Basic Information

Product Name: Anesthesia Machine

Product Model: X5/X6/X7/X8

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.

1.1 Safety

1.1.1 IFU Message Type

In the user manual, there are several types of warning message:

WARNING: This type of message alerts you to situations that may result in serious consequences or adverse events or endanger personal safety. Failure to observe the warning information may cause severe injury or even death of user or patient.

CAUTION: This type of message alerts you to potential dangers or unsafe operations. If not avoided, it may lead to minor personal injury, product malfunction/damage, or property loss. It may also cause more serious damage in the future.

NOTE: This type of message emphasizes important precautions and provides instructions or explanations for better use of the product.

1.1.2 Safety Information

⚠ WARNING

Environment and operators:

- This anesthesia machine and its assemblies must NOT be applied in Magnetic Resonance (MR) Environment, otherwise the equipment will be attracted to the MRI scanner, potentially colliding with operators or patients and resulting in injury.
- The anesthesia machine can only be used in an environment with normal working condition. Inappropriate environmental conditions may cause machine malfunction and ventilation interruption, leading to patient hypoxia or brain damage
- Do not use the equipment in oxygen-enriched environment, or a place where there is explosive gas, or flammable anesthetic gas mixed with air, oxygen or nitrous oxide. Otherwise, explosion or fire could be caused.
- Operators of the equipment must be licensed anesthesiologists who is expected to be knowledgeable and have experience in anesthetic practices and monitoring patients.

- The equipment must be installed and set by personnel who have been authorized by the manufacturer. Without permission, no one shall install or disassemble the equipment.
- Due to the large size and the heavy weight of the anesthesia machine, it should only be moved by authorized personnel.
- Use under standard environmental conditions. If the atmospheric pressure range exceeds the specifications defined in the manual, contact the manufacturer or authorized agent for recalibration; otherwise, inaccurate concentration measurements may occur.

Electricity and Peripherals:

- The anesthesia machine can only be connected to a 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 machine's internal battery for power supply operation.
- Before inserting the power plug of the equipment to the socket, the equipotential conductor must be connected.
- Do not touch the AC inlet or multiple socket outlet of the device; otherwise, it may result in electric shock.
- It is forbidden to connect electrical equipment, which is not a part of the system, to the multiple socket outlet; otherwise, risks such as interference and overload will be caused.
- DO NOT place the power plug used to disconnect the equipment from mains power supply in a position not easily accessible by the operator.
- It is forbidden to use any non-medical peripheral within a distance of 1.8m (6 feet) from the patient, unless such non-medical peripheral is powered via the isolated power socket on the equipment or the isolation transformer complying with the medical safety standard.
- The equipment must be powered using a standard 3-pin earthed plug, and it is forbidden to use double plug or adapter. Meanwhile, the plug must be inserted into a hospital-level standard socket. Otherwise, the leakage current of the equipment may exceed the safety limit.
- No liquid shall splash onto or flow into the equipment; otherwise, the risk of electric shock will be caused. If any liquid enters the equipment, please stop using it immediately and contact the manufacturer's after-sales engineer.
- To prevent the patient from electric shock, it is forbidden to simultaneously touch the patient and the signal input/output port of the equipment.
- 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.

- To avoid interference from HF surgical equipment, DO NOT connect the HF surgical equipment and this equipment to the same power outlet, and keep the equipment away from the HF surgical equipment.
- All medical electrical equipment intended to be connected with this equipment must conform to IEC6060-1:2012, and the entire system should conform to IEC6060-1-1.
- Only use accessories supplied or accepted by the manufacturer. Use of other accessories could result in damage of the product and failure to achieve the expected performance set forth in the User Manual.

Before using:

- Before using this product, read and understand the entire User Manual. Any attempt to use this anesthesia machine (and all other medical devices) without full understanding of the operating instructions may cause injury to the patient or the user.
- Always read manufacturer precautions and guidelines for medications, anesthetic vapour used with this anesthesia machine.
- Attention should be paid to all warnings and prompts on the surface of the equipment so as to ensure the safety of the operator and the normal operation of the equipment. Otherwise, it may cause intraoperative emergence and/or postoperative functional cognitive impairment in the patient.
- Prior to use, the user must check whether the equipment, connecting cables and accessories can work normally and safely. The compatibility of the equipment and any accessories should be checked according to any criteria for safe use.
- Prior to use, the user must check whether the equipment, its accessories and all peripherals have no rust, sharp edge, protrusion or rough surface, which may cause injury.
- Before use, check the expired date of the anesthesia machine and its accessories. DO NOT use expired device or accessories, otherwise, they may fail to achieve the expected performance, potentially leading to patient hypoventilation and low oxygen saturation.
- Prior to use, the user must check the accessory packaging to ensure it is intact and undamaged. DO NOT use the disposable accessories with damaged packaging, as they may fail to achieve the expected performance and lead to biological contamination or malfunction.
- 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.

- 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 supports the use of non-flammable anesthetic agents like desflurane, isoflurane, or sevoflurane.
- Only one type of anesthetic agent can be applied at one time.

After use:

- If the screen becomes unresponsive, stop using the anesthesia machine and contact the manufacturer for service. Otherwise, the operator cannnot adjust and monitor the ventilation parameters, which may cause barotrauma/hypoxia in the patient.
- Do not open the device housing without permission. Maintenance and device upgrade can only be performed by personnel trained or approved by Comen.
- After use of the equipment, please maintain and store it according to the User Manual for the equipment. Improper or imperfect maintenance or storage could cause the cross-infection risk to patients and operators, or cause damage of the equipment and degrade its performance.
- To protect the environment, single-use accessories must be recycled or disposed properly.
- After use, please check the CO_2 absorbent inside the CO_2 absorbent canister and anesthetic agents inside the anesthesia vaporizer, ensuring a normal running of the anesthesia machine.
- When the anesthesia machine is connected to a patient, do not remove or replace fuses or perform any maintenance tasks. Such tasks must only be carried out when the anesthesia machine is not in use with a patient.
- Before removing or replacing a fuse, ensure that the AC power cord has been unplugged.
- Only the fuses specified in the user manual shall be used, and fuse replacement shall only be carried out by designated service personnel. Otherwise, the fuses may fail or be damaged during use, resulting in unexpected ventilation interruption and subsequently leading to low oxygen saturation in the patient.
- Please promptly replace worn or aging consumable parts (such as oxygen sensors, breathing circuits, filters, flow sensors, etc.). Otherwise, the device may fail to provide ventilation support, leading to low oxygen saturation in the patient.
- If the expiratory valve or inspiratory valve is found to be aged or malfunctioning, please promptly contact the manufacturer's authorized service personnel for replacement; otherwise, it may cause hypoxia, brain damage, or barotrauma in the patient.

Others:

- The device does not provide dosing guidance or alter the dose that is prescribed by the clinician.
- The anesthesia machine uses 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.
- Before starting any delivery, always confirm the anesthetic delivering and ventilation setting to the patients need and clinical practices, otherwise might cause inappropriate delivery, which can result in serious injury or death.
- During use of the equipment, the distance between the operator and the equipment should be less than 1m.
- To avoid interrupting the examination due to functional abnormality of the equipment, it is suggested to prepare a standby equipment in the examination room.
- The performance of the equipment and its accessories could be affected over time. To ensure safe use of the equipment, please carry out periodic maintenance as required in the manual.
- The accuracy of the respiratory gas monitor is not maintained when used with Oxygen 93. Therefore, the respiratory gas monitor shall not be used with gas supplied from oxygen concentrators.
- The pipeline components of the anesthesia machine have been degreased and ultrasonically cleaned before assembly.

When the anesthesia machine is used on patients with MH susceptibility:

- 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 CO2 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.

⚠ CAUTION

- Compressed gas supply (pipeline or cylinder): To avoid damaging the device(s) attached to a gas supply, use medical gases only. Pay particular attention to national and international standards regulating the use of medical gases.

- It is recommended continuously monitoring the delivered anesthetic 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.
- When the anesthesia machine is used with anesthesia vaporizer, please use an anesthetic gas monitor conforming to ISO 80601-2-55 to monitor the content of anesthetic vapour in the inspiration gas as protection against dangerous output.
- This equipment 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 equipment may lose its balance if it is tilted more than 10°. Be careful when moving or placing this equipment on a slope that exceeds 10°. Do not hang objects on both sides of the equipment 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.
- 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.
- Breathing system with high resistance of can affect breathing and result in the delivery of incorrect concentration.
- 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 oxygen concentration (FiO_2) shall be monitored when using an auxiliary O_2/air supply flowmeter. If O_2 monitoring is not performed, the concentration of O_2 delivered to the patient will be unknown.
- Unlocking the casters may cause unexpected movement. The operator shall lock the casters while using this device.
- Unmounted devices may slide off the top plate. The device shall be securely mounted on the top plate.
- The power input of the device connected to the MSO shall be within the range of the output of MSO.
- 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 anesthesia machine shall not be operated at home.
- When the device, internal batteries and its accessories exceed their service life, they (include the package material) 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. Otherwise, environmental pollution could be caused.

⚠ NOTE

- Please put the equipment in a place where observation, operation and maintenance are convenient.
- This manual introduces the equipment with the most complete configurations. Some configurations or functions may not be available on the product you have purchased.
- Please keep this manual near the equipment for easy and prompt access when needed.
- The equipment can be used for only one patient at a time.
- Tidal volume and minute ventilation are expressed at BTPS, while fresh gas flowrate are expressed at STPD.
- Changes in inlet pressure, outlet resistance, or ambient temperature may affect the accuracy of the flow rate.

- This device does not contain ortho-phthalaldehyde (OPA).
- The software of this equipment has been developed in accordance with the requirements of IEC 62304:2015 to minimize the probability of risks caused by program error.
- 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 Symbols

⚠ NOTE

- The symbols on the equipment and package may not be exactly the same as above.

1.3 Product Overview

⚠ WARNING

- Avoid mistaking the auxiliary flowmeter for the fresh gas compensation flowmeter. Otherwise, fresh gas cannot be supplied to the breathing system, posing a risk of patient hypoxia.
- Please ensure that the ACGO connection hose is correctly connected to the ACGO outlet and that the message "ACGO in Use" appears on the interface. If it is mistakenly connected to the breathing system port, the device may stop ventilation, resulting in patient hypoxia.
- Do not misuse the manual ventilation function as the ACGO function; otherwise, it may lead to inadequate ventilation, resulting in patient hypoxia.
- Never use antistatic breathing tubes and face masks, which may cause a fire if they are used nearby surgical equipment for high frequency surgery.
- When switching between manual ventilation mode and mechanical ventilation mode, please confirm that the manual/mechanical switch is set to the correct side. Risk of patient hypoxia could be caused if the manual/mechanical switch is set to a wrong position.
- When rotating the APL valve, please confirm that it is turned in correct direction. Otherwise, barotrauma or hypoxia in the patient could be caused.
- The vacuum suction system shall only be operated by the healthcare professional.

- MAX mode is strictly prohibited to be used on patients. Excessive vacuum will hurt the patient's tissues and cause injury to the patient.
- The vacuum suction device is a high vacuum/high flow suction device, which is strictly prohibited in thoracic suction and abortion surgery suction. The excessive vacuum value will hurt the patient's fragile body tissue and the patient's well-being.
- Before vacuum suction, select the appropriate tube at patient end based on the patient's body part, and vacuum suction should only be performed by designated personnel. Otherwise, it may result in excessive negative pressure at the suction site in the patient's airway.
- IEC 60601-1 is applicable to connections between all medical electrical equipment, and is also applicable to connections involving at least one medical electrical equipment and one or more non-medical electrical devices. Even if there were no functional connection between single equipment, a medical electrical system is formed once they are connected to a multiple socket outlet. When multiple devices are connected to the multiple socket outlet, there is a risk that the leakage current may increase and exceed the allowable limit.
- The equipment connected to the auxiliary output power supply shall fall within the voltage/current specifications of the auxiliary output power supply. The equipment connected to the auxiliary output power supply shall be equipment specified by the manufacturer; otherwise, the leakage current may exceed limits, endanger patient or operator, or even damage the anesthesia machine or external equipment.
- If your anesthesia machine is not equipped with a separating transformer, the equipment connected to the auxiliary output power supply may increase the leakage current. The leakage current shall be tested regularly. In order to reduce the total leakage current, it is suggested to select anesthesia machines equipped with a separating transformer.
- If the equipotential system works unreliably, the equipment shall be powered by internal power supply.
- 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 devices, ensure that any connected device is free of

malware.

⚠ NOTE

- In the bellows assembly, there is a transparent cover with scale marks from 300 to 1500 ml on it. The scale marks are for reference only and the users should take the reading of VT on the screen. The delivered VT is the sum of the bellows displacement and the fresh gas flow.
- The values on the APL valve are for reference only. Calibrated patient airway pressure is displayed on the user interface.
- Set the selection switch to "OFF" if the vacuum suction device is not used currently.
- DO NOT install the liquid collection bottle at an incline. Ensure that the bottle is in a horizontal position.
- X5/X7 anesthesia machines do not support electrical ACGO.
- When interconnecting with other devices to transmit data, the signal inadequacy is also recorded in the data stream, so that the user can make judgment and processing based on the quality of the signal.

