A5/A3/A1

Anesthesia System

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CE 0123

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NOTE: This equipment must be operated by skilled/trained clinical professionals.

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Foreword

The Operator's Manual for the A5/A3/A1 Anesthesia System (hereinafter referred to as Anesthesia System, Equipment, A5/A3/A1) contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

Intended Audience

This manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practices and terminology as required for monitoring of critically ill patients.

Illustrations

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your anesthesia system.

1.0 *Safety*

1.1 Safety Information

WARNING — Indicates a potential hazard or unsafe practice that, if not avoided, could result in death, serious injury or property damage.

CAUTION — Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury, product fault, damage or property loss.

NOTE — Highlights important precautions and provides descriptions or explanations for better use of this product.

1.1.1 Warnings

WARNING: Do not operate the anesthesia system before reading this manual.

WARNING: All analog or digital equipment connected to this system must be certified passing the specified IEC standards (such as IEC 60950 for data processing equipment and IEC 60601-1 for medical electrical equipment). All configurations shall comply with the valid version of IEC 60601-1. The personnel who are responsible for connecting the optional equipment to the I/O signal port shall be responsible for medical system configuration and system compliance with IEC 60601-1.

WARNING: The Anesthesia System is only to be used by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law for the application of general anesthesia.

WARNING: Before putting the system into operation, the operator must verify that the equipment, connecting cables, and accessories are in correct working order and operating condition.

WARNING: The equipment must be connected to a properly installed power outlet with protective earth contacts only. If the installation does not provide for a protective earth conductor, disconnect it from the power line or operate from the equipment's internal battery supply.

WARNING: **Multiple AC power outlets are provided on the rear of the equipment. These outlets are intended to supply power to additional equipment that form a part of the anesthesia system (i.e. vaporizers, etc.). Do not connect other equipment to these outlets, as patient leakage current may be affected. Each outlet is rated 3 A. The total current that may be drawn through all outlets is 5 A on the system. Do not attempt to exceed these load ratings. Do not connect additional MPSOs (Multiple Portable Socket Outlets, i.e. multiple outlet extension cords) or extension cords to these outlets.**

WARNING: **Do not place MPSOs on the floor.**

WARNING: **Connect the anesthesia system to an AC power source before the internal battery is depleted.**

WARNING: **Do not open the equipment housings. All servicing and future upgrades must be carried out only by trained and authorized Mindray personnel.**

WARNING: **Do not rely exclusively on the audible alarm system for patient monitoring.**

WARNING: **Adjustment of alarm volume to a low level may result in a hazard to the patient.**

WARNING: **Alarm settings should be customized according to different patient situations. Constantly keeping the patient under close surveillance is the most reliable way for safe patient monitoring.**

WARNING: **The physiological parameters and alarm messages displayed on the screen of the equipment are for the caregiver's reference only and cannot be directly used as the basis for clinical treatment.**

WARNING: **Dispose the packaging material, observing the applicable waste control regulations and keeping it out of children's reach.**

WARNING: **To avoid the possibility of explosion, do not use the equipment in the presence of flammable anesthetic agents, vapors or liquids. Do not use flammable anesthetic agents such as ether and cyclopropane for this equipment. Use only non-flammable anesthetic agents that meet the requirements specified in 80601-2-13. The anesthesia system can be used with Isoflurane, Sevoflurane, Halothane and Desflurane. Only one anesthetic agent can be used at a time.**

WARNING: **Fresh gas flow must never be switched off before the vaporizer is switched off. The vaporizer must never be left switched on without a fresh-gas flow. Otherwise, anesthetic agent vapor at a high concentration can get into the equipment lines and ambient air, causing harm to people and materials.**

WARNING: **To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.**

WARNING: **The use of anti-static or electrically conductive breathing tubes, when utilizing high frequency electric surgery equipment, may cause burns, and is therefore not recommended in any application of this equipment.**

WARNING: **Possible electric shock hazard may exist. The equipment may only be opened by authorized service personnel.**

WARNING: **The patient should be visually monitored by by appropriately trained healthcare professionals. In certain situations, life-threatening circumstances may occur that may not necessarily trigger an alarm.**

WARNING: **Set the alarm limits properly based on the patient conditions so that the alarm is triggered before a hazardous situation occurs. Incorrectly set alarm limits may result in operating personnel not being aware of drastic changes in the patient's condition.**

WARNING: **Connection of both medical and non-medical equipment to the auxiliary mains socket outlet(s) may increase the leakage currents to values exceeding the allowable limits.**

WARNING: **Electric shock and fire hazard. Do not clean the equipment while it is powered on and/or plugged into an outlet.**

WARNING: **Disconnect the power plug from the mains supply before removing the rear panels or servicing the equipment.**

WARNING: **Malfunction of the central gas supply system may cause more than one or even all devices connected to it to stop their operation simultaneously.**

WARNING: **The anesthesia system will cease to deliver gas when the gas supply pressure is smaller than 200 kPa.**

WARNING: **Standard gas terminal connectors tailored to the attributes of gases should be used on the gas supply hose assembly to avoid damage to people and materials from improper connectors used.**

WARNING: **Use care in lifting and manipulating vaporizers during the mounting process as their weight may be greater than expected, based on their size and shape.**

WARNING: **Do not use talc, calcium stearate, corn starch or similar materials, as these materials may enter the patient's lungs or airway, causing irritation or injury.**

WARNING: **All gas supplies should be of medical grade.**

WARNING: **Single use respiratory hoses, face masks, sensors, soda lime, water traps, sampling lines, airway adapters, and other single use items may be considered potential biologically hazardous items and should not be reused. Dispose of these items in accordance with hospital policy and local regulations for contaminated and biologically hazardous items.**

WARNING: **To avoid endangering the patient, do not perform test or maintenance when the equipment is in use.**

WARNING: **Review the performance specifications of the disposal system that the transferring and receiving systems are intended to be used with, to ensure compatibility.**

WARNING: **The equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.**

WARNING: **Ensure that the current alarm presets are appropriate before use on each patient.**

WARNING: **A hazard can exist if different alarm presets are used for the same or similar equipment in any single area.**

WARNING: **Due to the size and weight of the equipment, it should only be moved by qualified personnel.**

WARNING: **Overloading machine may cause tipping. Equipment attached to the side of the equipment should be within the rated weights to prevent dumping of the machine.**

WARNING: **Excess load may cause a tip hazard while moving the equipment. Before moving, remove all equipment from the top shelf and all monitoring equipment installed to the side of the equipment. Use care when moving the equipment up or down a slope, around a corner, and across threshold. Do not attempt to roll the equipment over hoses, cords, or other obstacles.**

WARNING: **Leaks or internal venting of sampled gas may affect accuracy. Perform proper preoperative tests to ensure that the equipment is operating properly. Leaky circuits can not be used.**

WARNING: **Connecting the equipment's exhaust port to the hospital's waste gas scavenging system is strongly recommended to prevent exposure of hospital personnel to the waste gas.**

WARNING: **Pins of connectors identified with the ESD warning symbol should not be touched. Connections should not be made to these connectors unless ESD precautionary procedures are used.**

WARNING: **Operation of the equipment below the minimum flow values may cause inaccurate results.**

WARNING: **This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the equipment, or shielding the location it was placed.**

WARNING: **Ensure that an independent means of ventilation (e.g. a self-inflating manual resuscitator with mask) is available whenever the equipment is in use.**

WARNING: **The use of accessories with damaged packaging may cause biocontamination or failure. The operator should check the integrity of accessory packaging before use.**

WARNING: If the equipment is damaged in any way that compromises the safety of the patient or user, discontinue use and attach a visible label indicating that the equipment is unusable. Please contact Mindray Technical Support.

WARNING: Oxygen, when present in high concentrations, can significantly increase the chance of fire or explosion. Oil and grease may be ignited at the same time. Therefore, oil and grease should not be used where oxygen enrichment may occur.

WARNING: Low-pressure regulators and flowmeters are susceptible to high pressure, and may burst if improperly maintained or disassembled while under pressure. Changing or disassembling connectors should be performed only by the authorized personnel.

WARNING: Do not disassemble the low-pressure regulator, flow-metering device, or connector while under pressure. Sudden release of pressure may cause injury.

WARNING: Check the specifications of the Anesthesia Gas Scavenging System (AGSS) and the specifications of the anesthesia system to ensure compatibility and to prevent a mismatched processing system.

WARNING: Avoid connecting two or more hose assemblies in series as this may cause a loss of pressure and flow.

WARNING: A hazard may exist due to the use of improper connectors. Ensure all assemblies use the proper connectors.

WARNING: Avoid replacing a high-pressure flexible connection with one of lower nominal inlet pressure.

WARNING: Reusing breathing circuits or reusable accessories that are not disinfected may cause cross-contamination. Disinfect the breathing circuits and reusable accessories before use.

WARNING: Inspect all breathing system components carefully before each use. Ensure all components contain no obstructions or debris that can cause a potential hazard to the patient.

WARNING: Use breathing circuits and manual bags in accordance with ASTM F1208 and compatible with standard 22mm male conical fittings per ASTM specifications F1054.

WARNING: The mains plug is used to isolate the anesthesia system circuits electrically from the supply mains. Do not place the anesthesia system to a place where it is difficult to operate the plug.

WARNING: Do not touch the patient when connecting external devices via the I/O signal ports or replacing the oxygen cell to prevent patient leakage current from exceeding the requirements specified by the standard.

WARNING: If the Drive Gas Pressure Low alarm occurs when the gas supply pressure is greater than 200 kPa, contact the service personnel or Mindray Technical Support.

WARNING: **Make sure that CO_2 can be fully absorbed by the absorbent after the CO_2 absorbent is replaced or a CO_2 absorbent canister is installed.**

WARNING: **Before moving the anesthesia system, remove the objects from the top shelf and bracket to prevent the system from tilting.**

WARNING: **AGSS is not recommended to be used when the breathing tubes between the waste gas disposal system and AGSS get clogged, the extracted flow of the waste gas disposal system is deficient or the waste gas disposal system fails to work properly, as the waste gas in the AGSS may flow out to the atmosphere at a rate higher than 100 mL/min.**

WARNING: **When anesthetic gas delivery equipment needs to be configured for the anesthesia system, make sure to configure a monitor that is compliant with the ISO 80601-2-55 standard for monitoring the anesthetic gas concentration monitoring, and make sure that the anesthetic gas concentration monitoring range of the monitor can fully cover the adjustable range of values of the anesthetic gas delivery equipment.**

WARNING: **When the Isoflurane anesthetic vaporizer is used, confirm whether the set concentration of the vaporizer exceeds the monitorable range of the AG module. If it is the case, the anesthesia system will not be able to guarantee the monitoring precision of the AG module.**

WARNING: **As required by the relevant laws and regulations, oxygen concentration should be monitored when the equipment is used on the patient. If the equipment is not configured with this feature, please use a monitor compliant with the corresponding standards for O_2 concentration monitoring. The gas sampling tube of the monitor should be connected to the Y-shaped three-way valve of the breathing system of the equipment.**

WARNING: **CO_2 concentration monitoring is recommended when the equipment is applied to patients. If the equipment is not configured with this feature, please use a monitor compliant with the corresponding standards for CO_2 concentration monitoring. The gas sampling tube of the monitor should be connected to the Y-shaped three-way valve of the breathing system of the equipment.**

WARNING: **The anesthesia system may lose its balance if it is tilted more than 10 degrees. Use extreme caution when moving or resting the equipment on slopes of over 10 degrees. Do not hang articles on the sides of the unit that would cause an excessive imbalance.**

WARNING: **The anesthesia system may only be unpacked by authorized service personnel. The user cannot move the anesthesia system before unpacking.**

WARNING: **General anesthesia procedure-related risks are found in the literature search for clinical risk situations, such as: nausea, vomiting (postoperative nausea and vomiting); postoperative pain; residual neuromuscular block; emergence agitation; jaw-clenching, shivering; connected consciousness/ intraoperative awareness; postoperative delirium; postoperative cognitive dysfunction; hypotension; tachycardia; malignant hyperthermia as a reaction to potent inhalation anesthetics or succinylcholine (postoperative) pulmonary complications (hypoxemia, acute respiratory distress syndrome, pulmonary infiltrates, pneumonia, pleural effusions, atelectasis, pneumothorax, barotrauma, bronchospasm, cardiopulmonary edema, aspiration pneumonitis); airway complications, airway obstruction, cough, desaturation, laryngospasm, hoarseness, and breath holding; postoperative complications (overall cardiac events, myocardial infarction, acute renal failure, hepatic failure, disseminated intravasal coagulation, extrapulmonary infection, gastrointestinal failure, coma); psychogenic coma; cardiopulmonary complications; thrombosis; postoperative right shoulder pain; urinary retention; headache; hypersensitivity reactions; and anesthesia-related death.**

