CCA-JL820

Multifunctional Anesthesia Unit

User's Manual

CONTENT

Important Safety Indication

1. Thank you for your choosing CCA-JL820 Anesthesia Unit. Please carefully read and keep this User's Manual for future use.

2. Declaration on the language in this manual:

Warning: You should know how to protect the patient or doctor from hurt.

Caution: You should know how to protect the machine from being broken

Notice: Emphasizing important information.

3. Please make the storage battery well connected to avoid bad influence to the patient caused by sudden blackout.

4. The alternation current connected to the machine should have good grounding protection.

5. This machine is not an explosion-proof equipment, so please DO NOT operate the machine in any place with explosive or flammable gases. Also 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.

6. The ventilation pipes and spile should be thoroughly cleaned and sterilized before using.

7. Please make sure the machine is in good condition, NEVER operate the machine if there is malfunction.

8. In order to avoid explosion, NO flammable anesthetic like aether or cyclopropane can be used.

9. This machine does not use flammable anesthetic like aether or cyclopropane, so it is not necessary to use antistatic ventilation pipes or masks, which may cause burning when using high frequency electric surgical equipment, so we DO NOT suggest this kind of pipes or masks.

10. The performance of this machine may be influenced by nearby high frequency surgical instruments or short-wave equipments.

11. There should be independent ventilation mode, such as simple respirator with mask, no matter what kind of anesthesia system is being used.

Explanation to words and figures

DANGER: Alert to high danger

WARNING: Alert to middle danger

NOTICE: Attention to low danger

B type equipment

Please refer to attached documents

Important Announcement

1. The assorted pressure testing instrument should accord with ISO8835-2:1999.
2. The assorted O2 monitor should accord with ISO7767:1997
3. The assorted CO2 monitor should accord with ISO9918:1993
4. The assorted adult anesthesia ventilation system should accord with ISO8835-2:1999.
5. The assorted anesthetic gas transportation device should accord with ISO8835-4
6. The assorted anesthetic gas monitor should accord with ISO11196:1996
7. The assorted anesthetic gas cleaning, transportation and inception system should accord with ISO8835-3:1997.
8. This machine is equipped with anesthesia ventilator, the ventilator should accord with ISO8835-5.
9. This anesthesia system or any independent devices is not suitable for MRI environment.
10. No flammable anesthetic like aether or cyclopropane can be used in this system. Only anesthetic according with the nonflammable anesthetic requirements in appendix DD of GB9706.29-2006.
11. The operator should be aware of the danger of high current caused by creepage when the equipment is connected to assistant power socket.
12. There should be independent ventilation mode, such as simple respirator with mask, no matter what kind of anesthesia system is being used
13. The malfunction of central gas supply system may cause one or more, or even all the related devices stop working.
14. This system does not include anesthetic gas monitor, if you want to use the monitor, please take sample at the patient end of the inspiration valve in the ventilation system.
15. This anesthesia system or any independent devices is not suitable for environment with strong radiation or electromagnetic interruption, like MRI. Otherwise, the performance of the equipment may be influenced.
16. If anybody who want to use any independent devices, inspection devices, alarming devices, protection devices, or assemble a complete anesthesia system, he should provide the inspection list of the system.
17. Before use, the system should be equipped with a device which can limit the pressure of the patient connection port. This pressure should not be more than 12.5kPa, if the machine is in good

condition or single malfunction.

18. If there is assistant power socket, the current may be higher than the allowed value.

Process Inspection List

Power On

1. Please make sure if the power supply is well connected before power on the machine.
2. Before use, please check if the pipes are connected correctly, if there is leak in the airway.
3. If there is liquid inside the pipes, please clean them and then connect them to the machine.
4. Connect the simulate lung, and adjust the tidal volume according to the patient weight.

During operating

1. Judge the performance of the machine by the movement of the leather bag.
2. Keep paying attention to the inspiration and expiration valves, make sure the valves work well.
3. DO NOT put any liquid container on the machine, or the liquid may enter into the machine.

After Use

1. Please turn off the machine first and then cut down the power.
2. Please take the silicon tubes off the machine.
3. Please sterilize the machine according to the user's manual.

Note: Please DO NOT imPact the machine or distort the pipes while move the machine

1 Summary

CCA-JL820 Anesthesia Unit is a necessary anesthesia equipment in the surgical room, the main function is to provide O2 to the patient, help the patient to inhale anesthetic and manage the respiration.

CCA-JL820 Anesthesia Unit is equipped with precise vaporizer, safety device which can avoid anoxic, and also necessary alarming system. During the process of anesthesia, the computerized gas-driven electric-control anesthesia ventilator can manage the patient's respiration. All the joints are standard joints. The big CO_2 absorber can reduce the repeated inhaling of CO_2.

Normal Working Condition:

Environment Temperature: 10~40℃

Relative Humidity: ≦80%

Atmospheric Pressure: 86KPa~106KPa

Power Supply: AC 220V±10%, 50±1Hz, 40VA, single phase alternation current with good grounding protection.

Note: Alternation current connected to the anesthesia unit must have good grounding protection.

This equipment is a normal equipment which is not liquid-proof, but it can work continuously.

This machine is not an explosion-proof equipment, so please DO NOT operate the machine in any place with explosive or flammable gases.

2. Structure Feature and Working Principle

The whole system is composed with main unit, circle cycle, anesthesia ventilator, vaporizer and flow system.

2.1 Main Unit

The anesthesia unit uses compressed O_2, compressed N_2O and compressed air which come from cylinder or central gas system in the hospital. In order to insure the safe use of the machine, the

machine is also equipped with backup O_2 connection. Pressure of all the gases should be 0.35MPa~0.5MPa. There are filters at all the connections, in order to stop grain bigger than 100μm entering into the working system of the machine.

After entering into the machine, both the O_2 and backup O_2 become one gas which will be divided into four gases then.

The first one enters the decompressor, becomes 300KPa, and then enters the flow meter. The pressure of gas from cylinder or central gas system may change along with the temperature or stored gas volume. Decompressor can make the gas pressure stable and meet the requirement of the anesthesia machine. The pressure value after being decompressed can show on the O_2 pressure meter and N_2O pressure meter.

The second gas goes to the pressure inspection device, the machine will alarm if the gas pressure is lower than 200 KPa±50 KPa.

The third gas goes to the common gas exit through the quick O_2 supply valve, so as to quickly supply O_2 to the patient in emergency.

The fourth gas will be connected to the anesthesia ventilator, and will become the driven gas of the ventilator.

The compressed N_2O will go alonely through the decompressor and then enter into the flow meter after the pressure being reduced to 250KPa and 300KPa.

The flow meter adjust all the gases and transport the mixed gas to the vaporizer, then the mixed gas, together with anesthetic, will be sent to the anesthesia cycle through the common gas output to send to patient.

A pressure adjuster must be used when using cylinder. The output pressure should be 400KPa. The variety of pressure from the output port should be not more than 8KPa if the input pressure variety is about 1000KPa. There is safety valve on the output end of the adjuster, if there is malfunction or if the output pressure is too high because of man-made reason, the safety valve will exhaust gas automatically to make the output pressure become rating value. The exhausting pressure of the safety valve is 500KPa~600KPa.

The structural working principle is as in Figure 1.

