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## Ventilator

## AV-2000B<sub>3</sub>

# User Manual

Please Read the Manual before Use

### **Important Safety Indication**

- 1. Please read Users' Manual carefully before using ventilator, and strictly follow all the warning and explanation in this Users' Manual.
- 2. The O<sub>2</sub> monitor used for the respiratory system should meet the specification of YY 0601-2009(ISO 7767:1997)
- 3. The hose component which connects the ventilator and medical gas supply system should meet the specifications of YY/T 0799-2010(ISO 5359:2000).
- 4. The breathing tubes used in the respiratory system of the ventilator should meet the specifications of YY 0461-2003.
- 5. The gas storage bag used in the respiratory system of the ventilator should meet the specifications of ISO 5362-2000.
- Any SPO2 meter and CO<sub>2</sub> monitor built in the ventilator or recommended to be used with ventilator should meet the specifications of YY 0601-2009.
- Any humidifier or heat and moisture exchanger built in the ventilator or recommended to be used with ventilator should meet the specifications of YY 0786-2010(ISO 8185:1997)或 YY/T 0735.1-2009 (ISO 9360-1:2000)和 YY/T 0735.2-2010(ISO 9360-2:2001).
- 8. Any gas mixing system built in the ventilator or recommended to be used with ventilator should meet the relevant specifications of ISO 11195: 1995.
- 9. To avoid the adverse effect of the sudden power failure on the patients, the emergency battery should be connected to the ventilator before use.
- 10. The A.C. power of the ventilator should have good protective grounding. If the integrity of the protective grounding cannot be assured, the battery has to be used to keep the ventilator working. Remember to make sure to access to the network power as soon as possible, so the machine can maintain a normal work;
- 11. This machine is not explosion-proof equipment, so please DO NOT operate the machine in any place with explosive or flammable gases.
- 12. This machine is not a liquid-proof equipment, if there is liquid on the surface, please wipe it off immediately. DO NOT let any liquid enter into the machine.
- 13. The ventilator should be thoroughly cleaned and disinfected before using, and make sure the machine is in good condition. NEVER operate the machine if there is malfunction.
- 14. The ventilator should be placed some distance away from the wall. Do not place it against the wall or near the barriers, or it will interfere with the cold air flow, thus causing the overheating of the equipment.
- 15. The expiratory phase of the ventilator does not use negative pressure (lower than the atmospheric pressure).
- 16. The flow sampling tube are not the part which is sensitive to the gas flow direction. However, they have to be connected in accordance with the instructions, otherwise the ventilator will not work properly.
- 17. The operators are not allowed to replace the battery by themselves. If there are any problems, please contact with the after-sale service department of our company.
- 18. In case the power supply of the ventilator is switched from A.C power to the emergency battery, its respiratory function will not be influenced.
- 19. The compressed air has to be medical air or oxygen.
- 20. Installation, adjustment, checking and use of the ventilator all should be operated by professional persons to avoid unexpected malfunction or damage.
- 21. The ventilator should not use antistatic or conductive hose or duct so as to avoid the potential dangers

such as electric shock.

- 22. If any damage to Ventilator is found during transportation, you should contact transportation company immediately and claim compensation; if you find the content of products is not the same as the content in the shipping list, you should immediately inform manufacturer or authorized agency.
- 23. Grease is not allowed to be used on oxygen decompressor and respiratory equipment because oxygen is the combustion-supporting gas, otherwise there will be strong oxidation combustion driven by 100% oxygen.
- 24. The filter, warming humidification device and water cup are added during gas path connection, which may increase the respiratory resistance of VBS system.
- 25. Components and materials of the ventilator are offered by our company, and if you replace them with others, danger may be caused.
- 26. If the self-test cannot be passed, you may press the button of shuttle twice quickly ,then you can skip that step and enter into the weight setup interface. At the moment, the ventilator must be connected to the external monitoring device (like pressure, flow) and work with them. In addition, the control mode of the ventilator is only MUNUAL mode, otherwise it may cause danger.
- 27. When the self-test cannot be passed caused by air source input alarm, moreover, the patient just needs oxygen concentration of  $45\% \sim 98\%$ , you can press the button of shuttle twice, then you skip the step and enter into the weight setup interface, at the same time, enter into the alarm setup interface to turn off air-alarm, and you can only eliminate the alarm sound and the alarm cue will be existent in this way.
- 28. The ventilator should be supervised on the spot by the medical staffs when being in use. They should adjust the ventilator to the state suitable for the patient and make analysis on relevant blood gas, so as to carry out the corresponding medical solutions.
- 29. If the ventilator starts without any weight setup, it will work in accordance with the parameters set in the last operation. You should pay attention to the applicability of those settings.
- 30. When you change parameters according to the weight setup, the parameters are recommended by the experts. If some parameters are not suitable for the users, they can be made proper adjustment.
- 31. When AC power works, it displays the power plug icon. If the current storage battery is charging, the icon will turn yellow. After finishing charging, the icon will turn white.
- 32. The adjustable pressure range of the oxygen pressure reducer is  $0.28 \text{ Mpa} \sim 0.6 \text{Mpa}$ . If the pressure is beyond the range, the ventilator will not work properly. If gas source is not available, the backup ventilation mode should be immediately employed to assist the patient in breathing.
- 33. The value of PEEP is generally set between  $3 \sim 5$  cmH<sub>2</sub>O,it is better not to set it too high, for it may lead to emphysema if you use it for a long time.
- 34. When there is trigger, the pilot lamp of the inspiratory and expiratory working will turn red.
- 35. When the pressure limit is initiated, the pressure monitoring value will show red color.
- 36. In the diaplay interface, if 🗹 is displayed before the alarm setting, it indicates that the alarm is started. The red refers to high priority alarm, and the yellow refers to medium priority alarm .
- 37. In the case that no "?? "appears, it indicates the Oxygen probe stays short time in the air and leads to the 21% of Oxygen concentration is not accurate. So you should save the value until it doesn't descend.
- 38. In the case that no "??? " appears, it indicates the Oxygen probe stays short time in the air and leads to the 99% of Oxygen concentration is not accurate. So you should save the value until it doesn't descend
- 39. As all the parameters have been set in the ventilator, what the operator should do is to set parameters as required in manual mode. In addition, you can adjust the shuttle and corresponding tidal volume, and those parameters should be adjusted by the professionals.
- 40. In order to prevent the value of system setup is changed arbitrarily, we will use on/off of system setup for control. Each time you want to change the parameter of system, you have to open system setup first, and after the setting, system setup will be closed automatically. If you have other requirements, you should turn on it again for other setup.

- 41. If spontaneous breathing frequency is too fast, you should set the breathing frequency close to spontaneous breathing frequency, and decrease the tidal volume appropriately at the moment.
- 42. In VCV mode, tidal volume may not be set arbitrarily within the range of it. It is normal condition because that tidal volume and frequency has mutual restricted, which can be understood by: tidal volume times frequency  $\leq 20L$ .
- 43. In VCV mode, the tidal volume may be displayed red, which indicates that the tidal volume limitation function of the ventilator is initiated. If the monitoring value is much larger than the set value, the ventilator will initiate the tidal volume limitation.function After the monitoring value is within in the specified range, the tidal volume will be displayed normally.
- 44. In PCV mode, if pressure limit is set so high that the monitoring value of tidal volume is much higher than the its set value, the monitoring value of tidal volume will be displayed red and the tidal volume limitation function will be initiated. At the moment, PCV cannot reach the set pressure. It is necessary to increase the set value of the tidal volume to a certain degree in this case.
- 45. The setup of tidal volume in PCV mode is to prevent the excessively high pressure when pressure sensor does not work well, in addition, it won't exceed the set value of tidal volume, thus preventing the airway from damage caused by over-high pressure.
- 46. In VCV mode, Trigger method should be set flow trigger.
- 47. SIMV frequency must be lower than machine controlled frequency. While you set SIMV frequency, if the SIMV frequency is set higher than machine controlled frequency, then the machine controlled frequency will automatically adjust itself higher than SIMV frequency once.
- 48. The humidifier also needs single-phase AC power supply with good protective grounding. Connecting to the humidifier might increase resistance in VBS airway.
- 49. When using the humidifier, you should pay close attention to the temperature in the outlet and amount of water in the humidifier to prevent dry burning.
- 50. The humidifier also need single-phase AC power supply with good grounding protection. Connecting to the humidifier might increase resistance force in VBS airway.
- 51. The air compressor should not be started under load. You will hear exhaust sound when the power supply is cut off. It is normal, just for removing the pressure for the next start. The exhaust value is closed tightly in normal operation.
- 52. To avoid the single failure of the air compressor, the safety overflow valve is installed in the airway. The valve has automatic overflow function when the output pressure of the air compressor is over 300kPa.
- 53. You must not shut the ventilator before it is removed from the patient, in case of causing suffocation of patients! After using the ventilator, it should be immediately cleaned and disinfected. Necessary maintenance and repair should be done.
- 54. If you are not clear of the causes of the ventilator failure, do not dismantle the machine. Please promptly contact our company's after-sale service department!
- 55. Water in Ventilator tube is prone to transmit diseases and pollute the environment. Treatment of the water must strictly comply with the "Management of Medical Waste in Medical and Health Institutions" issued by Ministry of Health and the relevant specifications and requirements regulated by government environmental protection agencies.
- 56. Breathing circuit used for connecting the Ventilator should be consistent with the requirement of YY0461-2003. Adverse reactions arise due to the use of other pipes which do not meet the requirements has nothing to do with the company. The respiration duct equipped by the company should be exclusive for adjustment.
- 57. The power switch of ventilator is the switch of AC power and emergency battery. The working ventilator will stop working immediately by flipping this switch.
- 58. How to replace the fuse box, can refer to the rear panel diagram of ventilator in the chapter 5.1.
- 59. Hose Components are carefully used in the worksite with excessively high working environment temperature or with chemical gas in the working space, for it might cause the hose to be softened,

therefore, the pressure resistance will be dramatically decreased, or it might be quickly aged and cracked due to chemical gas corrosion.

- 60. Please don't store hose Components in a damp environment or in a warehouse directly exposed to sunlight for too long time, and rupture phenomenon might be caused due to damp hydrolysis.
- 61. Don't let the hose wind in friction, don't stretch and warp excessively, otherwise, the hose will be damaged and will affect the working pressure.
- 62. Using lubricating oil in the oxygen inlet pipeline might cause the danger of burning and explosion.
- 63. Components and materials are approved and provided by our company, and replacing them with others will decrease the minimum safety limit.
- 64. After the double silicone tube which is connected to flow sampling tube is cleaned and disinfected, it needs to be cleared with dry gas for more than 30 seconds to prevent water and foreign gas from blocking the vent hole and avoid inaccurate tidal volume monitoring to make the machine work normally.
- 65. The waste water generated by cleaning the ventilator is prone to transmit diseases and pollute the environment. The treatment of these contaminants must strictly comply with the "Management of Medical Waste in Medical and Health Institutions" issued by Ministry of Health and the relevant specifications and requirements regulated by government environmental protection agencies.
- 66. Disposable items should not be reused. The reusable items , for the reusable item, its use age is 1 year. It must be replaced if it influences the normal work within 1 year.( silicone product has hardened, cracked and leaked within 1 year which influences the normal work and can be called disqualified, so it must be replaced.)
- 67. You cannot discard the useless emergency battery as you wish since it will contaminate environment. You must comply with the rule and requirement regulated by national environmental protection institute.
- 68. The operator must not replace the emergency battery by himself, please do contact our after-sale service department.
- 69. You cannot discard the useless oxygen concentration sensor as you wish since it will contaminate environment. You must comply with the rule and requirement regulated by national environmental protection institute.
- 70. The ventilator must be running in the specified working environment. When the ventilator storage environment is not the specified environment, you must place it in the working environment for four hours before using it, which, otherwise, influences the performance of the ventilator.
- 71. The ventilator is professional medical equipment, and its maintenance must be performed by trained professionals, and our company can provide related information (such as electric circuit diagrams, components list, legend and correction rules, etc.).
- 72. The ventilator should be set, adjusted and tested on the r bag before being connected to the inpatient's airway.
- 73. The power line and breathing tube should not interfere with patients' activities. The ventilation pipeline should not be pressed so as to avoid the deformation and blockage. The ventilator should not be moved randomly when being in use so as to avoid the accidents like disconnection of the pipes or power line and the falling down of the oxygen bottle.
- 74. The ventilator should be supervised on the spot by the medical staff when being in use. In order to adjust the ventilator to the state suitable for the patients, the operators should pay attention to not only the working status of the ventilator and humidifier but also the patient's vital signs and relevant blood gas analyzing data.
- 75. Although the ventilator has been designed in full consideration, it is also possible that some problems may occur in some cases. Therefore, there will be another ventilator with good performance or simple ventilator available for alternative use.
- 76. The function of this machine may be influenced by nearby high frequency surgical instruments or short-wave equipment.

- 77. The total bracket load of this suspended breathing tube should not exceed 1 kgf,
- 78. Even though the power supply of the ventilator is switched from A.C power to the emergency battery, its function will not be influenced.
- 79. The two flow sampling tube of the ventilator should be connected in accordance with the instructions, otherwise it will not work properly.
- 80. The changes of all parameters could only be saved after being adjusted and confirmed. The parameters will not be changed if the button of confirm is not pressed. The parameters include mode, control parameters, alarm parameters, and contents of system setup. And the ventilator runs according to parameters set last time, however, the control mode will be always "Auto".
- 81. The default parameters of the system will not be changed. Even if the operator has changed part of parameters, all parameters will be recovered to the aforementioned parameters if the system default is resumed after entering into the system settings, except the tidal volume calibration, pressure calibration and oxygen concentration calibration.

