CHAPTER ONE INTRODUCTION

1.1 Introduction

1.1.1 Performance

The HFS3100A Model ventilator, researched and developed by Henan Huirui Biomedical Electronics Co., Ltd., is a electro-pneumatically controlled time/pressure switched ventilator that is monitored by a micro-processor. The ventilator adopts pressure triggering, supplies AC、SIMV、SIGH、SPONT ventilation modes; adopts imported parts and components with high quality as primary ones, to enhance its reliability and stability; adopts touching button to make the parameters setting quite convenient and fast; adopts a 240×128 lattice LCD screen, to display the ventilation mode, ventilation frequencies, dynamic pressure waveform and warnings. Besides, it adopts the advanced double-circuit universal input voltage on-board power supply, and uses direct current outside and lithium cell (continuous working time at least 5h) inside, to accommodate various environments. The ventilation frequency, I/E ratio and tidal volume are all adjustable. It's compact, lightweight, portable and multifunctional.

1.1.2 The purpose intended

The HFS3100A portable ventilator is applied to emergency centers, Operation Room, ICU, inner and out of hospital transportation and the ambulances.

The ventilator should not be used on children under 20 kg body weight.

1.1.3 Operator

The operator of the ventilator should be a doctor or nurse who has received adequate training for HFS3100A portable ventilator. The ventilator should be maintained by the person who has been authorized by Henan Huirui Biomedical Electronics Co., Ltd.

1.1.4 Symbols

Symbol	Explanation
SN	Serial No
	Manufacturer :with address and contact details.
	Production date: The date on which the product was produced.
	Protection against electric shock: class II device.

	Application part requirement: Type B.
	Silence: silence time 120s.
	ON/Stand-by: press this key to open the ventilator; press 3s to enter stand-by state.
	A/C mode: Press this key to enter A/C mode.
	SIMV mode: Press this key to enter SIMV mode.
	SIGH mode: Press this key to enter SIMV mode.
	SPONT mode: Press this key to enter SIMV mode.
	MANUAL: Press MANUAL key,other ventilation modes stop, after 5s other ventilation modes recover.
	O_2%:50% or 100%.
	Built-in battery remaining power.
	Low battery alarm: when the low battery alarm is issued, the battery can keep the ventilator working time are not less than 30 minutes.
	External power: car socket, DC 12V 4A.
	External power: adapter socket. DC18V1.7A.
	Confirm key: confirm the parameters setting by pressing this key. Long press the key to lock the front panel operation; long press to release lock.
	Tidal volume: Set the tidal volume by this knob.
	External power supply indicator.
	Built-in battery power indicator.

○ Trigger	Trigger: when patients inspiratory effort reach the setting trigger pressure, the yellow light on.
○ Charge	Charge: Indicating the built-in battery is charging,

1.2 Features

1.Ventilation modes: A/C、SIGH、SIMV、SPONT、MANUAL；

2.Stable and reliable performance: the ventilator is micro-processor controlled and programmable with digital integrated circuit, to realize the automatic recognition and control of ventilation parameters in different ventilation modes. The primary parts and components adopts high quality imported ones, and all the elements have passed the aging test, which enhances the stability and reliability of this equipment;

3.Powerful display：

a. Dynamic monitoring parameters: Tidal volume、Minute ventilation volume、peak pressure、Total frequency、I:E ratio.

b. Setting parameters: Tidal volume、ventilation frequency、inspiration time、trigger pressure、upper airway pressure limit、lower airway pressure limit、control pressure.

c. LED status indicator: trigger、AC/DC power supply、charging、O2、stand-by；

d. Alarms Display: Low tidal volume、High airway pressure、Low airway pressure alarm、Apnea、Low battery、Low gas supply、External power failure.

e. Alarming modes: Sound-light alarm.

1.3 Technical performance

1.3.1 Technical parameters

1）Ventilation modes: A/C、SIGH、SIMV、SPONT、MANUAL；

2）Tidal volume: 0, 30ml～2400ml continuously adjustable. tolerance = ±15%;

3) Max. minute ventilation volume: ≥18 L/min, continuously adjustable;

4) Oxygen concentration: 50% or 100%.

5) System compliance: < 4ml/100Pa;

6) A/C ventilation frequency: 2bpm～80bpm (tolerance = ±5%);

7) I/E ratio: 5：1～1：5 (inspiration time: 0.2s~ 6s) (tolerance = ±5%) ;

8) Max. working pressure: ≤6kPa;

9) Inspiration trigger pressure: continuously adjustable from 0cmH2O to -20cmH2O (tolerance = ±0.5 cmH2O);

10) Sigh (Deep breath SIGH）: after every 100 breath cycles, supply the patient with once deep breath with 1.5 times of the former tidal volume.

11) SIMV Ventilation frequency : 1bpm～30bpm (tolerance = ±5%);

12) Inspiration-expiration switching pressure: 6cmH_2O – 40cmH_2O

13) Gas supply pressure: 280 kPa～600 kPa; normally, the full oxygen cylinder (2.8L) accompanied the ventilator can work continuously for at least 1 hour.