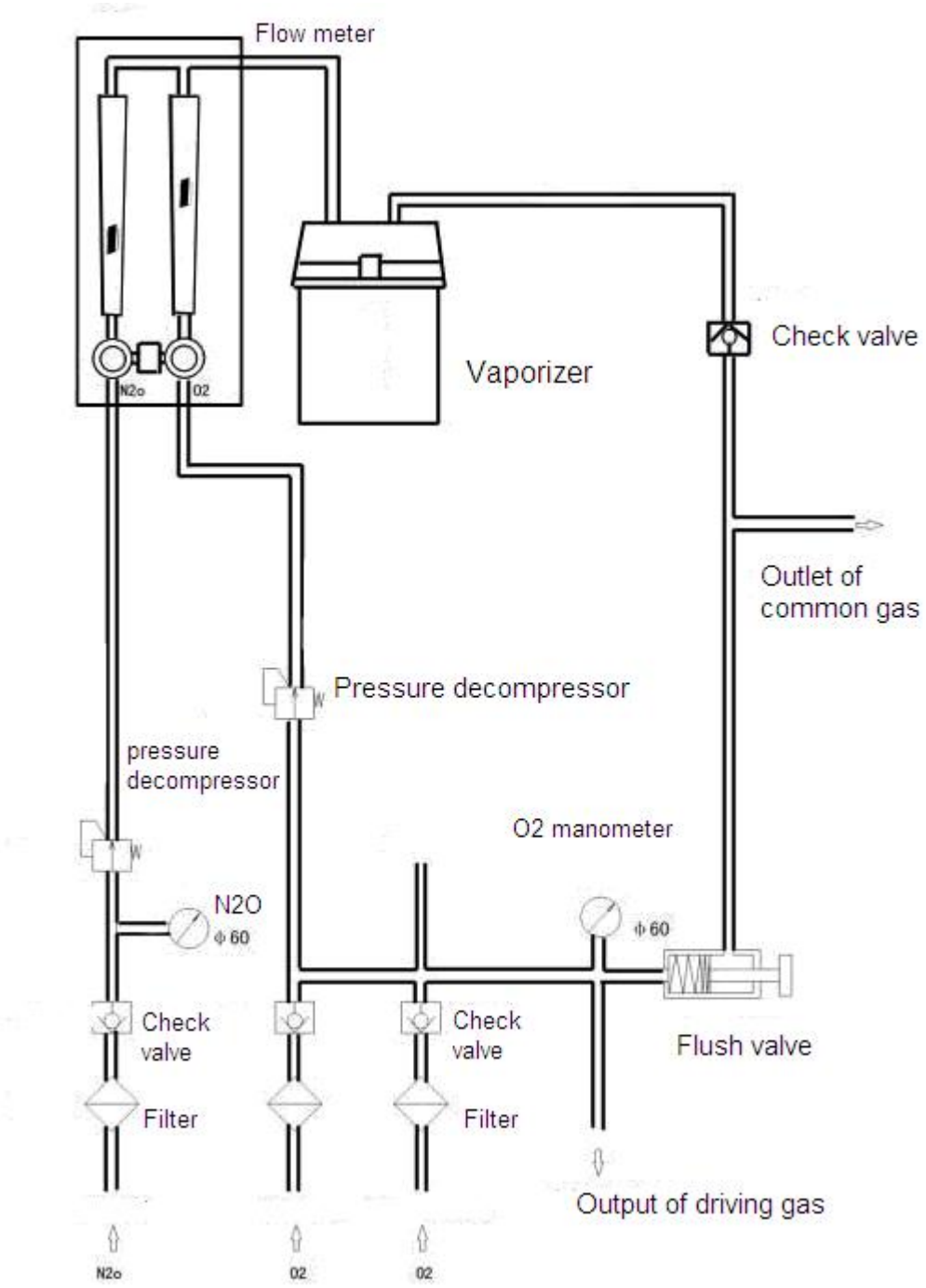


Figure 1Working principle figure of anesthesia unit

The flow meter can not only display the flow, but also adjust the flow of O_2 and N_2O. There is O_2 and N_2O linkage device and N_2O closure device in the flow meter. So that, if only turn on the O_2 valve, the N_2O may be closed, but, if turn on the N_2O valve, there will be no N_2O, if the O_2 valve is closed, this can ensure the O_2 concentration. If turn on both O_2 and N_2O, the N_2O flow will decrease along with the reduction of O_2 flow. If the O_2 pressure entering into the flow meter is less than 200 KPa±50 KPa, the flow meter will automatically cut down N_2O.

2.2 The anesthesia circle

Anesthesia circle, also called patient circle, is a liaison airway device to the patient. The main purpose is to deliver the mixed gas to the patient, and meanwhile, the patient completes the regular respiration like breathing in oxygen and breathing out CO_2 via this circle. It has two modes: Auto and Manual. Under Auto mode, the patient's respiration is controlled by the machine; and under Manual Mode, the patient's respiration is controlled by the doctor by pressing the leather bag that connected to the circle.

The structural working principle is as in Figure 2.

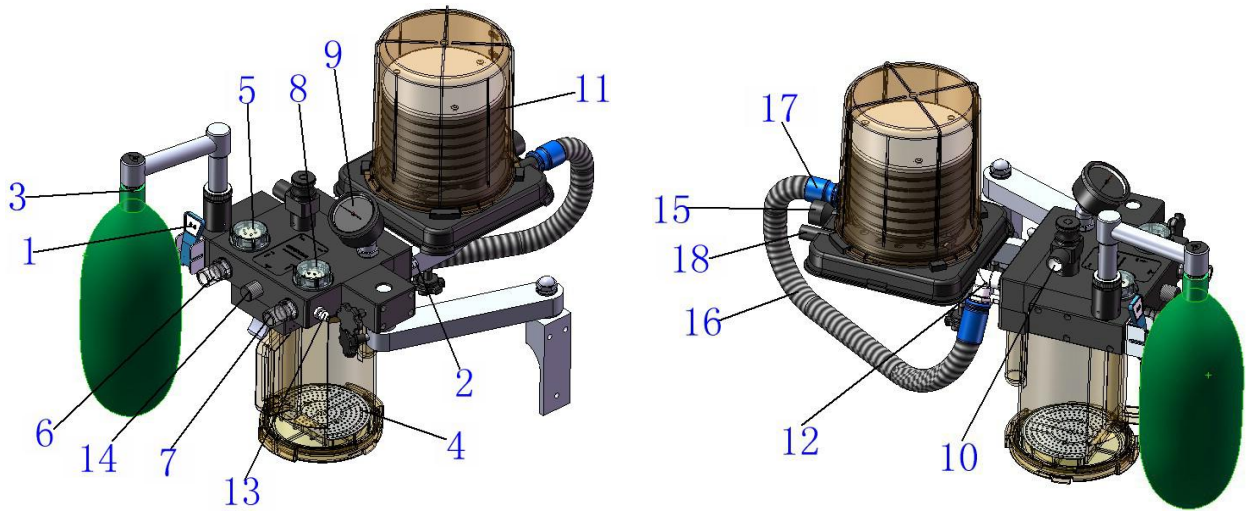


Figure 2. Integrated anesthetic circle

1—Manual/Auto switch	2—Inlet of mixed gas(comes from the mainunit)
3—Connector of leather bag	4—CO_2 absorber(Sodium lime tank)
5—Expiration valve	6—Connector of corrugated tube
7—Connector of corrugated tube	8—Inspiration valve
9—Pressure Gauge	10—APL safety valve
11—Bellows	12—Inlet of driving gas
13—Sampling point of pressure signal	14—Interface of oxygen concentration sensor
15—Outlet of exhaust gas	16 —Corrugated tube
17—Outlet of bellow	18—Inlet of bellows' driving gas

The anesthesia circuit works at "Manual" Mode when switch the "Manual/Auto" valve to "Manual"(see figure 3). Firstly, press the "Flush" valve, the O_2 will go to "3- leather bag" through "2- interface of mixed

gas". When squeezing the leather bag, gas in the leather bag will go to the patient with mixed gas from anesthesia unit through "4-CO_2 absorber", "8-inspiration valve" and "7-Interface of inspiration corrugated tube" . Inspiration valve is a check valve which allow gas flow from cycle circuit to corrugated tube only while inverse current not. The expired gas from the patient comes to cycle circuit and back to the leather bag through "5-expiration valve "and "expiration corrugated tube". The expiratory valve is also a check valve which allows gas flow from corrugated tube to cycle circuit only. Back flow is not allowed. Repeat this again and again.

The CO_2 in expired gas from the patient will be absorbed by sodium lime when it comes to of CO_2 absorber before flowing to expiration valve. While the anesthesia unit send oxygen and anesthetic gas that patient need to the cycle circuit continuously through "2-input of mixed gas".

You can read the airway pressure from pressure gauge each time you press the leather bag. Adjust "10-APL valve" to set the maximum of airway pressure. Spare gas will be discharged when airway pressure exceed the set value.

Figure 3 "Manual" control state of anesthesia cycle circuit

Figure 4. “ Automatic” control state

When “1-manual/auto” valve switch to auto, “11-bellow” works instead of leather bag in “Manual “. Driving gas flows into bellow through “Inlet of bellows’ driving gas” and forms driving pressure at the outside of folded leather of bellow to instead “manual” mode.

The gas patient expirating is more than the gas in the bellow leather. Because patient inspirating gas is not only the gas in bellow leather, there is also fresh mixed gas from anesthesia unit. There is an automatic adjusting device which will discharge the extra gas. You can connect gas purification system to “15-exhaust emission “.