## Illustration by Words and Figures

DANGER	Alert to high danger	
WARNING	Alert to moderate danger	
NOTICE	Attention to low dander	
*	It refers to the B-type application part.	
$\land$	Please refer to attached documents	
	AC power supply	
	DC power supply	
	Indication generated by alarm	
	Alarm reminder	
	Mute	
Ι	Power ON	
0	Power OFF	

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#### **1** General description

#### 1.1 Application Scope and Main Features

AV-2000B3 ventilator is an electric and pneumatic control ventilator with basic features of timing, constant volume and constant pressure. The function is required comprehensive and the doctor can have more freedom to choose and configure it in order to deal with different conditions of respiratory failure. The machine intelligence has been improved to make approach to the physiologic respiratory pattern. There is no absolute contraindications but the relative contraindications which are as fallows: patients with pneumothorax and mediastinal emphysema and those who are not operated a chest drainage, and those who suffer severe pulmonary hemorrhage, bullae of lung, hypovolemic shock, acute myocardial infarction. It is mainly used to assist the critical patient in breathing during life-saving process, help the patient to get through the critical moment, and assure the implementation of the treatment of the basic diseases. It provides an alternative way for patients with the irreversible pathological changes of the respiratory muscle or irreversible harm to the upper airway to help them maintain the respiratory function. It can also provide assisted respiration for the patient during the treatment and surgical recovery process. The ventilator cannot automatically save the relevant information. The main features are listed as follows:

- a. It is an electric and pneumatic control ventilator with basic features of timing, constant volume and constant pressure.
- b. The ventilator has two working modes, namely standby and ventilation, and two ventilation modes, namely, invasive mode and noninvasive mode.
- c. It has air-oxygen mixer with high performance, which can easily and accurately adjust the oxygen concentration.
- d. It has electronic PEEP with continuous adjusting function.
- e. Inspiratory triggering has two modes, i.e. pressure triggering and the flow triggering.
- f. The pressure sensor and flow sensor with high sensitivity and quick response detects, controls and displays the airway pressure and gas flow. In addition, it has tidal volume with automatic compensation function. Leakage compensation volume is less than 12L/min.
- g. It has many ventilation modes: VCV(Volume Control Ventilation), PCV(Pressure Control Ventilation), PSV(Pressure Support Ventilation), SIMV(Synchronized Intermittent Mandatory Ventilation), and CPAP(Continuous Positive Airway Pressure).
- h. It uses TFT LCD monitor to display real-time monitoring parameters such as control frequency, tidal volume, ventilation volume per minute, sum frequency of respiration, spontaneous respiration frequency, oxygen concentration, average airway pressure, power, etc.
- i. Monitoring waveform: pressure-time waveform, flow velocity-time waveform, flow velocity-volume loop, and pressure-volume loop.
- j. It has functions of inspiratory plateau, sign, negative pressure, manual respiration, inverse ratio ventilation (IRV), etc.
- k. When there are abnormal conditions or wrong operations, the ventilator will send sound and light alarm signals with low, medium and high priority level.

- 1. It has functions like alarm message display, power supply mode display, inspiratory trigger display, etc.
- m.As long as the respiratory tube is connected to the atmosphere, it will not hold the patient's breathing even if there is power failure.
- n. It is equipped with the medical air compressor and can adjust the oxygen concentration of the ventilator when its range is between 21% and 98%.
- o. The medical air compressor has standby function.

#### 1.2 Electromagnetic Compatibility Requirements

The respiratory system should not be used in the environment with strong radiation and strong electromagnetic interference, e.g. MRI. Otherwise, the performance of the device will be influenced adversely to some degree.

#### 1.3 Requirements for the Working Environment

- The Ventilator of AV-2000B3 belongs to Class I, Type B Application Equipment according to GB 9706.1 2007 Medical Electrical Device: Part one: General requirements for safety », the symbol" <sup>\*</sup>/<sub>\*</sub>"in back panel of the ventilator represents Type B application part.
- —— There is power supply in the ventilator
- The machine is normal equipment which is IPX0.
- The machine is not explosion-proof equipment, so please don't operate the machine in the circumstance with explosive or flammable gases.

AV-2000B3 ventilator is a kind of mobile medical equipment required to work under climatic environment Group II and mechanical environment Group II, which is specified by the GB/T 14710 Environmental Requirements and Test Methods for the Medical Electric Equipment. The normal working condition is as follows:

- Environment Temp:  $10 \sim 40$  °C , Relative Humidity:  $\leq 80$  %;
- ——Atmospheric Pressure:96 kPa~104 kPa;
- Gas source: Oxygen :Range of pressure input: 280kPa $\sim$ 600kPa,and rated pressure :400kPa , and flow velocity  $\leq 200$ L/min.
  - Air:Range of pressure input:280kPa $\sim$ 600kPa,and rated pressure :400kPa , and flow velocity  $\leq$  200L/min.
- Power Supply: AC 220V 50 Hz , Besides, it has good protective grounding. The input power is 400VA
- ——Specification of Fuses: The section of network power: 5RF/ F5AL250V; Lithium battery: 5RF/ F5AL250V.
- ——Specification of Emergency battery: DC 14.8V 4.4AH.

**M**NOTICE: The ventilator is not the explosion proof product; therefore it cannot be used in the environment with flammable and explosive gas.

**MOTICE:** The A.C. power supply for the ventilator should have good protective grounding. If the integrity of the protective grounding cannot be assured, the emergency battery has to be used for the ventilator.Remember to make sure of access to the net power as soon as possible, so the machine can maintain a normal work.

**M**NOTICE: The ventilator is not liquid-proof product. The liquid on it should be wiped off to avoid it entering into the machine.

**MOTICE:** The anesthesia respirator should be placed some distance away from the wall. Do not place it against the wall or near the barriers or near the curtains or cover covering the machine or it will interfere with the cold air flow, thus causing the overheating of the equipment.

#### 2 Structure Feature and Working Principle

#### 2.1 The Schematic diagram of gas path in the Ventilator



The Airway Diagram for AV-2000B3 Ventilator

#### 2.2 The Working Principle of the Ventilator

AV-2000B3 ventilator takes compressed oxygen or compressed air as the power and forms a kind of pressurized mixed gas consisting of medical oxygen and ambient air, which is delivered to the patient's respiratory passage through the pipe of the ventilator which is called mechanical ventilation. In this process, the solenoid vale, flow sensor, pressure sensor, and single-chip control system are used to measure, adjust and control the ventilation pressure, ventilation time, ventilation volume per minute of the patient.

#### 2.3 Real-time Monitoring Parameter

The ventilator displays the following important parameters real time.

- ----- Working mode and I:E of the ventilator
- -----set control frequency of the ventilator
- —— Tidal volume numerical value of the patient's every respiration.
- ------ the appearnce of the patient's spontaneous respiration and the spontaneous respiration frequency.
- ----- Display of expiratory phase and inspiratory phase; the actual respiration frequency
- ----- Minute ventilation
- ----- Inhaled oxygen concentration
- ----- Plateau pressure, peak airway pressure, average pressure and end-expiratory positive pressure
- ----- Battery power
- ----- The real-time changes of the pressure in the airway
- Pressure limit
- ——Pressure-time waveform, flow velocity-time wave, flow velocity-volume loop, and pressure-volume loop.

#### 2.4 Alarm System

The Ventilator has three Alarm Systems: High Alarm Systems, Medium Alarm Systems, Low Alarm Systems .

High priority alarm:upper airway pressure limit alarm, sustained high-voltage alarm ,suffocation alarm ,tube drop alarm ,low power alarm ,low oxygen concentration limit alarm .

Medium priority alarm:low oxygen source alarm, low air source alarm, low tidal volume limit alarm, upper volume alarm alarm, low airway pressure limit alarm, upper minute ventilation limit alarm, low minute ventilation limit alarm, upper oxygen concentration limit alarm, upper frequency limit alarm, low freqency limit alarm and low power alarm.

No	Alarm	Priority	Conditions	to Alar	Handling Methods		
	Contents	Level	Triggering				
1	High	Medium	The tidal volum	ne monitorir	1. Decrease the tidal vol	ume.	
	tidal	priority	value is higher the	han the alar	2. There is something w	rong with the flo	ow
	volume		set value, then it	t immediate	sampling pipe, so rep	lace it with n	ew

Low priority alarm: DC supply alarm

			alarms	flow sampling pipe
2	Low tidal volume	Medium priority	The tidal volume monitoring value is below the alarm set value, and it alarms after two respiration cycles.	<ol> <li>Check the respiration airway pipeline to see if the pipeline is leaking or not.</li> <li>Check up to see if excessively low tidal volume is caused by airway blockage or not, and then suck up phlegm, and use expectorant.</li> <li>Increase the tidal volume.</li> <li>There is something wrong with the flow sampling pipe, so replace it with a New one .</li> </ol>
3	High ventilatio n volume	Medium priority	The ventilation volume monitoring value is higher than the alarm set value, and it alarms in one minute.	<ol> <li>Decrease the tidal volume.</li> <li>There is something wrong with the flow sampling pipe, so replace it with a new one.</li> </ol>
4	Low ventilatio n volume	High priority	The ventilation volume monitoring value is below the alarm set value, and it alarms in one minute.	<ol> <li>Check the respiration airway pipeline to see if it's leaking or not.</li> <li>Check if excessively low tidal volume is caused by airway blockage or not, and then suck up phlegm, and use expectorant.</li> <li>Increase the tidal volume.</li> <li>There is something wrong with the flow sampling pipe, and replace it with new flow sampling pipe.</li> </ol>
5	High airway pressure	High priority	The airway pressure monitoring value is higher than the alarm set value, and it will immediately alarm.	<ol> <li>Turn down the tidal volume.</li> <li>The autonomous respiration of the patient is out of sync with machinery ventilation of the respirator, thus causing the problem of man-machine counteraction, so readjust the trigger sensitivity.</li> <li>The patient has tracheospasm or the secreta makes the air resistance to ascend, so suck up the phlegm, and use the expectorant.</li> <li>There is something wrong with the pressure sensor, and replace it with new pressure sensor.</li> </ol>

	1	1		
6	Low	Medium	The airway pressure	1. Air source pressure is insufficient, so
	airway	priority	monitoring value is below the	check the air source pressure.
	pressure		alarm set value, and it will	2. There is something with the oxygen
			immediately alarm.	bottle decompressor or oxygen cathete
				failure, so replace new oxygen
				decompressor or oxygen transmission
				pipeline.
				3. The vent line is leaking, the patient
				presents the hypoxia symptom, check
				the humidifier to see if it's tightly
				fastened, and see if the vent line is
				leaking or not.
				4. The tidal volume and air suction current
				speed is not properly adjusted, and
				increase the current speed and tidal
				volume
7	High	Medium	The oxygen concentration	1. There is sir source deficiency, so check
	oxygen	priority	monitoring value is higher	up the air compressor or externally
	concentra		than the alarm set value, and it	connected air source.
	tion		will immediately alarm.	2. Decrease the oxygen concentration.
8	Low	High	The oxygen concentration	1. There is Oxygen gas source deficiency,
	oxygen	priority	monitoring value is below the	so full replace
	concentra		alarm set value, and it will	oxygen bottle or check up the central
	tion		immediately alarm.	oxygen supply.
				2. There is something wrong with the
				oxygen bottle decompressor or oxygen
				transmission pipeline, and replace
				new deoxygen bottle decompressor or
				oxygen
				transmission pipeline
				3. Increase the oxygen concentration.
9	High	Medium	Autonomous inspiratory	1. The patient's autonomous respiration is
	frequency	priority	trequency monitoring value is	out of sync with the mechanical
			higher than alarm set value,	ventilation of the ventilator, then
			then it will alarm in a minute	man-machine counteraction is formed,
				so at the moment you should readjust
				the trigger sensitivity.
				2. Increase the frequency alarm value
10	Low	Medium	The autonomous inspiratory	Decrease the frequency alarm value

	i			
	frequency	priority	frequency monitoring value is	
			lower than the alarm set value,	
			and it will alarm in one	
			minute.	
11	Consecuti	High	VBS pressure is consecutively	1. The patient has tracheospasm or the
	ve high	priority	above 30cm H <sub>2</sub> O and maintain	secreta makes the air resistance to
	pressure		it, and it starts alarm within	ascend, so suck up the phlegm, and use
			17s.	the expectorant.
				2. Make the vent port to exhaust smoothly.
12	Tube	High	When the situation that the	1. Check the leakage, connect the
	drop	priority	pressure is consecutively	breathing tube or the heating humidifier
			below 5cmH <sub>2</sub> O and tidal	well.
			volume is no more than 30ml	2. There is something wrong with the flow
			lasts for 15s±5s, it begins to	sampling pipe, so replace it with new
			alarm	flow sampling pipe.
				3. There is something wrong with the
				pressure sensor, so replace it new
				pressure sensor
13	Suffocati	High	When the situation that the	1. The patient has tracheospasm or the
	on	priority	pressure is consecutively	secreta makes the air resistance to
			higher than 10cmH <sub>2</sub> O, and the	ascend, sp suck the phlegm, use the
			tidal volume is lower than	expectorant.
			$50$ ml lasts for $15s\pm 5s$ it begins	2 There is something wrong with the flow
			to alarm	sampling pipe so replace it with a new
				one.
				3 There is something wrong with the
				pressure sensor so replace it with new
				pressure sensor
14	DC	Medium	It immediately alarms when	1 Resume the AC power supply as soon
	nower	priority	the AC power supply is cut	as possible
	supply	priority	and is converted into DC	2 There is something wrong with the
	suppry		nower supply	2. There is something wrong with the
			power suppry.	ope
				3 There is something wrong with the
				fue co replace it with pow fue
				A There is something wrong with the
				4. There is something wrong with the
				switch power supply or power supply
				board, so replace it with new switch
				power supply or power supply board .

