Product Information

Name: Anesthetic Workstation

Model:X30

Production date: see the nameplate information on the back of the anesthetic workstation

Equipment service life: 8 years after the production date (excluding worn-out parts)

Manufacturer Information

Company name： Beijing Sired Medical Device Co., Ltd.

Registered address: Room 501, Block A, Room 502, Block B, Building 17, Yard 8, Liangshuihe Second Street, Beijing Economic and Technological Development Zone

Production address: Room 501, Block A, Room 502, Block B, Building 17, Yard 8, Liangshuihe Second Street, Beijing Economic and Technological Development Zone

Telephone：400-602-2016 Fax：010-87576012

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Version

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Declaration

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Any user must read this manual carefully before using the company's products. This manual will describe in detail the operation steps that the user must pay attention to, operations that may cause failure, and risk of harm to equipment or persons when using the company's anesthetic workstation. If all abnormal phenomena or dangers and injuries to persons and machines caused by operations that must be avoided as stipulated in this manual occur, the company will not assume responsibility for safety, reliability or performance guarantees! The company will not provide maintenance for free for such failures!

The company has the final right to interpret this manual; the company reserves the right to modify the content of the manual without prior notice.

The company reserves the right to change the technology without prior notice; the company reserves the right to modify product specifications without prior notice.

Guarantee:

The company considers to be responsible for the safety, reliability and performance of the equipment only under the following circumstances:

- This product is used in accordance with the Operator's Manual.
- Assembly operation, expansion, re-adjustment, improvement and repair are all carried out by personnel approved by the company
- The supporting electrical equipment and application environment meet the requirements of national standards, industry standards and this manual.
- Damage caused by non-human factors (such as accidentally falling, deliberate damage, etc.).

Importance

- If the hospitals or institutions responsible for using the equipment cannot implement an effective repair plan, it may cause equipment failure and harm personal health.
- The system should always be used in conjunction with other vital sign monitoring equipment and/or professional judgments on the patient's condition.

- When this equipment is in use, it should be used together with the oxygen concentration detection device, and the user must switch on the oxygen concentration detection device that complies with the ISO 80601-2-55.
- When this equipment uses an anesthesia vaporizer, the user should also configure an anesthetic gas monitor that meets the ISO 80601-2-55 standard.
- If this equipment adopts CO_2 detection, the user shall confirm that it is equipped with a CO_2 monitor that meets the ISO 80601-2-55 standard.
- The anesthesia vaporizer used with this equipment should meet the requirements of the ISO 80601-2-13.
- When this equipment is in use, it should be used together with the anesthetic gas scavenging system (AGSS system) that meets the ISO 80601-2-13 standard.
- A checklist should be provided for the anesthesia gas delivery system, monitoring device, alarm system and protection device expected to be used in the anesthetic workstation.
- When this equipment uses the central air supply system, the failure of the system may cause more than one connected device or even all connected devices to stop working at the same time.
- IEC 60601-1 is applicable to the connection between all medical electrical equipment and the connection between at least one medical electrical equipment and one or more non-medical electrical equipment. Even if there is no functional connection between the individual parts of the equipment, when they are connected to an auxiliary network power socket, a medical electrical system is formed. The operator must be aware that there is a risk of increased leakage current when the equipment is connected to the auxiliary power socket.
- Explosion hazard: This equipment must not use flammable anesthetics, such as ether and cyclopropane. Only anesthetics that meet the requirements for non-flammable anesthetics in the ISO 80601-2-13 appendix DD are suitable for this equipment.
- To avoid false alarms caused by high-intensity electric fields:

Please place the electrosurgical leads away from the anesthesia ventilation system and the sensor probe, lead, and interface.

Do not place electrosurgical leads on any part of the anesthetic workstation.

- If the following situations occur, the company is not responsible for the safety, reliability and operating conditions of the product:

The components are disassembled, stretched, and re-commissioned;

The product is not used correctly in accordance with the "Operator’s Manual.”

The use or storage environment of the equipment does not meet the requirements of this manual.

Maintenance Service

Free service range:

All equipment that meets the company's warranty service regulations can enjoy service for free.

Charged service range:

For equipment beyond the scope of the company’s warranty service regulations, the company will implement fee-based services;

Even during the warranty period, the product needs to be repaired with payment due to the following reasons: man-made damage; the voltage of the power grid exceeding the specified range of the equipment; natural disasters that are irresistible.

The company hereby is not responsible for the direct, indirect or final damage and delay caused by the following circumstances (including but not limited to):

Improper use; replacement of parts not approved by the company or maintenance of the machine by personnel not authorized by the company.

Return Procedure

If you need to return the products to our company, please follow the steps below:

- Obtain the return right. Contact the customer service department of our company and inform them of the product serial number. This serial number has been marked on the outer packing box and the nameplate. If the serial number is not clear for identification, ,the return of product will not be accepted. Please indicate the product model, serial number, and briefly describe the reason for the return.
- Freight: The user must bear the freight (including customs fees) when the equipment is shipped to our company for maintenance.

After-Sale Service Unit

Name: Beijing Siriusmed Medical Device Co., Ltd.

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Contents

Chapter 1 Safety

1.1 Safety Terms

Warnings, cautions, notes and im interfaceant matters used in this manual

⚠Warning

◆ It indicates a situation that may cause serious harm as well as serious property damage to the patient or user, and demands a high degree of alertness.

⚠Caution

◆ It indicates that there may be potential risks or unsafe operations. If not avoided, it may cause minor injuries, product failures, or property losses. Attention should be paid.

⚠Note

◆ It indicates that the instructions or operating steps must be followed, and provides instructions or explanations to ensure that the product can be used safely and efficiently.

1.2 Warnings and Contraindications

◆ This equipment can only be operated and used by well-trained and authorized medical personnel. The equipment must be operated in strict accordance with the instructions of this manual.

◆ Check the equipment, accessories and connections carefully before use to ensure normal and safe operation.

◆ To avoid the risk of electric shock, plug the power cable of the device into a main power supply socket with grounding protection.

◆ The anesthetic workstation should be checked immediately if there is any abnormality related to the equipment.

◆ Do not open the machine without authorization, otherwise there will be a risk of electric shock. It should be repaired by professional personnel approved by our company.

◆ In order to ensure the safety of patients, the audible alarm and alarm threshold values should be set appropriately. Too high the value or too low the value is not appropriate. If the alarm volume is too low, the sound is hard to be heard and the patient may be in danger. However, users cannot only rely on the sound alarm system to monitor the patient, but should pay close attention to the actual clinical condition of the patient.

◆ The physiological parameters and alarm information displayed on the device cannot be directly used as a basis for clinical treatment, and can only be used as a reference for clinicians.

- ◆ In order to avoid fire hazard, please pay attention to the environment of this equipment. Make sure the environment is far away from flammable and explosive materials.
- ◆ The packaging materials should be kept away from children, and the waste should be disposed of in accordance with local regulations and hospital regulations.
- ◆ Combustible anesthetics cannot be used in this equipment.

Contraindications:

This product has no absolute contraindications. For specific usage, please refer to the contraindications of the anesthetics used.

1.3 Caution

- Use the accessories specified in this manual to ensure patient safety.
- When the used parts and accessories are replaced or the accessories and this equipment expire, they must be handled in accordance with the hospital and local regulations.
- The electromagnetic field will adversely affect the performance of the anesthetic workstation. When using other equipment near it, pay attention to the relevant EMC requirements. Electromagnetic radiation from mobile phones, MRI equipment, and X-rays can cause interference to this equipment.
- Please avoid false alarms caused by high-intensity electric fields. This system can work normally under the electromagnetic interference conditions specified in the IEC 60601-1-2. If the interference level is higher than it is specified, an alarm may occur.
- Please pay attention to whether the voltage and frequency of local power supply meet the requirements of this equipment.
- In the process of trans interfaceation and installation, please ensure that the machine is not damaged by external forces, and avoid collisions, drops, heavy blows, etc.

1.4. Notes

- Please place this product in an appropriate place for use, operation, and observation, etc.
- The manual should be placed next to the anesthetic workstation for use conveniently.
- Class I special waste

Used batteries that cannot be used normally must be replaced and discarded in accordance with relevant local regulations. It is not possible to dispose of used batteries in the same way as normal waste products. In some areas, recycling facilities may not be provided.

- **Class II special waste**

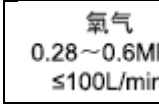
The used oxygen concentration sensor must be replaced and discarded in accordance with relevant local regulations. It is not possible to dispose of used oxygen concentration sensors in the same way as normal waste products.

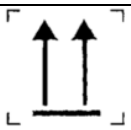
- **Hazardous waste (infectious)**

Some parts of this equipment cannot be processed in the same way as normal waste products.

- All disposable parts must be disposed of in an environmentally safe manner in accordance with hospital regulations.
- Do not use sharp instruments to touch the screen.
- To avoid sudden power failure and other abnormal situations, it is recommended to keep at least one battery as a backup power source in the anesthetic workstation at all times.

1.5 Equipment Symbols

	AC power		Fuse
	Battery		Equipotential column
	AC power symbol		Battery symbol (indicating battery status, showing current remaining power)
	Inspiratory flow		Expiratory flow
	The equipment is running.		The equipment is off.
	Adjust the lower limit alarm parameters		Adjust upper limit alarm parameters
	Type BF applied part		Type B applied part
	Audio Pause		Production date
	Service life		Batch code
	Back to main screen		O_2 Flush button
	Manual ventilation		Mechanical ventilation
	Lock		Unlock
	Lighting		Flow meter knob
	Assisted breathing sysmbol		Interface of the oxygen concentration sensor
	O_2 supply connector		AGSS outlet

空气 0.28～0.6MPa ≤100L/min	Air supply connector		USB interface
	Standby button		Caution
	Spare cylinder		Manufacturer
	Serial number		Refer to the Operator's Manual
	Classification number		Possible danger
	Identifies the user need to perform the operation		Do not touch the interface where the mark appears
	Risk of electric shock		Keep dry
	Refer to instruction manual		up
	Fragile items		According to the WEEE Directive, waste equipment should be recycled at a designated place and cannot be discarded as domestic waste.
	No tumbling		Used batteries should not be disposed in the same way as normal waste products. (In some areas, recycling facilities may not be provided)
	Class I special waste product (Used batteries that are exhausted must be replaced and discarded in accordance with local regulations)		Hazardous waste product (infectious) Some parts of this equipment cannot be disposed of as normal waste products.
	Class II special waste product (Used O_2 sensors must be replaced and discarded in accordance with relevant local regulations. The used O_2 sensors cannot be disposed of in the same way as normal waste products)		Containing or presenting natural latex

	Temperature limit		

1.6 Introduction of Terms

Abbreviations	Full name in English
AGSS	Anesthesia Gas Scavenging System
ACGO	Auxiliary Common Gas Outlet
APL	Adjustable Pressure Limit
Cdyn	Dynamic Compliance
cmH_2O	cmH_2O
CO_2	Carbon dioxide
DES	Desflurane
ENF	Enflurane
Et	End-tidal concemtration
Esens	Expiratory Trigger Sensitvity
Exp	Expiratory
Fi	Fraction of inspired gas
Freq	Frequency
ftotal	Total respiratory rate
fspn	Spontaneous respiratory rate
Fsens	Flow Trigger Sensibility
HAL	Halothane
I:E	Inspiratory-Expiratory ratio
Insp	Inspiratory
ISO	Isoflurane
L/min	L/min
kPa	kilopascal
Manual	Manual ventilation
MV	Minute volume
O_2	Oxygen
Paw	Airway pressure
Pause	Inspiratory pause time
Psens	Pressure Trigger Sensibility
PCV	Pressure control ventilation
PEEP	Positive end-expiratory pressure
Pinsp	Pressure control level of inspiration
Plimit	Pressure limit level
Pmean	Mean airway pressure
Ppeak	Peak pressure
Pplat	Plateau pressure
PSV	Pressure support ventilation
Psupp	Pressure support level
R	Resistance
SEV	Sevoflurane
SIMV	Synchronized intermittent mandatory ventilation
SIMV rate	Frequency of SIMV
VT	Tidal volume

VCV	Volume control ventilation
Volume	Volume
Vte	Expired tidal volume
Vti	Inspired tidal volume

Chapter 2 Overview

2.1 Introduction

2.1.1 Intended use

This device provides inhalation anesthesia and life support for respiratory management. It is suitable for general anesthesia. It provides anesthetic and mechanical ventilation support for patients during inhalation anesthesia operations. The device can provide pressure or volume controlled ventilation.

Applicable patients: children and adults over 5kg.

 Warning:

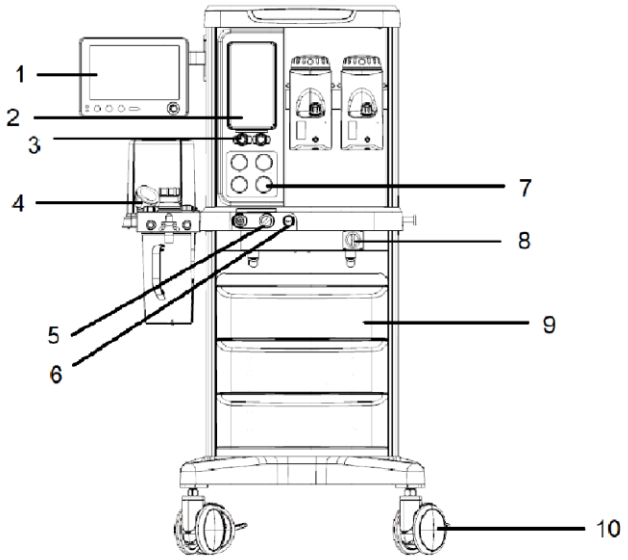
- The machine should be operated only by specialized anesthesiologist trained in the use of the anesthetic workstation. The untrained personnel are prohibited from using it to avoid danger.
- This product cannot be used in an MRI environment.
- The clinical environment is the operating room or the emergency room.

2.1.2 Product performance and structure

This equipment is mainly composed of anesthesia host, anesthesia ventilator, breathing circuit, anesthesia vaporizer, and flow meter, etc. Optional components are as follows: the anesthesia vaporizer (models including VP10 sevoflurane, VP20 isoflurane, Penlon SigmaDelta or Dräger Vapor 2000 are optional. Applicable anesthetics types: sevoflurane and isoflurane for SigmaDelta, sevoflurane and isoflurane for Vapor 2000), oxygen concentration monitoring module, CO_2 monitoring module, anesthetic gas scavenging system (AGSS), auxiliary common gas outlet (ACGO)), auxiliary oxygen flow meter, the connection device of the spare gas cylinder connection device (Yoke).

2.2 Product External View

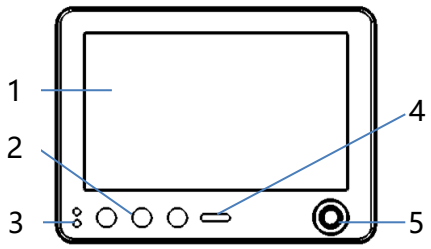
2.2.1 Front view of the anesthetic workstation



Front view of the anesthetic workstation (Figure 2-1)

1.	Display screen
2.	Fresh gas flowmeter （O_2&Air or O2&N_2O）
3.	Fresh gas flow control knob ■ Turn flow control counterclockwise to increase gas flow. ■ Turn flow control Clockwise to decrease the gas flow.
4.	Circuit
5.	ACGO outlet and ACGO switch ■ Turn on the ACGO switch: the system stops mechanical ventilation, and delivers fresh gas to the external artificial breathing circuit through the ACGO outlet; the system stops part of the monitoring function, but it can monitor the oxygen concentration. ■ Turn off the ACGO switch: The patient can be ventilated mechanically or manually through the breathing circuit.
6.	Quick oxygen button
7.	Air source pressure gauge (up) and cylinder pressure gauge (down)
8.	Power switch : Turn on the power and turn on the anesthetic workstation system (hereinafter referred to as “the system”). : Turn off the power and turn off the anesthetic workstation system.
9.	Drawer
10.	Caster

LCD Screen Diagram



1 Display screen

2 Buttons (from left to right as follows)

A Alarm Silence

Press this button to enter the 120s alarm silence state, the top of the screen displays the alarm silence icon and the 120s alarm silence countdown.

B Home

If there is a pop-up menu on the display screen, press this button to clear all the menus and the screen will return to the main screen.

C Start/Standby

- Enter standby mode: In the working state, press this button, select [Activate standby mode] in the pop-up menu, and the system enters standby mode.
- Enter working state: In the standby state, press this button to enter the working state.

3 Power indicator light

Up Battery indicator light

- Yellow light: the battery is charging.
- Green light: The anesthetic workstation is powered by the battery.
- Indicator lights off: No battery is installed or the battery is fully charged.

Down AC indicator light

- On: AC indicator light is on when the power is turned on.
- Off: The AC power indicator is off when the anesthetic workstation is not connected to AC power.

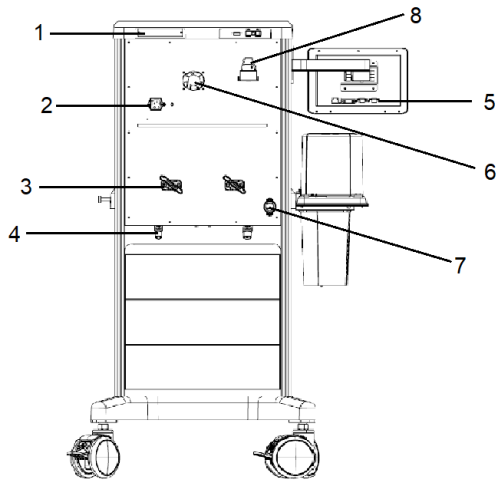
4 Alarm light

- The upper red indicator light flashes: There is an advanced alarm in the system.
- The lower yellow indicator light flashes: There is a intermediate alarm in the system.
- The lower yellow indicator light is on: There is a low-level alarm in the system without intermediate alarm.

5 Control knob

- Rotation: Rotate clockwise or counterclockwise to move the focus.
- Press: Press the knob to perform an operation, such as entering a menu or executing a command.

2.2.2 Back view of anesthetic workstation Ⅰ



Back view of anesthetic workstation (Figure 2-2)

1. Battery compartment
2. Power cord socket and protective ground
3. Cylinder yoke
4. Interface of air source (oxygen and air or N_2O)
5. External device interface (see Figure 2-3)

External device interface (Figure 2-3)

From left to right

A. Network Interface
B. USB interface
C. LCD screen line interface
D. Calibration interface (connects to external calibration equipment when the machine is being calibrated, but cannot connect to external calibration equipment and other equipment when the machine is working)
E. VGA interface (connect to an external projector during teaching or presentation, but cannot connect to an external projector or other equipment when the machine is working)

6. Fan
7. Exhaust outlet
8. Water trap of EtCO2

2.3 Display

See Chapter 6 User Interface for details.

2.4 Battery

⚠**Note**

- In order to prolong the life of the battery, the battery should be used at least once a month, and the battery should be charged in time after the battery is completely exhausted.
- The life of a lithium battery is about two years. It is recommended to replace the battery regularly. The battery life depends on the frequency of use and proper maintenance and storage.
- The battery pack can only be repaired and replaced by professionals authorized by our company.

The anesthetic workstation has a built-in lithium battery pack, which can be used as a short-term backup power supply when there is no main power supply. In sufficient power and a good working environment, the standard built-in battery pack can supply power for about 1.5 hours under normal settings. The battery condition and charging situation are not always at their best. Therefore, conservatively speaking, the battery pack can provide 1 hour of reliable power supply. When the anesthetic workstation is connected to an appropriate AC power source, the battery can be continuously recharged.

When installing and removing the battery module, first remove the battery cover on the back of the host, put the battery into the slot and clamp it tightly, and plug in the power cord. After installing the battery, put the battery cover back into the battery fixing slot, align the mounting screw hole, and tighten the screw.

Basic Principles

When the main power fails, the system automatically switches to the battery module (if connected) to supply power. In any case, the settings and stored data of the anesthetic workstation will be intact.

The anesthetic workstation will issue an advanced low battery alarm and a battery exhausted alarm based on the remaining power. At this time, the user should immediately plug in the AC power or enable manual ventilation or use backup equipment to avoid danger.

Battery charging time/working time (fully charged) (see Table 2-1)

Table 2-1 Battery charging time/working time (fully charged)

Power module	Charging time	Operating hours
1 pack of batteries	About 4 hours	About 90 minutes

⚠**Note**

- **If a battery has been discharged and stored for a period of time, it may take longer time of charging than the time listed in the table.**

Chapter 3 Installation and Connection

Warning

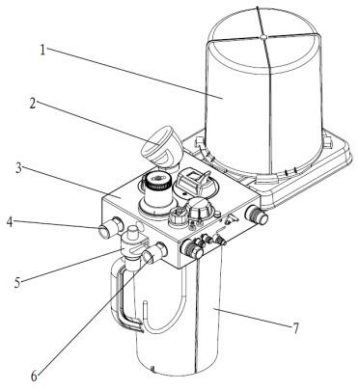
- This equipment must be installed by professionals designated by the company.
- When using electrosurgical equipment, please keep the leads away from the breathing circuit, oxygen concentration sensor, flow sensor and other parts of the anesthetic workstation, and ensure that the manual ventilation equipment for the anesthetic workstation is available at any time to avoid the electrosurgical equipment from interfering with the normal use of the ventilator. At the same time, please pay attention to the correct operation of all monitoring equipment and life support.
- Never use antistatic or conductive masks or breathing pipelines.
- This anesthetic workstation has a waste gas discharge interface, and the user shall reasonably handle the discharged breathing residual gas.
- The use environment and power supply of this anesthetic workstation must meet the requirements in B.2 Environmental Specifications and B.3 Power Specifications.
- Before installing and using this anesthetic workstation, all packages of the anesthetic workstation should be completely removed.

3.1 Installing the Breathing Circuit

Note

- After the anesthetic workstation is used, the breathing circuit should be processed, and the absorbent in the CO_2 absorption tank and the anesthetic in the anesthetic vaporizer should be detected to ensure that the equipment is in good condition.
- The breathing circuit is not interchangeable between different anesthetic workstations.

3.1.1 Overall diagram of breathing circuit



1 Bellows assembly

2 Airway pressure gauge

3 Circuit body

4 Exhalation interface

5 Bag support arm

6 Inhalation interface

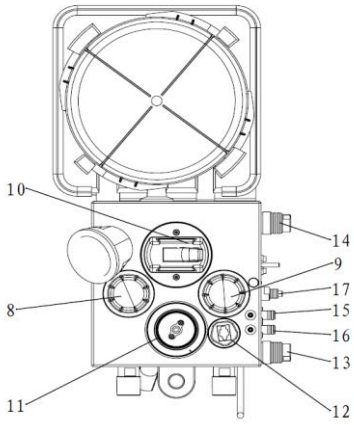
7 Absorber canister

8 Exhalation check valve

9 Inhalation check valve

10 Manual/Vent switch

11 APL valve



12 Oxygen Sensor

13 Exhaust port

14 Drive gas port

15 High flow

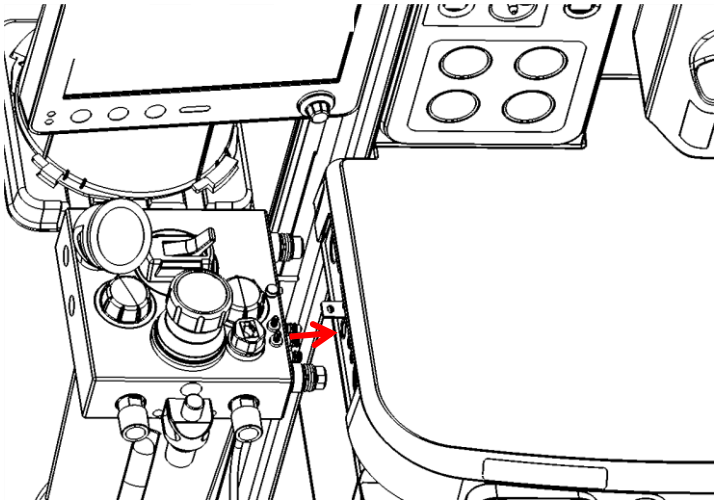
16 Low flow

17 Fresh gas

3.1.2 Installing the circuit body

1) Place the fixed lock on the adapter block of the anesthetic workstation circuit body in the position.

2) Align the two positioning pins on the side of the circuit body with the corresponding mounting holes of the circuit body adapter block, and insert the circuit body into the circuit body adapter block in the direction shown in the figure.



3) Place the fixed lock on the circuit body adapter block in status and confirm that the circuit body has been locked.

Warning

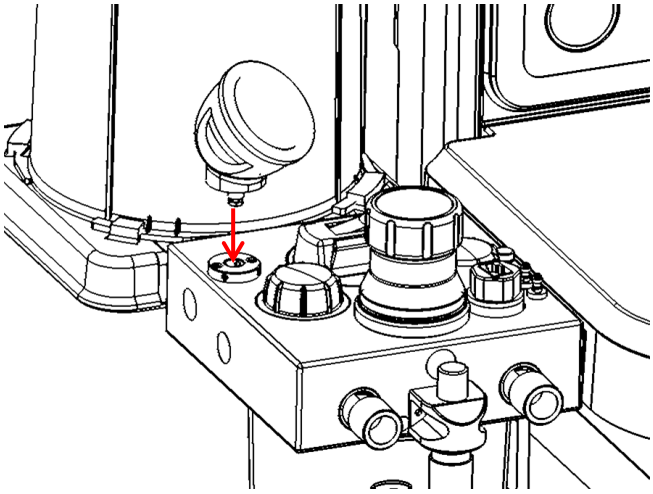
After the circuit body is installed on the circuit body adapter block, the fixed lock must be placed in the position, and the circuit body must be confirmed to be locked. If the circuit body is not locked, the circuit body will be separated from the connection seat during use, causing serious leakage of fresh gas and driving gas, and will cause the failing of manual machine control switch.