The flow of gas output from the anesthesia ventilator can be read from the flow sensor that is between the expiration valve and expiration corrugated tube when the machine works. You can sampling at “14-inlet of oxygen concentration sensor” when oxygen concentration detection is needed

Connect $EtCO_2$ tube to “6-expiration corrugated tube connection”. Sampling anesthetic gas at “2-inlet of mixed gas”

⚠ **Notice: Silicon rubber contains corrugated tube and leather bag. Operators should tell disposable corrugated tube from reusable one when cleaning and disinfecting. Leather bag is of reusable.**

2.3 Anesthesia Ventilator

CCA-JL820 anesthesia unit applies gas-driving and electric control ventilator.

Oxygen from the output of driving gas forms gas of certain volume which will flows to the anesthesia circuit to drive the movement of bellow and ventilate to patients mechanically.

The anesthesia ventilator adopts high-speed electromagnetic valve, high sensitivity flow sensor , pressure sensor and single chip -control system. It can adjust the parameters such as ventilation pressure, ventilation time, and ventilation volume, etc. When the anesthetic works and the patient have no spontaneous respiration, the Inhalator will take mechanical ventilation to the patient based on the set frequency, I/E ratio, and tidal volume. When the operation ends and the patient regains some spontaneous respiration, the Inhalator will take synchronous ventilation to the patient.

If the anesthesia circle is under Manual mode, the Inhalator will not control the patient's respiration, but it displays real time value of tidal volume, ventilation frequency, and airway pressure.

2.4 Vaporizer

⚠ **Notice: The performance of the vaporizer will be degraded if the vaporizer and the anesthesia unit are unmatched.**

CCA-JL820 Anesthesia Unit is equipped with a special vaporizer which has the variable bypass, and the stroke flow return circle. The vaporizer has an excellent pressure and temperature compensation. When it is off, the entrance and exit to the vaporizer are directly connected, thus the fresh gas does not pass through the vaporizing chamber, which prevent the leakage of anesthetic. When it is on by turning the concentration dial, the fresh gas will be divided by the bypass temperature compensator valve when it flowing through the ON/OFF valve. One of the streams goes into the vaporizing chamber through the pressure compensator, take some anesthetic vapor along with it and goes to the control valve, and then join in another stream which coming directly from the fresh gas inlet, and then goes into the anesthesia circle. Turn the concentration dial can adjust the caliber of valve for controller, which adjust the concentration of anesthetic as well. The main purpose of the pressure compensator is

to prevent the affection on gas output from the fluctuation between the higher and lower pressure in the vaporizer. The ventilation gap of the bypass temperature compensator valve changes automatically along with the change of temperature, which compensates the temperature.

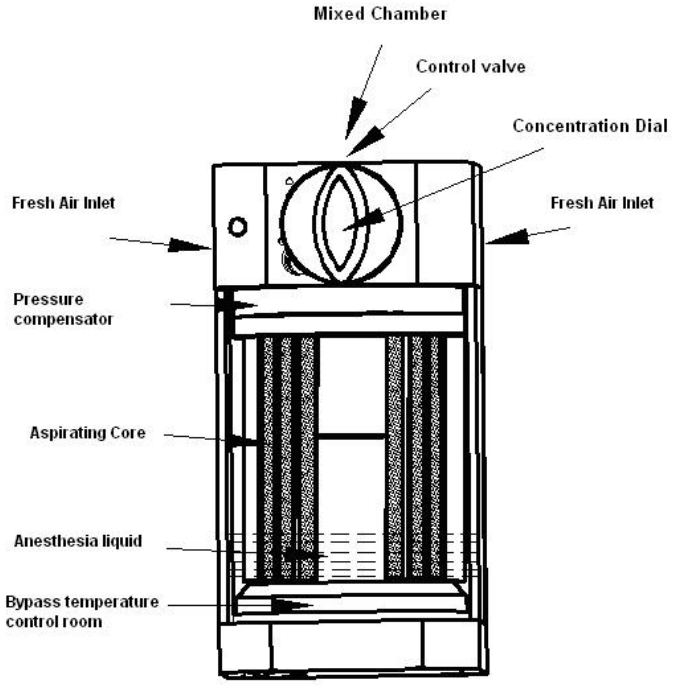


Figure 5. Working principle drawing of vaporizer

3 Technical Specifications

3.1 Work mode: closed-recycling, semi-closed, semi-open

3.2 Gas requirement: Medical O_2, N_2O and air with pressure of 0.35MPa ~ 0.5MPa.

3.3 The error of manometer does not exceed ± (4% of full calibration+8% of actual reading)

3.4 Separate O_2, N_2O and air Special pressure regulators with safety valve. Relieving pressure of the safety valve is not more than 60hPa.

3.5 Indication range of O_2, N_2O flow meter: 0.1L/min~10L/min.

3.6 Assemble the flow meter with an O_2/N_2O ratio-controlling device to ensure that the O_2 concentration is not less than 21%.

3.7 Oxygen Flush: 25L/min~75L/min

3.8 The adjusting range of anesthetic concentration in the vaporizer: 0~5%, within an error of ±20%

3.9 Ventilator

3.9.1 Ventilation mode: IPPV, SIPPV（VCV）, SIMV, PEEP, MAN

3.9.2 Respiration frequency: 1~99bpm, allowance error is ±15%

3.9.3 IMV ventilating frequency: 1~12bpm, allowance error is ±15%

3.9.4 I/E ratio: 4：1, 3：1, 2：1, 1：1, 1：1.5, 1：2, 1：2.5, 1：3, 1：4;
allowance error is ±15%

3.9.5 Tidal volume range: 0mL~1500mL,
allowance error: For less than 100ml: ±20 mL; others: ±20%

3.9.6 Ptr range: -10hPa~10hPa;
allowance error: ± 50 Pa for -4 hPa ~ 10 hPa, others: ± 200 Pa

3.9.7 Conversion time of control respiration and assistant respiration: 6s,
allowance error: +1s,-2s

3.9.8 Time for Inspiration Plat: 0 ～ 1S ; allowance error: ±10%

3.9.9 PEEP: 1 ～ 10 hPa

3.9.10 Sigh: one deep respiration of each 80 respiration,
inspiration time is 1.5 times of set value

3.9.11 Maximum safe pressure: no more than 60hPa

3.9.12 Pressure limitation: 1 ～ 60 hPa, allowance error: ±2 hPa

3.9.13 Airway pressure alarm:

Upper limit: 0 ～ 60 hPa, it will alarm immediately once the airway pressure up to the alarm value in a respiration cycle. Pressure value will display in red when it alarms.

Lower limit: 2 ～ 50 hPa, lower limit alarm delay: 4~15s, pressure value will display in yellow when lower limit alarms. Allowance error: ±2 hPa or ±15%(choose the bigger one)

3.9.14 Tidal volume alarm:

alarm range of upper limit: 0 ～ 2.00 L, allowance error: ±20%

alarm range of lower limit: 0 ～ 1.80 L ,allowance error: ±20%

It will alarm immediately once the tidal volume up to the alarm value in a respiration cycle.

3.9.15 Alarm will sound when oxygen pressure up to 200 KPa±50 KPa,it will display low pressure of gas.

3.9.16 It will alarm when the airway pressure keeps no less than 15 hPa±1 hPa in 15s±1s,it will

continuous display high pressure.

3.9.17 Power supply alarm:

a) It will alarm when the input power supply is less than AC190V±5V, and it will display low power.

b) It will alarm when the voltage of battery is lower than DC10V±1V, and it will display low battery power.

c)Alarm will sound when both of the power supply and batter stop supplying, the alarm will sound for more than 120s

3.9.18 Working status of storage battery: The rated output voltage of the storage battery is DC 12V.

The anesthesia unit can work continuously for more than 30 minutes when the battery is abundant. You can hear a sound last for 30s that remind you that abundant battery is used.

Press the shutter for 2s, current voltage of the storage battery will display at the lower right of the screen.

3.9.19 The silence time is less than 120s after it alarms. Light alarm will not stop until the alarm has been cancelled.

3.9.20 Parameters of the ventilator: tidal volume, ventilatory capacity, airway pressure, oxygen concentration, total respiration frequency, self-breathing frequency, airway resistance, lung compliance, system power.

3.9.21 The minimum tidal volume that the machine can detect is 50ml, resolution is 10ml.

3.9.22 Press silence shutter for 2S,the alarm menu will display,you can check current alarm and the reason of last alarm.

3.9.23 All displayed testing value conditions are on STPD condition.

3.9.24 All the alarm limit are set randomly before leaving the factory, you should reset them according to the needs before using.

4 Size and Weight

4.1 Size: 620 mm×630 mm×1300 mm

4.2 Weight: 70 Kg

5 Installation and Debugging

⚠**Notice: The installation, debugging, checking and operating should performed by qualified**

specialist. The machine has been debugged by specialist before leaving the factory, so there is no need debugging in case of any unexpected malfunction or damage.

