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Shenzhen Comen Medical Instruments Co., Ltd.

Product Information

Product Name: Anesthesia Machine

Models: AX-900, AX-900A

Software Version: V5

CE information：CE 1639

Address: Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China

Statement

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Edition number of the User's Manual is subject to upgrading without prior notice due to any changes in software, technical specification or other causes.

The User's Manual is only applicable to the anesthesia machines AX-900 and AX-900A manufactured by the Comen Company.

Warranty

Comen Company will be responsible for the safety, reliability and performance of its products on the conditions that the following restrictions are complied with:

- The products are operated as per the User's Manual;
- The products are installed, maintained and upgraded by personnel approved or authorized by Comen company.
- Storage environment, working environment and electrical environment of the products conform to the product specifications;
- The product serial number label or indication of manufacture is clear and legible so that Comen

may identify that the products are authentically manufactured by Comen Company;

- The damages are not caused by human factors (such as dropout by accident, deliberate damage etc.);

Comen Company will provide free services for all products satisfying the Comen's warranty conditions. Comen may charge service fees for any services not within the product's warranty. User has to bear all transportation cost (including custom's duties) for sending the products to Comen.

⚠Caution

- **This equipment must not be operated at home.**

⚠Warning

- **It is not a medical treatment device.**

Return the product

If the product is really necessary to be returned, please follow the steps given below:

Acquire the right of return: Contact the After-sale Service Department of Comen company and inform the personal of the serial number of Comen instrument. The serial number can be found on the name plate. If serial number of the equipment is not clear and legible, returning may not be accepted. Furthermore, please indicate the serial number and date of production of the equipment, and describe briefly the reason for returning.

After-sales Service

Provider: After-sales Service Department, Shenzhen Comen Medical Instruments Co., Ltd.

Address:Floor 10 of Building 1A , FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, 518106, Guangdong, China

Tel: +86 755 26431236

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Preface

This User's Manual describes the performance, operating procedures and other safety messages of anesthesia machines AX-900 and AX-900A manufactured by the Company. The manual offers the best starting point for a new user to begin operating the anesthesia machines.

Structure and Composition

The anesthesia machine consists of a host, an anesthesia ventilator, a flow control system, a control monitoring display panel, an vaporizer (Dräger vapor2000, D-vapor®. Applicable anesthetics: enflurane, isoflurane and sevoflurane for Dräger vapor2000; desflurane for D-vapor®), a ventilation system, a anesthetic gas scavenging system, a vacuum suction device, an anesthesia gas monitoring module, a dual-frequency index module, a CO_2 monitoring module, and accessories.

Scope of Application

The product is applicable to the inhaling anesthesia and respiration management in adult and pediatric patients during the surgical operation.

Contraindication

Pneumothorax and severe pulmonary insufficiency are prohibited.

Figure

All figures in this User's Manual are given for reference only. The menus, setup and parameters given in the figures may be not completely consistent with those that you see on the anesthesia machine.

Customs and Usages

- →: The symbol is used to indicate the operational procedures.
- [Characters]: Used to indicate the character strings of software.

Product Service Life

The expected service life of this product is 5 years.

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Chapter 1 User Responsibility

1.1 Declaration

The product shall be assembled, operated, maintained and repaired as per the User's Manual. The product must be regularly checked. In case that the product requires replacement and maintenance due to fault, unserviceability, damage/loss/wearing/deformation or contamination of components, contact immediately local customer service center or agent of Comen for help. The product and any components of the product must be repaired by trained personnel as per the written instruction provided by the Company. The product must not be modified without written approval from Shenzhen Comen Medical Instruments Co., Ltd. User of the product shall undertake full responsibility of any faults caused by misapplication, improper maintenance/repair, damage, or replacement conducted by anybody who is not authorized by Shenzhen Comen Medical Instruments Co., Ltd

1.2 Intended Readers

The User's Manual is only applicable to anesthetists who have participated in professional trainings. Unless otherwise stated, information offered herein is only applicable to the anesthesia machines AX-900 and AX-900A manufactured by the Company.

1.3 Environmental Requirements

⚠Warning

- **The product and its correlative standalone assemblies must not be applied in nuclear magnetic resonance (MRI) environment.**
- **The parts contacting the patient are free of natural emulsion.**
- **No hazardous substances are generated by the part of this product contacting with anesthetic agent.**
- **No hazardous substances are generated by the mixture of the air source of this product and anesthetic agent.**
- **To avoid explosion hazards, inflammable Anesthetics, such as ether and cyclopropane, must not be applied to the equipment. Only the non-inflammable Anesthetics conforming to IEC 60601-2-13(GB 9706.29) requirements can be adopted. The equipment allows the adoption of**

non-flammable Anesthetics like enflurane, isoflurane, or sevoflurane, and only one type of Anesthetics can be applied at one time.

- **Discarded anesthesia machines and packaging materials must be disposed in accordance with local relevant laws and regulations, or wastes treatment schedule specified by the hospital. In addition, they must be put in places out of the reach of children, and corresponding measures shall be taken to prevent their harm to the ambient environment.**
- **The gas flow rate, volume and leakage specifications are expressed at STPD except for those associated with Anesthetic breathing system are expressed at BTPS.**

1. Normal Working Condition

   Operating ambient temperature: 10°C ~ 40°C;

   Operating ambient relative humidity: ≤93%, non-condensation;

   Atmospheric pressure: 70.0kPa~106.0kPa.

2. Vacuum suction system Normal Working Condition

   Operating ambient temperature: -20°C ~ 50°C;

   Operating ambient relative humidity: ≤80%, non-condensation;

   Atmospheric pressure: 70.0kPa~106.0kPa.

3. Storage and Transportation Condition.

   Storage ambient temperature: -20°C~60°C (oxygen sensor: -20°C~50°C);

   Storage ambient relative humidity: ≤93%, non -condensation;

   Atmospheric pressure: 50.0kPa~106.0kPa

1.4 Safety Information

1.4.1 Symbols

This manual provides several symbols to indicate various important matters and instructions.In order to operate the machine correctly,please note the following symbols:

⚠Warning

- **To warn you of the conditions where serious consequence, disadvantageous matters or danger may occur. Failure to comply with the warning will result in severe personal injury or death of the user or the patient.**

⚠Caution

- **To indicate potential danger or unsafe operation. If not avoided, it may lead to mild personal injury, product malfunction, damages or property loss. It may also give rise to more severe harm.**

⚠Attention

- **To emphasize the critical announcements and provide explanations so as to better use this product.**

Note

- **To provide extra information to explain the sentences.**

1.4.2 Warning,Caution and Attention

⚠Warning

- **Do not operate the device before reading this Manual.**
- **The device can only be operated by trained and skilled medical personnel.**
- **Before operating the device, the operator must ensure that the device, connecting cables, and accessories are intact and function properly.**
- **The device can only be connected to a correctly installed power socket with protective grounding. If the power socket is not connected to a protective grounding wire, disconnect from the power cord, or use the device's internal battery for power supply operation.**
- **All analog and digital devices connected to the device must be certified by the specified IEC standards (such as IEC 60950 Data processing equipment and IEC 60601-1(GB 9706.1)**

Medical electrical equipment standards). All configurations shall comply with the valid version of IEC 60601-1(GB 9706.1). The personnel responsible for connecting the optional equipment to the input / output signal port shall be responsible for configuring the medical system and ensuring that the system complies with the provisions of IEC 60601-1(GB 9706.1).

- **Multiple auxiliary output power sockets are provided on the rear of the device. These sockets are used to provide power to additional equipment (i.e. anesthetic vaporizer, gas analyzer, etc.) of the device. Do not connect other equipment to these sockets as it may affect patient's leakage current.**
- **The alarm shall be set according to different patient conditions. Continuous and close monitoring of patients is the surest way to ensure patient safety.**
- **The physiological parameters and alarm information displayed on the screen of this device are only for the reference of medical personnel, and cannot be directly used as a basis for clinical treatment.**
- **Connect the device to AC power supply before the internal battery runs out.**
- **Do not open the device housing. All repairs or upgrades to the device can only be carried out by personnel trained and authorized by the Company.**
- **You cannot rely on the audible alarm system only to monitor the patient.**
- **Adjusting the volume of the alarm to a small volume may cause the patient to be dangerous.**
- **In order to avoid explosion hazard, flammable anesthetics such as ethyl ether and cyclopropane cannot be used in this device. Use only non-flammable anesthetics that meet the requirements of ISO 80601-2-13, IEC 60601-2-13(GB 9706.29), or ISO 8835-2(YY 0635) standard. This device can use non-flammable anesthetics such as enflurane, isoflurane, and sevoflurane. Only one anesthetic can be used at a time.**
- **When disposing of abandoned anesthesia machines and packaging materials, abide by relevant local regulations or hospital waste disposal systems. Place them out of reach of children. Prevent damage to the surrounding environment.**
- **Do not turn off fresh gas until the anesthetic vaporizer is turned off. The anesthetic vaporizer cannot be turned on without fresh gas. Otherwise, a high concentration of anesthetic vapor can enter the equipment pipe and the surrounding air, causing harm to people and objects.**
- **Qualified personnel shall check the condition of the patient. In some cases, some life-threatening situations may occur, but they do not necessarily trigger an alarm.**

- **Always set alarm limits to trigger an alarm before a dangerous situation occurs. Incorrect alarm limit settings may cause the operator not to know that the patient condition has changed dramatically.**
- **Connecting medical device and non-medical device to an auxiliary power socket at the same time may increase the leakage current, thus exceeding the permissible value.**
- **Electric shock and fire hazard. Do not clean the device when it is turned on and / or powered on.**
- **In order to prevent electric shock, this device can only be connected to the power wiring with protective grounding.**
- **When using high-frequency electrosurgical equipment, the use of anti-static or conductive breathing tubes can cause burns. Therefore, it is not recommended to use them in this device.**
- **There may be a risk of electric shock. This device can only be opened by authorized service personnel.**
- **Disconnect the network power supply before removing the rear panel of this device or before servicing this device.**
- **Failure of the central air supply system may cause multiple or even all devices connected to it to stop working at the same time.**
- **Use a cleaning and disinfection program that meets your disinfection and risk management regulations.**
- **Refer to applicable material safety data.**
  - **Refer to the operation and maintenance manual for all disinfecting equipment.**
  - **Do not inhale smoke from any disinfection process.**
- **Care must be taken when disposing of absorbent as it is a corrosive irritant.**
- **Care must be taken when lifting and operating the anesthetic vaporizer, as its weight may be greater than expected, depending on the size and shape of the anesthetic vaporizer.**
- **Do not use talc, calcium stearate, corn starch or similar materials to prevent the bellows from sticking. These materials may enter the patient's lungs or airways, causing irritation or damage.**
- **All gas sources shall be medical grade.**
- **Disposable items may be considered as potentially biohazardous and shall not be reused.**

When disposing of these items, the relevant regulations for the hospital as well as local pollutants and biohazards shall be observed.

- **In order to avoid injury to the patient, do not test or maintain the device during use.**
- **Check the performance specifications of the processing system with which the receiving and transmitting systems are to be used to ensure compatibility.**
- **It is not possible to use this device close to or stacked with other devices. If necessary, the device shall be closely observed to ensure that it operates properly in the configurations used.**
- **Make sure that the current alarm preset for the device is appropriate for each patient.**
- **In any area, it is dangerous to use different alarm presets for the same or similar devices.**
- **Subject to the size and weight of this device, the device shall be removed by qualified personnel.**
- **Excessive machine load may result in dumping. Equipment connected to the side of the machine shall be within the rated weight range to prevent the machine from tipping over.**
- **When moving the device, excessive load on the device may result in danger of dumping. Before moving the device, remove all devices on the top panel of the device and all monitoring devices installed on the side of the device. Be careful when moving the device up and down ramps, turning corners, and crossing the threshold. Do not attempt to run over hoses, cables, or other obstacles when moving the device.**
- **Leakage may affect accuracy. Test before proper operation to ensure proper operation of the device. Do not use leaked circuits.**
- **It is recommended to connect the vent of the device to the hospital's exhaust emission system to prevent hospital personnel from being exposed to the gases emitted by the device.**
- **Operating the device below the minimum flow rate may result in inaccurate results.**
- **Improperly cleaned materials can cause biological contamination. Use a cleaning and disinfection program that meets your disinfection and risk management regulations**
  - **Refer to applicable material safety data.**
  - **Refer to the operation and maintenance manual for all disinfecting equipment.**
- **Users shall follow recommended daily disinfection procedures for this device and any reusable accessories.**
- **If this device is damaged in any way that endangers the safety of the patient or user, stop**

using the device and attach a visible mark to indicate that the device is not available. Contact the Company for technical support.

- **High concentrations of O_2 greatly increase the likelihood of fire or explosion. Oil and grease may burn at the same time. Therefore, oil or grease cannot be used in oxygen-rich environments where possible.**
- **Use this device only by professional medical personnel. This device may cause radio interference or interrupt the operation of nearby devices. It is necessary to take circumvention measures, such as repositioning the orientation or position of the device, or shielding the place where the device is placed.**
- **Make sure that there is an independent ventilation mode available at any time during the use of this device.**
- **The use of damaged accessories in packaging may result in biological contamination or malfunction. The operator shall check the accessory packaging before use to ensure the integrity of the storage.**
- **Before using this anesthesia machine after cleaning or disinfection, power on the system and follow the on-screen instructions to perform a leak test.**
- **Use of lubricants not recommended by the Company will increase the risk of fire or explosion. Use the lubricants approved by the Company.**
- **Low pressure regulators and flowmeters are susceptible to high pressure and may explode under pressure if improperly maintained or disassembled. Only qualified personnel should replace or disassemble the connector.**
- **Do not disassemble low pressure regulators, flowmeter devices, or connectors under pressure. Sudden release of pressure may cause injury.**
- **Check the specifications of the AGSS transmitting and receiving systems and the specifications of this device to ensure compatibility and prevent the receiving system from being mismatched.**
- **Repeated use of non-sterile breathing circuits or reusable accessories can cause cross-infection. Sterilize the breathing circuits and reusable accessories before use.**
- **Before each use, carefully inspect all parts of the breathing system. Make sure that all parts are free of any obstacles or debris that pose a potential hazard to the patient.**
- **The power plug is used to separate the anesthesia system circuit from the power supply. Do**

not place the device where it is difficult to operate the plug.

- **When connecting an external device through the input / output signal port or replacing the O_2 battery, do not touch the patient to prevent the patient from leaking current exceeding the standard requirements.**
- **Avoid connecting two or more hose assemblies in series, which can cause pressure and flow losses.**
- **When the pipe between the exhaust gas treatment system and the AGSS is clogged, the extraction flow of the exhaust gas treatment system is insufficient, or the exhaust gas treatment system cannot work, the exhaust gas in the AGSS may overflow the atmosphere at a speed exceeding 100ml/min. At this time, AGSS is not recommended.**
- **Use of incorrect connectors can be dangerous. Ensure that all components use the correct connectors.**
- **Avoid using lower nominal pressure flexible connectors to replace high-pressure flexible connectors.**
- **After changing the CO_2 absorbent or installing a CO_2 absorption canister, make sure that CO_2 is fully absorbed by the absorbent.**
- **Before moving the device, remove the spare cylinder and the objects on the top plate and bracket to prevent the device from tipping.**

⚠Caution

- **In order to ensure patient safety, use the parts and accessories specified in this Manual.**
- **This device can operate normally at the level of interference immunity identified in this Manual. If the interference level is higher than this level, it may trigger an alarm and may cause mechanical ventilation to stop. Pay attention to false alarms caused by high-intensity electric fields.**
- **The device may lose its balance if it is tilted more than 10°. Be careful when moving or placing this device on a slope that exceeds 10°. Do not hang objects on both sides of the device to avoid excessive imbalance.**
- **Follow the checklist for daily inspections. In the event of a system failure, do not operate this**

device until the fault is cleared.

- **Before starting the device, the user must be familiar with the information contained in this Manual. The device must be inspected and repaired by qualified service personnel as required.**
- **If the device cannot be operated as described in the Manual, it must be inspected and repaired by qualified service personnel as required before being put back into use.**
- **Handle the device with care to prevent damage or malfunction.**
- **When the device and its accessories will exceed their service life, they must be disposed of in accordance with the guidelines for the management of such products and local regulations for the management of contaminated and biohazardous goods.**
- **Electromagnetic fields will affect the performance of this device. Ensure that all external equipment used near this device must comply with the appropriate EMC requirements. Mobile phones, X-rays, and MRI equipment are all possible sources of interference, as they emit high-intensity electromagnetic radiation.**
- **Make sure that the gas sources of the device always meet the relevant technical specifications.**
- **Prior to clinical use, the device must be properly calibrated and / or tested as described in this Manual.**
- **If a system malfunction occurs during the initial calibration or test, the operation of this device shall be stopped until qualified service personnel have eliminated the malfunction.**
- **In order to prevent damages to the device:**
- **Refer to the information provided by the cleaner manufacturer(s).**
- **Do not use organic, halogenated, or petroleum-based solvents, anesthetics, glass cleaners, acetone, or other harsh cleaning agents.**
- **Do not use abrasive cleaners (such as steel wool or silver polish) to clean the parts.**
- **All liquids shall be placed away from electronic components.**
- **Do not allow liquid to infiltrate into the device housing.**
- **All used cleaning solvents must have a pH of 7.0-10.5.**
- **Do not immerse the O_2 battery or its connector in any type of liquid.**
- **Dispose of the O_2 battery according to the manufacturer's specifications.**

- **Do not use peracetic acid or formaldehyde fumigation.**
- **After maintenance, functional tests, sensor tests, and system tests must be performed before clinical use.**
- **Only anesthetic vaporizers with a Selectatec interlock system can be applied to this device.**
- **After each replacement of the anesthetic vaporizer, perform a leak test on the breathing system circuit.**
- **Use cleaners with care. Excessive liquid may enter the device, thus causing damage.**
- **Do not subject any part of this device to high temperature and high pressure unless it is specifically stated in this Manual that it is a high-temperature and high-pressure part. Clean the device as specified in this Manual.**
- **The valve of each inhalation and respiration valve assembly on the breathing system is fragile and must be handled with care when removing the valve seat from the valve assembly.**
- **If the bellows are moistened with water after cleaning, the bellows surface may have creases that can cause the bellows to fail to unfold. Make sure to wipe out all moisture from the bellows after cleaning.**
- **Do not connect any non-isolated device to the DB9 connector of this device.**
- **Do not connect any device to the USB port of the device except for the USB storage devices approved by the Company.**
- **Do not clean the inner surface of the O_2 battery.**
- **Do not subject the following parts to high temperature and high pressure: airway pressure gauge, O_2 battery, and flow sensor. These parts cannot withstand soaking or the heat and pressure of high-temperature and high-pressure processing. If the breathing system is configured with a disinfectant flow sensor, the flow sensor can be subjected to high-temperature and high-pressure vapor disinfection.**
- **This device is not suitable for use in magnetic resonance (MRI) environments.**
- **In order to ensure accurate measurement and avoid damage to the device, use only cables and accessories approved by the Company.**
- **Use the accompanying power cord. For replacement, use only power cords that meet the specifications.**
- **Do not press down on the manual arm or hang a heavy weight on it. Excessive weight may**

bend or damage the manual arm.

- **Since sudden release of pressure may cause injury, be careful when disconnecting the "quick connector".**
- **Avoid factors that may damage the hose assembly, including excessive bending, rolling, wear, system pressure and temperature exceeding the hose rating, and incorrect installation.**
- **When removing the breathing system, care must be taken to raise and manipulate the breathing system. Given the importance and shape of the breathing system, these operations can be tricky.**
- **When the electronic flow control system fails, the backup flow control system will be enabled. The O_2 basic flow of the backup flow control system is 0.2 L/min. The backup flow control system displays only one total flowmeter. The total flowmeter can display a maximum flow of 15L/min.**
- **The flow control knob of the backup flow control system shall be slowly rotated to avoid damaging the control valve. Do not rotate the flow control knob when the flowmeter reading exceeds the range. When the flow control knob is rotated clockwise to reduce the flow, the flowmeter reading shall reach 0L/min before reaching the clockwise mechanical stop position. When the knob has reached the stop position, do not rotate it again. Rotate the flow control knob counterclockwise to increase the flow.**
- **Do not use damaged device or accessories. During normal use, check all cables (such as AC power cord and patient connection cable) regularly for damage. If damaged, replace it.**
- **The O_2 ratio (FiO_2) shall be monitored when using an auxiliary O_2 / air supply flowmeter. If O_2 monitoring is not performed, the concentration of O_2 delivered to the patient will be unknown.**
- **Unlocking the casters may cause unexpected movement. The operator shall lock the casters while using this device.**
- **Unmounted devices may slide off the top plate. The device shall be securely mounted on the top plate.**
- **The voltage on the auxiliary socket shall be the same as the voltage of the socket into which the device is plugged. Make sure that the voltage rating of the device plugged into the auxiliary socket is the same as the supply voltage of this device.**
- **During transportation and storage of the anesthetic vaporizer, a plug shall be used to block**

the inlet and outlet of the anesthetic vaporizer, thus preventing impurities from entering the vaporizer.

- **Do not use any flow outlet as a handle when moving this device. Flow outlets may be damaged. Use the metal side bar on the unit to move the device.**

⚠Attention

- **Install the device in a place convenient for observation, operation and maintenance.**
- **The quick opening of the cylinder valve may cause an unexpected pressure difference. Due to potential fire or explosion hazards from O_2 pressure shocks, the cylinder valve shall be opened and closed slowly.**
- **If the anesthesia machine is configured with a total flowmeter, the total flowmeter will be calibrated at 100% O_2. For other gases or gas mixtures, the accuracy of the flowmeter may be reduced.**
- **Changes in inlet pressure, outlet resistance, or ambient temperature may affect the accuracy of the flow rate.**
- **There are regional or national regulations that apply to medical device manufacturers.**
- **This product does not contain any latex components.**
- **The operator shall be located directly in front of the device and within 4 meters of the screen to observe the display information of the device.**
- **Some alarm settings of this device cannot be changed by the user.**
- **The figures in this Manual are for reference only. The interface may differ depending on the system configurations and the selected parameters.**
- **Place this Manual near the device so that it can be easily accessed when needed.**
- **The software of this device is developed in accordance with the requirements of YY/T 0708, thus minimizing the possibility of danger caused by software errors.**
- **This Manual describes the product according to the most complete configurations. The device you purchased may not have certain configurations or functions.**
- **The device uses its own respiratory pressure monitoring during operation.**
- **The device uses its own respiratory pressure limiting device during operation.**

- **The device uses its own respiratory capacity monitoring during operation.**
- **The device uses its own integrity alarm system for the breathing system during operation.**
- **The device uses its own continuous pressure alarm during operation.**
- **The device uses its own O_2 monitoring during operation.**
- **The anesthesia gas conveying equipment is used in conjunction with the anesthesia gas monitoring module complying with YY 0601. The patient circuit and the anesthesia gas monitoring module shall be connected through an adsorption tube.**
- **When using this device, the concentration of anesthetic shall be continuously monitored to ensure that the output of the anesthetic is accurate.**
- **Before performing all operations and during operation, the level of the anesthetic fluid shall be checked. Liquid shall be added when the liquid level is below the warning line. For the addition of anesthetic to the anesthetic vaporizervaporizer and other information, refer to the instructions for use of the anesthetic vaporizer.**
- **The device system is designed with the anesthesia gas conveying equipment that complies with YY 0635.3.**
- **The battery of this device is not a user-serviceable part. Only authorized service representatives can replace the battery. If the system is not used for a long time, contact a service representative to disconnect the battery. Dispose of the battery in accordance with relevant local regulations. When the battery reaches its service life, dispose of it in accordance with relevant local regulations.**
- **The place designated for servicing O_2 equipment shall be clean, grease-free, and not used for repairing other equipment.**
- **The device material does not contain any designated phthalates.**

Chapter 2 Product Overview

This chapter gives an overview of the anesthesia machine and its functions.

2.1 Introduction to the Anesthesia machine Series

An anesthesia machine is a minitype, integrated and intuitionistic anesthesia delivery system that is characterized by its advanced design and is equipped with the gas-feed, respiration monitoring and breathing systems. The anesthesia machines AX-900 and AX-900A are applicable to the respiratory anesthesia and respiratory management in adult and pediatric patients during surgery, and combine respiratory,CO_2,BIS,and AG monitoring.

AX-900A and AX-900 anesthesia machines provide the following common functions:

- Log storage: Capable of storing 2000 alarm review logs, including technical alarm logs, physiologic alarm logs, indicate logs and setting logs.
- Trend: Allowing you to view the data stored in the 60-hour trend table.
- Automatic leak detection
- Circuit gas leakage compensation and automatic compliance compensation
- Gas input provides pipe gas supply connections and can also provide spare cylinders or standby oxygen connections
- Electronically adjustable PEEP
- Timer, displaying the time from the start to the end of the operation
- Operation ceiling lamp
- Dovetail rails connected to an external monitor
- Auxiliary O_2 / air supply
- High-pressure oxygen source
- Exhaust emission system (AGSS) (optional)
- N_2O cut-off
- Vaporizer
- Float-type total flowmeter
- Carbon dioxide module (CO_2 module)
- Anesthetic dosage monitoring function (AG module is required)
- Dual-frequency index module (BIS module) (optional)
- Auxiliary common gas outlet (ACGO)
- Electronic flow control system
- Fresh gas flow level indication function
- Optimal flow indication function (optional)

⚠Attention

- **This Manual describes the device according to the most complete configurations. The device you purchased may not have certain configurations or functions.**
- **AX-900A has no internal vacuum suction system compared to AX-900. AX-900A is no longer described in this Manual.**

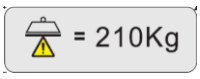
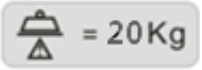
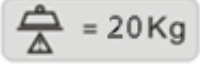
2.1.1 Anesthesia machine AX-900

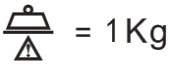
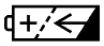
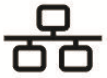
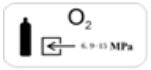
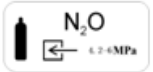
Fig. 2-1 Anesthesia machine AX-900

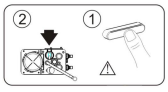
2.1.2 Anesthesia machine AX-900A

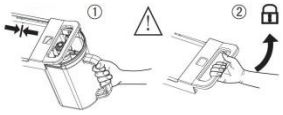
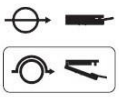
Fig. 2-2 Anesthesia machine AX-900A

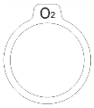
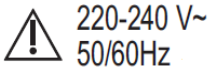
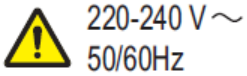
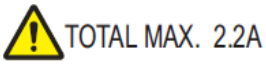
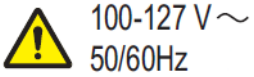
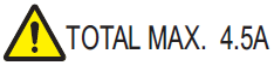
2.2 Symbols used in the Manual or on the Equipment

Notes	Symbol
Adjustable top light	
The maximum bearing weight of the entire machine is 210kg.	
The maximum bearing weight of the top plate is 20kg	
The maximum bearing weight of the workbench is 20kg	

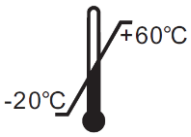
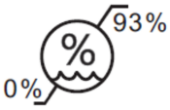
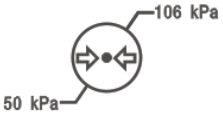
Notes	Symbol
The maximum bearing weight of the top drawer is 1kg.	
The maximum bearing weight of the bottom drawer is 3kg.	
The maximum bearing weight of the circuit hook is 1kg.	
General warning,caution,risk of danger	
High voltage warning	
Flowmeter back lighting	
Flow regulation	
Alternating current	
Battery indicator lamp	
Operating indicator lamp	
Battery	
AUDIO PAUSED	
Alarm	
Network port	
Standby	
Cylinder O_2-inlet	
Cylinder N_2O-inlet	
Cylinder AIR-inlet	

Notes	Symbol
An anesthesia-vaporizer mounting labeling	
Oxygen flow meter flag	
N_2O flowmeter flag	
Air-flow meter flag	
Oxygen flush flag	O_2+
CO_2 module relevant flag	CO_2
AG module relevant flag	AG
BIS module relevant flag	BIS
Gas supply inlet	O_2、N_2O、AIR  280~600kPa
Equipotentiality	
Protective grounding flag	
System turn-on flag	
System turnoff flag	
Backup gas cylinder	
Circuit removal flag	
Manual drain valve flag	

Notes	Symbol
CO_2 absorbent canister installation and lockup flag	
AGSS gas vent	
PEEP gas vent	
Isolation transformer	
Pipeline	Pipeline
Inspiratory/expiratory flag	Insp → Exp ←
Inspiratory/expiratory valve removal/assembling flag	
Autoclavable	134°C
Not Autoclavable	
Oxygen cell flag	O_2%
BY-Pass flag	
APL valve	
Bag position/Manual ventilation	
Mechanical ventilation	
Material explanation	>PPSU<
Maximum volume of Canister (carbon dioxide absorbent)	MAX

Notes	Symbol
Canister (carbon dioxide absorbent) components	
Bellows cover’s sealing ring on-the-top flag	
USB port	
Video output	
Hot Caution!	
Oxygen pressure gauge flag and backup gas-cylinder oxygen pressure gauge flag	
Nitrous oxide pressure gauge flag and backup gas-cylinder nitrous oxide gauge flag	
Air pressure gauge flag and backup gas-cylinder Air gauge flag	
Power-supply general input (220 to 240V)	
Power-supply general input (100 to 127V)	
Auxiliary output socket flag(220 to 240V)	
Total Max Output power(Total Max.2.2A)	
Auxiliary output socket flag(100 to 127V)	
Total Max Output power(Total Max.4.5A)	
Serial port flag	
High pressure oxygen supply outlet flag	

Notes	Symbol
Auxiliary air / oxygen supply outlet flag	
Auxiliary oxygen-supply flow meter flag	
Type of negative pressure equipment	
Negative pressure maximum pressure and flow flag	
Non-protected against water	**IPX0**
Date of manufacture	
Defibrillation-proof type BF applied part	
Serial Number	
Complies with medical device directive 93/42/EEC	
Authorised representative in the European Community	
Address of manufacture	
The device contains batteries and electrical components. Consequently it cannot be disposed of in domestic waste but must be collected separately in accordance with local laws and regulations.	
MR Unsafe	
This way up	

Notes	Symbol
Fragile	
Do not stack	
Keep away from rain	
Do not roll	
center of gravity	
recyclable	
Environmental protection	
Temperature limitation	
Humidity limitation	
Atmospheric pressure limitation	

Notes	Symbol
Refer to instruction manual/ booklet	

2.3 Abbreviation of Specific Terms

Abbrev	Definition
A	
AA	Anesthetic
ACGO	Auxiliary Common Gas Outlet
AGSS	Anesthetic gas scavenging system
APL	Adjustable pressure limiting
C	
CO_2	Carbon dioxide
Compl	Compliance
CPB	Cardiopulmonary bypass
CPAP/PSV	Continuous Positive Airway Pressure/Pressure-support ventilation
E	
Et	Exhale gas concentration
$EtCO_2$	Expiratory-end tidal CO_2 concentration
EtO_2	Expiratory-end tidal O_2 concentration
Exp	Expiratory
F	
Fi	Inspired gas concentration
FiO_2	Fraction of inspired oxygen
$FiCO_2$	Fraction of inspired CO_2
I	
I:E	Inspiratory:Expiratory time ratio
Insp	Inspiratory
M	
MAC	Minimum alveolar concentration

Abbrev	Definition
MV	Per minute ventilation
MinRate	Minimum Rate
N	
N_2O	Nitrogen dioxide
O	
O_2	Oxygen
P	
P-F	Pressure-Flow loop
P-V	Pressure-Volume loop
Paw	Airway pressure
PCV	Pressure-control ventilation
PEEP	Positive end expiratory pressure
Pinsp	Inspiratory pressure
Plimit	Limiting pressure
Pmean	Mean pressure
Ppeak	Peak pressure
Pplat	Plateau Pressure
∆Pps	Support pressure
PRVC	Pressure regulated volume control ventilation
PSVPro	Pressure-support ventilation protection
R	
Raw	Resistance
S	
SIMV-PC	Synchronized intermittent mandatory ventilation-pressure control (pressure controlled)
SIMV-VC	Synchronized intermittent mandatory ventilation–volume control (volume controlled)
SIMV-PRVC	Synchronized intermittent mandatory ventilation-Pressure regulated volume control synchronous ventilation
T	
VT	Tidal volume
VTexp	Expiratory tidal volume
VTinsp	Inspiratory tidal volume

Abbrev	Definition
Tinsp	Inspiration time
Trigger	Inspiratory trigger
Tslope	Pressure slope
Tpause	Inspiratory pause
V	
VCV	Volume control ventilation
Vol	Volume
V-F	Volume-Flow loop

2.4 System Construction

2.4.1 Front

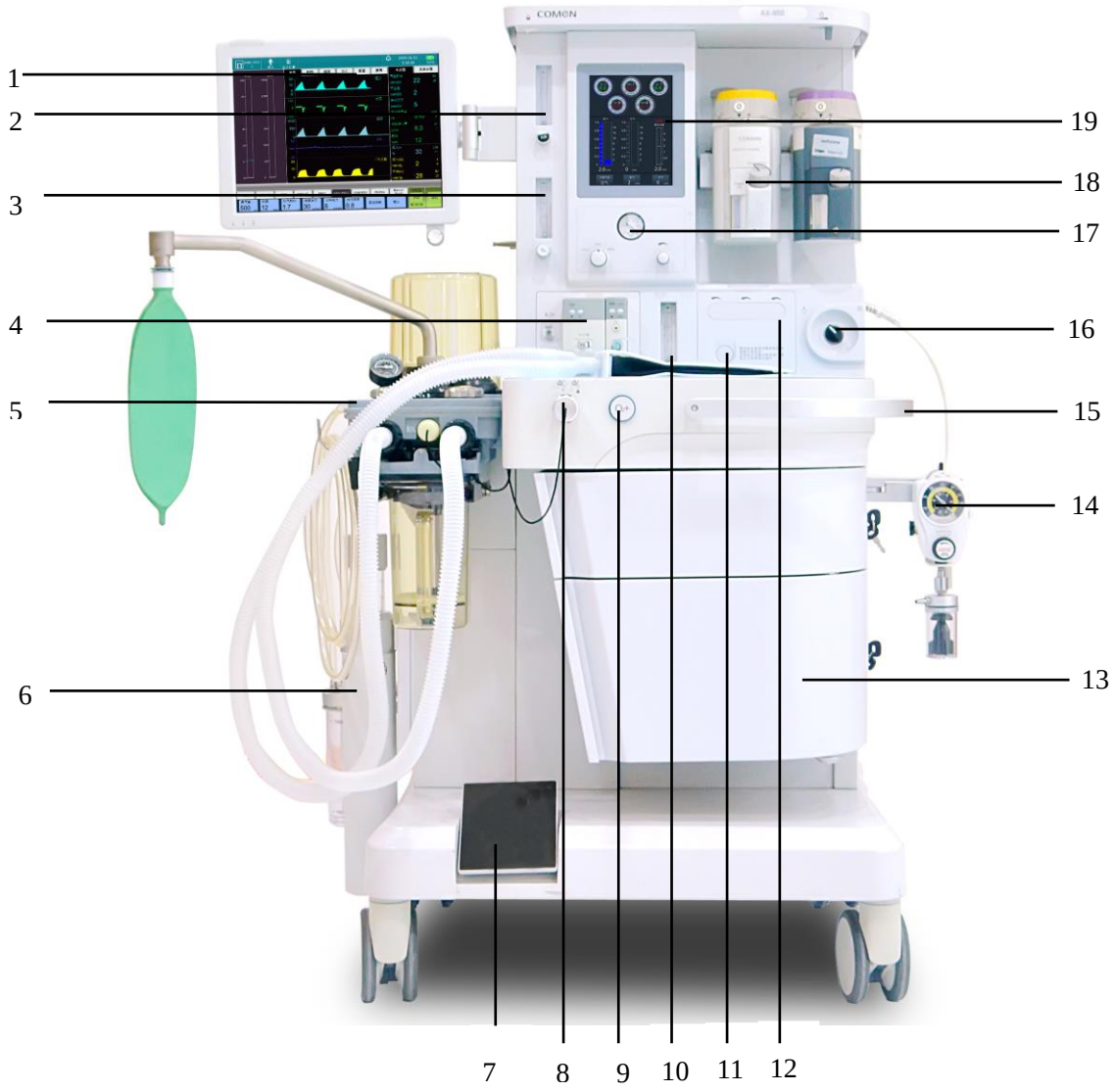


Fig. 2-3 Front View of Anesthesia machine AX-900

1	Ventilator/monitor display	11	Backup flow control system button
2	Auxiliary Air flowmeter	12	Flow regulation knob of the backup flow control system
3	Auxiliary O_2 supply flowmeter	13	Storage drawer
4	module area	14	External vacuum suction
5	Breathing system	15	Armrest
6	AGSS	16	System switch
7	Central brake	17	Internal vacuum suction
8	ACGO switch	18	Anesthesia Vaporizer
9	Oxygen flush button	19	Flow control（full electronic flowmeter）
10	Total flowmeter		

⚠Attention

- **External vacuum suction and internal vacuum suction choose one of them for configuration,AX-900A can be optionally equipped with external vacuum suction,AX-900 can be optionally equipped with internal vacuum suction.**

The Control Functions to be implemented through the Front of Anesthesia machine AX-900/900A

Item	Name	Notes
1	Ventilator/monitor display	For details, refer to Section *2.5.6.3 CONTROL PANEL*.
2/3	Auxiliary air / oxygen flow meter	It is used for auxiliary air / oxygen flow output display. For details, refer to Section *2.5.8 AUXILIARY OXYGEN AND AIR FLOWMETER*.

4	module area	The CO_2 module, AG module and BIS module mentioned in this Manual can be inserted and identified.
6	AGSS	Exhaust emission system.
7	Central brake	Press the bottom end of the central brake pedal with your foot to  , to apply brake to the anesthesia machine; press the upper end of the central brake pedal to  to release the brake (see the figure below). After the brake is released, the anesthesia machine can be moved. 
8	ACGO switch	it is used to enable / disable the ACGO function.
9	Oxygen flush button	Push the 'O_2 +', oxygen flush button to supply high-flow oxygen to the breathing system. 
10	Total flow meter	It is used for displaying the combined flow of oxygen, air and nitrous oxide.
11	Backup flow control system button	Press the button to expand the flow regulation knob of the backup flow control system.
12	Flow regulation knob of the backup flow control system	It is used for regulating the nitrous oxide, air and oxygen flux. Rotate the knob counterclockwise to increase the flow. Rotate the knob clockwise to decrease the flow.

13	Storage drawer	Provide two storage drawers (lockable).
15	Armrest	It helps move the metal rod of this device.
16	System switch	Set the switch to its position "⊙" to enable gas input and turn on the system; set the switch to its position "○" to turn off gas input and turn off the system, as shown in the figure below: 
17	Vacuum suction	Internal vacuum suction（AX-900）: It consists of a pressure gauge, vacuum regulating gears and a vacuum adjustable knob, which can be set to [**FULL**], [**OFF**] or [**REG**]. [**FULL**] indicates that the vacuum suction device operates with continuous maximum pressure, and thus the regulation knob does not function. [**OFF**] indicates that the vacuum suction device does not function after turning off the vacuum. [**REG**] indicates that it is able to regulate the pressure of the vacuum suction device through the vacuum regulation knob for operation. Rotate the vacuum regulation knob counterclockwise to increase the vacuum. Rotate the vacuum regulation knob clockwise to decrease the vacuum. The pressure gauge is used for displaying the pressure. 

14		External vacuum suction（AX-900A）: The function button is the same as the internal vacuum suction. 
19	Flow control (full electronic flow meter)	Touch the touch screen to control the input. Set the [**Balance gas**], [**Oxygen**] and [**Air**].

Note

- **When using a backup flow control system, make sure that the oxygen,air and nitrous oxide flow controllers are fully closed at the start and end of each ventilation.**
- **The safety system in this device prevents the delivery of hypoxic mixture to the patient. In the absence of oxygen, it will not deliver nitrous oxide. The gas circuit safety system ensures that oxygen is set at a minimum of 25% in the mixture of oxygen and nitrous oxide.**

2.4.2 Back

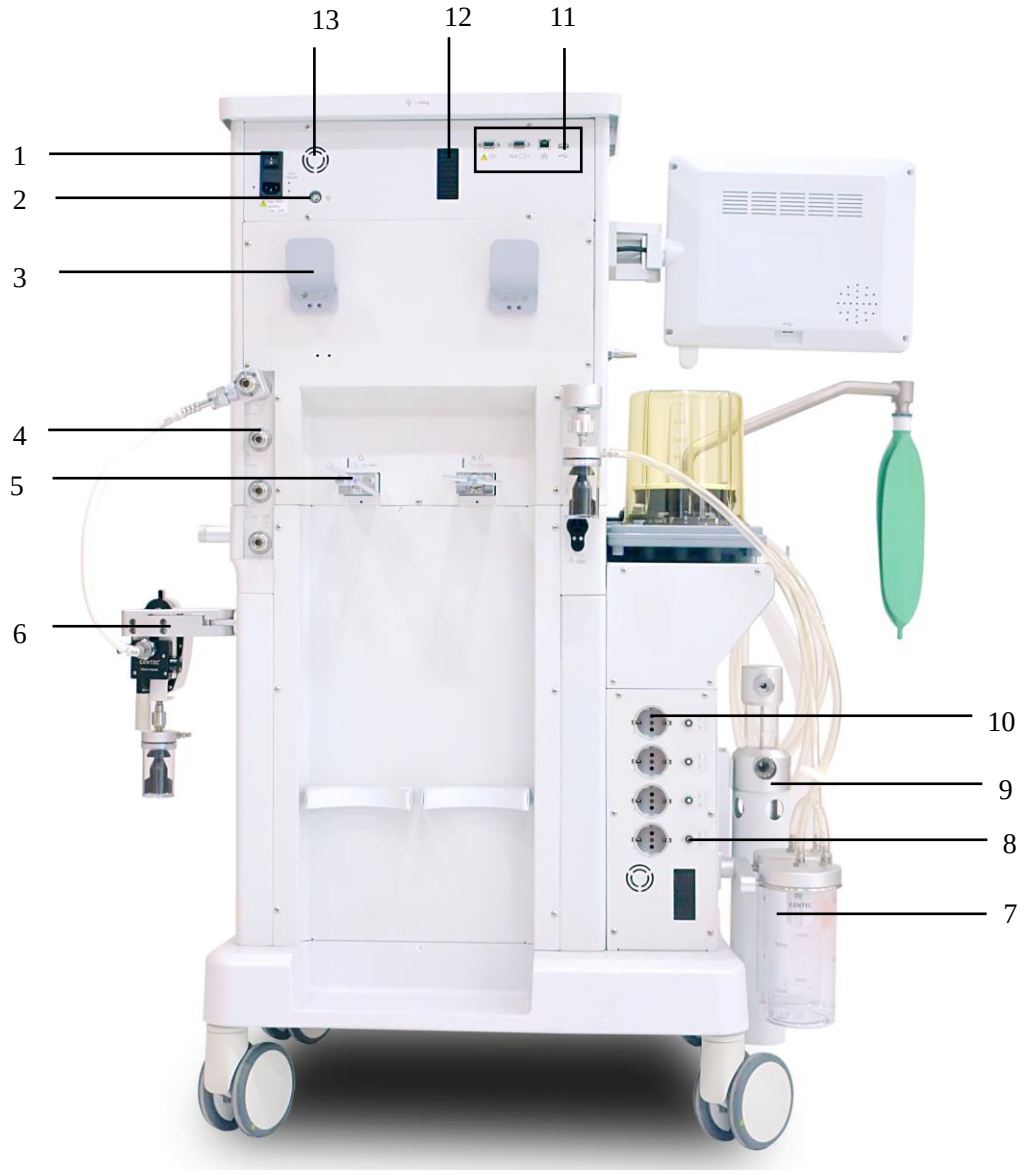


Fig. 2-4 Back View of Anesthesia machines AX-900 and AX-900A

1	Main power socket and its system circuit breaker	8	Auxiliary power output socket's circuit breaker
2	Equipotential stud	9	AGSS
3	Hook	10	Auxiliary power output socket
4	Pipe's gas supply interface	11	Communication interface
5	Spare gas cylinder's gas supply inte	12	Ventilation cooling window

rface

6 External vacuum suction

7 Liquid collection bottle

13 Exhaust fan

The control functions on the rear of the AX-900/900A anesthesia machine:

Item	Name	Description
1	Main power socket and its system circuit breaker	Used for connecting the network power cord, turning on / off the AC power input.
2	Equipotential stud	Provide wiring points. Eliminate the ground potential difference between different devices to ensure safety.
3	Hook	Allow users to hang or wrap cables.
4	Pipe's gas source interface	O_2, air and N_2O connection interface.
5	Spare gas cylinder's gas supply interface	Connection interface of high-pressure cylinder (O_2, air or N_2O).
8	Auxiliary power output socket's circuit breaker	Circuit breaker of each auxiliary output power socket.
9	AGSS	Exhaust emission system.
10	Auxiliary power output socket	Only authorized personnel can use these sockets.
12	Ventilation cooling window	Ventilation and heat dissipation.
13	Exhaust fan	An electronic device that forces air cooling and prevents the accumulation of O_2 concentrations. Do not block the exhaust fan.

⚠Warning

- **Port connectors used for other specific purposes are not compatible with ISO 5356-1, ISO 5356-2 or ISO 594-2. (luer lock).**

2.4.3 Left

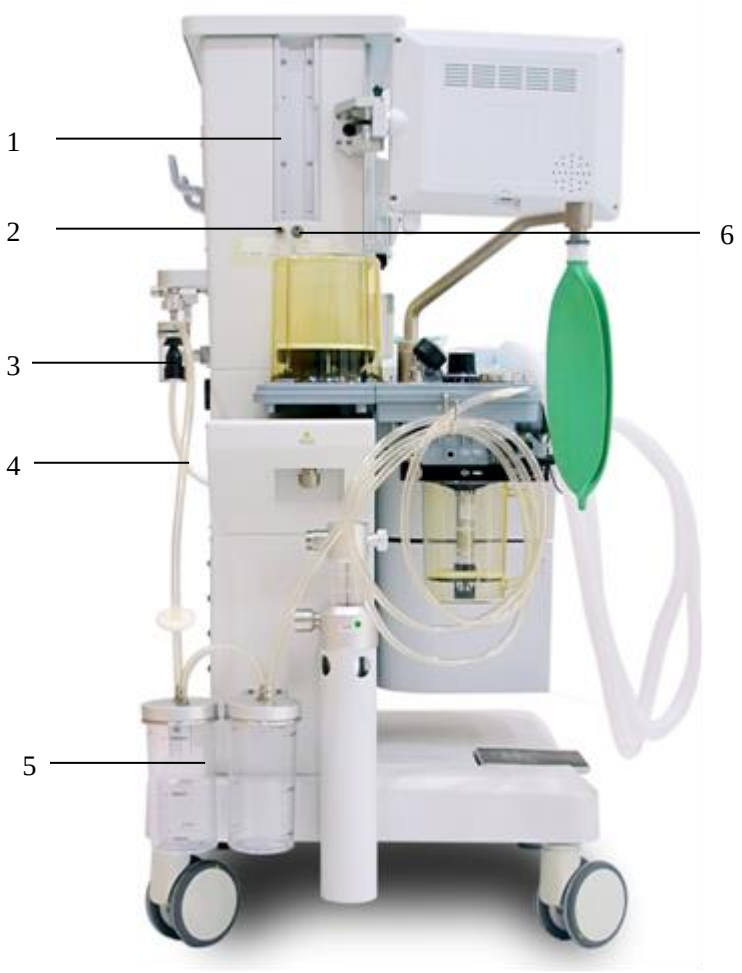


Fig. 2-5 The Left of Anesthesia machines AX-900

The control functions on the left of the AX-900 anesthesia machine:

Item	Name	Description
1	Dovetail rail	Standard accessory arms for mounting monitors and other equipment. There are dovetail rails on the left and right sides of the device.
2	Auxiliary high-pressure oxygen outlet	High-pressure O_2 outlet for connecting external equipment, such as air-breathing ventilators.
3	Overflow protection	Overflow protection of the vacuum suction device, which is used to prevent backflow of the waste liquid when it is full, thus ensuring the safety of pipes.
4	Suction tube	Used to transport medical waste. The suction tube is inserted directly into the interface.
5	Liquid collection	Used to collect medical waste.

	bottle	
6	Auxiliary O_2 / air outlet	Nozzle for auxiliary O_2 / air output. The outlet merges the auxiliary O_2 / air supply flowmeter into a single output.

2.4.4 Right

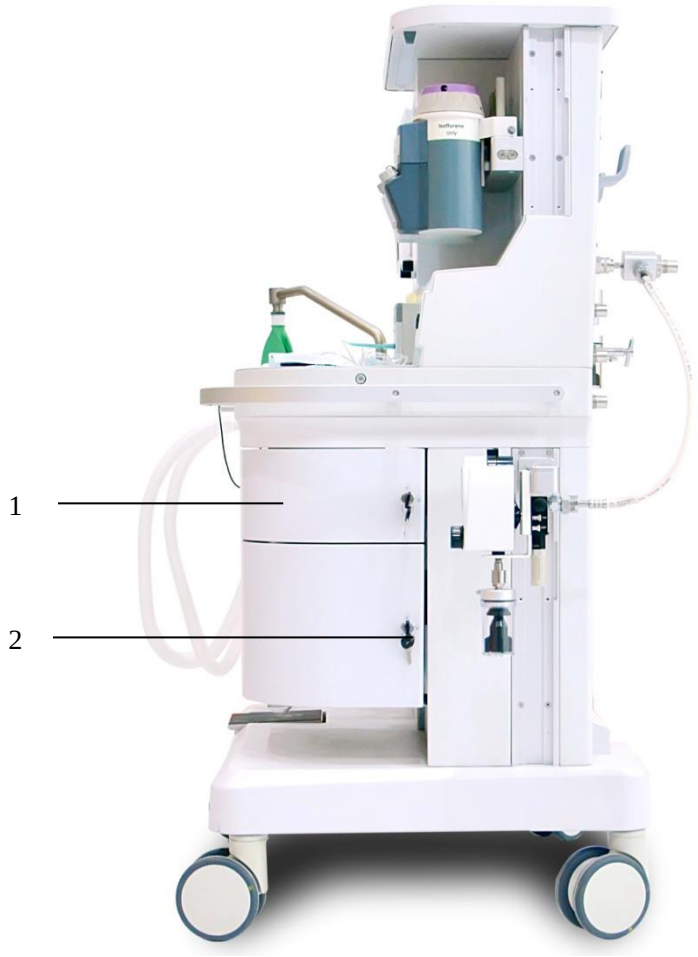


Fig. 2-6 The Right of Anesthesia machines AX-900

The control functions on the right of the AX-900 anesthesia machine:

Item	Name	Description
1	Storage drawer	Two storage drawers are available (lockable).
2	Key lock	Key and lock for locking the drawer.

2.5 Introduction to the Machine Components

⚠Warning

- **Beware of explosion hazard. Never use inflammable anesthetics in the system.**
- **Never use antistatic breathing tubes and face masks, which may cause a fire if they are used nearby surgical equipments for high frequency surgery.**

2.5.1 Breathing System Components

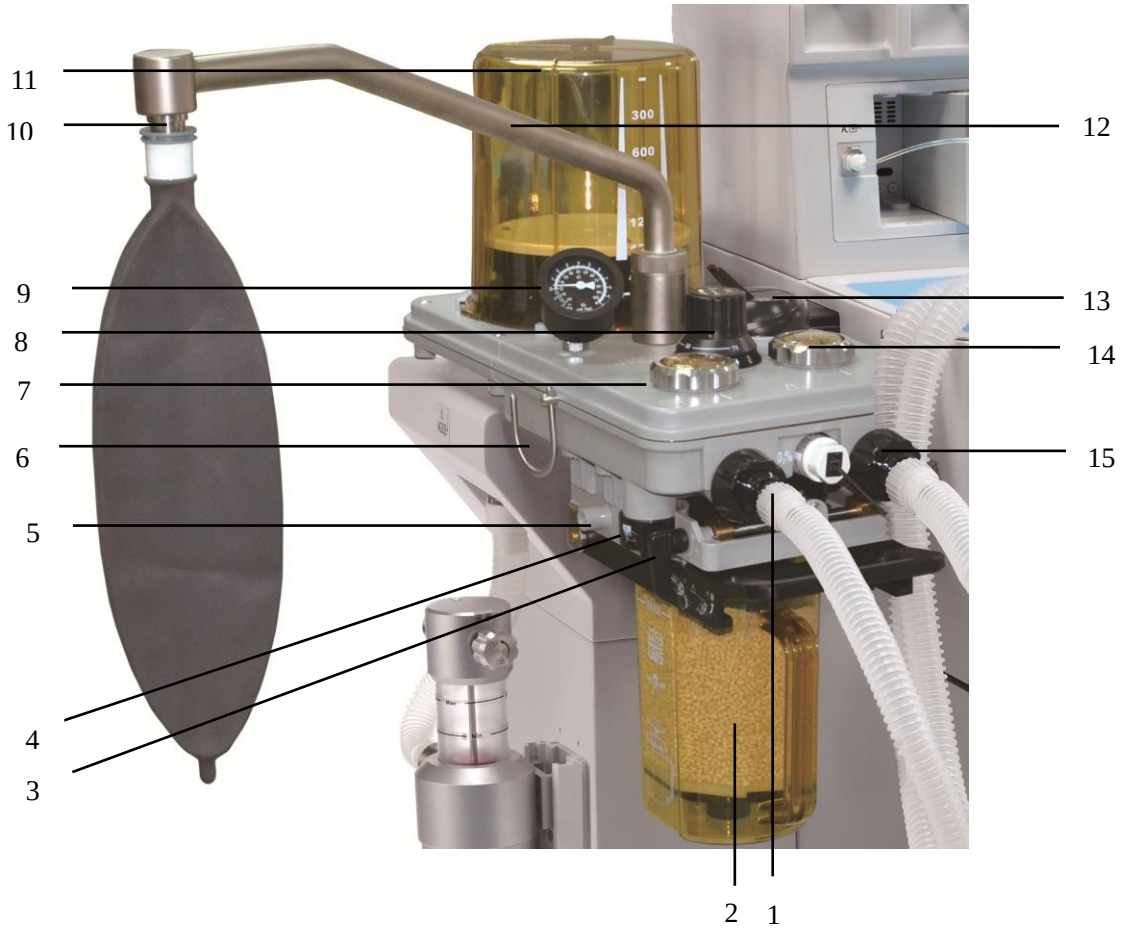


Fig. 2-7 Breathing System of Anesthesia machine Series

1	Expiration port	9	Pressure gauge (airway)
2	Canister (carbon dioxide absorbent)	10	Manual bag port
3	Canister release	11	Bellows assembly
4	Manual drain valve	12	Manual bag support arm
5	Leak test plug	13	Manual/mechanical ventilation switch
6	Breathing tube hook	14	Inspiratory check valve
7	Expiratory check valve	15	Inspiration port

8 APL (adjustable pressure limiting) valve

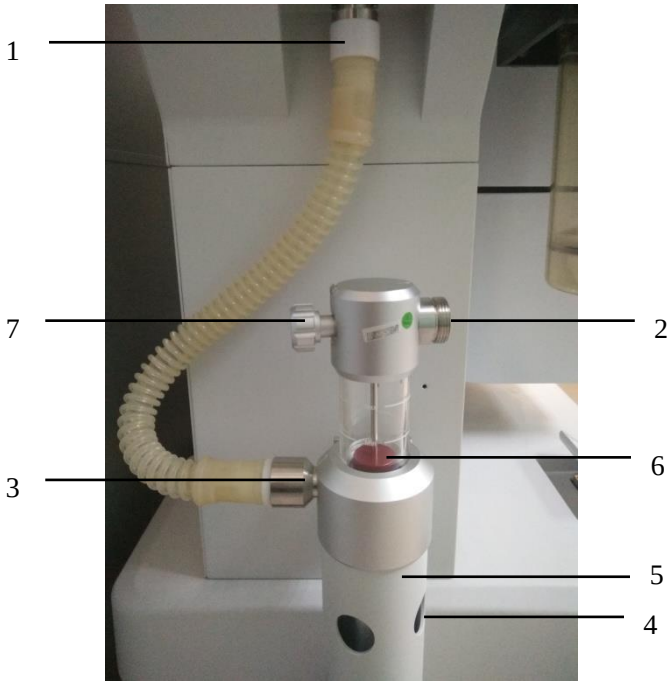
No.	Item	Notes
1	Expiration port	Breathing circuit's Expiration port.
2	Canister (carbon dioxide absorbent)	A container for carbon dioxide absorbent.
3	Canister release	A device used to release the canister by turning counterclockwise.
4	Manual drain valve	Discharge the water collected by the canister.
5	Leak test plug	Used to block the breathing tube of the patient end interface when detecting a leak in the breathing system.
6	Breathing tube hook	The hook can suspended breathing line.
7	Exhalation check valve	Allow the patient's exhaled gas to flow to the breathing system and prevent backflow.
8	APL valve	In manual/spontaneous mode, adjust the pressure limit of breathing system. Its scale marks may indicate the approximate pressure values. Adjust it clockwise to increase the value, or adjust it anticlockwise to reduce the value. The minimum scale is "MIN", and the maximum scale is "75". 
9	Pressure gauge	Indicate airway pressure.

10	Manual bag support	Artificial Manual bag suspension arm. 
11	Bellows assembly (including bellows cover)	Used to separate the breathing system's gas from the driving gas O2 / air.
13	Manual/mechanical ventilation switch	Select manual/spontaneous (Manual bag) or volume control (ventilator). When manual/spontaneous is selected, set the manual switch to its position "Manual" (). If volume control is selected, set the mechanical control switch to its position "Mechanical Control" (). 
14	Inspiratory check valve	Allow the inhaled gas to flow to the patient and prevent backflow.
15	Inspiration port	Breathing circuit's inspiration port.

⚠Attention

- **The bellows cover is a transparent cover with scale marks from 300 to 1500ml. These scale marks are for reference only. VT shall be read from the user interface. The delivered VT is the sum of the bellows displacement and the fresh gas flow.**
- **The values on the APL valve and the airway pressure gauge are for reference only. Calibrated patient airway pressure is displayed on the user interface.**

2.5.2 Structural Composition of AGSS



No.	Notes	Description
1	Waste gas exhaust nozzle connector	The inlet of the gas emitted by the breathing system. The exhaust gas transmission hose connects the inlet with the exhaust gas discharge port to transfer the discharged gas.
2	AGSS waste gases outlet	Head to the hospital's exhaust gas treatment system.
3	Outer cone connector for hose of transfer system	/
4	Pressure Compensation Port	Pressure release device
5	Main body of AGSS system	/
6	Float (red)	Indicate the exhaust flow, which can be adjusted by rotating the flow adjustment knob until the float is located between the Min and Max scales.
7	Flow regulation knob	Adjust the flow in AGSS clockwise or counterclockwise until the float is located between the Min and Max scales.

2.5.3 Vacuum suction device

Vacuum suction refers to the suction device with vacuum generated by the venturi device. The intended use is negative pressure for sputum discharge in clinical respiratory tract and esophagus and surgery. It mainly consists of negative pressure generator, negative pressure regulating valve, negative pressure indicator, overflow cup, filter, liquid collecting bottle and suction tube, and is mainly used in the collection of medical waste liquid. It is designed with overflow protection function to prevent backflow of fully collected waste so as to ensure the safety of the gas pipeline. The schematic drawing is as follows.

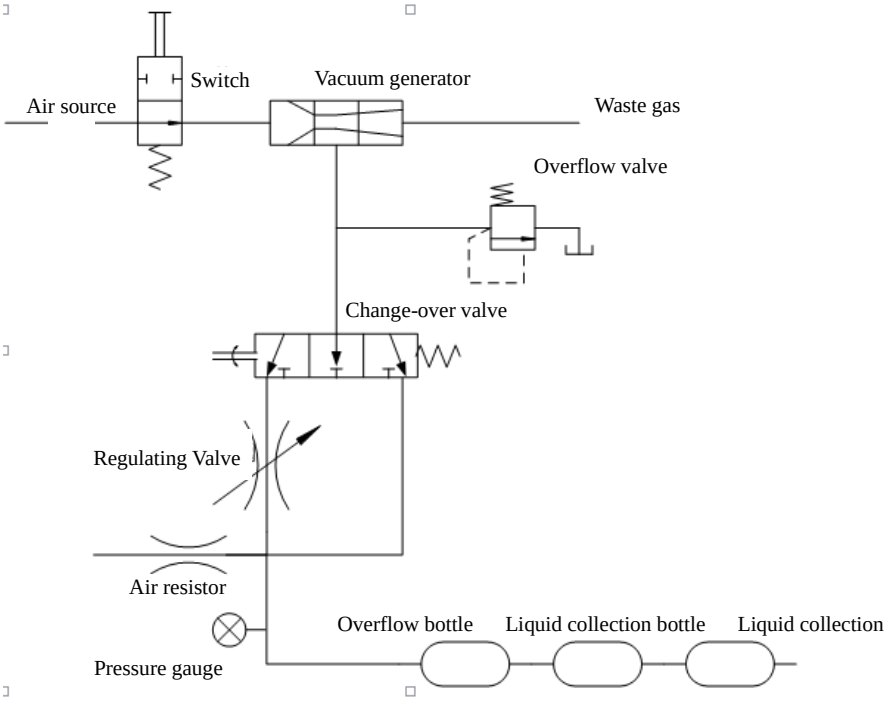


Fig. 2-8 Schematic Drawing of Vacuum Suction

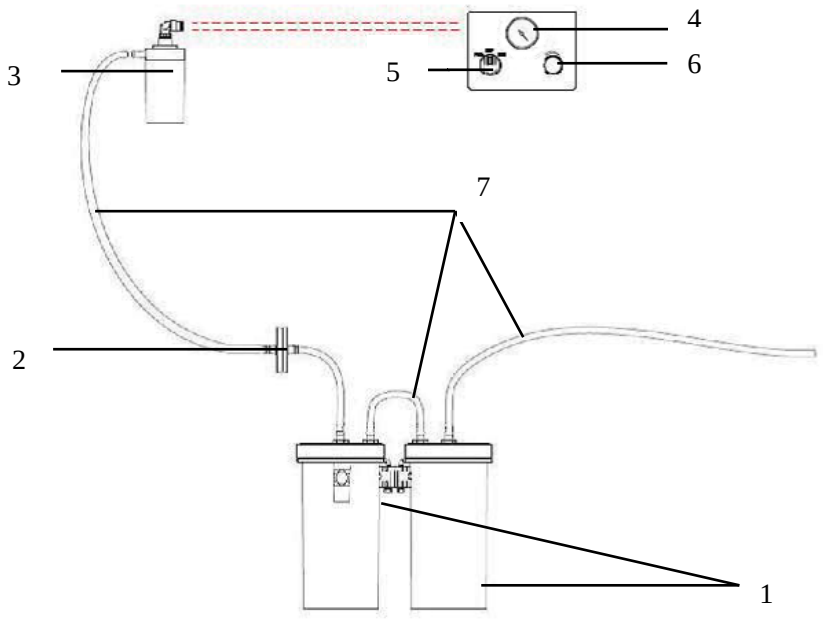


Fig. 2-9 Vacuum suction device

Item	Name	Note
1	Liquid collection bottle	Used to collect waste medical liquid. The useable volume of each collection container is 1L.
2	Filter	Used to filter water vapor and impurities.
3	Overflow protection	Used to prevent backflow of fully collected waste so as to ensure the safety of the gas pipeline.
4	Negative pressure gauge	Used to indicate negative pressure value.
5	Negative pressure adjustment knob	Used to adjust the pressure of the vacuum suction device
6	Selection switch	Used to switch the work mode of the vacuum suction device. It may be set as FULL, OFF or REG. "FULL" indicates that the vacuum suction device operates at a continuous maximum pressure and the adjustment knob does not work. "OFF" indicates that the negative pressure is off and the vacuum suction device does not work. "REG" indicates that the vacuum adjustment knob can be used to adjust the operation of the vacuum suction device. Rotate the vacuum adjustment

		knob counterclockwise to increase the negative pressure. Rotate the vacuum adjustment knob clockwise to decrease the negative pressure.
7	Suction tube	Used to transfer waste medical liquid. The suction tube has an inner diameter of Φ8 (5/16 "). The suction tube is inserted directly into the interface.

⚠Note

- **Refer to the user's manual supplied with the external vacuum suction system for specific information.**

⚠Warning

- **The vacuum suction system shall only be operated by trained personnel.**
- **FULL mode is strictly prohibited to be used for patient attraction.Excessive negative pressure will hurt the patient's tissues and cause injury to the patient.**
- **The device is a high negative pressure suction device.Thoracic suction and abortion are strictly prohibited.The excessive negative pressure value will hurt the patient's fragile body tissue and cause damage to the patient's life.**

2.5.4 Auxiliary Common Gas Outlet (ACGO)

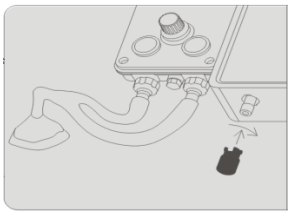
1. **ACGO Mode:**

   When ACGO cover is opened and the anesthesia machine is set to its position ACGO, fresh gas flow passes through the ACGO outlet in the front of the machine, and the interface is changed into ACGO mode.

   Do not use external ventilator on the ACGO. Do not use the ACGO to drive an external ventilator.

2. **Non-ACGO mode:**

   Mechanical ventilation or manual/spontaneous ventilation for patient may be achieved by the breathing system.



3. **When ACGO offers fresh gas to respiration apparatus:**
   - Mechanical ventilation is disabled.
   - Pressure gauge, Manual/mechanical ventilation switch, APL valve and Manual bag support column are spontaneous of external circuit devices.
   - Volume and pressure monitoring and control functions are disabled.
   - Do not use external ventilator on the ACGO.
   - Do not use the ACGO to drive an external ventilator
   - Flow control system is valid.

