the central gas supply as gas source.
- 4 Make sure that gas has no oil, water, or impurity 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 400kPa±20kPa, 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.
- 1) the flow direction of filter face the machine;
- 2) the gasket between filter and air input port can not be dropped;

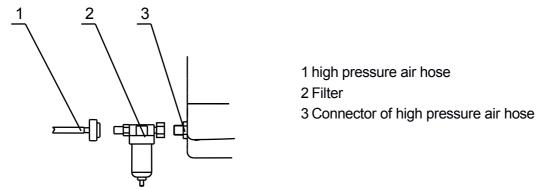
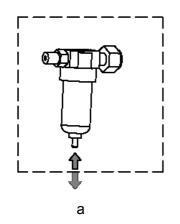


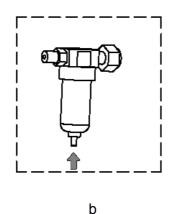
Fig 5 Air source connection

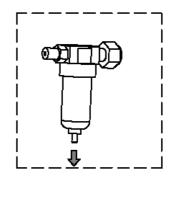
Filter drain

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.







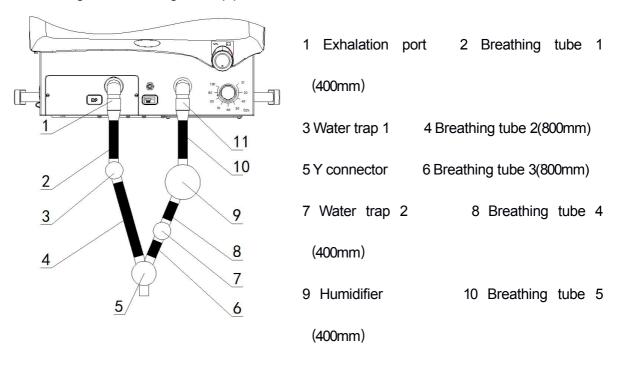
С

Fig 6 The way of filter drain

Connection of breathing circuit pipe

1. 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 2 breathing circuit equipped on ventilator should meet the standards ISO 5367.

Refer Fig 7 for breathing circuit pipe connection



11 Inhalation port

Fig 7 Connection of breathing circuit pipe

- 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 use 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.

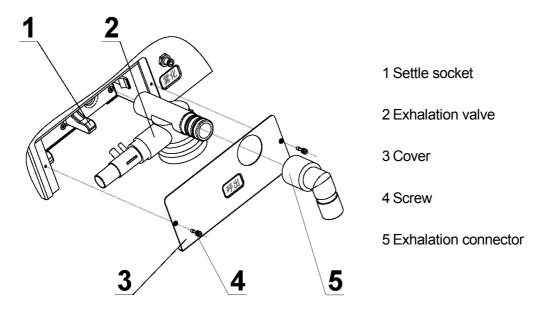


Fig 8 The installation and connection of exhalation valve

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).

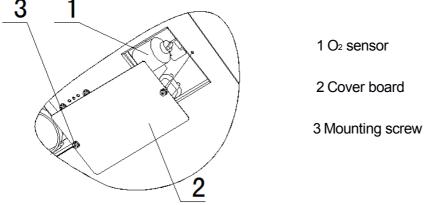
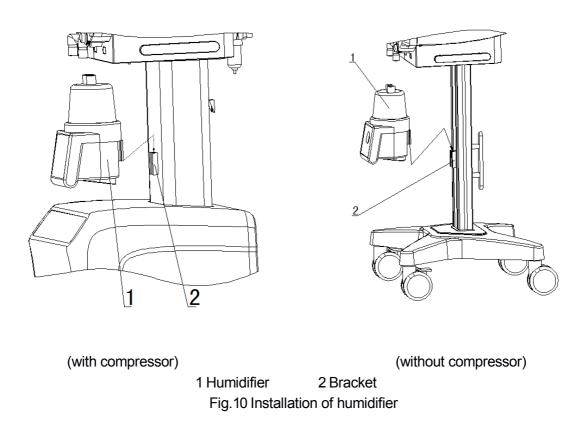


Fig 9 The installation and connection of O2 sensor

Installation of humidifier

Refer Fig 10 for installation and connection of humidifier.



Installation of nebulizer

nebulizer should be registered in national or provincial medical administration.

- ----connection of nebulizer port and nebulization port (Item 9 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 O_2 monitor, CO_2 monitor and Oximeter, please refer to the operation manual to install and connect them.

Installation and use of pressure regulator

Installation and use

- 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.

- 1 The pressure regulator should meet the requirement of Standard of ISO10524.
- 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.



Mote:

The main power is \sim 220 V±10%, and frequency is 50Hz±2%.

Mains plug is intended to be used as isolation device from the supply mains. Please always make mains plug easily to operate.

Main power—AC

- —If equipped with air compressor
- Insert the power plug into the power input socket (item 14 in Fig 1) at the rear panel of the ventilator and the AC socket:
- Connect the power input socket (item 17 in Fig 1) at the rear panel with the auxiliary socket (Item 15 in Fig 1) by the power cord.
- —Without air compressor
- Insert the power plug into the power input socket (item 17 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 at the panel is on (Item 10 in Fig 12).
- ——When the power is supplied by AC:
- The power state indication place will display the signal of "

 "or" or" (when charging)

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
- 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 "".
- If the installation and integrity of the external protection wires have some problem, equip ment should be run by standby battery.

Low voltage of back-up battery

- When the voltage of back-up battery is low (11V±0.3V), the power state indication place will display the signal of "im", 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

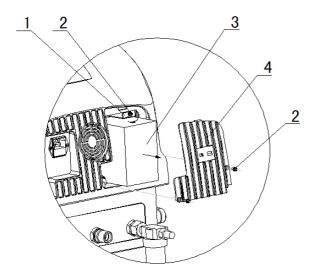
- When the equipment is supplied by AC power, the battery will be charged automatically, the power state indication place will display the signal of " —". And the power state indication place will display the signal of " —" after charging fully.
- When the equipment is supplied by AC power and starting switch is off, power supply indicator (item 10 of Fig.12) is on (green for a long time), if battery is charging, back-up battery status (item 9 of Fig.12) lights (green), if battery is fully charged, back-up battery status indicator (item 9 of Fig.12) is off.
- Charge can be carried out continually, or intermittently.
- The back-up 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 "image".
- 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

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 18 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 14 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 10 in Fig 12) isn't on, switch on the ventilator (Item 18 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 17 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: 5T-6.3AL250V) of compressor 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 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 18 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	2AL250V.

