Basic Information

Product Name: Anesthesia Machine

Product Model: AX-400, AX-400A, AX-500, AX-500A

Manufacturer: Shenzhen Comen Medical Instruments Co., Ltd.

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

Introduction

This document summarizes the product's safety and performance information.

Chapter 1 Safety information

1.1 User Responsibility

1.1.1 Environmental Requirements

⚠Warning

- **The product and its correlative standalone assemblies must not be applied in nuclear magnetic resonance (MR) environments.**
- **To avoid explosion hazards, inflammable anesthetic agents such as ether and cyclopropane must not be used. Only the non-inflammable anesthetic agents as specified in ISO 80601-2-13 and that is license for specific use in European can be adopted. The equipment allows the adoption of non-flammable anesthetic agents like desflurane, isoflurane, or sevoflurane, and only one type of anesthetic agent can be applied at one time.**
- **When disposing of abandoned anesthesia machines, accessories, lithium battery, O_2 sensor, soda lime and packaging materials, abide by relevant local laws and regulations or wastes treatment rule of the hospital. Place them out of reach of children. Corresponding measures shall be taken to prevent their harm to the ambient environment.**
- **The use environment of the equipment should meet the environmental requirements specified in this manual. If the use environment exceeds the specified range, it may affect the accuracy of the instrument and cause damage to components and circuits.**
- **Do not use this equipment in an environment where flammable or explosive materials are placed to prevent fire or explosion. When using oxygen, keep the ventilator away from various sources of ignition.**
- **Avoid use the device in wet environment. Caution any liquid spillage.**
- **To avoid contaminating the ambient environment and endangering the patient, always double-check to make sure the vaporizer to be opened is a correct one.**
- **The shock and vibrations caused by transportation may lead to mechanical failure.**
- **For securely installation, the application of ceiling mounting should be designated for Ceiling Pendant.**

- **Do not use the anesthesia machine for mobile facilities such as ambulances, helicopters, or ships.**
- **According to the regulatory requirement, the use of an anesthetic gas scavenging system is required. Ambient air may become contaminated with anesthetic agent if the scavenger hoses are functionally inhibited. The scavenger hoses must not be pinched, kinked, or blocked in any manner.**

1.1.2 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.**

⚠Note

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

1.1.3 Warning, Caution and Attention

⚠Warning

- **It is not a medical treatment device.**
- **Do not operate the device before reading this Manual. The operator must participate in pre-use training before using the device and must strictly follow this user manual during use.**
- **The device can only be operated by trained and skilled healthcare professional. Otherwise, hazards may be caused by improper use.**

- **The anesthesia machine use medical gases such as oxygen, nitrous oxide, or volatile anesthetic agents. Strictly follow the instructions for use of the medical gases. Pay particular attention to the contraindications of the medical gases used.**
- **The device does not provide dosing guidance or alter the dose that is prescribed by the clinician.**
- **Always read manufacturer precautions and guidelines for medications, anaesthetic vapour used with this Anesthesia Machine.**
- **Before starting any delivery, always confirm the anaesthetic delivering and ventilation setting to the patients need and clinical practices, otherwise might cause inappropriate delivery, which can result in serious injury or death.**
- **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 equipment connected to the device must be certified by specified IEC standards (e.g. standard IEC 60950-1, IEC 62368-1 or IEC 60601-1). All configurations should follow the contents of the latest version of IEC 60601-1. The personnel responsible for connecting the additional equipment to the signal I/O interface should configure the medical system and be responsible for the system's compliance with IEC 60601-1.**
- **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 Comen.**
- **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 danger to the patient.**

- **In order to avoid explosion hazard, flammable anesthetic agents such as ethyl ether and cyclopropane cannot be used in this device. Use only non-flammable anesthetic agents that meet the requirements of ISO 80601-2-13 standard. This device can use non-flammable anesthetic agents such as desflurane, isoflurane, and sevoflurane. Only one anesthetic agent can be used at a time.**
- **When disposing of abandoned anesthesia machines, accessories, lithium battery, O_2 sensor, soda lime and packaging materials, follow relevant local laws and regulations or wastes treatment rule of the hospital. Place them out of reach of children. Corresponding measures shall be taken to prevent their harm to the ambient 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.**
- **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 a medical device and a non-medical device to an auxiliary power socket at the same time may increase the leakage current, thus exceeding the permissible value.**
- **In order to prevent electric shock, this device can only be connected to a power cord with protective ground.**
- **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 together with this device.**
- **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.**
- **Care must be taken when disposing of the CO_2 absorbent as it is a corrosive irritant.**
- **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 on a patient.**
- **Check the performance specifications of AGSS 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.**
- **Excessive machine load may result in imbalance. 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 imbalance. 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 of doors and elevators. Do not attempt to run over hoses, cables, or other obstacles when moving the device.**
- **Leakage may affect accuracy. Test for leaks to ensure proper operation of the device prior to using it. Do not use leaking tubes or connectors.**
- **The disposal gas from the device shall be connected to the hospital's scavenging system.**
- **Operating the device below the minimum flow rate may result in inaccurate results.**
- **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 Comen for technical support.**
- **High concentrations of O_2 greatly increase the likelihood of fire or explosion. Oil and grease are flammable materials and should not be used in oxygen-rich environments where possible.**
- **Only professional medical personnel should use this device. This device may cause radio interference or interrupt the operation of nearby devices. It is necessary to take preventative 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 that the storage integrity of the accessory has not been compromised.**
- **Before using this anesthesia machine after cleaning or sterilization, power on the system and follow the on-screen instructions to perform a self test.**
- **Use of lubricants not recommended by Comen will increase the risk of fire or explosion. Use the lubricants approved by the Comen.**

- **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 device from the supply mains. 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 thereby preventing the patient leakage 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 over.**
- **Make sure that all patient system components are tightly connected. If the breathing circuits are wrongly connected, the patient might be inadequately ventilated and supplied with fresh gas**
- **Always have immediate access to an alternative means of ventilation, which is ready for use, in order to reduce the possibility of patient death or additional deterioration of health. Always keep a manual resuscitator at hand.**
- **Breathing bags used must comply with ISO 5362.**

- **The anesthesia machine is intended to be used medical oxygen, and cannot be used with oxygen 93.**
- **The flow and volume measurement and the flow and volume delivery are not corrected for influences of N_2O, CO_2 and volatile anesthetic agents.**
- **Keep RFID equipment away from the anesthesia machine.**
- **To avoid risk of fire:**
  - **Do not use substances containing alcohol.**
  - **Do not allow flammable or explosive substances to enter the breathing system or the breathing circuit.**
  - **Do not use cyclopropane or ether.**

⚠Caution

- **Compressed gas supply (pipeline or cylinder): To avoid damaging the device(s) attached to a gas supply, use only medical gases. Pay particular attention to national and international standards regulating the use of medical gases.**
- **When the anesthesia machine is used with anesthesia vaporizer, it deems to use an anaesthetic gas monitor conforming to ISO 80601-2-55 to monitor the content of anaesthetic vapour in the inspiration gas as protection against dangerous output.**
- **It is recommended continuously monitoring the delivered anaesthetic agent using upper and lower alarm thresholds to detect hazardous values through changes in concentration, leakage, or incorrect filling.**
- **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 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 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 complies 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.**
- **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.**
- **The Anesthesia Machine (without accessories) is not made with natural rubber latex. To minimize the risk of exposure to latex, use latex-free breathing bags and ventilation breathing system accessories.**
- **Breathing circuit system with high resistance of can affect breathing and result in the delivery of incorrect concentration.**
- **This device is not suitable for use in magnetic resonance (MR) environments.**
- **In order to ensure accurate measurement and avoid damage to the device, use only cables and accessories approved by Comen.**
- **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 weight and shape of the breathing system, these operations can be tricky.**
- **Do not use damaged devices 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 inspired O_2 concentration (FiO_2) shall be monitored when using an auxiliary O_2/air 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 power input of the device connected to the MSO shall be within the range of the output of MSO.**
- **Do not connect any device to the USB port of the device except for the USB storage devices approved by Comen.**
- **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.**
- **This equipment shall not be operated at home.**

