Product Information

Product name: Anesthesia Machine

Product Model: Okuman 620

Registered Address: Kazım Karabekir Cad. No: 95/95 06060 Iskitler Ankara TURKEY

Factory Address: IVOGSAN Arı San. Sit. 1417. Sok No:51 Yenimahalle Ankara TURKEY

Date of manufacture: See label

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Identification Number : 1984

Version Information

The version number of this user manual may be updated due to the software upgrades;

OKUMAN reserves the right to change it without giving prior notice.

The version information:

- Version: 7.0
- Release date: Dec. 2015

CE Mark

The product is marked with CE, as it conforms to European Council Directive for Medical Devices (93/42/EEC), and meets basic requirements of appendix I in the directive.

This product is the Type Ⅰ,Class B radio jamming protective equipment that complies with the EN55011. It meets the requirements of EN60601-1-2 standard “Medical electrical equipment-Electromagnetic compatibility”.

Declaration

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Users can, if need, ask for other technical information separately from the Company in order to understand, operate and maintenance the equipment, but should ensure the information not obtained by the third party.

User’s Responsibility

Please check the product and accessories firstly when you receive the product, make sure it conforms to the contract. If any damage of the package or the product is found before or after you open the packing case, please contact the local office or the franchiser immediately.

Users must perform the installation, operation, maintenance and carry out regular inspection according to the instruction described in the manual. Replace the components immediately if any damage, loss, distortion or contamination is found. Stop use when malfunction occurs. Please contact the after service department of the Company for repairing and replacing. Any change of the product is verboten without agreement of the Company. Users must accept responsibility for any malfunction which results from non-compliance with the servicing requirements detailed in this manual.

Free Maintenance

The user reserves the right to be served for free repairs and replacement within 12 months from the order delivered date only in the event that the product is purchased from the Company or the authorized distributor, it must be new product when purchased and it is operated according to the “User’s Responsibility”. Otherwise, the Company has no responsibility for any damages to the product.

Trademark

OKUMAN is registered trademark of OKUMAN Company.

OKUMAN is registered trademark of the anesthesia and ventilator products of OKUMAN.

Preface

Description

This manual describes the intended use, function, installation, operation and maintenance of the product. Please read and understand the contents carefully before use to ensure the proper performance and patient safety. When you begin using the anesthesia machine, we deem that you have read the manual carefully.

In order to use the equipment accurately, effectively and avoid the accident, please read the manual carefully and comply with it strictly, especially pay attention to the “Warning”, “Caution” and “Note”.

The optional features may not be completely included in the manual, if you have any questions, please contact the Company.

Please read this manual carefully and keep within reach of the device.

Illustration

The illustration in the manual is only for reference. Some settings and data may not be consistent with the real display, and please refer to the real product.

Conventions

- ***Bold Italic***: The quoted section.
- **【Character】：** The character string on the user interface or on the control panel.

Content

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Chapter 1 Safety Information

The safety information described in this chapter explains the unsafe conditions that may occur if not performed correctly according to the manual. Please review all the Warning, Caution and Note prior to operating the anesthesia machine.

This chapter contains important safety information of the anaesthesia machine, and some other safety information throughout each chapter of the manual. Please read and understand all the safety information before use to avoid security risks.

The ponderance of the safety requirements has no relation with the list order.

⚠Warning:

Identify conditions or practices that could result in serious adverse reactions or potential safety hazards.

⚠Caution:

Identify conditions or practices that could result in damage to the anesthesia machine or other equipment.

Note:

Identify supplemental information to help you better understand how the anesthesia machine works.

1.1 Warning

⚠Warning

Preparing warning：

- Before using the device please ensures that all the connections of the pipelines are accurate and reliable, not twisted, knotted, pressed or blocked.
- The auxiliary mains socket-outlet of this equipment can only be used for the specified facilities, otherwise it may result in safety risks.
- Other additional and movable multi-functional sockets or extended cable can not be connected to the auxiliary mains socket-outlet of this equipment, otherwise it may result in safety risks.
- In the patient environment, the operator should not touch the parts of the non- medical electrical equipment and patients at the same time, otherwise it may result in safety risks.
- Before using the equipment please make sure that the balanced terminal of the potential has been connected to the spot grounded point, otherwise, unpredictable risks may occur.
- This equipment can only be operated by the qualified personnel, please make sure the operators have corresponding qualifications before using.
- Only the specified and with protective earthing power supply can be used. If you have any questions about the installation of the external line, the equipment must be operated by the internal power supply.
- The inflammable anesthetic agent such as aether and cyclopropane can not be used. Only the anesthetic agent that according with the requirements about the non-flammable anesthetic described in the appendix DD of the IEC-60601-2-13 can be used in this anesthetic system.
- Only O_2, N_2O, Air and non-flammable anesthetic are compatible with the 620.
- For any independent region using the same or similar equipment with different alarm preset will occur potentially dangerous, such as ICU operation room or heart operation

Warning

room.

- This equipment can only be used in the specified environment, should not be used in the inflammable or explosive environment, magnetism resonance imaging (MRI) environment, or in the environment with other strong electromagnetism interfere.
- Only those conform to the latest IEC-601-1 standard accessories and auxiliary equipment can be connected to this anesthesia machine. If peripheral equipment such as computer, monitor, and humidifier has been connected to the anaesthetic ventilator, the whole system should meet the IEC-601-1 standard.
- Do not use flammable agent in the patient absorber.
- The container with water should not be placed on the equipment in order to prevent liquid entering the equipment and lead to malfunction.
- The equipment will produce some castoff such as the sodium- calcareousness, the one-off parts or the damageable parts which will lead to serious pollute or cross infection if discarded randomly, and should be managed and disposed according to the relative regulations.
- Before operating please ensure that all the separate facilities that work with this anesthesia machine such as the anesthesia gas monitoring apparatus and the anesthesia gas purifying apparatus are in good condition.
- Before operating please ensure that the gas supply needed by the equipment is in good condition, the malfunction may make the equipment unable to work if connected to the central gas supply system.
- When the system stops supplying gas, the pressure gauge will indicate the current pipeline gas pressure.
- A malfunction of the central gas supply system may cause more than one or even all devices connected to it to stop their operation simultaneously.

Operating warning：

- Once the abnormal alarms occur or it cannot start-up normally during the startup process, please stop using the equipment and contact the maintaining personnel

Warning

immediately.

- Do not open the outer casing of the equipment so as to avoid electric shock.
- Do not touch the power supply so as to avoid electric shock.
- Do not pull the display wire during in use, otherwise it may result in invalidity to alarm volume.
- The volume of the alarm sound should be kept at an appropriate level, and it should not disturb others or be ignored because of the inaudible volume.
- This equipment should only be used with the recommended accessories and materials, otherwise unpredictable risks may occur.
- The machine must not be used if any of the alarm, monitoring device is not functioning correctly.
- When worked with the high frequency electrical surgical equipment, should avoid mechanical damages to this equipment or its components that caused by the electrical surgical equipment.
- Those medical equipments that worked together with this anesthesia machine should also conform to the corresponding safety requirements.
- Do not use the antistatic or conductive mask or breathing tubes.
- Additional equipment placed on the top shelf must be securely attached. Take care when moving a fully loaded machine, particularly when negotiating ramps. Check that hoses or power leads are not trailing on the floor.
- The exhausted gas should be discharged through the exhaust outlet and cannot be discharged to the room, do not block the outlet.
- Do not replace the canister during the ventilation period, otherwise there may exist risks.
- Prevent the absorbent turning dry, please replace the absorbent timely if it becomes dry.
- The vent of the PEEP will discharge little air and oxygen continuously, so do not block the vent, otherwise the anesthesia machine cannot work.

Warning

- During operation please ensure there is no testing plug or other foreign body in the absorber.
- The expiratory valve of the anesthesia machine is with constantly open design, when power failure or abnormal occurs, the valve is open and connected to the atmosphere through the AGSS to ensure patient can breath freely. During use, please do not block the AGSS to avoid suffocate the patient.
- If the system is connected to the peripheral equipment (such as VGA), it may increase the leakage currents to the patient.
- If one or more devices are connected to the auxiliary mains socket-outlet, it will lead to the increase of the leakage current risks, the leakage current should be checked termly.
- Before using any additional electrical equipment powered by the auxiliary sockets on the machine, check that the additional equipment is correctly wired and is earthed through its plug. A missing or defective protective earth conductor may increase earth leakage currents to the patient to values exceeding the allowable limits, resulting in ventricular fibrillation, or interference with the pumping action of the heart.
- Remember to do a circuit leak test after reinstalling the CO_2 canister.
- When installing the oxygen sensor, please check if the sealed ring is in good condition, replace a new oxygen sensor if the sealed ring is damaged or there is no sealed ring.
- In order to ensure the compatibility, please check the performance of AGSS, the system belongs to the low flow disposal system and its extract flow is below 50L/min.

Maintenance Warning:

- Please clean and disinfect the parts that have been repeatedly used and contacted with the patient according to the ways that recommended in the user manual every time before use.
- Please shut off the equipment and the power supply while cleaning.
- While cleaning the parts of the equipment, users must be away from the equipment.
- While cleaning the outer casing, please make sure that no liquid enters into the

Warning

controlling components, and it cannot be connected to the AC power supply until the parts have turned dry after cleaned.

- Cooling the equipment for at least half an hour before disassembling it.
- While disassembling the outer casing of the equipment, the supply must be cut off and should only be operated by experienced personnel.
- Please dispose the wrapper according to the local regulations or the hospital waste disposal system.
- Do not throw the batteries or the oxygen sensors to the fire so as to avoid exploder.
- The exhausted batteries should be replaced or discarded according to the local regulations and should not be disposed in a normal way.
- The oxygen sensor and the flow sensor should not be dipped in the liquid or disposed by high temperature and high pressure.
- The immersion time in hot water of the bellows components should be not more than 15 min, to prevent dissolving or aging.
- The heating accessories of the flow sensor are electriferous, so that it should be cleaned with a soft cloth soaked in alcohol and should not be disinfected by way of dipping in the liquid.
- Do not use lube that contains oil or liquid.
- The moving parts and the knock-down components may lead to pinched or crushed dangers, please pay more attention when moving or replacing the parts of the system.
- Do not implement the calibration process when the system is connected to the patient.
- Please use the accessories provided by the Company in order to avoid the value incorrect or the equipment failure.
- The one-off accessories can be used only once, repeated use may lead to performance degradation or cross-infection.
- If there appear any problems about the accessory’s wrapping or the accessories, do not use accessories.

1.2 Caution

⚠Caution

Preparation Caution:

- All parts are suitable for use in the patient environment.
- Please double-check the power cord before connected to the city electricity, make sure it has no damage, scratch or other factors which will lead to the inside conductor exposed issues.
- Ensure that the sensitive parts are installed in proper branch of the breathing system.
- When the equipment or the accessories are about to exceed the limit time, they should be disposed according to the local regulations or the hospital systems.
- The electromagnetic fields may affect the performance of this device, so the other facilities used around this must meet the corresponding EMC requirements.
- This equipment complies with the electromagnetic compatibility regulations of the IEC 60601-1-2 standard. If the interfering grade exceeds the limit grade, it may lead to the stop of the mechanical ventilation.
- Please install or transport the equipment appropriately to avoid falling, hitting, serious vibrating or other outside forcing damages.
- The anesthetic gas delivering device that used together with the anesthesia system must comply with the ISO 8835-4 requirements.
- This equipment should be used together with the anesthesia gas monitoring apparatus that comply with the ISO 11196 requirements.
- AGSS is to be used with an Anesthetic system complying with the requirements of ISO 8835-3.
- Any of the anesthesia ventilation systems that used together with the anesthetic gas delivery system should meet the requirements of the ISO 8835-2
- The anesthesia ventilator that used together with the anesthesia system must comply with the requirements of the ISO 8835-5.
- If the anesthesia system need to used together with the anesthetic gas scavenging

Caution

delivery or receiving systems that accorded with the ISO 8835-3 requirements to connect to the AGSS port.

- AGSS is intended to be used withOKM 620 Anesthetic system, to ensure compatibility.
- Pressure-measuring device is to be used with an Anesthetic system complying with the requirement of ISO 8835-28.1.
- Pressure-limiting device is to be used with an Anesthetic system complying with the requirement of IEC 60601-2-13 51.101.1.
- Exhaled gas monitor is to be used with an Anesthetic system complying with the requirement of IEC 60601-2-13 51.101.4.
- Ventilation system with alarm system is to be used with an Anesthetic system complying with the requirement of IEC 60601-2-13 51.101.5.
- O_2 monitor is to be used with an Anesthetic system complying with the requirement of ISO 7767:1997.
- The Anesthetic system is equipped with an CO_2 monitor that complies with ISO 9918 before using.
- The measuring conditions shown in this user manual are the ambient temperature and pressure saturated (ATPS) conditions.
- The pressure in the medical gas pipeline keeps the original unchanged when the anesthetic system stops delivering gas.
- When the pressure of the gas supply inlet is at twice the maximum rated inlet pressure, the pipeline will not rupture or cause any security risk. But it is recommended to keep the pressure in the specified range.

Operation Caution

- In order to prolong the battery life, please use the battery at least once per month, and charge or discharge it fully.
- Please open the device and check the battery if not been used for a period of time to avoid the battery malfunctions.

Caution

- The battery life lies on the frequency and time of used. The lithium battery life is about 3 years if maintenance and used in a proper way.
- Please pay attention to the position of the gas pipeline so as to avoid falling off.
- Please make sure that the power supply cable exposed outside the equipment is not twisted to the patients, operators, other personnel or objects(including tubes), otherwise, dangers may occur.
- When installing the breathing tube, please hold the joints on the two ends of the tube in order to avoid damages of the tube.
- This equipment can use three kinds of anesthetic agents: the enflurane, the isoflurane and sevoflurane, only one anesthetic can be used at a time.
- This equipment may bring interference to other products.
- Do not use this equipment if it not passed the test before using, please contact the after service department of the Company.

Maintenance Caution:

- Please use the methods recommended in this manual to clean or disinfect this equipment.
- Take care when transporting, moving or disassembling the equipment to avoid damages to the personnel.
- Do not use the abrasive detergents (such as the steel wool, silver polish or detergent).
- The display should be cleaned with a dry, soft and lint-free cloth; it should not be cleaned by liquid.
- Please contact the repairing personnel or the Company if the calibration of the equipment failed many times.
- Please use the parts that produced or sold by the Company to replace the damaged parts. And have a test after replacing to ensure that the equipment accorded with the specifications and requirements of the manufacturer.

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Chapter 2 Equipment Description

2.1 Brief Introduction

2.1.1 Intended use

This equipment is a pneumatic controlled anesthesia machine which is used to manage and control the respiration and anesthesia of the single patient during the anesthesia operation, it is suitable for both adult and Pediatric (Above 5Kg). This anesthesia machine can provide controlled concentrations and flows of anesthesia gases into a patient breathing system, (the concentration of oxygen is no less than 21%) and also provide the respiratory support.

The anesthesia machine is intended to use only in the operating rooms and emergency rooms, not suitable for other places, and it can only be operated by the professional anesthetist.

⚠Warning:

- This equipment should be operated by the professional anesthetist or under the guidance of the professional anesthetist. Personnel not authorized or trained can not carry out any operations.
- The clinical environment of this equipment is operating rooms and emergency rooms.

2.1.2 Main feature

This anesthesia machine consists of the anesthetic ventilator, patient absorber, CO_2 canister, vaporizer assembly, AGSS, flow meter assembly and gas connecting tubes, display, and so on.

This anesthesia machine has following functions and features:

1. Use the touch screen to select setting parameters and functional buttons easily and conveniently.
2. Automatically leakage compensation and compliance compensation.
3. Make tidal volume compensation according to altitude.
4. Electronic adjustable PEEP, range: OFF, 4～30 cmH_2O.
5. The two-station vaporizer mounting systems with interlock function.
6. Electronic flowmeters display on interface.
7. With Cardio pulmonary bypass function.
8. The accurate monitoring and displaying of the ventilation parameters.
9. Clear and differentiable auditory and visual alarms.
10. Storing and reviewing the alarm events functions.
11. Optional high pressure cylinder interface.
12. Displaying the anesthesia parameters in big words.
13. With auxiliary oxygen configuration, the AGSS functions.
14. With the function of connecting to the monitor.

2.2 System overview

⚠Caution：

- The illustrations in this chapter are only for reference, due to the different configurations, the illustrations may be not entirely consistent to the product.

2.2.1 External connection view

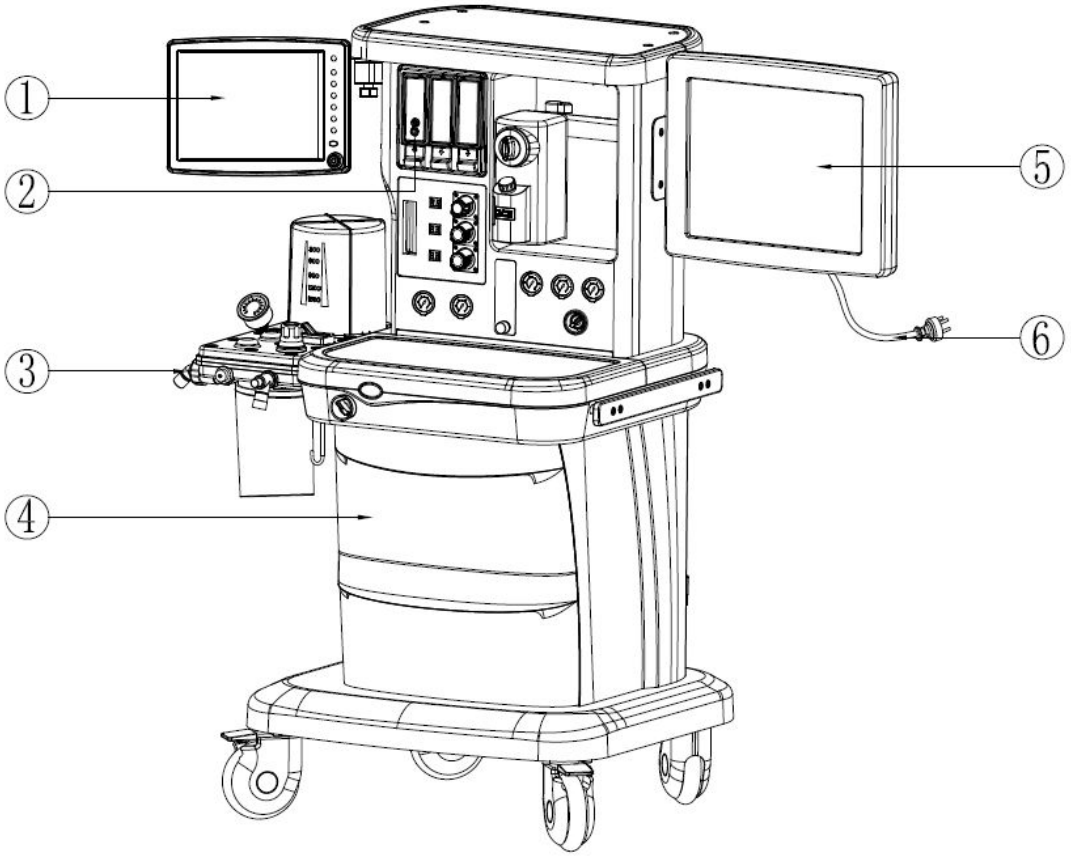


Figure 2-1 External connection view

1. Display screen	4. Drawers(two)
2. CO_2 module connecting port	5. Anesthesia information recording system
3. Patient absorber	6. Main power connector

2.2.2 Front view

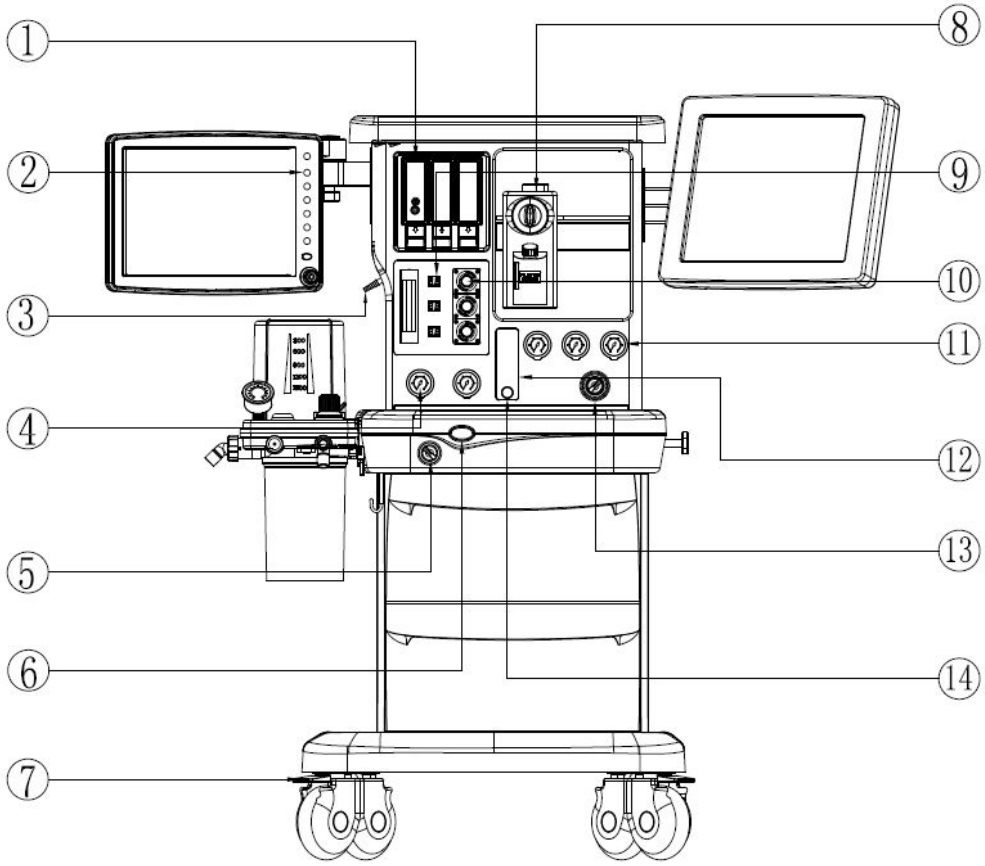


Figure 2-2 Front view

1. Modules installation position
2. Anaesthetic machine controlling buttons Refer to the section *2.13.2*
3. Auxiliary oxygen outlet
4. High pressure gas cylinder gauge Indicates the pressure at cylinder inlets.
5. ACGO switch
6. Oxygen flush button Refer to the section *2.8*
7. Castors brake
8. Vaporizer
9. Electronic flowmeter Refer to the section *2.7*

10. Electronic flowmeter controlling knobs

Refer to the section *2.7*

11. Gas supply gauge

Indicates the pressure at pipeline inlets for O_2, N_2O and AIR.

12. Auxiliary oxygen flowmeter

There is a round float inside of the flowmeter, and the central plane scale of float is indicates the current flow. Range: 0~15L/min.

13. System switch

Refer to the section *2.6.*

14. Auxiliary oxygen flowmeter knob

It is used to adjust the auxiliary oxygen flow, and turn the knob clockwise to decrease the flow and counterclockwise to increase.

2.2.3 Side view

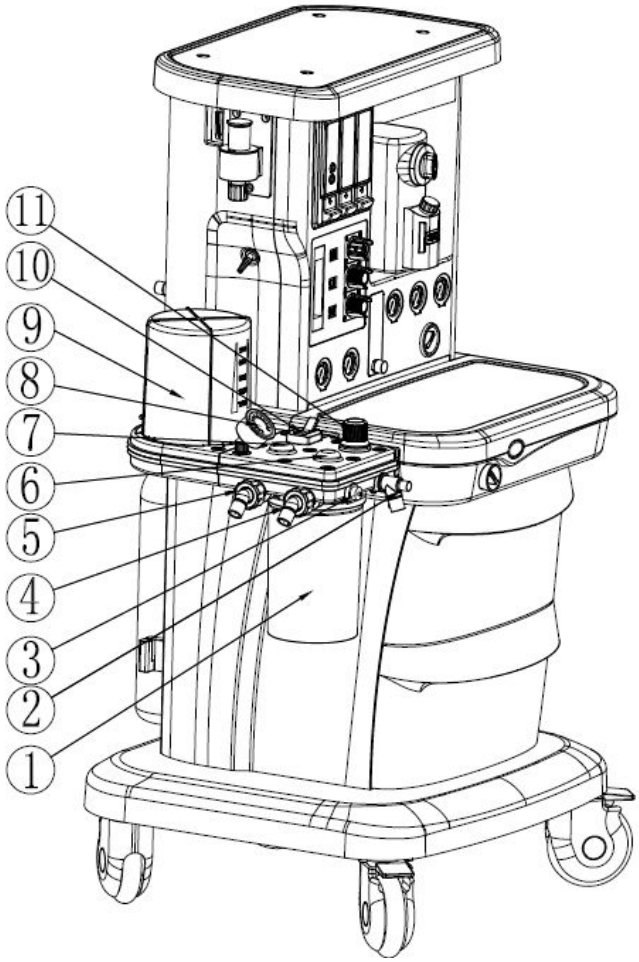


Figure 2-3 Side view

1. CO_2 canister Be used for CO_2 absorbent material fill.
2. Manual bag port The port for connecting the manual ventilation bag.
3. Oxygen sensor port The port for installing the oxygen sensor.
4. Inspiratory Limb /ACGO outlet
5. Expiratory Limb
6. The non-return valve in the inspiratory Limb
7. The non-return valve in the expiratory Limb
8. Airway pressure gauge

Indicates the patient airway pressure.
9. Bellows housing
10. Bag/Ventilator switch When switch to “  ”, manual ventilation mode is selected, and switch to “  ”, mechanical ventilation mode is selected.
11. APL valve Adjusts breathing system pressure limit during manual ventilation. Turn clockwise to increase the pressure, and counterclockwise to decrease, when the pressure exceeds the preset value, it will be automatically relieved by APL.

2.2.4 Rear view

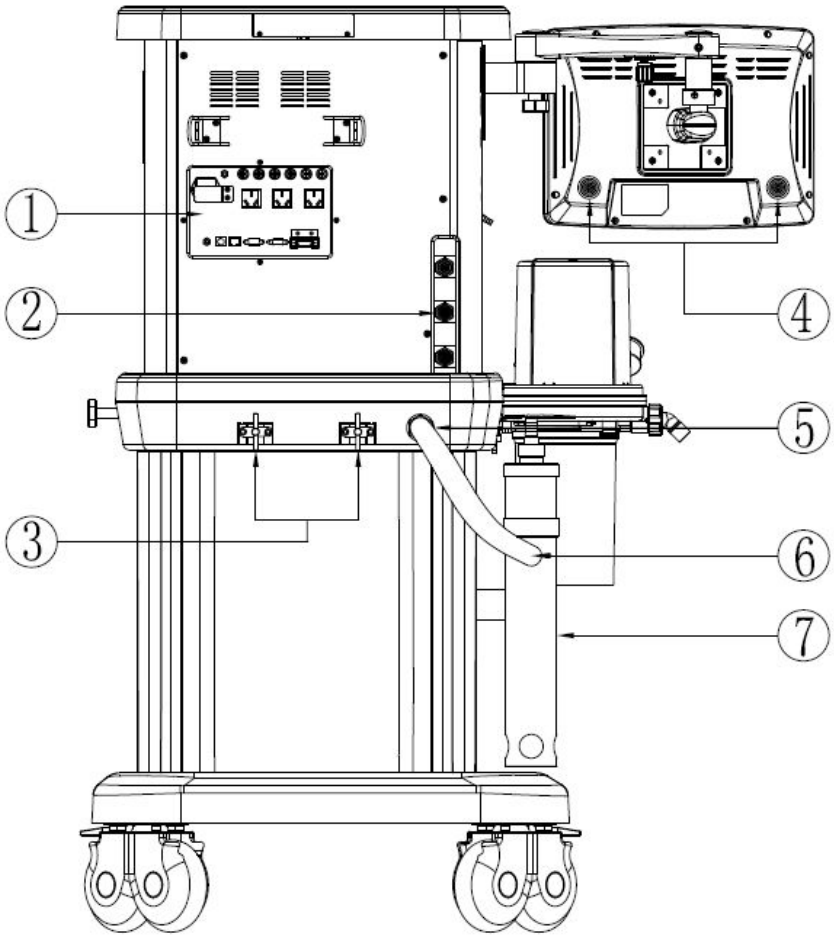


Figure 2-4 Rear view

1. Rear interface plate
2. Gas pipeline supply inlet Provides the gas input connection for Oxygen, N_2O, AIR
3. Backup gas cylinder relief device inlet Input pressure <15MPa, output pressure: 400~450KPa
4. Alarm speaker
5. AGSS exhaust port
6. AGSS inlet port
7. AGSS (Anesthetic Gas Scavenging System)

2.2.5 Rear interface plate view

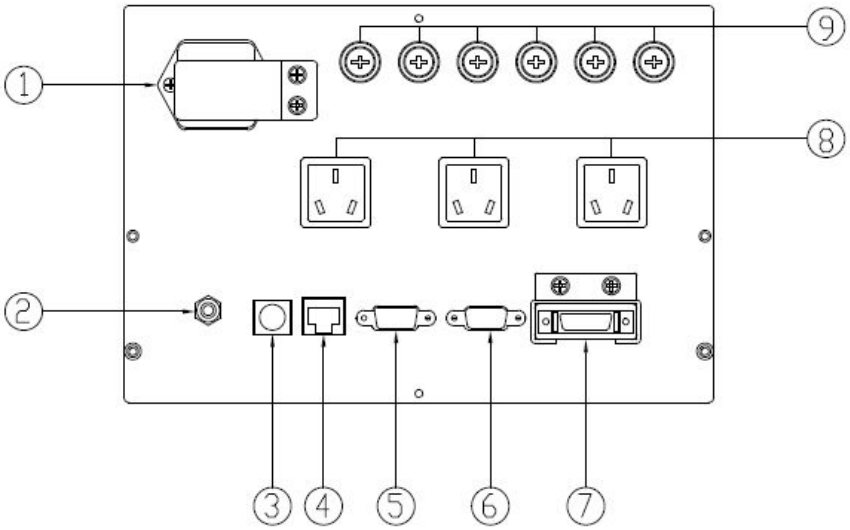


Figure 2-5 Rear interface plate view

1. Mains inlet	6. VGA port
2. Equipotential stud	7. Monitor port
3. RS232 port 1	8. Auxiliary AC outlets
4. Ethernet port	9. T2AL/250V Circuit Breaker holder
5. RS232 port 2	

2.3 Power supply

1. AC Power supply specification: 100～240VAC, 50/60Hz.
2. Auxiliary mains power supply: 100～240 VAC, 50/60Hz, 2A×3.
3. Circuit Breaker specification: T10AL/250V.
4. When AC power cord is connected, the AC indicator will be light; when AC power cord is disconnected, the light will be off.