14) Apnea time: 20s

15) Power supply: supply power to A/C adapter, 100V～240V，50Hz/60Hz.
16) Internal battery: Recharging battery 14.8V,2200mAh, the internal battery can works for at least 4 hours continuously, the recharging time is about 6 hours.
Battery dimension: 38mm(L)x 37mm(W) x66mm(H)
17) Oxygen cylinder: volume: 2.8L; storage pressure: 14.7MPa; flow: 60L/min.
18) Dimensions: 266x100x244 mm
19) Weight of the ventilator: 2.5Kg(main unit)
20) Operating temperature：5℃ ~ 50℃;
21) Atmospheric pressure: 700hPa ~ 1060 hPa;
22) Relative humidity: 10% to 80%

1.3.2 Alarming performance

1.3.2.1Alarming conditions

1) High airway pressure alarm: alarm information will be displayed on the right side of screen when the airway pressure reaches or exceeds its upper limit , pressure upper limit arrange: 20 cmH2O ~ 80 cmH2O (tolerance = ±5%).
2) Low airway pressure alarm: alarm information will be displayed on the right side of screen when the airway pressure reaches or falls below its lower limit , pressure lower limit arrange: 0cmH2O~ 20 cmH2O (tolerance = ±5%).
3) Low tidal volume alarm: alarm information will be displayed on the right side of screen when the tidal volume is smaller than 100 ml (tolerance = ±5%);
4) Apnea alarm: alarm information will be displayed on the right side of screen when the patient's spontaneous respiration stops for over 20s.
5) Low battery alarm: alarm information will be displayed on the right side of screen when the voltage of external on-board power supply or internal battery ≤ 14.8 V.
6) Low air pressure alarm: alarm information will be displayed on the right side of screen when the air pressure≤0.28MPa.
7) External power off alarm: alarm sound when the external power off and auto switch to built-in battery supply, without alarm information display; It should be turn off the power supply and reconnect the power supply to lift alarm.
8) System fault alarm: Alarm sound with red light flash if no gas input or no airway pressure monitoring data.

1.3.2.2 Alarm mode

1) State indicating: the four indicator lamps on the left upper corner of the ventilator's front side will flash at a certain frequency to display relevant alarms, and a bright triangle will be displayed on the right side of screen to display a state alarm.
2) Sound signal: the sound signal consists of intermittent beeps with sound level of at least 60dB（A）The alarm shall sound for at least 5s， and stop with the disappearance of actual alarm conditions.

CHAPTER TWO PREPARATION FOR USE

Warning:

- **Before use, check the supply pressure of the oxygen cylinder by reading the pressure gauge.**
- **If it is less than 280kPa, the cylinder should be refilled or replaced.**
- **Do not smoke or ignite naked flame during refilling or replacing the oxygen cylinder or using the ventilator for O2 therapy.**
- **Storage the oxygen cylinder in cool and breezy environment.**

2.1 Connections

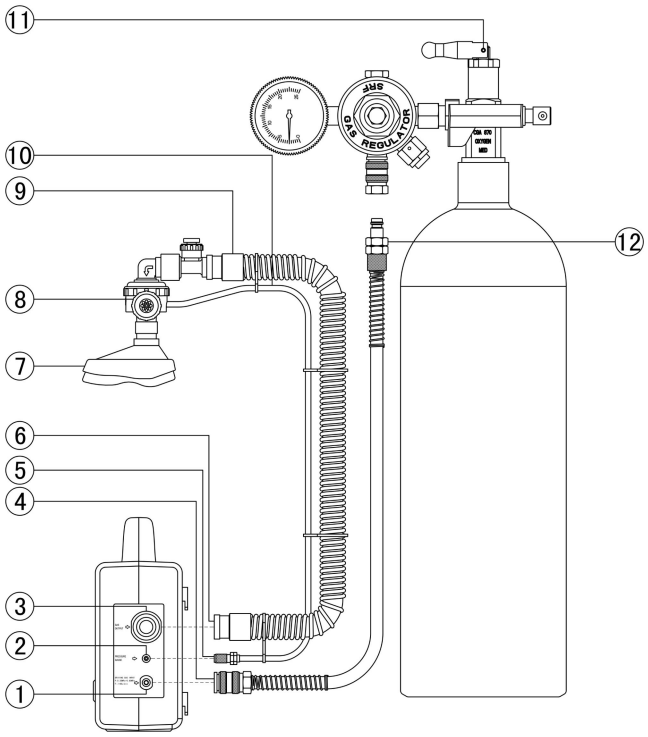


Figure 1 Installation Diagram

1. Driving gas input.
2. Pressure measurement port.
3. Gas outlet.
4. Gas supply hose.
5. Pressure measurement hose port.
6. Breathing circuit connector.
7. Face mask.
8. Breathing valve.

9. Breathing circuit.

10. Pressure measure hose.

11. Oxygen cylinder.

12. Oxygen supply hose.

2.1.1 Breathing circuit connection

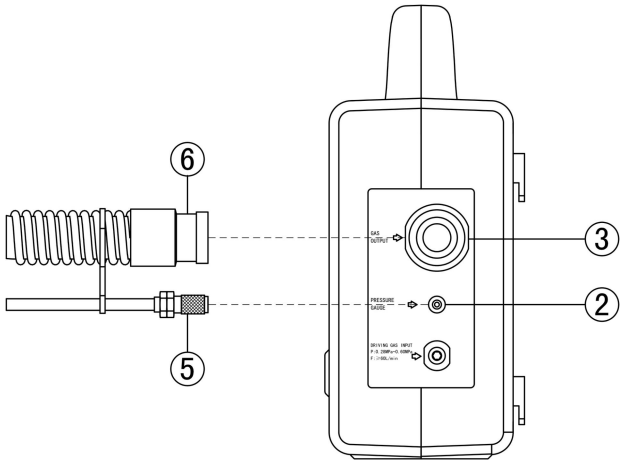
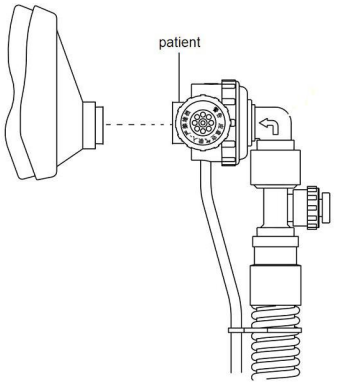
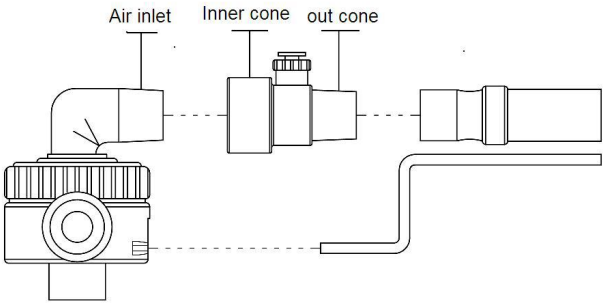