5.1 Preparation before installation

1）Ensure the anesthesia unit and its accessories are in good condition. Keep the packing box and the shockproof pad well so as to use next time.

⚠ **Notice: If there is any damage found when opening the packing, inform the forwarder immediately and lodge a claim.**

2、Read the user's manual carefully and familiar with the working principle , structure character and the control board of the machine

3、Check the compressed O_2 and N_2O and make sure the pressure is 0.35 ～ 0.5 mPa. If cylinders are used for supplying gas, make sure the gas is sufficient and the pressure regulator is in good condition and installed correctly.

4、Check whether the power supply matches the voltage that marks on the machine. It should be grounded well. Make sure the storage battery has been installed correctly.

5.2 Installation

1、Install the four truckles. The two truckles with brakes should be installed in front while the rest installed at back.

2、Pull the anesthesia unit to the location you want and step on the brake to make the anesthesia unit can not move randomly.

3、Install the vaporize on its bracket, tighten the hexagon screw.

4、Fixed the integrated respiration circle on the bracket that is on the down left of the machine. Then connect the bellows and the leather bag to the respiration circle.

5、Install CO_2 absorber 1）Add proper soda lime to the absorber before power on the machine. Then seal the absorber and the cab according to below. You should pay more attention to parts that should joint together. Namely, make "6" and "5" in figure 6 at the same location. There are totally four slots on the absorber body, namely "1","2","3","4" marked in figure 6.

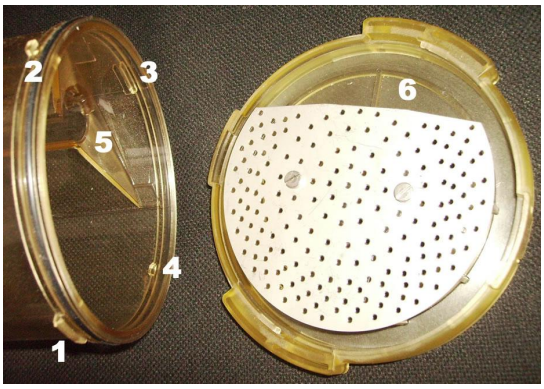


Figure 6. Before Installation

Figure 7. Before Installation

2）Adjust the location of the four slots to make them block in corresponding slots on the cab completely.

Figure 8. Before Installation

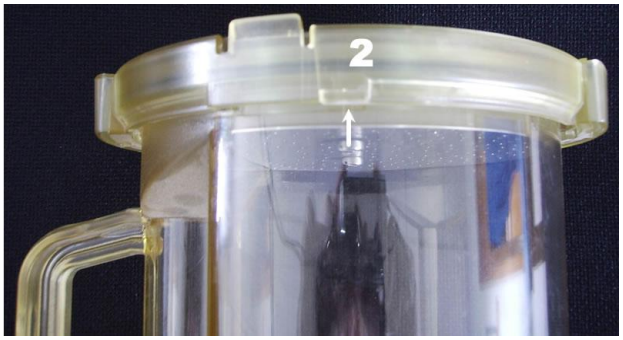


Figure 9. After Installation

3）Figure 8 and figure 10 shows the state when all slots haven been blocked completely. Rotate part “7” in figure 10 clockwise and check if part”2” is at the location showed in figure 9. You can hear “click” which shows the slot has been locked. At this time, you can not rotate part”7” clockwise any more.

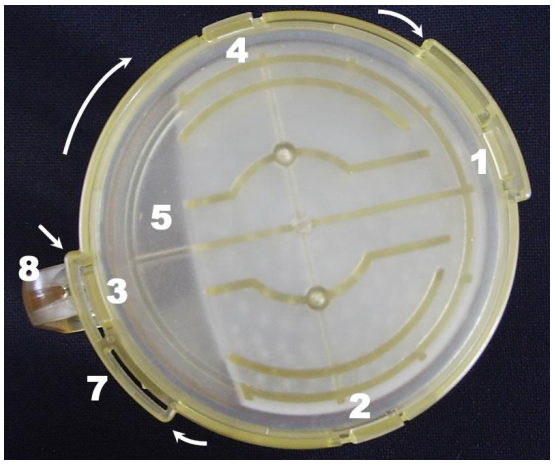


Figure 10. Before Installation

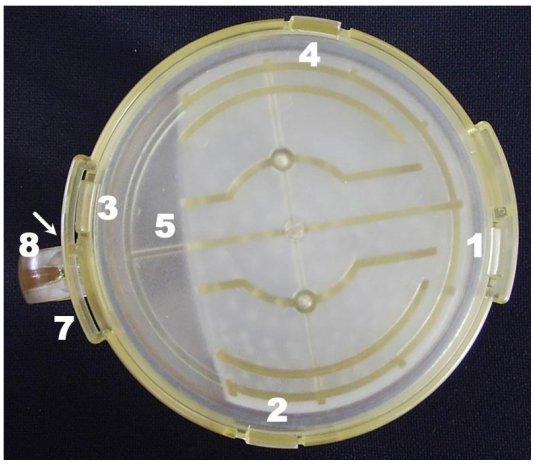


Figure 11. After Installation

⚠ **Notice: Filter and filter sponge must be installed before adding soda lime.**

⚠ **Notice: Base sealed ring and filter sponge must be replaced periodically.**

6、Installed the storage batter. Connect the ventilator to the respiration circle with corrugated tube.

7、Connect the rest two corrugated tubes to the Y shape tube. And the other side of the two tubes to the inspiration valve and expiration valve separately.

8、Before connecting the Y tube to the leather bag or test lung, connect the bigger port of the flow sensor to the output of the common gas while the other port to test lung or leather bag. Please pay more attention to the direction of sampling tube, blue tube should be close to the smaller port

9、Connect the anesthesia machine to the compressed O_2 and N_2O.

⚠ **Notice: Oxygen tube is blue ,5×8 mm; N_2O tube is orange , 5×8 mm;**

10、Insert the power socket and power on the machine.

⚠ **Notice: The machine can keep balance if it lean 10 degree on horizontal condition and normal collocation. The stability of the machine will be reduced if other device has been placed on.**

5.3 Preset

1、Check if pointers of each pressure gauge on the anesthesia unit are all point at zero.

2、Check if the readings on each pressure gauge on anesthesia circle are all zero. If not ,adjust the zero bolt to make it zero with screw driver.

3、Check if readings of the two pressure regulator is in the range of 0.35 ～ 0.5 MPa. Check if the readings of the two manometers on the front panel are the same with those manometer readings on the pressure regulator after connecting the compressed O_2 and N_2O.

⚠**Notice: Using the pressure regulator correctly.**

A. Firstly, connect the pressure regulator to the cylinder and fixed it up.

B. Ensure the pressure regulator is closed (rotate the knob to the location that is most loose)

C. Open the valve of the cylinder

D. Tighten the adjusting knob clockwise until the pressure up to the required value.

E. Close the valve of the cylinder firstly after operation. Press the flush switch to remove the rest pressure. Rotate the adjusting knob of the pressure regulator to the loosest location

4、You can see the stuff float move flexibly without any obstacle when turning the regulating knob of flow meter. The stuff float does not twitter after adjusting the flow meter.

5、Switch the “Auto-Manual” valve to “Manual” and block the Y shape tube. The leather bag (3L) should be filled in 3~5s when pressing the “Flush” switch. And there are readings on the manometer that is on the integrated respiration circle.

6、Switch the “Auto/Manual” to “Auto”, power on the machine. Set parameters as below:

Tidal volume: 0.50L; ventilating frequency: 10 bpm; I:E: 1:2 ;

You can see that the test lung or leather bag will rise and fall according to the ventilating frequency you set. And inspiration valve and expiration valve up and down without any obstacle.

5.4 Acceptable test after installation and debug

1、Airproof performance test of pressure duct

Close the adjusting knob of flow meter, open the gas source, pressure of driving gas should be the same with the compressed oxygen. Readings of O_2 manometer and N_2O manometer should be about 0.35MPa. Then, cut off the compressed gas, readings on the three manometer (on the front of the machine) should not reduce in 5 minutes.

2、Airproof performance test of low pressure duct

Switch the “Auto-Manual” to “Manual”, block up the Y shape tube. Press “Flush” valve to supply oxygen. Then you can see that the leather bag will inflate because of inflation. It will stop supplying gas when the airway pressure ups to 3KPa, and you will see that the reading of the manometer will reduce to 0.4KPa in one minute.