⚠Warning:

- If the system is connected to the peripheral equipment (such as VGA), the patient leakage current may be increased.
- If one or more devices are connected to the auxiliary mains socket-outlet, it will lead to the increasing of the leakage current risks, the leakage current should be checked termly.

2.4 Batteries

The anesthesia machine is equipped with built-in rechargeable lithium batteries to ensure that the anesthesia machine can still work when the power supply is cut off. When the anesthesia machine is connected to the AC power and switched on, the batteries are charging if not already full charged. When the power supply is cut off, the system will automatically switch to the battery power supply, simultaneously, it will generate an AC power supply failure alarm to prompt users, and will not lead to interruption of the anesthesia ventilator work.

The fill amount of the battery icon on the interface indicates the amount of battery power remaining.

-  Full charge.
-  Low battery capacity, it needs to be charged.
-  The battery is exhausted and needs to be charged immediately.
-  Battery is not installed.

When the battery power is low, the anesthesia machine will generate a medium alarm, and the alarm message 【low battery capacity!!】displays in the alarm area, it indicates greater than 10 minutes of battery power remaining. When the battery is exhausted, there will be a high alarm, and the alarm message 【No Battery Capacity!!!】 displays in the alarm area, it means greater than 3 minutes of battery power remaining, then the anesthesia machine must be connected to the AC power supply.

⚠Caution

- Use a AC power source supply before the internal battery power source is depleted.
- The batteries can not be replaced by user, if need, contact the authorized equipment maintenance personnel or the after service department of our company.
- The exhausted batteries should be replaced or discarded according to the local regulations.
- Long-term battery life depends on how frequent and how long the battery supply is used, for a improperly maintained, stored lithium battery and the aggressive usage, its life can be shortened.
- It should be remembered that the exhausted battery is charged. When the Anaesthesia machine is connected to an AC power source, the battery is automatically charged.
- It is recommended that the stored battery is charged once every 6 months.
- If the battery is stored for a long period and it has been discharged, it needs a extended period to be charged.
- Please take out the battery if the system is not used for a long period.

2.5 Gas supply

There are three kinds of gas input: oxygen, air and N_2O. They can be connected to the central gas supply system, and the required rated pressure range is 0.28～0.6Mpa, there is a filter, manometer and a non-return valve installed in each pipeline of the gas. The machine can also be connected to the O_2 and N_2O cylinder, the pressure inside the full O_2 cylinder is about 15.0Mpa and it is about 8.0Mpa inside the full N_2O cylinder, there is a filter, a manometer, a adjust pressure valve and a non-return valve installed in each cylinder, if the output pressure of the cylinder exceeds 0.6Mpa, it will be regulated to 0.28 ～ 0.6Mpa by the adjust pressure valve. And there is a pressure-relief valve connected to each of the gas supply, which is as a security role to prevent high pressure of the gas supply, the releasing pressure is 758kPa（110psi), when the pressure is above 758Kpa, it begins to release the pressure, the pipeline will not rupture or cause any security risk. But it is recommended to keep the pressure within the specified range.

The curve below displays the output pressure after the gas supply passes though the pressure-relief valve.

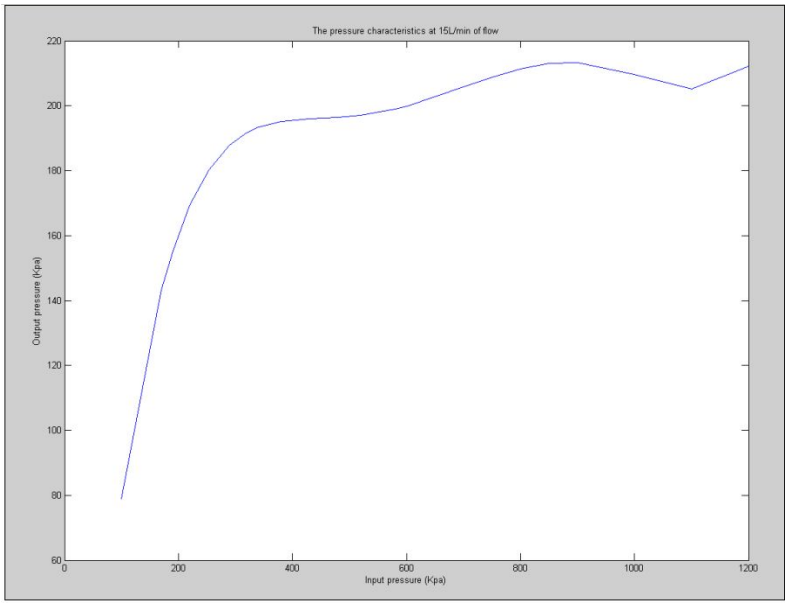


Figure 2-6 Output pressure curve view

The gas supply is mainly used as below:

1） The oxygen is the power source of the ventilator.

2） Proving fresh gas for the patient.

2.6 System switch

There is a system switch designed in order to achieve the functions of opening and cutting off the anesthesia circuit fresh gas and the system circuit at the same time. When the system switch is turned on, users can adjust the gas flow by adjusting the electronic flowmeter to make the fresh gas pass through the ACGO into the circuit, at the same time, the system is connected to the power supply and begins to run according to the pre-set state; when the system switch is turned off, the gas through the flowmeter is cut off, there is no fresh gas output, the system is disconnected to the power supply, and the anesthesia machine can not be operated, but can be operated manually.

Turn the system switch to the ⊙ position: the system is turned on.

Turn the system switch to the ○ position: the system is turned off.

2.7 Flowmeter

The flowmeter displays the flow of the gas: O_2, N_2O and Air. Their flow can be read directly.

The flowmeter range: 0.1~10L; Accuracy: 0.1L; The unit: L/min.

The user can adjust gases flow by the controlling knob, turn the flowmeter controlling knob counterclockwise to increase the flow and clockwise to decrease.

- O_2 and N_2O knobs consist of a linkage device. (O_2, N_2O linkage device).
- While counterclockwise rotation of N_2O knob, and N_2O flow is increased to a certain extent, O_2 knob would be rotated together with N_2O knob, and the O_2 flow would be increased, such a system could ensure the O_2 concentration in the fresh gas over than 21%
- While clockwise rotation of O_2 knob and O_2 flow is decreased to a certain extent, O_2 knob would be rotated together with N_2O knob, and the N_2O flow would be decreased, such a system could ensure the O_2 concentration in the fresh gas over than 21%.

Auxiliary oxygen flowmeter: turn the knob counterclockwise to increase the flow. Turn the knob clockwise to decrease the flow.

There is a round float inside of the flowmeter, and the central plane scale of float is indicates the current flow. See the graphic below:

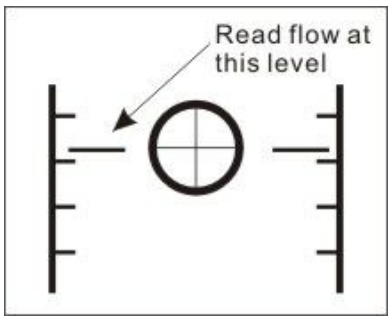


Figure 2-7 Flowmeter float indication

2.8 Oxygen flush button

The oxygen flush supply is provided by the oxygen supply separately, it passes through the oxygen flush button and the gas resistance then enters the patient absorber. Oxygen flow will rush into the gas path when the oxygen flush button" O_2+" is pushed, and the gas path is cut off when the button is released. The gas resistance is to reduce the impact of the rapid oxygen flow on the patient and regulate the flow rate to the range of 25～75L/min.

2.9 Auxiliary Common Gas Outlet（ACGO）

The inspiratory limb and the ACGO share a common port.

- When the ACGO switch is activated, this outlet may be used to provide fresh gas to atmosphere or an external manual breathing circuit. Mechanical ventilation is not available when the auxiliary outlet is selected.

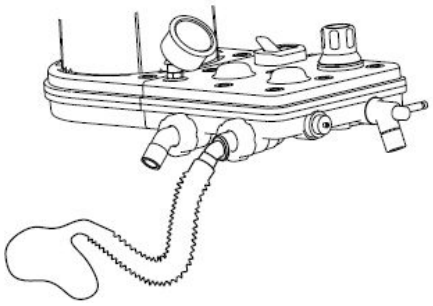


Figure 2-8 ACGO connection view

When the ACGO is closed, the breathing circuit is selected.

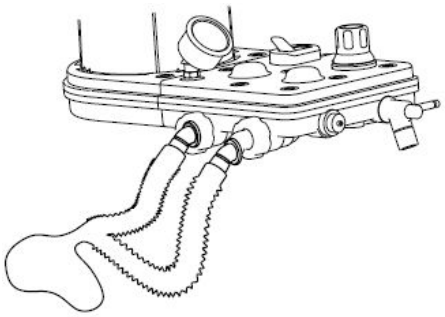


Figure 2-9 Breathing circuit connection view

2.10 Patient absorber and bellows assembly

In this anesthesia machine, the patient absorber is integrated with the bellows assembly.

The patient absorber is used in conjunction with the anesthesia machine as a part of the closed respiratory system, connected with the appropriate respiratory pipeline, gas reservoir bag and patient port, and absorbs CO_2. According to the different gas flow set by the anesthetist, the expiratory gas can completely or partially circulates and enter the inspiratory port, achieve the closed, semi-closed ventilation.

The patient absorber and the bellows integrated system is connected to the anesthesia machine by connecting the interface board on its side with the interface board on the side of the host, after installed, lock the system by the locking device on the left front of the anesthesia machine to prevent loosing or falling off and lead to gas leakage.

There is a Sodium lime canister at the bottom of the patient absorber, which is used to absorb the exhalant CO_2 and prevent the intraoperative excessive CO_2 retentate which may lead to hypercapnia. If you need to replace the sodium lime in use, remove the sodium lime canister and the gas path will be closed automatically, it will not affect the ventilation or use, but it is not recommended to undergo surgery using the anesthesia machine in the case of the sodium lime canister absent and the sodium lime disabled.

The inspiratory non-return valve, inspiratory flow sensor and the expiratory non-return valve, expiratory flow sensor are there installed respectively on the inspiratory limb and the expiratory limb of the patient absorber, which are used to monitor the inspiratory and expiratory flow rate, the airway pressure as well as achieve the gas circulating circuit.

The system is integrated with an oxygen sensor, it is connected to the anesthesia ventilator through the cable, then displays the inspiratory oxygen concentration on the user interface. It is accorded with the ISO 7767 standard.

There is also a micro-manometer installed above the patient absorber, it will display the airway pressure, the display range is : -20～+100cmH_2O.

The APL valve above the patient absorber is used to restrict the pressure during the manual ventilation mode, the design range is 2～70cmH_2O, when extruding the bag manually, if the pressure exceeds the limited value, the gas will be vented from the valve vent, and the exhausted gases are collected to the AGSS outlet and vented.

The system is integrated with the Bag/Ventilator switch valve, achieving the following functions:

1) Spontaneous respiration or manual ventilation in manual mode.
2) Using the anesthesia machine to ventilate in mechanical ventilation mode.

2.11 Anaesthetic Gas Scavenging System (AGSS) （Optional）

The device is used in the operation room of hospital, and it is the system for collection and delivery of exhausted gas from anesthesia machine to the hospital exhaust centralized disposal system. This is the solution to avoid the pollution of anesthetic exhausted gas in the operation room. The device is well-structured, simply-operated, safe and reliable.

AGSS consists of the exhaust port, float pump, float, cylinder, and inlet port.

AGSS has two models: OKM 200A and OKM 200B.

There is difference between OKM 200A and OKM 200B, OKM 200A cylinder with the metal material and OKM 200B with the plastic material.

Anesthetic Gas Scavenging System:

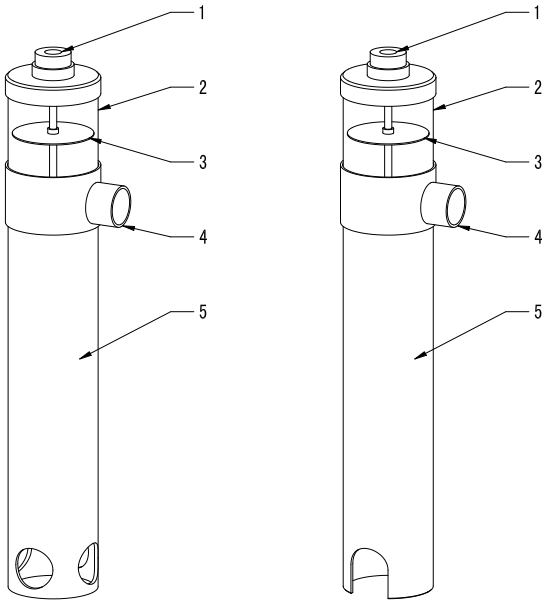


Figure 2-10 AGSS (Top, Front, and Right Views)

1. Exhaust port: it is a specified screw thread connecting port matched with the specified corrugation hose which connects to the hospital's waste gas disposal system.
2. Float pump: it is a transparent and plastic pump used for observing float" s position, and marked the minimum scale line on the surface.
3. Float: it is a plastic disc that indicates AGSS's intake flow.

4. Inlet port: it is the inner cone port (30mm) that complies with the standard of ISO 5356-1 and with a transfer hose connects to the anesthetic machine" s exhaust gases outlet.
5. Cylinder: it is hollow cylinder that collects exhaust gases from the breathing system.

2.12 Vaporizer

The vaporizer delivers the anesthetic agent to the patient respiratory system to anesthetize the patient. Different anesthetic agent should be used with the corresponding vaporizer; otherwise it will result in inaccurate output concentration.

The anesthesia machine adopts IBIS 200 vaporizer designed by the company, and also the imported PENLON vaporizer. The Halothane, enflurane, isoflurane, sevoflurane and Desflurane vaporizers are available as option. There are two vaporizer seatings, when the two vaporizers are installed, the interlocked function makes it only output one kind of anesthetic at the same time.

The vaporizer used in this anesthesia machine should be accorded with the ISO-8835-4 requirements.

For the particular operation of the vaporizer please refer to the user manual provided by the vaporizer manufacturer.

2.13 Anaesthesia ventilator

The anaesthesia ventilator is an auto-controlling equipment which replaces the traditional manual ventilation, which adopts the pneumatic electronically controlling to achieve different modes and parameters changes of the driving gas, and provides the monitoring of the corresponding physiological and ventilation parameters as well as the auditory and visual alarms for the abnormal events.

In order to control the flow of the driving gas accurately, accurate pressure-regulation valve is used to adjust the driving gas supply pressure to 0.2Mpa, and then solenoid proportional valve is used to achieve the different flow rate adjustment through electrically controlling. The output gas passes through the machinery over-pressure valve and the bellows to achieve the automatically ventilation for the patients. The over-pressure valve is to guarantee the pressure of the driving gas circuit less than the safe pressure, and its release pressure is designed to be 10.8kPa (110cmH_2O). The expiratory valve is closed during inspiration, and during expiration, the gas inside the bellows passes through the valve(the path is Φ 18mm to the bellows interface and Φ 15mm to the PEEP valve gas path interface) and enters the AGSS vent , to reduce the exhaust emission pollutions to the operating environment.

In order to prevent the exceeding high pressure in the gas path which may bring dangers to the patient or equipment, the anesthesia ventilator monitors the pressure and flow value of inspiratory and expiratory gas, and emits the auditory and visual alarms for the abnormal events, besides the design of the over-pressure valve to ensure the driving gas not exceed the safe pressure.

2.13.1 Display

The anesthesia machine adopts the color TFT LCD, which can display various parameters and graphics clearly. The diagram below contains the main interface of the anesthesia machine.

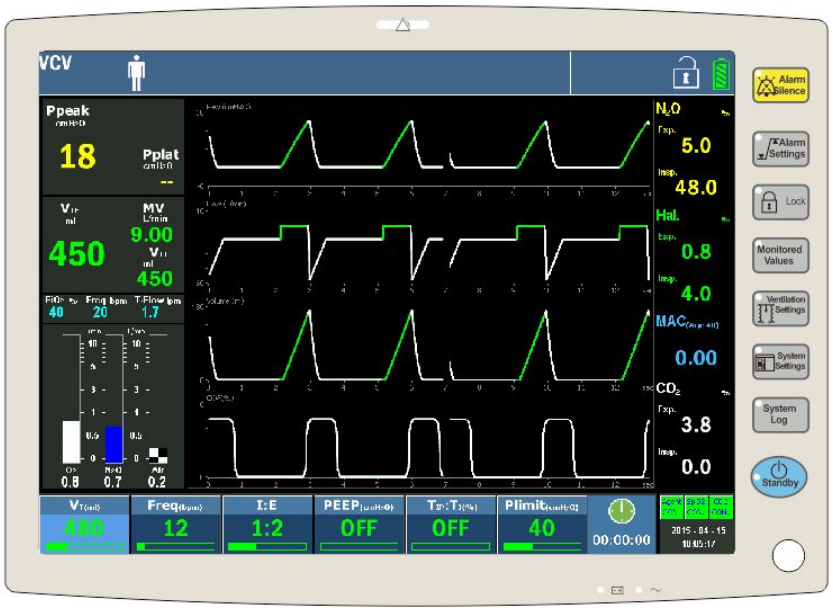


Figure 2-11 Display screen view

2.13.2 Membrane button

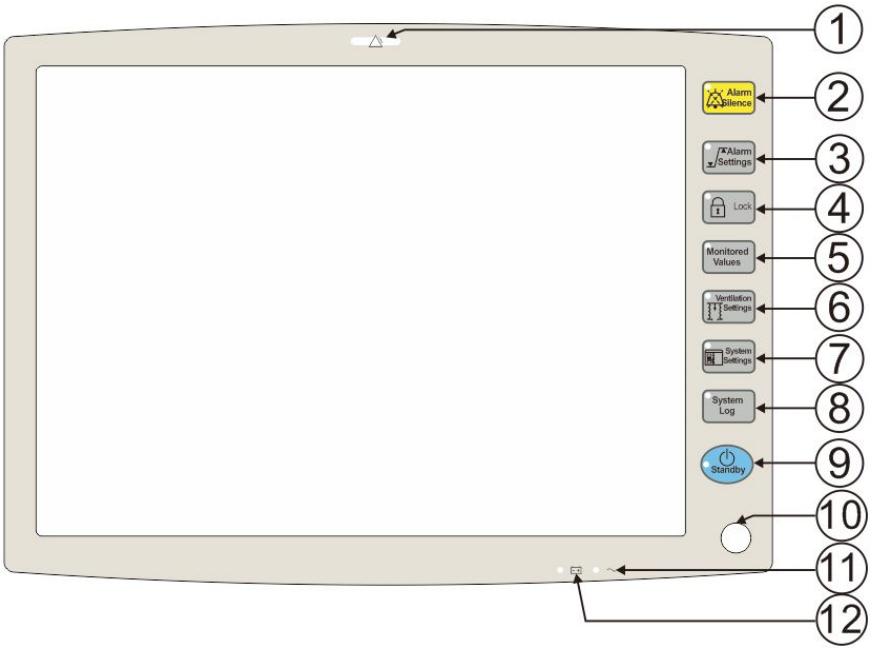


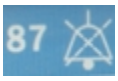
Figure 2-12 Membrane button view

1. Alarm indicator light:

No practical function. Response to the anesthetic ventilator alarms, the light is red for the high priority alarm and yellow for the medium and low priority alarms. (Please refer to *5.11 Alarm settings* for more information)

2. Alarm Silence:

（1） The 【Alarm Silence】button is invalid when no alarm occurs.

（2） When alarm sounds, push this button to mute the alarm, the duration is 100 seconds, the alarm silence icon 

and 100 seconds count down will display on the top right corner of the interface.

（3） Push this button again to resume the alarm sound.

（4） Alarm silence will be canceled when a new alarm occurs, it will generate the new alarm.

3. Alarm Setting:

Push the 【Alarm Settings】button to access the alarm settings menu.

4. Lock:

Push the 【Lock】button to lock the screen, the icon “  ” will display on the interface, push this button again to unlock the screen. The icon “  ” will display on the interface.

5. Monitored Value:

Push the 【Monitored Values】button to access the respiratory parameters monitoring interface.

6. Ventilation Setting:

Push the 【Ventilation Settings】button to access the ventilation modes and parameters setting interface.

7. System Setting:

Push the 【System Settings】button to access the system settings interface.

8. System Log:

Push the 【System Log】button to access the system log interface.

9. Standby:

Push the 【Standby】button to access the Standby interface.

10. Navigation wheel:

（1） Turn: to switch among the membrane buttons or the function options, turn it clockwise to increase the parameter value, or anticlockwise to decrease the parameter value.

（2） Push it down to confirm the settings.

11. AC power indictor:

（1） The indicator light is on: the anesthesia machine is connected to the AC power.

（2） The indicator light is off: the anesthesia machine is disconnected to the AC power.

12. Battery indicator light:

（1） The full battery power capacity: green.

（2） The insufficient battery power capacity: orange.

（3） Battery is not fitted or battery failure: Not illuminated.

2.13.3 User interface

Refer to the *Chapter 5 Operations and settings.*

2.13.4 Ventilation modes

2.13.4.1Manual ventilation mode

1. Switch the Bag/Ventilator switch to manual  position, the “Manual” will be displayed in the ventilation modes display area.
2. Turn the controlling knob of the APL valve to adjust the pressure in the patient absorber to an appropriate range.

⚠Caution：

◆ In the manual ventilation mode, all the ventilation setting parameters are disabled.

2.13.4.2Mechanical ventilation mode

⚠Caution：

◆ The default mechanical ventilation mode of the anesthesia machine is【VCV】mode. Users can set other mechanical ventilation modes in the ventilation setting interface.

◆ Ensure that there is an independent backup ventilation (such as a simple respirator with mask) whenever the system is in use.

2.13.4.2.1VCV mode

1. Principle description

VCV (volume control ventilation) mode is a basic completely mechanical ventilation mode. Preset the tidal volume【V_T】,the breathing frequency 【Freq】and the expiratory and inspiratory rate 【I:E】. When the inspiration begins, the gas flow will enter the lung at a constant speed and it will reach the preset tidal volume within the preset inspiratory time and then expire.

In the 【VCV】mode, users can set the 【T_{IP}:T_I】(inspiratory hold) to improve the gas distribution conditions in the patient's lung; and set the 【PEEP】(positive end-expiratory pressure) to improve the vent of CO_2 in end-expiratory and increase oxygen in the breathing process.

When the peek pressure exceeds【P_{limit}】,the system will release the pressure and give an alarm.

2. Selecting the VCV mode

1) Push the 【Ventilation Settings】 key, the modes setting interface will display.
2) Push the modes option frame and select the 【VCV】 mode in the drop-down menu.
3) When the 【VCV】 mode is selected, the information display area will display 【VCV】.

3. Parameter need to be set

In VCV mode, following parameters need to be set:

- 【V_T】
- 【Freq】
- 【I:E】
- 【T_{IP} :T_I】
- 【PEEP】
- 【P_{limit}】
- 【Sigh】

2.13.4.2.2 Sigh function（Optional）

1. Principle description

In volume control mode, the user can set sigh by ventilation mode interface （range:OFF,10~100）, the extra volume will be increase by 50% above the tidal volume set by the user(1.5xset volume) in the next inspiration cycle of the sigh setting value.

Note that sigh function is canceled when the unit is powered off.

2. Selecting Sigh

1) Push the 【Ventilation Settings】 key, the modes setting interface will display.
2) Set the 【Sigh】parameter in the modes setting interface (only volume control mode).

2.13.4.2.3 PCV mode

1. Principle description

PCV (pressure control ventilation) mode is a basic completely mechanical ventilation mode. Preset the airway pressure 【P_{insp}】,the breathing frequency【Freq】and the expiratory and inspiratory rate 【I:E】. When the inspiration begins, the gas flow will enter the patient's lung quickly, when it reaches the preset pressure level, it will reduce the flow rate through the response system, and at the same time it will keep the airway pressure at the preset pressure value till the end of the inspiratory and then expire.

In the 【PCV】mode, users can also set the 【PEEP】(positive end-expiratory pressure).

2. Selecting the PCV mode

1) Push the 【Ventilation Settings】 key, the modes setting interface will display.
2) Push the modes option frame and select the 【PCV】 mode in the drop-down menu.
3) When the 【PCV】 mode is selected, the information display area will display 【PCV】.

3. Parameter need to be set

In PCV mode, following parameters need to be set:

- 【P_{insp}】
- 【Freq】
- 【I:E】
- 【PEEP】

2.13.4.2.4 SIMV (V) +PS mode

1. Principle description

The SIMV (V) +PS mode is a mixed ventilation mode; it is the SIMV (synchronized intermittent mandatory ventilation) mode under the volume controlling.

In the SIMV mode, the independent breathing frequency and tidal volume are controlled by the patient, and a synchronous control is activated at a certain interval of time; if the trigger level (flow trigger) is met in the waiting trigger window, the anaesthetic ventilator will provide a synchronized volume control ventilation for the patient; if the trigger level is not achieved in the trigger window, at the end of the trigger window, the anaesthetic ventilator will give a volume control ventilation.

2. Selecting the SIMV (V) +PS mode

1) Push【Ventilation Settings】 key, the modes setting interface will display.
2) Push the modes option frame and select【SIMV(V)+PS】 mode in the drop-down menu.
3) When【SIMV(V)+PS】 mode is selected, the information display area will display 【SIMV(V)+PS】.

3. Parameters need to be set

In SIMV (V) +PS mode, following parameters need to be set:

- 【Freq】
- 【F_{TRIG}】
- 【V_T】
- 【T_I】
- 【PEEP】
- 【P_{limit}】
- 【P_{supp}】
- 【Sigh】

2.13.4.2.5 SIMV (P) +PS mode

1. Principle description

The SIMV (P) +PS mode is a mixed ventilation mode; it is the SIMV (synchronized intermittent mandatory ventilation) mode under the pressure controlling.

In SIMV mode, the independent breathing frequency and tidal volume are controlled by the patient, and a synchronous control is activated at a certain interval of time; if the trigger level (flow trigger) is met in the waiting trigger window, the anaesthesia ventilator will provide a synchronized pressure control ventilation for the patient; if the trigger level is not achieved in the trigger window, at the end of the trigger window, the anaesthesia ventilator will give a pressure control ventilation.

2. Selecting the SIMV(P)+PS mode

1) Push the 【Ventilation Setting】 key, the modes setting interface will display.
2) Push the modes option frame and select the **【SIMV(P)+PS】** mode in the drop-down menu.
3) When the **【SIMV(P)+PS】** mode is selected, the information display area will display**【SIMV(P)+PS】**.

3. Parameter need to be set

In**【SIMV(P)+PS】**mode, following parameters need to be set:

- 【P_{insp}】
- 【Freq】
- 【F_{TRIG}】
- 【T_I】
- 【PEEP】
- 【P_{supp}】

2.13.4.2.6 SPONT mode（Optional）

1. principle description

SPONT (spontaneous ventilation mode). In the SPONT mode, the patients will control the breathing rhythm themselves, when the triggered level is met, the ventilator will support with the pre-set inspiratory pressure; keep the pressure till the inspiratory flow decreased to the pre-set value and then enter the expiration phase.

2. Selecting the SPONT mode

1) Push the 【Ventilation Setting】 key, the modes setting interface will display.
2) Push the modes option frame and select the **【SPONT】** mode in the drop-down menu.
3) When the **【SPONT】** mode is selected, the information display area will display **【SPONT】**.

3. Parameter need to be set

In the**【SPONT】**mode, the following parameters need to be set:

- 【V_T】
- 【Freq】
- 【Ti】
- 【P_{supp}】
- 【PEEP】
- 【P_{limit}】
- 【Sigh】
- 【F_{TRIG}】

Users can set the backup ventilation in the SPONT mode, providing the mandatory ventilation when the patient is asphyxial.

2.13.4.2.7 PRVC mode（Optional）

1. principle description

PRVC (Pressure Regulated Volume Control), in PRVC mode, inspiration is accomplished at the pre-set tidal volume and respiratory rate within the pre-set inspiratory time, each inspiration is automatically adapt to the controlled inspiratory pressure, which changes the characteristic of the lung or thoracic to ensure using of the minimum pressure to deliver the pre-set tidal volume and minute volume. The inspiratory pressure keeps constant throughout the whole pre-set inspiratory time.

2. Selecting the PRVC mode

1) Push the 【Ventilation Setting】 key, the modes setting interface will display.
2) Push the modes option frame and select the 【**PRVC**】 mode in the drop-down menu.
3) When the 【**PRVC**】 mode is selected, the information display area will display 【**PRVC**】.