- 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

- 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 circuit pipe 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 "-" 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 audio paused, and the power state indication place will display the signal of "——" or "——".
- When needed or every 3 months, depletion alarm of back-up battery should be test, the machine is not connected with AC, switch on the ventilator, the machine will be powered by back-up battery. When the voltage of back-up battery is low (11V±0.3V), the power state indication place will display the signal of "indication", and there will be sound alarm.

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±20 kPa.
- If the compressor is equipped, switch on the compressor (Item 5 in Fig 3), pressure gauge on the compressor panel should be 400kPa±20 kPa when the compressor is working stably.

Ventilation function check

Check the ventilation function as the following steps;

- Connect the machine with power and gas source, and connect the Y connect with breathing bag.
- Switch on the ventilator, and check if tidal volume, frequency, Mv, O2 concentration, and airway pressure are normal under various ventilation mode.
- Breath at the Y connector under A/C mode to check if the trigger function is good or not.
- Open the atomization function, check if the atomization function is good or not.
- When carrying out above steps, disconnect O₂ and air supply, ventilator shall switch over to residual gas automatically, it can maintain normal use according to current setting parameters except oxygen concentration, the screen will display the follow alarm hint "air supply low !!" or "O₂ supply low !!".

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 bpm;			
	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:			

-When the Ppeak overpass 2.0 L/min, there will be an alarm for High Ppeak alarm. When

—Reset the tidal volume to make the Ppeak over the high Ppeak limit;

–Set the upper limit of Ppeak to 20 cmH₂O;

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 cmH ₂ O; ——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 circuit pipe; ——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 cmH ₂ O, delay 16 seconds, there should be a continuous pressure alarm.
•	Check for High O ₂ concentration alarm: ——Set the upper limit of O ₂ concentration to 80% ——Adjust the O ₂ and air blender adjusting valve, and set the O ₂ concentration over 80%; ——There will be an alarm for high O ₂ concentration.
•	Check for low O_2 concentration alarm: ——Set the low limit of O_2 concentration to 40%; ——Adjust the O_2 and air blender adjusting valve, and set the O_2 concentration under 40%; ——There will be an alarm for low O_2 concentration.
•	Set the Apnoea time under the SIMV mode, check if the Apnoea 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 changed to the former ventilation mode.
Δ	Warning: In order to ensure the excellent performance in operation, the safety feature and ventilation

function must be checked before operation.

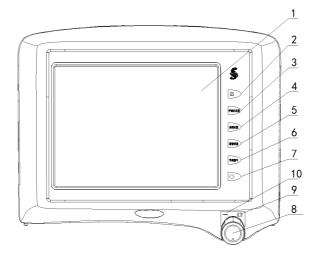
Operation

- 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 screen

4 system setting key

7 standby key

10 power indicator

2 audio paused key 5 alarm setting key

8 adjusting shuttle /confirmation key

3 ventilator setting key 6 manual ventilation key

9 battery indicator

Fig 12 Panel of ventilator

Start-up

- Connect the power supply 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 VTL/VTH ventilation mode selection surface.
 Refer to Fig 13.

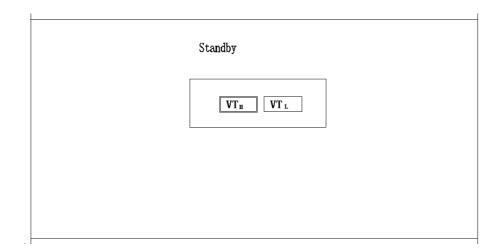


Fig 13 VTL/VTH ventilation mode selection surface

Selection of VTL or VTH ventilation mode

- Enter the surface of VTL/VTH ventilation mode selection
- ——Switch on the ventilator:
- ——Press Standby key (Item 7 in Fig 12) on the operation panel, and the machine will enter the surface of VTL/VTH mode selection.
- choose VTL/VTH mode
- —Turn adjusting shuttle /confirmation key (Item 8 in Fig 12)to choose VTL/VTH mode, press adjusting shuttle /confirmation key for confirmation, then machine will work under chosen mode.

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 VTL/VTH mode, and press confirmation key;
- ——Press ventilator setting key (Item 3 in Fig 12) in working surface, you can reset ventilation mode and parameters.
- ——Fig . 14.15.16.17.18.19 are the VT_H ventilation mode and parameters setting surface under IPPV, PCV, A/C, SIMV, SPONT/CPAP and PSV mode.
- Ventilation mode selection:
- ——Turn shuttle/Confirmation key (Item 8 in Fig 12) to required mode, and press it for confirmation.
 - Setting of parameter:
- ——Turn Shuttle/Confirmation key to the required parameter, and press it for confirmation;
- —Turn Shuttle (Item 8 in Fig12) for setting (Turning clockwise will max the parameter; Turning anticlockwise will minimum the parameter). Press Shuttle for confirmation when the required parameter is set already.
- —When confirmation is done, turn shuttle(Item 8 in Fig12) to " \boxtimes ", press shuttle to exit the setting surface.
- ——The machine will work under the set mode and parameters.