WARNING: **Device-specific risks of anesthesia systems are found in the literature search for clinical risk situations, such as: device failure including material defects, occlusion, leakage, user error, misuse; breathing circuit malfunction; monitoring device malfunction; ventilator malfunction; anesthesia system malfunction; accidental over-delivery of vaporizing agent; accidental under-delivery of vaporizing agent; administration of an incorrect agent; water condensation in flow sensor causing erroneous measurement of tidal volume; raised airway pressures due to the lack of timely maintenance (draining of the condenser water daily); impossible to ventilate the patient's lungs due to leak in the breathing circle system; raised end-tidal carbon dioxide and fraction of inspired carbon dioxide values due to an empty absorbent canister; erroneous ventilation failure message; false low capnography values due to partial opening of the solenoid zero valve allowing entrainment of room air causing artifactual dilution of the gas sample; ventilation failure due to temporary malfunctioning of adjustable pressure limiting (APL) valve (gas sample line coiled around the APL valve); erroneous detection of enflurane despite of the agent not being used due to lack of timely maintenance (sensor of gas monitor not replaced monthly); mask ventilation impossible due to a large gas leak (gas-sampling tubing had become lodged in the gap between the adjustable pressure-limiting valve dial and its housing); steadily increasing inspired carbon dioxide level due to missing rubber seal on the soda lime canister; anesthesia system problems resulting in hypoxemia, hyperoxia, hypercarbia, or hypocarbia; and anesthesia-related death.**

WARNING: **In order to avoid the occurrence of clinical risk situations found in the literature search, the operator of the anesthesia system is required to have professional qualification certificates. In addition to ensuring that professional skills are guaranteed, please use drugs under supervision with the doctor's dosing recommendations. Most clinical risks and postoperative sequelae are caused by side effects of drugs. Therefore, during the operation of the system, the doctor's medication should be evaluated based on the patient's disease history, allergy history, and medication status. Avoid clinical risks to patients caused by medication reactions.**

WARNING: **If any error occurs or auxiliary ventilation is affected during the use of the anesthesia system, the operator should stop using the anesthesia system immediately. And using manual ventilation or replacing the anesthesia equipment to avoid injury to the patient.**

WARNING: **The service life of this equipment is 10 years.**

1.1.2 Cautions

CAUTION: **To ensure patient safety, use only parts and accessories specified in this manual.**

CAUTION: **At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products, and in accordance with local regulations for contaminated and biologically hazardous items.**

CAUTION: **Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. Ensure that all external devices operating in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phones, x-ray equipments, and MRI equipments are possible sources of interference as they may emit higher levels of electromagnetic radiation.**

CAUTION: **This system operates correctly at the electrical interference levels identified in this manual. Higher levels can cause nuisance alarms that may stop automatic ventilation. Be aware of false alarms caused by high-intensity electrical fields.**

CAUTION: **Perform the daily checks specified on the checklist. In case of a system fault, do not operate the system until the fault has been corrected.**

CAUTION: **Before starting the equipment, users must be familiar with the information contained in this Operator's Manual and must have been trained by an authorized representative.**

CAUTION: **If the equipment does not function as described, it must be examined and repaired as necessary by qualified service personnel before being put back to use.**

CAUTION: **Ensure that the gas supply of the equipment always complies with the technical specifications.**

CAUTION: **Before clinical use, the equipment must be correctly calibrated and/or the respective tests must be performed, as described in this Operator's Manual.**

CAUTION: **If system faults occur during the initial calibration or testing, the equipment should not be operated until those faults have been corrected by a qualified service personnel.**

CAUTION: **After servicing, functional, sensor, and system tests must be performed before clinical use.**

CAUTION: **Only vaporizers with Selectatec Interlock-Systems may be used with this equipment.**

CAUTION: **Each time you replace the vaporizer, please carry out leak test for the breathing circuit.**

CAUTION: **Use cleaning agent sparingly. Excess fluid could enter the equipment and cause damage.**

CAUTION: **Do not autoclave any parts of the equipment unless specifically identified as autoclavable in this manual. Clean the equipment only as specified in this manual.**

CAUTION: **Do not fumigate using peracetic acid or formaldehyde.**

CAUTION: **The valve disc in each of the inhalation and exhalation valve assemblies on the breathing system is fragile and must be handled with care while removing the valve cage from the valve assembly.**

CAUTION: **Only connect Mindray approved devices to the equipment's communication ports. Devices connected to the ethernet ports must comply with IEC 60950.**

CAUTION: **Monitoring oxygen percentage (FiO_2%) is recommended when using the auxiliary O_2/Air flowmeters. Without oxygen monitoring, it would be impossible to know the concentration of oxygen delivered to the patient.**

CAUTION: **To ensure measurement accuracy and to avoid possible damage to the equipment, use only Mindray-approved cables and accessories.**

CAUTION: **Use the power cord provided with the product. If a substitute is necessary, use power cord in compliance with the specification.**

CAUTION: **Do not use a damaged device or accessory. Periodically check all cables (e.g., AC line cord and patient connection cables) for damage that may occur through normal use. Replace cables if damaged in any way.**

CAUTION: **Use of other oxygen sensors may cause incorrect oxygen concentration.**

CAUTION: **Unintended movement may occur if the casters are not locked. The operator should lock casters during use of the equipment.**

CAUTION: **Unsecured devices may slide off the top shelf. Devices should be securely attached to the top shelf.**

CAUTION: **The voltage on the auxiliary outlets should be the same voltage as the outlet into which the equipment is plugged. Ensure that devices plugged into the auxiliary outlets are rated for the same supply voltage as the equipment.**

CAUTION: **During the transport and storage of the vaporizer, block the gas inlet and outlet of the vaporizer with plugs to prevent foreign substances from entering the vaporizer.**

CAUTION: **Do not use any flow outlets as handles when moving the equipment. The flow outlets may become damaged. Use the metal side bars on the main body when moving the equipment.**

CAUTION: **Do not push down on the bag arm forcefully or hang heavy objects onto it. Excessive weight may bend and damage the bag arm.**

CAUTION: **Use caution when disconnecting "quick connectors", as the sudden release of pressure may cause injury.**

CAUTION: **Avoid factors that can contribute to deterioration of the hose assemblies. Factors include excessive bending, crushing, abrasion, pressures and temperatures that exceed hose ratings, and improper installation.**

CAUTION: **Be careful in lifting and manipulating the breathing system during disassembly of the system.**

CAUTION: **Turn the flow control knob slowly. To avoid damaging the control valves, do not turn further when the flowmeter reading is out of range. Do not turn any further when the knob has reached the mechanical stop (off) position.**

CAUTION: **Prevent or avoid using and storing the gas supply hose assembly in an environment exposed to ultraviolet light or oxidizing agents, or in a high-temperature or moist environment to avoid damage to people and materials because of the release of pressure from aged hoses in the assembly.**

1.1.3 Notes

NOTE: **Figures in this manual are provided for reference purposes only. Screens may differ based on the system configuration and selected parameters.**

NOTE: **Put the equipment in a location where you can easily see the screen and access the operating controls.**

NOTE: **Keep this manual close to the equipment so that it can be obtained conveniently when needed.**

NOTE: **The software was developed in compliance with IEC 60601-1. The possibility of hazards arising from software errors is minimized.**

NOTE: **This manual describes all features and options. Your equipment may not have all of them.**

NOTE: **The equipment is intended to be operated with its integral Breathing Pressure monitoring in use.**

NOTE: **The equipment is intended to be operated with its integral Breathing Pressure limiting devices in use.**

NOTE: **The equipment is intended to be operated with its integral Expiratory Volume monitoring in use.**

NOTE: **The equipment is intended to be operated with its integral Breathing System Integrity Alarm System in use.**

NOTE: **The equipment is intended to be operated with its integral Continuous Pressure Alarm in use.**

NOTE: **The equipment is intended to be operated with its integral O_2 monitoring in use.**

NOTE: **An Anesthesia Vapor Delivery Device is to be used with an Anesthetic Agent Monitor complying with ISO 80601-2-55. The connection of patient circuit and agent monitor should be made by a sampling line.**

NOTE: **Continuously monitor the anesthetic agent concentration when using the anesthesia system to ensure accurate output of the anesthetic agent.**

NOTE: **Check the liquid level of the anesthetic agent before and during all operations. When the liquid level is below the warning line, more anesthetic agent needs to be added. Refer to the vaporizer Instructions For Use for filling the vaporizer and other information.**

NOTE: **The system is designed to be equipped with an anesthetic vapor delivery device that complies with ISO 80601-2-13.**

NOTE: **The battery supply of this equipment is not a user serviceable component. Only an authorized service representative can replace the battery supply. If the system is not used for a long time, contact a service representative to have the battery supply disconnected. The disposal of battery should comply with local regulations. At the end of the battery life, dispose of the battery supply in accordance with local regulations.**

NOTE: **Areas designated for the servicing of oxygen equipment shall be clean, free of oil and grease, and not be used for the repair of other equipment.**

NOTE: **Opening the cylinder valve quickly may cause unexpected pressure difference and lead to potential fire or explosion hazard due to the oxygen pressure shock. Open and close the cylinder valve slowly.**

NOTE: **Changes in inlet pressure, outlet resistance or ambient temperature may affect the accuracy of flow values.**

NOTE: **The power supplies, terminal units and pipeline systems can be supplied by one or several different manufacturers.**

NOTE: **Regional or national regulations applicable to manufacturers of medical equipment can exist.**

NOTE: **The product does not contain latex parts.**

NOTE: **The operator should stay right in front of the equipment within four meters away from the display to facilitate observation of the displayed information on the equipment.**

NOTE: **Some alarm settings on this equipment are not configurable by users.**

NOTE: **The tidal volume and minute ventilation displayed on this equipment are measured in BTPS conditions. The fresh gas flow is measured in STPD conditions.**

NOTE: **For the method of connecting this equipment to an external monitor or other devices, please see Anesthesia System Bracket Installation Instructions.**

NOTE: **All the materials of this equipment exposed to gases are compatible with O_2, air and N_2O.**

NOTE: **To avoid abnormal gas supply, the anesthesia system has a 758 kPa pressure relief valve installed at the gas supply inlet. When the gas supply pressure is abnormally elevated, the pressure relief valve is turned on to ensure the proper operation of the anesthesia system. When the pressure relief valve is on, the anesthesia system and the O_2 flush are both operating properly, and their P-F (pressure/flow) characteristics are consistent with those under rated conditions. The pressure at the high-pressure O_2 outlet will be elevated to 758 kPa, and the maximum flow rate meets requirements in the specifications.**

NOTE: **The defibrillation restoration time is 15 seconds unless otherwise stipulated.According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations. Thus, no residual risk associated with using the medical device should be disclosed.**

2.0 *Product Description*

2.1 Introduction

2.1.1 Intended Use

2.1.1.1 Intended Purpose Statement

The Anesthesia System is a device used to deliver fresh gas, to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation through mechanical or manual ventilation.

2.1.1.2 Indication for Use

The Anesthesia System is applicable to patients who need inhalation anesthesia to achieve general anesthesia and maintain ventilation.

2.1.1.3 Intended Users

The Anesthesia System is only to be used by appropriately trained healthcare professionals who are qualified or accredited in accordance with national law for the application of general anesthesia.

2.1.1.4 Intended Patient Population

The Anesthesia System can be used in adult, pediatric, and neonate populations. The application in pregnant and breastfeeding patients is excluded.

2.1.1.5 Intended Medical Conditions

The Anesthesia System is used within a health care facility by licensed clinicians in the administration of general anesthesia.

2.1.1.6 Contra-indications

There is no absolute contraindication to the Anesthesia System. However, for some specific situation (such as malignant hyperthermia susceptible patients, pneumothorax, bullae, severe pulmonary hemorrhage, acute myocardial infarction) requires the anesthesiologist to make a careful decision according to the patient's situation.

2.1.1.7 Side Effects

According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects caused from the Anesthesia System. There are side effects related to the applied inhalation anesthetic.

2.1.1.8 Clinical Benefits

Patients generally benefit from insensibility to pain and prevention of awareness during General Anesthesia, while their ventilation is maintained and effective gas exchange and oxygenation throughout the applied procedure are ensured.

WARNING: This equipment is not suitable for use in an MRI environment.

2.2 Applied Parts

Applied parts of the anesthesia system are the breathing tubes, masks, BIS electrodes, NMT electrodes and cables.