1.4 Installation

⚠ 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 pose a risk of burn; therefore, never use antistatic or conductive masks or breathing tubes.
- The equipment shall be installed by engineers specified by the manufacturer.
- After the absorbent gets dry, it may pose a danger to the patient if it continues to be used. Replace the soda lime inside the CO_2 absorbent canister if it gets dry. Otherwise, CO_2 concentration in the circuit may increase, resulting in hypercapnia in the patient.
- 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.
- Please follow the instructions in this chapter for installation and detachment. For further installation and detachment, please contact Comen After-sales Service Department. Improper disassembly may result in system leakage and affect the normal use.
- Hostile ambient temperature may affect the precision and accuracy of the device, and cause damage to the components and circuits.
- During operation, it is necessary to ensure that the device is free from condensation. To avoid unnecessary troubles, if condensation occurs, leave the device dry before use.
- When the breathing system is assembled onto the breathing system adapter, ensure that the breathing system is firmly locked. If not, it may separate from the adapter during operation, resulting in severe leak of fresh gas and mismeasurement of tidal volumes.
- Before assembling the bellows housing, check whether 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.
- Follow the instructions in the manual to install the bellows assembly; otherwise, the breathing system may leak, causing hypoxia to the patient.
- Tighten the breathing connector locking nut when installing the flow sensor, otherwise the flow sensor measurement may be invalid.
- Please move the anesthesia machine carefully to avoid collision at the inspiratory port and expiratory port and damage to the flow sensor.
- After replacing the flow sensor, maintenance personnel or personnel authorized by the manufacturer must calibrate it. An inaccurate flow sensor may lead to barotrauma/hypoxia in the patient.
- 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.
- Before assembling an absorbent canister, check the color of CO_2 absorbent inside the absorbent canister so as to determine whether or not to change the CO_2 absorbent first.
- 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.

- Change absorbent frequently to prevent sedimentation of non-metabolic gas when the system is not in use.
- Use of dry CO_2 absorbent may endanger the patients. Before use, please check the CO_2 absorbent inside the canister and ensure the absorbent is not dry. All gas supplies shall be turned off after each use of the system.
- The 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, otherwise, skin or eyes burns could be caused. 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 canister properly; Otherwise, the patient may repeatedly inhale the carbon dioxide they give off.
- CO_2 concentration monitoring is highly recommended. The equipment may be connected to a CO_2 analyzer conforming to ISO80601-2-55 for monitoring the CO_2 output concentration. The CO_2 analyzer to be used is not limited to Masimo brand.
- Please clean CO_2 absorbent and replace the sponge of the absorbent canister regularly; Otherwise CO_2 absorbent powder settled inside the absorbent canister may go into the breathing system.
- Please clean the absorbent canister rim regularly. Otherwise the CO_2 absorbent particles sticking on the rim may result in leakage in the breathing system.
- To assemble the CO_2 absorbent, check 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.
- Only medical-grade gas supplies are allowed to be used. Other types of gas supplies might contain water, oil or other contaminants, causing blockage in pipeline and patient hypoxia.
- Please check the O_2 supply port carefully to avoid leakage. If there is leakage, the O_2 concentration of ambient environment may get higher than normal condition, making the ambient environment a dangerous oxygen-enriched environment.
- Ensure the O_2 supply pressure ranges from 280 to 600 kPa. Excessively high O_2 supply pressure may trigger pressure relief. This can exposed the equipment in an oxygen-rich environment, posing a fire hazard.
- Connect the gas supply hose properly before use; otherwise, breathing system may leak and result in patient hypoxia.
- 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.
- If the vaporizer is incompatible with the anesthesia machine, their performance may be degraded. Please use a compatible vaporizer.

- The anesthesia vaporizer shall conform to ISO 80601-2-13. For installation, addition, discharge, and other information about the anesthesia vaporizer, see the User Manual of the anesthesia vaporizer.
- Only the vaporizers recommended by Comen can be used in conjunction with the anesthesia machine. 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 two anesthesia vaporizers onto an anesthesia machine, the two anesthesia vaporizers must not be turned on simultaneously for concentration control.
- The anesthesia machine may be connected to an anesthesia concentration analyzer that conforms to ISO80601-2-55. It is suggested that the user may assemble an anesthesia concentration analyzer if an anesthesia vaporizer is used, so as to monitor the output of anesthesia concentration.
- The anesthetic vaporizer cannot be used if the control dial is set between the position of “0” and “ON” (next indicated setting position).
- Do not exceed the volume limit when adding anesthetic agents, as this may lead to inaccurate concentration control and result in patient over-anesthesia. It is recommended to monitor the concentration of the anesthetic agent during use of the anesthesia machine.
- 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.
- Before use, please check the liquid level of anesthetic agent inside the vaporizer. When the liquid level reaches the MIN scale mark, please fill the vaporizer.
- During use, monitor the liquid level of the anesthesia vaporizer; in the event of an alarm related to anesthetic gas concentration, also check the liquid level of the anesthetic agent. Otherwise, inadequate anesthesia concentration may occur, leading to patient awakening during surgery.
- 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 anesthetics as follows: USED ANESTHETIC AGENTS.
- Using no gasket or using more than one gasket may result in leakage.
- When pipeline gas supply is in use, do not open the backup gas cylinder valve. Otherwise, the gas cylinder may be exhausted.
- AGSS should be used together with a breathing system complied with ISO 80601-2-13.
- The disposal system should be a Low-vacuum High-flow suction device corresponding with AGSS.
- Before installation, please check the specification of both AGSS and the anesthesia machine, ensuring that they are compatible.

- DO NOT cover the equipment or place in a position that affects proper operation. Do not block the gas intake port, thereby interfering with patient therapy.
- Do not add any attachments or accessories to the equipment that contravene the instructions for use of the equipment or accessory, as the equipment might not function correctly leading to the risk of degradation of health of the patient.
- To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only use tubes with a retention force in conformance with ISO 5367 or ISO 80601-2-74.
- Do not lubricate fittings, connections, tubing, or other accessories of the equipment to avoid the risk of fire and burns.
- Oxygen makes it easier for a fire to start and spread. Do not leave the nasal cannula or mask on bed coverings or chair cushions, if the equipment is turned on, but not in use; the oxygen will make the materials more flammable. Turn the equipment off when not in use to prevent oxygen enrichment.
- The respiratory high-flow therapy is to be equipped with a humidifier that conforms with ISO 80601-2-74:2021 before being put into service.

⚠ CAUTION

- 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 gas supply 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.
- Please place the O_2 supply hose carefully in an environment without potential damages like heat and cutting.
- The PEEP exhaust port may continuously discharge small quantities of oxygen. Never block the outlet; otherwise the anesthesia ventilator cannot work.
- Do not vent anesthetic exhaust gases directly into the operating room, exposing operators to these gases. Otherwise, operators may inhale anesthetic fumes and become drowsy during surgery.
- Prior to an operation, the anesthesia machine shall be equipped with an anesthesia gas scavenging system conforming to ISO 80601-2-13 to purify the air inside the operating room.
- If your anesthesia machine is not equipped with active AGSS, please do not connect the waste gas exhaust port of anesthesia machine to the active waste gas disposal system of the hospital.

⚠ NOTE

- DO NOT weigh down the manual support arm by hands or hang heavy objects onto it.
- When installing the breathing tube, hold both ends of the breathing tube to avoid damaging it.
- Ensure that the breathing tube connected to the inspiration and the expiratory connectors is facing downward. Otherwise, the water formed from condensed vapor may enter the connectors.
- Breathing tube, Y-piece and face mask are not parts of the anesthesia machine.
- Once the absorbent inside the canister absorbs CO_2, its color changes. However, the color change of the absorbent is for reference only. It is advisable to determine when to replace the absorbent by carbon dioxide concentration monitoring.
- Discolored absorbent shall be discarded in time 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 CO_2 monitor. Please check the color of CO_2 absorbent during or after an operation.
- MedisorbTM CO_2 absorbent is recommended by Comen.
- The filled CO_2 absorbent cannot be higher than the "-MAX-" mark on the CO_2 absorbent canister.
- The gas supply hoses shall meet the standards of ISO 5359.
- The hose connectors shall meet the standards of ISO 9170-1.
- For details of vaporizer assembling and operation, refer to instruction manual of corresponding vaporizers.
- Atmospheric pressure may differ from the calibration pressure of the anesthesia vaporizer, which may lead to inaccurate anesthetic output. During the use of the anesthetic system, the operator should continuously monitor the anesthetic concentration to confirm the 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 and do not allow the anesthesia vaporizer to rotate on the vaporizer base.
- If the vaporizer is tilted exceeds 30 degrees, the output concentration could be affected or the anesthetic agent may overfill.
- For the installation of the vaporizers other than Draeger Vapor 2000, please refer to their user manuals.
- The X5/X6/X7/X8 anesthesia machines support the configuration of O_2+Air gas cylinder or O_2+N_2O gas cylinder.
- The X6/X8 anesthesia machines additionally support the configuration of O_2+Air+N_2O gas cylinder.
- There is no O_2+Air+N_2O cylinder holder on X5/X7 anesthesia machine.

- During use, please check the liquid connection bottle for its fullness. Change a bottle or empty the bottle timely if it is full.
- 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.

1.5 Pre-use Check

⚠WARNING

- Make sure that the breathing system is connected properly and intact.
- When installing the absorption canister, check whether the seal ring is installed correctly. If the seal ring is not properly installed, leakage of the breathing system may occur.
- When an alarm indicating breathing system leakage occurs, stop using this anesthesia machine immediately and investigate the cause of the leak. If aging seals are found to be causing the breathing system leak, contact the manufacturer promptly for service. If the leak is caused by a disconnected breathing circuit, reconnect it. A leaking breathing system may result in patient hypoxia.
- If the breathing valve is damaged, contact the manufacturer promptly for repair. Otherwise, a damaged breathing valve may prevent the machine from ventilating properly, leading to patient hypoxia.
- If there is N_2O flowing through the system during this test, it should be collected and removed.
- An improper gas mixture can expose the patient to harm. Do not use the O_2-N_2O Ratio System if it does not provide a proper O2-N_2O ratio.
- Fresh gas contains sufficient O_2, but it does not necessarily prevent the presence of a low-oxygen mixture in the breathing system.
- Before this test, if N_2O is present and flows through the system during this test, it should be collected and removed using a safe and competent method.
- Improper gas mixtures can expose the patient to harm. If the O_2-N_2O Linkage System does not provide the proper ratio of O_2 and N_2O, it should NOT be used.
- Steps 5 and 6 below are for testing the N_2O system only.
- During steps 5 through 6, the oxygen sensors used must be calibrated correctly and the linkage system must be working.
- Adjust N_2O flow first before adjusting O_2 flow.
- To avoid injury, adjust all gas flows to minimum or off before use.

- The presence of a foreign body in the breathing system can block the flow of gas to the patient, which could result in death or injury. Make sure there are no test plugs or other foreign objects in the breathing system.
- The breathing system should be equipped with a ventilator that complies with ISO80601-2-13.

⚠ CAUTION

- The pre-use check must be performed in accordance with the instructions in the manual; otherwise, patient safety issues may occur, such as decreased blood oxygen saturation.
- When reading the flowmeter, the viewing angle should be at the same level as the float. Different viewing angles may result in different readings, posing a risk of low blood oxygen saturation in patients.

⚠ NOTE

- Prior to using the equipment, make sure to read the User's Manual and understand the operation and maintenance of all components.
- If the anesthesia machine fails to pass the pre-use check, stop using the machine and contact Comen.
- For anesthesia vapour 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.
- It is recommended to check whether the N_2O cut-off function and the O_2-N_2O ratio are normal before using the device. Use an O_2 concentration tester to monitor the concentration of O_2 in the output gas.
- When the pipeline gas supply is used, do not turn on the backup cylinder. Otherwise, the user may found the cylinder gas supply used up when turns on the backup cylinder.
- To conduct an N_2O pipeline test, connect O_2 supply first, and make sure that the O_2 supply pressure ranges from 280 to 600 kPa; Otherwise, N_2O flow cannot be regulated.
- If the electronic flow control system fails, the backup oxygen control system can be enabled. The mechanical flowmeter for backup oxygen can display a maximum flow rate of 15 l/min.
- The backup O_2 control knob should be rotated slowly. To avoid damage to the control valve, do not rotate the knob further when it has reached the stop position or when the flowmeter reading is out of range.
- Rotate backup O_2 control knob clockwise to decrease the flow rate, and rotate it anticlockwise to increase.
- System leak test includes the leak test of the anesthetic breathing system and the anesthetic ventilator.
- The leak test must be performed in standby mode.
- Ensure that the breathing system is properly connected and that the breathing pipelines are intact before the system leak test.