2.5.5 Anesthesia Vaporizer

AX-900 and AX-900A designed to work with Draeger Series Anesthesia Vaporizers for non-flammable anesthetic gases fed from Selectatec® (registered trademark of Ohmeda) fixed/interlocking devices.

⚠Caution

- **Please refer to the user's manual delivered along with the Anesthesia Vaporizer for specific information about relevant Anesthesia Vaporizers.**

Note

- **The "Draeger" described in this article is the English translation of "Dräger".**

2.5.6 Control of Anesthesia Ventilator

2.5.6.1 Optional Functions in Ventilation Mode

Various ventilation modes may be selected and configured for anesthesia machine

- VCV
- SIMV-VC
- PCV

- SIMV-PC
- CPAP/PSV
- PRVC
- SIMV-PRVC
- PSVPro
- Manual/Spont

2.5.6.2 Drive gas selection

Select **[config] →[Setting] →[Drive Gas]**,the interface has the option of **[O_2]** and **[AIR]**,you can choose O_2 or air as the driving gas.

2.5.6.3 Control Panel

The control panel components of an anesthesia ventilator include:

- Buttons
- Touch-control display screen
- Control knobs

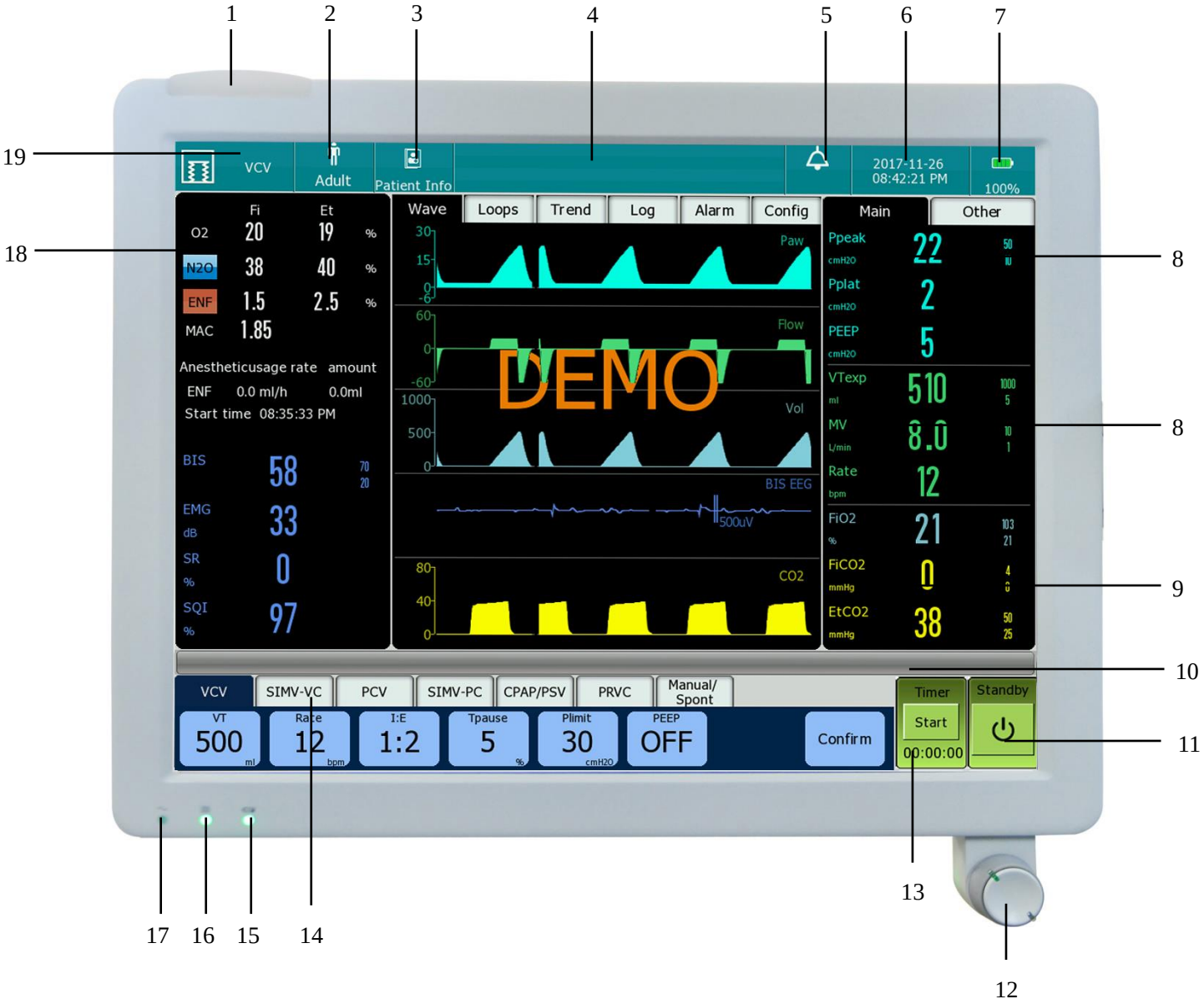


Fig. 2-10 Control Panel of Anesthesia machine

1	Alarm indicator	11	Standbybutton
2	Patient type	12	control knob
3	Patient information	13	Timer
4	Alarm Message Area	14	Ventilations Mode and Setting Parameters Area
5	Alarm sound pause icon	15	Battery status indicator
6	System Date and Time	16	Working indicator
7	Main Power Supply and Battery Status Icon	17	AC power indicator
8	Monitoring values of ventilator	18	Area for monitoring of Anesthetic gases concentration
9	Area for monitoring of CO_2 and O_2	19	Current Ventilation Mode

concentration

10 System prompt message area

⚠Caution

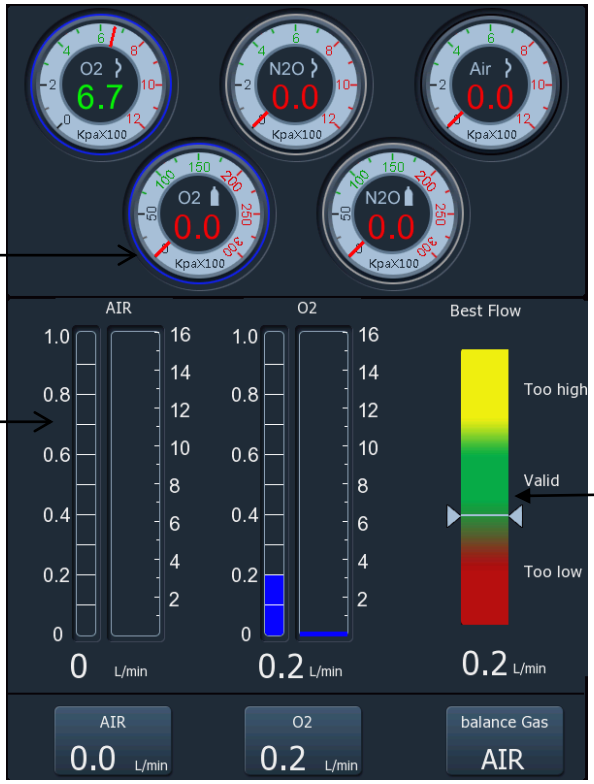
- **When anesthesia machine is restarted, patient type before the last shutdown will be reserved.**

2.5.7 Fresh Gas Flow Display

2.5.7.1 Electronic flow control system

The electronically controlled flow meter is called electronic flow control system. You can set the flow rate or oxygen concentration through the keypad. The anesthesia machine has a manual mechanical switch for turning on the backup flow. When the operator thinks that the flow meter control system of the electronic flow control system fails (such as communication exception and touch screen failure) or when the system has low battery power, if you turn on the switch above, the device will enter the backup flow meter control system.

This flow control system is able to display the real-time flow levels of oxygen and balance gas. Balance gas can be set to [**AIR**] or [**N2O**] or [**NULL**].



2

1

3

Item	Panel assembly	Description
1	Fresh gas flow area	It is used for displaying the real-time flow level of oxygen or balance gas.
2	Gas supply pressure monitoring	It is used for indicating the inlet pressure.
3	Optimal Flow	It is used to indicate the relationship betweensetting values and optimal values.

2.5.8 Auxiliary O_2 and air Supply Flowmeter

It is used for auxiliary air / O_2 flow output. Rotate the auxiliary O_2 / air supply flowmeter control knob counterclockwise to increase O_2 / air flow. Rotate the auxiliary O_2 / air supply flowmeter control knob clockwise to reduce the flow.

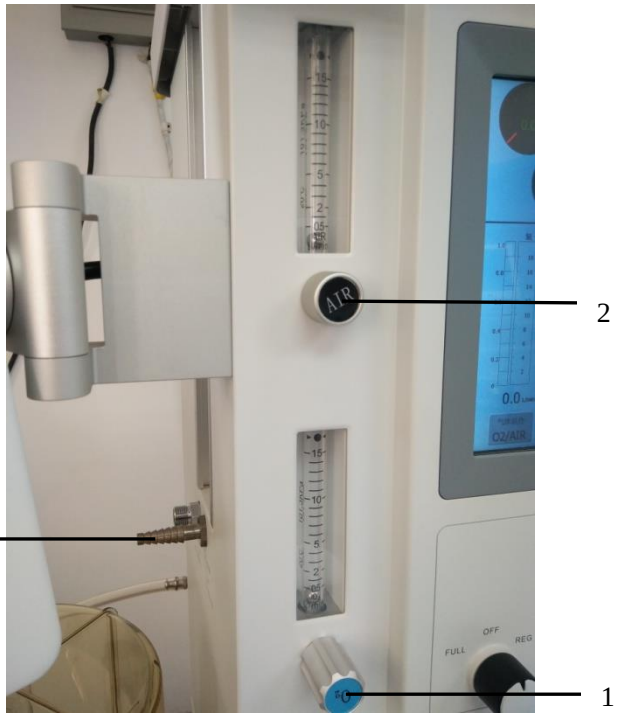


Fig. 2-11 Auxiliary O_2 Supply Flowmeter and Its Control

1 Auxiliary O_2-supply flowmeter control knob

2 Auxiliary air-supply flowmeter control knob

3 Auxiliary O_2 and air -supply outlet nozzle

⚠Caution

- **Turn anticlockwise the flow control knob to increase the oxygen flow, or turn it clockwise to reduce the flow.**

2.5.9 High pressure oxygen outlet

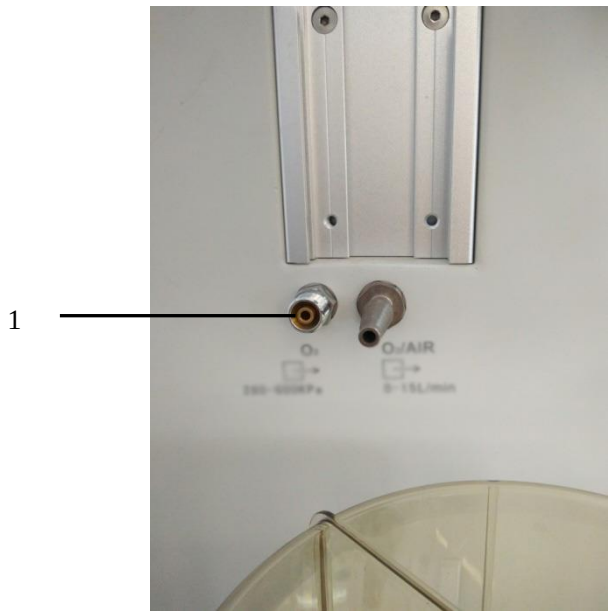


Fig. 2-12 High pressure oxygen outlet

1、High pressure oxygen outlet

2.5.10 Auxiliary Output Power Supply

Auxiliary output power supply is a type of safe and effective power supply that is alternating current output by isolation transformer, and mainly serves as auxiliary power supply for patient monitoring systems.

⚠Warning

- **IEC 60601-1(GB9706.1) is applicable to connection of all medical-use electrical rooms and connection of at least one piece of medical-use electrical equipment to one piece or pieces of non-medical-use electrical equipment. Even if there were no functional connection between single components of equipment, a medical-use electrical system is established once they are connected to 1 auxiliary network power outlet. If multiple equipment are connected to the auxiliary network power outlet, a risk (namely, leakage current rises and exceeds the allowable limits) may take place.**
- **To configure the auxiliary output power supply, the equipment connected to the auxiliary output power supply shall fall within the voltage/current specifications of the auxiliary output power supply. The equipment connected to the auxiliary output power supply shall**

be equipment specified by the manufacturer; otherwise, the leakage current may exceed relevant limits, endanger patient or operator, or even damage the anesthesia machine or external equipment.

- **If your anesthesia machine is not equipped with an isolation transformer, the equipment connected to the auxiliary output power supply may increase the leakage current. The leakage current shall be determined regularly. In order to reduce the total leakage current, we suggest that you select anesthesia machines equipped with isolation transformer.**

2.5.11 Dovetail groove

Dovetail groove is a type of mechanical structure that works with guide rails for guiding and supporting, and it may be used to connect other equipment such as monitoring equipment etc.

⚠Warning

- **With standard configuration, anesthesia machine may remain stable when it is inclined by 10°. Do not hang any articles from both sides of an anesthesia machine for fear of off-balance hazard.**

2.5.12 Operation ceiling lamp

Located below the top plate, it illuminates the workbench, allowing users to read the settings on the dial of the anesthetic vaporizer in a dark room. The brightness of the light can be adjusted by adjusting the operation ceiling lamp regulator below the top plate.

2.5.13 Flowmeter lighting

The lighting switch is located at the bottom left of the top plate, allowing users to read the scale display of the auxiliary O_2 supply flowmeter, auxiliary air flowmeter, and total flowmeter in a dark

room.

2.5.14 Workbench ergonomics

This device is a full-featured anesthesia delivery workstation. The protruding edge of its stainless steel workbench can prevent items placed on it from rolling out or sliding off the edge of the workbench. The wraparound armrests on the workbench can better position the device. Two large drawers are provided for storing items. Dovetail rails on both sides of the device are used to mount standard accessory arms for monitors and other equipment. In addition, non-slip foot pedals and central brake are available.

2.5.15 Breathing system hook

The hook on the side of the breathing system is used to suspend the breathing circuit.

2.5.16 Battery

The anesthesia machine is equipped with an internal rechargeable battery to ensure that the system can operate normally in the event of a power outage. When the device is connected to an AC power supply, the battery can be charged regardless of whether the device is turned on or not. In the event of a sudden power outage, the system will automatically switch to internal battery power without interrupting the operation. When the AC power supply recovers within a specified time, the battery starts to charge, and the system stops using the battery while automatically switching to the AC power supply to ensure the continuous operation of the system.

If the battery power is too low, it will cause the power supply to malfunction. The device will trigger an advanced alarm and display the alarm information in the technical alarm area. In this case, use an AC power supply to supply power to the anesthesia machine to get it back to work and charge the battery.

2.5.17 Serial Port

The symbol "  " marked on back cover of the equipment indicates the serial port of the equipment. That port is designed only for factory maintenance to be performed by the Company.

2.5.18 USB Port

The symbol "  " on the back cover of the equipment indicates the USB port. This port is used for data output and software update (by the Company).

2.5.19 Network Port

The symbol “  ” on the back cover of the equipment indicates the network port. This port is used for data transmission between the Medical Systems.

⚠Warning

- **All the simulation and digital equipment connected with this system must be the products certified by the designated IEC standards (e.g. IEC 60950 Data Processing Equipment Standard and IEC 60601-1 Medical Equipment Standard)**

2.5.20 VGA interface

on the rear shell of the instrument is used for an external display. The external display can simultaneously display the anesthesia machine’s LCD display interface.

2.5.21 Equal-potential Grounding

Equal-potential grounding means connecting the shell or metal part of equipment to the ground lead so as to avoid indirect-contact shock, explosion, fire hazard and transient overvoltage and interference caused by ground fault, and to protect the personal/equipment safety.

One end equal-potential ground lead shall be connected to the equal-potential ground pole fitted on the back cover of the equipment, and the other end shall be connected to one of the terminals of the equal-potential system. If the protective ground system is damaged, the equal-potential earthed system may undertake the safety function of the protective grounding lead.

Check whether or not the instrument is kept in good working order prior to each operation.

⚠Warning

- **If the protective ground system works unstably, the equipment shall be powered by internal power supply.**

Chapter 3 Basic Operations and Guidance

⚠Warning

- **Alarms given by an anesthesia ventilator indicate that the patient is being subjected to potential risks. The causes of all alarms shall be made certain so as to make sure the safety of patients.**
- **If sevoflurane is adopted, adequate fresh gas flow shall be maintained.**
- **When dry (dewatered) absorber material is exposed to inspiratory anesthetics, unsafe chemical reaction may take place. Caution: Do not allow the absorbent to get dry. Once the system operation is over, turn off all gas supplies.**
- **Do not place the power plug used to disconnect the monitor from grid power supply in a position not easily accessible by the operator.**
- **Before using the device on the patient, make sure that the device is installed correctly and intact.**
- **The operator shall not touch the patient and the charged equipment outside the device at the same time.**
- **The input / output signal port can only be connected with the specified external device.**

3.1 Turn on the system

1. Connect the gas source to ensure that the gas source has enough pressure (gas source pressure is between 280kPa and 600kPa).

2. Plug the power cord into a power socket. Turn on the main power switch on the back of the device. The AC power indicator lights up when connected to AC power supply. If the battery power is low, the battery is charging.

3. Set the system switch to ON "⊙" state and turn on the device.

   a) The alarm indicator flashes once in red-yellow order, and then the buzzer sounds a "beep".

   b) The system enters the ON state. The control panel screen displays the Comen LOGO. Then enter the [Self Test] interface.

   c) In the [Self Test] interface, the system automatically performs a series of self-tests and

displays the startup self-test progress bar. After the self-tests are completed, the self-test results are displayed.

d) After the completion of self-tests, click the [Continue] button to enter the [Check Before Use] interface.

e) After confirming that everything is normal, click [Continue] to enter the next step “Leak in vent mode”.

f) According to the prompt on the interface, select “Start” for “Leak in vent mode”. Enter “Leak in bag mode” in case of passing the test.

If the test fails, refer to “***4.5.2 Breathing System Leak Test in Mechanical Ventilation Mode***” for retesting.

g) According to the prompt on the interface, select “Start” for “Leak in bag mode”. Enter the “Standby” interface in case of passing the test. At this time, after setting the patient information and selecting the patient type “Adult” or “Child”, select “Ventilation Start” to enter the user interface.

If the test fails, refer to “***4.5.3 Breathing System Leak Test in Manual Ventilation Mode***” for retesting.

⚠Warning

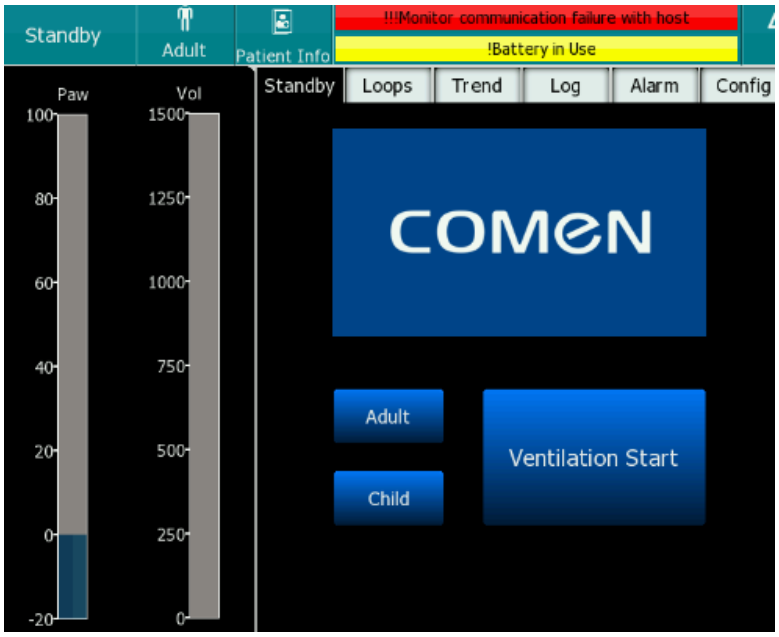
- **To run the equipment for patients, make sure that the system connection is errorless and is kept in good order and condition, and finish all tests specified in Chapter 4 *Tests Before Use*. If the equipment fails to pass the tests, never use the equipment. Please contact immediately an authorized service representative to repair the equipment.**
- **The anesthesia machine is equipped with built-in charge batteries to make sure that the anesthesia machine may still be used normally in case of power failure. Once the anesthesia machine is connected to AC power supply, it may charge the batteries, disregarding whether or not it is turned on. In case of sudden power cut, the system can power the anesthesia machine by its batteries so as to avoid interruption of anesthetization. When the AC power supply resumes at target time, the system can stop battery feed and enable AC power supply automatically in order to make sure normal work of the anesthesia machine.**
- **Battery feed can be maintained only for a period of time. Once the battery levelis too low, anesthesia machine may give out a high-level alarm, and display the alarm message [Low Battery Voltage] in the technical alarm zone.**

⚠Caution

- **Avoid short circuit of battery.**
- **Do not allow the batteries to be charged inside a sealed container.**
- **Keep batteries away from flammable and explosive materials.**

3.1.1 Patient type

1. Enter the standby screen, can set the patient type as [**Adult**] or [**Child**].
2. Click [**Adult**] or [**Child**] button to quickly switch the patient type and the default parameter settings for the patient type.

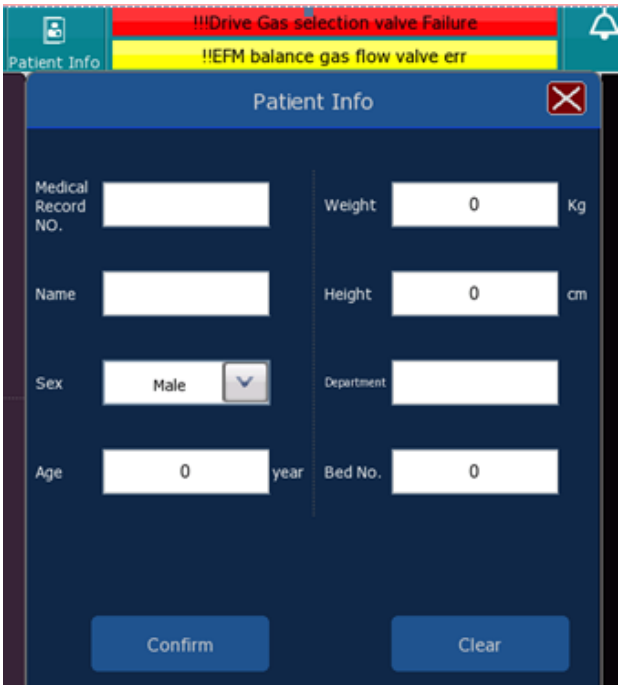


⚠Caution

- **The patient type is not optional in ventilation mode.**

3.1.2 Set Patient Information

1. Select the [**Patient Info**] soft button in the upper left corner of the main screen,and display [**Name**],[**Sex**],[**Bed NO.**],[**Age**],[**Height**],[**Weight**] patient information parameter options in the open menu.
2. If there is no operation,the patient information window will closed after 30s.After setting the patient information,click to confirm the current operation.



3.2 Configure Volume for Alarms, Prompts and Key Operations

1. Set the system switch to its status ON "⊙".
2. On the user screen, select [**Alarm**] menu → Access the [**Sound**] menu.
3. Set volume in grade "1-8" respectively for [**Alarm Sound Volume**] [1], set volume in grade "0-7" respectively for [**Indicate sound Volume**] [2] and [**Key sound Volume**] [3]. The length of cyan bar indicates the current volume grade. If no grid is cyan, the volume is muted, as shown in the figure below.

Fig. 3-1 Interface for Configuring Sound

Note

- **1: The alarm volume is set to adjust the volume of all high, medium, and low priority audible alarms.**
- **2: The prompt volume is the volume of the prompt message that appears in the alarm prompt area.**
- **3: The button volume is the volume of the sound produced by touching the soft buttons on the operation interface via a touch screen.**

3.3 Turn on/off Alarm

1. Set the system switch to its status "⊙".
2. Set the manual/mechanical ventilation switch to manual position, the screen displays [**Manual/Spont**].
3. Select **[Alarm]** ,push and turn the "control knob" key to switch over between **[ON]** or **[OFF].**
4. Select **[ON]** or **[OFF]** , push the "control Knob" to confirm the current option.

Fig. 3-2 Manual/Spont Alarm Menu

3.4 Open, close the extracorporeal circulation switch

In non-automatic circuit mode:

1. Set the system switch to ON "⊙".
2. Rotate the APL valve control knob to adjust the pressure in the breathing system to the proper range.
3. Set the manual/mechanical ventilation switch to manual position, the screen displays [**Manual/Spont**].
4. At the user interface, select the capacity [**Manual /Spont**] menu→Enter [**CPB**] menu in the lower part of the screen.
5. Click the **[CPB]** under the **[Manual/Spont]** menu and select **[ON]** or **[OFF]** in the pop-up window or or press and turn the "Control Knob" key to switch between [**ON**] and [**OFF**].
6. Select [**ON**] or [**OFF**] and then press the "Control Knob" to confirm the current option.

7. Rotate the "Control" button to return to the [**Manual/Spont**] menu and go back to the previous menu.

In mechanical ventilation mode, system set the [**CPB]** to **[OFF]** automatically, and the user cannot modify it.

⚠Warning

- **During [CPB] is set to [ON] , part of the physiologic alarm messages may not be triggered; therefore, the setting shall be applied cautiously. The physiologic alarms include: Apnea, Apnea>2min, Low Paw, High VTexp, Low VTexp,High MV, Low MV.**

3.5 Set the High/Low Alarm Limits

1. Set the system switch to its status "⊙".
2. On the user interface, select **[Alarm]** menu→ Access the **[ventilator]**、**[AG]**、**[CO_2]**or**[BIS]**[1]menu, and set the High/low alarm limits for the parameters.

Fig. 3-3 High/Low Alarm Limit Interface

Note

- **Note 1: See [Alarm setting] given in relevant chapter for details of High/low alarm limits for parameters of [ventilator] 、 [AG]、[CO_2]and[BIS].**

3.6 Vacuum suction operation

⚠Note

- **Please refer to the user manual supplied with the external vacuum suction system for operation information on the external vacuum suction system.**

3.6.1 Turn on the Internal Vacuum Suction Device

1. According to ***5.9.1 Installation of internal vacuum suction,*** assemble an external pipe collection system of a internalvacuum suction device to an anesthesia machine;
2. Confirm that the negative-pressure gear switch is in the OFF position, and the negative-pressure adjustment knob is in the minimum position adjusted counterclockwise;
3. Open the anesthesia machine's O_2 source, and confirm whether the pressure is within the applicable range of the anesthesia machine (280-600kPa);
4. Block the patient end of the negative-pressure suction tube, and turn the negative-pressure gear switch to the FULL position; observe whether the reading on the negative pressure gauge can reach 60kPa or above;
5. Turn the negative-pressure gear switch to the REG position; slowly rotate the negative-pressure adjustment knob clockwise; observe whether the reading on the pressure gauge changes with the adjustment; confirm that the negative pressure can be adjusted to 60kPa or above, and that the pressure can remain steady when not adjusting;
6. Confirm that there is no fault. Adjust the negative pressure to the desired pressure for use.

3.6.2 Turn off the Internal Vacuum Suction device

1. After use, rotate the negative-pressure adjustment knob counterclockwise until the negative pressure value returns to zero;
2. Turn the negative-pressure gear switch to the OFF position, and the vacuum suction device is completely turned off.

⚠Warning

- **Keep the vacuum suction switch in the OFF state when you are not using the vacuum suction device.**

3.6.3 Turn on the external vacuum suction device

1. According to ***5.9.2 Installation of external vacuum suction,*** assemble an external vacuum suction device to an anesthesia machine;

2. Press the driving gas switch to the OFF position; turn the negative-pressure gear switch to the OFF position as well;
3. Rotate the negative-pressure adjustment knob counterclockwise to the minimum position until it can no longer be rotated;
4. Open the O_2 source, and confirm that the gas source pressure is within the applicable range of the external vacuum suction (280-550kPa);
5. When the gas source pressure is appropriate, pull the driving gas switch to the ON position;
6. Block the patient end of the suction tube, and turn the negative-pressure gear switch to the FULL position; observe whether the reading on the negative pressure gauge can reach 60kPa;
7. Turn the negative-pressure gear switch to the REG position; slowly rotate the negative-pressure adjustment knob clockwise; observe whether the reading on the pressure gauge changes with the adjustment; confirm that the negative pressure can be adjusted to 60kPa or above, and that the pressure can remain steady when not adjusting;
8. Confirm that there is no fault. Adjust the negative pressure to the desired pressure for use.

3.6.4 Turn off the external vacuum suction device

1. After use, rotate the negative-pressure adjustment knob counterclockwise until the negative pressure value returns to zero;
2. Turn the negative-pressure gear switch to the OFF position, and press the driving gas switch to the OFF position. The vacuum suction is then completely shut down.

⚠Warning

- **Please keep vacuum suction switch at OFF when the vacuum suction device is not in use.**

3.7 Set Parameters of Ventilator

Parameters of ventilator are configured mainly through Control Knob and touch screen operations. When parameter settings are changed,bubble box appears for the corresponding parameter,indicating the current parameter range(or the correlation equation of the parameter).When switching modes, the [**Confirm**] key of the current ventilation mode menu flashes alternatively in yellow and light blue, reminding you to confirm settings. If you do not confirm settings within 15 seconds, the previous parameters before settings will be recovered and the [**Confirm**] key stops flashing.

Fig. 3-4

⚠Warning

- **Click on the system default, vent mode setting restored to system defaults.**

3.7.1 Set Tidal Volume

1. Select menu of [**VCV**] / [**SIMV-VC**] / [**PRVC**] / [**SIMV-PRVC**] mode→ [**VT**] .
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**VT**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

3.7.2 Set Respiratory Rate

1. Select the menu of ventilation mode→ [**Rate**] .
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**Rate**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

Note

- **[Rate] can be configured in [VCV],[SIMV-VC],[PRVC],[SIMV-PRVC],[PCV],[SIMV-PC], and [PSVPro] .**

3.7.3 Set the Minimum Respiratory Rate

1. Select the menu of [**CPAP/PSV**] mode → [**MinRate**] .
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**MinRate**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

3.7.4 Set Inspiratory:Expiratory Time Ratio

1. Select the menu of [**VCV**] /[**PCV**] or [**PRVC**] mode→ [**I:E**] .
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**I:E**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

3.7.5 Set Inspiratory Time

1. Select the menu of [**SIMV-VC**]/[**SIMV-PC**]or[**SIMV-PRVC**] mode→[**Tinsp**],or [**PSVPro**]→[**Extra Setting**] →[**Tinsp**].
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**Tinsp**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

3.7.6 Set Inspiratory Pause

1. Select the menu of [**VCV**] or [**SIMV-VC**] → [**Tpause**] .
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**Tpause**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

3.7.7 Set Inspiratory Pressure

1. Select the menu of [**PCV**] or [**SIMV-PC**] mode→ [**Pinsp**], or [**PSVPro**]→[**Extra Setting**] →[**Pinsp**].
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**Pinsp**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

3.7.8 Set Support Pressure

1. Select the menu of [**SIMV-VC**] , [**SIMV-PC**] , [**PSVPro**] , [**SIMV-PRVC**] or [**CPAP/PSV**] mode → [**Δ Pps**] .
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**Δ Pps**] to

the appropriate value.

3. Confirm the parameter setting via the control knob.

3.7.9 Set Limiting Pressure

1. Select the menu of ventilation mode → [**Plimit**] .
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**Plimit**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

3.7.10 Set Positive End-Expiratory Pressure

1. Select the menu of ventilation mode → [**PEEP**] .
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**PEEP**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

3.7.11 Set Pressure Slope

1. Select the menu of [**PCV**] , [**SIMV-PC**] , [**PSVPro**] , [**SIMV-PRVC**] , [**SIMV-VC**] or [**CPAP/PSV**] mode → [**Tslope**].
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**Tslope**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

3.7.12 Set Trigger Window

1. Select the menu of [**SIMV-VC**], [**PSVPro**], [**SIMV-PRVC**] or [**SIMV-PC**] mode → [**Extra Setting**] → [**Trig Window**] .
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**Trig Window**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

3.7.13 Set Inspiratory Triggering

1. Select the menu of [**SIMV-PC**], [**SIMV-PRVC**] or [**SIMV-VC**] mode → [**Extra Setting**] →

[**Trigger**], or select the menu of [CPAP/**PSV**] , [**PSVPro**] mode → [**Trigger**] .

2. Select the parameter via the control knob or touch control, and rotate the knob to set [**Trigger**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

3.7.14 Set Stop level

1. Select the menu of [**CPAP/PSV**], [**SIMV-PC**],[**SIMV-VC**] or [**SIMV-PRVC**] mode → [**Extra Setting**] → [**Exp%**], or select the menu of [**PSVPro**] mode → [**Exp%**] .
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**Exp%**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

3.7.15 Set Apnea Pressure

1. Select the menu of [**CPAP/PSV**] mode → [**Extra Setting**] → [**ΔPapnea**].
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**ΔPapnea**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

3.7.16 Set Apnea Respiratory Ratio

1. Select the menu of [**CPAP/PSV**] mode → [**Extra Setting**] → [**ApneaIE**].
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**ApneaIE**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

3.7.17 Set Apnea Time

1. Select the menu of [**PSVPro**] mode →[**Apnea Ti**].
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**Apnea Ti**] to the appropriate value.
3. Confirm the parameter setting via the control knob.

3.7.18 Set Exit Backup

1. Select the menu of [**PSVPro**] mode → [**Extra Setting**] →[**Exit Backup**].
2. Select the parameter via the control knob or touch control, and rotate the knob to set [**Exit Backup**] to the appropriate value.

3. Confirm the parameter setting via the control knob.

3.8 Electronic flow control system

The electronically controlled flow meter is called electronic flow control system. You can set the flow rate or oxygen concentration through the keypad. The anesthesia machine has a manual mechanical switch for turning on the backup flow. When the operator thinks that the electronically controlled flow meter control system fails (such as communication exception and touch screen failure) or when the system has low battery power, if you turn on the switch above, the device will enter the backup flow meter control system. The backup flow control system provides three independent flow control knobs to set the input flow of nitrous oxide, air and oxygen in the fresh gas flow.

The display accuracy of the numerical values on the flow meter is two decimal places in case of flow rate less than 1 L/min and is one decimal place in case of flow rate greater than 1 L/min.

For this device, the electronic flow control system includes two modes: total flow and single-pipe flow.

The method of setting flow control mode is as follows:

1. In the user interface, select the [**Config**] menu → Enter the [**Flow Meter Config**] label.

2. Set [**Flow Control**] to [**Single tube**] or [**Total Flow**].

3.8.1 Total Flow Control Mode

The total flow control mode of the electronic flow control system is shown in the figure below:

You can make the following settings in the total flow control menu:

1. Set the [**Balance gas**] to [**AIR**], [**N_2O**] or [**NULL**].
2. Set the total flow value through the soft keypad.
3. Set the oxygen concentration value through the soft keypad.

3.8.2 Single-pipe Flow Control Mode

The single-pipe flow control mode of the electronic flow control system is shown in the figure below:

You can make the following settings in the single-pipe flow control menu:

1. Set the [**Balance gas**] to [**AIR**], [**N_2O**] or [**NULL**].
2. Set the flow value of balance gas through the soft keypad.
3. Set the oxygen flow value through the soft keypad.

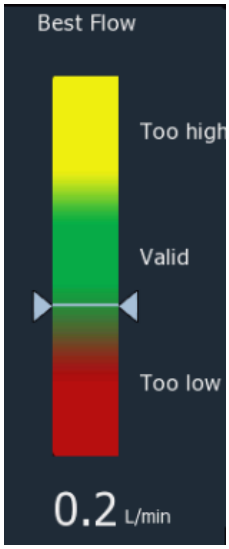
3.8.3 Optimal Flow

⚠ Note

- **The optimal flow is valid only when the anesthesia system is equipped with the AG module with paramagnetic oxygen and is in mechanical ventilation mode.**
- **When the data used for optimal flow calculation is invalid, the optimal flow function will be invalid.**
- **The function of optimal flow indicator is to save anesthetics.This function only serves as a reminder,and it does not involve the control function of the anesthesia machine control module.**

The principle of optimal flow rate is to monitor oxygen concentration and various anesthetic gas parameters through the AG module with paramagnetic oxygen,analyze and calculate the parameters to obtain the gas consumption,identify the relationship between fresh gas supply and gas consumption,and display the prompt information on the screen according to the relationship identified.

The optimal flow indicator is used for indicating the relationship between the total flow of fresh gas and the total consumption.The following figure is the optimal flow indicator function.The bar histogram shows the supply of fresh gas,and the value below the bar graph represents the total flow value.



Scope	Colour	Meaning
Too high	yellow	The triangle indicates in this region means the difference between total fresh gas flow and total consumption is greater than 1 L/min,which will cause the waste of anesthetics.
valid	green	The triangle indicates in this region means the difference between total fresh gas flow and total consumption is within 1 L/min,which will save the anesthetics.
Too low	red	The triangle indicates in this region means the total fresh gas flow is less than the total consumption,which the fresh gas is in short supply.

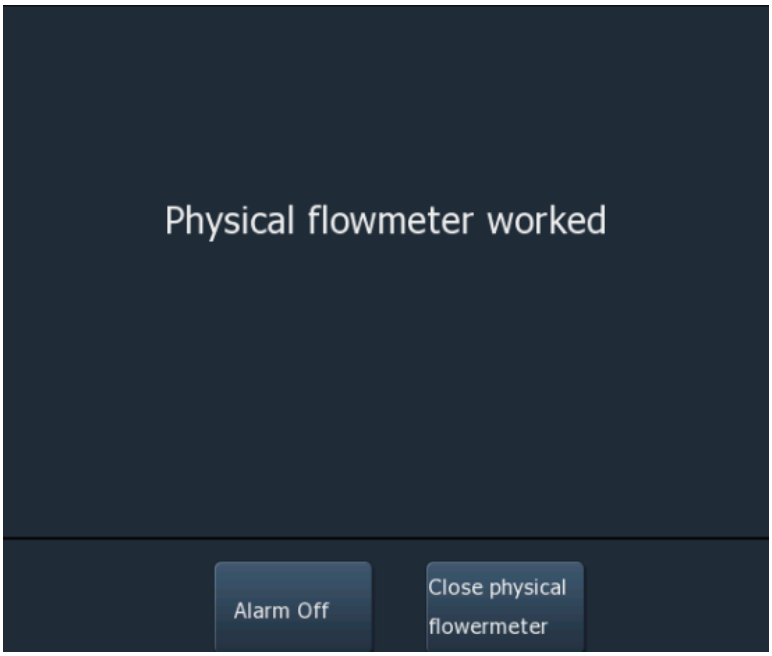
3.8.4 Gas Supply Pressure Monitoring

The anesthesia system electronically monitors the pipeline gas supply and the pressure of spare gas cylinder. When the alarm is triggered in case of abnormal gas supply pressure, the pressure value of the gas supply pressure is displayed in the corresponding color.

3.9 Backup Flow Control System

The anesthesia machine has a manual mechanical switch for turning on the backup flow. The flow meter control system of the electronic flow control system fails (such as communication exception and touch screen failure) or when the system has low battery power, if you turn on the switch above, the device will enter the backup flow meter control system.

The interface diagram of the backup flow control system is shown below:



After the backupflow control system is expanded, when using the backup flow control system, you can rotate the needle valve to regulate the flow. The total flowmeter is used to display the total flow. With the O_2 concentration value displayed on the interface, you can calculate the O_2 flow and balance gas flow in the gas. The alarm sound off function here can only disable the technical alarm of the backup flow control system and the failure alarm of the electronic flow control system.

When the electronic flow control system has not failed, you can press the backup flow control system button to expand the backup flow control system. When you want to turn off the backup flow control system, close all needle valves and press the [**Close physical flowermeter**] button on the interface. Select [**Yes**] in the pop-up dialog box to shut down the backup flow control system.

⚠ Warning

- **When using a backup flow control system, make sure that the oxygen ,air and nitrous oxide flow controllers are fully closed at the start and end of each ventilation.**
- **The backup oxygen flow meter shall be marked with pure oxygen for application. In case of using gas mixture, the accuracy will be affected.**

⚠ Note

- **The total flow meter is calibrated with 100% oxygen. For other gases or gas mixtures, the accuracy of flow meter may be reduced.**
- **When viewing the readings on a total flow meter, the line of sight shall be at the same level as the float. In case of different perspectives, the same scale readings may be different.**
- **If there is a difference between the readings displayed on the electronic flow meter and the total flow meter, take the reading on the electronic flow meter as a reference and the reading on the total flow meter as the approximate value.**

3.10 Control of Anesthesia Ventilator

Note

- **Anesthesia ventilator shall be configured to comply with breathing system in ISO 80601-2-13 and YY 0635.1, together with AGSS in ISO 80601-2-13 and YY 0635.2。**

3.10.1 Manual/Spont Mode

1. Rotate the control knob of the APL valve to adjust the pressure inside the breathing system to appropriate range.
2. Set the Manual/mechanical ventilation switch to "Manual" position, and [**Manual/Spont**] will be displayed on the screen.
3. If necessary, press the O_2+ "oxygen flush" button to inflate the manual bag.
4. In **[Manual/Spont]** mode, the APL valve is used to regulate the peak pressure in the breathing system and the gas volume in the manual bag. When the pressure in the breathing system reaches the threshold, the APL valve is opened to discharge the excessive gas in the breathing system.

The pressure waveform and flow rate waveform are shown in the figure below:

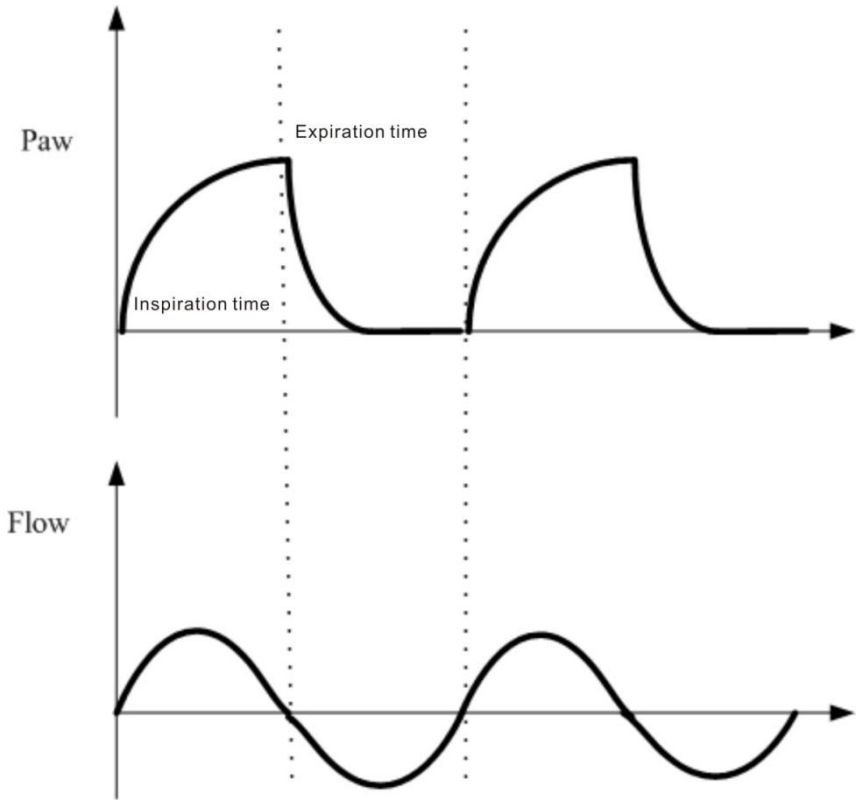


Fig. 3-5

Note

- **Make sure Manual/Spontaneous mode is always available when this device is used on patients.**

3.10.2 Mechanical Ventilation Mode

3.10.2.1 Start Mechanical Ventilation

1. Set the system switch to "⊙" (ON) status.
2. Set the proper patient type like [**Adult**] or [**Child**] on the user interface.
3. Select [**VCV**] → [**VT**] .
4. Enter the setting mode through the "Control Knob" or touch screen operation. Rotate the "Control Knob" to set a proper value for [**VT**] , and then confirm the parameter setting via the control knob or touch operation.
5. Select [**VCV**] → [**Confirm**] to confirm parameter settings for all modes.
6. Check ACGO switch, and make sure ACGO is OFF.
7. Set the Manual/mechanical ventilation switch to ⌧ "Mechanical Control" position..

8. If necessary, press the O_2+ "Oxygen flush" button to inflate bellows.
9. Start the mechanical ventilation by pressing the [**Ventilation Start**] button.

Note

- **Make sure all parameters are set properly before starting up the new mechanical ventilation mode.**
- **Ventilator mode settings will restore to system defaults after anesthesia machine shutdown.**

3.10.2.2 Select Mechanical Ventilation Mode

Ventilation modes are configured mainly through Control Knob and touch screen operations. When switching between ventilation modes, the [**Confirm**] key of the current ventilation mode flashes alternatively in yellow and light blue, reminding you to confirm settings. If you confirm settings within 15 seconds, the ventilator will enter the new mode; otherwise, it will remain in the current mode.

There are 8 modes for mechanical ventilation:

- VCV
- SIMV-VC
- PCV
- SIMV-PC
- PRVC
- SIMV-PRVC
- CPAP/PSV
- PSVPro

3.10.2.2.1 Select VCV Ventilation Mode

1. Select [**VCV**] tab→ set up parameters like [**VT**], [**Rate**] .
2. Select **[VCV**] tab→ [**Confirm**] to start the VCV mode.
3. At this time, the current mode [**VCV**] is displayed at the left top of the screen.

3.10.2.2.2 Select SIMV-VC Ventilation Mode

1. Select [**SIMV-VC**] tab → set up parameters like [**VT**] , [**Rate**] .
2. Select [**SIMV-VC**] tab → [**Confirm**] to start the SIMV-VC mode.
3. At this time, the current mode [**SIMV-VC**] is displayed at the left top of the screen.

3.10.2.2.3 Select PCV Ventilation Mode

1. Select [**PCV**] tab → set up parameters like [**Pinsp**] , [**Rate**] .
2. Select [**PCV**] tab → [**Confirm**] to start the PCV mode.

3. At this time, the current mode [**PCV**] is displayed at the left top of the screen.

3.10.2.2.4 Select SIMV-PC Ventilation Mode

1. Select [**SIMV-PC**] tab → set up parameters like [**Pinsp**] , [**Rate**] .
2. Select [**SIMV-PC**] tab → [**Confirm**] to start the SIMV-PC mode.
3. At this time, the current mode [**SIMV-PC**] is displayed at the left top of the screen.

3.10.2.2.5 Select PRVC Ventilation Mode

1. Select [**PRVC**] tab → set up parameters like [**VT**] , [**Rate**] .
2. Select [**PRVC**] tab → [**Confirm**] to start the PRVC mode.
3. At this time, the current mode [**PRVC**] is displayed at the left top of the screen.

3.10.2.2.6 Select SIMV-PRVC Ventilation Mode

1. Select [**SIMV-PRVC**] tab → set up parameters like [**VT**], [**Rate**] .
2. Select [**SIMV-PRVC**] tab → [**Confirm**] to start the SIMV-PRVC mode.
3. At this time, the current mode [**SIMV-PRVC**] is displayed at the left top of the screen.

3.10.2.2.7 Select CPAP/PSV Ventilation Mode

1. Select [CPAP/**PSV**] tab → set up parameters like [**Δ Pps**] , [**Rate**] .
2. Select [**Δ Pps**] tab → [**Confirm**] to start the CPAP/PSV mode.
3. At this time, the current mode [CPAP/**PSV**] is displayed at the left top of the screen.

3.10.2.2.8 Select PSVProVentilation Mode

1. Select [**PSVPro**] tab → set up parameters like [**ΔPps**],[**Trigger**].
2. Select [**PSVPro**] tab → [**Confirm**] to start the PSVPro mode.
3. At this time, the current mode [**PSVPro**] is displayed at the left top of the screen.

3.10.2.3 Introduction to Ventilation Modes

3.10.2.3.1 VCV Mode

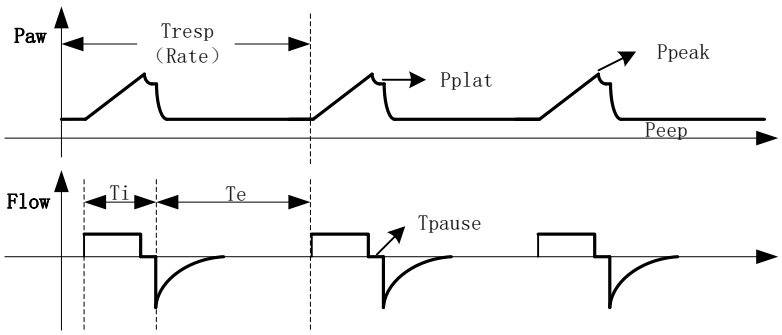


Fig. 3-6 Waveform of VCV Mode

Under the volume controlled VCV mode, a preset tidal volume will be provided. According to the preset [**VT]** , [**Rate]**, [**Tpause]**and **[I:E]** , the airflow delivered in the inspiration phase will be calculated by the ventilator. The inspiratory flow sensor detects the inhaled tidal volume in real-time fashion, and the exhaled tidal volume reaches the preset value through the feedback of inhaled tidal volume. As the output of the ventilator is adjustable, so the compliance of the breathing circuit system and the influence of the fresh airflow can be compensated.

Generally, under this mode, a constant flow is delivered during the inspiration phase, with the pressure increasing in the lungs; the flow is exhaled fastly in the expiration phase, and the pressure inside the lungs drops rapidly. By setting [**Tpause]** , the gas distribution in the patient's lungs can be optimized.

When the airway pressure exceeds the limit pressure, the ventilator will provide alarms and switch to expiration.

Setting [**PEEP]** (Positive End-Expiratory Pressure) to improve the expiratory-end CO_2 discharge and increase oxygenation during the respiratory process.

Settings of VCV Mode:

- VT
- Rate
- I:E
- Tpause
- Plimit
- PEEP

3.10.2.3.2 SIMV-VC Mode

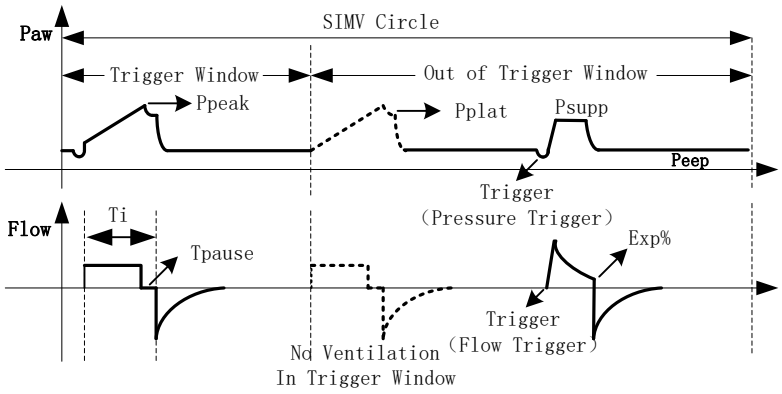


Fig. 3-7 Waveform of SIMV-VC Mode

Under the SIMV-VC mode, a preset tidal volume will be delivered to a patient at a preset [**Rate]**. In the respiratory interval (trigger window), the patient conducts spontaneous respiration at patient's respiratory rate and tidal volume.

The ventilator waits for the patient's spontaneous respiration as per the preset interval. [**Trigger]** includes flow triggering or pressure triggering. If the spontaneous respiration reaches the threshold of [**Trigger]** in the **[Trig Window]**, the ventilator uses the preset tidal volume and inspiratory time to deliver fresh gas synchronously, or it will conduct mechanical ventilation as per the preset clinical parameter of **[Rate]**.

Under this mode, spontaneous respiration can obtain the ventilator pressure to support ventilation. Thus the patient can overcome the resistance in the patient's circuit system and the artificial airway, so as to conduct ventilation with the preset support pressure.

Settings of SIMV-VC Mode

- VT
- Rate
- Tinsp
- Tpause
- △Pps
- Tslope
- Plimit
- PEEP
- Trig Window
- Trigger
- Exp%

3.10.2.3.3PCV Mode

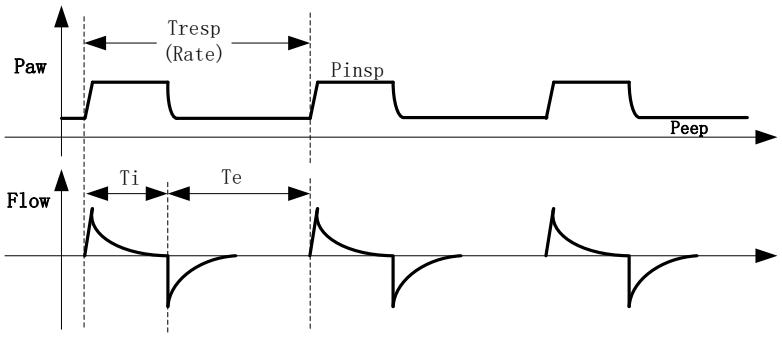


Fig. 3-8 Waveform of PCV Mode

Under the PCV mode, a constant inspiratory pressure will be provided. According to the preset [**Rate]** and **[I:E]** , the inspiratory time can be calculated by the ventilator. The ventilator increases pressure for patient side of the breathing circuit through a higher initial airflow, and reduce the airflow after the pressure reaches the preset value in order to maintain the preset inspiratory pressure, until the respiratory time turns to the expiratory time.

The ventilator pressure sensor monitors the airway pressure of the patient side of the breathing circuit in real-time fashion. The ventilator maintains the preset pressure through the feedback of flow corresponding to the pressure.

Under the PCV mode, setting [**PEEP]** also can improve the expiratory-end CO_2 discharge and increase oxygenation during the respiratory process.

Settings of PCV Mode:

- Pinsp
- Rate
- I:E
- Tslope
- Plimit
- PEEP

3.10.2.3.4SIMV-PC Mode

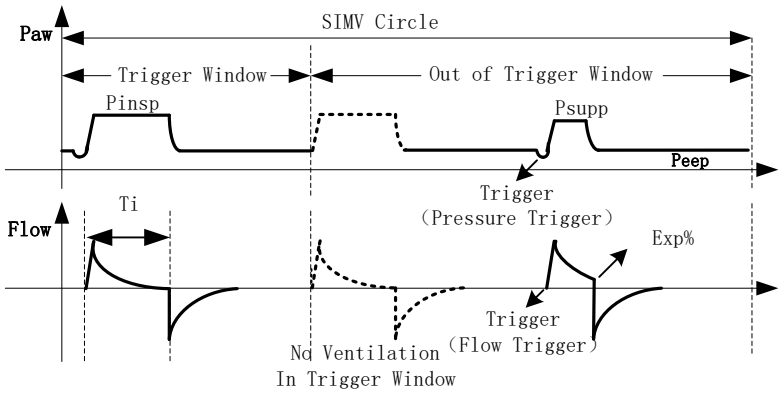


Fig. 3-9 Waveform of SIMV-PC Mode

Under the SIMV-PC mode, the ventilator use a preset [**Pinsp]** to conducts ventilation for a patient at a preset [**Rate]**. In the respiratory interval (trigger window), the patient conducts spontaneous respiration at patient's respiratory rate and tidal volume.

The ventilator waits for the patient's spontaneous respiration as per the preset interval. [**Trigger]** includes flow triggering or pressure triggering. If the spontaneous respiration reaches the threshold of [**Trigger]** in the **[Trig Window]** , the ventilator will use the preset inspiratory pressure and inspiratory time to deliver fresh air synchronously, or it will conduct mechanica lventilation as per the preset clinical parameter of **[Rate]** .

Under this mode, spontaneous respiration can obtain the ventilator pressure to support ventilation. Thus the patient can overcome the resistance in the patient's circuit system and the artificial airway, so as to conduct ventilation with the preset support pressure.

Settings of SIMV-PC Mode:

- Pinsp
- Rate
- Tinsp
- Tslope
- ΔPps
- Plimit
- PEEP
- Trig Window
- Trigger
- Exp%

3.10.2.3.5PRVC Ventilation Mode

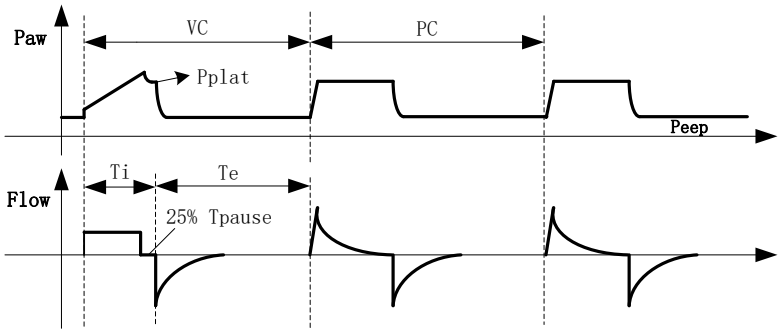


Fig. 3-10 Waveform of PRVC Mode

The PRVC mode is a controlled ventilation mode in which pressure regulates volume control.

In the PRVC mode, the first respiratory cycle is a trial ventilation for volume control, and trial ventilation is performed according to preset [**VT**], [**Rate**], [**I:E**] and the default 25% inspiratory pause. The measured plateau pressure during the inspiratory pause is used as the inspiratory pressure value for the next respiratory ventilation cycle. Starting from the second respiratory cycle, the inspiratory pressure value, [**Tslope**], [**Rate**], and [**I:E**] are used for pressure control ventilation. During ventilation, inspiratory pressure will be automatically adjusted according to the characteristics of the patient's lungs, in order to achieve transfer of the target tidal volume.

When the adjusted suction pressure reaches the preset [limit pressure], the system will provide alarm and change to expiration.

The settings of pressure regulating volume control ventilation mode inlude:

- VT
- Rate
- I:E
- Plimit
- PEEP
- Tslope

3.10.2.3.6SIMV-PRVC Ventilation Mode

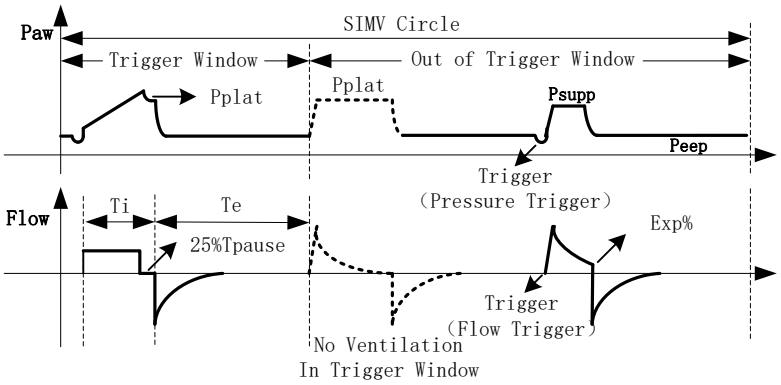


Fig. 3-11 Waveform of SIMV-PRVC Mode

SIMV-PRVC is a mode in which ventilation is delivered to a patient with synchronized intermittent command and pressure regulated volume control.

In the SIMV-PRVC mode, the ventilator waits for the patient to inspire at a specified time interval. The inspiratory trigger depends on the preset [**Trigger**] threshold. The inspiratory trigger can be set to the flow trigger or pressure trigger mode. If the inspiratory trigger threshold is reached within the [**Trig Window**] set time, the ventilator simultaneously deliver PRVC control ventilation according to the preset [**VT**], [**Rate**], [**Tinsp**], and [**Tslope**]. If the patient does not inspire in the trigger window, the ventilator sends PRVC control ventilation to the patient when the trigger window ends. During the pressure control ventilation process, the inspiratory pressure will be automatically adjusted according to the lung characteristics of the patient to achieve the transfer of the target tidal volume.

The first PRVC ventilation is a trial volume control ventilation, and the subsequent PRVC ventilation is pressure controlled ventilation with the plateau pressure measured at the trial ventilation stage as the control pressure.

In the SIMV-PRVC mode, spontaneous breathing outside the trigger window can obtain pressure support ventilation to help the patient overcome the resistance of the patient's circuit system and artificial airway and perform ventilation according to the preset [**ΔPps**].

The settings of pressure adjustment and control synchronization ventilation mode:

- VT
- Rate
- Tinsp
- Plimit
- ΔPps
- Tslope
- PEEP
- Trig window

- Trigger
- Exp%

3.10.2.3.7CPAP/PSV Mode

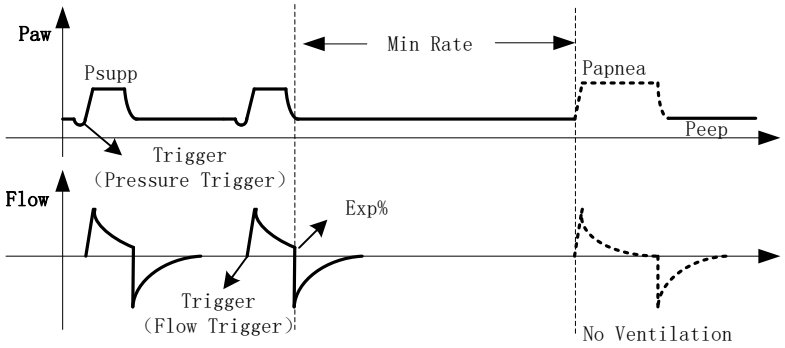


Fig. 3-12 Waveform of CPAP/PSV Mode

CPAP/PSV mode is an auxiliary respiratory ventilation mode.

Under this mode, the ventilator conducts ventilation at the preset [**MinRate]** . In the preset interval, if the spontaneous respiration reaches the level of [**Trigger]** , the ventilator starts to deliver gas to increase the pressure in the airway to the preset [**ΔPps]** quickly, and then maintain the pressure at the same level. After the spontaneous inspiratory flow reduces to [**Exp%]**, the ventilator stops delivering gas and the patient starts to exhale; If the spontaneous respiration does not reach the triggering level, the ventilator will conduct mandatory ventilation for once with the [**ΔPapnea]** ,[**Apnea.IE]** , ensuring the minimum ventilation volume for the patient.

Under this mode, the tidal volume is the monitored value, which depends on various factors like the inspiratory force of the patient, preset [**ΔPps]** level, the compliance and the resistance between the patient and the whole system of the ventilator, etc.

Settings of CPAP/PSV Mode:

- Δ Pps
- MinRate
- Trigger
- Tslope
- Plimit
- PEEP
- Exp%
- ΔPapnea
- Apnea.IE
-

3.10.2.3.8PSVPro ventilation mode

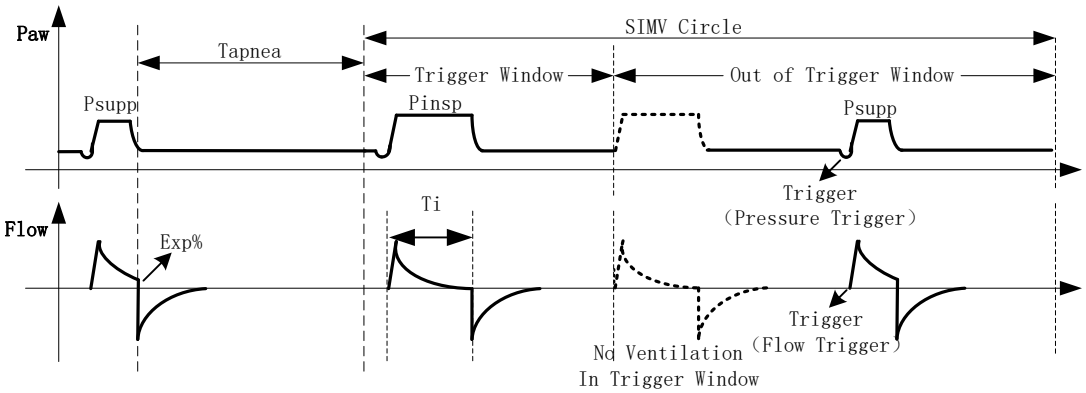


Fig. 3-13 Waveform of PSVPro Mode

PSVPro is a pressure support ventilation mode with Apnea reserve ventilation.

In PSV Pro mode, when the patient's spontaneous respiration reaches the [**Trigger**] threshold, the ventilator provides pressure support ventilation to the patient according to the preset [**ΔPps**], [**Exp%**], and [**Tslope**]. During pressure support ventilation, the amount of inspiratory time and tidal volume are determined by the patient's inspiratory strength and preset [**ΔPps**] levels, as well as the compliance and resistance of the patient and the ventilator's entire system.

ventilate according to the preset [**Trig Window**], [**Pinsp**], [**Tslope**] and [**ΔPps**], and provide alarm of Apnea ventilation;

When the ventilator is switched to backup ventilation mode, the Apnea ventilation alarm will continue until the PSVPro restarts. When the number of continuous triggering ventilations of the patient reaches the preset [**Exit Backup**] set value, the ventilator will restart PSVPro ventilation. When [**Exit Backup**] is set to OFF, you must manually select PSVPro ventilation mode again to switch back to PSVPro ventilation mode.

PSVPro mode settings:

- **ΔPps**
- In**Trigger**
- Termination **Exp%**
- Apnea ti
- Limit pressurePlimit
- Positive pressure at end PEEP
- Inspiratory pressure**Pinsp**
- Pressure **Tslope**
- Inspiratory time **Tinsp**
- FrequencyRate
- Trigger window**Trig Window**

- Exit backup

3.10.2.4 Stop Mechanical Ventilation

1. Make sure that the manual Circuit has been set before stopping mechanical ventilation, and set the APL valve at 20cmH_2O.
2. Set the Manual/mechanical ventilation switch to “Manual” or directly set the ACGO switch as the auxiliary outlet, so as to stop mechanical ventilation.