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

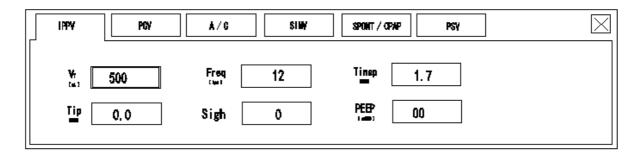


Fig 14 Setting of mode and parameter under IPPV

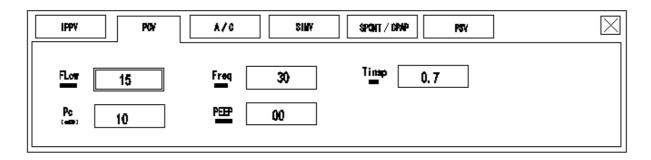


Fig 15 Setting of mode and parameter under PCV

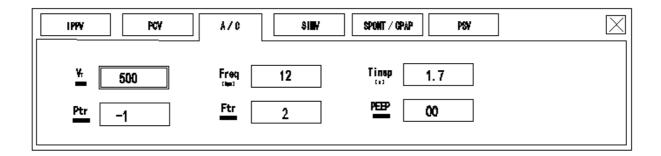


Fig 16 Setting of mode and parameter under A/C

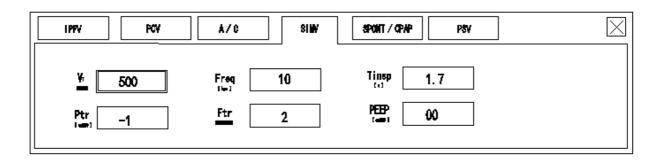


Fig 17 Setting of mode and parameter under SIMV

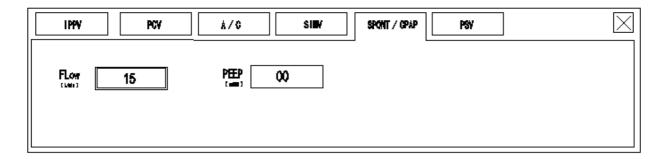


Fig 18 Setting of mode and parameter under SPONT/CPAP

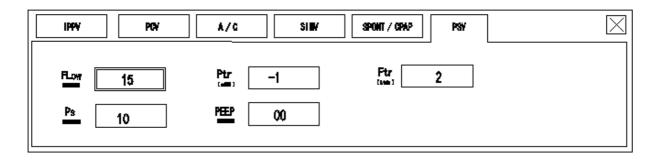


Fig 19 Setting of mode and parameter under PSV

Reset of alarm parameter

- Reset of alarm parameter:
- ——Press alarm setting key (Item 5 in Fig 12), the machine will enter Reset of alarm parameter surface. Refer to Fig 20.
- Reset of the alarm parameter value:
- ——Turn shuttle (Item 8 in Fig 12) to the parameter to be adjusted;
- ——Press shuttle for confirmation;
- —Turn Shuttle (Item 8 in Fig12) for setting (Turning clockwise will max the parameter; Turning anticlockwise will minimum the parameter). Press Shuttle for confirmation when the required parameter is set already;
- ——Repeat the previous step if there is a next alarm value to be adjusted;
- —Turn shuttle to " \boxtimes ", press shuttle to exit the setting surface, and the machine will work under set values.
- Alarm clearance
- ——press alarm setting key(Item 5 in Fig12) to enter the alarm setting surface.

Refer to Fig 20.

——Turn shuttle (Item 8 in Fig12) to "info", Press Shuttle Item 8 in Fig12) for confirmation and enter the "info" surface.

Refer to Fig 20.

- ——Turn shuttle (Item 8 in Fig12) to "alarm reset", Press Shuttle Item 8 in Fig12) for confirmation
- —Turn shuttle (Item 8 in Fig12) to " press shuttle Item 8 in Fig12) to exit the setting surface

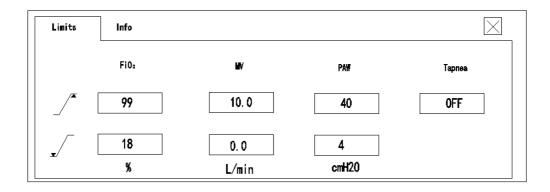


Fig 20 Reset of alarm parameter surface (one)

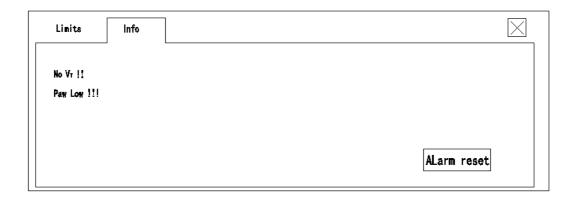


Fig 21 Reset of alarm parameter surface(two)

Hint:

Only under the modes of SIMV、SPONT/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 ,press "system setting" key (Item 4 in Fig12)
- ---- "system setting" surface, see Fig 22.
- Parameter adjustment:
- ——Turn shuttle (Item 8 in Fig 12) to the parameter to be adjusted;
- ——Press shuttle (Item 8 in Fig 12), parameter setting value become opposite color;
- —Turn shuttle (Item 8 in Fig 12) to the parameter to be adjusted;
- ——Press shuttle (Item 8 in Fig 12) for confirmation;
- ——Repeat the previous step if there is a next parameter to be adjusted;
- ——Turn shuttle to " \boxtimes ", press shuttle to exit the setting surface, and the machine will work under set values.

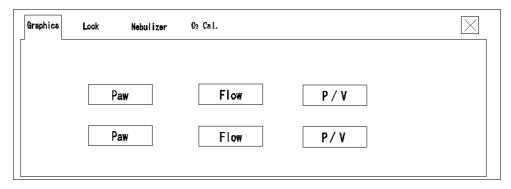


Fig 22 system setting surface

Start up for operation——IPPV ventilation mode

- Enter IPPV mode:
- ——Choose IPPV mode under the surface of ventilation mode and parameter setting in Fig. 14;
- ——Press Shuttle (Item 8 in Fig12)for confirmation and machine will enter standby status;
- —Turn shuttle (Item 8 in Fig12)to " ", and press it for exit, and the machine will work under mode of IPPV.
- Working surface of IPPV mode:
 Please refer to Fig 23.

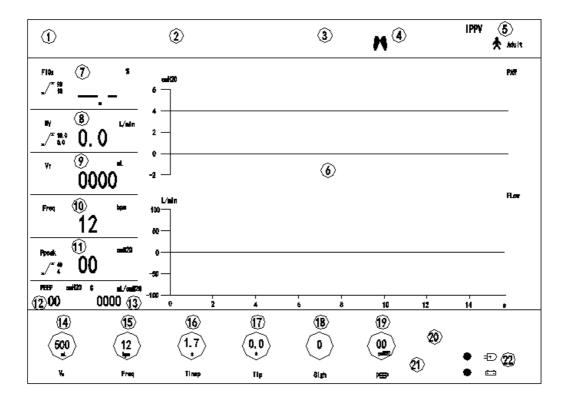


Fig 23 Working surface of IPPV mode

Illustration for the surface:
——(1) is Alarm audio paused indication place.
(2) is respectively indication place for alarm of High continuous pressure, High (Low) Airway
pressure, High (Low) O ₂ concentration, High (Low) MV, No tidal volume.
——(3) is place for manual ventilation lock or unlock indication.
——(4) is indication for the trigger condition (this mode is no trigger).
——(5) is indication place for ventilation mode and VTL/VTH mode.
——(6) is respectively indication place for waveform of time-airway pressure and time-flow.
(7) are the monitoring values of O2 concentration, the presetting values of upper and low limit
for O ₂ concentration alarm .
(8) are the monitoring values of MV, the presetting values of upper and low limit for MV
alarm .
——(9) is the monitoring values of tidal volume.
——(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) is the monitoring values of dynamic lung compliance.
$(14)\sim$ (19)are respectively indication place of the presetting values for tidal volume, frequency
inhalation time, inhalation platform. Sigh time and PEEP.
——(20) is place for nebulizer on or off indication.
——(21) is place for display lock or unlock indication.
(22) is indication place for power supply status, including AC, Battery, and low voltage of
battery.

Start up for operation——PCV ventilation mode

- Enter the mode of PCV:
- ——Choose mode PCV under the surface of ventilation mode and parameter setting in Fig. 15;
- ——Press Shuttle (Item 8 in Fig12) for confirmation and machine will enter standby status;
- ——Turn shuttle (Item 8 in Fig12) to " ", and press it for exit, and the machine will work under mode of PCV.
- Working surface of PCV mode:

Please refer to Fig 24.