Figure 2 Breathing circuit connection

As shown in Figure 2, breathing circuit ⑥ connect to the gas outlet ③, pressure measurement hose port ⑤ connect to pressure measurement port ②.

2.1.2 Face mask, Breathing valve、oxygen supply hose connection





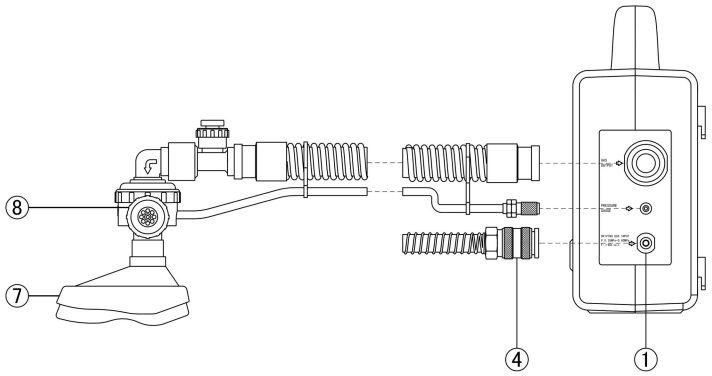


Figure 3 Face mask、Breathing valve、oxygen supply hose connection

2.1.3 Gas supply connection

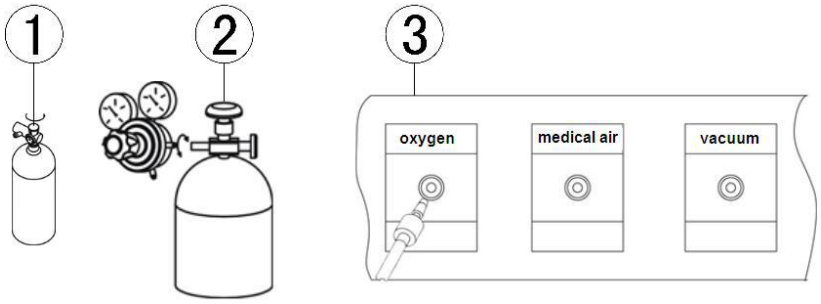


Figure 4 gas supply connection

1.small oxygen cylinder(<10L) 2. Big oxygen cylinder(40L) 3.central oxygen supply system
If the central oxygen supply system is used, it shall be connected to the oxygen supply terminal. The ventilator applies DISS standard quick-connecting probe as gas supply probe. If other probes are needed, please contact us.

2.1.4 Patient connection

Fix the face mask ① onto the patient's face, or insert the endotracheal cannula ② into the patient's airway for ventilation.

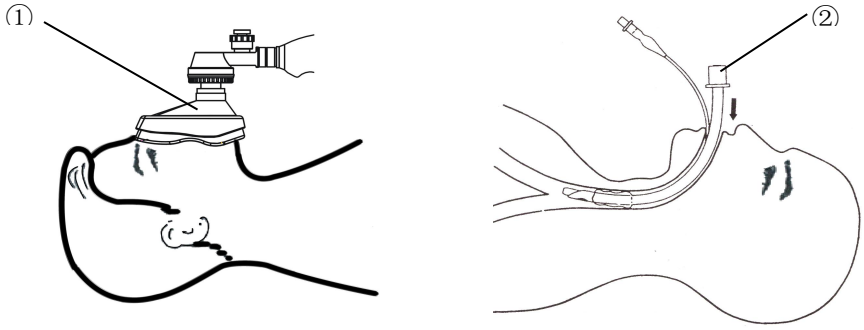


Figure 5 patient connection

2.2 Pre-use examination

No.	Items	Actions
1	Open case and check contents for missing items	Repair or replace it if necessary
2	Check the cylinder contents by opening cylinder valve and reading pressure gauge	Refill or replace the cylinder if necessary
3	Check whether the oxygen supply hose's probe is matchable with the gas supply connector.	If any problem, please contact the manufacturer for solutions.
4	Connect the gas supply hose to the ventilator and connect the other end to the face mask; open the oxygen cylinder valve and adjust the parameter(s) to operate the ventilator; check whether the adapters leak or if abnormal situations occur	Tighten the loosely connected adapters if leaking.
5	Adjust the adjustable parameters accordingly, and confirm each parameter is exact when the ventilator is working.	See Chapter Three
6	Press the manual button down to confirm whether the ventilator is in good working under manual ventilation mode.	See Frong panel.
7	Check the internal battery	Recharge or replace one

2.2.1 Gas supply/power supply examination

1.After connecting the power supply and gas supply, check whether they can work normally;
2.Turn on the power switch, press ON/Stand-by key ⏻ for 3s to enter standby mode, press ON/standby key, ventilator start to work and disconnect the power cord after 5 minutes, ensure external power off alarm sound normally.
3.Observe the pressure gauge, when the supply gas pressure <0.28Mpa,ensure there is low gas pressure alarm. When pressure recover to 0.28Mpa,alarm automatically disappear.