3.11 Compliance of Circuit

Calculate the compressible volume in the patient’s circuit:

1. Set the ventilator on the mechanical ventilation mode.
2. Set the VT to around 500 mL.
3. Set the Rate to 10 bpm.
4. Set the I:E to 1:1.
5. Set the Plimit to 20 cm H_2O.
6. Block the patient’s port of the Y-piece. Pay attention to keep the port clean.
7. Start mechanical ventilation.
8. Monitor VTexp (Expired Tidal Volume) and Ppeak (Peak Pressure measured in the airway)

VTexp is intended to measure the needed gas volume in the patient’s circuit.

The example below shows how to calculate the tubing compliance factor

VTexp ／(Ppeak-2.5 [1] cmH_2O)= Compliance Factor; Unit: mL/cm H_2O

Example: Ppeak=20 cm H_2O, VTexp =24mL, 24/(20-2.5) =1.4 mL/cm H_2O

The factor is used to calculate the gas compression volume in the patient’s circuit. For example, if a patient needs 30 cmH_2O to conduct ventilation, then 42mL (calculated by 30 X 1.4= 42 mL) gas shall be compressed in the tubing at each respiration. The 42 ml gas is part of the indicated tidal volume, but it won’t be delivered to the patient.

Note 1: Force applied in the bellows.

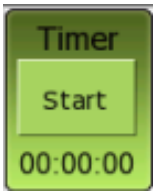
3.12 Fresh Gas Compensation

Range of fresh gas compensation: 200m L /min~18L/min;

Gas composition: oxygen, N_2O, air, and anesthetic.

3.13 Timer

The timer is seated in the right bottom corner of the ventilator interface. It is helpful for an anesthetist to record duration of an operation or count time for some special operations during the operation. It is operated by the control knob and touch control panel. The default state is OFF, as shown in the figure below.



3.13.1 Start Timer

1. Press the control knob or tap [**Timer]** → **[Start]** to start the timer.
2. The timer starts counting, [**Start]** changes to [**Stop]** .

3.13.2 Stop Timer

1. Press the control knob or tap [**Timer]** → [**Stop]** to stop the timer.
2. After the timer stops counting, the [**Stop]** changes to [**Reset]** .

3.13.3 Reset Timer

1. Press the control knob or tap [**Timer]** → [**Reset]** to reset the timer.
2. After the limit value turns to "00: 00: 00", the [**Reset]** changes to [**Start]** .

3.14 Parameter Monitoring Of Ventilator

The parameter monitoring of ventilator falls into two categories: waveform monitoring and parameter monitoring of breathing mechanics.

Currently, the system displays 5 breathing waveforms: pressure waveform , flow waveform, volume waveform, $EtCO_2$waveform,and EEG waveform.

The system monitors breathing-related parameters: **[Ppeak] , [Pplat] , [PEEP] , [VTexp] , [MV] , [Rate] , [FiO_2] , [$FiCO_2$] , [$EtCO_2$] , [I：E] , [Pmean] , [VTinsp] , [Compl] , and [Raw] .**

Under the non-standby interface, the parameter interface is divided to the [**Waveform]** parameter area in the center and the parameter display area on the right, as shown in the figure below:

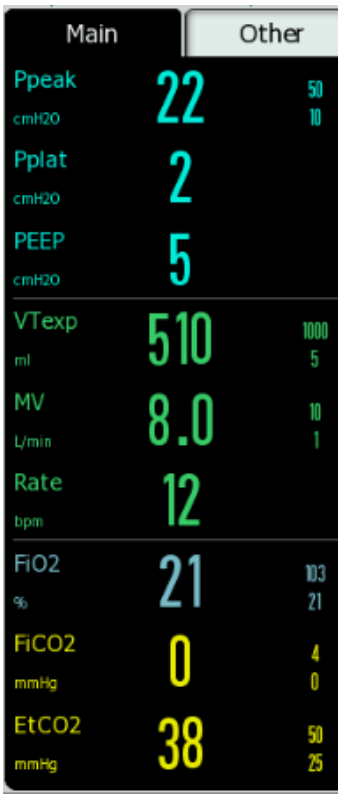


Fig. 3-14

3.14.1 Parameter Display

The system can display the monitoring parameter in 2 ways: Large Font Interface and Non-Large Font Interface. In the large font interface, only the parameter values are displayed; but in the non-large font interface, both the parameter waveform and parameter values are displayed.

The default interface of the system is the non-large font interfacet. Select [**Config] → [Setting] → [Big Font] → [On] / [OFF]** to display the large font interface or the non-large font interface**.**

The large font interface is shown as below.

Fig. 3-15

3.14.2 Automatic Waveform Adjustment

At the end of six consecutive respiratory cycles, if the pressure, flow, capacity, and VT measurements are greater than the boundary, the system will automatically adjust the waveform at the beginning of the next respiratory cycle.

At the end of six consecutive respiratory cycles, if the pressure, flow, capacity, and VT measurements are less than the boundary minus the amplitude, the system will automatically adjust the waveform at the beginning of the next respiratory cycle.

3.14.3 Set Waveform

Select [**Config**] →[**Screen**] →[**Waveform**] menu,you can set the waveform style to [**line**] or [**fill**].

3.14.4 Pressure Monitoring

Under the non-standby interface, you can monitor the airway pressure waveform and the parameter values of airway peak pressure, platform pressure, positive end-expiratory pressure, mean pressure.

The unit of the pressure parameter can be configured. Currently, the system provides three units: [**cmH$_2$O**], [**kPa]** and [**mbar]** , of which the [**cmH$_2$O**] is the default unit. You can select one unit by choosing **[Config]** → **[Setting]** → [**Pressure Unit]** .

3.14.5 Tidal Volume Monitoring

Under the non-standby interface, you can monitor the real-time flow waveform and expired tidal volume, inspired tidal volume, per-minute volume.

The display of the flow waveform is optional. To enable/disable this display, you can select [**Config] → [Screen] → [Flow Wave] →** [**On] / [OFF] .**

The display of the [**VTinsp**] is optional. To enable/disable this display, you can select [**Config] →** [**Setting] →** [**VTi Display] → [On] / [OFF] .**

3.14.6 Volume Monitoring

Under the non-standby interface, you can monitor the real-time volume waveform.

The display of the volume waveform is optional. To enable/disable this display, you can select [**Config] → [Screen] → [Volume Wave] →** [**On] / [OFF] .**

3.14.7 BIS Monitoring

When the BIS module communicates with the anesthesia machine normally,and the BIS display waveform switch is turned on.Under the non-standby interface, you can monitor the real-time bis waveform.

The display of the volume waveform is optional. To enable/disable this display, you can select [**Config] → [Screen] → [BIS Wave] →** [**On] / [OFF] .**

3.14.8 Oxygen Concentration Monitoring

3.14.8.1 Turn on Oxygen Sensor Monitoring

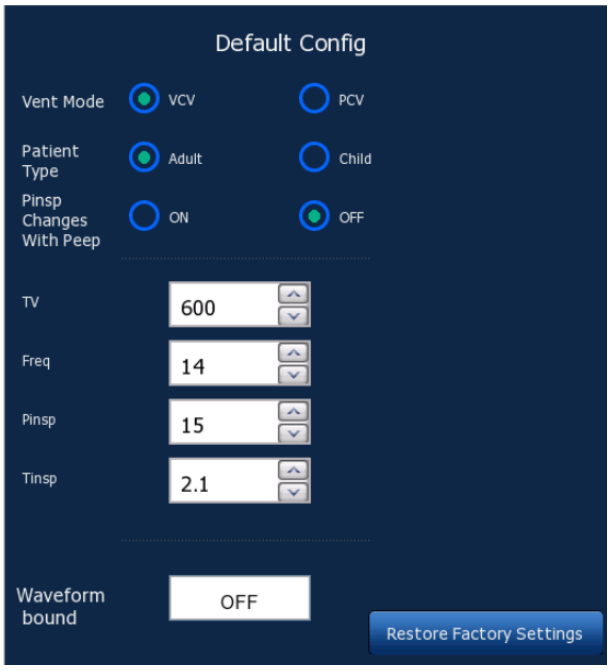
1. Select **[Config] → [Setting] →[O_2 Sensor Monitor]**.
2. Set Oxygen Sensor **to [On] / [OFF]** under **[O_2 Sensor Monitor]** menu as required.

⚠Caution

- **When you use the oxygen sensor for the first time or replace the oxygen sensor, please check whether the oxygen concentration monitoring is accurate. If the monitoring error is obvious, please calibrate the sensor.**
- **When the [O_2 Sensor Monitor] is set to [OFF] , FiO_2 will display a void value, and the sensor cannot be calibrated; meanwhile, the oxygen concentration monitoring and the related alarms of the sensor will be disabled.**
- **When the [O_2 Sensor Monitor] is set to [ON], and the Oxygen Monitoring Source is set to [OFF] , FiO_2 will display a void value, and the sensor cannot be calibrated; meanwhile, the oxygen concentration monitoring and the related alarms of the sensor will be disabled.**
- **According to international regulatory requirements, the machine shall conduct oxygen concentration monitoring before applied to patients. If your machine is not equipped with this function, please conduct oxygen concentration monitoring with a qualified monitor according with the related global standard.**

3.15 Default settings

Select [**Maintain**] → [**Config**] → [**Default config**] to set default settings.



3.16 Spirometry Loop

The spirometry loop reflects mechanical ventilation conditions and patient's lung function, such as patient's compliance, circuit leakage condition, airway blocking, etc., which plays an important role in the clinical test. 2 loops and related respiratory mechanics parameters of the reference loop are displayed in the interface, which is shown as below:

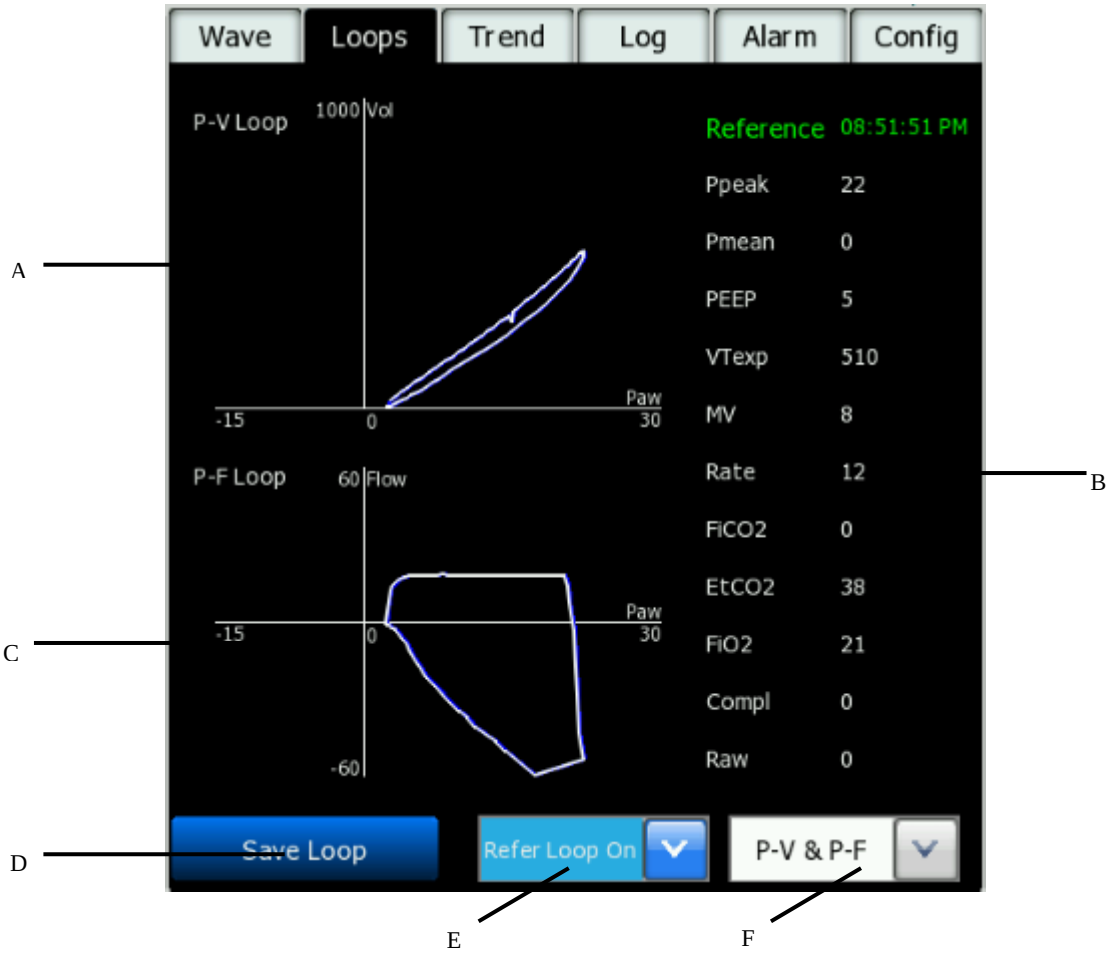


Fig. 3-16

A P-V(Pressure-Volume) Loop

B Loop Parameters

C P-F(Pressure- Flow) Loop

D Save Loop

E Switch of Reference Loop

F Display Loop option

Three Spirometry Loop Available:

- Pressure–Volume (P-V)
- Flow-Volume (V-F)
- Pressure–Flow (P-F)

3.16.1 Select Loop

2 loops can be displayed in the system loop interface, including 3 types of combinations: [**P-V]**

loop and [**P-F]** loop; [**P-V]** loop and [**V-F]** loop; [**V-F]** loop and [**P-F]** loop. You can switch to display among the 3 pairs of loops by selecting **[Loops]** → [**Select Loop]** . Take [**P-V]** loop and [**P-F]** loop as example, as shown in the figure below:

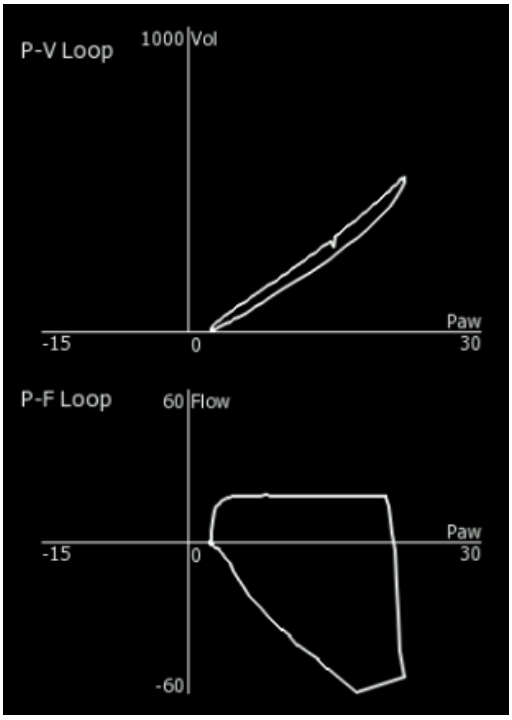
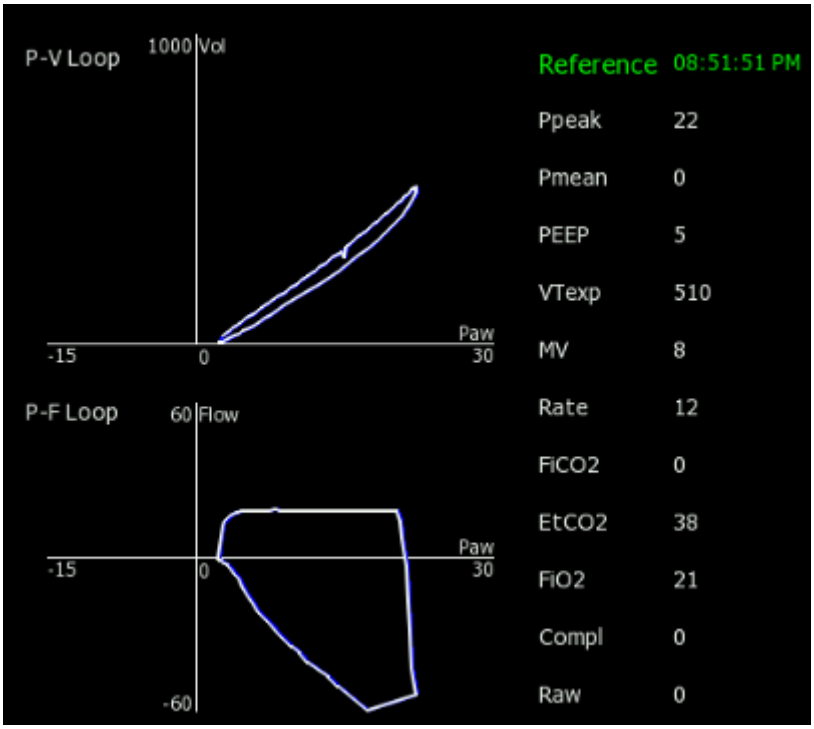


Fig. 3-17

3.16.2 Save Reference Loop Diagram

Select [**Loops]** → [**Save Loop]** to save the loop. The saved reference loop will be displayed in another color, and the related respiratory mechanics parameters of the reference loop will be displayed on the right of the loop area. Take [**P-V]** loop and [**P-F]** loop as example, as shown in the figure below:



3.17 Turn Off the System

Please follow the steps below to shut down when you do not intend to use the machine:

1. Ensure the machine can be ended
2. If the system switch is set to OFF "⏻" in bag mode or in any mechanical ventilation mode, the system will wait for 12s until it is fully turned off. During this 12-second shutdown delay, the screen will display a 10-second countdown. Click [Shut down now] will immediately shut down the ventilator. If the device is in mechanical ventilation, the ventilator will continue to ventilate the patient in the current ventilation mode.
3. If the system switch is set to OFF "⏻" in standby mode, the system will wait for 5s until it is fully turned off. During this 5-second shutdown delay, the screen will display a 3-second countdown. Click [Shut down now] will immediately shut down the ventilator.
4. When the user turns on the device during a shutdown delay, the countdown will disappear, and the ventilator will return to its previous state.
5. Turn off the AC power switch. Unplug the power cord to disconnect the power.
6. Remove the gas source hose to disconnect the gas source.

.

Chapter 4 Tests Before Use

⚠Warning

- **Prior to using the equipment, make sure to read the User's Manual and understand the operation and maintenance of all components.**
- **If the equipment fails to pass the pre-use tests, do not use it,and contact the Company.**
- **As to anesthesia gas delivery system, monitoring devices, alarm system and protective devices intended to serve an anesthesia systems, they are no matter singly used or assembled for an anesthesia machine, a checklist of the anesthesia system shall be submitted.**

⚠Attention

- **This guideline can be changed according to different situations of local clinical practice. Such changes shall be subject to appropriate peer review.**
- **It is recommended that you check whether the N_2O blocking function and the O_2-N_2O ratio are normal before using the device. Use an O_2 concentration tester to monitor the concentration of O_2 in the output gas.**

4.1 Test Procedures

4.1.1 Test Interval

Pre-use tests shall be conducted in the following cases:

Before the anesthesia machine is used on the first patient every day

Before the anesthesia machine is used on each patient.

After anesthesia machine is repaired or maintained.

The recommended testing time and test items is given as follows:

Test items	Before the anesthesia machine is used on the first patient every day	Before anesthesia machine is used on each patient	After anesthesia machine is repaired or maintained

Systematic inspection	√		√
Alarm test	√	√	√
Gas supply pipeline and gas cylinder test	√		√
Flow control system test	√		√
Anesthesia vaporizer installation test	√		√
Anesthesia vaporizer back pressure test	√		√
Breathing system leak test	√	√	√
Oxygen flush test	√	√	√
AGSS transfer and receiving system test	√		√
Vacuum suction device test		√	√

4.1.2 Before the Anesthesia Machine Used on the First Patient Every Day

1. Verify that the required emergency equipment is kept ready and in good condition.
2. Conduct test and verify that the equipment is kept in good order and condition, and the components are connected correctly.
3. Verify the connection of gas supply system, and verify that the gas cylinders are already assembled, and the displayed pressure values are correct.
4. Verify the liquid anesthetic level inside the anesthesia vaporizer is appropriate, and check that the anesthesia vaporizer fits its mounting perfectly.
5. Verify that the respiration circuit is connected correctly and intact.
6. Verify that there is enough renewed CO_2 absorbent inside the CO_2 canister.
7. Connect the scavenging system, and verify that the system works well.
8. Turn the system switch to “ON”, the system automatically performs a series of self-tests. Verify that the system passes all the self-tests.
9. If the system passes the self-tests, perform “Automatic circuit leak testing” and “Manual circuit leak testing”.
10. Make sure that the oxygen supply is adequate.
11. Select correct patient types like **[adult]** or **[Child]**.

12. Start ventilation.
13. Set proper controlling values and alarm limits for the patient.

4.1.3 Before Anesthesia Machine Used on Each Patient

If you have finished tests as described in section 4.1.2 Before the Anesthesia machine is Used on the First Patient Every Day, it is unnecessary to conduct this test, that is the test before the machine is used on each patient, for the first patient..

1. Verify that the required emergency equipment is kept ready and in good condition.
2. Verify that the level of liquid anesthetic inside the anesthesia vaporizer is appropriate.
3. Verify that the respiration circuit is connected correctly and intact.
4. Verify that the breathing system is filled with enough absorbent.
5. Connect the vacuum suction device and verify that the system is working properly.
6. Conduct gas leak testing of the breathing system.
7. Turn off the APL valve (set it to 30cmH_2O).
8. Start ventilation.
9. Set proper controlling values and alarm limits for the patient.

4.1.4 After anesthesia machine is maintained or is subjected to preventive maintenance

Please refer to ***4.1.2 Before the Anesthesia machine used on the First Patient Every Day***.

4.2 Check the System

⚠Warning

- **Make sure that the breathing system is connected properly and intact.**
- **When installing the absorption canister, check whether the seal ring is installed correctly. If the seal ring is not properly installed, leakage of the breathing system may occur.**
- **The maximum bearing weight of the top support is 20kg.**
- **The maximum bearing weight of the workbench is 20kg.**

Check the system and make sure that the following requirements are satisfied:

1. Equipment is kept in good condition

2. All components are connected correctly.
3. Check the flowmeter, anesthetic vaporizer, barometer, and gas supply pipes for damage.

4. Breathing system is connected properly, and the respiratory pipelines are intact, equip with sufficient CO_2 Pre-Pak absorbent or CO_2 bulk absorbent. Manual ventilation device is available and functional.

5. Anesthesia vaporizer is locked up correctly and is filled with adequate anesthetics.
6. Gas supply system is connected correctly, and its pressure is kept normal.
7. If equipped with a spare cylinder, make sure that it is installed correctly, and close the connected cylinder valve.
8. Check whether auxiliary oxygen supply is available and functioning properly.
9. Required emergency equipment is kept ready and in good condition.
10. All equipment for airway maintenance and tracheal intubation are kept ready and in good condition.
11. Applicable anesthetic agents and emergency drugs are kept ready.
12. Check the color of soda lime in the absorber. If the color changes significantly, replace soda lime immediately.
13. Make sure that the castor brake or central brake is locked up without damage or looseness, to prevent the anesthesia machine from moving.
14. Make sure that the breathing system of anesthesia machine is fixed onto the adapter, and verify that the breathing system is already locked up.
15. Connect the power cord to the AC power supply. When AC power supply is connected, the AC power indicator and battery indicator are on. If the indicators are off, the system is not powered.
16. Make sure the anesthesia machine can be turned on and turned off.

4.2.1 Gas Supply Pipeline Test

4.2.1.1 Gas Supply Pipeline

⚠Caution

- **During the pipeline ventilation, do not set the backup cylinder valve to "ON". Otherwise, the gas cylinder may be exhausted and result in short supply in case the pipeline ventilation gets faulty.**

4.2.1.2 O_2 Pipeline Test

1. If anesthesia machine is equipped with a backup cylinder, turn off the backup cylinder valve. Connect the pipeline of O_2 supply.
2. Set the system switch to the position “ON” (⊙).
3. Rotate the electronic flow control panel to the medium level of measuring range.
4. Make sure that the pressure value indicated by O_2 pipeline pressure gauges is in the range of 280 to 600kPa.
5. Cut off O_2 pipeline supply.
6. As O_2 pressure drops, alarms” No O_2 Pressure”.
7. Make sure that O_2 pressure gauge returns to its zero position.

4.2.1.3 N_2O Pipeline Test

To conduct N_2O pipeline test, turn on O_2 first.

⚠Caution

- **To conduct N_2O gas supply pipeline test, turn on O_2 first, and make sure that the O_2 gas supply pressure ranges from 280 to 600kPa; Otherwise, N_2O flow cannot be regulated.**
- **When N_2O pipeline supply is cut off, the system will not given alarms related to the N_2O pressure as N_2O pressure drops.**

1. If the anesthesia machine is equipped with a spare cylinder, close all spare cylinder valves. Access to O_2 pipe source and N_2O pipe source.
2. Set the system switch to the ON “⊙” position.
3. In the user interface, select the [Config] menu → Enter the [Flowmeter Config] tab. Set the flow control to [Single Bar].
4. Set “balance gas” to “N_2O” in the electronic flow control system.
5. Adjust the electronic flow control screen to adjust the flow control to the medium level of the measurement range.
6. Check whether the pressure indication on the N_2O pipe pressure gauge is within the range of 280-600kPa.
7. Make sure that the N_2O pressure gauge returns to zero.
8. Disconnect the N_2O pipe source.

4.2.1.4 Air Pipeline Test

1. If the anesthesia machine is equipped with a spare cylinder, close all spare cylinder valves. Access to AIR pipe source.
2. Set the system switch to the ON “⊙” position.
3. In the user interface, select the [Config] menu → Enter the [Flowmeter Config] tab. Set the flow control to [Single Bar].

4. Set “balance gas” to “AIR” in the electronic flow control system.
5. Adjust the electronic flow control screen to adjust the flow control to the medium level of the measurement range.
6. Check whether the pressure indication on the AIR pipe pressure gauge is within the range of 280-600kPa.
7. Make sure that the AIR pressure gauge returns to zero.
8. Disconnect the AIR pipe source.

⚠Caution

- **When air pipeline supply is cut off, the system will not given alarms related to the air pressure as air pressure drops.**

4.2.2 Backup Gas Cylinder Test

If anesthesia machine is not equipped with a backup cylinder, it is unnecessary to conduct the test.

4.2.2.1 Check the Fullness of the Cylinder

1. Set the system switch to the position “OFF” (⏻), and connect the gas cylinder to be checked.
2. Turn on the valves of all backup cylinders.
3. Make sure that the pressure inside all gas cylinders is adequately high. If not, turn off corresponding gas cylinder valve, and replace the cylinder with a fully-filled one.
4. Turn off the valves of all backup cylinders.

4.2.2.2 High-pressure Gas Leak Test of O_2 Cylinder

1. Turn on the valves of all backup cylinders.
2. Set the system switch to the position “OFF” (⏻) and stop O_2 pipeline gas supply.
3. Rotate O_2 flow control knob, and turn off the O_2 flowmeter.
4. Turn on the valve of O_2 gas cylinder.
5. Read and record the values displayed in backup cylinder pressure gauge.
6. Turn off the valves of O_2 cylinders.
7. In a minute, read and record the values indicated in the backup cylinder pressure gauges.

If the values indicated by the backup cylinder pressure gauges decrease greater than 5000kPa (725psi), it means that gas leak exists. Replace with a new gas cylinder washer as described in ***5.6 Assemble the Anesthesia Vaporizer***. Repeat the steps 1~ 6 in section ***4.2.2.2 High-pressure Gas Leak Test of O_2 Cylinder***. If gas leak still exists, do not use the cylinder.

4.2.2.3 High-pressure Gas Leak Test of N_2O Cylinders

Please conduct high-pressure gas leak test of N_2O cylinders as per the steps described in ***4.2.2.2 high-pressure gas leak test of O_2 gas cylinders***. If the value indicated in the N_2O high-pressure pressure gauge decreases greater than 700kPa (100psi) in 1 minute, it indicates that gas leak exists.

4.2.2.4 High-pressure Gas Leak Test of Air Cylinders

Please conduct high-pressure gas leak test of air gas cylinders as per the steps described in ***4.2.2.2 high-pressure gas leak test of O_2 gas cylinders***. If the value indicated in the air high-pressure pressure gauge decreases greater than 700kPa (100psi) in 1 minute, it indicates that gas leak exists.

4.2.3 Electronic Flow Control System Testing

⚠Warning

- **If nitrous oxide exists and flows through the system during the test, it shall be collected and removed using a safe and acceptable method.**
- **Improper gas mixture can cause injury to the patient. Do not use this system if oxygen-nitrous oxide proportioning system is unable to provide appropriate proportion of oxygen and nitrous oxide.**

⚠ Caution

- **When the electronic flow control system fails, the backup flow control system will be enabled. The basic oxygen flow of the backup flow control system is 0 L/min. The backup flow control system displays only one total flow meter. The total flow meter can display the maximum flow of 15 L/min.**
- **Slowly rotate the flow control knob of the backup flow control system. In order to avoid damaging the control valve, do not rotate the flow control knob again when the reading on the flow meter is out of range. When rotating the flow control knob clockwise to lower the flow, the reading on the flow meter shall be up to 0 L/min before the knob reaches the clockwise mechanical off position. Do not rotate again when the knob has reached the off**

position. Rotate the flow control knob counterclockwise to increase the flow.

- **Slowly turn on the gas cylinder valve to prevent damage. Do not force to regulate the flow control knob. After the spare gas cylinder testing, if spare gas cylinder does not used for gas supply, turn off each gas cylinder valve.**

1. Connect the pipe for gas supply or connect the gas cylinder. Turn on the gas cylinder valve to ensure normal gas supply.
2. Set the system switch to on "⊙" position, and the machine enters the standby host interface.
3. Select the [**Config**] menu → Enter the [**Flowmeter config**] label to set [**Flow Control**] to [**Single tube**].
4. Set "balance gas" to "AIR" on the display of the full electronic flow meter.
5. Regulate the air flow. Ensure that the reading on the electronic flow meter is consistent with the set value.
6. Set "balance gas" to "N_2O".
7. Gradually regulate the nitrous oxide flow, so as to ensure that the oxygen flow increases with the nitrous oxide flow, and that the flows of oxygen and nitrous oxide meet the ratio of 1: 3.
8. Set the oxygen flow and nitrous oxide flow to 5 L/min.
9. Turn off the gas supply of oxygen pipeline and gas cylinder.
10. Press the rapid oxygenation button to release the internal pressure of the machine.
11. Confirm that the technical alarm of "insufficient oxygen supply pressure" shows up, and that the display value of nitrous oxide flow and oxygen flow turns to zero.
12. Maintain the oxygen flow at 5 L/min. After confirming that the gas supply of the oxygen pipeline or gas cylinder is turned on, the nitrous oxide flow appears and stabilizes at 5 L/min.

⚠ Note

- **After the use of backup flow control system, turn off all needle valves, then shut down the backup flow control system.**
- **When viewing the readings on a total flow meter, the line of sight shall be at the same level as the float. In case of different perspectives, the same scale readings may be different.**

4.2.4 Backup Flow Control System Testing

1. Connect the pipe for gas supply or connect the gas cylinder. Turn on the gas cylinder valve to ensure normal gas supply.
2. Set the system switch to on "⊙" position.

3. Press the backup flow system's control button to ensure that the backup flow system can pop up normally. Ensure that the backup flow system pops up in place, and that there is a prompt of "backup flow meter is on" during the display interface switch of the full electronic flow meter.
4. After confirming that the backup flow control system pops up, visually check whether the flow display of the total flow meter is 0 L/min.
5. Regulate the nitrous oxide needle valve. Gradually increase the nitrous oxide flow to confirm the increase in total flow. Turn off the nitrous oxide needle valve to confirm that the total flow recovers to 0 L/min.
6. Regulate the air needle valve. Gradually increase the air flow to confirm that total flow can rise up to greater than 10 L/min. Turn off the air needle valve.
7. Regulate the oxygen needle valve so that total flow is 2 L/min.
8. Regulate the nitrous oxide needle valve so that total flow is 8 L/min.
9. Disconnect the gas supply of oxygen pipeline and gas cylinder.
10. Press the rapid oxygenation button to release the internal pressure of the machine.
11. Confirm that the technical alarm of "insufficient oxygen supply pressure" shows up after the reading on the total flow meter is gradually reduced to zero.
12. Confirm that the reading on the total flow meter restores to 8 L/min and the technical alarm of "insufficient oxygen supply pressure" disappears after turning on the gas supply of oxygen pipeline or gas cylinder.
13. Turn off the oxygen and nitrous oxide needle valves.
14. After confirming that all needle valves are turned off, select the backup flow meter shutdown button on the display of the full electronic flow meter to confirm the normal retraction of the backup flow meter.

4.2.5 O_2 and N_2O linkage Test without O_2 Sensor

⚠Warning

- **Even if fresh gas contains enough oxygen, it may mix the low oxygen gas in breathing system.**
- **If N_2O exists and flows through the system during the testing, the N_2O gas shall be collected and eliminated as per safe and acceptable methods.**
- **Improper mixed gas may injure the patients. If the oxygen-N_2O linked system cannot**

provide well-proportioned O_2 and N_2O, the system shall not be used.

⚠Caution

- **To avoid damage, turn on the gas cylinder valve slowly.**
- **When backup gas cylinder testing is over, turn off all the gas cylinder valves if the backup cylinders are not intended for gas supply.**
- **Turn the gas flow switches slowly, and do not turn them forcibly when the maximum or minimum flow range is exceeded to protect, the control valve from damage and to avoid control failure. When flowmeter is adjusted to the minimum value, the reading shall be zero.**

Conduct the flow control system testing as per the following steps when O_2 sensor is not equiped with:

1. Connect pipeline or turn on gas cylinder valve slowly.
2. Rotate clockwise all flow control knobs of flowmeter to the end (minimum flow).
3. Set the system switch to the position "ON" (⊙).
4. If battery charge is low or other ventilator malfunction alarms are given, do not use the system.
5. Adjust all gas flows to the minimum positions.
6. Test the flow increasing of O_2-N_2O linked system;

Rotate clockwise O_2 and N_2O flow control knobs respectively to adjust the flow of O_2 and N_2O to the minimum. Then rotate counterclockwise N_2O flow control knob, adjust N_2O flow and to the values given the table below successively. Observe the values of oxygen flow at each step, and make sure that they meet the requirements listed in the table.

Step	N_2O flow (L/min)	Oxygen flow (L/min)
1	0.6	≥0.2
2	1.5	≥0.5
3	3.0	≥1.0
4	7.5	≥2.5

7. Test the flow decrease of O_2-N_2O linked system;

Rotate clockwise O_2 and N_2O flow control knobs to adjust the flow of O_2 and N_2O to over 9.0L/min and 3L/min respectively. Then rotate counterclockwise N_2O flow control knob, and adjust N_2O flows to the values given the table below successively. Observe the values of oxygen flow at each step, and make sure that they meet the requirements listed in the table.

Step	N_2O gas flow (L/min)	Oxygen flow (L/min)
1	7.5	≥2.5
2	3.0	≥1.0
3	1.5	≥0.5
4	0.6	≥0.2

8. Cut off oxygen pipeline supply or turn off oxygen gas cylinder.

⚠Caution

- **When O_2 supply is cut off, alarms "No O_2 Pressure" is given as O_2 pressure drops.**

9. Set the system switch to the position "OFF" (⏻).

4.2.6 O_2 and N_2O linkage test with O_2 Sensor

Before start this section test, test the oxygen monitoring device as described in "Alarm Testing". Then conduct the flow control system testing as per the following steps when O_2 sensor is equipped with:

1. Connect pipeline supply or turn on gas cylinder valve slowly.
2. Rotate clockwise all flow control knobs of flowmeter to the end (minimum flow).
3. Set the system switch to the position "ON" (⏻).
4. If battery charge is low or other ventilator malfunction alarms are given,do not use the system.
5. Adjust all gas flows to the minimum positions.

The following steps 6 and 7 are only applicable to N_2O system testing.

⚠ Warning

- **During steps 6 and 7, the utilized oxygen sensor must be calibrated correctly, and the linked system must be kept in its functional mode.**
- **Adjust the testing control only (N_2O described in step 6 and O_2 described in step 7).**
- **Adjust N_2O before O_2, and regulate the flows according to priority.**

6. Test the flow increase of O_2-N_2O linked system;

Rotate clockwise O_2 and N_2O flow control knobs respectively to the end (minimum flow).

Rotate counterclockwise the N_2O flow control knob slowly.

Make sure that the O_2 flow is increasing, and the measured O_2 concentration must be equal to or greater than 25% in the whole process.

7. Test the flow reduction of O_2-N_2O gas linked system:

   Rotate N_2O flow control knob to 9.0L/min.

   Rotate O_2 flow control knob to 3L/min or higher.

   Rotate counterclockwise the O_2 flow control knob slowly.

   Make sure that the N_2O flow is increasing, and the measured O_2 concentration must be equal to or greater than 25% in the whole process.

8. Cut off the O_2 pipeline supply or turn off the O_2 cylinder valve.
9. Make sure:

   Stop N_2O flow, and O_2 flow is cut off finally.

   If an air supply is connected, air flow shall be maintained.

   Ventilator may give alarm related to inadequate gas supply.

10. Rotate clockwise all flow control knobs to the end (minimum flow).
11. Connect the O_2 pipeline supply or turn on the O_2 gas cylinder valve again.
12. Set the system to standby mode.

4.3 Anesthesia Vaporizer Back Pressure Test

⚠Warning

- **During testing, the anesthetic shall come from the fresh gas outlet. These agents shall be discharged and collected as per safe and acceptable methods.**
- **To avoid any damage, rotate clockwise the flow control knob to the end (minimum flow or turn it off) prior to use.**

1. Set the system switch to the position “ON”. An alarm might be given.
2. Set the O_2 flow to 6L/min.
3. Make sure that the O_2 flow is constant, and that the float of oxygen flow meter (for AX-600) or main flowmeter (for AX-700/AX-700A/AX-800) can move freely..
4. Adjust the concentration of anesthesia vaporizer between 0 ~ 1%. The O_2 flow must not decrease greater than 1L/min in the whole process. If O_2 flow decreases greater than 1L/min:
   - Replace the anesthesia vaporizer with a new one;

- If O_2 flow decreases less than 1L/min after the replacement, the old anesthesia vaporizer is faulty.
- If O_2 flow decreases still greater than 1 L/min after the replacement, the anesthesia machine system is faulty.

5. For each anesthesia, vaporizer steps 2 and 3 shall be conducted.

4.4 Alarm Tests

Anesthesia machine automatically performs self-test once it is turned on. The alarm lamp flashes once as per red- orange sequence, and a beep is given. Then startup screen is displayed. When "Check before use","Leak in vent mode" and "Leak in bag mode" are finished, the equipment accesses its standby screen directly. This indicates that the audible and visual alarm indicator works normally.

⚠Caution

- **During alarm testing, stay in a place where you can observe the alarm lamps and alarm prompts and hear the alarm sound.**

4.4.1 Monitoring the O_2 Concentration and Alarms

⚠Warning

- **In accordance with international laws and regulations, oxygen concentration shall be monitored during the equipment is applied on a patient. If your equipment is not provided with the said function, please use a monitoring instrument conforming to corresponding international standards to monitor the oxygen concentration.**

⚠Caution

- **It is unnecessary to conduct the testing if O_2 sensor is not equipped with.**

1. Set the Manual/mechanical ventilation switch to the position "Manual" ( ).
2. Take the O_2 sensor out of breathing system and wait for 2~3 minutes; measure the indoor air, and verify that the measured O_2 concentration **[FiO_2]** is approximately at 21%
3. Set the **[Low Limit]** of **[FiO_2]** : On the screen, select **[Alarm]** menu → Access **[ventilator]** → Select **[FiO_2] [Low Limit]** menu, and set the low alarm limit of the parameter to 50%.
4. Observe the alarm message area on the screen, make sure that [**Low FiO_2]** is displayed.

5. Set the **[Low Limit]** of [**FiO_2]** to a value lower than the current monitored value of [**FiO_2]** , and make that the alarm of **[Low FiO_2]** is cleared.
6. Re-install the O_2 sensor into the breathing system.
7. Set the **[High Limit]** of O_2 alarm: Select **[Alarm]** menu → Access **[ventilator]** → Select **[FiO_2] [High Limit]** menu, and set the high alarm limit of the parameter to 50%.
8. Connect the manual respiration manual bag to corresponding connector of breathing system. Push the oxygen flush button to fill the manual/spontaneous manual bag, an d make sure that the O_2 concentration **[FiO_2]** measured by sensor is of approximate ly 100%.
9. Observe the physiological alarm message on the screen, and make sure that [**High FiO_2]** is displayed.
10. Set the **[High Limit]** of **[FiO_2]** alarm to 100%, and make sure that [**High FiO_2]** is cleared.

4.4.2 Test the Minute Volume (MV) Alarm

1. Make sure [Per-minute ventilation Amount] alarm is set to " ON ".
2. Set the [**Low Limit]** alarm of [**MV]** : On the screen, Select **[Alarm]** menu → access **[Ventilator]** → Select **[MV] [Low Limit]** menu, and set the low alarm limit of the parameter to 6.0L/min.
3. When **the MV is lower than the low alarm limit**, observe the alarm message area on the screen, and make sure that [**Low MV]** is displayed.
4. Set the **[High Limit]** alarm of **[MV]** : On the screen, select **[Alarm]** menu → Access **[ventilator]** → Select **[MV] [High Limit**] menu, and set the high alarm limit of the parameter to 9.0L/min.
5. When **the MV is higher than the high alarm limit**, observe the alarm message area on the screen, and make sure that [**High MV]** is displayed.

4.4.3 Test the Apnea Alarm

1. Connect the manual respiration manual bag to the corresponding connector of the breathing system.
2. Set the Manual/Mechanical Control switch to "Manual" ( ).
3. Rotate the APL valve control knob to the position with the minimum opening pressure.
4. Pinch the manual respiratory manual bag, and make sure that one complete respiratory cycle takes place.
5. Stop pinching the manual respiratory manual bag,and wait for at least 20±3 seconds. Make sure that **[Apnea]** alarm is displayed on the screen.
6. Pinch the manual respiratory manual bag for several times, and make sure that the **[Apnea]**

alarm displayed on the screen disappears.

4.4.4 Test the Sustained Airway Pressure Alarm

1. Connect the manual respiratory manual bag to the corresponding connector of the breathing system.
2. Rotate the O_2 flow control knob to the low limit.
3. Rotate the APL valve control knob to the position of 30cmH_2O.
4. Set the Manual / Mechanical Control switch to its position “Manual” ( )
5. Push and hold the oxygen flush button for approximately 15 seconds, and make sure that **[Continuous Pressure]** alarm is displayed on the screen.
6. Turn on the patient-end outlet, and make sure that **[Continuous Pressure]** alarm displayed on the screen disappears.

4.4.5 Test the High Paw Alarm

1. Set the Manual/mechanical ventilation switch to its position “ mechanical” ( ).
2. On the screen, Select **[Alarm]** menu → Access **[ventilator]** → Select **[Ppeak] [High Limit]** menu, and set the alarm limits of the parameter to 0cmH_2O **([Low Limit])** and 5cmH_2O **([High Limit]).**
3. Make sure that **[High Paw]** is displayed on the screen.
4. Set the **[High Limit]** of airway peak pressure to 40cmH_2O.
5. Make sure that **[High Paw]** displayed on the screen disappears.

4.4.6 Test the Low Paw Alarm

1. Set the Manual / Mechanical Control switch to its position “Mechanical Control “( )”.
2. On the screen, select **[Alarm]** menu → access **[Ventilator]** →Select **[Ppeak] [High limit]** menu, and set the **[Low Limit]** alarm limit of the parameter to 2cmH_2O.
3. Remove the manual respiratory leather-bag from the Y-shaped patient-end port.
4. Wait for 20 seconds, observe the alarm message area on the screen, and make sure that **[Low Paw]** alarm is displayedon the screen.
5. Connect the manual respiration manual bag to manual respiration leather-bag port on the breathing system.
6. Make sure that **[Low Paw]** displayed on the screen disappears.

4.4.7 Test the CO_2 Monitor Alarm

1. Refer to “***Chapter 7 Physiological Alarms and Technical Alarms***”.
2. Connect a carbon dioxide gas sampler to a CO_2 analyzer.

3. Select [**Alarm]** menu → access [**CO_2]** → Select the [**High Limit]** alarm menu of **[$FiCO_2$]** and [**$EtCO_2$]** , and set the alarm [**High Limit]** to 20 mmHg.
4. Make sure that the alarm [**High $FiCO_2$] / [High $EtCO_2$]** are displayed on the screen when the concentration of inspired CO_2 / expiratory-end CO_2 are higher than the alarm limit respectively.
5. Set the **[Low Limit]** menu of [**$FiCO_2$] [$ETCO_2$]** alarms of **[CO_2]** to 10 mmHg.
6. Set the [**Low Limit]** of CO_2 to a value higher than the standard gas concentration.
7. Make sure that the alarms [**Low $FiCO_2$] / [Low $EtCO_2$]** are displayed on the screen when the concentration of $FiCO_2$/$EtCO_2$ are lower than the alarm limit respectively.

4.5 Breathing System Testing

⚠Warning

- **Foreign objects inside the breathing system may block up the gas flow to the patient, and may result in a casualty accident. Make sure that no testing plugs or other foreign objects exist inside the breathing system.**
- **The resistance at 2,5, 15 and 30 l/min, and compliance of those breathing accessories,please refer to the attached specification for details.**
- **The range of internal volume of any Anesthetic breathing system less than 3.5L.**
- **Breathing system shall be equipped with a ventilator conforming to ISO 80601-2-13 and YY 0635.4.**

1. Make sure that the breathing system is connected properly and is kept in good condition.

   Once the breathing system is disconnected, the anesthesia machine can give an alarm “No Breathing System”.
2. Make sure that the check valves in the breathing system work fine.

   If the inspiratory check valve turns on during inspiration, and immediately turns off when expiration begins, it indicates that the inspiratory check valve (unidirectional valve) works fine.

   If the expiratory check valve turns on during expiration, and immediately turns off when inspiration begins, it indicates that the expiratory check valve (unidirectional valve) works fine.

4.5.1 Bellows Tightness Test

1. Set the system to standby mode.
2. Set the Manual/mechanical ventilation switch to the position “Mechanical” (▣).
3. Rotate all flow control knobs to the minimum gas flow.
4. Block up the patient-end outlet, and close the breathing system.
5. Push the oxygen flush button to have the folded sack of bellows risen to its top end.
6. Make sure that the pressure indicated in the airway pressure gauge must not exceed 15cmH_2O.
7. The folded sack of bellows shall not fall down. If it falls down,it indicates that gas leak exists in the bellows. Re-install the bellows.

4.5.2 Breathing System Leak Test in Mechanical Ventilation Mode

⚠Caution

- **System leak test includes the leak test of anesthesia breathing system and anesthesia ventilator.**
- **System gas leak test must be conducted in its standby mode.**
- **To conduct system gas leak test, make sure that the breathing system is connected correctly, and the respiratory pipelines are kept in good condition.**

Conduct gas leak test as per the following procedures:

1. Make sure that the system is already set to its standby mode; Otherwise, push the standby soft key to access [**Standby**] screen.
2. Make sure that the gas supply pressure is adequate.
3. Set the Bag/vent Control switch to its position “Mechanical Control” (▣).
4. Insert the Y-piece of corrugated pipe to the leak testing plug of breathing system to block up the gas outlet of Y-piece.
5. Rotate the flow control knob to turn off the O_2, N_2O and air flow completely.
6. Push the oxygen flush button to have the folded sack of bellows risen to the top end.
7. Select [**Leak Test]** menu → **[Leak in vent mode].**
8. Push the **[Start]** button. The system begins respiratory-system gas leak test and displays simultaneously the prompting message: **[Testing is Performing]**.
9. If the system passes the test, it displays a prompting message:[**Leak Test PASS]**. Otherwise, it displays a prompting message: [**Leak Test FAIL].** In such a case, check the breathing

system connection, and pipelines tightness. Conduct leak test again when problems are solved.

⚠Caution

- **The progressive gas leak testing can be terminated if you push [Stop] button. That does not mean the system gas leak testing fails, only means that the testing gets invalid.**
- **If gas leak testing fails, check all possible causes of gas leak, such as leakage from bellows, breathing system pipeline, CO_2 canister and other connecting devices. During the check of CO_2 canister, pay attention to the seal components of canister to find if any CO_2 absorbent particles are attached on the canister, and remove them if any.**
- **If leaks exist in the breathing system, do not use the equipment. Contact in time the equipment service personnel or after-service department of the Company.**
- **Loose connection between the bellows and the intubation tube will result in leakage of the breathing circuit, and will affect the VT supply anomaly of the anesthesia machine.**

4.5.3 Breathing System Leak Test in Manual Ventilation Mode

1. Make sure that the system is already set to the standby mode; Otherwise, push the standby key to access [**Standby]** screen.
2. Set the Manual/mechanical ventilation switch to the position “Manual” ( ).
3. Connect the manual respiration manual bag to corresponding connector on the breathing system.
4. Rotate the APL valve control knob to the position of its maximum value (75cmH_2O).
5. Rotate the flow control knob to turn off the O_2, N_2O and air flow completely.
6. Insert the Y-piece of corrugated pipe into the leak testing plug of Manual/spontaneous leather-bag port to block up the gas outlet of Y-piece.
7. Push the oxygen flush button to allow the value indicated by the airway gauge rise to approximately 30cmH_2O.
8. Release the oxygen flush button, and select [**Leak Test]** menu → [**Leak in bag mode]** .
9. Push the [**Start]** button. The system begins manual circuit leak test and displays simultaneously the prompting message: [**Testing is Performing]** .
10. If the equipment passes the test, the system displays a prompting message [**Leak Test PASS]** .Otherwise, it displays a prompting message: **[Leak Test FAIL]** . In such a case, check the connection of breathing system and condition of pipelines. Conduct leak test again when problems are solved. If gas leak still exists, contact the equipment maintenance personnel of After-service Department of the Company.

11. Leaks may also be verified by observing the readings indicated by the airway pressure gauge during testing. If the readings drop,it indicates that gas leak exists.

4.5.4 APL Valve Accuracy Test

1. Make sure that the system is already set to its standby mode; Otherwise, push the standby key to access [**Standby]** screen.
2. Set the Bag/vent Control switch to the position “Manual” ().
3. Connect the manual respiration manual bag to the corresponding connector on the respiratory circuit.
4. Insert the Y-piece of corrugated pipe into the leak testing plug of Manual/spontaneous leather-bag port to block up the gas outlet of Y-piece.
5. Rotate the APL valve control knob to 30cmH_2O.
6. Push the oxygen flush button to fully fill the manual/spontaneous manual bag.
7. Make sure that the readings indicated by airway gauge are in the range from 20 to 40cmH_2O.
8. Rotate the APL valve control knob to the position of the minimum value for the opening pressure of APL valve (position MIN).
9. Set the O_2 flow to 3L/min, and turn off other gases.
10. Make sure that the reading indicated by the airway pressure gauge is less than 5cmH_2O.
11. Push the oxygen flush button, and make sure that the reading indicated by airway pressure gauge does not exceed 10cmH_2O.
12. Rotate the O_2 flow control knob to the minimum value, and verify that the reading indicated by theairway pressure gauge does not drop to below 0cmH_2O.

4.5.5 Check Valve Inspection and Test

1. Check whether or not valves evenly stay inside the base when the system is turned off.
2. Turn on the system.
3. Make sure that the gas supply pressure is adequate.
4. Make sure that ACGO is already set to its non-ACGO mode
5. Set the Manual/mechanical ventilation switch to the position “Mechanical” ().
6. Start ventilation.
7. Check whether or not the respiration check valve moves in the open-close cycle. If not, the check valve is faulty.

4.6 Ventilator Test

⚠Caution

- **Ventilator shall be equipped with an anesthesia system conforming to IEC 80601-2-13 and IEC 60601-2-13(GB 9706.29).**

1. Make sure that the gas supply pressure is adequate.
2. Make sure that the relevant parameters and alarm limits of ventilator are properly set. For specific settings, refer to the chapter "*15.11 Principle and Parameter Specifications of the Ventilator*".
3. Set the Bag/vent Control switch to the position "Mechanical".
4. Connect the manual manual bag to the patient-end port;
5. Set the parameters like different tidal volumes, respiratory rates and inspiratory/expiratory ratios of anesthesia machine. Observe the monitored value and set values of the anesthesia machine, and check whether or not the actual tidal volumes of bellows hood of the breathing system can meet the clinical requirements.

4.7 AGSS Transfer and Receiving System Test

Assemble the AGSS properly as per*5.10.2 Assemble the AGSS*,and start AGSS. Check whether or not the floater rises up and exceeds the scale mark MIN. If the floater sticks during movement or the floater is damaged, contact the manufacturer for maintenance.

⚠Caution

- **Do not block up the pressure compensation port of AGSS during the test.**

If the floater cannot rises up, possible causes include the following:

- Floater adhesion. Turn the AGSS upside down, and check whether or not the floater may move up and down freely.
- Floater rises slowly. Filtering net is possibly blocked Contact the manufacturer for checks and maintenance.
- The high-flow AGSS transfer and receiving system is not working or the pumping flow rate is less than 50L / min (normal working rate). Contact the manufacturer for inspection and repair.
- The low-flow AGSS transfer and receiving system is not working or the pumping flow rate is less than 25L / min (normal working rate) . Contact the manufacturer for inspection and repair.

4.7.1 Connection Leakage Test for AGSS and the Exhaust Gas Outlet of Anesthesia Machine

1. Remove the rear cover of the host,and remove internal corrugated tube that is connectod to the air-capacitor.
2. Connect the tubing sets to be tested onto the inlet of air-capacitor. Connect the pressure gauge.
3. Remove the corrugated tube connected on the AGSS, and then block this port so that the corrugated tube can be connected onto the exhaust gas outlet.
4. Ventilate 10 ± 0.5ml of air per minute into the tubing sets to be tested. The leakage amount shall be no more than 100 ml/min in the transfer and receiving system.
5. If the leakage amount exceeds the above value, re-connect the tubing sets of the exhaust gas outlet, and then retest according to the above steps.

4.8 Vacuum Suction System Test

⚠Caution

- **Before use must check ensure that the vacuum suction system is qualified.**
- **For the safety and health of patients and others,the negative pressure generator switch should be at the OFF position before opening the power gas source(or inserting into the socket hole of the terminal),the negative pressure regulator mode selection switch should be set to the middle position(OFF position) and the adjustment knob should turn counterclockwise to the zero position.**

4.8.1 Internal vacuum suction testing

1. Assemble the external pipe collection system with internal negative pressure to the anesthesia machine according to the installation instructions;
2. Turn the negative-pressure gear switch to the OFF position;
3. Rotate the negative-pressure adjustment knob counterclockwise until it can no longer be rotated;
4. Open the O2 source, and confirm whether the gas source pressure is within the applicable range of the anesthesia machine (280-600kPa);
5. Block the patient end of the suction tube, and turn the negative-pressure gear switch to the FULL

position; observe whether the reading on the negative pressure gauge can reach 60kPa or above;

6. If there is no reading on the negative pressure gauge, check whether the collecting liquidbottle, suction tube, overflow bottle, and filter are not installed well, or check for damage and gas leakage;
7. After confirming that the gas circuit connection is intact, turn the negative-pressure gear switch to the OFF position, and observe whether the pressure on the negative pressure gauge has returned to zero;
8. Turn the negative-pressure gear switch to the REG position; slowly rotate the negative-pressure knob clockwise; observe the pressure gauge; confirm whether the pressure can be continuously adjusted and stabilized at a certain pressure;
9. After completing the inspection, turn the negative-pressure adjustment knob counterclockwise to adjust the negative pressure to the minimum;
10. Turn the negative-pressure gear switch to the OFF position to avoid gas waste.

4.8.2 External vacuum suction testing

1. Assemble external negative pressure to the anesthesia machine according to the installation instructions;
2. Press the driving gas switch to the OFF position; turn the negative-pressure gear switch to the OFF position as well;
3. Rotate the negative-pressure adjustment knob counterclockwise until it can no longer be rotated;
4. Open the O_2 source, and confirm whether the gas source pressure is within the applicable range of the external negative-pressure system (280-550kPa);
5. Pull the driving gas switch to the ON position;
6. Block the patient end of the suction tube, and turn the negative-pressure gear switch to the FULL position; observe whether the reading on the negative pressure gauge can reach 60kPa or above;
7. If there is no reading on the negative pressure gauge, check whether the collecting liquid bottle, suction tube, overflow bottle, and filter are not installed well, or check for damage and gas leakage;
8. After confirming that the gas circuit connection is intact, turn the negative-pressure gear switch to the OFF position, and observe whether the pressure on the negative pressure gauge has returned to zero;
9. Turn the negative-pressure gear switch to the REG position; slowly rotate the negative-pressure knob clockwise; observe the pressure gauge; confirm whether the pressure can be continuously adjusted and stabilized at a certain pressure;
10. After completing the inspection, turn the negative-pressure adjustment knob counterclockwise to adjust the negative pressure to the minimum;

11. Turn the negative-pressure gear switch to the OFF position, and press the negative-pressure driving gas switch to the OFF position, so as to avoid gas waste.

⚠Note

- **Refer to the user manual supplied with the external negative suction system for testing information.**
- **The vacuum suction system must be inspected before use, accordint to the requirement specified in the user manual supplied with the vacuum suction system.**

⚠Caution

- **During the test, observe the drive gas discharge vent behind the anesthesia machine, so as to ensure that the discharge vent is unobstructed.**

Chapter 5 Installation and Connection

⚠Warning

- **If electrosurgical equipment is used, keep their leads away from the breathing system, oxygen sensor and other components of the anesthesia machine, make sure that the standby manual/spontaneous equipment of anesthesia machine are ready for use, and ensure that masked simple respirator are available in case the electrosurgical equipment prevents safe use of the ventilator. In addition, ensure that all life supporting and monitoring equipment may be correctly operated.**
- **If high frequency surgical equipment is used, antistatic or conductive masks or breathing tubes may cause heat injuries; therefore, never use antistatic or conductive masks or breathing tubes.**
- **The equipment shall be installed by engineers specified by the manufacturer.**
- **The equipment is provided with a waste gas exhaust port. The users shall pay attention to the disposal of residual breathing gase scavenged.**
- **After the absorbent gets dry, it may pose a danger to the patient if it continues to be used. Appropriate precautions shall be taken to ensure that the soda lime in the CO_2 absorption canister is not dry. After each use of the system, all gas sources shall be turned off in time.**
- **The anesthesia system has an exhaust outlet. During use, pay attention to the disposal of discharged respiratory residual gas.**

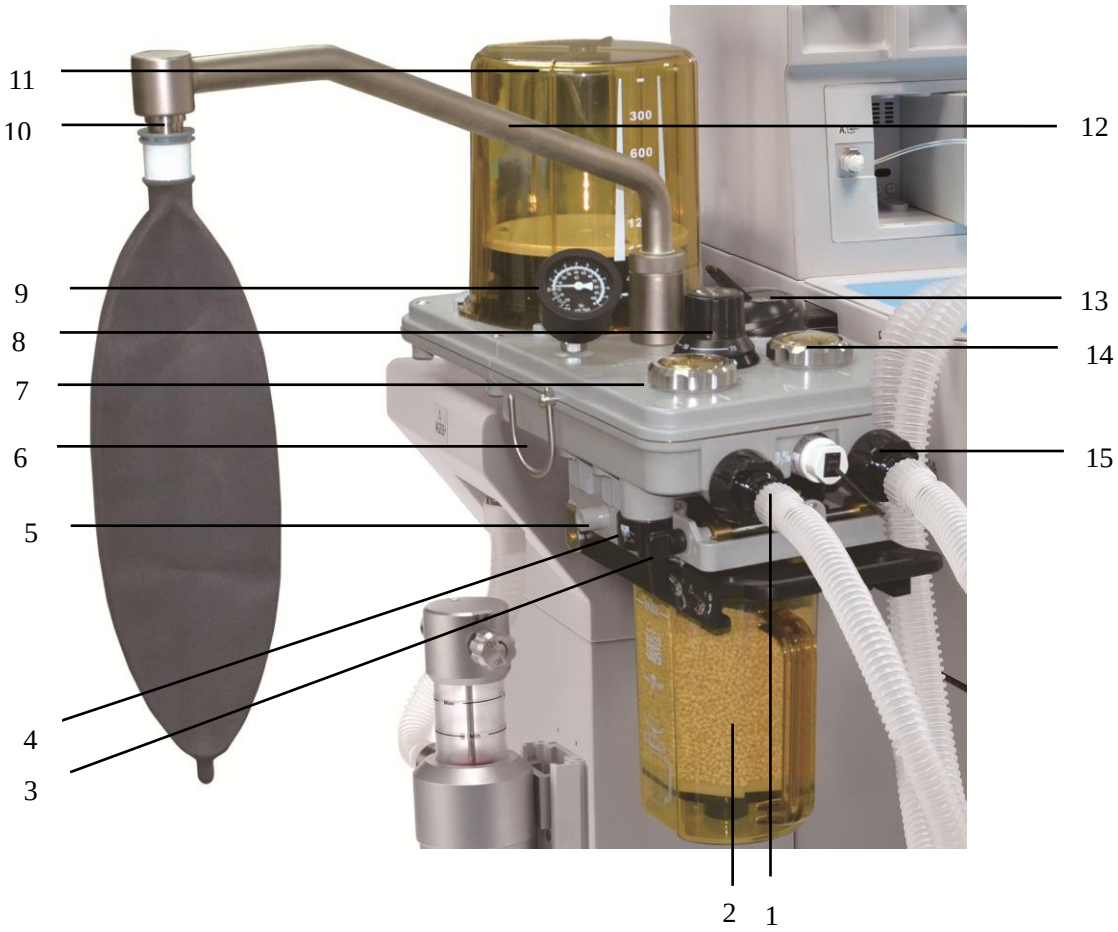
5.1 Assemble the Breathing System

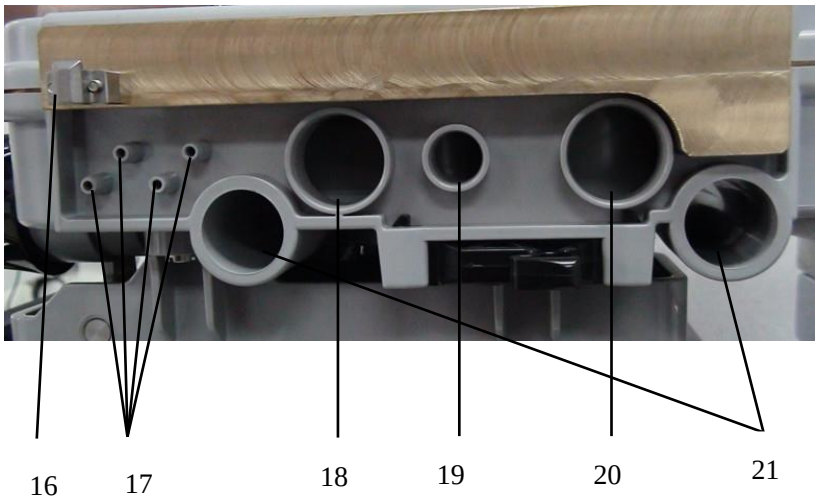
⚠Caution

- **After the use of the equipment, pay attention to the disposal of the breathing system, the test of the CO_2 absorbent inside Canister (carbon dioxide absorbent) and anesthetics inside the Anesthesia Vaporizer so as to guarantee normal running of the equipment.**
- **Please do not weigh down the manual support column by hands or by hanging other heavy objects onto it.**

- **If the difference between airway pressure gauge reading and the parameter value displayed on the screen is large, contact the Company.**

Breathing System Structure

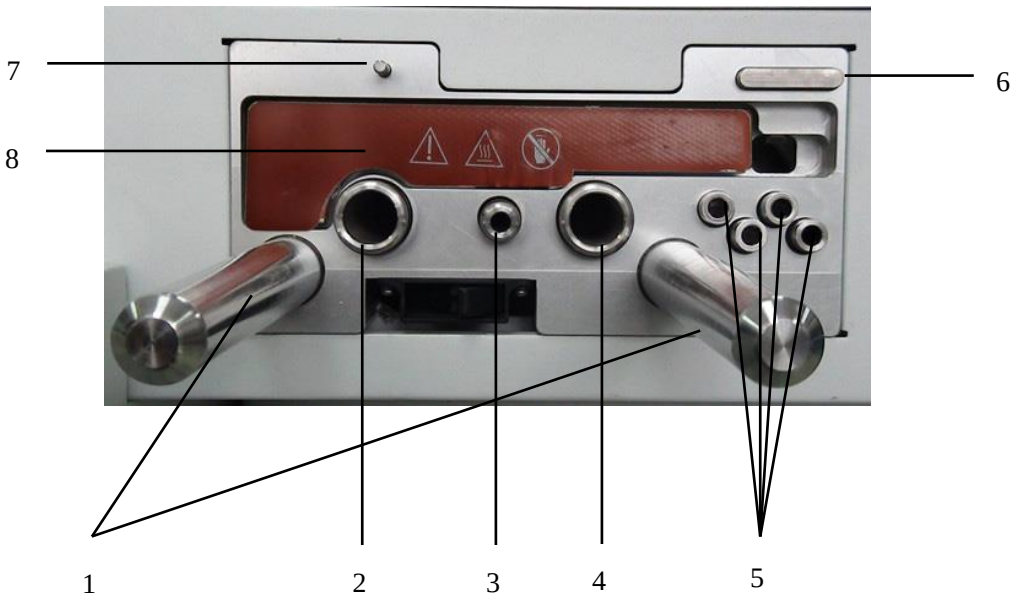




1	Expiratory port	12	Manual bag Support Arm
2	Canister (carbon dioxide absorbent)	13	Manual/mechanical ventilation switch

3	Canister release device	14	Inspiratory check valve
4	Manual drain valve	15	Inspiratory port
5	Leak test plug	16	Circuit Lock Hook
6	Breathing tube hook	17	Pressure Sampling Port
7	Expiratory check valve	18	Waste Gas Outlet
8	APL (Adjustable Pressure Limiting) Valve	19	Fresh Gas Inlet
9	Airwany pressure gauge	20	Driving Gas Inlet
10	Manual bag port	21	Guide Post Hole
11	Bellows assembly		

- **Circuit Adapter Structure**



1	Circuit Support Guide Post	5	Pressure Sampling Connector
2	Drive Gas Connector	6	Circuit Disassembling Button
3	Fresh Gas Connector	7	Manual/Mechanical Control Axle
4	Waste Gas Exhaust Connector	8	Heater Sheet

5.1.1 Assemble the Breathing Circuit System

1. Align the guide post hole on the side of breathing circuit system with the guide post of circuit adapter.

2. Push the breathing circuit system into the circuit adapter forcibly such that the breathing circuit system is connected to the circuit adapter without gap. Verify that the breathing circuit system has been locked.