3.0 *Installations*

WARNING: **This equipment must be installed by a factory authorized representative.**

WARNING: **Continuous use of desiccated soda lime may endanger patient safety. Adequate precautions should be taken to ensure that the soda lime in the CO_2absorbent canister does not become desiccated. Turn off all gases when finished using the system.**

WARNING: **When electrosurgical equipment is used, keep the electrosurgical leads away from the breathing system, the O_2 sensor, and other parts of the anesthesia system. Keep available backup manual ventilation and a respirator with mask in case the electrosurgical equipment prevents safe use of the system. Ensure the correct operations of all life support and monitoring equipment.**

WARNING: **Do not use masks or breathing tubes that are antistatic or conductive. They can cause burns if they are used near high frequency electrosurgical equipment.**

WARNING: **This anesthesia system has waste gas exhaust ports. Pay attention to the disposal of the residual breathing gas scavenged.**

CAUTION: **The operational environment and the power source of the equipment must comply with the requirements as specified in the 8.0 (Pages 8-1) "Product Specifications".**

CAUTION: **Only vaporizers with Selectatec® Interlock Systems may be used with this equipment.**

WARNING: **Use vaporizers compliant with ISO 80601-2-13. Refer to the vaporizer manufacturer's Instructions For Use for installing, filling or draining the vaporizer and other information.**

WARNING: **Use care in lifting and manipulating vaporizers during the installing process as their weight may be greater than expected.**

NOTE: **The barometric pressure may differ from the calibration pressure of the anesthetic vaporizer. This may cause an inaccurate output of the anesthetic agent. The operator should continuously monitor the concentration of anesthetic agent during system use to determine if the output concentration is accurate.**

NOTE: **If installing a Desflurane vaporizer, refer to the manufacturer's Instructions For Use on installation and use of the vaporizer.**

WARNING: **For the anesthesia system, using or turning on more than one vaporizer simultaneously is prohibited and prevented by a mechanical interlock. Do not ignore the safety mechanism.**

WARNING: **Ensure that the correct anesthetic agent is used. The vaporizer is designed with the specific anesthetic agent named on it and further indicated by color coded labeling. The actual output concentration of the anesthetic agent will vary if the vaporizer is filled with the wrong agent.**

WARNING: **The anesthetic liquid discharged from the vaporizer must not be used again. Please regard it as a dangerous chemical and dispose of it properly in accordance with local regulations.**

4.0 *Preoperative Tests*

4.1 Requirements of Preoperative Tests

Preoperative tests on the equipment should be performed according to the test intervals listed below. Refer to special procedures or precautions in this manual.

NOTE: **This is a guideline which can be modified to accommodate variations in local clinical practice. Such local modifications should have appropriate peer review.**

NOTE: **Ensure that the NO_2 cutoff and O_2/N_2O ratio are normal before use. Use an O_2 concentration tester to monitor the O_2 concentration in the gas output.**

Perform the preoperative tests listed below at these events:

- After the equipment is repaired or maintained, all test items should be tested.
- Every day before the equipment is used on the first patient:
  - Inspect the System
  - Pre-operation Preparations
  - Power Failure Alarm Test
  - Pipeline Test
  - Basic Ventilation Test
  - Backup Gas Cylinder Test
  - Flow Control System Test
  - Vaporizer Test
  - Breathing System Test
  - Alarm Tests
  - Inspect the AGSS

  - Inspect the Negative Pressure Suction Device
  - Pre-operation Preparations
- Before using the equipment on each patient:
  - Inspect the System
  - Pre-operation Preparations
  - Pipeline Test
  - Vaporizer Test
  - Breathing System Test
  - Inspect the AGSS
  - Inspect the Negative Pressure Suction Device
  - Pre-operation Preparations

NOTE: **Read and understand the operation and maintenance of each component before using the anesthesia system.**

NOTE: **Do not use the anesthesia system if a test failure occurs. Please contact Mindray Technical Support for any additional assistance.**

5.0 Operations

WARNING: **Before using the anesthesia system on the patient, ensure that the system is correctly assembled and in good condition, and that all the tests described in the Preoperative Tests are already completed. In case of test failure, do not use the system. Contact a qualified Mindray service representative to repair the system.**

WARNING: **Entering Standby mode will stop ventilation and parameter monitoring. Do not select Standby mode if the patient requires continuous ventilation.**

NOTE: **In the manual ventilation mode, you can use the APL valve to adjust the pressure limit of breathing system and gas volume in the manual bag. When the pressure in the breathing system reaches the pressure limit set for the APL valve, the valve opens to release excess gas.**

NOTE: **The APL valve adjusts the breathing system pressure limit during manual ventilation. Its scale shows approximate pressure.**

NOTE: **Before activating a new automatic ventilation mode, ensure that all related parameters are set appropriately.**

6.0 *Alarms and Messages*

WARNING: **Do not rely exclusively on the audible alarm system when using the anesthesia system. Adjustment of alarm volume to a low level may result in a hazard to the patient. Always keep the patient under close surveillance.**

NOTE: **The auditory alarm signal A-weighted sound pressure level which is measured in 2.5 m of radius shall be no less than 45 dB and no more than 85 dB.**

WARNING: **During equipment use, pay frequent attention to the alarm limits of parameters to ensure that they are appropriately set. Setting the alarm limits to limiting values will render the alarming system unhelpful.**

NOTE: **When using the anesthesia system, ensure that the alarm limits of each parameter are set to the appropriate values for the patient.**

NOTE: **When the anesthesia system restarts within 60 seconds after an abnormal power outage, the system can automatically restore the recent profile. If the power outage lasts longer than 120 seconds, the anesthesia system will automatically load the user profile before the shutdown. If the power outrage lasts between 60 to 120 seconds, the anesthesia system may automatically restore the recent profile or automatically load the user profile before the shutdown.**

NOTE: **If the equipment is powered off for less than 30 seconds and then powered on, the alarming settings will be restored to the status before the system was powered off.**

NOTE: **When the monitoring value on the main screen flashes due to an alarm, select the flashing area to open the corresponding Alarm Limits setting menu.**

7.0 Maintenance

WARNING: **Do not use a malfunctioning anesthesia system. Have all repairs and service done by an authorized service representative.**

WARNING: **Use a cleaning and disinfection schedule that conforms to your institution's disinfection and risk-management policies.**

- **Refer to the material safety data sheet as applicable.**
- **Refer to the operation and maintenance manuals of all disinfection equipment.**
- **Do not inhale fumes produced during any disinfection process.**

WARNING: **Only use lubricants approved for anesthesia or O_2 equipment.**

WARNING: **Do not use lubricants that contain oil or grease. They can burn or explode in the presence of high O_2 concentrations.**

WARNING: **Abide by disinfection control and safety procedures as used equipment may be contaminated by blood or body fluids.**

WARNING: **Movable parts and removable components may present a pinch or a crush hazard. Use care when moving or replacing system parts and components.**

WARNING: **Do not use O3 for disinfection. Otherwise, the breathing system may be damaged.**

CAUTION: **To prevent system damage:**

- **Refer to the documentations provided by the manufacturer of the cleaning agent.**
- **Never use organic, halogenated or petroleum-based solvents, anesthetic agents, glass cleaning agents, acetone or other irritant agents.**

- **Never use abrasive agents (i.e. steel wool or silver polish) to clean components.**
- **Keep all liquids away from electronic components.**
- **Prevent liquid from entering the equipment.**
- **All cleaning solutions used must have a pH value between 7.0 and 10.5.**

NOTE: **Personnel with no servicing experience for such a type of equipment shall not engage in servicing of the equipment. Replace damaged parts with components manufactured or sold by Mindray. Then test the unit to ensure that it complies with the manufacturer's published specifications.**

NOTE: **If necessary, contact Mindray for the circuit diagram, list of parts and calibration instructions of products or other information related to equipment maintenance.**

7.1 Maintenance Schedule

The schedules listed below are the minimum frequency based on 2,000 hours of usage per year. The equipment should be serviced more frequently if used more than this yearly usage. Maintenance should be performed by a trained technician.

NOTE: **During cleaning and setup, inspect the parts and seals for damage. Replace or repair as necessary.Breathing System Service**

7.2 Flow Sensor Calibration

WARNING: **Do not calibrate the flow sensor when the system is connected to a patient.**

NOTE: **During calibration, do not operate the pneumatic parts. Do not move or press the breathing tubes.**

NOTE: **Calibrate the flow sensor after re-installing the cleaned or disinfected flow sensor, after replacing with a new flow sensor, or when tidal volume measurement is inaccurate.**

NOTE: **In case of repeated calibration failure, contact Mindray Technical Support.**

7.3 O_2 Sensor Calibration

WARNING: **Do not perform the calibration when the system is connected to a patient.**

WARNING: **To calibrate an O_2 sensor, the ambient pressure must be identical with the ambient pressure for O_2 transport monitoring of the breathing system. Otherwise, the monitoring may exceed the specified range.**

WARNING: **Prior to the O_2 sensor calibration, remove the O_2 sensor. Make sure there is no water on the O_2 sensor or where it is installed before installing the O_2 sensor.**

WARNING: **No O_2 calibration is required if O_2 sensor is not equipped or not used.**

WARNING: **Observe related biohazard regulations during disposal of discarded O_2 sensors. Do not burn O_2 sensors.**

7.3.1 21% Oxygen Calibration

NOTE: **The breathing system automatically seals off the O_2 sensor port when the O_2 sensor is removed.**

7.3.2 100% Oxygen Calibration

NOTE: **If the 100% O_2 calibration failed, check for any technical faults and alarms. After the fault is cleared, calibrate the sensor again.**

NOTE: **If the calibration failed for several times, replace the O_2 sensor and calibrate the sensor again. If the calibration failure persists, contact Mindray Technical Support.**

7.4 Battery

NOTE: **To extend the service life of the battery, please use the battery at least once a month. Charge the battery before the battery runs out.**

NOTE: **Check and replace the battery regularly. The service life of the battery depends on the frequency and duration of use. Improper use of the battery may shorten its service life. It is recommended that the lead acid battery be replaced once every three (3) years.**

NOTE: **The battery's power supply time depends on the equipment configuration and operation.**

NOTE: **In the event of a fault with the battery, contact our company's maintenance personnel for replacement.**

7.5 Handling of Water Condensation

WARNING: **Check water build-up inside the flow sensor before every system use. Accumulated water in the flow sensor causes erroneous readings.**

WARNING: **Ensure that all breathing system parts are completely dried after the breathing system is cleaned and disinfected.**

WARNING: **Water may gather in the patient's breathing tube if the Auto Ventilation mode is used for a long time (such as longer than four hours). Clear the gathered water in time to avoid impact on the ventilation or ingress of water into the patient circuit.**

7.6 Cleaning and Disinfection

ISO 17664 compliance:

The process for autoclave sterilization of the Anesthetic Breathing System has been tested and found to be in compliance with ISO 17664-1: 2021. Compliance to ISO 17664-1: 2021 only applies when bacterial/ viral filters are used to filters air coming in from the patient and returning air to the patient. Filters must be properly installed.