3、Test of O_2 to N_2O function

Connect the anesthesia machine to the compressed gas source and the output of the machine to the atmosphere. You should observe :

① Turn the adjusting valve of the flow meter, N_2O flow should be off when you turn on the O_2 flow only.

② O_2 will open at the same time when you turn on the N_2O valve only.

③ When O_2 and N_2O are turned on at the same time, turn down the O_2 and the N_2O will turn down subsequently until N_2O has been turned off. The flow must be stable under normal ventilation. The ratio of O_2 and N_2O is 1：2

4、Test for N_2O automatic cut-off and O_2 alarm

Connect the anesthesia machine to the compressed gas source and the output of the machine to the atmosphere. Open the O_2 valve and N_2O valve of the flow meter. Reduce the pressure of compressed O_2 gradually, you can see from the O_2 manometer that N_2O pressure reduce (0.2MPa± 0.05 MPa) with the pressure reduction of O_2 until the N_2O has been cut-off completely. And this time, the alarm will sound.

5、Tidal volume test

Close the O_2 valve and N_2O valve of the flow meter. Set the ventilation frequency as 20 bpm, I:E

as1:2.Adjust the tidal volume and you will see the tidal volume reading becomes stable after 3-4 ventilation. The adjusting range is no less than 0 ml ～ 1500 ml. If test lung is used, you can observe that the maximum error between tidal volume after stable and the readings of test lung is no more than 20%.

6、Test for alarm function

This test should be done every time after you power on the machine and before using.

Test condition: Close the O_2 valve and N_2O valve of the flow meter. Set the ventilation frequency as 20bpm, I:E as 1:2.

a）Set the upper limit of airway pressure as 4 KPa. Block up the outlet of the Y shape tube and turn up the tidal volume when the machine is working normally. Check if it there is any sound and light alarm when the airway pressure ups to the upper limit. At the same time, it should change to expiration phase.

b）Turn down the tidal volume, if will alarm when the airway pressure up to the set value and last for 4~15s.

c）Adjust the tidal volume, it will alarm when the tidal volume up to the upper limit/lower limit of tidal volume and last for 4~15s .

d）Power malfunction alarm: unplug the power socket and the wire of storage battery(not switch the power switch to “OFF”), then it will alarm immediately, the alarm should sound not less than 120 s.

e）The silence time of sound alarm is no more than 120s. Sound and light will continues unless the alarm has been cancelled.

7、Power delay test

The anesthesia unit should work back up with the storage battery after unplugging the power plug of the machine (not switch off the machine). There will be a battery mark display on the top of the screen and a hint sound.

6 Usage and Operation

6.1 Preparation and Examination before Operating

6.1.1. Check the gas source:

① Check if the O_2 and N_2O is sufficient.

② Check if the output pressure of the cylinder or central gas supply system is in the range of 0.35～0.5MPa.

③ Check if tubes that connects the gas source to the machine has been connected properly.

6.1.2 Check the power supply:

① Check if the voltage of the power supply matches the voltage that labeled on the back of the machine.

② Check if the machine is grounded well and the power socket has been connected well.

6.1.3 Examine the using record and disinfect record of the anesthesia unit. Make sure the machine is of good performance.

⚠**Warning: Avoid working without thorough disinfection. Never use the anesthesia unit with safety potential.**

6.1.4 Examine the CO2 absorber:

Clean away the used soda lime and wipe the inside of the absorber. Then fill the absorber with fresh soda lime.

6.1.5 Adding drug into the vaporizer. Steps as below:

a. Examine the dial of the vaporizer. The dial should be at “0” location when adding drug into the vaporizer. Namely, the vaporizer should be at off state.

⚠**Warning: The drug is of high volatility. Lash and vibration when the drug flows to the vaporizer will make a large and disorder vapor pressure in the vaporizer. Anesthetic vapor may pour out together with the drug liquid if the dial is not at “O” location. And this will cause unpredictable consequence.**

b. Check if the anesthetic is the right one that the vaporizers allows and the validity of the drug. Clean and disinfect the doser.

⚠**Dangerous: Chemical reaction will occur when different anesthetics mixed together. This will endanger the patients’ safety. So it is prohibited to use anesthetic mixed of different drug.**

⚠ **Warning: Each vaporizer is calibrated for special anesthetic because different anesthetic has different evaporation characteristic. The output concentration of vapor may not accurate if the anesthetic is not what the vaporizer specified.**

c. Turning the adding knob to open the doser. Then add the anesthetic slowly via the doser port with injector. The liquid surface should not exceed the maximum level of the monitoring window.

⚠**Notice: You should add the anesthetic slowly. Otherwise, the lash and vibration will**

accelerate the volatilization of the anesthetic.

d. Tighten the adding knob in time after refilling anesthetic in case of any volatilization.

e. After refilling drug, wait for 10 min at least before using.

⚠**Notice: Though safeguard has been set up, the vaporizer must be closed when it is not used.**

6.1.6 Imitating the method of ventilating to patients, press the “Flush” valve to inflate to the anesthesia loop to remove the exhaust gas in the loop and the respiration tubes.

6.1.7. Adjust and setup the parameters of the anesthesia unit

6.2 Usage

6.2.1. The most critical operation is the supply of anesthetic concentration and the management of breath. There are two ways to manage the patients’ breath: Manual and Auto.

Pay more attention to the readings of each parameter during operation to meet the patient’s need. Generally, the patient’s condition is the most fundamental basis while the readings of those meters are just a reference.

6.2.2. Estimation of the dosage of drug

Dosage（mL）≈the output anesthetic concentration of the vaporizer（Vol％）×fresh airflow（L/min）×anesthesia time(hour)×3

This formula is summarized from experience. For example: the output concentration of anesthetic from vaporizer is 1.5 VOL%, the set gas flow which is the sum of O2 and N2O flow is 2L/min, the predicted operation time is 8 hours, then, the dosage of anesthetic should be not less than 1.5 * 2 *8 * 3 = 72 mL.

For sake of safety, supply more anesthetic to the vaporizer than the estimated quantity.

6.2.3 Installation of vaporizer: Assemble the vaporizer to the seat of unit support bracket by M10 hexangular wrench. Make sure the vaporizer is vertically assembled .The lean should be no more than 45°.

6.2.4 Check whether oxygen is used as carrying gas for the vaporizer .The ventilator must be on off position.

6.2.5 When adding anesthetic, it should be about 135ml between the maximum of liquid scale and the minimum of liquid scale

6.2.6 Pressure at the input of pipeline should be 0.35MPa,and flux should be less than 60 L/min. It is suggested that more than 2L/min flux should be used during ventilating and 0.7-1 L/min oxygen flux during manual cycling lock anaesthesia. So as to ensure there is sufficient oxygen for patient.

6.2.7 The way to adjust the concentration of the drug: turn the dial to the concentration you want.

⚠**Notice: It is sure that the output concentration is in the range of allowance error only on condition that the airflow is in the range of 0.5~10L/min and the output concentration is 0.5 ～ 5 Vol％ . The vaporizer is prohibited from using in the range of "OFF"/"O" ~"the first scale.**

6.2.8 Check whether oxygen is used as carrying gas for the vaporizer .The ventilator must be on off position.

6.2.9 Shut off the vaporizer before withdraw anesthesia. Turn the concentration dial to "0", make sure the dial is ejected and the vaporizer has been locked.