Note:
1.Before examination, please connect the test lung with the patient valve.
2.It's forbidden to use the ventilator if any problem found during the examination.

2.3 Functional examination

1. Standard parameters setting

Set the ventilation parameters to the following standard values:

Ventilation mode: A/C
Frequency: 20 bpm

Inspiration time： 1s
Upper limit of airway pressure： 25 cmH2O
Lower limit of airway pressure： 4 cmH2O
Trigger pressure： -2 cmH2O
Control pressure: 6 cmH2O
Tidal volulme： 600 ml
Oxygen concentration: 50%

2.Tidal volume examination

After the ventilator starts to work, adjust the minute ventilation volume knob to view whether tidal volume displayed in the display and monitoring area changes synchronistically along with the adjustment of knob.

3.Examination of Frequency

Set the frequency to be 10bpm,record the ventilation frequency during 1 minute, it should to be 9~11bpm;

Set the frequency to be 20bpm, record the ventilation frequency during 1 minute, it should to be 18~22bpm;

4.Examination of alarm for the airway pressure's upper limit

Adjust the airway pressure's upper limit to be 25 cmH2O; adjust the tidal volume to increase the peak airway pressure gradually, when it reaches or exceeds 25 cmH2O, a warning with triangle icon will be displayed on the right side of screen, for high airway pressure, the alarm indicator lamp at the left upper corner of prong panel will flash and the buzzer will beep. Meanwhile, the ventilator expires to reduce the patient's airway pressure.

5.Examination of alarm for the airway pressure's lower limit

Lift up the airway pressure release valve 1 (as shown in the figure) to open the release valve. when the peak airway pressure ≤4cmH2O; low airway pressure alarm information will displayed on the screen with a beep.

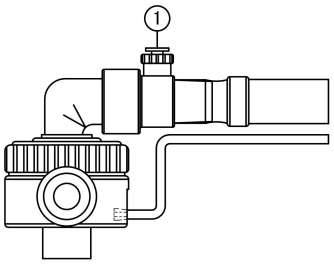


Figure 6 Airway pressure release valve

6.Trigger pressure examination

Set the trigger pressure to be -1cmH2O, put on the face mask and inspire. When the airway pressure is slightly lower than -1cmH2O, the inspiration will start and the trigger indicator lamp will flash.

7.Examination of SIMV mode

Press the SIMV mode key, and the key indicator lamp will flash to show that the ventilator has started to work in SIMV mode. Adjust the ventilation frequency from 20bpm to 10bpm, and the frequency will become 10bpm 1 minute later.

8.Examination of SIGH ventilation mode

Press the SIGH key in A/C mode, and both A/C and SIGH key indicator lamp will flash to show that the ventilator has started to work in the A/C+SIGH mode. Adjust the tidal volume to be 400ml to 500ml, and view the tidal volume value displayed. The tidal volume will be displayed since the second respiration after the setting above, with a sigh during which the tidal volume is 600ml to 750ml, then the patient will have a sigh once after 100 times of respiration.

9.Examination of SPONT ventilation and apnea alarm

Set the ventilation mode to be SPONT, adjust the trigger pressure to be -3 cmH2O or so, and put on the face mask, the ventilator will start to ventilate. When the inspiration stops, the airway pressure will rise; as the airway pressure rises to 6 cmH2O, the ventilator will start to exhaust and wait for the patient's next spontaneous inspiration. If no trigger within 20s, the alarm of "apnea" will be displayed in the alarm display area 4s to15s later, the alarm indicator lamp will flash and the buzzer will beep. Meanwhile, the apnea alarm will stop 2 minutes after the ventilator has started to work in the A/C mode.

10.Examination of MANUAL mode

Press the MANUAL button on the right upper corner of front panel, and check whether the gas outlet ventilate; loosen the button and the ventilator will return to the preset ventilation mode within 5s.

CHAPTER THREE OPERATING PROCEDURE

After finished the connection, the ventilator work system as shown in the figure 7.

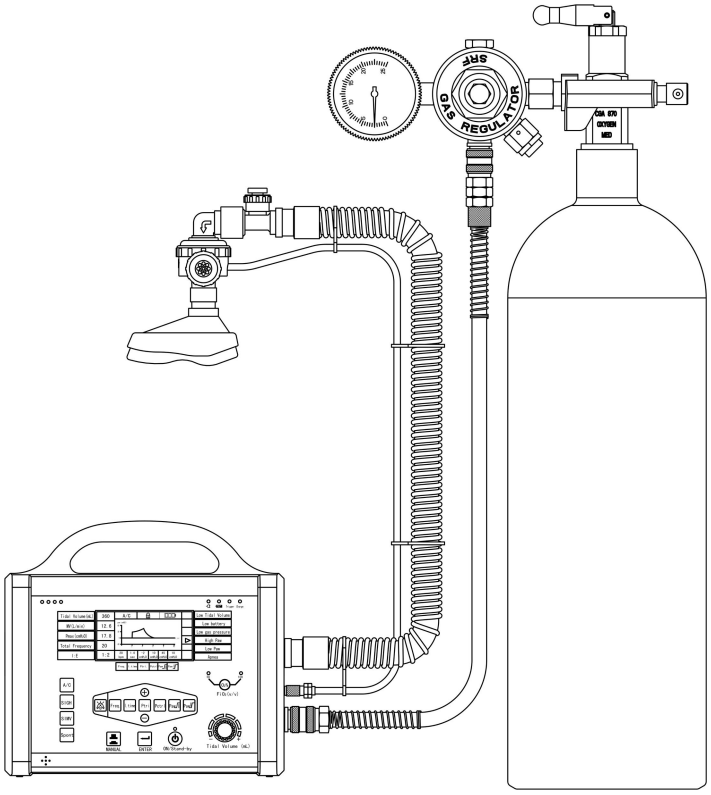


Figure 7 ventilator work system

3.1 Operators' qualifications

The operator of this ventilator shall meet the essential requirements as follows:

1) A doctor or nurse or others who have received training for clinical emergent rescue;

2) Be familiar with respiratory physiology, pathology of respiratory failure, the ventilator's working principle and performance features, the significance and clinical application of respiration monitoring, as well as how to adjust and use the ventilator.

3) Be agile, proficient in emergency and in good health.

3.2 Preparation before use

1) Connect the ventilator as specified in Chapter Two, if necessary and fix it. Check whether all the accessories have been correctly connected.

2) Get familiar with operating the ventilator, and do functional examination for each function of this ventilator according to Chapter 2.

3) If no problems, the ventilator can be used.

3.3 Ventilator structure

1.Turn on the power switch on the left side.

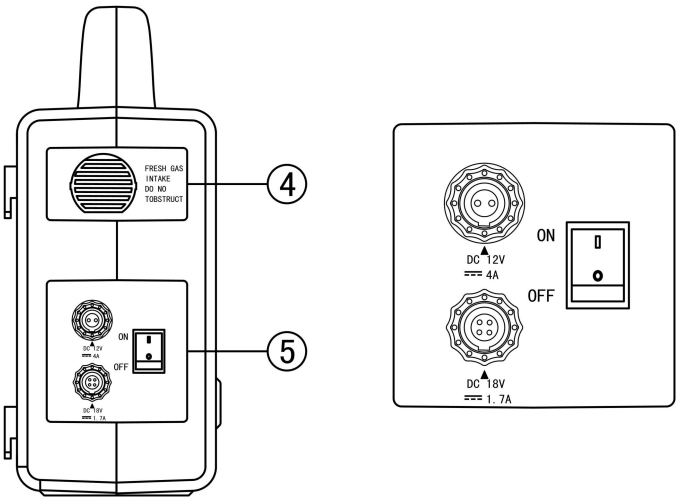


Figure 8 Power switch

2.Power supply indicator light up.

Figure 9 Power supply indicator

3.Press ON/Standby key for 3s, screen start to work after 3s,and the standby indicator light up, now the ventilator in standby status, press standby key to open the ventilator.

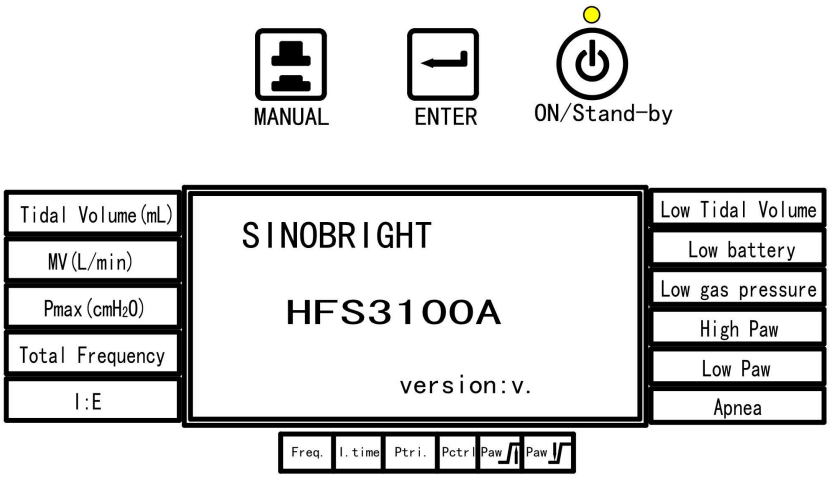


Figure 10 power on

4.Open the gas supply, ventilator start to work.

3.4 Mode select

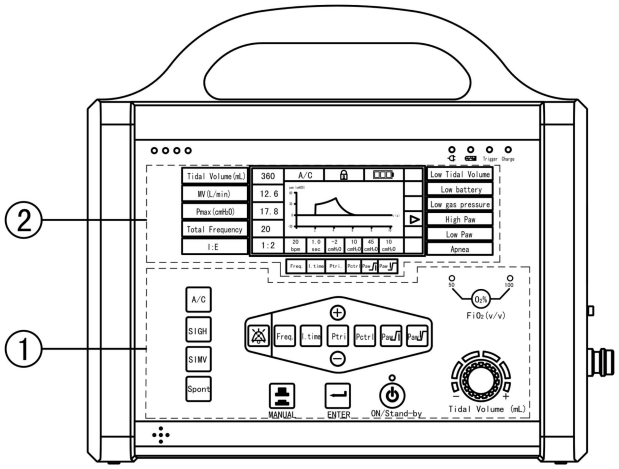


Figure 11 Front panel

As shown in Figure 11 ,1 is operation part, select ventilation mode and O2%,set tidal volume and other parameters. 2 is display part, monitoring parameters, setting parameters, alarm and battery information will display in this part.