				I.
15	Low	High	It immediately alarms when	1. Resume AC power supply as soon as
	power	priority	the power of battery is below	possible.
			14.5V±0.5V.	2. There is something wrong with the
				power line, so replace it with new
				power line.
				3. There is something wrong with the
				fuse, so re replace it with new fuse.
				4. There is something wrong with the
				switch power supply or power supply
				board, so replace it with new switch
				power supply or power supply board.
16	Excessive	High	When power is lower than	1. Resume AC power supply as soon as
	ly low	priority	13.5V $\pm$ 0.5V, then it will alarm	possible.
	power		immediately	2. There is something wrong with the
				power line, so replace it with new
				power supply cable.
				3. There is something wrong with the
				fuse, so replace it with new fuse.
				4. There is something wrong with the
				switch power supply or power supply
				board, so replace it with new switch
				power supply or power supply board.
17	Power-cu		The ventilator has alarm	1. Resume AC power supply as soon as
	t alarm		reminding no less than 120s	possible.
			when both the AC and DC	2. There is something wrong with the
			power supplies are invalid (the	power line, so replace it with new
			buzzer will beep)	power line.
				3. There is something wrong with the
				fuse, and replace it with new fuse.
				4. There is something wrong with the
				switch power supply or power supply
				board, and replace it with new switch
				power supply or power supply board.
				5. There is something wrong with the
				storage battery, so replace it with new
				storage battery.

The difference among high priority alarm, medium priority alarm and low priority alarm is as follows:

Color	Priority of Alarm Information		Measures to Be Taken
Red	Warning	High priority alarm	Measures should be taken immediately so
Keu			as to prevent serious dangers
<b>W</b> - 11	Attention	Medium priority alarm	Measures should be taken immediately so
renow			as to prevent dangers
Yellow	reminder	Low priority alarm	Pay attention to the measures taken

- 2.Alarm message: the color of the words in high priority alarm message is red, and the color of the words in medium and low priority is yellow.
- 3. Alarm cue: the pilot lamp of high priority alarm is red, and its flash frequency is quick. The pilot lamp of medium priority alarm is yellow, and its flash frequency is low. The pilot lamp of low priority alarm is red and it is always on.
- 4. Alarm sound: the high priority alarm sound includes two groups of 3 long and 2 short sounds, the time interval of every two groups of alarm is 10s. The medium priority alarm sound is 3 short sounds in series, with the time interval of 25s. The low priority alarm sound is 3 short sounds with the time interval of 25s.
- 5.Alarm volume: the high priority alarm volume is  $\geq$ 55dB(A), the medium priority alarm volume is  $\geq$ 50dB(A) and the low priority alarm volume is  $\geq$ 45dB(A)

Attention: as for the same or similar equipment used in the same surgery, using different alarm preset might have potential dangers!!

Attention: the AC is directly converted into DC power supply after power-cut. In this state, the alarm function will not be invalid. Under the circumstance that both the AD and DC power supplies are invalid, then the alarm contents will be automatically saved.

#### 2.5 Safety protection

The maximum safety pressure of the airway pressure is 12.5kPa. When the airway pressure exceeds its maximum safety pressure, the valve will be open automatically to relieve pressure. The upper airway pressure limit alarm which can be set is  $5 \sim 60 \text{cmH}_2\text{O}$ . When the airway pressure is too high due to pipeline blockage, there will be automobile alarm. The pressure limitation function will shift the work state into expiratory phase when the pressure reaches its set value and relieve excessively high pressure.

When the external power of the ventilator is invalid, the power supply of the ventilator will be automatically shifted into emergency battery power supply and the function setup and monitoring of the ventilator will remain the same and can work normally. When internal and external power are invalid at the same time, the patient can spontaneously breathe at the expiratory port and ensure his safety.

1.

## $igtsymbol{\Lambda}$ Attention: expiratory phase of the ventilator can't use negative pressure.

#### 2.6 Device installation instruction

The pressure reducing valve, one-way valve, propositional valve and solenoid valve in the ventilator are sensitive to the air current direction, therefore the installation direction can't be wrong. For example, there are direction arrow at the bottom of the pressure reducing valve and propositional valve, meaning "from air inlet to air outlet. There are direction arrow on the one-way valve body, representing the air current direction. The flow sampling tube is external device and the both ends of it has different size. The end of  $\Phi 15$  external cone is connected to the Y-shaped joint of the screw thread tube and the end of  $\Phi 22$  external cone will be connected to the patient end. In order that users connect the two sampling tubes in a wrong way, the conical degree of them are designed different. The end close to  $\Phi 15$  external cone has  $\Phi 4$  external cone, and the end close to  $\Phi 22$  external cone has  $\Phi 6$  external cone. In silicone gel double tubes, one is onnected to  $\Phi 6$  external cone. The other end of the double tube are connected to "flow signal baby blue" interface and "flow signal baby blue" interface on the front panel. How to connect the sampling tube can refer to the content in chapter 4.2 2)

Attention: the flow sampling tube is not sensitive to the air current direction, so you just connect the sampling tube according to the relevant content in the instruments, otherwise, the ventilator can't work normally.

#### **3** Technical Specifications

#### 3.1 The main performance

#### 3.1.1 The basic function

- —— Inverse ratio ventilation;
- ----- Positive end-expiratory pressure;

#### 3.1.2 Ventilation mode

- PCV (pressure control ventilation)
- ——PSV (pressure support ventilation)
- ------ PSV+ SIMV (pressure support ventilation+synchronized intermittent mandatory ventilation)
- —— CPAP (continuous positive airway pressure)

#### 3.2 Basic Parameters of the ventilator

- Tidal volume range:20ml~1800ml, permissible error: $\leq 100$ ml,  $\pm 20$ ml,  $\leq 100$ ml~1500ml,  $\pm 15\%$ ,  $\leq 1500$ ml $\pm 20\%$ .
- Maximum ventilation volume per minute:≥18 L/min。
- Respiratory frequency:2~120bpm, or2~100bpm, permissible error:±1bpm, other range:±2% of the set value.
- —— SIMV frequency:2~20bpm, permissible error:±1bpm.
- —— Inspiratory plateau: $0 \sim 50\%$  of the inspiratory time, permissible error: $\pm 15\%$ .
- ----- Sigh(deep breathing):controlled respiration every  $60 \sim 120$  times can produce inspiratory time of 1.5 times.permissible error:±15%. Off represents closing the function of "sigh"
- Time control:1 $\sim$ 10s; permissible error $\pm$ 1s. (in PSV mode)
- Maximum safety pressure:≤12.5kPa.
- —— Compliance of the ventilator:  $\leq 3 \times 10^{-2}$  ml / Pa.
- ----- Inspiratory trigger sensitivity:pressure:- $10 \sim 10 \text{cmH}_2\text{O}$ , permissible error: $\pm 2 \text{cmH}_2\text{O}$ , or  $\pm 10\%$  of the set value, subject to the greater value.flow velocity: $1 \sim 20 \text{L/min}$ , slope: $1 \text{L/min}_{\circ}$
- Expiratory trigger sensitivity:adjustment range:10%~90%, gradient:1%. (in PSV and PSV+SIMV mode)
- Positive end-expiratory pressure: $0 \sim 25 \text{ cmH}_2\text{O}$ , permissible error: $\pm 2 \text{ cmH}_2\text{O}$  or  $\pm 10\%$  of the set value, subject to the greater value.0 represents shut PEEP.
- ----- Pressure limit:5  $\sim$  60cmH<sub>2</sub>O, permissible error:±2cmH<sub>2</sub>O or±10% of the set value, subject to the greater value
- ----- Pressure control:3 $\sim$ 50cmH<sub>2</sub>O, permissible error: $\pm$ 2cmH<sub>2</sub>O or  $\pm$ 10% of the set value, subject to the greater value (in PCV mode)
- Oxygen concentration:adjustment range:21%  $\sim$  98%, permissible error:= (2.5% of volume percent +gas concentration of 2.5%) .
- ——Flow control:adjustment range: $1 \sim 10$ , gradient:1. (in PSV and PSV+SIMV mode)
- —— Pressure slope ratio:adjustment range:1~10, gradient:1. (in PCV mode)
- continuous working time: the ventilator can work for 24 hours continuously when you use AC power
   Supply. The ventilator can work for 30 minutes continuously when you use emergency battery.

#### Monitoring requirement

- Tidal volume:0~2000ml, permissible error: $\leq 100$ ml,  $\pm 20$ ml,  $\leq 100$ ml $\pm 15\%$ .
- Minute ventilation: $0 \sim 30 \text{L/min}$ , permissible error: $\pm 15\%$ .
- ----- Breathing frequency:0~99bpm, permissible error:±2bpm.
- ——Airway pressure:-20 $\sim$ 80cmH<sub>2</sub>O, permissible error:= (4% of the full scale +8% of actual reading).
- Oxygen concentration:15% $\sim$ 100%, permissible error:= (2.5% of volume percent+gas concentration of 2.5%)  $_{\circ}$

Alarm content:

— Upper minute ventilation limit alarm: $1 \sim 20$ L/min; limit minute ventilation limit alarm: $0 \sim 19$ L/min;

permissible error:±15%.

- Upper tidal volume limit alarm:10~1800ml; low tidal volume limit alarm:0~1700ml; permissible error:≤100ml, ±20ml, ≤100ml~1500ml±15%,≤1500ml±20%。
- Upper pressure limit alarm:5  $\sim$  60cmH<sub>2</sub>O; low pressure limit alarm:0  $\sim$  50cmH<sub>2</sub>O; permissible error:±2cmH<sub>2</sub>O or ±15%, subject to the greater value
- Upper oxygen concentration limit alarm: $21\% \sim 99\%$ ; low oxygen concentration limit alarm: $18\% \sim 80\%$ ; permissible error: $\pm 5\%$ .
- Upper frequency limit alarm:  $10 \sim 99$  times/min; low frequency limit alarm:  $0 \sim 50$  times/min; permissible error:  $\pm 15\%$ .
- ----- Suffocation alarm: when the pressure is higher than  $10 \text{cmH}_2\text{O}$ , and tidal volume is lower than 50ml, there will be alarm at  $15s\pm5s$ .
- Tube drop alarm: when pressure is lower than  $5 \text{cmH}_2\text{O}_2$  and tidal volume is no more than 30 ml, there will be alarm at  $15 \text{s}\pm 5 \text{s}$ .
- ---- Continuous over-high pressure alarm :the pressure of VBS continuously exceeds  $30 \text{cmH}_2\text{O}$ , start alarm,the maximum delay time  $\leq 17$ s.
- —— When AC power supply is shifted into DC power supply, there will DC power supply alarm.
- Low power alarm: it will alarm when battery voltage is lower than 14.5V±0.5V.
- Excessively low power alarm: it will alarm when battery voltage is lower than 13.5V±0.5V.
- —— Gas shortage alarm:
  - Low oxygen source alarm: when oxygen source pressure is lower than  $0.18 \sim 0.2$  MPa, the system will alarm.

Air source source alarm: when air source pressure is lower than  $0.18 \sim 0.2$  MPa, the system will alarm.

- Power-cut alarm: when AC power supply is shifted into DC power supply, then AC icon is shifted into DC icon on the screen and DC power supply alarm will be produce. When AC and DC power supply are invalid, then alarm cue which lasts for no less than 120s will be sent
- ---Alarm mute:  $\leq 120 s_{\circ}$
- ----- Alarm system display:current alarm content has rolling display

#### **3.3** Air compressor

- ----- Continuous flow  $\geq 20$ L/min;
- Standby function: if the central compressed system can't supply gas, then the air compressor can supply compressed air; when it return to the normal, and its pressure ≥320kPa, the air compressor will stop supplying gas.

#### 3.4 Working noise

The noise  $\leq 65$ dB (A) when the ventilation is in normal condition

#### 3.5 Gas source

When the ventilator is in normal condition, gas inlet end is needed to offer medical compressed air,

medical compressed oxygen. The pressure should be  $280 \sim 600$ kPa and flow is no more than 200 liters/minute. When one gas is lacked, then the system will automatically connect another gas and at the same time send medium priority alarm and prompt the gas source which is lacked. Air and oxygen supply rated pressure of the respiratory system is 400kPa.

## Attention:compressed gas is medical air or oxygen.

#### 4 Size and weight

#### 4.1 Size

380×320×1160 (mm)

#### 4.2 Weight

50kg

#### 5 Installation and Adjustment

Attention: the installation, adjustment, check and use of the ventilator is required to be finished by the professional to avoid the accidental failure or damage.

Attention: the ventilator should not use antistatic or conductive hose or conduit to avoid potential safety hazard like electric shock.

#### 5.1 Preparation before installation

1) Ensure that the ventilator and its supporting device are intact during transportation and the content in the container is as required in the packing list. Store container and the shockproof pad in the container well for future use.

Attention: If you find something damaged during transportation, you can inform the relevant transportation company instantly and claim the compensation. If the container is not as required in the packing list, please notify our company and our authorized agency instantly.

 Be familiar with front and rear control panel of the ventilator Front control panel is shown as follows



- 1. Display screen: display all the parameters of monitoring, setup and alarm.
- 2. Power switch: main power switch of the ventilator. Don't turn off the main power when you don't use the ventilator to avoid using up the power when emergency battery works continuously.
- 3. Key sign: enter into the switch of all setup interface.
- 4. Shuttle: the key is used to choose, adjust and confirm data. In the system, shuttle can be used as flow adjustment in MUNUAL mode. If you press it again, you can enter into the adjustment state. Rotate left is to decrease flow, while rotate right is to increase it. Pressing the key means confirming the current state.
- 5. Air input port: the input port of the fresh air and emergency air the patient needs. Warning: emergency air inhaled, no blocking !!
- 6. Heated Humidifier body: it is used when you install the Heated Humidifier.
- 7. Air compressor operation pilot lamp: display whether the air compressor operates.
- 8. Air compressor switch: control the on-off switch of the air compressor.
- 9. Air compressor power pilot lamp: display the AC power-cut of air compressor.
- 10. Pressure gauge: monitor the output pressure of the air compressor.
- 11. Inspiration: it is both the ventilator gas supply output port and patients'inspiratory port.
- 12. Flow signal(baby blue): flow signal baby blue input port.
- 13. Flow signal(transparency): flow signal transparency input port.
- 14. Expiration: patients' expiratory passage, usually connect screw thread tube.
- 15. Exhaust port: patients' exhaled gas exhaust port. No blocking !!