⚠**Notice: When the vaporizer does not match, it will cause leakage or anesthetic gas concentration changed. Even lower the performance of the machine or invalidity.**

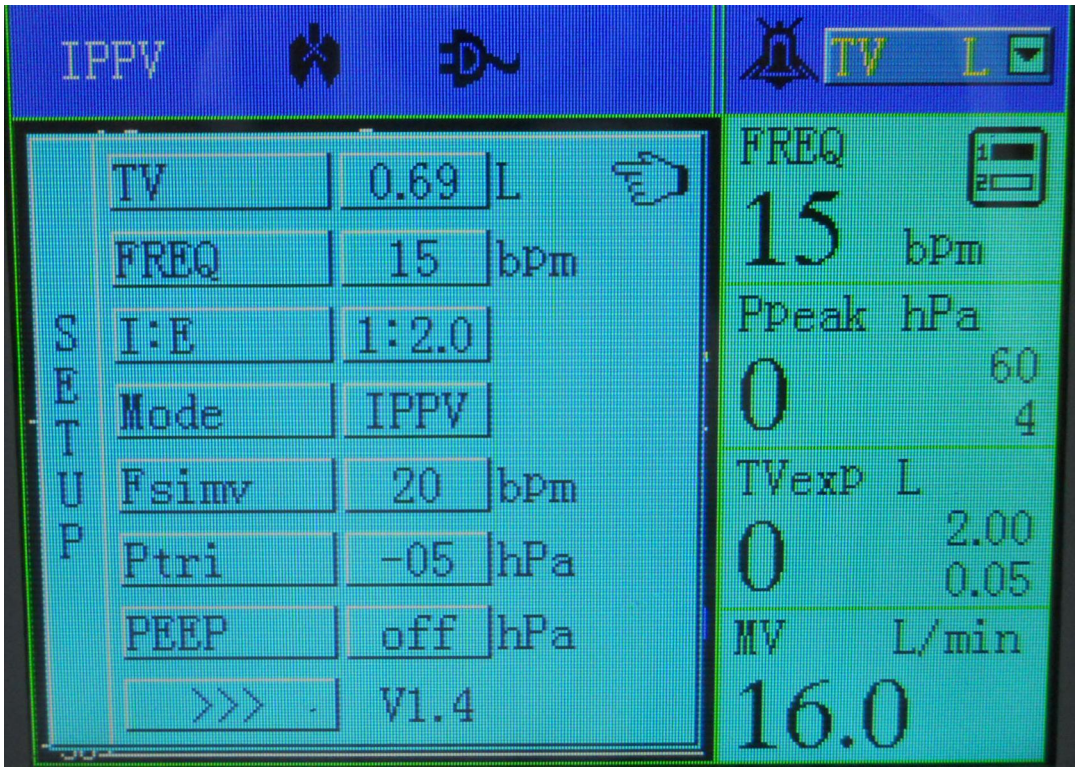
6.2.10 Low oxygen alarm and N_2O cut-off device are to cut off the N_2O when it can not work normally because of the pressure reduction of medical O_2.

6.2.11 A heavy repair is needed after 2 years usage, including the vaporizer.

6.3 Usage of the ventilator

6.3.1 Operation

6.3.1.1 Power on: Power on and it will display as below:



At this interface, you see and set the parameter, press “ENTER” to make the TV ready to be adjusted, then adjust it by press “+” or “-”. Finally press “ENTER” to make the adjustment work. If you do not want to adjust TV, just press “MENU” or just wait for about 10 seconds, the machine will enter into work interface and work according to the parameters already set.

6.3.1.2 Interface 1: after entering into work status, the LCD will display as below:

1. Frequency: refers to the respiration frequency, it is the auto frequency when it works in IPPV mode.
2. Peak value: the maximum airway pressure of each breath cycle.
3. Tidal Volume: The tidal volume of expiration phase
4. MV(ventilatory capacity) : accumulate sum of the tidal volume in 1min.

In this interface, IPPV indicatesthe work mode of the machine, the iconlung indicates the inspiratory and expiratory status, the icon of power indicates the power supply status (DC or AC), the waves show the Paw-T and Flow-T.

6.3.1.3 In the interface 1, press “+” or “-“, the machine will enter the interface 2 automatically, showing as below:

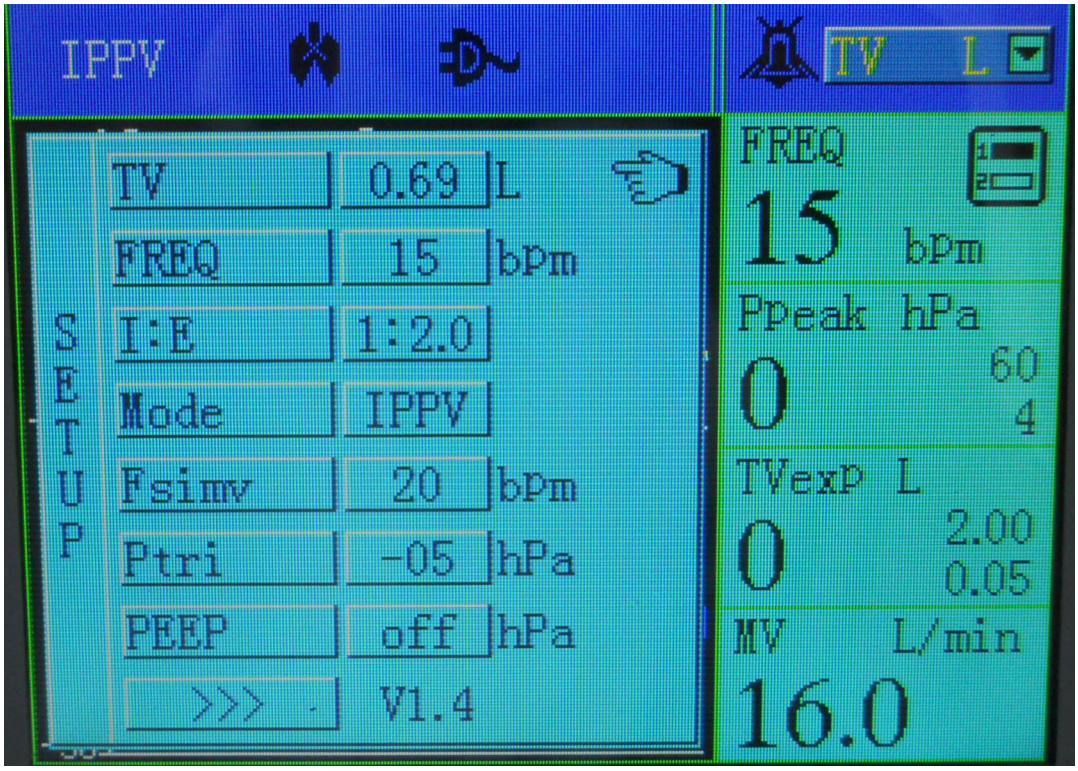
In this interface, the parameters showing in the LCD are:

1. Inspiratory Rate: the rate of the patient’s breath detected by the machine
2. I:E: the ratio of inspiratory time to expiratory time.
3. Airway resistance
4. Lung conformability

Press “+” or “-” again, the system will switch between interface 1 and 2 automatically.

6.3.1.4 Setup interface 1: In the work interface, press “SELECT, the machine will show interface 1 as

below:



The sequence of parameter setup is as below:

1. TV: 0.05~1.5L
2. Frequency: 1~99bpm
3. I:E: 4:1.0~1:4.0
4. Mode: IPPV, SIPPV(VCV), IMV, SIMV, MAN
5. SIMV Frequency: Under the mode of IMV, SIMV, from 1 to 12bpm
6. Ptr.: -10hPa~+10hPa
7. PEEP: 1~10hPa
8. >>>: Enter into interface 2

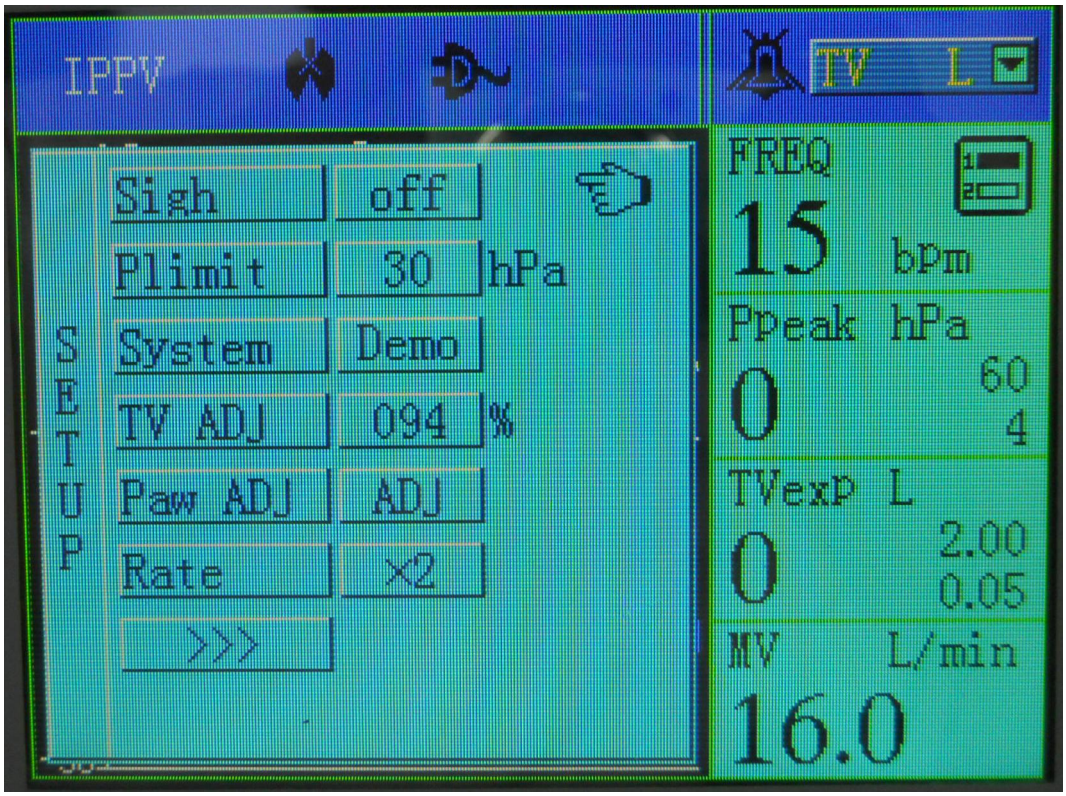
Method of setup: Press “+” or “-“ to move the hand-shape cursor to the item you want to select, press “ENTER”, the selected item will change into different color. Then press “+” or “-“ to set the parameter, and finally press “ENTER” to finish modifying the parameter.