⚠Warning

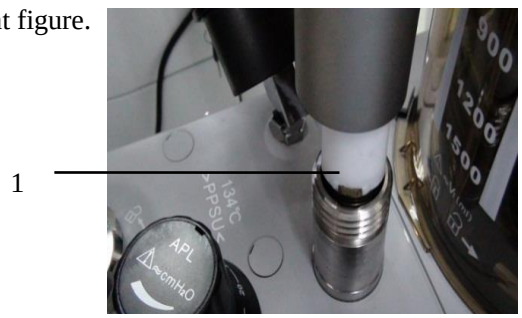
- **When breathing circuit system is assembled onto the circuit adapter, you must verify that the breathing circuit system is firmly locked. If not, it may be separated from the circuit adapter during operation, resulting in severe leak of fresh gas and mismeasurement of tidal volumes.**

⚠Caution

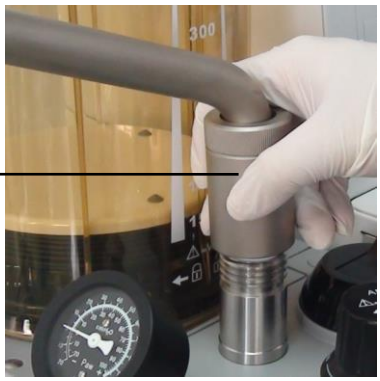
- **If it is very hard to push the breathing circuit system in, check whether or not the nuts on the downside of the breathing circuit system are tightened. The nuts may get stuck on the top of AGSS if they are not tightened.**
- **If it is very hard to push in or take out the breathing circuit system, it is necessary to apply small quantity of lubricating oil (du pont Krytox high-performance fluorine grease) onto the seal rings of air ports of the circuit adapter.**

5.1.2 Assemble the Manual Support Column

1 Assemble the screw-down nut to the manual support column, aligning the buckle on the support column to the buckle of the breathing system connector, as shown in the right figure.



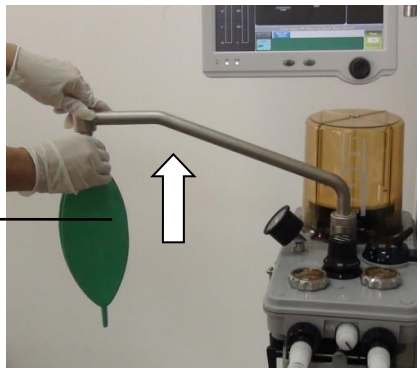
2 Assemble the manual support column connector to the breathing system connector, as shown in the right figure.



3 Tighten the screw-down nut clockwise, as shown in the right figure:

5.1.3 Assemble the Manual bag

1. Fit on the manual bag upward, and screw it onto the manual support column.



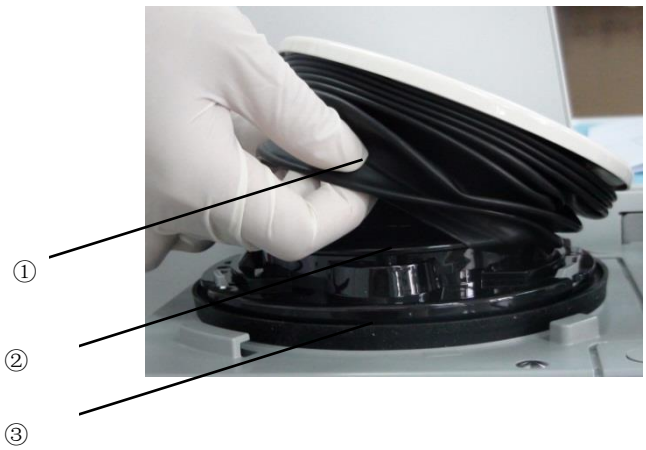
5.1.4 Assemble the Bellows Components

1 Attach the bottom ring of folded sack onto the bellows base of the breathing system, as shown in the figure below: To make sure that the folded sack is tightly connected to the bellows base, check whether or not the folded sack is assembled properly as per the following procedures: Push the oxygen flush“O_2+”, the folded sack shall be normally charged and gets upright.

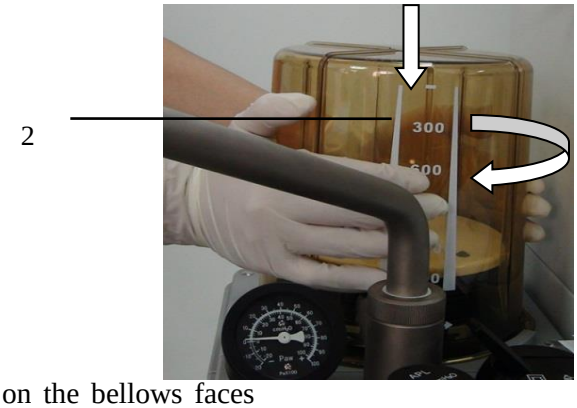
① Folded Sack

② Bellows base

③ Seal Component



2 Align the bayonet of bellows cover with the slots on the breathing system. Press downward the bellows cover to the end. Hold the outer side of bellows cover by both hands, and screw down it clockwise. as shown in the right figure:



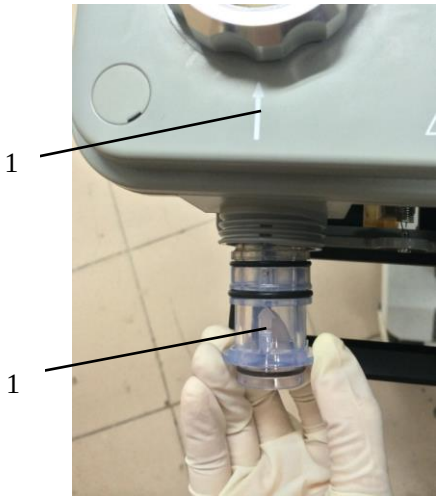
3 Please make sure the degree scale on the bellows faces right ahead when tightening the bellows.

⚠Warning

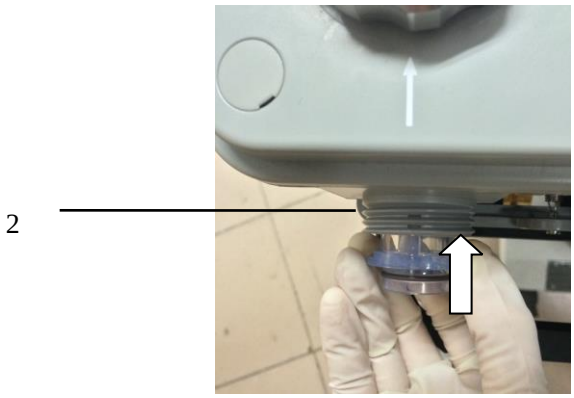
- **Before assembling the bellows cover, check whether or not the seal components of breathing system are normal. If any backing-off or warpage is found, assemble the seal components properly before bellows cover is assembled.**

5.1.5 Assemble the Flow Sensor

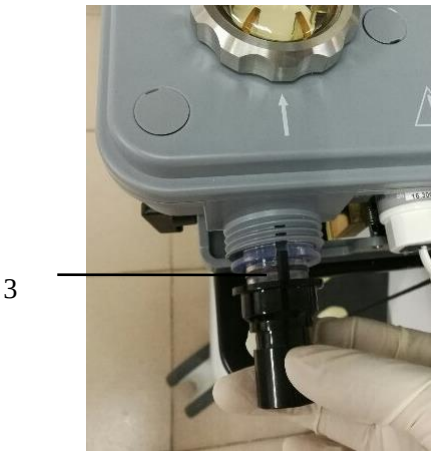
1. Ensure that the direction of arrow marked on the flow sensor is same to that on the breathing system, and the side with arrows is facing upward, as shown in the figure below:



2. Align the flow sensor to the slot and insert it horizontally.

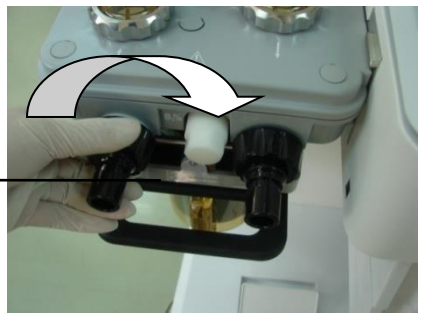


3. The breathing joint slot is aligned with the upper and lower slot of the flow sensor,as show in the figure.



4. Align the breathing joint and the lock nut to the flow sensor interface and tighten the lock nut clockwise.

4



⚠Warning

- **When flow sensor is assembled, tighten the respiration connector rotary-cap locknut; otherwise flow sensor measurement may be disabled.**

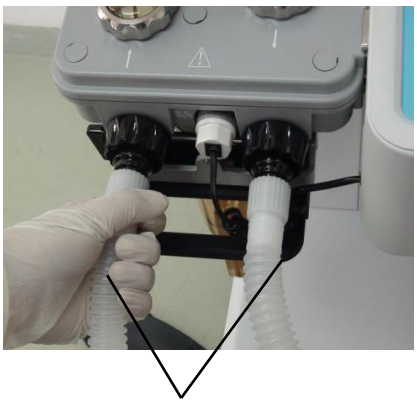
5.1.6 Assemble the Breathing Tube , Y-piece and mask

⚠Caution

- **To assemble the breathing tube, hold the connectors at both ends of the breathing tube so as not damage the breathing tube.**

1 Connect mask, filter to the Y-piece.

2 Assemble the expiratory tube and inspiratory tube onto the expiratory port and inspiratory port on the breathing system respectively.



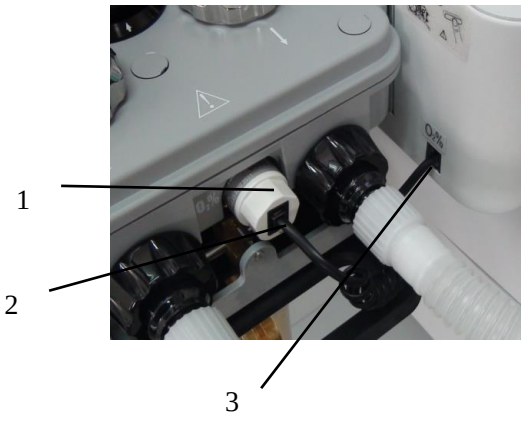
2

5.1.7 Assemble the Oxygen Sensor

⚠Warning

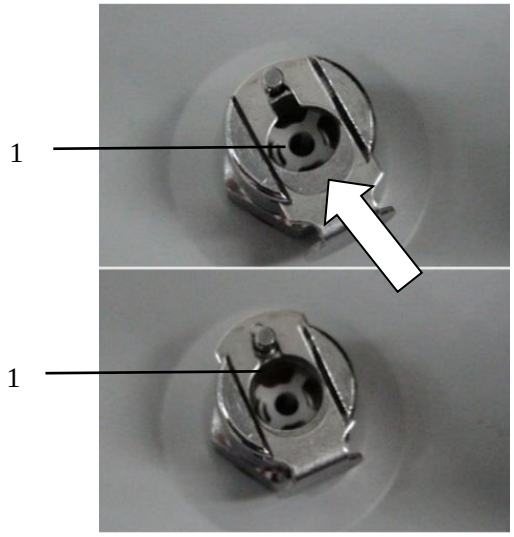
- **Before assembling the oxygen sensor, check if the seal rings of oxygen sensor is in good condition. Replace the oxygen sensor with a new one if no seal rings is installed or the seal is damaged.**
- **The O_2 sensor unpacking combination must be correct,screwed in place and not skew.**
- **Oxygen sensor must be assembled properly; otherwise gas leakage may occur in the breathing system.**

1. Align the oxygen sensor with the oxygen sensor port "O_2%" on the breathing system, and insert it into the port and assemble it securely.
2. Insert one end of oxygen sensor cable into the jack of oxygen sensor.
3. Insert the other end of oxygen sensor cable into corresponding oxygen sensor port "O_2%" on the main machine, as shown in the right figure:

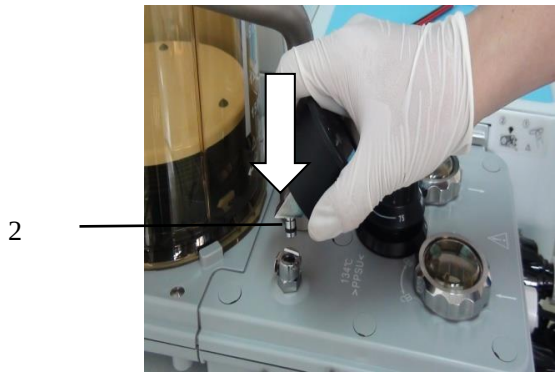


5.1.8 Assemble the Airway Pressure Gauge

1. Before assembling the airway pressure gauge, please check whether the slot is unlocked. If locked, press the buckle to unlock the slot before proceeding to the next step.



2. Directly insert the airway pressure gauge into the buckle of CPC connector. The airway pressure gauge is securely assembled if a sound “De” is heard.



5.2 Install the CO_2 Absorbent Canister

⚠Warning

Please observe the following applied provisions for safety protection:

- **Do not use the CO_2 absorbent canister with chloroform or trichloroethylene.**
- **Change absorbent frequently to prevent sedimentation of non-metabolic gas when the system is not in use.**
- **Use of desiccated CO_2 absorbent may endanger the patients. Proper preventive measures shall be taken to guarantee that the CO_2 absorbent inside the Canister (carbon dioxide absorbent) may not get dry. All gas supplies shall be turned off every time when finished using the system.**
- **Disposable Canister (carbon dioxide absorbent) is a sealed devices, and may not be opened or refilled with CO_2 absorbent.**
- **Do not allow your skin or eyes to be exposed to substance contained inside the CO_2 absorbent canister. In case skin or eyes are exposed to the substances, rinse the affected parts with fresh water immediately, and take medical treatment.**
- **If anesthesia machine is not provided with BYPASS function, replacement of CO_2 absorbent during ventilation might cause leakage in the breathing system.**
- **Be sure to assemble and lock up the Canister (carbon dioxide absorbent) properly; Otherwise, the patient may inhale repeatedly the carbon dioxide he gives off.**
- **CO_2 concentration monitoring is strongly recommend. The equipment may be connected to a CO_2 analyzer conforming to ISO80601-2-55 for monitoring the CO_2 output concentration. The CO_2 analyzer to be used is not limited to PHASEIN brand. For details of**

the operation guide and precautions, see the attached specification sheets for attachments.

- **Before assembling a Canister (carbon dioxide absorbent), check the color of CO_2 absorbent inside the Canister (carbon dioxide absorbent) so as to determine whether or not to change the CO_2 absorbent first.**
- **Every time a case is finished or during operation, check the color of CO_2 absorbent, and take corresponding treatment measures. For details of changes in color of CO_2 absorbent, refer to the label attached on the package of CO_2 absorbent. Color of the CO_2 absorbent may possibly restore to its original color during the period of time when it is not in use.**
- **Please take appropriate preventive measures to ensure that the CO_2 absorbent inside canister may not get dry. All gas supplies shall be turned off in time when finished using the system. If thoroughly dry CO_2 absorbent is exposed to anesthetics, it may release carbon monoxide (CO), and its continuing in service may do harm to the patients. Replace CO_2 absorbent in time for the safety of patients.**
- **Please clean CO_2 absorbent and replace the sponge of Canister (carbon dioxide absorbent) regularly; Otherwise CO_2 absorbent powder settled inside the Canister (carbon dioxide absorbent) may go into the breathing system.**
- **Please clean the Canister (carbon dioxide absorbent) rim regularly. Otherwise the CO_2 absorbent particles sticking on the rim may result in leakage in the breathing system.**
- **To assemble the CO_2 absorbent, check Canister (carbon dioxide absorbent) rim, strutting piece and seal for attached CO_2 absorbent particles. If any, remove the particles; otherwise they might result in leakage in the breathing system.**

⚠Caution

- **Gradual color change of absorbent inside the canister indicates that absorption of carbon dioxide. The color change of absorbent is only a rough indication. It is advisable to determine when to replace the absorbent by carbon dioxide concentration monitoring.**
- **Discolored absorbent shall be discarded. If left standing for several hours, it may regain its original color giving a misleading indication.**
- **Prior to operating the product, read the operating instruction completely.**
- **The breathing system of anesthesia machine includes the self closed- circuit system and non-closed- circuit system. The difference between them is that the former is equipped with the Bypass function.**

1 Check whether the support and rim of the CO_2 absorbent canister,are attached with absorbent particles or powder. If any, please remove them. The filled CO_2 absorbent cannot be higher than the “-MAX-” mark on the CO_2 absorbent canister.

2 Pinch the CO_2 absorbent canister lock catch with the left hand and rotate it rightward to unlock the canister bracket ,as shown in the right figure.

3 Align the CO_2 absorbent canister with the mounting slot of the canister bracket, as shown in the right figure.

4 Push the CO_2 absorbent canister to the end of the mounting slot of the canister bracket until it is fixed, as shown in the right

figure:

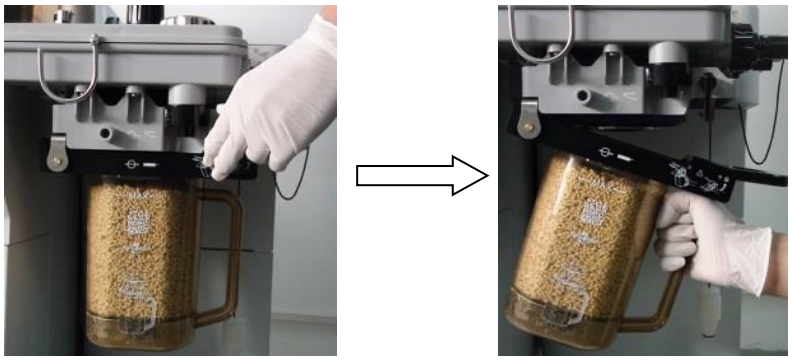
5 Lift up the handle of the bracket until it is locked, as shown in the right figure:

6 The CO_2 absorbent canister has been assembled successfully, as shown in the right figure:

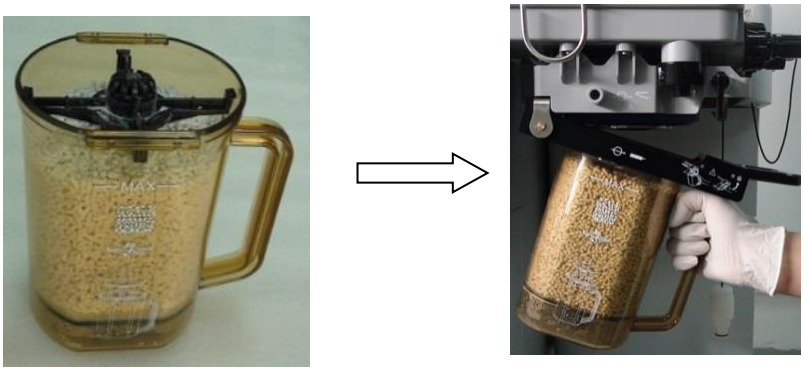
5.3 Replace the Canister (carbon dioxide absorbent)

As the breathing system includes the closed-circuit system with the Bypass structure, so the gas won't leak out to the atmospheric air during the process of replacing CO_2 absorbent canister. But be sure to timely replace the CO_2 absorbent and install the CO_2 canister to prevent CO_2 retention.

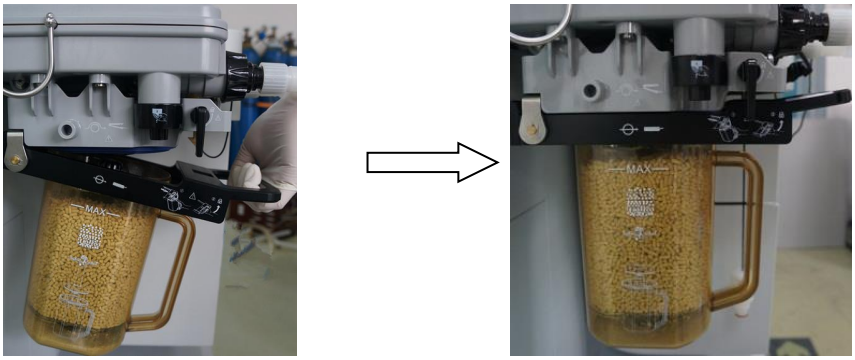
1. Push the release device of CO_2 absorbent canister to remove the CO_2 absorbent canister, as shown in the figure below.



2. The filled CO_2 absorbent cannot be higher than the "-max-" mark on the CO_2 absorbent canister. Check whether the CO_2 canister strutting piece, seal ring and the rim are attached with CO_2 absorbent particles or powder. If any, please remove them. Push the CO_2 absorbene canister to the end of the mounting slot until it is fixed  , as shown in the right figure:



3. Lift up the handle of the bracket until it is locked, as shown in the right figure:



5.4 Replace CO_2 Absorbent

⚠Caution

- **Gradual color change of absorbent inside the canister indicates that absorption of carbon dioxide. The color change of absorbent is only a rough indication. It is advisable to determine when to replace the absorbent by carbon dioxide concentration monitoring.**
- **Discolored absorbent shall be discarded as per local correlative laws and Regulations or waste disposal system of the hospital. If left standing for several hours, it may regain its original color giving a misleading indication. To avoid the misleading effect, we suggest that CO_2 absorbent shall be replaced by new one prior to each operation, or carbon dioxide monitor may be used.**
- **"Medisorb TM" CO_2 absorbent is recommended.**

1. Disassemble the CO_2 absorbent canister, referring to the reverse process of CO_2 absorbent canister assembling in the section 5.2 of this chapter.
2. Pinch the lock catch of the CO_2 absorbent canister with your left hand and rotate it rightward, as shown in the flag, open the canister bracket and take it out with your right hand  .
3. Take out the discolored CO_2 absorbent.
4. Fill the new CO_2 absorbent into the CO_2 absorbent canister along the inside periphery to prevent absorbent entering the ventilation hole of the strutting piece, otherwise, it may increase airway resistance.
5. Check whether the CO_2 canister strutting piece, seal ring and the rim are attached with CO_2 absorbent particles or powder. If any, please remove it. The placed CO_2 absorbent cannot be more than the "-max-" mark on the CO_2 absorbent canister.
6. Please refer to the procedure in the section 5.2 of this chapter to reassemble the CO_2 absorbent canister.

⚠Warning

- **To remount Canister (carbon dioxide absorbent) after replacement of the absorbent (carbon dioxide absorbent), be sure to check Canister (carbon dioxide absorbent) for locking so as to ensure proper assembling.**

⚠Caution

- **The CO_2 absorbent must not exceed the "-MAX-" level marked on the Canister (carbon dioxide absorbent)**

5.5 Connection of Gas Supplies

The anesthesia machine is provided with 2 types of gas supplies pipeline gas supplies (O_2, O_2, N_2O and AIR) and gas cylinder (O_2 ,N_2O and AIR).

One type of configuration is provided for pipeline gas supplies:

- O_2, O_2,N_2O and AIR

Threetypes of configuration are provided for cylinder gas supplies:

- O_2
- O_2 and N_2O
- O_2 and AIR

⚠Warning

- **Only medical-use gas supplies are allowed to used. Other types of gas supplies might contain water, oil or other contaminants.**
- **If the central gas supply system develops a fault, one or more equipments connected to it may quit work. In such a case,turn on the standby cylinders to make sure normal work of the anesthesia machine.**
- **When gas supplies are turned off, pressure still exists inside the pipelines. Therefore, release the gases from the pipelines before you unplug the gas pipes.**

5.5.1 Pipeline Inlets

The anesthesia machine provides 3 types of pipeline gas supplies namely O_2, N_2O and AIR,the O_2 pipeline gascontains two gas source interfaces. The gas supply hoses are marked with different colors, and the hose connectors of different types cannot be interchanged. The steps to connect gas supply hoses to the anesthesia machine are given below:

1 To connect the gas supply pipeline, check whether or not the seal rings of connectors for good condition.If the seal rings are damaged, the pipeline cannot be used, and seal rings must be replaced; otherwise gas leak may take place.

2 Align the gas supply hose and connectors with the gas-supply inlet on the back of anesthesia machine and insert it.

3 Ensure that the gas supply hoses are securely connected to the gas supply inlets, and tighten the hose nuts by hand.

⚠ Caution

- **The gas supply hoses shall meet the standards of ISO 5359 and YY/T 0799.**
- **The hose connectors shall meet the standards of ISO 9170-1 and YY 0801.1.**

5.5.2 Waste Gas Exhaust

There are two exhaust components, located on the left and the rear of the workbench, respectively. There are two exhaust ports, which are the exhaust port of the AGSS and PEEP generating device and the exhaust port with internalnegative-pressure driving gas.

For waste gas exhaust, the following shall be adopted:

1 PEEP exhaust port and internal vacuum suction vent, which may directly discharge oxygen gases indoors.

2 Outside diameter of AGSS connector is 30mm, with a taper of 1:20. Please connect Anesthetic gas scavenging system or passive waste gas disposal system.

⚠Warning

- **The PEEP exhaust port may continuously discharge small quantity of oxygen. Never block the outlet; otherwise the anesthesia ventilator cannot work.**
- **Prior to an operation, anesthesia machine shall be equipped with an anesthesia gas scavenging system conforming to ISO 80601-2-13 and YY 0635.2 to purify the air inside the operating room.**
- **If your anesthesia machine is not equipped with active AGSS, please do not connect the waste gas exhaust port of anesthesia machine to the active waste gas disposal system of the hospital.**

5.6 Assemble the Anesthesia Vaporizer

Anesthesia machine is applicable to Anesthesia Vaporizer Draeger series of Selectatec® (registered trade mark Ohmeda) fixation and interlocking mechanism for non-flammable anesthesia gas.

⚠Warning

- **If the vaporizer is incompatible with the anesthesia machine, their performance may be degraded. Please use the vaporizer matching the equipment.**
- **Please use an anesthesia vaporizer that complies with the ISO 80601-2-13 standard. For installation, addition, discharge, and other information about the anesthesia vaporizer, see the instructions of the manufacturer of the anesthesia vaporizer.**
- **The position of the anesthesia vaporizer between "0" and the minimum scale above "0" is not available and may cause accidental injury to the patient.**
- **Care should be taken to lift and operate the anesthesia vaporizer during installation,as the weight of the anesthesia vaporizer may be greater than expected,depending on the size of the anesthesia vaporizer.**
- **Only Selectatec series vaporizers can be used. To conduct testing, ensure that the anesthesia vaporizer is already locked up.**
- **Do not remove the locked anesthesia vaporizer from the anesthesia machine.**
- **To assemble 2 anesthesia vaporizers onto 1 anesthesia machine, the 2 anesthesia vaporizers must not be turned on simultaneously for concentration control.**
- **The anesthesia machine may be connected to an anesthesia concentration analyzer that conforms to $ISO_2$1647. We suggest that the user may assemble an anesthesia concentration analyzer if an anesthesia vaporizer is used, so as to monitor the output of anesthesia concentration.**
- **The anesthetic vaporizer cannot be used if it is set between "0" and "ON".**

⚠Caution

- **For details of vaporizer assembling/running, refer to instruction manual of corresponding vaporizers.**
- **Atmospheric pressure may differ from the calibration pressure of the anesthesia vaporizer,which may lead to inaccurate anesthetic output.During the use of the anesthetic system, the operator should continuously monitor the anesthetic concentration to confirm the accurancy of the output concentration.**
- **If the top of anesthesia vaporizer is not horizontal, remove the anesthesia vaporizers and reassemble it. If the anesthesia vaporizer cannot be set horizontally onto the vaporizer base,**

do not use the system.

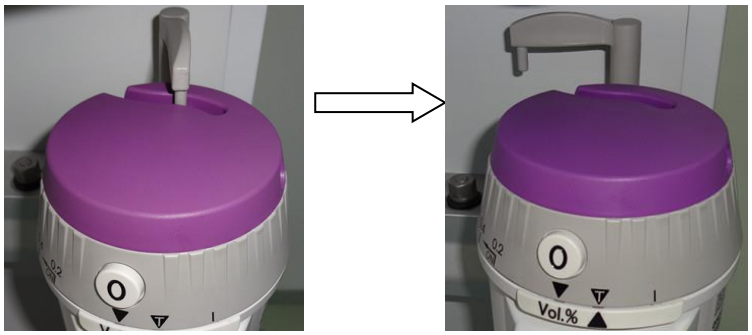
- **Set the locking bar of anesthesia vaporizer to its locking position.**
- **Lift each anesthesia vaporizer upward in so far as possible such that it may be separated from the vaporizer base. However, do not pull it forward. Be careful! Do not allow the anesthesia vaporizer to rotate on the vaporizer base.**

5.6.1 Assemble the Anesthesia Vaporizer

In the following assembling steps, anesthesia evaporator Draeger Vapor 2000 is given as an example:

1. Hang the Anesthesia Vaporizer onto the vaporizer base of the anesthesia machine, and ensure that the Anesthesia Vaporizer completely fits the vaporizer base without gap, as shown in the figure below:

2. Turn clockwise the locking bar to fix the Anesthesia Vaporizer onto the vaporizer base, as shown in the figure below:



3. Ensure that top of the Anesthesia Vaporizer is horizontal. If not, remove the vaporizer and reinstall it.
4. To reinstall it, lift up each Anesthesia Vaporizer vertically (90 degrees) such that it is separated from the vaporizer base, but do not pull it forward. Be careful not to allow the Anesthesia Vaporizer to rotate on the vaporizer base.
5. When the Anesthesia Vaporizer is separated from the vaporizer base, reinstall the

vaporizer and perform steps 1~3. If the Anesthesia Vaporizer cannot be positioned horizontally on the vaporizer base, do not use the system.

6. Try to turn on one or more Anesthesia Vaporizers.

7. Test each possible combination. If one or more anesthesia vaporizers can be turned on simultaneously, remove and reinstall the anesthesia vaporizers , and perform steps 1 to 6.

5.6.2 Fill the Anesthetics

For filling of anesthetics, please refer to specification sheets attached to the Anesthesia Vaporizers

⚠Warning

- **Ensure that anesthetics are filled correctly. Anesthetic names are already indicated on the vaporizers, and they are also marked with different colors. If anesthetics are incorrectly filled, the actual output concentration of anesthetics may be changed.**

5.6.3 Drain the Anesthetics

For drain of anesthetics, please refer to specification sheets attached to the anesthesia evaporators.

⚠Warning

- **Anesthetics drained from the vaporizer must not be reused, and it shall be disposed as hazardous chemicals.**
- **Please mark the bottles containing the drained anesthetics as follows: used anesthetics.**

5.7 Assemble the Gas Cylinders

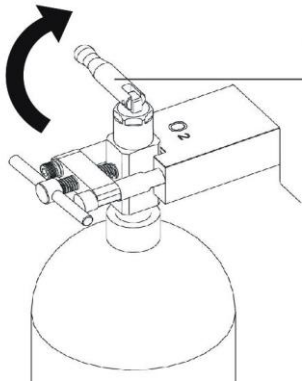
⚠Warning

- **Using no gasket or using more than one gasket may cause leakage.**
- **Do not leave the spare cylinder valve open while using the pipe for gas supply. Otherwise, in the event of a pipe gas supply failure, gas supply to the gas cylinder may be exhausted, resulting in insufficient reserve supply.**

5.7.1 Gas Cylinder (1)

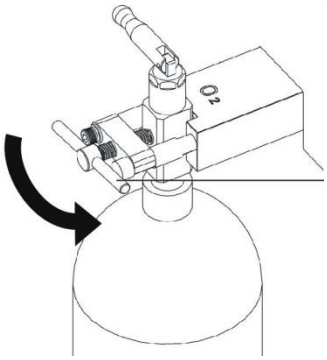
Install or replace the gas cylinder

1. Turn clockwise the handle of gas cylinder valve to turn off the valve of the gas cylinders to be replaced.



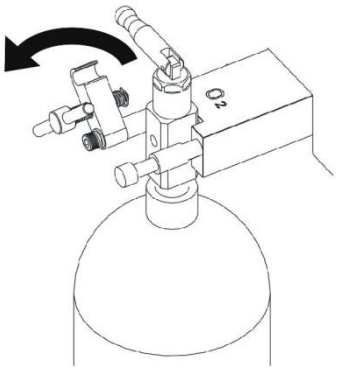
Handle of cylinder valve

2. Unscrew the T-type handle anticlockwise.

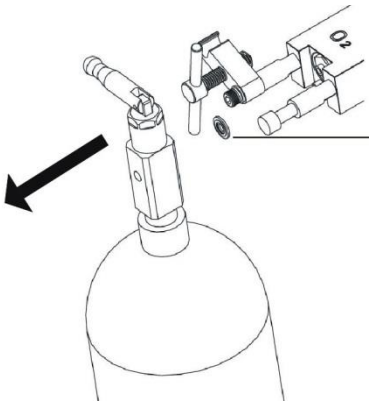


T-type handle

3. Loosen T-type handle completely, and open the buckle.



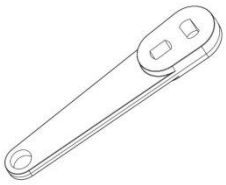
4. Remove the gas cylinder, and remove the old washer.



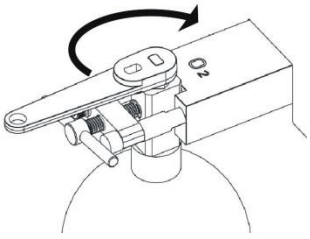
5. Ensure gas cylinder outlet is kept away from all articles that may be damaged by released high pressure gas.
6. Turn on and off the gas cylinder valve quickly to remove the dust on the gas cylinder outlet.
7. Assemble the new composite sealing washer.
8. Align the positions of gas cylinder and index pin.
9. Close the buckle and tighten the T-type handle.
10. Test the gas cylinders. For specific steps, refer to "***4.2.1 Gas Supply Pipeline Test***".

5.7.2 Gas Cylinder (2)

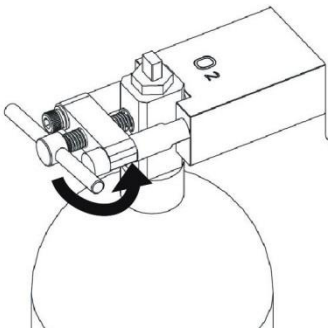
1. Get the wrench for the gas cylinder valve.



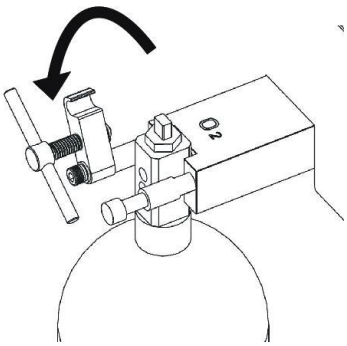
2. Shut off the valve of the gas cylinder to be replaced.



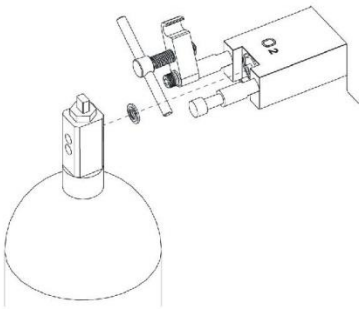
3. Loosen the T-type handle completely.



4. Open the buckle.



5. Remove the gas cylinder and the old sealing washer.

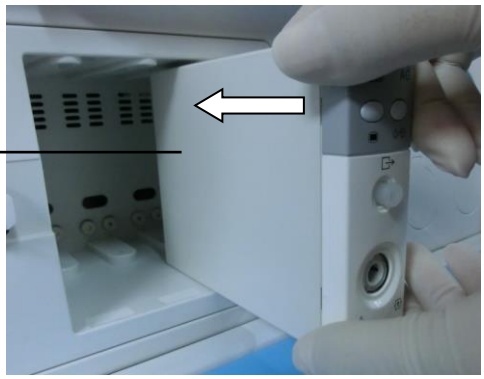


6. Remove the screw cap on the valve of the new gas cylinder.
7. Ensure that the gas cylinder outlet is kept away from any articles that may be damaged by released high pressure gas.
8. Turn on and off the gas cylinder valve quickly to remove the dust on the gas cylinder outlet.
9. Assemble the new composite sealing washer.
10. Align the gas cylinder and index pin.
11. Close the buckle and tighten the T-type handle.
12. Assemble gas cylinder plugs and composite sealing washers to all gas cylinder buckles.
13. Perform high pressure leak testing. For specific steps, refer to "***4.2.1 Gas Supply Pipeline Test***".

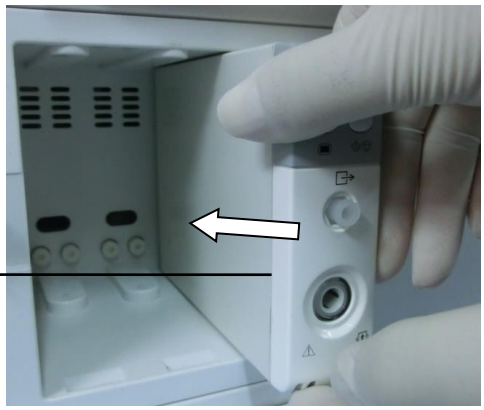
5.8 Assemble Module

5.8.1 Assemble Sidestream AG Module

1. Insert the module into the slot.

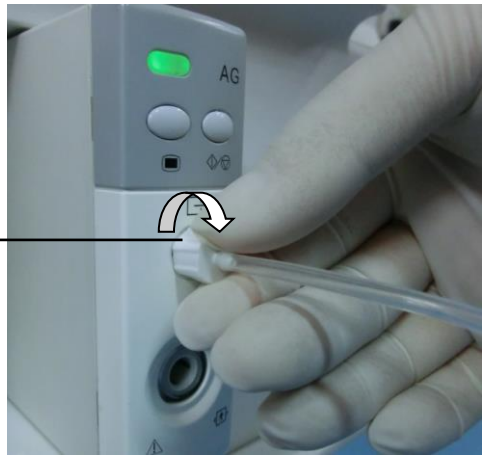


2. Push the module into the place until the lever at its bottom gives a “Click” sound, indicating that the module is fixed properly.

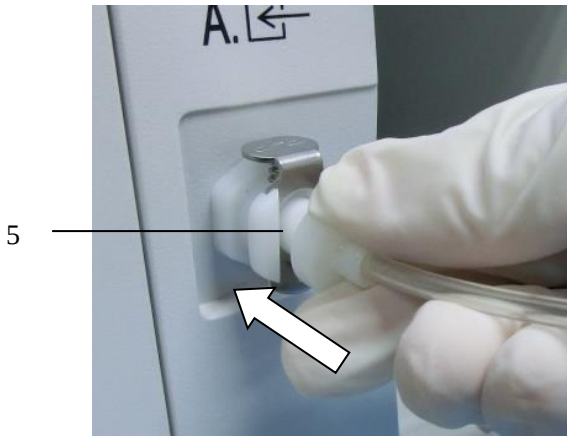


3. The indicator light on the module turns on, indicating the module is installed properly.

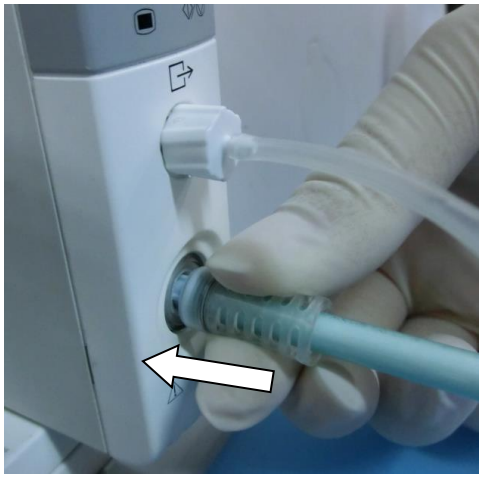
4. Insert one end of the exhaust tube into the exhaust outlet on the module, and rotate it clockwise to tighten it.

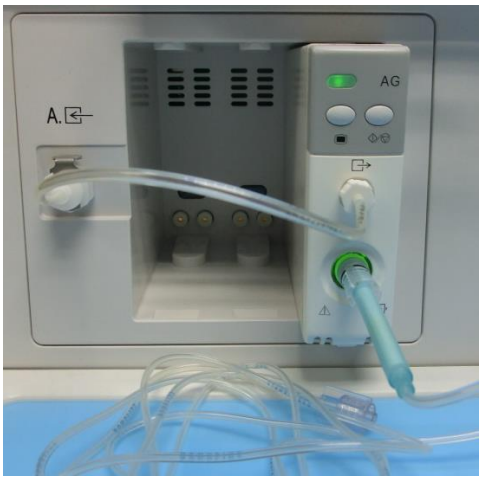


5. Insert the other end of the exhaust tube into the exhaust inlet on the anesthesia machine. A “Click” sound indicates the tube is installed in place.



6. Insert the sampling line into the sampling port.





5.8.2 Assemble Sidestream CO_2 Module

For details,,please refer to the section of " *5.8.1 Assemble Sidestream AG Module* ".

5.8.3 Assemble the Sidestream AG + O_2 Module

For details, refer to the section of " *5.8.1 Assemble Sidestream AG Module* ".

5.8.4 Assemble Mainstream CO_2 Module

1. Install the module into the module slot.

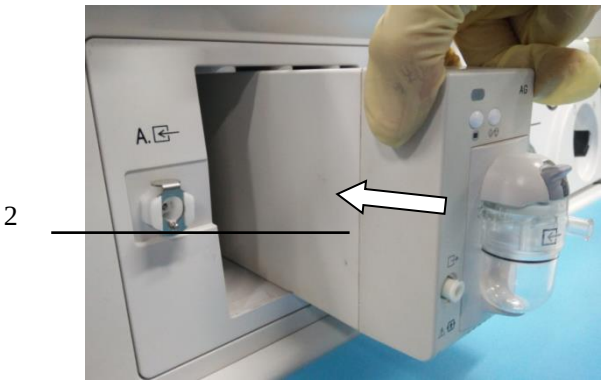
2. Push the module into the place until the lever at its bottom gives a “Click” sound, indicating that the module is fixed properly. The indicator light on the module turns on, indicating the module is installed properly.

3. According to the triangular mark of the connector, insert one end of the connector into the sample port.

5.8.5 Assemble Artema Sidestream AG Module

1. Push the watertrap firmly into the watertrap socket as shown the figure below.
   A "click" sound indicates that the watertrap is installed in place.

2. Install the module into the module slot.



3. Push the module into the place until the lever at its bottom gives a “Click” sound, indicating that the module is fixed properly. The indicator light on the module turns on, indicating the module is installed properly.

4. Insert one end of the exhaust tube into the exhaust outlet on the module, and rotate it clockwise to tighten it.

5. Insert the other end of the exhaust tube into the exhaust inlet on the anesthesia machine. A “Click” sound indicates the tube is installed in place.

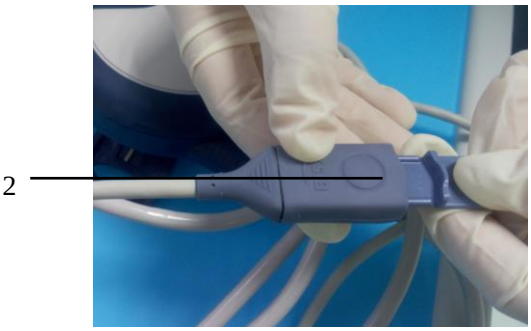
6. Insert one end of the sampling tube into the sampling tube port, then rotate it clockwise to tighten it.

5.8.6 Assemble Artema Sidestream AG+O_2 Module

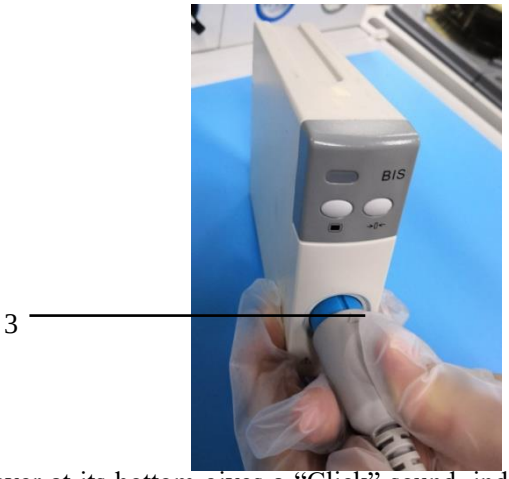
For the detailed installation procedure, please refer to ***5.8.5 Assemble ARTEMA Sidestream AG Module***.

5.8.7 Assemble BIS module

1. Firstly paste the BIS sensor (as instructed in the attached document of the BIS sensor) onto the patient's head.
2. Plug the sensor connector into the BISx device cable connector.



3. Plug the BISx device cable connector into the BIS module connector, as shown in the figure:

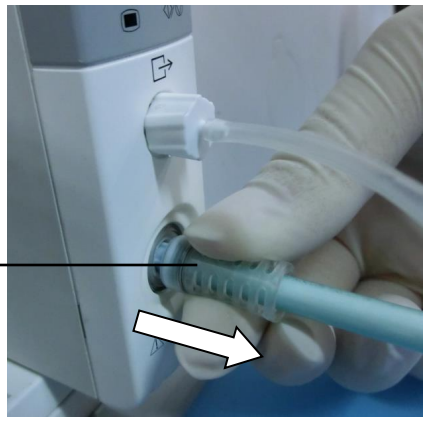


4. Push the module into the place until the lever at its bottom gives a “Click” sound, indicating that the module is fixed properly.

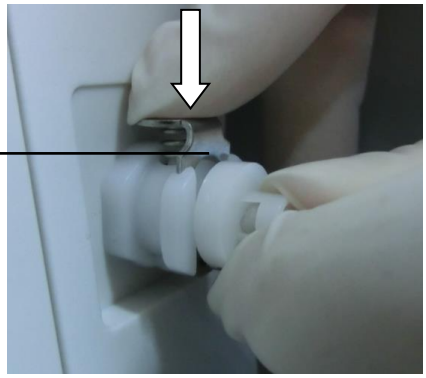
5. The indicator light on the module turns on, indicating the module is installed properly.

5.8.8 Disassemble Sidestream AG Module

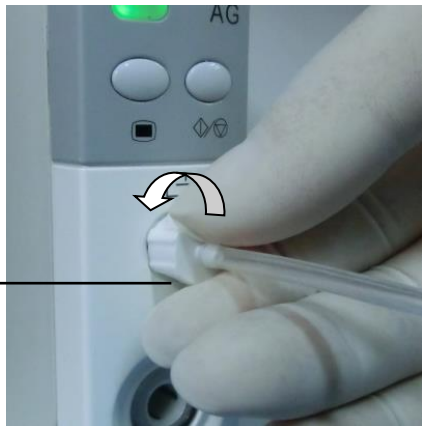
1. Pull out the sampling line, as shown in the right figure.



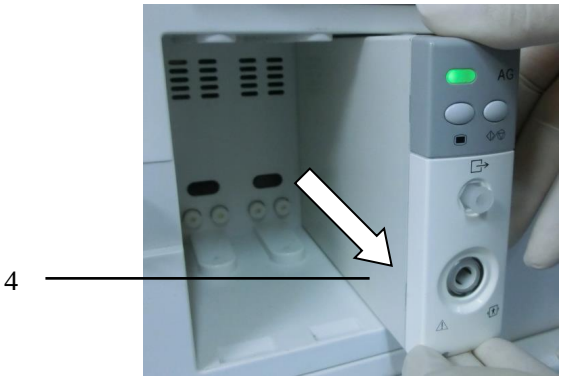
2. Press down the clip at the exhaust outlet of the anesthesia machine to pop out the exhaust tube, and then remove the tube, as shown in the tight figure.



3. Rotate the tightening knob of the exhaust tube anticlockwise, and then pull out the tube.



4. Push the tab at the bottom of the module upwards, and pull out the module.



5.8.9 Disassemble Sidestream CO_2 Module

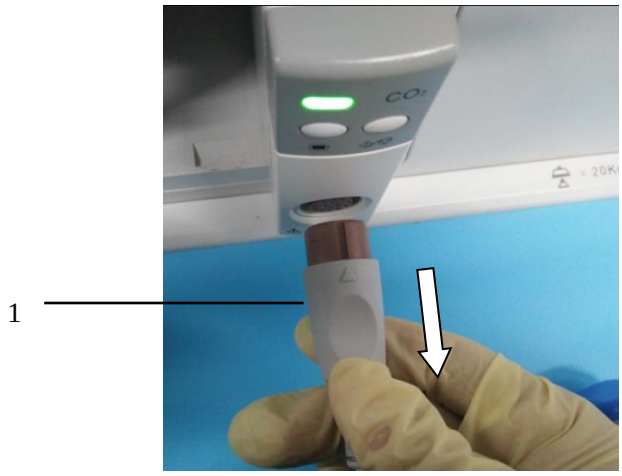
For details, please refer to the section of " ***5.8.8 Disassemble Sidestream AG Module*** " .

5.8.10 Disassemble Sidestream AG + O_2 Module

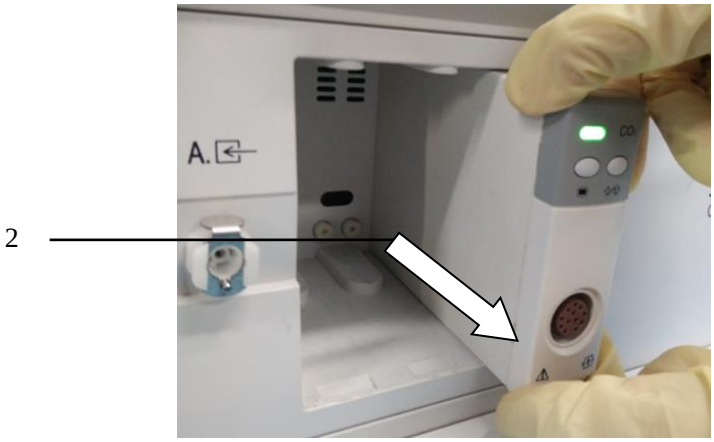
For details, please refer to the section of ***5.8.8 Disassemble Sidestream AG Module.***

5.8.11 Disassemble Mainstream CO_2 Module

1. Pull the connector cable out of the sampling port.



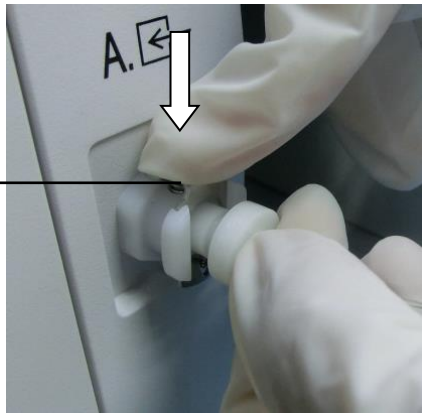
2. Push the tab at the bottom of the module upwards, and pull out the module.



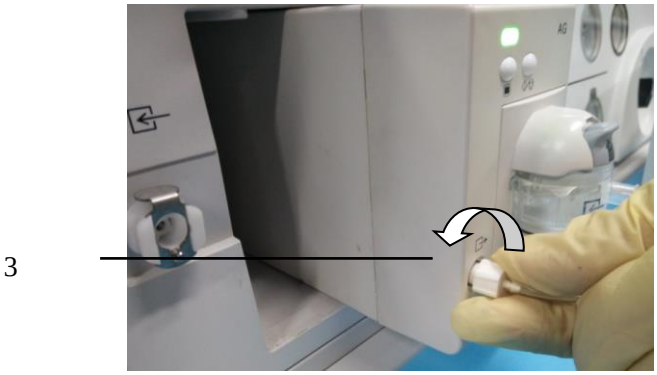
5.8.12 Disassemble Artema Sidestream AG Module

1. Rotate the sample tube anticlockwise. As shown in the figure:

2. Press down the clip at the exhaust outlet of the anesthesia machine to pop out the exhaust tube, and then remove the tube, as shown in the tight figure:



3. Rotate the tightening knob of the exhaust tube counterclockwise , and then pull out the tube.



4. Push the tab at the bottom of the module upwards, and pull out the module.

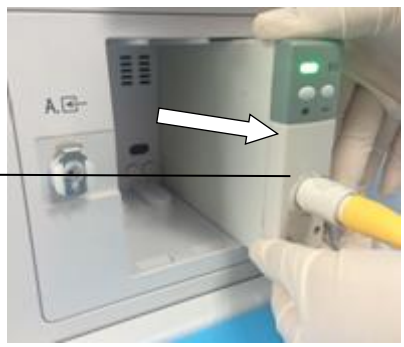
5. Push the buckle upwards as shown in the figure to remove the watertrap.

5.8.13 Disassemble Artema Sidestream AG+O_2 Module

Please refer to ***5.8.12 Disassemble Artema Sidestream AG Module*** for detailed disassembling steps.

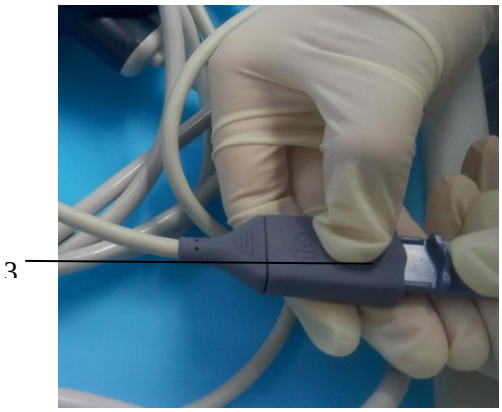
5.8.14 Disassemble BIS module

1. Push the tab at the bottom of the module upwards, and pull out the module.



2. Pull the BIS module cable connector out of the BIS module connector, as shown in the figure:

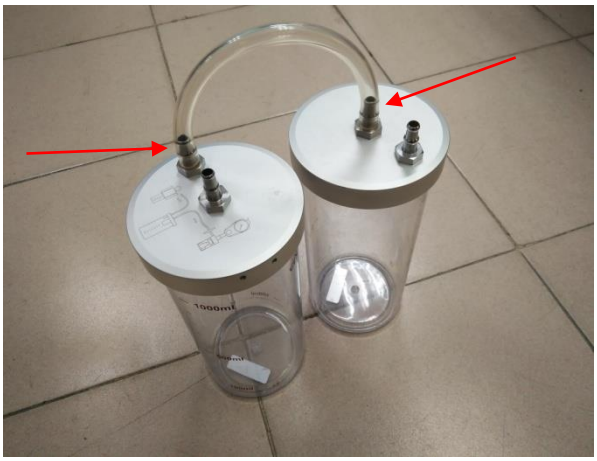
3. Press and hold the circular button on the patient interface cable with right hand. Pull out the sensor connector with left hand, as shown in the figure:



5.9 Installation of the Vacuum Suction System

5.9.1 Assemble Internal Vacuum Suction System

1. Place the collecting bottle in the bracket.Connect the suction and the collecting bottle according to the mark on the collecting bottle.



2. As shown in the figure,rotate the nut,install the overflow cup,and insert the suction tube into the overflow protection interface.

3. Connect the suction tube to both sides of the filter.After connecting,connect one end of the tube to the overflow cup and the other end to the collecting bottle,as shown below:

⚠Caution

- **When installing the filter to the suction tube,please note that the side with an IN is facing the collecting bottle.**
- **When using the collecting bottle,always check the filling of the collecting bottle,and replace or clean the waste liquid in the bottle before it is full,so as to avoid interruption of suction and delay of treatment.**

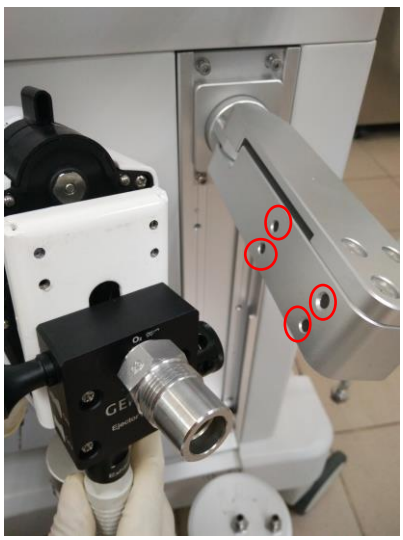
5.9.2 Installation of External Vacuum Suction

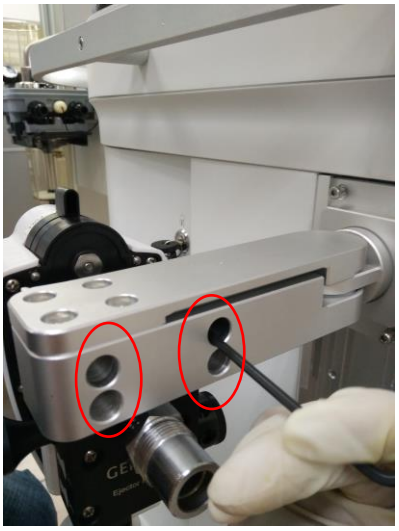
1. As shown in the figure, connect the back-up oxygen supply hose to the O_2 supply port (in case of

air-driven, use backup air supply hose).

2. Fix the bracket by tightening the screws at the four corners.

3. Fix external vacuum suction by tightening the four screws on the bracket.





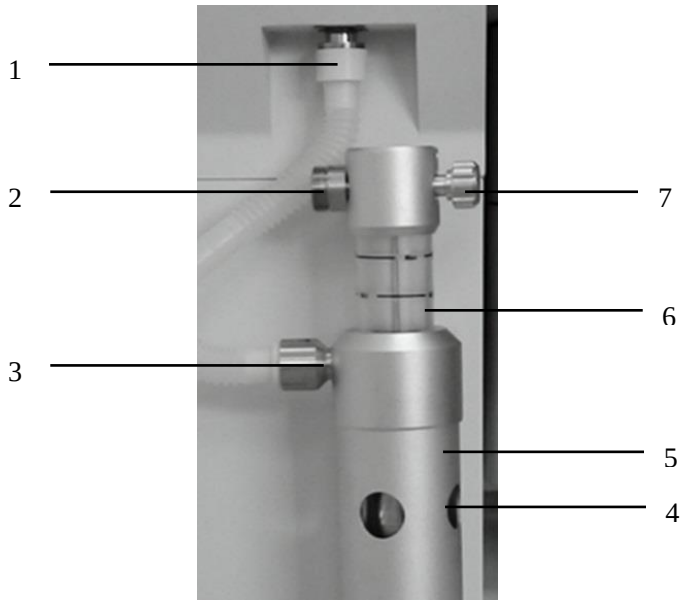
4. Connect the other end of the backup oxygen supply hose to the external negative pressure suction port and tighten the nut to fasten it.

5.10 AGSS Transfer and Receiving System

⚠Warning

- **AGSS transfer and receiving system shall work with a breathing system conforming to YY 0635.1 and ISO 80601-2-13.**
- **Processing system shall be 1 H-type low-vacuum high-flow negative pressure suction system.**

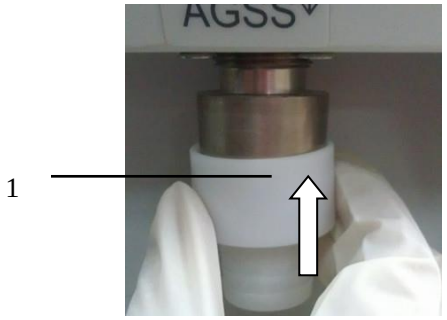
5.10.1 Structur Composition of AGSS



No.	Notes
1	Waste gas exhaust nozzle connector
2	AGSS exhaust gase outlet
3	Transfer system hose **c**onical connector
4	Pressure Compensation Port
5	Main body of AGSS system
6	Float (red)
7	Flow regulation knob

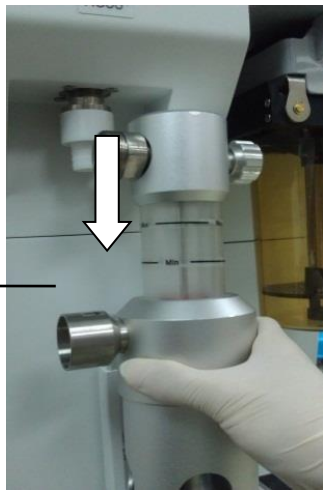
5.10.2 Assemble the AGSS

1 Assemble the waste gas exhaust nozzle connector to the gas outlet of breathing system：



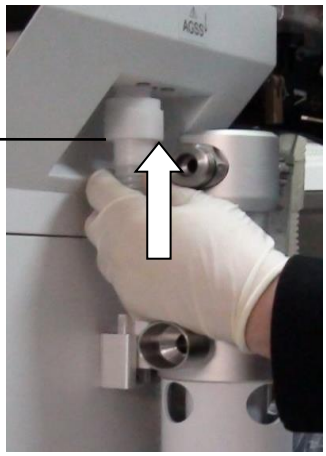
2 Hang a AGSS system onto the AGSS bracket.

2



3 Connect the transfer system hose to the waste gas exhaust nozzle connector.

3

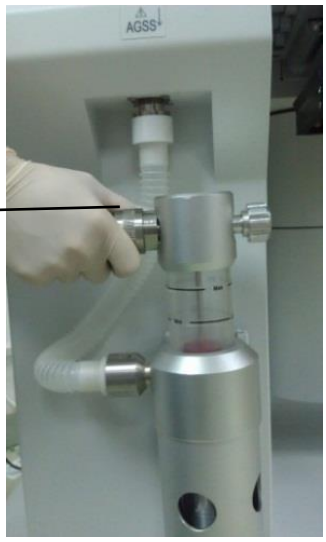


4 Connect the 30mm **c**onical connector of transfer system hose to the inlet of AGSS system.

4

5 Connect the AGSS exhaust gas outlet to the exhaust gas disposal system of the hospital through AGSS active scavenging hose.

5



⚠Caution

- **Do not block the pressure compensation port during the process of assembling and using AGSS.**
- **Prior to transport or movement, remove the AGSS system from the anesthesia machine.**

5.10.3 Waste Gas Disposal System

1. AGSS transfer and receiving system is 1H-type high-flow low-vacuum model, and conforms to Standard ISO 80601-2-13 and YY 0635.2. The adjustable range of pump rate of the AGSS transfer and receiving system is 50 ~80 L/min.
2. The AGSS transfer and receiving is a 1L-type low flow low vacuum type, and conforms to ISO 80601-2-13 and YY 0635.2 standards. The adjustable range of pump rate of the AGSS transfer and receiving system is 25 ~50 L/min.
3. Prior to use, verify that the waste gas disposal system is a high-flow disposal system, and is able to reach the flow range.
4. Prior to use, verify that connector of the waste gas disposal system is BS 6834 standard connector.

⚠Caution

- **During testing, do not block the pressure compensation port of the AGSS transfer and receiving system.**

⚠Warning

- **The AGSS transfer and receiving system cannot be used with flammable Anesthesia gases.**

- **If the hose between waste gas disposal system and AGSS is blocked, or the extract flow of the waste gas disposal system is insufficient, exhaust gas from the expiratory system exceeds the tidal volume 1L specified in ISO 80601-2-13 and YY 0635.2, or exceeds the required semi-sine gas flow of 20 times/minute, or the waste gas disposal system fails to work, gas inside the AGSS may exceed 100 mL/min and overflow into the atmosphere. In such a case, it is inadvisable to use the AGSS.**

Chapter 6 Alarm

6.1 Overview

Alarms given by the anesthesia machine have the audible and visual indications to the medical care personnel when the patients using the anesthesia machine show abnormal changes in vital signs or the anesthesia machine can not work normally due to its fault.

⚠Caution

- **When the equipment is turned on, the system tests the alarm tones and alarm lamp functions if they can work normally. If yes, the equipment gives a sound "Beep", and the alarm lamp blinks once in red and yellow each. If the tones and alarm lamp functions are abnormal, do not use the equipment. Please contact the Company immediately.**
- **In case multiple different alarms occur simultaneously, the equipment will give audible and visual alarms as per the alarm of the highest level among them.**
- **User shall set the alarm volume and alarm limits as per actual conditions of the patients. Do not only rely on the audible alarm system for patient monitoring. If the alarm tone is adjusted to a lower volume, patients' safety may be endangered. User shall pay close attention to actual clinical status of the patients.**
- **Information such as physiological parameters and alarms displayed in the screen of the equipment are for clinicians' reference only, and must not be directly used as basis for clinical treatment.**
- **A potential hazard can exist if different alarm pre-sets are used for the same or similar equipment in any single area.**
- **Alarm system could restore the previous alarm setting no matter the duration of power interruption.**

6.1.1 Alarm Types

Alarms given by the anesthesia machine are divided into physiologic alarms, technical alarms and prompting messages as per the properties of alarms.

1 Physiological Alarms

Physiological alarms are usually given when the physiological parameter measurement of the patient exceeds the preset High/Low alarm limits or some physiological abnormality

of the patient takes place. The alarm messages of physiological alarms are displayed in the physiological alarm area at the upper part of the screen.

2 Technical Alarms

Technical alarms, which are also known as system error messages, indicate the alarms triggered when some system function cannot work normally resulting from misoperation or system malfunction, or the monitoring results are distorted. Alarm messages of technical alarms are displayed in the technical alarm area at the upper part of the screen.

3 Prompting Messages

Strictly speaking, prompting messages do not fall into the scope of alarms. Apart from the physiological alarm messages and technical alarm messages, the Anesthesia machine can display prompting messages which are related to the system state. The prompting messages usually do not relate to the vital signs of patients. The prompting messages are displayed in the system prompting message area.