⚠ Note

- **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.**
- **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.**
- **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 vaporizer and other information, refer to the instructions for use of the anesthetic vaporizer.**
- **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 the end of 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 phthalates.**
- **Patients with MH susceptibility may be anesthetized in an outpatient environment without using volatile anesthetic agents and Succinylcholine, while following the national guidelines for outpatient general anesthesia.**
- **During machine preparation, the tidal volume of the adult patient can be set to 600 ml, respiratory rate to 15 bpm, and fresh gas flow to >10 l/min in mechanical ventilation.**
- **When AGSS or CO_2 canister is connected and the breathing circuit and the soda lime canisters have been replaced, it is recommended to reduce the fresh gas flow rate from >10 l/min to 3 l/min.**
- **To ensure the accuracy of oxygen monitoring, replace an exhausted O_2 battery as soon as possible or use an external monitor that complies with ISO 80601-2-55.**
- **If, in relation to the use of the anesthesia machine, a death or a serious deterioration of health has occurred, this should be reported to the manufacturer and the competent authority of your country.**

1.2 Product Overview

⚠Warning

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

- **IEC 60601-1 is applicable to connection of all medical-use electrical rooms and connection of at least 1 medical-use electrical equipment to 1 or more 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 a multiple socket outlet. If multiple pieces of equipment are connected to the multiple socket outlet, a risk (namely, leakage current rises and exceeds the allowable limits) may take place.**
- **To configure the multiple socket outlet, the equipment connected shall fall within the voltage/current specifications of the multiple socket outlet. The equipment connected to the multiple socket outlet 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 multiple socket outlet 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 an isolation transformer.**
- **If the equipotential system works unreliably, the equipment shall be powered by internal power supply.**

⚠ Note

- **This Manual describes the device according to the most complete configurations. The device you purchased may not have certain configurations or functions.**
- **AX-400A has no Auxiliary O_2-supply flowmeter compared to AX-400.**
- **AX-500A has no Auxiliary O_2-supply flowmeter compared to AX-500.**
- **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.**
- **The breathing circuit is equipped with heating function, which can effectively remove water accumulation in the circuit. The volume of the breathing circuit is not greater than 3.5 l.**
- **Risks could be caused if the Bag/Vent switch is set to a wrong position.**
- **Please refer to the user's manual delivered along with the anesthesia vaporizer for specific information about relevant anesthesia vaporizers.**

- **Risks could be caused if the regulation knob of the vaporizer is set incorrectly and is turned in a wrong direction.**
- **When the anesthesia machine is restarted, it will revert to the patient type that was present before the last shutdown.**
- **Turn the flow control knob anticlockwise to increase the oxygen flow, or turn it clockwise to reduce the flow.**

1.3 Basic Operations and Guidance

⚠Warning

- **Alarms given by an anesthesia machine indicate that the patient is being subjected to potential risks. The causes of all alarms must be clarified and rectified prior to commencing any treatments, to ensure the safety of patients.**
- **If sevoflurane is adopted, adequate fresh gas flow shall be maintained.**
- **When dry (dewatered) absorbent 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 device from the supply mains 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.**
- **To run the equipment for patients, make sure that the system connection is fault free and is kept in good order and condition, and finish all tests specified in Chapter 4 Test 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.**
- **Battery feed can be maintained only for a period of time. Once the battery level is too low, a high-level alarm [Low Battery] is triggered. Please connect to the AC power immediately.**
- **When [CPB] is set to [ON], some 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.**

⚠ Note

- **Avoid short circuiting the battery.**
- **Keep batteries away from flammable and explosive materials.**
- **The user cannot set the patient type during ventilation mode.**
- **[Rate] can be configured in [VCV], [SIMV-VC], [PRVC], [SIMV-PRVC], [PCV], [SIMV-PC], and [PSVPro].**
- **The Anesthesia machine shall be configured to comply with the anesthesia ventilator in ISO 80601-2-13, together with AGSS in ISO 80601-2-13.**
- **Make sure Manual/Spontaneous mode is always available when this device is used on patients.**
- **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.**
- **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 [O2 Sensor Monitor] is set to [OFF], FiO2 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 [O2 Sensor Monitor] is set to [ON], and the Oxygen Monitoring Source is set to [OFF], FiO2 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.**
- **The anesthetic workstation is to be provided with an oxygen monitoring equipment conforming to ISO 80601-2-55 before the anesthetic workstation is put into service.**

1.4 Test 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 Comen.**
- **For anesthesia gas delivery systems, monitoring devices, alarm systems and protective devices which are intended to be used as an anesthesia system, and regardless of whether they are to be used individually or as a complete system, a checklist of the anesthesia system should be provided.**

- **Make sure that the breathing system is connected properly and intact. Improper installation, tests or maintenance of the breathing circuit system can cause device faults and bring risks to the patient.**
- **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.**
- **Even though fresh gas contains enough oxygen, hypoxic mixed gases may be present in the breathing system.**
- **If N_2O exists and flows through the system during the testing, the N_2O gas shall be collected and eliminated using 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.**
- **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.**
- **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 the flow control knob clockwise to the end (minimum flow or turn it off) prior to use.**
- **In accordance with international laws and regulations, oxygen concentration shall be monitored during the time 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.**
- **Foreign objects inside the breathing system may block 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.**

⚠ Note

- **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 N2O blocking function and the O2-N2O ratio are normal before using the device. Use an O2 concentration tester to monitor the concentration of O2 in the output gas.**

- **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.**
- **A malfunction of the medical gas pipeline system can cause one or more anesthetic workstations or anesthetic workstation components connected to the medical gas pipeline system to stop their operation simultaneously.**
- **To conduct N2O gas supply pipeline test, turn on O2 first, and make sure that the O2 gas supply pressure ranges from 280 to 600 kPa; Otherwise, N2O flow cannot be regulated.**
- **When N2O supply is cut off the system will not give alarms related to the N2O pressure as N2O pressure drops.**
- **When air supply is cut off, the system will not give alarms related to the air pressure as air pressure drops.**
- **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 the flowmeter is adjusted to the minimum value, the reading shall be zero.**
- **When O2 supply is cut off, the alarm for "No O2 Pressure" occurs as O2 pressure drops.**
- **During alarm testing stay in a place where you can observe the alarm lamps and alarm prompts and hear the alarm sound.**
- **It is unnecessary to conduct the testing if O2 sensor is not fitted.**
- **The range of internal volume of any anesthetic breathing system less than 3.5L.**
- **The breathing system shall be equipped with a ventilator conforming to ISO 80601-2-13.**
- **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.**
- **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 is invalid.**
- **If gas leak testing fails, check all possible causes of gas leaks, such as leakage from bellows, breathing system pipeline, CO2 canister and other connecting devices. During the check of the CO2 canister, pay attention to the seal components of canister to find if any CO2 absorbent particles are attached on the canister, and remove them if any are present.**

- **If leaks exist in the breathing system, do not use the equipment. Contact the equipment service personnel or after-service department of Comen.**
- **A 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.**
- **The ventilator shall be equipped with an anesthesia system conforming to ISO 80601-2-13.**
- **Do not block the pressure compensation port of AGSS during the test.**

1.5 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 is ready for use, and ensure that a simple respirator with a mask is 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 discharged respiratory residual gas.**
- **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 CO2 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.**
- **To protect the patient from particles and dust, a filter must be used between the inspiratory limb of the breathing system and the patient.**
- **When the breathing circuit system is assembled onto the circuit adapter, you must verify that the breathing circuit system is firmly locked. If not, it may become separated from the circuit adapter during operation, resulting in severe leak of fresh gas and mismeasurement of tidal volumes.**