6.3.1.5 Setup interface 2: in the interface 1, press “>>>”, the system will automatically enter into interface 2, showing as below:

The sequence of parameter setup in this interface is as below:

1. Inspiratory time: set this parameter as the expiratory stop time: from 0 to 1s
2. Upper limit of pressure: 0~60hPa
3. Lower limit of pressure: 2~50hPa
4. Reservation: for the future upgrade of software
5. Reservation: for the future upgrade of software
6. Upper limit of TV: 0.05~2L
7. Lower limit of TV: 0.05~1.8L
8. >>>: Enter into interface 3.

6.3.1.6 Setup interface 3: in the interface 2, press “>>>”, the system will automatically enter into interface 2, showing as below:



The sequence of parameter setup in this interface is as below:

1. Sigh: 80~150
2. Pressure limit: 10~60hPa
3. System Setup: Setup of waveforms, there are 4 selections:

DEMO: The system is in DEMO status

REAL-TIME: The system is working

FILLING: The waveforms of pressure time and flow speed are filled with color

BLANK: The waveforms of pressure time and flow speed are blank

4. TV calibration: Adjust TV coefficient for calibrating
5. Airway pressure calibrating: Pressure 0 calibrating
6. Coordinate Ratio: Set the magnification ratio of vertical coordinate of the pressure time and flow speed wave forms.
7. >>>: Quit from the setup interface to the work interface

All the setup method is the same to the setup interface 1, in the setup interface, press “SELECT” to quit from setup interface to the work interface. Or the system will automatically return to the work interface after 10s of no operation.

6.3.1.7 Keypad Operation:

There are altogether 6 keys on the keypad, they are “MEDE”, “SELECT”, “SILENCE”, “+”, “ENTER”, “-”,

functions of each key are as below:

“MODE”: Switch between SIPPV and MAN.

“SELECT”: Enter quit the setup interface, to modify any parameters.

“SILENCE”: If there is alarming beep, press this key can make the machine keep silent for 100s. If you press the key for 2s, there will be alarm menu, by which you see the reasons of all alarms. Then the menu will disappear 5s later.

“+”: In the setup interface, you can modify the parameters by press this key. In the work interface, you can switch between different interfaces by pressing it.

“ENTER”: In the setup interface, press this key to confirm and save the modification. In the work interface, press this key for 2s, you can see the voltage of the battery on right bottom of the screen.

“-”: In the setup interface, press this key to modify the parameter. In the work interface, you can switch between different interfaces by pressing it.

6.3.2 SIPPV

SIPPV is the mode that used mostly. The mode mainly adapts to patients without spontaneous breath or patients whose breath is weaken and intermittent. If the patient without spontaneous breath, the ventilator will perform IPPV mode namely control breath according to pre-set parameters. When spontaneous breath continues, the ventilator will perform SIPPV mode namely assisted breath. The switch interval between IPPV and SIPPV is 6s.

Test lung must be connected to the Y shape tube when preset the working parameters, steps as below:

1）Connect the anesthesia machine to the gas source and power on. Make sure the machine works in SIPPV mode

2）Adjust the SIPPV frequency

3）Select the I;E according to the patient’s need.

4）Set the tidal volume. For adult, you can set as 10ml/KG firstly then adjust according to the condition of the patient.

5）Adjust the airway pressure limit carefully according to the airway pressure peak value. And the airway pressure limit should be more than the airway pressure peak value.

6）Set “Ptr” : Ptr will supply synchronized ventilation signals to the anesthesia unit when patients had recovered spontaneous breathing. In general, Ptr can be set as 1 hPa less than the minimum of

airway pressure when there is no spontaneous breathing.

7）Adjust “PEEP” : Judge whether the PEEP has been set properly according to the minimum airway pressure that the manometer display after breathing

The test lung can be disassembled after above setup. Connect the anesthesia unit to the patient after remove the test lung.

After connect the anesthesia unit to the patient, carefully check patient’s state and the fluctuation of chest. Adjust the ventilator in terms of patient monitor and artery blood gas analyzer so as to reach the best effect of ventilation.

⚠**Notice:Tidal volume is affected by factors such as frequency of IPPV, I/E ratio and so on.**

⚠ **Notice: “Spontaneous Breath Frequency” displays the times of breath in previous minute .The display will renew every minute.**

⚠**Notice: “Total Breath Frequency” displays the sum of actual spontaneous breath times and actual compulsive breath frequency in previous minute. The display value is not always equal to the sum of “Frequency of IPPV” and “Spontaneous Breath Frequency”. The display will renew every minute.**

6.3.3 IPPV Mode:

The mode only adapts to patients without spontaneous breath.

Enter into IPPV mode in terms of 6.3.2. Settings of parameters is the same as 6.3.2

PEEP function and Sign function can also be selected (or not selected) in this mode

6.3.4 IMV Mode:

The period of IMV depends on the setup of “Frequency of SIMV”. The mode can gradually reduce dependence of patients on ventilator. Patients can gradually reduce the dependence on the anesthesia ventilator and helps patients to separate from ventilator. The instrument performs IMV ventilation each certain time. Patients can breathe spontaneously during the interval.

The period of IMV depends on the setup of “Frequency of SIMV”

1）Enter into SIMV according to 6.3.2

2）Adjust frequency of IPPV, I/E ratio, Tidal Volume, Pressure Limit, Ptr and etc., so as to meet the best breath indices for patients

3）”Ptr “ should be adjusted from “0 hPa” to “－10hPa” gradually in order to exercise and control the ability of spontaneous breath and breath volume. The adjustment of tidal volume for this mode should be more carefully. Because under the influence of Ptr, the value of tidal volume may change breath parameters of patients. For example, time of inspiration, breath frequency, tidal volume and other related life indices.

4）PEEP function and Sign function can also be selected (or not selected) in IMV mode.

6.3.5 AC/DC

The machine will switch to DC status and work according to the preset parameters if the AC power supply has been cut off. If the storage battery has been cut off as well, the machine will stop supplying gas except for fresh airflow. At this time , the machine should be switch to “Manual” state.

6.3.6 Pressure maintenance

Pressure supplied by the medical tube will maintain after the anesthesia unit stop supply gas.

6.4 Shutdown Operation

The anesthesia machine can be removed only when the patient regain his spontaneous respiration after operation and all the life indices of the patient reach relevant standard,.

Firstly, take off the Y-piece connecting to the patient, check that the spontaneous respiration is in good condition. And then, take off the oxygen mask and pull out the spile in the windpipe. And then, follow the procedures described in the coming text:

1）Press” Flush” valve to disperse the waste gases in the circle;

2）Turn off O_2 cylinder, N_2O cylinder or pull off the joint from the central gas system;

3）Turn on the O_2 ,and N_2O control valve to discharge the residential compressed gas in the machine, and turn them off when pointer in the O_2 and N_2O manometer reaches Zero position;

4）Power off the machine and plug off the power plug;

5）Take off the parts that need to be cleaned and disinfected;

6）Fill in the record of operation.

7. Daily Maintenance

7.1 Cleaning

Wipe off the dust on the crust with a clean and soft cloth moistened with water and standard detergent, and then dry it with another dry and soft cloth. During cleaning, never let any liquid run into the machine (including inhalator, monitor, etc.), or it will damage the machine even cause current leakage resulted from short circuit.