## Mwarning:emergency air inhaled——no blocking.

Rear panel is shown as follows:



1.Fan inspiratory port

2. Power supply socket of the ventilator

3.Cooling hole

4.Mechanical arm mounting bracket

5.Air source input port

6.Oxygen source input port

7.Catchment cup exhaust port

8.Air compressor air inhaled port

9.Diagrammatic representation of opening fuse holder(drawer)

3) Check the medical compressed oxygen source and air source and confirm its pressure is within the range of  $280 \sim 600$  kPa. If you use oxygen supplied by the steel cylinder, you also need to check and confirm if the oxygen in cylinder is sufficient or not, the performance of decompressor on the oxygen cylinder is good or not and its installation is right or not.

**D**anger: because the oxygen is combustion-supporting gas, the grease is definitely not allowed to be used on the oxygen decompressor and respiratory equipment, otherwise, there will be Oxidation combustion in 100% oxygen environment.

4) Check and confirm that single-phase AC power voltage of the ventilator should meet the requirement of AC220V, 50Hz and have good protective grounding.

#### 5.2 Installation and pre-adjustment of the ventilator

1) Installation of pedestal bracket caster

Install the front caster with two brake devices to the installation under chassis in front of the ventilator and install the caster with two no-brake devices to the installation under chassis behind the ventilator. After finishing the installation of four casters, you should adjust its height and then use specified wrench to tighten the locking nut on the caster.(clockwise tighten it on the base plate)

2) The connection of breathing tube and sensor is shown as follows:



11, 12, 13, 14 are marks of relevant interface on the front panel of the ventilator

3) If the filter, Heated Humidifier and water cup are equipped, then the relevant pipeline is shown as follows:





Attention: if the filter, Heated Humidifier and water cup are added in the gas circuit connection, then VBS airway resistance may be increased.

Attention: the component and material of the ventilator are approved and offered by our company, and there may be danger if you replace them with others.

#### 5.3 Operation of the ventilator

Connect gas source and power supply, the ventilator is started and enter into the self-test state, which will last for 10s. After passing the test, the ventilator will work normally according to the parameters set last time. If there is something with the system check, then it can not enter the system. The picture of self-test is shown as follows:



If passing the self-test, it will display "YES", otherwise, it will display "No". Not passing the self-test, the ventilator will not enter the system and the ventilator won't work normally.

Warning: when self-test can't be passed, you can press the key of shuttle twice instantly, thus skipping the step and entering the weight setup interface. However, at the moment, the ventilator must be connected to the external monitoring device like pressure and flow and work with them, and the control mode can only be "Manual" mode, otherwise, there will be danger when the ventilator is working.

Attention: when self-test can't be passed caused by air source input alarm and the patient only needs 45%~98% of the oxygen concentration, you can press the key of shuttle, thus skipping the step and entering the weight setup interface and in the meantime enter alarm setup interface to close "Air-alarm", however, you can just eliminate the alarm sound, and there is still alarm cue.

**Warning:** there must be medical staff on the spot when you use the ventilator, they will always be there to adjust the ventilator to the state suitable for the patient and appropriately make analysis on blood gas and carry out the corresponding medical treatment.

Its setup interface is shown as follows



If you are not familiar with the ventilator setup, you can directly set corresponding parameters according to the user's weight. The in-built parameters are set in accordance with the expert's suggestion. If there is some parameters not suitable for the patient, you can make appropriate adjustment. The parameter setup is equipped with the memory function. If it is stated again and the weight value is not set, the ventilator will work according to parameters set last time. If you reset the weight value, the corresponding parameters will refer to the in-built parameters which is set according to the expert's suggestion.

When you set weight value, parameters which is set involve tidal volume, frenquency, I:E, oxygen concentration, pressure limit, inspiratory trigger,SIMV frequency and flow. Alarm parameters involve: upper and low tidal volume limit alarm, upper and low pressure limit alarm, upper and low frequency limit alarm.

The set range of the weight: $5 \sim 200 \text{Kg}_{\circ}$ 

Within 5s after the setup interface is finished, it will enter the state of normal work.

Attention: if you don't set weight value after the ventilator is open. The ventilator will work according to parameters set last time. Please confirm the parameters is set suitable for the patient.

Attention: you set or change parameters according to the patient's weight, and those parameters are in-built parameters which is set according to the expert's suggestion. If there are some parameters unsuitable for the user, you can make appropriate adjustment.

When the ventilator is in normal condition, then its working interface is shown as follow:



- 1. Respiratory mode instruction: respiratory modes include VCV, PCV, PSV, SIMV, PSV+SIMV, CPAP
- Inspiration and expiration working instrument: the icon will be ups and sowns along with the inspiration and expiration in Auto mode. Compression represents inspiration, while stretch represents respiration. The hand-shaped icon beside the icon represents the tidal volume is adjusted by men or shuttle adjustment in Manual mode.
- 3. Alarm cue: it displays alarm content. The alarm cue contents are displayed in roll. The red pilot lamp flashes when it is the high priority alarm, at the same time, red will be displayed in front of alarm set value accordingly alarm, at the same time, yellow will be displayed in front of alarm set value accordingly. Yellow pilot lamp will be always on when there is low priority alarm. The color of words in high priority alarm message is red, while the color of words in medium and low priority alarm message is yellow. If there is different level of alarm, the high priority alarm will be the first one to show. If there are more than two same-level alarms, its order of showing alarm contents will be based on the order of alarm sound. After the alarm is being eliminated, the medium and low priority alarm message, yellow alarm pilot lamp and alarm sound will be eliminated automatically, however, the wording of high priority alarm wordings will not be eliminated, which are displayed still in roll (the red alarm pilot lamp does not flash, and there won't be the high priority alarm sound ). Enter into the alarm inquiry interface to eliminate the high priority alarm, and press the ventil to eliminate the high priority alarm pilot lamp and message.
- 4. Alarm bell: when there is alarm, is flashes. When there is mute, the icon will become A. When there is no alarm, then two icon shown above won't show.
- 5. Time display: display the time of the ventilator continuous work after it is started.
- 6. Power working mode instruction: the icon of power supply plug shows in AC power supply working state; the icon of battery shows in emergency working state.

Attention: power supply plug icon will show in AC power supply working state. If it is charging emergency battery, the icon will turn yellow. If the battery is fully charged, the icon will turn white.

- 7. Value: the opening of adjusting valve. The more the numerical value is, the more the opening is and the more the corresponding flow is.
- 8. Tidal volume monitoring area: numerical value in the front is monitoring tidal volume. There are two numerical values in upper and lower arrangement in the back. The numerical value in upper value is upper tidal volume limit alarm set value and the numerical value in lower arrangement is low tidal volume limit alarm set value.
- 9. Airway pressure peak value monitoring area: numerical value in the front is monitoring airway pressure peak value. There are two numerical values in upper and lower arrangement in the back. The numerical value in upper value is upper airway pressure limit alarm set value and the numerical value in lower arrangement is low airway pressure limit alarm set value.
- 10. Minute ventilation monitoring area: numerical value in the front is monitoring minute ventilation. There are two numerical values in upper and lower arrangement in the back. The numerical value in upper value is upper minute ventilation alarm set value and the numerical value in lower arrangement is low minute ventilation limit alarm set value.
- 11. Oxygen concentration monitoring area: numerical value in the front is monitoring oxygen concentration. There are two numerical values in upper and lower arrangement in the back. The numerical value in upper value is upper oxygen concentration limit alarm set value and the numerical value in lower arrangement is low oxygen concentration limit alarm set value.
- 12. I/E: display set I/E
- 13. FiO2: display set fraction of inspiration O2
- 14. PEEP: display set positive end-expiratory pressure.
- 15. Plimt: display set pressure limit.
- 16. Trigger: display set trigger sensitivity. When system setup trigger mode is "pressure", the voltage trigger response rate (Vtr) displays; when it is "flow", the flow trigger response rate displays.
- 17. Capacity or pressure display: in VCV state, set capacity (Vt) shows; in PCV state, set pressure (Psupp) shows.
- f:auto frequency displays inVCV, PCV state; SIMV frequency displays in SIMV state or PSV+SIMV mode
- 19. Velocity wave: the velocity-time waveform displays when you set waveform P-T F-T in the system setup; when you set P-V F-V, velocity-volume loop and pressure-volume loop displays.
- 20. Pressure wave: display pressure-time waveform.
- 21 Pressure limit: the line is pressure limit line.
- 22. Pressure override display: when pressure monitoring value is less than 40cmH2O, then the override is unit  $\times$  10. When it is more than 40cmH2O, then the override is unit×20. Waveform will adjust itself according to the change of override.

#### **6** Use and Operation

#### 6.1 Usage note

1) You must check the usage record and cleaning and disinfection record to confirm that the ventilator

not only has good performance but also is thoroughly cleaned and disinfected before use. If it is used for the first time, you should thoroughly clean and disinfect it. The cleaning and disinfection methods can refer to the content in chapter 9.

- 2) Check and confirm if power supply and gas source meet the requirement according to the content in chapter 5.1, and check if functions of the ventilator are normal according to appendix C before use
- 3) When you use the ventilator, there must be medical staff on the spot monitoring. They pay attention to not only the work state, but also the patient's vital signs and blood gas analysis data. In addition, they should adjust the ventilator to the work state suitable for the patient to reach the best medical result.

Warning: when you use the ventilator, there must be medical staffs on the spot monitoring and adjust the ventilator to the state most suitable for the patient at any time, in addition, they need to appropriately make blood gas analysis on the patient and carry out corresponding medical treatment.

4) If you use gas supplied by oxygen cylinder, you need to use oxygen decompressor. When you use it, you should adjust the pressure adjusting handle to the minimum and turn on the main switch on the oxygen cylinder and then adjust the pressure adjusting handle slowly until the necessary pressure value is reached. When you turn it off, you should close gas source first and then power supply.

 $\triangle$  Attention: pressure range that oxygen decompresser adjusts is 0.28MPa ~ 0.6MPa.If it is beyond the range, the ventilator can't work normally. If there is no gas source, you should adopt standby ventilation mode to assist the patient in breathing.

Attention: the ventilator must be thoroughly cleaned and disinfected, In addition, you should guarantee that every performance of it is good and definitely don't allow broken ventilator to operate before use.

#### 6.2 Ventilation mode and working parameters setup

#### 6.2.1 The key sign and shuttle instruction

1. Mute:press the key, the alarm sound will last for less than 120s before it is off but the alarm can't be eliminated. Press the key of mute, the current alarm sound is still continuing and it is real mute after 30s. If it is wrong operation, you can press the key again, the alarm mute can be removed. During the mute, there will be no new alarm sound. Once there is, then alarm mute is invalid. If you don't remove alarm failure within 120s, there will be alarm sound again. When you enter into alarm inquiry interface, the key can be used to refresh inquiry information, namely, press the key, you can remove all alarm content which does not exist currently and save the content which exists currently. In the meantime, you can eliminate

high priority alarm cue which does not exist currently in alarm display window .



3. Alarm setup: press the key and enter into the alarm setup interface. Press the key a bit longer and enter into the alarm inquiry interface.

4. System setup: press the key and enter into the system setup interface.

5. Monitoring parameters: press the key and enter into the monitoring parameters interface.

6. Standby: press the key a bit longer and enter into the state of standby. The state is used when the breath pauses during breathing process. Sputum suction is needed during breathing process, the function can be used. Press the key a bit longer, if you want breathing recovery.

7. Shuttle: the key is used to choose, adjust and confirm data. In the system control, the shuttle can used to adjust flow in MANUAL mode. Press it once and enter into the adjustment state. Rotate left, the value of value decreases, flow decreases and tidal volumes can be decreased and vice versa. Press it and confirm the current state.

#### 6.2.2 Mode interface

MUTE

MODE

ALARM

SYSTEM

MONITOR

STANDBY

Press the key of mode interface, the display interface of the ventilator is as shown in the following:



Modes of the ventilator involve VCV, PCV, PSV, SIMV, PSV+SIMV, CPAP. Press ">>>> "in the interface and enter into parameters setup in the chosen mode. It displays as follows:



1. RR:set range is  $2 \sim 120$  bpm;

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- 2. Vt : set range is 20~1800ml;
- 3. I:E : set range is 4:1.0~1:8.0;
- 4. O<sub>2</sub>% :set range is 21%~98%;
- 5. PEEP (positive end-expiratory pressure) :set range:  $0 \sim 25 \text{cmH}_2\text{O}$ ;PEEP can make withered small airway and alveolus expand, prompt interstitial lung and alveolar edema to vanish, enhance lung compliance, add functional residual volume, reduce physiological dead space, increase alvelous ventilation volume, improve ventilation / bloodstream disproportionality, lower lung arteriovenous shunt,work of breathing and oxygen consumption, thus increasing arterial partial pressure of oxygen. PEEP can improve gas exchange function of accurate respiratory distress syndrome and increase arterial partial pressure of oxygen.

# $\triangle$ Attention: PEEP value is usually set 3~5cmH<sub>2</sub>O and it is not appropriate to set too high. If so, emphysema may appear after you use it for a long time.