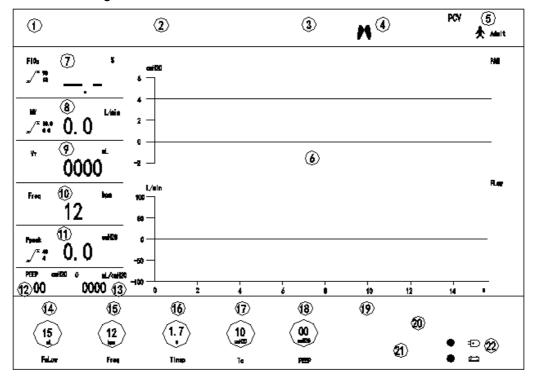


Fig 24 PCV ventilation mode surface

Illustration for the surface:
——(1) is Alarm audio paused indication place.
——(2) is respectively indication place for alarm of High continuous pressure, High (Low) Airway
pressure, High (Low) O ₂ concentration, High (Low) MV, No tidal volume.
——(3) is place for manual ventilation lock or unlock indication.
——(4) is indication for the trigger condition (this mode is no trigger).
——(5) is indication place for ventilation mode and VTL/VTH mode.
——(6) is respectively indication place for waveform of time-airway pressure and time-flow.
(7) are the monitoring values of O2 concentration, the presetting values of upper and low limit
for O ₂ concentration alarm .
(8) are the monitoring values of MV, the presetting values of upper and low limit for MV
alarm .
——(9) is the monitoring values of tidal volume.
——(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) is the monitoring values of dynamic lung compliance.
$$ (14) \sim (18)are respectively indication place of the presetting values for flow, frequency,
inhalation time, control pressure and PEEP.
——(19) is place for nebulizer on or off indication.
——(20) is place for display lock or unlock indication.
(21) is indication place for power supply status, including AC, Battery, and low voltage of
battery.

Start up for operation——A/C ventilation mode

- Enter the mode of A/C
- ——Choose mode A/C under the surface of ventilation mode and parameter setting in Fig. 16;
- ——Press Shuttle (Item 8 in Fig12) for confirmation and machine will enter standby status;
- ——Turn shuttle (Item 8 in Fig12) to " ", and press it for exit, and the machine will work under mode of A/C.
- Working surface of A/C mode:

Please refer to Fig 25.

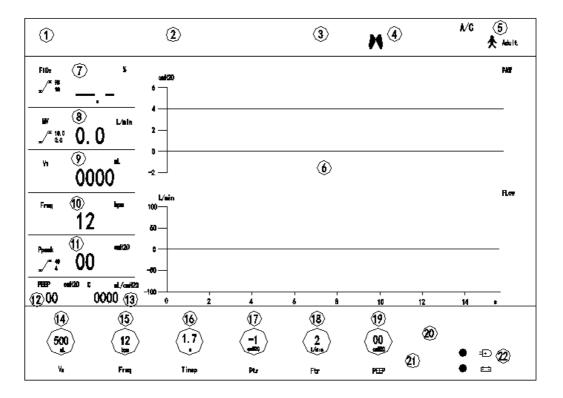


Fig 25 Working surface of A/C mode

Illustration for the surface:
——(1) is Alarm audio paused indication place.
——(2) is respectively indication place for alarm of High continuous pressure, High (Low) Airway
pressure, High (Low) O2 concentration, High (Low) MV, No tidal volume and Apnea.
——(3) is place for manual ventilation lock or unlock indication.
——(4) is indication for the trigger condition (this mode is no trigger).
——(5) is indication place for ventilation mode and VTL/VTH mode.
——(6) is respectively indication place for waveform of time-airway pressure and time-flow.
(7) are the monitoring values of O2 concentration, the presetting values of upper and low limit
for O ₂ concentration alarm .
(8) are the monitoring values of MV, the presetting values of upper and low limit for MV
alarm .
——(9) is the monitoring values of tidal volume.
——(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) is the monitoring values of dynamic lung compliance.
$(14)\sim(19)$ are respectively indication place of the presetting values for tidal volume, frequency,
inhalation time, trigger pressure. Trigger flow and PEEP.
——(20) is place for nebulizer on or off indication.
——(21) is place for display lock or unlock indication.
(22) is indication place for power supply status, including AC, Battery, and low voltage of
battery.

Start up for operation——SIMV ventilation mode

- Enter the mode of SIMV:
- ——Choose mode SIMV under the surface of ventilation mode and parameter setting in Fig. 17;
- ——Press Shuttle (Item 8 in Fig12) for confirmation and machine will enter standby status;
- ——Turn shuttle (Item 8 in Fig12) to " ", and press it for exit, and the machine will work under mode of SIMV.
- Working surface of SIMV mode:

Please refer to Fig 26.

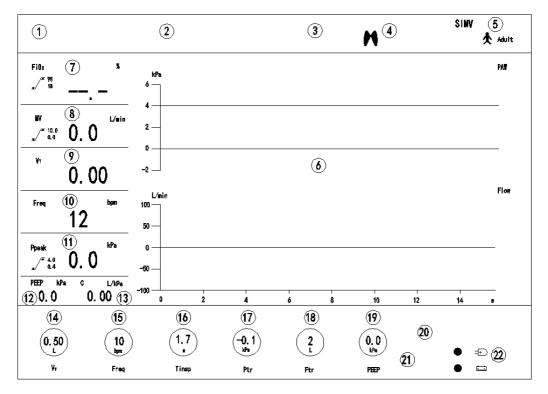


Fig 26 Working surface of SIMV mode

Illustration for the surface:
——(1) is Alarm audio paused indication place.
——(2) is respectively indication place for alarm of High continuous pressure, High (Low) Airway
pressure, High (Low) O ₂ concentration, High (Low) MV, No tidal volume and Apnoea.
——(3) is place for manual ventilation lock or unlock indication.
——(4) is the trigger condition.
——(5) is indication place for ventilation mode and VT _L /VT _H mode.
——(6) is respectively indication place for waveform of time-airway pressure and time-flow.
——(7) are the monitoring values of O ₂ concentration, the presetting values of upper and low limit
for O ₂ concentration alarm .
—(8) are the monitoring values of MV, the presetting values of upper and low limit for MV
alarm .
——(9) is the monitoring values of tidal volume.
——(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) is the monitoring values of dynamic lung compliance.
$$ (14) \sim (19)are respectively indication place of the presetting values for tidal volume, frequency,
inhalation time, trigger pressure. Trigger flow and PEEP.
——(20) is place for nebulizer on or off indication.
——(21) is place for display lock or unlock indication.
(22) is indication place for power supply status, including AC, Battery, and low voltage of
battery.