- **Before assembling the bellows cover, check whether or not the seal components of the breathing system are normal. If the seal comes out or tilts up, please place it back into the right position before assembling the bellows.**
- **Tighten the breathing connector locking nut when installing the flow sensor, otherwise the flow sensor measurement may be invalid.**
- **Before assembling the oxygen sensor, check if the seal rings of the oxygen sensor are in good condition. Replace the oxygen sensor with a new one if no seal rings are installed or the seal is damaged.**
- **The unpacking of the O_2 sensor and the assembly of its components must be correct. They should be screwed in place correctly and not misaligned.**
- **The O_2 sensor must be assembled properly; otherwise gas leakage may occur in the breathing system.**
- **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 may not get dry. All gas supplies shall be turned off every time when finished using the system.**
- **Disposable canister is a sealed device, and may not be opened or refilled with CO_2 absorbent.**
- **Do not allow your skin or eyes to be exposed to the substances 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 the 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 CO_2 absorbent canister properly; Otherwise, the patient may repeatedly inhale the carbon dioxide they give off.**
- **CO_2 concentration monitoring is strongly recommended. The equipment may be connected to a CO_2 analyzer conforming to ISO80601-2-55 for monitoring the CO_2 concentration.**
- **Before assembling a canister, check the color of CO_2 absorbent inside the canister 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 when finished using the system. If thoroughly dry CO_2 absorbent is exposed to anesthetics, it may release carbon monoxide (CO), and its continuing use 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 the canister regularly; Otherwise CO_2 absorbent powder settled inside the canister may go into the breathing system.**
- **To assemble the CO_2 absorbent, check the canister rim, support piece and seal for attached CO_2 absorbent particles. If there are any, remove the particles; otherwise they might result in leakage in the breathing system.**
- **To remount canister after replacement of the absorbent, be sure to check the canister is locked in place to ensure it has been properly assembled.**
- **Only medical-use gas supplies are allowed to be 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 pieces of equipment connected to it may fail to work. In such a case, turn on the standby cylinders to guarantee continued correct functioning of the anesthesia machine.**
- **When the gas supplies are turned off, pressure still exists inside the pipelines. Therefore, release the gases from the pipelines before you unplug the gas pipes.**
- **The PEEP exhaust port may continuously discharge small quantities of oxygen. Never block the outlet; otherwise the anesthesia ventilator cannot work.**
- **Prior to an operation, the anesthesia machine shall be equipped with an anesthesia gas scavenging system conforming to ISO 80601-2-13 for anesthesia gas disposal. .**
- **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.**
- **If the vaporizer is incompatible with the anesthesia machine, their performance may be degraded. Please use the vaporizer matching the equipment.**
- **The interchangeable anesthetic vapour delivery system used with the anesthetic gas delivery system shall conform to ISO 80601-2-13.**
- **This equipment must not be used when the position of the anesthesia vaporizer control dial is set between "0" and the first indicated setting position shown on the control dial (for example 0.2) as it may cause accidental injury to the patient.**

- **Care should be taken when lifting and moving 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 in place.**
- **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.**
- **It is recommended continuously monitoring the delivered anaesthetic agent using AG gas monitor complying with ISO 80601-2-55 with alarm system to detect hazardous values through changes in concentration, leakage, or incorrect filling.**
- **The anesthetic vaporizer cannot be used if the control dial is set between the positions of "0" and "ON" (next indicated setting position).**
- **Ensure that anesthetic agents are filled correctly. Anesthetic agent names are already indicated on the vaporizers, and they are also marked with different colors. If anesthetic agents are incorrectly filled, the actual output concentration of anesthetic agents may be changed.**
- **Anesthetic agents drained from the vaporizer must not be reused, and it shall be disposed of as hazardous chemicals.**
- **Please mark the bottles containing the drained anesthetic agents as follows: USED ANESTHETIC AGENTS.**
- **Failure to use a washer or using two or more washers may result in leakage.**
- **When pipeline gas supply is in use; do not set the backup cylinder valve to position "ON". Otherwise, the gas cylinder may be exhausted and result in short supply in case the pipeline ventilation gets faulty.**
- **The AGSS transfer and receiving system cannot be used with flammable Anesthesia gases.**
- **If the hose between the 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, 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.**

⚠ Caution

- **The gas supply hoses shall meet the standards of ISO 5359.**
- **The hose connectors shall meet the standards of ISO 9170-1.**

⚠ Note

- **After the use of the equipment, pay attention to the disposal of the breathing system, the test of the CO_2 absorbent inside canister and anesthetics inside the anesthesia vaporizer so as to guarantee normal running of the equipment.**
- **Please do not weigh down the manual support arm by hands or by hanging other heavy objects onto it.**
- **If the difference between the airway pressure gauge reading and the parameter value displayed on the screen is large, contact Comen.**
- **If it is very hard to push the breathing circuit system in to place, 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 may be necessary to apply a small quantity of lubricating oil (Du Pont Krytox high-performance fluorine grease) onto the seal rings of the air ports of the circuit adapter.**
- **To assemble the breathing tube, hold the connectors at both ends of the breathing tube so as not damage the breathing tube.**
- **Gradual color change of the absorbent inside the canister indicates absorption of carbon dioxide. The color change of the 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 immediately. It may regain its original color after several hours, giving a misleading indication.**
- **Prior to operating the product, read the operating instruction completely.**
- **The breathing system of the 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.**
- **Gradual color change of the absorbent inside the canister indicates absorption of carbon dioxide. The color change of the 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 since the absorbent may regain its original color after several hours. To avoid the misleading indication, it is suggested to replace CO_2 absorbent prior to each operation, or use a carbon dioxide monitor.**
- **"Medisorb TM" CO_2 absorbent is recommended.**
- **For details of vaporizer assembling and operation, refer to instruction manual of 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 accuracy 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.**
- **If the vaporizer is tilted exceeds 30 degrees, the concentration will become uncontrollable.**
- **If the vaporizer tilts or drops, or is vibrated during use, the output concentration could be affected.**
- **The pressure relief valve of the vaporizer ensure that the vaporizer can endure 0.2 MPa pressure.**
- **Monitor the concentration of the anesthesia agent during using the anesthesia machine.**
- **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.**
- **During testing, do not block the pressure compensation port of the AGSS transfer and receiving system.**

1.6 Alarms

⚠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.**
- **When selecting Restore Factory Settings, the minimum alarm volume is set to level 5. However, if the Default Config minimum alarm volume is set to a level greater than 5, the minimum alarm volume will be changed to the Default Config level instead.**
- **If an alarm is cleared in manual mode, alarms such per-minute ventilation amount and expiratory tidal volume will not be triggered.**
- **When the anesthesia machine is restarted, the alarm settings before the last shutdown will be reloaded.**

⚠ Note

- **Due to the limit validity of the contrast agent during the imaging process, the imaging parameters need to be preset before injecting the contrast agent in order to avoid affecting the consistency of the image during the imaging process.**
- **When the equipment is turned on, the system tests the alarm tones and alarm lamp functions to check that they are working correctly. If they are, the equipment gives a "Beep" sound and the alarm lamp illuminates once yellow/red. If the tones and alarm lamp functions are abnormal, do not use the equipment. Please contact Comen immediately.**
- **In case multiple different alarms occur simultaneously, the equipment will give audible and visual alarms relevant to the highest priority alarm that is occurring.**
- **The 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. The user shall pay close attention to the actual clinical status of the patients.**
- **Information such as physiological parameters and alarms displayed on the screen 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.**
- **The alarm system will restore the previous alarm setting no matter the duration of a power interruption.**
- **When the parameter value is higher than the high alarm limit or lower than the 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. If the settings are beyond the valid range, the alarm system may be ineffective.**
- **In the alarm audio paused state, all alarm modes work normally except for audible alarm.**
- **In alarm audio paused state, even if there is a new technical or physiological alarm, the alarm will continue to be suspended.**
- **Once the 120s countdown ends, the anesthesia machine will automatically exit the current alarm audio paused status and reactivate the audible alarms.**

- When the anesthesia machine is turned off (or completely powered off), the status of the AG module alarm is retained. The next time the machine is switched on, the AG module alarm status will be the same as prior to previous power off.
- 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.