6.1.2 Alarm Levels

As per the severity of alarms, physiological alarms given by the anesthesia machine are divided into high level alarms, medium level alarms, and low level alarms.

1. High Level Alarms

   Patient is in a critical condition endangering patient life, and immediate emergency treatment is required.

2. Medium Level Alarms

   Physiological sign of patient appears abnormal, and corresponding measures shall be taken or treatment shall be conducted immediately.

3. Low Level Alarms

   Physiological sign of patient appears abnormal, and corresponding measures may possibly be taken or treatment may possibly be conducted.

Levels of all technical alarms and some physiological alarms are already preset before the anesthesia machines are shipped, and cannot be modified by the users. Levels of some physiological alarms may be modified.

6.2 Alarm Indications

When an alarm occurs, the anesthesia machine prompts the user through the following audible and visual indications:

- Visual alarms
- Audible alarms
- Alarm messages
- Parameter flashing

Of which, the alarm levels of visual alarms, audible alarms and alarm messages are presented in different ways respectively.

6.2.1 Visual Alarms

When an alarm occurs, alarm lamp prompts alarms of different levels by different colors and flashing frequencies.

- High level alarms: red, the flashing frequency is 2.5Hz.
- Medium level alarms: yellow, the flashing frequency is 0.625Hz.
- Low level alarms: yellow, always on, without flashing.

6.2.2 Audible Alarms

When an alarm occurs, anesthesia machine prompts alarms of different levels by different sound characteristics.

- High level alarms: Di-Di- Di - Di - Di ----- Di - Di - Di - Di - Di.
- Medium level alarm: Di - Di - Di.
- Low level alarms: Di.
- Information: Do

6.2.3 Alarm Messages

Alarm messages are displayed in the physiological alarm area or technical alarm area of anesthesia machine when an alarm occurs. System adopts different background color to differentiate levels of alarm messages.

- High level alarms: Red
- Medium level alarm: yellow
- Low level alarm: yellow
- Information : no background,except Module alarm off is yellow

The following marks are added before alarm messages to differentiate level alarm messages:

- High level alarms: !!!
- Medium level alarm: !!
- Low level alarm: !
- Information: no “!”mark

6.2.4 Parameter Flashing

When a parameter alarm occurs, the parameter flashes once every second.

6.2.5 Alarm Status Icons

In addition to the above-mentioned alarm modes, the following alarm status icon may also be displayed on the screen to indicate the alarm status.

-  : The icon indicates that alarm sound is temporary muted,temporary mute 120S.

6.3 Set the Alarm Volume

1、 On the screen, select **[Alarm]** →**[Sound]**→ Access **[Alarm Sound Volume]** menu

2、 Select a volume from the range of 1~8. “1” indicates the minimum volume, and “8” indicates the maximum volume.

⚠Warning

- **When using the equipment, you cannot just depend upon audible alarms. If the alarm tone is adjusted to a lower volume, the patient’s safety may be endangered. Keeping the patient under close surveillance is the most reliable way.**
- **Minimum alarm sound volume can be adjusted in maintenance mode.**
- **Click on the system default, when the set minimum alarm volume is less than or equal to level 5, the alarm volume is restored to level 5 when the default value is restored or when the minimum alarm volume set is greater than level 5, the alarm volume is restored to the minimum alarm volume when the default value is restored.**

6.4 Set the Alarm Limits

⚠Caution

- **When the parameter value is higher than high alarm limit or lower than low alarm limit , an alarm will be triggered.**
- **Click on the system default, the ventilator parameter alarm high and low limit is restored to the default alarm high and low limit corresponding to the patient type.**
- **When using the equipment, always ensure that the alarm limits are set to suitable values. Set High alarm limit and low alarm limit as per clinical requirements. If the settings are beyond the valid range, the alarm system may be ineffective.**

6.4.1 Set the Alarm Limits of Ventilator

1. On the screen, select **[Alarm]** menu → **[ventilator]** .
2. On the alarm screen of ventilator, set one by one the alarm **[High Limit]** and **[Low limit]** of parameters like **[MV]** , **[Ppeak]** , **[FiO_2]** and **[VT]** .
3. Or select [Load Default Alarm Limit] to use the default high/low alarm limits.

Fig. 6-1 Set the Ventilator's Alarms

Range of High/Low alarm limits:

Parameter Name	High Limit	Low limit	Adult default alarm	Child default alarm	Unit	Step size
MV	2~100	0~ (High limit-2)	1（low limit） 10（high limit）	1 （ low limit） 5（high limit）	L/min	1
Ppeak	2~100	0~ (High limit-2)	10（low limit） 50（high limit）	8 （ low limit） 40（high limit）	cmH_2O	1
	0.2～9.8	0～（High limit －0.2）	1.0（low limit） 4.9（high limit）	0.8 （ low limit） 3.9（high limit）	kPa	0.1
	2～98	0～（High limit －2）	10（low limit） 49（high limit）	8 （ low limit） 39（high limit）	mbar	1
FiO_2	20~105	18~ (High limit-2)	21（low limit） 103（high limit）	21（low limit）103（high limit）	%	1
VT	5~1600	0~ (High limit-5)	5（low limit） 1000（high limit）	5 （ low limit） 200（high limit）	mL	5

⚠Warning

- **If an alarm is cleared in manual mode, alarms such per-minute ventilation amount and expiratory tidal volume will not be triggered.**

- **The alarm setting can be saved before and after shutdown for 30S,and the setting before shutdown can be maintained.**

6.4.2 Set the CO_2 Alarm Limits

1. On the screen, select **[Alarm]** menu → **[CO_2]** .
2. On the alarm screen of CO_2, set the **[High Limit]** and **[Low Limit]** for **[FiCO_2]** and **[EtCO_2]** alarms, as shown in the figure below:

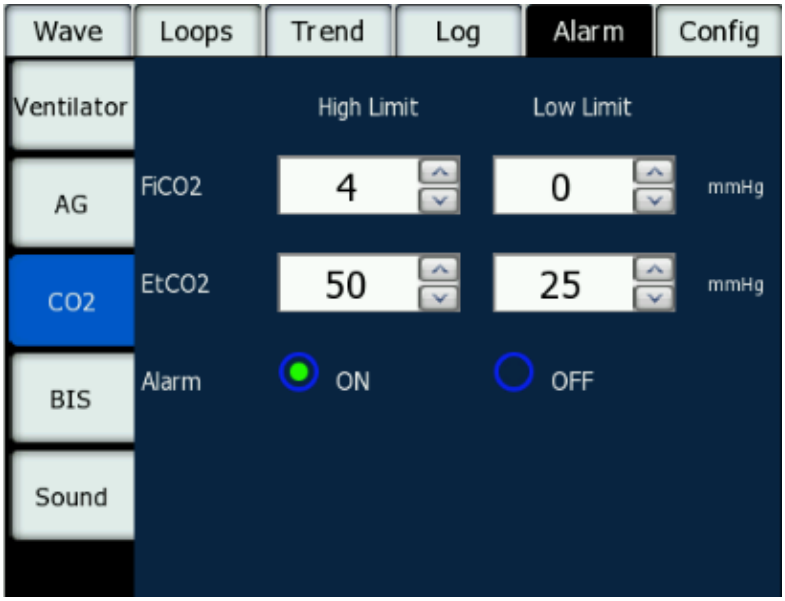


Fig. 6-2 Set the Carbon Dioxide Alarms

Range of High/Low Alarm Limits:

Respironics CO_2:

Parameter Name	High limit	Low limit	Adult default alarm	Child default alarm	Unit	Step size	Remarks
FiCO_2	(low limit+1)～76	0～74	0（low limit） 4（high limit）	0（low limit） 4（high limit）	mmHg	1	N/A
EtCO_2	(low limit+2)～150	0～（high limit-2）	25（low limit） 50（high limit）	25（low limit） 50（high limit）	mmHg	1	N/A

Masimo CO_2:

Parameter Name	High limit	Low limit	Adult default alarm	Child default alarm	Unit	Step size	Remarks
$FiCO_2$	(low limit+1)～99	0～97	0（low limit） 4（high limit）	0（low limit） 4（high limit）	mmHg	1	N/A
$EtCO_2$	(low limit+2)～190	0～（high limit-2）	25（low limit） 50（high limit）	25（low limit） 50（high limit）	mmHg	1	N/A

6.4.3 Setting BIS Warning Limits

1. On the screen, select **[Alarm]** menu → **[BIS]** .

2. On the alarm screen of BIS, set the **[High Limit]** and **[Low Limit]** for **[BIS]** alarms, as shown in the figure below:

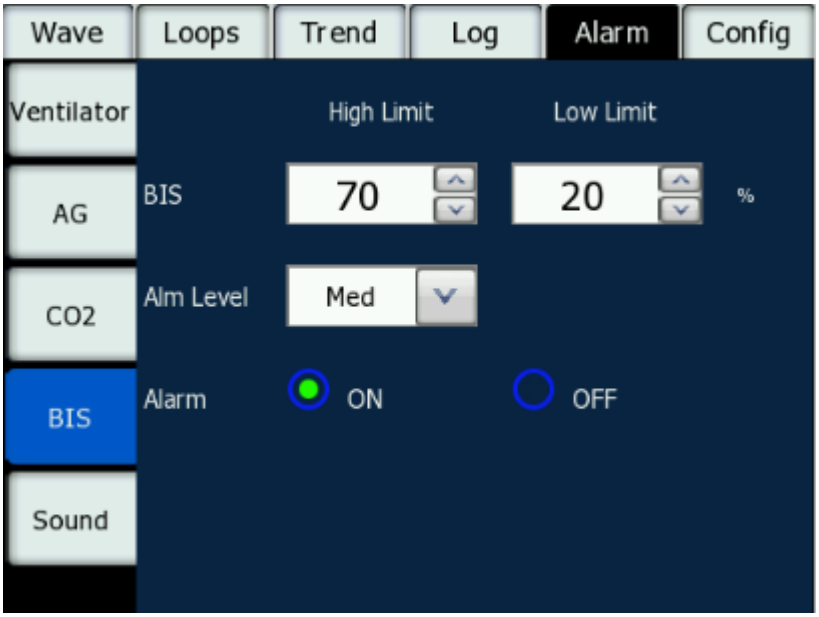


Fig. 6-3 Setting Anesthetic Gas Alarm

Parameter Name	High limit	Low limit	Adult default alarm	Child default alarm	Unit	Step size	Remarks
BIS	2～100	0～98	20（low limit） 70（high limit）	20（low limit） 70（high limit）	/	1	N/A

6.4.4 Setting the AG Alarm Limits

1. On the screen,select **[Alarm]**menu → **[AG]**.

2. Set the [**High Limit]** and **[Low Limit]** of the parameters of [**FiN₂O]** , [**EtN₂O]** , [**FiAA**] and [**EtAA**] on the [**AG]** Alarm screen. See the following figure:

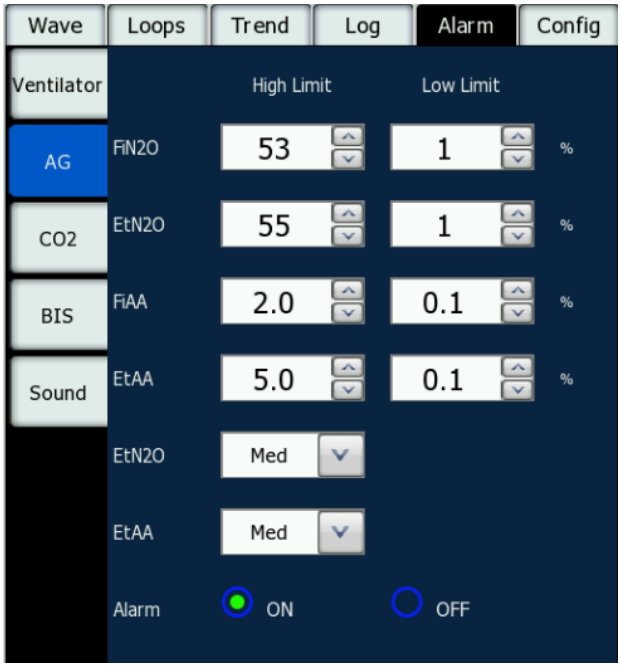


Fig. 6-4 Setting Anesthetic Gas Alarm

Range of the High/Low alarm limit:

Name	High Limit	Low Limit	Adult default alarm	Child default alarm	Unit	Step size	Remarks
$FiCO_2$	(Low Limit＋2）～99	0～(High Limit－2)	0（low limit） 4（high limit）	0（low limit） 4（high limit）	mmHg	1	N/A
$EtCO_2$	(Low Limit＋2）～190	0～(High Limit－2)	25（low limit） 50（high limit）	25（low limit） 50（high limit）	mmHg	1	N/A
FiN_2O	(Low Limit＋2%）～100%	0 % ～ (High Limit－2%)	0（low limit） 53（high limit）	0（low limit） 53（high limit）	%	1	N/A
EtN_2O	(Low Limit＋2%）～100 %	0 % ～ (High Limit－2%)	0（low limit） 55（high limit）	0（low limit） 55（high limit）	%	1	N/A
Inhalation of AA	(Low Limit＋0.2%）～25.0 %	0 % ～ (High Limit－0.2%)	0（low limit） 2.0（high limit）	0（low limit） 2.0（high limit）	%	0.1	N/A

Exhalation of AA	(Low Limit＋0.2%）～25.0%	0 % ～ (High Limit－0.2%)	0（low limit） 5.0（high limit）	0（low limit） 5.0（high limit）	%	0.1	N/A

6.5 Set the Alarm Levels

Set CO_2 alarm level:

1. Select [**Alarm]** menu → [**CO_2]** → [**Alarm Level]**..
2. The **[High Limit]** of CO_2 alarm levels can be set to, [**Medium],default** [**Medium],not modifiable**.

Set AG alarm level:

1. Select [**Alarm]** menu → [AG**]** → [**Alarm Level]**.
2. The **[High Limit]** and [**Low Limit**] of AG can be distinguished as follows:
   - EtN_2O high limit alarm（High,Medium,Low）
   - EtAA high limit alarm（High,Medium）
   - AG FiAA ,FiN_2O the high limit is Medium alarm
   - AG FiAA,FiN_2O the low limit is low alarm

Set BIS alarm level:

1. Select [**Alarm]** menu → **[BIS]** → [**Alarm Level]**.
2. Set the **[High Limit]** of BIS to [**High]** , [**Medium]** or [**Low]**.

6.6 Alarm pause

6.6.1 Set the Alarm pause

Push the alarm softkey to set the system to alarm pause status, namely all alarm tones of the system are shielded, and "" icon and 120 s counting-down are displayed in the upper right corner of the screen.

⚠Caution

- **In the alarm pause status, all alarm modes works normally except for audible alarm.**
- **In alarm pause status, even if there is a newalarm pause technical or physiological alarm,the alarm will continue to be suspended.**
- **Once 120s counting down expires, the system will automatically exit the current alarm pause status and reactivate the audible alarm.**

6.6.2 Cancelling the Alarm pause

If the alarm pause soft key is pushed,the system will exit current alarm pause status and reactivate audible alarm, and the alarm pause icon turn into  ,and 120s counting down displayed in upper right corner of the screen disappear simultaneously.

6.7 Setting the Alarm Switch

Set the **CO_2** module alarm switch:

1. Select the [**Alarm**] menu → [**CO_2**].
2. Set the **CO_2** module alarm to [**ON**] or [**OFF**].

Set the **AG** module alarm switch:

1. Select the [**Alarm**] menu → [**AG**],.
2. Set the **AG** module alarm to [**ON**] or [**OFF**].

Set the **BIS** module alarm switch:

1. Select the [**Alarm**] menu → [**BIS**].
2. Set the **BIS** module alarm to [**ON**] or [**OFF**].

⚠Caution

- **When the anesthesia machine is completely powered off or turned off, the stored module alarm switch may not be deleted.**

6.8 Measures when an Alarm Occurs

If anesthesia machine gives an alarm, take corresponding measures as per the following steps:

1. Check the status of patients.
2. Verify the alarming parameter or alarm types.
3. Find out the causes of the alarm.
4. Take measures to eliminate the alarm condition.
5. Check whether or not the alarm condition is corrected.

For specific measures for each alarm, refer to "***Chapter 7 Physiological Alarms and Technical Alarms***".

6.9 Testing Alarm System

The alarm system includes three types of alarms, i.e. physiological alarm, technical alarm and prompt message respectively. You can test the alarm system through the condition of visual alarm, audible, parameter flashing and message. For example:

1. Make preparations according to the "Measure Steps and Examination" in Chapter CO_2 , and enter the [**CO_2**] Alarm screen to set [**High Limit]** and [**Low Limit] o**f the parameters of **[FiCO_2]** , **[EtCO_2]** as 15 mmHg and 6 mmHg respectively.
2. On the screen, select [Alarm] →enter the menu of [**Sound]** and [**Indicate Sound Volume]** , and set the volume to "0~7".
3. When the measured values exceed high limit and low limit of alarm, select **[Alarm]** → **[CO_2]** → **[Alarm Level]** , and set the [**Alarm Level]** to [**High]** and [**Medium]** respectively**.** Observe the changes of sound, light and parameter flashing. See the contents of "Visual Alarms", "Audible Alarms", "Parameter Flashing" in this chapter for details. Meanwhile, it indicates that CO_2 is too high or too low in the physiological alarm area.
4. In normal condition, when the measured values exceed the high limit or low limit of alarm, the equipment will provide indications in the form of light, sound and message, and the average delay of alarm does not exceed 5 seconds.
5. Pull out the sampling tube of CO_2 from the anesthesia machine, and the following message prompts out in the technical alarm area: Without Adsorption Tube.

⚠Attention

- **When several alarms are triggered at the same time, the system will only give the visual and audible indications for the alarm of highest level.**

Chapter 7 Physiologic Alarms and Technical Alarms

Most of the essential physiological and technical alarm messages are listed in this chapter, however, some alarm messages are not necessarily listed.

⚠Caution

- **In this chapter, H indicates high level, M indicates medium level ,L indicates low level.**

Corresponding measures are listed for each alarm message. In case the problem still exists after action is taken, contact the service technician.

7.1 Physiologic Alarms

Alarm messages	Alarm level	Causes and Measures
High Paw	H	Airway peak pressure (Ppeak) is higher than the set value of high alarm limit. Reduce the set value of tidal volume, or increase the set value of upper Paw alarm limit.
Low Paw	H	Airway peak pressure Ppeak is lower than the set value of low Paw alarm limit (lasting for 20 seconds). Increase the set value of tidal volume, or reduce the set value of high Paw alarm limit.
High MV	M	MV value is higher than the high alarm limit. Reduce the tidal volume, slow the respiratory frequency, or increase the high alarm limit.
Low MV	M	MV is lower than the low alarm limit. Increase the tidal volume, increase respiratory frequency, or reduce the low alarm limit.
High VTexp	H	Expiratory Tidal Volume value is higher than high alarm limit. Reduce the preset tidal volume or increase the high alarm limit.
Low VTexp	H	Expiratory Tidal Volume value is lower than low alarm limit. Increase the preset tidal volume or reduce the low alarm limit.
High FiO_2	M	FiO_2 value is higher than high alarm limit. Reduce fresh-gas oxygen flow or increase the high alarm limit.
Low FiO_2	H	FiO_2 value is lower than the low alarm limit. Increase fresh-gas oxygen flow or reduce the low alarm limit.
Apnea	M	Two (2) triggering conditions are satisfied simultaneously: 1. Airway pressure is continuously lower than (PEEP +3) cmH_2O for more than 30 seconds.

Alarm messages	Alarm level	Causes and Measures
		2. Expiratory tidal volume is continuously lower than 10ml for more than 30 seconds. Increase the set values of tidal volume and respiratory frequency, or set it to Manual/spontaneous mode.
Apnea>2min	H	No respiration takes place within the latest 120 seconds. Check status of the patient. Use Manual/spontaneous mode to aid the patient to breathe. Check whether or not any pipeline drops out.
Pressure Limiting	L	Paw value is higher than Plimit. Increase the Plimit or reduce the tidal volume or the respiratory rate.
Continuous Pressure	H	In the respiratory circuit, Paw value is higher than the continuous airway pressure. If the continuous airway pressure is too high, the equipment reports an alarm lasting for 15 seconds.
Negative Pressure	H	Pressure is 10cmH_2O lower than the atmosphere. Check whether or not the patient is conducting autonomous respiration. Increase the fresh gas flow. Check whether or not there is high air flow through the scavenging system. If yes, check the negative pressure relief valve on the receiver.
Apnea Ventilation	M	Can not detect patient's respiration over the set Apnea time, and the ventilation for Apnea is undergoing. Check patient's respiration or increase the setting of Apnea time.
High $EtCO_2$	M	$EtCO_2$ concentration is higher than the alarm high limit. Increase the high limit of the alarm setting.
Low $EtCO_2$	M	$EtCO_2$ concentration is lower than the alarm low limit. Reduce the low limit of the alarm setting.
High $FiCO_2$	M	$FiCO_2$ concentration is higher than the alarm high limit. Increase the high limit of the alarm setting.
Low $FiCO_2$	M	$FiCO_2$ concentration is lower than the alarm low limit. Reduce the low limit of the alarm setting.
High FiO_2	M	(When using the module with paramagnetic oxygen sensor) FiO_2 value is higher than the alarm high limit. Decrease the O_2 flow in the fresh air or increase the high limit of the alarm setting.
Low FiO_2	M	(When using the module with paramagnetic oxygen sensor) FiO_2 value is lower than the alarm low limit. Increase the O_2 flow in the fresh air or reduce the low limit of the alarm setting.

Alarm messages	Alarm level	Causes and Measures
High EtN_2O	M	EtN_2O concentration is higher than the alarm high limit. Decrease N_2O flow or increase the high limit of the alarm setting.
Low EtN_2O	M	EtN_2O concentration is lower than the alarm low limit. Increase N_2O flow or reduce the low limit of the alarm setting.
High FiN_2O	M	FiN_2O concentration is higher than the alarm high limit. Decrease N_2O flow or increase the high limit of the alarm setting.
Low FiN_2O	M	FiN_2O concentration is lower than the alarm low limit. Increase N_2O flow or reduce the low limit of the alarm setting.
High EtHAL	M	EtHAL concentration is higher than the alarm high limit. Decrease HAL flow or increase the high limit of the alarm setting.
Low EtHAL	M	EtHAL concentration is lower than the alarm low limit. Increase HAL flow or reduce the low limit of the alarm setting.
High FiHAL	M	FiHAL concentration is higher than the alarm high limit. Decrease HAL flow or increase the high limit of the alarm setting.
Low FiHAL	M	FiHAL concentration is lower than the alarm low limit. Increase HAL flow or reduce the low limit of the alarm setting.
High EtENF	M	EtENF concentration is higher than the alarm high limit. Decrease ENF flow or increase the high limit of the alarm setting.
Low EtENF	M	EtENF concentration is lower than the alarm low limit. Increase ENF flow or reduce the low limit of the alarm setting.
High FiENF	M	FiENF concentration is higher than the alarm high limit. Decrease ENF flow or increase the high limit of the alarm setting.
Low FiENF	M	FiENF concentration is lower than the alarm low limit. Increase ENF flow or reduce the low limit of the alarm setting.
High EtISO	M	EtISO concentration is higher than the alarm high limit. Decrease ISO flow or increase the high limit of the alarm setting.
Low EtISO	M	EtISO concentration is lower than the alarm low limit. Increase ISO flow or reduce the low limit of the alarm setting.
High FiISO	M	FiISO concentration is higher than the alarm high limit. Decrease ISO flow or increase the high limit of the alarm setting.
Low FiISO	M	FiISO concentration is lower than the alarm low limit. Increase ISO flow or reduce the low limit of the alarm setting.
High EtSEV	M	EtSEV concentration is higher than the alarm high limit. Decrease SEV flow or increase the high limit of the alarm setting.

Alarm messages	Alarm level	Causes and Measures
Low EtSEV	M	EtSEV concentration is lower than the alarm low limit. Increase SEV flow or reduce the low limit of the alarm setting.
High FiSEV	M	FiSEV concentration is higher than the alarm high limit. Decrease SEV flow or increase the high limit of the alarm setting.
Low FiSEV	M	FiSEV concentration is lower than the alarm low limit. Increase SEV flow or reduce the low limit of the alarm setting.
High EtDES	M	EtDES concentration is higher than the alarm high limit. Decrease DES flow or increase the high limit of the alarm setting.
Low EtDES	M	EtDES concentration is lower than the alarm low limit. Increase DES flow or reduce the low limit of the alarm setting.
High FiDES	M	FiDES concentration is higher than the alarm high limit. Decrease DES flow or increase the high limit of the alarm setting.
Low FiDES	M	FiDES concentration is lower than the alarm low limit. Increase DES flow or reduce the low limit of the alarm setting.
High BIS	H	BIS value is higher than the alarm high limit. Check the anesthetics supply. Increase the anesthetics flow rate or alarm high limit.
Low BIS	H	BIS value is lower than the alarm low limit. Check the anesthetics supply. Reduce the anesthetics flow rate or alarm low limit.

7.2 Technical Alarms

7.2.1 Monitor wafer Alarms

Alarm messages	Alarm level	Causes and Measures
Calibrate Flow Sensor	L	No calibration data was found in memory or the calibration data did not match. Use Manual/spontaneous mode to assist patient to breathe. Calibrate the flow sensor.
Calibrate Pressure Sensor	L	No calibration data was found in memory or the calibration data did not match. Use Manual/spontaneous mode to assist patient to breathe. Calibrate the pressure sensor.
Calibrate O_2 Sensor	L	No calibration data was found in memory or the calibration data did not match. Calibrate or replace oxygen sensors.
Power Failure	H	Three way valve 12V,safety valve 5V or 12V,proportional valve

Alarm messages	Alarm level	Causes and Measures
		7.5V,internal AD reference voltage 3.3V and external AD reference voltage 2.5V,at least one way power supply failure. Use Manual/spontaneous mode to assist patient to breathe. Contact the manufacturer for service.
Self Check Error	L	MCU hardware error. Contact the manufacturer for service.
Watchdog Failure	H	The external watchdog is burnt out and out of order. Please contact the manufacturer for service.
Internal A/D Converter Failure	H	The internal ADC is out of order. Please contact the manufacturer for service.
External A/D Converter Failure	H	The external ADC is out of order. Please contact the manufacturer for service.
Zero Valve Failure	L	Connection or control of zero valve gets faulty. The device can still work, but the monitoring is unreliable. Use manual/spontaneous mode to aid the patient to breathe if necessary.
Expiration Valve Failure	M	Connection or control of expiratory valve is faulty. Use Manual/spontaneous mode to assist patient to breathe. Please contact the manufacturer for service.
Flow Valve Failure	M	There exists connection or control failure in the flow valve. Use Manual/spontaneous mode to assist patient to breathe. Please contact the manufacturer for service.
Safe Valve Failure	M	Connection of safe valve is faulty. Use Manual/spontaneous mode to assist patient to breathe. Please contact the manufacturer for service.
Safe Valve Control Failure	H	Connection or control of safe valve is faulty. Use Manual/spontaneous mode to assist patient to breathe.
No O_2 Pressure	H	Pressure of oxygen supply is inadequate. Make sure O_2 supply of adequate pressure is connected;If an air supply is connected, you may use Manual/spontaneous to aid the patient to breathe.
No Breathing System	H	Breathing system is not assembled, or the connecting wires of breathing system mounting are connected incorrectly. Contact the manufacturer for service.
O_2 Flush Failure	M	The button of “O_2 Flush”cannot be pressed down. Or the oxygen flush cannot be started after the button is pressed down. Contact the manufacturer for service.

Alarm messages	Alarm level	Causes and Measures
ACGO in Use	L	The ACGO is being used. Check the cover condition of ACGO.
Connect O_2 Sensor	L	Oxygen sensor is not or poorly connected to the cable. Ensure that oxygen sensor and cables are connected.
Replace Oxygen Sensor	M	Oxygen sensor exhaustion or gets faulty. Replace the oxygen sensor.
Flow Sensor Failure	L	Flow sensor breathe in or breathe out beyond the range. The device can still work, but its accuracy is low. Calibrate or replace the flow sensor.
Check Flow Sensor	H	The inhalation or exhalation sensor has reverse flow, check the flow sensor.
Pressure Sensor Failure	M	Failure of pressure sensor or abnormal at zero. Use Manual/spontaneous mode to assist patient to breathe.
Patient Circuit Leak	M	Leakage is detected in the breathing system. Check the connection of breathing system and flow sensors.
Pinsp Not Achieved	L	The inspiratory pressure does not reach the set value. Check whether there is gas leakage, whether the gas supply pressure is normal, and whether the expiratory valve and proportional valve work properly.
VT Not Achieved	L	The expiratory tidal volume does not reach the set tidal volume. Check patient's condition, and inspect airway connection and flow sensor.
Breathing System Heater Failure	L	The circuits of the heating module is faulty. Contact the manufacturer for service.
Power Supply Fan Stat	M	Power fan is disconnected, or the fan is faulty. Check the fan connection and condition. Contact the manufacturer for service.
CPU Failure	H	Abnormal software reset or power failure. Please contact the manufacturer for service.
CPU Temperature Abnormal	M	The CPU temperature is too high. Please contact the manufacturer for service.
Abnormal VPM-CPU Temperature	H	VPM-CPU internal temperature anomaly. Please contact the manufacturer for service.
UCOS Error	L	The software is out of order. Please contact the manufacturer for service.
Monitor Communication Fail	H	Communication failure between monitor board and backup CPU.The serial line is not connected or the chip of the serial port is broken.

Alarm messages	Alarm level	Causes and Measures
With Bk CPU		
Bk CPU Communication Failure With Host	H	Communication failure between backup CPU and host. The serial line is not connected or the chip of the serial port is broken.
Host Communication Fail With Bk CPU	H	Communication failure between backup CPU and host. The serial line is not connected or the chip of the serial port is broken.
Host Communication Failure With Monitor	H	Communication failure between monitor board and host. The serial line is not connected or the chip of the serial port is broken.
VPM Communication Failure With EFM	H	Abnormal communication between VPM and EFM main control board. Please contact the manufacturer for service.
FS Communication Failure With VPM	H	Abnormal communication between FS and VPM. Please contact the manufacturer for service.
Key Board Failure	H	Communication failure between key board and host. The serial line is not connected or the chip of the serial port is broken.

7.2.2 Full electronic flowmeter Alarms

Alarm messages	Alarm level	Causes and measures
Calibrate the Gas Pressure	L	No calibration data was found in memory or the calibration data did not match. Please contact the manufacturer for service.
Calibrate EFM O_2 Flow valve	L	No calibration data was found in memory or the calibration data did not match. Please contact the manufacturer for service.
Drive Gas selector valve Failure	H	Drive gas select valve connection line fault or select valve fault. Please contact the manufacturer for service.
EFM O_2 select valve err	M	Oxygen select valve connection line fault or select valve fault. Please contact the manufacturer for service.
EFM N_2O select valve err	M	Nitrous Oxide select valve connection line fault or select valve fault. Please contact the manufacturer for service.
EFM air gas select valve err	M	Air select valve connection line fault or select valve fault. Please contact the manufacturer for service.
EFM O_2 Flow valve err	M	Oxygen flow valve connection line fault or select valve fault. Please contact the manufacturer for service.
EFM balance gas flow valve err	M	Balance gas flow valve connection line fault or select valve fault. Please contact the manufacturer for service.
EFM O_2 Flow Sensor Failure	H	Oxygen flow sensor connection line fault or select valve fault. Please contact the manufacturer for service.
EFM balance gas fl ow sensor err	H	Balance gas flow sensor connection line fault or select valve fault. Please contact the manufacturer for service.
Backup flowmeter select valve err	H	Backup flowmeter gata valve connection line fault or select valve fault. Please contact the manufacturer for service.
Backup flowmeter drive valve err	M	Backup flowmeter drive valve connection line fault or select valve fault. Please contact the manufacturer for service.
Back-up Flowmeter Abnormal Status	M	Microswitch of the back up flowmeter connection line fault or microswitch fault,or the back up flowmeter did not jam and did not pop up completely. Please contact the manufacturer for service.

O_2 and N_2O ratio abnormal	H	The oxygen flow valve or balance gas valve flow valve is abnormal. Please contact the manufacturer for service.
No Fresh Gas	L	Fresh gas is less than 100mL/min.Please check if the air pressure is sufficient.If the air pressure is sufficient,the flow valve may fault,please contact the manufacturer for maintenance.

7.2.3 Battery Alarms

Alarm messages	Alarm level	Causes and measures
Low Battery Voltage	H	The battery voltage is below 9.5V. Please connect alternating current immediately. In case of power cut-off, use Manual/spontaneous to aid the patient to breathe. If the battery cannot be fully charged within 24 hours, contact the manufacturer for service.
System Down For Battery Depletion	H	The battery voltage is below 9.1V. Please connect AC supply immediately. In case of power cut-off, use Manual/spontaneous to aid the patient to breathe. If the battery cannot be fully charged within 24 hours, contact the manufacturer for service.
No Battery	M	Battery is not assembled, or the battery cable is disconnected with power module. Please contact the manufacturer for service.
On Battery Power	L	Battery is in use. Please check the AC power connection status.

7.2.4 AG Module Alarms

Alarm messages	Alarm level	Causes and measures
AG Init Error	H	Error AG occurs in the AG module initializing process. Restart the Monitor to try again. If the error still exists, contact us for service.
AG Comm Stop	H	The AG module fails to communicate with the main system. Restart the Monitor to try again. If the error still exists, contact us for service.
AG Comm Error	H	The AG module fails to communicate normally with the main system. Restart the Monitor to try again. If the error still exists, contact us for service.
AG Alm Lmt Err	L	The alarm limit of parameter AG is accidentally changed. Contact us for service.
AG overrange	L	The measured value of parameter AG goes beyond the specified measurement range. Contact us for service.
AG Start Zeroing	L	AG analyzer is in calibration.Waiting for zero correction to end.
Need Air Calibrate	L	Oxygen sensor need be calibrated in air.Calibrate oxygen sensor in 21% air.
Need O2 Span Calibrate	L	Oxygen sensor need to be calibrated in pure oxygen. Calibrate oxygen sensor in pure oxygen. If user can’t meet the requirement, please return it back to factory.
O2 Sensor Error	L	Module fails. Reseat oxygen sensor orreboot.
O2 Port Failure	L	
Hardware Error,Replace Sensor	H	
AG Sampling Line Clogged	L	Sampling tube blocking. Check and replace the sampling tube, if the faultpersists, please contact themanufacturer for maintenance.

AG No Sampling Line	L	Sampling tube is not connected or in badcontact. Check and replace the sampling tube, if the faultpersists, please contact themanufacturer for maintenance.
Replace AG Adapter	M	Adapter abnormal. check and replace the adapter,if fault persists, please contactthemanufacturer for maintenance.
AG No Adapter	L	Adapter is not connectedor in bad contact. Check and replace the adapter,if fault persists, please contactthemanufacturer for maintenance.
CO2 Outside Specified Accuracy Range	L	The measured valueexceeds the claimed scope of accuracy. Please follow the precisionrange of measurement claimed by manufacturers.
O2 Outside Specified Accuracy Range	L	
N2O Outside Specified Accuracy Range	L	
AX Out Of Accuracy Range	L	
Temp Out Of Range	L	Module fails. Return to factory for maintenance.
Atmospheric Pressure Beyond	M	
AG Speed Out Of Bounds	L	
AG Factory Calibration Lost	L	
Zero reference	L	AG Analyzer requires zero. enter AG settings for zero Here zero is equal

calibration required		to calibration.
AG Conc.Unreliable	L	AG Analyzer does not recognize the existence of other gas. check the gas.
Replace O2 Sensor	L	Beyond usage time. Replace oxygen sensor.
AG Software Error	L	Software error occurs. Reboot
Found Two AG Gases	M	There is only one mainnesthetic gas waveformand value shown in thekinds of anesthesia gasfor tips. Check the patient'sphysiological signs andanesthesia.
AG Is Sleeping	L	AG Analyzer operatingmode is on standby. Measurement mode of AG Analyzer is selected.

7.2.5 CO_2 Module Alarms

Alarm messages	Alarm level	Causes and measures
CO2 Init Err	H	Error CO2 occurs in the CO2 module initializing process. Restart the Monitor to try again. If the error still exists, contact us for service.
CO2Comm Stop	H	The CO2 module fails to communicate with the main system. Restart the Monitor to try again. If the error still exists, contact us for service.
CO2 Comm Err	H	The CO2 module fails to communicate normally with the main system. Restart the Monitor to try again. If the error still exists, contact us for service.
CO2 Alm Lmt Err	L	The alarm limit of parameter CO2 is accidentally changed. Contact us for service.
CO2 overrange	L	The measured value of parameter CO2 goes beyond the specified measurement range. Contact us for service.
CO2 is sleeping	L	[Standby] is selected as the CO2 work mode. Select [Measure] as the CO2 work mode.
CO2 Line Blocked	L	The sampling tube is clogged. Check and replace the sampling tube. If the fault still exists, contact us for service.
CO2 No Sampling Line (Masimo)	L	The sampling tube is in poor contact or not connected. Check and replace the sampling tube. If the fault still exists, contact us for service.
CO2 Outside Specified	L	The measured value goes beyond the specified accuracy range. Follow the specified accuracy range.

Accuracy Range		
CO2 Temp Out Of Range	L	The module has a fault. Return to us for repair.
CO2 Span Calibration Error (Masimo)	L	
CO2 Factory Calibration Lost (Masimo)	L	
CO2 Speed Out Of Bounds (Masimo)	L	
Atmospheric Pressure Beyond (Masimo)	L	
CO2 Span Calibrating.....(Masimo)	L	The CO2 span is being calibrated. Return to us.
Replace CO2 Adapter (Masimo)	L	The adapter has a fault. Check and replace the adapter. If the fault still exists, contact us for service.
CO2 No Adapter (Masimo)	L	The adapter is in poor contact or not connected. Check and replace the adapter. If the fault still exists, contact us for service.
CO2 Need Zero (Masimo)	L	The CO2 module needs zeroing. Enter [CO2 Setup] to select [Zero].
CO2 Software Error (Masimo)	L	The software has a fault. Restart the Monitor.
CO2 Hardware Error (Masimo)	L	The hardware has a fault. Check and replace the sensor. If the fault still exists, contact us for service.

7.2.6 BIS Module Alarms

Alarm messages	Alarm level	Causes and measures
BIS Init Err	H	Error BIS occurs in the BIS module initializing process. Restart the

		Monitor to try again. If the error still exists, contact us for service.
BIS COMM STOP	H	The BIS module fails to communicate with the main system. Restart the Monitor to try again. If the error still exists, contact us for service.
BIS Comm Error	H	The BIS module fails to communicate normally with the main system. Restart the Monitor to try again. If the error still exists, contact us for service.
BIS Alm Lmt Err	L	The alarm limit of parameter BIS is accidentally changed. Contact us for service.
BIS overrange	L	The measured value of parameter BIS goes beyond the specified measurement range. Contact us for service.
BIS No Sensor	L	BIS sensor is connected unreliably. Check if the BIS sensor is connected properly. If the fault still exists, contact us for service.
impedance too high	L	Electrode of the sensor falls off or the skin is too dry. Check patient cable connection and check electrode-to-skin contact. If necessary, clean and dry the skin.
IMPEDENCE CHECKING	L	Prompt information for ten-minute ground electrode impedance check. No action necessary
BIS COMM STOP	H	Data communication between monitor and BIS module stops. Reinitialize BIS module. If there is still malfunction, please contact the manufacturer to maintain it.
BIS SENSOR EXPIRED	L	Sensor is out of its service life. The initialization of sensor can be still conducted and the data waveform data and parameter can be also captured. This alarm merely reminds the users that this sensor is out of service life, but it depends on users whether to replace it.
INVALID BIS SENSOR	L	Invalid sensor. Change Sensor
REPLACE THE SENSOR!	L	During the process of initialization and monitoring, the sensor over current and incorrect ground impedance have been detected by the system. Change Sensor.
POOR SIGNAL QUALITY （SQI < 50%）	L	Weak signal. SQI value is too low. Check the status of patient and the connection of sensor.
BAD SIGNAL QUALITY （SQI < 15%）	L	Poor Signal. SQI value is too low. Check the status of patient and the connection of sensor.

7.3 Prompt Information

7.3.1 The prompt message displayed in the alarm bar

Alarm messages	Causes and countermeasures
BIS module alarm closed	This information will appear when BIS module alarm is switched off.
AG Module Alarm closed	This information will appear when AG module alarm is switched off.
CO_2 Module Alarm closed	This information will appear when CO_2 module alarm is switched off.
CO_2 Alarm closed	This alarm will appear when the AG module is used and the CO_2 module is closed.
Anesthesia module standby	This information will appear when anesthesia module is in standby status,
CO_2 Module Standby	This information will appear when CO_2 module is in standby status,
VTexp Alarm, MV Alarm and Apnea Alarm closed!!	This information will appear when the manual/spontaneous switch is pressed to the manual and the alarm option is set to off.

7.3.2 The prompt message displayed in the information bar

Alarm messages	Causes and countermeasures
Set the Bag /Vent switch to the "..." position.	This prompt message will appear when you switch to manual/spontaneous mode without clicking OK.
You can press the "Confirm" button switch to "…"	This prompt message will appear when you switch to Mechanical ventilation mode without clicking OK.
Machine Ventilation Stop	This information will appear when the ACGO switch is turned on and an external gas outlet is used.
O_2 Flush	This prompt message will appear when you press O_2 Flush button.
Ventilate Manually	This prompt message will appear when the manual/spontaneous switch is pressed to the manual.

Chapter 8 CO_2 Monitoring

8.1 Overview

CO_2 monitoring function of the anesthesia machine adopts infrared absorption technology to determine the CO_2 concentration inside the respiratory circuits of the patient.. Its principle is based on such a fact that CO_2 molecules have an attraction for energy contained by infrared light of specific wavelength, and the quantity of absorbed energy is direct related to CO_2 concentration. When infrared light emitted by an infrared light supply penetrates a gas sample containing CO_2, part of the energy may be absorbed by CO_2 entrained in the gas. A photoelectric detector is set up on the opposite side of the infrared light supply to determine the residuary energy of infrared light and convert it into electrical signals. The electrical signals are compared with the energy infrared light supply and adjusted, and the concentration of CO_2 contained in the gas sample may be precisely reflected.

- **CO_2 Measuring Methods:**

  Sidestream

  Sample the respiratory gases inside the patient-respiration airway at constant sampling flow, and analyze the samples by CO_2 sensor built in the module.

  Mainstream

  For this measurement, CO_2 sensors are installed on the airway adapter that plugs directly into the patient's breathing system.

- **CO_2 Measurement provides:**

1. CO_2 waveform.
2. $EtCO_2$: value of CO_2 measured at the end of expiratory phase.
3. $FiCO_2$: minimum CO_2 value measured during inspiratory period.

⚠Warning

- **In accordance with international standards, CO_2 concentration shall be monitored while the equipment is connected with a patient. If your equipment does not have the function, please use a monitor conforming to corresponding international standards for CO_2 concentration monitoring.**

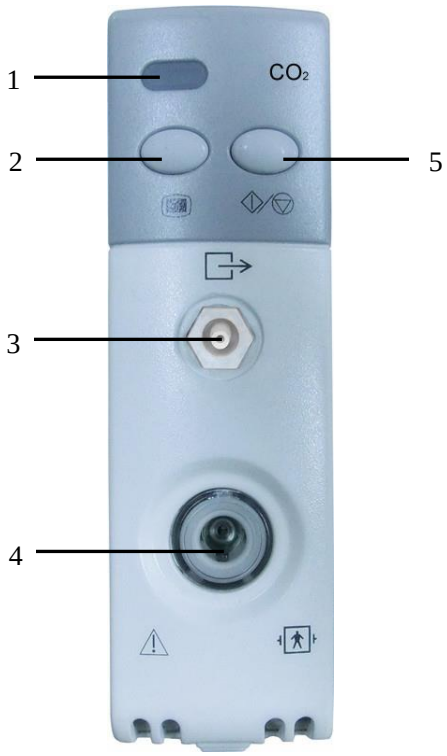
⚠Caution

- **To make sure the safety of patient, perform CO_2 monitoring while use this equipment.. If**

your equipment does not have the function of CO_2 monitoring, please use an equipment with CO_2 monitoring function which conforms to corresponding international standards.

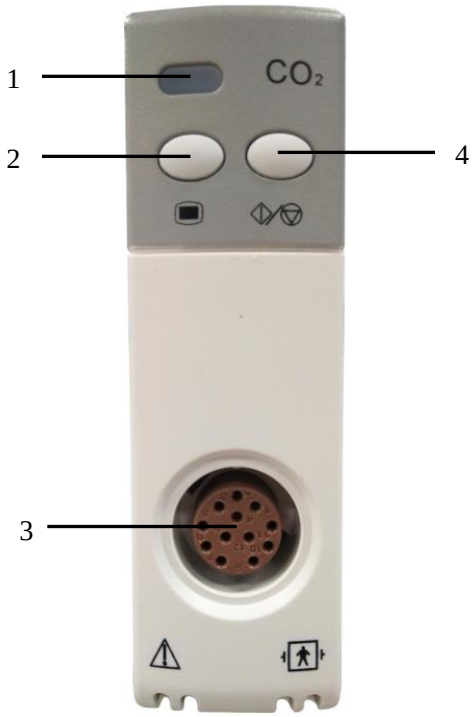
8.2 Identification of CO_2 Modules

8.2.1 MASIMO CO_2 Module(Sidestream)



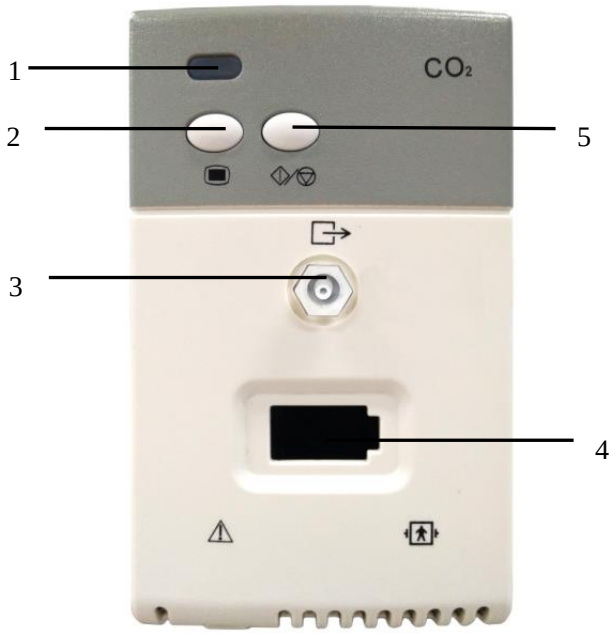
1	Module working indicator	4	Sampling line port
2	CO_2 setting menu button	5	Measure/Standby button
3	Gas outlet		

8.2.2 MASIMO CO_2 Module (Mainstream)



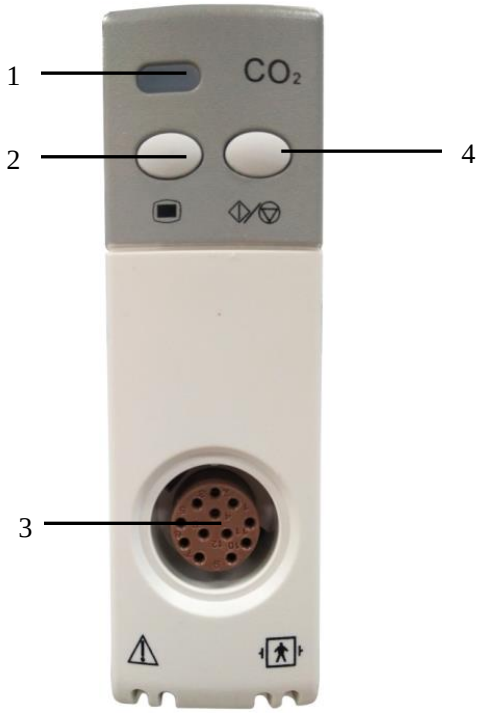
1	Module work indicator	3	12-pin data interface
2	CO_2 Settings menu button	4	Measurement / standby button

8.2.3 Respironics CO_2 Module (Sidestream)



1	Module working indicator	4	Sampling line port
2	CO_2 Settings menu button	5	Measurement / standby button
3	Gas outlet		

8.2.4 Respironics CO_2 Module (Mainstream)



1	Module working indicator	3	12-pin data interface
2	CO_2 Settings menu button	4	Measurement / standby button

8.3 Nomoline Family sampling lines

samples gas from the respiratory circuit through the Nomoline Family sampling line at a rate of 50 sml/min, making measurements of CO_2 possible for adult, pediatric patients.

The Nomoline Family sampling lines incorporate a unique water separation (**NO MO**isture) section, which removes condensed water. The NOMO section is also fitted with a bacteria filter that protects the gas analyzer from water intrusion and cross contamination.

As long as no sampling line is connected, the CO_2 module remains in a low-power sleep mode. Once the sampling line is connected, the CO_2 module switches to measuring mode and starts delivering gas

data.

The Nomoline Family sampling lines are available in a wide variety of versions for both intubated and spontaneously breathing patients and in both disposable and re-sposable configurations –intubated patients can for instance be monitored using the disposable Nomoline Airway adapter Set or a com-bination of the multiple patient use Nomoline Adapter and a disposable Nomoline Extension / T-adapter. Spontaneously breathing patients could similarly be monitored using a disposable Nomoline Nasal CO_2 Cannula or a combination of the multiple patient use Nomoline Adapter and a disposable Nomoline Nasal CO_2 Cannula with Luer Connector.

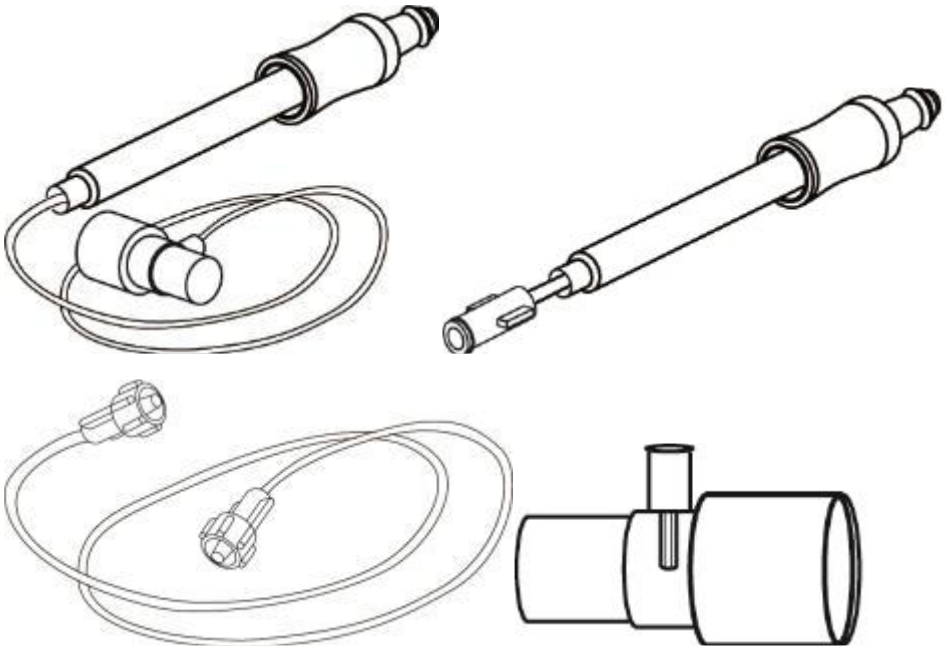


Figure 1.The disposable Nomoline Airway Adapter Set is an alternative to using a combination of the multiple patient use Nomoline Adapter and a disposable Nomoline Extension / T-adapter.

The Nomoline Adapter may be used with other third party sampling lines and cannulas. Please however note that the Nomoline Family of sampling lines are designed for optimal performance and measure-ment fidelity when used with the CO_2 module. For instance, when connecting to a respiratory circuit, the Masimo T-adapter provides a central gas sampling point thereby minimizing the risk of sampling line occlusion (see below)

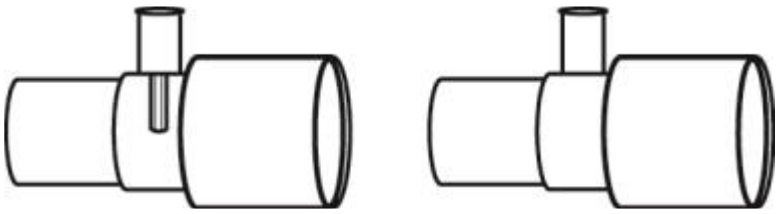


Figure 2. For optimal water handling, always use T-adapters with the sampling point in the center of the adapter, as shown to the left above.

Note

- **Using sample lines or cannulas with larger inner diameter than 1 mm will increase**

module's total system response time.

8.4 Measuring Procedure of MASIMO Sidestream, Mainstream Modules

⚠Caution

- **The section is only applicable to Sidestream and Mainstream CO_2 module of anesthesia machines.**

⚠Warning

- **MASIMO Sidestream CO_2 module cannot be used in flammable anesthetic gases.**

8.4.1 Measuring Procedures and Testing of Sidestream Module

- **Measuring Procedures**

  Set the Sidestream CO_2 module to perform gas analysis:

  a) Install the module to the corresponding position of the anesthesia machine plug slot.

  b) Connect one end of Nomoline sampling line to the input port of CO_2 module, and the other end of the sampling line to the patient.

  c) Turn the system switch to the right side to start the anesthesia machine. The indicator at the top left corner of the CO_2 module is in green.

  d) In **[Config]** menu, select [**Gas Module]**→set the options like **[Unit]**,[**O_2 Compensation**], [**Balance gas**], **[Altitude].**

  e) Click [**Zero Sensor**]. While zeroing, the screen shows: In zero calibration, please wait for 30s, and start to measure CO_2 after the prompt is finished.

  f) When CO_2 monitoring function is turned on, its working mode is "measure" by default. However, to ensure the set mode, access **[CO_2 module]** and verify that its **[work mode]** is set to **[Measure]** mode.

  g) Connect the gas sample outlet to the scavenging system, or allow the gas to flow back to the patient circuit.

h) Check the equipment as per "*Chapter 4* **Tests Before Use**".

i) Testing result is normal, and start CO_2 monitoring.

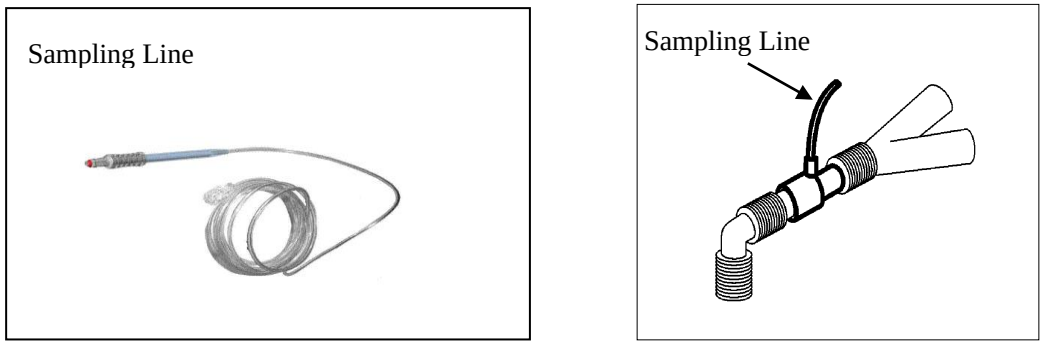


Fig. 8-1 Connection Diagram

- **Checks before Use**

  Before connect the Nomoline sampling line to patient respirotary circuit, perform the following steps:

  a) Connect the sampling line to the gas inlet port of CO_2 module;

  b) Verify that the green lamp of indicator lightis on;

  c) Verify that the indicator at the top left corner of the CO_2 module is in green..

  d) Exhale to the sampling line, and verify that valid CO_2 waveforms and values are displayed on the anesthesia machine.

  e) Block the sampling line mouth with fingertip for 10 seconds.

  f) Check whether or not a clogging alarm is triggered and flashing red light is on gas inlet port

  g) If necessary, perform leak check of patient circuit that is connected to the sampling line.

⚠Caution

- **The end of airway adapter connecting to the sampling line shall point upwards to prevent condensed water drops from entering the sampling line and resulting in clogging.**

8.4.2 Measuring Procedures and Tesitng of Mainstream Module

- **Measuring Procedures**

Set the mainstream CO_2 module to perform gas analysis:

a) Install the mainstream module to the corresponding position of the anesthesia machine slot .

b) Plug the end of the 12Pin connector of the patch cord into the 12Pin data interface of the mainstream CO_2 module. Connect the other end to the MASIMO mainstream CO_2 probe. Install the probe on the airway adapter. Finally, connect the airway adapter to the patient's breathing circuit.

c) Turn the system switch to the right side to start the anesthesia machine. The indicator at the top left corner of the CO_2 module is in green.

d) In the [**Config**] menu, select [**Gas Module**], and then set up options of **[Unit]**, [**O_2Compensation**], [**Balance gas**], **[Altitude]**, etc.

e) Click [**Zero Sensor**]. While zeroing, the screen shows: In zero calibration, please wait for 30s, and start to measure CO_2 after the prompt is finished.

f) When CO_2 monitoring function is turned on, its working mode is **[measure]** by default. However, to ensure the set mode, access **[CO_2 module]** and verify that its **[work mode]** is set to **[Measure]** mode.

g) Check the equipment as per ***Chapter 4 Pre-use Tests (Section 4.5)***".

h) Testing result is normal, and start CO_2 monitoring..

- **Checks before Use**

Before connect the adapter to patient respirotary circuit, perform the following steps:

a) Verify that the 12-pin adapter cable is connected to the 12-pin connector of mainstream CO_2 module.

b) Verify that the working indicator at the top left corner of the mainstream plug-in is constantly in green .

c) Verify that the probe indicator is in green steadily.

d) Expire to the adapter, and verify that valid CO_2 waveforms and values are displayed on the anesthesia machine.

⚠ Caution

- **The end of the airway adapter connecting to the sampling line shall point upwards to prevent the condensed water droplets from entering the sampling line and resulting in clogging.**

8.5 Measuring Procedures of Respironics Mainstream and Sidestream Modules

8.5.1 Measuring Procedures and Testing of Sidestream Module

- **Measuring Procedures**

Set the sidestream CO_2 module to perform gas analysis:

a) Install the sidestream module to the corresponding position on the anesthesia machine.

b) Connect one end of Respironics sampling line to the sampling port of Respironics CO_2 module, and the other end to the patient end.

c) Turn the system switch to the right side to start the anesthesia machine. The indicator at the top left corner of the CO_2 module is in green.

d) In the [**Config**] menu, select [**Gas Module**], and then set up options of **[Unit]**, [**O_2Compensation**], [**N_2O compensation**], **[Zero Sensor]**, etc.

e) Click [**Zero Sensor**]. While zeroing, the screen shows: In zero calibration, please wait for 30s, and start to measure CO_2 after the prompt is finished.

f) When CO_2 monitoring function is turned on, its working mode is **[measure]** by default. However, to ensure the set mode, access **[CO_2 module]** and verify that its **[work mode]** is set to **[Measure]** mode.

g) Connect the gas sample outlet to the exhaust system or allow the gas to flow back to the patient circuit.

h) Check the equipment as described in ***Chapter 4*** **Tests Before Use**.

i) Testing result is normal, start the CO_2 monitoring.

- **Checks before Use**

Before connect Respironics sampling line to the patient's respiratory circuit, perform the the following steps:

a) Connect the Respironics sampling line to the Respironics CO_2 module gas inlet.

b) Verify that the working indicator at the top left corner of the mainstream module is constantly in green (indicating that the plug-in module is powered on normally)

c) Expire to the adapter on the sampling line, and verify that valid CO_2 waveforms and values are displayed on the anesthesia machine.

d) Block the sampling line mouth for 10 second.

e) Check whether the clogging alarm is displayed on anesthesia machine.

f) If necessary, perform a leak test on the patient circuit connected to the sampling line.

8.5.2 Measuring Procedures and Testing of Mainstream Module

- **Measuring procedures**

Set the mainstream CO_2 module to perform gas analysis:

a) Install the mainstream module to the corresponding position on the anesthesia machine.

b) Plug the end of the 12Pin connector of the patch cord into the 12Pin data interface of the mainstream CO_2 module. Connect the other end to the mainstream CO_2 probe. Install the probe on the airway adapter. Finally, connect the airway adapter to the patient’s breathing circuit.Turn the system switch to the right side to start the anesthesia machine. The indicator at the top left corner of the CO_2 module is in green.

c) In the [**Config**] menu, select [**Gas Module**], and then set up options of **[Unit]**, [**O_2Compensation**], [**N_2O compensation**], **[Zero Sensor]**, etc.

d) Click [**Zero Sensor**]. While zeroing, the screen shows: In zero calibration, please wait for 30s, and start to measure CO_2 after the prompt is finished.

e) When CO_2 monitoring function is turned on, its working mode is **[measure]** by default. However, to ensure the set mode, access **[CO_2 module]** and verify that its **[work mode]** is set to **[Measure]** mode.

f) Check the equipment as described in ***Chapter 4 Tests Before Use.***

g) Testing result is normal, start the CO_2 monitoring.

- **Checks before Use**

Before connect the adapter to the patient's respiratory circuit, perform the the following steps:

a) Verify that the 12-pin adapter cable is connected to the 12-pin connector of the mainstream CO_2 module

b) Verify that the working indicator at the top left corner of the mainstream module is constantly in green .

c) Expire to the adapter and verify that valid CO_2 waveforms and values are displayed on the anesthesia machine.

⚠Note

- **The end of the gas adapter connecting to the gas sampling line shall point upwards to prevent the condensed water drops from entering the gas sampling line and resulting in clogging.**

8.6 Set the CO_2

On the screen, select [**Config]** menu → **[Gas Module]** or press the CO_2 setting button on the module to enter [**Gas Module**], and you can set the CO_2 parameters.

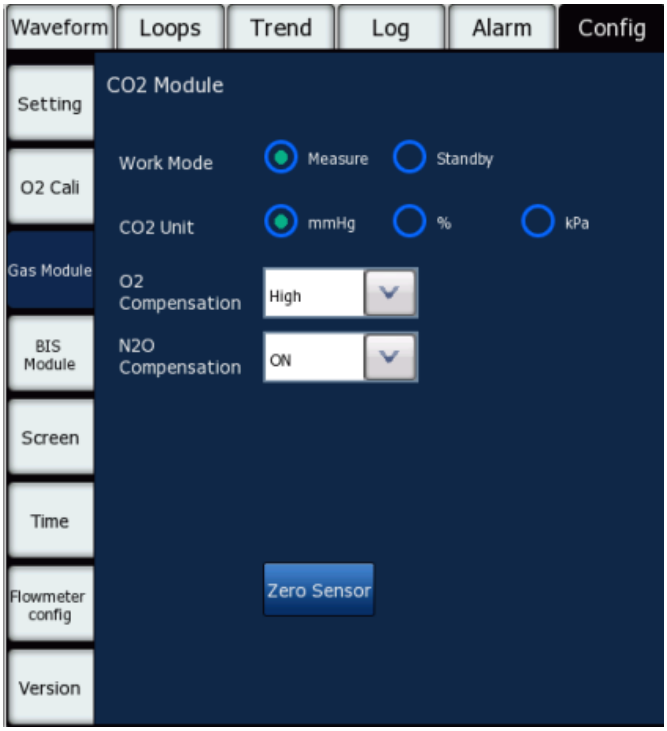


Fig. 8-2 Set the Configuration of Carbon Dioxide

8.6.1 Set the Work Mode

Work Mode: standby, measure

Standby:

When CO_2 module remains in its standby mode, the gas pump stops so as to extend the lifespan of module; in addition, a prompt "CO_2 Module Standby" is displayed in the message area.

Measure:

When CO_2 module is working, the indicator of CO_2 module is constantly in green, and measured data is sent to the anesthesia machine simultaneously.

In normal condition, when CO_2 module is connected to the anesthesia machine, the module automatically set the operating mode to "Measure". However, the user must verify that the CO_2 module is set to measuring mode.

When the anesthesia machine is used for the first time, the **[Work Mode]** in CO_2 monitoring is set to **[Measure]** by default . If CO_2 monitoring is in standby mode, you can start CO_2 monitoring by selecting **[Config]** menu → **[Gas Module]** → **[CO_2 Module]**→ **[Work Mode]** , and set it to: **[Measure]**, or by

pressing the Measure/Standby button on the module to switch between the Standby/Measure mode.

Note

- **During sensor calibration, press the Measure/Standby button cannot switch the operating mode. At this time, the Measure/Standby button on the screen does not function either.**
- **When anesthesia machine is restarted, all the setting of CO_2 module before the last shutdown will be reserved.**

8.6.2 Set the Units

On the screen, select **[Config]** menu → **[Gas Module]** → **[CO_2 Module]** → **[CO_2Unit]** , and set it to: **[mmHg]** , **[%]** or **[kPa]** .

8.6.3 Set the Gas Compensation

⚠Warning

- **Please set all sorts of compensation in accordance with actual conditions; otherwise measuring results may deviate from actual values, resulting in misdiagnosis.**

1. In User Interface→access **[Config]** menu.
2. Select **[Gas Module]**.
3. Set the gas compensation concentration of **[CO_2 module]** in accordance with actual conditions:

[O_2 Compensation] :

Three options i.e. **[High]**, **[Medium]** and **[Low]**. **[High]** indicates oxygen compensation is 85%;**[Medium]** indicates oxygen compensation is 50 %; **[Low]**indicates oxygen compensation is 21%. When an O_2 module is equipped, an O_2 sensor automatically performs O_2 compensation according to the O_2 concentration. Therefore, this option is in the default state. When no O_2 sensor provides automatic O_2 compensation, the compensation level can be manually set according to the actual O_2 concentration (as shown in the table below).