6. Pressure trigger pressure:  $-10 \sim 10 \text{cmH}_2\text{O}$  flow trigger  $1 \sim 20 \text{L/min}$ ;

## Attention:when there is trigger, inspiration and expiration work instruction will display red.

- 7. Inspiratory plateau(end-inspiratory breath hold): set range:  $0 \sim 50\%$ ; the advantage is that it is good for gas distribution and dispersion, which is applicable to the patient with respiratory failure mainly characterized by gas uneven distribution and hypoxia like impeded diffusion or ventilation / bloodstream disproportionality. Positive pressure of end-inspiratory breath hold should not be that long, otherwise mean airway pressure may be increased, heart burden added and hemodynamics influence. It is suggested that it should not exceed 15% of inspiratory time. It can be used when the patient passively or compulsively shoots chest X-ray film in the state of full inspiration.
- 8. Sign( deep breathing): set range:  $60 \sim 120$  bpm, off means closing the sign. Sign can make it easier to let the alveolus timing expand, improve the ventilation of the alvelous to avoid atelectasis, which is beneficial to long-term bedridden patient who accept the mechanic ventilation treatment.
- 9. Pressure control: set range:  $3 \sim 50 \text{ cmH}_2\text{O}$ . The setup is to control airway pressure only in PCV mode.
- 10. Pressure slope ratio: set range:  $1 \sim 10$ . The setup is to control limit pressure rise speed only in PCV mode. 1 means that pressure set value is reached with the normal inspiratory time. 10 means the pressure set value is reached within 1/10 of inspiratory time. The usual setup is 1.
- 11. Pressure limit: set range  $5 \sim 60 \text{cmH}_2\text{O}$ . the setup is to control peak airway pressure no higher than the set value to prevent the damage to the lung caused by excessively high pressure.

## Attention: when pressure limit is started, pressure monitoring value is displayed red.

12. SIMV frequency: set range2~20bpm; the setup can be valid in SIMV and PSV+SIMV mode.

- 13. FLOW:set range:  $1 \sim 10$ ; flow is set when the ventilation is supported. The setup can be valid in PSV and PSV+SIMV mode. 1 refers to the minimum flow while 10 the maximum flow. The usual setup is 3.
- 14. Time limit: set range:  $1 \sim 10$ s; when pressure supports ventilation, the patient should be offer timing ventilation according to the setup without autonomous inspiratory trigger, which aims to offer the intermittent ventilation which ensure the ventilation that patients' vital signs require. The setup can be valid in PSV mode. The usual setup is  $5 \sim 8s$ ;
- 15. Expiratory sensitivity : set range:  $10\% \sim 90\%$ ; The setup can be valid in PSV and PSV+SIMV mode; the inspiratory phase enters into expiratory phase when peak flow velocity reduces to the percentage of the peak value(sensitivity set value). The usual setup is 80%;

#### 6.2.3 Alarm setup interface

Press the key of alarm setup once and the display interface of the ventilator is shown as follows:



Its parameters are set as follows:

VT—H (high tidal volume limit)  $10 \sim 1800$ ml

VT—L (low tidal volume limit)  $0 \sim 1700$ ml

MV—H (high minute ventilation limit)  $1 \sim 20$ L/min

MV—L (low minute ventilation limit)  $0 \sim 19$ L/min

Ppeak—H (high peak airway pressure limit)  $5\sim 60 \text{cmH}_2\text{O}$ 

Ppeak—L (low peak airway pressure limit)  $0 \sim 50 \text{cmH}_2\text{O}$ 

O<sub>2</sub>%—H (high oxygen concentration limit) 21~99%

 $O_2\%$ —L(low oxygen concentration)  $18 \sim 80\%$ 

F—H (high frequency limit)  $10 \sim 99$  bpm

F—L (low frequency limit)  $0\sim$  50bpm

Air-alarm on (low air source alarm switch, on means opening, off means being closed

The operator should stand in front of the machine, which makes it possible to set all alarm parameters and see the relevant information clearly 1 meter away from the machine.

Attention:the frequency alarm refers to autonomous inspiration frequency alarm!!

Warning: the operator should check if current alarm preset is suitable for the patient before use. If it adjusts alarm limit value according to the patient and necessary treatment.

Attention: be careful of the patient's injury caused by wrong setup.using different unit to different alarm limit value on the same or similar ventilator may cause danger to the patient.

Warning: don't set alarm limit value more than its extreme value, otherwise, the invalidity of the alarm system will be caused.

Press the key of alarm setup a bit longer inder the alarm setup interface and enter into alarm inquiry interface. The interface displays the current alarm content and the past alarm content. Press the ventil and refresh alarm inquiry interface in the interface, which only displays the current alarm content. The interface is shown as follows:



Vt-up-alarm (tidal volume upper limit alarm)

Vt-down-alarm (tidal volume lower limit alarm)

MV-up-alarm (ventilation upper alarm)

MV-down-alarm (ventilation lower limit alarm)

Ppeak-up-alarm (airway pressure upper limit alarm)

Ppeak-down-alarm(airway pressure lower limit alarm)

O2%-up-alarm (Oxygen concentration upper limit alarm),

O2%-down-alarm (Oxygen concentration lower limit alarm)

F-up-alarm (frequency upper limit alarm)

F-down-alarm (frequency lower limit alarm)

O2-in-alarm (Oxygen supply low alarm)

Air-in-alarm (Air supply low alarm)

Battery-L-alarm (Battery voltage low alarm)

P-Continuous(Continuous high pressure alarm)

Attention: in the display interface, 🗹 is displayed befor the alarm setup. Red refers to high priority alarm, and yellow refers to medium priority alarm.

#### 6.2.4 System setup interface

Press the key of system setup and then enter into the system setup system.



Its content is displayed as follows:

- Self-test:on/off on represents opening self-test function. Namely the ventilator enters into self-test
  mode after it is started and the "self-test after it is started" shows on the screen, which lasts for about
  10s. If the system is tested abnormally, th machine can't enter into system. Off means closing self-test
  function. Namely the ventilator works according to parameters set last time after it is started.
- 2. Trigger: Press/Flow, which represents two kinds of trigger ways. Press refers to pressure trigger. Flow represents flow trigger.
- 3. Respiratory correction :0  $\sim$  200 gear. it is the accuracy correction of inspiratory tidal volume. If you find the inspiratory tidal volume is different from the actual one, you can use this setup to rectify, and you should amend it according to standard simulated lung. Only experts are allowed to do so to avoid any accident. Generally, it has been set before the product is sold, so you needn't rectify it.
- 4. Inspiratory correction  $0 \sim 200$  gear. Its function is as same as mentioned above
- 5. Pressure correction:  $1 \sim 99$  gear. The function is to correct the accuracy of peak pressure.
- 6. Oxygen concentration L: correction of 21% of Oxygen concentration. The method is as follows: After putting probe still in the air for 1 min, it will enter system setup interface. Make the cursor on Oxygen concentration L, and you can check the reading. When the reading doesn't descend, you can press Shuttle twice, and now the cursor turns red. If no "??" appears, it indicates that the value we measured is within the acceptable range, otherwise it indicates the value is beyond the range. Press again for quitting. The reason why "??" appears is that concentration probe drops and has bad connection, or it drains. In addition, or the time of it staying in air is too short, in addition, there's something wrong with the signal circuit.

## Attention: In the case that no "? ? " appears, it indicates the Oxygen probe stays short time in the air and leads to the 21% of Oxygen concentration is not accurate. So you should save the value until it doesn't descend.

7. Oxygen concentration H: :correction of 100% oxygen:put the Oxygen probe into the pure O2 for 1min, it will enter system setup interface. Put the cursor on Oxygen concentration H and you can check the reading. When the reading doesn't descend, you can press Shuttle twice, and the cursor turns red. At the same time, if no "??" appear, it indicates that the value we measured is within the acceptable range, otherwise it indicates the value is beyond the range. Press again for quitting. The reason why "??" appears is that the time of staying in pure O2 is too short, the oxygen probe drains or there's something wrong with the signal circuit.

Attention : In the case that no "??" appears, it indicates the Oxygen probe stays short time in the air and leads to the 100% of Oxygen concentration is not accurate. So you should save the value until it doesn't descend.

- Waveform option:P-T F-T / P-V F-V. It is the option of monitoring waveform. P-T F-T mean that monitoring waveform display pressure-time waveform and velocity -time waveform. P-V F-V mean monitoring waveform pressure-volume loop and velocity-volume loop besides pressure-time waveform. You needn't turn on system setup switch at the time of setup.
- 9. Control:Auto/Manual .Auto represents machine controls itself. Namely the ventilator ventilates according to in-built parameters. Manual represents machine is controlled by men. This control can be used when there is something wrong with VCC and PCV. For example, when there is something wrong with flow sensor and pressure controlled can't be ensured in VCV mode, you can set the control. The method is that enter into the system control, open system setup, choose "control"column and set it "Manual". Quit the system control, enter into the mode setup, choose the mode appropriate for the current user , then set the corresponding parameters and the ventilator can work normally according to preset value. Press the key of shuttle, rotate left, and "value"in the interface will decrease, which represents flow increases. If you think the current tidal volume reaches the value you want, then press the key of shuttle to confirm.

Attention: in Manual state, all parameters are in-built parameters, so you just set the necessary parameters. You can also adjust shuttle and corresponding tidal volume. However those parameters should be adjusted by the professional.

<sup>10.</sup> System default: Load. Press the key of confirm to choose it, at the moment, "Load"turns red. Quit it, then the ventilator will work according to default system setup. When the system default ia aimed at

the patient weighing 50kg. The default setup of state, parameters and alarm is in the following:

Frequency:15 I:E:1:1.5

Pressure limit:35cmH<sub>2</sub>O Upper pressure limit alarm:30cmH<sub>2</sub>O Low pressure limit alarm:5cmH2O Upper oxygen concentration limit alarm:60% Low oxygen concentration limit alarm:20% Upper tidal volume limit alarm:1000ml Low tidal volume limit alarm:100ml Upper minute ventilation limit alarm:18L/min Low minute ventilation limit alarm:2L/min Upper frequency limit alarm:40bpm Low frequency limit alarm:0 Inspiratory trigger pressure:-5cmH<sub>2</sub>O Mode:VCV Positive end-expiratory pressure:0cmH<sub>2</sub>O Sigh:off Inspiratory plateau:0 SIMV frequency:8bpm Set tidal volume:500ml Power on self test:on Set oxygen concentration:35% Expiratory sensitivity:80% Pressure limit:15cmH<sub>2</sub>O Pressure slope:1 Flow:3 Time limit:8s Trigger mode:press Waveform choice:P-T F-T Flow trigger value:5L/min System setup:off

> Attention: to avoid adjusting system set value randomly, the system setup function is used. When parameters in the system setup need to be corrected, you must open the system setup. After finishing the setup, the system setup will be automatically closed. If you need to set something else, you still need to open system setup and then set something else.

Attention: the changed parameters can be saved after it is adjusted and confirmed. If not parameters won't be changed. Parameters include:mode, control parameter, alarm parameter system setup. The machine will work according to parameters set last time everytime it is star but its default mode will be"Auto".

11. System setup:on/off on represents being open. Off represents being closed.

Attention:parameters defaulted by system won't be changed. Even if the operator change part of parameters, all parameters will turn parameters mentioned above except the parameter of tidal volume correction, pressure correction and oxygen concentration.

#### 6.2.5 Monitoring parameter interface

Pressure the key of monitoring parameter and then enter into monitoring parameter interface. It is shown in the following:



Its monitoring content is shown as follows:

- 1. VTe:expiratory tidal volume, the volume of patients' exhaled gas.
- 2. MV: minute ventilation, the volume sum of patients' exhaled gas one minute.
- 3. Ppeak:peak airway pressure, the peak volume of airway pressure in every breath
- 4. Pmean:mean pressure, mean of the airway pressure in every breath.
- 5.  $FiO_2$ : fraction of inspiration  $O_2$ , the patient's oxygen concentration supplied by the machine.
- 6. Fpt:autonomous inspiratory frequency. Number of times of autonomous inspiration and trigger produced due to it.
- 7. Battery:battery power, monitor the power of the current emergency battery.
- 8. VTi:inspiratory volume, the gas capacity offer by the machine to the patient.

#### 6.2.6 Respiratory mode instruction

#### 6.2.6.1 VCV (Volume Control Ventilation)

Press the key of mode setup and then enter into mode setup interface. There is finger-shaped icon in the

interface. Rotate the shuttle to VCV and press the key of shuttle, then the white finger-shaped icon will turn red, which represents you have set it successfully. Press the red finger-shaped icon again and you quit the setup. Choose" $\rangle\rangle\rangle\rangle$  "and press it twice, then you enter int parameter setup in the corresponding mode. The working interface is shown as follows:



VCV is the most basic ventilation mode. Positive pressure can produce at the time of inspiration. Positive pressure presses the gas into lung, then the patient can exhale gas by his own pressure. If the patient has no autonomous breathing, then he can breath accrding to preset parameters of frequency, tidal volume,I:E and oxygen concentration. If he has, the ventilator can sense the patient's autonomous breathing and is sync with his breathing.

Parameters that can be set in VCV mode involve:frequency,tidal volume, I:E, oxygen concentration, PEEP, trigger, inspiratory plateau, sign, pressure limit.

Frequency setup: normal breathing fequency setup is  $12 \sim 20$  times/min.

Tidal volume setup: it ha something to do with breathing frequency. When you set tidal volume for the first time, you should grasp some regulation to reduce blindness. Its usual set value is  $8 \sim 10$  ml/kg and it is adjusted later on in accordance with arterial blood gas analysis.specially, if there are bullae, Suspicious pneumothorax, blood volume reduction which has not been corrected yet and blood pressure drop, etc. You should set tidal volume to a lower level and increase breathing frequency appropriately to prevent the shortage of ventilation.

Attention: when autonomous breathing frequency is too fast, breathing frequency is set close to autonomous breathing and lower tidal volume level properly to reduce confrontation.

I:E: inspiratory time assists inhaled gas(oxygen) in its distribution while expiratory time helps the exhaust of CO<sub>2</sub>. The normal I:E is 1:1.5; when there is obstructive ventilation dysfunction, the I:E is 1:(2 $\sim$  2.5); when there is restrictive ventilation dysfunction, the I:E is 1: (1 $\sim$ 1.5). In addition, you can set it according to the degree of hypoxia and CO<sub>2</sub> retention and the target of hemodynamics. When there is mainly hypoxia, circulation condition permitted, inspiratory time can be prolonged properly. When there is mainly CO<sub>2</sub> retention, expiratory time should be prolonged properly. Later on, you should still make some adjustment according to arterial gas blood analysis and heart function condition.