1.7 Physiological Alarms and Technical Alarms

⚠ Note

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

1.8 CO_2 Monitoring

⚠ 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.
- MASIMO CO_2 module cannot be used with flammable anesthetic gases.
- Please set the type and level of the compensation in accordance with actual conditions; otherwise measuring results may deviate from actual values, resulting in misdiagnosis.
- 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.
- Check whether the gas sample flow rate is too high for the given patient category.
- Since successful zeroing requires ambient air (21% O_2 and 0% CO_2) in the CO_2 module, be sure to place the CO_2 module in a well ventilated location. Avoid breathing near the CO_2 module before and after performing the zeroing procedure.
- 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.
- 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 a 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 module is 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 anesthesia machine displays a "Sampling Line Occluded" message.**
- **No modification of this equipment is allowed without the 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 is not designed for MRI environments.**
- **During MRI scanning, the CO_2 module must be placed outside the MRI suite.**
- **Use of high frequency electrosurgical equipment in the vicinity of the CO_2 module/anesthesia machine may produce interference and cause incorrect measurements.**
- **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 since there is the risk of cross infection.**
- **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 adult/pediatric Nomoline Airway Adapter Set with infant patients.**
- **Do not use the infant Nomoline Airway Adapter Set with adult patients.**
- **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.**

⚠ Note

- **To ensure the safety of the patient, perform CO_2 monitoring while using this equipment. If your equipment does not have the function of CO_2 monitoring, please use equipment with a CO_2 monitoring function which conforms to corresponding international standards.**
- **Using sample lines or cannulas with a larger inner diameter than 1 mm will increase the module's total system response time.**
- **Nomoline Family sampling lines with proprietary water removal tubing is adopted in water handling.**
- **This section is only applicable to mainstream CO_2 module of anesthesia machines.**
- **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 blockage.**
- **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 blockage.**
- **During sensor calibration, pressing the Measure/Standby button cannot switch the operating mode. At this time, the Measure/Standby button on the screen does not function either.**
- **When the anesthesia machine is restarted, all the settings of the CO_2 module before the last shutdown will be reloaded.**

1.9 AG (Anesthetic Gas) Monitoring

⚠ Warning

- **Children cannot use the adult sink, or it 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 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 an incorrect reading.**
- **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.**
- **When the anesthesia machine is restarted, all the settings of AG module before the last shutdown will be used.**
- **Since a successful zeroing requires the presence of ambient air (21% O2 and 0% CO2), ensure that the module is placed in a well ventilated place. Avoid breathing near the AG module before or during the zeroing procedure.**

⚠ Note

- **The anesthetic gas delivery system is to be used with halogenated anesthetic agent monitoring equipment conforming to ISO 80601-2-55; if your equipment does not have the function, please use a monitor conforming to ISO 80601-2-55.**
- **Only use anesthetic gases specified by Comen.**
- **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, or other personal factors into consideration.**
- **The AG Module is equipped with automatic atmospheric pressure compensation.**

1.10 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 HF 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.
- To reduce the risk of burns during use of a 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.
- 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 to avoid any danger to the patient.
- Please make sure the patient's skin is dry. Wet sensors or salt bridges may cause false BIS and impedance values.

Note

- When the anesthesia machine is restarted, all the settings of BIS module before the last shutdown will be reloaded.

1.11 Logs

Note

- When the anesthesia machine is completely powered off or turned off, the stored alarm logs are not deleted, and the log contents remain, but the shutdown time will not be saved in the log.
- If auditory alarms do not generate any longer, you can access the alarm log to view the events that trigger alarms.

1.12 Cleaning, Disinfection and Sterilization

Warning

- Observe the applicable regulations for safety protection.
- Carefully read the safety instructions of each cleaning agent to understand their constituents.
- Read the instructions carefully for operation and maintenance of all sterilization equipment.

- **Wear safety gloves and spectacles. Damaged oxygen sensors may leak and result in inflammation (including potassium hydroxide).**
- **Reusing a 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, sterilized or reassembled, the operations described in *Chapter 4 Test before Use* must be performed before normal use.**
- **To prevent the breathing system from leaking, all components must not be damaged during disassembling and reassembling, and correct mounting should be checked carefully, especially the assembling of the seal rings. To conduct cleaning and sterilization, guarantee the correctness of the cleaning and sterilization methods and check their suitability to the components.**
- **Please perform removal and mounting as described in this chapter. For details of further removal and assembling, contact the After-service Department of Comen. Incorrect removal and assembling may cause a leak in the breathing system, and impact the safe working of the equipment.**

In order to prevent any damage to the device during cleaning:

- **Refer to the information provided by the cleaning and disinfection agent 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.**
- **Do not allow liquid to infiltrate into the device housing.**
- **Do not immerse the O2 battery or its connector in any type of liquid.**
- **Dispose of the O2 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.**
- **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.**
- **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 away all moisture from the bellows after cleaning.**
- **Do not clean the inner surface of the O2 battery.**
- **Improperly cleaned materials can cause biological contamination. Use a cleaning and sterilization procedure.**

- **Refer to applicable material safety data.**
- **Refer to the operation and maintenance manual for all sterilization equipment.**
- **Liquid infiltration into the control assemblies may damage the equipment or cause personal injury. During cleaning of 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 are thoroughly dry.**
- **Never disassemble the pressure relief valve. Otherwise, the pedestal and diaphragm may be damaged and further endanger patient safety.**
- **Never use talcum, zinc stearate, calcium carbonate, cornstarch or similar materials to avoid adhesion. These materials might access the lung of the patient or the gas duct, resulting in irritation or damage**
- **Check the components for damage, and replace them when necessary.**
- **The breathing circuit must be cleaned and sterilized before use by each patient. Strict follow the accompanying instruction from a third manufacturer.**
- **The anesthesia breathing circuit can be subjected to high temperature and high pressure sterilization for a maximum of 450 times. The parts should no longer be reused in case of signs of material degradation, e.g. dents, cracks, deformations, scratches or corrosion, or damaged markings on the device, etc.**

⚠ Caution

- **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).**
- **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.**
- **The maximum number of times that the respiratory circuit can be subject to steam sterilization is 450 times.**
- **Please perform removal and mounting as described in this chapter. For details of further removal and assembling, contact the After-service Department of the Comen. Incorrect removal and assembling may cause a leak in the breathing system, and impact the safe working of the equipment.**

- 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.

Note

- Use only dry soft lint-free cloth to clean the display screen, and do not use liquid to clean it.
- 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.
- If it is very hard to push in or take out the breathing circuit system, apply lubricating oil onto seal ring of the airway connector of the circuit adapter to reduce the friction.

1.13 Maintenance

Warning

- Do not use the anesthesia machine if it develops a fault. All repairs and maintenance shall be carried out by authorized service representatives.
- Adopt a cleaning and sterilizing plan that meets your risk management requirements.
- Be careful when handling an absorbent because it is a corrosive irritant.
- Please use lubricants approved for anesthesia or 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 pinching/crushing; therefore, move or replace system components with care.
- Limited operating lifetime: The expected service life of the device is 10 years, assuming the preventative inspection, maintenance and calibration servicing operations are performed as specified by the manufacturer. The maintenance and replace interval is indicated in chapter 13.2 below.