O_2 Range	**Parameter of SetO_2**
0-30vol%	21
30-70vol%	50

70-100vol%	85

[N_2O Compensation]

N_2O compensation can be set to ON or OFF. If the CO_2 module can measure N_2O, it can automatically perform N_2O compensation based on the N_2O concentration; therefore, the selection is by default. If the CO_2 module cannot measure N_2O, the compensation level can be set manually per actual N_2O concentration(as shown in the table below).

N_2O Range	Parameter of SetN_2O
0-30vol%	0
30-70vol%	50

8.6.3.1 Displaying CO_2 Waveform

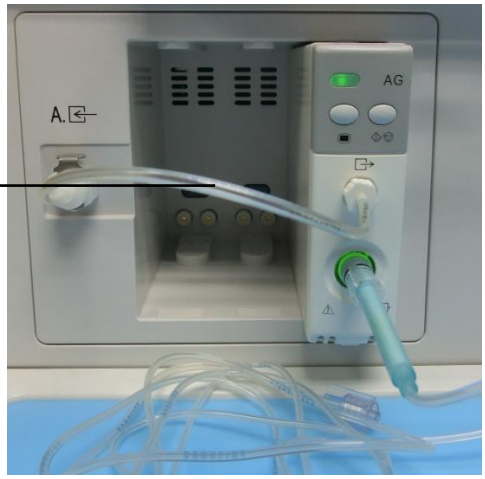
1. On the screen , access the **[Config]** menu.
2. Open the **[Screen]** menu.
3. Set the **[CO_2 Wave]** to **[ON]**.
4. Plug in CO_2 module,the main screen to view the CO_2 waveform. The CO_2 waveform is shown as the figure below.

Fig. 8-3 CO_2 waveform

8.7 Exhaust gas emission

Connect the exhaust tube to the gas outlet on the module, so as to discharge the sample gas into the scavenging system.

Exhaust tube



⚠Warning

- **Emitted gas shall be re-entered into the patient circuit or discharged into the discharge system.**
- **If the collected gas sample is to be supplied for breathing, always use a bacterial filter on the exhaust side.**
- **If the suction pressure is too high during discharge, the sample flow rate may be affected.**
- **If the positive or negative pressure in the patient circuit is too large, the sample flow rate may be affected.**
- **Check whether the gas sample flow rate is too high for the given patient category.**

8.8 Maintaining and Cleaning MASIMO Mainstream/Sidestream CO_2 Module

8.8.1 Zeroing

For sidestream CO_2 module, it is necessary to determine the zero reference level of carbon dioxide measurement. The purpose is to eliminate the impact of baseline drift occurring during measuring, and make sure the correctness of measurements. The zeroing calibration is herein referred to as “Zeroing”.

1. Automatic Zeroing

   Sidestream CO_2 module can automatically perform zeroing by switching the gas sampling from respiration circuit to ambient air. Sidestream CO_2 module spends less than 3 seconds to perform automatic zeroing once, and the frequency is 1time every day.

2. Manual Zeroing

Sidestream CO_2 module may automatic conduct zeroing when necessary. User may also perform manual zeroing when necessary: access **[Config]** menu, open the **[Gas Module]** menu, and select **[Zero Sensor]** in **[CO_2Module] .** It is unnecessary to disconnect the patient gas circuit prior to zeroing.

⚠Warning

- **Since successful zeroing requires ambient air (21% O_2 and 0% CO_2) in the sidestream CO_2 module, be sure to place the CO_2 module in a well ventilated location. Avoid breathing near the sidestream CO_2 module before and after performing the zeroing procedure.**

8.8.2 Failure Handling

When the sampling system of CO_2 module gets abnormal, check whether or not the sampling lines are entangled together. Once the indicator at gas inlet port flashes red, or Nomoline clogging message is displayed on the anesthesia machine, replace the sampling line.

8.8.3 Calibration

CO_2 module does not require routine calibration. However, it shall be calibrated every other year or when the deviation of measured values gets too high.

8.8.4 Analyzer cleaning

The “plug-in and measure” CO_2 module and Nomoline Adapter can be cleaned using a cloth moistened (not wet) with max 75% medicinal alcohol.

To prevent cleaning liquids and dust from entering the sidestream CO_2 module through its connector, keep the Nomoline Family sampling line connected while cleaning the sidestream CO_2 module.

⚠Warning

- **Nomoline adsorption tube is not a sterile device. In order to avoid damage, do not perform high-pressure sterilization on any part of the adsorption tube.**
- **Never sterilize or immerse the Sidestream CO_2 module in liquid.**

8.8.5 Lighting signals of the CO_2 module

A brief introduction of the LEGI indications:

Indication	Status
Steady green light	System OK
Blinking green light	Zeroing in progress
Steady red light	Sensor error
Blinking red light	Check sampling line

8.8.6 Adverse impact on performance

1. **The following factors are known to have adverse effects on indication performance:**

   - Quantitative impact of humidity and condensation
   - Quantitative impact of the atmospheric pressure;
   - Interfering gas and water vapor;
   - Other interference sources.

2. **Gas detector**

   Volume percentage is the unit for detecting gas concentration. Definition of gas concentration is as follows:

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

   The collective pressure of mixed gases is detected by the cup pressure sensor in the CO_2 module.

   It can be converted to other units using the actual atmospheric pressure sent from the CO_2 module.

   Carbon dioxide (mmHg)=(carbon dioxide concentration)x(atmospheric pressure from CO_2 module (kPa))x (750 / 100)

   For example: 5.0 vol% carbon dioxide @ 101.3 kPa 0.05 x 101.3 x 750 / 100 = 38 mmHg

3. **Impact of humidity**

   The partial pressure and volume percentage of carbon dioxide, nitrogen monoxide, oxygen and anesthetic gases depend on the water vapor content of the gas detected. Oxygen detection will be calibrated. After which, the displayed value in normal environmental temperature and humidity will

be 20.8 vol% instead of the actual partial pressure. 20.8 vol% oxygen corresponds to the actual oxygen concentration (vapor concentration is 0.7 vol%) of the air in the room. (e.g., when the atmospheric pressure is 1013 hPa, it corresponds to 25℃ and 23% RH).It always displays the real partial pressure under existing humidity level when measuring carbon dioxide, nitrous oxide and anesthetic gases (such as all the gases detected by the infrared pool).

The water vapor in the respiratory gas can get saturated (BTPS) in the patient's pulmonary alveolus at body temperature.

When the respiratory gas is collected and put into the sampling line, its temperature becomes close to environmental temperature before entering the sidestream CO_2 module. No water can get into CO_2 module when all condensed water is removed by Nomoline. The relative humidity of the gas collected is about 95%.

Carbon dioxide value under BTPS can be calculated with the following formula:

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

In which:

$EtCO_2$ = $EtCO_2$ value [vol %] from CO_2 module

Pamb = atmospheric pressure [kPa] from CO_2 module

3.8 = Typical partial pressure [kPa] of the water vapor condensed between patient's respiration circuit and CO_2 module

$EtCO_2(BTPS)$ = $EtCO_2$ concentration [vol%] under BTPS
It is presumed that the oxygen detection has been calibrated with the in-room air when the humidity level is 0.7 vol% H_2O.

8.8.7 Warnings

⚠Warning

- **The sidestream CO_2 module is intended for use by authorized healthcare professionals only.**
- **Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.**
- **Do not lift the CO_2 module by the sampling line as it could disconnect from the CO_2 module, causing the CO_2 module to fall on the patient.**
- **Dispose Nomoline Family sampling lines in accordance with local regulations for biohazardous waste.**
- **Use only airway T-adapters with the sampling point in the center of the adapter.**

- **Do not use T-adapter with pediatrics, as this adds 7 ml dead space to the patient circuit.**
- **Do not use the CO_2 module with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.**
- **Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2), ensure that the CO_2 module is placed in a well ventilated place. Avoid breathing near the sidestream CO_2 module before or during the zeroing procedure.**
- **Never sterilize or immerse the sidestream CO_2 module in liquid.**
- **The sidestream CO_2 moduleis intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.**
- **Measurements can be affected by mobile and portable RF communications equipment. Make sure that the sidestream CO_2 module is used in the electromagnetic environment specified in this manual.**
- **Replace the sampling line if the sampling line input connector starts flashing red, or the medical backboard device displays a "Check sampling line" message.**
- **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.**
- **The sidestream CO_2 module are not designed for MRI environments.**
- **During MRI scanning, CO_2 module must be placed outside the MRI suite.**
- **Use of high frequency electrosurgical equipment in the vicinity of the CO_2 module/medical backboard device may produce interference and cause incorrect measurements.**
- **Do not apply negative pressure to remove condensed water from the Nomoline Family sampling line.**
- **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 to a scavenging system.**
- **Due to the risk of patient cross-infection, always use a bacteria filter on the exhaust port side if sampled gas is intended to be re-breathed.**
- **Do not place the CO_2 module gas analyzer in any position that might cause it to fall on the patient.**
- **Do not re-use disposable single-patient use Nomoline Family sampling lines due to the risk of cross contamination.**
- **Do not sterilize or immerse Nomoline Family sampling lines in liquid.**
- **Do not operate the sidestream CO_2 module if the enclosure is damaged.**
- **Do not use the Nomoline Airway Adapter Set pediatric with pediatric patients.**

8.8.8 Sampling line clogged

If the anesthetic gas passage is clogged, an **[Sampling line clogged]** message will be displayed on the screen. In this case, replace the sampling line.

⚠Warning

- **The CO_2 module should be securely mounted in order to avoid the risk of damage to the CO_2 module.**
- **Do not operate the sidestream CO_2 module outside the specified operating environment.**
- **Federal law restricts this device to sale by or on the order of a physician.**
- **For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.**
- **Do not use sidestream CO_2 modules with metered-dose sprays or atomization treatments. Otherwise, the bacteria filters may be clogged.**

8.8.9 Consumables

The Nomoline Adapter is a multiple-patient use product.

The Nomoline Adapter should be replaced according to good clinical practice or when an occlusion message appears.Occlusion occurs when the sample flow is too low. This is indicated by a flashing red together with a message on the medical backboard device.

8.8.10 Maintenance

The user shall check the gas readings regularly, and contact the manufacturer engineers for maintenance if any anomaly is detected.

8.9 Maintaining and Cleaning Respironics Mainstream/Sidestream CO_2 Module

8.9.1 General Cleaning

Dip a cloth in 75% medicinal alcohol, water solution (bleach) containing 10% sodium hypochlorite, disinfecting spray cleaner (like Steris Coverage SprayHB), ammonia water or mild soapy water, wash it with water, wring it and then use it to clean the sensor. Dry it and make sure its sight glass is clean

before using the cleaned sensor.

8.9.2 Clean the Reusable Airway Adapter of Mainstream Sensor

Wash the airway adapter with mild soapy water, dip it in the disinfectant, like 75% medicinal alcohol, water solution (bleach) containing 10% sodium hypochlorite, 2.4% glutaraldehyde solvent (Cidex Plus, Steris System 1, etc.) or ammonia water, and then rinse it with sterile water and dry it.

8.9.3 Disinfection of Reusable Airway Adapter

Autoclave: applicable to the airway adapter for adults only.

ETO: disinfect the airway adapter for 1.5h.

Dip in Cidex Plus solvent for 10h.

Dip in Perasafe solvent for 10h.

U.S. Steris System 1 low-temperature sterilization cabinet.

Make sure it is not damaged in operations or in the cleaning/disinfection process and its sight glass is dry without any residue before using the disinfected airway adapter.

8.9.4 Disinfection Frequency of Reusable Airway Adapter

The above disinfection methods allow you to reuse the airway adapter for 100 times.

8.9.5 Zeroing

Please zero before using CO_2， The purpose is to eliminate the impact of baseline drift occurring during measuring, and make sure the correctness of measurements.

Usually, the CO_2 sensor will be auto zeroed when necessary. You can zero it manually when you consider it necessary: access [Config] menu, open the [Gas Module] menu, and select [Zero Sensor] in [CO_2Module] to zero the CO_2 sensor. Keep the patient circuit in the ambient air (21% O_2 and 0% CO_2) for 30s in the zeroing process,when the zero prompt for 30s of the interface is finished,it means that the zero is completed.

Chapter 9 Monitoring AG (Anesthetic Gas)

9.1 Overview

Anesthetic Gas (AG) can be used to measure the Anesthetic Gas and Respiratory Gas of the patient under anesthetization. The Anesthetic Gas module provides the numerical values at the end of expiration (Et) and the inspiration (Fi) of the following gases.

AG monitoring provides:

$EtCO_2$ waveform

Monitored Parameters: **FiO_2, EtO_2, $EtCO_2$, $FiCO_2$, EtN_2O, FiN_2O, EtAA, FiAA and MAC**

AA stands for one of the Anesthetic Gases among Des (Desflurane), Iso (Isoflurane), Enf (Enflurane), Sev (Sevoflurane) and Hal (Hhalothane).

⚠Warning

- **As required by international regulations, when this device is applied to a patient, AG concentration monitoring is required. If the device you are using is not equipped with this function, monitor the AG concentration using a monitor that complies with relevant international standards.**

⚠Attention

- **In accordance with international standard (ISO 80601-2-55), AG shall be monitored while the equipment is connected with a patient. If your equipment does not have the function, please use a monitor conforming to corresponding international standards for AG monitoring.**
- **Only use anesthetic gases specified by our company.**

9.2 Measurement Principle of Anesthetic Gas

The Anesthetic Gas can be analyzed by various measurement principles. The Dispersive

Infrared (DIR)Method or the Nondispersive Infrared(NDIR)Method are commonly used to insulate the absorption characteristics of the gas sample. The DIR Method is to use a single optical light filter and a prism or a diffraction grating to separate the wave length of each kind of anesthetic. And NDIR Method is to get the infrared light go through several narrow-band light filters and determine what kind of gas exists in the mixed gas.

The most commonly used gas analytical method is the one based on the medium of NDIR Method. The measurement principle is based on that many gases absorb the infrared energy of a certain wave length.

The multiple gas analyzer of by-pass flow, sampling and infrared usually sucks up the gas sample from the junction of the patient's breathing circuit and air passage device (such as mask, tracheal tube or laryngeal mask tube).The rate at which the modern gas analyzer gets a sample from the breathing circuit is between 50 ml/min and 250ml/min. The sample gas goes through a little cup or a sample room, passing by the infrared transmitter, light filter and infrared detector. The signal sent out by the infrared detector is in proportion with the infrared energy absorbed by the gas. In order to quantize and identify various gases, such as laughing gas, CO_2 and the five type of inhalational an esthetic gases, several light filters are needed. The detected signal is amplified, and is converted by the complex calculation of the microprocessor. Note that oxygen cannot be detected by the infrared spectrometry.

The gas analyzer analyzes the oxygen by the affiliated technologies, such as the paramagnetic or the oxygen sensor.

9.3 MAC (Minimum Alveolar Concentration) Calculation

MAC (MAC: minimum alveolar concentration) is a standard for comparing the effect of the inspiratory Anesthetic Gases. The MAC value stands for the density of Anesthetic Gas in the pulmonary alveolus (one barometric pressure) which is the density that will not provoke muscular movement response for 50% people tested on standardized pain stimulation.

If the mechanism of determining MAC value is carried out in the host equipment, the algorithm applied in the calculation process must be recorded in detail. The following formula can be used to calculate and show the MAC value by the density of the (exhaled) air at the end of the

exhalation.

$$MAC = \frac{\%Et(AA1)}{Xage(AA1)} + \frac{\%Et(AA2)}{Xage(AA2)} + ... + \frac{\%Et(N2O)}{Xage(N2O)}$$

$1MAC$： $X(AA) : HAL = 0.75\%, ENF = 1.7\%, ISO = 1.15\%, SEV = 2.05\%, DES = 6.0\%, \mathrm{N2O} = 100\%$

$1MAC - age - corrected - for, Xage(AA) : Xage(AA) = X(AA) * 10^{(-0.00269*(age-40))}$

For example, when using one or several anesthetics, the anesthesia module measures and get that a 60-year-old patient's air at the end of the inhalation contains 4% DES, 0.5% HAL and 50% N_2O. So the MAC value is equal to

$$MAC = \frac{4\%}{6\% * 10^{-0.00269*20}} + \frac{0.5\%}{0.75\% * 10^{-0.00269*20}} + \frac{50\%}{100\% * 10^{-0.00269*20}} = 2.08$$

⚠Attention

- **The above formula is only applicable to patients over 1 year old, 1 year old or below is calculated as 1 year old.**
- **The above formula does not take the altitude, other personal factors into consideration.**

9.4 Paramagnetic Oxygen Sensors

Paramagnetic Oxygen Analysis is to measure the suction produced by the high magnetic fields against the oxygen molecules in the mixed gas. The paramagnetic analyzer identify oxygen and other gases according to the magnetization susceptibility of the magnetic field.

As oxygen is paramagnetic, the oxygen will be attracted by the magnetic field, but most of other gases will not be attracted. In terms of proportion, if the magnetization susceptibility of the magnetic field of oxygen is designated as 100,that of most other gases is close to zero.

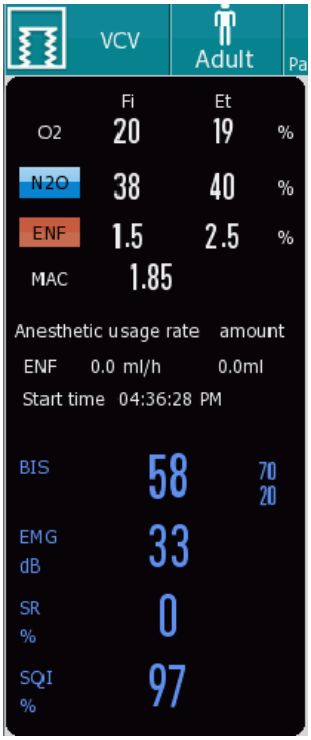
The main advantages of the Paramagnetic Oxygen Sensors include:

- short rise time
- stability and precision
- No need to change or supply chemicals

- Generally dispense with maintenance

9.5 Calculating the Rate and Dosage of Anesthetic

When the AG module is configured, Anesthesia Machine can calculate the rate and dosage of anesthetic agents.Anesthetic dosage is displayed on the standby screen.When the anesthesia machine is out of standby mode,the anesthetic dosage accumulates from 0 and the rate of anesthetic use is calculated. When the anesthesia machine go into the standby mode, anesthetic dosage stopped accumulating.



9.6 Identifying the AG Module

9.6.1 MASIMO AG Module(Sidestream)

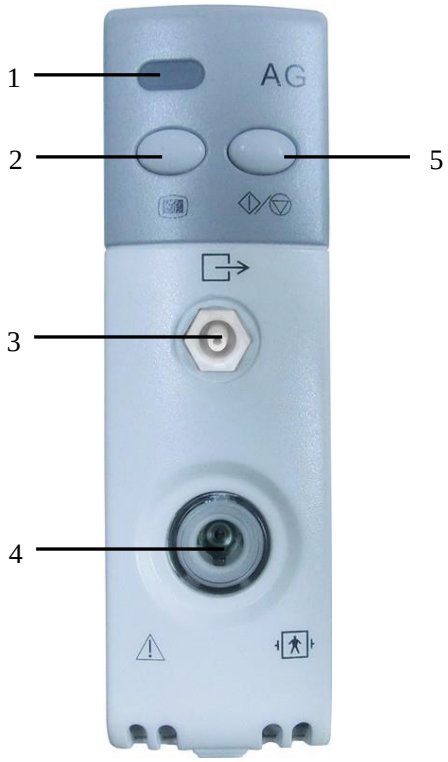


Fig. 9-1 Sidestream AG Module

1	Working indicator	4	Sampling line connector
2	AG setting menu button	5	Measure/Standby button
3	Gas outlet		

Note

- **The AG Module has been equipped with automatic atmospheric pressure compensation.**

9.6.2 MASIMO AG+O_2 Module (Sidestream)

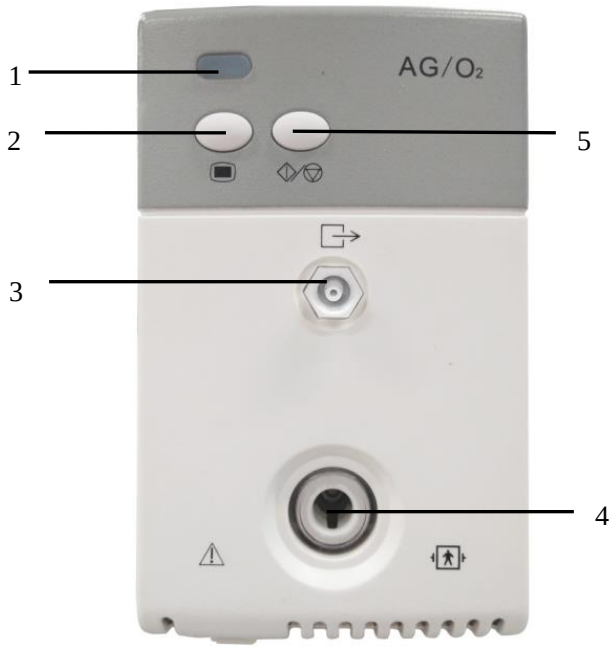


Fig. 9-2 MASIMO AG+O_2 monitoring(sidestream)

1	Module working indicator	4	AG/O_2 universal module connector
2	AG setup menu	5	Measurement / standby button
3	Gas outlet		

9.6.3 ARTEMA AG Module (Sidestream)

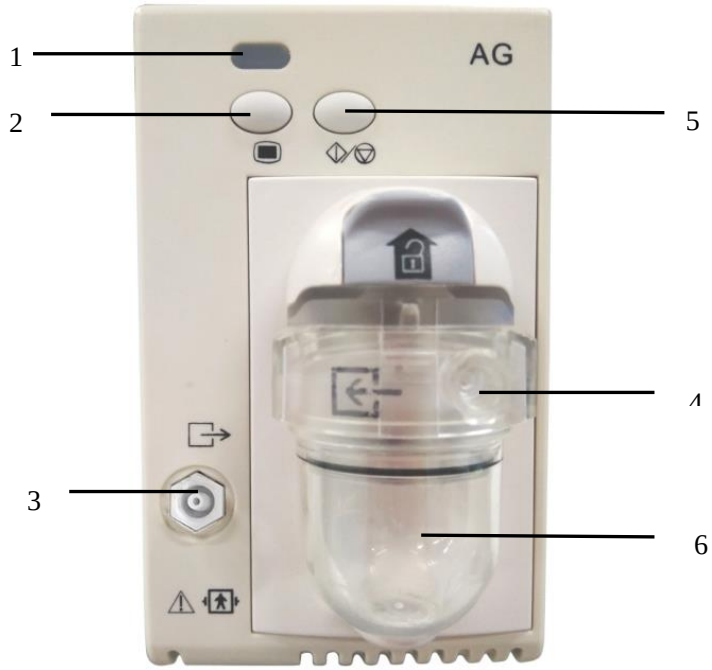


Fig. 9-3 ARTEMA AG Monitoring(Sidestream)

1	Module working indicator	4	Sampling line connector
2	AG setup menu	5	Measurement / standby button
3	Gas outlet	6	Watertrap

9.6.4 ARTEMA AG+O_2module (sidestream)

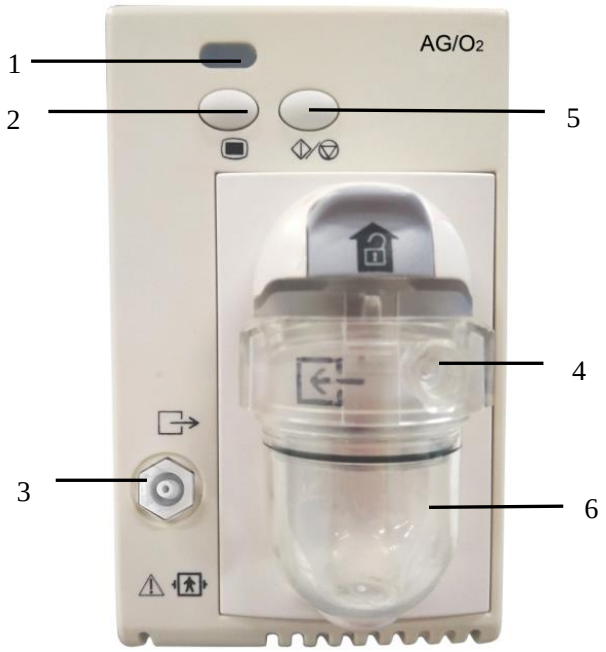


Fig. 9-4 ARTEMA AG+O_2 Monitoring(Sidestream)

1	Module working indicator	4	Sampling line connector
2	AG setup menu	5	Measurement / standby button
3	Gas outlet	6	Watertrap

⚠Attention

- **The watertrap is used to collect condensing water droplets from the sampling gas to prevent them from entering the module.When the water collected in the watertrap reaches a certain amount,the water must be poured out before it can be used again,so as to avoid blocking the airway.**
- **The watertrap contains filtering material to prevent bacteria/water vapor and patient secretions from entering the module.When used for a long time,dust or other foreign matter will reduce the air permeability of the filter material in the watertrap,and in serious cases,the air passage will be blocked,At this time,the watertrap must be replaced.It is recommended to replace the watertrap once a month or when a leak/damage or serious contamination is found.**

9.7 AG module Measurement preparation

9.7.1 MASIMO AG Module(Sidestream)

- Measuring Procedures

Set the anesthesia machine to start gas analysis:

a) Install the sidestream AG module to the corresponding position on the anesthesia machine.

b) Connect the Nomoline sampling line to the gas inlet of the AG module.

c) Turn the system switch to the right side to start the anesthesia machine. The indicator at the top left corner of the AG module is in green.

d) In the [Config] Menu→ select [Gas Module] → [AG Module]→set the items, such as [Unit] , [O_2 Compensation] , [Zero Sensor].

e) When the AG module is turned on, the working mode of the module is [Measure]. But in order to ensure that it is in the proper working state, please by all means enter the [AG Module] to make sure whether the [Work Mode] is in the [Measure] state.

f) To connect the outlet of the sample gas to the scavenging system, or to make the gas to flow back to the patient's circuit.

g) If it is green LED indication, Analyzer is available.

h) To carry out inspection before use according to the statement in the "*Chapter 4 Tests Before Use(Section 4.5)*".

i) If the inspection is normal, start to monitor the Anesthetic Gas.

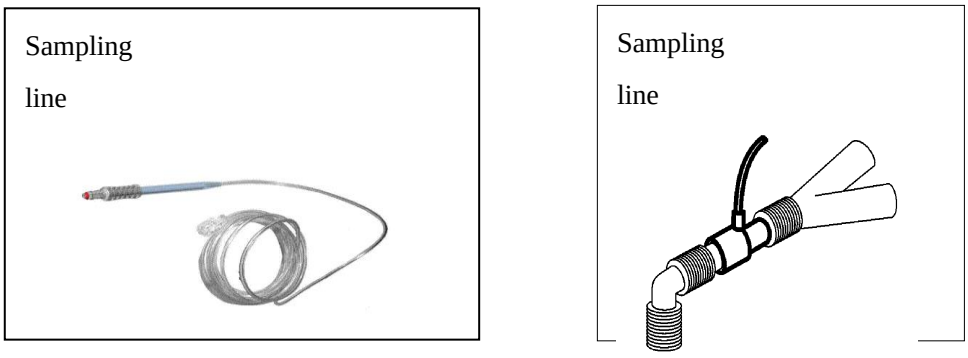


Fig. 9-5 The sketch map of preliminary work and connection

- Check before use

Before connecting the Nomoline sampling line to the breathing circuit, carry out the following steps:

a) Connect the sampling line to the interface of gas inlet of the Anesthesia Module.

b) Check whether the green light of AG Module is steadily on or not(The indication Module is normal.).

c) Check whether the connection port of the luminescent sample tube is steadily on or not(The indication system is normal.).

d) Breathe out air to the sampling pipe, and check whether the anesthesia machine shows the effective wave pattern and values of CO_2.

e) Use the finger tip to block up the sampling line, and hold on for 10s.

f) Examine whether there is obstruction warning and if the luminescent sample tube shows a red flashing light.

g) Under proper circumstances:Carry out enclosure check on the patient's circuit that is linked with the sampling line.

9.7.2 MASIMO AG+O_2 module(Sidestream)

- **Measuring Procedures**

Set the anesthesia machine to start gas analysis:

a) Install the sidestream AG module to the corresponding position on the anesthesia machine.

b) Connect the Nomoline sampling line to the gas inlet of the AG module.

c) Turn the system switch to the right side to start the anesthesia machine. The indicator at the top left corner of the AG module is in green.

d) If there is oxygen sensor, enter the maintenance mode, and choose **[Config]→[System Config]→[O_2 OPTION]→ [ON]** .

e) Click **[Zero Sensor]**. While zeroing, the screen shows: In zero calibration, please wait for 30s, and start to measure CO_2 after the prompt is finished.

f) In the **[Config] Menu→ select [Gas Module] → [AG Module]**→set the items, such as [**Unit**] , [**O_2 Compensation**] , [**Zero Sensor**].

g) When the AG module is turned on, the working mode of the module is "Measure". But in order to ensure that it is in the proper working state, please by all means enter the **[AG Module]** to make sure whether the **[Work Mode]** is in the **[Measure]** state**.**

h) To connect the outlet of the sample gas to the scavenging system, or to make the gas to flow back to the patient's circuit.

i) If it is green LED indication, Analyzer is available.

j) To carry out inspection before use according to the statement in the "***Chapter 4 Tests Before Use (Section 4.5)***".

k) If the inspection is normal, start to monitor the Anesthetic Gas.

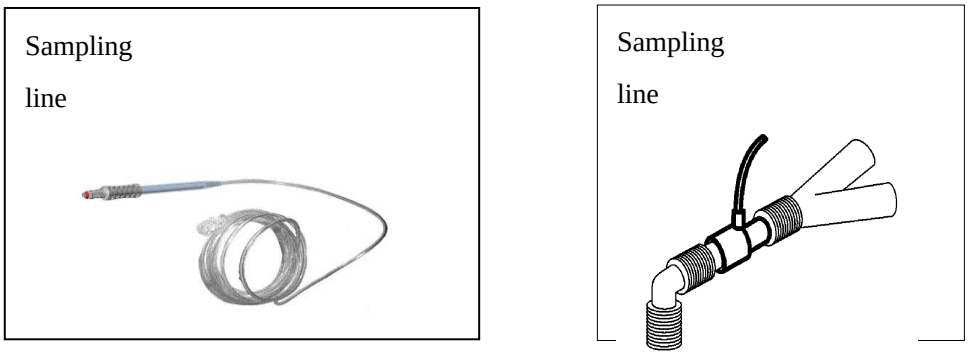


Fig. 9-6 The sketch map of preliminary work and connection

- **Check before use**

  Before connecting the Nomoline sampling line to the breathing circuit, carry out the following steps:

  a) Connect the sampling line to the interface of gas inlet of the Anesthesia Module.

  b) Check whether the green light of AG Module is steadily on or not(The indication Module is normal.).

  c) Check whether the connection port of the luminescent sample tube is steadily on or not(The indication system is normal.).

  d) As for the Anesthesia Module furnished with oxygen option:Check whether the oxygen reading on the host equipment is correct or not(21%).

  e) Breathe out air to the sampling pipe, and check whether the anesthesia machin**e** shows the effective wave pattern and values of CO_2.

  f) Use the finger tip to block up the sampling line, and hold on for 10s.

  g) Examine whether there is obstruction warning and if the luminescent sample tube shows a red flashing light.

  h) Under proper circumstances:Carry out enclosure check on the patient's circuit that is linked with the sampling line.

9.7.3 ARTEMA AG module(Sidestream)

- Measuring Procedures

  Set the anesthesia machine to start gas analysis:

a) Install the sidestream AG module to the corresponding position on the anesthesia machine.

b) Select the appropriate Watertrap according to the patient type and push the watertrap firmly into the watertrap socket.

c) Turn the system switch to the right side to start the anesthesia machine. The indicator at the top left corner of the AG module is in green.

d) In the **[Config] Menu→ select [Gas Module] → [AG Module]**→set the items, such as [**Unit**] , [**O_2 Compensation**] , [**Zero Sensor**].

e) When the AG module is turned on, the working mode of the module is "Measure". But in order to ensure that it is in the proper working state, please by all means enter the **[AG Module]** to make sure whether the **[Work Mode]** is in the **[Measure]** state**.**

f) To connect the outlet of the sample gas to the scavenging system, or to make the gas to flow back to the patient's circuit.

g) Connect one end of the sample tube to the sink and the other end to the patient's circuit.

h) To carry out inspection before use according to the statement in the "***Chapter 4 Tests Before Use (Section 4.5)***".

i) If the inspection is normal, start to monitor the Anesthetic Gas.

⚠ Warning

- **Children can not use the adult sink,or may cause damage to the patient.**
- **The sink is used to collect condensing water drops in the sample tube to prevent water drops from entering the module.When the water collected by the sink reaches a certain amount,the water must be discharged before it can continue to be used,so as to avoid blocking the the gas path.**
- **Make sure all connections are firm and reliable. Any leakage will result in the inclusion of ambient air in the patient's respiratory gas, which leads to a wrong reading.**

9.7.4 ARTEMA AG+O_2 Module(Sidestream)

Please refer to *9.6.3 ARTEMA AG module(Sidestream)*

9.8 Setting AG

Set the following items on the screen by pressing hotkey **[Config] → [Gas Module] → [AG Module]** . or Press the AG setting button on the module to enter [**Gas Module**], in which you can set the AG parameters.

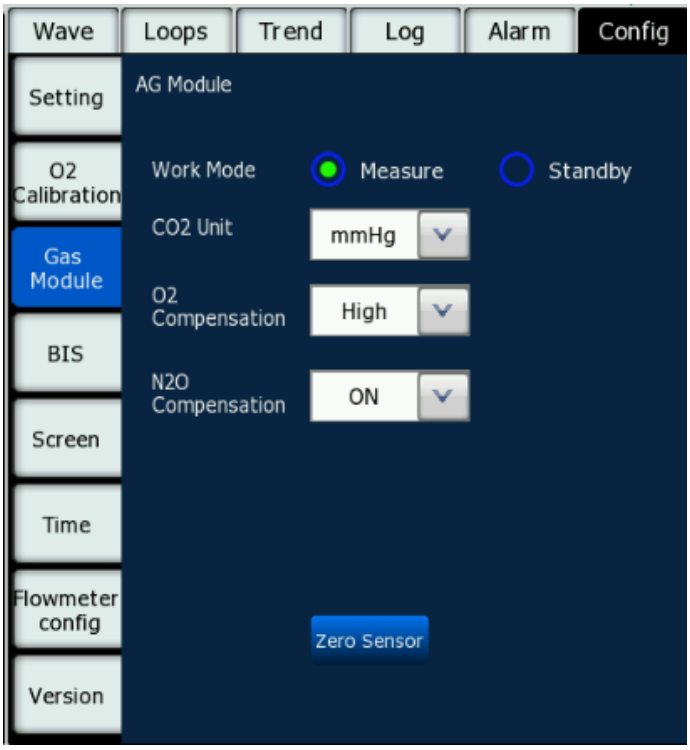


Fig. 9-7 AG Module Configuration

9.8.1 Setting work mode

Work mode: standby, detect

Standby: When the anesthesia module is in standby mode, the air pump stops working for the purpose to extend the life of the module. Meanwhile, it is displayed in the information area that "The anesthesia module is standing by".

Detection: When the anesthesia module is working, the green indicator light is steadily on, and detection data is sent to the monitor.

When the anesthesia module is connected to the monitor on the normal anesthesia interface, the anesthesia module can automatically change its work mode into "detection mode", but the user

must confirm that it is under detection mode.

When the anesthesia apparatus is turned on for the first time, the default [**Work Mode] is [Measure] .** If the current anesthesia module is in standby mode, user can start the anesthesia module on the screen by pressing hotkey **[Config] → [Gas Module] → [AG Module] → [Work Mode] → [Measure] .** Or press the Measure/Standby button on the module to switch between the Standby/Measure mode.

Note

- **During calibration of the sensor, press the Measure/Standby button cannot switch the operating mode. At this time, the Measure/Standby button on the screen does not function either.**
- **When anesthesia machine is restarted, all the setting of AG module before the last shutdown will be reserved.**

9.8.2 Set the Units

On the screen, select **[Config]** menu → **[Gas Module]** → **[AG Module]** → **[CO_2 Unit]** , and set it to: **[mmHg] , [%]** or **[kPa]** .

9.8.3 Setting Gas Compensation

⚠Warning

- **Please set the oxygen compensation based on the actual conditions, otherwise the detection result may severely deviate from the actual value, which may lead to misdiagnosis.**

There are 3 options for O_2 Compensation, namely “High”, “Medium” and “Low”. “High” refers to 85% of O_2 Compensation; “Medium” 50%; and “Low” 21%. When an O_2 module is equipped, an O_2 sensor automatically performs O_2 compensation according to the O_2 concentration. Therefore, this option is in the default state. When no O_2 sensor provides automatic O_2 compensation, the compensation level can be manually set according to the actual O_2 concentration (as shown in the table below).

Oxygen concentration（%）	Compensation level
0~30	High（21%）
30~70	Middle（50%）
70~100	Low（85%）

9.8.4 Zeroing

The infrared gas analyzer needs to establish a zero reference level for the CO_2, N_2O and anesthetic agent gas measurement. This zero calibration is here referred to as "zeroing".

1. Automatic zeroing

   AG module performs automatic zeroing by switching the gas samples from the breathing circuit to the environmental atmosphere. The automatic zeroing is performed every 24 hoursand takes less than 10 seconds. If the AG module is equipped with an oxygen sensor, automatic zeroing shall include calibration of air within the oxygen sensor

2. Manual zeroing

   The AG module can perform automatic zeroing when necessary. User can also perform manual zeroing by entering [**Config]** hotkey, opening the [**Gas Module]** manual, and choosing **[Zeroing]** in **[AG Module]** . It is unnecessary to disconnect the patient's air way during zeroing.

⚠Warning

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

9.8.5 Displaying CO_2 Waveform

1. In the User Interface, access the **[Config]** menu.
2. Open the **[Screen]** menu.
3. Set the **[CO_2 Wave]** to **[ON]** as per actual requirements.
4. Plug in AG module,CO_2 waveform may be viewed once you return to the **[waveform]** window of user interface(If it is Artema AG,the waveform will not be displayed until the warm-up is over and the waveform is in the working state). As shown in the figure below.

Fig. 9-8 CO_2 waveform

9.9 Anesthetic replacement

If the anesthetic in use is changed, the module can still detect the mixture of two gases during the transient phase. But the time needed for anesthetic replacement is decided by the type (low-flow or high-flow) and character (pharmacokinetics) of the anesthetic. No reminding notice will be given by the anesthesia apparatus for anesthetic replacement; and the MAC values displayed might be incorrect during replacement.

ISA analyzer can recognize the anesthetics automatically. When the content of one anesthetic is under the limit, while another anesthetic accounts for a major part, the anesthesia apparatus can detect this change, and indicate the name and data of an anesthetic.

9.10 Lighting signals of MASIMO AG module

A brief introduction of the indications:

Indication	Status
Steady green light	System OK
Blinking green light	Zeroing in progress
Steady blue light[2)]	There is an anesthetic gas
Steady red light	Sensor error
Blinking red light	Check sampling line

9.11 Adverse impact on performance

Please refer to content with corresponding of this section of " ***8.8.6Adverse impact on performance***" part.

9.12 Warnings

Please refer to content with corresponding of this section of " ***8.8.7Warnings*** " part.

9.13 Sampling line clogged

Please refer to content with corresponding of this section of " ***8.8.8Sampling line clogged*** " part.

9.14 Exhaust gas emission

Please refer to content with corresponding of this section of " ***8.7 Exhaust gas emission*** " part.

9.15 Consumables

Please refer to content with corresponding of this section of " ***8.8.9Consumables*** " part.

9.16 Maintenance

Please refer to content with corresponding of this section of " ***8.8.10 Maintenance*** " part.

Chapter 10 Monitoring BIS

⚠Warning

- **The conductive parts of the sensor and interface shall not be in contact with other conductive parts, including the ground contact.**
- **In high-frequency surgery, to avoid the risk of burns, the BIS sensor shall not be placed between the surgical site and the electrosurgical device return electrode.**
- **When using a defibrillator on a patient, BIS sensors shall not be placed between the defibrillator pads.**
- **BIS serves only as an adjunct to clinical diagnosis and training.**
- **Clinical efficacy, risk / benefit and application of BIS function have not been fully validated in pediatric patients.**
- **To reduce the risk of burns during use of the brain stimulation device (e.g. cranial stimulation of motor-induced potentials), place the stimulation electrodes as far away from the BIS sensor as possible and ensure that the sensor is placed as indicated in the instructions on the package.**
- **BIS monitoring anti-defibrillation recovery time is less than 30s.**

10.1 General Introduction

BIS monitors the electroencephalogram (EEG) signals of the cerebral cortex, and combines the frequency and power spectrum analysis methods to give a quantitative dual-frequency index. Meanwhile, by combining with the quality analysis of the EEG signals, BIS comprehensively evaluates the patient's current state of consciousness and thus identifies the dual-frequency index.

The system supports 4 measuring parameters of BIS, EMG, SR, and SQI. It provides a waveform that displays a BIS module's continuous detection of EEG signals, which is referred to as the BIS EEG waveform, and provides a dynamic trend of displaying BIS, which is referred to as the BIS Trend.

10.2 BIS module

Dual-frequency index monitoring is only possible when the anesthesia machine is equipped with BIS modules.

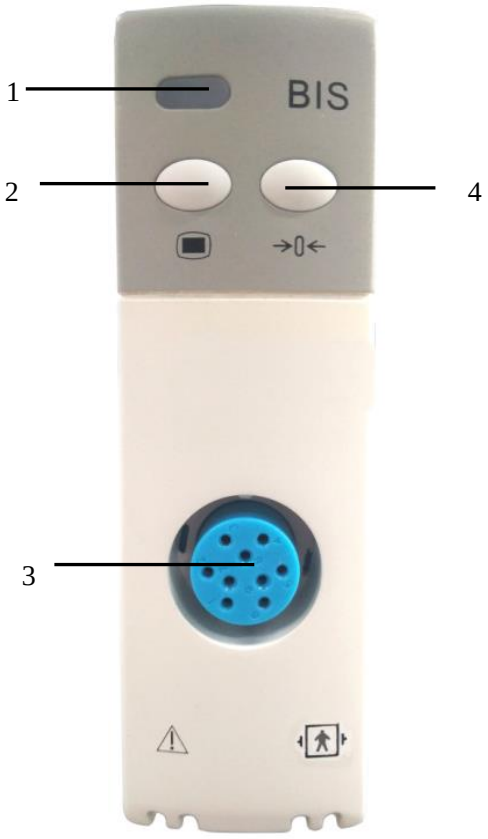


Fig. 10-1 BIS Module

1	Module working indicator	3	BIS module cable connector
2	BIS setup menu	4	Measurement / standby button

10.3 BIS display

BIS waveform area provides display modes: BIS EEG waveform.

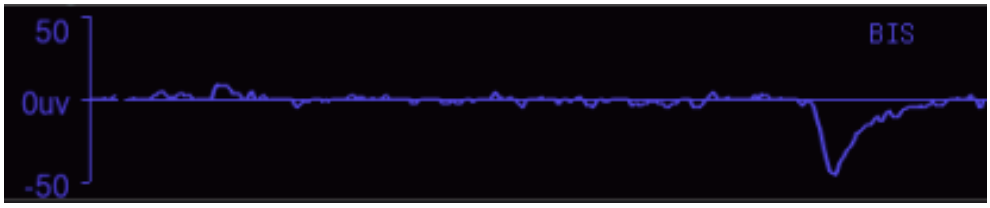


Fig. 10-2 BIS EEG Waveform

Parameter	English name	Meaning	Unit	Range
BIS	Bispectral Index	Reflecting the level of consciousness of the patient	/	0-100

EMG	Electromyogram	Reflecting the electric activity of muscle activity and high frequency artifacts.	dB	0-100
SR	EEG suppression ratio	SR is the percentage of time the EEG is considered inhibited in the last 60 seconds of the session.	%	0-100
SQI	Signal quality index	The SQI value reflects the quality of the signal and provides the reliability of the BIS, SR values during the last minute.	%	0-100
BIS Numeric Update Frequency	frequency range	BIS Numeric Update Frequency	/	Once per second
EEG Bandwidth	bandwidth	EEG Bandwidth	Hz	0.25 Hz to 100 Hz (-3 dB) +/- 10%

When "impedance check in progress", “the electrode impedance too high”, “poor signal quality”, or “replacing the sensor” occurs, the measured values of the above four parameters will be affected.

BIS	**Clinical status**
100	In a waking state
70	In a calm state, mild hypnosis, with low possibility of being awakened
60	In general anesthesia, moderate hypnosis state
40	In a loss of consciousness, deep hypnosis state
0	In deep anesthesia state, where the EEG waveform is straight and the patient has no EEG activity

EMG：

EMG < 55dB; acceptable EMG.

EMG≤30dB: Optimal EMG.

SQI:

0% ~ 15%, the value cannot be derived .

15% ~ 50%, the value cannot be reliably derived .

50%～100% , the value cant be reliably derived.

10.4 Safety Information

Due to limited clinical experience, the BIS values coming from patients with neurological abnormalities, psychoactive patients, and pediatric under one year old should be carefully interpreted.

⚠ Warning

- **The BIS shall not be taken as the only reference to adjust the anesthesia dose.**
- **The conductive parts of the sensor shall not be in contact with other conductive parts, including the ground contact.**
- **In high-frequency surgery, to reduce the risk of burns, the BIS module shall not be placed between the surgical site and the electrosurgical device return electrode.**
- **When using a defibrillator on a patient, BIS sensors shall not be placed between the defibrillator electrode pads.**

10.5 BIS Connection

1) The BIS module of this anesthesia machine uses a cable to receive the signal, first connect the BIS module to the anesthesia machine.
2) Fix the module in place on the patient through the clip on the back of the BIS module, which shall not be beyond the patient's head.
3) Connect the patient cable to the BIS module.
4) Attach the BIS sensor to the designated location on the patient as instructed by the sensor.
5) Connect the BIS sensor to the patient cable. Once the device detects a valid sensor, the impedance of all electrodes will be automatically measured and the result will be displayed in the electrode impedance test results window.

As shown in the following figure:

BIS plug-in module

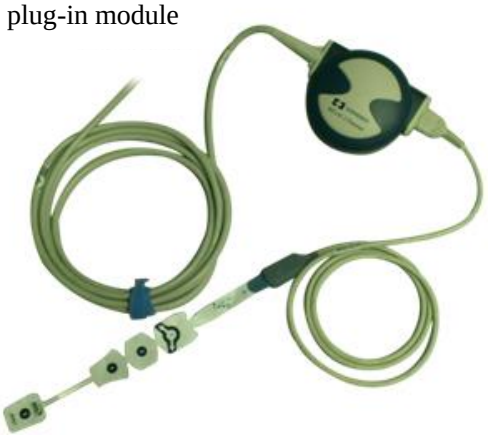


Fig. 10-3 BIS Connection Diagram

Electrode placement

No. of electrode pad	Position of Electrode Placement in English
1	Center of the forehead
3	On temple
4	Directly above eyebrow

⚠ Warning

- **It is of great importance that you place the electrode in the correct position to maintain proper operation of the BIS.**
- **The electrode can be placed on the left or right side of the scalp.**
- **Do not place the BIS module over the patient's head so as o avoid any danger to the patient.**
- **Pleasure make sure the patient's skin is dry. Wet sensors or salt bridges may cause false BIS and impedance values.**

10.6 Electrode impedance test results window

Select [**Config**] - [**BIS**], and select [**Impedance Test Results**] (equivalent to manually conduct the electrode impedance check) to enter this window, as shown below:

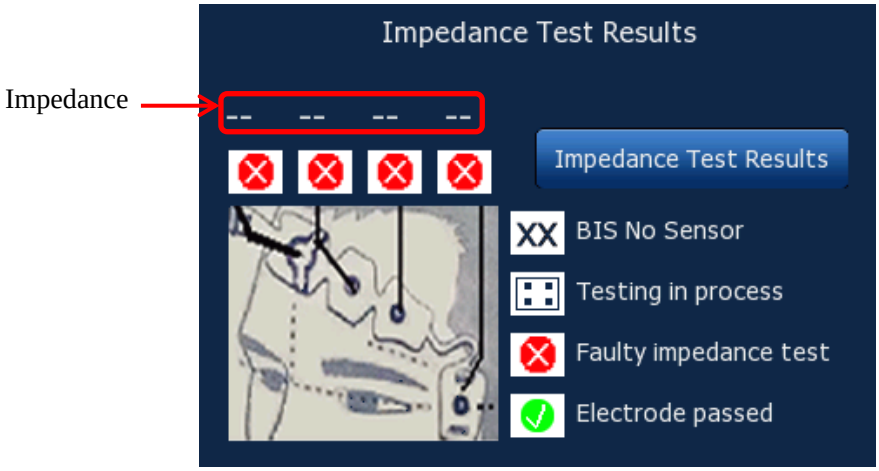


Fig. 10-4 Electrode Impedance Test Results Window

Click to **[Impedance Test Results]** to update the electrode impedance test results.The measured status and impedance values are displayed in the electrode impedance test results window:

Symbol	Status	Measures to Be Taken
	Electrode impedance test passed	No action required
	Electrode impedance test failed	Check the cable, electrode and skin contact status of the patient, if necessary, please clean and dry the skin.
	Electrode impedance test in progress	No action required
XX	BIS sensor not connected	No action required

10.7 Setting BIS

10.7.1 Set BIS smoothness

Smoothness determines how anesthesia machines averages the BIS data. The smaller the value is, the anesthesia machine responds more sensitively to changes in patient state. The larger the value is, the more smooth the BIS trend is, with less variation and less artifact interference.

1) Select [Config] →[BIS Module]→ [BIS smooth rate].
2) Select [10s], [15s] or [30s].

10.7.2 Sensor replacement confirmation

1) When the instrument is in the process of testing, a technical alarm "Replacing the sensor" appears,

replace the sensor.

2) Select [Config] →[BIS Module]→ [Confirm sensor replacement], suggesting that "Already replaced?," select [Yes].

10.7.3 Set filter switch

1) Select [Config] →[BIS Module]→ [filter switch].
2) Select [ON] or [OFF].

10.7.4 Set wave shift

1) Select [Config] →[BIS Module]→ [wave shift].
2) Select 50uV,100uV,200uV,400uV ,500uV ,625uV ,1000uV or 2000uV.

10.7.5 Set wave speed

1) Select [Config] →[BIS Module]→ [wave speed].
2) Select 6.25mm/s,12.5mm/s,25mm/s,or 50mm/s.

Note

- **When anesthesia machine is restarted, all the setting of BIS module before the last shutdown will be reserved.**

Chapter 11 Trend and Logs

11.1 Trend Table

Trend Table is used to review the data of physiological parameters of patients of corresponding time point, and describes the changes in parameter measuring results. Trend provides VTexp, VTinsp, MV, Ppeak, Pplat, Pmean, PEEP, Rate, FiO_2, BIS and $EtCO_2$, and it stores the data for review for continuous 60 hours. The Trend Table refreshes when the machine is restarted.

On the screen, select **[Trend]** → **[Table]** to open the window shown in the figure below:

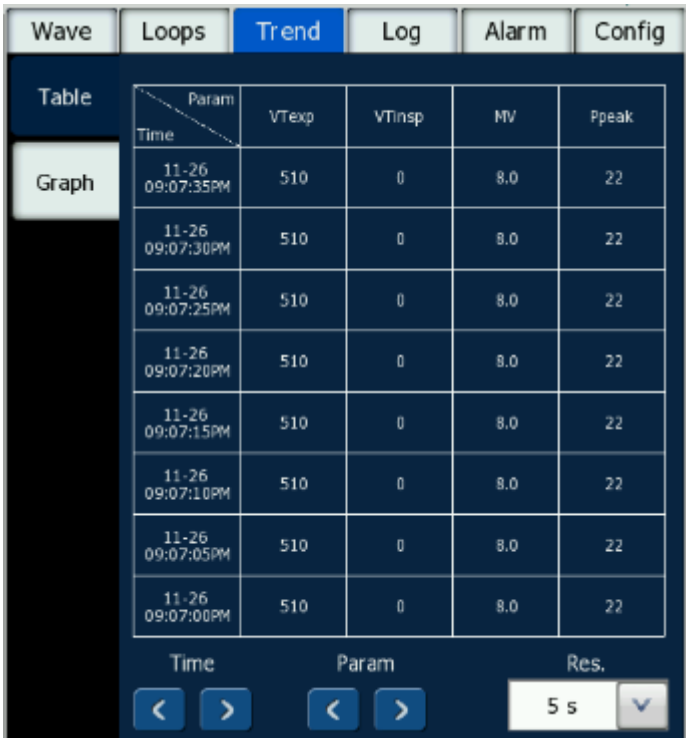


Fig. 11-1 Trend Table

1. Select **[Res.]**, and select **[1min], [2min], [4min], [5s]** or **[30s]** as required.
2. You can view the Trend Table by one of the follow ways:

Select [] and [] buttons of parameter to move the Trend Table leftwards or rightwards and view the data of other parameters.

Select [] or [] buttons of time to turn the pages of Trend Table leftwards or rightwards and view more data.

11.2 Trend Graph

Graph is used to review the trend of parameter values over the time. The measured physiological values corresponding to the time point are drawn into a curve which illustrates the patient parameter's trend. Trend graph provides data review for VTe, VTi, MV, Rate, Ppeak, FiO_2, $EtCO_2$, Plat, PEEP, Pmean,BIS, etc. for continuous 60 operating hours at the resolution of 5s. The trend graph refreshes when the machine is restarted.

Select **[Trend]** → **[Graph]** to open the window shown in the figure below:

⚠Attention

- **After the anesthesia system is powered down or restarted after shutdown, the trend graph will be cleared.**

A. Ordinate

B. Abscissa

C. Cursor Time

D. Cursor Parameter Display

E. Parameter Name of Trend Curve

F. Trend Curve

G. Time

H. Cursor

K. Parameter of the trend curve

L. Resolution

■ Select Parameter for review: Select [**Trend**] → **[Graph]** → [**Param**], and click the [**Param**] button

to the desired parameter. The parameters are VTe, MV, Ppeak, FiO_2 and $EtCO_2$ etc.

- View Trend Curve: Select [Trend] → [Graph] → [Time], and click the [Time] button to move the trend curve at an interval of a whole page.
- Move Cursor: Select [Trend] → [Graph] → [Cursor], and click [Cursor] button to move the cursor at an interval of 5s. The time and parameter values corresponding to the cursor place are displayed at right side of the trend graph,. The time and parameter values change as the cursor moves. You can change the time interval of the cursor by selecting [Trend] → [Graph] → [Res.]. The range is 5s- 4min.

11.3 Alarm Log

Alarm log can save up to 2000 messages. Log messages are stored chronologically. The earliest event will be overwritten if a new event takes place after 2000 messages has been stored. Alarm log storage includes both technical alarm logs , physiologic alarm logs,indicate logs and setting logs.

On the screen, select [Log] to open a window as shown in the figure below:

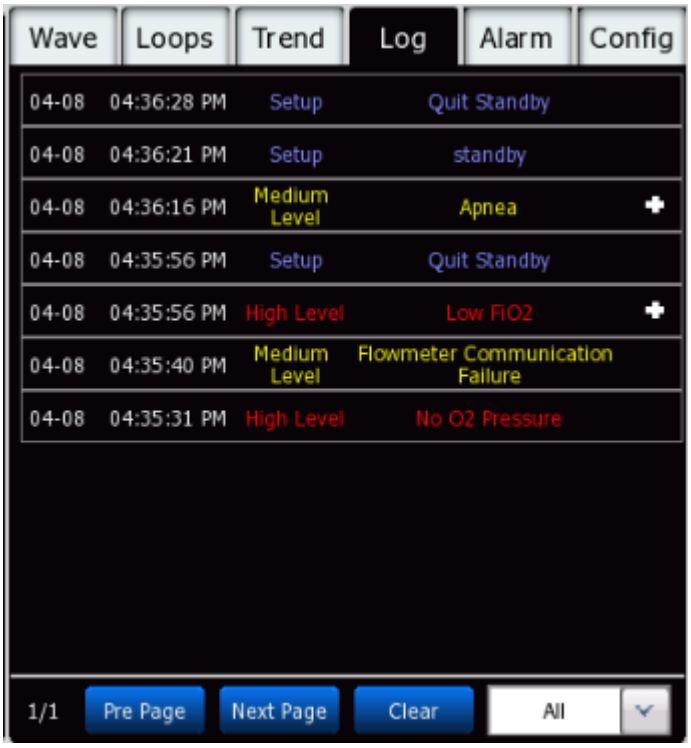


Fig. 11-2 Log Review

Alarm log can store all physiologic alarms, technical alarms, and setting information. The logging is timer-sequenced, and the latest event appears foremost.

In the menu, you can perform the following operations:

1. Click **[+]** behind the log information to expand the physiological parameter information during logging,click **[-]** tucked the physiological parameter information.
2. Select **[Pre page]** or **[Next page]** to view the alarm log one by one.

3. Select **[Clear]** to delete all logs.

4. Select menu “  ”, and select the arrow button to choose the desired log filter.You can select **[All](Display All), [Tech](Technical alarm), [Phys](Physiologic Alarm) , [Indicate], [Alarm record]** or **[Setting]** .

⚠Caution

- **When the anesthesia machine is completely powered off or turned off, the stored alarm log are not deleted, and the log contents remain,but the shutdown time will not be saved in log.**
- **If auditory alarms do not generate any longer, you can access the alarm log to view the events that trigger alarms.**

Chapter 12 Maintenance, Cleaning and Disinfection

⚠Warning

- **Observe the applicable regulations for safety protection.**
- **Carefully read the safety instructions of each cleaning agent to understand the applicable materials.**
- **Read carefully the instructions for operation and maintenance of all sterilization equipment.**
- **Wear safety gloves and spectacles. Damaged oxygen sensor may cause leakage and result in inflammation (including potassium hydroxide).**
- **Reusing non-sterilized breathing system and its reusable attachments may cause cross infection; therefore, they shall be sterilized prior to each surgical operation.**
- **Every time the equipment is disassembled, cleaned, disinfected or reassembled, the operations described in the chapter** *"Tests Before Use"* **must be performed before normal use.**
- **To prevent the breathing system from leaking, all components must not damaged during disassembling and reassembling, and correct mounting shall be guaranteed, especially the assembling of the seal rings. To conduct cleaning and sterilization, guarantee the applicability of cleaning and sterilization methods to the components, and guarantee the correctness of the cleaning and sterilization methods.**
- **Please perform removal and mounting as described in this chapter. For details of further removal and assembling, contact After-service Department of the Company. Incorrect removal and assembling may cause leak in the breathing system, and impact normal of the equipment.**
- **For the maintenance, cleaning, disinfection of the external vacuum suction system, please refer to the User Manual of vacuum suction system.**

⚠Caution

- **Prior to initial use, the equipment shall be cleaned and disinfected as required. The cleaning and sterilizing methods are described in this chapter.**
- **To avoid damages to the equipment, refer to data provided by manufacturer if you have any questions about the cleaning agents.**
- **Never use organic, halogenated or petroleum-base solvents, glass cleaners, acetone or other irritative cleaning agents.**
- **Please don't use any abrasive cleaning agents (for example steel wool, silver polishing materials or cleaning agents).**
- **Liquid shall be placed away from electronic components.**
- **Do not allow any liquid to infiltrate into shell body of the equipment.**
- **For parts made of synthetic rubber, the soak time must not exceed 15 minutes so as not to lead to expansion or accelerated aging.**
- **Only the parts marked with 134ºC allow sterilization by high-temperature vapor.**
- **PH value of cleaning solution must range from 7.0 to 10.5.**
- **The maximum using times of high temperature and high pressure sterilization of respirator y circuit is 2000 times.**
- **The breathing circuit must be cleaned and sterilized before use by each patient.**

12.1 Housing Cleaning and Disinfection of Anesthesia Machine

1. Turn off the anesthesia system and disconnect the AC power before cleaning.
2. Use distilled water to wet the lint-free cloth and properly clean the display, work table, and the outer surface of the main unit.
3. Please disinfect with sodium hypochlorite solution, then use medical alcohol (75%) deterge nt, PH value between 7.0 and 10.5, use a lint-free cloth to wipe the display, workbench, the outer surface of the main machine, etc.
4. The casing is free from signs of deterioration that can be detected by the naked eye, and the marking of the silk screen does not change.

⚠Warning

- **Liquid infiltrating into the control assemblies may damage the equipment or cause personal injury. During cleaning the housing, ensure that no liquid enters into the control assemblies, and the equipment shall be disconnected from AC supply. Ensure that AC**

supply is reconnected only when the cleaned components get dry thoroughly.

⚠Caution

- **Use only dry soft lint-free cloth to clean the display screen, and do not use liquid to clean it.**

12.2 Remove and Assemble the Cleanable and Disinfectionable Components of the Breathing System

To clean and sterilize the breathing system, you are required to disassemble the breathing system components that can be cleaned and sterilized.

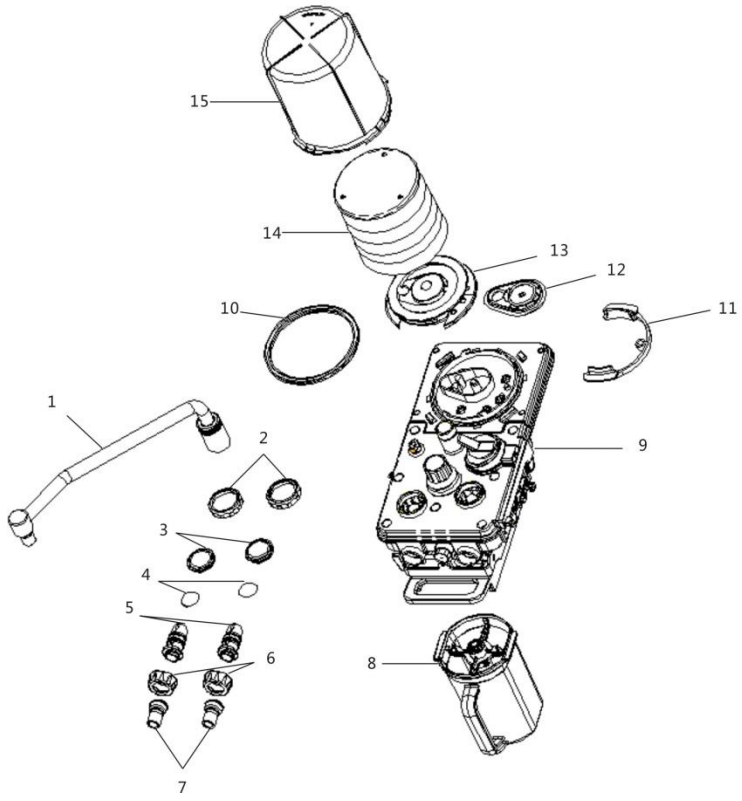


Fig. 12-1 Assemblies of the Breathing System

Item	Description	Item	Description
1	Bag support column	9	Main body, breathing

			system circuit
2	Expiratory/ Inspiratory check valve cap	10	Sealing Washer
3	Expiratory/ Inspiratory check valve pedestal	11	Collar Clamp
4	Expiratory/ Inspiratory check valve	12	POP-OFF Valve
5	Flow sensor	13	Folded Sack Holder
6	Connector nut of respiratory tube	14	Folded Sack
7	Respiratory Tube Joint	15	Bellows Cover
8	CO_2 canister		

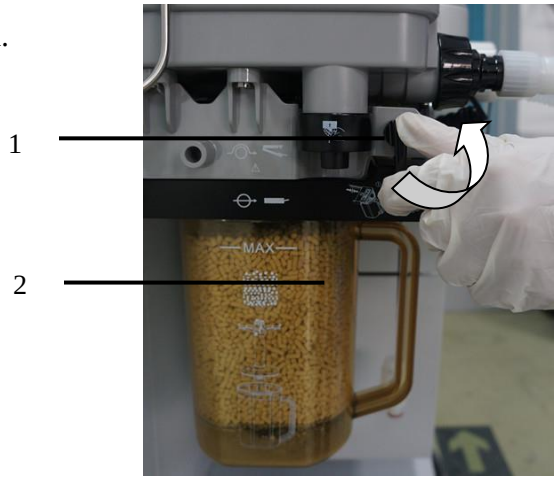
Components marked with 134 °C are high temperature and pressure resistant, They can be hand-washed or machine-washed (using soft cleaning agent with pH <10.5), and then be rinsed thoroughly and air-dried. All components, exception for the oxygen sensors, airway gauges and disposable flow sensors, can be washed.

If the flow sensors are made of plastics, please refer to the directive rules given in "*12.3.8 Flow Sensor*".

12.2.1 Disassemble the CO_2 Canister

1 Hold the canister with your right hand, and meanwhile push counterclockwise the release latch with your left hand so as to release the lock of the canister.

2 Take out the canister with your right hand.



⚠Warning

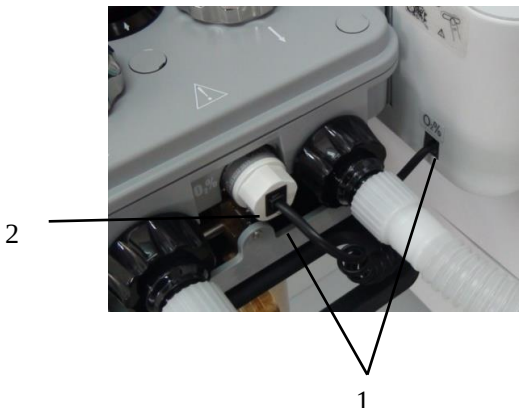
- **CO_2 absorbent is a type of high-causticity substance, and is very harmful to eyes, skin and breathing system of human beings. In case any body parts are stained with CO_2 absorbent by accident, wash parts with water. If irritation is not eliminated after washing, see a**

doctor for help immediately.

12.2.2 Disassemble the Oxygen Sensors

1 Remove one end of O_2 sensor cable from the corresponding oxygen sensor port "O_2%" of the host, and remove the other end of the oxygen sensor cable from the oxygen sensor port "O_2%".