3.1.3 Installing the circuit pressure gauge

Warning

- Before installing the circuit pressure gauge, check whether the seal ring of the circuit pressure gauge connector is off or damaged. If the seal ring is missing or damaged, it needs to be replaced immediately.

Align the circuit pressure gauge connector with the circuit pressure gauge fixing seat on the circuit body, and insert it.

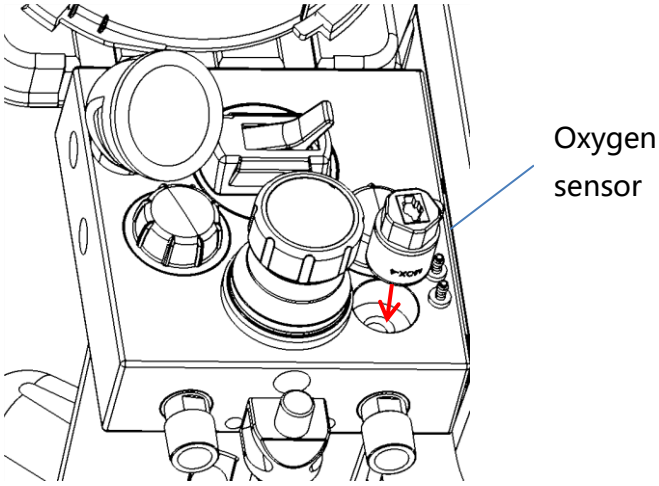


3.1.4 Installing the oxygen concentration sensor

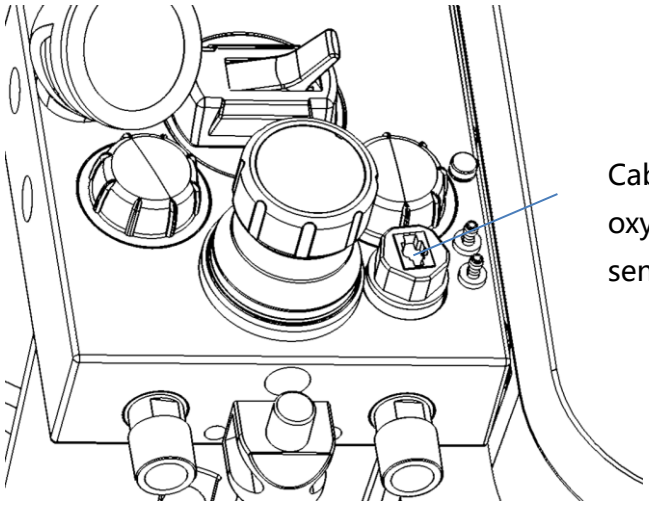
Warning

- **Install the oxygen concentration sensor under the condition that the seal ring on the oxygen concentration sensor is intact. If the seal ring is missing or damaged, it needs to be replaced immediately.**
- **The oxygen concentration sensor must be screwed tightly to avoid air leakage in the circuit.**

1) Align the thread of the oxygen concentration sensor with the position of the oxygen concentration sensor interface on the circuit body, and tighten it in a clockwise direction.

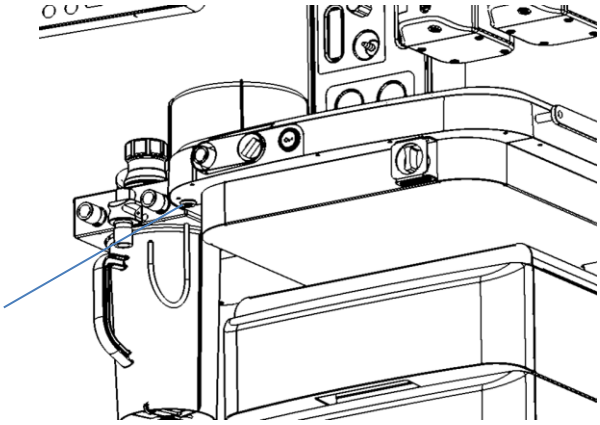


2) Insert one end of the oxygen concentration sensor cable into the socket of the oxygen concentration sensor on the circuit body.



Cable socket of the oxygen concentration sensor

3) Insert the other end of the oxygen concentration sensor cable into the oxygen concentration sensor interface on the side of the anesthetic workstation.



Cable socket of the oxygen concentration sensor

3.1.5 Installing the CO_2 absorption tank

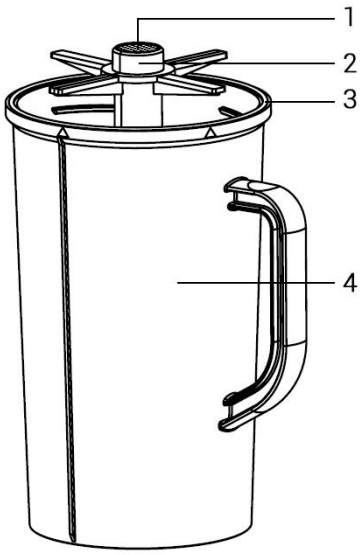
Warning

- It is required to follow the safety precaution procedures.
- After each case is completed, please check the color of the absorbent and take corresponding measures. Refer to the label on the absorbent package to determine the details of the color change. When the absorbent is not used, the color of the absorbent may return to the original color.
- Take necessary measures to ensure that the absorbent in the absorption tank does not dry out. After using the system, all air sources should be turned off. If the completely dry absorbent is brought into contact with the anesthetic, carbon monoxide (CO) gas will be generated, which may be dangerous to the patient, so please be sure to replace the absorbent in time.

Note

- Only air, oxygen, enflurane, isoflurane, and sevoflurane can be used in the CO_2 absorption tank.
- The absorbent should be replaced regularly to prevent the deposition of non-metabolic gases during the non-operation period of the system.

1) The figure below is the structure diagram of the CO_2 absorption tank.



1. Filter
2. Support bracket
3. The seal ring of CO_2 absorption tank
4. CO_2 absorption tank body

2) Hold the handle of the absorption tank, and align the CO_2 absorption tank logo ▲ with the ▼ line on the mounting base.

Note

- Check whether the seal ring fits tightly with the mounting base, otherwise it needs to be disassembled and reinstalled.
- After reinstalling the CO_2 absorption tank, a leak test must be done on the circuit to prevent gas leakage.

3.1.6 Replacing absorbent

Note

- Before installing the CO_2 absorption tank, the color of the absorbent in the CO_2 absorption tank must be checked to determine whether to replace the absorbent.
- It is recommended to use soda lime or calcium lime as the CO_2 absorbent. Please use and replace the absorbent correctly.
- When the color of the absorbent changes, it should be discarded immediately in case it misleadingly returns to its original colar after a few hours.
- If the CO_2 absorbent needs to be replaced when the anesthetic workstation is working, the CO_2 absorption tank can be removed directly. After replacing the CO_2 absorbent, please install the CO_2 absorption tank to the breathing circuit immediately; if the CO_2 absorbent is not used for a long time, the CO_2 concentration will increase and the patient's life will be risky.

1) Remove the CO_2 absorption tank: rotate the CO_2 absorption tank counterclockwise to the unlocking mark, and remove the CO_2 absorption tank downwards.

2) Pour out the absorbent and take out the support bracket.

3) Remove the water in the CO_2 absorption tank.

4) Clean and disinfect the CO_2 absorption tank (please refer to Chapter 9).

5) Put the cleaned bracket back into the empty CO_2 absorption tank.

6) Pour the new absorbent into the CO_2 absorption tank.

Note

- The level of the absorbent after it is smooth should not exceed the upper edge of the upper arm of the bracket, and the minimum level should be no less than the lower arm.

7) Wipe off the absorbent dust around the seal ring to prevent leakage.

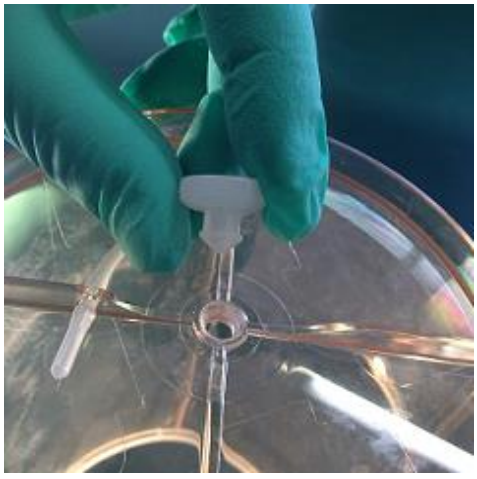
8) Install CO_2 absorption tank.

Warning

- Absorbent is a highly corrosive substance, which has strong irritation to human eyes, skin and respiratory system. If the user accidentally touches the absorbent, please wash the affected area with water for at least 15 minutes. If the irritation persists after washing, please seek medical help immediately.

3.1.7 Removing the water in the CO_2 absorption tank

When there is condensed water in the CO_2 absorption tank, there is no need to take out the absorbent. You can directly remove the water plug under the CO_2 absorption tank to drain the condensed water in the CO_2 absorption tank.



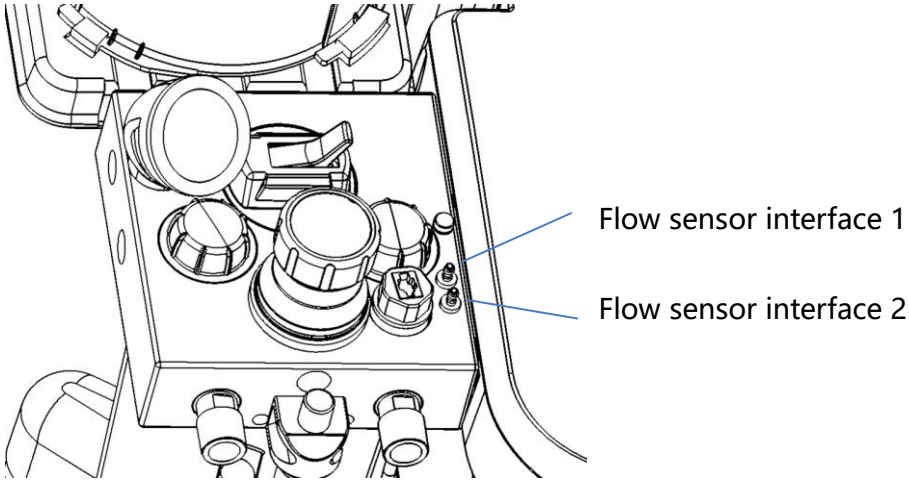
Warning

- When the anesthetic workstation is in use, it is prohibited to remove the water plug of the CO_2 absorption tank; if the water plug is removed, the respiratory system will leak;
- After removing the water plug to drain the water, remember to install the water plug back to the CO_2 absorption tank, and perform a respiratory system leak test.

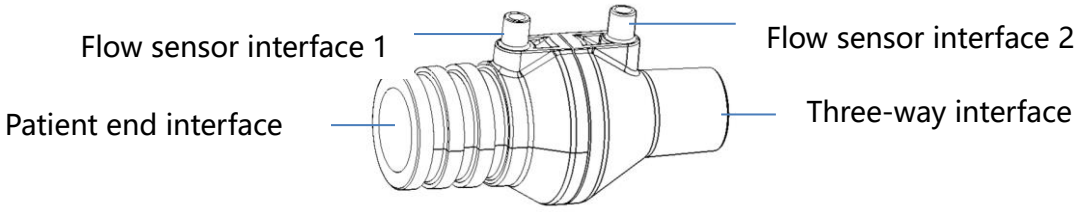
3.2 Installing the Flow Sensor

Note

- When in use, the flow sensor may have water vapor condensation, which affects the accuracy of the measurement data. The heating device of the flow sensor can greatly alleviate the water vapor condensation in the flow sensor.



Circuit end interface diagram 1



Flow sensor diagram 2

- Connect the flow sensor interfaces in diagram 1 and diagram 2, the flow sensor interface 1 corresponds to the flow sensor interface 1

Use blue and white sampling tubes for connection.

- Connect the flow sensor interfaces in diagram 1 and diagram 2, the flow sensor interface 2 corresponds to the flow sensor interface 2

Use white sampling tubes for connection.

- The three-way interface is connected to the ventilator end, and the patient end is connected to the patient's pipeline.

⚠Warning

- When replacing a new flow sensor, please calibrate the flow sensor to ensure the accuracy of tidal volume measurement.
- The flow sensor is standardized. Please install it according to the direction mark shown in the figure.

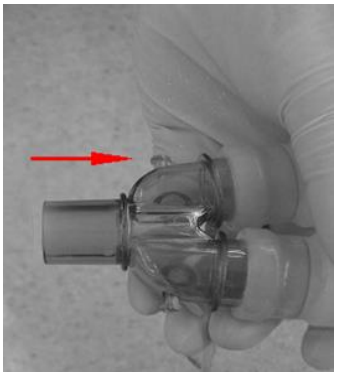
3.3 Installing Breathing Pipeline and Y Connector

⚠Note

- When installing the breathing pipeline, be sure to hold the joints at both ends of the breathing tube to ensure that the breathing pipeline is not damaged.

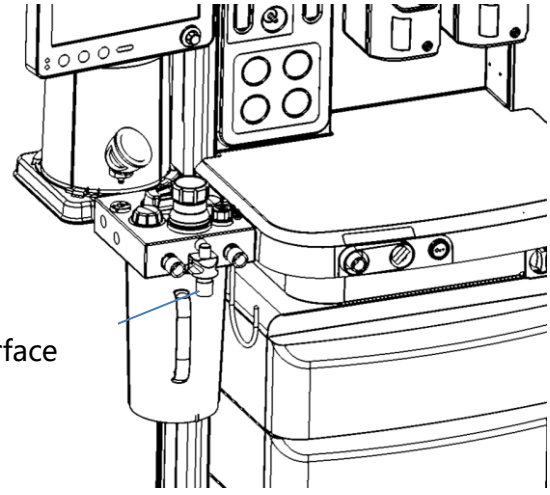
1) Connect the two breathing circuits to the exhalation interface and the inhalation interface on the circuit body respectively.

2) Connect the other ends of the two breathing pipelines to the two parallel interfaces of the Y connector.



3.4 Installing the Manual Breathing Capsule

Align the breathing capsule with the end interface of the manual breathing capsule on the circuit body, and then insert the capsule firmly.



Manual capsule interface

3.5 Installing the Bypass CO_2 Module

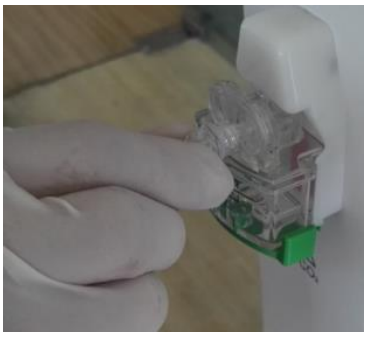
1) Hold the water cup with one hand and insert it upward into the mounting base;

⚠Warning

- **After the installation is completed, you must check whether the installation is in place. If it is not installed in place, the CO_2 concentration will not be correctly monitored and the respiratory system will leak.**
- **When the water level in the water collection cup reaches the position of the marking line, the water collection cup needs to be replaced.**

2) Connect the 15mm interface of the L connector to the Y connector of the breathing pipeline.

3) One end of the sampling tube is connected to the L connector, and the other end is connected to a water cup.



3.6 Installing the Anesthesia Vaporizer

⚠Warning

- When the anesthesia vaporizer and the anesthetic workstation do not match, their performance will be infected. Please use the anesthesia vaporizer that matches the anesthetic workstation.

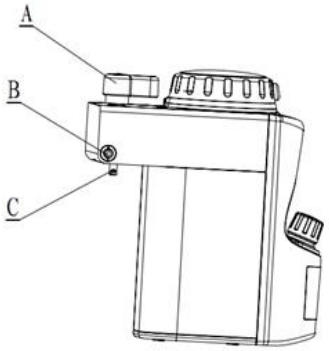
⚠Note

- In order to know more about how to install and use the anesthesia vaporizer, please refer to the Operator's Manual of the anesthesia vaporizer for details.

3.6.1 Installing the anesthesia vaporizer

1) Hang the anesthesia vaporizer on the anesthesia vaporizer mounting base of the anesthetic workstation.

2) Rotate the lock lever A clockwise to the position.

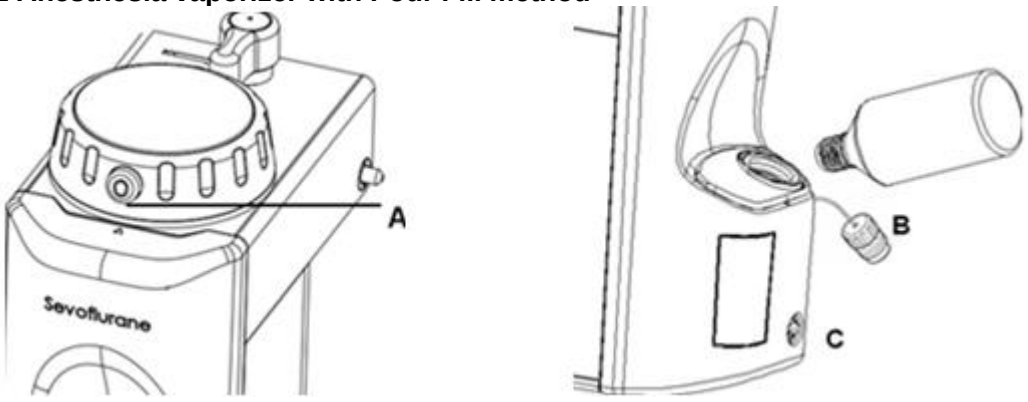


A Locking lever
B Interlocking bolts
C Locking hook

3) If two anesthesia vaporizers are installed at the same time, you need to test whether they can be opened at the same time; if they can be opened at the same time, you should remove these anesthesia vaporizers and reinstall them according to steps 1-2; if they can still be opened at the same time, contact after-sales personnel.

3.6.2 Adding anesthetics

3.6.2.1 Anesthesia vaporizer with Pour Fill method



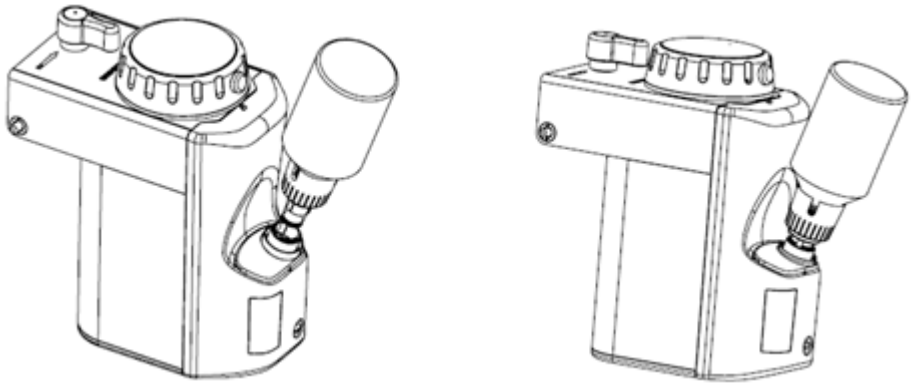
1) Check the concentration control knob A and put it at the zero position; check and tighten the drain screw C.

2) Unscrew the screw cap B of the filling interface counterclockwise.

3) Gently pour the anesthetic liquid into the anesthetic vaporizer. When pouring, observe the level of the liquid in the tank, and stop in time when the liquid level reaches the highest mark.

4) Tighten the screw cap B clockwise. Please do not over tighten it.

3.6.2.2 Anesthesia vaporizer with Quik-Fill method



1) Please check the concentration control knob and set it to the zero position.

2) Remove the yellow protective cap on the funnel of the anesthetic medicine bottle, and ensure that the medicine bottle and funnel device are not damaged.

3) Take off the lid of the anesthesia vaporizer funnel and insert the bottle mouth into the anesthesia vaporizer funnel. Turn the bottle so that the wedge bolt of the bottle is aligned with the slot in the funnel of the anesthesia vaporizer.

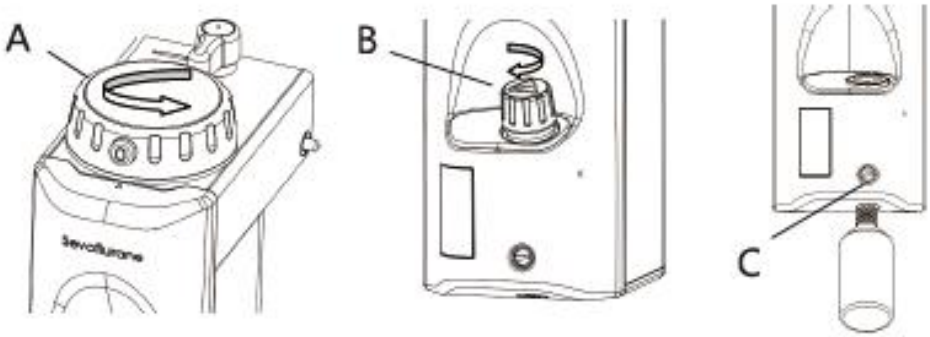
4) Please pay attention to the horizontal level scale of the medicine in the observation hole of the anesthesia vaporizer, and press the anesthetic bottle tightly into the funnel of the anesthesia vaporizer, with the help of the spring valve components. Make the liquid medicine flow into the anesthesia vaporizer until the liquid medicine reaches the maximum scale, and continue to observe the scale in the observation hole and the returning air bubbles of the air flowing into the bottle.

5) When the anesthesia vaporizer is filled with liquid medicine, let go of the bottle, and the rising bubbles stop.

6) Remove the bottle from the funnel of the anesthesia vaporizer, and reinstall the cap of the funnel of the anesthesia vaporizer and the yellow cap of the anesthetic bottle.

3.6.3 Discharging anesthetics

3.6.3.1 Drug release of anesthesia vaporizer with the Pour Fill method

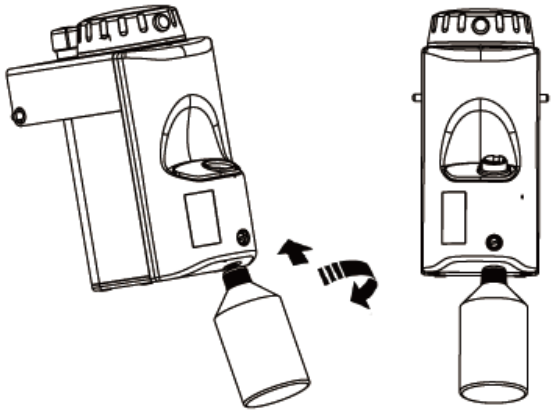


1) Check the concentration control knob A and set it to the zero position.

2) Unscrew the screw cap B counterclockwise.

3) Place a bottle with the corresponding name of the anesthetic under the anesthetic vaporizer, align the mouth of the bottle with the funnel under the drain tube, and loosen the drain screw C to ensure that the anesthetic flows into the bottle.

3.6.3.2 Drug release of anesthesia vaporizer with the Quik-Fill method



⚠Note

- In order to prevent the anesthetic liquid from overflowing, it is necessary to ensure that the medicine bottle has enough capacity to hold the discharged liquid medicine.

⚠Warning

- ◆ Before using the anesthesia vaporizer, reinstall the funnel cover.
- ◆ The anesthetic liquid discharged from the anesthetic vaporizer cannot be reused and must be treated as hazardous chemicals.

1) Take off the yellow protective cap of an empty sevoflurane bottle. Insert the bottle nozzle into the medicine funnel. Rotate the bottle so that the wedge bolt of the bottle is aligned with the slot in the funnel of the anesthesia vaporizer. Then screw the medicine funnel to the empty bottle.

2) Take off the lid of the anesthesia vaporizer funnel.

3) Completely insert the funnel containing the medicine into the wedge-shaped slot, and unscrew the stopper of the medicine. Pour out the liquid medicine in the anesthesia vaporizer until all the liquid medicine is poured out. Put the medicine stopper on and tighten it. Take away the open medicine funnel.

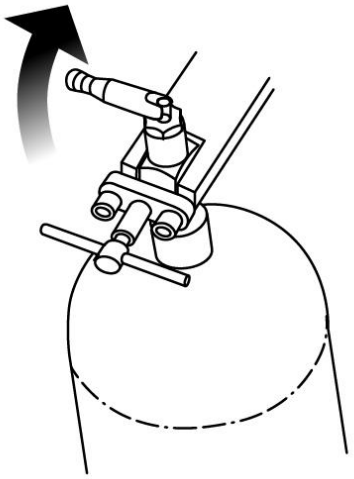
4) Loosen the screw, remove the funnel containing the medicine from the bottle, and reinstall the bottle cap and the funnel cap of the anesthesia vaporizer.

3.7 Installing/Replacing the Gas Cylinder

⚠Warning

- ◆ When using the pipeline for air supply, make sure that the spare cylinder valve is closed. Otherwise, when the gas supply pressure of the pipeline is lower than the output pressure of the gas cylinder, the gas in the gas cylinder may be exhausted, resulting in no backup gas supply.