⚠ Note

- **Personnel without experience in maintenance of this equipment of this type must not service it.**
- **Replace damaged parts with the ones produced or sold by Comen. After replacement, perform tests to ensure that the equipment conforms to the specification requirements of the manufacturer.**
- **If service and support are required, contact the after-service department of Comen.**
- **To find out further product information and relevant technical data, contact the after-service department of Comen, and we may provide additional data about components as required.**
- **Do not immerse the O2 sensor or its connector in any type of liquid.**
- **The minimum maintenance frequency is based on a typical use of 2000 operating hours per year. If the actual use time is more than 2000 hours in a year, the frequency of equipment maintenance shall be higher.**
- **When cleaning and installing, please check whether the parts and sealing rings are damaged and replace or repair them if necessary.**
- **Check regularly whether there is residual water in the breathing circuit system. Drain the water if there is any.**
- **To extend the service life of batteries, use the battery at least once a month, and charge them when the battery charge is low, or zero.**
- **Please check and replace batteries regularly. The service life of batteries depends on the frequency of use and service time. Based on proper maintenance and storage, the service life of the battery is approximately 3 years. However, if they are improperly used, their service life may be reduced. It is recommended that batteries be replaced every 3 years.**
- **If a battery fault occurs, contact the personnel of the manufacturer for replacement. The user must not replace the battery by themselves.**
- **The length of time that the device can run on battery power alone depends on the configurations and how the device is being operated at the time.**
- **After the main power supply is interrupted, and when the "ON-OFF" button is kept on, after the interruption time exceeds 30s, there is an internal power supply that can support normal operation.**
- **Use only the battery specified by the manufacturer.**
- **Do not disassemble the battery when the device is working.**
- **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 standby mode.**

- If calibration fails, check whether or not a technical alarm is given. Take measures to remove the alarm, and then calibrate the O_2 sensor again.
- If calibration fails repeatedly, replace the oxygen sensor, and perform calibration again. If calibration still fails, contact the service personnel or Comen in time.
- Discarded oxygen sensors shall be treated as per relevant regulations for biological hazards, and please do not have them incinerated.
- If 100% O_2 calibration fails, check whether or not a technical alarm is given. Take measures to remove the alarm, and then calibrate the O_2 sensor again.
- If calibration fails repeatedly, replace the oxygen sensor, and perform 21% O_2 calibration 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 Comen.
- After the accumulated water has been discharged, please set the manual drain valve to its original position, and make sure that the anesthesia machine can work normally.

1.14 Accessories

⚠ Warning

- Only the accessories specified in this chapter may be used. Using other accessories may lead to incorrect measured values or equipment failure.
- There are risks due to incompatible accessories. Use only spare parts recommended by the manufacturer to ensure proper function.
- Disposable accessories can be used only once, and their reuse may cause a reduction in performance or cross infection.
- If accessory packaging or an accessory is broken, do not use it.
- All accessories intended to contact the human body shall meet biocompatibility required by ISO 10993-1 Standard. They shall be compatible with non-inflammable anesthesia gases and anesthetics and are expected to cause no adverse reaction when they are exposed to the human body, and they shall not work with inflammable anesthesia gases.
- Discarded accessories shall be treated as per local laws and regulations, or hospital regulations. Please dispose of them appropriately.

- Accessories that are not in direct contact with the human body do not require sterilization. The detailed method for sterilization of accessories directly in contact with the human body is described in the manual for accessories.
- 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.
- Use the additional bacteria filters if the sample gas is to be returned to the breathing system.
- Check the accessories and their packages for damage. Do not use them if any sign of damage is detected.

⚠ Note

- Use only dry soft lint-free cloth to clean the display screen, and do not use liquid to clean it.
- Install accessories to the basic device in accordance with the Instructions for Use of the basic device. Make sure that there is a safe connection to the basic device system.
- Strictly observe the instructions for use of all accessories such as:
  - Soda lime canister
  - Breathing tubes
  - Masks
  - Breathing system filters
  - Endotracheal suction
  - Vaporizer
  - AGSS

1.15 Gas Circuits and Specifications

⚠ Warning

- Do not set the cylinder valve to “ON” when the pipeline gas supply is in use, or the cylinder gas supply will be exhausted, which will lead to inadequate gas supplies when a pipeline fault occurs.
- When the pressure of the O_2 supply is lower than 100 kPa, the N_2O supply is automatically cut off by the O_2-N_2O cut-off valve, but the air supply will not be affected.

- **The anesthesia machine provides three power sockets for auxiliary equipment of anesthetic systems (eg, vaporizer, gas analyzer). Do not connect other devices with these sockets, or it may affect the patient's leakage current. Overload is not allowed.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**
- **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**
- **Electromagnetic field may affect the performance of the equipment. Therefore, other devices used in the vicinity of the equipment shall conform to the applicable EMC requirements. Mobile phones, X-ray or MRI devices are all potential sources of interference since they all transmit high-intensity electromagnetic radiation.**
- **Do not add any attachments or accessories to the ventilator that are not listed as intended for use in combination with the ventilator in the instructions for use of the ventilator or accessory, as the ventilator might not function correctly leading to the risk of patient death or additional serious deterioration of health.**
- **DO NOT stack this product on/under or get it close to any other equipment. If you have to use it this way, observe and verify whether it works properly in such condition first.**
- **Operation of the ventilator below the minimum amplitude or minimum value stated in the manual may lead to inaccurate results.**
- **Do not use near active HF surgical equipment or in a RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.**
- **Other equipment compliant with the transmission requirements of CISPR may also cause interference to the ventilator.**

⚠ Note

- **The user needs to install and use the machine according to electromagnetism compatibility information which is attached with it.**
- **Guidance and manufacturer’s declaration are stated in the Chapter.**

1.16 Cybersecurity

⚠ Warning

- **Improper use of the anesthesia machine could cause hazards to patients and device performance.**
- **For embedded device, the security update is integrated with the software application program update. The update is only allowed locally by authorized user.**
- **The device supports change of user passwords with strong password policy enforcement. It also supports a reminder to change the default passwords during first access.**
- **When the anesthesia machine reaches the end of service, do erase patient data and configuration data before enforcing disposal policy.**
- **Before connecting the anesthesia machine to other instruments, ensure that any connected device is free of malware.**

Chapter 2 Performance Information

2.1 Classification

Anesthesia Machine System Classification:

Type of protection against electrical shock	Class I, Device With Internal Power Supply
Classification of applied part	Defibrillation-proof Type BF Applied Parts
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
Applicable standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-9, ISO 80601-2-13, IEC 80601-2-26, ISO 80601-2-55

The anesthesia machine is integrated with pressure limit device, an expiratory gas volume monitor, a breathing system equipped with an alarm system, a pressure measurement device, an anesthesia breather system, an anesthesia gas delivery device, an anesthesia respiration machine, an O_2 monitor and CO_2 monitor, and it can be installed with an active AGSS (anesthetic gas scavenging system). Where:

- AX-400, AX-400A, AX-500 and AX-500A anesthesia machines conform to the Standard ISO 80601-2-13.
- Pressure limit device, expiratory gas volume monitor and breathing system equipped with an alarm system conform to the Standard ISO 80601-2-13 and IEC 60601-1-8.
- Pressure measurement device and anesthesia ventilation system conform to Standard ISO 80601-2-13.
- Anesthetic gas scavenging system conforms to the Standard ISO 80601-2-13.
- Anesthesia gas delivery device conforms to the Standard ISO 80601-2-13.
- Anesthesia ventilator conforms to the Standard ISO 80601-2-13.
- CO_2 monitor conforms to the Standard ISO 80601-2-55.
- Alarm system conforms to the Standard IEC 60601-1-8.
- Anesthesia concentration monitor conforms to the Standard ISO 80601-2-55.