3. Parameter need to be set

In 【**PRVC**】mode, the following parameters need to be set:

- 【Freq】
- 【V_T】
- 【PEEP】
- 【I:E】
- 【P_{limit}】
- 【Prate】

2.13.5 Compliance compensation

The anesthesia machine affords compliance compensation for resolving the pipeline compliance loss in breathing system. The compliance compensation operates according to the system testing the compliance data from the tidal volume.

Cautions: the system will compensate for tidal volume loss according to default parameters, if the users do not carry out system testing.

2.13.6 Fresh mixed gas compensation

When the user changes the flow for O_2, N_2O and Air, the system will compensate for tidal volume loss so as to keep the tidal volume of patient's lung and the setting tidal volume consistent.

2.13.7 Alarm system

2.13.7.1General Description

The anesthesia machine is designed with a perfect alarm system to help insure patient safety. The anesthesia machine can signal 3 types of alarms according to different potential risks during the alarm activated: High Priority, Medium Priority and Low Priority.

When alarm occurs, it will remind the user by the alarm indicator light, alarm sound and alarm messages, different grades of alarms have different manifestation patterns.

Alarm signals are grouped into physiological alarms and technical alarms, according to their characters.

1) Physiological alarms: monitored gas parameters or patient physiological parameters exceed the specified range.

2) Technical alarms: Due to the improper operations or malfunctions of the technical or the equipment, the machine cannot monitor exactly.

According to the different risks when alarm activated, alarms are grouped into: High Priority, Medium Priority and Low Priority alarm.

1) High priority: when the high priority alarm generates, it may endanger the patient's safety or the equipment cannot work normally, so users must stop operating to deal with the malfunction.

2) Medium Priority: when the medium priority alarm generates, it may endanger the patient's safety if lasting a long time, or some reasonable settings, users should adjust the parameters to clear the malfunction.

3) Low priority: when the low priority alarm generates, it will not endanger the patient's

safety, there may be some unreasonable settings or some unimportant malfunctions, users could adjust the setting parameters properly or clear up the malfunctions when complete using the equipment.

When alarm generates, the ventilator will call users attention by following auditory and visual signals.

1) High priority:
   - Alarm indicator light: red flashes.
   - Alarm tone:du- du - du -- du - du ---- du - du - du - du – du.
   - Alarm message: red background, and displays “!!!” behind the alarm message.
2) Medium priority:
   - Alarm indicator light: yellow flashes.
   - Alarm tone: du - du - du ----- du - du – du.
   - Alarm message: yellow background , and displays”!!” behind the alarm message.
3) Low priority:
   - Alarm indicator light: yellow, static, not flashes.
   - Alarm tone: du-----du.
   - Alarm message: yellow background, and displays “!” behind the alarm message.

2.13.7.2 Alarm information and priority

Classification	Items	Message	Priority
Physiological alarm	Tidal volume alarm	Tidal Volume High !!	Med
		Tidal Volume Low !!	Med
	MV alarm	Minute Volume High !!	Med
		Minute Volume Low !!	Med
	Frequency alarm	Frequency High !	Low
		Frequency Low !	Low
	FiO_2 alarm	O_2 Concentration High !!	Med
		O_2 Concentration Low !!!	High
	PAW alarm	Airway Pressure High !!!	High
		Airway Pressure Low !!!	High
	continuous airway pressure alarm	High Continues Pressure !!!	High
	Negative pressure alarm	Airway Pressur＜(-10cmH2O) !!!	High
	Apnea alarm	Apnea !!!	High
	end-expiratory CO_2 alarm	Expiratory CO_2 High !!	Med
		Expiratory CO_2 Low !!	Med
	PAW limit alarm	PAW limit !!	Med
Technical alarm	O_2 supply pressure alarm	O_2 supply pressure is low !!!	High
	AC Power Failure alarm	AC Power Failure !!	Med
	Low Battery Voltage alarm	Low Battery Voltage !!	Med
	No Battery Capacity alarm	No Battery Capacity !!!	High
	Battery Failure alarm	Battery Failure !!	Med
	O_2 sensor disconnection or failure alarm	O_2 sensor disconnection or failure !!	Med
	Absorber Is Not Installed alarm	Absorber Is Not Installed !!!	High
	O_2 flush overtime alarm	O_2 flush overtime !!!	High
	No gas in bellow alarm	No gas in bellow !!	Med
	set value of flowmeter is too big alarm	set value of flowmeter is too big !!!	High
	inspiration valve error alarm	inspiration valve error !!!	High
	expiration valve error alarm	expiration valve error !!!	High
	Inspiration pressure sensor failure alarm	Inspiration pressure sensor failure !!!	High

	Expiration pressure sensor failure alarm	Expiration pressure sensor failure !!!	High
	5V power error alarm	5V power error !!!	High
	10V power error alarm	10V power error !!!	High
	12V power error alarm	12V power error !!!	High
	-12V power error alarm	-12V power error !!!	High

Table 2-1. Alarm information and priority

Caution：

- When different priorities of alarms occur simultaneously, only the alarm with highest priority will display.

2.13.7.3Alarm limit setting

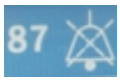
Refer to *5.11 alarm setting.* push【Alarm Setting】membrane button to enter the alarm setting interface and set alarm limit values.

⚠Caution：

- Please always pay attention to the alarm limit parameter and make sure it is set at a proper and reasonable level to avoid inaccurate alarms.
- When mains power is interrupted, the alarm limit setting does not change and the system saves the latest setting before interruption.
- To change the ventilation setting values, it will be changed together with alarm limit setting values.

2.13.7.4Alarm silence

When alarm generates, press the 【 

】membrane button, the alarm tone will be suspended, meanwhile, the alarm silence icon 

and 100 seconds countdown time will display in the status information area.

The alarm silence status lasts for 100 seconds, 100 seconds later, the alarm silence will be cancelled.

Press the 【 

】membrane button again before the 100 seconds period will cancel the “silence”.

Cautions：

- In alarm silence status, except for the alarm tone, the other alarm functions are working normally.
- In alarm silence status, if new alarms occur, the alarm silence will be cancelled and alarm tone will be activated according to the latest alarm.
- Pressing the 【 

】membrane button is invalid if no alarm occurs.

2.13.7.5Alarm volume setting

Refer to section ***5.14 System setting*** to set the alarm volume.

Warning:

- When operating the system, users can not rely on the audible alarm completely. The low alarm volume may lead to risk of patient. Users should pay attention to the actual clinical condition of the patient.

Chapter 3 Installation and connection

⚠Warning:

- Always ensure that there is no toxicity in the gas supply hose or the breathing circuit, will not cause allergic reactions in the patient's body, and will not react with the anesthetic agent to produce dangerous substance.
- When the absorbent becomes dry, it may cause dangerous to patients if used continuously. Appropriate preventive measures should be taken to prevent the absorbent in the vaporizer becoming dry.
- Before using please make sure that the locking organs have been locked or it may lead to unpredictable dangerous.
- Do not use antistatic or conductive mask or breathing hose.
- The installation of the equipment should be accomplished by engineers specified by the manufacturer.
- This equipment has an exhaust vent; users should pay more attention to the disposal of the exhalant residual gases.
- The operating environment and the power supply of this equipment must comply with the requirements of the ***B.2 Environment specifications*** and ***B.3 Power supply specifications.***
- The facilities that connected to the power outlet will lead to increase of the leakage current, so the leakage current should be tested regularly.

3.1 Connecting the gas supply

The anesthesia machine provides three gas supply inlet: O_2, N_2O and Air.

The following graphic indicates the pipelines of the gas supply are connected correctly:

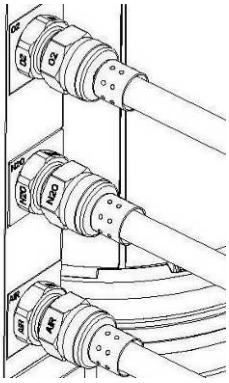


Figure 3-1 Gas supply connection view

⚠Warning：

- Only the medical gas supply can be used. Other types of gas supply may contain water, oil or other contaminations.
- After the system stops supplying gases, there will be gas pressure in Pipeline. Firstly, please release the pressure, and then disconnect the pipeline.

3.2 Installing / replacing the cylinder

The procedure of installing / replacing the gas cylinders is as below:

1. Rotate the handle of the cylinder clockwise, close the valve of the cylinder that to be replaced, unscrew the T-handle anticlockwise.

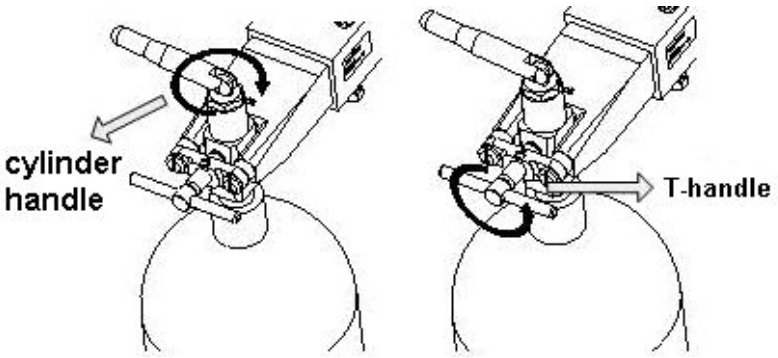


Figure 3-2 Gas cylinder connection view I

2. Release the T-handle fully, break apart the door and remove the cylinder.

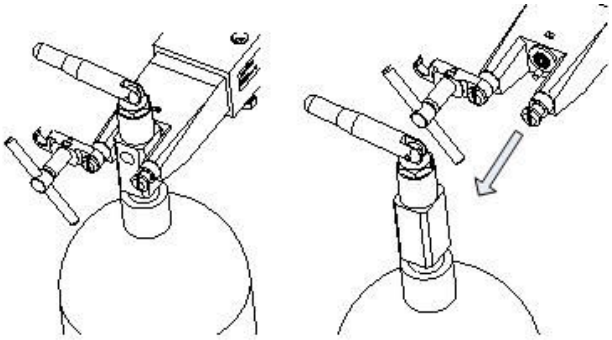


Figure 3-3 Gas cylinder connection view II

3. Do not place any objects that may be damaged easily due to the releasing of high pressure gas in front of the new cylinder mouth.
4. Open the cylinder valve and close it quickly, clear up the dust on the outlet of the cylinder.
5. Make the cylinder position align with the indexing pin.
6. Close the door and tighten the T-handle.
7. Perform a cylinder testing.

⚠Warning：

- When using gas supply from the pipeline, do not make the backup cylinder valve open, otherwise, when the gas supply of pipeline goes wrong, the gas of the cylinder may be exhausted and lead to inadequate reserves.

3.3 Installing the patient absorber assembly

Put absorber inwards along with the lead rail, as followed figures. While it clicks, that means it is all right.

Note: make sure the lock is open before installation. And lock it after installation.

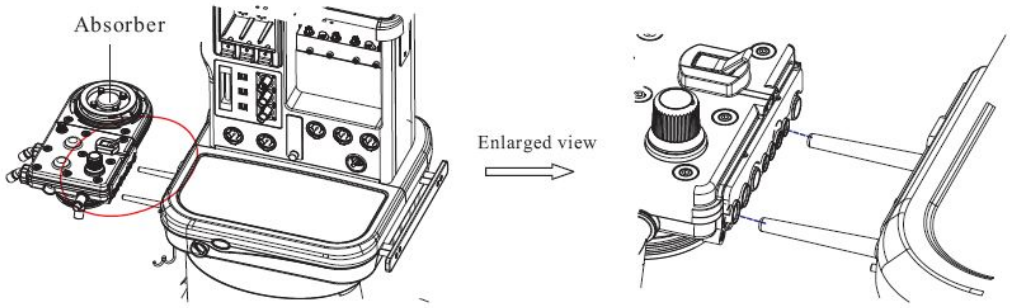


Figure 3-4 Absorber assembly view

3.4 Installing the folding bag and the bellows housing

1. Cover the bellows seating with the folding bag, and make sure the bottom of the folding bag can be nested tightly to the bellows seating. The graphic is shown as below.
2. Put the side with scale of the bellows housing to the front of the anesthesia machine, note that the four block spaces should be pointed at the corresponding four gaps of the absorber assembly.
3. Push it down slightly, and rotate the bellows housing clockwise until it cannot be moved.

Figure 3-5 Folding bag and bellows housing installation view

⚠Caution:

- Please make sure that the sealed ring inside the bellows cover can not be turned over or extruded transmutative.

3.5 Installing the micro manometer

As shown below, firstly, press and hold the button in the direction of arrow, and then hold the micro manometer and insert its head into the jack, when installation is completed, adjust its surface to the front of the anesthesia machine.

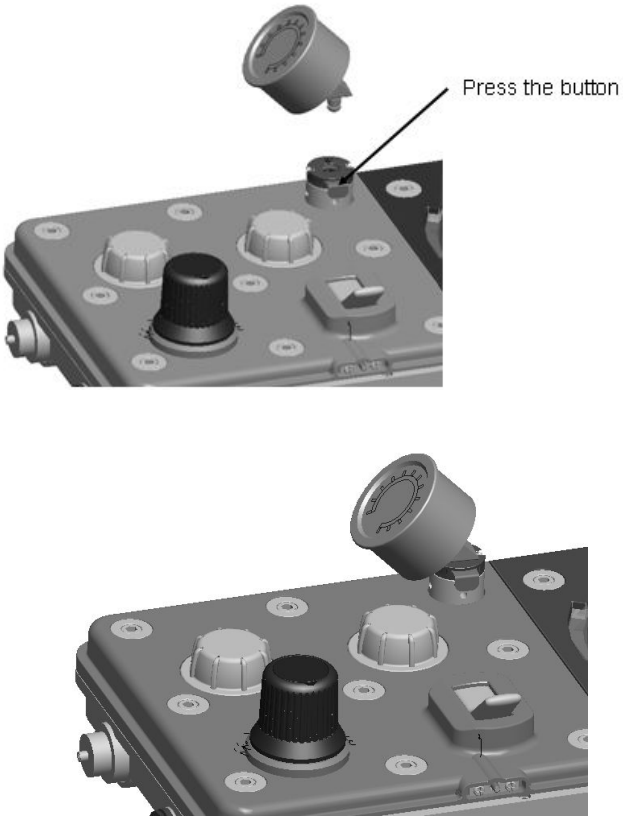


Figure 3-6 Micro manometer installation view

⚠Caution：

- Before installing or removing the micro manometer, always press the button first so as not to damage the micro manometer.

3.6 Installing the Oxygen sensor

Revolve the Oxygen sensor at the Oxygen sensor mounting hole clockwise. Hold the crystal head of the connecting line and inset it at the jack of the Oxygen sensor.

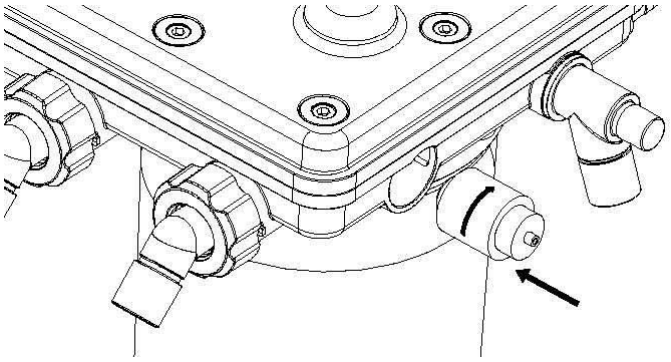


Figure 3-7 Oxygen sensor installation view

3.7 Installing the CO_2 canister

3.7.1 Canned absorbent

The structural graphic of the canister is as below:

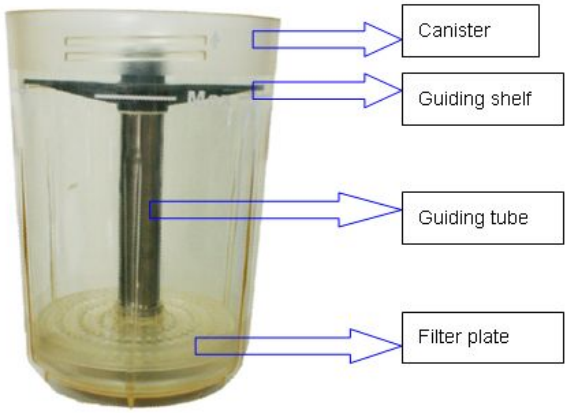


Figure 3-8 Canister view

1. Spill the used absorbent from the canister to specified position, take out the filter plate and the guiding shelf, clean away the dust and then put them back.(for the first time please implement the step2 directly).
2. Dump the sodium lime (1) slowly to the CO_2 canister to the specified position of the graphic below:

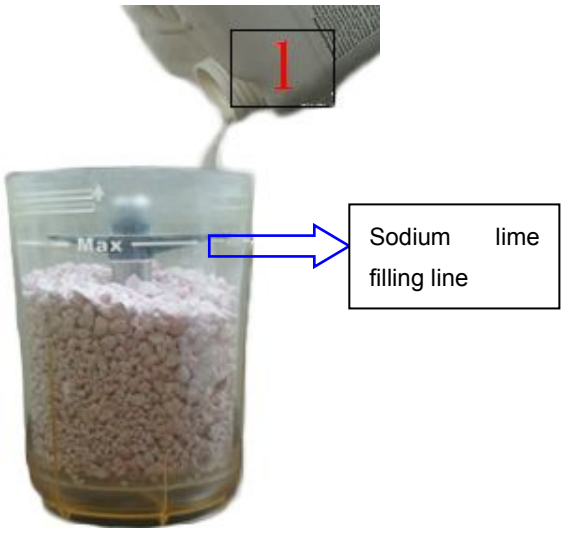


Figure 3-9 Absorbent filling view

3. Clean away the dust on the wall of the canister with special cloth.

3.7.2 Installing the canister

1. Hold the bottom of the canister, push it upward to be directed at the screw thread and align with silk-screen direction indicated by arrow.

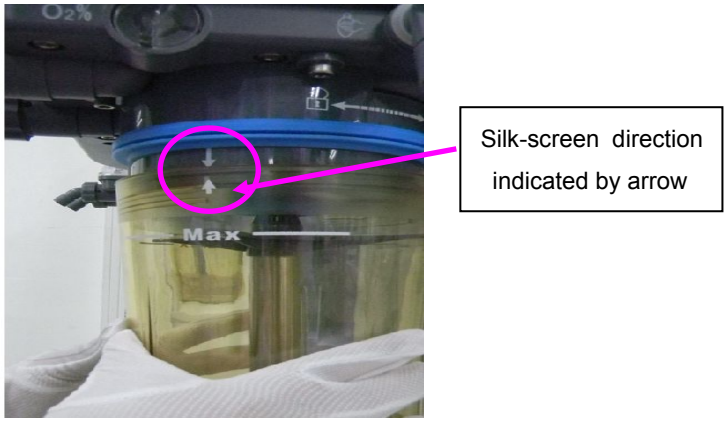


Figure 3-10 Canister installation view I

2. Rotate it counterclockwise, it shown as below:

Figure 3-11 Canister installation view II

3. Rotate the canister anticlockwise until it is turned to limit position block of BYPASS base, the following figure is shown as the installed canister.

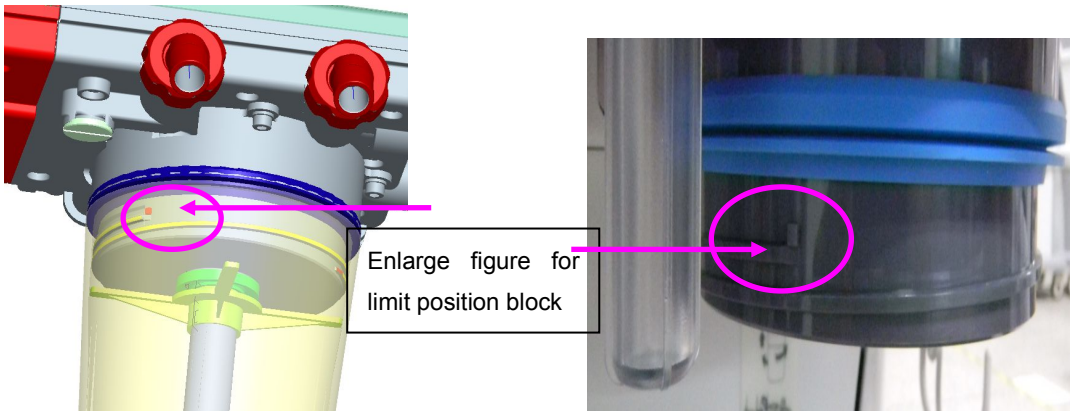


Figure 3-12 Canister installation view III

⚠Caution：

- Ensure the canister is in specified position after installing the canister.
- Please check whether the installation of the canister is in place or not after installation.
- It is recommended to keep your hands clean and dry when installing the canister.
- Please take circuit leakage detection after reinstalling the canister.
- Due to the company's BYPASS is automatic, if the user has installed the canister according to the above steps, BYPASS is in open state. If the user do not install the canister, BYPASS is in close state, the gas discharged through the AGSS outlet directly because the gas does not pass through the absorbent. According to the absorbent color or expiratory VT value to judge whether the BYPASS is normal or not.
- After installing or re-installing the canister, users must perform a system test (see section 2.13.3.2/2.13.3.3) to ensure that canister is placed properly and there is no leak, if system detects leak, please check the installation of the canister, and re-install the canister .

3.7.3 Replacing the absorbent

The steps for replacing the absorbent is the same as the steps described in ***3.7.1 canned absorbent.***

⚠Caution：

- There are two kinds of commonly used absorbent: Medical sodium lime and barium lime, it is recommended to use the medical sodium lime as absorbent.
- Before installing the canister, please check the color of the absorbent to decide whether you need to replace the absorbent.
- The change of the absorbent color is just for reference. Please use the CO_2 monitor to decide whether you should replace the absorbent.
- Please discard the absorbent if the color is changed. If placed a few hours, it may turn to its original color and lead to misusage.
- Appropriate defensive measures should be taken to ensure the absorbent not dry. Please cut off the gas supply when completing using the system. When the absorbent turns dry, if contacting with the anesthetic, it will emit carbon monoxide (CO) which will bring hazards to patients. Therefore, please replace the absorbent in time for the patients' safety.
- In order to ensure the humidity of the sodium lime and avoid the emission of CO, please pay attention to the following:
  - Reduce the flow of fresh gas in the sealed absorber.
  - Replace the sodium lime at least once a week.
  - Record the replacing date of sodium lime.
  - Avoid gases flow through the sodium lime when the machine not being used.
  - Users can add sodium lime temporarily in urgent conditions.
- During surgery or after a case, please check color of the absorbent and take corresponding measures. For detailed information about the color change of the absorbent, please refer to the instructions on the packaging of the absorbent.

3.8 Installing the breathing hose and the Y connector

⚠Caution：

- When installing the breathing hose, please grab the two ends of the hose to avoid damages.

1. Connect ends of the two breathing hoses to expiratory connector and inspiratory connector of the patient absorber.

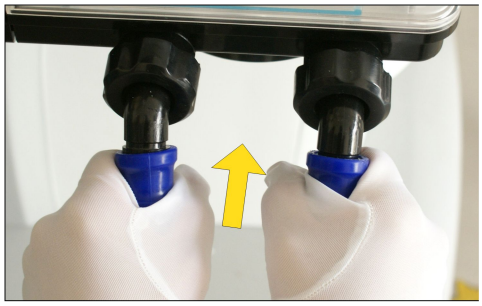


Figure 3-13 Breathing hose installation view

2. Connect the other end of the two breathing hoses to the two parallel interfaces of the Y connector:

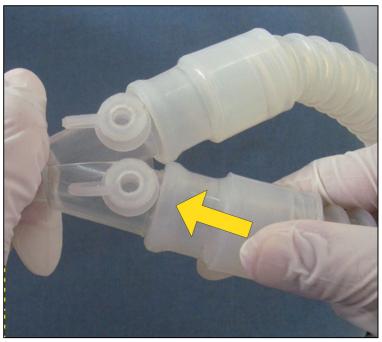


Figure 3-14 Y connector installation view

Note:

- It is recommended to install a bacteria filter to expiratory port of the breathing system.
- For disposable patient circuit accessories, the Y connector has been connected with the breathing hose, so cancel this step.

3.9 Installing the manual breathing bag

Put the manual bag forcibly to the manual bag connector (marked”1” in the graphic below):

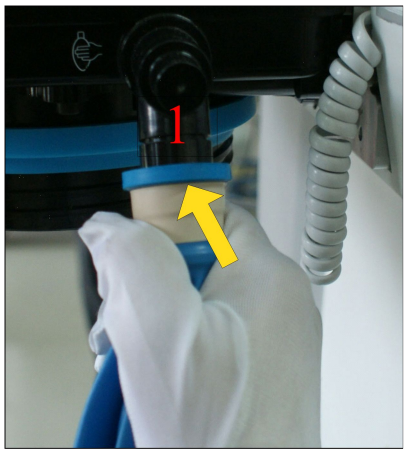


Figure 3-15 Manual breathing bag installation view

Note:

- If you feel the manual bag is too close to the machine, an adapter breathing hose can be connected to extend the distance between the machine and the manual bag, which will help more convenient operation.

3.10 Installing the vaporizer

⚠Warning：

- If the anesthesia machine and the vaporizer do not match, their performance will depressed. Please use the vaporizer that matches the anesthesia machine.

⚠Caution：

- For the detailed description of the installation and operation of the vaporizer, please refer to the manual of the corresponding vaporizer.
- When installing the vaporizer, make sure the vaporizer is locked well, otherwise it may lead to leakage.

1. Hang the vaporizer to the fixing seating of the anesthesia machine.
2. Rotate the locking pole and press it, fix the vaporizer to the fixing seating.
3. Make sure the top of the vaporizer is flat, otherwise it should be removed and installed again.
4. When re-installing the vaporizer, users should lift each of the vaporizer upward to let it fall off the fixing seating instead of pulling it forward, be careful not to let the vaporizer rotate on the fixing seating.
5. When the vaporizer is lifted off the fixing seating, install it again referring to the steps 1 to 3.
6. Try to open more than one vaporizer.

Test each possible combination. If the user is able to open more than one vaporizer at one time, these vaporizers should be removed and installed again, then complete the steps 1 to 6.

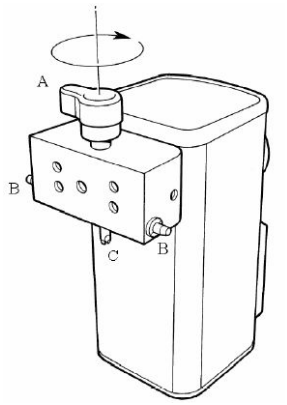


Figure 3-16 Vaporizer installation view

A: Locking pole B: Interlock bolt C: Tighten hook

Interlock device: Only one of the vaporizers can be opened at a time to avoid that one anesthetic agent is mixed with the another anesthetic agent.

3.11 Adding the anesthetic

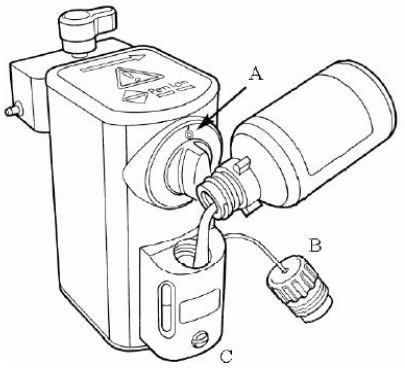


Figure 3-17 Adding anesthetic view

1. Check the controlling knob A and set it to Zero, and check and tighten the screw C.
2. Unscrew the screw cap B.
3. Pour the anesthetic agent slowly to the vaporizer. During the process of pouring the liquid, please pay attention to the height of the liquid inside the vaporizer, when it reaches the maximum level, stop pouring the liquid.
4. Tighten the screw cap B, but not overly.

⚠Caution：

- The maximum level of the anesthetic in the vaporizer is 250mL, and the minimum level is 30 mL.
- There is no flow output between the scale of 0 to 0.2.

3.12 Discharging the anesthetic

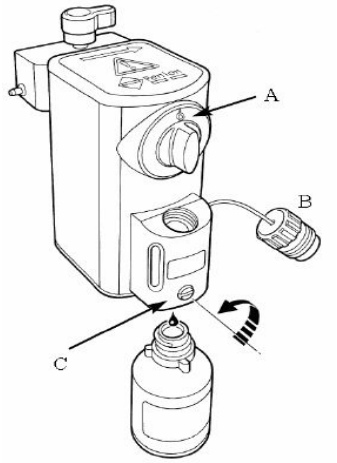


Figure 3-18 Discharging anesthetic view

1. Check the controlling knob A and set it to Zero.
2. Unscrew the screw cap B.
3. Place a bottle marked with the name of the corresponding anesthetic agent under the vaporizer, put the mouth of the bottle at the tundish which is under the discharging pipe, loosen screw C. Make sure the anesthetic agent flow into the bottle.

3.13 Connecting AGSS

Hang or fix AGSS tank to on the side of the machine and ensure that AGSS"s outlet port is upward and vertical. There is a certain space in AGSS tank so as to be good for air movement.

1. AGSS inlet port used with the specified transfer hose which connects to the anesthetic machine" s exhaust gases outlet. The one end of the corrugated hose with 30mm connects onto AGSS inlet port, and the other end connects onto anesthetic machine" s exhaust gases outlet, it shown as below:

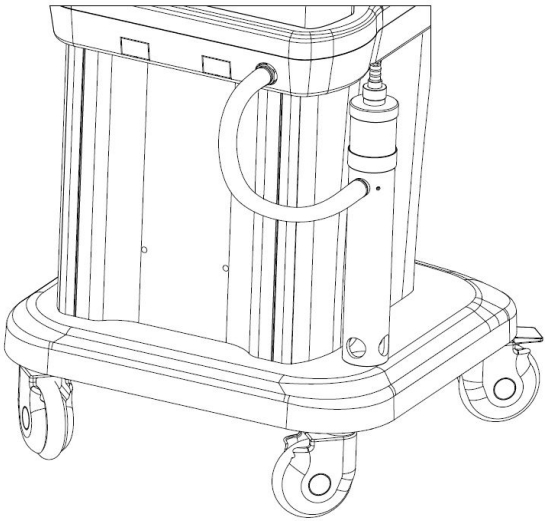


Figure 3-19 AGSS connection view

2. AGSS exhaust port used with the specified transfer hose and connector connects to the hospital's waste gases scavenging system, and tightens with nut.