- If the user press the stop button during a leak test, the ongoing leak test will be stopped and get invalid. This does not mean that the system has failed the leak test.
- If the leak test fails, check each possible source of leakage: the bellows, the breathing system pipeline, the CO_2 absorbent canister, and whether their connectors are intact or correctly connected. When inspecting the CO_2 absorbent canister, be sure to check for CO_2 absorbent particles adhered to canister seals and remove them if present.
- If the breathing system is leaking, the equipment must not be used. Please contact the service personnel or Comen's after-sales service department.
- Improper connection between the bellows and the intubation tube will result in a leak in the breathing circuit and the tidal volume supplied by the anesthetic machine may get abnormal.
- The ventilator should be equipped with an anesthesia system that complies with ISO 80601-2-13.
- Do not block the pressure compensation port of the AGSS when checking.
- For the safety and health of the patient and others, the vacuum generator switch and the selection switch should be set to OFF position, and the regulator should be turned anticlockwise to the zero position before turning on the air supply (or inserting it into the terminal socket).
- Observe the anesthesia machine's drive gas vent during the test to ensure that it is venting freely.
- When the overfill protection starts, the suction stops. Please empty the liquid collection bottle promptly.

1.6 Basic Operations

⚠WARNING

- Prior to this operation, ensure that you do want to restore to factory default parameters. Otherwise, there may be a risk of applying wrong ventilation parameters, and result in barotrauma or hypoxia in the patient.

⚠ NOTE

- The patient type can be changed only when the anesthesia machine is in standby mode.
- When the patient type is changed, the default settings for patient are changed accordingly.
- The device has a power-failure storage function.
- The warmer is disabled when the anesthesia machine is powered by batteries.
- Records that can be automatically saved by the machine include: reference loops, monitoring trends, event logs (including alarm logs), setting trends, patient settings, device settings, and alarm settings. When the

above data is changed, the system automatically saves the changed data in the flash memory chip on the main board. When the device is restarted, the data will be restored automatically.

- The alarm delay from the anesthesia machine to the center monitor system does not exceed 3s.
- The alarm delay from the anesthesia machine to the monitor does not exceed 3s.

1.7 Interface

⚠WARNING

- If backup oxygen control is enabled, ensure that the control knob is completely turned off at the start and at the end of each ventilation.

⚠ NOTE

- When the data used for the optimal flow calculation is invalid, the optimal flow function will fail.
- The Fresh Gas Optimum Flow Indication feature should not be used when a high flow rate of fresh gas is required.
- The purpose of the optimal flow indication is to save anesthetic agent. This function is a reminder only and it does not relate to the control functions of the anesthesia machine control module.
- The trend data in Standby Mode is not saved.
- The anesthesia machine can store at least 10,000 event records. After exceeding the system storage limit, the earliest occurring event record will be overwritten by the latest occurring event record.
- When the anesthesia machine is powered off, it saves the event log automatically. But the power-off time is not recorded in the event log. When the machine is powered on again, the previously saved event log can be viewed and the log will not be cleared.
- BIS waveform is not frozen even when the freeze function is enabled.

1.8 Start Ventilation

⚠WARNING

- Alarms on the anesthetic machine indicate a potentially dangerous situation for the patient. All alarms should be clarified to ensure patient safety.
- When using sevoflurane, sufficient flow of fresh gas should be maintained.

- Ensure that the equipment is installed correctly and is in good condition before using it on a patient.
- The operator should not touch both the patient and energized equipment outside of this equipment.
- The signal I/O ports can only be connected to specified external devices.
- If any accessories or components are changed, the system self-test must be re-performed.
- A system self-test must be run each time the anesthetic machine is used on a patient. If any test fails, stop using the anesthesia machine immediately. The anesthesia machine cannot be used again until the necessary repairs have been completed and all tests have passed.
- Before performing the system self-test, disconnect the patient from the device and ensure that patient ventilation is supported by other device.
- Before use, check whether the oxygen concentration of output gas corresponds to the set value.
- If the device malfunctions and mechanical ventilation cannot be continued, perform manual ventilation immediately.
- Before use, set the ventilation parameter for each patient. Do not rely entirely on the system default ventilation parameters, otherwise, it may result in barotrauma or hypoxia in the patient.
- Please monitor and ensure that the gas supply pressure is within the range of 280-600 kPa. Gas supply pressure outside this range may lead to inaccurate measurements, resulting in excessive ventilation or hypoxemia in the patient.
- After setting the ventilation parameters, the operator must tap [Confirm] or press the rotary knob to confirm the settings. Otherwise, the settings will not be saved. This could pose a risk of causing barotrauma or hypoxia in the patient.
- To prevent lack of ventilation support from harming the patient, ensure that there is alternative ventilation available before going into standby and make sure that no patient is connected to the anesthetic machine when going into standby.

⚠ CAUTION

- DO NOT perform these tests when a patient is connected via breathing tubes.

⚠ NOTE

- Ensure that the manual/spontaneous mode is available whenever the anesthesia machine is used on the patient.
- Ventilation parameters vary for different ventilation modes.
- The pressure and flow sensors are sampled in real time at a frequency of 1000 Hz.

1.9 Alarm

⚠ WARNING

- The waveforms, physiological parameters and alarm messages are for reference only and cannot be directly used as the basis for clinical treatment.
- Do not set different alarm limits or alarm indications for similar devices in an area (for example, ICU or operation room); otherwise, a potential hazard can exist.
- The user must set alarm sound volume and alarm limits for the patient's actual condition.
- Do not rely on audible alarms during patient monitoring. If the alarm sound is set to a lower volume, patients' safety may be endangered. Please pay close attention to the actual clinical condition of the patient.
- The alarm delay of the anesthesia machine does not exceed 1s.
- When the anesthesia machine triggers an abnormal pressure alarm, switch to manual ventilation and operate according to the procedures in Appendix III; otherwise, patient harm (e.g., hypoxia) could be caused.
- If the pressure sampling tube becomes blocked, the monitored patient pressure could be inaccurate and the anesthesia machine may continue delivering gas to the patient. When the machine triggers a pressure abnormality alarm, switch to manual ventilation first, then troubleshoot according to the method in Appendix III; otherwise, excessive airway pressure may be applied to the patient's lungs, causing pneumatic injury.
- When the anesthesia machine triggers an alarm related to abnormal pressure, please check whether the flow sensor gas tube is obstructed. If the tube is obstructed, stop using it immediately. Otherwise, excessive airway pressure may be applied to the patient's lungs, causing pneumatic injury.
- When the device triggers an alarm related to anesthesia concentration, check the anesthesia vaporizer for any abnormalities. An abnormal anesthesia vaporizer may lead to excessive or insufficient anesthesia concentration, resulting in postoperative cognitive dysfunction or intraoperative awakening of the patient.

- If an alarm related to oxygen concentration abnormality occurs, check whether there is water accumulation in the oxygen sensor. Replace or dry the O_2 sensor. Otherwise, water accumulation may lead to inaccurate measurements, posing a risk of low oxygen saturation to the patient.
- If an alarm related to flow abnormality occurs, check whether there is water accumulation in the flow sensor. If there is any, replace or clean the flow sensor. Otherwise, water accumulation may lead to inaccurate measurements, posing a risk of barotrauma/hypoxia to the patient.
- Before using the anesthesia machine, make sure that the current alarm limits are appropriate for the current patient.
- Avoid setting alarm limits to extreme values, which may cause the alarm system to fail or cause patient injury.
- Before use, set the alarm limits for each patient, or confirm whether the default alarm limits are suitable for the current patient. Do not rely entirely on the system's default alarm limits, otherwise, it may result in barotrauma or hypoxia in the patient.
- During alarm audio pause, close attention should be paid to the actual clinical condition of the patient and the anesthetic machine, ensuring that alarm messages are not ignored. If the alarm condition is allowed to persist without taking any action, it may cause harm to the patient or the anesthesia machine.
- When the alarm is switched off, the anesthesia machine cannot trigger an alarm even if one occurs. Therefore, the user should use this function with caution.
- According to international regulatory requirements, this device requires oxygen concentration monitoring when applied to patients. If the device you are using is not equipped with this function, please use a monitor that meets the requirements of the corresponding international standards for oxygen concentration monitoring.

⚠ NOTE

- When the anesthesia machine is turned on, it tests whether the alarm sound and alarm lamp can work correctly. If they work correctly, the machine gives a “Beep” sound, and the alarm lamp flashes in red and yellow once. If the alarm sound and alarm lamp fail to work correctly, do not use the anesthesia machine and contact Comen immediately.
- If multiple alarms occur simultaneously, the anesthesia machine gives audible and visual alarms of the highest priority among all current alarms.

- When multiple alarms of the same priority occur at the same time, the alarm message will be displayed in the order of alarm generation.
- The minimum alarm sound volume can be changed only in User Maintenance interface (user maintenance password is required).
- All technical alarm priorities, alarm message and alarm lamp of the system have been preset before the product leaves the factory, and cannot be modified by the users. Some physiological alarm priorities can be modified as per actual needs.
- When the alarm volume is set too low, the alarm sound may be overridden by the ambient sound, which could delay the handling of the patient's emergency situation. The minimum alarm volume should be higher than the ambient sound volume.
- When the parameter alarm limit is turned on, and the upper and lower parameter alarm limits are set manually, the anesthesia machine will continuously display the upper and lower parameter alarm limits set by the user without additionally providing the default alarm limits.
- During the use of the device, always pay attention to the parameter alarm limits, and check if they are set to the right values.
- This anesthesia machine is equipped with power failure protection. In the event of an unexpected power failure during use, all alarm settings prior to the power loss will be saved and can be retrieved after the machine is restarted.
- When the parameter value monitored by the machine is higher than the high alarm limit or lower than the low alarm limit, an alarm will be triggered.
- Some alarm limits may change when you choose factory default alarm limits.
- There is no auto alarm limit for AG module, CO_2 module and BIS module.
- During alarm audio pause, other alarm indications work normally.
- This test is not required if you do not have an oxygen sensor.

1.10 CO_2 Monitoring

⚠WARNING

- When placing sampling lines and other tubes, prevent the lines/tubes from wrapping around the patient's throat and causing apnea.
- Do not remove condensation by applying negative pressure to the Nomoline (e.g., using a syringe).

- Inspect the airway adapter before use. If the airway adapter is cosmetically damaged or broken, replace it promptly.
- When the CO_2 module is not in use, it must be switched off. Otherwise, the CO_2 module will remain in operation, which will shorten the service life of the CO_2 module.
- Unless using HME to protect the IRMA probe, the LED status indicator should always be facing upwards when placing the IRMA probe.
- Do not stretch the cable of the ISA sidestream gas analyzer.
- Operate the ISA sidestream gas analyzer in the specified working temperature environment only.
- Ensure that all connections are secure and reliable. If there is any leakage, ambient air will mix with the patient's breathing gas, resulting in a wrong reading.
- If the alarm "CO_2 needs to be calibrated" appears after zero calibration, please conduct zero calibration again.
- Please set gas compensations according to the actual situation. Otherwise, serious deviation of the measured results may be caused, which may lead to misdiagnosis.
- The anesthesia machine is not equipped with automatic barometric pressure compensation. It is important to set the correct altitude before using the CO_2 measurement for the first time. Incorrect altitude settings will result in incorrect CO_2 readings. For every 1000m difference in altitude, CO2 deviates by 5%.
- The gas vent on the module must be connected to the exhaust gas treatment system, the patient circuit (on the anesthesia machine or on the ventilator), to avoid inhalation of anesthetic gas by medical personnel.
- The ISA Sidestream Gas Analyzer is designed to be used only by authorized or trained medical personnel.
- Use only Nomoline sampling lines manufactured by MASIMO.
- The ISA Bypass Gas Analyzer must not be used in flammable anesthetic gases.
- Carefully disentangle the sampling line to reduce the risk of entangling or strangling the patient.
- Do not reuse disposable sampling lines. The disposable sampling lines that have been used should be disposed of according to local medical waste regulations.
- Do not lift the ISA by grasping the sampling line, as this may disconnect the sampling line from the ISA and cause the ISA to fall on the patient.
- Do not use adult/pediatric sampling lines on infants.
- Do not use infant model sampling line on adult/pediatric patients, as this may result in excessive resistance to flow.
- DO NOT use the ISA sidestream gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bio-filter.
- Check if the sample gas flow rate is too high for the given patient type.

- Successful zeroing requires the ambient air in the gas analyzer, so the sidestream module should be installed in a well-ventilated place. Avoid breathing near the sidestream gas analyzer before or during the zeroing procedure.
- The Nomoline sampling line and its interface are not sterile. In order to avoid damage, DO NOT sterilize any part of the sampling line under high pressure.
- Never sterilize or immerse the sidestream gas analyzer in liquid.
- The mobile and RF communication equipment will affect the measurement. Make sure that the sidestream gas analyzer is used in the electromagnetic environment specified in this Manual.
- The sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.
- Replace the sampling line if the sampling line input interface LED flashes red or the prompt message indicating the Nomoline sampling line is blocked appears on the screen.
- No modification to the device is allowed without authorization of the manufacturer. If this device is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.
- The sidestream gas analyzers are not designed for MRI environments.
- During MRI scanning, the ventilator must be placed outside the MRI suite.
- Use of high frequency electrosurgical equipment in the vicinity of the sidestream gas analyzer may produce interference and cause incorrect measurements.
- The condensed water should not be removed by exerting a negative pressure on the Nomoline sampling line (for example, use a syringe).
- An excess positive or negative pressure in the patient circuit may affect the sample gas flow rate.
- An excess exhaust suction pressure may affect the sample gas flow rate.
- The exhaust gas should be transferred to the exhaust system or returned to the patient circuit.
- If the acquired gas sample is used for respiration purpose, always use a bio-filter on the exhausting side.
- When placing the ISA Gas Analyzer, avoid placing it in a position where it could fall on the patient.
- DO NOT use the IRMA adult/pediatric airway adapter on infants as the adapter adds 6 ml of ineffective lumen to the patient circuit.
- DO NOT use the IRMA infant airway adapter for adults as this may result in excessive resistance to flow.
- If there are water droplets/condensation in the airway adapter, replace the adapter.
- Please use the oxygen sensors and IRMA airway adapters manufactured by MASIMO, and adapter cables approved by MASIMO AB.
- Adequate protection should be provided for the host equipment when in contact with live parts.
- When the anesthesia machine displays presentation data.