3.4.1 A/C mode

1.The default mode is A/C mode.

Long press ↵ key, when 🔓 display on the screen, press A/C mode, A/C display on the upper left screen.

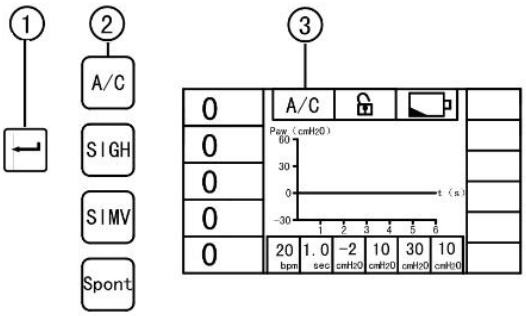


Figure 12 A/C mode select

2. A/C parameters setting

(1) O2%: The default O2% is 50%. Press O2% key to select O2% between 50% and 100%.

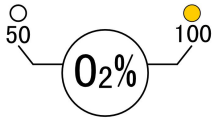


Figure 13 O2% select

(2) Tidal volume setting:

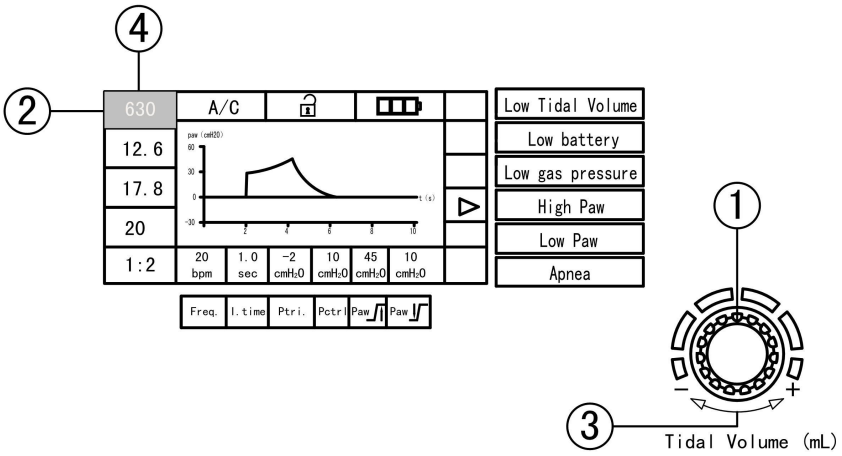


Figure 14 Tidal volume setting

As shown in Figure 14, Press tidal volume key ① for 3s, tidal volume monitoring window ② invert color, ④ is the memory tidal volume, adjust the tidal volume knob by knob ③.

(3) Other parameters setting: Frequency、inspiration time、trigger time、pressure upper limit、pressure lower limit etc parameters can be set in this area.

As shown in figure 15, press frequency key ①, the frequency window ② invert color, press "+""-"key ③ to set the frequency, then press ↵ to confirm and finish the setting.

Other parameters setting same with above steps.

"+" is increase,"--" is decrease.

Recommended parameters in AC mode:

Body weight（kg）	Frequency（bpm）	Minute ventilation volume（L/min)
10～30	25～30	2～6
30～60	15～25	6～12
60～90	10～15	12～18

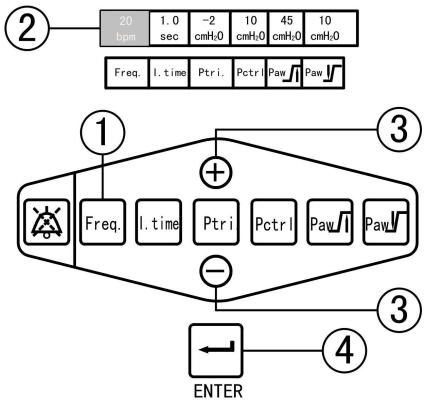


Figure 15 Parameter setting

3.4.2 SIGH

A/C+SIGH is SIGH mode，mode select、set items、item setting methods same as AC mode.

It provide 1.5 times tidal volume every 100 respiratory cycle.

3.4.3 SIMV

Mode select method and parameters setting method same with A/C mode, frequency range is 1bpm～40bpm, step is 1bpm,control pressure range is 10cmH20～15cmH2O.

3.4.4 SPONT

SPONT is spontaneous breathing mode, tidal volume、frequency、I:E Ratio were controlled by the patient, Mode select method and parameters setting method same with SIMV.

3.4.5 MANUAL

Manual flow is 36L/min, manual can be used at any time. Press Manual button, Manual mode displayed on the upper left screen.

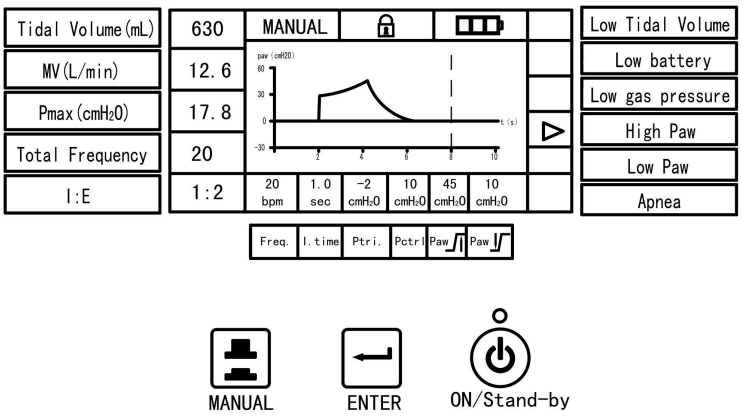


Figure 16 Manual

3.5 POWER OFF

ON/Standby key is composite key, long press this key to turn on/turn off the ventilator, and press this button can make the ventilator suspend or resume during ventilator running.