WARNING: **Before using the anesthesia system after cleaning or disinfecting, power on the system and follow the on-screen prompts to perform leak test and compliance test.**

NOTE: **Cleaning and disinfecting solutions not shown in the cleaning agents and disinfectors listed must have a pH of 7.0 to 10.5. Organic, halogenated or petroleum-based solvents, anesthetic agents, glass cleaners, acetone, or other harsh cleaning agents and disinfectors are not recommended.**

WARNING: **Use extreme care while handling the CO2 absorbent as it is a caustic irritant.**

CAUTION: **Never immerse the oxygen sensor or its connector into any type of liquid. Dispose the O2 sensor according to the manufacturer's specifications.**

CAUTION: **Do not wash the inner surface of the oxygen sensor.**

CAUTION: **Do not perform soaking or high-temperature processing on the O2 sensor.**

NOTE: **Do not use water or high pressure gas to flush the inside of the flow sensor; otherwise, the flow sensor will be damaged.**

NOTE: **Do not insert any object into the flow sensor for cleaning; otherwise, the flow sensor will be damaged.**

NOTE: **Please disassemble and clean the bottom of the CO2 absorbent canister regularly.**

NOTE: **When removing a breathing tube, hold the joints at both ends of the tube to prevent damage to the tube.**

NOTE: **Do not reuse the bacterial filter to prevent cross infection.**

WARNING: **Please dispose of discarded absorbent following the requirements of absorbent manufacturers.**

WARNING: **When removing the bypass assembly, hold the bypass assembly with one hand to prevent it from falling, and press the buckle on the bypass assembly with the other hand.**

CAUTION: **Do not autoclave the following components: PAW gauge and oxygen sensor. These components cannot withstand immersion or the heat and pressure of sterilization.**

NOTE: **Before disinfection, make sure that the components have been cleaned.**

CAUTION: **If moisture remains in the bellows after cleaning, the bellows surface folds may become tacky and prevent the bellows from properly expanding. Ensure all moisture is removed from the bellows after cleaning.**

NOTE: **Before reinstallation, make sure that the assembly has been handled and dried.**

NOTE: **Reinstall the breathing system at the point of use and at the designated clean area.**

WARNING: **Exercise caution when moving the anesthesia system to avoid damage to the flow sensor because of collision at the inspiratory and expiratory connector.**

WARNING: **Tighten the locking nut of the screw cap at the inspiratory and expiratory connector when reinstalling the flow sensor. Otherwise it may cause a failure of the flow sensor.**

WARNING: **Keep the breathing tube end that is connected to the inspiratory and expiratory heading downward when reinstalling the flow sensor. Otherwise the water formed by condensed vapor may flow into the inspiratory and expiratory connector and affect measurement of the flow sensor.**

NOTE: **When the bypass is enabled, gases in the breathing system do not go through the CO_2 absorbent canister.**

WARNING: **Use extreme care while handling the CO_2 absorbent as it is a caustic irritant.**

WARNING: **Check if the gasket is properly installed in place while re-installing the canister. If the gasket is not properly installed, it may cause breathing system leaks.**

WARNING: **Before locking the canister, make sure that the gasket on the bypass assembly has no residual absorbent particles or powder. Otherwise it may cause breathing system leaks.**

NOTE: **Before adding the absorbent, make sure that the canister is fully dry. The absorbent poured in should not surpass the Max mark on the CO_2 absorbent canister.**

NOTE: **Install the filter following the instructions in this manual to prevent dust or particles from entering the patient's lungs and prevent cross infection.**

CAUTION: **The bacteria filters shall comply with the requirements of ISO 23328-1 and ISO 23328-2.**

NOTE: **Filter is disposable accessory. Please follow local regulations to dispose of discarded filter.**

NOTE: **Before the reassembly, make sure that the assembly has been reprocessed and dried.**

7.7 Periodic Maintenance

WARNING: **To avoid endangering the patient, do not perform test or maintenance when the equipment is in use.**

8.0 Product Specifications

NOTE: The released functions and parameters may be different in different sales regions.

8.1 Standards Compliance

The anesthesia system shall be used together with the monitoring devices, alarm system and protective devices below:

- The pressure measurement device in compliance with ISO 80601-2-13;
- The pressure restriction device in compliance with ISO 80601-2-13;
- The expiratory volume monitor in compliance with ISO 80601-2-13;
- The breathing system with alarm system in compliance with ISO 80601-2-13;
- The anaesthetic vapour delivery system in compliance with ISO 80601-2-13;
- The anaesthetic gas scavenging system in compliance with ISO 80601-2-13;
- The anesthetic gas delivery device in compliance with ISO 80601-2-13;
- The anesthetic ventilator in compliance with ISO 80601-2-13;
- The O_2 monitor in compliance with ISO 80601-2-55;
- The CO_2 monitor in compliance with ISO 80601-2-55;
- The AG monitor in compliance with ISO 80601-2-55.

The anesthesia system is integrated with the pressure measurement device, pressure restriction device, expiratory volume monitor, anaesthetic breathing system with alarm system, anaesthetic gas delivery system, anaesthetic vapour delivery system, anaesthetic ventilator, AG monitor in compliance with the afore mentioned standards, where:

- The pressure restriction device, expiratory volume monitor and breathing system with alarm system also comply with ISO 80601-2-13.
- AG monitor in compliance with ISO 80601-2-55.

8.2 Safety Designations

Type of Protection against Electric Shock:	Class I equipment with internal electric power supply. Where the integrity of the external protective earth (ground) in the installation or its conductors is in doubt, the equipment shall be operated from its internal electric power supply (i.e., battery supply).
Degree of Protection against Electric Shock:	Type BF, defibrillation-proof (Type CF for NMT Module)
Rated voltage and frequency of equipment:	External electric power supply: 220V to 240 VAC, 50/60 Hz 100V to 240 VAC, 50/60 Hz 100V to 120 VAC, 50/60 Hz Internal battery supply: Lithium-ion, 14.4VDC, 12.8Ah (2 batteries installed) Lithium-ion, 14.4VDC, 6.4Ah (1 battery installed)
Input power of equipment:	220 to 240VAC, 8A 100 to 240VAC, 8A 100 to 120VAC, 8A
Mode of Operation:	Continuous
Degree of Protection against Hazards of Explosion:	Not for use with flammable anesthetics.
Degree of Protection against Harmful Ingress of Water:	IPX1 (IPX4 for BIS Module)
Electrical Connection between Equipment and Patient:	Electrical connections
Degree of Mobility:	Mobile (including the base and casters)
Disinfection methods:	Steam autoclavable or disinfectable
Application parts with protection against electric shock:	All application parts
Signal input or output part:	Both signal input and output parts
Permanent or non-permanent installation:	Non-permanent installation

TABLE 8-1 Safety Designations

8.3 Physical Specifications

Dimensions:	Height: 1445 mm Width: 763 mm Depth: 766 mm
Weight:	Approximately 140 kg (Standard configured mass) Approximately 260 kg (Maximum configured mass)
Worktable (stainless steel):	Weight limit: 30kg Width: 462mm Depth: 352 mm Height: 830 mm
Auxiliary Work Surface:	Weight limit: 15kg Width: 303mm Length: 379 mm
Top Shelf:	Weight limit: 15kg Width: 478mm Depth: 310mm
Side Mounting Rails:	Supporting weight: 27 kg at a maximum distance of 0.41 m with a safety factor of 6 times the weight
Bag Arm:	Fixed Height Bag Arm: Length: 312 mm Height: 1130 mm Swiveling angle: ± 120 degrees Flexible Bag Arm: Length: 550mm The height and angle of the flexible bag arm can be adjusted freely.
Drawers (internal dimensions):	Weight limit: 5 kg Drawers are of equal size: Height: 123 mm Width: 275mm Depth: 340 mm
Caster:	4 casters Diameter: 125 mm Brake: central brake with lock/unlock indicator
System Noise (under the typical working mode):	≤45dB(A)

TABLE 8-2 Physical Specifications

8.4 Software Specifications

Host CPU	IMX8M Plus
Primary programming language	C++
Operating system	Linux
AC power input	1
Network connector(LAN1,LAN2,LAN3)	1, standard RJ45 connectors, 100 Base-TX
Serial bus connector (MSB)	1
USB connector	2, USB 2.0
Satellite module rack (SMR) connector	3
Video output connector (VP1,VP2)	1, HDMI
Nurse call connector	0
Equipotential grounding terminal	1

TABLE 8-3 Software Specifications

8.5 Environmental Specifications

Operating Temperature:	+10°C to +40°C
Storage Temperature:	-20°C to +60°C (Oxygen Cell: -20°C to 50°C)
Operating Humidity:	15 to 95% RH, non-condensing
Storage Humidity:	10 to 95% RH, non-condensing
Operating Atmospheric Pressure:	70 kPa to 106.7 kPa
Storage Atmospheric Pressure:	50 kPa to 106.7 kPa

TABLE 8-4 Environmental Specifications

8.6 Electrical Specifications

8.6.1 Main Electrical Power Specifications

Power Supply Input Voltage:	220V to 240 VAC, 50/60 Hz 100V to 240 VAC, 50/60 Hz 100V to 120 VAC, 50/60 Hz
Power Supply Input Current:	8 A maximum

TABLE 8-5 Main Electrical Power Specifications

Length of Power Cord:	5 m
Grade of Power Cord:	Normal grade

TABLE 8-5 Main Electrical Power Specifications

8.6.2 Battery Power Specifications

Battery Type:	Lithium-ion battery, One (1) battery: 14.4VDC, 6.4Ah Two (2) batteries: 14.4VDC, 12.8Ah
Battery Run-time:	≥ 90 minutes (powered by one piece new fully-charged battery under the typical condition) ≥ 180 minutes (powered by two pieces new fully-charged batteries under the typical condition)
Time to Shutdown from Lower Battery Alarm:	5 minutes at least (powered by new fully-charged batteries after the first low-power alarm)
Battery Charge Time:	New Battery: ≤ 8 hours (powered by new depleted batteries at 25°C ambient temperature under typical working mode).

TABLE 8-6 Battery Power Specifications

8.6.3 Auxiliary Electrical Outlets

Number of Outlets:	4
Output Voltage:	Corresponds to power supply input voltage
Output Current of Each Auxiliary Outlet:	3 A max.
Output Current for Total Auxiliary Outlet:	5 A max.
Fuse Rating Current of Each Auxiliary Outlet:	3.15 A
Fuse Rating Current for Total Auxiliary Outlet:	5 A

TABLE 8-7 Auxiliary Electrical Outlets

8.6.4 Communication Ports

RS-232 Communication Port:	One DB9 male connector. Connects to the external calibration device. An external medical device can be connected via this connector to communicate with the anesthesia system.
Network Port:	One separate RJ-45 network ports. Connects with a PC to perform software upgrading.

TABLE 8-8 Communication Ports

USB Ports:	Two USB ports. Exports configuration information and historical data. Transfers configuration data between machines of the same type. Connects the mouse.
Video Signal Port:	One HDMI female port. Output the video signal of the main display.
WIFI:	Connects with the external device and communicate with the external device.

TABLE 8-8 Communication Ports

8.7 Pneumatic Specifications

8.7.1 Pipeline Supply

Pipeline Input Pressure Range:	O_2: 280 to 600 kPa (40 to 87 psi) N_2O: 280 to 600 kPa (40 to 87 psi) Air: 280 to 600 kPa (40 to 87 psi)
Pipeline Input Flow Rate Range:	O_2: V'max. 190 L/min Air: V'max. 150 L/min N_2O: V'max. 20 L/min
Pipeline Connections:	DISS NIST
Gas Configuration:	N_2O, Air, O_2

TABLE 8-9 Pipeline Supply

8.7.2 Backup O_2 Supply

Backup O_2 Pressure Range:	280 to 600 kPa (40 to 87 psi)
Pipeline Input Flow Rate Range:	V'max. 190 L/min
Pipeline Connections:	DISS NIST

TABLE 8-10 Backup O_2 Supply

8.7.3 Cylinder Supply

O_2 Cylinder Input Pressure Range:	6.9 to 20.0 MPa (1000 to 2900 psi)
N_2O Cylinder Input Pressure Range:	4.2 to 6.0 MPa (600 to 870 psi)
Air Cylinder Input Pressure Range:	6.9 to 20.0 MPa (1000 to 2900 psi)

TABLE 8-11 Standard Cylinder Supply

Cylinder Input Flow Rate Range:	O_2: V'max. 190L/min Air: V'max. 150L/min N_2O: V'max. 20 L/min
Cylinder Connections:	Pin-Index Safety System (PISS)
Yoke Configuration:	Air, N_2O, O_2

TABLE 8-11 Standard Cylinder Supply

8.7.4 Auxiliary Common Gas Outlet (ACGO)

Control Type:	Mechanical
Connector:	Coaxial 22mm male/15mm female conical connector
Safety Pressure:	A relief valve limits fresh gas pressure at the ACGO outlet port to not more than 12.5 kPa.

TABLE 8-12 ACGO

8.7.5 Anesthetic Vaporizer

Vaporizer Positions:	Double (not including the vaporizer parking position mount)
Mounting Mode:	Selectatec®, with interlocking function (Selectatec® is registered trademark of Datex-Ohmeda Inc.) Plug-in®, with interlocking
Type:	Mindray V60 anesthetic vaporizers. Three types of vaporizers with anesthetic agents halothane, isoflurane, sevoflurane are available. Mindray V80 Desflurane anesthetic vaporizers.

TABLE 8-13 Anesthetic Vaporizer

8.7.6 Drive Gas

Air or O_2.

8.7.7 O_2 Controls

O_2 supply failure alarm: ≤220.6kPa.