2.2 Power Supply

AC Mains			
Input voltage	100 - 240 V		
Input frequency	50/60 Hz		
Input power	7.0A - 3.5A		
Fuse	T10 AH/250V		
Auxiliary Output Power Source (3-Way)			
	Auxiliary 1	Auxiliary 2	Auxiliary 3
Output voltage	100 to 240 V	100 to 240 V	100 to 240 V
Output frequency	50/60 Hz	50/60 Hz	50/60 Hz
Output power	1.0 A	1.0A	1.0A

Internal Battery	
Number of batteries	One battery
Battery Type	Li-ion battery
Rated battery voltage	11.1VDC
Battery capacity	4400 mAh
Shutdown delay	At least 30 min (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 4h (running mode or standby mode)

2.2.1 Power Cord

Length:	5m
Voltage Rating:	100 ~ 240Vac
Current capacity:	10A for 220~ 240Vac 15A for 100 ~120Vac
Type:	Three-wire conductor power cord (medical grade where required)

2.3 Specifications for CO_2 and AG Modules

2.3.1 Specifications of MASIMO^{TM} (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 H_2O (non-condensing) (95 %RH at 30 °C)
Storage humidity	5 to 100 %RH (condensing) (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 clause 201.15.3.5.101.2 and EN 1789 clause 6.3.4.2. OR+/AX+: Meets the impact and vibration requirements of ISO 80601-2-55 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: CO_2 CO_2 ET=ETnom×(125RR⁄) for RRth >125

	OR+/AX+ CO_2 ET=ETnom×√(70RR⁄) for RRth >70 N_2O, O_2, 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). O_2 measurements by Servomex's paramagnetic sensor.
Compensations	CO_2: Automatic compensation for pressure and temperature. Manual compensation for broadening effects on CO_2. OR+/AX+: Automatic compensation for pressure, temperature and broadening effects on CO_2.
Calibration	Zeroing recommended when changing Airway adapter (IRMA AX+). No span calibration is required for the IR bench.
Warm-up time	CO_2: < 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 ≤ 200 ms (ISA OR+/AX+ : ≤ 250 ms) ; N_2O ≤ 350 ms; ENF, ISO, SEV, DES, HAL ≤ 350 ms; O_2 ≤ 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	CO_2 < 3 seconds OR+/AX+ < 4 seconds (with 2 m Nomoline Airway Adapter Set sampling line)

4. Gas

The accuracy of all detected values meets the requirements of ISO 80601-2-55.

The following accuracy applys 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%	± (0.2 vol%+2% of reading)
	15 to 25vol%	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**
CO_2	±(0.3 kPa + 4% of reading)
N_2O	±(2 kPa + 5% of reading)
Agents	±(0.2 kPa + 10% of reading)
O_2	±(2 kPa + 2% of reading)

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	60 vol%	_ [2)]	_ [1)]	_ [1)]	_ [1)]
HAL	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				
C2H5OH (ethanol)	0.3 vol%	_ [1)]	_ [1)]	_ [1)]	_ [1)]
C3H7OH (isopropanol)	0.5 vol%	_ [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.

2.3.2 MASIMO CO_2 Mainstream Analyzer Specifications

Name	Specifications
$EtCO_2$ complies with the requirements of standard ISO 80601-2-55	
$EtCO_2$ specification of Masimo (Mainstream)	
CO_2 measurement range	0mmHg~190mmHg, 0~25% (at 760mmHg/101.3 kPa)
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
Warm up time	10s

2.3.3 $EtCO_2$ Specification of Respironics

$EtCO_2$ specification of Respironics Mainstream	
CO_2 measurement range	0~150 mmHg 0%~19.7% 0~20.0kPa (at760 mmHg)
CO_2 resolution	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%;
Sampling flow velocity	/
Sampling Rate	100Hz
$ETCO_2$ Calculation	Method: Peak of the expired CO_2 waveform Selections: 1 breath, 10 second, 20 second Note: the minimum reported differential value between the baseline and the CO_2 value shall be 5 mmHg.
$ETCO_2$ and Respiration rate	/

accuracy method	
Respiration Rate Calculation	Range: 0 to 150 breaths per minute (BPM) Accuracy: ± 1 breath
Total system response time	<1s
CO_2 Rise Time	/
Warm up time	2min
Whether there is automatic barometric pressure compensation	None

2.4 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%

2.5 EMC and Radio Management Compliance

Anesthesia machines AX-400, AX-400A, AX-500 and AX-500A conform to EMC Standard IEC 60601-1-2, ISO 80601-2-13, ISO 80601-2-55 and IEC 80601-2-26.

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The anesthesia machines AX-400, AX-400A, AX-500 and AX-500A are intended for use in the electromagnetic environment specified below. The customer or the user of the SECP-II should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The anesthesia machines AX-400, AX-400A, AX-500 and AX-500A use RF energy only for their internal function. Therefore, their 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-400, AX-400A, AX-500 and AX-500A are suitable for use in all establishments other than domestic and those directly connected to the
Harmonic emissions	Class A	

IEC 61000-3-2		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-400, AX-400A, AX-500 and AX-500A are intended for use in the electromagnetic environment specified below. The customer or the user of the anesthesia machines AX-400, AX-400A, AX-500 and AX-500A should ensure 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 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±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 input AC and DC power input port ± 1 kV for SIP/SOP port 100 kHz repetition frequency	± 2 kV for input AC. and DC power input port ± 1 kV for SIP/SOP port 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	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	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0° 0% UT; 250/300 cycles	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0° 0% UT; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the anesthesia machine requires continued operation during power mains interruptions, it is recommended that the anesthesia machine be

			powered from an uninterruptible power supply or a battery.
Power frequency magnetic field IEC 61000-4-8	30 A/m(50/60 Hz)	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-400, AX-400A, AX-500 and AX-500A are intended for use in the electromagnetic environment specified below. The customer or the user of the anesthesia machines AX-400, AX-400A, AX-500 and AX-500A should ensure 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 3V/m 80MHz to 2.7GHz	3Vrms (emf), 6Vrms (emf) in ISM and amateur radio bands 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the anesthesia machines AX-400, AX-400A, AX-500 and AX-500A, 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 2.7GHz 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, ashould be less than the compliance level in each frequency range. 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-400, AX-400A, AX-500 and AX-500A are used exceeds the applicable RF compliance level above, the anesthesia machines AX-400, AX-400A, AX-500 and AX-500A 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-400, AX-400A, AX-500 and AX-500A.

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

Recommended separation distances between portable and mobile RF communications equipment and the AX-400, AX-400A, AX-500 and AX-500A.

The AX-400, AX-400A, AX-500 and AX-500A are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AX-400, AX-400A, AX-500 and AX-500A can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AX-400, AX-400A, AX-500 and AX-500A 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.

Declaration - IMMUNITY to proximity fields from RF wireless communications equipment						
AX-400, AX-400A, AX-500 and AX-500A are intended for use in an electromagnetic environment in which RF wireless communications equipment are controlled.						
Immunity test	**IEC60601 test level**				**Compliance level**	**Electromagnetic environment - guidance**
	Test frequency	**Modulation**	**Maximum power**	**Immunity level**		
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m	
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m	
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m	
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m	
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m	
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m	
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m	
Note * - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.						

2.6 Physical Specifications

Dimensions of the Complete Machine	
Size	678 mm *580 mm *1370 mm
Weight	90kg (standard configuration) (without anesthesia vaporizer and gas cylinder)
Top Plate	
Maximum supporting capacity	Maximum load-bearing of top plate is 20kg
Operational dimensions	535mm*235mm
Workbench	
Maximum supporting capacity	Maximum supporting weight of workbench is 20kg
Operational dimensions	465mm*275mm
Handrail	
Length	412mm
Drawers	
Drawers	416mm*395mm*170mm
Manual Bag Support Arm	
Size	Length: 425mm Height: 240mm
Caster Wheels	
Caster wheel	4 inch
Display Screen	
Type	TFT LCD, allowing touch control
Size	AX-400/AX-400A 8.4 inch AX-500/AX-500A 10.4 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 status 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 occur simultaneously).
Audible Indication	
Speaker	It gives out alarm tone and key-stoke tones; supports multiple-level volume function; the alarm tones conform to IEC 60601-1-8.
Buzzer	It may give out alarm tone in case the system cannot work normally.

Connector	
Power supply	1 AC power supply connector 3 multiple socket outlets
Equal-potential	1 equal-potential grounding terminal
Communication ports	1 RJ45 port 1 USB port 1 DB9 port

2.7 Environmental Specifications

Host			
Item	**Temperature (ºC)**	**Relative humidity (Non-condensation)**	**Atmospheric pressure (hPa)**
Work	10~40	≤93%	700~1060
Transportation and storage	–20~60 (oxygen sensor: –20~50)	≤93%	500~1060

2.8 Performance Specifications

Under normal and single fault conditions and when operating under non-transient electromagnetic phenomena according to IEC 60601-1-2, either at least the performance listed in the following table is provided or failure to provide this performance is readily identifiable by the user.