- There is alarm system alerting the user in situations that could result in death or serious harm to the patient's health.
- The alarm message corresponding to each bit in the IRMA Status Summary field must be implemented in the host device.
- The IRMA probe is not designed for patient contact.
- Incorrect zeroing of the probe can result in false gas readings.
- The IRMA probe is intended to be used only by authorized or licensed medical personnel.
- The IRMA probe must not be used in flammable anesthetic gases.
- Disposable IRMA airway adapters should not be reused. Reuse of disposable adapters can lead to cross-contamination. The disposable airway adapters that have been used should be disposed of according to local medical waste regulations.
- DO NOT open the oxygen sensor. The oxygen sensor in the IRMA probe is a disposable product containing corrosive electrolytes and lead.
- The IRMA probe serves as an aid to patient assessment. It must be used in conjunction with other vital sign and symptom assessment equipment.
- Do not place the IRMA airway adapter between the endotracheal tube and the elbow tube, as this may cause patient secretions to block the adapter window.
- To prevent secretions and moisture from collecting in the window and oxygen sensor port, always place the IRMA probe in the upright position with the LED facing up.
- Do not use the IRMA airway adapter with dosing sprays or sprays, as this may affect light transmission through the airway adapter window.
- Mobile and RF communications equipment can affect measurements. Ensure that the IRMA Probe is used in the electromagnetic environment specified in this user manual.
- Do not disinfect the IRMA probe or immerse it in liquid.
- IRMA O_2 sensors and IRMA airway adapters are not sterile devices. Do not autoclave the equipment as this may result in damage to the equipment.
- Do not install an oxygen-depleted O_2 sensor on the IRMA probe, even if it is not being used.
- Do not stretch the sensor cable.
- Do not operate the module outside the environmental temperature specified in this user manual.
- Replace the airway adapter when there is water accumulation/condensation in it.
- DO NOT use the IRMA Adult/Pediatric airway adapter for infant as the adapter adds 6 ml dead space to the patient circuit.
- DO NOT use the IRMA Infant airway adapter for adults as this may cause excessive flow resistance.

⚠ CAUTION

- When a patient is receiving nebulization therapy, the measured $EtCO_2$ value may be inaccurate. Therefore, it is not recommended to monitor CO_2 during nebulization therapy.
- The $EtCO_2$ values measured by the CO_2 module may differ from the CO_2 partial pressure values measured by blood gas analysis.

⚠ NOTE

- The CO_2 module triggers a physiological alarm only after a respiratory wave has been monitored. When monitoring a patient with the CO_2 module, make sure that the device is properly connected to the patient.
- In order to prevent the condensed water dropping into the gas sampling line and blocking it, the gas sampling line connection end of the airway adapter always be facing upwards.
- For Respironics module, perform zero calibration after a 5-minute warm-up period for best calibration results.
- Using sample lines or cannulas with inner diameter greater than 1 mm will increase the response time of ISA system.

1.11 AG Monitoring

⚠ WARNING

- To avoid explosion, DO NOT use flammable anesthetic agents.
- When placing catheters such as sampling lines, prevent the tube from wrapping around the patient's throat and causing asphyxiation.
- Ensure that all connections are secure and reliable. If there is any leakage, ambient air will mix with the patient's breathing gas, resulting in a wrong reading.
- Do not stretch the sensor cable.
- Only operate the AG module in the working environment with specified temperature.
- Please set gas compensations according to the actual situation, otherwise, a significant deviation between the measured results and the actual values may be caused and lead to misdiagnosis.

- To zero the AG module successfully, please ensure that the AG module is placed in a well-ventilated environment (the ambient air: 21% O_2 and 0% CO_2). Avoid breathing near the AG module before and after performing zeroing.

⚠ CAUTION

- Please perform AG monitoring in a well-ventilated environment.
- The value of $EtCO_2$ measured by the AG module may differ from the value of CO_2 partial pressure measured by the blood gas analyzer.
- For the adverse effects on performance, please refer to the section *9.3 Adverse Effects on Performance*.

⚠ NOTE

- The AG module triggers a physiological alarm only after a respiratory wave has been monitored. When using the AG module to monitor a patient, make sure the device is properly connected to the patient.
- When the anesthetic concentration falls, the highest gas level for a single halogenated anesthetic gas in a gas mixture cannot be detected.
- If the screen of the anesthesia machine indicates that the O_2 sensor is not connected, please reinstall the O_2 sensor.
- The end of the airway adapter that connects to the sampling line should be facing upwards, so as to prevent condensation from entering and clogging the sampling line.
- Factors such as age and weight may affect the effectiveness of inhaled anesthetic agents.
- The above formula is only applicable to patients over one year old. If the patient is less than one year old, the anesthesia machine uses one year as the age for correction.
- Only one anesthetic waveform and value can be displayed at a time.

1.12 BIS Monitoring

⚠ WARNING

- Never use a BIS value as the sole reference for anesthetic dose adjustment.
- Do not allow the sensor and its conductive parts to contact any other conductive part or the ground.

- To reduce the risk of burns do not place the BIS module between the surgical site and the return electrode of the electrosurgical unit in high-frequency surgeries.
- When using a defibrillator on a patient do not place the BIS sensor between the defibrillator electrodes.
- When using a brain stimulator, such as motor evoked potentials by cranial electrical stimulation, keep the stimulation electrodes as far away as possible from the BIS sensor, and place the electrodes and the sensor according to the instructions on the packaging to avoid burns.
- The clinical effects, risks, benefits and application of BIS function are validated and evaluated only for adult patients.
- The monitoring values of the BIS module (indicating excessive depth of anesthesia) shall not be used to determine brain death. Otherwise, it may result in misdiagnosis/delayed treatment, leading to brain damage and hypoxia in patients.
- To ensure accurate BIS monitoring, it is important to place the electrodes in the correct position.
- The electrodes can be placed on the left or right side of the scalp.
- To avoid danger to the patient, the BIS module should not be placed above the patient's head.
- Make sure the patient's skin is dry. Wet sensors or salt bridges may cause incorrect BIS & impedance values.

⚠ CAUTION

- Avoid long-term contact between the BIS module and the skin, otherwise it will generate heat and make the patient uncomfortable.
- Use the BIS sensor immediately after it is turned on.
- When electroconvulsive therapy (ECT) is to be performed during BIS monitoring, please keep the ECT electrodes as far away as possible from the BIS sensor to minimize interference. Since some ECT devices may interfere with the normal BIS monitoring, it is necessary to confirm their compatibility.
- BIS measurements based on EEG signals are very sensitive; please do not use electrical radiation devices near BISx or BISx4.
- BIS measurement results may be inaccurate due to abnormal or excessive electronic interference or EMG activities, such as trembling, muscle activity or stiffness, or continuous eye, head or body movement. Improper placement of the BIS sensor and poor skin contact (high impedance) may also lead to artifacts that interfere with BIS measurement.
- Poor signal quality may lead to inaccurate BIS measurement results.

1.13 NMT Module

⚠ WARNING

- Use of cables or accessories not supplied by Comen may result in serious injury.
- This module can only be purchased and used by licensed anesthesiologists. Its use must strictly comply with the laws and regulation of the country/state where the doctor practices.
- This module may only be maintained by the manufacturer or personnel authorized by the manufacturer.
- Do not use this module near any equipment that generates strong electromagnetic fields, such as high-frequency electrosurgical units. Never use cable leads as antennas, or there could be dangerous currents generated.
- The NMT stimulating current pulses may interfere with other sensitive devices, such as implantable pacemakers. Therefore, NMT monitoring should not be used on patients with implanted medical devices unless directed by a specialist.
- Do not touch the stimulating electrode before the electrical stimulation is stopped.
- When used in conjunction with an electrosurgical unit this module may burn the stimulated part in rare cases and its measurement accuracy may be affected. Make sure the neutral electrode of the electrosurgical unit is connected properly to the patient, in order not to burn the patient at the NMT stimulating electrode.
- Do not use NMT monitoring near any shortwave or microwave therapy equipment, or the measurement results may be affected.
- The patient should not contact with grounded metal objects, in order not to form conductive connections with other devices and/or cause capacitive coupling.
- The stimulating cable should not contact with an external pacemaker or other cables.
- Using electrodes near the chest will increase the risk of heart fibrillation.
- The cables should be positioned in such a way that they do not contact either the patient or other cables.
- Each time before use, please check all components for any damage. Never use any damaged or worn out components.
- If the conductive surface of this module or any cable is exposed it may cause electric shock injury to the operator. In such cases, do not use the module or cable but contact the manufacturer for the repair service.

⚠ CAUTION

- Make sure the ECG electrodes are not damaged or dried.

- Large current densities associated with failing ECG electrodes may cause superficial burns
- The operator should exercise extra caution when using electrodes of >2mA/cm2 current density.
- NMT monitoring is designed as an auxiliary method for patient evaluation. The patient's clinical signs and symptoms must be always observed.
- To avoid electric shock, do not touch the electrodes until the NMT stimulation stops.
- When placing the two electrodes, make sure they do not touch each other.

⚠ NOTE

- To prevent muscle contraction and tension from affecting the determination of reference response amplitude, please perform NMT calibration before injecting muscle relaxants.
- During the NMT measurement, moving or touching the patient may result in inaccurate measurement results.
- Avoid hitting the NMT sensor.
- When the patient moves to a different position, please check whether the NMT sensor is placed properly at the correct position and whether the patient's thumb can move freely.
- If more than one nerve is stimulated, the detected responses may be affected by other muscle activities.
- The farther the sensor is placed on the thumb, the stronger the acceleration signal will be. The signal strength can be adjusted by changing the sensor's position.
- During the NMT measurement, the arm where the electrodes and sensors are placed should remain stable at all times.
- Interval measurement is not applicable to PTC mode.
- After completing the measurement, do not pull the sensor cable when removing the sensor.
- If there is an emergency requiring the termination of NMT monitoring, disconnect the NMT patient cable from the module.

1.14 Other Function

⚠ WARNING

- HFNC can only be used for open or semi-open ventilation such as nasal cannula or mask. Do not use sealed patient interfaces with this equipment, to avoid the risk of suffocation or barotrauma.
- HFNC is only suitable for spontaneously breathing patients.

- Oxygen therapy must be used under the supervision of a healthcare professional. If there is a malfunction or if the patient is not breathing spontaneously enough, the healthcare professional should take corresponding measures.
- During HFNC, respiratory parameters, like Paw, MV, apnea, are not monitored.
- All physiological alarms (except O_2 concentration physiological alarms) are blocked during HFNC.
- For patients who require increased oxygen concentration for treatment, the SpO_2 monitoring device should be used to monitor SpO_2. Otherwise, deterioration of the patient's condition may not be recognized effectively.
- Inadequate air supply pressure may result in inaccurate control of oxygen concentration.
- Turn off mechanical ventilation before enabling HFNC. Otherwise, the accuracy of mechanical ventilation may be inaccurate, or the regulation of HFNC may be limited.
- There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the equipment or accessories near sparks or open flames.
- Open flames during oxygen therapy are dangerous and is likely to result in fire or death. Do not allow open flames within 2 m of the equipment or any oxygen-carrying accessories.
- Smoking during oxygen therapy is dangerous and is likely to result in facial burns or death. Do not allow smoking or open flames within the same room as the equipment or any oxygen-carrying accessories. If the patient intends to smoke, always turn the equipment off, remove the cannula and leave the room where the equipment is located. If unable to leave the room, wait 10 minutes after you have turned the equipment off.
- Ensure a sufficient intended leakage between the breathing system and the patient to allow the patient to exhale.
- Use only water-based lotions or salves that are oxygen-compatible before and during oxygen therapy. Never use petroleum-based or oil-based lotions or salves to avoid the risk of fire and burns.
- The cardiopulmonary bypass function should only be used if the patient is receiving extracorporeal oxygenation with a cardiopulmonary bypass machine. These ventilation modes are not intended to provide metabolic level ventilation to the patient.
- Cardiopulmonary bypass is only available in mechanical ventilation mode.

⚠ NOTE

- Make sure there is as least one inspiratory phase between two expiratory holds.