After connection and check, AGSS system could be used normally.

Check the following items at any time during using:

1. Check if float can rise and exceed the minimum scale line.
2. Check if cylinder's inlet ports on the underneath are blocked.
3. Check if inlet and exhaust hoses are smooth.

If occurs the above malfunction, it must be solved immediately, otherwise AGSS will not be used normally.

3.14 Connecting the power supply

1. In order to avoid the power plug off, fix the power cord by tightening the screw on the clamp, it shown as below.
2. Enlace the power cord to fixing bracket, it shown as below.
3. Plug the main power cord into the socket(AC220V, 50HZ).

Figure 3-20 Power supply connection view

Chapter 4 Pre-use check

Before using this equipment, please read the user manual and understand the operation and maintenance of each part of the equipment, and make sure it meets the following requirement:

1. The using environment should meet the relative requirements of the *Appendix B*.
2. The equipment is in good condition with no damages.
3. All the components are connected correctly.
4. The respiratory system is connected accurately with no damage.
5. Check whether the absorbent need to be replaced or not before installing the canister.
6. The canister is installed to the proper position, refer to the section *3.7.2*.
7. Manual/vent switch is set to the proper position.
8. The vaporizer is installed to the proper position, refer to the section *3.10.*
9. Check the connection of display wire is correct, the screen is normal.
10. Check whether the alarm occurs or not.
11. Check the protection device should meet requirement (such as safety relief valve >12.5KPa, vaporizer station bar >25KPa, red cap safety valve >650kPa), when the pressure is over specified value, it will release pressure immediately.
12. The gas supplying system is connected accurately, the pressure is normal.
13. All emergency equipments are in ready and in good condition.
14. All equipments that used for the maintenance of pipeline and the intubatton of the windpipe are available and in good condition.
15. Make sure there is no loose phenomenon on the truckle and the brake has been locked and the anesthesia machine cannot be moved.
16. Patient absorber locking switch is set to the lock position.
17. Connect the power cord to the AC power outlet, switch on the AC power supply, the AC power indicator and the battery indicator will light, if not, that means the system has no electricity.

18. Checking the negative pressure of waste gas processing system is enough or not. Observe AGSS system buoy, if it is on the minimum scale, it means the negative pressure is normal, and can work, but if the negative pressure is not enough, the AGSS system can not work.
19. Checking the air inlet is jammed or not which is under the AGSS system. If it is jammed, Use it till need clear the blockage.
20. The gas supply connection test:

1) Connect the O_2, N_2O and Air source (please refer to the section ***3.1 Connecting the gas supply***).
2) Connect the power supply and switch on the system.
3) View O_2, N_2O and Air manometers, make sure the reading of the each manometer is in the range of 0.28~0.6MPa.
4) Cutoff the gas supply and discharge the gas in the pipeline view the manometers and make sure the readings zero.

⚠Warning：

- It should take pre-use check no matter which side to install a anesthesia system from parts or assemblies.
- Please always take pre-use check before the anesthesia machine is connected to the patient.
- Please connect the power cord to a protective grounded power outlet in order to avoid electric shock.
- If any functional failures detected, and the failures persist, the anesthesia machine cannot be connected to the patient.
- Perform a leak test before the system is connected to the patient, refer to the section *5.4* and *5.5*.

Chapter 5 Operation and setting

⚠Caution：

- The user interface may be different due to the different configurations, please take the material object as valid.

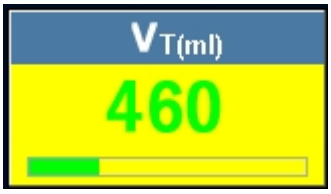
5.1 Touch key

The touch keys will display different colors to indicate different status:

1. The dark blue key pad indicates the normal status, you can select the key by using the dial or touch. For example:

2. The blue key pad indicates the selected status, and the parameter cannot be adjusted currently. For example:

3. The yellow key indicates the active status, and the user can adjust the parameter by the navigation wheel. Rotate the navigation wheel with clockwise to increase the parameter, and rotate the navigation wheel with counterclockwise to decrease the parameter. For example:



5.2 Start-up

1. Connect the power cable to the power outlet, and make sure the power supply works normally.
2. Turn on the system switch located on the front of the equipment.

⚠Warning：

- If abnormal alarms occur when the system starts up, do not use the equipment, contact the authorized serviceman or the after service department of the Company.
- Only the specified, protective grounded power supply can be used in this equipment.

5.3 Power-up screen

Power-up screen is the first screen displayed when the anesthetic machine is turned on.

Figure 5-1 Power-up screen

In Power-up screen, the system performs the functional check.

The check items include power (10V, 5V, 12V, -12V), inspiratory pressure sensor, expiratory pressure sensor, oxygen sensor and so on.If the failure occurs, the error information is displayed in the screen and the system stops running. Please contact the Company Technical Support if need.

The system continue to the next screen until the failure is solved.

5.4 Manual mode leakage test

After the finish of self-testing, the system enters the manual mode leakage test, as shown below:

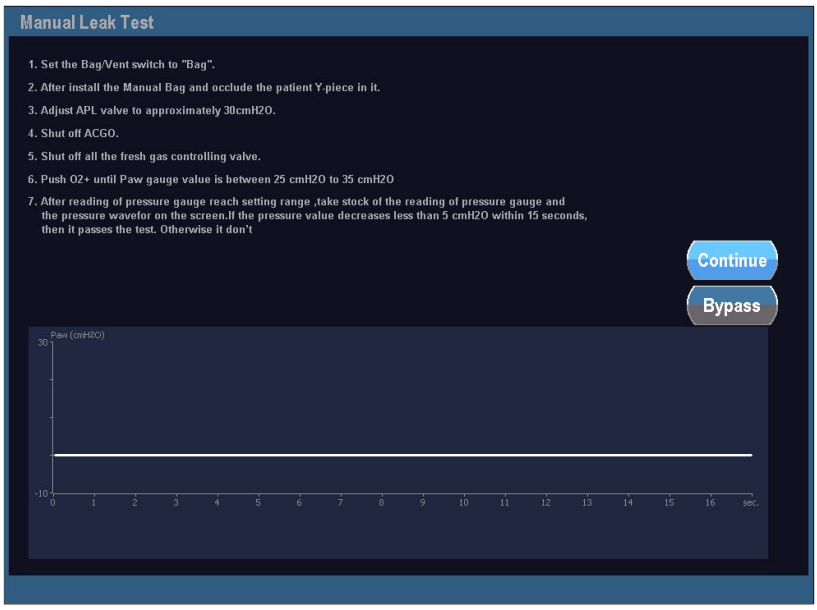


Figure 5-2 Manual mode leakage test screen

Manual mode leakage test is focus on the checking of below points:

1. The leakage value of system in the manual mode.
2. APL valve.

Preparation for manual mode leakage test:

1. Set the Bag/Vent switch to Bag.
2. After install the Manual Bag and occlude the patient Y-piece in it.
3. Adjust APL valve to approximately 30cmH_2O.
4. Shut off ACGO switch.
5. Shut off all the fresh gas controlling valve.
6. Push O_2+ until Paw gauge value is between 25 cmH2O to 35 cmH_2O.
7. After reading of pressure gauge reach setting range, take stock of the reading of pressure gauge and the pressure waveform on the interface. If the pressure value decreases less than 5 cmH_2O within 15 seconds, then it passes the test. Otherwise it doesn't.

Remark: Select【Bypass】, the system enters "Start-up" interface.

5.5 Vent mode leakage test and compliance test

After manual mode leakage test, select【Continue】, then the system enters Vent mode leakage test and compliance test, as shown below:

Figure 5-3 Vent mode leakage test and compliance test screen

The test is focus on below points:

1. Test the system leakage value.
2. Check O_2 valve and PPEP valve.
3. Check the compliance of circuit.

Preparations for Vent mode leakage test and compliance test:

1. Set the Bag/Vent switch to Vent.
2. Occlude the patient Y-piece.
3. Press O2+ to fill the bellows.
4. Shut off all fresh gas controlling valve.

After preparation of self-test, press【Start】, the system begins self-testing.

a) If the test passed, the interface displays the information of 【Test passed】, 【Leakage value】,【Compliance value】.

b) If the test failed, the interface displays the message such as 【Test failed】, 【Leakage value】, 【Insufficient gas in the folding bag】,【Please shut off fresh gas】.

Remark: Select 【Bypass】, the system enters “Start-up” interface.

⚠Warning:

- Please perform the system test before using the anesthesia unit and wait until the test is completed. If system detects leak, please check connections of the patient absorber assembly, if leaks still exist, please contact the after service dept. of the company.
- Small amount of leakage does not affect the function of this equipment, please consider whether to continue using this equipment.
- If you find the leakage is serious, please contact the after service dept. of the Company.

5.6 O_2 sensor calibration

After finish of Vent mode leakage test and compliance test, select【Continue】, then the system enters O_2 sensor calibration, as shown below:

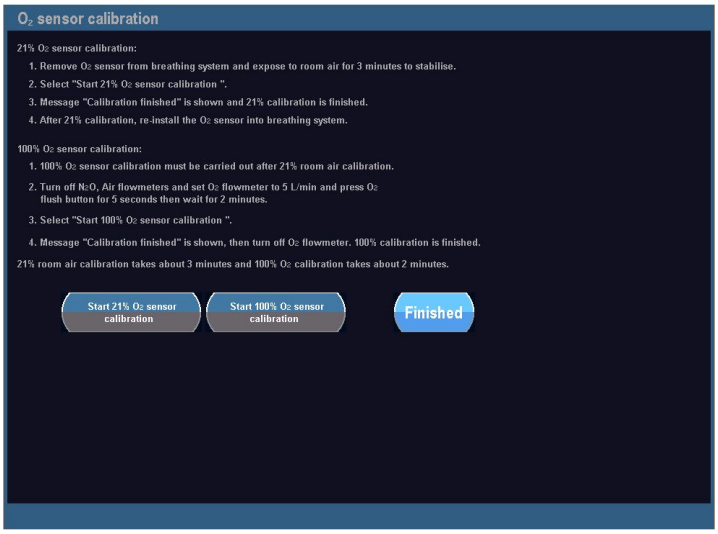


Figure 5-4 O_2 sensor calibration screen

O_2 sensor calibration is focus on the checking of below points

1. 21% O_2 sensor calibration
2. 100% O_2 sensor calibration

Perform “Start 21% O2 sensor calibration” and “Start 100% O_2 sensor calibration”, according to the steps are shown in screen.

Warning:

- Never perform the O_2 sensor calibration procedures when the anesthesia machine is connected to patient.

Note:

- 100% O_2 sensor calibration must be carried out after 21% O_2 sensor calibration.
- It is unnecessary to perform the O_2 sensor calibration if O_2 sensor is not fitted or not used.
- Please perform the O_2 sensor calibration if the measured O_2 has obvious error or after replacing O_2 sensor.

5.7 Flow sensor calibration

After finish of O_2 sensor calibration, select【Continue】, then the system enters flow sensor calibration, as shown below:

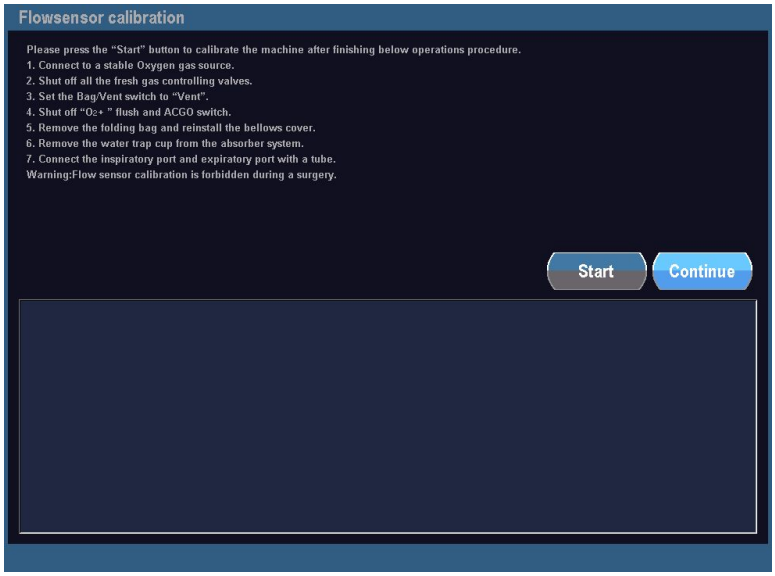


Figure 5-5 Flow sensor calibration screen

Perform " flow sensor calibration", according to the steps are shown in the screen.

⚠ Warning:

- Do not perform Flow Sensor calibration when the unit is connected to the patient.

Caution:

- Perform Flow Sensor calibration when the measured value of flow has a large deviation from other reference sources or when the Flow sensor is replaced.

5.8 Start-up screen

After finish of self-test, the anaesthetic ventilator will enter the start-up screen, shown as below:

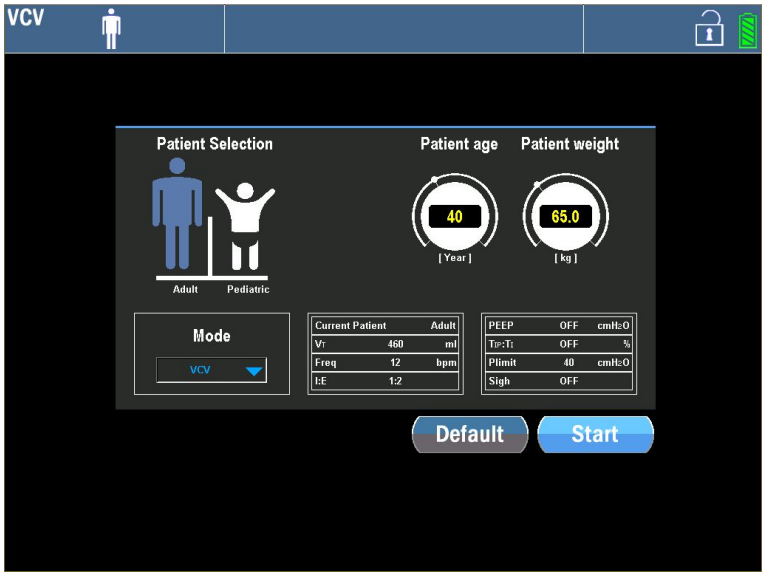


Figure 5-6 Start-up screen

1. Patient Category Selection

【Adult】 and 【Pediatric】.

In this screen, you can set the needed patient category.

Different parameter setting and operation is confirmed by selecting different patient categories.

Please follow the below procedures to set the patient category:

1) Touch or rotate the navigation wheel to select the needed patient category.

2) Press the navigation wheel to confirm setting.

If you select the needed patient category, the symbol of the selected patient category will appears in the status message display area.

2. Patient age setting

The user could set the patient age in the start-up interface. The system calculates corresponding MAC value based on the different ages.

Patient age range:

- Adult: 15-100 years old
- Pediatric:1-14 years old

1) Touch or rotate the navigation wheel to select【Patient age】.
2) Press the navigation wheel to confirm.
3) Adjust the patient age through navigation wheel.
4) Press navigation wheel to confirm the setting, the area turn to be light blue

3. Weight setting

You can set the patient's weight in this screen. The system calculates the referenced tidal volume value in the volume ventilation mode according to different weight of the patient.

For different patient categories, the setting range of the weight is different:

- Adult: 20-150kg
- Pediatric: 5-20kg

1) Touch or rotate the navigation wheel to select【Patient weight】.
2) Press the navigation wheel to confirm.
3) Rotate the navigation wheel with clockwise to increase the value, and rotate the navigation wheel with counterclockwise to decrease the value.
4) Push the navigation wheel to confirm the value.

4. Mode setting

1) Touch or rotate the navigation wheel to 【Mode】.
2) Push the navigation wheel to confirm.
3) Select the mode in the drop-down menu.

5. Select【Default】to restore all setting parameters to default values.

6. Startup to enter main screen

Touch or rotate the navigation wheel to 【Start】, and confirm by pressing the navigation wheel.

Note:

- ◆ In Start-up and Standby screen, only technical alarm can be activated, physiological alarm is invalid.
- ◆ In the start-up interface, buttons are invalid, except for【Alarm Silence】and 【Lock】button.

5.9 Standby

If needed, the system can be selected to Standby mode, in this mode, the system stops the mechanical ventilation and monitored parameters function.

Press 【 

】 membrane button and comfrim by pressing the navigation wheel to enter Standby mode. It shown as below.

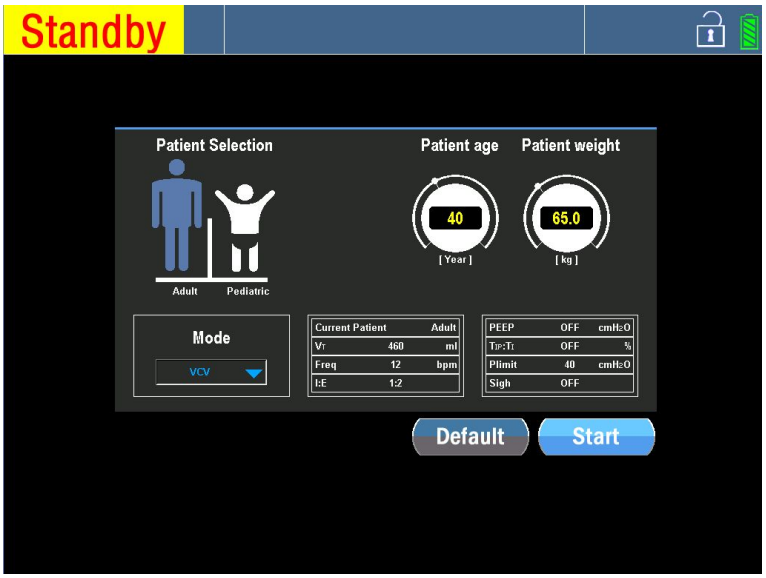


Figure 5-7 Standby screen

In the standby mode, press【Default】touch key, then push the navigation wheel to confirm, it will restore all setting parameters to default values.

Exit the standby mode:

1) In the standby mode, press【start】touch key.
2) Push the navigation wheel to exit standby mode to the main interface.

5.10 Main screen

The Main screen provides the operator with displays of current mode of ventilation, alarm status, battery charge status, monitored parameters, waveforms display and so on. It shown as below:

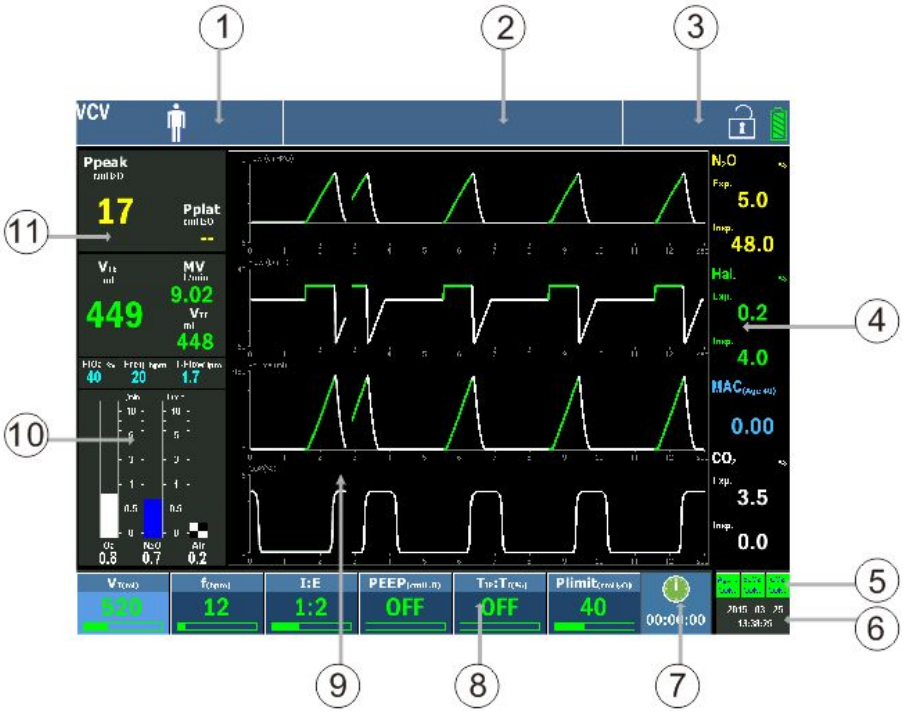


Figure 5-8 Main screen

1. **Information display area:**
   1) Display the current ventilation mode.
   2) Display the current patient category.
   3) Display spontaneous breathing icon.
   4) Display the oxygen flush icon.
2. **Alarm information display area:**

   Display the current alarm information.
3. **Status information display area:**

   Display the battery capacity status.

   Display the Lock/Unlock icon.

   Display the Alarm silence icon and count down time.

4. **Anesthetic agents monitored parameters area:**

   Display the current monitored parameters of the anesthetic agents.

5. **Module status display area:**

   Display the current connection status of the modules.

6. **System time display area:**

   Display the current date and time.

7. **Elapsed Timer**

8. **Key parameters setting area:**

   Besides using the membrane button 【Ventilation settings】, users can set the relative ventilation parameters of the current ventilation mode in the main interface directly, the gray touch key cannot be adjusted.

9. **Waveform display area:**

   According to different configuration of models and different settings by users, it will display the waveform, Loop or the trend.

10. **Electronic flowmeter, qCON values, and SPO_2 display area**

    You can select the different display in the parameter area of the system setting screen.

    When selecting【Electronic flowmeter】, O_2, nitrous oxide, air, bar chart, scales, unit, and their flow are displayed in this area.

    When 【qCON values】 are selected, qCON values are displayed in this area.

11. **Monitored parameter area:**

    Display the current monitored parameters of the patient.

    When PEEP is set to be OFF, the PEEP monitored parameters are not displayed in the area of Monitored values and Big Font interface.

Note:

- The module status display area indicates the connection status of CO_2, anesthetic agents, SPO_2 modules.
- Modules are optional functions, the main interface above displays when the anesthetic

agents or CO_2 module is connected. If no module connected, the anesthetic agents monitored parameters area will display waveforms.

◆ The modules support plug-in and measure function.

5.11 Alarm settings

In this screen, users can adjust the alarm upper and lower limit parameters.

The parameters between the upper limits and the lower limits are the current monitored parameters.

The alarm setting screen is shown as below.

Figure 5-9 Alarm setting screen

Adjust the alarm upper and lower limits as per the following procedures:

1) Touch or rotate the navigation wheel to select the parameter until it is highlighted.

2) Confirm by pressing the dial, and rotate the navigation wheel to adjust the parameter.

3) Then confirm the setting by pressing the navigation wheel.

Select 【Defalt】 to restore the defalt values, it will restores the upper and lower limit values to the default values.

Move the focus to select 【Close】, and then press the navigation wheel, the system will save your settings and exit the alarm setting screen.

The alarm parameters and setting range refer to the *Appendix B.6.3*

The alarm default settings refers to the *Appendix F.*

5.12 Measured values

The measured values interface is shown as below:

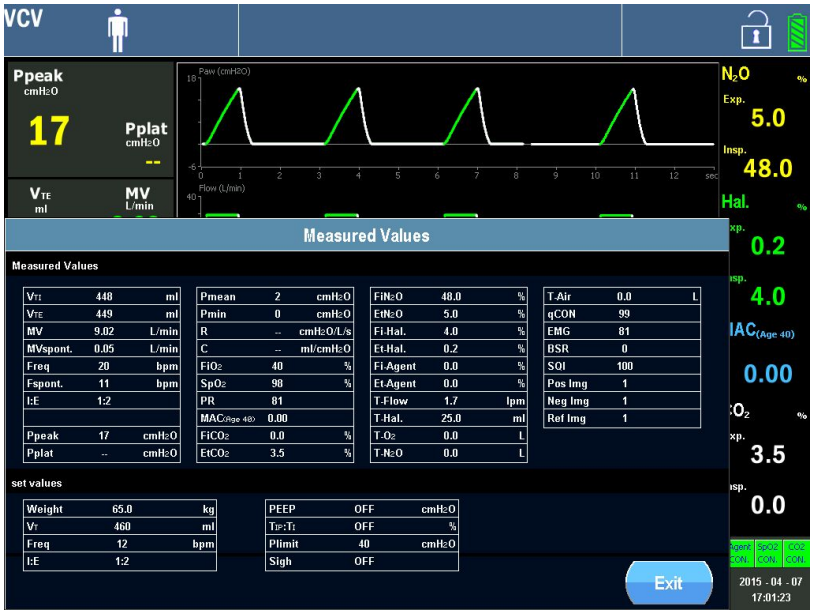


Figure 5-10 Measured values screen

The monitored parameters screen displays measured values and setting parameters.

- Real-time monitoring of ventilation parameters.
- 【R】-- real-time monitoring of gas resistance while setting breath holding time.
- 【C】-- real-time monitoring of dynamic compliance.
- 【T-Agent】Calculate and display of anesthetic agent consumption through anesthetic agent concentration monitoring.
- 【MAC_{Age}】calculate and display corresponding MAC according to the patient age.
- 【Pos/Neg/Ref imp】-- Measure and display of impedance of the patient cable in contacting with the skin of the patient (namely the positive electrode sheet impedance, a negative electrode sheet impedance and reference electrode sheet impedance).

5.13 Ventilation setting

Select 【Mode Setting】 membrane button to enter the mode setting screen, it shown as below:

Figure 5-11 Ventilation setting screen

1. Modes and parameters setting:

1) In ventilation setting screen, press【Mode】 option frame and select the ventilation mode in the drop-down menu.

2) Select the ventilation parameter that you need to set, turn the navigation wheel to adjust the value and push the navigation wheel to confirm the setting.

3) Press 【Exit】touch key to exit the current screen.

2. Cardio pulmonary bypass

Cardio bypass mode could be started in the manual mode, and it is used for special equipment that replaces the work of patient's heart and lungs for blood circulation and gas exchange.

When Cardio pulmonary bypass is set, the following alarms will be disabled:

Apnea alarm

Tidal volume low alarm

Minute volume low alarm

Anaesthetic Agent low alarm

CO_2 ($EtCO_2$ and $FiCO_2$) low alarms

Frequency low alarm

Paw low alarm

When the mechanical ventilation is turned back on, Cardiac pulmonary bypass returns to “Disable”, and alarms become active.

3. Altitude

Altitude setting range: 100~5000 meter.

If the absolute pressure sensor is installed in the pneumatic control board, the system could make tidal volume compensation automatically, otherwise, the tidal volume compensation has to be realized by altitude setting.

Note：

- The design of the anesthesia machine makes the parameters setting correspond with the current ventilation mode, in other words, when you select a ventilation mode, the interface will only display the parameters related to the current ventilation mode.

5.14 System setting

Figure 5-12 System setting screen

1. Common settings

Users can set Date/Time, Alarm Volume and Language of the system.

1) Touch the parameter value that you desire to set, the frame turns yellow.

2) Turn the navigation wheel to adjust the value and push the navigation wheel to confirm the setting.

2. View settings

Users can configure the Waveform, Waveform+ Loop, and Trend displayed on the interface, the system can display four waveforms simultaneously.

1） The first waveform options:

- Paw-T
- Flow-T
- V-T
- SpO_2(optional)
- EEG

2） The second waveform options:

- Flow-T
- Paw-T
- V-T
- SpO_2 (optional)
- EEG

3） The third wave options:

- V-T
- Paw-T
- Flow-T
- SpO_2 (optional)
- CO_2 (optional)
- EEG

4） The fourth waveform options:

- CO_2 (optional)
- N_2O
- Anesthetic agent (e.g.Enflurane)
- O_2
- SPO_2 (optional)
- EEG

5） Loop save/contrast

- Cancel
- Loop save
- Loop contrast

If Waveform + Loop is selected in display format, Loop Save is selected in Loop save/contrast, the system will save the currently plotting loop. If selecting the Loop Contrast, the Loop Contrast will be displayed in main screen.

If selecting Cancel, the Loop Contrast will be canceled.

6） The display Font options:

- Normal
- Wave+Loop
- Big Font
- Trend

If you select 【wave】, the interface will only display the waveform, if you select 【wave+Loop】, the Loop will display on the right side of the interface, the Loop contains following types:

- Flow-Pressure (F-P)
- Pressure-Volume (P-V)
- Flow-Volume (F-V)
- Volume-CO2 (V-CO2) (optional)

if you select 【Trend】, the time of the Trend can be set:

- 1 Hour
- 4 Hours
- 8 Hours
- 12 Hours
- 24 Hours

7） Parameter area

- Electronic flowmeter
- SPO_2
- qCON Values
- CO_2

After the option is selected, it will be displayed in the Monitored Parameters Area of the Main Interface.

3. Special settings

1）Information

Select 【Information】, the system goes to the version information interface, as shown in the following figure.