7.2 Disinfection

The parts that contact to the patient, such as respiratory pipelines, leather bag, inspiratory valve, expiratory valve, impeller of flow sensor, can be taken off to have it cleaned and disinfected. Wash the inside wall of the tubes with soft detergent, especially pay attention to the cleaning of phlegm, blood, oil, and other remains, and then clean them with water. These parts should be soaked in 70% medical alcohol for 1 hour and then disinfect it with the following method:

Method 1: Leave the cleaned respiratory pipelines, mask and the other parts soaking in disinfectant for 30~60 minutes (Note: Silica gel ware is damageable for being over-soaked). After soaking, flush the inside and outside of the tubes with sterile water or distilled water, and hang them to dry.

Method 2: Put the cleaned respiratory pipelines, mask and the other parts into disinfectant tank of ethylene oxide for regular disinfection.

If the patient is an infector of epidemic, soak the parts in 70% medical alcohol for another 1.5 hour and then repeat the above disinfecting procedure.

⚠ **Caution: The waste liquid from anesthesia unit may infect diseases and pollute environment, therefore, follow the relevant regulations or requirements strictly when disposing them.**

Silica gel parts are: mask. corrugated tube, signal sampling tube, connector of gas circuit and O sealed ring.

7.3 Daily Maintenance

Parts that have been cleaned and disinfected should be connected to the machine in time. Then check

each performance of the machine according to the Chapter 5" Installation and Debugging" to ensure each performance is well.

7.4 Filter parts maintenance

Filter parts that need cleaning and replacing includes the sponge washer(at the air interface of the machine) and fabric filter at the interface of O_2 and N_2O . It is better to replace the sponge washer after used for 10 times. For fabric filter, just disassemble and clean them.

8 Troubleshooting

Failure	Cause	Solution
Leakage in the anesthesia circuit	The CO_2 absorber was not installed properly.	Install it properly.
	Connector of corrugated tube loose or break	Connect the connector well or replace the corrugated tube.
The shuttle is not flexible	The inside has been fastened due to long time use	Daub some Vaseline to inside of the switch
The tidal volume is not sufficient	The pressure of driving gas is less than 0.35MPa	Increase the pressure of the compressed gas source.
The tidal volume is not stable	The flow sensor loosen	Tighten the flow sensor
	The plug of flow sensor loosen	Connect the plug again or replace it.
	The flow sensor is broken	Replace the flow sensor
	Vapor remains in the flow signal.	Replace the flow sensor or disassemble the flow senor and dry it in nature air.
It is difficult to refill the drug	Refilling knob is not open	Open the refilling knob
	The speed of refilling is too quick	Refill slowly
Readings on manometers are not correct	Low pressure of compressed gas	Adjust the pressure of gas source
	Air leaks from the tubes	Check the connector of trachea and replace if it is broken
	There is something wrong with the pressure regulator	Adjust or replace it

Failure	Cause	Solution
Lower limit of airway pressure alarms continuously.	Power of storage battery is insufficient after the AC power has been cut off.	Replace with a storage battery with sufficient power
	The pressure of O_2 cylinder is not enough. Low pressure of oxygen	Check the inner pressure of the O_2 cylinder and replace the cylinder if needed.
	Failure of pressure regulator or oxygen pipe	Adjust or replace the pressure regulator
Airway pressure alarm. airway pressure limitation and upper limit of airway pressure alarm continuously	Improper adjust of tidal volume and I:E	Adjust the I:E and the tidal volume
	The patient's respiration collides with the inhalator under Assistant or Intermittent Indication mode	Adjust the Ptr
	Improper of the pressure upper limit	Adjust the pressure upper limit
	Tracheal spasm or secretion of the patient make gas-resistance goes up.	Suck out phlegm or use detergent that can wipe off phlegm
The alarm sound continuously	Tidal volume is too low because of leakage in the pipe and block in air tube.	Suck out phlegm or use detergent that can wipe off phlegm
	There is something wrong with flow senor	Repair the flow sensor
	The drainage tube of the flow sensor break off	Connect the drainage of the flow sensor properly.
	The storage battery is not installed after AC power supply has been cut off	Install the storage battery that with sufficient power
	The storage battery has been exhausted or broken	Replace the storage battery
The storage battery works when the AC	The AC power socket break off	Plug the power socket again.
	Fuse has been melted	Replace the fuse.

9 Safe Guard and Accident Treatment

1）In order to prevent mixing up the O_2 ,N_2O, and air, we apply different diameters and colors to the

tubes. O_2 tube is 8mm; blue, and N_2O tube is 6mm, and we also paint different colors to the decompressor marks, which for O2 is blue, N_2O is gray.

2）Colors of inner tubes:

O_2 ---- Blue

N_2O----Orange

Mixed gas------Light blue or colorless and transparent

3）Do not exceed the maximum scale when refilling drugs

4）The inclination of the vaporizer cannot be more than 45°. Press down the Zero Lock button before turn the Anesthetic Concentration Dial. DO NOT use too high pressure on vaporizer, or damage might be caused. Do not dismount the module at random, precise testing has been conducted before leaving factory. Do not apply disinfection process, instead, use compressed O2 method to blow it to dry. If any problem occurs, it should be solved by specialized maintenance staff or sent back to the factory.

5）The vaporizer should be taken off from the machine and packed separately during transportation. Completely clean the inside of it and dry it with medical O2 before packing.

6）Manometers and regulating valve of oxygen flow must far away from oil to avoid any burning.

7）The machine must be grounded well to ensure the safety.

8）The oxygen concentration in the working environment should not exceed 24%.

9） Driving gas of the machine have nothing to do with the content of gas that patients' breath. Therefore, the oxygen flowmeter must be open to supply proper fresh oxygen in case of any oxygen-poor accident when the ventilator of the machine is used for ventilating

10）If the leather bag can not be compressed completely when the patient is inspiriting, it will lead to insufficient tidal volume . You should check if the airway is clear and turn up the tidal volume and lower the compensation of oxygen flow. It shows that air leaks from the respiratory circuit if the leather bag can not return to the original condition when the patient is expirating. At this time, compensation for oxygen flow should be increased to ensure enough MV.

11）Charge the storage battery in time after using it, and the interval should be less than 12 hours. The charging current should be in accordance with the requirement in the user's manual of the battery. While not in use, the battery should still be recharged every month to ensure sufficient power when required for use again. When replacing the battery, pay more attention to polarity—the red line should be connected to positive anode while the blue line connected to cathode. Lines should be

connected firmly to avoid open circuit, heat, strike fire etc.

The storage battery must be vertical during transportation and using. It is prohibited from inversing or placing horizontally. Avoid fiercely shaking.

Specifications of the storage battery: 12V, with capacity no less than 7Ah. Otherwise, it will affect the using time.

⚠**Caution: The waste battery will pollute the environment. Therefore , it can not be disposed at will. Stick to related standard and requirement strictly when**

⚠**Notice: Inner power supply should be there to make the machine work if there is any doubt about the integrality of GND line.**

12）The fuse of the machine is $\phi 5\times 20$2$\times$RT 0.5A$\times$250V(glass cover). The power supply must be cut off firstly before replacing the fuse. Install the fuse box after replacing.

13） Output pressure and flow characteristics driving gas that is in the range of rated input pressure and twice of maximum rated input pressure have not changed.

10 Packing, Transportation and Storage

10.1 Packing

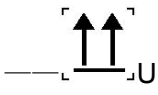
Each machine should be fixed firmly in the package, and there should be sufficient soft material between the package and the machine to avoid friction during transportation. There should be moisture-proof and rain-proof measures in the package to protect the machine against natural damage.

10.2 Transportation

1）Packing the machine in the original package and shockproof pad

2）Transport according to the signs and graphics. They are:


Fragile


Upward


Avoid rain

3） For outdoor transportation, assemble the unit with a cover to avoid sunshine, rain and strong vibration. Never place the package upside down or throw the package hard during loading and unloading.

10.3 Storage

——Temperature: －10 ～ 40 ℃

—— Relative humidity: no more than 90%

—— Atmospheric pressure: 86 KPa ～ 106 KPa

—— Storing in the room with good ventilation and no corrosive gas

11 Others

Besides the disinfection and daily maintenance after each operation, you should disassemble the anesthesia loop and clear away the waterlogging and soda lime powder monthly.

A through disinfection and maintenance is needed every 6 month.

The vaporizer should be examined every 6 month.

The flow sensor should be tested every two years

The machine should be maintained by specialist .And related records should be kept to look it up.

The machine should be tested thoroughly when powered on after stop work for 6 month.

If any malfunction is caused by quality related problems within one year from the date of purchase, the product can be repaired for free or returned to the factory,. Extra cost will be charged if the damage is caused by incorrect operating or disassemble and change.