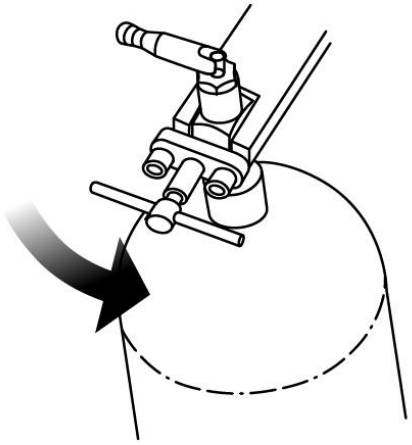
1) Turn the handle of the gas cylinder valve clockwise to close the valve of the gas cylinder to be replaced.



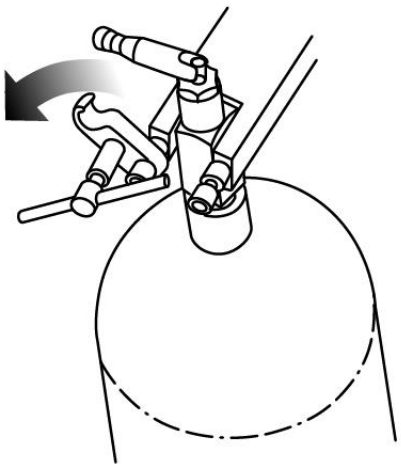
2) Make sure that the pressure gauge of the spare gas cylinder is reset to zero and then unscrew the T-handle counterclockwise. If it is not reset, open the flow meter to reset the pressure gauge.

⚠Warning

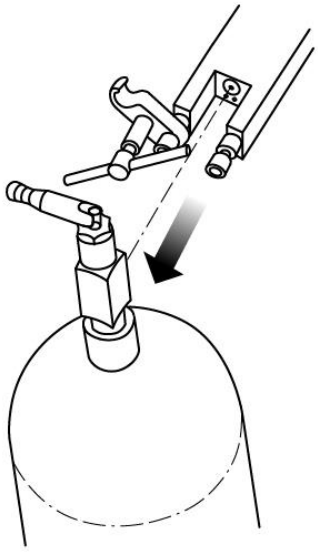
- If the pressure gauge of the spare gas cylinder is not reset to zero, the high-pressure gas in the spare gas cylinder may cause injury to the user.



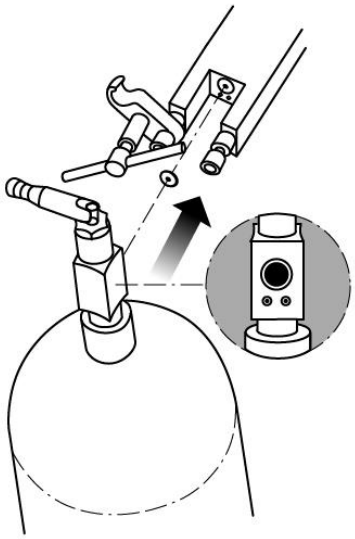
3) Loosen the T-handle completely and open the buckle door by hand.



4) Remove the gas cylinder outwards.



5) Align the upper limit hole of the gas cylinder with the upper limit post of the YOKE mounting base, and push the gas cylinder inward horizontally.



⚠Note

- Before installing the gas cylinder, check whether the gasket is damaged. If it is damaged, it shall be replaced with a new one.

7) Close the buckle door and tighten the T-handle clockwise.

8) Test gas cylinder (see spare gas cylinder test)

3.8 Power Interface

⚠Warning

- Devices connected to the power socket can increase leakage current. Therefore, the leakage current should be tested at set intervals. In order to reduce the total leakage current, users should choose equipment with isolation transformers.

3.9 Air Source Interface

This anesthetic workstation provides two interfaces: pipeline air source (O_2, Air or O_2, N_2O) interface and gas cylinder air source (O_2, Air or O_2, N_2O) interface.

Medical gas pipeline connection: connect one end of the gas connection pipeline to the gas connection interface of the anesthetic workstation pipeline, and the other end to the central gas supply terminal.

⚠ Note

- The gas connection interfaces are not interchangeable. Pay attention to the gas name and identification color code when connecting.

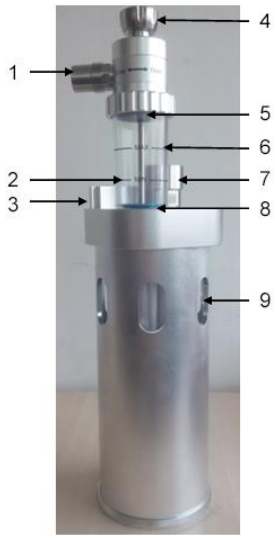
⚠ Warning

- Only for medical gas supply. Other types of gas sources may contain water, oil, and other pollutants.
- The failure of the central air supply system may cause more than one connected device or even all connected devices to stop working at the same time.

3.10 Installing and Connecting the Anesthetic Gas Scavenging System (AGSS)

⚠Warning

- When this equipment is in use, it should be used together with the anesthetic gas scavenging system (AGSS system) that meets the YY0635.2 standard.
- If the anesthetic workstation is not equipped with active AGSS, do not connect the exhaust gas outlet of the anesthetic workstation to the active exhaust gas treatment system of the hospital.
- The AGSS outlet cannot be cleaned and sterilized by high temperature and high pressure.
- In the case of a single failure such as blockage or failure of the processing system between the processing system and AGSS, the gas may escape to the atmosphere at a rate exceeding 100L/min. When it happens, stop using AGSS.



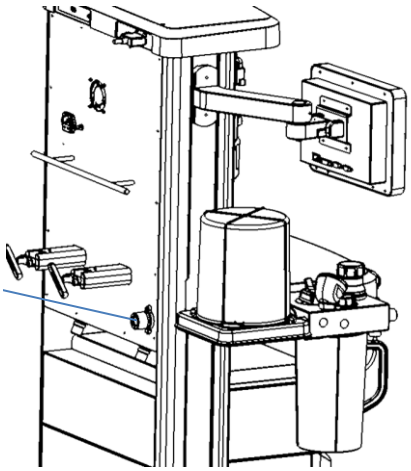
1. Negative pressure input
2. “MIN” mark
3. Hanging block
4. Flow control knob
5. Filter screen
6. “MAX” mark
7. AGSS inlet
8. Float
9. Pressure relief devices

3.10.1 Installing the AGSS

1) Insert the AGSS hanging block vertically into the AGSS bracket.

2) Connect one end of the AGSS transfer pipeline to the exhaust outlet of the anesthetic workstation, and the other end to the AGSS.

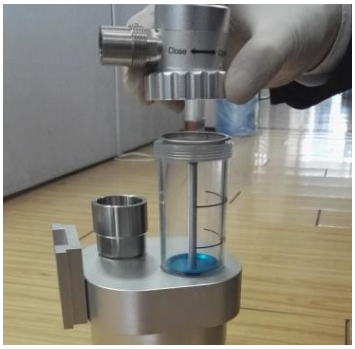
AGSS pipeline interface



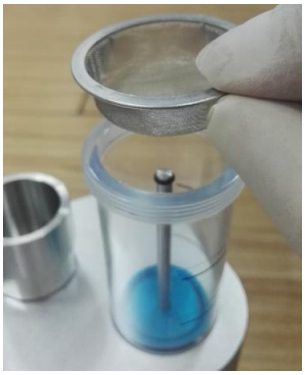
3) The AGSS negative pressure input interface connects the pipeline to the hospital’s active exhaust gas treatment system.

3.10.2 Replacing the Filter

1) Unscrew the screw cap counterclockwise.



2) Replace the filter.



⚠ Note

- The filter needs to be replaced once a year.

Chapter 4 Test Before Operation

4.1 Test Steps Before Operation

Test interval

Pre-operation test should be conducted in below conditions:

1) Before the use of the anesthetic workstation by every patient

2) After repair or maintenance of the anesthetic workstation

Suggested test schedule is shown below:

	Daily check before the use of the first patient/after repair or maintenance of the anesthetic workstation	Before the use of every patient
System check	4.2	
Cylinder yoke	4.3	
Anesthesia vaporizer back pressure test	4.4	
APL valve test	4.5	
Alarm test	4.6	
Oxygen flush test		4.7
Preparations before system operation		4.8

Note

- Before using this equipment, please be sure to read this manual and understand the maintenance and operation of each component.
- If it fails the pre-operation test, do not use the equipment. Please contact the company's after-sale service department.

4.2 Checking the System

Note

- Make sure that the breathing circuit is connected correctly and is intact.
- The factory configuration state of the equipment can ensure that the equipment is not unbalanced when the device is tilted 10°. If the user needs to add other equipment to this equipment, it is required to ensure that the equipment cannot be out of balance when the equipment is tilted 5° at any position in normal use. (A maximum of 15kg of the equipment with a height of less than 450mm can be placed on the top of the anesthetic workstation, and a maximum of 15kg of the equipment with a force arm of no more than 30cm can be added to the side.

During the system inspection, the following requirements shall be met:

1) The equipment is intact.

2) All components are connected correctly.

3) The breathing circuit is connected correctly and intact, and the CO_2 absorption tank contains sufficient absorbent.

4) The anesthesia vaporizer is in a locked state. Make sure that multiple vaporizers cannot be opened at the same time. Confirm that there is enough anesthetic.

5) Connect the O2 supply system correctly to ensure that the O2 source pressure is within the range of 280-600kPa.

6) If there is a spare gas cylinder, the gas cylinder must have enough gas. Ensure that the cylinder valve is closed.

7) If you install AGSS, make sure that the AGSS is connected correctly and the float can be adjusted smoothly.

8) The equipment for airway maintenance and tracheal intubation has been prepared and in good condition.

9) The required emergency equipment has been prepared and in good condition.

10) All necessary narcotic drugs and emergency medicines have been prepared.

11) Make sure that the casters are not loose and the anesthetic workstation cannot be moved.

12) Connect the power cord to the AC power source. After the AC power is connected, the AC power indicator and battery indicator light up. If the indicator does not light up, it means that the system is not powered on.

4.3 Spare Cylinder Test

Note

- If the spare gas cylinder is not used for gas supply after the spare gas cylinder test, please close the valve of each gas cylinder. Otherwise, when the pipeline gas supply pressure is lower than the output pressure of the gas cylinder, the gas in the gas cylinder may be exhausted, resulting in no backup gas supply.
- To prevent damage, slowly open the spare cylinder valve.

4.3.1 Checking the Spare Cylinder

1) Cut off the gas supply pipe and connect the gas cylinder to be tested.

2) Open the valve of each spare cylinder.

3) Ensure that the internal pressure of each cylinder is sufficient. If the pressure in the cylinder is not sufficient, close the relevant cylinder valve and replace with a fully-filled cylinder with sufficient pressure.

4) Close the valves of all spare cylinders.

4.3.2 High pressure leak test of O_2 spare gas cylinder

1) Cut off the gas supply to the O_2 pipeline.

2) Adjust the O_2 flow control knob to turn off the O_2 flow meter.

3) Open the O_2 cylinder valve.

4) Observe and record the current value of the O_2 high pressure gauge.

5) Turn off the valve of the O_2 cylinder.

6) Wait for one minute then observe and record the value of the O_2 high pressure gauge.

- If the value of the O_2 high pressure gauge drops by less than 5000kPa, it means that the O_2 cylinder is not leaking.
- If the value of the O_2 high pressure gauge drops by more than 5000kPa, it means that a leak has occurred. Please replace/install the gas cylinder and replace gas cylinder gasket. Then repeat the steps from 1 to 6 to test high pressure leak again. If the gas is still leaking, do not use this spare cylinder gas supply system.

4.3.3 High pressure leak test of AIR or N_2O spare gas cylinder

Please refer to the procedure of O_2 spare gas cylinder high pressure leakage test for the high pressure leakage test of AIR or N_2O gas cylinder.

4.4 Back Pressure Test of Anesthesia Vaporizer

⚠Warning

- Only use Selectatec series anesthesia vaporizers. Make sure that the anesthesia vaporizer is locked during the test.
- During the test, the anesthetic comes out of the fresh gas outlet. Safe and qualified methods should be used to collect and discharge these agents.
- Before use, please adjust the flow control knob clockwise to the minimum flow or close it to avoid damage.

Please make sure that the anesthesia vaporizer has been installed correctly before testing.

1) Connect the O_2 pipeline to gas supply or open the O_2 spare gas cylinder valve.

2) Adjust the O_2 flow control knob to set the O_2 flow to 6L/min. Make sure that the O_2 flow float does not change.

3) Adjust the concentration of the anesthesia vaporizer within the range of 0-1%, pay attention to the change of the O_2 flow float, and ensure that the decrease of the O_2 flow is less than 1L/min during the whole process of adjusting the concentration of the anesthesia vaporizer. Otherwise, replace it with a new anesthesia vaporizer and retest. If the problem persists, there is a problem with the anesthesia system and the system should not be used anymore.

4) Test each anesthesia vaporizer according to the above method.

4.5 APL Valve Test

1) Put the system in a standby state.

2) Ensure that the manual/machine control switch is set to the manual position.

3) Install a manual breathing capsule.

4) Connect the inhalation and exhalation interfaces of the circuit to the Y-shaped three-way connector and then to the circuit test plug.

5) Adjust the scale of the APL valve to 30cmH_2O.

6) Press the oxygen flush button, the pressure value of the circuit pressure gauge is lower than 45cmH_2O; when the oxygen flush is released, the pressure value of the circuit pressure gauge is not lower than 15cmH_2O.

4.6 Alarm Test

Note

- Please set the upper/lower alarm limit according to Chapter 8.4
- After the alarm test is completed, the user needs to set a reasonable upper/lower alarm limit.

4.6.1 Preparation before alarm test

1) The inhalation and exhalation interfaces of the circuit are connected to the Y-shaped three-way, and the Y-shaped three-way is connected to the capsule or test lung.

2) Set the manual/machine control switch to the machine control position.

3) Set system switch to ⊙ position.

4) Have system enter standby state

5) The ventilator settings are as follows:

- Ventilation mode: select [Mode] -> [VCV].
- Tidal volume [Vt]: 500 mL.
- Respiratory rate [f] is: 12 BPM.
- Respiration ratio [I:E]: 1:2.
- Positive end-expiratory pressure[PEEP]: [OFF].

6) Press quick oxygen filling button to let the folding bag inside the bellow rise to the top of the bellow.

7) Adjust the oxygen flow rate to about 2 L/min.

8) Press the [Start] button to enter the working state.

9) Ensure that the monitoring values of the various parameters are normal, and the bellows works normally (periodically rising and falling).

4.6.2 Oxygen concentration alarm test

Note

- There is no need to perform this test on an anesthetic workstation without an oxygen concentration sensor.

1) Set the manual/machine control switch to the machine control position.

2) In the alarm menu, set the [Oxygen Concentration] alarm lower limit to 60%, and the [Oxygen Concentration] alarm upper limit to 80%.

3) Set the flow rate of the Air flow meter to 4 L/min, and ensure that other flow meters are closed.

4) [Low Oxygen Concentration] alarm should appear in the alarm display area.

5) Set the flow rate of the O_2 flow meter to 4L/min, and ensure that other flow meters are closed.

6) [High oxygen concentration] alarm should appear in the alarm display area.

7) Set the upper/lower alarm limit of [oxygen concentration] to the default value or the value that the user needs to set.

4.6.3 Low alarm test of the minute ventilation

1) Set the alarm lower limit of [Minute Ventilation] to 10L in the alarm menu.

2) [Low Minute Ventilation] alarm should appear in the alarm display area.

3) Set the upper/lower alarm limit of [Minute Ventilation] to the default value or the value that the user needs to set.

4.6.4 Airway pressure alarm test

1) Set the lower limit of [Pressure] alarm in the alarm menu to be higher than the monitoring value of the current airway peak pressure (Ppeak).

2) [Low Airway Pressure] alarm should appear in the alarm display area.

3) Set the upper limit of [pressure] alarm in the alarm menu to be lower than the monitoring value of the current airway peak pressure (Ppeak).

4) [High Airway Pressure] alarm should appear in the alarm display area.

5) Set the [pressure] alarm upper/lower limit to the default value or the value that the user needs to set.

4.6.5 The high alarm test of the continuous excessive airway pressure

1) Ensure that the manual/machine control switch is set to the manual position.

2) Adjust the scale of the APL to 30cmH_2O.

3) The inhalation and exhalation interfaces of the circuit are connected to the Y-shaped three-way, and the Y-shaped three-way is connected to the circuit test plug.

4) Connect a manual breathing capsule.

5) Press oxygen flush button for 15 seconds. Watch the screen to make sure [Continuous high airway pressure] alarm appears.

6) Disconnect the Y-shaped three-way to ensure that the [Continuous high airway pressure] alarm is eliminated.

4.7 Oxygen Flush Test

1) Connect the O_2 pipeline to gas supply or open the O_2 spare gas cylinder valve.

2) Ensure that the manual/machine control switch is set to the manual position.

3) The inhalation and exhalation interfaces of the circuit are connected to the Y-shaped three-way, and the Y-shaped three-way is connected to the circuit test plug.

4) When the system is off or in standby mode, press and hold the button for oxygen flush, and the folding bag needs to rise to the top of the bellows within 1-4 seconds. Release oxygen flush button.

4.8 Preparations Before System Operation

1) Make sure that the relevant parameters of the ventilator and the upper/lower alarm limits are set to the applicable clinical level.

2) Ensure system enters standby state.

3) The following equipment needs to be prepared: airway maintenance, tracheal intubation equipment, CO_2 absorbents, anesthetics and emergency medicines.

4) Ensure that the manual/machine control switch is set to the manual position.

5) Connect manual breathing capsule interface to the manual breathing capsule.

6) Turn off all anesthesia vaporizers.

7) Set the APL valve scale to the MIN position to fully open it.

8) Configure the flow of all gases to minimum value by turning the control knob of each gas flow.

9) Ensure that the breathing circuit is properly connected and intact.

⚠Warning

- Before connecting the device to the patient, flush the device with O_2 at a flow rate of 5L/min for at least 60 seconds. This is to remove useless mixed gas and other debris in the system.

Chapter 5 Basic Operation

5.1 Starting the System

1) Plug the power cord into the AC socket and turn on the power.

2) Turn on the system switch to the  state.

3) The red and yellow warning lights on the control panel will light up at the same time, and then a beep sound can be heard.

4) The boot progress bar is displayed on the screen. After the progress bar comes to an end, a pop-up window of asking "Whether to enter the system test?”shows up. Select [Accept] to enter the system test interface, or select [Cancel] to enter the standby interface.

⚠Warning

- If an abnormal alarm signal occurs when the equipment is started, or it fails to work normally, please do not use it, and you should immediately contact the relevant professional maintenance engineer or after-sales service department.

⚠Note

- This anesthetic workstation can only be used after the pre-operation test (Chapter 4) is completed as well as the system is fully and normally started.

5.2 Standby

The way to enter the standby state is as follows:

1) Turn on the system switch, the system enters the standby state after normal startup.
2) In the working interface, press the ventilation/standby button, select [Activate Standby Mode] in the menu to enter the standby state.

In the standby interface, press the ventilation/standby button to exit the standby state and enter the working interface.

5.3 Shuting down the System

The steps to turn off the anesthetic workstation are as follows:

1) Make sure you can stop using the anesthetic workstation.
2) Turn off all flow meters.
3) Turn off the anesthesia vaporizer.
4) The system switch is set to  .

5.4 Using Touch Screen

Some operations can be completed quickly by tapping the touch screen. The hot key area or icon on the screen can be directly touched for operation.

5.5 System Setup

Chapter 5 only introduces the basic settings of the anesthetic workstation. For other functions and parameter settings, please refer to the relevant chapters.

5.5.1 Adjusting the alarm volume

1) Select [System] -> [Settings] -> [Alarm Volume].
2) Select [Alarm Volume]: 10%—100%, 10% is the lowest, and 100% is the highest.

5.5.2 Date & Time

1) Select [System] -> [Date & Time].
2) Set [Time] and [Date].
3) Select [Apply].

5.5.3 Configuring the sensor switch

1) Select [System] -> [Settings] -> [Sensor On/Off].
2) In the [Sensor On/Off] menu, select the switch you need to turn on or off.

5.5.4 Configuring the language

1) Select [System] -> [Settings] -> [Language Settings].
2) In the [Language Setting] menu, select the language you need.

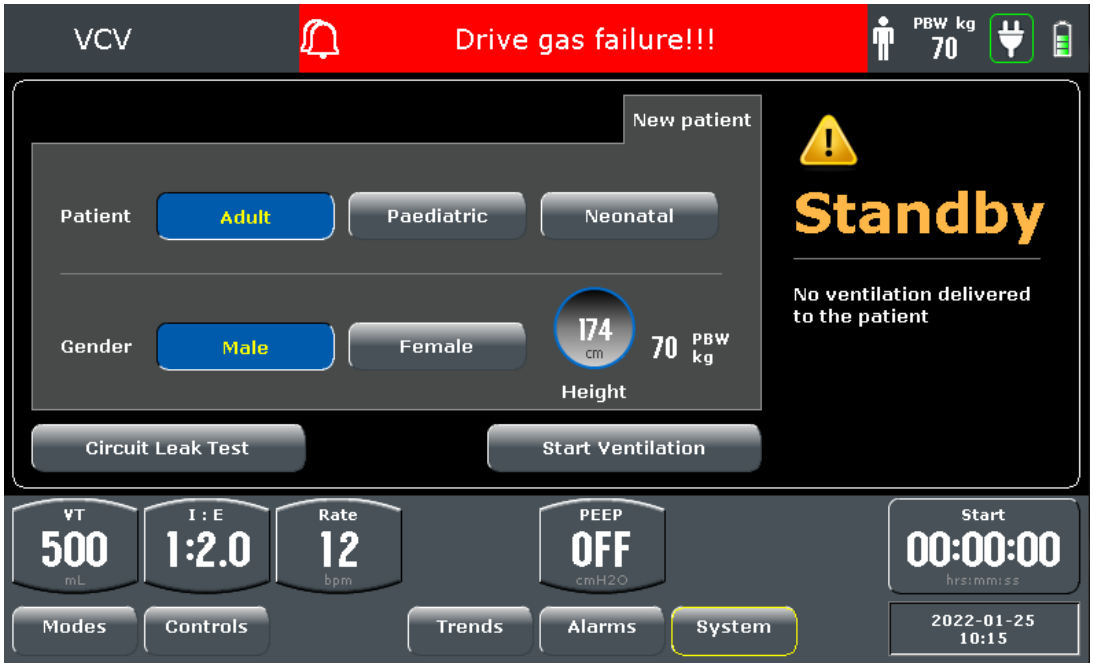
Chapter 6 User Interface

6.1 Outline

There are two kinds of user interfaces:

- Standby interface
- Work interface

6.2 Standby Interface



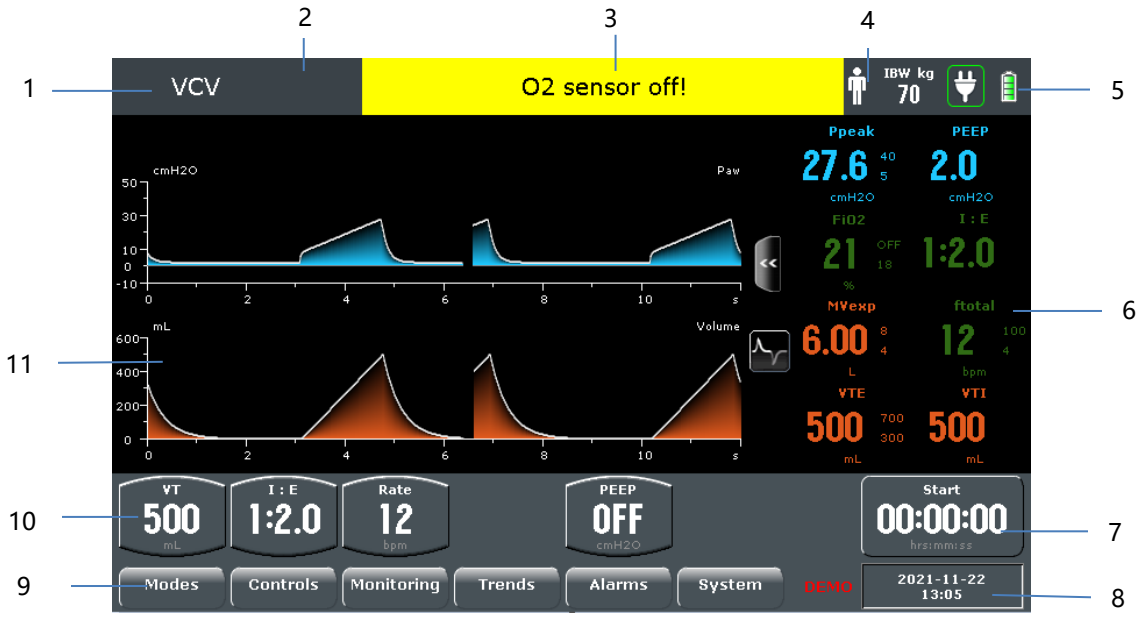
When the anesthetic workstation is on and not in use for a short time, it enters standby mode to save energy and prolong its life span.

The anesthetic workstation automatically enters the standby mode after it is turned on; the anesthetic workstation can also be switched to the standby mode when it is working, or you can press the ventilation/standby button and click the “Activate Standby Mode” button in the pop-up prompt to switch to the standby interface.

The system will have below changes when the anesthetic workstation is in standby mode:

- Monitoring parameter display and wave display is closed. Displays standby interface and the system is in standby state.
- The ventilator machine no longer delivers gas.
- Can configure parameters and ventilation mode. When exiting the standby mode, the system works according to the last settings in standby mode.
- Will automatically clear physiological parameter alarm. If a technical alarm is issued, the alarm function is normal.

6.3 Work Interface



1. Mode display area
2. Trigger mark display area
3. Alarm display area
4. Patient information display
5. Battery/AC power display area
6. Quick parameter display area
7. Timing area
8. Time display area
9. Menu bar
10. Parameter display area
11. Waveform display area

6.3.1 Mode

Mode setup

1) Select the [Mode] menu to enter the mode setting menu.

2) Select the mode to be set, and click [OK].

3) The mode display area displays the current ventilation mode.

Note: Refer to Chapter 7.4 Mechanical Ventilation Mode for details of each mode setting.

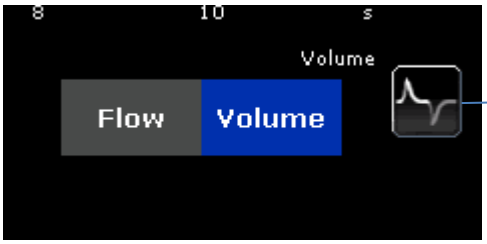
6.3.2 Waveform

6.3.2.1 Parameter waveform selection

The default display of waveform is [pressure]waveform at the top and the [flow]waveform at the bottom.

To select parameter waveform:

Touch the waveform selection area, then the waveform selection menu will pop up. Select the parameter waveform to be displayed.



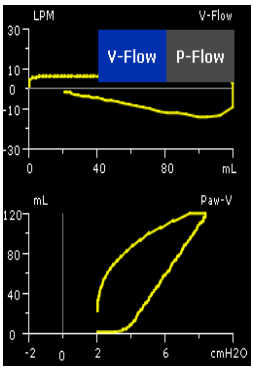
1. [Flow] Flow-Time waveform

2. [Volume] Volume-Time waveform

Note: The pressure-time waveform must be displayed by default

To select the loop diagram of the pulmonary function:

Click on the right side  of the pressure waveform to display the loop diagram of the pulmonary function; the following loop diagram of the pulmonary function will be displayed in the waveform box on the left side of the waveform display area:



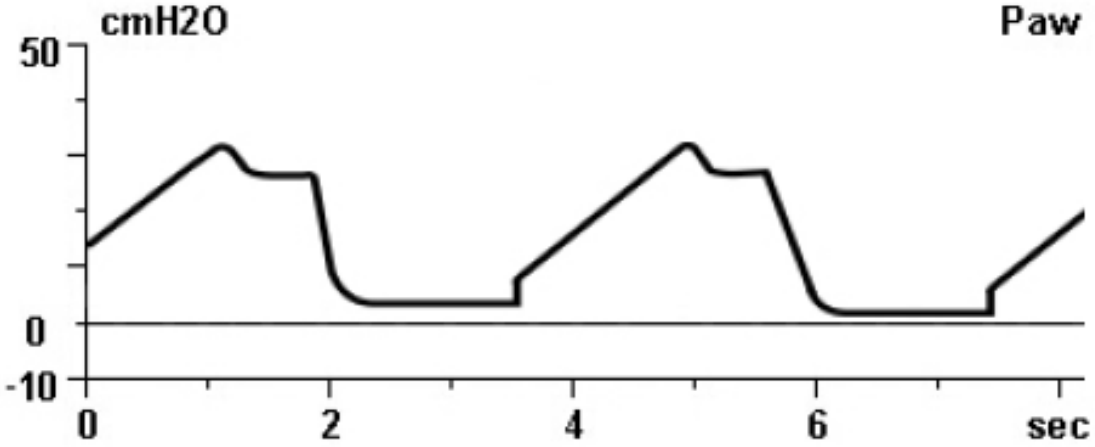
1. [Paw-V] Airway pressure-volume waveform 2. [V-Flow] Volume-flow waveform

Note: Click the  on upper left corner to switch between V-Flow and P-Flow waveform display.

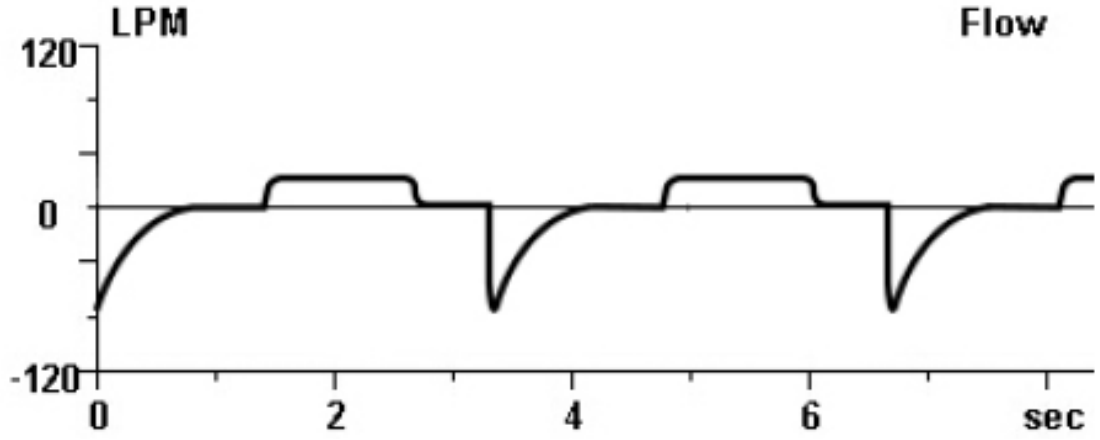
6.3.2.2 Parameter waveform

Note: All the following waveforms are schematic diagrams, and the waveforms in clinical use may be inconsistent with the following waveforms.

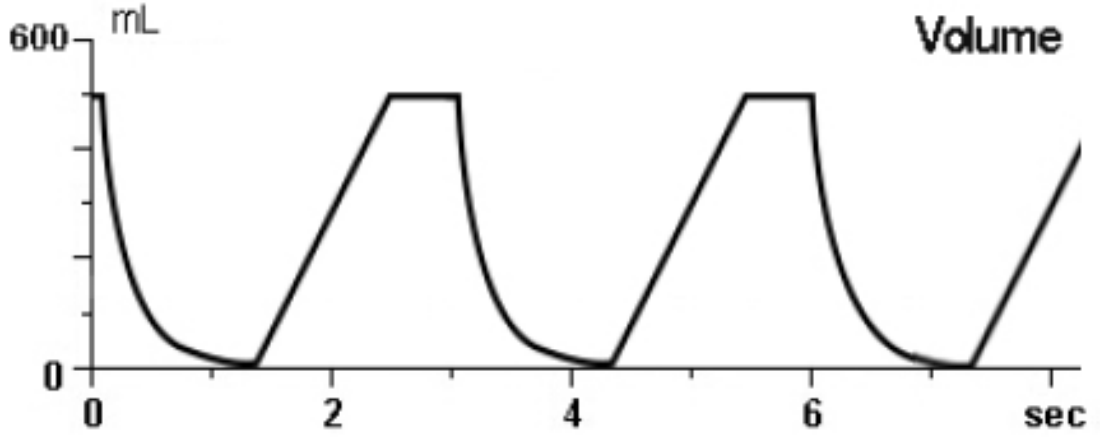
1. [Paw] Airway pressure waveform



2. [Flow] Flow waveform

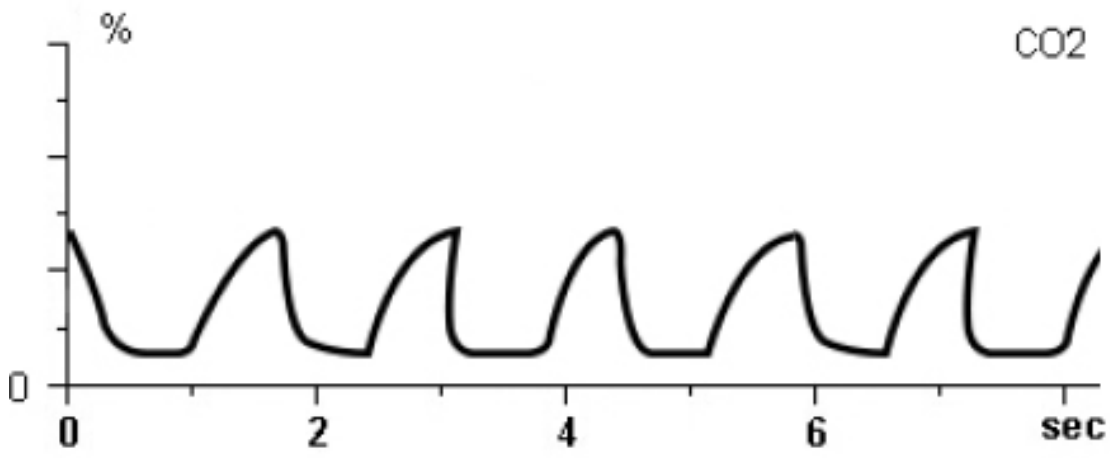


3. [Volume] Volume



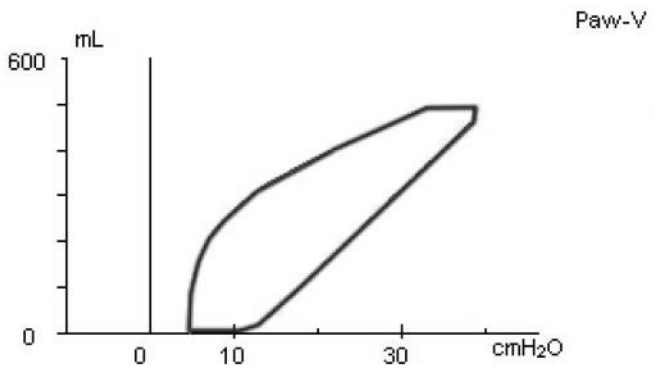
4. [$EtCO_2$] End-tidal carbon dioxide concentration waveform

Note: The end-tidal carbon dioxide concentration waveform can only be selected when the anesthetic workstation is equipped with a by-pass CO_2 module.

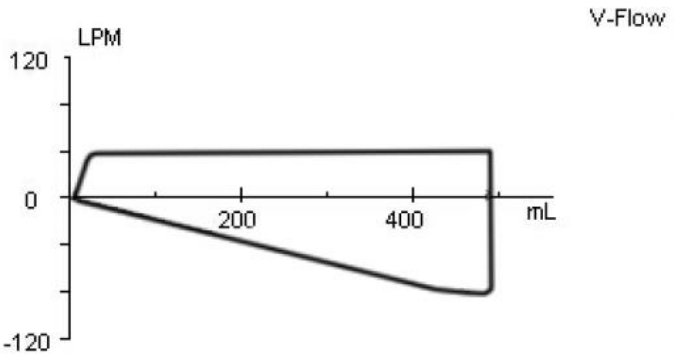


5. Pulmonary function ring

(1) [Paw-V] Pressure-Volume Ring



(2) [V-Flow] Volume-Flow Ring



6.3.3 Quick parameter display area

Note

- When the anesthetic workstation is not equipped with a monitoring module (such as an oxygen concentration sensor) or the switch is set to be off, the monitoring parameter is displayed as "---".
- The alarm upper/lower limit setting value will be displayed on the right side of the quick parameter.

The parameters displayed by the quick parameter of the anesthetic workstation are as follows.

[Ppeak]: Airway peak pressure

[Pmean]: Mean airway pressure

[PEEP]: Positive end-tidal pressure

[MV]: Minute ventilation

[VTE]: Expiratory tidal volume

[VTI]: Inspiratory tidal volume

[I:E]: Inhale-to-exhale ratio

[FTOTAL]: Total frequency

6.3.4 Monitoring menu

Note

- There is no monitoring menu button on the standby interface.

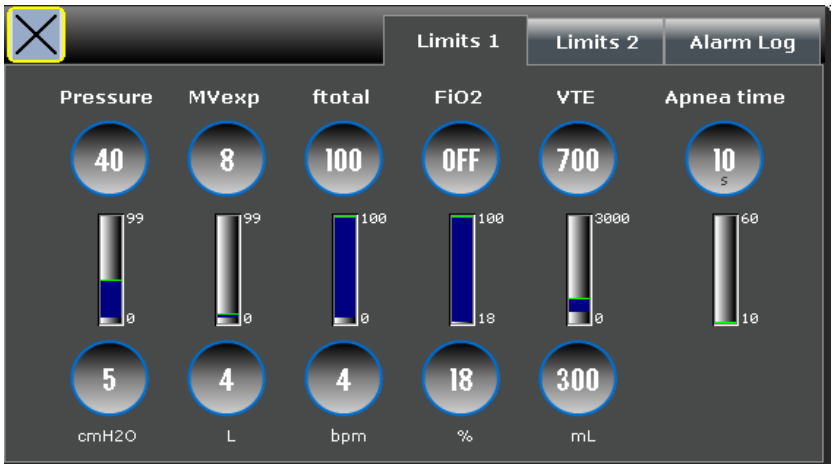
In order to view more parameter monitoring values, in the working interface, click the [Monitoring] button in the menu to enter the monitoring menu.

Monitoring data

6.3.5 Alarm

Select the [Alarm] button in the menu area to enter the alarm upper and lower limit setting menu, click the upper and lower limit circular buttons under the parameters, and set the upper and lower alarm limits by adjusting the knob.

6.3.5.1 Alarm-Setting 1

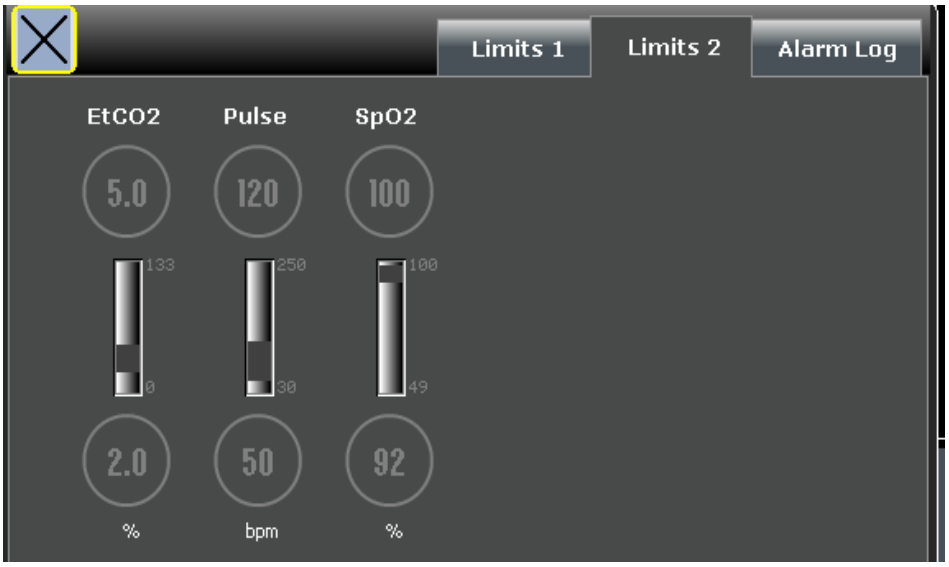


1. Pressure (cm water column)
2. Minute ventilation (liter)
3. Respiratory rate (times/minute)
4. Oxygen concentration (percent)
5. Expiratory tidal volume (ml)
6. Asphyxia time (second)

Note: The figure shows the default value of the alarm setting. This value is the factory default value. The user has no right to modify this default value. Each time the anesthetic workstation is turned on, the upper and lower alarm limits are automatically restored to the default values.

6.3.5.2 Alarm-Setting 2

If no CO_2 or anesthetic gas module is configured, the upper and lower limits of the alarm parameters in the setting 2 menu are set to a non-triggerable state.

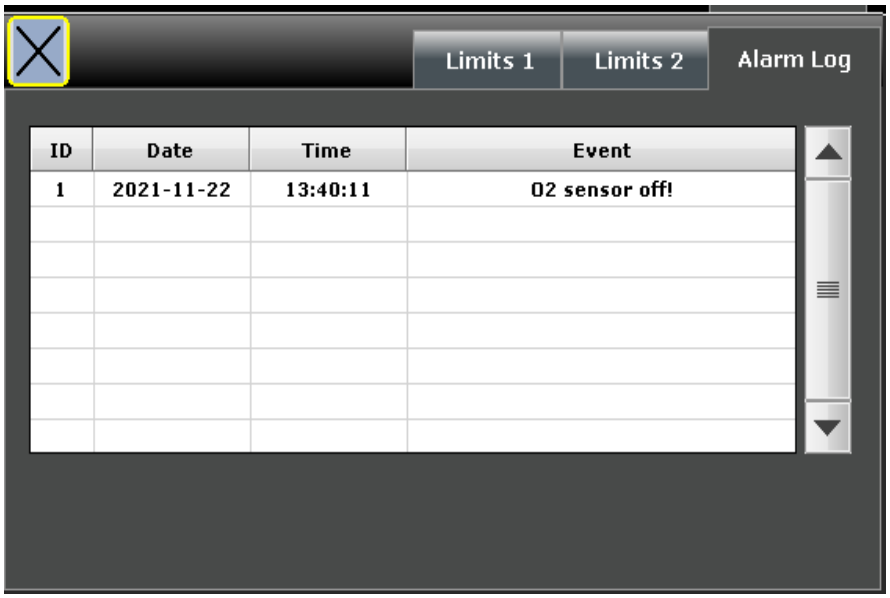


1. End-tidal CO_2 (%)
2. Pulse rate (bpm)
3. Blood oxygen saturation (%)

Note: The figure shows the default value of the alarm setting. This value is the factory default value. The user has no right to modify this default value. Each time the anesthetic workstation is turned on, the upper and lower alarm limits are automatically restored to the default values.

6.3.5.3 Alarm records

When the above parameters exceed the setting range, the alarm display area will display a prompt, and at the same time record the date, time, and event in the alarm records. Displaying ! ! ! after the event indicates that it is an advanced alarm. Displaying ! ! after the event indicates that it is a intermediate alarm. Displaying ! after the event indicates that it is a low-level alarm. Users can only view alarm records but not modify them.

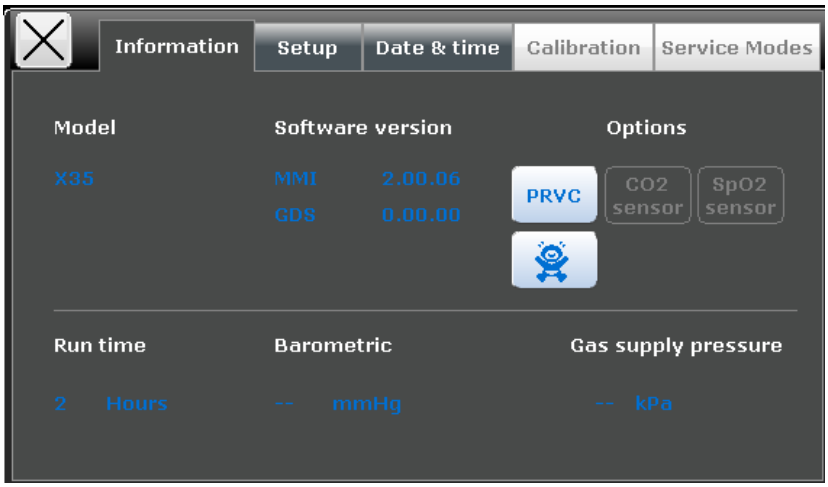


6.3.6 System

In the the menu area, select the [System] button to enter the system Menu. In this menu, you can view system information, set system parameters, set system date & time, and perform system calibration.

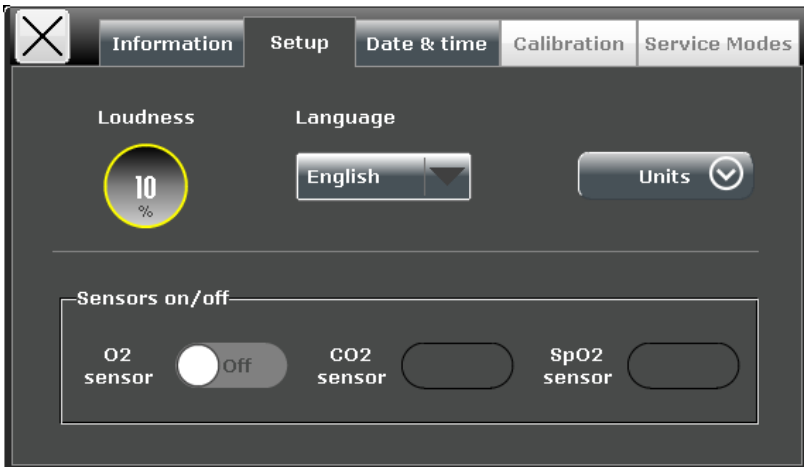
6.3.6.1 System information

The system information menu displays the model, system software version, atmospheric pressure, gas source status, running time and optional information. The parameter values of this interface are read-only and cannot be modified.



6.3.6.2 Settings

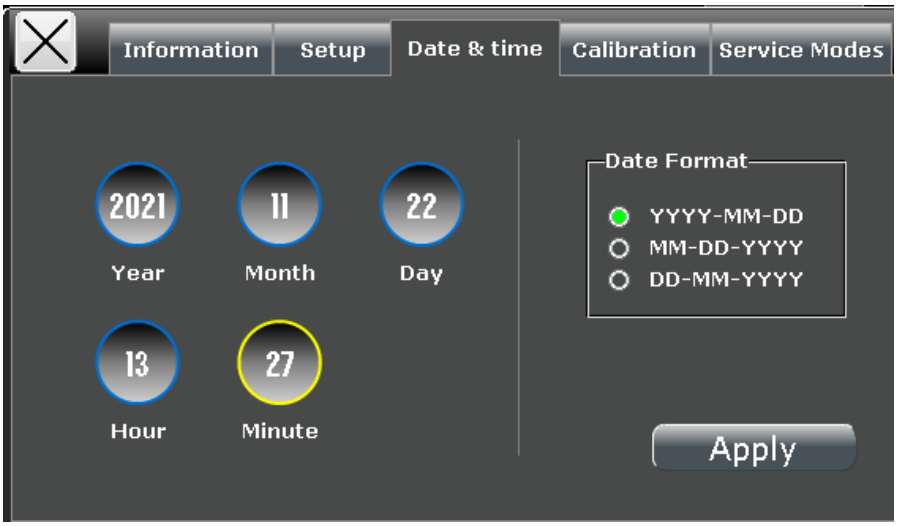
In the setting menu, the system can be set as shown in the figure below.



1. Alarm volume setting: 10%~100%
2. Language setting: English/ Francais/Espanol
3. gas source monitoring switch: ON/OFF
4. Oxygen concentration monitoring switch: ON/OFF
5. Carbon dioxide monitoring switch: ON/OFF
6. Blood oxygen monitoring switch: ON/ OFF
7. Unit: including the settings of CO_2, Barometric,Airway pressure,Gas supply pressure, height, and weight.

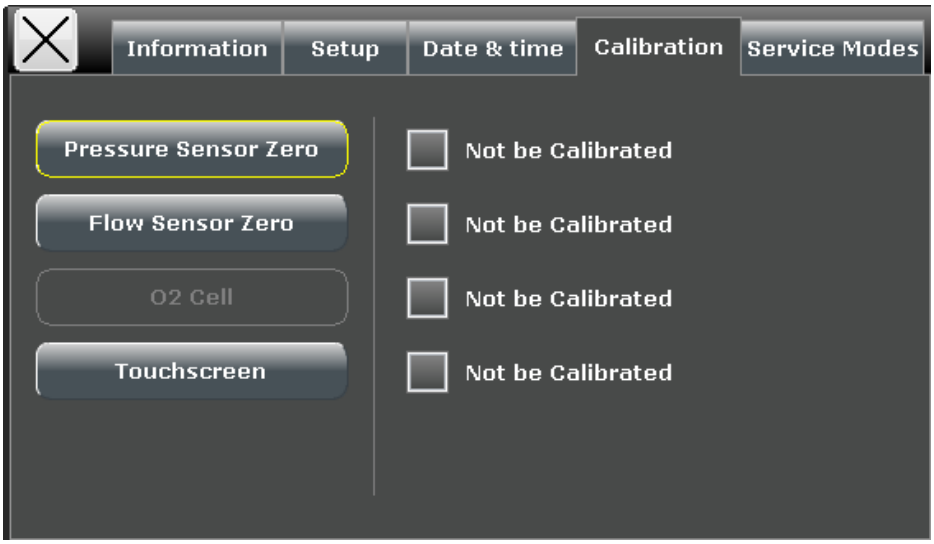
6.3.6.3 Date& time

Set the date and time, and click "Apply" after the modification to make the modification take effect. The date and time settings will be saved by the machine.



6.3.6.4 System calibration

System verification can only be performed on the standby interface, where the engineer mode is only allowed to be used by professional maintenance personnel (see Chapter 10 User Maintenance for details).



Chapter 7 Operation and Parameter Settings

⚠Warning

- Before using the anesthetic workstation, make sure that the equipment is in good condition and the system connection is completely correct; all relevant tests in chapter 4 Pre-Operation Test need to be completed. If the anesthetic workstation does not pass the test, please do not use it, so as not to endanger the life of the patient; you should contact authorized professionals or our company's after-sales personnel.

7.1 Input Fresh Gas

7.1.1 Flow meter settings

1) Connect the O_2 and Air pipeline gas source or open the spare gas cylinder valve, and make sure that the gas source has sufficient pressure.
2) Adjust the flow meter control knob clockwise to decrease the flow volume; adjust the flow meter control knob counterclockwise to increase the flow volume.

⚠Note

- This anesthetic workstation can be used as a ventilator alone, and the oxygen concentration in the patient circuit can be controlled by setting the ratio of O_2 and Air flow.
- The oxygen concentration in the patient circuit may be of great difference from the oxygen concentration in the fresh gas.

7.1.2 Settings of anesthetics

1) Confirm that the anesthetic vaporizer to be used has been installed correctly and has sufficient anesthetics.

2) Adjust the concentration adjustment knob of the anesthesia vaporizer to set the appropriate anesthetic gas concentration.

3) By setting the flow meter, the flow passes through the anesthesia vaporizer to form fresh gas with a certain concentration of anesthetic gas.

⚠Note

- This anesthetic workstation can use anesthetics including enflurane, isoflurane, sevoflurane. It is recommended to use only one anesthetic at a time.
- If the flow meter is not set, the anesthetic gas will not enter the patient end.
- Before using the anesthetic, please check the color of the absorbent in the CO_2 absorption tank. If there is a significant change in color, the absorbent should be replaced immediately.
- When not using or stopping the use of anesthetics, please turn off the anesthesia vaporizer in time.

- It is recommended not to use the range between 0% and 0.2% of the anesthesia evaporator dial, otherwise there may be no anesthetic output, causing harm to the patient.
- This anesthetic workstation can be equipped with anesthesia vaporizer models including VP10 sevoflurane, VP20 isoflurane and VP30 enflurane, SigmaDelta and Vapor 2000. Applicable types of anesthetics: Sevoflurane and isoflurane for SigmaDelta, Sevoflurane and isoflurane for Vapor 2000. For detailed instructions, please refer to the corresponding anesthesia vaporizer's Operator's Manual.

7.2 ACGO Mode

In ACGO mode, the breathing circuit is bypassed and an open system is created; the fresh gas will be output directly from the ACGO interface without passing through the CO_2 absorption tank. At this time, the anesthetic workstation will switch from mechanical ventilation or manual ventilation mode to ACGO mode.

In ACGO mode, it is allowed to perform the settings of fresh gas flow and anesthetic gas concentration.

7.3 Manual Ventilation Mode

In the manual ventilation mode, the function of the APL valve is to adjust the peak pressure of the patient circuit and the amount of gas in the manual breathing capsule. When the pressure of the patient circuit continues to rise until it reaches the pressure limit set by the APL valve, the APL valve will be automatically opened to release the excess gas in the patient circuit.

In manual ventilation mode, the APL valve limit pressure is generally set between 20-30cmH_2O.

Note

- The scale of the APL valve is approximate, and there is a certain error range.

Use manual ventilation mode:

1) Set the manual/machine control switch to the manual position.
2) Set the appropriate APL valve pressure limit.
3) The manual breathing capsule interface is connected to the manual breathing capsule.
4) The inhalation and exhalation interfaces of the circuit are connected to the Y-shaped three-way to the patient end.
5) Pinch the capsule to help the patient to breathe.

Note

- When using the anesthetic workstation, please ensure that there is an independent backup ventilation method.
- When only using air in manual ventilation mode, make sure that the fresh air flow is set high enough to prevent re-inhalation.

- During autonomous ventilation, always use carbon dioxide (CO_2) monitoring and maintain visual control over the manual capsule.

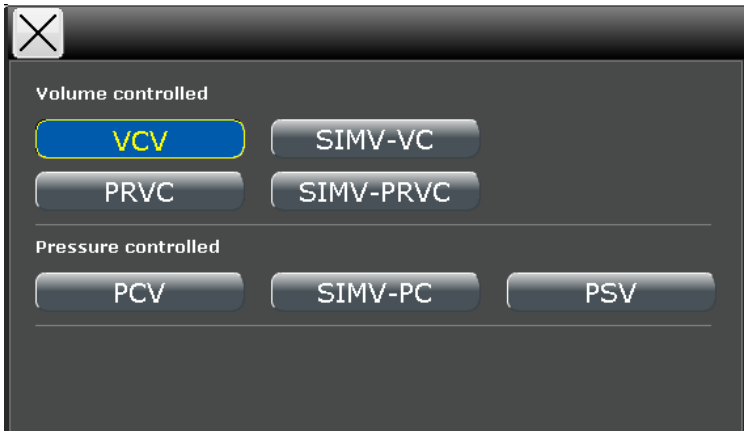
7.4 Mechanical Ventilation Mode

7.4.1 Settings before starting the mechanical ventilation mode

1) Make sure the system enters standby state.
2) Set the appropriate upper and lower alarm limits of airway pressure: select [Alarm] -> [Setting 1] -> [Pressure].
3) Ensure that the ACGO switch is turned off.
4) Set the manual/machine control switch to machine control position.
5) The inhalation and exhalation interfaces of the circuit are connected to the Y-shaped three-way.
6) When necessary, press the oxygen flush button to fill the bellows to the top.

7.4.2 Mechanical ventilation mode setting

1) Select [Mode] to enter the mode setting menu.



2) Select the mode that needs to be set, the parameters of the selected mode will pop up, and click to accept.
3) The mode display area displays the current ventilation mode.

Note

- Only in VCV mode can you select +SIGH (sigh).
- The backup ventilation mode can only be set in SPONT/PSV mode.

7.4.3 Volume control (VCV) mode

7.4.3.1 Brief description of the principle

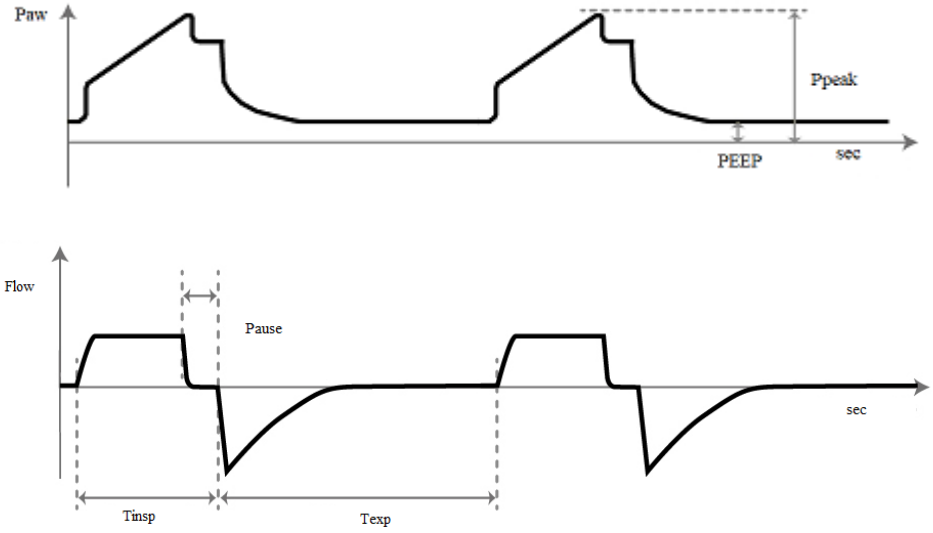
The VCV mode (volume control mode) ensures that the patient can receive the preset tidal volume. In this control mode, the system delivers a constant flow of the set tidal volume during the set inspiration time.

Airway pressure depends on tidal volume, PEEP setting, inspiratory time, and the resistance and compliance of the respiratory system. The system always delivers the set tidal volume. Increased resistance and decreased compliance can lead to increased airway pressure.

Note

- In order to protect the patient's lungs from excessive pressure, it is very important to set an appropriate upper limit of the pressure alarm.
- If the peak airway pressure reaches the upper limit of the pressure alarm, inhalation will stop, exhalation will begin, and an high airway pressure alarm will be issued.

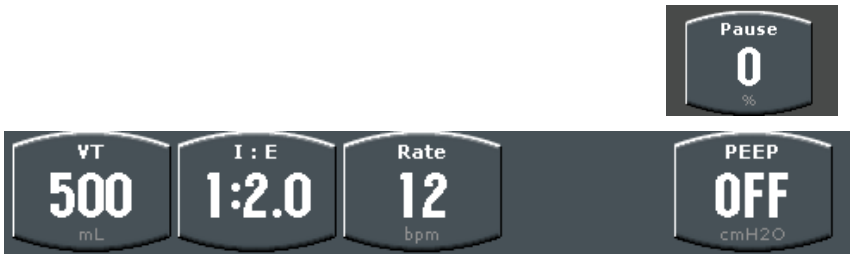
7.4.3.2 Waveform diagram



Under normal circumstances, the flow waveform in the [VCV] mode maintains constant during the inhalation period, and the pressure waveform increases in pressure during the inhalation period.

7.4.3.3 Parameter setting

Parameters to be set in VCV mode are as follows:



1. [VT] Tidal volume
2. [I:E] Inhale-to-exhale ratio
3. [RATE]: Respiratory rate
4. [Pause] Inhalation pause
5. [PEEP]: Positive end-tidal pressure

7.4.4 Pressure control (PCV) mode

7.4.4.1 Principle description

Pressure-controlled ventilation mode (PCV) is a controlled breathing mode that targets pressure. In the inhalation phase, with forced ventilation according to the preset pressure, it stabilizes the patient's airway pressure at the set value during the entire inhalation cycle, and its flow curve shows a downward

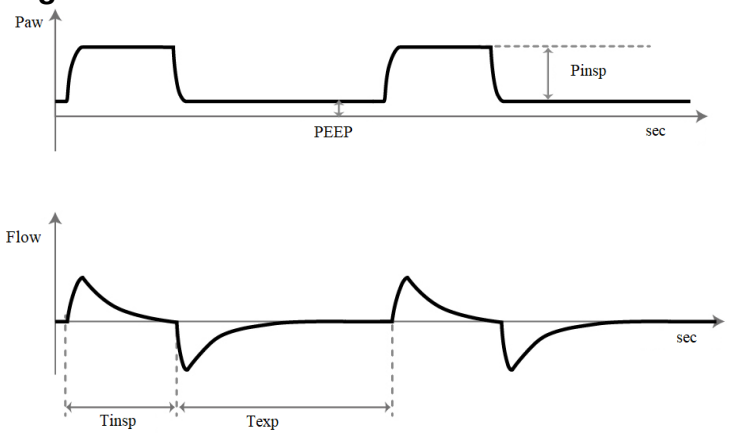
trend.

The delivered volume depends on lung compliance and the resistance of the patient's piping system and airway. This means that the tidal volume may change.

Note

- PCV mode Pinsp (pressure control level) is based on PEEP.

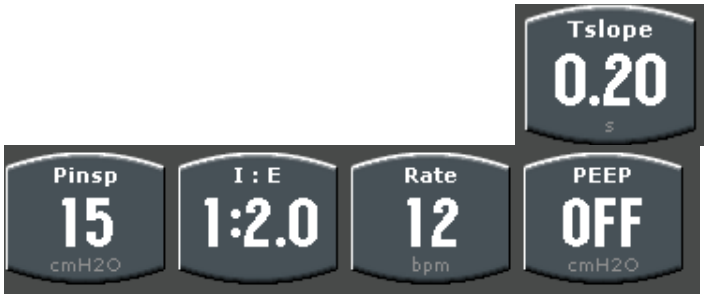
7.4.4.2 Waveform diagram



Generally, the pressure waveform in the [PCV] mode has a steeper pressure rise during inhalation, a longer plateau time, and no spikes; during inhalation, the flow waveform has a downward trend.

7.4.4.3 Parameter settings

Parameters to be set in the PCV mode are as follows:



1. [Pinsp] Pressure control level
2. [I:E] Inhale-to-exhale ratio
3. [RATE]: Respiratory rate
4. [Tslope] Pressure rise time
5. [PEEP]: Positive end-tidal pressure

7.4.5 Synchronized intermittent mandatory ventilation (SIMV) mode

7.4.5.1 Brief description of the principle

SIMV mode: Each SIMV breathing cycle is divided into two phases, namely the mandatory ventilation phase and the autonomous ventilation phase. During the mandatory ventilation phase, the ventilator provides mandatory ventilation and keeps synchronization with the patient's spontaneous breathing attempts at a preset frequency. Forced ventilation may be volume controlled ventilation or pressure controlled ventilation.

- SIMV-VC (Volume Control) + Pressure Support
- SIMV-PC (Pressure control) + pressure support

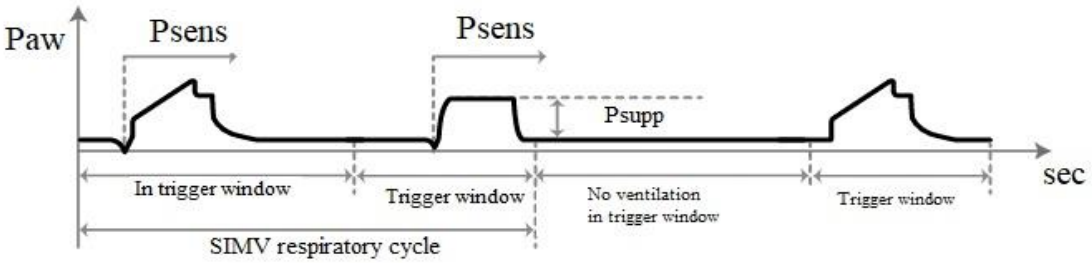
If the inspiratory trigger condition (which can be setup) is reached within the mandatory ventilation

phase, the system will provide a mandatory ventilation synchronously; if the inspiratory trigger condition is not reached within the mandatory ventilation phase, the system will automatically provide it once before the end of the mandatory ventilation phase, and then enter the autonomous ventilation phase.

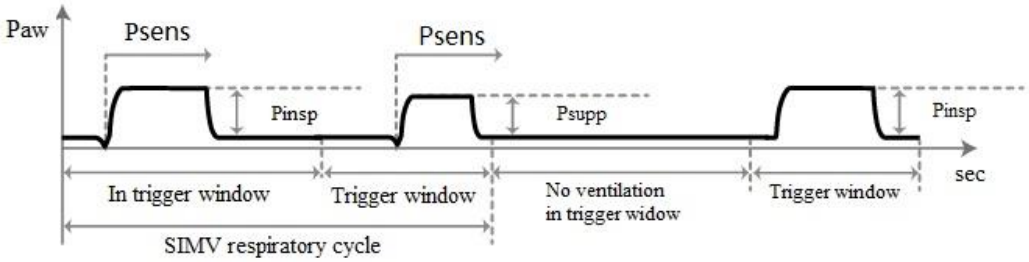
If the inspiration trigger condition is reached during the spontaneous ventilation phase, the ventilator will simultaneously provide pressure support ventilation. You can choose to follow the [PSV] mode (pressure support mode) for ventilation. [PSV]For the description of the mode, please refer to the PSV mode.

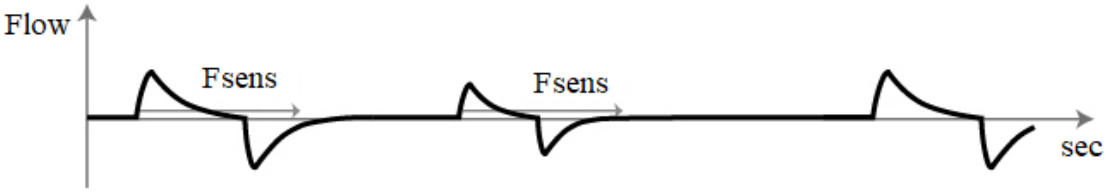
7.4.5.2 Waveform diagram

SIMV-VC mode waveform diagram:



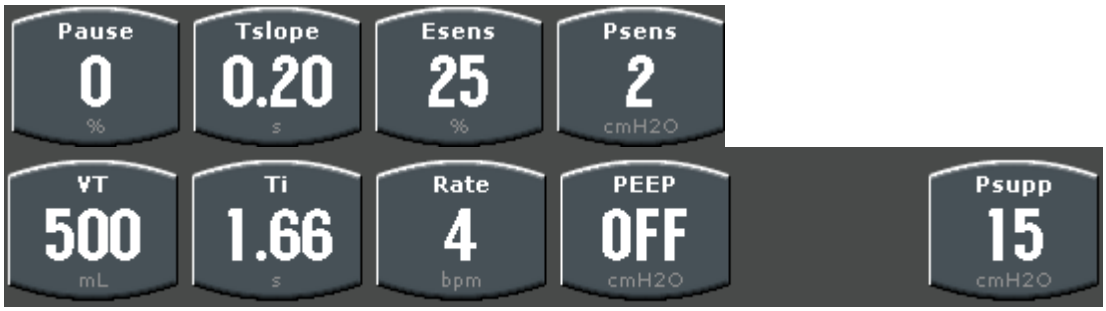
SIMV-PC mode waveform diagram:





7.4.5.3 Parameter settings

Parameters to be set in the SIMV-VC mode are as follows:

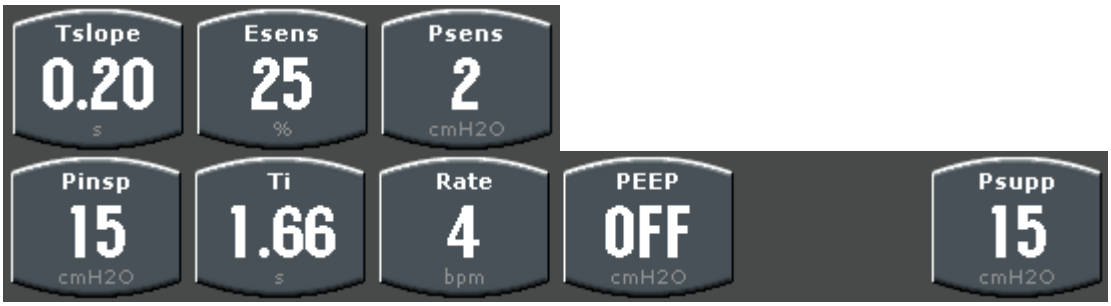


1. [VT] Tidal volume

6. [Tslope] Pressure rise time

2. [TI] Inspiratory time
3. [RATE]: Respiratory rate
4. [Psupp] Pressure support level
5. [Pause] Breath-holding time
7. [Psens]/[Fsens] Pressure trigger/flow trigger
9. [PEEP]: Positive end-tidal pressure
10. [Esens] Exhalation trigger sensitivity

Parameters to be set in the SIMV-P mode are as follows:



1. [Pinsp] Pressure control level
2. [TI] Inspiratory time
3. [RATE]: Respiratory rate
4. [Psupp] Pressure support level
5. [Tslope] Pressure rise time
6. [Psens]/[Fsens] Pressure trigger/flow trigger
7. [PEEP]: Positive end-tidal pressure
8. [Esens] Exhalation trigger sensitivity

7.4.6 SPONT/PSV mode

7.4.6.1 Brief description of principle

Pressure Support Ventilation (PSV) mode is a breathing mode triggered by the patient. The ventilator provides the patient with preset constant pressure support. When the patient actively triggers, the ventilator supports the patient's inhalation according to the preset constant pressure. In this mode, the patient determines the respiratory rate and duration, and the flow curve shows a downward trend. The inspiratory time course is changed by the patient's control of the inspiratory flow.

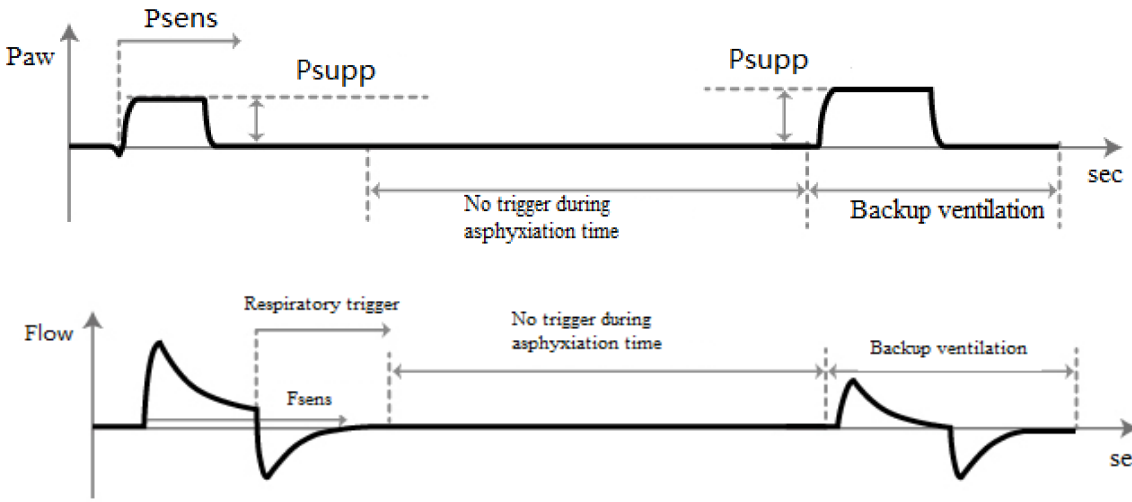
In [PSV] mode, when the patient's spontaneous inhalation reaches the predetermined inhalation trigger condition, the ventilator starts to deliver gas to the patient, so that the airway pressure reaches the preset pressure support level during the set pressure rise time [Psupp]. After that, the feedback system is used to slow down the rate of air delivery and maintain the airway pressure at the level of [Psupp]. When the inspiratory flow drops to the trigger condition of [Esens], the inhalation stops and the patient starts to exhale.

In [PSV] mode, [VT] is not constant, [VT] depends on the patient's inspiratory strength and the set pressure support level, as well as the patient and ventilation system compliance and resistance and other factors. [PSV] mode can only be used when the patient has a reliable breathing drive (the patient must trigger all breathing during ventilation).

When the [SPONT/PSV] mode is used, the system is equipped with a backup [Backup Ventilation] mode. If the patient does not breathe spontaneously or the spontaneous breathing does not reach the trigger condition of inspiration within the set [Asphyxia time], the system will automatically start the standby [Backup Ventilation] mode after the end of the set [Asphyxia Time], and perform forced mechanical ventilation. [Backup Ventilation] can be set to [Volume Mode] and [Pressure Mode].

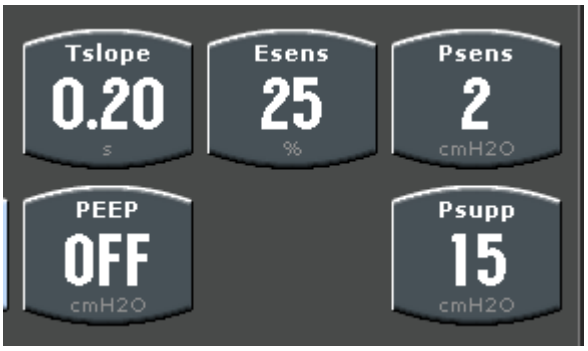
[PSV] mode can be used together with [SIMV-V] or [SIMV-P] mode.

7.4.6.2 Waveform diagram



7.4.6.3 Parameter settings

1.Parameters to be set in the SPONT/PSV mode are as follows:



1. [Tslope] Pressure rise time
2. [Esens] Exhalation trigger sensitivity
3. [Psens]/[Fsens] Pressure trigger/flow trigger
4. [PEEP]: Positive end-tiidal pressure
5. [Psupp] Pressure support level

2. Backup ventilation settings

1) Set the appropriate [Asphyxia time (backup ventilation start time)] in the [Alarm] -> [Settings 1] menu.

2) Set the backup ventilation mode and mode parameters in the [Control] -> [Backup Ventilation] menu.

Volume mode:

Pressure mode:

Note

- Before using the SPONT/PSV mode, you need to set the asphyxia time, backup ventilation mode, and parameters in the mode in advance. Otherwise, when the patient does not breathe spontaneously or the spontaneous breathing does not reach the inspiration trigger condition, the patient will not get proper ventilation after backup ventilation is switched, causing harm to the patient.

7.5 Ventilator Parameter Settings

Note

- You must confirm the parameters after setting them, and then adjust other parameters.
- When adjusting parameters, if the parameter exceeds the range, the system will display relevant prompt information.

7.5.1 Setting tidal volume

1) Select the [VT] hot key.
2) Rotate the knob to set [VT] to an appropriate value.
3) Press the control knob or touch to confirm the setting of [VT].

7.5.2 Setting respiratory rate

1) Select the [RATE] hot key.
2) Rotate the knob to set [RATE] to an appropriate value.
3) Press the control knob or touch to confirm the setting of [RATE].

7.5.3 Setting inhale-to-exhale ratio

1) Select the [I:E] hot key.
2) Rotate the knob to set [I:E] to an appropriate value.
3) Press the control knob or touch to confirm the setting of [I:E].

7.5.4 Setting pressure control level

1) Select [Alarm] -> [Setting 1] -> [Pressure].
2) Rotate the knob to set the upper and lower limits of [pressure] to appropriate values.
3) Press the control knob or touch to confirm the upper and lower limits of [Pressure].

7.5.5 Setting positive end-tidal pressure

1) Select the [PEEP] hot key.
2) Rotate the knob to set [PEEP] to an appropriate value.
3) Press the control knob or touch to confirm the setting of [PEEP].

7.5.6 Setting pressure control level

1) Select the [Pinsp] hot key.
2) Rotate the knob to set [Pinsp] to an appropriate value.
3) Press the control knob or touch to confirm the setting of [Pinsp].

7.5.7 Setting pressure support level

1) Select the [Psupp] hot key.
2) 2) Rotate the knob to set [Psupp] to an appropriate value.
3) Press the control knob or touch to confirm the setting of [Psupp].

7.5.8 Setting trigger conditions for inspiration

In [SIMV] mode, it is necessary to set the trigger condition of inspiration.

1) Select [Menu Bar] -> [Control] -> [Trigger Type]: Pressure trigger/Flow trigger.
2) Rotate the knob to set [Psens]/[Fsens] to an appropriate value.
3) Press the control knob or touch to confirm the setting of [Psens]/[Fsens].

7.5.9 Setting inhalation pause

1) In VCV mode, select [pause] hot key.
2) Rotate the knob to set [pause] to an appropriate value.
3) Press the control knob or touch to confirm the setting of [Asphyxia time].

7.5.10 Setting pressure rise time

1) Select the [Tslope] hot key.
2) Rotate the knob to set [Tslope] to an appropriate value.
3) Press the control knob or touch to confirm the setting of [Tslope].

7.6 Starting Mechanical Ventilation

When the pre-use check is completed and the relevant parameters are set, you can enter the mechanical ventilation mode in the following step: Press the "Start/Standby" button to enter the mechanical ventilation.

7.7 Ring Diagram of the Pulmonary Function

Pulmonary function ring diagram can reflect:

1) Patient’s lung function

2) Ventilation
3) Lung compliance
4) Whether the lungs are over-inflated
5) Whether there is a leak in the circuit?
6) Whether there is a blockage of the airway

The anesthetic workstation provides two types of ring diagrams of the pulmonary function :

1) [Paw-V Ring] (Pressure-volume ring)
2) [V-Flow ring] (Volume-flow ring)

7.8 Stopping Mechanical Ventilation

When you need to stop mechanical ventilation, please follow the steps:

1) Confirm that mechanical ventilation can be stopped.
2) Set the appropriate APL valve to limit the pressure and connect the manual breathing capsule.
3) To stop mechanical ventilation:

- Press the [Start/Standby] button to enter the standby mode.
- Set the manual/machine control switch to manual.
- Turn on ACGO.

⚠Note

- **After stopping mechanical ventilation, please choose manual ventilation instead of immediately stopping ventilation on the patient. After a few minutes, when the patient regain consciousness and is able to breathe on his own, switch to spontaneous breathing of the patient.**

Chapter 8 Alarm

8.1 Outline

When patients that are using anesthetic workstation have abnormal changes in vital signs or changes in basic life parameters, the anesthetic workstation makes discrimination according to the alarm limits set by the operator and send alarms to doctors or nurses by means of sound, light, etc. The anesthetic workstation also sends sound and light alarm to remind medical personnel when the machine itself fails so that patients can't use the anesthetic workstation smoothly.

⚠Note

- When the machine is powered on, the system will detect whether the alarm sound function and the alarm light function are normal. Under normal circumstances, the anesthetic workstation will have a "beep beep" alarm sound. If the alarm sound function is abnormal, please do not use this anesthetic workstation and contact the maintenance department of our company.
- When several alarms of different levels are generated at the same time, the anesthetic workstation will follow the highest level of all current alarms and emit an audible alarm.

8.1.1 Alarm types

Alarms are divided into: physiological alarms and technical alarms.

1) Physiological alarm

If a certain physiological parameter of the patient exceeds the range of the high/low limit of the set alarm, or the patient has a physiological abnormality, a physiological alarm will be issued.

2) Technical alarm

When a certain system function cannot work normally caused by improper operation or system failure, or when the detection result is abnormal, a technical alarm will be issued.

8.1.2 Alarm level

The alarm level of the anesthetic workstation is divided into advanced alarm, intermediate alarm and low-level alarm according to the severity of the alarm.

1) Advanced alarm

The alarm information is displayed with a red background with "!!!" following the alarm content. The alarm indicator is red and it flashes at a high frequency (2 times per second)； the alarm sound is made up of 10 scales is repeated every 10 seconds. Advanced alarm means that the patient is in a critical state which may be life-threatening. Medical staff must immediately conduct rescue or eliminate technical failures or improper operations.

2) Intermediate alarm

The alarm information is displayed with a yellow background with "！ ！ " following the alarm

content.

The alarm indicator is yellow and it flashes at a high frequency (once per 2 seconds); the alarm sound is made up of 3 and is repeated every 25 seconds. If the patient's vital parameters are abnormal or have potential risks, medical staff should promptly treat or deal with it.

3) Low level alarm

The alarm information is displayed with a yellow background with "！" following the alarm content. It is displayed with orange background. The alarm indicator is yellow and it is on without flashes; the alarm sound is made up of 2 scales without any repetition. If the patient's vital parameters or equipment are abnormal, medical staff should pay attention to observation or take measures to deal with it.

⚠Note

- The levels of all technical alarms and some physiological alarms have been set when the anesthetic workstation leaves the factory and cannot be changed by the user.

8.2 Alarm mode

When an alarm occurs, this anesthetic workstation uses below sound or image alarm to remind medical personnel or other operators:

Sound alarm, alarm information, and alarm record.

8.2.1 Light Alarm

When an alarm occurs, according to different levels of alarm, the alarm indicator will send out alarm signals in different colors and flashing frequencies.

Advanced alarm: The alarm indicator is red and it flashes at a high frequency (2 times per second).

Intermediate alarm: The alarm indicator is yellow and it flashes at a high frequency (once per 2 seconds).

Low level alarm: It is displayed with orange background. The alarm indicator is yellow and it is on without flashes.

8.2.2 Sound Alarm

The sound alarm means that the anesthetic workstation uses different sound characteristics to prompt different alarm levels.

An advanced alarm is made up of 10 scales and is repeated every 10 seconds.

An intermediate alarm is made up of 3 scales and is repeated every 25 seconds.

A low level alarm is made up of 2 scales without any repetition.

8.2.3 Alarm information

The alarm information displayed in the alarm display area of the anesthetic workstation uses different background colors to distinguish the level of the alarm information:

1) Advanced alarm: red background

2) Intermediate alarm: yellow background

3) Low level alarm: yellow background

8.2.4 Alarm records

In the alarm information displayed in [Alarm]-[Alarm Record], the date and time of alarm occurrence, alarm level and alarm information are recorded.

8.3 Setting the Alarm Volume

1) Select [System] -> [Settings] -> [Volume Setting].
2) Select [Alarm Volume]: 10% is the lowest, and 100% is the highest. Adjust 10% each time.

⚠Warning

- When using the anesthetic workstation, you cannot rely solely on the audible alarm. If the alarm volume is too low, the sound is hard to be heard and the patient may be in danger. Users should pay close attention to the actual clinical situation of the patient.

8.4 Setting the Alarm Upper/Lower Limit

⚠Note

- **When using the anesthetic workstation, pay attention to observe whether the parameter alarm limit is set appropriately.**
- **The setting values of the upper and lower limit of parameter alarms can be viewed in the quick parameter display area.**
- **The upper and lower alarm limits of the anesthetic workstation are automatically restored to the default values each time the anesthetic workstation is turned on.**

1) Select > -[Alarm] -> [Setting 1]/ [[Setting 2] menu.
2) Set appropriate [Alarm Lower Limit] and [Alarm Upper Limit] in the [Setting 1] / [Setting 2] menu respectively.

8.5 Alarm Silence

Setting alarm silence

When there is an advanced alarm or an intermediate alarm, the alarm enters temporarily silent mode with the alarm silence button pressed. That is to say, the alarm sound is temporarily muted, and

the icon  will be displayed at the top of the screen together with a 120s countdown.

When an alarm is muted, other alarm types still work normally.

When an alarm is muted, if a new technical alarm or physiological alarm is generated, the current alarm's sound pause state will be canceled by the system, and the alarm sound can be resumed.

When the 120s countdown is completed, the pause state of the alarm sound will be canceled, and the alarm sound will resume.

8.6 Alarm Response Measures

When an anesthetic workstation issues an alarm, please check the following steps and take corresponding measures:

1) Check the patient's condition.
2) Confirm the current alarm parameters and alarm types.
3) Identify the cause of the alarm.
4) Cancel the alarm.
5) If the alarm cannot be canceled, please switch to manual ventilation mode or use a backup anesthetic workstation.

Please refer to 8.7 Alarm Information for the specific countermeasures for each alarm.

8.7 Alarm Information

8.7.1 Physiological alarm information

No.	Alarm information	Alarm level	Reason	Measures
1	Apnea!!!	Advanced	No spontaneous breathing triggers after the set apnea interval	Check ventilator settings; Check the patient's spontaneous breathing ability; Check if the pipeline is bent or blocked;
2	Continuous pressure high!!!	Advanced	The monitored value of airway pressure exceeds (PEEP + 15) cmH2O for 2 consecutive ventilator cycles or 5S	Check if the pipeline is bent or blocked;
3	Pressure high!!!	Advanced	The monitoring value of airway peak pressure is higher than the upper limit of airway pressure alarm	Decrease the tidal volume or pressure setting; Increase the upper limit of airway pressure alarm; Check if the pipeline is bent or blocked;
4	MV low!!!	Advanced	The monitoring value of minute ventilation is less than the alarm lower limit of minute ventilation	Increase the tidal volume or respiratory setting rate. Reduce the alarm lower limit of minute ventilation;

5	MV high!!!	Advanced	The monitoring value of the minute ventilation is greater than the alarm upper limit of the minute ventilation	Reduce the tidal volume or respiratory setting rate Increase the alarm upper limit of minute ventilation;
6	Pressure < -10cmH_2O!!!	Advanced	Airway pressure monitoring value is lower than -10cmH_2O	Check if the pipeline is bent or blocked; Check whether the patient is breathing spontaneously;
7	Rate low!!!	Advanced	The respiratory rate monitoring value is lower than the lower alarm limit	Set a suitable lower limit of respiratory rate alarm; Increase the respiratory rate setting value;
8	Fio_2 high !!!	Advanced	The monitoring value of the inhaled oxygen concentration is higher than the upper alarm limit	Set the appropriate upper limit of oxygen concentration alarm; Check the oxygen setting of the flow meter; Recalibrate the oxygen sensor;
9	Fio_2 Low!!!	Advanced	The monitoring value of the inhaled oxygen concentration is lower than the lower alarm limit	Set the appropriate lower limit of oxygen concentration alarm; Check the oxygen setting of the flow meter; Recalibrate the oxygen sensor;
10	EtCO_2 High!!!	Advanced	The monitoring value of the end-tidal CO_2 concentration is higher than the upper alarm limit	Check the patient's condition. Set the appropriate upper limit of end-tidal CO_2 concentration alarm; Check whether the carbon dioxide absorbent needs to be replaced;
11	FiCO_2 high!!!	Advanced	The monitoring value of the inhaled CO_2 concentration is higher than the upper alarm limit	Check the patient's condition. Set the appropriate upper limit of inhaled CO_2 concentration alarm Check whether the carbon dioxide absorbent needs to be replaced;
12	Pressure low!!!	Advanced	Airway pressure monitoring value is lower than the lower alarm limit	Increase tidal volume or pressure setting; Increase the lower limit of airway pressure alarm;
13	Vte high!!!	Advanced	The monitoring value of expiratory tidal volume is higher than the upper alarm limit	Decrease the setting value of the tidal volume; Decrease the upper limit setting value of tidal volume alarm;
14	Vte low!!	Intermediate	The monitoring value of expiratory tidal volume is lower than the lower alarm limit	Increase the tidal volume setting value; Increase the lower limit setting value of the tidal volume alarm; Check for leaks in the respiratory system;
15	Rate high!!	Intermediate	The monitoring value of the respiratory rate is higher than the upper alarm limit	Set the appropriate upper limit of the respiratory rate alarm; Decrease the set value of expiratory frequency;

16	$EtCO_2$ low!!	Intermediate	End-tidal carbon dioxide monitoring value is lower than the lower alarm limit	Check whether the pipeline is leaking or blocked; Set a suitable lower limit of end-tidal carbon dioxide alarm;

8.7.2 Technical alarm

No.	Alarm information	Alarm level	Reason	Measures
1	O2 SUPPLY DOWN !!!	Advanced	The monitoring pressure value of the oxygen source is lower than 280kPa	Ensure that the oxygen gas source pipeline or gas cylinder is properly connected and the gas source pressure is normal;
2	BATTERY DISCHARGED !!!	Advanced	The battery power can only keep the anesthetic workstation working for ≥5 minutes	Connect AC power; Check whether the AC indicator light is on;
3	O2 SENSOR FAILURE!!!	Advanced	Oxygen sensor failure;	Check whether the oxygen sensor cable is connected; Re-calibrate the oxygen battery; Contact the designated maintenance personnel;
4	BATTERY LOW !!!	Advanced	The battery power can only keep the anesthetic workstation working for ≥10 minutes	Connect AC power; Check whether the AC indicator light is on;
5	Gas supply down!!	Intermediate	The monitoring pressure value of the gas source is lower than 280kPa	Ensure the air gas source pipeline or gas cylinder is properly connected and the gas source pressure is normal;
6	ETCO2 LINE OCCLUSION!!	Intermediate	CO2 sampling tube is blocked	Check whether the carbon dioxide sampling tube is broken or blocked;
7	MAINS FAILURE !	Low	AC power is not connected	Connect AC power; Check whether the AC indicator light is on;

Chapter 9 Cleaning and Sterilization

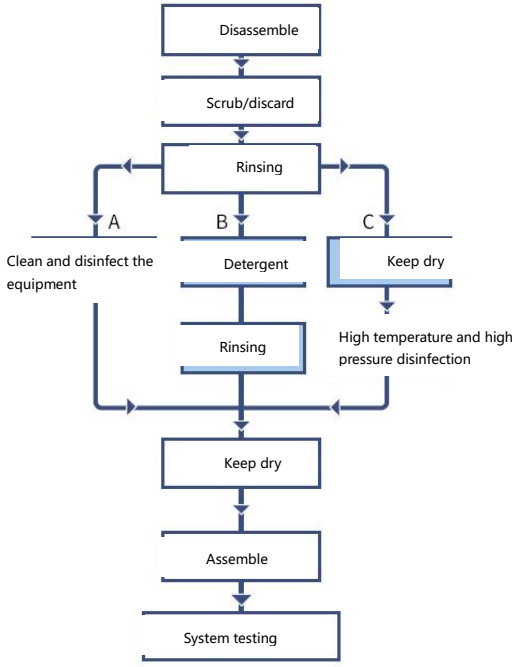
⚠Warning

- It is recommended that you should use the verified effective methods described in this manual. Other methods may be equally effective, but unless the company provides written permission, it is not guaranteed in this manual.
- Please read the safety data of each cleaning agent carefully, and prohibit the use of organic, halogenated, petroleum-based solvents, glass cleaners, acetone or other harsh detergents.
- Please carefully read the operation and maintenance manual of the sterilization equipment.
- If the oxygen concentration sensor is damaged, it may leak and cause combustion (it includes potassium hydroxide).
- Please wear safety gloves and glasses for cleaning and sterilization.
- Do not inhale fumes.
- After disassembly, cleaning and sterilization or reinstallation, the machine can only be used after the pre-operation test in Chapter 4 is performed.
- In order to prevent leakage of the respiratory system, please pay attention to avoiding damage to various parts and ensure the correctness of the installation during disassembling and reinstalling, especially the installation of the seal ring.

⚠Note:

- It is recommended that the bacteria/virus filter is always connected to the patient's breathing circuit. This minimizes the risk of carryover.
- If possible, clean the equipment before disinfection/sterilization and immediately after use. Blood or other residues are not allowed to dry out on the equipment.
- All personnel should be aware that contamination of certain parts is possible during the disassembling or cleaning of the system.
- All disposable parts must be disposed of in an environmentally safe manner in accordance with hospital regulations.
- Do not use abrasive cleaners (such as steel wool, silver polish or cleaners).
- The cleaning liquid should be placed far away from the electronic components, and the liquid should not flow into the inside of the device along the shell.
- It is recommended to use detergent with PH≤10.

The cleaning and sterilization process is as follows:



9.1 Cleaning and Sterilization Method

⚠Warning

- ◆ It is forbidden to immerse the oxygen concentration sensor in liquid or perform high temperature and high pressure sterilization.
- ◆ During the cleaning process, be careful not to make the cleaning liquid flow into the machine to cause damage. Cut off the power before cleaning, and after cleaning, make sure that all parts of the anesthetic workstation are completely dry before use.
- ◆ High temperature and high pressure steam cannot be used to sterilize the flow sensor for more than 10 times. Please replace it as needed.
- ◆ The oxygen concentration sensor cannot be immersed in any liquid for sterilization.

⚠Note

- ● Water quality will affect the cleaning/sterilization effect. It is recommended to use deionized water. The water quality should not be lower than the drinking water quality.
- ● Wash all parts thoroughly in water (<35℃). Let water flow through the components to remove organic matter such as blood and other residues. If it is washed in water with a temperature higher than 35°C, it may cause solidification of organic substances.

The various parts of the anesthetic workstation can be cleaned and sterilized, and the requirements for the cleaning and sterilization of different parts are different.

It is necessary to choose an appropriate method according to the actual situation to clean and sterilize each part of the anesthetic workstation timely and correctly to prevent carryover of patients.

The recommended cleaning and sterilization methods are as follows:

A: Use cleaning and sterilization equipment for cleaning and sterilization.

B: Use detergent to clean and sterilize (it is recommended to use a mild detergent with a pH of less than 10, for example: soak in a 2% glutaraldehyde solution for more than 45 minutes).

C. High temperature and high pressure steam sterilization (maximum temperature is 134°C).

D. Wipe with a damp cloth (70% ethylene glycol or isopropanol) soaked in a mild detergent solution.

Component name	Cleaning and disinfection methods			
	A	B	C	D
Anesthetic Workstation shell				√
Flow sensor		√	√	√
One-way valve cover and protection bracket	√	√	√	
One-way valve plate		√		√
Oxygen concentration sensor				√
Circuit pressure gauge				√
Bellow components	√			√
CO_2 absorption tank components	√	√	√	
Circuit body	√	√	√	

9.1.1 Using cleaning and sterilization equipment

Note

- **In order to minimize the impact on the environment, it is recommended to use only water when sterilizing the equipment. The maximum temperature during sterilization is generally in the range of 90°C-95°C.**
- **If the detergent is used with a washer-disinfector, it is recommended to use the detergent with pH <10.**

Processes of using cleaning and sterilization equipment for cleaning and sterilization:

1) Use clean water to scrub or clean.

2) Use cleaning and sterilization equipment for cleaning and sterilization.

3) Dry the cleaned and sterilized components.

4) Assemble, store or spare the components, etc.

9.1.2 Using cleaning and disinfection detergent

Note

It is recommended to use detergent with pH < 10.

Soak the synthetic rubber components for no more than 14 minutes to prevent aging and swelling.

1) Use clean water to scrub or clean.

2) Use detergent to clean and sterilize (it is recommended to use a mild detergent with a pH of less than 10, for example: soak in a 2% glutaraldehyde solution for more than 45 minutes).

3) Use clean water to clean the residual disinfectant.

4) Dry the cleaned and sterilized components.

5) Assemble, store or spare the components, etc.

9.1.3 High temperature and high pressure sterilization

Note

- Steam and high pressure sterilization will shorten the service life of the components.
- The components of this system should be autoclaved using a validated process, generally at a temperature of 121°C (250°F) for 15 minutes or at a temperature of 134°C (275°F) for 4 minutes.
- The components of the system can also be autoclaved for 18 minutes at a temperature of 134°C (275°F). Using this method will further reduce the life of each component.

1) Use clean water to scrub or clean.
2) Dry the components.
3) Use steam and high temperature autoclave sterilization.
4) Dry the cleaned and sterilized components.
5) Assemble, store or spare the components, etc.

9.1.4 Wiping with a gentle detergent

Note

- **The screen can only be cleaned with a soft lint-free cloth, and liquids cannot be used for cleaning the screen.**

1) Soak a cotton cloth with a soft cleaning liquid to wipe the screen.
2) Please use a dry, soft, lint-free cloth to wipe off the remaining cleaning solution.

9.2 Assembling

Note

- **Please ensure that all cleaned and sterilized components are in a dry state before assembly.**
- **When installing the components, make sure that the components and the seal ring are intact, otherwise it may cause the respiratory system to leak or that other equipment cannot be used normally.**

Please refer to Chapter 3 Installation and Connection of this manual to assemble the respiratory system and AGSS.

9.3 System Testing

Note

- **It is required to perform system testing on the anesthetic workstation after cleaning and sterilization.**

Please perform a complete system testing according to Chapter 4 Pre-use Test.

Chapter 10 User Maintenance

10.1 Maintenance Principles

⚠Warning

- Lubricants containing oil or grease are forbidden to use because lubricants containing oil or grease may burn or explode when oxygen reaches a certain concentration.
- Please use approved anesthesia equipment or special lubricant for O_2 equipment.
- Blood or body fluids are very likely to contaminate the equipment. Safety regulations and sterilization control must be followed.
- Moving parts and detachable parts may pinch the hands or be crushed. Be careful when moving or replacing system components.
- The faulty equipment cannot be used. You need to notify the company's after-sales department to repair it, or let specially trained personnel do the maintenance and replacement of the parts.
- In order to ensure the normal operation of the machine, check and test the machine after the repair, making sure it meets the standard stated in the specification.
- The maintenance, repair, cleaning, sterilization of the anesthetic workstation should be carried out when the anesthetic workstation is not in operation.

⚠Note

- People who have no experience in repairing such equipment should not repair this machine.
- The company can provide circuit diagrams, component lists, figure annotations, calibration rules, or necessary information for repairable equipment parts specified by the manufacturer. Please replace damaged parts with components produced or provided by the company. System testing is required after the replacement to ensure that manufacturer's specifications are well met.
- If you need service support, please contact our company's after-sales department.

Class I special waste product

Used batteries that are exhausted must be replaced and discarded in accordance with local regulations) It is not possible to dispose of used batteries in the same way as normal waste products. In some areas, recycling facilities may not be provided.

Class II special waste product

Used O_2 sensors must be replaced and discarded in accordance with relevant local regulations. The used O_2 sensors cannot be disposed of in the same way as normal waste products)

Hazardous waste product (infectious)

Disposal of consumables such as non-reusable breathing tubes and capsules that have been used by patients with infectious diseases may cause environmental pollution. It needs to be disposed of in an environmentally safe manner in accordance

with local regulations or hospital regulations.

Disposable parts

Only use disposable parts and spare parts provided by the equipment provider. All disposable parts must be disposed of in an environmentally safe manner in accordance with hospital regulations.

10.2 Maintenance Schedule

⚠Note

- The following is the minimum number of maintenance times specified by the use of 2000 hours per year; if the actual use time is greater than 2000 hours, the frequency of maintenance of the equipment should be increased accordingly.
- Local policies or regulations may require maintenance to be performed more frequently.

The following is the maintenance schedule:

Minimum time of maintenance	Maintenance
Daily	Clean the outer surface of the anesthetic workstation. Zero point calibration of flow sensor and pressure sensor. 100% oxygen concentration calibration.
Monthly	21% oxygen concentration calibration. Empty the anesthesia vaporizer.
Yearly	Replace the outer O-ring on the patient circuit interface. Replace the AGSS filter. Calibrate the anesthesia vaporizer.
Every two years	Replace the air source input filter. Replace the internal battery.
During cleaning and installation	Check if the parts are damaged, and replace or repair if necessary.
As needed	Replace a new gasket of the spare gas cylinder. Replace the absorbent in the CO_2 absorption tank. Replace the gas module adapter or sampling tube and liquid accumulation bottle. Replace the oxygen concentration sensor (under normal circumstances, the sensor performance can meet the technical requirements for at least one year. 21% and 100% oxygen concentration calibration is required after the sensor is replaced). Replace the flow sensor if the diaphragm of the flow sensor is worn, twisted and deformed, causing inaccurate monitoring of the tidal volume (replacement of the flow sensor requires professional calibration).

10.3 System Maintenance

10.3.1 Maintenance of the respiratory system

During the cleaning and sterilization or installation of the respiratory system, if the components are found to be broken, cracked, worn, or twisted, they should be replaced. For specific operations, please refer to Chapter 3 Installation and Connection and Chapter 9 Cleaning and Sterilization.

10.3.2 Flow sensor calibration

 **Note**

- When the tidal volume of the equipment is not on time, after repair and maintenance, the flow sensor needs to be zeroed.
- If the zero-point calibration fails several times, please contact the company's after-sales personnel.

The operation steps are as follows:

1) Disconnect the tubing on the breathing system or let the Y connector of the breathing tubing vent open to the atmosphere.

2) Turn off all flow meters.

3) Make sure that the bellow folding bag falls to the bottom.

4) In the standby interface, select -> [System]-> [System Check]-> [Flow Sensor Calibration].

5) After the calibration is completed, the screen displays [Calibration succeeded!] or [Calibration failed!].

10.3.3 Pressure sensor zero calibration

 **Note**

- When the pressure monitoring of the equipment is incorrect, after repair and maintenance, the pressure sensor needs to be zeroed.
- If the zero-point calibration fails several times, please contact the company's after-sales personnel.

The operation steps are as follows:

1) Disconnect the tubing on the breathing system or let the Y connector of the breathing tubing vent open to the atmosphere.

2) Turn off all flow meters.

3) Make sure that the bellow folding bag falls to the bottom.

4) In the standby interface, select -> [System]-> [System Check]-> [Pressure Sensor Calibration].

5) After the calibration is completed, the screen displays [Calibration succeeded!] or [Calibration failed!].

10.3.4 Flow sensor calibration

 **Note**

- **Replace the flow sensor if the diaphragm of the flow sensor is worn, twisted and deformed, causing inaccurate monitoring of the tidal volume; After replacing the flow sensor, a flow sensor calibration is required.**

- **The calibration of the flow sensor requires the use of professional equipment. If the calibration of the flow sensor is required, please contact the company's after-sales personnel.**

10.3.5 Oxygen concentration calibration

Warning

- **Calibration cannot be performed while the system is connected to the patient.**

Note

- After replacing the oxygen concentration sensor or in the case of large errors in the oxygen concentration monitoring value, oxygen concentration calibration is required.
- Please confirm that the oxygen concentration sensor has been applied and installed and connected correctly.
- The oxygen concentration sensor is a consumable. If you confirm that the oxygen concentration sensor is normal and the calibration fails multiple times, please contact the company's after-sales personnel.

10.3.5.1 21% oxygen concentration calibration

The operation steps are as follows:

1) Enter the standby interface.

2) Disconnect the tubing on the breathing system.

3) Method 1: Remove the oxygen concentration sensor and expose it to the air for more than 2 minutes to calibrate;

4) Method 2: Turn on the ACGO switch (if configured) or switch to manual mode, and set the air flow to be greater than 10L/min (make sure that other flow meters and vaporizers are closed, and the air source pressure is normal).

5) Select -> [System]-> [System Calibration]-> [Oxygen Concentration Sensor Calibration]-> [21%]-> [Confirm].

6) After the calibration is completed, the screen displays [Calibration succeeded!] or [Calibration failed!].

10.3.5.2 100% oxygen concentration calibration

The operation steps are as follows:

1) Enter the standby interface.

2) Disconnect the tubing on the breathing system.

3) Switch to manual mode, and set the O_2 flow to be greater than 10L/min (make sure that other flow meters and vaporizers are closed).

4) Select -> [System]-> [System Calibration]-> [Oxygen Concentration Sensor Calibration]-> [100%]-> [Confirm].

5) After the calibration is completed, the screen displays [Calibration succeeded!] or [Calibration failed!].

10.3.6 Touch screen calibration

Note

- **When the focus of the touch screen is severely shifted, and the screen buttons cannot be selected, double-click the knob on the startup progress bar interface to enter the touch screen calibration by.**
- **After entering the touch screen calibration interface, if the calibration is unsuccessful and the touch screen verification interface is exited, the anesthetic workstation needs to be restarted.**

1) Method to enter the interface of the touch screen calibration:

Method 1: In the startup progress bar interface, double-click the knob to enter the touch screen calibration.

Method 2: Select -> [System] -> [System Calibration] -> [Touch Screen Calibration].

2) After entering the touch screen verification interface, a cross cursor appears; click on the center of the cursor. If you don't click on the center for three consecutive times, it will return to the first cursor position.

3) After the calibration is completed, the screen automatically returns to the standby interface.

10.4 How to Prevent Water Accumulation

Water accumulation is due to the condensation of the water vapor exhaled by the patient and the chemical reaction of the carbon dioxide absorbent. If the flow of fresh gas is slow, it will result in reduced emissions and increased water accumulation; The more carbon dioxide remains in the CO_2 absorption tank, more water is produced by chemical reactions. If there is water inside the flow sensor, the accuracy of the measurement data will be seriously affected.

Measures to prevent water accumulation in the flow sensor:

1) When the absorbent is replaced, clean the water in the CO_2 absorption tank.

2) The use of a filter at the connection of the breathing circuit can reduce the condensation of water vapor in the breathing circuit.

10.5 Fault Diagnosis and Elimination

Fault content	Cause	Action
Leak in the respiratory system	The CO_2 absorption tank is not tightened or the sealing ring is damaged	Tighten the CO_2 absorption tank or replace the seal ring
	The breathing system is not installed in place	Reinstall the breathing system to the adapter block and lock it
	The one-way valve cover is not tightened or the seal ring is damaged	Tighten the one-way valve cover or replace the seal ring
	The bellows cover is not installed in place or the seal ring is damaged	Reinstall the bellows cover or replace the seal ring

	Damaged breathing circuit or pipe connection problem	Replace pipeline or reconnect it
Folding bag drops	The bellows valve plate components are not installed in place	Reinstall the bellow components
	Leak in the respiratory system	Refer to the solution of respiratory system leak
The folding bag at the end of expiration cannot reach the top of the bellows cover	Leak in the respiratory system	Refer to the solution of respiratory system leak
	The flow control system is not turned on	Turn on the flow control system
The folding bag does not fall or falls insufficiently during inhalation	Manual/machine control switch is in manual position	Set manual/machine control switch to machine control position
	The protective cover of the AGSS interface of the anesthetic workstation is not removed	Remove the AGSS protective cover
	The bellows cover leaks or the bellows cover seal ring is damaged	Reinstall the bellows cover or replace the seal ring
	Blocked airway	Remove obstruction
Mode cannot be selected	Currently in manual or ACGO mode	Set to machine control mode
The anesthetic workstation does not ventilate	ACGO switch is on	Turn off the ACGO switch
	Manual/machine control switch is in manual position	Set manual/machine control switch to machine control position
	Insufficient air pressure	Check the air source connection
The anesthetic workstation cannot be started	The fuse is broken	Replace the fuse which is approved by the company
	The current is not connected and the battery is low	Connect AC power
The battery indicator does not light up	Battery is damaged	Replace the battery (Note: The battery will be damaged if the battery is not charged or discharged for a long time)
	The battery is fully charged	Not a problem
	Power management board or cable is broken	Contact the company’s after-sales personnel
AC power indicator does not light up	The power cord is not connected	Connect the power cord.
	The power cord is damaged	Replace the power cord approved by the company
Low oxygen alarm	Insufficient oxygen source	Ensure that the air source pressure is normal
	The oxygen source sensor is broken	Contact the company’s after-sales personnel

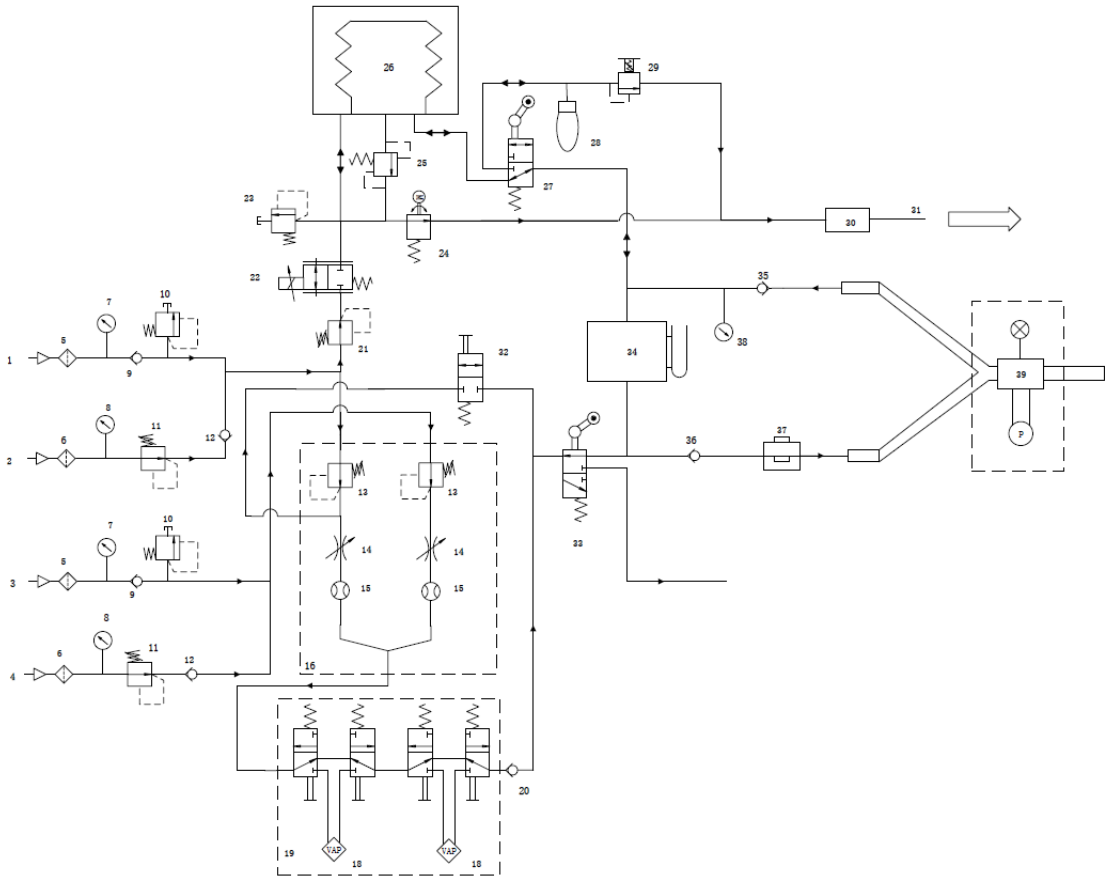
Chapter 11 Accessories List

No.	Accessory name	Replacement cycle
1	Adult folding bag	Replace according to usage
2	AGSS（Optional）	Replace according to usage
3	Oxygen concentration sensor MOX-4	1 year, or until the expiration date
4	Battery	Two years
5	Anesthesia vaporizer	8 years

Chapter 12 Appendix

Appendix A Working Principles

A.1 Airway system



A.1.1 Parts list

1	O_2 pipeline air supply interface	22	Proportional valve flow control valve
2	O_2 Spare cylinder air source interface	23	Safety valve
3	Air pipeline air source interface	24	Peep valve
4	Air source interface of standby air cylinder	25	Popoff
5	Pipeline air source inlet filter	26	Bellows
6	Air source inlet filter of standby gas cylinder	27	Manual machine control valve
7	Pipeline air source pressure gauge	28	Bag
8	Spare gas cylinder air source pressure gauge	29	APL valve
9	Pipeline air source inlet check valve	30	AGSS
10	Safety valve	31	Exhaust gas collection end
11	Pressure reducing valve at air source inlet of standby gas cylinder	32	Fast oxygenation switch
12	Air source inlet check valve of standby gas cylinder	33	ACGO valve
13	Pressure reducing valve	34	CO2 absorption tank
14	Throttle valve	35	Check valve
15	Flowmeter	36	Check valve
16	Electronic flowmeter	37	Oxygen battery
18	Anesthesia vaporizer	38	Airway pressure gauge
19	Bypass valve	39	Sensor
20	Check valve		

21	Pressure relief valve		

A.1.2 Principle description

Air source part

There are two types of pipeline gas sources: O_2 and AIR, which enter the system through the pipeline, and the working pressure is 280kPa～600kPa. There are two kinds of spare gas cylinder gas sources: O_2 and AIR, which respectively enter the system through the spare gas cylinder gas source interface respectively. The working pressure ranges from 2000 to 15000 KPa, and the pressure is reduced to 350 to 450 kPa through the pressure regulating valve 10. Each interface has a clear mark, and has the function of preventing misplugging to prevent the user from connecting the wrong air source. There are filters (5, 6) and one-way valves (9,12) in all interfaces, and the pressure gauge with color code is used to display the pressure of the pipeline gas source and the spare gas cylinder.

Fresh gas part

During operation, the gas source is connected to the flow meter 16, and the pressure of the input gas source is reduced to 250 kPa through the pressure reducing valves 13, so as to ensure the stability of the flow meter input pressure. The O_2 pressure sensor 10 is used to monitor the pressure of the O_2 gas source. When the pressure of the O_2 gas source is lower than 280 kPa, the ventilator will send out an alarm signal indicating low gas source pressure. Two gases, oxygen and air, are mixed through a flowmeter. The mixture passes through an open anesthetic carburetor 18, then carries part of the anesthetic to form fresh gas. The fresh gas passes through the check valve 20 to the ACGO selector switch 22. When the ACGO selector switch is on, the anesthesia ventilator stops mechanical ventilation, and fresh gas is output directly through the ACGO interface; when the ACGO selector switch is off, the fresh gas is delivered to the breathing circuit system to provide fresh air to the patient during mechanical ventilation gas. The O_2 output from the rapid oxygenation button 32 does not pass through the flow meter components and the anesthesia vaporizer, but is directly delivered to the breathing circuit system. Quick oxygen filling range: 25 L/min -75L/min。

Anesthesia ventilator

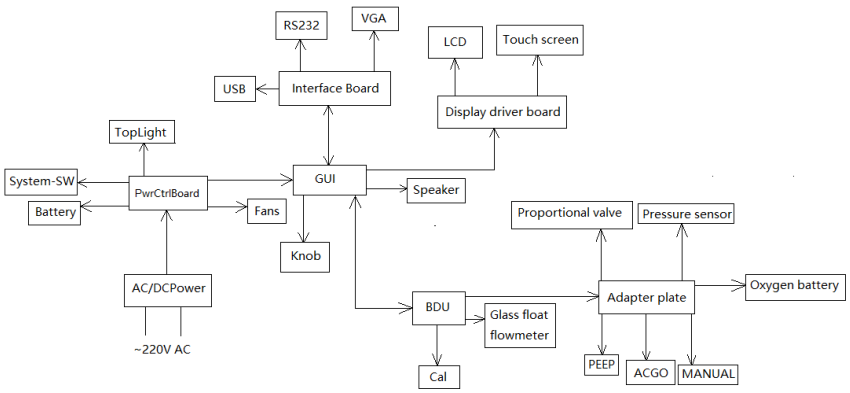
By switching the manual/machine control valve 27, manual or machine control ventilation can be selected. If select machine control ventilation, it is driven by an anesthesia ventilator. This anesthesia ventilator is gas-driven and microprocessor-controlled. The driving gas comes from an O_2 gas source. The pressure regulating valve 21 stabilizes the input driving gas pressure at about 250 kPa. The inspiratory flow control valve 22 is used to control the inspiratory flow; The PEEP valve 24 is used to control the opening and closing of the exhalation valve 25, and at the same time it can generate a positive end expiratory pressure (PEEP). In the inspiratory phase, the inhalation valve 22 is controlled by the microprocessor to generate the set inspiratory flow, and the exhalation valve 25 is closed at the same time, driving the air into the bellows 26 of the breathing circuit. The gas in the folding bag continues to enter the patient's lungs through the CO_2 absorption tank 34 until the end of the inhalation phase; in the expiration phase, the inhalation valve 22 is closed and the exhalation valve 25 is opened at the same time, and the patient can exhale freely. The patient's exhaled air is mixed with the fresh air

from the airway into the skin bag, causing the capsule in the bellows to rise, and the driving gas outside the capsule is discharged from the ventilator to the exhaust gas treatment system until the end of the expiration phase. During ventilation, the breathing machine monitors the patient's airway pressure and tidal volume in real time. If the airway pressure or tidal volume is not within the alarm limit preset by the user, a visible and audible alarm will be generated. When the airway pressure is higher than the limit value, the breathing machine automatically enters the expiratory phase to avoid excessive airway pressure from causing harm to the patient. In addition, the ventilator has a built-in pressure safety valve 23 (safety valve pressure relief range: 85 to 125 cmH_2O) to prevent excessive airway pressure from causing harm to the patient.

If you choose manual ventilation, in the inspiratory phase, press the manual breathing capsule 28 by hand so that the gas in it passes through the manual mechanical control valve 27 and the CO_2 absorption tank 34. The gas then is mixed with the fresh gas that is replenished at the same time. The mixed gas passes through the inhalation check valve and the inhalation interface to enter the patient's respiratory tract. At this time, the inspiratory phase ends. By adjusting the APL valve 29, the maximum airway pressure can be limited. When the limit pressure is exceeded, the APL valve interface will open and the gas will be discharged to the exhaust gas treatment system through the APL valve; in the expiratory phase, the exhaled air passes through the exhalation interface and the exhalation one-way valve and is mixed with fresh air into the manual breathing capsule, and the inspiratory phase ends.

A.2 Electrical System Structure

A.2.1 Electrical system structure diagram



Appendix B Product Specifications

B.1 Safety Specifications

According to the classification of the State Food and Drug Administration of China, this anesthetic

workstation is a Class III device.

Electric shock protection type	Class I, with internal power supply. When there is doubt about the integrity of the external protective grounding of the equipment or the protective grounding wire, the power status of the equipment must be changed to: internal power supply (battery)
Application Part	Type BF
Operating mode	Continuously working
Explosion protection level	No explosion protection (ordinary equipment). Do not use flammable anesthetics
IP classification	IP21
Mobile level	Mobile device

B.2 Environmental Specifications

Working environment	Temperature	10 ~ 40 ºC
	Humidity	5 ~ 95%, non-condensing
	Environmental pressure	50 ~ 106 kPa
Transportation and storage environment	Temperature	-20 ~ 60 ºC
	Humidity	≤ 95%, non-condensing
	Environmental pressure	50 ~ 106 kPa

B.3 Power Specifications

Parameters	Specification
External AC power supply	
Input voltage	100-240V
Input frequency	50/60Hz
Input power	≤90 VA
Internal battery	
Number of batteries	1 Battery pack
Battery type	Lithium battery
Rated battery voltage	12VDC
Battery capacity	2600mAh
Minimum power supply time	90min
Charging time	About 4 hours

B.4 System Specifications

parameters	Specification
Whole machine	
Size	1370×900×630 (H×W×D)
Weight	90kg
Maximum weight capacity of the top cover	30kg
Display screen	
Type	Color TFTLCD (touch screen)
Size	10.2 inches
Audio instructions	
Speaker	Alarm sound, prompt sound: support multi-level volume function. The alarm sound

	meets the requirements of IEC 60601-1-8 standard.
Control	
Knob	Quantity: 1 Supports clockwise/counterclockwise rotation and press operation
Interface	
Power	1 AC power input interface
Monitor	1 standard color VGA monitor interface, 15-PIN D-sub socket
Equipotential	1 equipotential ground terminal
USB	1 standard USB interface
Mobile device	
Scroll wheel	4 casters
Brake	
Brake plate	4-wheel brake; stepping on them for braking.
Toolbox	
Drawer	Two, each size: 100×372×320 (H×W×D)
Respiratory system	
Bellows capacity	About 1500mL
CO_2 absorption tank capacity	About 1600mL
Connection	Inhalation/ACGO interface: standard outer diameter 22mm, inner diameter 15mm, tapered connector; Exhalation interface: standard outer diameter 22mm, inner diameter 15mm, tapered connector. Manual breathing capsule interface: outer diameter 22mm
System leak	In any working mode, the system leakage is not more than 150ml/min when the system is at a pressure of 30cmH_2O
System compliance	The gas volume lost due to the internal compliance of the system (airbag mode) is: adult mode ≤ 4 mL/cmH_2O, child mode ≤ 3 mL/cmH_2O
Respiratory system resistance	Inhalation resistance: no more than 0.6 kPa; Expiration resistance: no more than 0.6 kPa (two-way sine wave airflow with a frequency of 20 times per minute and a tidal volume of 1L).

B.5 Parameter Specifications

Note:

1. All technical specifications are rated values. Non-main parameters may be changed without notice.

2. The conditions for displaying the measured value of the flow of all fresh gas in this equipment are the temperature of 20℃ and the atmospheric pressure of 101.3 kPa (14.7 psi).

B.5.1 Anesthetic workstation parameter Specifications

Table 1 Main technical parameters

Parameters		Description
Display screen		10.2 inches
Drive	Pneumatic electric control.	Pneumatic electric control
	Gas source type	O_2&Air or O_2&N_2O
	Gas source input pressure	0.28～0.6 MPa

	Maximum flow of gas source	≤100 L/min
Operating mode		Manual
		VCV、SIMV-VC，PCV、SIMV-PC、PSV 、(optional)：PRVC、SIMV-PRVC
		ACGO (Optional)
		StandBy
Display screen		Waveform: pressure-time (Paw-T), flow-time (Flow-T),Volume-Time (V-T) Loop diagram: pressure-volume loop, flow-volume loop，pressure- flow loop
Anesthesia vaporizer		Double tank positions, with interlocking function. It allowed to choose: VP10 sevoflurane, VP20 isoflurane. Penlon SigmaDelta: isoflurane and sevoflurane. Dräger Vapor 2000: isoflurane and sevoflurane.
Electronic flowmeter	Type	O2&Air or O_2&N_2O
	Adjustment range	O_2: 0～10 L/min; Air: 0～15 L/min or N_2O：0~12 L/min
Safety pressure		The system pressure does not exceed 12.5 kPa.
Data communication interface		Serial RS232, VGA interface, USB interface.
Select configuration		CO_2 monitoring module, ACGO, spare gas cylinder connection device

Table 2 Main configuration parameters

Parameters	Description
Tidal volume	Range: 10～1500 mL； Increment： 10～100 mL：5 mL； 100～1500 mL：10 mL；
Respiratory frequency	Range: 1～100 bpm; increment: 1 bpm.
Inspiratory time	Range: 0.1～12.0 s; increment: 0.1 s.
[I:E]: Inhale-to-exhale ratio	Range: 4:1～1:10 AM; increment: 0.5.
Inhalation pause percentage (Pause)	Range: 0～50%; increment: 5%.
positive end-expiratory pressure	Range: OFF, 3～20 cmH_2O; increment: 1 cmH_2O.
Pressure support	Range: 0～70 cmH_2O; increment: 1 cmH_2O.
Pressure control	Range: 5～70 cmH_2O; increment: 1 cmH_2O.
Flow trigger	Range: 0.5～20 L/min; increment: 0.1 L/min.
Pressure trigger	Range: 0～20 cmH_2O; increment: 1 cm cmH_2O.

Table 3 Main monitoring parameters

Parameters	Description
Inspiratory tidal volume	Range: 0～2500 mL; resolution: 1 mL.
Expired tidal volume	Range: 0～2500 mL; resolution: 1 mL.
MV	Range: 0～60 L/min; resolution: 0.1 L/min.
Spontaneous minute ventilation	Range: 0～60 L/min; resolution: 0.1 L/min.
respiratory frequency	Range: 0～100 bpm; resolution: 1 bpm.
Spontaneous respiratory rate	Range: 0～100 bpm; resolution: 1 bpm.
[I:E]: Inhale-to-exhale ratio	Range: 9: 1～1:99; resolution: 0.5.

Airway peak pressure	Range: 0～100 cmH_2O; resolution: 1 cmH_2O.
Mean airway pressure	Range: 0～100 cmH_2O; resolution: 1 cmH_2O.
positive end-expiratory pressure	Range: 0～100 cmH_2O; resolution: 1 cmH_2O.
Plateau pressure	Range: 0～100 cmH_2O; resolution: 1 cmH_2O.
Inhaled oxygen concentration (optional)	Range: 15～100%; resolution: 1%.
Compliance (optional)	Range: 0～300 cmH_2O; resolution: 1 mL/cmH_2O。
Resistance (optional)	Range: 0～600 cmH_2O/(L/s); resolution: 1 cmH_2O/(L/s).
End-tidal CO_2 (optional)	Range: 0～13.3 %; resolution: 0.1 %.
Inspired CO_2 (optional)	Range: 0～13.3 %; resolution: 0.1 %.

B.5.2 Alarm parameter specifications

Table 4　Alarm Function

Alarm item		**Description**
Tidal volume	Upper limit	20～3000 mL
	Lower limit	OFF，10～2990 mL
MV	Upper limit	1～99 L
	Lower limit	0～98 L
Inhaled oxygen concentration	Upper limit	19～100%，OFF
	Lower limit	18～99%
Airway pressure	Upper limit	6～ 99 cmH_2O
	Lower limit	0～ 98 cmH_2O
respiratory frequency	Upper limit	1～100 bpm
	Lower limit	OFF,1～79bpm
$EtCO_2$	Upper limit	0.1～13.3 % ；
	Lower limit	0～13.2 %；
Continuous high airway pressure alarm		Issue an alarm when continuous airway pressure of the anesthesia ventilator is higher than (PEEP+15) cmH_2O, and the holding time is longer than 15 s.
Apnea alarm		The adjustment range of the suffocation alarm time is 10～60 s, and the alarm will be issued when there is no trigger within the set suffocation time
Low oxygen alarm		The oxygen source pressure is less than 0.28 MPa.
AC power failure alarm		Sound and light alarm will be issued when AC power is cut off, and it will be automatically converted to battery power supply
Low battery alarm		The battery power supply time after the alarm is not less than 10 min.
Battery drain alarm		The battery power supply time after the alarm is not less than 5 min.
Alarm silence timing		≤120 s
Negative pressure alarm		The airway pressure is less than -10 cmH_2O.

B.5.3 Respiratory system pressure-flow characteristics

Opening pressure of inhalation valve and exhalation valve

Dry: 0.03 kPa opening pressure

Wet: 0.06 kPa opening pressure

When the pressure-flow characteristics of the inhalation valve and the expiration valve are tested, the fresh gas flow rate is 10L/min±1L/min.

Pressure-flow characteristics under machine control

	Inhalation interface		Exhalation interface	
Flow rate (L/min)	Pressure (kPa, dry)	Pressure (kPa, wet)	Pressure (kPa, dry)	Pressure (kPa, wet)
5	0.05	0.06	0.05	0.06
30	0.23	0.25	0.22	0.24
60	0.56	0.59	0.49	0.52

Manual pressure-flow characteristics

	Inhalation interface		Exhalation interface	
Flow rate (L/min)	Pressure (kPa, dry)	Pressure (kPa, wet)	Pressure (kPa, dry)	Pressure (kPa, wet)
5	0.05	0.06	0.05	0.06
30	0.21	0.23	0.21	0.23
60	0.50	0.53	0.46	0.49

Circulating absorption module pressure-flow characteristics

Circulating absorption component	
Flow rate (L/min)	Pressure (kPa, dry)
5	0.01
30	0.15
60	0.34

B.5.4 APL valve pressure-flow characteristics

Opening pressure of APL valve

Dry: 0.05 kPa opening pressure

Wet: 0.08 kPa opening pressure

APL pressure-flow characteristics (APL valve is fully open)

Flow rate (L/min)	Pressure (cmH_2O, dry)	Pressure (cmH_2O, wet)
3	0.95	1.03
30	1.86	2.10
40	2.08	2.45
50	2.29	2.72
60	2.57	3.14
70	3.02	3.41

B.5.5 AGSS technical parameters (optional)

Executive standard	ISO 80601-2-13

Connection processing system type	Low flow processing system, absorption flow is less than 50L/min
Inhalation flow resistance	1.8-1.2KPa
Inhalation flow range	0-50L/min
Filter specifications	Stainless steel filter, 140~150μm

Appendix C Carbon dioxide module (optional)

Class II special waste product

Used CO2 modules, components and packaging must be replaced and discarded in accordance with relevant local regulations. It is not possible to dispose of used CO2 modules, components and packaging in the same way as normal waste products.

C.1 Product Description and Application

The C200 end-tidal CO_2 module can be assembled in a multi-parameter monitor, ventilator or anesthetic workstation for sampling or real-time monitoring of the real-time CO_2 concentration, end-tidal CO_2 concentration, inhaled CO_2 concentration and respiratory rate, and inhalation and exhalation time. The module can also measure atmospheric pressure and report status data such as pipeline blockage to the host. Take precautions to avoid the possibility of reverse flow of the air flow in the equipment sampling pipe. This module can be used for intubated patients (sampling via three-way) and bedside monitoring patients (sampling via nasal sampling tube). In the European Union and North America, the end-tidal CO_2 parameter is one of the necessary parameters for conventional monitors, and most high-end ventilators and anesthetic workstations are also equipped with this function. Some manufacturers make it separately into end-tidal CO_2 monitor for use. The C200 end-tidal CO_2 module can be used for newborns, children and adults.

⚠Note!

This module has been calibrated before leaving the factory, and it is not recommended that users calibrate by themselves. If the user finds that the measurement result deviates significantly, he needs to return the module to the factory for calibration. This module also has a zero point automatic calibration function, which will automatically calibrate the zero point drift during use. Warm up the engine for at least 10 minutes after starting the machine. The zero-clearing pipe must not be blocked, and CO_2 gas must not be discharged near the zero-clearing pipe. The dehydration bottle must be replaced after it is blocked. In this way, the deviation of the module measurement result is less than 1mmHg.

C.2 Product performance indicators

Table 11-1 Function parameters of end-tidal CO_2 module

Power requirements (see note 1)	5.0V±0.2V DC
Power consumption	80mA in normal condition, 300mA in extreme cases
Working temperature	5～50℃
Storage temperature	-20～+70℃
Relative humidity	0-85% (non-condensing)
Size	77×50×30mm
CO_2 **measuring range**	0-20% volume ratio (0-150mmHg@BTPS)
CO_2 measurement accuracy (see note 2)	<5.0%CO_2(ATPS)：±2mmHg >5.0% CO_2(ATPS)：<5% of the reading
Respiratory rate	2～150BPM
Respiration rate measurement accuracy	1%@±1BPM
Preheat time	10S
Response time	Detector 28mS, system response time depends on execution, flow setting and dehydration technology
Flow control (see note 4)	50～250ml/min adjustable
Interface	Programmable serial interface, TTL, RS232 optional
Fully automatic offset calibration	Automatically calibration according to time and temperature, or according to instructions

Note 1: When the power supply system or battery voltage fluctuates within ±0.2V, it has no effect on the accuracy of the measurement. When the fluctuation exceeds this range, this module cannot guarantee the required accuracy.

Note 2: The module has automatic zero point calibration and balance gas compensation under different oxygen concentrations to ensure the accuracy and precision of the measurement.
The module has automatic atmospheric pressure compensation.

Note 3: After the external power supply is interrupted, the anesthetic workstation will automatically switch to battery power supply, and the external power supply will not affect the monitoring of the module.

Note 4: The exhaust speed of the built-in module is 100ml/min for standard configuration

The influence of interference gas and steam on CO_2 measurement accuracy is shown in Table 11-2.

Table 11-2 The influence of interference gas and steam on CO_2 measurement accuracy

Gas or steam	Gas concentration	CO_2
Nitrous oxide	60% volume percentage	1)
Halothane	4% volume percentage	1)
Enflurane	5% volume percentage	+10% of the reading
Isoflurane	5% volume percentage	+10% of the reading
Sevoflurane	5% volume percentage	+10% of the reading
Xenon	80% volume percentage	-12% of the reading
Helium	50% volume percentage	-10% of the reading
Metered (medicament) inhaled propellant gas	Do not use metered (medicament) inhalation of propellant gas	
Desflurane	15% volume percentage	+14% of the reading value
Ethanol	0.3 % volume percentage	1)
Isopropanol	0.5 % volume percentage	1)
Acetone	1 % volume percentage	1)
Methane	3 % volume percentage	1)
1) Under the normal working conditions allowed by the module, interference and influence can be ignored.		

Warning!

When the anesthetic workstation is moving, the accuracy of the CO_2 module may be affected.

C.3 Safety Guidelines

For your safety, please read the following and follow the instructions of the medical device product.

Warning!

Warning! This module only provides the patient's exhaled CO_2 concentration and respiration rate data, which only provide reference for the diagnosis. Please make the diagnosis based on the clinical manifestations and symptoms.

Warning! Single-use sampling tubes must not be reused to avoid cross-infection.

Note!

Note! This module is for trained professionals or professional medical centers. The operator must be proficient in the contents of the manual before using the module.

Note! The single-use dehydration bottle (water trap) must not be reused. Otherwise, it will cause inaccurate readings and even damage the module. Different patients cannot share dehydration bottles.

Otherwise, it may cause cross-infection.

Note! All disposable parts must be disposed of in an environmentally safe manner in accordance with hospital regulations.

Note! Please make sure that the sampling tube is unblocked. If the sampling tube is bent or in other blocked conditions, it will cause the sampling pump to be overloaded for a long time, which will affect the service life of the pump and the module and even the accuracy of the measurement.

Note! Repairs can only be performed by certified or specially trained personnel. It is recommended to return the damaged parts to the factory for repair in most cases.

Note! If the module is used incorrectly by the user or operator, or is contrary to the way it is designed to be used, the manufacturer will not take any responsibility.

Note! The module can only be operated and stored under environmental conditions that comply with the technical specifications.

Note! Do not use this module to measure the exhaled air of the human body without connecting the dehydration bottle. The moisture exhaled by the human body may cause measurement errors. At the same time, the accumulation of moisture can easily damage the life of the module.

Note! If there is no warm-up after power-on, the reading will show a slight deviation.

Note！ Using the equipment under strong electromagnetic interference sources, such as electrosurgical equipment, MRI equipment, etc., may have negative effects.

Note! When the monitor is operated in front of the CT equipment, it may have negative effects.

Note! Only the sampling tube provided by the manufacturer can be used. If unauthorized sampling tube is used, the module data may be inaccurate.

Note! Using this module in an environment with drastic temperature changes may cause inaccurate measurement data, so try to use it in an environment with a relatively stable temperature.

Note! Any situation that obstructs the flow of sampling gas, such as serious bending of the sampling tube, contaminants blocking the sampling tube, serious blockage of the filter or dehydration bottle, etc., may cause inaccurate measurement and decrease the service life of the module. When the system is blocked and the obstruction has not been removed for 20 seconds, the module will shut down the sampling pump.

Note! The danger caused by software errors has been minimized, and the hazard detection has met the EN1441:1997 and EN62366:2008.

Note! No matter what causes the pipeline leaks, it will seriously affect the accuracy of the measurement data and the shape of the waveform.

Note! When using the equipment with the humidity exceeding the range of the humidity standard

working state, the measurement accuracy of the module will be greatly affected. Please use it with caution in this condition.

Air connection definition

A total of 3 pipelines are drawn from the module, two of which are drawn from the white solenoid valve in the center of the module, and one is drawn from the green sampling pump. The definition is as follows:

The silicone tube closest to the center of the module is the pipeline that normally collects human exhaled air. This pipeline should be connected to the air interface of the dehydration bottle holder installed on the equipment panel;

The white silicone tube near the outer edge of the module (near the black cuboid sensor) is the zero collection pipeline. It should be connected to a two-way socket on the equipment panel to ensure that the pipeline can collect the concentration of ambient gas as zero position.

The pipe from the green sampling pump is the exhaust pipe, which should also be connected to a two-way on the equipment panel to discharge the gas that has been measured to the outside of the equipment. Note that the interface between the exhaust pipe and the zero sampling gas pipe must be kept far away to avoid collecting the gas rich in CO_2 discharged from the exhaust pipe during zero sampling. This will result in a falsely high zero position, which will result in the low indication value under normal measurement.

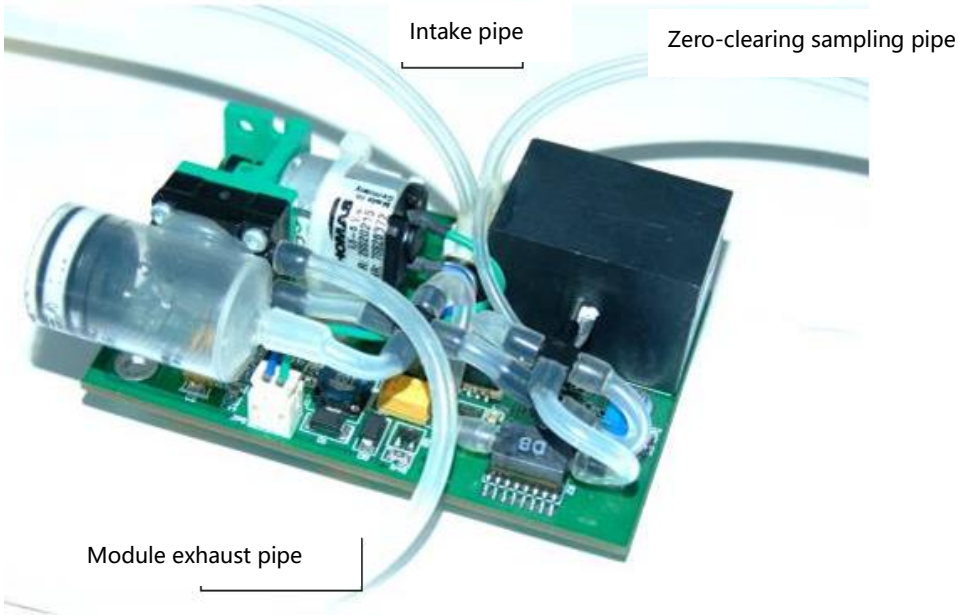


Figure 11-2 Definition of gas circuit connection

After the module is installed inside the equipment, the intake pipe, exhaust pipe and clearing pipe need to be connected. The usual connection method is:

1. Install the dehydration bottle holder on a relatively flat surface of the equipment;

2. Clip the dehydration bottle onto the dehydration bottle holder;

3. Connect the module air inlet pipe to a mouthpiece of the dehydration bottle holder extending into the inside of the equipment. The mouthpiece is on the right side of the holder;

4. Install a two-way in the appropriate position of the equipment, connect the module clear tube to the end of the two-way that extends into the equipment, and the end that extends out of the equipment is

directly open to the air;

5. Install a two-way in the appropriate position of the equipment, connect the module exhaust pipe to the end of the two-way that extends into the inside of the equipment, and the end that extends out of the equipment directly leads to the air. Note that the location of the exhaust pipe connecting two interfaces should be at least 10cm apart from the location of the zero clearing pipe connecting two interfaces to avoid the clearing pipe collecting CO_2 gas discharged from the exhaust pipe;

6. For intubated patients, screw one end of the extended sampling tube (pressure extension tube) on the LUER connector on the right side of the dehydration bottle, and screw the other end of the sampling tube on the three-way LUER connector provided by our company. Then connect the three links in series into the pipeline of the anesthetic workstation;

7. For bedside monitoring patients (non-intubated patients), screw one end of the LUER mouthpiece of the nasal cavity sampling tube on the LUER mouthpiece on the right side of the dehydration bottle, hang the other end of the sampling tube on the patient's face, and put the nasal congestion into the patient's nasal cavity.

Appendix D EMC (Electromagnetic Compatibility)

D.1 Product Composition and Cable Information

Product composition

No.	Component name	Model/specification
1	Anesthetic Workstation host	X30
2	Oxygen concentration monitoring module	/
3	CO_2 Monitoring module	/
4	Breathing circuit, CO_2 absorption tank, bellow, glass float flow meter, spare cylinder hooking device	/

Cable information

No.	Cable name	Length(m)	Whether to block it
1	Power cord	5	No
2	Oxygen concentration sensor cable	2.5m	Yes

D.2 EMC Performance

This product complies with the emission limits specified in the YY0505-2012 Group 1 Class A medical equipment standard. However, the company does not guarantee that there will be absolutely no interference in individual installation environments.

If interference with this device is found (which can be determined by turning the device on and off), the user (or qualified maintenance personnel) should try to take one or more of the following measures to solve the interference problem:

- Adjust the direction or position of the affected device;

- Increase the distance between this device and the affected device;
- Consult the supplier or service representative for other suggestions.

The manufacturer is not responsible for any interference caused by the following conditions: unauthorized changes or modifications to this equipment. Unauthorized changes or modifications may cause the user to lose the authority to operate this device.

Do not use devices that can emit RF signals, such as cellular phones, radio transceivers, or radio control products, near this equipment, as they may make the performance of this equipment unable to meet the specified specifications. When such devices are close to this equipment, please turn off the power of these devices. The medical personnel in charge of this device should instruct technicians, patients and other personnel who may be close to this equipment to fully comply with the above requirements.

All types of electronic devices may cause electromagnetic interference to other equipment through the air or other cables connected to it. The term EMC (Electromagnetic Compatibility) refers to the ability of a device not to be affected by electromagnetic interference generated by other devices, and at the same time not to affect other devices through similar electromagnetic radiation.

In order to fully achieve the specified EMC performance, the user should install the product correctly according to the steps described in the manual. If there is a problem related to EMC, please contact the repair personnel.

Basic performance: The error of tidal volume is ±20 mL or ±15% of the set value. Adopt the greater value.

D.3 Precautions for Product Installation

Separation distance and impact of fixed radio communication equipment: magnetic field strength generated by fixed transmitters, such as base stations of wireless (cellular/cordless) telephones, land mobile radio receivers, amateur radio receivers, AM and FM radio broadcasts, and TV broadcasts Generators, etc., cannot be accurately measured theoretically. To assess the electromagnetic environment generated by fixed RF transmitters, measurement of the electromagnetic field should be considered. If the measured value of the magnetic field strength at the location of the equipment exceeds the corresponding radio frequency level specified in the "Anti-Interference Statement", the equipment should be inspected to ensure that it can operate normally. If abnormal operation is found, additional measurements should be considered, such as reorienting or relocating the device, or using an anti-radio frequency room. The device should not be used close to or stacked with other devices. If it must be used close or stacked, it should be observed to verify that it can work normally under the configuration used.

Warning

The X30 anesthetic workstation should not be used close to or stacked with other non-designated equipment. If it must be used close or stacked, it should be observed and verified that it can work normally under the configuration used.

D.3.1 General precautions

1. Use the specified cable that can be connected to the oxygen concentration sensor connection of this product.

Using the oxygen concentration sensor connection cable provided or specified by our company will not damage the EMC performance of this product. If you use unspecified output cables and probes, the EMC performance of this equipment may be significantly reduced.

2. Precautions for prohibiting modification

The user should not modify this product, otherwise the EMC performance of this product may decrease.

The modification of the product includes the following changes:

a) Equipment installation/layout;

b) Equipment configuration/components;

c) Equipment protection parts (cover opening/closing and cover fixing parts).

3. All covers should be closed when operating the equipment. If the cover is not closed for some reason, make sure to shut down the system before starting/continuing operation.

4. When the cover is open, the operating system may affect the EMC performance of the system.

D.3.2 Electrostatic protection

Warning

The pins of connectors marked with the electrostatic discharge warning symbol should not be touched, and should not be connected to these connectors unless electrostatic discharge precautions are used.

Warning

Provisions on the basic content of training on electrostatic discharge preventive measures:

a) All staff must be reminded that unless the following appropriate precautions have been taken, do not touch the accessible connector contacts marked with an electrostatic discharge warning symbol with your hands or hand tools. Preventive measures include:

- Methods to prevent static charge accumulation (such as air conditioning, humidification, conductive floor coatings, non-synthetic clothing);
- Make human body discharge to the frame of the equipment or system or to the ground or large metal objects;
- Connect yourself to the device or system or ground it with the help of a wrist strap.

b) All staff who may touch the connector marked with the electrostatic discharge warning symbol should receive this explanation and training. This also includes clinical/biomedical engineering and healthcare personnel.

c) Electrostatic discharge training should include an introduction to the physics of electrostatic charge and the voltage levels that may be generated in normal practice, as well as the damage of electronic components if an operator with electrostatic charges touches the electronic components. Furthermore, it should explain the ways to prevent the accumulation of static charge, and how and why the human body should discharge to the ground or the frame of the equipment or system, or the way that

wrist strap is used to connect operator to the equipment or system or to the ground before working.

Warning

This equipment needs EMC protection, and it needs to be installed and used in a regulated electromagnetic environment.

Warning

Portable and mobile RF communication equipment may affect the performance of this equipment.

Warning

This equipment cannot be used in an MRI environment.

Table 1: Guidelines and manufacturer's declaration-electromagnetic radiation-for all equipment and systems

Guidelines and manufacturer's declaration-electromagnetic radiation		
The X30 anesthetic workstation is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:		
Launch test	**Compliance**	**Electromagnetic Environment-Guide**
GB 4824 Radio frequency emission	Group 1	The X30 anesthetic workstation uses radio frequency energy only for its internal functions. Therefore, its radio frequency emission is very low, and the possibility of causing interference to nearby electronic equipment is very small.
GB 4824 Radio frequency emission	Class A	X30 anesthetic workstation is suitable for use in non-domestic and all facilities that are not directly connected to the residential public low-voltage power supply network for households.
GB 17625.1 Harmonic emission	Not applicable	
GB 17625.2 Voltage fluctuation/flicker emission	Not applicable	

Table 2: Guidelines and manufacturer's declaration-electromagnetic immunity-all equipment and systems

Guidelines and manufacturer's declaration-electromagnetic immunity			
The X30 anesthetic workstation is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment-guide**
Electrostatic discharge (ESD)	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge	The floor material should be wood, concrete or ceramic

GB/T 17626.2		±8 kV air discharge	tiles. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient pulse group GB/T 17626.4	±2kV to power cord ±1kV to input/output cord	±2kV to power cord Not applicable	The network power supply should have the quality used in a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV for line to line ±2kV for line to earth	±1kV for line to line ±2kV for line to earth	The network power supply should have the quality used in a typical commercial or hospital environment.
Voltage temporary drop, short-term interruption and voltage change on the power input cord GB/T17626.11	<5% U_T to 0.5 week (within (on U_T, >95% temporary drop) 40% U_T to 5 weeks (within (on U_T, >60% temporary drop) decrease 60%) 70% U_T to 25 weeks (within (on U_T, >30% temporary drop) (U_T decrease by 30%) <5% U_T to 5 seconds (within (on U_T, >95% temporary drop)	<5% U_T to 0.5 week (within (on U_T, >95% temporary drop) 40% U_T to 5 weeks (within (on U_T, >60% temporary drop) decrease 60%) 70% U_T to 25 weeks (within (on U_T, >30% temporary drop) (U_T decrease by 30%) <5% U_T to 5 seconds (within (on U_T, >95% temporary drop)	The network power supply should have the quality used in a typical commercial or hospital environment. If the user of the X30 anesthetic workstation needs continuous operation during the power interruption, it is recommended to use an uninterrupted power supply or battery power supply.
Power frequency magnetic field (50/60Hz) GB/T 17626.8	3 A/m	3 A/m	The power frequency magnetic field should have the power frequency magnetic field level characteristics of a typical place in a typical commercial or hospital environment.
Note: UT is the AC grid voltage that is preferentially applicable to test level.			

Table 3: Guidance and manufacturer's declaration-electromagnetic immunity-for life support equipment and systems

<table>
<tr><th colspan="4">Guidelines and manufacturer’s declaration-electromagnetic immunity</th></tr>
<tr><td colspan="4">The X30 anesthetic workstation is expected to be used in the following electromagnetic environment, and the purchaser or user should ensure that it is used in this electromagnetic environment:</td></tr>
<tr><th>Immunity test</th><th>IEC60601 test level</th><th>Compliance level</th><th>Electromagnetic environment-guide</th></tr>
<tr><td rowspan="3">Radio frequency conduction
GB/T 17626.6</td><td>3 Vrms
150kHz ~ 80MHz
(Except for engineering medical band[a])</td><td>3Vrms</td><td rowspan="3">Portable and mobile radio frequency communication equipment should not be used closer to any part, including cables, of the X30 anesthetic workstation than the recommended isolation distance. This distance should be calculated based on the formula corresponding to the transmitter frequency.
Recommended isolation distance:
d =1.2 $\sqrt{P}$</td></tr>
<tr><td>10 Vrms
150 kHz ~ 80 MHz
(Engineering medical band[a])</td><td>10Vrms</td></tr>
<tr><td>Radio frequency radiation
GB/T 17626.3</td><td>10V/m
80 MHz ~ 2.5 GHz</td><td>10V/m</td><td>d =1.2 $\sqrt{P}$ 80MHz to 800MHz;
d = 2.3 $\sqrt{P}$ 800 MHz to 2.5GHz
In the formulation,
P---According to the maximum rated output power of the transmitter provided by the transmitter manufacturer. The unit is watt (W);
d---Recommended isolation distance. The unit is meter (m). The field strength of the fixed radio frequency transmitter is determined by surveying the electromagnetic field[a], and in each frequency range[b] should be lower than the compliance level. Interference may occur in the vicinity of equipment marked with the following symbols.
  </td></tr>
</table>

Note 1: At 80 MH and 800 MHz frequency points, the higher frequency band formula is used.
Note 2: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and humans.

a The engineering and medical frequency bands between 150 kHz and 80 MHz refer to 6.765 MHz ~ 6.795 MHz, 13.553 MHz ~ 13.567 MHz, 26.957 MHz ~ 27.283 MHz and 40.66 MHz ~ 40.70 MHz.

b The coincidence level in the engineering and medical frequency band between 150 kHz and 80 MHz and the frequency range between 80 MHz and 2.5 GHz is used to reduce the possibility of interference caused by mobile/portable communication devices accidentally brought into the patient area. For this reason, an additional factor of 10/3 is used to calculate the recommended isolation distance for transmitters in these frequency ranges.

c The field strength of fixed transmitters, such as base stations for wireless (cellular/cordless) telephones and ground mobile radios, amateur radio, AM and FM radio broadcasting, and television broadcasting, etc., cannot be accurately predicted in theory. In order to assess the electromagnetic environment of fixed radio frequency transmitters, the survey of electromagnetic fields should be considered. If the measured field strength of the [equipment or system] is higher than the above applicable RF compliance level, the [equipment or system] should be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be necessary, such as readjusting the direction or position of [equipment or system].

d In the entire frequency range of 150 KHz to 80 MHz, the field strength should be lower than 3V/m.

Table 4: Recommended isolation distances between portable and mobile radio frequency communication equipment and equipment or systems-ME equipment and ME systems for life support

Recommended separation distance between portable and mobile radio frequency communication equipment and X30 anesthetic workstation				
The X30 anesthetic workstation is expected to be used in an electromagnetic environment with controlled radio frequency radiation disturbance. According to the maximum rated output power of the communication equipment, the purchaser or user can maintain the minimum distance between the portable and mobile radio frequency communication equipment and the X30 anesthetic workstation through the following recommendations to prevent electromagnetic interference.				
The maximum rated output power of the transmitter W	Isolation distance corresponding to the transmitter at different frequencies/m			
	150 kHz to 80 MHz (Except for engineering medical band) $1.2\sqrt{P}$	150 kHz to 80MHz (Engineering medical band) $1.2\sqrt{P}$	80 MHz to 800 MHz $1.2\sqrt{P}$	800 MHz to 2.5 GHz $2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3

10	3.8	3.8	3.8	7.3
100	12	12	12	23

For the maximum rated output power of the transmitter not listed in the above table, the recommended isolation distance d , measured in meter (m), can be determined by the formula in the frequency column of the corresponding transmitter. Here P is the maximum rated output power of the transmitter provided by the transmitter manufacturer. The unit is in watt (W).

Note 1: At 80 MHz and 800 MHz frequency points, the higher frequency band formula is used.

Note 2: The engineering and medical frequency bands between 150 kHz and 80 MHz refer to 6.765 MHz ~ 6.795 MHz, 13.553 MHz ~ 13.567 MHz, 26.957 MHz ~ 27.283 MHz and 40.66 MHz ~ 40.70 MHz.

Note 3: An additional factor of 10/3 is used to calculate the recommended isolation distance of transmitters in the engineering and medical frequency bands of 150 kHz ~ 80 MHz and the frequency range of 80 MHz ~ 2.5 GHz to reduce the possibility of interference when portable/mobile communication devices are accidentally brought into the patient's area.

Note 4: These guidelines may not be suitable for all situations. Electromagnetic propagation is affected by absorption and reflection from buildings, objects and humans.