After using the machine,first close the air supply source, when confirm the ventilator without gas outlet, close the ventilator.

1.Long press ENTER key ① for 3s, then unlock symbol ② displayed on the screen

2.Long press ON/Standby KEY ③ for 3s, power off interface displayed on the screen ④.

3.Loose the ON/Standby key, press ”+”key to choose “YES” or “NO”, then press ENTER to confirm. If not confirmed after 5s, ventilator continue to work.

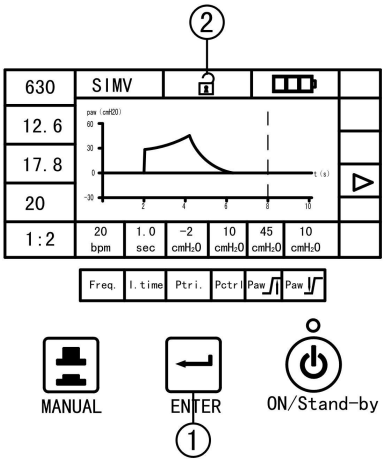


Figure 17 power off

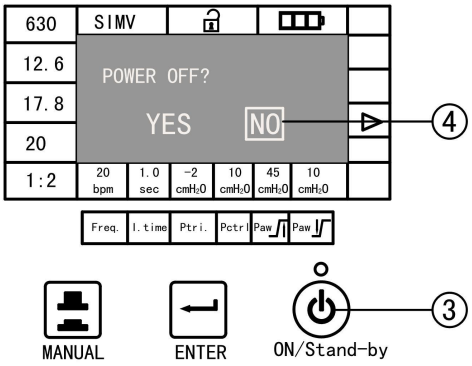


Figure 18 Power off reminder

4. During ventilator running, press ON/Standby key can enter standby status, Standby displayed on the upper left screen and the indicator light on.

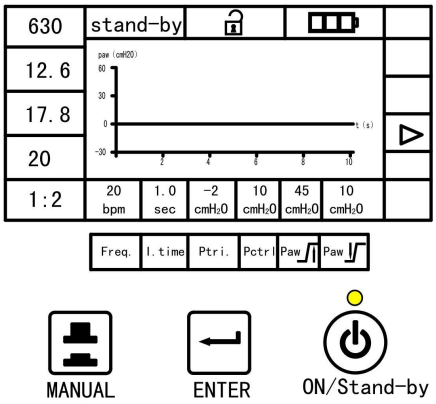


Figure 19 Stand-by

Under standby status, press ON/Standby key, the standby symbol disappear and indicator light off, ventilator continue to work as per the former model.

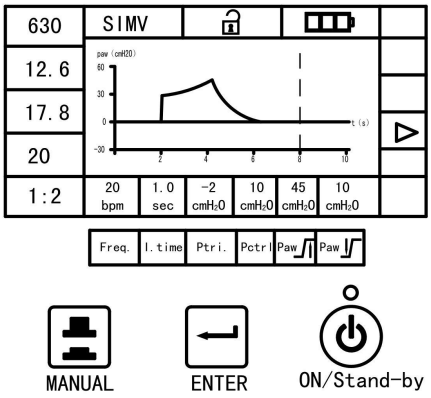


Figure 20 Running status

CHAPTER FOUR TROUBLE SHOOTING

4.1 Faults

No.	Faults	Causes	Actions
1	The indicator lamp and screen doesn't flash.	Power off	Power on
2	The low battery alarm still work when the external power supply is being used.	Electric failure	Switchover to manual ventilation for power supply check.
3	The power supply lamp blinks.	1.The power plug is not fixed. 2.Battery was damaged.	1.Fix the plug. 2.Contact the manufacturer.

4.2 Clinical judgment

No.	Faults	Causes	Actions
1	The trigger pressure indicator lamp blinks, with faster spontaneous respiration.	Overhigh trigger pressure sensitivity is likely to trigger the patient's spontaneous respiration.	Set the trigger pressure again.
2	Alarm for low airway pressure	1） Bending or block of pressure sampling hose or block of patient's trachea 2） Block of patient's airway by phlegm 3） The preset upper limit is too low 4） Change of patient's compliance and resistance 5） Patient's mascular tension and cough	1） Examine patient's trachea for correction 2） Auscultation, chest shake, phlegm suction, physical therapy 3） Set the parameter again according to patient's state 4） Reevaluate the patient's ventilation parameters and set them again
3	Alarm for high airway pressure	1. Leakage of pipeline 2. Overhigh lower limit of airway pressure 3. Change of patient's compliance	1） Check the oxygen hose for correction 2） Set the parameter again according to patient's state 3） Reevaluate patient's state and adjust the ventilation parameters
4	Inadequet spontaneous respiration, low minute ventilation volume and frequency	Improper setting of frequeny, inspiratory trigger pressure and tidal volume.	Reevaluate patient's state and adjust the ventilation parameters

4.3 Treatment to the patient's vomit

If the patient's vomit enter into the breathing valve during resuscitation, the following steps should be followed to clear the vomit. Please refer to the figure 21. Remove each parts and clean the vomit, after cleaning the vomit, reinstall them and use.