2 Move outward the oxygen sensor along the channel, and take it out.



⚠Caution

- **Never immerse an O_2 sensor or its connector in any type of liquid. Dispose of the O_2 sensor according to the manufacturer's specifications.**
- **Do not clean the inner surface of the O_2 sensor.**

12.2.3 Disassemble the Breathing Hose and Y-piece

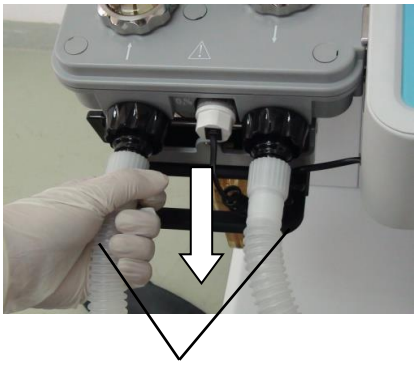
⚠Caution

- **To disassemble the Breathing Tube, hold the connectors at both ends of the Breathing Tube so as not to damage the Breathing Tube.**
- **Do not reuse filters. Discarded filters shall be disposed as per local laws and regulations, or hospital disposal regulations. Do not directly throw them away.**

1 R emove the mask from the joint;

2 Remove the filter from Y-piece, and then remove the Y-piece.

3 Remove the expiratory hose from expiratory connector,and inspiratory hose from inspiratory connector of the breathing system.

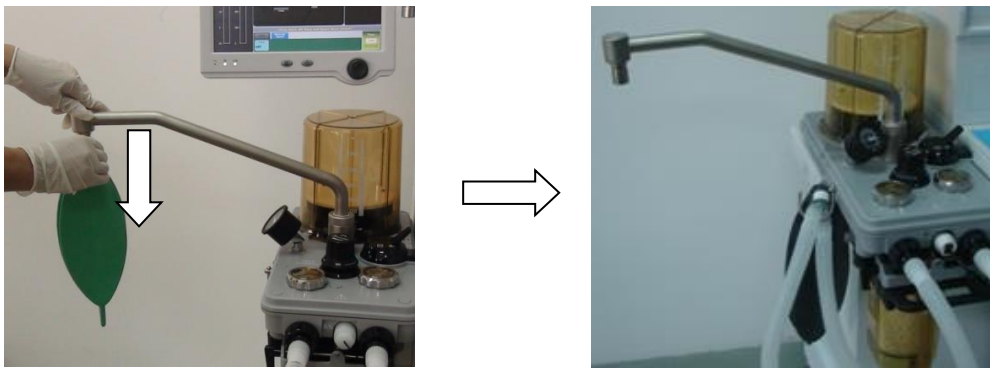


2

12.2.4 Disassemble the Manual bag

Just remove the manual bag from the breathing system, as shown in the figure below:

■ The anesthesia machine is provided with manual support column.

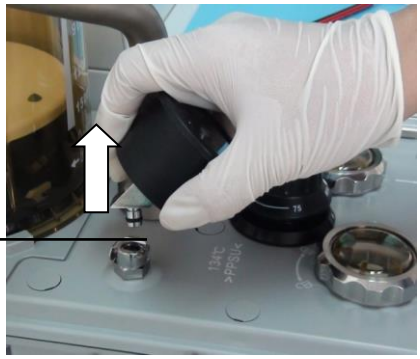


12.2.5 Disassemble the Airway Gauge

1. Forcibly push away the CPC connector latch with your left hand, and lift up the airway gauge with your right hand.

1

2. When the CPC connector latch is released, pull out the airway gauge.

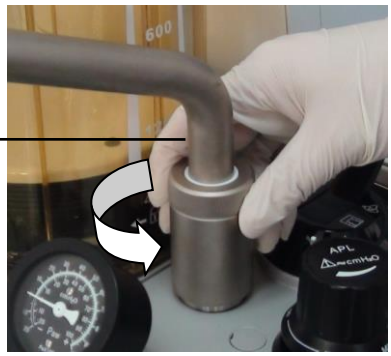


2

12.2.6 Disassemble the Manual Support Column

1 Rotate the locking nut counterclockwise.

1



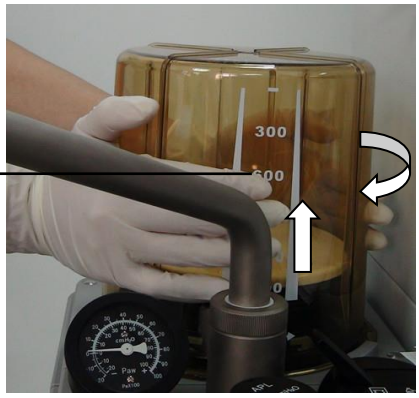
2 Hold the manual support column with your right hand, and remove the manual support column from breathing system with your left hand.

2

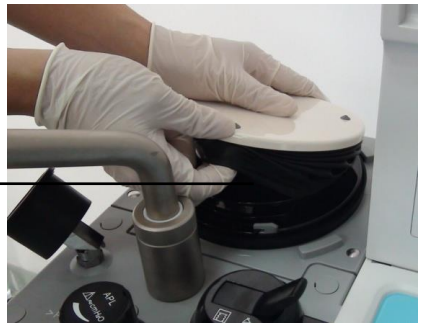
12.2.7 Disassemble the Bellows Assembly

1 Hold the bellows cover with both hands, and then rotate the bellows cover conterclockwise. Lift up the bellows cover when the bellows cover is separate from the latch on the base.

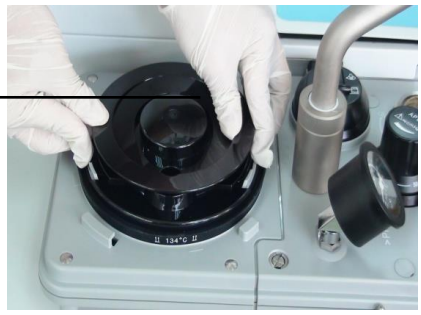
1



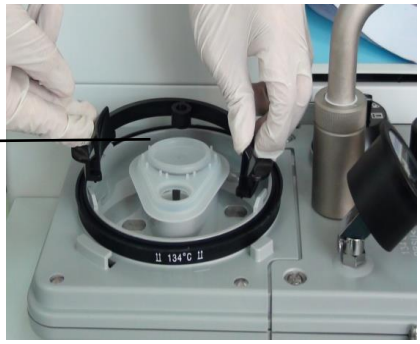
2 Remove the folded sack from the folded sack holder.



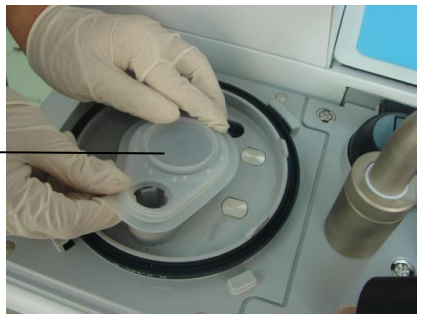
3 Press the collar clamp towards the center, and remove the folded sack holder.



4 Remove the collar clamp.



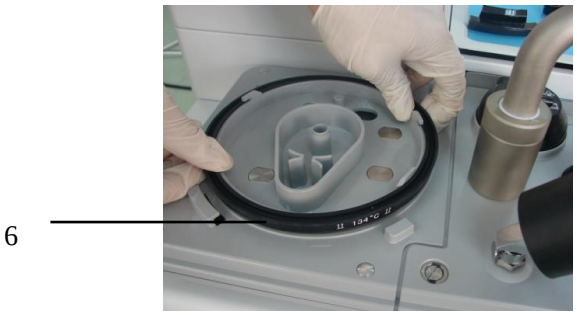
5 Remove the POP-OFF valve.



⚠Warning

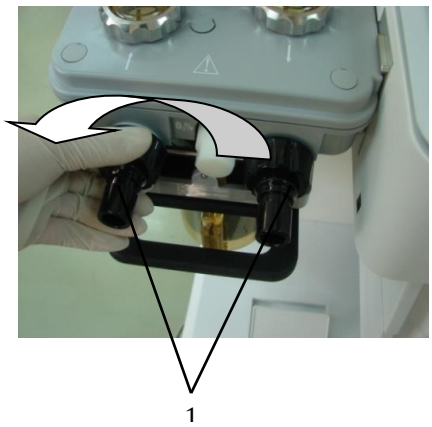
- **Never disassemble the pressure relief valve. Otherwise, the pedestal and diaphragm may be damaged and further endanger patient safety.**

6 Remove the sealing washer.

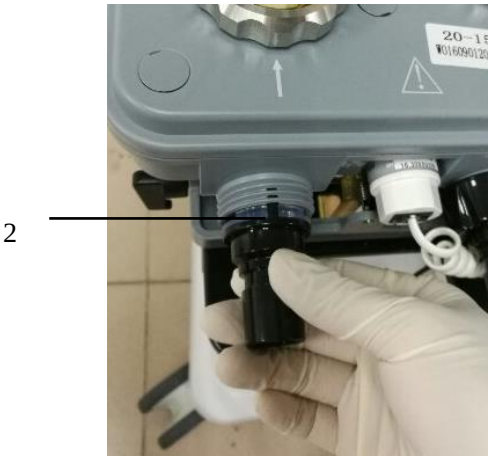


12.2.8 Disassemble the Flow Sensor

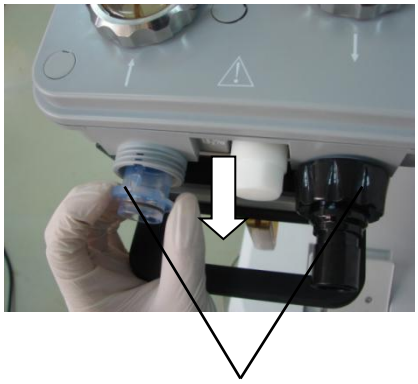
1 Rotate the respiration connector nut counterclockwise, and remove the nut.



2 Remove the breathing tube connector from the breathing interface horizontally.



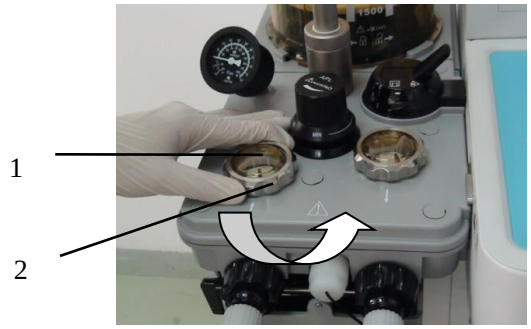
3 Pull the flow sensor out of the respiration port horizontally.



12.2.9 Disassemble Expiratory Check Valve Assembly

1 Hold the nut of check valve cap by hand, unscrew it counterclockwise, and take it out.

2 Take out the check valve cap.



3 Take out the seal ring.

4 Take out the valve.

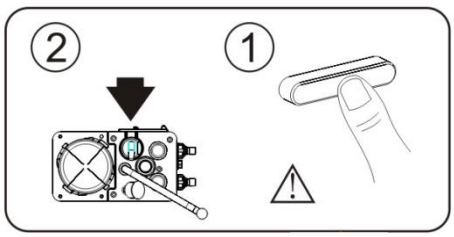
5 Take out the valve base.

12.2.10 Disassemble Inspiratory Check Valve Assembly

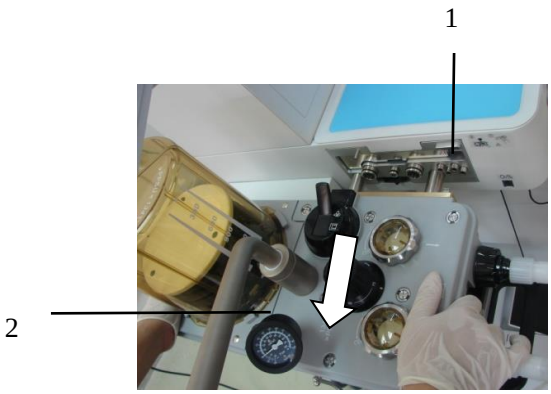
For disassembling procedure of Inspiratory check valve assembly, refer to ***12.2.9 Disassemble Expiratory Check Valve Assembly***.

12.2.11 Disassemble the Breathing Circuit System

1 Ensure that all the above-mentioned assemblies are disassembled. Then hold up the breathing circuit system by one hand, and push and open the fixation latch of the circuit adapter by the other hand.



2 Remove the breathing circuit system by both hands from the circuit adapter.

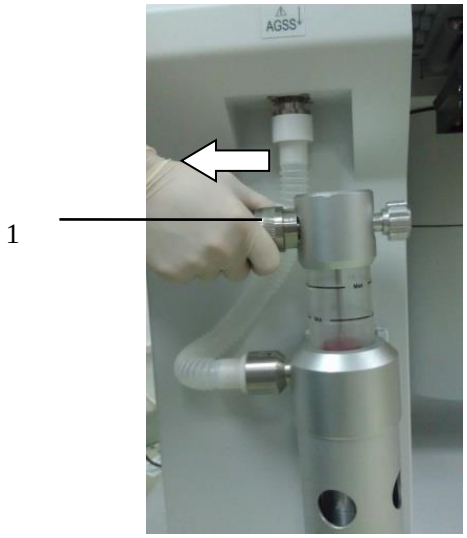


⚠Caution

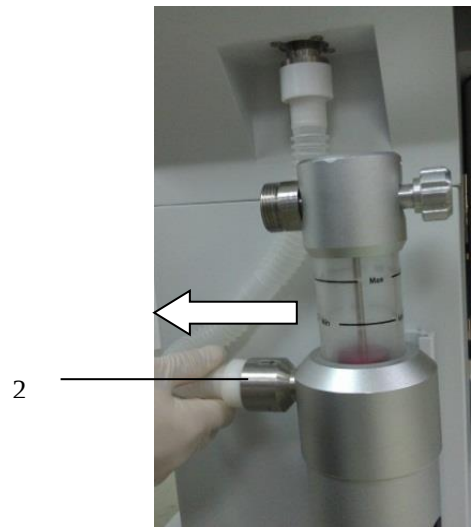
- **If it is very hard to push in or take out the breathing circuit system, apply lubricating oil onto seal ring of airway connector of circuit adapter to reduce the frictional force.**

12.2.12 Disassemble the AGSS Transfer and Receiving System

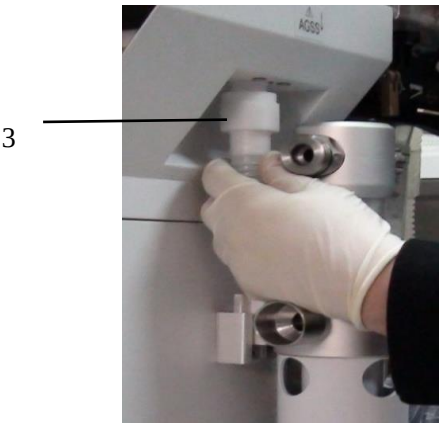
1 Remove the AGSS active discharge pipe on the AGSS gas outlet from hospital scavenging system.



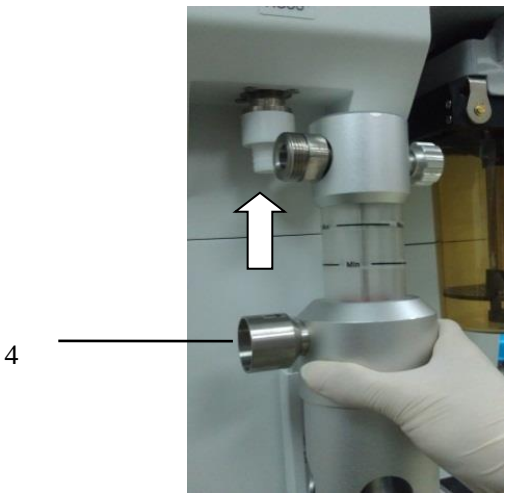
2 Remove the 30mm outer cone connector of hose of the transfer system.



3 Remove the 30mm internal cone connector of hose of the transfer system.



4 Lift up the AGSS system from AGSS bracket and take it out.

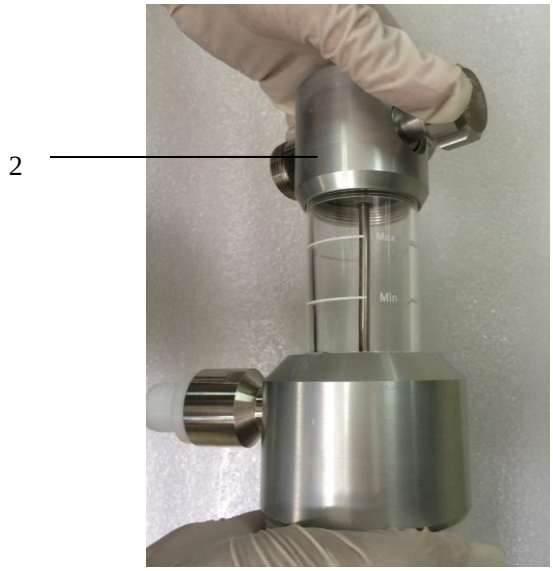


12.2.12.1 Disassemble the Filter of AGSS Transfer and Receiving System

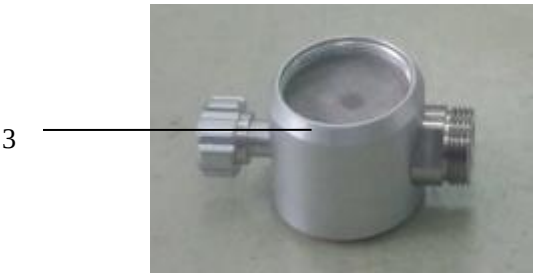
1. Refer to section ***12.2.12 Disassemble the AGSS Transfer and Receiving System*** for dismantling AGSS

components from anesthesia machine;

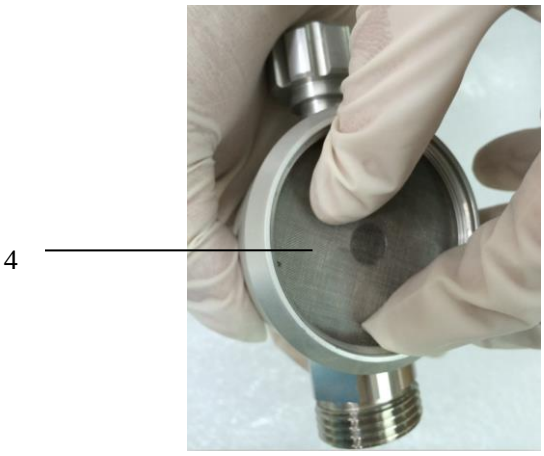
2. Hold the AGSS cover with left hand, and rotate it to the right, as shown in the following figure

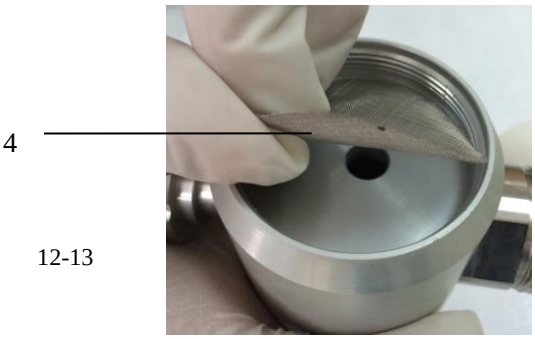


3. Dismantle the AGSS cover, as shown in the following figure

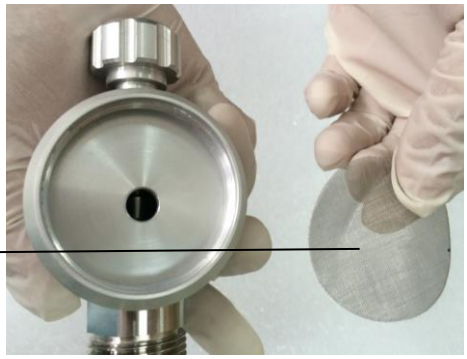


4. Take out the filter of AGSS transfer system, as shown in the following figure





5. Clean the filter.



12.2.12.2 Replace the Filter of AGSS Transfer and Receiving System

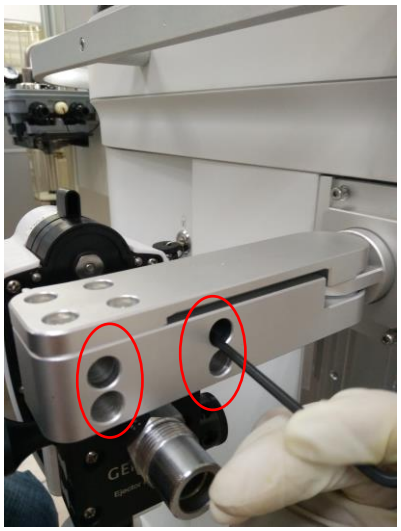
Refer to section *12.2.12.1 Disassemble the Filter of AGSS Transfer and Receiving System* for the steps of replacing filter gauze.

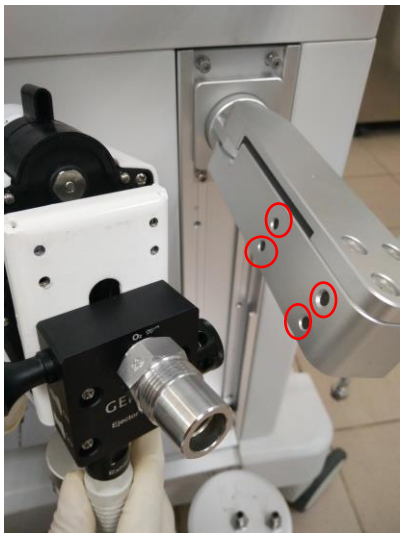
12.2.13 Disassemble Vacuum Suction System

12.2.13.1 Disassemble External Vacuum Suction System

1. Loosen the nut, so that one end of the backup oxygen supply hose is separate from the connector of external vacuum suction system.

2. Unscrew the four screws between the external vacuum suction system and its support.



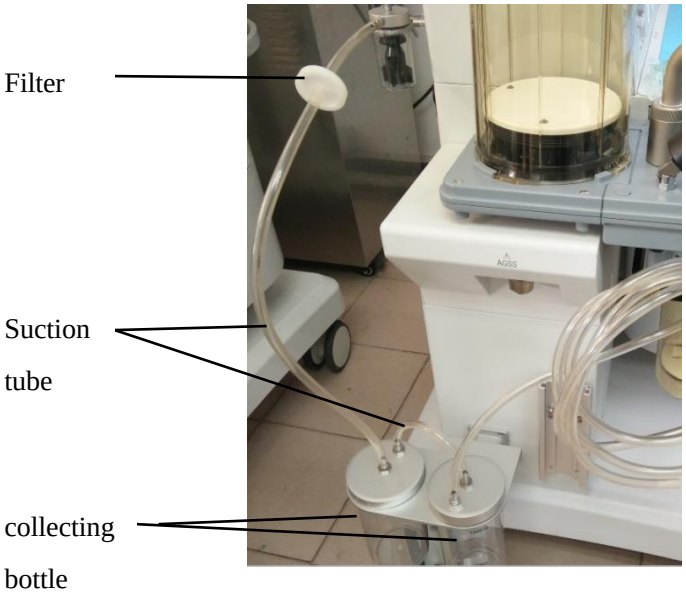


3. Unscrew the support screws.

4. Disconnect the backup oxygen supply hose / backup air supply hose from the gas supply port.

12.2.13.2 Disassemble Internal Vacuum Suction System

Pull out the suction tube,take out the collecting bottle,and discard the filter.



⚠Caution

- **When replacling the filter,please follow the local treatment rules to dispose the old filter.**

12.3 Clean,Disinfect, Sterilize and Assemble the Breathing System

Components indicated with “134ºC” mark are sterilized through high-temperature vapor. For example, components made of metal or glass can be sterilized in high-pressure high-temperature vapor (not more than 134ºC for 4-6min). Utilize autoclave to raise the vapor pressure, and temperature raises along. The bacterial protein may be solidified quickly in high temperature. The method is quick and reliable for sterilization.If sterilization may be maintained for at least 30 minutes at 121ºC, all bacteria and most of brood cells may be killed.This type of components may also be cleaned by hands. Brush thoroughly all components of the breathing system with soft cleaning agent with pH value of 7.0 ~ 10.5, and have them air-dried.

The flow sensors are plastic products, and the specific cleaning procedures are described in *12.3.8 Flow Sensor*.

⚠Warning

- **Never use talcum, zinc stearate, calcium carbonate, cornstarch or similar materials to avoid**

adhesion. These materials might access lung of the patient or the gas duct, resulting in irritation or damage.

- **Never soak breathing system and oxygen sensor into the liquid together or treat them in high-pressure and high-temperature environment.**
- **Check the components for damages, and replace them when necessary.**
- **The breathing circuit must be cleaned and sterilized before use by each patient.**
- The maximum using times of high temperature and high pressure sterilization of respiratory circuit is 2000 times.

All components of breathing system of the anesthesia machine can be cleaned and sterilized. Different components have their own cleaning and sterilizing requirements.

Components of breathing system of the anesthesia machine shall be cleaned and sterilized in time as per actual conditions in order to avoid cross infection of patients served by the anesthesia machine.

The following cleaning ,disinfecting and sterilizing methods for components are recommended by the Company.

Table 12.3-1 Recommended method for cleaning and disinfecting various components

Component	Cleaning	Intermediate disinfection	Sterilization
CO_2 Canister			★
Oxygen sensor	★		
Breathing Tube,Y-piece and mask			★
Manual bag			★
Airway pressure gauge	★		
Manual support column			★
Bellows Assembly			★
Flow sensor		★	
Expiratory Check Valve Assembly			★
Inspiratory Check Valve Assembly			★
Breathing circuit system			★
AGSS Transfer and Receiving System	★		

★: It indicates that this recommended cleaning and disinfection method can be utilized.

Cleaning: Gently wipe the surface of the cleaning parts with a damp cloth or cleaning cotton that has been soaked in a soft, recommended cleaning agent (see Table 12.3-2 recommended

cleaning disinfectant table) to ensure that all surfaces of the parts are cleaned while This cleaning requirement complies with the disinfection regulations and procedures of the medical institution. After cleaning, gently wipe the surface of the cleaning part with a lint-free cloth or medical cleaning cotton that has been soaked in medical clean water (recommended water temperature is 40 °C). Finally, dry it with a dry, lint-free cloth.

Intermediate disinfection: First use the hospital-approved disinfectant or recommended disinfectant (see Table 12.3-2 recommended cleaning disinfectant table) to soak the parts for about 3 minutes for intermediate disinfection, and the intermediate disinfection requirements meet the disinfection regulations and procedures of medical institutions. If there is any conflict, the disinfection regulations and procedures of the medical institution shall prevail. After the disinfection is completed, gently wipe the cleaning parts with a lint-free cloth or medical cleaning cotton that has been soaked in medical clean water (recommended water temperature is 40 °C). The surface would be dry naturally or dry it with a dry, lint-free cloth.

Sterilization: First use the recommended cleaning agent (see Table 12.3-2 recommended cleaning disinfectant table) to rinse clean parts, then use high temperature and high pressure steam sterilization, and require this sterilization to meet the disinfection regulations and procedures of reference medical institutions, recommended method 1: Maintain effective sterilization time at temperature 121 ° C for at least 30 min; recommended method 2: maintain effective sterilization time at temperature 134 ° C for about 4 min-6 min; After disinfection and sterilization, remove the parts and drain the remaining distilled water, then rinse with medical clean water (recommended water temperature of 40 ° C), and dry it naturally or in a ventilated place with a temperature of less than 70 ° C.

The following table is the recommended cleaning and disinfecting agent:

The cleaning disinfectants listed below have been tested that didnot damage the breathing components. The listed cleaning disinfectants may not be available in all countries or regions. Please comply hospital's instructions for the cleaning disinfectants.

⚠Caution

- **For the cleaners that are not in the cleaner list, their PH value should be between 7.0 and 10.5.**

Table 12.3-2 Recommended Cleaning Disinfectant Table

Cleaning and	Recommended cleaning disinfectant	Concentration

disinfection method		
Cleaning	Medical clean water	/
	Soap water (weakly alkaline)	/
	Pure distilled water	/
Intermediate disinfection	Medical alcohol	75%
	Sodium hypochlorite solution	10% effective chlorine

12.3.1 CO_2 Canister

⚠Caution

- **Care must be taken when handling the absorbent as it is a corrosive irritant.**
- **Check the seals before installing the CO_2 canister assembly. If not, replace the seals.**

1. Please refer to*12.2.1 Disassemble the CO_2 Canister*for Removal of the CO_2 canister.
2. Clean and sterilize the CO_2 canister as per the methods recommended in the table 12.3-1 recommended methods for cleaning and disinfecting various components given in *12.3 Clean,Disinfect,andAssemblethe Breathing System.*
3. After cleaning and sterilization is completed,the CO_2 canister is thoroughly dried, pour CO_2 absorbent into the CO_2canister.
4. Please refer to *5.2 Install the CO_2 Absorbent Canister*,assemble the CO_2 Absorbent Canister onto the breathing system.
5. Check and test the system before use. For details, see *4.5.2 Breathing System Leak Test in Mechanical Ventilation Mode*.

12.3.2 Oxygen Sensor

⚠Warning

- **Never soak breathing system and oxygen sensor into the liquid together or treat them in high-pressure and high-temperature environment.**
- **Oxygen concentration measurement may fail if there is condensed moisture on the measuring surface of oxygen sensor. In such a case, take out the oxygen sensor, remove the**

condensed water from the measuring surface, and reassemble the oxygen sensor into the breathing system.

1. Please refer to ***12.2.2 Disassemble the oxygen sensor*** for disassembling the oxygen sensor;
2. Please clean the oxygen sensor as per the methods recommended in the table 12.3-1 recommended methods for cleaning and disinfecting various components given in ***12.3 Clean, Disinfect,Sterilize and Assemble the Breathing System.***
3. After cleaning is completed,the oxygen sensor is thoroughly dried, assemble oxygen sensors as per ***5.1.7 Assemble the Oxygen Sensor.***
4. Check and test the system before use. For details, see ***4.5.2 Breathing System Leak Test in Mechanical Ventilation Mode***.

12.3.3 Breathing Tube ,Y-piece and mask

⚠Caution

- **When you assemble, clean or sterilize the breathing tube, hold the connector fitted at both ends of the breathing tube, so as not to damage the breathing tube.**

1. See ***12.2.3 Disassemble the breathing tube, Y-piece and mask*** for removal of the breathing tube, Y-piece and mask.
2. Clean and sterilize the Breathing Tube,Y-piece and mask as per the methods recommended in the table 12.3-1 recommended methods for cleaning and disinfecting various components given in ***12.3 Clean,Disinfect,Sterilize and Assemble the Breathing System.***
3. After cleaning and sterilization is completed,the Breathing Tube,Y-piece and mask are thoroughly dried, please refer to***5.1.6Assemble the Breathing Tube,Y-piece and mask***, assemble the Breathing Tube ,Y-piece and mask onto the breathing system.
4. Check and test the system before use. For details, see ***4.5.2 Breathing System Leak Test in Mechanical Ventilation Mode***.

12.3.4 Manual bag

1. Please refer to ***12.2.4 Disassemble the Manual bag*** for disassembly of the Manual bag.
2. Clean and sterilize the manual bag as per the methods recommended in the table 12.3-1 recommended methods for cleaning and disinfecting various components given in***12.3 Clean, Disinfect, Sterilize and Assemble the Breathing System.***
3. After cleaning and sterilization is completed,verify that the manual bag is thoroughly dry, and then assemble the manual bag as per***5.1.3Assemble the Manual bag.***
4. Check and test the system before use. For details, see ***4.5.3 Breathing System Leak Test in***

Manual Ventilation Mode.

12.3.5 Airway Pressure Gauge

1. Please refer to *12.2.5 Disassemble the airway gauge* for disassembly of the airway pressure gauge.
2. Clean the airway pressure gauge as per the methods recommended in the table 12.3-1 recommended methods for cleaning and disinfecting various components given in*12.3 Clean, Disinfect,Sterilize and Assemble the Breathing System.*
3. After cleaning is completed,verify that theairway pressure gauge is thoroughly dry, and then assemble the airway pressure gauge as per*5.1.8 Assemble the Airway Pressure Gauge.*
4. Check and test the system before use. For details, see *4.5.2 Breathing System Leak Test in Mechanical Ventilation Mode*.

12.3.6 Manual support column

1. Please refer to *12.2.6 Disassemble the Manual support column* for disassembly of the Manual support column.
2. Clean and sterilize the Manual support column as per the methods recommended in the table 12.3-1 recommended methods for cleaning and disinfecting various components given in*12.3 Clean, Disinfect,Sterilize and Assemble the Breathing System.*
3. After cleaning and sterilization is completed,verify that theManual support column is thoroughly dry, and then assemble the Manual support column as per*5.1.2Assemble the Manual Support Column.*
4. Check and test the system before use. For details, see *4.5.3 Breathing System Leak Test in Manual Ventilation Mode*.

12.3.7 Bellows Assembly

⚠Caution

- **The folded sack assembly shall not be soaked in warm water and cleaning solution for more than 15 minutesto prevent expansion or aging.**
- **When you air-dry the folded sack, hang and expand it adequately. Otherwise, adhesion might occur in the folded sack.**
- **Disassemble the bellows assembly for cleaning; otherwise, drying may take a long time.**
- **To conduct high-pressure and high-temperature sterilization to the bellows assembly, assemble the bellows assembly properly. During the high-pressure and high-temperature sterilization, the bellows assembly shall be positioned upside down.**

1. See *12.2.7 Disassemble the Bellows Assembly* for Removing the Bellows Assembly.

2. Clean and sterilize the bellows assembly as per the methods recommended in the table 12.3-1 recommended methods for cleaning and disinfecting various components given in*12.3 Clean, Disinfect,Sterilize and Assemble the Breathing System.*

3. After cleaning and sterilization, spread out the components of the bellows assembly and hang them in a ventilated place with a temperature less than 70 °C to dry;.

4. When the bellows assembly is thoroughly air-dried, check the components for damages, and then conduct assembling as per the procedures described in ***5.1.4 Assemble the BellowsComponents***. Connect the bellows assembly, ventilator and breathing system.

5. Check and test the system before use. For details, see ***4.5.1 Bellows Tightness Test***.

12.3.8 Flow Sensor

1. See ***12.2.8 Disassemble the Flow Sensor*** for Disassembly of the Flow Sensor.

2. Clean the flow sensor as per the regulations issued by the hospital or as per the methods recommended in the table 12.3-1 recommended methods for cleaning and disinfecting various components given in ***12.3 Clean, Disinfect, Sterilize and Assemble the Breathing System***.

3. After the cleaning and disinfection is completed, after the flow sensor is completely dry, please refer to 5.1.5 Assemble the Flow Sensor to install the flow sensor;

4. Check and test the system before use. For details, see ***4.5.2 Breathing System Leak Test in Mechanical Ventilation Mode***.

⚠Caution

- **Never have the flow sensors in high-pressure and high-temperature environment for disinfection.**
- **Never use high pressure gas or brush to clean the flow sensors.**
- **Never use unapproved cleaning agent containing polycarbonate.**
- **Do not clean the inner surface of flow sensor, only use a damping cloth to wipe its outer surface.**
- **The flow sensor must be completely dry before it can be used.**

⚠Warning

- **To assemble a flow sensor, tighten the locknut of respiration port; otherwise the measuring function of flow sensors may be disabled.**
- **The respiration port that is connected to the respiration hose shall face downward;**

Otherwise condensed moisture may flow into the breathing system and impact the flow sensor measurement.

12.3.9 Expiratory check valve assembly

1. See ***12.2.9 Disassemble Expiratory Check Valve Assembly*** for Disassembly of the Expiratory check valve assembly.
2. Clean and sterilize the Expiratory check valve assembly as per the methods recommended in the table 12.3-1 recommended methods for cleaning and disinfecting various components given in***12.3 Clean, Disinfect, Sterilize and Assemble the Breathing System.***
3. After the cleaning and sterilization is completed, after the Expiratory check valve assembly is completely dry, assemble the Expiratory check valve assembly according to the reverse process of dismounting the Expiratory check valve assembly, according to ***12.2.9 Disassemble Expiratory Check Valve Assembly***.
4. Check and test the system before use. For details, see ***4.5.5 Check Valve Inspection and Test.***

⚠Warning

- **Never disassemble the check valve diaphragm and check valve cover.**
- **Push the check valve downwards forcibly to ensure secure assembling.**

12.3.10 Inspiratory check valve assembly

1. See ***12.2.10 Disassemble Inspiratory Check Valve Assembly*** for Disassembly of the Inspiratory check valve assembly.
2. Clean and sterilize the Inspiratory check valve assembly as per the methods recommended in the table 12.3-1 recommended methods for cleaning and disinfecting various components given in***12.3 Clean, Disinfect, Sterilize and Assemble the Breathing System.***
3. After the cleaning and sterilization is completed, after the Inspiratory check valve assembly is completely dry, assemble the Inspiratory check valve assembly according to the reverse process of dismounting the Inspiratory check valve assembly according to ***12.2.10 Disassemble Inspiratory Check Valve Assembly***.
4. Check and test the system before use. For details, see ***4.5.5 Check Valve Inspection and Test***.

⚠Warning

- **Never disassemble the check valve diaphragm and check valve cover.**
- **Push the check valve downwards forcibly to ensure secure assembling.**

12.3.11 Breathing Circuit system

1. After ensuring that the components described above have been removed, see ***12.2.11 Disassemble the Breathing Circuit System*** for Disassembly of the Breathing Circuit System.
2. Clean and sterilize the breathing circuit system as per the methods recommended in the table 12.3-1 recommended methods for cleaning and disinfecting various components given in***12.3 Clean,Disinfect,Sterilize and Assemble the Breathing System.***
3. After sterilization is completed, the breathing circuit system is hung upside down in a ventilated place with a temperature less than 70 ° C to dry;
4. After cleaning and sterilization, after the Breathing System has completely dried, please refer to ***5.1.1 Assemble the Breathing Circuit System***to install the breathing circuit system, and then install the components as described above to ensure the formation of a complete breathing system.
5. Check and test the system before use. For details, see ***4.5.2 Breathing System Leak Test in Mechanical Ventilation Mode***.

12.3.12 AGSS Transfer and Receiving System

1. See ***12.2.12 Disassemble the AGSS Transfer and ReceivingSystem*** for Disassembly of the AGSS transfer and receiving system.
2. Shake the removed filter and shake the dust and impurities from the filter net until it reaches a satisfactory cleaning effect;
3. Clean the AGSS transfer and receiving system as per the methods recommended in the table 12.3-1 recommended methods for cleaning and disinfecting various components given in***12.3 Clean, Disinfect, Sterilize and Assemble the Breathing System.***
4. After the cleaning is completed, after the AGSS Transfer and Receiving System is completely dry, please refer to ***5.10.2 Assemble the AGSS to install the AGSS system***.
5. Check and test the system before use. For details, see ***4.7 AGSS Transfer and Receiving System Test.***

12.3.13 Vacuum Suction System

⚠Caution

- **Before use must check ensure that air pressure in the rang of 280-550kPa for external vacuum suction system.**

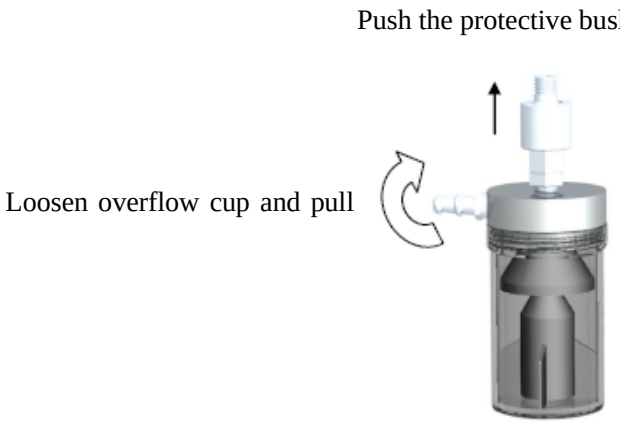
- **The maximum negative pressure of vacuum suction system is not less than 75kPa.**

⚠Warning

- **The negative pressure regulator is prohibited from cooking in the sterilizer, and the use of liquid disinfectant which is harmful to plastics is prohibited to disinfect the negative pressure regulator, which will cause serious damage to the plastic parts of the negative pressure regulator. Influence the function of negative pressure regulator.**

12.3.13.1 Internal vacuum suction

1. Please refer to ***12.3 Clean, Disinfect, and Assemble the Breathing System*** for the recommended methods on cleaning and disinfecting the vacuum suction system.
2. The suction tube (including suction head), the filter are for disposable use only and shall be disposed after use without repeated use. Please replace with new suction tube, head and filter before the use next time. (Suction tube, filter manufacturers and models available for replacement are shown in ***Chapter 14 Accessories.***)
3. The collection bottle is repetitive use items. Unscrew the collection bottle after each use, clean the collected liquid and then sterilize the the collection bottle (can be sterilized at high temperature).
4. The overflow cup is repetitive use items, As shown in the figure below, the overflow cup is first removed from the negative pressure regulator, then the cup is removed, the float and sealing seat are taken out, each part is washed and disinfected with disinfectant, and then cleaned with clean water.



5. When not in use, the overflow cup and the collecting bottle can be separately stored and disinfected;
6. After the negative pressure suction system is disinfected, vacuum suction should be placed in a well-ventilated environment,so that residual moisture or disinfectant can be volatile.Then please refer to ***5.9 Installation of the Vacuum Suction System*** to install the vacuum suction system.

⚠Warning

- **The life of collection bottle and overflow cup is ten years.**

12.3.13.2 external vacuum suction system

⚠Note

- **Please refer to the user manual supplied with the external vacuum suction system for cleaning, disinfection and installation information.**

12.3.14 Battery

⚠Caution

- **To extend the service life of batteries, use the battery at least once a month, and charge them when the battery charge is used up.**
- **Please check and replace batteries regularly. The service life of batteries depends on frequency of use and service time. Based on proper maintenance and storage, the service life of battery is approximately 3 years. In case they are improperly used, their service life may be reduced. It is recommended that batteries be replaced every 3 years.**
- **In case of battery fault, contact the personnel of the manufacturer for replacement. The user must not replace it by themselves.**
- **The time the battery is powered depends on the configurations and operation of the device.**
- **After the main power supply is interrupted, when the "ON-OFF" button is kept on, after the interruption time exceeds 30s, there is internal power supply that can support normal operation.**

Chapter 13 Maintenance and Failure Recovery

13.1 Maintenance Basics

⚠Warning

- **Do not use the faulty anesthesia machine.All repairs and maintenance shall be carried out by authorized service representatives.**
- **Adopt a cleaning and disinfection plan that meets you disinfection and risk management requirements.**
- **Be careful when handling an absorbent because it is a corrosive stimulus.**
- **Please use approved anesthesia equipment or special lubricant for O_2 equipment.**
- **Please don't use lubricant containing oil or grease, which may have a fire or explosion hazard when O_2 reaches a certain concentration.**
- **Used equipment might be contaminated by blood or body fluid. Please observe relevant disinfection control and safety regulations.**
- **Moving parts and detachable components may cause hazard of hand nipping/crushing; therefore, move or replace system components with more care.**

Do not use faulty equipment. Contact the service representative authorized by the Company to fulfill all required maintenance, or the qualified professionals to fulfill the replacement and maintenance of parts listed in the User's Manual.

When maintenance is over, test the equipment and ensure that the equipment works normally and meet the requirements of specifications.

⚠Caution

- **Personnel without experiences in maintenance of such equipment must not service the equipment.**
- **Replace damaged parts with the ones produced or sold by the Company. When replacement is over, perform testings to ensure that the equipment conform to the specification requirements of manufacturer.**
- **If service and support are required, contact the after-service department of the Company.**
- **To find out further product information and relevant technical data, contact the after-service department of the company, and we may provide documentary data about**

some components.

- **Do not immerse the O_2 sensor or its connecter in any type of liquid.**
- **Do not clean the inner surface of the O_2 sensor.**

13.2 Maintenance Schedule

⚠Caution

- **In this schedule, the minimum maintenance frequency is based on a typical use of 2000 operating hours per year. If the actual use time is longer than 2000 hours, the frequency of equipment maintenance shall be higher in a year.**
- **When cleaning and installing,please check whether the parts and sealing rings are damaged and replace or repair if necessary.**

Minimum maintenance frequency	**Maintenance**
Daily	Clean the outer surfaces. 21% O_2 calibration (oxygen sensors of the breathing system). APL accuracy check in Manual/spontaneous ventilation.
Every 2 weeks	Drain the Anesthesia Vaporizer.
Monthly	100% O_2 calibration (oxygen sensors of the breathing system). AGSS filter check vacuum suction system checking
During cleaning and assembling	Check if components and seal rings are damaged, and replace or repair them when necessary.
Yearly	Replace the vaporizer base and seal rings of the breathing system port. For details, contact the after-service department of the Company. CO_2 module calibration.
Every 3 years	Replace the built-in battery. For details, please contact the after-service department of the Company.

Minimum maintenance frequency	Maintenance
When necessary	Use a new washer on the backup cylinder port every time a new backup cylinder is to be assembled. If the colour of CO_2 absorbent varies, replace CO_2 absorbent of the canister. If the measured deviation of oxygen sensors is too high and cannot be corrected after being calibrated many a time, replace the oxygen sensors. If the seal ring of flow sensor is damaged, the diaphragm is cracked or deformed, or the sensors show deformation or cracking, replace the flow sensors. If the hoses and silicone hose of the transfer system are broken, replace them.

13.3 Maintenance of Breathing System

If any parts are found to be cracked, broken, deformed or worn during breathing system cleaning, replace them. For details, refer to ***12.2 Remove and Assemble the Cleanable and Disinfectionable Components of the Breathing System*** and ***5.1 Assemble the Breathing System***.

13.4 O_2 Calibration

⚠Warning

- **Please do not implement the calibration procedure when the system is connected to a patient.**
- **When calibrating an oxygen sensor, the environmental pressure must be identical with the environmental pressure where oxygen transfers in the breathing system. If not, the monitoring values may exceed the limits.**
- **Before calibrating an oxygen sensor, disassemble the oxygen sensor. Verify that oxygen sensor and the assembling place do not have accumulated water, and then re-assemble the oxygen sensor.**
- **If oxygen sensor is not equipped with or not intended to use, it is unnecessary to perform O_2 calibration.**

13.4.1 21% O_2 Calibration

⚠Caution

- **If the measurement error of oxygen concentration is too high or if an oxygen sensor is replaced with a new one, O_2 calibration shall be performed.**
- **O_2 calibration must be performed in the standby mode.**
- **If calibration fails, check whether or not some technical alarm is given. Take measures to remove the alarm, and then calibrate the O_2 sensor again.**
- **If calibration fails many a time, replace the oxygen sensor, and perform calibration over again. If calibration still fails, contact the service personnel or the Company in time.**
- **The discarded oxygen sensors shall be treated as per relevant regulations for biological hazards, and please don't have them burnt.**

Specific Operation Steps:

1. Verify that the system is in its standby mode; otherwise push the standby soft key to access the screen of **[Standby]**.
2. Select **[O_2 Calibration]** menu → **[21% O_2 Calibration]** , and open the **[21% O_2 Calibration]** menu, and access the 21% O_2 Calibration screen.
3. Remove the oxygen sensor from breathing system, and place it in the air for 2~3 minutes. The disassembling procedures are described in 10.2.2 Disassemble the Oxygen Sensors
4. In the **[21% O_2 Calibration]** menu, select **[Timer]** button to time for 3 minutes. When timing is over, push the **[Start]** button, the system starts "21 % O_2 Calibration", and **[Calibrating]** is displayed on the screen.
5. In process of calibration, push the **[Stop]** button to stop the calibration in progress.
6. If the equipment passes the testing, a prompting message **[Calibration Result PASS]** is displayed on the screen. Otherwise, prompting messages **[Calibration Result FAIL]** and **[Repeat]** will be displayed, and recalibration is required in such a case.
7. Select **[Exit]** .

13.4.2 100% O_2 Calibration

⚠Caution

- **If 100% O_2 calibration fails, check whether or not some technical alarm is given. Take measures to remove the alarm, and then calibrate the O_2 sensor again.**
- **If calibration fails many a time, replace the oxygen sensor, and perform 21% O_2 calibration**

over again. When 21% O_2 calibration is successful, perform 100% O_2 calibration. If 100% O_2 calibration still fails, contact the service personnel or the Company in time.

Specific Operation Steps:

1. Ensure that "21% O_2 Calibration" is finished and calibration is successful. Ensure that **[No O_2 Pressure]** does not occur.
2. Verify that the system is in its standby mode; otherwise push the standby soft key to access the interface of **[Standby]** mode.
3. Select **[O_2 calibration]** menu → **[100% O_2 calibration]** , and open the **[100 % O_2 calibration]** menu, and access the 100 % Oxygen calibration screen.
4. Ensure the patient is disconnected from the system.
5. Align the patient port to the atmosphere.
6. Turn on O_2 supply, the regulated flow shall be at least 8L/min; turn off other gas supply.
7. Wait for 2~3 minutes, or in the **[100% O_2 Calibration]** menu, select **[Timer]** button to time for 3 minutes. When timing is over, push the **[Start]** button, the system starts "100% Oxygen Calibration", and **[Calibrating]** is displayed on the screen.
8. In process of calibration, if you push the **[Stop]** button, the calibration in progress will be stopped.
9. If the equipment passes the testing, a prompting message **[Calibration Result PASS]** is displayed in the menu. Otherwise, prompting messages **[Calibration Result FALL]** and **[Repeat]** will be displayed, and recalibration is required in such a case.
10. Select **[Exit]** to complete the calibration.

13.5 Airway Gauge Zeroing

When Mechanical or Manual/spontaneous stops, the airway pressure should be about zero. If the pointer of airway gauge does not return to zero, the pressure indication of airway gauge may become inaccurate. In such a case, it is necessary to zero the airway gauge as per the steps given below:

1. Stop Mechanical or Manual/spontaneous, connect the respiration pipeline to the breathing system, allow the patient end port of respiration pipeline to be open to the atmosphere, and make sure that the folded sack drops completely
2. Use a small flat screwdriver to open the latch of the airway gauge lens,and then remove it.
3. Use a screwdriver to adjust the zeroing screw, and adjust the pressure gauge pointer to zero.

4. Set the Manual/mechanical ventilation switch to its mechanical control mode.
5. Insert the Y-piece into the leak hunting plug to seal the respiratory airway.
6. Push the oxygen flush valve repeatedly to make the pressure gauge pointer swinged.
7. Remove the Y-piece from leak hunting plug and release the oxygen flush button. Then check whether or not the gauge pointer returns to zero
8. If the pointer fails to return to zero, repeat the above-mentioned procedures.
9. If pointer can return to return to zero normally, directly press the lens of airway gauge, and assemble the gauge properly. If the pointer still fails to return to zero, please contact the after-service department of the Company.

13.6 Maintain AGSS Transfer System

13.6.1 Maintain the Hose of AGSS Transfer System

Check the hose of transfer system. If there is any damage, please replace it.

13.6.2 Maintain the Filter of AGSS Transfer System

Impurities and dusts may clog the filter during using AGSS transfer system. Use the following two ways to check the filter:

- When using the filter, if the AGSS float isn't floating, the filter may be clogged.
- Place the AGSS canister at horizontal level to see whether the filter is clogged.

If the filter is clogged, please refer to section ***12.3.12 AGSS Transfer and Receiving System*** to clean or replace it.

13.7 Vacuum Suction System Maintenance

⚠Warning

- **Removal and maintenance of equipment is recommended if liquid or solids are drawn into the vacuum pump.**

13.7.1 Internal Vacuum Suction System Maintenance

Check whether the overflow cup, liquid collection bottle, filter, suction pipe and suction head are damaged. If there are any damages, make replacement in time. If the vacuum system is unable to function normally due to internal system failure of the machine, contact the manufacturer for inspection and maintenance in time.

After each use, remove all the suction pipe, filter, suction head and liquid collection bottle.

13.7.2 External vacuum suction system Maintenance

⚠Note

- **Please refer to the user manual supplied with the external vacuum suction system for Maintenance information.**

13.8 Remove the Water Accumulated in Breathing System

1. Connect inspiratory port and expiratory port with a piece of hose.
2. Set the system switch to "ON" (⊙).
3. Access the system and select **[ventilation start]** .
4. Set the Manual/Mechnical ventilation Control switch to its position "Mechanical" (⊠).
5. Make sure that adequate gas supply is available.
6. Turn on the O_2 supply, and regulate the flow to at least 10L/min.
7. Keep the ventilation mode and allow the instrument to run for approximately 1~2 hours, till the water accumulated inside the breathing system is removed.

13.9 Drain Way of Manual Drain Valve

The water accumulated in the breathing system comes from the condensation of the expiratory water vapor and the chemical reaction of the CO_2 absorbent. The lower the fresh gas flow rate is, the more water will be accumulated:

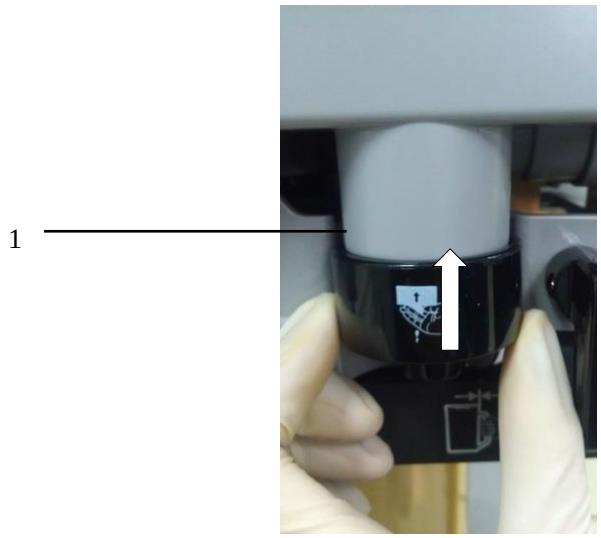
1. The more CO_2 is stored in the CO_2 canister, the more water will be produced by the chemical reaction.
2. The more moisture and expiratory gas are stored in the breathing system and the CO_2 canister, the more water will be produced by condensation.

If the water accumulated exits, it may affect the normal use of the breathing system. Please remove

the water accumulated with the manual drain valve before use again.

Please drain with the manual drain valve in the following steps:

1. Hold the manual drain valve and press upwards to open the drain valve. The water accumulated will be discharged, as shown in the right figure:



2. After the water accumulated has been discharged, release your hand, the manual drain valve will auto reset.

⚠Attention

- **After the water accumulated has been discharged, please reset the manual drain valve, and make sure that the anesthesia machine can work normally.**

Chapter 14 Accessories

⚠Warning

- **Only the accessories specified in this chapter may be used. Using other accessories may lead to incorrect measured values or equipment failure.**
- **Disposable accessories can be used only once, and their reuse may cause performance reduction or cross infection.**
- **If an accessory package or an accessory is broken, do not use it.**
- **All accessories intended to contact human body shall meet the organism compatibility required by ISO 10993-1 Standard. They shall be compatible with non-inflammable anesthesia gasses and anesthetics and are expected to cause no adverse reaction when they are exposed to human body, and they shall not work with inflammable anesthesia gasses.**
- **The discarded accessories shall be treated as per local laws and regulations, or hospital regulations, Do not throw them directly.**
- **Accessories that are not in direct contact with the human body do not require disinfection. The detailed method for disinfection of accessories directly in contact with the human body is described in the attached Manual.**
- **When the device and its accessories reach the end of their service life, they must be disposed of in accordance with the guidelines for the management of such products as well as local regulations for contaminated and biohazardous goods.**
- **To use additional bacteria filter if sample gas is to be returned to the breathing system.**

Plug-in monitoring module list

Name	Remarks	PN	model	Recommended replacement period	manufacturer
Anesthetic gas monitoring module	Masimo AG (sidestream)	115-003990-00	C-26	5 years	Shenzhen Comen Medical Instruments Co., Ltd.
	Masimo AG+O_2 (sidestream)	115-004499-00	C-28	5 years	
	Artema AG	115-004498-00	C-27	5 years	

	(sidestream)				
	Artema AG+O_2 (sidestream)	115-002238-00	C-29	5 years	
Carbon dioxide monitoring module	Masimo CO_2 (sidestream)）	115-003994-00	C-13	5 years	
	Masimo CO_2 (mainstream)	115-001861-00	C-17	5 years	
	Respironics CO_2 (mainstream)	115-003993-00	C-11	5 years	
	Respironics CO_2(sidestream)	115-003996-00	C-16	5 years	
Dual frequency index module	BIS	115-003992-00	C-31	5 years	

Plug-in monitoring module attachment list					
Accessory name	Remarks	PN	Model	Recommended replacement period	manufacturer
Anesthetic gas monitoring module accessories	MASIMO bypass CO_2/AG sampling tube	040-000017-00	CAT.NO.108210	Single use	Masimo Sweden AB
	ARTEMA DRYLINE II Adult Water Cup	040-000708-00	100-000080-00	per month	ARTEMA Technology
	ARTEMA DRYLINE II Children's Water Cup	040-000709-00	100-000081-00	per month	
	ARTEMA DRYLINETM ™	040-000710-00	60-152	Single use	

	Adult Gas Sampling Tube (2.5M)		00-00		
	ARTEMA DRYLINETM ™ Child Gas Sampling Tube (2.5M)	040-000711-00	60-153 00-00	Single use	
Carbon dioxide monitoring module accessories	MASIMO mainstream CO_2 external module	099-000006-00	CAT.NO.200101	5 years	Masimo Sweden AB
	MASIMO mainstream CO_2/AG adapter	040-000216-00	CAT.NO.106220	Single use	
	MASIMO mainstream CO_2/AG adapter	040-000217-00	CAT.NO.106260	Single use	
	MASIMO sidestream CO_2/AG sampling tube	040-000017-00	CAT.NO.108210	Single use	
	Respironics mainstream CO_2 external module	099-000005-00	REF:1015928	5 years	RespironicsNovametrix，LLC
	Respironics mainstream adult airway adapter	040-000021-00	REF:6063-00	Single use	
	Respironics mainstream neonatal airway adapter	040-000022-00	REF:6312-00	Single use	
	Respironics Sidestream child/adult airway	040-000024-00	REF:3473ADU-00	Single use	

	adapter (with dehumidification tube)				
	Respironics Sidestream child/baby airway adapter (with dehumidification tube)	040-000026-00	REF:3473INF-00	Single use	
Dual Frequency Index Module Accessories	COVIDIEN BIS module	099-000132-00	186-0195-SF	5 years	Covidienllc
	BIS adult 4-electrode sensor	040-000630-00	186-0106	Single use	
	BIS child electrode	040-001145-00	186-0200	Single use	
Oxygen Sensor	\	040-000196-00	MOX-3	1 year	City Technology Ltd.

Anesthesia breathing circuit and accessories list					
Name	Remarks	PN	model	Recommended replacement period	manufacturer
Anesthesia circuit	Rubber Breathing Bag (Latex Free, 0.5L)	040-001027-00	504-012	Single use	Vincent Medical (Donggua n) Mfg. Co. Ltd.
	Rubber Breathing Bag (Latex free, 1 L)	040-001028-00	504-012	Single use	
	Rubber Breathing Bag (Latex free, 2 L)	040-001029-00	504-012	Single use	
	Rubber Breathing Bag (Latex free,	040-001030-00	504-012	Single use	

	3 L)				
	Disposable adult bellows kit	040-000272-00	504-001	Single use	
	Disposable Pediatric Bellows Kit	040-000273-00	504-002	Single use	
Anesthesia breathing tube set	Reusable adult breathing tube(150cm)	040-001016-00	9014-08	1 year	VADI MEDICAL TECHNOLOGY CO., LTD
	Reusable pediatric breathing tube(150cm)	040-001017-00	9013-08-01	1 year	
	Reusable adult breathing tube(120cm)	040-001019-00	9014-06	1 year	
	Reusable pediatric breathing tube(120cm)	040-001020-00	9013-06-01	1 year	
	Y-type connector (adult, without sampling port)	040-001001-00	G-311030	1 year	
	L-connector (adult)	040-001002 -00	G-311025	1 year	
	Y-type connector (pediatric, with sampling port)	040-001003-00	G-313005-11	1 year	
	Straight connector (pediatric)	040-001004-00	G-311003-3	1 year	
Pipeline assembly	High temperature Y-type connector	040-000275-00	73001	1 year	GaleMed Medical

Pipeline assembly	High temperature L-type connector	040-000274-00	72201	1 year	
Pipeline assembly	Rubber bag (3L)	040-000501-00	70140	Single use	
Oxygen mask	Soft silicone mask (big pediatric 1 #)	040-000697-00	5121	1 year	
	Soft silicone mask (pediatric 2#)	040-000283-00	5122	1 year	
	Soft silicone mask(big pediatric 5#)	040-000286-00	5135	1 year	
Pipeline assembly	Reusable adult breathing tube(120cm)	040-000703-00	38006	1 year	
Oxygen mask	Inflatable anesthesia mask(big pediatric 1 #, disposable)	040-000700-00	5312	Single use	
	Inflatable anesthesia mask (pediatric 2#, disposable)	040-000288-00	5313	Single use	
	Inflatable anesthesia mask (big pediatric 3#, disposable)	040-000701-00	5314	Single use	
	Inflatable anesthesia mask (adult 4#,	040-000702-00	5315	Single use	

	disposable)				
	Inflatable anesthesia mask (big adult 5#, disposable)	040-000291-00	5316	Single use	
Anesthesia mask	Silicon round face mask#0	040-001010-00	S-100-0	1 year	VADI MEDICAL TECHNOLOGY CO., LTD
	Silicon round face mask #1	040-001011-00	S-100-1	1 year	
	Silicon round face mask #2	040-001012-00	S-100-2	1 year	
	Silicon round face mask #3	040-001013-00	S-100-3	1 year	
	Silicon round face mask #4	040-001014-00	S-100-4	1 year	
	Silicon round face mask #5	040-001015-00	S-100-5	1 year	
	Inflatable mask#0	040-001031-00	6001	Single use	
	Inflatable mask#1	040-001032-00	6002	Single use	
	Inflatable mask#2	040-001033-00	6003	Single use	
	Inflatable mask#3	040-001034-00	6004	Single use	
	Inflatable mask#4	040-001035-00	6005	Single use	
	Inflatable mask#5	040-001036-00	6006	Single use	
Vacuum suction	Filter of suction equipment	082-000226-00	FILTM-01	Single use	Gentec (Shanghai) Corporation
	Suction tube of suction equipment	082-000227-00	ST8-4	Single use	

Chapter 15 Installation and Specifications

15.1 System Gas Circuits

15.1.1 Gas Circuit Diagram

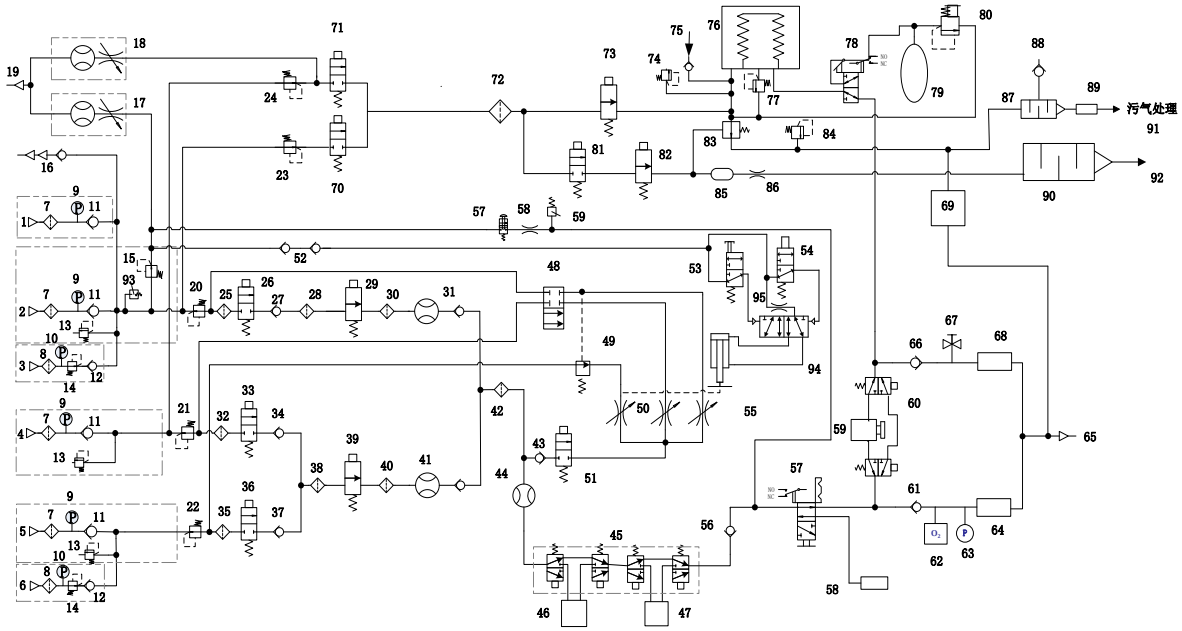


Fig. 15-1 Gas Circuit Diagram

Serial No.	Description	Serial No.	Description
1	Pipeline oxygen inlet	51	Two-way two-port electromagnetic valve (always on)
2	Pipeline oxygen inlet	52	Check valve
3	Oxygen cylinder inlet	53	Hand control valve (mechanical)
4	Pipeline air inlet	54	Two-way three-port electromagnetic valve
5	Pipeline nitrous oxide inlet	55	Cylinder
6	Nitrous oxide cylinder inlet	56	Check valve

7	Filter	57	ACGO
8	Filter	58	ACGO outlet
9	Pipeline gas pressure sensor	59	Absorption tank
10	Gas cylinder pressure sensor	60	by-PASS
11	Check valve	61	Suction check valve
12	Check valve	62	Oxygen sensor
13	Safety valve (0.7MPA)	63	Airway pressure gauge
14	Pressure regulating valve (0.4MPA)	64	Suction flow sensor
15	Pressure regulating valve (0.2MPA)	65	Patient
16	Self-closing check valve connector	66	Exhalation check valve
17	Tubular flow meter (0-15L/min)	67	Drain valve
18	Tubular flow meter (0-15L/min)	68	Expiratory flow sensor
19	Gas nozzle	69	Module exhaust channel
20	Pressure regulating valve (0.2MPA)	70	Tree-way two-port electromagnetic valve (always on)
21	Pressure regulating valve (0.2MPA)	71	/
22	Pressure regulating valve (0.2MPA)	72	Filter
23	Pressure regulating valve (0.2MPA)	73	Electromagnetic proportional valve
24	Pressure regulating valve (0.2MPA)	74	Safety valve (100cmH_2O)
25	Filter	75	Negative pressure valve (-6cmH_2O)
26	Two-way two-port electromagnetic valve (always off)	76	Bellows
27	Check valve	77	pop-off valve

28	Filter	78	Manual machine control
29	Electromagnetic proportional valve	79	Manual bag
30	Filter	80	APL valve
31	Flow sensor	81	Two-way two-port electromagnetic valve (always off)
32	Filter	82	Electromagnetic proportional valve
33	Two-way two-port electromagnetic valve (always off)	83	Peep valve
34	Check valve	84	Safety valve (10cmH_2O)
35	Filter	85	Gas capacity
36	Two-way two-port electromagnetic valve (always off)	86	Gas resistance
37	Check valve	87	Gas capacity base
38	Filter	88	Negative pressure valve
39	Electromagnetic proportional valve	89	30 external cone connectors
40	Filter	90	Silencing gas capacity
41	Flow sensor	91	AGSS
42	Filter	92	Atmosphere
43	Check valve	93	Pressure switch (0.2MPA)
44	Tubular flow meter (0-15L/min)	94	Two-way five-port bistable mechanical valve
45	Evaporator seat	95	Throttle valve
46	Evaporator	96	/
47	Evaporator	97	Check valve
48	Manual machine control	98	Check valve
49	Oxygen and nitrous oxide cut-off valve	99	Flow sensor

50	Needle valve for oxygen, nitrous oxide and air	100	

15.1.2 Gas Supply

Gasses are delivered from gas supplies to the system through connected pipeline or gas cylinders. Pipeline gas supplies include 3 types i.e. O_2 N_2O and AIR, they enter into the system respectively through pipeline gas supply ports 1, 2,4,5, and their operating pressure measured at the flowmeter front-end is 200kPa. Backup cylinder gas supplies include 3 types i.e. O_2, AIR and N_2O(only allow to select two of the three gases. Oxygen and nitrous oxide are taken as the examples in the figure below), they enter into the system respectively through backup-cylinder gas supply ports3 and 6. Their ranges of operating pressure are respectively 6.9 ~15 Mpa and 4.2~6Mpa, and are reduced to 300 ~500kPa by pressure regulat or 14. Each type of port is provided with a clear flag and is capable of anti-misplug function to prevent users from connect gas supplies incorrectly. Insides of all ports are fitted with filter and check valve, and pressure gauges with color codes are used to display the pressure pipeline gas supplies and backup cylinders. Pressure relief valve 13 is used to avoid too high input pressure of gas supplies.