The essential performance consists of: –Supplying the anesthesia workstation with O_2 with oxygen supply failure protection device. If the O_2 supply (medical gas supply system or gas cylinder) fails, technical alarms are generated. –Delivery of a non-hypoxic gas mixture to the patient. If breathing gas contains insufficient O_2, technical alarms are generated. –Non-delivery of excessive concentrations of a volatile anesthetic agent and equipped with anesthetic agent monitoring equipment If excessively high anesthetic gas concentrations are delivered, technical alarms are generated. – Monitoring the airway pressure and the expiratory minute volume – For BIS module, Measurement of Bispectral Index (BIS). Accuracy of amplitude and rate of variation, Input dynamic range and differential offset voltage, Input noise, Frequency response, Common mode rejection, and indication of invalid data of overload, saturation of any part of the amplifier and disconnected lead wires. –Displaying data according to primary operating functions of BIS waveform and Bispectral Index, FiO_2, $EtCO_2$, N_2O, EtAA (through AG gas analyzer), and alarm signals. –Indication of validity of measured values or generating a technical alarm condition, or failure that is readily identifiable by the operator. –Electrosurgery interference recovery –Defibrillation proof Accuracy can be founded on technical specifications in Chapter 15. Alarms are generated depending on the set alarm limits. See Alarm management (list) in Chapter 7.
Alarms, related to gas delivered 1) A high priority technical alarm condition of oxygen supply failure, when the oxygen supply, whether derived from a medical gas pipeline system or from a cylinder, is about to fall, or has already fallen, below a value

necessary for normal operation. 2) Gas reading alarm condition 3) Alarm system that detects an anesthetic breathing system integrity alarm condition 4) Exhaled volume monitoring 5) Alarm system that detects an anesthetic breathing system continuing-positive-pressure alarm condition
Alarms, related to equipment operation 1) Cross-flow between input ports of different gases can exceed 10 ml/h, and alarm condition generated; 2) Upon battery depletion, an alarm signal with medium priority, at least 10 min prior to the loss of function, and high priority at least 5 min prior to the loss of function 3) Detect a power supply failure technical alarm condition when the power supply is outside the rated range

2.8.1 Gas Circuit Specifications

Gas Supply	
Pipeline gases	O_2, N_2O, AIR
Backup gas-cylinder gases	O_2, N_2O, AIR
Pipeline gas connection	NIST
Backup cylinder connection	YOKE-CGA
Pressure range at inlet	280~600kPa
Filter	60-80um

2.8.2 Gas Supply

Tube-type Flowmeter		
Display range and accuracy	Air range	0~10 l/min, the flow can be adjusted to 50ml/min
	O_2 range	0~10 l/min, the flow can be adjusted to 50ml/min
	N_2O range	0~10 l/min, the flow can be adjusted to 50ml/min
Auxiliary Oxygen Supply Flowmeter		
Display range	Type	Float flowmeter
	Range	0~15 l/min
Oxygen/N_2O linked system		
Type	Mechanical type proportional control device	
Range	O_2 concentration shall not be lower than 25%	

2.8.3 ACGO Connector

ACGO	
Connector	A coaxial 15 mm/22 mm conical connector
Back pressure generated at the	Not greater than 2 kPa

rear end of Anesthesia Vaporizer and the front-end of ACGO during quick oxygen charging	

2.8.4 Oxygen Flush

Oxygen Flush	
Oxygen Flush	When the button of "O_2+" is pressed, the quick inflation valve provides the fresh gas outlet with high flow (25-75 l/min) of oxygen.

2.8.5 Anesthesia Breathing System Specifications

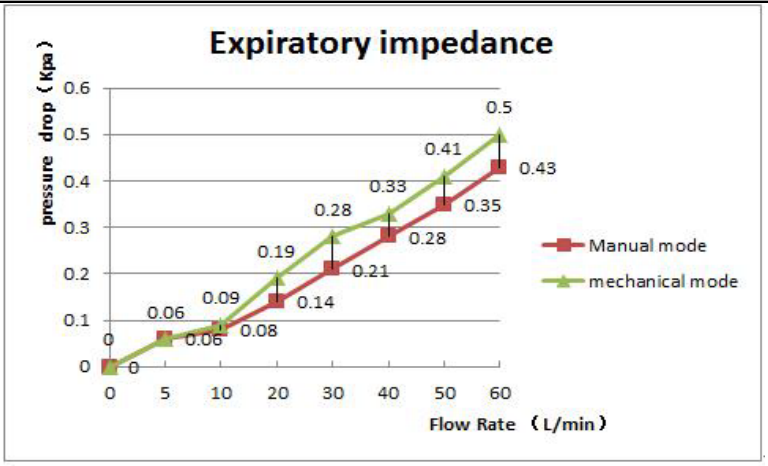
Leakage and Compliance	
Leak in breathing system and its cycle absorption assembly (including Manual/ spontaneous mode and mechanical control mode)	The leakage shall not be greater than 65ml/min at 3kPa.
Compliance of breathing system and its cycle absorption assembly (Manual/spontaneous mode)	Adult mode ≤4 ml/100Pa, pediatric mode ≤3 ml/100Pa
Leak in circle absorber assemblies	Not be greater than 50ml/min at 3kPa.
APL valve leak	Not be greater than 50ml/min at 3kPa (APL valve scale mark is 75)
CO_2 Absorption Apparatus	
Volume of CO_2 absorption apparatus	2000 ml
Ports and Connectors	
Expiratory end	A coaxial 15 mm/22 mm conical connector
Inspiratory end	A coaxial 15 mm/22 mm conical connector
Manual bag end	A coaxial 15 mm/22 mm conical connector
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)
Expiratory impedance	The expiratory pressure/flow rate characteristics at a fresh gas flow rate of 10±1 l/min of the anesthetic breathing system, including the flow at 15 l/min, 30 l/min, 60 l/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 of the anesthetic breathing system, including the flow at 15 l/min, 30 l/min, 60 l/min, the inspiratory impedance of the breathing system should not exceed 0.6 kPa.

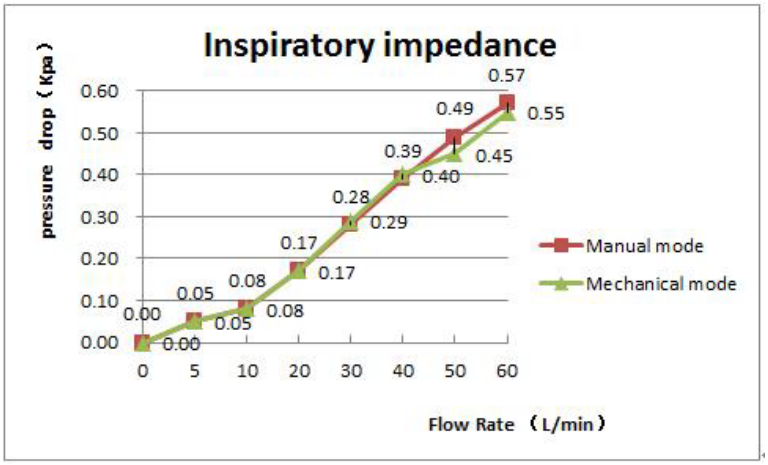
Pressure-flow Curve of APL Valve

Flow (l/min)	APL pressure cmH_2O, dry gas
3	0.17
10	0.21
20	0.26
30	0.33
40	0.42
50	0.53
60	0.71
70	0.93

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)



2.9 Principle and Parameter Specifications of Anesthesia Ventilator

2.9.1 Principle

The principle of this ventilator is pneumatically controlled.

Pneumatic devices of ventilator are fitted inside the workbench of the anesthesia machine. The anesthesia machine can control the gases flowing from electromagnetic valve to the patient. During the inspiratory period, the gas flow turns off the expiratory valve and pushes the bellows downwards. 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 is connected to the monitoring module through two tubes. The monitoring module measures the change in pressure of gas flow that passes through the flow sensors, while pressure varies along with the flow.