Start up for operation——SPONT/CPAP ventilation mode

- Enter the mode of SPONT/CPAP:
- ——Choose mode SPONT/CPAP under the surface of ventilation mode and parameter setting in Fig. 18;
- ——Press Shuttle (Item 8 in Fig12) for confirmation and machine will enter standby status;
- ——Turn shuttle (Item 8 in Fig12) to " , and press it for exit, and the machine will work under mode of SPONT/CPAP.
- Working surface of SPONT/CPAP mode:

Please refer to Fig 27.

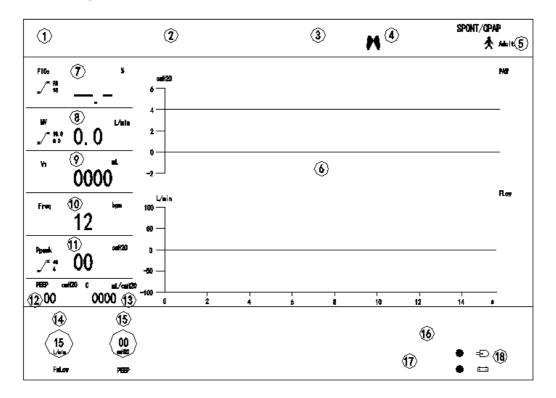


Fig 27 Working surface of SPONT/CPAPV mode

Illustration for the surface:
——(1) is Alarm audio paused indication place.
——(2) is respectively indication place for alarm of High continuous pressure, High (Low) Airway
pressure, High (Low) O ₂ concentration, High (Low) MV, No tidal volume and Apnoea. ——(3) is place for manual ventilation lock or unlock indication.
——(4) is the trigger condition (the mode is non-trigger).
——(5) is indication place for ventilation mode and VT∟/VTн mode.
——(6) is respectively indication place for waveform of time-airway pressure and time-flow.
(7) are the monitoring values of O2 concentration, the presetting values of upper and low limit
for O ₂ concentration alarm .
(8) are the monitoring values of MV, the presetting values of upper and low limit for MV
alarm .
——(9) is the monitoring values of tidal volume.
——(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) is the monitoring values of dynamic lung compliance.
——(14)(15)are respectively indication place of the presetting values for flow and PEEP.
——(16) is place for nebulizer on or off indication.
——(17) is place for display lock or unlock indication.
(18) is indication place for power supply status, including AC, Battery, and low voltage of
battery.

Start up for operation——PSV ventilation mode

- Enter the mode of PSV:
- ——Choose mode PSV under the surface of ventilation mode and parameter setting in Fig. 19;
- ----Press Shuttle (Item 8 in Fig12) for confirmation and machine will enter standby status;
- ——Turn shuttle (Item 8 in Fig12) to " ", and press it for exit, and the machine will work under mode of PSV.

Working surface of PSV mode: Please refer to Fig 28.

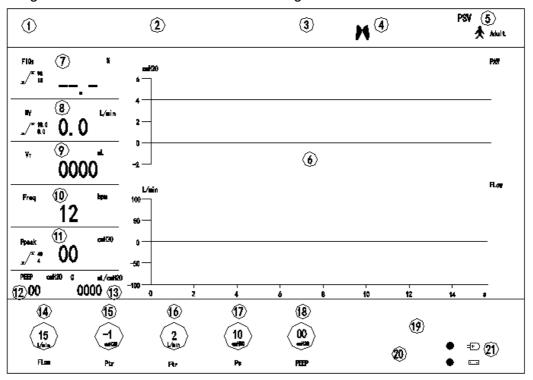


Fig 28 Working surface of PSV mode

——(1) is Alarm audio paused indication place.
——(2) is respectively indication place for alarm of High continuous pressure, High (Low) Airway
pressure, High (Low) O ₂ concentration, High (Low) MV, No tidal volume and Apnoea. —(3) is place for manual ventilation lock or unlock indication.
——(4) is the trigger condition.
——(5) is indication place for ventilation mode and VT _L /VT _H mode.
 (6) is respectively indication place for waveform of time-airway pressure and time-flow. (7) are the monitoring values of O₂ concentration, the presetting values of upper and low limit for O₂ concentration alarm .
——(8) are the monitoring values of MV, the presetting values of upper and low limit for MV alarm .
——(9) is the monitoring values of tidal volume.
——(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) is the monitoring values of dynamic lung compliance.
——(14) \sim (18)are respectively indication place of the presetting values for flow, trigger pressure, trigger flow, support pressure and PEEP.
——(19) is place for nebulizer on or off indication.
——(20) is place for display lock or unlock indication.
(21) is indication place for power supply status, including AC, Battery, and low voltage of
battery.

Start up for operation——MANU ventilation mode

Press MANU key (Item 6 in Fig12), the machine will supply the gas to the patient, and the screen

will have indication of "S". The machine will stop gas supply if you do not press the MANU key.

Start up for operation——Apnoea function

hint: Only under the ventilation mode of SIMV SPONT/CPAP PSV, apnoea time can be set.

- Before Choose of apnoea mode, please set the proper ventilation parameters under the mode of A/C.
- Choose apnoea ventilation under mode of SIMV SPONT/CPAP PSV and set the apnoea time.
- If there is no spontaneous or assisted ventilation during Apnoea time, the mode will change to AC, and there is alarm hint "Apnoea !!!" (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 is alarm hint "Apnoea!!!".

Note: When the sigh time is set to OFF, there will be no apnoea ventilation or alarm hint "Apnoea!!!".

Start up for operation——SIGH function

• Under the mode of IPPV, choose sigh function and set sigh times .

Start up for operation—nebulization function

- ——Under the every ventilation mode,press system setting key (item4 in Fig. 12),enter system setting surface;
- ——Turn shuttle (Item 8 in Fig12)and choose "nebulizer";
- ——press shuttle (Item 8 in Fig12)to enter "nebulizer" surface, refer to Fig 29;
- ——Turn shuttle (Item 8 in Fig12)to " and press it, the indication " will be on the screen;
- —When confirmation is done, turn shuttle(Item 8 in Fig12) to " in press shuttle to exit the setting surface;
- ——The machine will work under the set mode

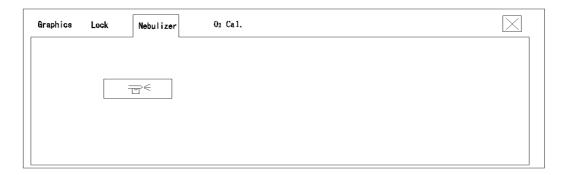


Fig 29 nebulizer surface

Start up for operation——Audio paused function

• When an alarm occurs, the alarm will resume within 2 minutes by pressing audio paused

key" (item2 in Fig. 12).after audio paused time (2 minutes), alarm will remain unless the problem is solved properly.