Oxygen concentration: to rectify hypoxemia,  $FiO_2$  ( > 60% ) should be used. After hypoxemia is

rectified, FiO<sub>2</sub> should gradually lower to  $\leq 60\%$ . When hypoxemia is not completely rectified, then the way used above should be abandoned and you should adopt other way like PEEP instead. When hypoxemia is obviously improved, you just need to set FiO<sub>2</sub> 40% $\sim$ 50% at best.

PEEP:when you use the ventilation for the first time, it is suggested that PEEP should not be used or set instantly. If you need to set it, you can refer to the content in chapter 6.2.2.

Trigger: when the patient's autonomous breathing is recovered, inspiratory trigger sensitivity will send synchronous ventilation signal to the ventilator. Usually, inspiratory trigger sensitivity is  $2\text{cmH}_2\text{O} \sim 10\text{cmH}_2\text{O}$ lower than the minimum airwa pressure when the patient has no autonomous breathing. If PEEP is started, trigger pressure triggers based on PEEP pressure. The usual trigger pressure is  $-2\text{cmH}_2\text{O} \sim -10\text{cmH}_2\text{O}$  lower than PEEP pressure. If trigger mode is flow trigger, then its set range is  $0 \sim 20\text{L/min}$ . Its normal setup is 5L/min, the less the value is, the smarter it is.

Inspiratory plateau: its setup can refer to the relevant content in 6.2.2

Sign: its setup can refer to the relevant content in 6.2.2.

Pressure limit: pressure limit parameters is set 10cmH<sub>2</sub>O higher than normal airway pressure peak value.

In the mode, the patient without autonomous respiration breathes according to parameters of frequency,tidal volume,I:E, and oxygen concentration. If the patient has autonomous breathing, the ventilator will be triggered by the patient's autonomous breathing and is sync with it.

▲ Attention: in VCV mode, the tidal volume may be set randomly even beyond its set range. It is normal. Due to the fact that tidal volume restricts frequency, which can be judged by the formula tidal volume times frequency≤20L.

Attention: in VCV mode, tidal volume may display red ,which means the start of its limitation function. If the ventilator monitoring value is higher than its set value, the tidal volume limitation function is started once the ventilator is started. When monitoring value is within the regulated range, it will display normally.

#### 6.2.6.2 PCV (Pressure Control Valve)

Press the key of mode setup and enter into mode setup interface. There is a finger-shaped icon in the interface. Rotate shuttle to PCV, and press the shuttle again, at the moment, the white finger-shaped icon will turn red, which represents it has been set successfully. Press the red finger-shaped icon again and you will quit the setup. Choose " $\rangle\rangle\rangle\rangle$ " and press it twice and enter into parameter setup in corresponding mode. Its work interface is shown as follows:



In PCV mode, airway pressure and pressure rise speed can be preset. After the inspiration starts, air current speed can be faster. When it reaches the preset pressure level, it will slow down by feedback system and keep preset pressure level until end-inspiratory, and then expiration starts. In PCV mode, airway pressure decreases, there is no peak pressure, and wind-contusion rarely happens, which can help alvelous that is not easy to fill gas fill gas, improve ventilation /blood flow ratio and better change gas. PCV is often applicable to the patient with accurate respiratory distress syndrome or respiratory failure caused by chronic obstructive pulmonary disease and severe ventilation/blood flow ratio imbalance duet to the fact that it can ensure the tidal volume can be offered even when there is breathing tube leakage.

In PCV mode, parameters that can be set involve: frequency, tidal volume, I:E, oxygen concentration, PEEP, trigger, sign, control pressure, pressure slope ratio and pressure limit.

There is something different between PCV mode and VCV mode. VCV is used to control tidal volume, and PCV is used to control inspiratory pressure.

Parameter setup of limit pressure and pressure slope ratio is just in PCV mode.

Limit pressure: control positive airway pressure formed in lung of the ventilator.

Pressure slope ratio: control pressure rise speed. 1 is the minimum while 10 is the maximum. Its normal setup is 1.

Attention: in PCV mode, if pressure limit is set so high that tidal volume monitoring value is far roo higher than its set value. At the moment, tidal volume monitoring value is displayed red, which means tidal volume limitation function is started. In addition, PCV can't reach its set pressure value, so tidal volume needs to be increased properly. In PCV mode, tidal volume is set to avoid the situation when there is something wrong with pressure sensor, pressure may be too high thus damaging airway due to the fact that it can limit tidal volume and don't let it exceed 1.5 times of its set value to protect airway.

#### 6.2.6.3 **PSV** (Pressure-Support Ventilation)

Press the key of mode setup and enter into mode setup interface. There is a finger-shaped icon in the interface. Rotate shuttle to PSV, and press the shuttle again, at the moment, the white finger-shaped icon will turn red, which represents it has been set successfully. Press the red finger-shaped icon again and you will

quit the setup. Choose """" and press it twice and enter into parameter setup in corresponding mode. Its work interface is shown as follows:



PSV is a kind of assisted ventilation mode, namely, when there is autonomous breathing, every inspiration can accept pressure support to assist the patient in the inspiration and strengthen the inspiration function, increase inspiratory extent and inhaled gas volume. Every mandatory or autonomous inspiration of the patient is supported by pressure and pressure support degree needs to be set. Mandatory inspiration means that when the ventilator works without trigger, the ventilation will offer the limited ventilation within the set time. Autonomous inspiration ventilation means after the patient's autonomous inspiration trigger, the ventilator offers the synchronous ventilation once. During the autonomous breathing, when the patient can reach or exceed trigger sensitivity, the machine will offer the synchronous ventilation according to the set flow. Inspiratory phase can enter into expiratory phase when airway pressure rises and the peak flow velocity reduces to expiratory sensitivity set value, namely inspiratory flow reduces to the percentage of its peak value. When airway pressure reduces to PEEP pressure level and stays the same, then just wait for the next trigger. Trigger mode: when the trigger mode of autonomous breathing shifts from expiratory phase to inspiratory phase, now it has two trigger modes--pressure trigger and flow trigger. Pressure trigger is shifting from expiration to inspiration when the flow of inspiratory end is judged to be lower than trigger sensitivity. Flow trigger is shifting from expiration to inspiration when the flow of inspiratory end is higher than trigger sensitivity. Sensitivity: it refers to the trigger's difficult degree. The smaller the value is, the easier the trigger is. Clinic applies to the patient who lacks autonomous breathing but whose neuroregulation is not obviously abnormal. In PSV, under the pressure support to some extent, the machine body will get over the disease caused by increasing respiratory passage resistance and decreasing compliance and obtain sufficient tidal volume. When you feel better, the pressure support level can be gradually reduced. It is used to dismantle the mechanical ventilation and it applies to the patient with severe asthema, chronic obstructive pulmonary disease and thoracic injury who need long-term mechanical ventilation after operation. In this mode, pressure support is controlled by the flow of FLOW.

In PSV mode, parameters that can be set involve: oxygen concentration, PEEP, trigger, pressure limit, flow setup, time limit and expiratory sensitivity.

Attention: in PSV mode, the trigger mode should be set as flow trigger.

#### 6.2.6.4 SIMV (Synchronized Intermittent Mandatory Ventilation)

Press the key of mode setup and enter into mode setup interface. There is a finger-shaped icon in the interface. Rotate shuttle to SIMV, and press the shuttle again, at the moment, the white finger-shaped icon will turn red, which represents it has been set successfully. Press the red finger-shaped icon again and you will quit the setup. Choose " $\gg$ » and press it twice and enter into parameter setup in corresponding mode. Its work interface is shown as follows:



The SIMV mode is applicable to the patient who has autonomous breathing which is not stable enough. If there is no autonomous breathing in the period of waiting trigger, which is called synchronous trigger shutter. The ventilator will offer auto breathing at the end of trigger shutter. When there is autonomous breathing which is relatively faint but no trigger in trigger shuttle, then the breathing frequency and tidal volume are controlled by the patient himself. If there is trigger in trigger shutter, the ventilator offer synchronous breathing, then UAV confrontation is formed. This mode can reduce the patient's dependence on the ventilator, help the ventilator get rid of the ventilator gradually. Before you remove the ventilator, you can estimate how much minute ventilation volume the patient needs beforehand. You can give mandatory ventilation support of higher frequency, then lower the frequency until it is completely removed.

## Parameters which can be set involve frequency, tidal volume,I:E, oxygen concentration,PEEP, trigger, inspiratory plateau,sign, SIMV frequency.

In this respiratory mode, the setup of frequency and I:E control inspiration time and mandatory ventilation period depends on the setup of SIMV frequency.

Attention: SIMV frequency must be auto frequency. So if set SIMV frequency is set higher than auto frequency, auto frequency will adjust itself higher than SIMV frequency once at the time of SIMV frequency setup.

#### 6.2.6.5PSV+SIMV (Pressure-Support Ventilation+Synchronized Intermittent Mandatory Ventilation)

Press the key of mode setup and enter into mode setup interface. There is a finger-shaped icon in the interface. Rotate shuttle to PSV+SIMV, and press the shuttle again, at the moment, the white finger-shaped icon will turn red, which represents it has been set successfully. Press the red finger-shaped icon again and you will quit the setup. Choose "》》》 "and press it twice and enter into parameter setup in corresponding

mode. Its work interface is shown as follows:



PSV+SIMV is compound mode. The difference from SIMV is the switching mode of mandatory ventilation inspiratory and expiratory phase, which changes the situation of volume switching mode. The mode is used to exercise respiratory muscle and prevent respiratory muscle fatigue. Pressure support can offer some assisted pressure, increase inspiratory pressure and breathing extent and exercise the patient's respiratory muscle passively prevent the patient chronic obstructive pulmonary disease from the difficulty in removing the ventilator caused by respiratory muscle failure to the patient with chronic obstructive pulmonary disease. Before you remove the ventilator, you can estimate how much minute ventilation volume the patient needs beforehand. You can give mandatory ventilation support of higher frequency, then lower the frequency until it is completely removed. In this mode, pressure support is controlled by the flow of FLOW.

In this mode, parameters that can be set involve:frequency, tidal volume, I:E, oxygen concentration, PEEP, trigger, pressure control, pressure limit, FLOW, expiratory sensitivity.

Attention: in this respiratory mode, the trigger mode is set as flow trigger. If pressure control is set relatively low, gas supply is according to pressure control. If pressure control and pressure limit are set relatively high, the tidal volume setup can limit tidal volume. If tidal volume is set higher than its set value, then tidal volume monitoring value is displayed red to remind users and tidal volume can be controlled not much higher than its set value. If pressure limit, pressure limit, tidal volume is set comparatively high, the expiration will be controlled by expiratory sensitivity, namely, the flow which is reduced to the percentage of its set peak flow is shifted into expiratory phase. Inspiratory time of the breathing will no longer the time controlled by frequency.

#### 6.2.6.6 CPAP (Continuous Positive Airway Pressure)

Press the key of mode setup and enter into mode setup interface. There is a finger-shaped icon in the interface. Rotate shuttle to CPAP, and press the shuttle again, at the moment, the white finger-shaped icon will turn red, which represents it has been set successfully. Press the red finger-shaped icon again and you will quit the setup. Choose "》》》 "and press it twice and enter into parameter setup in corresponding mode.

Its work interface is shown as follows:

Sensitive airway pressure monitoring and adjusting system is installed in the ventilator to adjust the flow velocity of positive pressure air current and stay airway pressure constantly at CPAP predicted level. Flow velocity setup can be divided into 10 gears. If you think the gear you set can not meet the requirement of the patient, then you can adjust the flow by manual rotating shuttle. The CPAP of intubated patients can start with  $(2\sim5)$  cmH<sub>2</sub>O, the maximum not exceeding 15cmH<sub>2</sub>O. CPAP can only be applicable to the patient with autonomous breathing who has normal apneustic center function due to the fact that it can be assisted breathing, thus exercising respiratory function. CPAP can be applied to the patient with hyoxemia caused by increasing pulmonary shunt.

In CPAP mode, parameters that can be set include: oxygen concentration, pressure limit and FLOW.

Its work interface is shown as follows:



#### 6.3 Humidifier (if equipped)

**6.3.1** Any humidifier or heat and moisture exchanger which meet the requirement of YY 0786-2010(ISO 8185:1997) or YY/T 0735.1-2009 (ISO 9360-1:2000) and YY/T 0735.2-2010(ISO 9360-2:2001) is recommended to be used with the ventilator .

#### 6.3.2 Usage method

Usage method details can refer to the relevant content in its attached instrument.

Attention: humidifier needs to use single-phase AC power which has good protective grounding. When the humidifier is connected to the ventilator, the increase of VBS airway resistance can be caused.

Attention: when you use humidifier, you should pay close attention to the output temperature and water in humidifier to avoid dry burning.

#### 6.4 Filter valve

Its working condition is shown as follows:

The maximum working pressure: 1.0 MPa Working temperature: $5 \sim 60^{\circ}$ C Filtration degree:5um Condensate water storage capacity: 12ml

Attention: when air compressor works for a long time, condensate water will be accumulated in the filter valve. The water should be drained, otherwise it will make the ventilator unable to work normally due to the fact that excess water may be pressed in the pipeline by pressure.

#### 6.5 Air compressor

#### 6.5.1 Technical parameter

—— Continuous flow≥20 L/min;

——Output pressure:300kPa~450kPa;

—— It has standby function: if the central compressed air gas supply system fails to supply gas, the air compressor can offer compressed air; when it returns to the normal and its pressure exceeds 320kPa, air compressor will stop supplying gas automatically.