The ventilator uses the values related to volumes and alarms on the basis of the data provided by the expiratory gas flow sensors. The ventilator utilizes the other inhaling flow sensor to adjust its output so as to adapt to the variance in fresh gas flow, minor gas leaks, and the gas compliance of the respiration circuit. Patient circuit allows compliance compensation. To obtain further higher accuracy, small quantity of gas assists in maintaining the constant pressure of the expiratory valve by gas resistance penetration.

2.9.2 Parameter Specifications

Parameter Setting Range of Ventilator			
Parameter	**Setting range**	**Step**	**Working mode**
Plimit (Limited Pressure)	10-100 cmH_2O	1 cmH_2O	VCV,SIMV-VC, PCV, SIMV-PC, CPAP/PSV, PRVC, PSVPro, SIMV- PRVC
Pinsp (Inspiratory pressure)	5-70 cmH_2O	1 cmH_2O	PCV, SIMV-PC, PSVPro
ΔPps (Support Pressure)	OFF, 3-60 cmH_2O	1 cmH_2O	SIMV-PC, SIMV-VC, CPAP/PSV, PSVPro, SIMV-PRVC
Apnea Pressure	3-60cmH_2O	1 cmH_2O	CPAP/PSV
PEEP (Positive end-expiratory pressure)	OFF, 3-30 cmH_2O	1 cmH_2O	VCV, SIMV-VC, PCV, SIMV-PC, CPAP/PSV, PRVC, PSVPro, SIMV- PRVC

VT (Tidal volume)	15-1500 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	2-60 bpm	1 bpm	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: -20 ~ -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)	0-2.0 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	0-70 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	
Respiratory Rate	0-120 bpm	
Compl (Compliance)	0-300 ml/cmH_2O	
Resistance	0-600 cmH_2O/(l/s)	
O_2 concentration of oxygen sensor	18%-100%;	
Flow control system	Main flow control system	Monitoring range: 0 l/min -10 l/min
Monitoring Parameters of Positive end-expiratory Pressure PEEP		
Range	0-70 cmH_2O	

2.9.3 Accuracy of Anesthesia Ventilator

Parameters		
VT	15-60 ml: ±10 ml; 60-210 ml (except 60 ml): ±15 ml; 210-1500 ml (except 210 ml): ± 7% of set value.	
Paw	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.IE	I:E: 2:1-1:4: ±10% of actual reading Other scope: ±25% of actual reading. Apnea.IE: 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	When the full scale is between 10% and 100%, the accuracy of the scale should be within ± 10% of the indicated value,

	system	and other ranges are not defined.
Measurement Parameters		
VTexp	0-60ml (excluding 60ml): ±10 ml; 60-3000ml: ± 20ml or ± 7% of the actual reading, whichever is greater; other ranges are not defined.	
Inspiratory tidal volume	The set value ± 20ml or ± 7% of the actual reading, whichever is greater; other ranges are not defined.	
Paw	Pressure monitoring error: -20~120 cmH_2O: ±2.0 cmH_2O or ± 4% of setting value, whichever is greater; other ranges are not defined. End-expiratory positive pressure error: 0-70 cmH_2O: ±2.0 cmH_2O or ± 4% of setting value, whichever is greater; other ranges are not defined. Platform monitoring error: 0-120 cmH_2O: ±2.0 cmH_2O or ± 4% of setting value, whichever is greater; other ranges are not defined. Average pressure monitoring error: -20~120 cmH_2O: ±2.0 cmH_2O or ± 4% of setting value, whichever is greater; other ranges are not defined.	
Rate	±1 bpm or ±5% of the setting value, whichever is greater; 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	0-30 l/min: ±1 l/min or ±15% of the setting value, whichever is greater; >30 l/min: not defined.	
Compl	0-250 ml/cmH_2O: ±0.5 ml/cmH_2O or ± 15% of the actual reading, whichever is greater; other ranges are not defined.	
Resistance	0-20 cmH_2O/(l/s): ±10 cmH_2O/(l/s); 20-500 cmH_2O/(l/s);±50% of the actual reading; other ranges are not defined.	
Flow control system	Main flow control system	When the full scale is between 10% and 100%, the accuracy of the scale is within ± 10% of the indicated value, and 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	2~100 l/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 Preset	High limit	Low limit +2mmHg-150mmHg	High limit greater than

(Respironics CO_2)	Low limit	0mmHg~High limit -2mmHg	low limit
$FiCO_2$ Alarm Preset (Respironics CO_2)	High limit	Low limit +1mmHg~76mmHg	High limit greater than low limit
	Low limit	0mmHg~74mmHg	
$EtCO_2$ Alarm Preset (Masimo CO_2)	High limit	Low limit +2mmHg~190mmHg	High limit greater than low limit
	Low limit	0mmHg~High limit -2mmHg	
$FiCO_2$ Alarm Preset (Masimo CO_2)	High limit	Low limit +1mmHg~99mmHg	High limit greater than low limit
	Low 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.		
Apnea 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, Low: 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	High limit greater than low limit
	Low alarm limit	0mmHg~(high limit -2mmHg)	
$FiCO_2$	High alarm limit	(Low limit +2mmHg)~99mmHg	High limit greater than low limit
	Low alarm limit	0mmHg~(high limit -2mmHg)	
EtN_2O	High alarm limit	(low limit + 2%)~100 %	High limit greater than low limit
	Low alarm limit	0%~(high limit - 2%)	
FiN_2O	High alarm limit	(Low limit + 2%)~100%	High limit greater than low limit
	Low alarm limit	0%~(high limit - 2%)	
EtHAL/EtENF/EtISO/EtSEV/EtDES	High alarm limit	(low limit+0.2%) ～25.0%	High limit greater than low limit
	Low alarm limit	0%~ (high limit - 0.2%)	
FiHAL/FiENF/FiISO/FiSEV/ FiDES	High alarm limit	(low limit+0.2%)~25.0%	High limit greater than low 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%.

2.10 Principle of Oxygen Sensors

The oxygen monitoring device may measure the oxygen concentration inside the patient circuit. The oxygen concentration measured by the oxygen sensor is displayed in the display screen of the anesthesia machine.

The oxygen sensor is a type of electrochemical equipment. Oxygen penetrates into the battery through a diaphragm and oxidizes 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, a signal processing and analysis circuit is used to translate battery signaling into corresponding percentage values of oxygen concentration. System displays the value, and compares it to the stored alarm limits. If the value falls outside the limits, anesthesia machine gives an appropriate alarm.

2.11 Specifications of AGSS Used in Conjunction with Anesthesia Machine

2.11.1 Physical Parameters

Physical parameters of AGSS transfer and receiving system	
Weight	2.2 Kg
Dimension	535×120×155mm (H×W×T)
Applicable laws and regulations	ISO 80601-2-13
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	ISO 9170-2 standard connector

2.11.2 Performance Parameters

Model / Parameter		AGSS-H	AGSS-L
Applicable for treatment system types		1H-type high-flow system: drawing flow rate not less than 75 l/min	1L low-flow system: drawing flow rate 25 ~ 50 l/min
Adjustable rated suction flow range		50-80 l/min	25-50 l/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 normal conditions	75 l/min intake flow impedance	No more than 3.5 cmH_2O	
	Induced flow	Not more than 50 ml/min	
	Rated maximum suction flow pressure drop impedance	AGSS air outlet no lower than 10 cmH_2O	
	Rated minimum suction flow pressure drop impedance	AGSS air outlet no lower than 20 cmH_2O	
	Spillage	Not more than 100 ml/min	
	Leakage	Under inlet air condition of 10 ± 0.5 l/min , less than 90 ml/min	
Under single failure condition	75 l/min intake flow impedance	No more than 10 cmH_2O	
	Induced flow	Not more than 100 ml/min	
	Rated maximum suction flow pressure drop impedance	AGSS air outlet pressure drop resistance no greater than 0.5 cmH_2O	
	Spillage	Exceed 100 ml/min	

2.12 Alarm Specifications

2.12.1 Sound Pressure Alarm

Sound Pressure 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

2.12.2 Air Source Pressure Alarm

Air Source Pressure Alarm	
The range of air source pressure alarm	190-220kPa