• When the sound alarm is audio paused, the alarm indication" "on the sreen will remain unless the problem is solved properly.

Start up for operation—key lock function

- ——Under the every ventilation mode, press system setting key (item4 in Fig.12), enter system setting surface;
- ——Turn shuttle (Item 8 in Fig12)and choose "Lock";
- ----press shuttle (Item 8 in Fig12)to enter "Lock" surface, refer to Fig 30;
- ——Turn shuttle (Item 8 in Fig12)to "and press it, the indication " will be on the screen all the keys will be locked and not be operated except system setting key and manual ventilation key.
- ——Turn shuttle (Item 8 in Fig12)to "and press it, all the keys will be unlocked.

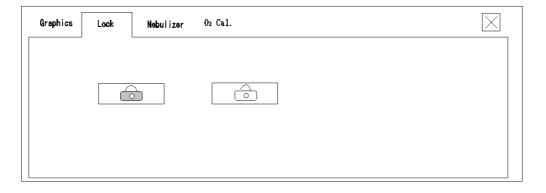


Fig. 30 key lock surface

Oxygen concentration calibration

——Under the every ventilation mode, press system setting key (item4 in Fig.12),enter system setting surface;

——Turn shuttle (Item 8 in Fig12)and choose "O2 Cal";

- —press shuttle (Item 8 in Fig12)to enter "O2 Cal" surface, refer to Fig 31;
 —Turn shuttle (Item 8 in Fig12)to "21%" and press it till the indication "Complete "will be on the screen;
 —Turn shuttle (Item 8 in Fig12)to "100%" and press it till the indication "Complete "will be on

Fig 31 Oxygen concentration calibration

Hint: Calibrate the oxygen concentration before each use.

Operation of Air and O₂ blender

Turn O₂ and Air blender adjusting knob(Item 3 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 Fig3), and it will start working,pressure gauge on the compressor panel should be 0.4Mpa when the compressor is working stably.

On completion

the screen;

When the operation is completed:

- Switch off the starting switch of ventilator (Item 18 in Fig 1);
- Switch off the power of humidifier;
- If equipped with air compressor ,Switch off the switch of the air compressor (Item5 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

- 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			
"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			
"O2 supply low !!"	O₂supply pressure is lower than 280 kPa			
"Fan fault !!"	Fan doesn't work			
"Apnoea !!!" (Red)	There is no spontaneous or assisted ventilation during SIGH time, the mode will change to AC, and there is alarm indication of Apnoea (Red color)			
"Apnoea !!!"	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 Apnoea			
" + - "	Main power disconnection or problem, and the power is supplied by Battery.			
" + - "	Power supplied by Battery and the battery low voltage (Lower than 11V±0.3V)			
×	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
	Audio paused
	Lock
	Unlock
VT _H	High MV mode
VTL	Low MV mode
M	Trigger mark
G	Manual ventilation

Clearance and disinfection

- 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.
- 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 disinfector, 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 disinfector.
- Wash and dry the high-pressure hoses.
- Wash breathing circuit pipes, 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 circuit pipes 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 circuit pipe 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 disinfector. Never use organic solvent.

Maintenance

- 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
- 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.
- Λ 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 and 4 in Fig.7). 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.

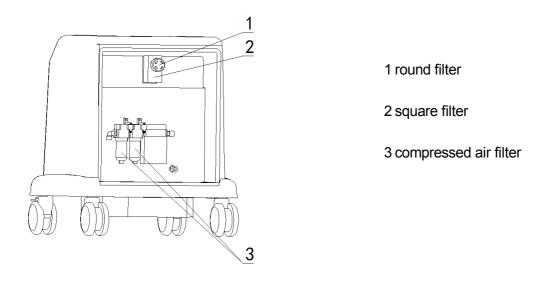


Fig 32 Clearance and replacement of input gas filter net

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.
- 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 "im", 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 32)

Waste disposal

Disposal of battery and O₂ sensor

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

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

- 1) If there is alarm during the operation, safeguard the patient firstly, then check immediately to fix the fault
- 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 Ppeap alarm	High	20 ∼ 100 cmH₂O	40 cmH₂O	When the monitoring value over the upper limit of Ppeak, there will be a sound alarm and display "High Ppeak!!".
Low Ppeak alarm	High	0∼ 20 cmH₂O	4 cmH₂O	When the monitoring value under low limit of Ppeak, there will be a sound alarm and display "Low Ppeak!!!".
High MV alarm	Medium	adult $5 \sim 99 \text{L/min}$ child $1 \sim 30 \text{L/min}$	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 tidal volume!!".
High O₂ 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 "O ₂ high!!".

Alarm	Priority	Setting range	Default value	Alarming way
Low O₂ 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 " O ₂ low!!".
Continuous pressure alarm	High			If the airway pressure (PEEP+15 cmH ₂ 0) over or under the set upper or low limit of continuous pressure alarm in 16 seconds, there will be a sound alarm and display"Continuous pressure too high!!!".
Apnoea 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 "Apnoea "(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 "Apnoea "(Green color).

Alarm	Priority	Setting range	Default value	Alarming way
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 (11V±0.3V), the power state indication place will display the signal of " ", and there will be a sound alarm.
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 failure", 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	Block of breathing circuit pipe Block of patient airway. Upper limit of alarm is too low.	1 Check the breathing circuit pipe 2 Check the patient status 3 Re-set the upper limit of alarm.
alarm	4 Ventilation parameters are set improperly.	4 Reset ventilation parameters.
Low Ppeak	Leakage or disconnection of breathing circuit pipe	1 Check and reconnect the pipe.
alarm	2 Low limit of alarm is too high.3 The compliance of patient changes.	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	Low limit of MV is too high. Leakage or disconnection of breathing circuit pipe	1 Reset the low limit of MV. 2 Check and reconnect the pipe.
Low IIIV didiiii	3 Low frequency or tidal volume4 No input gas5 Problem with flow sensor	3 Reset frequency or tidal volume4 Check the input gas supply5 Check the flow sensor
High O ₂	1 Upper limit of alarm is too low.	1 Reset the upper limit of O ₂ .
concentration alarm	2 Problem with Air and O ₂ blender adjustment	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 O₂ sensor. 3 Problem with Air and O₂ 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 circuit pipe. b. No input gas. c. No tidal volume	a.Check the breathing circuit pipe b.Check the patient status a.Check and reconnect the pipe b.Check input gas supply c.Check the patient status.
Apnoea alarm	 3 Problem with flow sensor 1 Problem with breathingcircuit 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 	3 Check the 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
	o Prodiem with flow sensor	6 Check the flow sensor