#### 6.5.2 Usage method

1. Make sure that the working power supply of the air compressor is AC220V 50Hz and it has good protective grounding.

2. After the power has been connected and the switch of the air compressor is turned on, then the power pilot lamp in front of air compressor and its operation pilot lamp are all on and the air compressor work normally. If the central compressed air is connected to the ventilator, and its pressure is no less than 320kPa, then the air compressor stops working and its operation pilot lamp is off.

#### 6.5.3 Gas path schematic diagram of air compressor



Attention: the air compressor can't be started with load, so you can hear the exhaust sour at the time of power failure, which is exhausting gas for next start of the air compressor. It normal. The exhaust is off when it works normally.

Attention: to avoid the single failure of the air compressor, so safety overflow valve is installed in the gas path. Its output pressure reaches more than 320kPa and it overflows

#### 6.6 Power failure protection

The ventilator has the function of power failure protection: when AC power supply is cut, the state of emergency battery power supply is replaced, at the moment, the power indication will display the icon of storage battery at the upper left corner of the screen and at the same time the low priority alarm is started; when AC power supply works again, the power indication will display the icon of power source plug at the upper left corner of the screen, the power source plug displays yellow , which shows that the electric circuit makes trickle charge on the emergency battery, and the icon will display white after its full charge. When the power of the ventilator is supplied by the emergency battery again, the function of the ventilator can't be affected.

What needs paying attention to is the capacity of the storage battery is limited and it is just used in emergency.

More details about the use and maintenance of the emergency storage battery can refer to the relevant content in 10.2 section.

#### 6.7 Ventilator withdrawal

When every vital sign of the patient meets the requirement of ventilator withdrawal, then the ventilator can be withdrew. Before that, Y-shaped joint connected to the patient should be removed first, then you should observe the patient's autonomous breathing. After his autonomous breathing is recovered, the mask can be removed or cannula in the trachea can be pulled out and then the ventilator can be turned off. You are absolutely not allowed to turn off the ventilator first and then remove Y-shaped joint.

Warning: you are absolutely not allowed to turn off the ventilator befor the ventilator withdrawal to avoid the patient suffocation. After using the ventilator, it should be cleaned and disinfected at once, then cared and maintained.

Malfunction phenomenon	Cause of analysis	Removal method
Self test after it is	Pressure sensor failure	Replace pressure sensor
started is not passed	Flow sensor failure	Replace flow sensor

#### 7 Malfunction Analysis and Removal

	Oxygen concentration sensor failure	Replace oxygen concentration sensor
	Low or lacking air source input	Supply or increase air source input
	Low or lacking oxygen source	Supply or increase air source input
	Input pressure of the ventilator id no more than 0.28MPa	Increase compressed oxygen source input pressure
Insufficient tidal volume of the ventilator	There is something wrong with the pressure reducing valve and the pressure flow can't meet the requirement.	Replace pressure reducing valve
	The pressure limit may be set too low	Properly increase pressure limit value
Unstable tidal	Flow sampling tube is blocked by steam or remains	Use high pressure air to lash the sampling port to get rid of the remains
volume of the	Silicone tube at the sampling port is blocked by steam or remains	Use high pressure air to lash the sampling tube to get rid of the remains
ventilator	There is something wrong with flow sensor	Replace flow sensor
	Flow sampling tube is blocked by steam or remains	Use high pressure air to lash the sampling port to get rid of the remains
There is a big difference between	Silicone tube at the sampling port is blocked by steam or remains	Use high pressure air to lash the sampling tube to get rid of the remains
monitoring value and its actual value	There is leakage in the breathing circuit	Check the airtightness of breathing circuit
	There is something wrong with flow sensor	Replace flow sensor
Tidal volume set value is different from its monitoring value	In system setup, the control mode is set Manual	Under the control mode, tidal volume adjustment is not controlled by proportional valve, but completely controlled by manual rotating shuttle. If it can enter into system setup in this situation, the control mode can be changed into Auto
	There is something wrong with proportional valve control system	Contact our company to replace the corresponding system
In PCV mode, pressure monitoring value is different from its set value	During system setup, the control mode is set Manual	Under the control mode, tidal volume adjustment is not controlled by proportional valve, but completely controlled by manual rotating shuttle. If it can enter into system setup in this situation, the control mode can be changed into Auto
	It has volume limit function. Under the condition that pressure can not reach its set value and tidal monitoring value turns red.	In this mode, tidal volume is set higher.(the volume protection volume in PCV mode)

	There is something wrong with proportional valve control system	Replace proportional valve control system
	Improperly adjust tidal volum	Adjust tidal volume
	The patient's autonomous breathing confronts against mechanical ventilation of the ventilator	Readjust synchronous trigger value
High airway	High pressure limit is set improper	Adjust high pressure limit set value
pressure limit alarm	The patient's tracheospasm or secretion increase air resistance	Recommend to eliminate sputum and sputum elimination agent
	In VCV, SIMV mode, flow sensor failure causes tidal volume monitoring value to be so low that airway pressure changes	Replace flow sensor
	In VCV mode,part of flow sampling system failure causes its monitoring value much higher than its set value	Replace flow sampling system
Low pressure limit	Part of pressure sensor failure causes low monitoring pressure value	Replace pressure sensor
	Low pressure limit alarm value is set improper	Adjust low pressure limit alarm value
	There is leakage in breathing circuit	Check the airtightness in breathing circuit and pipeline
Tidal volume or airway pressure is not adjusted	During system setup, the control mode is set Manual	Under the control mode, tidal volume adjustment is not controlled by proportional valve, but completely controlled by manual rotating shuttle. If it can enter into system setup in this situation, the control mode can be changed into Auto
	There is something wrong with proportional valve control system	Replace proportional valve control system
Oxvgen	Oxygen concentration sensor soaks in the water	Take out oxygen concentration and drain the excessive water
concentration monitor	Oxygen concentration sensor is depleted completely	Replace it with new oxygen concentration sensor
displays''''	Plug wire of oxygen concentration doesn't have good contact	Check if plug wire is good or replace it with new plug wire
Electric continuous	The ventilator is not connected to storage battery after AC power supply is cut.	Make storage battery with full power well connected
alarm	The power of storage battery runs out or has been damaged	Replace storage battery
When power grid         AC power source plug drops		Make power source plug well plugged

supplies power normally, it displays storage battery is working

Warning: when you are not clear about the ventilator malfunction, please do not dismantle it easily and you should contact after-sale department our company.

8 Safety Protection and Accident Treatment

#### 8.1 Sealing performance of the respiratory system

Choose the respiratory mode of VCV, adjust tidal volume to 420 ml, ventilation frequency to 4times / min, I:E:1:2, high pressure limit 6.0 kPa and time of inspiratory plateau 50%. Connect gas storage bag to Y-shaped joint. Under this condition, observe the pressure waveform every time ventilation is at inspiratory plateau stage and see if there is obvious downward tendency. If so, there must be leakage in respiratory system.

It there is leakage, check the pipeline or plug all joints again and see if there is leakage point.

If the problem still can not be solved after taking all these measures, please notify our company and its authorized agency.

#### 8.2 Humidifier (if equipped)

If you use humidifier, you should observe the humidity of export gas and water in the humidifier. Excessively high-temperature gas inhaled by the patient will have adverse reactions, more severely, like respiratory tract burn and it may burn out the humidifier for the lack of water.

#### 8.3 Ventilation pipeline

When you use humidifier a bit longer, the water in the pipeline of the ventilator should be drained in time.

Warning: the water in the pipeline of the ventilator may transmit disease and pollute the environment. The treatment of the water must strictly comply with *measures for the management of medical waste in medical and health institutions* issued by national ministry health and relevant specification and requirement of government environmental protection agency.

Warning: the breathing tube connected to the ventilator should meet the requirement of YY 0461-2003. Using other tube which is not meet requirement has adverse reactions, which has nothing to do with our company. Breathing tube produced by our company is specially used for adjustment.

#### 8.4 Fuses

The fuses of anesthesia ventilator are installed in the power socket of rear panel.

If the fuse is judged to be broken, then the steps of replacing the new fuse must be taken as follows:

1) Do not turn on the power switch when the Ventilator is working. Just pull out the Ventilator power line from the power socket and the Ventilator will automatically be converted to mode of emergency battery power supply. Now you can change the fuse.

# Warning: The power switch of the ventilator is the switch both of AC power and emergency battery. The working ventilator will stop working immediately by turning on this switch.

2) Open the cover of fuse base and replace fuse tube.

3) The specification of the fuse tube is 5RF/ F5AL250V. The specification of fuse of emergency battery is the same, but the fuse is installed inside the machine.

## Attention: the method of changing the fuse can refer to rear panel picture in 5.1 section.

#### 8.5 Low pressure hose component

The oxygen, nitrous oxide conduits used on the machine are low pressure hoses. The hose material is inner layer PE, middle layer of high intensity terylene fiber, and the exterior layer of rubber. The inner layer PE will not have chemical reactions with oxygen, nitrous oxide, Without toxic substance, without harmful effluents, and it has a favorable compatibility with the gas. The inner diameter of the hose is 6mm, and the outer diameter is 12.5mm.

Attention: please use it meticulously in a working environment with excessively high temperature or a worksite with chemical gas, because it might cause the hose to be softened with pressure resistance dramatically decreaseing or cause quick aging and cracking caused by corrosion from the chemical gas.

Attention: Please don't store it in a damp environment or store it too long time in a warehouse with direct sunlight exposure, for the moist hydrolysis might cause rupture phenomena.

Attention: Don't let the hose wind in friction, don't stretch and warp excessively, otherwise, the hose will be damaged and the working pressure will be affected.

Attention: The pressure and flow loss might exist when two or more hose components are connected in series.

### ${igstack}$ Danger: Use lubricating oil in the gas inlet pipeline might cause fire and explosion.

#### 8.6 Improper operation and consequence treatment

1. If there is no well-grounded network power supply, it is easy to make the machine have static electricity, and it may lead to electric shock on patient or operator. The solution is to use well-grounded network power supply.

2.If the trigger sensitivity is set incorrectly, it may appear the phenomenon of continuous trigger. Solution: At this point the trigger is just at the critical value, that's why that phenomenon appears, all you need to do is to reduce the trigger sensitivity again.

#### 8.7 The replacement of quick-wear parts and consumables

The quick-wear parts include fuse and flow sampling tube

Consumables include breathing tube and oxygen concentration sensor

The replacement method can refer to the content in chapter8.4

The replacement method of flow sampling tube: this ventilator is equipped with standby flow sampling tube, if the original one is damaged, you can replace a new one. Its installation method refers to the content in chapter .2 6.

The breathing tube is usually the disposal attachment. The installation can refer to the content in chapter 5.2.

The replacement of oxygen concentration sensor: oxygen concentration sensor belongs to consumables, which is installed in the ventilator. If oxygen concentration sensor needs replacing because of excessive depletion, you must contact after-sale service department of our company.

#### 9 Cleaning and Disinfection of the Ventilator

#### 9.1 Cleaning and Disinfection Procedures

The working ventilator needs daily disinfection, in other words, a new or disinfected pipeline should be used every day (including the pipeline used for the first time). Patient's exhaled pipelines should be cleaned and disinfected. Two ventilators can be used and disinfected alternately.

When the patient stops using the ventilator, the ventilator should be terminally disinfected, that is, ventilator should be installed for use again after a thorough cleaning and disinfection. The ventilator which hasn't been used for a long time should be cleaned and disinfected when it is used again.

Record of cleaning and disinfection work should be archived for future reference.

The machine after cleaning and disinfection must be checked thoroughly for use the next time according to the checklist.

#### 9.2 The Focus of Cleaning and Disinfection

The focus parts which need cleaning and disinfecting include filtermesh, flow sampling tube and parts on the surface of the machine.

#### 9.3 Cleaning method

**9.3.1** Cleaning of filtermesh at the inlet port of the ventilator: use clean water to flush the filtermesh. After it is clean, dry it and you can put it back to the original place. The ventilator usually is checked and cleaned every 24 hours during its use.

**9.3.2** Cleaning of flow sampling tube: use clean water to flush the flow sampling tube, and clear out sputum, bloodstain, greasy dirt and other dirty remains. And use neural scrubbing solution to clean dirty remains inside.

**D**anger: there are two small holes st the air current sampling port of flow sampling tube, and please make sure that the two small holes are not blocked. Use dry gas to lash it for more than 30 seconds to prevent gas remains from blocking small holes, thus causing inaccurate tidal volume monitoring value and make the machine unable to work normally.

Danger: after double silicone tube connected to flow sampling tube is cleaned and disinfected, similarly, it needs to be lashed by dry gas for more than 30 seconds to prevent gas remains from blocking small holes, thus causing inaccurate tidal volume monitoring value and make the machine unable to work normally.

**9.3.3** The cleaning of the ventilator: use soft cloth washed with warm water or neural scrubbing solution to clean dirt and dust on the surface and pulley bracket and then dry them. During the cleaning, any liquid is not allowed to enter into the ventilator.

Warning: The waste water generated when you clean the anesthesia machine is prone to transmit diseases and pollute the environment. The treatment of these contaminants must strictly comply with the "Management of Medical Waste in Medical and Health Institutions" issued by Ministry of Health and the relevant specifications and requirements regulated by government environmental protection agencies.

Warning: Disposable items should not be reused. For reusable parts, the useful life is usually one year. And if it has just been used for less than a year but affected the normal work, then it must be changed.(for example, the silicone products which has been hardened, cracked and leaked affect the normal work of ventilator which can be called unqualified, so they should be discarded.)

#### 9.4 Disinfection method

Method one: soak cleaned flow sampling tube and other items in disinfector for 30-60 mins( attention: silicone product should not be soaked too long because it is easy to be damaged). The usual disinfector includes Bromo Geramine solution, peroxide caproic acid and 84 disinfector. Use sterile brine or distilled water to flush the disinfector inside and outside of the flow sampling tube and hang it to dry it.