- The expiration hold function cannot be activated in Standby mode, HFNC, ACGO, or Manual Ventilation.
- The expiration hold function cannot be activated in CPAP mode unless apnea ventilation occurs.
- Make sure there is as least one expiratory phase between two inspiratory holds.
- The inspiration hold function cannot be activated in Standby mode, HFNC, ACGO, or Manual Ventilation.
- The inspiration hold function cannot be activated in CPAP mode unless apnea ventilation occurs.
- This function can be enabled in both mechanical ventilation and manual/spontaneous ventilation modes.
- When the system is in the flow pause state, the mechanical ventilation is suspended, fresh gas flow is turned off, and gas-related physiological alarms are disabled. They are restored after the system exits the flow pause state.
- The P-V tool function is disabled in the following cases:
  - In standby, VS, CPAP/PSV, CPRV, PPS, non-invasive and apnea ventilation modes.
  - When the patient type is Pediatric or Infant.
  - Within 1 minute after the last P-V loop test is finished.
- It is not suggested to use the P-V Tool function when there is large leakage in the breathing circuit or when the patient has spontaneous breathing. Feature points provided by the P-V Tool function are for reference only.
- Lung recruitment is only available in mechanical ventilation mode.
- Pure oxygen or high concentration oxygen is used for lung recruitment ventilation.
- Lung recruitment is not recommended for a patient with spontaneous breathing.
- Terminate lung recruitment immediately when the patient's physiological state is abnormal.
- During lung recruitment process, please pay attention to changes in parameters. Stop lung recruitment if the parameters change too much.
- Ensure that the relevant parameters have been set to the appropriate values before starting lung recruitment ventilation.

1.15 Battery

⚠ WARNING

- Do not disassemble the battery without authorization and do not short-circuit the battery cable to avoid danger.
- Batteries should only be replaced by authorized service personnel. The users should not replace them themselves. Incorrect replacement of lithium batteries will lead to unacceptable risks.

- Install the battery designated by the manufacturer only. For the battery specification, please refer to Appendix IV 4) Power Specifications. Using non-specified batteries may result in equipment fire, leading to burns to personnel.
- Charge the battery only by connecting the anesthesia machine to the external power supply.
- When the screen indicates low battery voltage, connect the anesthesia machine to AC power timely. Otherwise, the anesthesia machine will shut down automatically when the battery runs out, and the ventilation may be interrupted, resulting in patient hypoxia.
- To prolong the service life of the battery, the battery should be used at least once a month and recharged before running out of power.
- To reduce risk of power failure, please pay close attention to the battery level. Battery service duration is affected by anesthetic machine settings, discharge and re-charge cycles, battery life and room temperature. Battery power decreases below room temperature or in the case of continuous alarms.
- Battery electrolyte is harmful. If battery electrolyte accidentally comes into contact with the skin or enters the eyes, immediately rinse with clean water and seek medical attention.
- Keep the battery out of the reach of children.
- When the battery power is too low, please charge the battery immediately, otherwise the anesthesia machine will shut down automatically when the power is low.
- Do not disassemble or short-circuit the battery, or throw it into a fire, as this may cause a fire, explosion, leakage of harmful gases, or other hazards.

⚠ NOTE

- Ensure that the battery has sufficient power and must be recharged after each use.
- In order to prolong the service life of the rechargeable battery, if the battery is stored for a long period of time, it is suggested that the battery should be charged every three months to prevent excessive discharging.
- The power supply time of the battery depends on the configuration and operation of the device.
- Do not store the battery in an environment with temperature above 38°C (100°F) for a long time, since this will significantly reduce the expected service life of the battery.

1.16 Cleaning, Disinfection and Sterilization

⚠ WARNING

- Use only the recommended detergents and disinfectants. Use of other detergents and disinfectants can cause damage to the anesthesia machine or result in a safety hazard.
- Please observe applicable safety precautions.
- The anesthesia machine and its accessories may be subject to microbial contamination during use. Please follow the instructions and recommended cycles for cleaning, disinfecting, and sterilizing. Otherwise, cross-infection between patients and operators could be caused.
- Please regularly clean and disinfect the breathing system; otherwise, bacteria may enter the patient's airway during ventilation, leading to bacterial infection.
- Before cleaning the anesthesia machine, it must be switched off and disconnected from the AC power supply.
- Do not mix different detergent solution, as this can be dangerous.
- This chapter describes reprocessing methods for reusable accessories only. To avoid cross-contamination, DO NOT clean and disinfect single-use accessories or reuse them.
- Oxygen sensor, if damaged, may leak and cause combustion (contains potassium hydroxide). Please wear safety gloves and glasses during reprocessing.
- Reuse of the breathing system and its reusable accessories without reprocessing may lead to cross-contamination. It is recommended to clean and disinfect them before each operation.
- During reprocessing, please ensure that the cleaning and disinfecting method is applicable to the components and that the cleaning and disinfecting method is correct.
- Liquid penetration into the control assembly can damage the anesthesia machine or cause injury. Ensure that no liquid enters the control assembly during cleaning of the enclosure, and always disconnect the anesthesia machine from the AC power supply. After cleaning, ensure that all relevant parts are totally dry before connecting to AC power supply again.
- Do not use talc, zinc stearate, calcium carbonate, corn starch or similar materials. These materials may cause adhesion and have the potential to enter the patient's lungs or airways and cause irritation or injury.
- DO NOT disassemble the pressure relief valve, otherwise damage to the base or diaphragm and injury to the patient may be caused.

⚠ NOTE

- Never use organic, halogenated or petroleum-based solvents, glass cleaners, acetone or other harsh cleaners.
- The breathing system must be cleaned and disinfected before using on each patient.
- Do not use abrasive cleaners (e.g. steel wool, silver polish or detergents).
- If there are any questions about the detergent, please refer to the data provided by the detergent

manufacturer.

- Keep liquids away from electronic components and do not allow liquids to penetrate into the equipment housing.
- Synthetic rubber parts should not be immersed in liquid for more than 15 minutes, which can cause swelling or accelerated deterioration.
- After cleaning, disinfecting or sterilizing, please carry out the system self-test and ensure the test is passed before using the anesthesia machine again.
- Only parts marked with “134ºC” are autoclavable.
- The pH value of the detergent solution must be between 7.0 and 10.5.
- DO NOT sterilize accessories, unless otherwise indicated in the accompanying user manual.
- Do not soak the bellows assembly in warm water and detergent solution for more than 15 minutes.
- When drying the bellows of the bellows assembly, it should be hung and fully unfolded.
- When cleaning, please disassemble the bellows assembly first. Otherwise, it may take a long time to dry.
- Disassemble the bellows assembly before autoclaving. During autoclaving, place the bellows assembly with the top end facing down.
- After reprocessing, ensure that the float of AGSS is completely dry before installation, because small amount of liquid may stick the float.
- Do not immerse the oxygen sensor in liquids or subject it to high temperatures and pressures.
- Do not brush the flow sensor.
- Do not clean the inner surface of the flow sensor and O_2 sensor.
- Flow sensors that are not resistant to high-temperature and high-pressure sterilization should not be subjected to high-temperature and high-pressure treatment.
- Do not separate the check valve diaphragm from the check valve cover.
- If the breathing system main body is difficult to push in or out, the user can apply lubricant to the seals of the breathing system adapter connector to reduce friction.
- Careful lift the breathing system main body when removing it from the installation pin. These operations may be hard due to the weight and shape of the breathing system main body.
- When detaching the breathing circuit, hold both ends of the breathing circuit to prevent damage.
- Components marked with “134ºC” are autoclavable.
- The recommended temperature for autoclaving is 134°C (273°F).
- If the equipment is used in dusty environments, shorten the cleaning and disinfection intervals, ensuring the

anesthesia machine is dust-free.

- The flow sensor must be fully dried before use.

1.17 Maintenance and Troubleshooting

⚠ WARNING

- Improper use of the anesthesia machine could cause hazards to patients and device performance.
- Do not use the anesthesia machine in a faulty condition.
- All safety checks or maintenance that require disassembly should be conducted by professional maintenance personnel. Otherwise, device failure or safety hazard could be caused.
- Extra care is needed when handling absorbents as they are corrosive irritants.
- Do not use lubricants containing oil or grease. Lubricants containing oil or grease may pose a risk of combustion or explosion when O_2 reaches a certain concentration.
- Damaged parts should be replaced with parts manufactured or sold by Comen. After replacement, it is necessary to conduct a pre-use test, ensuring that the anesthesia machine meets the manufacturer's specifications.
- Moving parts and removable components may be damaged or pinch your hands when they are moved or replaced. Please pay extra caution when moving or replacing system components.
- Do not modify the device without permission.
- Pressure regulation valve and flowmeter susceptible to high-pressure impacts. If they are repaired or detached improperly, the regulation valve and flowmeter may explode under pressure. Therefore, only qualified personnel are allowed to replace connectors or disassemble them.
- Perform timely maintenance and calibration of flow sensors, oxygen sensors, pressure sensors, etc. Otherwise, it may lead to equipment malfunction, resulting in inadequate ventilation and low oxygen saturation in the patient.
- DO NOT perform O_2 concentration calibration while the anesthesia machine is connected to a patient.
- When calibrating the oxygen sensor, the ambient pressure must be the same as the ambient pressure used for oxygen delivery monitoring. Otherwise, the monitored value may be exceed the specified range.
- Before calibrating the oxygen sensor, ensure that there is no water accumulation on the oxygen sensor and its mounting area.
- O_2 concentration calibration is not required if the oxygen sensor is not configured or used.
- When moisture enters the breathing circuit, it may cause inaccurate tidal volume measurements, leading to over- or under-ventilation and resulting in barotrauma or hypoxia in patients. Therefore, remove any

accumulated water from the breathing circuit timely.

- After drainage, the operator must reinstall the drain valve, otherwise, leakage in the breathing system may be caused, which potentially leads to inadequate ventilation for the patient.
- Please promptly clean the water accumulation inside the drain valve; otherwise, the device may fail to provide adequate ventilation support, resulting in low oxygen saturation in the patient.

⚠ NOTE

- If you want to know more about the product information and its related technical data, please contact the After-sales Service Department of Comen. Comen provides the documentation of some parts according to the specific situation.
- Perform 21% and 100% O_2 calibration when the O_2 concentration monitoring value is in large error, or after replacing the oxygen sensor.
- If 21% or 100% O_2 calibration fails, please check if there is an associated technical alarm. Perform the calibration again after troubleshooting.
- O_2 calibration must be performed in Standby mode.
- If the calibration fails several times, replace the oxygen sensor and re-calibrate. If the calibration still fails, contact Comen after-sale service department.
- If the calibration fails several times, replace the oxygen sensor first and perform 21% O_2 calibration. After 21% O_2 calibration, perform a 100% O_2 calibration. If the 100% O_2 calibration still fails, please contact Comen after-sale service department.
- After calibration, the gas for calibration should be discharged to the anesthetic gas scavenging system.
- Stop NMT measurement or calibration before performing sensor test.
- Avoid hitting the NMT sensor.
- This section is only applicable for Comen NMT module.

1.18 Accessories

⚠ WARNING

- Use the accessories designated by the manufacturer only. Using other accessories may lead to incorrect measured values, equipment failure, or fail to meet the biocompatibility requirements for contact, causing allergic reactions or skin damage in patients.

- Disposable accessories are intended for single use only. Do not reuse or clean and disinfect. Repeated use may result in reduced performance or cross-contamination.
- If the packaging of an accessory is broken, do not use it.
- All accessories intended to contact the human body meet the biocompatibility requirement of ISO 10993-1 and ISO 18562 Standard. They are compatible with non-inflammable anesthesia gases and anesthetic agents and are expected to cause no adverse reaction when in contact with the human body. These accessories must not be used with inflammable anesthesia gases.
- When the device and its accessories reach the end of their service life, they must be disposed of in accordance with the local regulations for contaminated and biohazardous materials.

1.19 EMC

⚠ WARNING

- DO NOT stack this equipment 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.
- Class-A devices are intended to work in industrial environments. Considering this product's conduction disturbance and radiation disturbance, it may be difficult to ensure its EMC in non-industrial environments.
- The use of accessories, transducers or cables other than those specified with equipment and systems may result in an increase in anesthesia machine emissions or a decrease in immunity.
- Using any accessory or cable other than those sold by the manufacturer as spare parts may cause higher electromagnetic emission or lower electromagnetic immunity.
- Operation of the anesthesia machine at values lower than the minimum amplitude or minimum values specified in this manual may lead to inaccurate consequences.

⚠ NOTE

- The equipment complies with the applicable EMC requirements in IEC60601-1-2.

- Please follow the EMC instructions in the User Manual to install and use the equipment.
- Portable and mobile RF communication devices may affect the performance of the device. To protect the device against strong electromagnetic interference, please keep it away from mobile phones, microwave ovens, etc.
- Refer to the attached guide and manufacturer's statement.
- Although the anesthesia machine has low RF emission, and is less likely to cause interference to nearby electronic devices, it is suggested to maintain distance from other equipment.

Chapter 2 Performance Information

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 breath system, an anesthesia gas delivery device, an anesthesia ventilation, an O_2 monitor and CO_2 monitor, and it can be installed with an AGSS system. Where:

- The anesthesia machine conform to the Standard of ISO 80601-2-13.
- Pressure limit device, expiratory gas volume monitor and breathing system equipped with an alarm system conform to the Standard ISO 80601-2-13.
- Pressure measurement device and anesthesia ventilation system conform to the Standard ISO 80601-2-13.
- Anesthetic gas scavenging system conforms to the Standard ISO 80601-2-13.
- Vacuum suction system conforms to the Standard ISO 10079-3.
- Anesthesia gas delivery device conforms to the Standard ISO 80601-2-13.
- Anesthesia ventilator conforms to the Standard ISO 80601-2-13.
- Alarm system conforms to the Standard IEC 60601-1-8.
- Anesthesia concentration analyzer, O_2 monitor and CO_2 monitor conform to the Standard ISO 80601-2-55.
- NMT Module conforms to IEC 60601-2-40.