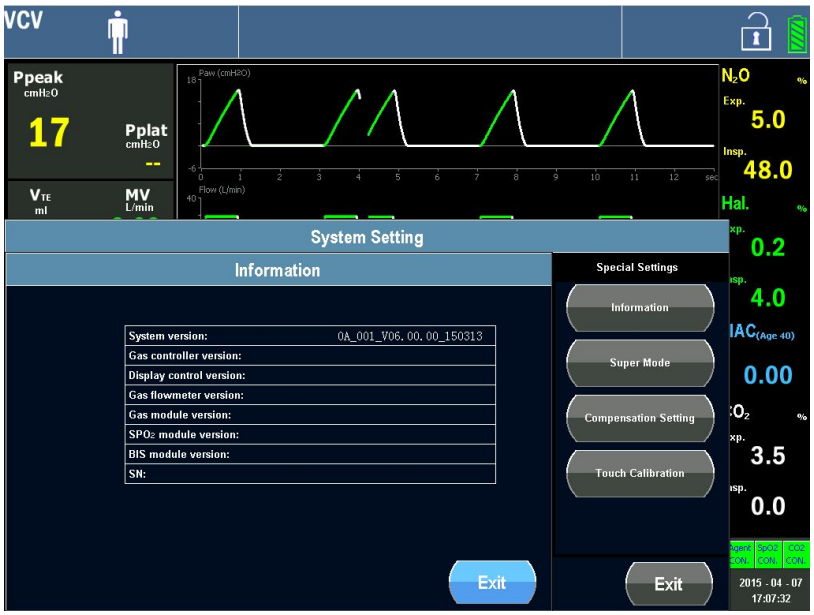


Figure 5-13 Version information screen

The system version, gas controller version, display control version, gas flowmeter version, gas module version, qCON module version and SPO_2 module version are displayed in this interface.

2) Super mode

Select 【Super Mode】 to access the super mode interface.

Figure 5-14 Super mode screen

The “Super Mode” only supports the company’s engineers for operating the machine, like calibrating, updating, configuration and so on, and needs to input the corresponding password.

3) Compensation Setting

Select 【Compensation setting】to access the compensation interface.

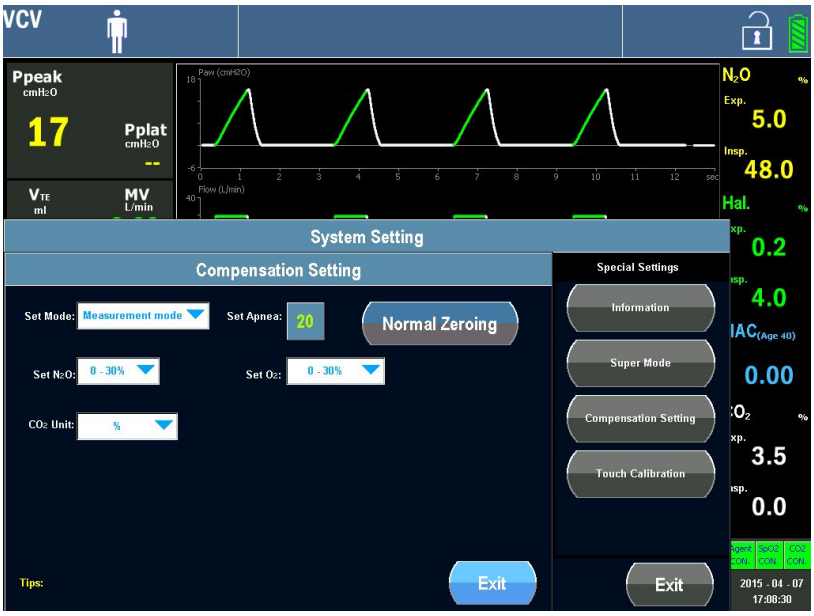


Figure 5-15 Compensation setting screen

The O_2 and N_2O compensation settings

The presence of oxygen and nitrous oxide can cause some interference in the CO_2 measurement. So they should be compensated.

O_2 compensation is performed automatically for ISA sidestream analyzers capable of O_2 measurements and all the IRMA probes with the oxygen sensor fitted. When using an ISA sidestream gas analyzer without this capability or using an IRMA without an oxygen sensor, i.e. when oxygen measurement is performed by the host equipment, Set O_2 command should be applied to transmit current oxygen concentration to the IRMA probe or the analyzer.

For most applications, sufficient accuracy in CO_2 measurement will be achieved by dividing the oxygen concentration into three ranges: “high”, “medium” and “low”. By using these ranges, the maximal relative CO_2 error will be limited to 1.2%.

Set O_2 range:

0-30 vol%

30-70 vol%

70-100 vol%

Setting N_2O compensation:

N_2O is measured and automatically compensated for the ISA sidestream analyzers capable of N_2O measurements and for all IRMA probes except for in IRMA CO_2.

When using an ISA sidestream gas analyzer without this capability, or using the IRMA CO_2, Set N_2O command should be applied to transmit current N_2O concentration to ISA gas analyzer or IRMA Probe.

For most applications, sufficient accuracy in CO_2 measurement will be achieved by setting N_2O to one standard concentration used always with N_2O in use, as recommendation span 30-70 vol% N_2O. When N_2O is not in use, set N_2O range 0-30 vol%.

By using this range, the maximum CO_2 error with N_2O compensation on (30-70%) will be limited to 3.2% relative.

Set N_2O range:

- 0-30 vol%
- 30-70 vol%

By using this range, see table below, the maximum CO_2 error with N_2O compensation on (30-70%) will be limited to 3.2% relative.

Set-mode

For normal use, the ISA sensor has three operating modes: Self test, Sleep, Measurement.

Self test:

The sensor performs a self test and does not respond to commands from the host.

Sleep：

Low-power standby state. The host can communicate with the sensor, but all functions are disabled.

Measurement:

The sensor is measuring gas concentrations.

Set Apnea:

The apnea setting range is from 20 to 60 seconds.

Normal Zeroing:

For all IRMA mainstream multigas analyzers, they need to establish a zeroing every time after replacing the adapter or you have any doubts about the accuracy of the measured values.

Push【Normal Zeroing】touch area, the analyzer will begin normal zeroing.

Unit:

For N_2O and anesthetic agent gases, the gas unit is “%”

For CO_2 gas, the following three can be set:

- %
- kPa
- mmHg

4) Touch screen calibration

Select 【Touch calibration】, the system goes to the touch screen calibration interface. You can carry out the calibration according to the steps are shown in screen.

5.15 System Log

The System log screen provides the operator with reviews of previous alarm messages and setting, and it records time and contents.

The time of system logs are stored in accordance with their generated time sequence.

Touch to select【Page up】 or 【Page down】 to review more logs.

In the system log screen, the 【Close】 icon is highlighted, touch it to exit the screen.

Note：

- The anesthesia machine can store up to the least 500 logs for your view.
- When mains power is interrupted, the system log does not change and the system saves the latest log before interruption.

5.16 System shut off

When you have completed using the system, please shut off the system as following procedures:

3) Disconnect the pipeline that connected to the patient.
4) Turn off the system switch.
5) Shut off the AC power supply.
6) Clean the surface of the equipment if need.

Chapter 6 MASIMO multi-gas analyzers (optional)

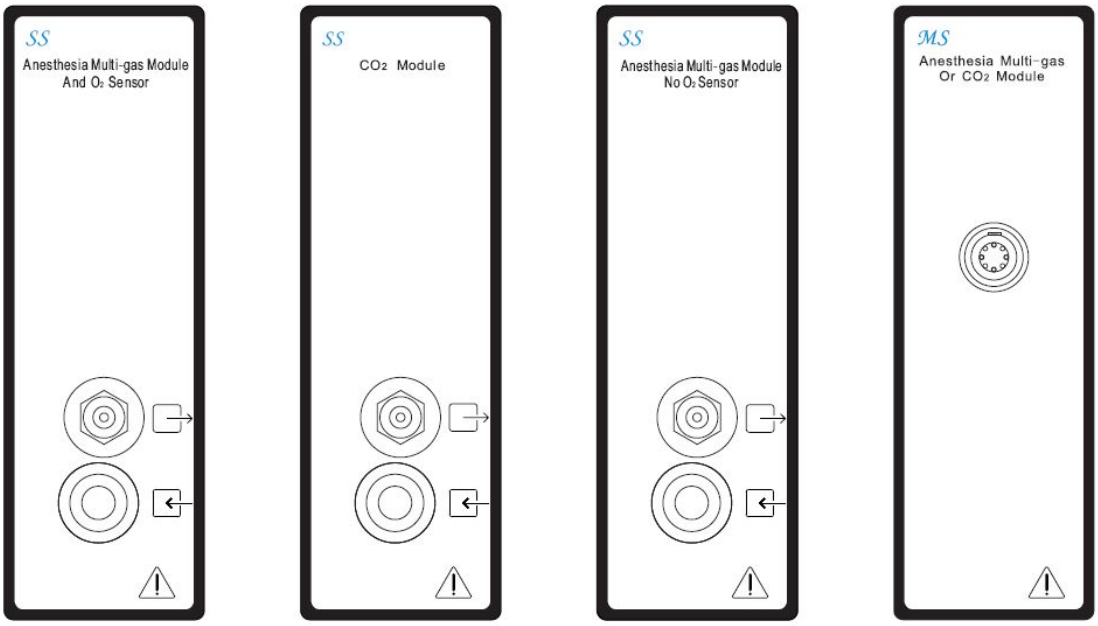
6.1 Summarize

The anesthesia machine adopts the MASIMO multi-gas analyzer, it has the ability to measure CO_2, O_2, N_2O, anesthetic agents (Enflurane, Isoflurane, Sevoflurane), and displays the real-time measuring value and waveform according to the settings; it can provide automatic agent identification and are available in different configurations.

The anesthesia machine has two configurations: ISA side-stream gas analyzers and IRMA mainstream analyzers. Users can select the following configurations:

Model	**Gases**	**Description**	**Interface**
ISA AX+	CO_2, N_2O, anesthetic agents	“Plug-in and measure ”sidestream multi-gas analyzer	RS-232
ISA OR+	CO_2, N_2O, Anesthetic agents，O_2	“Plug-in and measure” sidestream multi-gas analyzer with paramagnetic oxygen sensor	RS-232
IRMA AX+	CO_2, N_2O, Anesthetic agents	Mainstream multi-gas analyzer	RS-232

The MASIMO multigas analyzer is shown as below:



6.2 ISA sidestream multi-gas analyzer

⚠Warning：

- The ISA sidestream gas analyzer is intended for use by authorized and trained medical personnel only.
- Use only Nomoline sampling lines manufactured by MASIMO.
- The ISA sidestream gas analyzer must not be used with flammable anesthetic agents.
- Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.
- Do not re-use disposable sampling lines.
- Do not lift the ISA/host device by the sampling line as it could disconnect from the ISA/host device, causing the ISA/host device to fall on the patient.
- Used disposable sampling lines shall be disposed of in accordance with local regulations for medical waste.
- Do not use infant type sampling line configurations with adults, as this may cause excessive flow resistance.
- Do not use the ISA sidestream gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.
- Check that the gas sample flow is not too high for the present patient category.
- Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2) in the gas analyzer; ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.
- The Nomoline sampling line and its interfaces are non-sterile devices. To avoid damage, do not autoclave any part of the sampling line.
- Never sterilize or immerse the ISA sidestream gas analyzer in liquid.
- Measurements can be affected by mobile and RF communications equipment. Make sure that the ISA sidestream gas analyzer is used in the electromagnetic environment

specified in this manual.

- ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.
- Replace the sampling line if the sampling line input connector starts flashing red, or a Nomoline occlusion message is displayed on the host.
- No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.
- ISA sidestream gas analyzers are not designed for MRI environments.
- During MRI scanning, the host device must be placed outside the MRI suite.
- Use of high frequency electrosurgical equipment in the vicinity of the ISA/host device may produce interface and cause incorrect measurements.
- Do not use external ambient cooling of the ISA device.
- Do not apply negative pressure to the Nomoline (i.e. by a syringe) to remove condensed water.
- Too strong positive or negative pressure in the patient circuit might affect the sample flow.
- Strong scavenging suction pressure might affect the sample flow.
- Exhaust gases should be returned to the patient circuit or a scavenging system.
- Always use a bacteria filter on the evac side if sampled gas is intended to be re-breathed.
- Do not place the ISA gas analyzer in any position that might cause it to fall on the patient.

⚠Caution：

- The ISA “plug-in and measure” analyzers should be securely mounted in order to avoid the risk of damage to the ISA.
- Do not apply tension to the ISA sidestream gas analyzer cable.

- Do not operate the ISA sidestream gas analyzer outside the specified operating temperature environment.

6.2.1 Intended use

The ISA product family consists of different types of side-stream gas analyzers, intended to be connected to other medical devices for display of real time and derived monitoring data of a selection of CO_2,N_2O,O_2 and the anesthetic agents（Isaoflurane, Enflurane, Sevoflurane）.

The ISA product family is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. It may be used in the operating suit, intensive care unit, patient room and for applicable versions emergency medicine/emergency transport settings for adult, pediatric and infant patients.

The ISA product family is not intended to be used as the only means of monitoring a patient. They shall always be used in combination with other vital signs monitoring devices and/or professional human judgments of patient condition. Products in the ISA product family are intended to be used by trained and authorized health care professionals only.

They are only intended to be connected to medical devices approved by MASIMO AB.

Note：

- An ISA sidestream gas analyzer should never be used as the only means of monitoring a patient.
- An ISA sidestream gas analyzer shall only be connected to medical devices approved by MASIMO.

6.2.2 Patents and Trademarks

Patents

MASIMO AB holds the following patents regarding products described in this manual: SE519766; SE519779; SE523461; SE524086. Other patents pending.

Trademarks

MASIMO IRMA™, MASIMO ISA ™, MASIMO XTP™, Sigma Multigas Technology™, LEGI™, Nomoline™, IRMAEZ Integrator™, MASIMO GasMaster™ and ISA MaintenanceMaster™ are trademarks of MASIMO AB.

Tygothane® is a registered trademark of Saint-Gobain Performance Plastics Corporation.

6.2.3 Consumables

The following sampling lines and other approved consumables can be ordered from MASIMO.

Product	Description	Catalog No.
Nomoline with Luer Lock connector, 2m. Box of 25	Sampling line with male Luer Lock connector. For general use, with integrated water removal and hydrophobic bacteria filter. Length 2 meters. Delivered in boxes of 25 pcs.	108210
Nomoline with Luer Lock connector, 2m. 4 x Box of 25	Sampling line with male Luer Lock connector. For general use, with integrated water removal and hydrophobic bacteria filter. Length 2 meters. Delivered as 4 boxes of 25 pcs.	108211

Ordering information

To place an order for a MASIMO product, please access www.MASIMO.com. You can get detailed availability information for the products and order the products. Alternatively, you can also contact our Company for information.

6.2.4 Adverse effects on performance

The performance of the ISO analyzer may be affected due to the following:

- Quantitative effects of humidity or condensate
- Quantitative effects of barometric pressure
- Interfering gases or vapors
- Other sources of interference

6.2.4.1 Quantitative effects of barometric pressure

Gas measurement units

Gas concentration is reported in units of volume percent. The concentration is defined as:

$$\%gas = \frac{Partial\ pressure\ of\ gas\ component}{Total\ pressure\ of\ gas\ mixture} * 100$$

The total pressure of the gas mixture is measured by a cuvette pressure sensor in the ISA gas analyzer.

For conversion to other units, the actual atmospheric pressure sent from the ISA sidestream analyzer may be used, e.g.

CO_2 in mmHg= (CO_2 concentration) × (atm.pressure value in kPa from ISA) × (750/100).

Example: 5.0 vol% CO_2@101.3 kPA → 0.05 × 101.3 × 750/100 = 38mmHg

6.2.4.2 Effects of humidity or condensate

The partial pressure and the volume percentage of CO_2, N_2O, O_2 and anesthetic agents depend on the amount of water vapor in the measured gas. The O_2 measurement will be calibrated to show 20.8 vol% at actual ambient temperature and humidity level, instead of showing actual partial pressure 20.8 vol% O_2 corresponds to the actual O_2 concentration in room air with 0.7 vol% H_2O concentration (at 1013 hPa this equals for example 25℃ and 23% RH). The measurement of CO_2, N_2O, and anesthetic agents (e.g. all gases measured by the IR-bench) will always show the actual partial pressure at the current humidity level.

In the alveoli of the patient, the breathing gas is saturated with water vapor at body temperature (BTPS).

When the breathing gas is sampled, and passing the sampling line, the gas temperature will get close to the ambient temperature before reaching the ISA sidestream gas analyzer. As the Nomoline removed all condensed water, no water will reach the ISA gas analyzer. The relative humidity of the sampled gas will be about 95%.

If CO2 values at BTPS are required, the following equation can be used:

$$EtCO2(BTPS) = EtCO2 * \left(1 - \left(\frac{3.8}{Pamb}\right)\right)$$

Where:

$ETCO_2$=$ETCO_2$ value sent from ISA [vol%]

Pamb=Ambient pressure sent from ISA [kPa]

3.8=Typical partial pressure of water vapor condensed between patient circuit and ISA [kPa]

$EtCO_2$ (BTPS) =$EtCO_2$ gas concentration at BTPS [vol%]

O_2 is assumed to be room air calibrated at a humidity level of 0.7 vol% H_2O.

Spectral broadening

The present of oxygen and nitrous oxide can cause some interference in the CO_2 measurement. This is known as spectral broadening.

For the detailed information, please refer to the section ***5.14 System settings.***

Interfering gases and vapor

For the detailed information, please refer to the ***B.9.2 Interfering gas and vapor effects.***

6.2.5 Analyzer system set-up

To set up the host device for gas analysis, follow these steps:

1. Connect the ISA analyzer interface cable to the host device.
2. Connect a Nomoline sampling line to the ISA analyzer input connector.
3. Connect the gas sample exhaust port to a scavenging system or return the gas to the patient circuit.
4. Power up the host device.
5. A green LED indicates that the ISA analyzer is ready for use.
6. Perform a pre-use check as described in section ***6.2.6pre-use check.***

The installation of the sidestream analyzer is shown as the graphic below:

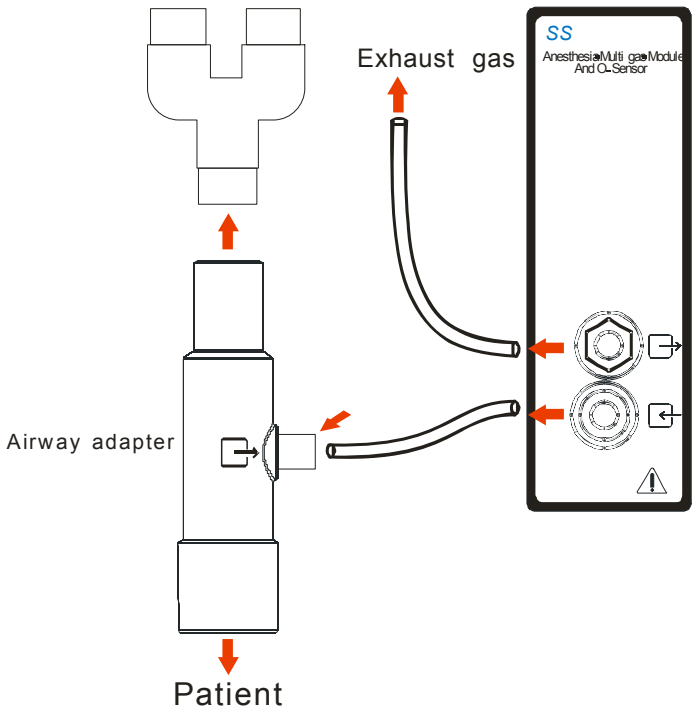


Figure 6-1 Sidestream analyzer connection view

6.2.6 Pre-use check

Before connecting the Nomoline sampling line to the breathing circuit, do the following:

1. Connect the sampling line to the ISA gas inlet connector (LEGI)
2. Check that the LEGI shows a steady green light (indicating that the system is ok)
3. For the ISA module with O_2 fitted: check that the O_2 reading on the monitor is correct (21%)
4. Breathe into the sampling line and check that valid CO_2 waveforms and values are displayed on the host device.
5. Occlude the sampling line with a fingertip and wait for 10 seconds.
6. Check that an occlusion alarm is displayed and that the LEGI shows a flashing red light.
7. If applicable: perform a tightness check of the patient circuit with the sampling line attached.

Note: LEGI is the abbreviation of "light emitting gas inlet", which detects the presence of a Nomoline sampling line and presents color-coded status information.

6.2.7 Zeroing

The infrared gas analyzer needs to establish a zero reference level for the CO_2,N_2O and anesthetic agent gas measurement.

ISA sidestream gas analyzers perform zeroing automatically by switching the gas sampling from the respiratory circuit to ambient air. The automatic zeroing is performed every 24 hours, and takes less than 3 seconds for ISA CO_2 gas analyzers and less than 10 seconds for ISA multigas analyzers.

The ISA sidestream gas analyzer is fitted with an oxygen sensor, the automatic zeroing will also include room air calibration of the oxygen sensor

⚠Warning：

- Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2) in the gas analyzer, ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.

6.2.8 Alarms

The overview of the status indicated by the LEGI is described as the table below:

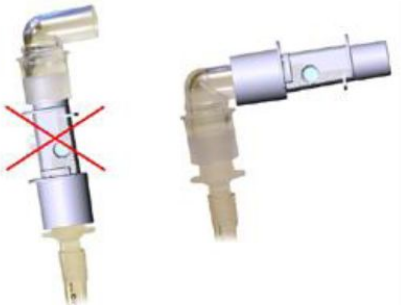
Indication	**Status**
Steady green light	System ok
Blinking green light	Zeroing in progress
Steady blue light	Anesthetic agent present
Steady red light	Sensor error
Blinking red light	Check sampling line

Table 6-1. Alarm indication light and status

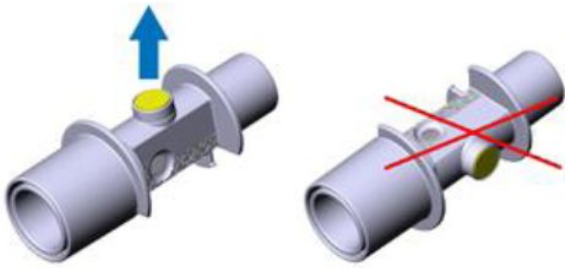
6.3 IRMA mainstream multigas analyzer

⚠Warning：

- The IRMA probe is intended for use by authorized and trained medical personnel only.
- The IRMA probe must not be used with flammable anesthetic agents.
- Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.
- Used airway adapters shall be disposed of in accordance with local regulations for medical waste.
- Use only MASIMO manufactured oxygen sensor cells. Depleted oxygen sensors shall be disposed of in accordance with local regulations for batteries.
- Do not use the IRMA Adult/Pediatric airway adapter with infants as the adapter adds 6 ml dead space to the patient circuit.
- Do not use the IRMA infant airway adapter with adults as this may cause excessive flow resistance.
- Measurements can be affected by mobile and RF communications equipment. It should be assured that the IRMA probe is used in the electromagnetic environment specified in this manual.
- Do not use the IRMA airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.
- Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.



- To keep secretions and moisture from pooling on the windows or oxygen sensor port, always position the IRMA probe in a vertical position with the LED pointing upwards.



- The IRMA probe is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.
- Do not try to open the oxygen sensor assembly. The oxygen sensor is a disposable product and contains a caustic electrolyte and lead.
- The IRMA probe is not intended to be in patient contact.

⚠Caution：

- Never sterilize or immerse the IRMA probe in liquid.
- The IRMA oxygen sensor cell and IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.
- Do not apply tension to the probe cable.
- Do not operate the IRMA probe outside the specified operating temperature environment.
- Do not leave depleted oxygen sensors mounted in the IRMA probe, even if the probe is not in use.

6.3.1 Intended use

The IRMA main stream multi-gas probe is intended to be connected to other medical devices for display of real time and derived monitoring data of CO_2, N_2O, O_2, and the anesthetic agents （Enflurane, Isoflurane, Sevoflurane ）.

It is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room and emergency medicine settings for adult, pediatric and infant patients.

It is not intended to be used as the only means of monitoring a patient. It shall always be used in combination with other vital signs monitoring devices and /or professional human judgments of patient condition. The IRMA probe is intended to be used by trained and authorized health care professionals only.

6.3.2 System assembly instruction

Please follow the procedures below:

1. Plug the IRMA connector into the IRMA input of module and switch the power on, the connection method shown as below:

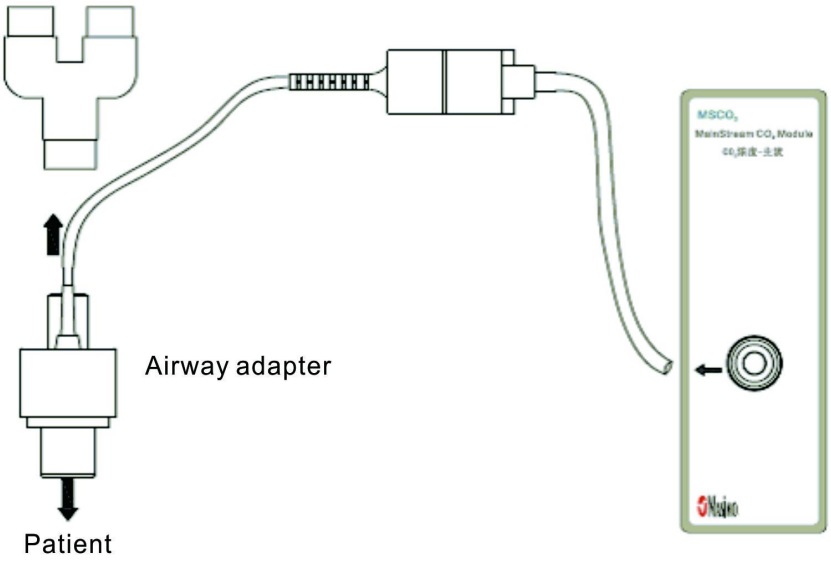


Figure 6-2 Mainstream analyzer connection view

2. Snap the IRMA probe on top of the IRMA airway adapter. It will click into place when properly seated.

Figure 6-3 IRMA probe connection view

3. A green LED indicates that the IRMA probe is ready for use.

Figure 6-4 LED indication view

4. Connect IRMA / airway adapter 15 mm male connector to the breathing circuit Y-piece.

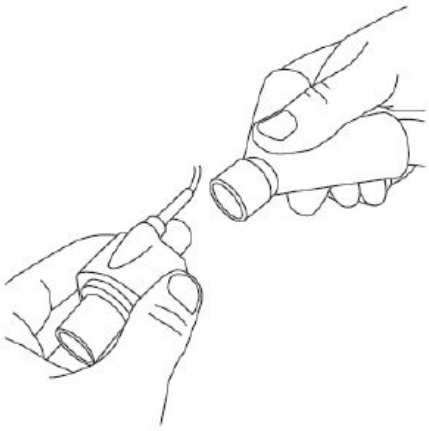


Figure 6-5 IRMA airway adapter connection view I

5. Connect the IRMA / airway adapter 15mm female connector to the patient's endotracheal tube.

Figure 6-6 IRMA airway adapter connection view II

Alternatively, connect an HME (Heat Moisture Exchanger) between the patient's endotracheal tube and the IRMA probe. Placing an HME in front of the IRMA probe protects the airway adapter from secretions and effects of water vapor and eliminates the need of changing the adapter. It allows free positioning of the IRMA probe as well.

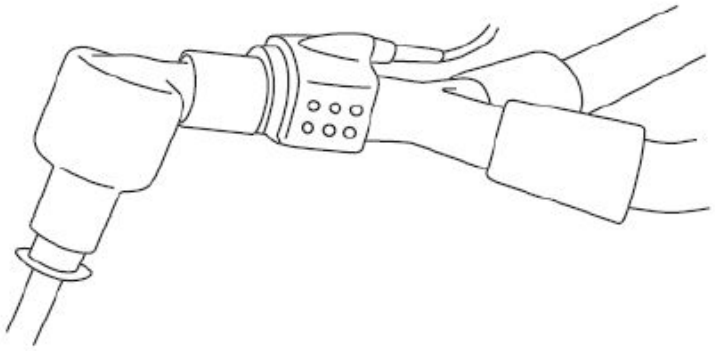


Figure 6-7 IRMA airway adapter connection view III

6. Unless the IRMA probe is protected with an HME always position the IRMA probe with the status LED pointing upwards.

Figure 6-8 LED pointing upward

⚠Warning：

- The IRMA probe is not intended to be in patient contact.

6.3.3 Pre-use check

Prior to connecting the IRMA airway adapter to the breathing circuit, verify the O_2 calibration by checking that the O_2 reading on the monitor is correct (21%).

Always verify gas readings and waveforms on the monitor before connecting the airway adapter to the patient circuit.

Perform the tightness check of the patient circuit with the IRMA probe snapped on the IRMA airway adapter.

6.3.4 Zeroing procedure

⚠Warning：

- Incorrect probe Zeroing will result in false gas readings.

In order to secure high precision of the IRMA probe measurements the following zeroing recommendations should be followed.

Zeroing is performed by snapping a new IRMA airway adapter onto the IRMA probe, without connecting the airway adapter to the patient circuit, and then using the host instrument to transmit a zero reference command to the IRMA probe.

Special care should be taken to avoid breathing near the airway adapter before or during the Zeroing procedure. The presence of ambient air (21% O_2 and 0% CO_2) in the IRMA airway adapter is of crucial importance for a successful Zeroing.

Always perform a pre-use check after zeroing the probe.

Zeroing should be performed every time the IRMA airway adapter is replaced, or whenever an offset in gas values or an unspecified gas accuracy message is displayed.

Allow 30 seconds for warm up of the IRMA probe after power on and after changing the IRMA airway adapter before proceeding with the Zeroing Procedure. The green LED on the probe will be blinking for approximately 5 seconds while zeroing is in progress.

6.3.5 Alarms

The description of the status LED situated on the IRMA probe is as below:

Steady green light	System OK
Blinking green light	Zeroing in progress
Steady blue light	Anesthetic agent present
Steady red light	Sensor error
Blinking red light	Check adapter

Table 6-1. Alarm indication light and status

Chapter 7 MASIMO CO_2 analyzer and SPO_2 module (optional)

7.1 MASIMO CO_2 analyzer

7.1.1 Summarize

The anesthesia machine adopts the MASIMO CO_2 analyzers. Users can select IRMA sidestream CO_2 analyzer or ISA mainstream CO_2 analyzer to measure the CO_2 concentration.