8.8 Breathing System Specifications

8.8.1 Breathing System Volume

Mechanical Ventilation:	1800mL
Manual Ventilation:	1950mL

TABLE 8-14 Breathing System Volume

8.8.2 Bellows Volume

Bellows	1500mL

TABLE 8-15 Bellows Volume

8.8.3 CO_2 Absorber Assembly

Absorber Capacity:	1 Pre-Pak (1500ml)
Absorber Canister Contents:	1 Pre-Pak canister or Loose Fill absorbent

TABLE 8-16 CO_2 Absorber Assembly

8.8.4 Breathing System Connections

Exhalation Connection:	Coaxial 22mm male/15mm female conical connector
Inhalation Connection:	Coaxial 22mm male/15mm female conical connector
Manual Bag Connection:	Coaxial 22mm male/15mm female conical connector
Exhaust Port:	30mm male conical connector

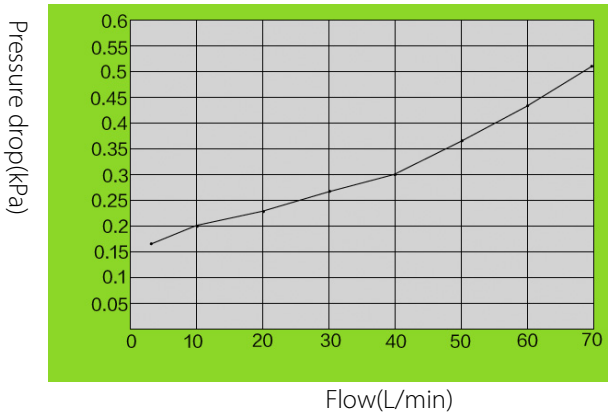
TABLE 8-17 Breathing System Connections

8.8.5 APL Valve

Range:	SP, 5 to 70 cmH_2O
Control Accuracy:	± 3 cmH_2O or ±15% of the setting value, whichever is greater, but is not more than +10 cmH_2O
Adjustable Range of Motion:	> 300 degrees
Tactile Knob Indication:	30 cmH_2O and above
Opening Pressure:	≤ 0.2kPa (test gas flow of 20mL/min in dry or wet conditions)

TABLE 8-18 Breathing System Connections

Resistance of APL valve in dry gas:



Resistance of APL valve in wet gas:

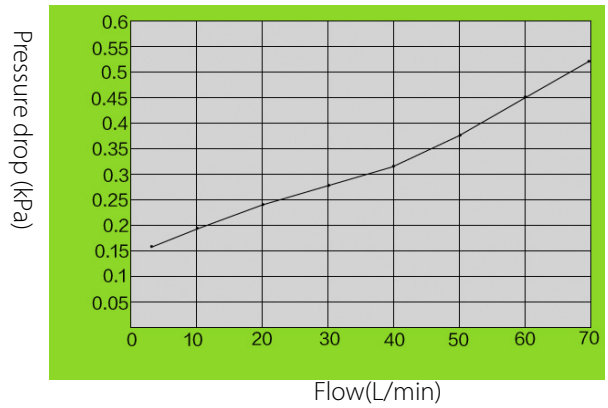
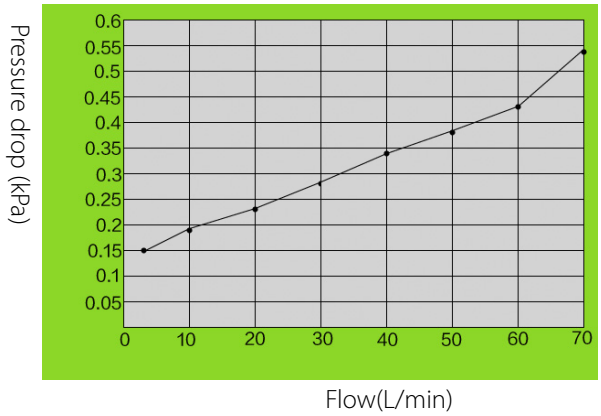


TABLE 8-18 Breathing System Connections

Resistance of APL valve in dry gas (Lift the APL Valve):



Resistance of APL valve in wet gas (Lift the APL Valve):

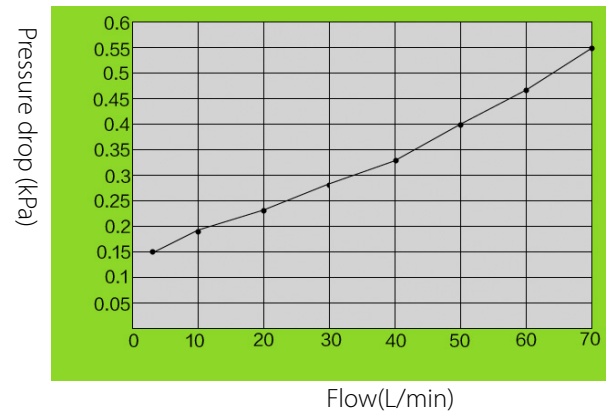
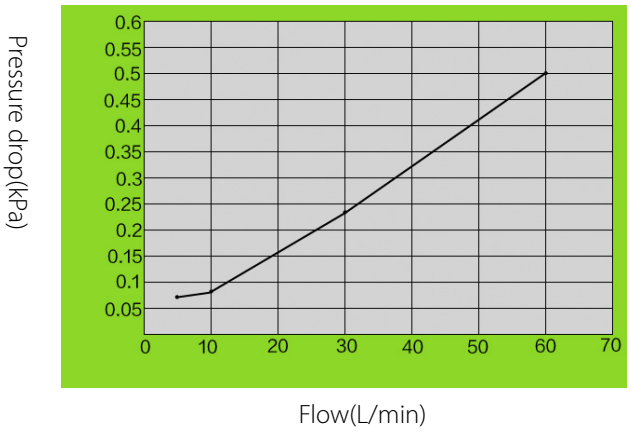


TABLE 8-18 Breathing System Connections

8.8.6 Resistance

Expiratory resistance in mechanical ventilation mode:



Inspiratory resistance in mechanical ventilation mode:

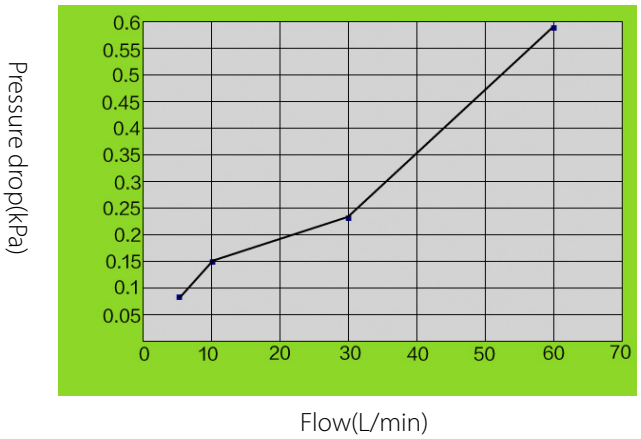


TABLE 8-19 Resistance

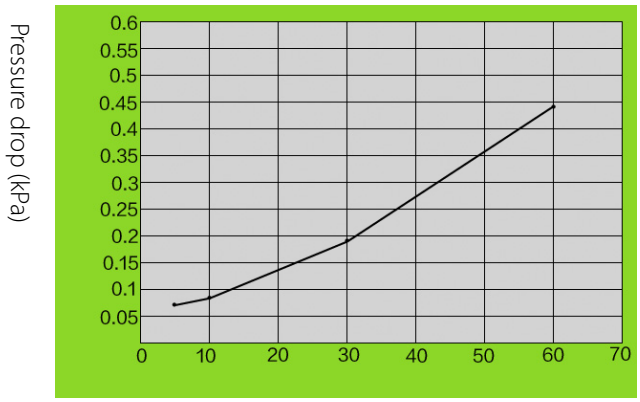
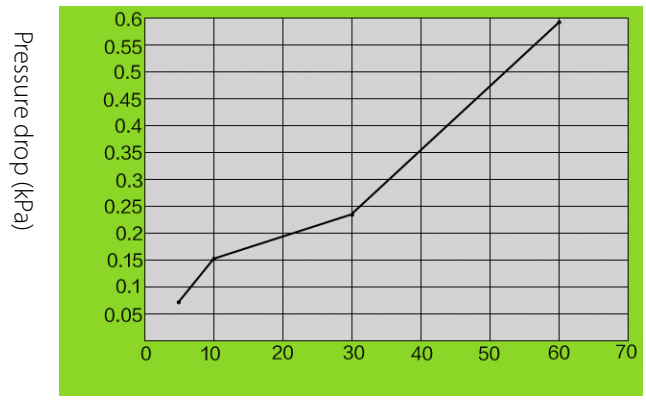
Expiratory resistance in manual mode:

Inspiratory resistance in manual mode:


TABLE 8-19 Resistance

8.8.7 Breathing System Temperature Controller

10°C≤T(Ambient temperature)≤20°C:	ΔT=T (Temperature at metal test point of the pressure sampling body near the inspiratory check valve)-T (Ambient temperature)≥11°C
20°C≤T Ambient temperature)≤40°C	T (Temperature at metal test point of the pressure sampling body near the inspiratory check valve)≥31°C

Note: The block heater does not operate while the system is being powered by the internal battery supply.

TABLE 8-20 Breathing System Temperature Controller

10°C≤T(Ambient temperature)≤40°C	ΔT=|T (Temperature at test point of Y-piece patient connection)-T (Ambient temperature)|≤2°C and T (Temperature at test point of Y-piece patient connection)≤41°C
Single Fault Condition	T (Temperature at test point of Y-piece patient connection)≤41°C

Note: The block heater does not operate while the system is being powered by the internal battery supply.

TABLE 8-20 Breathing System Temperature Controller

8.8.8 Breathing Circuit Parameters

System Compliance:	≤ 2 ml/cm H_2O
Resistance:	≤ 0.6 kPa
Leakage:	≤ 50 ml/min @ 3.0 kPa (under BTPS condition)
System Safety Pressure on Breathing System:	110 cmH_2O

TABLE 8-21 Breathing Circuit Parameters

8.9 Anesthetic Gas Scavenging System (AGSS)

Type of the Applicable Disposable System:	Low flow
Extract Flow:	25 to 50 L/min
Resistance:	≤ 0.05 kPa @ 25 L/min ≤ 0.05 kPa @ 30 L/min ≤ 0.35 kPa @ 50 L/min ≤ 0.35 kPa @ 75 L/min

TABLE 8-22 Anesthetic Gas Scavenging System with Low Flow (AGSS)

Type of the Applicable Disposable System:	High flow
Extract Flow:	75 to 105L/min
Resistance:	≤ 0.05 kPa @ 35 L/min ≤ 0.35 kPa @ 75L/min ≤ 0.35 kPa @ 105 L/min

TABLE 8-23 Anesthetic Gas Scavenging System with High Flow (AGSS)

8.10 Negative Pressure Suction device

8.10.1 Continuous Suction Regulator

Performance Category:	Pharyngeal Suction
Gas Supply:	Negative pressure of medical pipeline
Gas Supply Connections:	NIST, DISS
Gas Supply Pressure Range:	-72 kPa to -40 kPa
Maximum Vacuum:	≥ 65 kPa (gas supply pressure: -72 kPa)
Maximum Flow:	≥ 40 L/min (gas supply pressure: -72 kPa)
Vacuum Gauge Accuracy:	± 5% of full scale

TABLE 8-24 Continuous Suction Regulator

8.10.2 Venturi Suction Regulator

Performance Category:	Pharyngeal Suction
Gas Supply:	Medical compressed air
Gas Supply Connections:	NIST, DISS
Gas Supply Pressure Range:	280 kPa to 600 kPa
Drive Gas Consumption:	<35 L/min with drive gas at 280 kPa <55 L/min with drive gas at 600 kPa
Maximum Vacuum:	≥ 50kPa
Maximum Flow (without suction bottle and filter):	≥ 25 L/min
Vacuum Gauge Accuracy:	± 5% of full scale

TABLE 8-25 Venturi Suction Regulator

8.11 Monitor Module

8.11.1 AG Module

Warm-up Time:	ISO accuracy mode: < 45 s Full accuracy mode: <10 min
Sampling Rate:	Sampling rate: Adult/Pediatric AG watertrap and sample line: 150/180/200 ml/min Neonate AG watertrap and sample line: 100/110/120 ml/min Accuracy: ± 10 ml/min or ± 10% of the setting value, whichever is greater

TABLE 8-26 AG Module

Watertrap Emptying Interval [1]	Neonate AG watertrap: ≥24h@100ml/min [2] ≥22h@110ml/min ≥20h@120ml/min Adult/Pediatric AG watertrap: ≥19h@150ml/min ≥18h@180ml/min ≥17h@200ml/min
Gas:	CO_2, O_2, N_2O, and any of the five anesthetic agents: DES, ISO, ENF, SEV and HAL.
Range:	CO_2 : 0.0 to 30% (0.0 to 30 kPa, 0.0 to 226 mmHg)
	O_2 : 0 to 100%
	N_2O : 0 to 100%
	DES : 0.0 to 30%
	SEV : 0.0 to 30%
	ENF : 0.0 to 30%
	ISO : 0.0 to 30%
	HAL : 0.0 to 30%
Resolution:	CO_2 : 0.1%
	O_2 : 1%
	N_2O : 1%
	DES : 0.1%
	SEV : 0.1%
	ENF : 0.1%
	ISO : 0.1%
	HAL : 0.1%
ISO Accuracy Mode	Add ± $0.3\%_{ABS}$ to full accuracy for CO_2; Add ± $8\%_{REL}$ to full accuracy for all agents; N_2O accuracy is ± ($8\%_{REL}$ + $2\%_{ABS}$).