1) Product Classification

Item	Type
Type of protection against electric shock	Class I, with internal power supply
Level of protection against electric shock	CO_2 and AG sampling line, BIS sensor, breathing pipeline and mask: Defibrillation-proof type BF applied part NMT: Defibrillation-proof type CF applied part
Degree of ingress protection	IP21
Safety degree of protection against hazards of explosion	Not for use with flammable anesthetic agents.

Permanent or non-permanent installation	Non-permanent installation
Operation Mode	Continuous operation
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

2) Environmental Specifications

Main Unit			
Item	Temperature (ºC)	Relative humidity (Non-condensing)	Atmospheric pressure (kPa)
Operating environment	10~40	≤93%	70.0~106.0
Transportation and storage environment	-20~60 (O_2 Sensor:-20~50)	≤93%	50.0~106.0

Range of operating altitude: not higher than 3000m

3) Physical Specifications

Dimensions of the main unit	
Noise (under typical working mode)	Not more than 45 dB(A)
Size	(900±30)mm×(700mm±30)mm×(1400±30)mm (width×depth×height)
Bearing weight of the top plate	20kg
Size of the top plate	(360mm±10)mm×(280±10)
Maximum bearing weight of the workbench	20kg
Size of the workbench	(485±10) mm× (460±10) mm× (850±20) mm (width×depth×height)
Inner size of drawers	(360±10) mm× (300±10) mm× (130±10) mm (width×length×height)
Weight	200kg
Caster size	5 inch
Screen	
Type	Display: TFT screen Touchscreen: capacitive touch screen
Size	X5/X6: 15.6 inch

	X7/X8: 18.5 inch
Resolution	1920 pixel ×1080 pixel
Rotation range	≥ 360 degrees
LED light	
AC power indicator	1 green LED
Battery status indicator	1 green LED
Alarm indicator	1 indicator light
Port	
Name	Function
HDMI port	1 port for connection to an external monitor. It outputs a video signal with the same content as that displayed on the main screen.
RJ45 network port	1 port (supports TCP/IP communication protocol) for connection with PC to upgrade the software online.
USB port	4 ports (support standard USB2.0 communication protocol) for upgrading the software or exporting data.
Multifunctional port	1 port. It supports connection to external calibration device for pressure calibration. It can also connect to medical-grade external devices to enable bidirectional communication with the anesthesia machine.

4) Power Specifications

External AC power supply	
Input voltage	220-240V~ 100-240V~ (no isolation transformer is configured)
Input frequency	50Hz/60Hz
Input current	3.5A 7.0-3.5A (no isolation transformer is configured)
Fuse	T10AH250V
Multiple socket outlet (4 outlets)	
Output voltage	220-240V~ 100-240V~ (no isolation transformer is configured)
Output frequency	50Hz/60Hz
Output current	Total not more than 2.2A Total not more than 4.4-2.2A (no isolation transformer is configured)

Internal Battery	
Number of batteries	1 or 2 pieces
Battery type	Rechargeable lithium battery
Rated Battery Voltage	14.4VDC
Battery capacity	1 Li-ion battery 6700 mAh; 2 Li-ion batteries 13400 mAh
Maximum time required to fully charge the internal battery	Not less than 4h (power-on working state or standby state)
Battery runtime	Under typical working mode, the runtime of a fully charged new battery is not less than 155 min, and the runtime of two fully-charged new batteries is not less than 310 min.

Note:

Typical working mode refers to the operating state of the anesthesia machine with the following parameter settings (without configuring any plug-in module):

- Ventilation mode: volume-controlled ventilation mode
- Respiratory rate: 10 bpm (20 bpm in pediatric mode)
- I:E : 1:2
- VT: 500 ml (300 ml in pediatric mode)
- PEEP: OFF
- Plimit: 40 cmH_2O
- Tpause: OFF
- Rated working pressure of gas source: 400 kPa ± 100 kPa.
- Analogue lung parameters:

  Compliance: 0.05 l/cmH_2O ~ 0.15 l/cmH_2O (adults)

  0.003 l/cmH_2O ~ 0.05 l/cmH_2O (pediatric)

  Air resistance: 0.5 cmH_2O/(l/s) ~ 5.0 cmH_2O/(l/s) (adults)

  5 cmH_2O /(l/s) ~ 40 cmH_2O /(l/s) (pediatric)

For tidal volumes of 50 ~ 300 ml, a pediatric analogue lung is used; for tidal volumes above 50 ml, an adult analogue lung is used.

5) Data Review

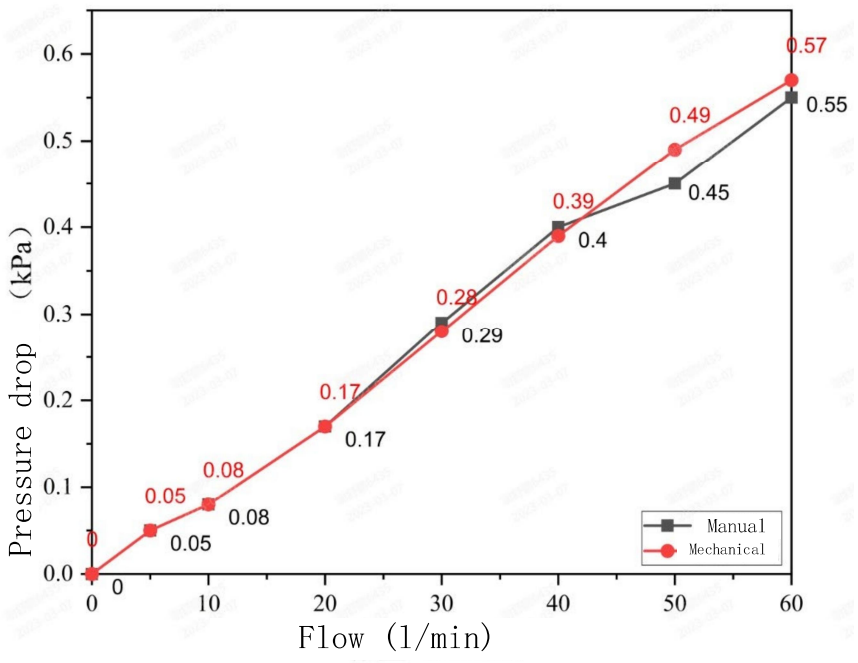
Item	Specification
Screenshot storage	50 screenshots
Loops	10 loops
Graphic trend	Continuous storage for 168 hours; the data is saved even after shutdown
Numerical trend	Continuous storage for 168 hours; the data is saved even after shutdown
Event log	10000 logs

6) Circuit Specifications

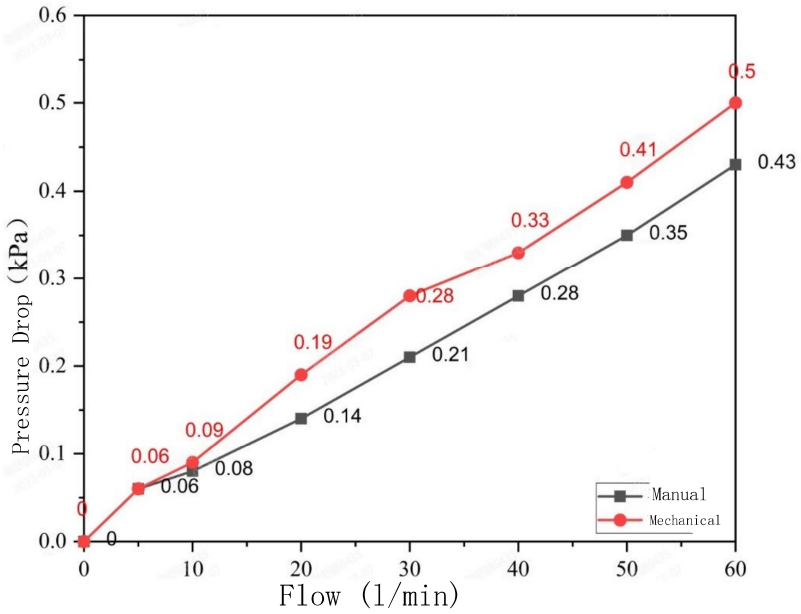
Gas Supply	
Pipeline gas	O_2 (two), N_2O (optional), Air
Backup cylinder gas	O_2, N_2O, Air
Monitoring range	Pipeline gas: 0 ~ 1000 kPa Backup cylinder gas: 0 ~ 20000 kPa
Pipeline gas connections	NIST
Backup cylinder connection	YOKE-CGA
Pipeline inlet pressure	280 kPa ~ 600 kPa, peak flow rate is not more than 200 l/min
Gas requirement	Dry and clean medical compressed O_2, Air and N_2O
Flowmeter Adjustment	
Direct flow control	**O_2:** 0 l/min (Standby), 0.2 l/min ~ 15 l/min **Air/N_2O:** 0 l/min ~ 15 l/min
Total flow control	21%~100% (Air balance gas) 25%~100% (N_2O balance gas) Total flow: 0 l/min (Standby), 0.2 l/min ~ 20 l/min
Backup flow control (O_2)	0 l/min ~ 15 l/min
High Pressure O_2 Supply	
Pressure range	280 ~ 600 kPa
Flow range	≥90 l/min
O_2-N_2O Linkage System	
Type	Electronic proportional controls

Range	O_2 concentration is not less than 25%. When the O_2 supply pressure is lower than 100 kPa, N_2O is turned off immediately
Ventilator Performance	
Drive pressure	280-600 kPa
Inspiratory flow	Maximum inspiratory flow rate is not less than 180 l/min at a gas supply pressure of 280 kPa.
Range of flow valves	1~180 l/min
Ventilator pressure limit control methods	1. Controlled by means of an electronic pressure relief valve inside the ventilator. 2. Controlled by a mechanical pressure relief valve inside the ventilator.
Leakage of Breathing System	
Leakage of the breathing system and its circulatory absorption components (including manual/spontaneous ventilation and mechanical ventilation modes)	Breathing system leakage is no more than 49.5 ml/min at 3 kPa pressure
CO_2 absorbent canister leakage	Not greater than 40.0 ml/min at 3 kPa pressure
APL valve leakage	Not greater than 40.0 ml/min at 3 kPa (APL valve scale is 75)
Breathing Circuit	
Breathing circuit volume	Not greater than 2.5 l
Compliance and Resistance	
Compliance of the breathing system and its circulatory absorption components (including manual/spontaneous ventilation mode)	Manual ventilation mode: ≤4 ml/cmH_2O at 30 cmH_2O pressure Mechanical ventilation mode: automatic compliance compensation
Inspiratory resistance	Not greater than 6 cmH_2O
Expiratory resistance	Not greater than 6 cmH_2O
CO_2 Absorbent Canister	
CO_2 absorbent canister volume	2000 ml
Ports and Connectors	

Expiratory end	22 mm outer, 15 mm inner tapered coaxial connector	
Inspiratory end	22 mm outer, 15 mm inner tapered coaxial connector	
Manual bag end	22 mm outer, 15 mm inner tapered coaxial connector	
Airway Pressure Gauge		
Range	-20 ~ 100 cmH_2O	
Accuracy	± (4% of full scale reading + 4% of actual reading)	
APL Valve		
Range	2~75 cmH_2O	
Tactile knob indication	Above 30 cmH_2O	
Minimum opening pressure	0.2 kPa (dry), 0.2 kPa (wet)	
APL Valve Pressure Flow Curve (APL valve completely open)		
Flow (l/min)	APL Pressure (kPa, dry)	APL Pressure (kPa, wet)
3	0.17	0.18
10	0.21	0.22
20	0.26	0.27
30	0.33	0.34
40	0.42	0.43
50	0.53	0.54
60	0.71	0.73
70	0.93	0.94
Expiratory impedance of the breathing system and its circulating absorptive components (CO_2 absorbent canister filled with Medisorb™ CO_2 absorbent)		



Inspiratory impedance of the breathing system and its absorption components (CO_2 absorbent canister filled with Medisorb™ CO_2 absorbent)



7) Anesthesia machine specifications

Anesthesia machine control parameter specifications and accuracy			
Setting parameters	Setting range	Step	Accuracy
VT	10 ml ~ 1500 ml (VCV, SIMV-VC) 5 ml ~ 1500 ml (PRVC, SIMV-PRVC)	5 ~ 50 ml: 1 ml 50 ~ 100 ml: 5 ml 100 ~ 300 ml: 10 ml 300 ~ 1500 ml: 25 ml	In the range of 5 ml ~ 10 ml: ± (set value- 1 ml); In the range of 10 ml ~ 60 ml (excluding 10 ml): ±10 ml;