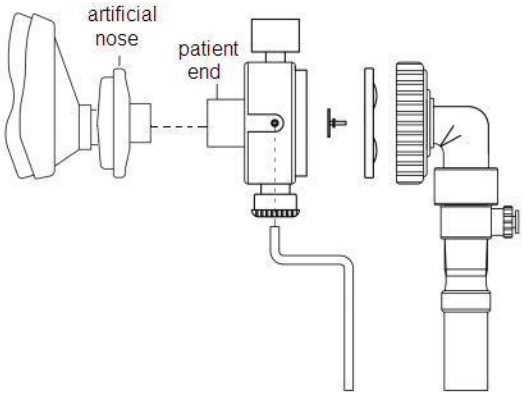


Figure 21 vomit clearing

CHAPTER FIVE MAINTAINANCE

5.1 Cleaning and disinfection

5.1.1 Cleaning and disinfection of ventilator

1) It is recommended to use 500 ppm, 1:100 and 5000ppm, 1:10 diluted bleaching solution at a dosage determined according to the volume of organic matters (blood or body fluids) residual on the surface, wipe the surface by a rag soaked with disinfection solution and dry it in the shade.

--Or wipe the surface by hot soap water and disinfect it by ultraviolet radiation.

--Strong oxidizer solutions such as peroxyacetic acid or acetone solution as well as gas fumigation by formaldehyde shall not be used for disinfection.

2）Disinfection by ultraviolet radiation

The ventilator can be disinfected by ultraviolet radiation for 1 hour.

3）Patient with respiratory tract infection

After used by the patient whose respiratory tract is infected, the ventilator's panel and surface shall be wiped with 2% saponated cresol solution, then cleaned by clean water, to avoid cross infection.

5.1.2 Disinfection of accessories

--The multi-use accessories shall be cleaned by hot soap water and clean water in sequence, then soaked in the alcohol solution (≥70%) or 1:1000 activated glutaraldehyde solution for 30 minutes, then cleaned by clean water and dried thoroughly for storage.

--Or use formaldehyde suffocating for 60 minutes, and then scour them by oxygen to remove the odor of formaldehyde.

The patient tube shall not be disinfected by ultraviolet radiation.

5.1.2.1 Disinfection of Breathing valve

Dismount the breathing valve and diaphragm, and soak them in clean water to remove the residual substances expired by the patient in the pipeline, then disinfect them by soak in disinfection solution. Especially, the valve used by a patient suffering from infectious disease should be suffocated with formalin for 12 to 24 hours.

5.1.2.2 Disinfection of patient tube

After each time of use, the patient tube shall be cleaned completely by soak in clean water first, then disinfected by soaking in disinfection solution after removing the residual substances expired by the patient in the pipeline. Especially, the respiratory pipeline used by a patient suffering from infectious disease should be suffocated with formalin for 12 to 24 hours.

After use, the single use accessories shall be disposed according to the local laws and regulations.

5.1.3 Cleaning of air inlet port

The air inlet port is intended for filtration and amortization. The sponge should be replaced or cleaned, if necessary, to facilitate the entry of air. For cleaning, the sponge should be taken out, cleaned by soap water and dried for fe-fixing.

The fresh air inlet on the right side shall not be blocked or covered to ensure the normal work.

5.2 Maintenance

5.2.1 Routine maintenance

To ensure the ventilator's normal work and smooth operation, a person shall be assigned specially for monthly examination of the ventilator according to Chapter 2.

5.2.2 Replacement of connecting hoses

If a connecting hose, i.e. gas supply hose, thread hose and pressure sampling hose, becomes aging, it should be replaced in time by contacting the company.

WARNING

- **Before the replacement of the The protector tube must be powered off before replacement, to avoid any danger.**
- **The new protector tube shall be the same as the old one in model and size.**

5.2.3.1 Charging

The fully charged battery can work for 5 consecutive hours, and it can be recharged by the power adapter. The charge indicator on right upper corner of the panel will flash to be red during charging, while yellow after charging. The charging time is about 6 hours. When the low battery indicator lamp flashes or the low battery alarm sounds, charge the battery or use external DC power supply instead.

5.2.3.2 Maintenance of battery

The ventilator uses high performance lithium ion battery, which has a wide temperature range, no memory functions. The cell has dense charges with over-discharge,over-charge and protection circuits inside,to prevent damages caused by improper charge method.

The ventilator shall not be used if the battery's electric quantity is unenough.

The suitable storage temperature shall be 10℃ to 30℃. The battery has an excellent electronic storage capacity, so it can still work after being laid up for a long time. It's recommended to charge the battery at the intervals of two months if it is seldom used, to ensure it contains at least 80% of full charge.

The user shall not replace the battery at will but contact the company for replacement.

CHAPTER SEVEN TRANSPORT AND STORAGE

7.1 TRANSPORT

If packaged suitably, the product can be transported via highway, flight or railway, with measures taken to avoid bumping, heavy vibration or moisture proof during the transport. (If any other requirements, refer to the order.)

7.2 STORAGE

The product shall be stored in a well-ventilated room free from corrosive gases at -20℃ to 50℃.

CHAPTER EIGHT AFTER-SALES SERVICE

Warning

◆ **Any disassembly of the ventilator will invalidate any warranty.**

- The company promises a 2 year warranty of maintenance against defects caused by inartificial factors. After this warranty period, the device can still enjoy the company's maintenance service, but the user shall bear the cost for replacement of parts and components.
- If any faults occur to the ventilator or its accessories, please contact the manufacturer in time.
- The user shall not dismantle the device, to avoid troubles. The company will not perform the for said promise if the "maintenance label" outside the device is damaged.
- The company reserves the right to modify this manual without prior notice.
- The company reserves the right to interpret this manual if it sees fit.