TABLE 8-26 AG Module

Full Accuracy Mode	Gas	Range (%)	Accuracy (vol.%)
	CO_2	0 to 1	± 0.1
		1 to 5 (not including 1)	± 0.2
		5 to 7 (not including 5)	± 0.3
		7 to 10 (not including 7)	± 0.5
		> 10	Unspecified
	N_2O	0 to 20	± 2
		20 to 100 (not including 20)	± 3
	O_2	0 to 25	± 1
		25 to 80 (not including 25)	± 2
		80 to 100 (not including 80)	± 3
	DES	0 to 1	± 0.15
		1 to 5 (not including 1)	± 0.2
		5 to 10 (not including 5)	± 0.4
		10 to 15 (not including 10)	± 0.6
		15 to 18 (not including 15)	± 1
		> 18	Unspecified
	SEV	0 to 1	± 0.15
		1 to 5 (not including 1)	± 0.2
		5 to 8 (not including 5)	± 0.4
		> 8	Unspecified
	ENF, ISO, HAL	0 to 1	± 0.15
		1 to 5 (not including 1)	± 0.2
		> 5	Unspecified

TABLE 8-26 AG Module

Rise Time	Gas	Measured by using adult/pediatric water trap and 2.5m sampling line	Measured by using neonatal water trap and 2.5m sampling line
	CO_2	≤300ms@150ml/min ≤300 ms@180ml/min ≤250 ms@200ml/min	≤400 ms@100ml/min ≤400 ms@110ml/min ≤250 ms@120ml/min
	N_2O	≤300ms@150ml/min ≤300 ms@180ml/min ≤250 ms@200ml/min	≤400 ms@100ml/min ≤400 ms@110ml/min ≤250 ms@120ml/min
	O_2	≤600ms@150ml/min ≤600ms@180ml/min ≤500ms@200ml/min	≤800ms@100ml/min ≤800ms@110ml/min ≤600ms@120ml/min
	HAL	≤550ms@150ml/min ≤550ms@180ml/min ≤300ms@200ml/min	≤600ms@100ml/min ≤600ms@110ml/min ≤300ms@120ml/min
	ENF	≤400ms@150ml/min ≤400 ms@180ml/min ≤350 ms@200ml/min	≤500 ms@100ml/min ≤500 ms@110ml/min ≤350 ms@120ml/min
	DES, SEV, ISO	≤400ms@150ml/min ≤400 ms@180ml/min ≤350 ms@200ml/min	≤450 ms@100ml/min ≤450 ms@110ml/min ≤300 ms@120ml/min
System Total Response Time	**Gas**	**Measured by using adult/pediatric water trap and 2.5m sampling line**	**Measured by using neonatal water trap and 2.5m sampling line**
	CO_2	≤5 s @150ml/min ≤5 s @180ml/min ≤5 s @200ml/min	<5 s @100ml/min <5 s @110ml/min <5 s @120ml/min
	N_2O	≤5 s @150ml/min ≤5 s @180ml/min ≤5 s @200ml/min	<5 s @100ml/min <5 s @110ml/min <5 s @120ml/min
	O_2	≤5 s @150ml/min ≤5 s @180ml/min ≤5 s @200ml/min	<5 s @100ml/min <5 s @110ml/min <5 s @120ml/min
	DES, SEV, ISO, HAL, ENF	≤6 s @150ml/min ≤6 s @180ml/min ≤6 s @200ml/min	<6 s @100ml/min <6 s @110ml/min <6 s @120ml/min
Primary Agent ID Threshold (during full accuracy mode)	0.15%		
Secondary Agent ID Threshold (during full accuracy mode)	Primary agent ≤ 10%: 0.3% Primary agent >10%: 5%$_{REL}$ of primary agent		

TABLE 8-26 AG Module

Measurement Accuracy Drift	Meets accuracy requirements within 6 hours
Rate Measurement	Measurement range: 2 bpm to 100 bpm Resolution: 1 bpm Measurement accuracy: 2 bpm to 60 bpm: ± 1 bpm 61 bpm to 100 bpm: ± 2 bpm

TABLE 8-26 AG Module

1. *Experiment condition: temperature of sampled gas is 37 °C, ambient temperature is 23 °C, relative humidity of sampled gas is 100%.*
2. *Cleaning time of watertrap ≥24h means that the liquid level will not exceed the MAX line within 24 hours.*

NOTE: **Inaccuracy specifications are affected by the breath rate and I:E change. The end-tidal gas reading is within specification for breath rate below 15BPM and I:E ratio smaller than 1:1 relative to the gas readings without breath; Add ±6%$_{REL}$ to inaccuracy for HAL and O2 for breath rate larger than 15 BPM; Add ±6%$_{REL}$ to inaccuracy for all gases for breath rate larger than 30 BPM (inaccuracy for HAL and O2 are unspecified in this case); inaccuracy is unspecified for breath rate larger than 60 BPM.**

NOTE: **The ability to properly resolve end-tidal values can be measured by using the set-up described in ISO 80601-2-55:2011 figure 201.101. In short, the method consists of sampling gas from two different sources connected to an electrically controlled pneumatic valve to permit rapid switching between the two sources. During the test, the valve is set to switch gas source at a number of frequencies (simulating the range of specified breath rates) and for each frequency the end-tidal value presented by the gas analyzer is noted. From a diagram of end-tidal value over frequency, the frequency at which the gas analyzer is no longer able to resolve end-tidal values according to specification is identified. This ability to properly resolve end-tidal values is listed in the corresponding AION^{TM} Multigas Analyzer technical specification.**

NOTE: **Data sample rate 25 Hz. Data presentation is 50 Hz, every second data point is interpolated.**

NOTE: **Inspiratory and end tidal CO_2 concentration readings are identified by AION^{TM} Platinum Multigas Analyzers using the lowest and highest values respectively of the temporal CO_2-curve. Corresponding readings of N_2O and anesthetic agents are taken at the same point in time. Inspiratory and end-tidal O_2 concentration readings are identified by the O_2 mean value during the respiratory phase as identified by the temporal CO_2 curve. Once correctly identified, the highest and lowest O2 concentration readings during each part of the phase will be presented as inspiratory and end-tidal O_2 respectively.**

NOTE: **The rated respiration rate measurement range for AG module is 2 to 100 bpm. The data sample rate is 25 Hz. The $EtCO_2$ concentration reading uses the highest value of the CO_2 waveform within the breathing cycle. The EtN_2O and EtAA concentration readings use the value measured at the moment when the $EtCO_2$ concentration is recorded. The FiO_2 concentration reading uses the highest value of the O_2 waveform within the breathing cycle.**

NOTE: **The rated respiration rate measurement range for AG module is calculated based on the CO_2 waveform. The test method used to determine the rated respiration rate range: Utilize the valves to switch the two sampling gases at different frequencies (simulating specified breath rates). Record the $EtCO_2$ value at each frequency. By drawing the coordinate diagram which indicates the corresponding relationship between end-tidal value and breathing frequency, the range of breathing frequency can be obtained.**

8.11.1.1 Alarms

AG Alarm Limits	Range	Step	Unit
$EtCO_2$ High Limit	Off, 2 to 99	1	mmHg (% and kPa should be optional)
$EtCO_2$ Low Limit	Off, 0 to 97		
$FiCO_2$ High Limit	Off, 1 to 99		
EtO_2 High Limit	Off, 12 to 100	1	%
EtO_2 Low Limit	Off, 10 to 98		
FiO_2 High Limit	20 to 100, off		
FiO_2 Low Limit	18 to 98		
EtN_2O High Limit	Off, 2 to 100	1	%
EtN_2O Low Limit	Off, 0 to 98		
FiN_2O High Limit	Off, 2 to 100		
FiN_2O Low Limit	Off, 0 to 98		
EtHal High Limit	Off, 0.2 to 5.0	0.1	%
EtHal Low Limit	Off, 0.0 to 4.8		
FiHal High Limit	Off, 0.2 to 5.0		
FiHal Low Limit	Off, 0.0 to 4.8		
EtEnf High Limit	Off, 0.2 to 5.0	0.1	%
EtEnf Low Limit	Off, 0.0 to 4.8		
FiEnf High Limit	Off, 0.2 to 5.0		
FiEnf Low Limit	Off, 0.0 to 4.8		

TABLE 8-27 Alarms

EtIso High Limit	Off, 0.2 to 5.0	0.1	%
EtIso Low Limit	Off, 0.0 to 4.8		
FiIso High Limit	Off, 0.2 to 5.0		
FiIso Low Limit	Off, 0.0 to 4.8		
EtSev High Limit	Off, 0.2 to 8.0	0.1	%
EtSev Low Limit	Off, 0.0 to 7.8		
FiSevHigh Limit	Off, 0.2 to 8.0		
FiSev Low Limit	Off, 0.0 to 7.8		
EtDes High Limit	Off, 0.2 to 18.0	0.1	%
EtDes Low Limit	Off, 0.0 to 17.8		
FiDes High Limit	Off, 0.2 to 18.0		
FiDes Low Limit	Off, 0.0 to 17.8		

TABLE 8-27 Alarms

8.11.1.2 Effect of Interfering Gas on AG Measured Value

Gas Under Test	**Concentration**	Quantitative Effect (Volume Fraction)							
		CO_2	N_2O	HAL	SEV	ISO	ENF	DES	O_2
N_2O	**60%**	0.1%	/	0.1%	0.1%	0.1%	0.1%	0.1%	0.2%
HAL	**4%**	0.1%	0.1%	/	0.1%	0.1%	0.1%	0.1%	1.0%
SEV	**5%**	0.1%	0.1%	0.1%	/	0.1%	0.1%	0.1%	1.0%
ISO	**5%**	0.1%	0.1%	0.1%	0.1%	/	0.1%	0.1%	1.0%
ENF	**5%**	0.1%	0.1%	0.1%	0.1%	0.1%	/	0.1%	1.0%
DES	**15%**	0.1%	0.1%	0.1%	0.1%	0.1%	0.1%	/	1.0%

NOTE: Test GAS LEVELS shall be ±20% of the specified level.

TABLE 8-28 Effect of Interfering Gas on AG Measured Value

8.11.2 CO_2 Module

8.11.2.1 Sidestream CO_2 Module

Measurement Range:	CO_2: 0 to 20% (0 to 152 mmHg)
Resolution:	CO_2: 0.1% (1 mmHg)
Accuracy*:	CO_2: 0%(0 mmHg) to 5%(40 mmHg): ±0.2 vol.%(±2 mmHg) 5%(41 mmHg) to 10% (76 mmHg)(not including 5%): ± 5% of the reading 10%(77 mmHg) to 20% (152 mmHg)(not including 10%): ± 10% of the reading

TABLE 8-29 Sidestream CO_2 Module

Accuracy Drift:	Meet the requirement for measurement accuracy within 6 hours		
Sampling Rate:	Sampling rate: Adult and Pediatric: 120 ml/min, 150 ml/min Neonate: 100 ml/min, 120 ml/min Accuracy: ±15 ml/min or ±15% of the setting value, whichever is greater.		
Watertrap Emptying Interval [1]:	Neonate watertrap: ≥24h@100ml/min [2] ≥20h@120ml/min Adult/Pediatric watertrap: ≥20h@120ml/min ≥19h@150ml/min		
Start-up Time:	< 90 s		
Rise Time (10%~90%):	**Gas**	**Measured by using adult/pediatric water trap and 2.5m sampling line**	**Measured by using neonatal water trap and 2.5m sampling line**
	CO_2	≤300ms@120ml/min ≤300 ms@150ml/min	≤250 ms@100ml/min ≤250 ms@120ml/min
System Total Response Time:	**Gas**	**Measured by using adult/pediatric water trap and 2.5m sampling line**	**Measured by using neonatal water trap and 2.5m sampling line**
	CO_2	≤5 s @120ml/min ≤5 s @150ml/min	<4.5 s @100ml/min <4.5 s @120ml/min
Rate Measurement:	Measurement range: 0 bpm to 150 bpm Resolution: 1 bpm Measurement accuracy: 0 bpm to 60 bpm: ± 1 bpm 61 bpm to 150 bpm: ± 2 bpm		

** Accuracy applies for the following conditions:*
1. Measurements begin after the CO_2 module warms up;
2. Ambient pressure is from 750 to 760 mmHg, and ambient temperature from 22 to 28℃;
3. The measured gas is a dry gas and the balance gas N_2O;
4. Gas sample flow rate is 100 ml/min, respiration rate is 50 bpm with a fluctuation between ± 3 bpm, and I:E is 1:2.
When the operating temperature (near the module detector) is 15-25℃ or 50-55℃, or the respiration rate is greater than 50 bpm, the measurement accuracy is: ± 4 mmHg (0 to 40 mmHg) or 12% of the reading (41 to 99 mmHg).