			In the range of 60 ml ~ 210 ml (excluding 60 ml): ±15 ml; In the range of 210 ml to 1500 ml (excluding 210 ml): ±7% of the set value.
Respiratory Rate (RR)	2 bpm ~ 100 bpm	1 bpm	±1 bpm or ±5% of set value, whichever is greater
I:E	4:1 ~ 1:10	0.5	In the range of 2:1 ~ 1:4, the error is ±10% of the set value; Error in other ranges: ±25% of the set value.
Tpause	OFF, 5% ~ 60 % of inspiratory time	1%	In the range of 5% ~ 8%: ± (set value-0.1% (absolute value)); In the range of 8% ~ 60% (excluding 8%): ± 8% (absolute value).
Pinsp	5 cmH_2O ~ 90 cmH_2O	1 cmH_2O	±2 cmH_2O or ±7% of the set value, whichever is greater
Plimit	10 cmH_2O ~ 100 cmH_2O	1 cmH_2O	±2 cmH_2O or ±7% of the set value, whichever is greater
Psupp	OFF, 3 cmH_2O ~ 60 cmH_2O	1 cmH_2O	±2 cmH_2O or ±7% of the set value, whichever is greater
PEEP	OFF, 3 cmH_2O ~ 50 cmH_2O	1 cmH_2O	The error is not defined in the OFF state In the range of 3 cmH_2O ~ 50 cmH_2O: ±2.0 cmH_2O, or ±7% of the set value, whichever is greater.
▵int.PEEP	OFF, 3 cmH_2O ~ 40 cmH_2O	1 cmH_2O	± (2 cmH_2O + 4% of set value), whichever is greater
Inspiratory time (Tinsp)	0.2 s ~ 10 s	0.1 s	±0.19 s
Tslope	0 s ~ 2.0 s	0.1 s	In the range of 0.1 s ~ 0.2 s: ± (set value-0.01 s); In the range of 0.2 s ~ 2.0 s (excluding 0.2 s): ± 0.2 s or ± 20% of the set value, whichever is greater
SIMV Rate	2 bpm ~ 60 bpm	1 bpm	±1 bpm or ±10% of set value, whichever is greater

MinRate	2 bpm ~ 60 bpm	1 bpm	±1 bpm or ±5% of set value, whichever is greater
Apnea pressure (Papnea)	3 cmH_2O ~ 60 cmH_2O	1 cmH_2O	±2 cmH_2O or ±7% of the set value, whichever is greater
Apnea I:E	4:1 ~ 1:8	0.5	Error in the range of 2:1 ~1:4 is ±10% of the set value Error in other ranges: ±25 % of the set value
Tapnea	10 s ~ 30 s	1 s	±3s or ±20% of set value, whichever is greater
Trigger window	5%~ 90%	1%	In the range of 5% ~ 10%: ± (setting value -0.1% (absolute value)); In the range of 10% ~ 90% (excluding 10%): ± 10% (absolute value)
Inspiratory trigger	Trigger pressure: -20 cmH_2O to-1 cmH_2O	-0.5 cmH_2O	In the range of-2 cmH_2O to-1 cmH_2O: ± (set value +0.1 cmH_2O) In the range of-20 cmH_2O to -2 cmH_2O (excluding-2 cmH_2O): ±2 cmH_2O
	Trigger flow: 0.2 l/min ~ 15 l/min	0.1 l/min	In the range of 0.2 ~ 1.0 l/min: ± (set-0.01 l/min); In the range of 1.0 l/min ~ 15 l/min (excluding 1.0 l/min): ±1 l/min
Exp%	5%~ 80 %	1%	In the range of 5% ~ 10%: ± (setting value- 0.1% (absolute value)); In the range of 10% ~ 80% (excluding 10%): ± 10% (absolute value)
Backup exist	OFF, 1 ~ 5	1	/
High pressure level (Phigh)	3 cmH_2O ~ 90 cmH_2O	1 cmH_2O	±2 cmH_2O or ±7% of the set value, whichever is greater
Low pressure level (Plow)	OFF, 3 cmH_2O ~ 50 cmH_2O	1 cmH_2O	±2 cmH_2O or ±7% of the set value, whichever is greater

High pressure time (Thigh)		0.2 s~10s	0.1s	±0.19s or ±10% of set value, whichever is greater
Low pressure time (Tlow)		0.2 s~10s	0.1s	±0.19s or ±10% of set value, whichever is greater
MV%		25-350%	1%	±10% (absolute) or ±10% of the set value, whichever is greater
Electronic flowmeter	Direct flow control mode O_2 flow	0.2 l/min ~ 15 l/min	In the range of 0.2 l/min ~ 1 l/min: 0.05 l/min; In the range of 1 l/min ~ 15 l/min: 0.1 l/min.	Between 10~100 % of the full scale: within ±10% of the indicated value
	Direct flow control mode Air/N_2O flow	0 l/min ~ 15 l/min	In the range of 0.2 l/min ~ 1 l/min: 0.05 l/min; In the range of 1 l/min ~ 15 l/min: 0.1 l/min.	Between 10~100 % of the full scale: within ±10% of the indicated value
	Total flow control mode oxygen concentration (Air balance gas)	21%~100%	1%	Not more than ±3% (V/V)
	Total flow control mode oxygen concentration (N_2O balance gas)	25%~100%	1%	Not more than ±3% (V/V)
	Total flow control mode flow	0.2 l/min ~20 l/min	0.2 l/min ~ 1 l/min: 0.05 l/min; 1 l/min ~ 20 l/min: 0.1 l/min.	Between 10~100 % of the full scale: within ±10% of the indicated value
	Backup Oxygen Control	0 l/min ~15 l/min	/	Between 10~100 % of the full scale: within ±10% of the indicated value; Other ranges are not defined.
Auxiliary O_2 supply or auxiliary O_2 supply+ air flow		0 l/min ~ 15 l/min	/	Between 10~100 % of the full scale: within ±10% of the indicated value;

control (tubular flowmeter is oxygen calibrated)				Other ranges are not defined.
HFNC	Oxygen concentration	21% ~ 100 %	1%	±5 % (V/V)
	Flow	2 l/min ~ 80 l/min	0.5 l/min	In the range of 2 l/min ~ 80 l/min: ±1 l/min or ±10% of the set value, whichever is greater

Anesthesia machine monitoring parameter specifications		
Parameters	Range	Monitoring Accuracy
Ppeak	-20 cmH_2O ~ 120 cmH_2O	±2.0 cmH_2O or ±4% of the actual reading, whichever is greater; other ranges are not defined
PEEP	0 cmH_2O ~ 70 cmH_2O	±2.0 cmH_2O or ±4% of the actual reading, whichever is greater; other ranges are not defined
Pplat	-20 cmH_2O ~ 120 cmH_2O	±2.0 cmH_2O or ±4% of the actual reading, whichever is greater; other ranges are not defined
Pmean	-20 cmH_2O ~ 120 cmH_2O	±2.0 cmH_2O or ±4% of the actual reading, whichever is greater; other ranges are not defined
Paux	-20 cmH_2O ~ 120 cmH_2O	±2.0 cmH_2O or ±4% of actual reading, whichever is greater; other ranges are not defined
ACGO Pressure	-20 cmH_2O ~ 120 cmH_2O	±2.0 cmH_2O or ±4% of the actual reading, whichever is greater; other ranges are not defined
VTexp	0 ml ~ 3000 ml	0 ml ~ 60 ml: ±10 ml; 60 ml ~ 210 ml (excluding 60 ml): ±15 ml; 210 ml ~ 3000 ml (excluding 210 ml): ±7% of the actual reading; other ranges are not defined
VTinsp	0 ml ~ 3000 ml	0 ml ~ 60 ml: ±10 ml; 60 ml ~ 210 ml (excluding 60 ml): ±15 ml; 210 ml ~ 3000 ml (excluding 210 ml): ±7% of the actual reading; other ranges are not defined

MV		0 l/min ~ 100 l/min	0 l/min ~ 100 l/min: ±0.1 l/min or ±8% of the actual reading, whichever is greater.
RR		0 bpm ~ 120 bpm	±1 bpm or ±5 % of actual reading, whichever is greater. Other ranges are not defined
I:E		4:1 ~ 1:12	2:1 ~ 1:4: ± 10 % of the actual reading; 4:1 ~ 2:1 and 1:4 ~ 1:12 (excluding 2:1 and 1:4): ± 25 % of the actual reading. Other ranges are not defined
Tinsp		0.2s ~ 10s	± 0.2 s, or ± 25 % of the actual reading, whichever is greater; other ranges are not defined
RCexp		0.00s ~ 5.00s	± (0.20 s + 20 % of actual reading); other ranges are not defined
Compliance		0 ml/cmH_2O ~ 300 ml/cmH_2O	0 ml/cmH_2O ~ 300 ml/cmH_2O: ± (10 ml/cmH_2O + ± 20% of actual reading)
Elastance		Not less than 0.003 cmH_2O/ml ~ 10 cmH_2O/ml	/
Resistances		0 cmH_2O/(l/s) ~ 600 cmH_2O/(l/s)	In the range of 0 cmH_2O/(l/s) ~ 20 cmH_2O/(l/s): ±10 cmH_2O/(l/s); In the range of 20 cmH_2O/(l/s)~ 600 cmH_2O/(l/s) (excluding 20 cmH_2O/(l/s)): ±50% of the actual reading
Stress index (SI)		0.50 ~ 1.50	± 0.10; other ranges are not defined
C20/C (coefficient of pulmonary over-expansion)		0.00 ~ 2.50	±0.20 or ±10 %, whichever is greater; other ranges are not defined
Electronic flowmeter	O_2 flowmeter	0.2 l/min ~ 15 l/min	Between 10~100 % of the full scale: within ±10% of the indicated value Other ranges are not defined.
	Air/N_2O flowmeter	0 l/min ~ 15 l/min	Between 10~100 % of the full scale: within ±10% of the indicated value Other ranges are not defined.
	Backup O_2 control O_2 flowmeter	0 l/min ~15 l/min	Between 10~100 % of the full scale: within ±10% of the indicated value Other ranges are not defined.
HFNC	Oxygen concentration	21%-100 %	±5% (V/V); other ranges are not defined
	Total flow	0 l/min-80 l/min	±1 l/min or ±10 % of actual reading, whichever is greater; other ranges are not defined

	Oxygen flow	0 l/min-50 l/min	±1 l/min or ±10 % of actual reading, whichever is greater; other ranges are not defined
	Air flow	0 l/min-50 l/min	±1 l/min or ±10 % of actual reading, whichever is greater; other ranges are not defined
O_2 concentration Sensor		18 % ~ 100 %	±3% (V/V), other ranges not defined
Auxiliary O_2 supply or auxiliary O_2 supply + Air flow control (tubular flowmeter is oxygen calibrated)		O_2 flowmeter: 0 l/min ~ 15 l/min	Between 10~100 % of full scale: within ± 10 % of the indicated value; other ranges are not defined

8) CO_2 Module Specifications

Sidestream CO_2 Module	
Standards	ISO 80601-2-55
Measurement range	Comen sidestream: 0 mmHg ~ 150 mmHg, 0%~19.7%, 0 kPa ~ 20 kPa (at 760 mmHg)
	Respironics CapnoTrak sidestream: 0 mmHg ~ 15 0mmHg, 0%~19.7%, 0 kPa ~ 20 kPa (at 760 mmHg)
	Masimo ISA Capno sidestream: 0 mmHg ~ 190 mmHg, 0~25% (at 760 mmHg)
Error	Comen sidestream: 0 mmHg ~ 40 mmHg: ±2 mmHg; 41 mmHg ~ 70 mmHg: ±5% of the actual reading; 71 mmHg ~ 100 mmHg: ± 8% of the actual reading; 101 mmHg ~ 150 mmHg: ± 10% of the actual reading; Other ranges are not defined.
	Respironics CapnoTrak sidestream: 0 mmHg ~40 mmHg: ±2 mmHg; 41 mmHg ~ 70 mmHg: ±5% of the actual reading; 71 mmHg ~ 100 mmHg: ± 8% of the actual reading; 101 mmHg ~ 150 mmHg: ± 10 % of the actual reading; Other ranges are not defined.
	Masimo ISA Capno sidestream: all conditions: ±{0.3% (V/V) + 4% of reading}; Other ranges are not defined.
Sampling rate and rate control accuracy	Comen sidestream: Sampling rate: 50 ml/min; Sampling rate control accuracy: ±10 ml/min
	Respironics CapnoTrak sidestream: Sampling rate: 50 ml/min; Sampling rate control accuracy: ±10 ml/min
	Masimo ISA Capno sidestream: Sampling rate: 50 ml/min; Sampling rate control accuracy: ±10 ml/min.

System total response time	Masimo ISA Capno sidestream: <6s (using 2m sampling line) Respironics CapnoTrak and Comen Sidestream: <6 s, includes transport time and rise time for water filter assembly and airway adapter. (Up to 3 seconds for sidestream sampling sleeves with dehumidification and extension tubes)
10% to 90% rise time for a diverting RGM	≤1s
Warm-up time	Masimo ISA Capno sidestream: <10s (if used immediately after storage in a-40°C environment, warm-up time is 10min) Respironics CapnoTrak sidestream/Comen sidestream: Acquire waveform: <10s Achievement of full accuracy specification: ≤3min, at 25° C.
Drift in measurement accuracy	Masimo ISA Capno sidestream: meets the measurement accuracy requirement within 6 hours of operation Comen/ Respironics CapnoTrak: Short-term drift: meets the measurement accuracy requirement within 6 hours of operation Long-term drift: accuracy specifications are maintained for more than 120 hours.

Mainstream CO_2 Module Specifications	
CO_2 measuring range	Comen Mainstream: 0 mmHg ~ 150 mmHg, 0%~19.7%, 0 kPa~20 kPa (at 760 mmHg);
	Respironics CAPNOSTAT 5 Mainstream: 0 mmHg ~ 150 mmHg, 0%~19.7%, 0 kPa~ 20 kPa (at 760 mmHg);
	Masimo IRMA™ Mainstream: 0 mmHg ~ 190 mmHg, 0 ~ 25% (at 760 mmHg)
CO_2 accuracy	Comen Mainstream: 0 mmHg ~ 40 mmHg: ±2 mmHg; 41 mmHg ~ 70 mmHg: ±5% of the actual reading; 71 mmHg ~ 100 mmHg: ± 8% of the actual reading; 101 mmHg ~ 150 mmHg: ± 10 % of the actual reading; Other ranges are not defined.
	Respironics CAPNOSTAT 5 Mainstream: 0 mmHg ~ 40 mmHg: ±2 mmHg; 41 mmHg ~ 70 mmHg: ±5% of the actual reading; 71 mmHg ~ 100 mmHg: ± 8% of the actual reading; 101 mmHg ~ 150 mmHg: ± 10 % of the actual reading; Other ranges are not defined.
	Masimo IRMA™ Mainstream: all conditions: ±{0.3% (V/V) + 4% of reading}; Other ranges are not defined.

Warm-up time	Comen/ Respironics Mainstream: Acquire waveform: <15s Achievement of full accuracy specification: ≤ 2min, at 25° C. Masimo IRMA™ Mainstream: <10s (warm-up time to reach CO_2 full accuracy specification is 15min, if used immediately in a 20°C environment after storage in a-40°C environment)
System total response time	<6 s
10% to 90% rise time for a diverting RGM	≤1s
Drift in measurement accuracy	Masimo IRMA™ Mainstream: meets the measurement accuracy requirement within 6 hours of operation Comen/ Respironics Mainstream: Short-term drift: meets the measurement accuracy requirement within 6 hours of operation Long-term drift: accuracy specifications are maintained for more than 120 hours.

CO_2 Alarm Specifications			
Name	Range	Step	Note
$EtCO_2$ and $FiCO_2$ Alarm Limits	Comen, Respironics CO_2 modules: $EtCO_2$ alarm high limit: Low limit +2mmHg ~ 150 mmHg $EtCO_2$ alarm low limit: 0mmHg ~ high limit-2 mmHg $FiCO_2$ alarm high limit: Low limit +2mmHg ~ 76 mmHg $FiCO_2$ alarm low limit: 0 mmHg ~ 74 mmHg	1 mmHg	The high limit is greater than the low limit
	Masimo CO_2 module: $EtCO_2$ alarm high limit: low limit +2 mmHg ~ 190 mmHg $EtCO_2$ alarm low limit: 0mmHg ~ high limit-2 mmHg $FiCO_2$ alarm high limit: low limit +2 mmHg ~ 99 mmHg $FiCO_2$ alarm low limit: 0 mmHg ~ 97 mmHg		

9) AG Module Specifications

<table>
<tr><th>Name</th><th colspan="3">Specification</th></tr>
<tr><td>AG gas</td><td colspan="3">CO_2, O_2, N_2O, one of four anesthetic agents (isoflurane (ISO), sevoflurane (SEV), halothane (HAL), desflurane (DES))</td></tr>
<tr><td colspan="4">Specifications for Masimo/Comen AG (Mainstream), Masimo/Comen AG (Sidestream) and Masimo/Comen AG+O_2 (Sidestream) Modules</td></tr>
<tr><td>AG measurement method</td><td colspan="3">Infrared radiation absorption</td></tr>
<tr><td>AG warm-up time</td><td colspan="3">< 20 s</td></tr>
<tr><td>Total response time</td><td colspan="3">< 6s</td></tr>
<tr><td>10% to 90% rise time for a diverting RGM</td><td colspan="3">≤1s</td></tr>
<tr><td rowspan="11">AG measuring range and accuracy</td><td colspan="3">Accuracy of all measured values meet the requirement of EN ISO 21647 and EN IS0 80601-2-55
The following accuracy specifications apply to a dry gas at 22 ± 5 °C and 1013 ± 40 hPa.</td></tr>
<tr><td rowspan="2">CO_2</td><td>Range</td><td>0% ~25%</td></tr>
<tr><td>Accuracy</td><td>± (0.2% (V/V) + 2% of reading) in the range of 0% ~15%;
Accuracy is not defined in the range of 15% ~ 25%</td></tr>
<tr><td rowspan="2">N_2O</td><td>Range</td><td>0% ~ 100%</td></tr>
<tr><td>Accuracy</td><td>± (2 % (V/V) + 2 % of reading)</td></tr>
<tr><td rowspan="2">Isoflurane (ISO)
Halothane (HAL)</td><td>Range</td><td>0% ~ 25%</td></tr>
<tr><td>Accuracy</td><td>± (0.15% (V/V) + 5% of reading) in the range of 0% ~ 8%;
Accuracy is not defined in the range of 8% ~ 25%</td></tr>
<tr><td rowspan="2">Sevoflurane (SEV)</td><td>Range</td><td>0% ~ 25%</td></tr>
<tr><td>Accuracy</td><td>± (0.15% (V/V) + 5% of reading) in the range of 0% ~ 10%; accuracy is not defined in the range of 10% ~ 25%</td></tr>
<tr><td rowspan="2">Desflurane (DES)</td><td>Range</td><td>0% ~ 25%</td></tr>
<tr><td>Accuracy</td><td>± (0.15% (V/V) + 5% of reading} in the range of 0%~22%; accuracy is not defined in the range of 22% ~ 25%</td></tr>
<tr><td rowspan="2">Paramagnetic oxygen (O_2) (only for Comen/Masimo AG+O_2 (sidestream))</td><td>Range</td><td>0% ~ 100%</td></tr>
<tr><td>Accuracy</td><td>± (1% (V/V) + 2% of reading)</td></tr>
</table>

Sampling flow rate and control accuracy (sidestream AG module only)	Sampling flow rate: 50 ml/min Sampling flow rate accuracy: ±10 ml/min

AG Alarm Specifications				
Parameter		Range	Step	Note
$EtCO_2$	High limit	(low limit + 2 mmHg) ~ 190 mmHg	1mmHg	High limit is greater than the low limit
	Low limit	0 mmHg ~ (High limit-2 mmHg)		
$FiCO_2$	High limit	(low limit + 2 mmHg) ~ 99 mmHg	1mmHg	
	Low limit	0 mmHg ~ (High limit-2 mmHg)		
EtN_2O	High limit	(low limit + 2 %) ~ 100 %	1mmHg	
	Low limit	0 % ~ (High limit- 2 %)		
FiN_2O	High limit	(Low limit + 2 %) ~ 100 %	1%	
	Low limit	0 % ~ (High limit- 2 %)		
EtHAL/EtISO /EtSEV/EtDES	High limit	(low limit + 0.2 %) ~ 25.0 %	0.1%	
	Low limit	0 % ~ (High limit-0.2 %)		
FiHAL/FiISO /FiSEV/FiDES	High limit	(low limit + 0.2 %) ~ 25.0 %	0.1%	
	Low limit	0 % ~ (high limit-0.2 %)		

10) BIS Specifications

Name	Specification		
BIS Measuring Range	BIS: 0~100 SQI: 0~100% EMG: 0~100 dB SR: 0~100%		
BIS Alarms and Resolution	Alarm Range	Alarm Limit	Resolution
	0 ~ 100	High limit: 2~100 Low limit: 0~98	1

11) NMT Module Specifications

Name	Specification	
Stimulus output range and accuracy	Pulse width	100us, 200us, 300us, measurement error ± 10%
	Output waveform	Pulse waveform

	Stimulation current range	0mA ~ 60mA. Adjustment step: 5mA Measurement error: ±5% or ±2mA (whichever is greater)
	Maximum skin impedance	When the skin impedance is 3kΩ, the stimulation current peak output supports 60mA maximum; when the skin impedance is 5kΩ, the stimulation current peak output supports 40mA maximum.
ST mode	Interval time	Manual, 1 second, 10 seconds, 20 seconds
	Measurement range	0%~200%
TOF mode	Interval time	Manual, 12 seconds, 15 seconds, 20 seconds, 30 seconds, 1 minute, 2 minutes, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 60 minutes
	TOF-T1% measurement range	0%~200%
	TOF-Ratio measurement range	5%~160%
	TOF-cnt measurement range	0~4
DBS mode	Interval time	Manual, 15 seconds, 20 seconds, 30 seconds, 1 minute, 2 minutes, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 60 minutes
	DBS-Count measuring range	0~2
	DBS-ratio measuring range	5% to 160%
PTC model	PTC measuring range	0~20
	Measuring interval	Set manually
Block Recovery Threshold	Off, 1, 2, 3, 4, 5%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, 100%	

12) Oxygen Sensor Specifications

Name	Specification
Respond time (21% air to 100% O_2)	< 15 s
Drift in measurement accuracy of chemical oxygen sensors	<5% after more than 1 year
Drift in measurement accuracy of paramagnetic oxygen sensors	First 24 hours: <±0.4% Next week (additional): <±0.2% Monthly thereafter (additional): <±0.2%

13) Other function

One-Step Recruitment		
Parameters	**Range**	**Step**
Psupp	20~60 cmH_2O	1 cmH_2O
Hold time	10~40 s	1s
PEEP On Exit	OFF, 3~50 cmH_2O	1 cmH_2O
Multi--Step Recruitment		
Parameters	**Range**	**Step**
Step setting	OFF, No. of the current step	/
PEEP	OFF, 3~50 cmH_2O	1 cmH_2O
Psupp	OFF, 3~60 cmH_2O	1 cmH_2O
Ventilation cycles	3 ~ 10	1
Respiratory Rate	2-100 bpm	1 bpm
I:E	4:1 ~ 1:10	0.5
PEEP On Exit	OFF, 3~50 cmH_2O	1 cmH_2O
P-V tool		
Parameter	**Range**	**Step**
Pstart	OFF, 2~50 cmH_2O	1 cmH_2O
Ptop	3~60 cmH_2O	1 cmH_2O
Ppause	0~30 s	1 s
Ramp Speed	1~5 cmH_2O/s	1 cmH_2O/s
End PEEP	OFF, 2~50 cmH_2O	1 cmH_2O

14) Anesthesia machine alarm

Parameter		Range	Step	Note
VT	High limit	5 ml ~ 1600 ml	1 ml	The high limit is greater than the low limit
	Low limit	0 ml ~ (high limit-5) ml		
MV	High limit	2 l/min ~ 100 l/min	1 l/min for adult 0.2 l/min for pediatric	
	Low limit	0 l/min ~ (high limit-2) l/min		
RR	High limit	2 bpm ~ 100 bpm	1 bpm	
	Low limit	0 bpm ~ (high limit-2) bpm		
FiO_2	High limit	20% ~ 105%	1%	
	Low limit	18% ~ (high limit-2)%		
Paw	High limit	2 cmH_2O ~ 100 cmH_2O	1 cmH_2O	The high limit is greater than the low limit. There is a negative pressure alarm when the Paw is less than-10 cmH_2O
	Low limit	0 cmH_2O ~ (high limit-2) cmH_2O		

15) Sigh

Parameter	Setting Range	Step
Switch	ON, OFF	/
Interval of sigh	20 s~180 min	20 s ~ 1 min: 1 s 1 min ~ 180 min: 1 min
Sigh Cycle	1 ~ 20	1
△int.PEEP	OFF, 3 cmH_2O ~ 40 cmH_2O	1 cmH_2O

16) External AGSS

For the specification of the external AGSS, please refer to the user manual provided by AGSS manufacturer.

17) Vacuum suction

Vacuum suction (High vacuum/high flow)

Physical specifications	The internal diameter of collection bottle inlet is not more than 14 mm and a suction tube is not less than 1.3 m in length.
Positive pressure protection	The maximum positive pressure at the suction port is not greater than 1 kPa under single fault and normal use.
Maximum negative pressure	The maximum negative pressure of internal vacuum is ≥75 kPa
Maximum suction flow	≥ 30 l/min

18) ACGO

ACGO	
Connector	22 mm/15 mm coaxial tapered joints
Back pressure generated at the back end of the anaesthesia vaporizer, front end of the ACGO during O_2 flush	Not greater than 2 kPa

19) Oxygen flush

Oxygen **flush**
When O_2 flush button is pressed, a high flow rate (between 25~75 l/min) of oxygen is supplied to the fresh gas outlet.

20) Anesthesia vaporizer specifications

For the use of Draeger anesthesia vaporizer, Please refer to the user manual of Draeger V2000 anesthesia vaporizer (Page 132-140 and Page 142-145).

For the use of Delta anesthesia vaporizer, Please refer to the user manual of Delta Vaporizer (52771, Chinese, Page 10 and Page 35-37).

For the use of Ibis anesthesia vaporizer, Please refer to the user manual of Ibis 200 anesthesia vaporizer (20160823, Page 47, Page 39-41 and Page 52-56).