Method two: put cleaned flow sampling tube and other items in epoxyethane disinfection box and disinfect them. If the patient has infectious disease, another step needs to take. That is to soak all parts which need to be cleaned and disinfected in medical alcohol with a concentration of 70%. After the step has been taken for 1.5 hours and then use the disinfection treatment mentioned at the very beginning.

#### **10** Care and Maintenance

#### 10.1 Care and maintenance of ventilator

Equipment with functional failure should not be used. Guarantee should be made that any maintenance of the ventilator should be completed by our company or authorized agents. The performance of ventilators must be verified to comply with the description of this manual after repair.

A thorough cleaning, disinfection and maintenance of the ventilator should be carried out every six months. Specially-assigned person should be responsible for that. Maintenance records should archived. Before restarting the ventilator which hasn't been used for six months, a comprehensive performance test should be carried out..

The "Malfunction Analysis and Failure Elimination" provided by this guide are the basic methods to deal with the ventilator failure. If failure still cannot be ruled out, or failure repeatedly occurs by those methods, please promptly notify our company and authorized service agencies.

#### **10.2** Care and maintenance of emergency battery

DC14.8V-4.4AH emergency battery is the attachment of the ventilator, which can make the ventilator work continuously for no less than 30 mins . When AC power supply works, the icon of power source plug will display. If the emergency battery is charging, the pattern will display yellow. The pattern will turn white if it is fully charged. When AC power supply is invalid, the emergency battery power supply will replace it and there will be AC power supply alarm. When emergency battery works, the pattern of plug will turn the pattern of the battery. When monitoring battery voltage is lower than  $14.5V\pm0.5V$ , the pattern of battery turn yellow, at the same time, there will be excessive low power alarm. When monitoring battery voltage is lower than  $13.5V\pm0.5V$ , there will excessively low power alarm.

The storage emergency battery should be charged in time after use, the time interval cannot be longer than 24 hours.

If the emergency battery does not discharge for 6 months, it must conduct a maintenance treatment of charge-discharge operation. That is to operate the anesthesia ventilator powered by the emergency battery until the emergency battery cannot continue to drive the anesthesia ventilator, and then recharge the emergency battery power until it is fully charged..

When changing the emergency battery, you should pay special attention to the polarity——red line is connected to the anode, and black line to cathode——you definitely cannot connect it in a wrong way. The

polarity wiring should be connected tightly to avoid open circuit, heating or striking a light.

Don't put the emergency battery near heat sources (such as the radiator). Don't expose it to strong direct sunlight. Don't cover anything on the battery to prevent damage to the battery due to the high temperature. Keep the battery surface clean. If there is liquid spilled on the battery, it must be immediately wiped clean.

During the process of transportation, storage and use, the storage emergency battery must be placed upright, not upside down or horizontal to avoid furious vibration.

Warning: the operator must not replace storage battery by himself, please contact after-sale service department of our company.

Attention: when the power of the ventilator is supplied by emergency storage battery instead of AC power, the function of the ventilator will not be affected.

Warning: You cannot discard the waste emergency battery as you wish since it will pollute environment. You must comply with the relevant regulation and requirement of the environmental protection institute of government.

#### **10.3** Care and maintenance of the air compressor

Due to the fact that the temperature of compressed gas is comparably high, our company has installed the manual filter in gas path. When the water inside influences normal ventilation, then you should drain water in time.

#### 10.4 Care and maintenance of the oxygen concentration sensor

- —— Model: MAX-13-250
- ----- Working Principles: electrochemical principles
- ----- Manufacturing process: use the patent weak acid electrolyte
- Measuring range: 0~100%
- Output range:  $12mv \sim 17mv$  (20.9%O<sub>2</sub>,  $23 \pm 2^{\circ}$ C, 1013Mb)
- —— System response time (90%):  $\leq 25s$
- Electric circuit connection: 3.5mm earphone socket
- Zero point output: <0.5mv (in the 100%N<sub>2</sub> environment)
- Linearity output: within the  $\pm 1\%$  full range
- Working temperature:  $0 \sim 40^{\circ}$ C
- Limit storage temperature: 15℃~50℃
- —— Ideal storage temperature:  $5^{\circ}C \sim 25^{\circ}C$
- Working temperature: 5%~95%RH (non-condensation)

—— Stability: <1% full range, more than 8 hours (constant pressure, temperature and humidity)

—— Interference:

In 75% nitrous oxide: <2% full range

In 5% fluorine alkane: <2% full range

In 5% isoflurane: <2% full range

In 5% enflurane: <2% full range

In 6% sevoflurane: <2% full range

In 15% desflurane,  $\leq 2\%$  full range

In 10% carbon dioxide: <2% full range

In 70% helium: <2% full range

Temperature compensation:  $<\pm3\%$  (15°C $\sim$ 40°C)

Pressure compensation:  $0 \sim 50$ kPa, within  $\pm 1\%$  full range; under the pressure of 50kPa $\sim 150$ kPa, the output linearity and decompression oxygen is  $\leq \pm 2\%$  full range

The oxygen concentration sensor belongs to a consumable, so it's not within the range of warranty.

The oxygen concentration sensor is installed at the inspiratory end of the ventilator and what's monitored is inhaled oxygen concentration. Although it cannot get in touch with the breath of patient, however, it cannot avoid contacting moisture, so every time you finish using it, pull out the breathing tube to dry the oxygen concentration sensor for the next use.

The oxygen concentration monitoring is a function of the anesthesia ventilator, and it's not a separate monitoring equipment, so the external power supply and internal supply during normal working are relevant powers of the ventilator., if the oxygen concentration monitoring can work normally, please ensure the input power is within the normal range. The power supply of our company belongs to a broad voltage input, so as long as the input voltage fluctuation is within the range as regulated, it will not affect the normal operation of the oxygen concentration monitoring.

When the machine is converted from AC into DC working, the oxygen concentration monitoring and alarm function are not affected, and it could normally work. When there appears low power alarm, attention should be paid to the short power supply, and at the moment the AC power supply should be resumed as soon as possible.

Warning: the discarded oxygen concentration sensor will contaminate the environment, should not be disposed randomly, and must strictly follow relevant specifications and requirements from the government environmental protection organization.

#### 10.5 Care and maintenance of low pressure hose components

Because the low pressure hose doesn't touch the patients, so only cleaning is ok. Please clean it with neutral solution and dry it. clean and sort out it every time after finishing use, put it in the drawer, so as to prevent from accelerating the aging of hose by exposure to ultraviolet irradiation.

Refer to the contents in chapter 8.5 about relevant maintenance.

#### **10.6 Daily maintenance**

The parts of the ventilator should be reinstalled on the ventilator in time after disinfection, and examine the basic performance of machine according to in Chapter 5 "Installation and Adjustment" to confirm that each function keeps good.

#### **11** Transport and Storage

#### 11.1 Transport

**11.1.1** Using original packaging carton and shockproof pad according to regulation.

**11.1.2** Transportation according to icons and symbol on packaging carton. They are:

—— The way up

----- Far from rain

**11.1.3** Covers to prevent sunshine, rain or furious vibration during the transportation in the open air. No inversion or throw during load and unload period.

#### 11.2 Storage

— Environment temperature:  $-10 \sim 55$  °C.

-----Relative humidity: not more than 93 %.

——Atmospheric pressure:500 hPa  $\,\sim\,$  1060 hPa .

----- Storage in the room with no caustic gas but good ventilation.

**M**Note: The ventilator must be running under the specified working environment. When the ventilator storage environment is beyond the specified environment, you must place it in the working environment for four hours before using it, otherwise it cannot work properly.

#### 12 Others

Decompressor and bacteria-proof filter used on oxygen steel cylinder, humidifier and atomizer which warm and wet the ventilator output gas do not belong to the standard configuration of AV-2000B3 type ventilator. You can purchase them from other company if necessary.

If there is quality problem of the ventilator within one year, our company will repair it for free. If there is damage caused by improper use or dismantling or changing it by yourself, our company will charge repair and flat fee at our discretion.

Welcome the ventilator users to inquire our company. We will offer further technical data.

Attention: the ventilator is relatively professional medical apparatus and instruments, which must be repaired by professionals, in addition, our company will offer the relevant materials like electric circuit, list of components and parts needed by those professionals, explanatory text and detailed rules of correction.

# Appendix A: the data of inspiratory and expiratory resistance at the time of the ventilator power failure or part of it power failure

	Flow velocity (liter/min)	pressure (kPa)
	5	<0.2
Inspiration	15	< 0.5
	30	<1.5
	60	<3.0
Funitation	5	<0.2
	15	< 0.2
Expiration	30	< 0.5
	60	<1.5

### Appendix B: The checklist of items before use

Check interval before use

Test before operation should be carried out under the following conditions;

- 1. Before the first patient use it every day.
- 2. Before each patient use it.
- 3. Performed as required after repair or maintenance.

NO.	Check items	
		results
Ι	Check of the ventilator	
1	Check if the network power source is within the range (AC220V 50Hz)	
2	Check if the network power source is well grounded or the power source plug is inserted	
	tightly	
3	Check if the breathing tube is connected right	
4	Check if flow sampling tube is good, dry or lashed by high-pressure gas. Check if	
	collecting tube is good, dry or lashed by high-pressure gas. Check if the installation of	
	flow sampling tube and collecting tube is right.	
5	Connect the air source and power source, open the ventilator to check if the key and	
	shuttle can work normally	
6	Set mode of the ventilator VCV, frequency 6 times/min, I:E:1:8, increase tidal volume,	
	block the breathing tube, observe pressure waveform of the ventilator after it reaches	
	pressure peak value and see if pressure has obvious downward tendency.	
7	Let the ventilator work normally. Connect the gas storage bag to the place connecting the	
	patient, observe if folding bag can heave normally, see pressure waveform and flow	
	velocity waveform is complete and see parameters of tidal volume, ventilation volume,	
	pressure and oxygen concentration display.	
8	Set the ventilator mode IPPV, frequency: 10 times/min, I / E ratio: 1:2, tidal volume:	
	500ml, and let it work normally. Let the upper tidal volume alarm set value lower than	
	500ml and see if upper tidal volume alarm will happen and alarm cue will exist after two	
	respiratory cycles. Set low tidal volume alarm value higher than 500ml and see if low tidal	
	volume will happen and alarm cue will exist after two respiratory cycles.	
9	Set the ventilator mode VCV, frequency: 10 times/min, I / E ratio: 1:2, tidal volume:	
	500ml, and let it work normally. Set upper pressure alarm limit value lower than pressure	
	monitoring value and see if the upper pressure alarm will happen instantly and alarm cue	
	will exist. Set low pressure alarm value higher than pressure monitoring value and see if	
	the low pressure alarm will happen instantly and alarm cue will exist. Hear if there is any	
	difference between the two kinds of alarm sounds.	
10	Set the ventilator mode VCV, frequency: 10 times/min, I / E ratio: 1:2, tidal volume:	
	500ml, and let it work normally. Set the upper ventilation volume alarm value lower than	

	the ventilation volume monitoring value see if the upper ventilation volume alarm will	
	happen and alarm cue will exist in 1 minute. Set the low ventilation volume alarm value	
	higher than the ventilation volume monitoring value and see if the low ventilation volume	
	alarm will happen and alarm cue will exist	
11	Let the ventilator work normally. Set the upper oxygen concentration alarm value lower	
	than the oxygen concentration monitoring value and see if the upper oxygen concentration	
	alarm will happen and alarm cue will exist. Set the low oxygen concentration alarm value	
	higher than the oxygen concentration monitoring value and see if the low oxygen	
	concentration alarm limit will happen and alarm cue will exist. Hear if there is any	
	difference between the two kinds of alarm sounds.	
12	Set the ventilator mode VCV, frequency: 10 times/min, I / E ratio: 1:2, tidal volume:	
	500ml, and let it work normally. Simulate autonomous breathing manually. Set the upper	
	frequency alarm value lower than frequency monitoring value and see if the upper	
	frequency alarm will happen and alarm cue will exist in 1 minute. Set the low frequency	
	alarm value higher than frequency monitoring value and see if the low ventilation volume	
	alarm will happen and alarm cue will exist.	
13	Block expiratory valve port of the ventilator. When pressure in breathing circuit is	
	constantly higher than 25cmH <sub>2</sub> O, you should see if there will be high priority alarm and	
	alarm cue at 15+1s.	
14	Set the ventilator mode VCV, frequency: 10 times/min, I / E ratio: 1:2, tidal	
	volume:500ml, and let it work normally. Pull out the simulated lung and see if there is	
	tube drop alarm at 15s±5s when pressure is lower than 5cmH <sub>2</sub> O and tidal volume is no	
	higher than 30ml	
15	Set the ventilator mode VCV, frequency: 10 times/min, I / E ratio: 1:2, tidal volume:	
	500ml, and let it work normally. Block the patient end and see if there is asphyxia alarm at	
	$15s\pm5s$ when pressure is constantly higher than $10cmH_2O$ and tidal volume is lower than	
	50ml.	
16	Connect AC power source and gas source to make the ventilator operate normally . cut AC	
	power supply to see the ventilator can automatically be transferred into DC power supply	
	and it can operate unaffectedly and the DC power supply alarm happens.	
17	Set the ventilator mode VCV, frequency: 10 times/min, I / E ratio: 1:2, tidal volume:	
	500ml and let it work normally. Set pressure limit lower than pressure monitoring value	
	and see if pressure limit can work normally.	
II	The check of matching instruments which do not belong to the machine(if they are	
	equipped, then check according to the check content in the manual	
1	Check if end-expiratory carbon dioxide monitor works normally	
2	Check if oxygen concentration monitor works normally	
3	Check if pressure monitoring facilities work normally	

4	Check if exhaled gas volume monitoring facilities work normally	
5	Check if gas monitoring facilities work normally	
III	Software information	
1	The application, cleaning and disinfection records of the ventilator	