Alarm	Cause	Solution of alarm
Continuous pressure alarm	Problem with breathing circuit pipe Block of patient airway Alarm limit of is too low 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	Main power disconnection or problem Problem with fuse	1 Check the main power supply
Alarm of low voltage of battery	1 Low voltage of battery	2 Replace the fuse 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	1 Ventilation of working place is not good, and temperature of working place is too high.	1 Improve the condition of working place
pump (if equipped with air compressor)	2 Block of ventilation port. 3 Problem with fan	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	1 The main power is off	1 Check the power supply in the working
on screen and	2 Power line disconnection	place
ventilator do not	3 The starting switch is off.	2 Connect the power line
work.	4 Fuse is broken	3 Switch on the ventilator
		4 Change the fuse
Abnormal display of	1 Loose connection of flow sensor sampling tube	1 Re-connect the flow sensor sampling tube
tidal volume	2 Leakage of breathing circuit pipe	2 Re-connect or change pipe
	3 Leakage of exhalation valve	3 Check exhalation valve
Leakage of breathing	1 Pipe broken or connector loose	1 Re-connect or change pipe
circuit pipe	2 Leakage of exhalation valve	2 Check exhalation valve
The output pressure		
of compressor is low	1 Leakage of the compressor	1 Check the airway of compressor
(if equipped with air	2 Block of air filter	2 Change new air filter
compressor)		
Compressor do not	1 Power supply disconnection	1 Connect machine to main power
work (if equipped with air compressor)	2 Low voltage of main power	2 Check voltage of main power

Main technical specification

Environment conditions

Working environment:

Ambient temperature $5 \,^{\circ}\text{C} \sim 40 \,^{\circ}\text{C}$

Relative humidity ≤80 %

Atmospheric pressure 700 hPa ~1060 hPa

• Storage environment:

Ambient temperature $-20 \,^{\circ}\text{C} \sim +50 \,^{\circ}\text{C}$

Relative humidity ≤93 %

Atmospheric pressure 500 hPa ~1060 hPa

Classification

Classified according to IEC60601-1, S1100 belong to:

- Class I equipment, internally powered equipment;
- Category B equipment;
- Common equipment;
- Continuous operation;
- please refer to the Chapter "clearance and disinfection"
- Do not operate the machine in the mixer gas of air and flammable anesthetic gas or nitrous oxide.

Gas supply

Gas source
 O₂ (For medical use) Vmax=70L/min

Air (For medical use) or compressed air, Vmax=70L/min

Rated working pressure
 400 kPa

Input pressure range
 280 kPa∼600 kPa

Output pressure of regulator

(gas cylinder supply)Safety valve750kPa

Power supply

Voltage ~220 V±22 V
 Frequency 50 Hz±1 Hz

• Input power 900VA (if equipped with air compressor)

80 VA (if not equipped with air compressor)

Internal power
 DC12V, 1.5A, 4Ah

When the back-up battery is fully charged, the battery will

supply power for the ventilator about 2 hours.

Fuse

----Mains power T1AL250V

T10AL250V (if equipped with air compressor)

T6.3AL250V (if equipped with air compressor)

——Internal power T2AL250V

Electromagnetism compatibility

- 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 circuit pipe

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: ≤0.01L/ kPaInternal capacity: ≤0.6L

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

Ventilation mode

---IPPV

----A/C

----PCV

---SIMV

----SPONT/ CPAP

----PSV

---SIGH

----MAUN

Ventilation parameter adjustment

Frequency

——Adjusting range 1 bpm \sim 100 bpm

(Under SIMV: 1 bpm∼ 40 bpm

All mode except SIMV: VTH 4 bpm ~ 40 bpm

 VT_{L} 20bpm \sim 100 bpm)

----Allowable error ± 15 %

• Inhalation time (I:E) (Tinsp)

——Adjusting range $0s \sim 12s(4:1 \sim 1:8)$

——Allowable error ± 15 %

Tidal volume (V₁)

——Adjusting range 0 mL \sim 2000 mL

And:

 VT_H 250 mL \sim 2000 mL VT_L 0 mL \sim 300 mL

Minute ventilation (MV)

-Max MV VТн ≥18 L/min VT_{L} ≥10 L/min PEEP $0 \text{ cmH}_2\text{O} \sim 40 \text{ cmH}_2\text{O}$ —Adjusting range ——Allowable error ±(2 cmH₂O + 5% setting valve) CPAP $0 \text{ cmH}_2\text{O} \sim 20 \text{ cmH}_2\text{O}$ ——Adjusting range ----Allowable error ±(2 cmH₂O + 5% setting valve) Continuous flow VT_H 7 L/min \sim 60 L/min ——Adjusting range VT_L 2 L/min ~ 30 L/min —Allowable error >3L/min, ±15% \leq 3L/min, \pm 0.5 L/min Pressure trigger (PTr) $-20 \text{ cmH}_2\text{O} \sim 0 \text{ cmH}_2\text{O} \text{ (Under PEEP)}$ ——Adjusting range —Allowable error ± (1 cmH₂O +10 % setting valve) Pressure control (Pc) ----Adjusting range $5 \text{ cmH}_2\text{O} \sim 80 \text{ cmH}_2\text{O}$ ----Allowable error \pm (2 cmH₂O + 5% setting valve) Pressure support (Ps) $0 \text{ cmH}_2\text{O} \sim 80 \text{ cmH}_2\text{O}$ ——Adjusting range ——Allowable error \pm (2 cmH₂O + 5% setting valve) Flow trigger (FTr) ——Adjusting range $0.5 \, \text{L/min} \sim 30 \, \text{L/min}$ -Allowable error >3L/min: ±15% ≤3L/min: ±0.5 L/min O₂ concentration ——Adjusting range 21 %~100 % ——Allowable error \pm 3 % (V/V) or \pm 10 % setting valve, whichever is greater Holding time (Inhalation platform) (TIP) ----Adjusting range $0 \sim 6s(0\%\sim50\%)$ inhalation time) ——Allowable error \pm 0.1s or \pm 10 % setting valve, whichever is greater Sigh 0, $1/100 \sim 5/100$ —Adjusting range (Sigh tidal volume is 1.5 to 2 times higher than setting valve of tidal volume) Apnoea ventilation ——Adjusting range OFF, 5s \sim 60s Maximal Inspiratory Flow Rate

—Maximal Inspiratory Flow Rate: ≥ 60 L/min

Max set working pressure

(pressure limit range) 20 cmH₂O \sim 100 cmH₂O

Max pressure ≤125 cmH₂O
 Output MV under manual ventilation ≥25L/min

 Nebulizer gas maximum output pressure≤0.2 MPa maximum output flow≥8 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 bpm ∼ 100 bpm	1 bpm	±15 %
Tidal volume (VT)	0 mL~2500mL	10 mL	>100 mL: ±15% ≤100 mL: ±20 mL
Minute ventilation (MV)	0 L/min∼99 L/min	0.1 L/min	>3L/min: ±15% ≤3L/min: ±0.5 L/min
(Ppeak)	0 cmH₂O ~100 cmH₂O	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	1~1000mL/ cmH₂O	1mL/ cmH₂O	