All connections are fitted with flagged gas-supply inlet port connectors, filters and check valves. Pressure gauge displays the pressure of gas cylinders and pipelines. Regulator can reduce the gas cylinder pressure to a proper systemic pressure. Pressure relief valve can assist to protect the system from being damaged by high pressure.

To Avoid Gas Supply Problems:

- Connections of all air cylinders are fitted with collar clamp plugs.
- When supply pipelines are connected, keep the gas cylinder valves in their OFF position.
- When the system is not in use, cut off the gas supply lines.

⚠Warning

- **When pipeline gas supply is in use, do not set the cylinder valve to "ON". Cylinder gas supply will exhaust. In such a case, gas supplies may be inadequate when a pipeline fault occurs.**

15.1.3 O_2 Flow

O_2 is directly transmitted to the O_2 channel of gas mixer at line pressure or regulated gas cylinder pressure. O_2 may be also directly transmitted to the respiration machine if O_2 is set as driving gas. If the pressure is too low, alarm may be displayed in the display screen. Secondary controller may reduce the pressure of quick charging valve and auxiliary O_2 supply flowmeter.

When O_2 button is pushed to start O_2 charging, quick charging valve may provide high O_2 flow (between 25 and 75l/min) to the fresh gas outlet.

15.1.4 Air and N_2O

Air is directly transmitted to the air passage of gas mixer at line pressure or regulated gas cylinder pressure. Air may also be directly transmitted to the respiration machine if air is set as driving gas. If the air pressure is too low, alarm may be displayed in the display screen. N_2O may be directly transmitted to the N_2O channel of gas mixer at pipeline pressure or regulated gas cylinder pressure. When oxygen pressure is too low, N_2O flow may be interrupted, and the oxygen pressure may not impact the air.

⚠Warning

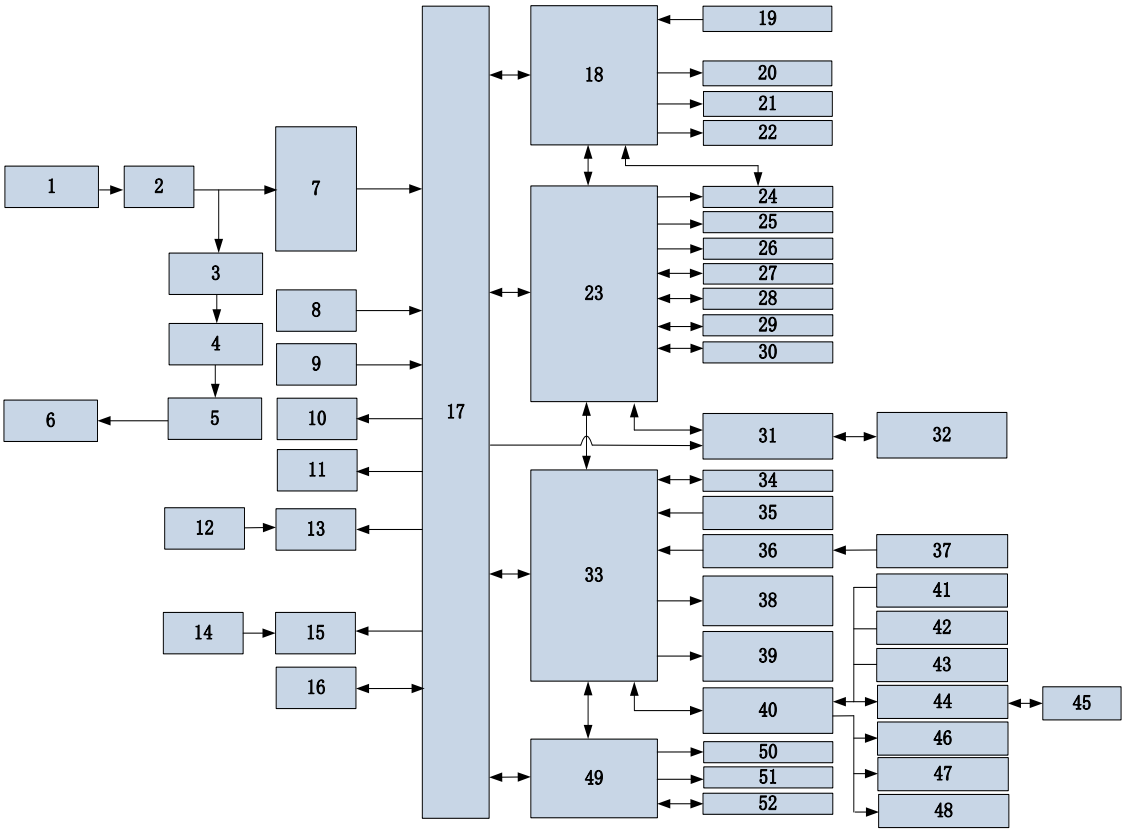
- **When the pressure of O_2 supply is lower than 100 kPa, N_2O supply is automatically cut off by O_2-N_2O cut-off valve, but the air supply will not be affected.**

15.1.5 Mixed Gas

Mixed gas passes through the flowmeter outlet and Anesthesia Vaporizer that is set to its ON position, flows toward the fresh gas outlet, and enters into the breathing system. Pressure relief valve is set to the maximum outlet pressure.

15.2 Electrical Connections

15.2.1 Electrical Circuit Diagram



15.2.2 Component List

No.	Component	No.	Component
1	AC input filter socket	27	SD card
2	Fuse	28	USB1
3	Isolation transformer board	29	Network connector
4	Isolation transformer	30	VGA
5	Breaker	31	Infrared relay board
6	AC auxiliary output socket	32	CO_2/AG/BIS Plug-in module
7	AC/DC power switch	33	Monitoring board
8	Lithium battery	34	Calibration serial port
9	System switch	35	Switch signal 1
10	Power fan	36	O_2 sensor adaption board
11	Isolation transformer fan	37	O_2 sensor
12	Flowmeter backlight switch	38	Zero valve, proportional valve, safety valve

No.	Component	No.	Component
13	Single tube flowmeter backlight board	39	AIR、O_2 source driven selector valve
14	Workbench lighting switch	40	Sensor board
15	Workbench lighting board	41	Switch signal 2
16	Circuit Heater	42	Pipeline pressure sensor
17	DC/DC power board	43	Cylinder pressure sensor
18	Keyboard	44	Sensor signal adaption board
19	Shuttle	45	Flow sensor
20	Indicator light	46	Mechanical/Electronic flowmeter selector valve
21	Alarm light	47	O_2、N_2O、AIR gate valve
22	Buzzer	48	Proportional valve
23	Main control board 1	49	Main control board 2
24	LCD screen 1	50	LCD screen 2
25	Touch screen 1	51	Touch screen 2
26	Alarm speaker	52	USB2

15.3 IEC 60601-1(GB9706.1) Applied Standard for Classification and Components of Products

Anesthesia machine System Classification:

Classified by category of anti-electric shock	Class I, Device With Internal Power Supply, Normal Mobile Device
Classified by degree of anti-electric shock	Defibrillation-proof Type BF Apply Part
Defibrillation-proof recovery time	BIS: < 30 s; Others: <5 s
Classified by the safety degree under coexistence of flammable anesthetic gas and air or oxygen or nitrous oxide	Not suitable to apply in the place with flammable anesthetic gas
Classified by the work mode	Continuous-working Device
Classified by degree of water proof	IPX0 Type
Applicable standard	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-9, ISO 80601-2-13, IEC 60601-2-26, ISO 10079-3

The anesthesia machine is integrated with pressure limit device, expiratory gas volume monitor, breathing system equipped with alarm system, pressure measurement device,

anesthesia breather system, vacuum suction system,anesthesia gas delivery device, anesthesia respiration machine, O_2 monitor and CO_2 monitor,and it can be installed anesthesia-gas purification/transfer and receiving system. Where:

- AX-900 and AX-900A anesthesia machines conform to the standard of ISO 80601-2-13;
- Pressure limit device, expiratory gas volume monitor and breathing system equipped with an alarm system conform to Standard IEC 60601-2-13(GB 9706.29);
- Pressure measurement device and anesthesia ventilation system conform to Standard ISO 80601-2-13 and YY 0635.1;
- Anesthesia gas purification, transfer and receiving system conforms to Standard ISO 80601-2-13 and YY 0635.2;
- vacuum suction system conforms to Standard ISO 10079-3 and YY 0636.3;
- Anesthesia gas delivery device conforms to the Standard ISO 80601-2-13 and YY 0635.3;
- Anesthesia respiration machine conforms to Standard ISO 80601-2-13 and YY 0635.4;
- CO_2 monitor conforms to Standard ISO 80601-2-55 and YY0601;
- Alarm system conforms to Standard IEC 60601-1-8 and YY 0709;
- Anesthesia concentration analyzer conforms to Standard ISO 80601-2-55 and YY0601.

15.4 Power Supply

AC mains				
Input voltage	220-240V~			
Input frequency	50/60 Hz			
Input power	3.5 A			
Fuse	T10 AL/250V			
Auxiliary power supply (4-Way)				
Output voltage	220 to 240 V	220 to 240 V	220 to 240 V	220 to 240 V
Output frequency	50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz
Total max output power	2.2A			

AC mains	
Input voltage	100-127 ~
Input frequency	50/60 Hz
Input power	7.0-6.0 A

Fuse	T10 AL/250 V			
Auxiliary power supply (4-Way)				
Output voltage	100 to 127 V	100 to 127 V	100 to 127 V	100 to 127 V
Output frequency	50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz
Output power	4.0A	4.0A	4.0A	4.0A
Total max output power	4.5A			

⚠Warning

- **The system connected with auxiliary power must be certified by the designated IEC standards (e.g. IEC 60950 Data Processing Equipment Standard and IEC 60601-1 Medical Equipment Standard).**
- **The device provides four power sockets for auxiliary equipment of anesthetic systems (eg, evaporator， gas analyzer), do not connect other devices with the sockets, it may effect the patient's leakage current. Overload is not allowed.**

Internal battery	
Number of battery	1piece
Battery Type	Li-ion battery
Rated battery voltage	11.1VDC
Battery capacity	7000mAh
Shutdown delay	At least 30min (when a fully-charged new battery is used, shutdown takes place within 30 minutes after the first low battery alarm is given)
Minimum power-on time	120 min (when a new fully-charged battery is used, at ambient temperature 25ºC)
Charging time	Approximately 6h (running mode or standby mode)

15.4.1 Power Cord

Length： 5m

Voltage Rating： 100 -240V~

Current capacity： 10A for 220-240V~

15A for 100 -127V~

Type： Three wire power cord (medical grade where required)

15.5 Specifications for CO_2 and AG modules

15.5.1 Specifications of MASIMO™ (CO_2, AG) sidestream gas analyzer

Detection method: infrared gas detection (infrared sensor)

1. General

Description	Compact, low-flow sidestream gas analyzers with integrated pump, zeroing valve and flow controller.
Operating temperature	CO2: 0 to 50 °C (32 to 122 °F) OR+/AX+: 5 to 50 °C (41 to 122 °F)
Storage temperature	−40 to 70 °C (−40 to 158 °F)
Operating humidity	< 4 kPa H2O (non-condensing) (95 %RH at 30 °C)
Storage humidity	5 to 100 %RH (condensing)2 (100 %RH at 40 °C)
Operating atmospheric pressure	525 to 1200 hPa (corresponding to a max altitude of 5211 m / 17100 feet)
Storage atmospheric pressure	200 to 1200 hPa (corresponding to a max altitude of 11760 m / 38 600 feet)
Ambient CO2	≤ 800 ppm (0.08 vol%)
Mechanical robustness	CO2: Meets the impact and vibration requirements for transport of EN ISO 80601-2-55:2011 clause 201.15.3.5.101.2 and EN 1789:2007 clause 6.3.4.2. OR+/AX+: Meets the impact and vibration requirements of EN ISO 80601-2-55:2011 clause 201.15.3.5.101.1
Power supply	4.5 to 5.5 VDC, CO2: < 1.4 W (normal op.), < 1.8 W (peak @ 5 VDC) AX+: < 1.6 W (normal op.), < 2.0 W (peak @ 5 VDC) OR+: < 2.0 W (normal op.), < 2.4 W (peak @ 5 VDC)
Recovery time after defibrillator test	Unaffected
Water handling	Nomoline Family sampling lines with proprietary water removal tubing.
Sampling flow rate	50 ± 10ml/min

2. Data output

Breath detection	Adaptive threshold, minimum 1 vol% change in CO2 concentration.

Respiration rate	0 to 150 ± 1 breaths/min
Fi and ET	Fi and ET are displayed after one breath and have a continuously updated breath average. ET will typically decrease below nominal value (ETnom) when respiration rate (RR) exceeds the RR threshold (RRth) according to the following formulas: CO2 CO2 ET=ETnom×(125RR⁄) for RRth >125 OR+/AX+ CO2 ET=ETnom×√(70RR⁄) for RRth >70 N2O, O2, DES, ENF, ISO, SEV ET=ETnom×√(50RR⁄) for RRth >50 HAL ET=ETnom×√(35RR⁄) for RRth >35
Automatic agent identification	OR+/AX+: Primary and secondary agent.

3. Gas Analyzer

Sensor head	2 to 9 channel NDIR type gas analyzer measuring at 4 to 10 μm. Data acquisition rate 10 kHz (sample rate 20 Hz / channel). O2 measurements by Servomex's paramagnetic sensor.
Compensations	CO2: Automatic compensation for pressure and temperature. Manual compensation for broadening effects on CO2. OR+/AX+: Automatic compensation for pressure, temperature and broadening effects on CO2.
Calibration	No span calibration is required for the IR bench. An automatic zeroing is performed 1 to 3 times per day.
Warm-up time	CO2: < 10 seconds (Concentrations reported and full accuracy) OR+/AX+: < 20 seconds (Concentrations reported, automatic agent identification enabled and full accuracy)
Rise time(10% to 90%)	$CO_2 \leq 200$ ms (ISA OR+/AX+ : ≤ 250 ms) ; $N_2O \leq 350$ ms; ENF, ISO, SEV, DES, HAL ≤ 350 ms; $O_2 \leq 450$ ms;
Primary agent threshold (OR+/AX+)	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol%
Secondary agent threshold (OR+/AX+)	0.2 vol% + 10% of total agent concentration
Agent identification time (OR+/AX+)	< 20 seconds (typically < 10 seconds)
Total system response time	CO2 < 3 seconds

	OR+/AX+ < 4 seconds (with 2 m Nomoline Airway Adapter Set sampling line)

4. Gas

The accuracy of all detected values meet the requirements of ISO 80601-2-55 and EN 864:1996.

Accuracy for standard conditions The following accuracy apply to a dry gas at 22±5°C and 1013±40hPa.

1) Accuracy –standard conditions(the range and accuracy of masimo AG as follow)

Gas	Range	Accuracy
Carbon dioxide	0 to 15vol% 15 to 25vol%	± (0.2 vol%+2%of reading) Not specified
nitrogen monoxide	0 to 100 vol%	± (2 vol%+2%of reading)
HAL, ENF, ISO	0 to 8 vol% 8 to 25 vol%	± (0.15 vol%+5%of reading) Not specified
SEV	0 to 10 vol% 10 to 25 vol%	± (0.15 vol%+5%of reading) Not specified
DES	0 to 22 vol% 22 to 25 vol%	± (0.15 vol%+5%of reading) Not specified
Oxygen	0 to 100 vol%	± (1 vol%+2%of reading)

2) Accuracy –all conditions

Gas	**Accuracy**
CO2	±(0.3 kPa + 4% of reading)
N2O	±(2 kPa + 5% of reading)
Agents	±(0.2 kPa + 10% of reading)
O2	±(2 kPa + 2% of reading)

Total system response time: CO2 ＜ 3s OR+/AX+ ＜4s

Breath detection: adaptive threshold value, minimum CO2 concentration change is 1vol%

Breath frequency: 0-150 times/minute

Threshold value of Anesthetic gases: main Anesthetic gas (OR+/AX+):0.15 vol% When an Anesthetic gas is marked, its concentration will be reported even if it is below 0.15 vol%.

5. Impact of interfering gases and water vapor

Gases or water vapor	Gas concentration	Carbon dioxide		Anesthetic gas	nitrogen monoxide
		Carbon dioxide	AX+		
nitrogen monoxide [4)]	60 vol%	_[2)]	_[1)]	_[1)]	_[1)]
HAL4)	4 vol%	_[1)]	_[1)]	_[1)]	_[1)]
Enflurane, isoflurane, sevoflurane	5 vol%	+8% of the reading 3)	_[2)]	_[1)]	_[1)]
Desflurane	15 vol%	+12% of the reading 3)	_[1)]	_[1)]	_[1)]
Xe(xenon)	80 vol%	-10% of the reading 3)		_[1)]	_[1)]
He(helium)	50 vol%	-6% of the reading 3)		_[1)]	_[1)]
Quantitative spray	Quantitative spray				
C2H50H(ethanol)	0.3 VOI%	_[1)]	_[1)]	_[1)]	_[1)]
C3H70H(isopropanol)	0.5 VOI%	_[1)]	_[1)]	_[1)]	_[1)]
CH3COCH3(acetone)	1 vol%	_[1)]	_[1)]	_[1)]	_[1)]
CH4(methane)	3 vol%	_[1)]	_[1)]	_[1)]	_[1)]
CO(carbon monoxide)	1 vol%	_[1)]	_[1)]	_[1)]	_[1)]
CO(nitric oxide)	0.02 vol%	_[1)]	_[1)]	_[1)]	_[1)]
Oxygen	100 vol%	_[2)]	_[2)]	_[2)]	_[2)]

Note 1: The abovementioned “Accuracy – all conditions” includes all negligible interferences and impacts.

Note 2: The abovementioned “Accuracy – all conditions” includes negligible interferences and impacts when concentrations of nitrogen monoxide and oxygen are correctly set.

Note 3: Interferences at specified gas concentrations. For example, 50 vol% helium can lower the carbon dioxide reading by 6%. That is to say, when a gas mixture with 5.0 vol% carbon dioxide and 50 vol% nitrogen is detected, the reading of carbon dioxide concentration is normally (1-0.06)* 5.0 vol%=4.7 vol% carbon dioxide.

15.5.2 MASIMO（CO_2）Mainstream Analyzer Specifications

Name	**Specifications**
$EtCO_2$ complies with the requirements of standard YY0601	
$EtCO_2$ specification of Masimo (Mainstream)	
CO_2 measurement range	0mmHg~190mmHg,0~25%(at760mmHg)

CO_2 resolution	1mmHg or 0.1kPa or 0.1%
CO_2 accuracy	All conditions： ±(0.3kPa+4% of the readings)
Total system response time	<1s
Respiration rate	0~150rpm
Whether there is automatic barometric pressure compensation	Configuration
Warm up time	10s

15.5.3 $EtCO_2$ specification of Respironics

$EtCO_2$ specification of Respironics (Mainstream)		**$EtCO_2$ specification of Respironics (Sidestream)**
CO_2 measurement range	0~150 mmHg 0%～19.7% 0~20.0kPa (at760 mmHg)	0~150 mmHg 0%～19.7% 0~20.0kPa (at760 mmHg)
CO_2 resolution	1mmHg or 0.1kPa or 0.1%	1mmHg or 0.1kPa or 0.1%
CO_2 accuracy	Should be ± 0.3% at 0%～5.3%; Should be ± 5% of the reading at 5.4%～9.2%; Should be ± 8% of the reading at 9.3%～13.2%; Should be ± 10% of the reading at 13.3%～19.7%;	Should be ± 0.3% at 0%～5.3%; Should be ± 5% of the reading at 5.4%～9.2%; Should be ± 8% of the reading at 9.3%～13.2%; Should be ± 10% of the reading at 13.3%～19.7%;
Sampling flow velocity	/	50±10 ml/min
Sampling Rate	100Hz	100Hz
$ETCO_2$ Calculation	Method: Peak of the expired CO_2 waveform Selections: 1 breath, 10 second, 20 second Note: the minimum reported	**LoFlo sidestream:**Method: Peak of the expired CO_2 waveform Selections: 1 breath, 10 second, 20 second **CapnoTrak sidestream:** Range: 0, 5 to 99 mmHg Method: Peak of the expired CO_2 waveform over

	differential value between the baseline and the CO_2 value shall be 5 mmHg.	selected time period. Minimum of 5 mmHg between peak and valley of waveform required. Time Period Selections: 10 second, 20 second
$ETCO_2$ and Respiration rate accuracy method	/	**CapnoTrak sidestream:**$ETCO_2$ and Respiration Rate accuracy is verified by using a solenoid test setup to deliver a square wave of known CO_2 concentration to the device. 5% and 10% CO_2 concentrations were used and respiration rate was varied over the range of the device. Pass/Fail criteria was a comparison of the respiratory rate output from the sensor to the frequency of the square wave. $EtCO_2$ measurements at those rates were compared to the CO_2 readings under static flow conditions.
Respiration Rate Calculation	Range: 0 to 150 breaths per minute (BPM) Accuracy: ± 1 breath	**CapnoTrak sidestream:Range:** 0, 2 to 100 breaths per minute (br/m) Accuracy: ± 1 breath per minute Method: 8 breath averaging
Total system response time	<1s	**LoFlo sidestream:** <4seconds - includes transport time and rise time(Typical rise time:250ms) **CapnoTrak sidestream:**Less than 4 seconds. Includes transport time and rise time with water filter assembly and airway adapter.(Up to an additional 3 seconds for sidestream sampling cannulas with dehumidification and extension tubing)
CO_2 Rise Time	/	**CapnoTrak sidestream:**Less than 340ms.(Up to an additional 70ms for sidestream sampling cannulas with dehumidification and extension tubing)
Warm up time	2min	/
Whether there is automatic barometric pressure compensation	None	/

15.5.4 Artema AG gas analysis Specification

Gas	Range	Accuracy
SEV	0 to 1vol% 1 to 5vol% 5 to 8vol%	±0.15 vol % ±0.2 vol % ±0.4 vol %
DES	0 to 1 vol% 1 to 5 vol% 5 to 10 vol% 10 to 15 vol% 15 to 18 vol%	±0.15 vol % ±0.2 vol % ±0.4 vol % ±0.6 vol % ±1 vol %
HAL/ISO/ENF	0 to 1 vol% 1 to 5 vol%	±0.15 vol % ±0.2 vol %
N_2O	0 to 20 vol% 20 to 100 vol%	±2 vol % ±3 vol %
O_2	0 to 25 vol% 25 to 80 vol% 80 to 100 vol%	±1 vol % ±2 vol % ±3 vol %
CO_2	0 to 1 vol% 1 to 5 vol% 5 to 7 vol% 7 to 10 vol%	±0.1 vol % ±0.2 vol % ±0.3 vol % ±0.5 vol %

15.6 BIS module specifications

15.6.1 BIS module specifications

Name	Specification
BIS measurement range and accuracy	BIS：0.0~100.0 SQI：0.0~100.0% EMG：0~100dB ESR:0.0~100.0%

15.7 EMC and Radio Management Compliance

Anesthesia machine AX-900 and AX-900A conform to EMC Standard IEC 60601-1-2.

⚠Caution

- **Anesthesia machines AX-900 and AX-900A meet the requirement of electromagnetic compatibility in IEC60601-1-2.**
- **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 Anesthesia machines AX-900 and AX-900A performance, so Anesthesia machines AX-900 and AX-900A should be kept away from them during using.**
- **Guidance and manufacturer's declaration stated in the appendix.**

⚠Warning

- **Anesthesia machines AX-900 and AX-900A should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Anesthesia machines AX-900 and AX-900Ashould be observed to verify normal operation in the configuration in which it will be used.**
- **When the plug-in slot is plugged into any one of the three modules, Masimo CO_2 (mainstream), Respironics CO_2 (mainstream) and BIS, EMC is of Class A. When the plug-in slot is not plugged into these three modules, EMC is of Class B.**

Table 1

Guidance and manufacturer's declaration –electromagnetic emissions		
The Anesthesia machines AX-900 and AX-900A is intended for use in the electromagnetic environment specified below. The customer or the user of the SECP-II should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Anesthesia machines AX-900 and AX-900A 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 CISPR 11	Class B	The Anesthesia machines AX-900 and AX-900A) is suitable for use in all establishments other than domestic

Harmonic emissions IEC 61000-3-2	Class A	and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The Anesthesia machines AX-900 and AX-900A is intended for use in the electromagnetic environment specified below. The customer or the user of the Anesthesia machines AX-900 and AX-900A 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	±8 kV contact ±2,4,8,15 kV air	± 8 kV contact ± 2,4,8,15 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	Mains 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	± 1 kV differential 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 IEC 61000-4-11	<5 % *U*T (>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 s	<5 % *U*T (>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 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Anesthesia machines AX-900 and AX-900A requires continued operation during power mains interruptions, it is recommended that the Anesthesia machines AX-900 and AX-900A be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity			
The Anesthesia machines AX-900 and AX-900A is intended for use in the electromagnetic environment specified below. The customer or the user of the Anesthesia machines AX-900 and AX-900A 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	3Vrms (emf), 6Vrms (emf) in ISM and amateur radio bands 150kHz to 80MHz 10V/m 80MHz to 2.7GHz	3Vrms (emf), 6Vrms (emf) in ISM and amateur radio bands 10V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Anesthesia machines AX-900 and AX-900A, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 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: 
NOTE 1 At 80MHz and 800MHz, 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.			

[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 VT 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 Anesthesia machines AX-900 and AX-900A is used exceeds the applicable RF compliance level above, the Anesthesia machines AX-900 and AX-900A)should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Anesthesia machines AX-900 and AX-900A.

[b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 6V/m.

Recommended separation distances between portable and mobile RF communications equipment and the AX-900 and AX-900A.

The AX-900 and AX-900A is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AX-900 and AX-900A can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AX-900 and AX-900A 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 $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2{,}3\sqrt{P}$
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.

15.8 Physical Specifications

Dimensions of the Complete Machine	
Size	689mm*800mm*1400mm
Weight	128kg (standard configuration) (without anesthesia vaporizer and gas cylinder)
Maximum Bearing Weight	The maximum bearing weight of the entire machine is 210kg

Top Plate	
Maximum Bearing Weight	Maximum load-bearing of top plate is 20kg
Operational dimensions	508mm*313mm
Dimensions with Additional Accessory	508mm*313mm*380mm
Workbench	
Maximum supporting weight	Maximum supporting weight of workbench is 20kg
Operational dimensions	472mm*248mm
Dimension with Additional Accessory	472mm*248mm*380mm
Dovetail Rail	
Maximum Installation Dimension	500mm*750mm*500mm
Handrail	
Length	750mm
Drawers	
Maximum Bearing Weight	Top: 1kg Bottom: 3kg
Drawers	Top: 462mm*287mm*141mm Bottom: 437mm*287mm*245mm
Gas-bag Sway Brace	
Size	Length: 425mm Height: 240mm
Loop Hook	
Maximum Bearing Weight of Loop Hook	1kg
Caster Wheels	
Caster wheel	5 inch
Display Screen	

Type	TFT LCD, allowing touch control
Size	15 inch+8 inch
Resolution	800×600 pixels
Brightness	Adjustable
LED Indication	
AC indicator lamp	Green LED It is on when the equipment is connected to external AC power supply.
Battery indicator lamp	Green LED Battery indicator lamp is constantly on while the equipment is connected to AC power supply. When the system is powered by battery, battery indicator lamp flashes as per a frequency of 1 Hz.
Working state indicator lamp	Green LED The indicator lamp is on when the equipment is turned on. The indicator lamp is off when the equipment is turned off.
Alarm indicator lamp	1 piece (yellow, red. It only flashes in red when high-level and medium-level alarms occurs simultaneously)
Audible Indication	
Speaker	It gives out alarm tone and key-stoke tones; supports multiple-level volume function; the alarm tones conform to IEC 60601-1-8and YY 0709.
Buzzer	It may give out alarm tone in case the system cannot work normally.
Connector	
Power supply	1 AC supply connector 4 auxiliary output power-supply connectors
Equal-potential	1 equal-potential grounding terminal
Communication connectors	1 RJ45 connector 2 USB connector 1 DB9 connector 1 VGA connector

15.9 Environmental Specifications

Host			
Item	**Temperature (ºC)**	**Relative humidity (Non-condensation)**	**Atmospheric pressure (kPa)**
Work	10~40	⩽93%	70.0~106.0
Transportation and storage	–20~60 (oxygen sensor: –20~50)	⩽93%	50.0~106.0

15.10 Performance Specifications

15.10.1 Gas Circuit Specifications

Gas Supply	
Pipeline gasses	O_2,N_2O,AIR
Backup gas-cylinder gasses	O_2,N_2O,AIR
Pipeline gas connection	NIST
Backup cylinder connection	YOKE-CGA
Pressure range at inlet	280~600kPa
Filter	60-80um

15.10.2 Gas Supply

Full electronic flow meter			
Display range and accuracy	Single-pipe control	Air / nitrous oxide range:	0L/min~15L/min,the flow can be adjusted to 50ml/min
		Oxygen range:	0L/min~15 L/min,the flow can be adjusted to 50ml/min
	Total flow control	Oxygen concentration regulating range:	21%~100% (Air balance gas) 25%~100% (Nitrous oxide balance gas)
		Flow regulation range:	0L/min~18L/min,the flow can be adjusted to 50ml/min
Backup flow control			

Display range	Oxygen / nitrous oxide / air range:	0 L/min~15L/min
Total flow meter		
Display range	Type:	Float flow meter
	Range:	0~15L/min,the flow can be adjusted to 50ml/min
Auxiliary Oxygen Supply Flowmeter		
Display range	Type	Float flow-meter
	Range	0~15L/min
Hyperbaric oxygen source		
Pressure range:	280~600kPa	
Flow range:	≥90L/min	
Standby oxygen/N_2O linked system		
Type	Mechanical type proportional control device	
Range	O_2 concentration shall not be lower than 25%	

15.10.3 ACGO Connector

ACGO	
Connector	Taper coaxial fitting of 22mm (outside) and 15 (inside)
Back pressure generated at the rear end of Anesthesia Vaporizer and the front-end of ACGO during quick oxygen charging	Not greater than 2kPa

15.10.4 Rapid Oxygenation

Rapid Oxygenation	
Oxygenation	When the button of “Rapid Oxygenation” is pressed, the quick inflation valve provides the fresh gas outlet with high flow (25-75 L/min) of oxygen.

15.10.5 Breathing System Specifications

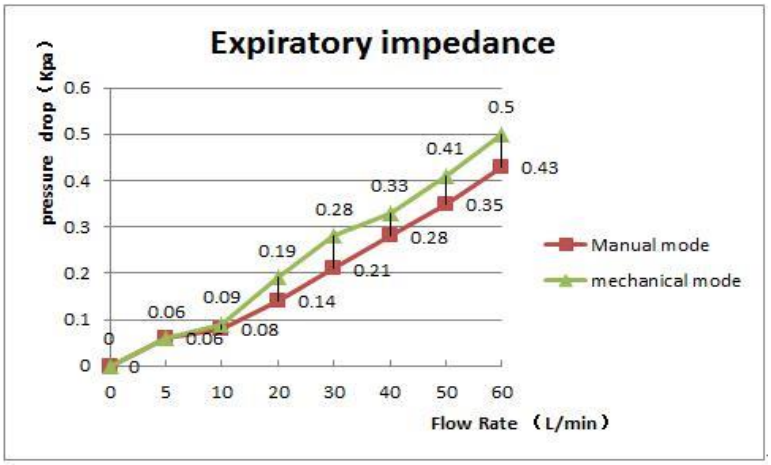
Leakage and Compliance	
Leak in breathing system and its cycle absorption assembly (including Manual/spontaneous mode and mechanical control mode)	The leakage shall not be greater than 65ml/min at 3kPa.
Compliance of breathing system and its cycle absorption assembly (manual/spontaneous mode)	Adult mode ≤4 mL/100Pa, pediatric mode ≤3 mL/100Pa
Leak in CO_2 canister	The leakage shall not be greater than 50ml/min at 3kPa.
APL valve leak	The leakage shall not be greater than 50ml/min at 3kPa (APL valve scale mark is 75)
CO_2 Absorption Apparatus	
Volume of CO_2 absorption apparatus	Approximately 2000ml
Breathing Circuit Heat	
The breathing circuit is equipped with heating function,which can effectively remove water accumulation in the circuit.	
Ports and Connectors	
Expiratory end	Taper coaxial fitting of 22mm (outside) and 15 (inside)
Inspiratory end	Taper coaxial fitting of 22mm (outside) and 15 (inside)
Manual bag end	Taper coaxial fitting of 22mm (outside) and 15 (inside)
Pressure gauge (airway)	
Range	-20~100 cmH_2O
Accuracy	± (4% of full scale reading ＋ 4% of actual reading)
APL Valve	
Range	1~75 cmH_2O
Touch indication	Great than 30 cmH_2O
Minimum opening pressure	0.3 cmH_2O (dry), 0.5 cmH_2O (humid)

Expiratory impedance	The expiratory pressure/flow rate characteristics at a fresh gas flow rate of 10±1 L/min, or the maximum fresh-gas inlet flow rate specified in the instructions for use (whichever is greater) of the Anesthetic breathing system,including the flow at 15L/min, 30L/min, 60L/min,the expiratory impedance of the breathing system should not exceed 0.6 kPa.
Inspiratory impedance	The inspiratory pressure/flow rate characteristics at a fresh gas flow rate of 10±1 L/min, or the maximum fresh-gas inlet flow rate specified in the instructions for use (whichever is greater) of the Anesthetic breathing system,including the flow at 15L/min, 30L/min, 60L/min,the Inspiratory impedance of the breathing system should not exceed 0.6kPa.

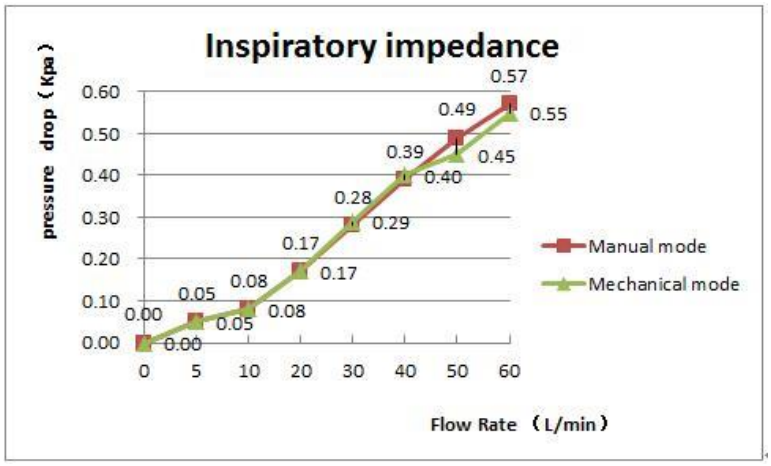
Pressure-flow Curve of APL Valve

Flow (L/min)	APL pressure CmH_2O, dry gas	APL pressure CmH_2O, humid gas
3	0.17	0.18
10	0.21	0.22
20	0.26	0.27
30	0.33	0.34
40	0.42	0.43
50	0.53	0.54
60	0.71	0.73
70	0.93	0.94

Expiratory impedance of breathing system cycle absorption assembly (CO_2 canister is filled up with "Medisord ™" CO_2 absorbent)



Inspiratory impedance of breathing system cycle absorption assembly (CO_2 canister is filled up with "Medisord ™" CO_2 absorbent)



15.11 Principle and Parameter Specifications of the Ventilator

15.11.1 Principle

The principle of this ventilator is pneumatically controlled.

Pneumatic devices of Ventilator is fitted inside the workbench of anesthesia machine. Anesthesia machine can control the gasses flowing from electromagnetic valve to the patient. During the inspiratory period, the gas flow turn off the expiratory valve and push downward the bellows. During the expiratory period, a small gas flow applies a pressure onto the expiratory flappers to provide end-expiratory positive pressure.

Volume and pressure measurements are provided by the flow sensors. Each flow sensor are connected to the monitoring module through 2 pieces of pipes. The monitoring module measures the change in pressure of gas flow that passes through the flow sensors, while pressure varies along with the flow.

Ventilator uses the values related to volumes and alarms on the basis of the data provided by the expiratory gas flow sensors. Ventilator utilizes the other inhaling flow sensor to adjust its output so as to adapt to the variance in fresh gas flow, minor gas leak, and the gas compliance of the respiration circuit. Patient circuit allows compliance compensation. To obtain further higher high accuracy, small quantity of gas conducts infiltration due to gas resistance so as to aid to maintain the constant pressure of expiratory valve.

15.11.2 Parameter Specifications

Parameter Setting Range of Ventilatior			
Parameter	**Setting range**	**Step**	**Working mode**
Plimit (Pressure limit)	0~100 cmH_2O	1 cmH_2O	VCV,SIMV-VC,PCV,SIM

			V-PC,CPAP/PSV,PRVC,PSVPro,SIMV- PRVC
Pinsp (Inspiratory pressure)	5~70 cmH_2O	1 cmH_2O	PCV,SIMV-PC,PSVPro
ΔPps(Support Pressure)	3~60 cmH_2O	1 cmH_2O	SIMV-PC,SIMV-VC,CPAP/PSV,PSVPro,SIMV-PRVC
Apnea Pressure	$3cm_2$～60cmH_2O	1 cmH_2O	CPAP/PSV
PEEP (Positive end-expiratory pressure)	OFF, 0~30 cmH_2O	1 cmH_2O	VCV,SIMV-VC,PCV,SIMV-PC,CPAP/PSV,PRVC,PSVPro,SIMV- PRVC
VT (Tidal volume)	15 mL ～ 1500 mL(VCV,SIMV-VC,SIMV-PC,CPAP/PSV,PRVC,SIMV-PRVC,PSVPro）； In the PCV mode,tidal volume can be detected to 5ml.	15~100 ml: 5 ml 100~300 ml: 10 ml 300~1500 ml: 25 ml	VCV,SIMV-VC,PRVC, SIMV- PRVC
Rate(Respiratory Rate)	4~100 bpm	1 bpm	VCV,SIMV-VC,PCV,SIMV-PC,PRVC,PSVPro,SIMV- PRVC
I:E (Inspiratory expiratory time ratio)	4:1~1:10	0.5	VCV, PCV ,PRVC
Apnea.IE(Apnea Respiratory Ratio)	4：1～1：8	0.5	CPAP/PSV
Tpause (Inspiratory Pause)	OFF, 5%~60% of inhaling time	1%	VCV, SIMV-VC
Trig window(Trigger window)	5%~90%	5%	SIMV-PC,SIMV-VC, PSVPro, SIMV-PRVC
Rate (SIMV Frequency)	4~60 bpm	1 bpm	SIMV-VC,SIMV-PC ,SIMV- PRVC
Apnea Time	10s～30s	1s	PSVPro
Exp%(Inspiratory Stop level)	5%～80%	1%	SIMV-VC,SIMV-PC, CPAP/PSV,PSVPro,SIMV-PRVC

Minrate	2～60bpm	1bpm	CPAP/PSV
Tinsp (Inspiratory time)	0.2~5.0 s	0.1 s	SIMV-VC,SIMV-PC,PSVPro,SIMV- PRVC
Trigger(Inspiratory triggering)	Pressure triggering: -20cmH_2O~-1 cmH_2O Flow rate triggering: 0.2~15 L/min	Pressure triggering: -0.5 cmH_2O Flow rate triggering: 0.1 L/min	SIMV-VC,SIMV-PC,CPAP/PSV,PSVPro,SIMV-PRVC
Tslope (Pressure slope)	0 s～2.0 s	0.1s	PCV,CPAP/PSV,PSVPrO, SIMV-VC,SIMV-PC,SIMV- PRVC

Performance of Ventilator	
Driving pressure	280~600 kPa
Inspiratory flow	Maximum inspiratory flow shall not lower than 120L/min when gas supply pressure is 280 kPa.
Range of flow valve	1~120 L/min
Pressure limit controlling means for ventilator	1. Controlled by the electronic relief valve fitted inside the ventilator; 2. Controlled by the mechanical relief valve fitted inside the ventilator.
Monitoring Parameters of Ventilator	
MV(Per-minute ventilation amount)	0~100 L/Min
VT(Inspiratory and expiratory tidal volume)	0~3000 mL
FiO_2(Oxygen concentration)	18~100%
Paw (Airway pressure)	-20~120 cmH_2O
Positive end expiratory pressure	0 cmH_2O～70 cmH_2O
Pmean(Mean pressure)	-20~120 cmH_2O
Pplat(Platform pressure)	0~120 cmH_2O
I:E(Inspiratory- expiratory ratio)	4:1~1:12
Rate (Respiratory rate)	0~120 bpm

Compl(Compliance)	0 ml/cmH_2O～300 ml/cmH_2O	
Resistance	0 cmH_2O/(L/s)～600 cmH_2O/(L/s)	
O_2 concentration of oxygen sensor	18%～100%；	
Flow control system	Main flow control system	Full electronic flow meter: ● Single-pipe control mode: Oxygen flow monitoring is within the range of 0.2 L/min to 15 L/min; Air / nitrous oxide flow monitoring is within the range of 0 L/min to 15 L/min; ● Total flow control mode: Flow monitoring is within the range of 0.2 L/min to 18 L/min; ● Backup flow control mode: Flow monitoring is within the range of 0 L/min to 15 L/min.
	Auxiliary gas flow control system	Monitoring range: 0 L/min ～ 15 L/min；
Depth of anesthesia testing and measurement	a) BIS:0.0～100.0 b) SQI:0.0～100.0% c) EMG:0～100dB d) ESR:0.0～100.0%	
Monitoring Parameters of Positive end-expiratory Pressure PEEP		
Range	0~70 cmH_2O	

15.11.3 Accuracy of Ventilator

Parameters	
VT	15 mL～60 mL：±10 mL； 60 mL～210 mL（except 60 mL）：±15 mL； 210 mL～1500 mL (except 210 mL): ± 7% of set value.

PCV	Inspiratory pressure: ± 2.5 cmH_2O or ± 7% of setting value, whichever is greater; Limit pressure: ± 2.5 cmH_2O or ± 7% of setting value, whichever is greater; End-expiratory positive pressure: the error is not defined at the OFF state 3 cmH_2O～30 cmH_2O: ±2.0 cmH_2O or ± 8% of setting value, whichever is greater; Support pressure: ± 2.5 cmH_2O or ± 7% of setting value, whichever is greater; Apnea pressure: ± 2.5 cmH_2O or ± 7% of setting value, whichever is greater; Trigger pressure: ±2 cmH_2O
Rate	±1 bpm or ±5% of the setting value, whichever is greater.
I:E and Apnea I:E	IE: 2：1～1：4：±10% of actual reading Other range: ±25% of actual reading。 Apnea I:E: Error within the range of 2：1～1：4: ±10% of the setting value, Other range: ±25% of the setting value
Tpause	Inspiratory time: ±0.2 s； Inspiratory pause: ± 15% of the set value in the range of 20% to 60%, not defined in other ranges.
Trigger window	±10%
Trigger flow rate	±1 L/min
Inspiratory Stop level	±10%

Flow control system	Main flow control system	Full electronic flow meter: Single-pipe control mode: In the case that the oxygen flow control accuracy is within 10% to 100% of the full scale, the scale accuracy shall be within ±10% of the indicated value; In the case that the air / nitrous oxide flow control accuracy is within 10% to 100% of the full scale, the scale accuracy shall be within ±10% of the indicated value; Total flow control mode: The oxygen concentration (air balance gas) control error is not greater than ±3% (V/V); the oxygen concentration (nitrous oxide balance gas) control error is not greater than ±3% (V/V); Flow control accuracy: In case of full scale within 10% to 100%, the scale accuracy shall be within ±10% of the indicated value; Backup flow control mode: The control accuracy is less than ±10% of the reading within the pure oxygen flow range of 0 L/min to 10 L/min. Other ranges are not defined.
	Auxiliary gas flow control system	When the full scale is between 10% and 100%, the accuracy of the scale should be within ± 10% of the indicated value, and the other ranges are not defined.
Measurement Parameters		
VTexp	0～60ml(excluding 60ml): ： ±10 ml； 60ml ~ 3000ml: ± 20ml or ± 7% of the actual reading, whichever is greater, the other ranges are not defined.	
Inspiratory tidal volume	± 20ml or ± 7% of the actual reading, whichever is greater, the other ranges are not defined.	
Paw	Pressure monitoring error: -20 cmH_2O～120 cmH_2O: ±2.0 cmH_2O or ± 4% of setting value, whichever is greater; the other ranges are not defined. End-expiratory positive pressure error: 0 cmH_2O～70 cmH_2O: ±2.0 cmH_2O or ± 4% of setting value, whichever is greater; the other ranges are not defined. Platform monitoring error: 0 cmH_2O～120 cmH_2O: ±2.0 cmH_2O or ± 4% of setting value, whichever is greater; the other ranges are not defined. Average pressure monitoring error: -20 cmH_2O～120 cmH_2O: ±2.0 cmH_2O or ± 4% of setting value, whichever is greater; the other ranges are not defined.	
Rate	±1 bpm or ±5% of the setting value, whichever is greater; the other ranges are not defined.	

I:E	2：1～1：4：±10% of actual reading 4：1～2：1 and 1：4～1：12 ±25% of actual reading Other ranges are not defined.	
MV	0 L/min～30 L/min: ±1 L/min or ±15% of the setting value, whichever is greater; >30 L/min: not defined.	
Compl	0 ml/cmH_2O～250 ml/cmH_2O: ±0.5 ml/cmH_2O or ± 15% of the actual reading, whichever is greater, the other ranges are not defined.	
Resistance	0 cmH_2O/(L/s) ～ 20 cmH_2O/(L/s)：±10 cmH_2O/(L/s)；20 cmH_2O/(L/s) ～ 500 cmH_2O/(L/s)：±50% of the actual reading;the other ranges are not defined.	
Flow control system	Main flow control system	Full electronic flow meter: Single-pipe control mode: In the case that the oxygen flow monitor accuracy is within 10% to 100% of the full scale, the scale accuracy shall be within ±10% of the indicated value; In the case that the air / nitrous oxide flow monitor accuracy is within 10% to 100% of the full scale, the scale accuracy shall be within ±10% of the indicated value; Backup flow control mode: within 10% to 100% of the full scale, the scale accuracy shall be within ±10% of the indicated value, and the other ranges are not defined;
	Auxiliary gas flow control system	When the full scale is between 10% and 100%, it should be within ± 10% of the indicated value, and the other ranges are not defined.
O_2 concentration of oxygen sensor	±3%（V/V），the other ranges are not defined.	

Alarm Setting			
Parameter		Setting range	Remarks
VT	High Limit	5~1600 mL	High Limit is greater than low limit
	High Limit	0~ (High Limit -5) mL	
MV	High Limit	2~100L/min	High Limit is greater than low limit
	Low limit	0~ (High Limit -2) mL	
FiO_2	High Limit	20~105%	High limit is greater than low limit
	Low limit	18~ (High Limit -2) %	
$EtCO_2$ Alarm	High alarm limit	Low limit +2mmHg～150mmHg	High limit is greater than

Preset (Respironics CO_2)	Low alarm limit	0mmHg～High limit -2mmHg	low limit
$FiCO_2$ Alarm Preset (Respironics CO_2)	High alarm limit	Low limit +1mmHg～76mmHg	High limit is greater than low limit
	Low alarm limit	0mmHg~74mmHg	
$EtCO_2$ Alarm Preset (Masimo CO_2)	High alarm limit	Low limit +2mmHg～190mmHg	High limit is greater than low limit
	Low alarm limit	0mmHg～High limit -2mmHg	
$FiCO_2$ Alarm Preset (Masimo CO_2)	High alarm limit	Low limit +1mmHg～99mmHg	High limit is greater than low limit
	Low alarm limit	0mmHg~97mmHg	
Ppeak	High Limit	2~100cmH_2O	High Limit is greater than low limit
	Low limit	0~ (High Limit -2) cmH_2O	
	Negative pressure alarm is given when airway pressure is lower than -10cmH_2O.		
Asphyxiation alarm time	20 s, with error of ±3 s		
BIS alarm limit	BIS alarm limit: 0～100 Resolution: 1 Alarm preset limit: High: 2～100,Lower: 0～98		
Alarm pause	120s		
The anesthesia system will provide a notification of a high priority alarm when the pressure of the anesthetic ventilation system exceeds the set continuous positive pressure alarm limit by (15 + 1) s.			

AG alarm range and resolution			
Parameter		Set range	Remark
$EtCO_2$	High alarm limit	(Low limit +2mmHg)～190mmHg	Upper limit greater than lower limit
	Low alarm limit	0mmHg～(High limit -2mmHg)	

$FiCO_2$	High alarm limit	(Low limit +2mmHg)～99mmHg	Upper limit greater than lower limit
	Low alarm limit	0mmHg～(High limit -2mmHg)	
EtN_2O	High alarm limit	(low limit + 2%) ～100 %	Upper limit greater than lower limit
	Low alarm limit	0%～(High limit - 2%)	
FiN_2O	High alarm limit	(low limit + 2%) ～100%	Upper limit greater than lower limit
	Low alarm limit	0%～(High limit - 2%)	
EtHAL/EtENF/EtISO/EtSEV/EtDES	High alarm limit	(low limit +0.2%) ～25.0%	Upper limit greater than lower limit
	Low alarm limit	0%～(High limit - 0.2%)	
FiHAL/FiENF/FiISO/FiSEV/FiDES	High alarm limit	(low limit +0.2%) ～25.0%	Upper limit greater than lower limit
	Low alarm limit	0%～(High limit - 0.2%)	

Note: * Typical conditions for accuracy measure:

Atmospheric pressure: 90~101 kPa;

Room temperature: 20 ~ 28 ºC;

Relative humidity: 50%~80%.

15.12 Principle and Specifications of Oxygen Sensors

15.12.1 Principle of Oxygen Sensor

Oxygen monitoring device may measure the oxygen concentration inside patient circuit. Oxygen concentration measured by oxygen sensor is displayed in the display screen of anesthesia machine.

Oxygen sensor is a type of electrochemical equipment. Oxygen penetrates into the battery through a diaphragm and oxidize the metal electrodes. This oxidation generates a current that is directly proportional to the oxygen partial pressure formed on the transducing surface of electric poles. Metal electrodes are progressively eliminated in the oxidation process.

For oxygen monitoring, signal processing and analysis circuit are adopted to translate battery signaling into corresponding percentage values of oxygen concentration. System displays the value, and compare it to the stored alarm limits. If the value falls outside the limits, anesthesia machine gives an appropriate alarm.

15.12.2 Specifications of Oxygen Sensors

Oxygen sensor	
Output	Output 9-13 mV at 210 mBar O_2
Expected operation life	0.94 x 10^6 % O_2 measurement time at 20°C 0.6 x 10^6 % measurement time at 40°C
Response time (from 21% air to 100% oxygen)	< 15s
Linearity	Linear 0-100% O_2
Operating temperature range	-20°C to +50°C
Thermal compensation	Fluctuation of ±2% within the range 0-40°C
Pressure range	50~200kPa
Relative humidity	0 to 99%
Output wandering at oxygen concentration 100%	Typical value< 5% (over 1 year)
Material	White ABS
Packaging	Sealed package
Period of Validity	Term of validity shall not exceed 13 months after the

	package is unpacked (under the terms defined by the manufacturer; otherwise the valid time may be somewhat different)

15.13 Specifications of AGSS Transfer and Receiving System

15.13.1 Physical parameters

Physical parameters of AGSS transfer and receiving system	
Weight	2.2Kg
Dimension	535×120×155mm（H×W×T）
Applicable laws and	ISO 80601-2-13 and YY 0635-2
Pressure relief device	Atmospheric pressure compensation port
Filter	Stainless steel mesh, with pore size of 60μm ~ 100μm
System status indication	AGSS-H: The float drops below the "MIN" mark on the viewing window when the system is not operating or when the suction flow rate is less than 50 L / min. AGSS-L: The float drops below the "MIN" mark on the viewing window when the system is not operating or when the suction flow rate is less than 25 L / min.
System connector	ISO9170-2 or BS6834 standard connector

15.13.2 Performance Parameter

Model / **Parameter**		**AGSS-H**	**AGSS-L**
Applicable for treatment system types		1H-type high-flow system: drawing flow rate not less than 75L / min	1L low-flow system: drawing flow rate 25 ~ 50L / min
Adjustable rated suction flow range		50L/min～80L/min	25L/min～50L/min
Observation window scale display		MIN tick mark, MAX tick mark	
Way of working		Continue to draw the flow, the float between the MIN and MAX tick marks	
Working mode		Continuous working system,to transfer and receive	
Under	30L / min intake flow	No more than 0.5cmH_2O	

normal conditions	impedance	
	75L / min intake flow impedance	No more than 3.5cmH_2O
	Induced flow	Not more than 50ml / min
	Rated maximum suction flow pressure drop impedance	AGSS air outlet no lower than 10cmH_2O
	Rated minimum suction flow pressure drop impedance	AGSS air outlet no lower than 20cmH_2O
	Overflow	Not more than 100ml / min
	Leakage	Under inlet air condition of 10 ± 0.5L / min , less than 90ml / min
Under single failure condition	75L / min intake flow impedance	No more than 10cmH_2O
	Induced flow	Not more than 100ml / min
	Rated maximum suction flow pressure drop impedance	AGSS air outlet pressure drop resistance no greater than 0.5cmH_2O
	Overflow	May exceed 100ml/min

15.14 Vacuum suction system specifications

15.14.1 External vacuum suction system specifications

Please refer to the user manual supplied with the external vacuum suction system for the specifications of the external vacuum suction system.

Vacuum suction system	
The performance category	high vacuum/high flow
Air source pressure range	280-550kPa
Recommended maximum negative pressure	75kPa
The largest suction tubing size	Φ8 mm

15.14.2 Internal Vacuum Suction System Specifications

Venturi vacuum suction	
The performance category	high vacuum/high flow
Maximum vacuum	In case of gas source pressure within the range of 280kPa to 600kPa, the maximum vacuum sputum excretion generated is greater than or equal to 75 kPa.
Maximum suction flow	In case of gas pressure within the range of 280kPa to 600kPa, the maximum suction flow generated is greater than or equal to 30 L/min (not configured with the liquid collection bottle and filter).

15.15 Alarm Specifications

15.15.1 The Sound Pressure Alarm

Alarm	
Range of alarm sound pressure	45dB-85dB
Peak sound pressure of high-priority alarm	82 dB
Peak sound pressure of medium-priority alarm	80 dB
Peak sound pressure of low-priority alarm	79 dB

15.15.2 Air Source Pressure Alarm

Air source pressure Alarm	
The range of air source pressure alarm	190-220kPa

15.16 AnestheticVaporizer Specifications

For the using of Draeger anesthesia vaporizer, Please refer to the Draeger anesthesia vaporizer user manual.

Chapter 16 Different types of Anesthesia Machine

<table>
<tr><td colspan="2">Model
References</td><td>AX-900A</td><td>AX-900</td></tr>
<tr><td colspan="2">TFT touch Screen size(inch)</td><td colspan="2">15+8 double screen</td></tr>
<tr><td colspan="2">Flowmeter</td><td colspan="2">Full Electronic Flowmeter</td></tr>
<tr><td colspan="2">Adjustment range of flowmeter</td><td colspan="2">Single tube range of control ：
Oxygen：0L/min～15L/min
Air/ nitrous oxide：0L/min ～15L/min
Total flow control：
21%～100%（Choose air as equilibrium gas)
25%～100%（Choose nitrous oxide as equilibrium gas)
Total flow：0.2L/min～18L/min
Standby flow control
（oxygen/nitrous oxide/air)：
0 L/min～15 L/min</td></tr>
<tr><td rowspan="2">Mode of mechanical ventilation</td><td>Standard configuration</td><td>VCV、PCV、SIMV-VC、SIMV-PC、CPAP/PSV</td><td>VCV、PCV、SIMV-VC、SIMV-PC、CPAP/PSV、PRVC</td></tr>
<tr><td>Selective configuration</td><td>PRVC、SIMV-PRVC、PSVPro</td><td>SIMV-PRVC、PSVPro</td></tr>
<tr><td rowspan="2">Gas supply and flow meter</td><td>Standard configuration</td><td colspan="2">Oxygen/Oxygen/Nitrous oxide/Air</td></tr>
<tr><td>Selective configuration</td><td colspan="2">/</td></tr>
<tr><td colspan="2">Back up gas cylinder support（selective configuration）</td><td colspan="2">Backup oxygen cylinder support, Backup oxygen-air cylinder support, Backup oxygen-nitrous oxide cylinder support</td></tr>
<tr><td>Waveform</td><td>Standard</td><td colspan="2">P-T waveform, F-T waveform, V-T waveform, $EtCO_2$ waveform, EEG waveform,</td></tr>
</table>

Model / References		AX-900A	AX-900
display	configuration	Pulmonary function(P-V，V-F，P-F)	
	Selective configuration	/	
ACGO		Selective configuration	Standard configuration
Breaker	Standard configuration	Central brake	
	Selective configuration	Foot brake	
Auxiliary Output		4 bit auxiliary output	
Anesthesia Vaporizer		It apply to nonflammable anaesthetized gas anaesthetized evaporator such as Draeger and Penlon	
Anesthesia Vaporizer tank position	Standard configuration	Double tank position	
	Selective configuration	/	
Heater		Standard configuration	
Auxiliary gas supply		Standard configuration (High pressure nitrogen source + oxygen-air mixture)	
ByPass		Selective configuration	Standard configuration
Vacuum suction system		Selective configuration (external)	Selective configuration (internal)
Isolation transformer		Selective configuration	
Oxygen battery		Selective configuration	Standard configuration
AGSS		Selective configuration	
Driving mode		Pneumatic-electronic control	
Propellant		Oxygen or Air	

Model / References	AX-900A	AX-900
Working mode	Manual、Mechanical and Standby	
MasimoCO2(Mainstream) MasimoCO2(Sidestream) Masimo AG(Sidestream) Respironics CO2(Mainstream) BIS	Selective configuration	
MasimoAG+O2Sidestream) Artema AG Artema AG+O2 Respironics CO2(Sidestream)	Selective configuration	
Monitoring parameter	[VTinsp] , [VTexp] , [MV] , [Rate] , [I：E] , [Ppeak] , [Pplat] , [PEEP] , [Pmean] , [Raw] . [Compl] , [FiO2] , [FiCO2] , Anesthetic gas concentration and Anesthesia depth	
The deictic function of optimum flow	Selective configuration	
Monitoring function for use of anesthetics (It need to configure AG module)	Selective configuration	
Cardiopulmonary bypass（CPB）	Selective configuration	

Chapter 17 Consideration for Environmentally Conscious Design

17.1 Instructions for Minimizing Environmental Impact during Normal Use

This part is compiled based on the requirements of Clause 4 Protection of Environment, 4.5.2 Instructions for minimizing environmental impact during normal use of IEC 60601-1-9.

According to the requirements of this clause, manufacturer shall provide instructions for minimizing the environmental impact of the ME equipment during normal use in the accompanying documents.

The instructions cover the following items (Table 1).

Table 1 The requirements of Clause 4.5.2 and Instructions provided by manufacturer

The requirements of Clause 4.5.2	**Instructions provided by manufacturer**
1) Instructions on how to install the ME EQUIPMENT in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;	Try to keep the integrity of the non-disposable packing material and put away the packing materials for future use or put into the specified location where complying with the rules and regulations of the Local and the Hospital. Avoid overusing the cleaning reagents and other substances. For the reusable accessories, clean it with specified reagent and put away, and for the disposable one, deal with it in a collective way and put into the specified location where complying with the rules and regulations of the Local and the Hospital. If not specified, please follow the rules and regulations of the Local and the Hospital.
2) Instructions on how to use and maintain the ME EQUIPMENT in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;	Use the specified accessories and cleaning and disinfection reagent to avoid harm to the machine and accessories and reduction of the service life. Use the medical device strictly following the instruction manual. And for maintaining the medical device, always dilute according to the manufacturer's instructions or use lowest possible concentration. Never use bleach. Do not mix disinfecting solutions

	(such as bleach and ammonia) as this may result in hazardous or poisonous gases or liquids. When there is a need to maintain, please follow the Instruction for Use or follow the rules and regulations of the Hospital.
3) Consumption during NORMAL USE (e.g. energy, consumable materials/parts, disposables, water, gasses, chemicals/reagents etc.);	During normal use of this device, it will consume electricity (alternate current and direct current-battery). The disposable electrode is also consumed and shall be disposed following the rules. For cleaning or disinfection for the cables and machine, the water and ethanol or isopropanol will be used and the waste liquid shall be thrown following the rules.
4) Emissions during NORMAL USE (e.g. WASTE water, WASTE consumable materials, acoustic energy, heat, gasses, vapours, particulates, HAZARDOUS SUBSTANCES and other WASTE);	During normal use, it is expected there will be some consumption of the medical device. To avoid unnecessary consumption such as acoustic energy, heat, gases, hazardous substances, etc, it's recommended that on the premise of normal operation, turn down the volume of alarm so that much interference will not be exerted to the environment. Also turn off the unused module in time to reduce the unnecessary heat emission and electricity consumption.
5) Information on the location within the ME EQUIPMENT of HAZARDOUS SUBSTANCES, radioactive sources and induced radioactive materials.	The battery is located on the back of the machine. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.

17.2 Information for End of Life Management

This part is compiled based on Clause 4 Protection of Environment, 4.5.3 Information for end of life management of IEC 60601-1-9.

According to the requirements of this clause, the manufacturer shall provide the responsible organization with information for the proper disposal of the ME equipment at End of Life (EOL). And the manufacturer shall make available information to waste treatment facilities necessary for the environmentally responsible management of end of life ME equipment.

The information shall contain the following items (Table 2).

Table 2 The requirements of Clause 4.5.3 and Instructions provided by manufacturer

The requirements of Clause 4.5.3	**Instructions provided by manufacturer**
1) The location of components and parts within the ME equipment that contain stored energy or pose other hazards that can result in an unacceptable risk to disassemblers or others and methods for controlling such risks.	The battery is located on the back of the device. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.
2) The identity and location of hazardous substances requiring special handling and treatment	The battery is located on the back of the device. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.
3) Disassembly instructions sufficient for the safe removal of these hazardous substances including radioactive sources and induced radioactive materials within the ME equipment.	For other hazards that may result in unacceptable risk, the main concern is the handling with battery: Risk of fire, explosion, or burns. Do not crush, puncture, disassemble or short circuit the battery. Do not dispose of the battery in fire or water. Do not place the battery in an environment whose temperature is above 60℃ （140℉）. Store the battery in the -20℃（-4℉）to 60℃(140℉) environment. Use the specified charger only. Read instructions for use. Maximum Recommended Ambient is 45℃ (125℉). Dispose of used batteries promptly and in an environmentally-responsible manner. Do not dispose of the battery in normal waste containers. Consult your hospital administrator to find out about local arrangements. As for disposing of the medical device, to avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate the medical device appropriately before disposing of it in accordance with your country’s laws for equipment containing electrical and electronic parts. For disposal of parts and accessories such as thermometers, where not otherwise

	specified, follow local regulations regarding disposal of hospital waste.