The ISA CO_2 analyzers are low-flow sidestream gas analyzers, designed for routine clinical use in environments that place special demands on the product's ruggedness. Its low power consumption and fast rise-time makes ISA CO_2 ideal for any application, ranging from the OR and ICU to transport monitoring of adult, pediatric and infant patients,

7.1.2 Installation

1. The installation of ISA sidestream CO_2 analyzer, please refer to ***6.2.5 Analyzer system set-up.***
2. The installation of IRMA mainstream CO_2 analyzer, please refer to ***6.3.2 system assembly instruction.***

7.1.3 Zeroing procedure

1. IRMA CO_2 probe：

Zeroing needs to be performed ONLY when an offset in gas values is observed, or when an unspecified accuracy message is displayed.

Allow 10 seconds for warm up of the IRMA CO_2 probe after power on and after changing the IRMA airway adapter before proceeding with the Zeroing Procedure. The green LED on the probe will be blinking for approximately 5 seconds while zeroing is in progress.

2. ISA CO_2 analyzer：

ISA sidestream gas analyzers perform zeroing automatically by switching the gas sampling from the respiratory circuit to ambient air. The automatic zeroing is performed every 24 hours, and takes less than 3 seconds for the ISA CO_2 gas analyzers.

⚠Warning：

- Incorrect probe Zeroing will result in false gas readings.

7.1.4 Spectral broadening

The presence of oxygen and nitrous oxide can cause some interference in the CO_2 measurement. This is known as spectral broadening, and must be compensated.

For the detailed information, please refer to the section ***5.14 System settings.***

7.2 SpO_2 Module

7.2.1 Introduction

The detecting of SpO2 adopts Pulse Oximetry. That is a method of the durative and untraumatic detecting HbO2 saturation (functional saturation). The process is that the light from the emitter to the receiver across patient's part of body like finger or ear. The quantity of penetrable light is dependent on numerous factors, the much of light is constant. But the arterial blood changes regularly with time, because it is pulsant. The module can get HbO2 saturation, By means of detecting the receiving light in patient pulse time, moreover can receive "volume drawing" waveform and pulse rate.

The SpO2 module is shown in the following figure.

Figure 7-1 SPO_2 module view

⚠Warning:

- If there are carboxyhaemoglobin, methemoglobin or attenuant chemical medicine, the SpO2 value occurs error probably.
- Need to clean the SpO2 probe before used.
- Don't put the SpO2 probe and blood pressure bond on one arm together, because that affects the SpO2 saturation reading.
- Environment light, movement, EMI, ornaments, hemoglobin dysfunction, blood coloration and so on can cause interference probably.

- The SpO2 detecting has no preventing defibrillation function, and don't use with the defibrillation equipment. That can cause interference probably.
- Clip one patient's part no more than 2 hours, for the skin needs to get some air.
- The probe sensor should avoid shinning from troubled light in the process of detecting SpO2.
- Please choose the type SpO2 probe to the needs of the sick before used, otherwise the SpO2 value occurs error probably.
- Check the sensor before used, if the sensor packing or itself is damaged, don't use.
- Don't make the cable and sensor cable twisting together.
- Don't put together the SpO2 probe on the arm which has conduit or injection syringe.

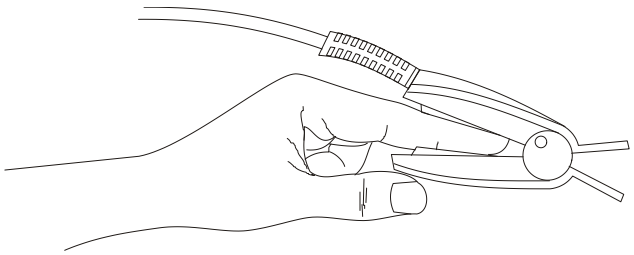
7.2.2 Connecting and operating

Detecting steps:

The SpO2 module works using probe clamping down the adult's finger or infant's palm or foot. Refer to the below steps:

1) Switch on the power.
2) Put the SpO2 probe on the patient's right place.
3) Connect the SpO2 probe cable and interface.

Be shown in the following figure.



Put the finger in the probe

⚠Warning:

- Check the using status and skin every 2 hours in a long continuous detecting process.

- Check the position of probe periodically in a long continuous detecting process, avoid moving to cause error probably.

⚠Attention:

- Choose right SpO2 probe to detect.
- Put the SpO2 probe cable on the hand, and make sure the nail face on the light from lamp-house.
- If the detecting part can not face on the probe, that maybe cause error, even don't search the pulse and don't detect, and now need to locate again.
- Move the detecting part can cause error probably, should make the patient quiet and replace detecting part, to minimize this impact.

Chapter 8 qCON Module

8.1 Summarize

The qCON module has been designed to be used in the monitoring of the level of consciousness of a person during the application of general anesthesia or in intensive care. It provides reliable information on the level of consciousness of the patient, helping the anesthesiologist to administer anesthetic drugs by inhalation or intravenously safely.

The qCON module is obtained from signals of electroencephalogram (EEG) recorded with three surface electrodes placed on the patient's forehead and analyzed by a digital process. The result is the index "qCON ", "Index of Consciousness", which serves as a guide to the experts to determine the patient's level of consciousness during anesthesia.

⚠Warning：

- The index of consciousness (qCON) should not be used as the only parameter to adjust the dose of anesthetic drugs.

8.2 Patient cable

The patient cable has two endpoints and is shown in below figure. One of them is connected to the qCOM module interface and the other end, which has three derivations (red, yellow and green), is connected to electrodes attached to the skin of the patient.

The cable is designed especially to measure the EEG with low interference levels. Among its features we can mention:

1) Each lead wire is individually shielded.
2) Short terminals that allow better interference rejection capacitive and inductive.
3) Main cable large, allowing for greater ease of use.

The connections have a certain color to facilitate proper placement and without errors. Care must be taken to place the electrodes in the right positions since the device will not function properly if you swap the positions of the electrodes.

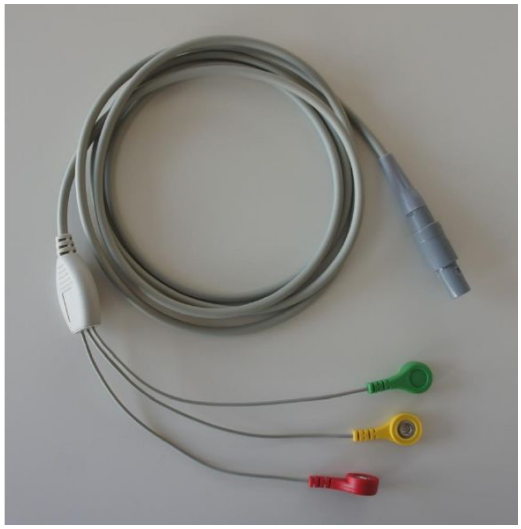


Figure 8-1 Patient cable

8.3 Skin preparation

For a correct measure of the EEG signal, it is advisable to prepare the skin for reducing the high impedance that exists in normal conditions. To this is recommended to use very fine sandpaper designed specifically to clean the surface layer of the skin of the patient. Before placing the electrodes clean the patient's skin using carefully the sand paper on the given area.

8.4 Connections

1) qCON module

The connection of the qCON module is shown as the graphic below:

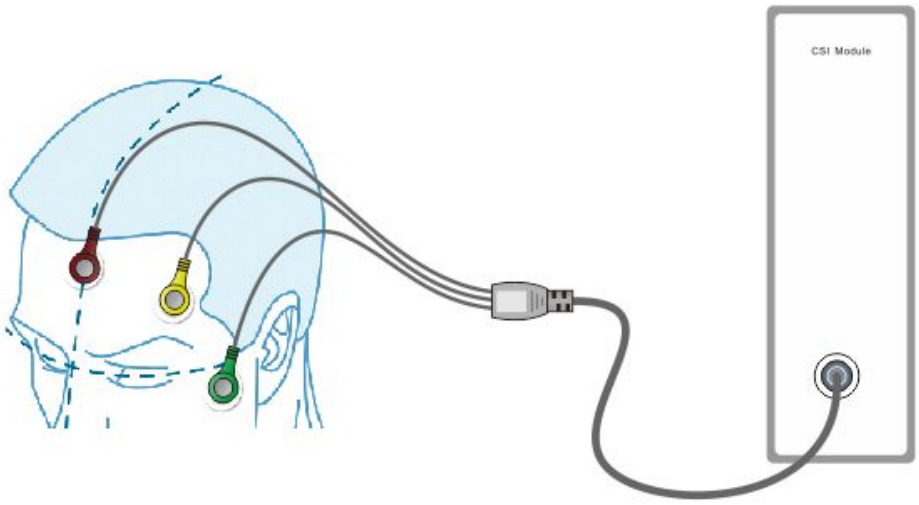


Figure 8-2 qCON module connection view

2) Placement of electrodes

As described above, one end of the patient cable has three snaps (red, yellow and green) that are connected to the electrodes when the patient's skin is cleaned, as shown in above figure. The connectors correspond to the end of the red wire (+), yellow (reference) and green (-). The proper placement is ensured by the three different colors of the snaps.

⚠Warning：

- If skin presents any rash or other unusual symptoms, remove the electrodes from the patient.
- It is important to take special care in patients with skin problems.
- Do not place the electrodes on wounds.

8.5 Operation

8.5.1 qCON (Range 0 – 99)

The qCON index is a continuous processed EEG parameter that correlates to the patient's level of hypnosis, where decreasing the qCON index values correspond to gradually loss of consciousness and a deepening of the level of anesthesia. The qCON-OEM board was designed to correlate with the level of consciousness and to track changes in the effects of anesthetics on the brain. The number qCON should not be used as the sole parameter for adjusting the anesthetic dose. In most individuals the qCON will be above 80 in awakes state. However, in some individuals, when they are calm or sedated can observe decreases to about 60 while they are awake.

The below table shows the relationship between the qCON index value and the patient's clinical state.

qCON	Clinical State
99 80	Awake Sedation
60 40	General anesthesia
0	DEEP ANESTHESIA ISOELECTRIC EEG

Table 8-1. qCON index and clinical state

8.5.2 Signal Quality Index SQI(Range 0-100)

The SQI is a measure of the signal quality for the EEG and it is calculated based on impedance data, artifact, and other variables. It is displayed in Green color and located at the left of the display screen.

8.5.3 Electromyogram EMG (Range 0-100)

The monitor includes an EMG filter that eliminates most of the potential interfering EMG activity. The EMG energy (in decibels) is in a frequencies range of 30-45 Hz and it is visualized in Green color on the left side of the display.
EMG activity can increase due to:

- Reflex reactions to painful stimuli during surgery.
- Activity or muscular rigidity.

The EMG bar should be checked frequently, especially in case of a sudden increase in the qCON index. If the increase in the qCON is accompanied by an increase in muscular activity, there is a risk that EMG is causing interference. When this happens, attention must be paid to the clinical signs of the patient during the procedure.

8.5.4 Electroencephalogram (EEG)

The EEG activity is visualized on the display using different menus. The amplitude can be changed between +/- 25, +/- 50, +/- 120, +/- 250 y +/- 475 μV.

8.5.5 EEG suppression ratio (Range 0-100%) BSR

The EEG Suppression ratio (ESR) is a parameter derived from the EEG typically occurring during deep levels of anaesthesia, characterized by the occurrence of periods of bursts followed by periods of suppression (almost iso-electric EEG). Suppression ratio is the percentage of time over the last 30s that the signal is considered to be in the suppressed state. The BSR is represented in Green color.

8.5.6 Artifact detection

The qCON-OEM board is designed to provide only highly reliable data. It has been equipped with an algorithm for rejection of artifacts.

8.6 Security advises

For security reasons it is advisable to follow all the recommendations presented in this section and those that have occurred throughout this manual.

It is important to follow each of them without exception:

- Do not attempt to replace any of the delivered pieces without contacting or informing the manufacturer.

Stop the use of the qCON module if any of the following situations have occurred:

- Any of the provided cables show any fault on the insulation or other damage of any kind.
- Any liquid or substance falls on any of the items. In this case the equipment must be switched off, the cables disconnected, and the manufacturer informed.
- Occurrence of any kind of electrical fault
- Any mechanical damage, lose of rigidity or a movement different from the original one.
- Any indication of a loose object inside any of the delivered items.

In all the cases the manufacturer should be contacted without acting in any way on any elements delivered with the qCON module.

8.7 Cleaning and maintenance

It is recommended to perform an annual revision of the equipment by qualified personnel authorized by the manufacturer.

Chapter 9 User maintenance

⚠Warning：

- Please comply with the appropriate safety precautions.
- Please read all the operation and maintenance instructions of the disinfection devices carefully.
- Please wear the safety gloves and glasses, the damages to the oxygen sensor may result in leakage and lead to fire (contains the potassium hydroxide).
- After every disassembled cleaning or reinstallation, it can be used regularly only after the ***pre-use check in chapter 4.***
- In order to prevent the leakage of the patient absorber system, during disassembling and re-installing process, please pay attention to avoid damages to the components and make sure the correctness of the installation, especially note the installation of the seal ring; during the process of cleaning and disinfecting, please make sure the way to clean and disinfect is applicable and correct.
- In order to prevent the scald for the heating module of the patient absorber system, please shut off the equipment for ten minutes before disassemble the patient absorber system.
- The used devices may be polluted by blood or body fluid, please apply to the disinfection controlling and safety regulations.
- The moveable parts and removable components may have pinching or crunching dangers, please pay more attention to those parts when moving or replacing the system components.
- Do not use the devices with malfunctions, the machine should be maintained, dismantled or operated only by the qualified personnel.
- After repairing, the equipment should be tested to ensure the normal function of the equipment.
- Everyone should realize that some parts of the anaesthetic ventilator may be in

danger of infection when dismantled and cleaned.

⚠Cautions：

- In order to prevent damages, if you have any problem about the cleanser, please see the data provided by the manufacturer.
- Do not use abrasive cleanser. (such as steel wool, silver polish or detergent)
- Place the liquids far away from the electronic components.
- Do not let liquid penetrate into the equipment.
- The soaking time of the synthetic rubber can not exceed 15 minutes, or it will lead to expansion or accelerated aging.
- Those personnel who don't have the experiences of repairing such equipment should not carry out the maintenance
- Use parts produced or sold by our company to replace those broken ones, and have a test after replacement to assure that they correspond with the specification requirements of the manufacturer.
- Certain parts of this equipment should not be disposed in a normal way.
- All the disposable (one –off) parts should be disposed in a safe and environmental way according to the hospital regulations.
- When taking any parts from the anesthesia machine, you should abide by the hospital rules and regulations about taking and disposing infectiousness materials. Because the way of cleaning, sterilizing in the Medical institutions is very different from the practice. Therefore the Company can not satisfy all the special needs and can not be responsible for cleaning, sterilizing or other hygienic measure taken by the hospital during therapeutic process. We suggest that you use the effective methods already proven in this user manual, specific equipment and steps. Other methods may be just as effectively, but we do not guaranteed unless the Company provides written authorization.

- We suggest that when cleaning or sterilizing, you should use drinking water at least or more healthful water, otherwise, the result may be affected.
- Cleaning is the most important step in cleaning and sterilizing process. If you clean the instrument improperly, it would be impossible to sterilize or high temperature sterilize effectively. Eliminating most of bacterium and filth by cleaning is significant guarantee for achieving the best sterilization.
- The instrument should be cleaned and sterilized immediately after using if possible. Filth like saliva or blood should not remain in the instrument and turn dry.
- If you need service or support, please contact the after service department of the Company.

9.1 Maintenance schedule

Maintenance Frequency	Maintenance
Every patient	Reusable breathing tube, manual bag, patient absorber.
Every day	The anesthesia machine surface, the alarm system testing
Every half year	The Pop-off valve assembly, BYPASS assembly, bellows assembly, flow sensor, batteries.
Every year	The Oxygen sensor, vaporizer.
When cleaning and installing	Check the parts intact or not, if necessary change or repair it
Do as necessary	Reusable breathing tube, manual bag, patient absorber assembly, bellows assembly, flow sensor.

9.2 Cleaning and disinfection

Components marked with 134°C are pressure-resistant and heat-resistant components, like metal、glass can be disinfected with the high-temperature and high-pressure steam, the recommended temperature is 134ºC. Use the high-pressure steam boiler to increase the steam pressure, and the temperature is also increased to make the bacterial albumen solidify rapidly. This method is rapid and credible. If kept in the conditions of 1.05 kg/cm^2 steam pressure and 121ºC temperature for 15 to 20 minutes, all bacilluse and most sporangium will be killed. These kinds of components can also be cleaned manually or by machines. Scrub the components of the patient absorber system (except the oxygen sensor) by mild detergent of which the PH value is less than 10 and make them dry.

⚠Warnings:

- Do not use the talc, zinc stearate, calcium carbonate, corn flour or the similar materials to avoid conglutination. These materials may enter the patient's lung or air channel, causing stimulation or damages.
- Do not soak the oxygen sensor in the liquid or dispose it by high-temperature and high pressure.
- Check if the parts have damages, replace them if necessary.

Each component on the absorber of the anesthesia machine can be cleaned and disinfected. The methods of cleaning and disinfecting for different components are different. Users should select the appropriate method according to the actual circs to clean and disinfect each component of the absorber in the anesthesia machine to prevent cross -infection of the patients while using the anesthesia machine.

AGSS is a corollary equipment of the anesthetic machine that must be cleaned and serviced synchronously.

The methods of cleaning and disinfection described in the form below are recommended by our company.

Components	The medium disinfection	The high level disinfection	
	A*	B*	C*
The breathing hose and Y-connector		√	
The flow sensor		√	
The bellows assembly		√	
Pop-off valve components		√	√
Bag/Ventilator switch assembly		√	√
The APL valve assembly		√	√
The inspiratory and expiratory non-return valve assembly		√	
Oxygen sensor	√		
The canister assembly		√	
The inspiratory and expiratory assembly		√	√
The patient absorber assembly		√	√
The reusable manual breathing bag		√	√

A*: Clean with the cloth that soaked in the mild cleanser and dry it by using a lint-free cloth;

B*: Wash it with clean water firstly, and then soak it in the water mixed with cleanser solution (the recommended temperature is 40°C) for about 3 minutes, finally, clean up with clean water and wipe it with 70% medical alcohol;

C*: The high-temperature and high-pressure steam sterilization (the maximum temperature is 134°C).

⚠Warning：

- The patient absorber assembly of the anesthesia machine has two optional configurations, one can only allow general disinfection and another allows high-temperature and high-pressure disinfection. Before disinfecting the patient absorber assembly, users must confirm its configuration and select correct disinfection method.

9.3 Maintenance of the anesthesia machine surface

1. Use the wet cloth that has been soaked in the mild cleanser solution (such as the 70% medical alcohol) to wipe the surface of the anesthesia machine;
2. After finish the clean of the surface, using dry, Lint-free clothe to wipe the residual detergent.

⚠Warning：

- If the liquid dip into the controlling components, it will damage the equipments or induce people in danger. So make sure there is no liquid dip into the controlling components, and disconnect the equipment and the AC power in the process of cleaning the surface. Reconnect the equipment to the AC power after all the parts that have been cleaned are dry.

⚠Caution：

- The screen must be cleaned by the cloth that is dry, soft and lint-free, can not be cleaned by liquid.

9.4 Maintenance of respiration system

In order to clean and disinfect the respiration system, firstly disassemble the parts that can be cleaned and disinfected. These parts are shown as below:

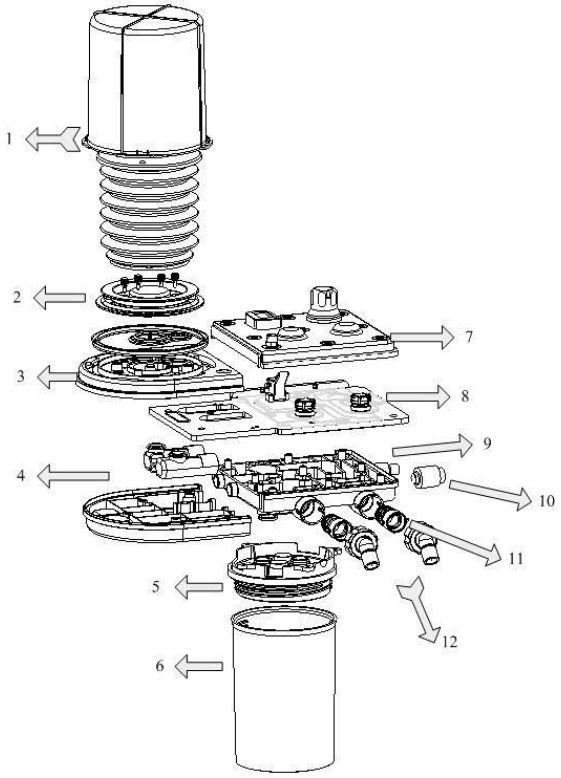


Figure 9-1 Respiration system view

1. Bellows assembly	7. The upper cover main parts of the absorber(including the APL)
2. Bellows seating assembly	8. Heat plate (including the Bag/Ventilator and non-return valve)
3. Pop-off valve	9. The lower cover main parts of the absorber(including the manual bag connector)
4. Gas block	10. Oxygen sensor
5. BYPASS adapter block	11. Flow sensor
6. Canister component	12. Inspiratory and expiratory connector assembly

9.4.1 Breathing tube and manual bag

1、 Disassembling:

1） Pull out all the breathing tubes that connected to the patients.

2） Remove the manual bag and place it with the tubes to the specified position for disinfection and depositary.

2、 Cleaning and disinfection: please refer to ***9.2 Cleaning and* disinfection.**

⚠Caution：

- When disassembling the breathing hoses, please grab the two ends of the hose to prevent damages to the hose.

9.4.2 Bellows assembly

1. Disassembling: please refer to ***3.4 Installing the folding bag and bellows housing.*** The method of disassembling is contrary to the method of installing.
2. Cleaning and disinfecting: please refer to ***9.2 Cleaning and* disinfection.**

9.4.3 Micro manometer and canister

1. Disassembling: please refer to ***3.5 installing the micro manometer***. The method of disassembling is contrary to the method of installing.
2. Cleaning and disinfecting: please refer to ***9.2 Cleaning and disinfecting.***

⚠Warning：

- The absorbent is strong corrosive substance which can irritate eyes、skins and respiration system badly. If the skin is touched carelessly, please flush with clean water for at least 15 minutes. If the irritating substance still remains after cleaning, please seek for the doctor’s help.

Cautions：

- The airway manometer of absorber can not be disinfected, please take and place it gently during the disassembling and installing process, cannot hit it violently.
- When disinfection of each component is completed, inset the manometer to its original place separately, and a click sound will be heard.

9.4.4 Pop-off valve assembly

1、 Disassembling:

1） Unlock the absorber, and remove the patient absorber;

2） Unscrew the four screws 1 by hands or tools, take out the base 2 and the Pop-off assembly 3, the diagram is shown as below:

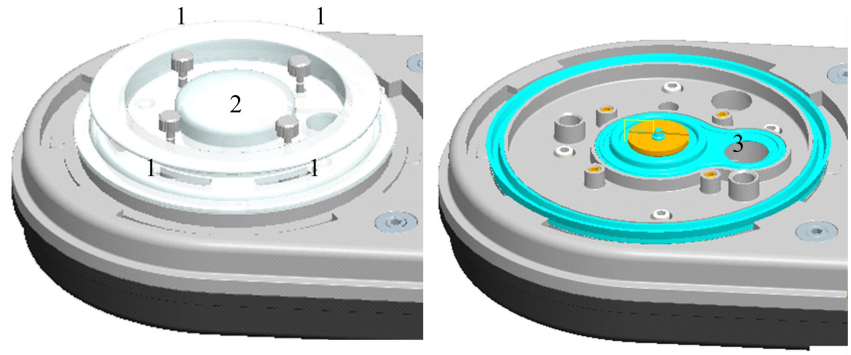


Figure 9-2 Pop-off valve view

2、 Cleaning and disinfection: please refer to ***9.2 Cleaning and disinfection.***

Caution：

- The damages of Pop-off valve may lead to gas leakage or serious malfunction, therefore, please take care to maintenance it.

9.4.5 Gas block and bellows cover

1. Disassembling:

1） Unscrew the four screws 1 and the six screws 6 , take out upper cover of the bellows component 2 and the lower cover 4;

2） Take out the gas block 5 from the heat plate. The diagram is shown as below:

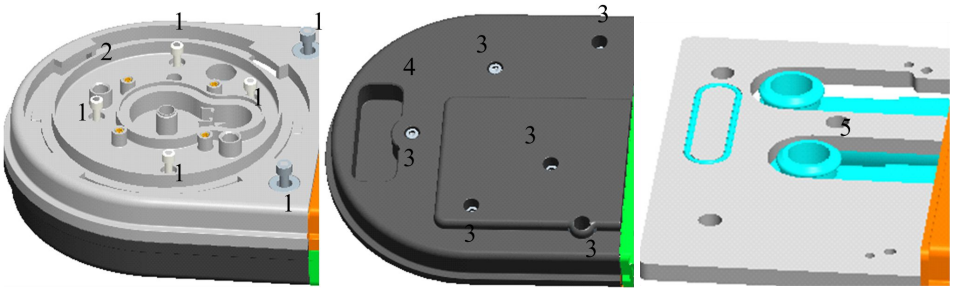


Figure 9-3 Gas block and bellows cover view

2. Cleaning and disinfection: please refer to ***9.2 Cleaning and disinfection.***

9.4.6 BYPASS assembly

1. Disassembling: unscrew the four screws 1 by tools, and take out BYPASS assembly 2.

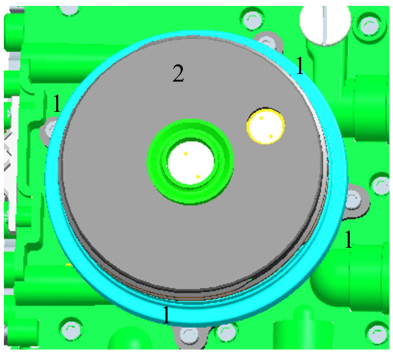


Figure 9-4 BYPASS view

2. Cleaning and disinfecting: please refer to ***9.2 Cleaning and disinfecting.***

9.4.7 Absorber upper cover and APL

1. Disassembling: Unscrew the micro manometer③ by a monkey wrench, and then take out the nine screws②. The diagram is shown as below:

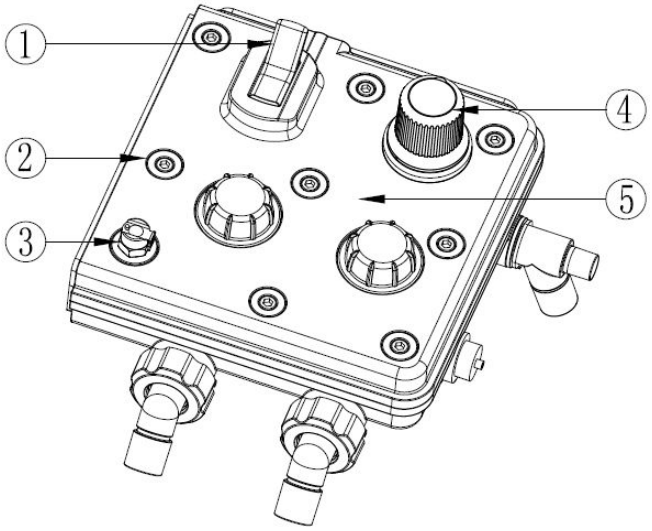


Figure 9-5 Absorber upper cover and APL view

2. Pull the manual/mechanical controlling handle① to the middle, and take out the upper cover⑤ with APL assembly④.
3. Cleaning and disinfection: please refer to ***9.2 Cleaning and disinfection.***

⚠Cautions：

- The APL assembly is fastened in the upper cover of the absorber; it can be disinfected without being disassembled.
- If you need to disassemble it, please keep the dismantled parts to prevent loss.

9.4.8 Baffle plate and bag/ventilator assembly and non-return valve assembly

1. Disassembling: Remove the upper cover, and then you can easily take out the heat plate 1 and the Bag/Ventilator assembly 2 (it is built in the baffle plate, and not recommended to be disassembled). Please see the diagram below:

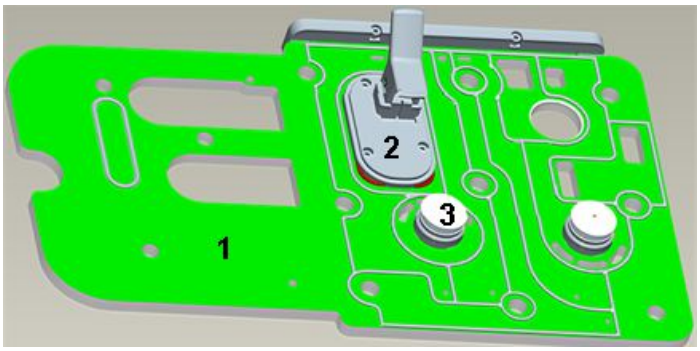


Figure 9-6 Baffle plate view

2. Hold the non-return valve assembly 3 forcibly and pull out it upwards, then take out the non-return valve.
3. Cleaning and disinfection: please refer to ***9.2 Cleaning and disinfection.***

9.4.9 Oxygen sensor

1. Disassembling: please refer to ***3.6 Installing the Oxygen sensor***. The method of disassembling is contrary to the method of installing.
2. Cleaning and disinfection: please refer to ***9.2 Cleaning and disinfection.***

⚠Warnings:

- Do not soak the oxygen sensor to liquid or dispose it through high-temperature and high- pressure.
- The vapor condensate on the surface of the Oxygen sensor will lead to failure of oxygen concentration measurement. Should take out the Oxygen sensor and clean away condensate on the surface and then install it to the absorber again.