TABLE 8-29 Sidestream CO_2 Module

1. *Experiment condition: temperature of sampled gas is 37 °C, ambient temperature is 23 °C, relative humidity of sampled gas is 100%.*
2. *Cleaning time of watertrap ≥24h means that the liquid level will not exceed the MAX line within 24 hours.*

Gas	Concentration	Quantitive Effect*
		CO_2
N_2O	60%	0.1% (1 mmHg)
HAL	4%	0.1% (1 mmHg)
SEV	5%	0.1% (1 mmHg)
ISO	5%	0.1% (1 mmHg)
ENF	5%	0.1% (1 mmHg)
DES	15%	0.2% (2 mmHg)

**: means an extra error should be added in case of gas interference when CO_2 measurements are performed between 0 to 40 mmHg.*

TABLE 8-30 Effect of Interfering Gas on Sidestream CO_2 Measured Value

Alarm Limit	Range	Step
$EtCO_2$ High	OFF, (low limit + 2) to 99 mmHg	1 mmHg
$EtCO_2$ Low	OFF, 0 to (high limit - 2) mmHg	
$FiCO_2$ High	OFF, 1 to 99 mmHg	

TABLE 8-31 Alarm Limit of the Sidestream CO_2 Module

8.11.2.2 Mainstream CO_2 Module

CO_2 Range:	0% (0 mmHg) to 20% (150 mmHg)
CO_2 Resolution:	0.1% (1 mmHg)
CO_2 Accuracy:	0% (0 mmHg) to 5% (40 mmHg): ±0.2 vol.% (±2 mmHg) 5% (41 mmHg) to 9% (70 mmHg) (not including 5%): ± 5% of the real reading 9% (71 mmHg) to 13% (100 mmHg) (not including 9%): ± 8% of the real reading 13% (101 mmHg) to 20% (150 mmHg) (not including 13%): ± 10% of the real reading
Accuracy Drift:	Meet the requirement for measurement accuracy within 6 hours
Rise Time:	< 60 ms
System Total Response Time:	< 2 s
Rate Measurement:	Measurement range: 0 bpm to 150 bpm Resolution: 1 bpm Measurement accuracy: ± 1 bpm

TABLE 8-32 Mainstream CO_2 Module

Alarm Limit		Range	Step	Unit
$EtCO_2$	High Limit	OFF, (low limit + 2) to 99	1	mmHg
	Low Limit	OFF, 0 to (high limit - 2)		
$FiCO_2$	High Limit	OFF, 1 to 99		

TABLE 8-33 Alarm Limit of the Mainstream CO_2 Module

8.11.3 Monitor Mode

The system supports **Monitor** mode when the anesthesia system is configured with an external AG module.

When the anesthesia system is in **Monitor** mode, the external AG module continues to function, while the ventilation monitors and alarms of the anesthesia system will be off.

8.11.4 Oxygen Monitor Using Oxygen Cell

Oxygen Monitor	Type	Galvanic Fuel Cell
	Range	18 to 100 vol% O_2
	Accuracy	±(volume fraction of 2.5%+2.5%gas level)
	Accuracy Drift	Meets accuracy requirements within 6 hours
	System Total Response Time (21% Air to 100% O_2)	< 20 s

TABLE 8-34 Oxygen Monitor Using Oxygen Cell

8.11.4.1 Alarms

O_2 Alarm Limits		Range	Step	Unit
FiO_2	**High Limit**	Off, 20 to 100	1	%
	Low Limit	18 to 98		

TABLE 8-35 Alarms

8.11.4.2 Effect of Interfering Gas on Oxygen Cell Measured Value

Gas Under Test	Concentration	Quantitative Effect (Volume Fraction)
		O_2
N_2O	**60%**	1.0%
HAL	**4%**	1.5% to 2.0%
SEV	**5%**	1.0% to 1.5%

NOTE: Test GAS LEVELS shall be ± 20% of the specified level.

TABLE 8-36 Effect of Interfering Gas on Oxygen Cell Measured Value

ISO	**5%**	1.2% to 1.8%
ENF	**5%**	1.2% to 1.8%
DES	**15%**	2.0%

NOTE: Test GAS LEVELS shall be ± 20% of the specified level.

TABLE 8-36 Effect of Interfering Gas on Oxygen Cell Measured Value

8.11.5 Agent Usage Calculation and Agent Usage Speed

Agent Usage Calculation	
Calculation Range:	0 to 3000 ml
Accuracy:	± 2 ml, or ± 15% of the actual reading, whichever is greater.
Agent Usage Speed	
Anesthetic Agents:	Desflurane, Isoflurane, Sevoflurane and Halothane
Usage Speed Range:	Desflurane: 0 to 900 ml/h Sevoflurane: 0 to 450 ml/h Isoflurane and Halothane: 0 to 250 ml/h
Accuracy:	± 2ml/h or ±15% of the actual reading, whichever is greater.

TABLE 8-37 Agent Usage Calculation and Agent Usage Speed

8.11.6 Anesthesia Prediction

Patient Information:	Height: 150 cm to 200 cm Weight: 40 kg to 140 kg Age: 18 years to 90 years	
Anesthetic Agents (AA):	Desflurane, Isoflurane, Sevoflurane and Halothane	
Prediction Deviation:	EtAA=0	≤ 0.05 vol.%
	EtAA≠0	-20% to 30% of the actual measured EtAA, or -5% to 7.5% of the vaporizer maximum setting, whichever is greater
	EtO_2	-10% to 15% of the actual measured EtO2, or -5 vol.% to 7.5 vol.%, whichever is greater

TABLE 8-38 Anesthesia Prediction

8.11.7 BIS Module

Measured Parameters:	**Type**	**BISx**	**BISx4**	**Parameter Range**
	Bispectral index	BIS	BIS L, BIS R	0 to 100
	Accuracy: Unspecified			
	Resolution: 1			

TABLE 8-39 BIS Module

Calculated Parameters:	Type	BISx	BISx4	Parameter Range
	Signal quality index	SQI	SQI L, SQI R	0% to 100%
	Electromyography	EMG	EMG L, EMG R	0 dB to 100 dB
	Suppression ratio	SR	SR L, SR R	0% to 100%
	Spectral edge frequency	SEF	SEF L, SEF R	0.5 Hz to 30.0 Hz
	Total power	TP	TP L, TPR	40 dB to 100 dB
	Burst count	BC	BC L,BC R	0 to 30
	BIS variability index	/	sBIS L, sBIS R	0 to 10.0
	EMG variability index	/	sEMG L, sEMG R	0 to 10.0
	Asymmetry	/	ASYM	0% to 100%
EEG Signal Amplitude:	50 uV/Scale, 100 uV/Scale, 200 uV/Scale, 500 uV/Scale			
Sweep Speed:	6.25 mm/s, 12.5 mm/s, 25 mm/s or 50 mm/s			

TABLE 8-39 BIS Module

Alarm Item	Setting Range	Step
BIS High Limit	2 to 100	1
BIS Low Limit	0 to 98	

TABLE 8-40 Alarms

8.11.8 NMT Module

Stimulation Output:	Pulse width	100 µs, 200 µs, or 300 µs; monophasic rectangle pulse Accuracy: ± 10%
	Stimulation current peak	Output range: 0 to 60 mA Step: 5 mA Accuracy: ± 5% or ± 2 mA, whichever is greater
	Maximum skin resistance	3 kΩ @ 60 mA, 5 kΩ @ 40 mA
Block Recovery:	OFF, 1,2, 3, 4, 5%, 10%, 20%, 30%, 40%. 50%, 60%, 70%, 80%, 90%, 100%	

TABLE 8-41 NMT Module

TOF (Train Of Four) Mode:	TOF-Ratio (response percentage)	5% to 160%
	TOF-Count (number of responses)	0 to 4
	TOF-T1% (response to the first stimulus as percentage of the reference value)	0% to 200%
ST (Single Twitch) Mode:	ST-Ratio (response percentage)	0% to 200%
DBS (Double-Burst Stimulation) 3.2/ 3.3 Mode:	DBS-Ratio (response percentage)	5% to 160%
	DBS-Count (number of responses)	0 to 2
PTC (Post-Tetanic Count) Mode:	PTC-Count (number of responses)	0 to 20

TABLE 8-41 NMT Module

8.12 Ventilator Specifications

General Ventilator Specifications	
Drive Pressure:	280 to 600 kPa
Maximum Inspiratory Flow:	120 L/min
Low Flow Anesthesia:	The accuracy of Tidal Volume shall be within the specification at 0.2 L/min to 1 L/min total fresh gas flow.

TABLE 8-42 General Ventilator Specifications

Ventilator Setting Parameter	**Range**
Vt (under BTPS condition):	20 to 1500 ml (VCV, SIMV-VC), 5 to 1500 ml (PCV-VG, SIMV-VG), Step: 1 ml
RR:	4 to 100 bpm, Step: 1 bpm
Min RR:	2 to 60 bpm, Step: 1 bpm
I:E	4:1 to 1:8, Step: 0.5
Apnea I:E:	4:1 to 1:8, Step: 0.5
Tinsp:	0.2 to 10 s, Step: 0.1 s
Pinsp:	5 to 70 cmH_2O, Step: 1 cmH_2O

TABLE 8-43 Ventilator Setting Parameter and Range

∆Psupp:	0, 3 to 60 cmH_2O Note: Under Pressure Support Ventilation Mode, ∆Psupp can be adjusted to 0, meaning CPAP mode. Step: 1 cmH_2O
∆Papnea:	3 to 60 cmH_2O, Step: 1 cmH_2O
Plimit:	10 to 100 cmH_2O, Step: 1 cmH_2O
PEEP:	OFF, 3 to 30 cmH_2O, Step: 1 cmH_2O
Tpause:	OFF, 5 to 60% of Tinsp, Step: 1%
Trig Window:	5 to 90%, Step: 1%
F-Trig (under BTPS condition):	0.2 to 15 L/min, Step: 0.1 L/min
P-Trig:	-20 to -1 cmH_2O, Step: 1 cmH_2O
Tslope:	0.0 to 2.0 s, Step: 0.1 s
Exp%:	5 to 80%, Step: 1%

TABLE 8-43 Ventilator Setting Parameter and Range

Ventilator Monitored Parameters	Range
PEAK:	-20 to 120 cmH_2O
PLAT:	-20 to 120 cmH_2O
MEAN:	-20 to 120 cmH_2O
PEEP:	0 to 70 cmH_2O
Vt (under BTPS condition):	0 to 3000 ml
Vti (under BTPS condition):	
MV (under BTPS condition):	0 to 100 L/min
MVi (under BTPS condition):	
RR:	0 to 120 bpm
I:E:	4:1 to 1:10
Raw:	0 to 600 $cmH_2O/(L/s)$
Compl:	0 to 300 mL/cmH_2O

TABLE 8-44 Ventilator Monitored Parameters and Range

Control Parameters	Accuracy
Vt (VCV, SIMV-VC, under BTPS condition):	20 to 60 ml: ± 10 ml 60 to 210 ml (not including 60 ml): ± 15 ml 210 to 1500 ml (not including 210 ml): ± 7% of the setting value

TABLE 8-45 Ventilator Control Accuracy

Vt (PCV-VG, SIMV-VG, under BTPS condition):	5 to 60 ml: ± 10 ml 60 to 210 ml (not including 60 ml): ± 15 ml 210 to 1500 ml (not including 210 ml): ± 7% of the setting value
Pinsp:	± 2.5 cmH_2O or ± 7% of the setting value, whichever is greater
∆Psupp:	± 2.5 cmH_2O or ± 7% of the setting value, whichever is greater
∆Papnea:	
Plimit:	
PEEP:	± 2.0 cmH_2O or ± 7% of the setting value, whichever is greater
Tslope:	± 0.2 s or ± 20% of the setting value, whichever is greater
RR:	± 1 bpm or ± 10% of the setting value, whichever is greater
Min RR:	
I:E:	2:1 to 1:4: ±10% of the setting value 4:1 to 2:1 and 1:4 to 1:8 (not including 2:1 and 1:4): ±25% of the setting value
Apnea I:E:	
Tinsp:	± 0.2 s
Tpause:	±8% (absolute error)
Trig Window:	±10% (absolute error)
F-Trig (under BTPS condition):	±1 L/min
P-Trig:	± 2 cmH_2O
Exp%:	±10% (absolute error)

TABLE 8-45 Ventilator Control Accuracy

Monitored Parameters	Accuracy
Vt (under BTPS condition):	0 to 60 ml: ± 10 ml 60 to 210 ml (not including 60 ml): ± 15 ml 210 to 3000 ml (not including 210 ml): ± 7% of the actual reading
Vti (under BTPS condition):	
MV (under BTPS condition):	± 0.1 L/min or ± 8% of the actual reading, whichever is greater
MVi (under BTPS condition):	
PEAK:	± 2.0 cmH_2O or ± 4% of the actual reading, whichever is greater
PLAT:	
MEAN:	
PEEP:	
RR:	± 1 bpm or ± 5% of the actual value, whichever is greater

TABLE 8-46 Ventilator Monitoring Accuracy

I:E:	2:1 to 1:4: ± 10% of the actual reading 4:1 to 2:1 and 1:4 to 1:10 (not including 2:1 and 1:4): ± 25% of the actual reading
Raw:	0 to 20 $cmH_2O/(L/s)$: ± 10 $cmH_2O/(L/s)$ 20 to 600 $cmH_2O/(L/s)$ (not including 20 $cmH_2O/(L/s)$): ±50% of the actual reading
Compl:	± (10 mL/cmH_2O+20% of the actual reading)

TABLE 8-46 Ventilator Monitoring Accuracy

Lung Recruitment		
Lung Recruitment Tool includes Multi-Step Recruitment and One-Step Recruitment.		
Parameters	**Pressure Hold:**	Range: 20 to 60 cmH_2O
	Hold Time:	Range: 10 to 40 s
	PEEP on Exit:	Range: OFF, 3 to 30 cmH_2O
	Cycle Interval:	Range: OFF, 1 to 180 min

TABLE 8-47 Lung Recruitment Tool

8.13 Displays and Controls Specifications

8.13.1 Electronic Controls

Main Display:	15.6 inch, 1920 * 1080 resolution with touch screen
AC Power Indicator:	Green illuminated = active AC power Not illuminated = inactive AC power
Battery Status Indicator:	Green illuminated = battery supply is charging Not illuminated = battery supply is discharging or not charging
Working Light:	Settings: Off, Low, High

TABLE 8-48 Electronic Controls

8.13.2 Pneumatic Controls

Line Pressure Gauges:	Gauges: O_2, N_2O, Air, Range: 0 to 140 psi (0 to 1000 kPa) Accuracy: ± (4% of full scale reading + 8% of actual reading) Units of measure: kPa, psi
Cylinder Pressure Gauges:	Gauges: O_2, N_2O, Air O_2: 0 to 3500 psi (0 to 25 MPa) N_2O: 0 to 1400 psi (0 to 10 MPa) Air: 0 to 3500 psi (0 to 25 MPa) Accuracy: ± (4% of full scale reading + 8% of actual reading) Units of measure: kPa, psi
Flowmeter, Control Needle Valve and Knob:	O_2 flow range: 0.00 to 15.0 L/min Air flow range: 0.00 to 15.0 L/min N_2O flow range: 0.00 to 12.0 L/min Accuracy: ± 0.12 mL/min or ± 10% of indicated value, whichever is greater O_2 concentration range in the O_2/N_2O mixed gas: ≥ 25% Glass tube flow display: Glass tube flowmeter display range: 0 to15 L/min Flowmeter display accuracy: ± 10% of the indicated value (under the condition of 20°C and 101.3kPa, for flow between 10% and 100% of full scale)
Auxiliary O_2 Flowmeter:	Flow adjustable range: 0.0 L/min to 15.0 L/min Flow control accuracy: ± 0.5 L/min or ± 10% of the indicated value, whichever is greater
Auxiliary O_2 and Air Flowmeters:	Total flow adjustable range: 0.0 L/min to 15.0 L/min Total flow control accuracy: ± 100 mL/min or ± 10% of the setting value, whichever is greater O_2 concentration adjustable range: 21% to 100% O_2 concentration control accuracy: Volume fraction of ± 5% Glass tube flowmeter display range: 0 L/min to 15 L/min Glass tube flowmeter display accuracy: ± 10% of the indicated value (under the condition of 20°C and 101.3kPa, for flow between 10% and 100% of full scale)
High Pressure Oxygen Outlet:	Pressure range: 280 to 600 kPa Maximum flow: ≥ 90 L/min
O_2 Flush:	Flow range: 25 to 75 L/min
Airway Pressure Gauge:	Range: -20 to 100 cmH_2O Accuracy: ± (2% of full scale reading + 4% of actual reading)

TABLE 8-49 Pneumatic Controls

8.14 Alarms

Alarm Indicators:	Audible: speaker Visual: alarm light and on-screen alarm messages (Audible and visual alarms comply with the requirements of IEC 60601-1-8.)
Alarm Categories:	Physiological alarms: three levels (high, medium, low) Technical alarms: three levels (high, medium, low)
Sound Levels:	10 alarm sound levels, adjustable (levels 1 to 10)

TABLE 8-50 Alarms

Vte:	High Limit	5mL to 1600mL
	Low Limit	OFF, 0mL to 1595mL
MV:	High Limit	0.2L/min to 100L/min
	Low Limit	0.0L/min to 99L/min
RR:	High Limit	4bpm to 100bpm, OFF
	Low Limit	OFF, 2bpm to 98bpm
Paw:	High Limit	2cmH_2O to 100cmH_2O
	Low Limit	0cmH_2O to 98cmH_2O
Apnea alarm delay time is adjustable, Range: 5s to 60s, Accuracy: ±3s CO2 apnea delay time is adjustable, Range: 10s to 40s, Accuracy: ±3s		
It has Negative Pressure alarm function, when **Negative Pressure in Airway** alarm is triggered, Paw shall be less than -10cmH2O.		

TABLE 8-51 Alarm Limits

A.0 *Accessories*

WARNING: **Please use the accessories specified in this chapter only. Using other accessories may lead to inaccurate measurements or equipment faults.**

WARNING: **Disposable accessories must be used only once. Repeated use may lead to deterioration in performance or cross-infection.**

WARNING: **Please do not use the accessory if its package or itself is damaged.**

WARNING: **At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products, and in accordance with local regulations for contaminated and biologically hazardous items.**

WARNING: **Parts which are intended to contact patients must comply with the biocompatibility requirement of ISO 10993-1 to prevent any adverse reactions arising from such contact.**

B.0

Electromagnetic Compatibility

B.1 EMC

A7 meets the requirements of IEC 60601-1-2:2014.

NOTE: **The anesthesia system needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**

NOTE: **Use of portable or mobile communications devices will degrade the performance of A7.**

NOTE: **A7 is intended for use in professional healthcare facility environment. If it is used in special environment, such as magnetic resonance imaging environment, A7 may be disrupted by the operation of nearby equipment.**

WARNING: **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.**

WARNING: **Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation. If such use is necessary, this device and the other device should be observed to verify that they are operating normally.**

WARNING: **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.**

WARNING: **Other devices may interfere with A7 even though they meet the requirements of CISPR.**

WARNING: When the input signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.

GUIDANCE AND DECLARATION - ELECTROMAGNETIC EMISSIONS

A7 is intended for use in the specified electromagnetic environment. The customer or the user of A7 should assure that it is used in such an environment as described below.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT-GUIDANCE
Radio frequency (RF) emissions CISPR 11	Group 1	A7 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radio frequency (RF) emissions CISPR 11 (configured with BIS and/or V80 and/or NMT and/ or Mainstream CO_2 module)	Class A	A7 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Radio frequency (RF) emissions CISPR 11 (not configured with BIS or V80 or NMT and/or Mainstream CO_2 module)	Class B	A7 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

TABLE B-1 Guidance and declaration - electromagnetic emissions

NOTE: The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

NOTE: Other devices may affect this device even though they meet the requirements of CISPR.

NOTE: When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.

NOTE: **The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.**

NOTE: **If the essential performance is lost or degraded, it may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME SYSTEM or shielding the location or stopping using the EQUIPMENT and contact the service personnel.**

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY

A7 is intended for use in the specified electromagnetic environment.The customer or the user of A7 should assure that it is used in such an environment as described below.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15kV air	±8 kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst (EFT) IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines (length greater than 3 m)	±2 kV for power supply lines ±1 kV for input/ output lines (length greater than 3 m)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and Voltage interruptions IEC 61000-4-11	0 % U_T for 0.5 cycle 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles 0 % U_T for 250/ 300 cycle	0 % U_T for 0.5 cycle 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles 0 % U_T for 250/ 300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.

TABLE B-2 Guidance and declaration - electromagnetic immunity

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY

A7 is intended for use in the specified electromagnetic environment.The customer or the user of A7 should assure that it is used in such an environment as described below.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RATED power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz/ 60 Hz	30 A/m 50 Hz/ 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

U_T is the A.C. mains voltage prior to application of the test level.

TABLE B-2(Continued) Guidance and declaration - electromagnetic immunity

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY

A7 is suitable for use in the electromagnetic environment specified below. The customer or the user of A7 should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Conducted RF IEC 61000-4-6	3 Vrms 150k to 80 MHz	3 Vrms (V1)	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 150k to 80 MHz $d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range [d]. Interference may occur in the vicinity of equipment marked with the following symbol: 
	6 Vrms in ISM bands and amateur radio bands[a] between 0,15 MHz and 80 MHz	6 Vrms (V2)	
Radiated RF EM fields IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz (for NMT or BIS function)	3 V/m (E1)	
	10V/m 80 MHz to 2.7 GHz (for RGM function)	10 V/m	
Proximity fields from RF wireless communications equipment IEC61000-4-3	27 V/m 380 MHz to 390 MHz	27 V/m	
	28 V/m 430 MHz to 470 MHz, 800 MHz to 960 MHz, 1700 MHz to 1990 MHz, 2400 MHz to 2570 MHz	28 V/m	
	9 V/m 704 MHz to 787 MHz, 5100 MHz to 5800 MHz	9 V/m	

TABLE B-3 Guidance and declaration - electromagnetic immunity

GUIDANCE AND DECLARATION - ELECTROMAGNETIC IMMUNITY

A7 is suitable for use in the electromagnetic environment specified below. The customer or the user of A7 should assure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
NOTE:	**At 80 MHz and 800 MHz, the higher frequency range applies.**		
NOTE:	**These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.**		

a. The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

b. Compliance level in the ISM frequency bands between 150 kHz to 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that portable/ mobile communication equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

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

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

TABLE B-3(Continued) Guidance and declaration - electromagnetic immunity

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF, COMMUNICATIONS EQUIPMENT AND A7

A7 is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of A7 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and A7 as recommended below, according to the maximum output power of the communication equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER (W)	**SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER** (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

TABLE B-4 Recommended Separation Distances between Portable and Mobile RF, Communications Equipment and A7

Test specifications and minimum distances for portable and mobile RF communications equipment and the A7 Anesthesia System.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE A7 ANESTHESIA SYSTEM

A7 Anesthesia System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the A7 Anesthesia System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the A7 Anesthesia System as recommended below, according to the maximum output power of the communications equipment. Portable and mobile radio communications equipment (e.g. two-way radio, cellular/ cordless telephones and similar equipment) should be used no closer to any part of this system, including cables, than determined according to the following method:

TEST FREQUENCY (MHZ)	BAND (MHZ)	SERVICE	MODULATION	MAXIMUM POWER (W)	DISTANCE (M)	IMMUNITY TEST LEVEL (V/M)
385	380 - 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 -470	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, tetra 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3,4,25,UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN, 802.11 a/n,	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

TABLE B-5

WARNING: Use A7 Anesthesia System away from heat penetration, diathermy, electrocautery, magnetic resonance imaging, RFID and security equipment (such as electromagnetic anti-theft system and metal detector). If some concealed RF transmitters that are not known to the user are exposed near the device and are disturbed by the device (for example, scanning mode changes or image disturbances affecting diagnosis), the user should immediately take mitigation measures, such as redirecting, repositioning or shielding away from the RF transmitter.

The essential performance verified during the immunity testing comprised of V_{del} control accuracy, V_{del} monitoring accuracy, CO_2 monitoring accuracy, O_2 monitoring accuracy, airway pressure monitoring accuracy, anesthetic gas monitoring accuracy, PEEP control accuracy and PEEP monitoring accuracy.

B.2 Radio Regulatory Compliance

ITEM	DESCRIPTION
Wi-Fi	IEEE 802.11 a/b/g/n/ac
Operating frequency	2412MHz to 2472MHz, 5180MHz to 5320Mz, 5500MHz to 5700MHz, 5745MHz to 5825MHz
Modulation mode	BPSK, QPSK, 16QAM, 64QAM, 256QAM
Output power (dBm)	<20 dBm (CE requirements, detection mode: RMS) <30 dBm (FCC requirements, detection mode: peak power)

TABLE B-6