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
All way piessure	Landing end		from multiple sampling
PEEP	Exhaling end	pressure- voltage、Simulated data	Choose average value
	LXHalling end	pressure- voltage, Simulated data	from multiple sampling
Contionous	Exhaling end	pressure- voltage Simulated data	Choose average value
pressure	Exhaining end	pressure- voltage, Simulated data	from multiple sampling
frog	built-in	time、simulated data	Choose average value
freq	Duiit-iii	time, simulated data	from multiple sampling
Inhalation time	e built-in time、simulated data		Choose average value
	Dulit-III	time, simulated data	from multiple sampling
Holding time	built-in	time、simulated data	Choose average value
	Dulit-III	time, simulated data	from multiple sampling
tidal volume	Exhaling end	flow- voltage \	Choose average value
lidai voidine	Exhaining end	Simulated data	from multiple sampling
flow	Exhaling end \	flow-voltage、	Choose average value
IIOW	inhaling end	simulated data	from multiple sampling
O ₂ concentration	Inhaling and	O ₂ concentration-voltage \	Choose average value
O2 CONCENTIATION	Inhaling end	simulated data	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

>45I /min

• Peak flow: When duration is 1 second, the peak flow is ≥120L/min

Dew point temperature: ≤ 5°C

Alarm temperature: temperature in compressor cabinets≥85°C±10°C

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 $(11V\pm0.3V)$, the power state indication place will display the signal of " \Box ", and there will be a sound alarm.

Alarm lasting time: >120 s

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 VTH: 5 L/min \sim 99L/min

VT∟:1 L/min ~ 30L/min

——Setting range of upper limit 0 L/min ∼20min

——Alarm accuracy \ge 3 L/min \pm 15 %

<3 L/min ± 0.5 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 $20 \text{ cmH}_2\text{O} \sim 100 \text{ cmH}_2\text{O}$

——Setting range of low limit $0 \text{ cmH}_2\text{O} \sim 20 \text{ cmH}_2\text{O}$

——Alarm accuracy ± (2%full scall+4%the actual reading)

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 O₂ concentration over the upper limit of O₂, or under the low limit, there will be a sound alarm and display of alarm hint.

——Setting range of upper limit 19% \sim 100 % ——Setting range of low limit 18 % \sim 99 %

——Alarm accuracy ± 3 %

Apnoea 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 hint "Apnoea!!!". (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 is alarm hint "Apnoea!!!".

——Apnoea time setting range

OFF, $5s \sim 60s$

When there is Apnoea alarm, the mode will change to A/C. So if set Apnoea 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 Apnoea alarm indication.

Audio paused

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

When there are new and different alarm conditions, sound restore.

——Audio paused 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 circuit pipes 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°C∼50°C, relative humidity not exceeding 93% and atmospheric pressure at 500 hPa ~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.
- Transportation environment

Ambient temperature $-20 \,^{\circ}\text{C} \sim +50 \,^{\circ}\text{C}$

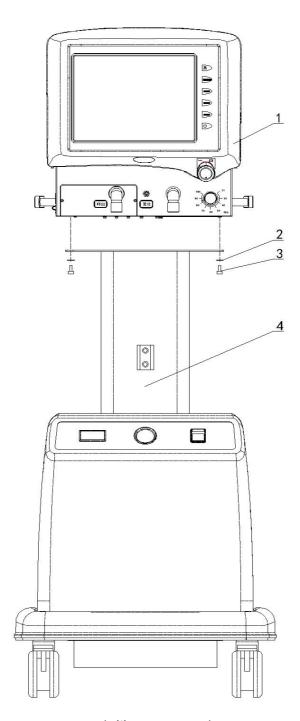
Relative humidity ≤93 %

Atmospheric pressure 500 hPa~1060 hPa

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 after delivery.
- Please do not dismantle the equipment without authorization If faults occur on the equipment, it shall be repaired by Service personnel authorized by our Company. If necessary, our company can provide necessary data.
- If ventilator and its accessories are at the end of their expected service life, please do not use them and dispose them according to the requirements of local environmental laws and regulations, ventilator expected service life is 8 years after delivery, its accessories expected service life see their accompanying documents.

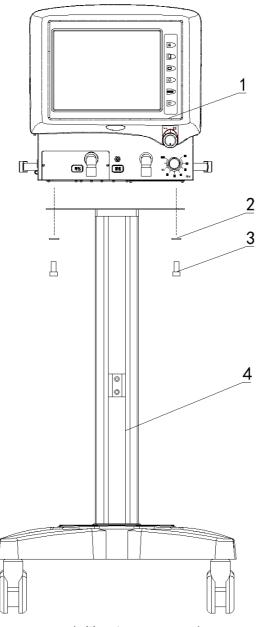
Appendix: Installation diagram



(with compressor)

(mar compressor)			
NO.	Name	Specification	Remark
1	Ventilator	2.782.074A	Packing box 1
2	Serrated saddle	φ5	
3	Screw	M5×12	
4	Bracket base	4.142.013A	packing box2(they have already
5	Air Compressor	2.782.076A	assembled together)

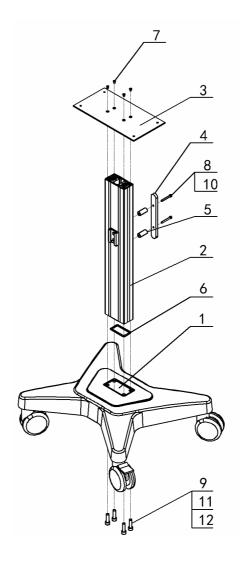
Fig.33 Installation diagram 1



(without compressor)

NO.	Name	Specification	Remark
1	Ventilator	2.782.074A	Packing box 1
2	Serrated saddle	φ5	
3	Screw	M5×12	
4	Main frame	8.039.017	packing box2(they have already assembled together)

Fig.34 Installation diagram 2



NO.	Name	Specification
1	enclose	8.074.018
2	main frame	8.039.017
3	connection plate	8.610.191
4	handle	8.333.006
5	handle pillar	8.039.001
6	dustband	8.683.024
7	screw	M4X10
8	screw	M6X45
9	screw	M10X35
10	spring washer	Ф6
11	spring washer	Ф10
12	flat gasket	Ф10

Fig.35 Installation diagram 3

2.782.027AS-A 2016.09.05

Thank you for choosing S1100 ventilators

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