9.4.10 Expiratory and inspiratory connector and flow sensor

1. Disassembling:

1） Unscrew the connector nut 1 anticlockwise by hand, hold the expiratory and inspiratory connector 2 and pull them out with the nut 1 from the lower cover unit. The diagram is shown as below:

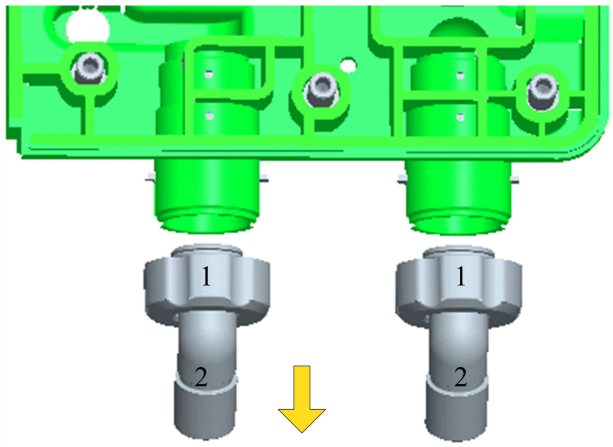


Figure 9-7 Expiratory and inspiratory connector view

2） Fasten the two button ears A of the flow sensor assembly 1, and pull out the flow sensor slightly. Shown as below:

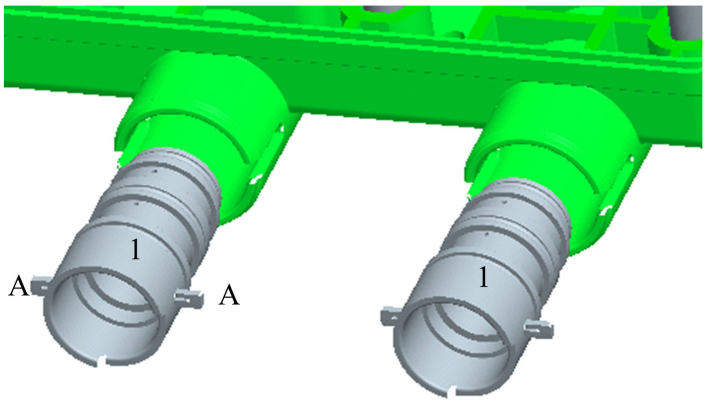


Figure 9-8 Flow sensor view

2. Cleaning and disinfection: please refer to ***9.2 Cleaning and disinfection***.

9.5 Maintenance of AGSS

9.5.1 Cleaning

Cleaning and maintenance refer to the *9.3 maintenance of the anesthesia machine surface*.

Cautions:

- Keep AGSS clean, no dust.
- If any parts is contaminated, use ethylene or ISO solution to wipe.
- Do not use strong solvent. (such as acetone or Three Cl)
- Using a wet cloth wipe all cleaning solution, and make sure all cleaning solution on equipment surface is completely removed.

9.5.2 Checking

Check the following items at regular or before using AGSS each time.

1） Check if AGSS is damaged or not.

2） Check if the outlet pipeline is jammed or damaged or not.

3） Check if the connctor of inlet and outlet is normal, no loose.

If find any damage, please contact the after service department of the Company.

9.5.3 Sterilization

As the AGSS does not have direct connection with the patient, so disinfection is not needed, only routine maintenance and repairment is required.

In order to avoid long-term damage to the product, it is suggested that seterilization is done only when it is necessary in regulations of the hospital, and it is recommended to be cleaned before sterilization.

9.5.4 Maintenance of filter

Check filter for dust and foreign matters. If find dust or foreign matters on the filter, it should be cleaned.

Disassembling:

Rotate the cover anticlockwise to remove the cover and then take out the filter from the cover. It shown as below.

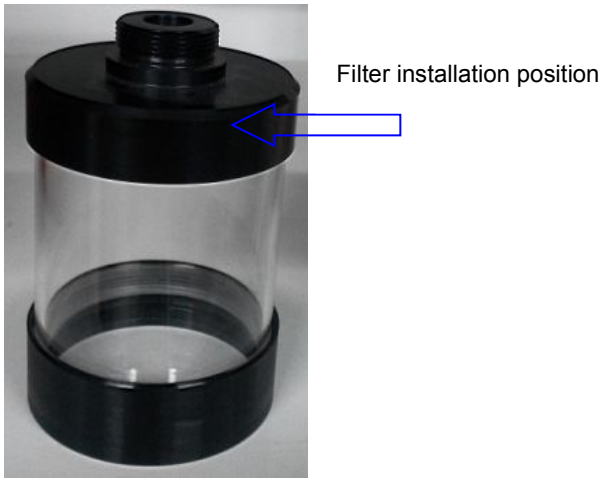


Figure 9-9 Filter installation position

9.6 ISA analyzer and IRMA probe

1） The cleaning of ISA sidestream gas analyzers

The “plug-in and measure” ISA sidestream gas analyzers should be cleaned on a regular basis. Use a cloth moistened with max 70% ethanol or isopropyl to clean the analyzer. To prevent cleaning liquids and dust from entering the ISA gas analyzer through its LEGI connector, keep the Nomoline sampling line connected while cleaning the analyzer.

2） The replacement of sampling line

The Nomoline sampling line is non-reusable.

Every two weeks or whenever “sampling line clogged” appears, whichever comes first, the Nomoline sampling line should be replaced.

3） The cleaning of IRMA probe

IRMA probe can be cleaned using a cloth moistened with maximum 70% ethanol or maximum 70% isopropyl alcohol.

Remove the disposable IRMA Airway Adapter prior to cleaning the IRMA probe.

4） Gas span check

Gas readings should be verified at regular intervals with a reference instrument. If great error of gas readings were found, please contact the manufacturers service department for maintenance by the after service engineers.

⚠Warnings:

- The Nomoline sampling lines are non-sterile devices. To avoid damage, do not autoclave any part of the sampling line.
- Never sterilize or immerse the ISA sidestream gas analyzer in liquid.
- Never sterilize or immerse the IRMA probe in liquid.

Chapter 10 Configuration list

⚠Warnings：

- Please use accessories provided by the Company in order to avoid the inaccurate data or equipment failure.
- The disposable accessories can be used only once, repeated using may lead to performance degradation or cross-infection.
- If you discover that the accessories package or the accessories are damaged, do not use the accessories.

The recommended accessories, damageable parts list:

No.	Name	Specification/Model
1	Oxygen sensor	MOX-4
2	Mask	Adult/Pediatric
3	Manual breathing bag	Adult Pediatric（Optional）
4	Sodium lime	The absorptivity is no less than 25%
5	ISA CO_2	800101 (optional)
6	IRMA CO_2	200101 (optional)
7	ISA OR+（CO_2, N_2O, O_2, Anesthetic agents）	800401 (optional)
8	ISA AX+ （CO_2, N_2O, Anesthetic agents）	800601 (optional)
9	IRMA AX+ （CO_2, N_2O, Anesthetic agents）	200601 (optional)

⚠Caution：

- The accessories listed above are recommended by the Company, we have no responsibilities for the result if accessories of other specification are used.

Appendix A Working Principle

A.1 Electrical insulation diagram

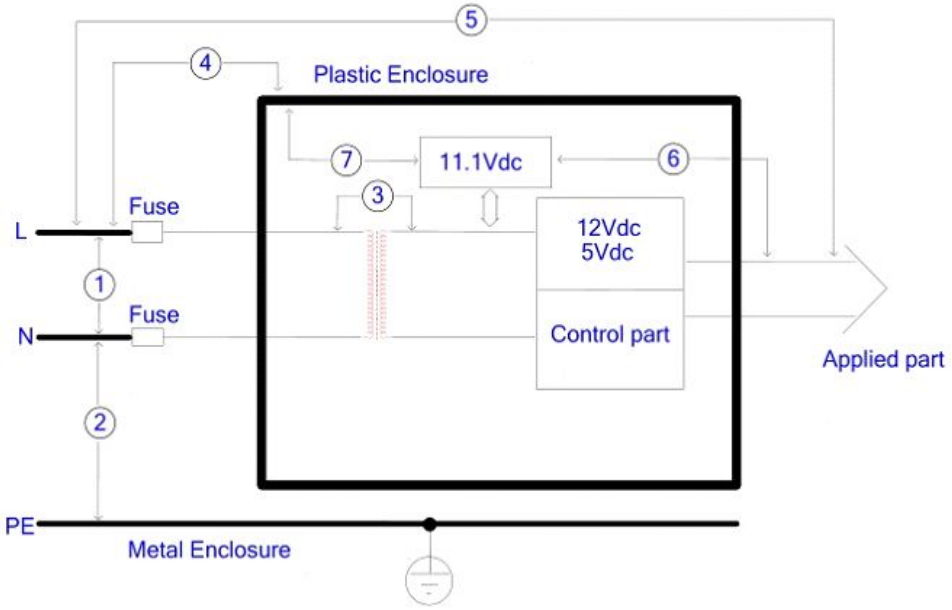


Figure A-1 Electrical insulation diagram

NO.	Isolation Name	Reference voltage	Creepage distance /mm	Electrical gap /mm	Test voltage/kV	Description
1	A-f/BI	240VAC	3.0	1.6	1500VAC	Between parts of opposite polarity of the Net power.
2	A-a1/BI	240VAC	4	2.5	1500 VAC	Between parts with electric and accessible metal parts which are protectively earthed
3	A-e/DI	240VAC	8	5	4000 VAC	Between the signal input/output part of the non-grounded protection and the non-signal input/output part
4	A-a2/DI	240VAC	8	5	4000 VAC	Between parts with electric and the non-grounded protection enclosure
5	B-a/DI	240VAC	8	5	4000 VAC	Net power-application part
6	B-a/DI	11.1VDC	3.4	1.6	500 VDC	Net power-application part
7	A-a2/DI	11.1VDC	3.4	1.6	500 VDC	Between internal power supply and the non-grounded protection enclosure

A.1 Vaporizer schematic diagram

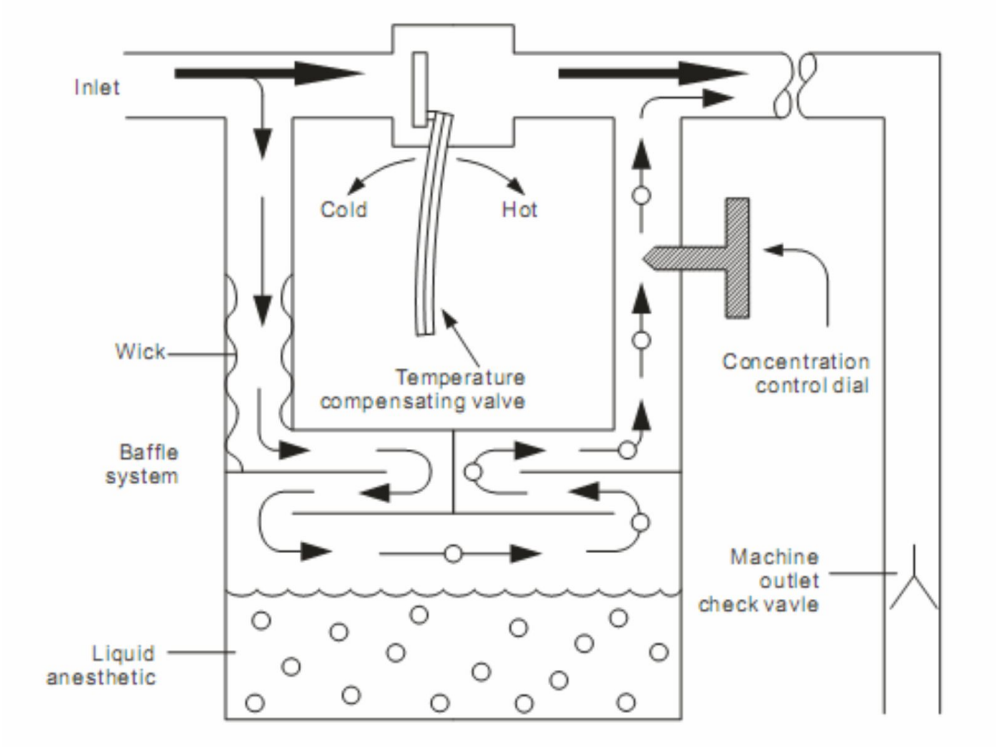


Figure A-2 Vaporizer schematic diagram

Appendix B Product specification

B.1 Safety specification

According to Turkey's State Standart Administration classification, this anesthesia machine is Class III device.

Electric shock protection type	Class Ⅰ, Containing the inner power supply If you have any doubt about the integrality of the external protective grounding or the protective grounding cable, the device must be replaced by: the internal power supply (batteries).	
Electric shock protection grade	Type B	
Working mode	Continuing working	
Explosion protection grade	Not providing the explosion protection (common device), do not use flammable anesthetic agents.	
Liquid protection grade	Not providing the liquid protection (common device) －IPX0（IEC 529）.	
The method of connecting the device with the patient	The connection between the device and the patient is non-electrical connection.	
Moving grade	Fixed devices: not including the anesthesia machine base and the truckle, including the fixed shelf; Mobile devices: including the anesthesia machine base and truckle.	
Disinfecting method	Use alcohol to clean the surface, some parts that contacted with the patient should be dipped in the ethylene oxide, and some parts can resist to the high temperature and high pressure steam and can be disinfected.	
Transportation	After packed according to the designed method, the anesthesia machine must meet the requirements of the test procedure 1A (requirements for containerized cargo)of the ISTA(International Safe Transit Association). The transporting carton must be marked with the allowable temperature、humidity and the altitude conditions of storage.	
Vibration test	frequency cycle range(Hz)	5~35~5
	amplitude value(mm)	0.35
	Frequency sweeping cycles frequency (time)	15
	frequency sweeping speed	≤1 octave/minute
	working state	Non-working state
Collision test	acceleration (m/s^2)	50
	pulse duration(ms)	11±2
	collision frequency (time)	1000±10
	pulse repetition frequency(Hz)	1.0~1.7

	pulse waveform	half sine wave
	working state	non-working state
Falling test	Meet the requirements of IEC 60601-1, clause:21.6 (rough handling)	
Spilled and the exudates	Meet the requirements of IEC 60601-1, clause: 44.3, and the requirements of the non-protective devices (IPX0) in IEC 529.	
Surface temperature	Meet the requirements of clause:42.1,42.2 and 42.3 in IEC 60601-1	
Mechanical stability	Meet the requirements of the clause 24.1 in IEC 60601-1.	
Incompatibility of the external connector	Meet the requirements of the clause 56.3 in IEC 60601-1 and FDA Reviewer Guidance for Premarket Notification Submission November1993，i2	
Shell stiffness and strength	Meet the requirements of clause: 21a, 16a and 21b in IEC 60601-1 Meet the requirements of clause 55 in UL 2601-1.	
Thermal conditions deteriorate	Meet the requirements of clause 52.5.5 in IEC 60601-1.	
Leakage current	Meet the requirements of clause 19 in IEC 60601-1/EN 60601-1	
Dielectric strength	Meet the requirements of clause 20 in IEC 60601-1/EN 60601-1	
Grounding impedance	Meet the requirements of Clause 18 in IEC 60601-1	
Protective earthing	Meet the requirements of Clause 58 in IEC 60601-1	

B.2 Environment specification

Climate environment division	II using in the general environment	
Mechanical environment division	II The devices that is allowed to general vibration and impact in use, generally refers to devices that are easy to move.	
Storage and transport environment	temperature	-20℃～+55℃
	humidity	≤93%, non-condensation
	atmospheric pressure	50 kPa～106 kPa
Operating environment	temperature	10℃～40℃
	humidity	≤80%, non-condensation
	atmospheric pressure	70 kPa～106 kPa

B.3 Power supply specification

Parameter	Specification
External AC power supply	
Input voltage	100～240 VAC
Input frequency	50/60Hz
Input power	10A
Auxiliary mains power	100～240 VAC, 50/60Hz, 2A×3
Internal battery	
Battery quantity	1
Rated battery voltage	11.1VDC
Battery capability	7800mAh
Shutdown delay	It can be used for at least 10 minutes after the first alarm for low power capability (using the new and fully charged battery).
The shortest supplying time	60 min (using the new and fully charged battery, the ambient temperature is 25ºC).
Charging time	The battery should be charged continuously for at least 10 hours for the first time, and about 5 hours in the future.

B.4 Gas supply specification

Parameters	Specification
Oxygen supply(O_2)	0.28MPa~0.6 MPa, dry and clean
Nitrous oxide supply(N_2O)	0.28MPa~0.6 MPa, dry and clean
Air supply	0.28MPa~0.6 MPa, dry and clean

B.5 System specification

Technical parameter	Specification
Host	
O2 flush flow	25～75L/min
Auxiliary oxygen supply	Non-pressure compensation, flow rate: 0 ～ 15L/min, Accuracy: ±200 mL/min or±10% of displayed value, whichever is greater
Pneumatic system safety pressure	Not above 12.5kPa
the noise of the whole device	≤65dB
The pressure resistance of the ventilation airway.	≥1200kPa
The leakage between the inlet and the flow controlling valve	≤25mL/min
The leakage between the flow controlling valve and the common gas outlet	Under the pressure of 3 kPa, the leakage is not more than 50 mL/min.
Breathing circuit leakage	Under the pressure of 3 kPa, the leakage is not more than 150 mL/min.
Inspiratory resistance of breathing circuit	Under the flow of 30 L/min, the resistance is not above 0.6 kPa
Expiratory resistance of breathing circuit	Under the flow of 30 L/min, the resistance is not above 0.6 kPa
The pressure generated by a dry non-return valve	≤0.15kPa
Driving mode	Pneumatic electronically control
Driving gas	Oxygen
Driving gas pressure	0.28～0.6 Mpa
Driving gas flow rate	≤120 L/min
Ventilation mode	PCV, VCV, SIMV(V)+PS, SIMV(P)+PS, PRVC, SPONT, Manual
Graph	Pressure-time, Flow-time, Volume-time, CO_2-time(optional), Pressure-volume loop, Flow-volume loop, Flow-pressure loop,SpO_2
Alarms	Inspiratory oxygen concentration, tidal volume, airway pressure, breathing frequency, minute ventilation, suffocation, negative pressure, continuous high pressure, end-inspiratory CO_2 concentration(optional), low battery capacity, battery failure, AC failure.
Alarm sound	>65dB (A)
System compliance	The losing gas volume caused by the system compliance (bag mode): adult mode≤3 mL/cmH_2O, Pediatric mode≤2 mL/cmH_2O
Breathing circuit assembly	Under the pressure of 3 kPa, The compliance (filled with fresh carbon dioxide absorbent recommended by the manufacturer) in bag mode is 0.87 mL/cmH_2O

compliance					
Breathing system typical pressure drop	Under the expiratory flow of 120 L, breathing system typical pressure drop is 20.8 cmH_2O, Under the inspiratory flow of 100 L, breathing system pressure drop is 78.1 cmH_2O.				
Every minute ventilation volume at maximum	≤18 L/min				
Flowmeter					
Three kinds of gas supplies	The oxygen, Nitrous oxide, air electrical flowmeter, 0.1～10L/min (20℃)				
Anesthetic vaporizer					
Two-station vaporizer mounting systems with interlock function. three anesthetic vaporizers can be selected :enflurane, isoflurane, sevoflurane					
Ambient temperature	Working: 15～35℃, storage: -20～50℃, transport（not exceed 7 days）: -40～60℃				
Capability	Maximum capability: 250 ml Minimum capability: 30 ml Remnants capability: 60±10 ml				
Back pressure	10～15kPa				
Flow rate	0.2～15L/min				
Test gas (recommendation)	Fresh gas				
Resistance(AIR, 22℃, Control position ”0”)	Flow rate(L/min):	1	2	4	8
	Resistance(cmH_2O):	1.8	3.4	8.0	20.3
Inversion or tipping	Do not tip or invert				
Effect of gas composition on output	Nitrous oxide: decrease by up to 15%, AIR: decrease by to below 5%.				
Pressure	Safety releasing pressure: 38 kPa Working pressure: 0～5kPa				
Scale	0～2% vol, 0.2% vol 2～max, 0.5% vol off status mark “0”.				

B.6 Specifications of parameters

B.6.1 Specification of setting parameter

Parameters	Pediatric	Adult	Step	Working mode	Control Accuracy
Tidal volume:VT	20～300mL	100～1500ml	20～100:5mL 100 ～ 1000: 10mL 1000 ～ 1500: 50mL	VCV SIMV(V)+PS	<100mL±20mL, ≥100mL±20mLor ±15% of the set value, whichever is greater
P_{insp}	5～70 cmH_2O	5～70 cmH_2O	1cmH_2O	PCV SIMV(P)+PS	±2cmH_2O or ±10% of the set value, whichever is greater
P_{limit}	5～100cmH_2O	5～100cmH_2O	1cmH_2O	VCV SIMV(V)+PS	
Freq	4～100 bpm	4～100 bpm	1 bpm	PCV, VCV	±2bpm or ±10% of the set value, whichever is greater
SIMV frequency	1～40 bpm	1～40 bpm	1bpm	SIMV(V)+PS SIMV(P)+PS	
I:E	4:1～1:10	4:1～1:10	0.5	PCV, VCV	±15% of the set value
PEEP	OFF, 4 ～ 30 cmH_2O	OFF, 4 ～ 30 cmH_2O	1cmH_2O	PCV, VCV	±2cmH_2O or ±10% of the set value, whichever is greater
P_{supp}	5～60 cmH_2O	5～60 cmH_2O	1cmH_2O	SIMV(V)+PS SIMV(P)+PS	
Inspiration pause	OFF, 5%～50%	OFF, 5% ～ 50%	5%	VCV	±10% of the set value
Inspiration time	0.1～10.0 s	0.1～10.0 s	0.1s	SIMV(V)+PS SIMV(P)+PS	±0.1s or ±5% of the set value, whichever is greater
F_{TRIG}	1～15 L/min	1～15 L/min	1 L/min	SIMV(V)+PS SIMV(P)+PS	±1L/min or ±15% of the set value, whichever is greater
SIGH	10~100	10~100	10	VCV SIMV(V)+PS SPONT	

B.6.2 Specification of monitoring parameter

Parameter	Range	Resolution	Control Accuracy
Inspiratory tidal volume	0～2500 mL	1mL	<100 mL±20 Ml, the other range±20 mL or ±15% of the set value, whichever is greater
Expiratory tidal volume	0～2500 mL	1mL	
Minute ventilation	0～60 L	0.1L	±1 L/min, or ±15% of the set value, whichever is greater
Spontaneous minute ventilation	0～60 L	0.1L	
Breathing frequency	0～100bpm	1bpm	±2bpm, or ±10% of the set value, whichever is greater
Spontaneous breathing Frequency	0～99 bpm	1bpm	
I:E	4:1～1:10	0.1	±15%
The average airway pressure	0～100cmH_2O	1cmH_2O	±2 cmH_2O, or ±10% of the set value, whichever is greater
PEEP	0～70cmH_2O	1cmH_2O	±2 cmH_2O or ±10%, whichever is greater
Inspiration platform pressure	0～100cmH_2O	1cmH_2O	±2 cmH_2O or ±10%, whichever is greater
Airway peek pressure	0～100 cmH_2O	1cmH_2O	±2 cmH_2O or ±10%, whichever is greater
Minimum airway pressure	0～100 cmH_2O	1cmH_2O	
Inspiratory oxygen concentration	21%～100%	1%	±3%（V/V）
Airway resistance	0～200cmH_2O/(L/S)	1 cmH_2O/(L/S)	<10 cmH_2O/(L/S)±2 cmH_2O/(L/S), the other ±20%
Compliance	0～200mL/cmH_2O	1mL/cmH_2O	<10 mL/cmH_2O ±2 mL/cmH_2O, the other ±20%
SPO_2(optional)	70～100%	1%	Absolute accuracy ±2%
PR(optional)	30～250bpm	1bpm	±2bpm
End-expiratory CO_2(optional)	0～99mmHg	1mmHg	< (0～40)mmHg±3mmHg, (41～99)mmHg ±5%
Inspiratory CO_2(optional)	0～99mmHg	1mmHg	

B.6.3 Specification of alarm parameters

Parameters	Range	Step	Control Accuracy
Upper-limit alarm of the airway pressure	1～100cmH2O	1 cm H_2O	±1 cmH_2O
Lower-limit alarm of the airway pressure	0～99cmH2O	1 cm H_2O	
Upper-limit alarm of the oxygen concentration	21～100%	1%	±1%
Lower-limit alarm of the oxygen concentration	OFF，21～99%	1%	
Upper-limit alarm of the tidal volume	30～1500mL，OFF	10mL	±10 mL
Lower-limit alarm of the tidal volume	20～1500mL		
Upper-limit alarm of the minute ventilation	1～40L，OFF	1L	±1L
Lower-limit alarm of the minute ventilation	0～40L	1L	
Upper-limit alarm of the breathing frequency	1～100 bpm	1 bpm	±1 bpm
Lower-limit alarm of the breathing frequency	0～99bpm	1 bpm	
Upper-limit alarm of the end-expiratory CO_2(optional)	1～99mmHg，OFF	1mmHg	±1 mmHg
Lower-limit alarm of the end-expiratory CO_2(optional)	0～99mmHg	1mmHg	
Suffocation alarm	10～40s	5s	±1 s or ±10% of the set value, whichever is greater
Lower-limit alarm of the SPO_2 (optional)	70～99%	1%	±2%
Continuous airway pressure	When the airway pressure is continuous above （PEEP+15） cmH_2O for 15 seconds, time: ±20%, pressure:±1 cmH2O		
Negative pressure alarm	When the airway pressure is less than（-10）cmH_2O, ±2 cmH_2O		
Oxygen supplying malfunction alarm	When the oxygen supplying pressure is less than 0.28Mpa, The alarm sound is no less than 60dB(A).		
The insufficient battery power	The battery working time is 10 minutes after alarm		
The exhausted battery power	The battery working time is 3 minutes after alarm		

B.7 Specification of hardware

Parameter	Specification
Complete unit	
Dimension	1450×1000×1330 mm （ H×W×D）
Weight(net weight)	About 108 kg
The maximum load capacity of the top shelf	34 kg（75lb）
Screen	
Type	Colour TFT LCD
Size	15 inch
Resolution	1024×768 Pixels
LED indication	
Alarm indicator light	one （yellow、red. If the high priority alarms and medium priority alarms happen at the same time, only the red light flashes.）
AC power indicator	One （the indicator light is green when connected to the AC power supply）
Battery indicator	One （green: the battery is full, Orange: the battery is below 80%）
Audio indication	
Speaker	Alarm sound, key tone, the alarm sound meets the requirements of IEC 60601-1-8:2003 standard.
Controlling	
Navigation wheel	One navigation wheel, it can be turned clockwise / anticlockwise and pressed down
Keys	Eight keys: Alarm Silence, Alarm Settings, Lock, Monitored values, Ventilation Settings, System Settings, System Log, Standby
Interface	
Power supply	One AC power interface and three assistant output power interface
Network	One Ethernet interface
Monitor	One standard color VGA monitor interface, 15-PIN D-sub jacks.
Equipotential	One equipotential grounding terminal
RS232 interface	Two
Mobile devices	
Trolleys	Four trolleys, diameter:12.5 cm
Brake	
Braking board	On the two front truckles, with the function of braking when trodden.
Toolbox	
Drawer	298×348×150 mm （Width×Depth ×Height）
Breathing system	
Bellows capacity	About 1500 mL
Canister capacity	1.5L（About 1.3kg）
Connections	Inspiratory/ACGO port: standard outside diameter 22 mm, inner diameter

	15mm, cone-shaped connector; expiratory port: standard outside diameter 22 mm, inner diameter 15mm, cone-shaped connector; manual breathing bag: outside diameter 22 mm.
Absorber leakage	The absorber pressure under 3 kPa, then the leakage is not more than 50 mL/min
Respiration system resistance	Inspiratory impedance：not more than 0.6 kPa ; expiratory impedance：not more than 0.6 kPa
Real time clock	
Range	Year 2000（00:00:00）～2099（23:59:59）
Accuracy	±1 minute/month（condition: 21±3°）
Display resolution	One second
Power supply	Independent power supply

B.8 MASIMO CO_2 analyzer（optional）

B.8.1 MASIMO ISA CO_2 analyzer

Parameter	Specification	
Measuring mode	sidestream	
Operation temperature	0 to 50 ºC	
Storage temperature	-40 to 70 ºC	
Operation atmospheric pressure	52.5 to 120kPa (corresponding to a max altitude of 4572 m/ 15000 feet)	
measuring range and accuracy	Measuring range	Accuracy
	0 to 15 vol%	±2 (0.2 vol%+2% of reading)
	15 to 25 vol%	unspecified
Total system response time	＜3 seconds (with 2 m sampling line)	

B.8.2 MASIMO IRMA CO2 module（optional）

parameter	specification	
Measuring mode	Mainstream	
Operation temperature	0-40℃/ 32-104 ℉	
Storage and transportation temperature	-40-75℃/ -40-167 ℉	
Operating humidity	10-95% RH， non-condensing	
Storage and transportation humidity	5-100 % RH，condensing	
Operation atmospheric pressure	525-1200 hPa (525hPa corresponding to an altitude of 4572 m/15000 feet)	
Storage and transportation pressure	500 to1200 hPa	
Total system response time	＜1 second	
Accuracy specifications(during standard conditions）	Range	accuracy
	0～15	± （0.2 vol%+ 2%of reading）
	15～25	unspecified
Accuracy specifications （during all conditions）	± （0.3 vol%+ 4% of reading）	

B.9 MASIMO ISA analyzer（optional）

B.9.1 General Specifications

parameters	specification			
Using environment		Operating	Storage	
	temperature	5 to 50℃ (41 to 122 ℉)	-40 to 70℃(-40 to 158℉)	
	humidity	<4 Kpa H_2O (non-condensing) (95% RH at 30℃)	5 to 100%RH(condensing) (100% RH at 40℃)	
	Operating atmospheric pressure	52.5 to 120kPa (corresponding to a max altitude of 4572 m/ 15000 feet)	20 to 120kPa	
Sampling lines	2±0.1 m and 3±0.1 m versions			
Sampling flow rate	50±10 ml/min			
Power supply	4.5 to 5.5 VDC, <2.0W(normal op.), <2.4W(Peak@5 VDC)			
Interface	USB or RS-232 serial interface. Software upgrade possible using the RS-232 serial interface.			
Warm-up time	<20 seconds(Concentrations reported, automatic agent identification enabled and full accuracy)			
Typical rise time at 50 ml/min sample flow	CO_2 ≤250 ms N_2O ≤350 ms Agents ≤350 ms O_2≤ 450ms			
Primary agent threshold	0.15 vol%. When an agent is identified, concentration will be reported even below 0.15 vol%			
Secondary agent threshold	0.2 vol% + 10% of total agent concentration			
Agent identification time	<20 seconds(typically<10 seconds)			
Total system response time	<3 seconds(with 2 m sampling line)			
Accuracy-standard conditions (the accuracy specifications are valid for single gases at 22±5℃ and 1013±40 hPa)	**Gas**	**Range**	**Accuracy**	
	CO_2	0 to 15 vol%	±(0.2 vol%+2% of reading)	
		15 to 25 vol%	unspecified	
	N_2O	0 to 100 vol%	±(0.2 vol%+2% of reading)	

	HAL,ENF,ISO	0 to 8vol%	±(0.15 vol%+5% of reading)
		8 to 25 vol%	unspecified
	SEV	0 to 10 vol%	±(0.15 vol%+5% of reading)
		10 to 25 vol%	unspecified
	DES	0 to 22 vol%	±(0.15 vol%+5% of reading)
		22 to 25 vol%	unspecified
	O_2	0 to 100 vol%	±(1 vol%+2% of reading)

Accuracy – all conditions (the accuracy specifications are valid for all specified environmental conditions)	**Gas**	**Accuracy**
	CO_2	±(0.3 kPa+4% of reading)
	N_2O	±(2 kPa+5% of reading)
	Agents	±(0.2 kPa+10% of reading)
	O_2	±(2kPa+2% of reading)

Note：

4) The accuracy specification is not valid if more than one anesthetic agent is present in the gas mixture. If more than two anesthetic agents are present, there will be an alarm.

B.9.2 Interfering gas and vapor effect

Gas or vapor	Gas level	CO_2		Agent	N_2O
		ISA CO_2	ISA AX+		
N_2O [4]	60 vol%	–[2]	–[1]	–[1]	–[1]
HAL[4]	4 vol%	–[1]	–[1]	–[1]	–[1]
ENF, ISO, SEV[4]	5 vol%	+8% of reading[3]	–[1]	–[1]	–[1]
Xe (Xenon) [4]	80 vol%	-10% of reading[3]		–[1]	–[1]
He(Helium) [4]	50 vol%	-6% of reading[3]		–[1]	–[1]
Metered dose inhaler propellants[4]	Not for use with metered dose inhaler propellants				
C_2H_5OH (Ethanol) [4]	0.3 vol%	–[1]		–[1]	–[1]
C_3H_7OH (Isopropanol) [4]	0.5 vol%	–[1]		–[1]	–[1]
CH_3COCH_3(Acetone) [4]	1 vol%	–[1]		–[1]	–[1]
CH_4 (Methane) [4]	3 vol%	–[1]		–[1]	–[1]
CO(Carbon monoxide)[5]	1 vol%	–[1]		–[1]	–[1]
NO(Nitrogen monoxide) [5]	0.02 vol%	–[1]		–[1]	–[1]
O_2[5]	100 vol%	–[2]		–[2]	–[1]

Note 1: Negligible interference, effect included in the specification “Accuracy, all conditions” above.

Note 2: Negligible interference with N_2O/O_2 concentrations correctly set, effect included in the specification “Accuracy, all conditions” above.

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO_2 and 50 vol% Helium, the actual measured CO_2 concentration will typically be (1-0.06)*5.0 vol%=4.7 vol% CO_2

Note 4: According to the EN ISO 21647:2004 standard.

Note 5: In addition to the EN ISO 21647:2004 standard.

B.9.3 MAC (Minimum Alveolar Concentration) calculation

Minimum alveolar concentration (MAC) is a standard for comparing the potency of inhalation anesthetics. The MAC value represents the alveolar concentration of an anesthetic (at one atmosphere) that, in 50 percent of a tested population, prevents gross muscular movement in response to a painful, standardized stimulus.

If a mechanism to determine MAC values is implemented in the host device, the algorithms used for this calculation must be adequately documented.

The MAC value may be calculated and displayed by using end-tidal(Et)gas concentrations according to the following formula:

$$MAC = \frac{\%Et(AA1)}{X(AA1)} + \frac{\%Et(AA2)}{X(AA2)} + \frac{\%Et(N2O)}{100}$$

X(AA): HAL=0.75%, ENF=1.7%, ISO=1.15%, SEV=2.05%,DES=6.0%.

Note：

5) Altitude, patient age and other individual factors are not considered in the formula above.

B.9.4 Electromagnetic compatibility (EMC)

Electromagnetic emission

This section constitutes the guidance and MASIMO's declaration regarding electromagnetic emissions for the ISA gas analyzers.

Isa gas analyzers are intended for use in the electromagnetic environment specified in the table below. Customers can end users of ISA gas analyzers should assure that they are used in such an environment.

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The ISA sensor uses RF energy only for its internal function. Therefore, Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CLSPR 11	Class B	The ISA sensor is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	

Electromagnetic immunity

This section constitutes the guidance and MASIMO's declaration regarding electromagnetic immunity for the ISA gas analyzers.

Isa gas analyzers are intended for use in the electromagnetic environment specified below. Customers or end users of ISA gas analyzers should assure that they are used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	AC power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	N/A	AC power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	＜5% U_T[1] (＞ 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles ＜5% U_T (＞ 95% dip in U_T) for 5 Sec	N/A	The power supply quality should be the same as in a typical commercial or hospital environment. If the user of the ISA sensor requires continued operation during power outages, the ISA sensor should be powered by an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical

field IEC 61000-4-8			location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz to 80 MHz 3 Vrms 80 MHz to 2.5 GHz	10 Vrms 20 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ISA sensor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** d=0.35 $\sqrt{P}$ d=0.18 $\sqrt{P}$ 80MHz to 800 MHz d=0.35 $\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] interference may occur in the vicinity of equipment marked with the following symbol. 

Note1： At 80 MHz and 800 MHz, the higher frequency range applies.

Note2: These guideline may not apply in all situations. Electromagnetic propagation is

affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio(cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which ISA is used exceeds the applicable RF compliance level above, ISA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating ISA.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Separation distance to RF communications equipment

In this section the recommended separation distances between portable and mobile RF communications equipment and the ISA gas analyzers are specified.

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

Rated maximum output power of transmitter[W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d=0.35\sqrt{P}$	80 MHz to 800 MHz $d=0.18\sqrt{P}$	800 MHz to 2.5 GHz $d=0.34\sqrt{P}$
0.01	0.035	0.018	0.035
0.1	0.11	0.057	0.11
1	0.35	018	0.35
10	1.1	0.57	1.1
100	3.5	1.8	3.5

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

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

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

⚠Warning

6) Measurements can be affected by mobile and RF communications equipment. Make sure that the ISA gas analyzer is used in the electromagnetic environment specified in this manual.

B.10 MASIMO IRMA multi-gas analyzers（optional）

B.10.1 General Specifications

<table>
<tr><th>parameters</th><th colspan="4">specification</th></tr>
<tr><td rowspan="4">Using environment</td><td></td><td>Operating</td><td colspan="2">Storage</td></tr>
<tr><td>Temperature</td><td>10 to 40℃ (50 to 104 ℉)</td><td colspan="2">-20 to 75℃(-4 to 167℉)</td></tr>
<tr><td>Humidity</td><td>10-95% RH， non-condensing</td><td colspan="2">5-100%， condensing</td></tr>
<tr><td>Operating atmospheric pressure</td><td>525-1200 hPa (corresponding to an altitude of 4572 m/ 15000 feet)</td><td colspan="2">500-1200 hPa</td></tr>
<tr><td>Power supply</td><td colspan="4">4.5~ 5.5 VDC, max1.4W(power on surge @ 5 V less than 350mA during 200 ms)</td></tr>
<tr><td>Interface</td><td colspan="4">Modified RS-232serial interface operating at 9600 bps</td></tr>
<tr><td>Automatic agent identification</td><td colspan="4">Primary and secondary agent.</td></tr>
<tr><td>Warm-up time</td><td colspan="4"><20 sec (concentrations are reported and the automatic agent identification is running within 20 seconds).</td></tr>
<tr><td>Primary agent threshold</td><td colspan="4">0.15 vol%. when an agent is identified, concentrations</td></tr>
<tr><td>Secondary agent threshold</td><td colspan="4">0.2 vol% + 10% of total agent concentration</td></tr>
<tr><td>Agent identification time</td><td colspan="4"><20 seconds(Typically＜10 seconds)</td></tr>
<tr><td>Total system response time</td><td colspan="4"><1 second</td></tr>
<tr><td rowspan="8">Accuracy specifications （during standard conditions）</td><td>Gas</td><td colspan="2">Range</td><td>Accuracy</td></tr>
<tr><td rowspan="3">CO_2</td><td colspan="2">0 ~ 10</td><td>±(0.2 vol%+ 2% of reading)</td></tr>
<tr><td colspan="2">10 ~ 15</td><td>±(0.3 vol%+ 2% of reading)</td></tr>
<tr><td colspan="2">15 ~ 25</td><td>Unspecified</td></tr>
<tr><td>N_2O</td><td colspan="2">0 ~ 10</td><td>±(0.2 vol%+ 2% of reading)</td></tr>
<tr><td rowspan="2">HAL,ENF,ISO</td><td colspan="2">0 ~ 8</td><td>±(0.15 vol%+ 5% of reading)</td></tr>
<tr><td colspan="2">8 ~ 25</td><td>Unspecified</td></tr>
<tr><td rowspan="2">SEV</td><td colspan="2">0 ~ 10</td><td>±(0.15 vol%+ 5% of reading)</td></tr>
<tr><td colspan="2">10 ~ 25</td><td>Unspecified</td></tr>
</table>

	DES	0 ~ 22	±(0.15 vol%+5% of reading)
		22 ~ 25	Unspecified
	O_2	0 ~ 100	±(1vol%+ 2% of reading)

Accuracy （during all conditions）	**Gas**	**Accuracy**
	CO_2	±(0.3 vol%+ 4% of reading)
	N_2O	±(2 vol%+ 5% of reading)
	Agents	±(0.2 vol%+ 10% of reading)
	O_2	±(2vol%+ 2% of reading)

B.10.2 Interfering gas and vapour effect

Gas or vapor	**Gas level**	**CO_2**		**Agent**	**N_2O**
		IRMA CO_2	**IRMA AX+/OR+**		
N_2O [4)]	60 vol%	_[1&2)]	_[1&2)]	_[1)]	_[1)]
HAL[4)]	4 vol%	_[1)]	_[1)]	_[1)]	_[1)]
ENF, ISO, SEV[4)]	5 vol%	+8% of reading[3)]	_[1)]	_[1)]	_[1)]
Xe (Xenon) [4)]	80 vol%	-10% of reading[3)]		_[1)]	_[1)]
He(Helium) [4)]	50 vol%	-6% of reading[3)]		_[1)]	_[1)]
Metered dose inhaler propellants[4)]	Not for use with metered dose inhaler propellants				
C_2H_5OH (Ethanol) [4)]	0.3 vol%	_[1)]		_[1)]	_[1)]
C_3H_7OH (Isopropanol) [4)]	0.5 vol%	_[1)]		_[1)]	_[1)]
CH_3COCH_3(Acetone) [4)]	1 vol%	_[1)]		_[1)]	_[1)]
CH_4 (Methane) [4)]	3 vol%	_[1)]		_[1)]	_[1)]
CO(Carbon monoxide)[5)]	1 vol%	_[1)]		_[1)]	_[1)]
NO(Nitrogen monoxide) [5)]	0.02 vol%	_[1)]		_[1)]	_[1)]
O_2[5)]	100 vol%	_[2)]		_[2)]	_[1)]

Note 1: Negligible interference, effect included in the specification “Accuracy, all conditions” above.

Note 2: For probes not measuring N2O and / or O2 the concentrations shall be set from host according to the instructions in section ***5.14 System setting*** (SetN_2O/SetO_2)

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO_2 and 50 vol% Helium, the actual measured CO_2 concentration will typically be (1-0.06)*5.0 vol%=4.7 vol% CO_2

Note 4: According to the EN ISO 21647:2004 standard.

Note 5: In addition to the EN ISO 21647:2004 standard.

B.10.3 Electromagnetic compatibility (EMC)

Electromagnetic emission

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

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The IRMA probe uses RF energy only for its internal function. Therefore, Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CLSPR 11	Class B	The IRMA probe is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	

Electromagnetic immunity

The IRMA probe is intended for use in the electromagnetic environment specified below. Customers or end users of ISA gas analyzers should assure that they are used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	AC power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	N/A	AC power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	＜5% U_T[1] (＞ 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles ＜5% U_T (＞ 95% dip in U_T) for 5 Sec	N/A	The power supply quality should be the same as in a typical commercial or hospital environment. If the user of the IRMA probe requires continued operation during power outages, the IRMA probe should be powered by an uninterruptible power supply or a battery.
Power frequency	3 A/m	3 A/m	Power frequency magnetic fields should

(50/60Hz) magnetic field IEC 61000-4-8			be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150kHz to 80 MHz 3 Vrms 80 MHz to 2.5 GHz	10 Vrms 20 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the IRMA probe, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** d=0.35 $\sqrt{P}$ d=0.18 $\sqrt{P}$ 80MHz to 800 MHz d=0.35 $\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] interference may occur in the vicinity of equipment marked with the following symbol. 

Note1： At 80 MHz and 800 MHz, the higher frequency range applies.

Note2: These guideline may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio(cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which ISA is used exceeds the applicable RF compliance level above, ISA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the IRMA probe.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Separation distance to RF communications equipment

In this section the recommended separation distances between portable and mobile RF communications equipment and the IRMA probe are specified.

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

Rated maximum output power of transmitter[W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d=0.35\sqrt{P}$	80 MHz to 800 MHz $d=0.18\sqrt{P}$	800 MHz to 2.5 GHz $d=0.34\sqrt{P}$
0.01	0.035	0.018	0.035
0.1	0.11	0.057	0.11
1	0.35	018	0.35

10	1.1	0.57	1.1
100	3.5	1.8	3.5

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

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

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

⚠Warning:

7) Measurements can be affected by mobile and RF communications equipment. Make sure that the IRMA probe is used in the electromagnetic environment specified in this manual.

Appendix C EMC

⚠ Cautions:

- Okuman 620 anesthesia machine should meet the requirement of electromagnetic compatibility in IEC60601-2-13.
- The user needs to install and use according to electromagnetism compatibility information which is attached with it.
- Portable and mobile RF communication devices may influence Okuman 620 anesthesia machine's performance, so it should be kept away from them during using.
- Please refer to the below section of guidance of electromagnetism compatibility and manufacturer's declaration.

⚠Warnings:

- Okuman 620 anesthesia machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, it should be observed to verify normal operation in the configuration in which it will be used.
- Type A equipment is intended for use in the industrial environment, due to the conduction and radiation disturbance of the Okuman 620 anesthesia machine. it is difficult to ensure the electromagnetic compatibility while using in other environments.

Guidance and manufacturer's declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">Okuman 620 anesthesia machine is intended for use in the electromagnetic environment specified below. The customer or the user of Okuman 620 anesthesia machine should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>Okuman 620 anesthesia machine uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">Okuma 620 anesthesia machine is suitable for use in all establishments including non-domestic and those not-directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
Okuman 620 anesthesia machine is intended for use in the electromagnetic environment specified below. The customer or the user of the Okuman 620 anesthesia machine should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles	< 5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Okuman 700 anesthesia

IEC 61000-4-11	70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec	70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec	machine requires continued operation during power mains interruptions, it is recommended that the Okuman 620 anesthsia machine be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer´s declaration – electromagnetic immunity			
Okuman 620 anesthesia machine is intended for use in the electromagnetic environment specified below. The customer or the user of the Okuman 620 anesthesia machine should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz Outside ISM band[a] 10 Vrms 150 kHz to 80 MHz In ISM band[a] 10 V/m 80 MHz to 2.5 GHz	3 Vrms 10 Vrms 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Okuman 620 anesthesia machine, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** *d* = $1.2\sqrt{P}$ *d* = $1.2\sqrt{P}$ 80 MHz to 800 MHz *d* = $2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF

			transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 :These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Okuman 620 anesthesia machine is used exceeds the applicable RF compliance level above, the Okuman 620 anesthesia machine should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Okuman 620 anesthesia machine.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Okuman 620 anesthesia machine

Okuman 620 anesthesia machine is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Okuman 620 anesthesia machine can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Okuman 620 anesthesia machine as recommended below, according to the maximum output power of the communications equipment

Rated maximum output of transmitter /W	**Separation distance according to frequency of transmitter/m**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix D Alarm and Troubleshooting

This chapter lists some of the most important parameters and technical alarm information; some information may not be listed.

Note that in this chapter:

- The “L” is the default alarm level: H for the high priority; M for the medium; L for the low;
- For each of the alarm information, there lists the corresponding solutions. If the problem persists after operated in accordance with the solutions, please contact the maintenance man.

Alarm information	L	Reasons and solution
Tidal Volume High	M	The expiratory tidal volume exceeds the upper limit of the alarm settings. Decrease the set tidal volume or increase the alarm upper limit
Low tidal volume	M	The expiratory tidal volume is less than the lower limit of the alarm settings. Increase the set tidal volume or decrease the alarm lower limit.
High minute ventilation	M	The minute ventilation volume exceeds the upper limit of the alarm settings. Decrease the set tidal volume or the respiratory frequency or increase the alarm upper limit.
Low minute ventilation	M	The minute ventilation volume is less than the lower limit of the alarm settings. Increase the set tidal volume or the respiratory frequency or decrease the alarm lower limit.
High breathing frequency	L	The ventilation frequency exceeds the upper limit of the alarm settings. Decrease the set respiratory frequency or increase the alarm upper limit.
Low breathing frequency	L	The ventilation frequency is less than the lower limit of the alarm settings. Decrease the set respiratory frequency or decrease the alarm lower limit.
High inspiratory oxygen concentration	M	The FiO_2 exceeds the upper limit of the alarm settings. Decrease the oxygen volume of the fresh gas or increase the alarm upper limit.
Low inspiratory oxygen concentration	H	The FiO_2 is less than the lower limit of the alarm settings. Increase the oxygen volume of the fresh gas or decrease the alarm lower limit.
High airway pressure	H	The airway peek pressure exceeds the upper limit of the alarm settings. Check if the ventilation pipeline bent or plugged up, if the pipeline

		connection is normal, the inspiratory pressure or the tidal volume should be decreased or increase the alarm upper limit.
Low airway pressure	H	The airway pressure (pressure waveform data) is less than the lower limit of the alarm settings. Check if the ventilation pipeline leak or fall off, if the pipeline connection is normal, the inspiratory pressure or the tidal volume should be increase or decrease the alarm lower limit.
High end-expiratory CO_2	M	The measuring value is more or less than the upper or lower limit of the alarm settings. Check the patient's physical conditions、 make sure if the patient type and the set alarm limit applicable to the patient.
Low end-expiratory CO_2	M	
Pressure limit	M	The peak pressure exceeds the pressure limit. Decrease the peak pressure or increase the alarm upper limit
continuous high airway pressure	H	The patient absorber airway pressure has been above the （PEEP+15）cmH2O more than 15 seconds. Check if the pipeline bent, plugged up or disconnected.
Negative pressure alarm	H	Lower than the atmospheric pressure 10cmH_2O. Check if the patient is breathing spontaneously. Increase the fresh gas flow. Observe whether there is high speed flow passing through the residual gas purging system. If there is, check the negative pressure-relief valve on the receiver.
Suffocation	H	In the Settings Tapnea time, no mechanical ventilation and manual breathing; Increase the settings of the tidal volume and respiratory frequency or begin manual ventilation.
O_2 supply pressure is low	H	The oxygen source pressure is lower than 0.28Mpa or oxygen failure. Use the backup cylinder immediately.
O_2 supply pressure is high	M	The oxygen source pressure is higher than 0.6Mpa. Adjust the pressure to the appropriate pressure range.
Low battery power	M	The battery power is low. The system is operable, connect it to the AC power at once. If the power supply is cutoff, please use manual ventilation to support the patient breath. If the batteries can not be charged fully within 24 hours, please contact the specified maintenance man.
Exhausted battery power	H	The battery power is too low, and the system will shut off within three minutes. Please connect it to the AC power at once. If the power supply is cutoff, please use manual ventilation to support patient breath. If the batteries can not be charged fully within 24 hours, please contact the specified maintenance man.

AC Power Failure!!	M	Please check the AC Power.
Battery Failure	M	Battery unconnected. Check and connect the battery.
O_2 sensor disconnection or failure	M	O_2 sensor unconnected. Check and connect the O_2 sensor wire.
Absorber Is Not Installed	H	Absorber is not mounted. Check and installed the absorber.
O_2 flush overtime	H	The time of pressing O_2 flush button is higher than 15S. please release the O_2 flush button.
No gas in bellow	M	The driving gas pressure is too low. Please check and ensure the pressure normal.
Set value of flowmeter is too big	H	The flow of the flowmeter is higher than VT/Ti value. Please adjust the flowmeter knob to decrease the flow value.
Inspiration valve error	H	Inspiration valve unconnected or failure. Check and connect it.
Expiration valve error	H	Expiration valve unconnected or failure. Check and connect it.
Inspiration pressure sensor failure	H	Inspiration pressure sensor is invalid. Please calibrate or replace.
Expiration pressure sensor failure	H	Expiration pressure sensor is invalid. Please calibrate or replace.
5V power error	H	5V voltage error. Please contact the after service dept. of the company.
10V power error	H	10V voltage error. Please contact the after service dept. of the company.
12V power error	H	12V voltage error. Please contact the after service dept. of the company.
-12V power error	H	-12V voltage error. Please contact the after service dept. of the company.

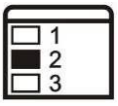
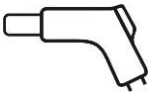
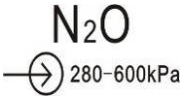
Appendix E Symbol and glossary

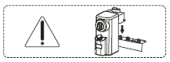
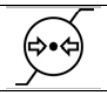
E.1 Glossary

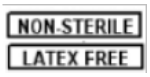
Abbreviation	Define
AA	Anesthetic agent
AGSS	Anesthesia Gas Scavenging System
ACGO	Auxiliary Common Gas Outlet
APL	Adjustable pressure-limiting valve
ENF	Enflurane
ISO	Isoflurane
SEV	Sevoflurane
BPM	Breaths per minute
BTPS	body temperature and pressure，Saturated
ATPD	Ambient temperature and pressure
Manual	Manual ventilation
PCV	Pressure control ventilation
SIMV	Synchronized intermittent mandatory ventilation
VCV	Volume control ventilation
SPONT	Spontaneous ventilation mode
PRVC	Pressure Regulated Volume Control
N_2O	N_2O
O_2	Oxygen
C	Compliance （Cdyn）
Paw	Airway pressure
T_I	Inspiratory time
PEEP	Positive end-expiratory pressure
P_{insp}	Pressure control level of inspiration
P_{mean}	Mean airway pressure
P_{peak}	Peak pressure
P_{plat}	Plateau pressure
P_{min}	Minimum pressure
P_{limit}	Limit pressure

P_{rate}	Slope
Freq	Frequency
$InCO_2$	Inspiratory CO_2
$EtCO_2$	End-Tidal CO_2
P_{supp}	Pressure support level
R	Resistance
FiO_2	Fractional concentration of O_2 in inspired gas
T_{IP}:T_I	Percentage of inspiratory plateau time in inspiratory time
V_T	Tidal volume
I:E	Inspiratory time: Expiratory time ratio
MV	Minute ventilation
PR	Pulse Rate
MV_{spn}	Spontaneously breathed minute volume
V_{TE}	Expired tidal volume
V_{TI}	Inspired tidal volume
T-Flow	Total Flow
MAC	Minimum Alveolar Concentration
CON	indicate the module is connected
DISC	indicate the module is not connected or disconnected
BTPS	Body Temperature and Pressure Saturated

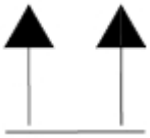
E.2 Equipment symbol

	Consult instructions for use		Year of manufacture
	Manufacturer		High pressure warning
	Alternating current		Fuse
	Battery		Equipotential pole
	System settings		Alarm settings
	Alarm Silence		Debug serial port
	The device is switched on		The device is switched off
	Ventilation settings		Start / Standby
	Alarm silence		Oxygen flush button
	Manual ventilation		Manual bag
	Lock		Unlock
	Monitor interface		pipeline
	Network interface		Flowmeter knob
	Light		Oxygen sensor interface
	Flowmeter backlight		N_2O supply connector

VGA/OUT	**VGA** interface	AIR 280-600kPa	Air supply connector
	Mouse interface	O_2 280-600kPa	O_2 supply connector
	Cylinder		Earthing
O_2 15MPa MAX	The maximum pressure at the oxygen cylinder inlet	N_2O 15MPa MAX	The maximum pressure at the N_2O cylinder inlet
	CO_2 canister		The maximum load capacity of the monitor arm
	Vaporizer		The maximum load capacity of the information system
N_2O	N_2O cylinder manometer	O_2	Oxygen cylinder manometer
	mechanical ventilation		**AGSS** vent
	TYPE B equipment	Class Ⅰ	Class Ⅰ equipment
	Consult instructions for use	EC REP	Authorised representative in the EUROPEAN COMMUNITY
	Consult instructions for use of ISA	SN	Serial number
LOT	Batch code		Use by date[YYYY-MM-DD] The device should not be taken into operation after the date accompanying the symbol
	Temperature limitation		Pressure limitation

	Humidity limitation		Do not re-use
	Waste Electrical and Electronic Equipment(WEEE)		CE mark
	Non-sterile, Latex free		Rx only
	ISA equipped to measure CO_2 only		ISA equipped to measure multiple gases
	Sigma Multigas Technology		Connection to patient circuit
	Connection to ISA		Proper disposal of products

E.3 Packing symbol

	THIS WAY UP		FRAGILE
	KEEP AWAY FROM RAIN		DO NOT STACK
	DO NOT ROLL		KEEP AWAY FROM SUNLIGHT

Caution:

- Due to the different configuration, some symbols may be not entirely consistent to the equipment, please take the equipment as valid.

Appendix F Default setting

This chapter lists some of the most important default settings of the anesthesia machine. Users can not change the factory settings, but can reset the anesthesia machine to the default settings when necessary.

F.1 Patient information

Patient information	Factory default setting	
Patient category	Adult	Pediatric
Weight	65kg	7.5 kg
Year	40	1

F.2 Default parameter

Factory default setting		
Patient category	Adult	Pediatric
Respiratory parameter settings		
Tidal volume V_T（mL）	460	50
Breathing frequency f（bpm）	12	30
Inspiratory pause TIP:TI(%)	OFF	OFF
I:E	1:2.0	1:2.0
T_I（S）	1.7	0.7
PEEP（cmH_2O）	OFF	OFF
Pressure limit P_{limit}（cmH_2O）	40	30
Pressure controlling level P_{insp}（cmH_2O）	PEEP+20	PEEP+15
Pressure supporting level P_{supp}（cmH_2O）	PEEP+20	PEEP+15

F.3 Alarm default setting

Alarm default setting	
Tidal volume (mL)	Upper limit: OFF, lower limit: 30
Minute ventilation volume (L)	Upper limit:20, Lower limit:3
Respiratory frequency (bpm)	Upper limit: 40, Lower limit: 0
Inspiratory oxygen concentration (%)	Upper limit: OFF, Lower limit: 21
Airway pressure (cmH_2O)	Upper limit: 40, Lower limit: 0
End expiratory CO_2 (mmHg)	Upper limit: 60, Lower limit: 30
Continuous airway pressure (cmH_2O)	The airway pressure is >（PEEP+15）cmH_2O for 15 seconds.
Suffocation (s)	Upper limit: 20

Appendix G Reference

EN 60601-1/IEC60601-1 Medical electrical equipment Part I: General requirements for safety

IEC 60601-1-2:2004 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility- Requirements and tests

IEC 60601-2-13:2003 Medical electrical equipment Part 2: Particular requirements for the safety and essential performance of anesthetic systems

ISO 8835-2:1999,Inhalational anaesthesia systems – Part 1:Anaesthetic breathing system for adults

ISO 8835-3:1997 Inhalational anaesthesia systems – Part 2: Anaesthetic gas scavenging systems transfer and receiving systems

ISO 8835-4:2004 Inhalational anaesthetic systems- Part 3: Anesthetic vapour delivery devices

ISO 15223-1:2007,Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

ISO 21647:2004, Medical electrical equipment – Particular requirements for basic safety and essential performance of respiratory gas monitors

EN 740 Anesthetic workstations and their modules - Particular requirements

IEC 60601-1-8:2003, IDT Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems