



SP1000

Endoscopic Instrument Control System

User Manual

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For Customer Service and Reporting of Complaints or Adverse Events

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Use the following information for customer service, including ordering, reporting complaints or adverse events, general information regarding Edge Medical or our products and services, if the product requires maintenance or service. Preventive maintenance is required and must be performed by authorized Edge Medical personnel.

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- All replaceable parts, accessories and consumables involved in maintenance are original or approved by the company.
- The electrical equipment complies with local standards and the requirements of this document.
- Carry out product operations according to this document.
- Any future changes to this manual may be updated without notice. If necessary, contact the manufacturer or your local representative for a copy.

About This Manual

Thank you for choosing SP1000 Endoscopic Instrument Control System (hereinafter referred to as “SP1000 System”) of Shenzhen Edge Medical Co., Ltd. The manual provides feature descriptions and operating instructions of the system. Please read the manual carefully before using, and keep the manual properly after reading.

Documentation Conventions

Symbol	Description
	Note: Indicates important information.
	Caution: Indicates situations that could cause equipment damage.
	Warning: Indicates situations that could cause personal injury or even death.

Notation Conventions

Format	Description	Example
“ ”	Denotes messages, directories, file names, and parameter values.	The screen displays “Emergency Stop”.
		In the text box, enter “1”.
Boldface	Denotes menus, tabs, parameter names, window names, dialogue names, and hardware buttons.	Press the Power button.
		Tap Restart .
>	Directs multi-level menus.	Go to Account > User Login .

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1. Introduction

This manual provides instructions for SP1000 Endoscopic Instrument Control System.



Note: Do follow all instructions provided with the applicable user manuals for SP1000 System, instruments and accessories not included in this manual.



Note: Disposable accessories are shipped sterile and are for single use only. Reusable instruments, endoscopes and accessories are shipped non-sterile and should be cleaned and sterilized thoroughly before first use and after every use. Refer to the reprocessing instructions manuals for instructions on cleaning and sterilization.

1.1 System Components

The system consists of one or two Surgeon Consoles (Model: MP1101), a Patient Cart (Model: SP1102), a Vision Cart and accessories.

The Vision Cart includes a Camera Control Unit (Model: MP1202) and a Signal Distributor (Model: MP1204).

The accessories include system cables (Model: CM1801/CM1802/CM1804), camera cables (Model: CM1806/CM1836/CM1821/CM1805) and an energy activation cable (Model: CM1807).

1.2 Intended Purpose/Indication for Use

The Endoscopic Instrument Control System (SP1000) is intended to assist in the accurate control of endoscopic Instruments including rigid endoscopes, scissors, forceps, needle drivers, hooks and accessories for endoscopic manipulation, ligation, electrocautery, suturing, and delivery and placement of accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, and thoracoscopic surgical procedures. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the professional instructions for use.

1.3 Intended Users

The device is intended for use by trained physicians in an operating room environment in accordance with the representative specific procedures set forth in the professional instruction

for use.

1.4 Intended Patient Population

Adult.

1.5 Training



Warning: Only trained users and those who have developed adequate robotic skills should use the system. Training provided by Edge Medical is limited to the use of SP1000 System and does not replace the necessary medical training and experience required to perform surgery.



Note: The adequate robotic skills are defined as theoretical learning, operation skills training, simulated surgery training and clinical practice provided by Edge Medical. Only when the users successfully passed the training and obtained the qualifications of the system, the adequate skills of SP1000 have been considered developed.

1.6 Clinical Benefits

The overall benefits of the Edge Medical SP1000 Endoscopic Instrument Control System include an expanded access to minimally invasive surgery for an increasing variety of procedures.

The potential clinical benefits of the Edge Medical SP1000 Endoscopic Instrument Control System as a minimally invasive tool include lower estimated blood loss and lower length of hospital stay. These clinical benefits/outcomes may depend on a number of factors, including, but not limited to patient characteristics, disease characteristics, surgeon experience, and hospital/national patient care and recovery pathways.

1.7 Clinical Risks

Patients should talk to their doctor to decide if Edge Medical surgery is right for them. Patients and doctors should review all available information on non-surgical and surgical options and associated risks in order to make an informed decision.

Serious complications may occur in any surgery, including Edge Medical surgery, up to and including death. Serious risks include, but are not limited to, injury to tissues and organs and conversion to other surgical techniques which could result in a longer operative time and/or increased complications.

These clinical risks may depend on a number of factors, including, but not limited to patient characteristics, disease characteristics, surgeon experience, and hospital/national patient care and recovery pathways.

1.8 Safety Information

The system should be used in accordance with this manual and should not be moved or used by any person who has not been trained by a representative of the company.

Please read all instructions of safety information carefully. Failure to properly follow the instructions, cautions and warnings related to the system may result in serious injury or surgical complications to the patient. While these instructions appear throughout the manual, this chapter provides some general precautions.

Precautions for Use in Smaller Patients

- Performance in smaller patients surgical procedures is based on similarity of tasks performed in adult surgical procedure, consideration must be given to patient size and workspace volume when using the system and instruments.
- As in any patient of smaller size, the possibility of misalignment of the remote center with the body exists. In order to minimize forces on the body wall, care must be taken to ensure the remote center is properly aligned with the body wall.

1.8.1 Contraindications

Any and all relative and absolute contraindications to endoscopic, thoracoscopic and laparoscopic surgical techniques applicable to the use of conventional endoscopic surgical instruments apply to the use of the Endoscopic Instrument Control System. The device is not intended for use when endoscopic techniques are contraindicated.

1.8.2 General Precautions



Warning: Each time before using the system, check the following safety precautions:

- Check whether the instruments are compatible with the system. Incompatible instruments may result in delayed treatment or even injury to the patient.
- Check for the status, performance and integrity of the system, no rough surfaces, sharp edges or protrusions occurred on the instruments, endoscope, cannula and obturator. Do not leave any defected or damaged parts in the patient.

- Check for the integrity of air-tight devices. Any damage to air-tight devices may result in fragments in the patient.
- Check for cleanliness of the instruments, endoscope, cannula, obturator and monopolar or bipolar energy instrument cord. Improper operation or ineffective sterilization may cause cross-contamination.
- Check for clearance between the patient and the instrument arm of the Patient Cart. Prolonged pressure on the patient may result in serious injury.
- Any damage to the system components, instruments, endoscope or accessories may delay surgery and cause serious injury or death to the patient.
- Any contaminated or damaged disposable drapes may cause protection failure, resulting in patient infection, serious injury or death.
- Check whether all cables are correctly connected. Faulty connections may result in device damage or even injury to the patient.



Warning: When a fault occurs, please stop using the system immediately, and safely remove the instruments from the body.



Warning: When connecting to AC power, put the system in a place where it can be easily disconnected from the power supply.



Warning: The following safety guidelines should be observed to avoid a pinch or crush hazard:

- When moving the instrument arm, keep your fingers clear of the joints located on the arm.
- When moving the drive box, keep your fingers clear of the area between the drive box and instrument arm.
- When the instrument drives perform self-test during the startup sequence, keep fingers away from the drives.



Warning: Avoid placing hands between the top of the instrument drives and the instrument arm, as these surfaces may be hot and may result in burn injury to the patient or user.



Warning: Reinstalling or upgrading system without authorization may cause the system to malfunction, serious injury or death to the patient.



Warning: The system shall not be used for any purpose other than the intended purpose.



Warning: Accessories, other ME equipment and/or non-ME equipment that are not specified or allowed by the manufacturer shall not be connected to the mechanical interfaces and other interface of the RASE.



Warning: Avoid the risks caused by the use of RASE together with accessories, other ME equipment and/or non-ME equipment within a robotic surgery configuration.



Warning: Do not re-sterilize or re-use disposable instruments and accessories. Reprocessing and/or reuse of products intended for single use may result in degraded instrument performance or loss of functionality, and in exposure to viral, bacterial, fungal, or prion pathogens.



Warning: To ensure the operating environment keep sterile, do not use disposable instruments and accessories if their package is opened or damaged.



Warning: A breach in the sterile packaging indicates possible contamination. Do not use if package is not intact.



Warning: The cannula must be used in conjunction with the appropriate cannula seal to maintain pneumoperitoneum. Do not insert instruments through the cannula that has external diameter less than the cannula seal. This situation may cause gas release and pneumoperitoneum loss.



Warning: The instruments inserted through the cannula should match the cannula in size. Otherwise, there is a risk of gas release or failure to move smoothly in and out of the cannula.



Warning: Ensure that the cannula or cannula seal outlet is not inadvertently blocked by patient anatomy, other instruments ports, kinked tubing, etc.



Warning: Follow the instructions to install the obturator to a cannula and seal assembly and ensure complete attachment. Otherwise, incomplete attachment and

unexpected detachment from the cannula may occur.



Warning: Do not remove the cannula assembly and instrument from the body simultaneously as this may damage the surrounding tissues and the instrument.



Warning: If the cannula incision is too small, it will cause insertion resistance or even insertion failure. If the cannula incision is too large, it will cause air leak or failure to fix the instrument.



Warning: Do not use a damaged cannula. The damaged cannula may abrade the instrument shaft and generate particles that may fall inside the patient.



Warning: Remove all accessories before cleaning. Failure to remove may result in incomplete cleaning and sterilization.



Warning: Failure to establish and maintain proper pneumoperitoneum in abdominal surgery may reduce available space and injure tissue inside or outside the field of view.



Warning: The circulating nurse could press the **Emergency Stop** button to lock the system when there's a potential accident.



Warning: Users should standardize the use of the system. Before docking to the cannula, the instrument arm should be kept at a safe distance of one fist from the patient to avoid excessive pressure on the patient by the instrument arm, endoscope and surgical instruments during the surgery.



Warning: Do not perform service or maintenance of the equipment while it is in use with a patient.



Caution: Only physicians having adequate training and experience with endoscopic techniques should perform endoscopic procedures with the system. Medical literature should be consulted regarding techniques, complications and hazards before performing any endoscopic procedure.



Caution: No interfaces are intended to connect to a network.



Caution: The components of the system for use in the patient environment include

the Patient Cart, instruments, endoscope, cannula, cannula seal, obturator, tip cover accessories and monopolar/bipolar energy instrument cord.



Caution: The system is not suitable for use in environments with flammable anesthetic mixture of air, oxygen and/or nitrous oxide.



Caution: Keep the cooling vents clean and move the system components to a location with adequate ventilation. Insufficient ventilation may cause overheating and damage.



Caution: Failure to adhere to approved operating practices may damage the instruments. Improper practices include: dropping, collisions, and improper cleaning and sterilization techniques, etc. A damaged instrument may result in fragments falling into the body.



Caution: Do not clean instrument tips with another instrument intraoperatively, as this may damage the instrument. If an instrument tip requires cleaning, remove the instrument from the cannula and gently clean the tip.



Caution: Be careful to insert or remove the instruments that have sharp edges or sharp angles to avoid damage to the air-tight devices.



Caution: Ensure the tip of the instruments are straightened before insertion or removal. Do not use excessive force when inserting or removing instruments.



Caution: Do not touch the patient at the same time as using the input and output cables (including connectors) of handheld devices.



Caution: This system cannot be used in conjunction with a cardiac defibrillator. If defibrillation is required, the system must be removed from the patient.



Caution: Do not suspend or place any objects over the instrument arm, boom or drive box of the Patient Cart.



Caution: Do not move the instrument arm of the Patient Cart frequently, or it may cause joint damage.



Caution: Some users who view 3D images may experience altered vision, dizziness and other symptoms. If users have any of the above symptoms, immediately discontinue use of this system and do not resume until the symptoms have subsided.



Caution: Any additional multiple socket outlets or extension cords shall not be connected to the system.



Caution: Only authorized software can be installed on the system. Installation of unauthorized software may result in improper operation of the system.



Note: Do follow all instructions for use supplied with the system, its components, instruments and accessories, including the user manual and reprocessing instructions manuals.



Note: Only electronic equipment that has been specified as part of the system or that has been specified as being compatible with the system can be connected to the system. The equipment unspecified by the company cannot be connected to the system.



Note: Anatomical characteristics of a patient may preclude using minimally invasive techniques. Environmental or equipment failures may cause the system to be unavailable. The surgical team should always have backup equipment and instruments available for conversion to alternative surgical techniques. The potential risk of such conversion should be communicated to the patient.



Note: If an emergency occurs, stop the system by pressing the **Emergency Stop** button or powering off the system.



Note: Consider the patient size and surgical workspace for any procedures when using the system and instruments.



Note: The remote center is the pivot point around which the system moves the arm. For some small patients, it is possible that the remote center is not aligned with the body. To exert minimal force on the patient's body wall, ensure the remote center is placed correctly.



Note: Endoscopic instruments which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.



Note: Performance in smaller patients surgical procedures is based on similarity of tasks performed in adult surgical procedures. As is appropriate with any surgical procedure, consideration must be given to patient size and workspace volume when using the system and instruments.



Note: Consider increasing the distance between the arm of the system and the edge of the surgical bed by padding the body of patient to avoid patient injury due to collision of the arm and surgical bed.

1.8.3 Endoscopic Procedure Precautions



Warning: When using the system with insufflation, only CO₂ should be used as the insufflating gas. Insufflation should be performed by personnel with adequate technical training and rich experience, otherwise hazards may exist with over-insufflation, such as gas embolism.



Warning: The highly concentrated light energy can cause the distal tip and the shaft to heat up (may exceed 41°C). This may cause tissue burns. The following safety guidelines should be observed to reduce the risk of injury:

- Avoid direct tissue contact with the endoscope distal tip.
- Avoid excessively long continuous direct tissue contact with the front of the endoscope.
- Avoid resting the endoscope on the patient or in direct contact with endoscopic instruments or accessories.
- Avoid direct contact with high-temperature parts of the endoscope during intraoperative removal or replacement of the endoscope, which may cause burns to the operator or patient.
- After using the endoscope, ensure all parts cool down before reprocessing. Improper operation may cause burns.



Warning: Do not contact the distal tip of the endoscope with the operator, patient, drapes or flammable materials.



Warning: When high frequency surgical equipment and the system are used simultaneously, observe the following:

- After cleaning, check and clean the residual liquid before high frequency surgery.
- During cleaning, disconnect the power supply of high frequency surgical equipment.
- To avoid electric shock or interference, keep the cables of high frequency surgical equipment as far away as possible.
- After starting high frequency surgical equipment, do not contact it with the metal parts of the endoscope or Camera Control Unit.
- Using high frequency surgical equipment may increase leakage current to the patient.
- The system should not be used adjacent to or stacked with high frequency surgical equipment, or it may cause interference.



Warning: When using the system, do not allow the metal parts of the system contact with each other, or it may cause electric shock to the operator or patient.



Warning: To avoid electric shock or damage to the equipment, do not attempt to open or remove the casing of the equipment.



Warning: Do not insert the endoscope to the patient's tissue to clean the endoscope.



Caution: Only a surgeon having adequate technical training and rich experience can use the system for endoscopic procedures.



Caution: If a feature failure occurs (such as illumination or image failure) during operating the endoscope, immediately remove the endoscope from the patient and never try to repair it before removal.

1.8.4 Energy Surgical Procedure Precautions



Warning: Due to the carcinogenic and infectious potential of by-products such as tissue smoke and suspended solids from energy sources, protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both

open and laparoscopic procedures.



Warning: To avoid electric shock, burns, or other hazards to the patient and medical personnel from HF electrosurgical procedures, comply with the following requirements:

- Avoid accidental excitation of electrosurgical instruments.
- Ensure the monopolar instruments should be equipped with the neutral electrode. Please configure a suitable neutral electrode and use it correctly according to the manufacturer's instructions for safety.
- Attach the entire neutral electrode stably to the patient, locate it in the operative field as closely as possible and connect it correctly to HF generator.
- For electrosurgery where HF current may flow through small cross-sectional areas of the body, use bipolar techniques whenever possible to prevent unintended tissue injury.
- Set the minimum output value required to meet the surgical requirements within the shortest time.
- When an output reduction or interruption occurs to HF surgical equipment that runs properly under normal settings, it indicates the neutral electrode in wrong application or poor contact. Check the application and contact of the neutral electrode before selecting higher output power.
- Do not use one instrument to energize the tips of other instruments. This may damage the instruments or injure tissue inside or outside the field of view. Tissue damage could occur at points near the tip or at the port site (cannula) of the energized instrument.
- Secure and route the energy instrument cords to the system to prevent damage and unintended disconnection.
- Avoid the surgical energy cords contact with the patient or other leads. Put the surgical energy cords that are not in use in a place that is isolated from the patient.
- Prevent the patient from coming into contact with grounded metal parts.
- Prevent skin-to-skin contact. For example, wrap the skin contact between the patient's arm and body with dry gauze.

- When HF surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended. In all cases, monitoring systems incorporating HF current limiting devices are recommended.
- Do not use flammable anesthetics or oxidizing gases such as nitrous oxide and oxygen.
- Do not contact with flammable materials, such as gauze and cotton fabrics, flammable reagents and anesthetics.
- Do not use flammable agents for cleaning. If flammable agents are used for cleaning or as solvents, they must be evaporated before using the instruments.
- There is a risk of pooling of flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before HF surgical equipment is used. Attention should be called to the danger of ignition of endogenous gases.



Warning: The rated voltage of the monopolar instruments and monopolar energy instrument cord should be 3 kV (electric cutting), use the HF generators verified by the company, and avoid higher peak voltage. Otherwise, it may cause serious injury to the patient and other surgical complications.



Warning: The rated voltage of the bipolar instruments and bipolar energy instrument cord should be 740 V (coagulation), use the HF generators verified by the company, and avoid higher peak voltage. Otherwise, it may cause serious injury to the patient and other surgical complications.



Warning: Maximum HF output voltage must not exceed the rated voltage.



Warning: Failure of HF surgical equipment can cause unintended increase in output power.



Warning: Unless stated, do not use instruments on cartilage, bone or hard objects. Otherwise, the instrument may be damaged and cannot be removed from the cannula.



Warning: Do not grasp tissue with instruments such as needle drivers or clip

appliers not intended to grasp tissue, as tissue injury may result.



Warning: When the instrument is completely bent to one side, use caution when applying force to the end of the instrument. Excessive force may cause instrument damage.



Warning: For HF instrument and associated equipment, requirements for separation between HF patient circuits and the enclosure including signal input/output parts, between HF patient circuits and the intermediate circuit and between different HF patient circuits are specified by the ME EQUIPMENT standards IEC 60601-1.



Warning: In sensitive structures, neuromuscular stimulation can still occur leading to secondary risks like injury caused by muscle contractions.



Warning: A thorough understanding of the principles and techniques involved in electrosurgical procedures is essential to avoid electric shock and burn hazards to the operator and patient, damage to equipment and other instruments. Ensure the electrical insulation and grounding. Never immerse an instrument in a liquid unless it is designed and labeled for the function.



Warning: Keep the tip in the field of view when manipulating the instrument.



Warning: Do not manipulate the instrument that is outside of the field of view. This may damage the instrument or injure tissue inside or outside the field of view.



Warning: Do not apply prolonged energy to an instrument when it is not in contact with tissue.



Caution: Only a surgeon having adequate technical training and rich experience can use the system for high frequency electrosurgical procedures.



Caution: High frequency electrosurgical equipment may cause an interference to other electronic equipment such as the Vision Cart, which prevents the proper operating.



Caution: High frequency electrosurgical procedures may cause interference with

pacemakers. If a patient has a pacemaker, please consult the manufacturer of the device.



Note: When the system is used in high frequency electrosurgical procedures, the instructions, cautions and warnings provided with high frequency generator should be followed.



Note: Ensure that the electrosurgical instrument audible output can be heard by the surgeon when using the electrosurgical instruments with the system.

1.8.5 Electrical Safety



Warning: Interference produced by the operation of the system may adversely influence the operation of other electronic equipment. For patients with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the active implant may occur, or the active implant may be damaged. In case of doubt, please consult the manufacturer of qualified device.



Warning: Leakage current from interconnected electrical equipment may exceed safe levels. In order to maintain patient and user safety, it is important to interconnect only with devices in compliance with IEC 60601-1 requirements. It is the responsibility of the user to ensure that any interconnected equipment not supplied by Edge Medical maintains compliance with IEC 60601-1 requirements.



Warning: Leakage currents from other endoscopic instruments may be additive. To ensure maximum safety for the patient, only Type CF endoscopic accessories should be used with the system.



Warning: To avoid the risk of electric shock, the system must only be connected to supply mains with protective earth.



Warning: To reduce risk of electric shock, do not open or remove the covers of the system except as instructed in the user manual.



Warning: The portable and mobile communications equipment and magnetic metal materials placed into the operating area of the Surgeon Console during procedures may cause irreversible injury to the patient resulting from unintended

movements of the instruments.



Warning: Check tip cover accessories before using instruments to ensure that tip cover accessories are intact. Broken tip cover accessories may cause unintended burns to patient's tissue.



Caution: Do not modify the adaptors, endoscope or instruments. Modifications can result in electrical hazards or performance degradation.



Caution: The system components should be connected to the dedicated power supply separately.



Note: Before each use, please check whether the isolation barriers of the cables and instruments are intact.



Note: Although the system complies with the requirements of IEC 60601-1-2 and IEC 60601-2-2, it may cause electromagnetic interference to other equipment. Ensure that other equipment in the operating room also meets the requirements of IEC 60601-1-2 and IEC 60601-2-2.



Note: Due to Electromagnetic Interference (EMI) hazards in the presence of MRI, CT, diathermy, or Electromagnetic Security Systems, the system should not be used in the vicinity of these devices.



Note: The system should not be used adjacent to or stacked with other equipment. However, if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it is used.



Note: This system is intended to be used in an operating room environment, and electromagnetic compatibility may be potentially difficult in other environments (such as family environments) due to conducted and radiated disturbances.



Note: Except the accessories and cables sold as spare parts for internal components, the use of unspecified accessories and cables can lead to an increase in radiated emissions or a decrease in immunity of the system.



Note: Portable and mobile communications equipment may produce EMI, which

may affect the function of the system. Use the equipment with EMI characteristics proven below recognized limits.

1.8.6 Installation and Maintenance Precautions



Warning: Do not modify the system without authorization, otherwise it may cause irreversible injury to the patient and medical personnel.



Warning: Replacements of parts may lead to unacceptable risks, if maintenance of the equipment is required, please contact the company.



Caution: The system can only be installed and serviced by authorized personnel from Edge Medical. Do not attempt to install or service the system without authorized personnel.



Caution: The system shall not be serviced or maintained while in use with a patient.



Note: If the system needs to be installed, serviced or maintained, please contact technical support of Edge Medical. Read Installation and Maintenance Guide, and Service Manual carefully before installation, service or maintenance.

1.8.7 Transportation and Storage Precautions



Caution: The system components (Surgeon Console, Patient Cart and Vision Cart) are heavy and may present a hazard (for example, tipping) if control is lost when moving. Only trained personnel should attempt to move the system.



Caution: Handle the instruments and endoscope with care. Avoid mechanical shock or stress that can cause damage to the instruments and endoscope.



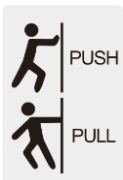
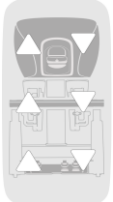
Caution: Do not place endoscope cables or accessory cables over the instrument arm of the Patient Cart. The cables may limit the range of motion of the arm, or become pinched or damaged.



Note: During transportation and storage, the instruments and endoscope should be removed from the Patient Cart, the Patient Cart and Vision Cart should be stowed, and the brakes of the Surgeon Console should be released.

1.9 Symbol Reference Tables

1.9.1 Surgeon Console

Symbol	Meaning	Symbol	Meaning
	“ON” (power)		“OFF” (power)
	Alternating current		Fuse
	Debugging		MS (Master-Slave) communication port
	MV (Master-Video) communication port		Indicates where to push or pull the Surgeon Console
	Do not walk or stand here		Do not push or pull here
	Standby		Emergency stop
	Ergonomic control buttons		Protective earth (ground)
	Maximum load	/	/

1.9.2 Patient Cart

Symbol	Meaning	Symbol	Meaning
	“ON” (power)		“OFF” (power)

Symbol	Meaning	Symbol	Meaning
~	Alternating current		Fuse
	Debugging		Manual movement
	Do not walk or stand here		Do not push or pull here
	Pinch/Crush hazard		Maximum load
	Standby		Emergency stop
	MS (Master-Slave) communication port		Type CF applied part
	Protective earth (ground)	EPO	Emergency power off
UPS	Uninterruptible Power Supply		Direction indicator for close or open
	Press to insert and retract the instruments and endoscope		Operate with one hand
	Lock		Unlock
	Type BF applied part	/	/

1.9.3 Camera Control Unit

Symbol	Meaning	Symbol	Meaning
	“ON” (power)		“OFF” (power)
	Alternating current		Fuse
	Equipotentiality		Debugging
	White balance		Increase brightness
	Decrease brightness		Enhance image sharpness
	Digital zoom		Standby
	Type BF applied part		Energy control port
	Protective earth (ground)		MV (Master-Video) communication port

1.9.4 Signal Distributor

Symbol	Meaning	Symbol	Meaning
	“ON” (power)		“OFF” (power)
	Alternating current		Fuse
	Debugging		Protective earth (ground)

Symbol	Meaning	Symbol	Meaning
	MS (Master-Slave) communication port		MV (Master-Video) communication port
	Standby		Energy control port

1.9.5 Package Labeling and Other Symbols

Symbol	Meaning	Symbol	Meaning
	This way up		Fragile, handle with care
	Keep dry		Stacking limit by number
	Do not stack		Do not roll
	CE mark		Caution
	Refer to instruction manual		Consult instructions for use
	Medical device		European authorized representative
	Manufacturer		Date of manufacture
	Dispose of in accordance with local regulations—particularly applies to electronic components		Temperature limit
	Humidity limitation		Atmospheric pressure limitation

Symbol	Meaning	Symbol	Meaning
SN	Serial number	#	Model number
REF	Part number	UDI	Unique device identifier

1.10 Lifetime

The system has a design life of 10 years; however, even after 10 years, the standard maintenance contract provides for preventive maintenance, inspection and re-qualification by qualified personnel of the company that extends the lifetime of the system until the next scheduled service, which occurs at least every 2 years.

1.11 Date of Manufacture

See product label for date of manufacture.

1.12 Installation Environmental Requirements

The system is suitable for use in an operating room environment, other than domestic establishments. For specific installation environmental requirements, please contact technical support of Edge Medical.

1.13 Combination Use

SP1000 Endoscopic Instrument Control System is designed for use with the following compatible equipment only.

Equipment provided by Edge Medical:

Product Name	Model	
Endoscope	SP1207, SP1207P	
Disposable Drape	DR1004, DR1006	
Endoscopic instruments and accessories	Maryland Bipolar Forceps	SP1304, SP3-BM
	Fenestrated Bipolar Forceps	SP1303, SP3-BF
	Needle Driver	SP1305, SP3-ND

Product Name	Model	
	Large Needle Driver	SP1335, SP3-LND
	Monopolar Curved Scissors	SP1301, SP3-MS
	Monopolar Hook	SP1302
	Medium-Large Clip Applier	SP1332, SP3-CA
	Cadiere Forceps	SP1334, SP3-CF
	Tip-up Fenestrated Grasper	SP1337, SP3-TG
	Round Tooth Retractor	SP1333
	Curved Needle Driver	SP1309
	Tip Cover Accessory	SP1306, SP4-S, SP1307, SP4-I, SP1403
	Monopolar Energy Instrument Cord	MS1801
	Bipolar Energy Instrument Cord	MS1802
Puncture Kits	Cannula	SP1406, TR1-SP
	Obturator	SP1502, TR2-SP
	Cannula Seal	SP0801, TR3-SP

Equipment provided by ERBE:

Product Name	Model
HF generator	VIO300S

2. System Overview

2.1 System Description

SP1000 Endoscopic Instrument Control System (hereinafter referred to as “SP1000 System” or “the system”) is designed to enable complex surgery using a minimally invasive approach. The system consists of one or two Surgeon Consoles, a Patient Cart, a Vision Cart (include a Camera Control Unit and a Signal Distributor) and accessories. Setup and intraoperative use may require sterile and non-sterile tasks performed by the following users: surgeon, circulating nurse (non-sterile user) or scrub nurse (sterile user).

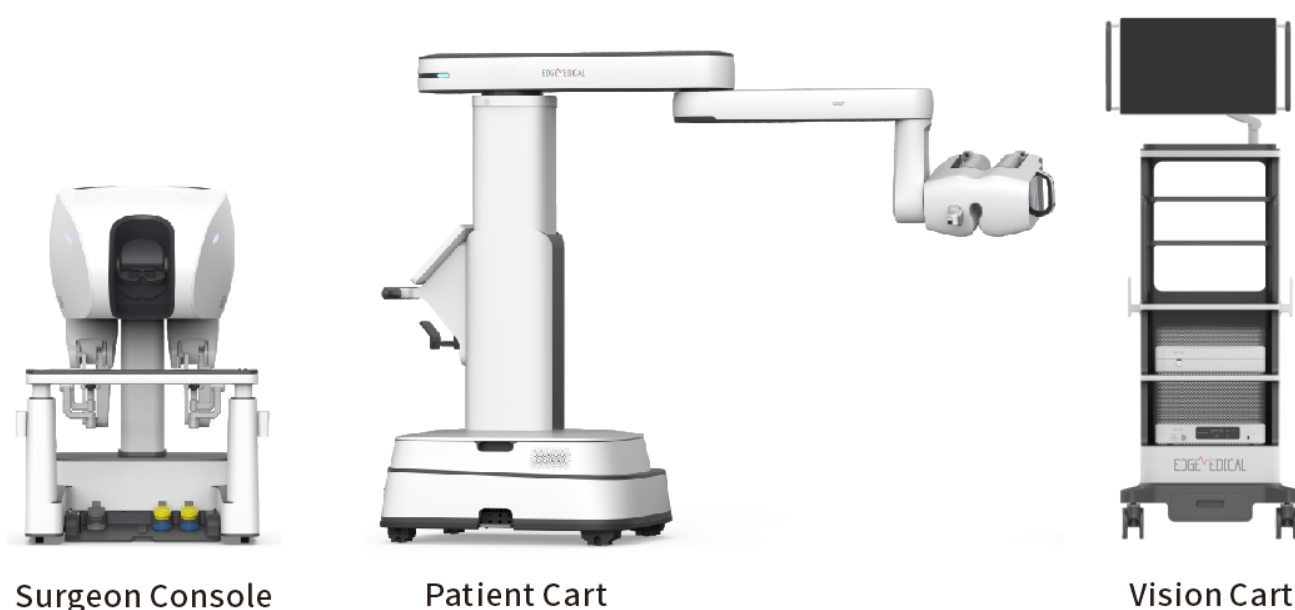


Figure 2.1 Main Components of the System

2.2 Surgeon Console

The Surgeon Console is the control center of the entire system. The surgeon seated at the Surgeon Console controls all movements of the instruments and endoscope by using two master controls and a set of foot pedals, and views the endoscopic image on the viewer to observe the view of patient anatomy and instruments along with icons and other user interface features.

There are a microphone and speaker installed on the Surgeon Console for bidirectional audio communication between the operating room staff and surgeon. The volume can be adjusted on the Surgeon Console touchscreen.

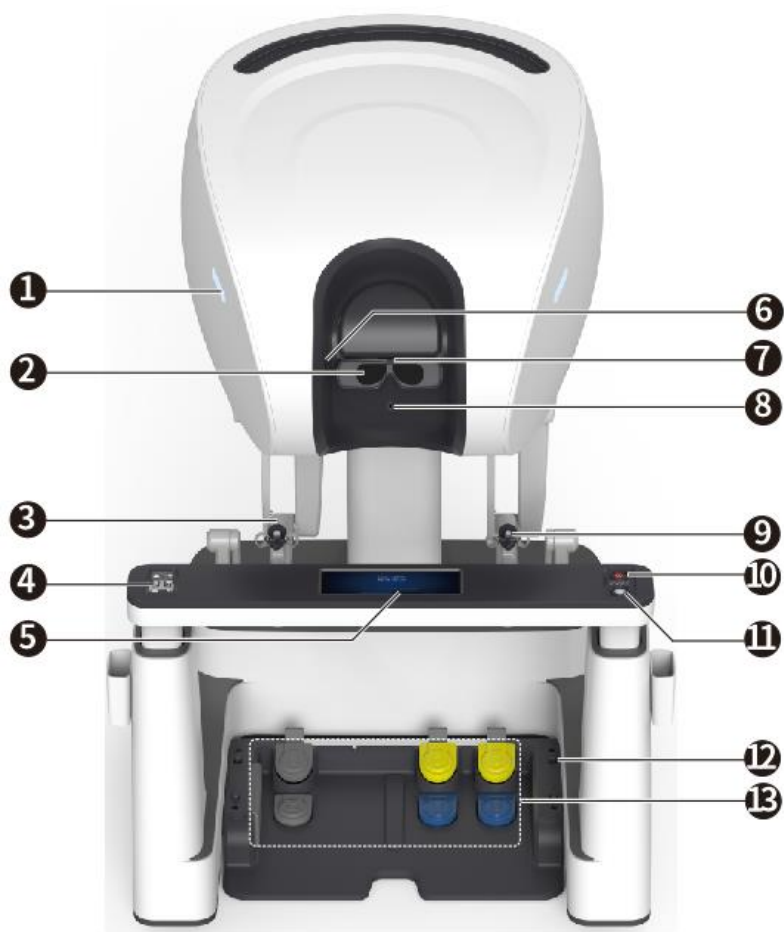
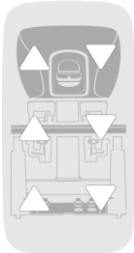


Figure 2.2 Surgeon Console

No.	Name		Description
1	Visual indicator		Turns on after the system starts up.
2	Viewer		Displays patient anatomy, system and component status information.
3	Master controls		Contain two master controls grasped by the surgeon to control all movements of the instruments and endoscope.
4	Ergonomic control buttons		Used to adjust the height of the Surgeon Console so that the surgeon's head can easily access to the viewer.
			Used to adjust the armrest height so that the surgeon's forearms can comfortably rest on the armrest.

No.	Name		Description
			Used to adjust the footswitch panel depth so that the surgeon's feet can easily press the footswitch panel controls.
5	Touchscreen		Used to create an account, log in to the system, and adjust settings.
6	Speaker		Used for voice communication (receiving) between the Surgeon Console and the Patient Cart.
7	Sensor		Used to determine whether the system is in use or not. If the surgeon's head is out of the viewer, he or she cannot take control of the instruments and endoscope.
8	Microphone		Used for voice communication (transmitting) between the Surgeon Console and the Patient Cart.
9	Finger clutches		Contain four finger clutches, which can decouple the master controls from instrument control and reposition the master controls while the instruments do not move.
10	Emergency stop button		Press the Emergency Stop button to stop the system, and the instruments and endoscope stay in their last commanded position.
11	Power button		Turns the component to standby mode or operating mode.
12	Lifting controls		Used to lift the footswitch panel when moving the Surgeon Console.
13	Foot pedals		Left Secondary Pedal (yellow): Activates the secondary function of the instrument controlled by the left master control (for example, cutting for monopolar instruments).

No.	Name		Description
			Right Secondary Pedal (yellow): Activates the secondary function of the instrument controlled by the right master control (for example, cutting for monopolar instruments).
			Left Primary Pedal (blue): Activates the primary function of the instrument controlled by the left master control (for example, coagulation for bipolar instruments).
			Right Primary Pedal (blue): Activates the primary function of the instrument controlled by the right master control (for example, coagulation for monopolar instruments).
			Master Clutch: Decouples both two master controls from the instrument control and repositions the master controls while the instruments do not move.
			Endoscope Control: Switches instrument control mode into endoscope control mode.
			Instrument swap pedal: Pressing the instrument swap pedal allows the surgeon to select which of the instruments is actively controlled by the master controls.

2.3 Patient Cart

The Patient Cart is positioned at the operating table, and is mainly composed of the base, column, helm, boom, vertical arm and drive box, which can realize minimally invasive surgery through one port. The instruments and endoscope are attached onto the instrument drives, and all movements are controlled by the surgeon at the Surgeon Console. The Patient Cart can be moved or rotated for positioning based on the patient anatomy and workspace. The patient-side assistant installs and removes the instruments and endoscope intraoperatively.

There are a microphone and speaker installed on the Patient Cart for bidirectional audio communication between the operating room staff and surgeon. The Patient Cart audio can be

adjusted on the touchscreen of the Surgeon Console or the Patient Cart.

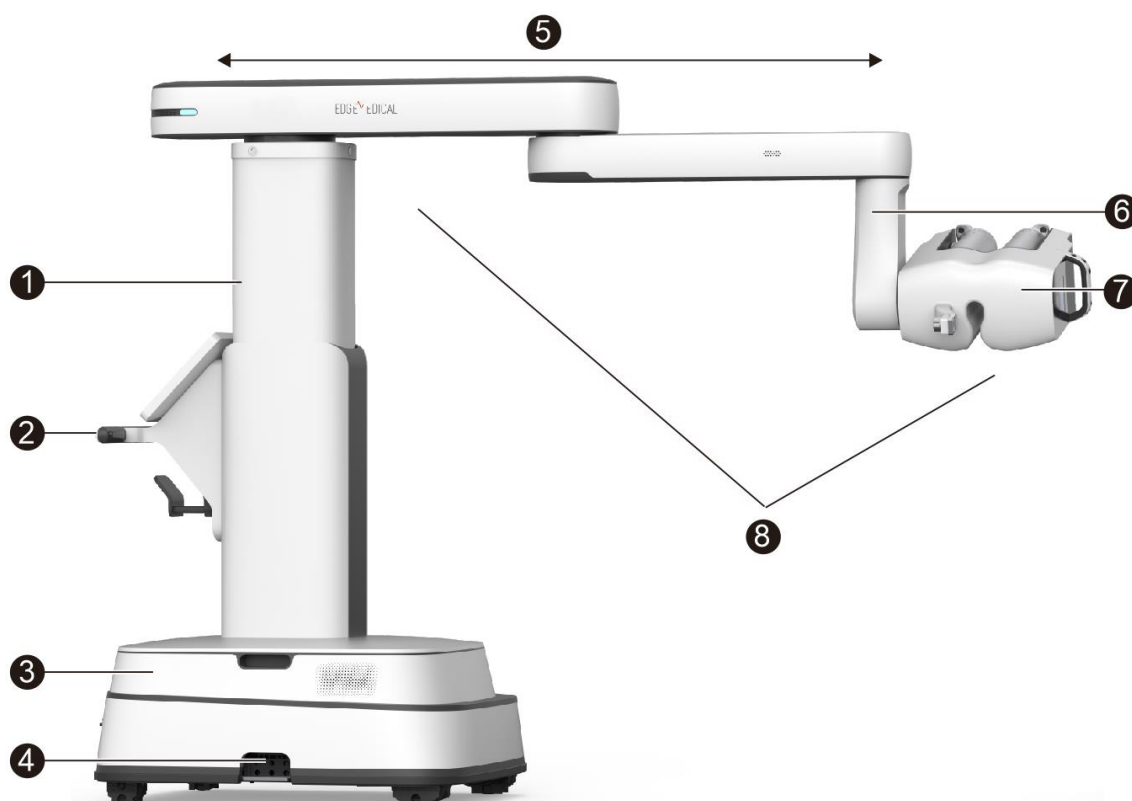


Figure 2.3 Patient Cart

No.	Name	Description
1	Column	Moves the boom up or down.
2	Helm	Used for moving the Patient Cart. Refer to Figure 2.4 Helm for more information.
3	Base	Includes a motorized cart drive for positioning and transportation, and the electronics and unlock pedals.
4	Unlock pedals	Unlocking and moving the Patient Cart in abnormal situations.
5	Boom	The boom is adjustable, rotating support structures for the drive box.
6	Vertical arm	Used to control the rotation of the drive box.
7	Drive box	Includes four instrument drives, function buttons and cannula interfaces for mounting and moving endoscopic instruments and endoscope. Refer to Figure 2.5 Drive for more information.

No.	Name	Description
8	Instrument arm	The instrument arm is the whole arm of the Patient Cart and contains the boom, vertical arm and drive box.



Figure 2.4 Helm

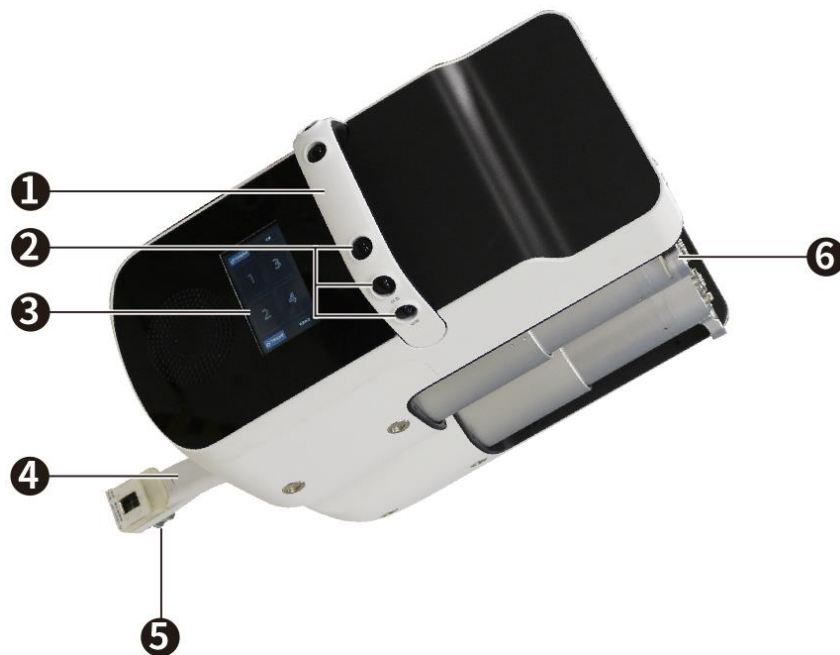




Figure 2.5 Drive Box

No.	Name	Description
1	Helm	Hand-operated use when adjusting the position of the drive box.
2	Arm function buttons	The drive box can be moved by pressing the buttons.
3	Touchscreen	Corresponding to four instrument drives, outputting commands, settings and displaying status
4	Clamping handle	Connecting the cannula to the drive box, and can also be used hand-operated when adjusting the position of the drive box
5	Fixing knob	Fixing the cannula to the clamping handle
6	Instrument drives	Includes four instrument drives with three instruments and one endoscope installed on top of the drives
7	Drive function buttons	Communicates the instrument drive identity and status and allows to insert and retract the instruments and endoscope.
8	Drive hold buttons	Allows to insert and retract the instruments and endoscope.

2.4 Vision Cart

The Vision Cart includes a Camera Control Unit and a Signal Distributor. Auxiliary surgical

equipment including the monitor, high frequency generator, suction irrigator and pneumoperitoneum apparatus can be also placed on the Vision Cart.

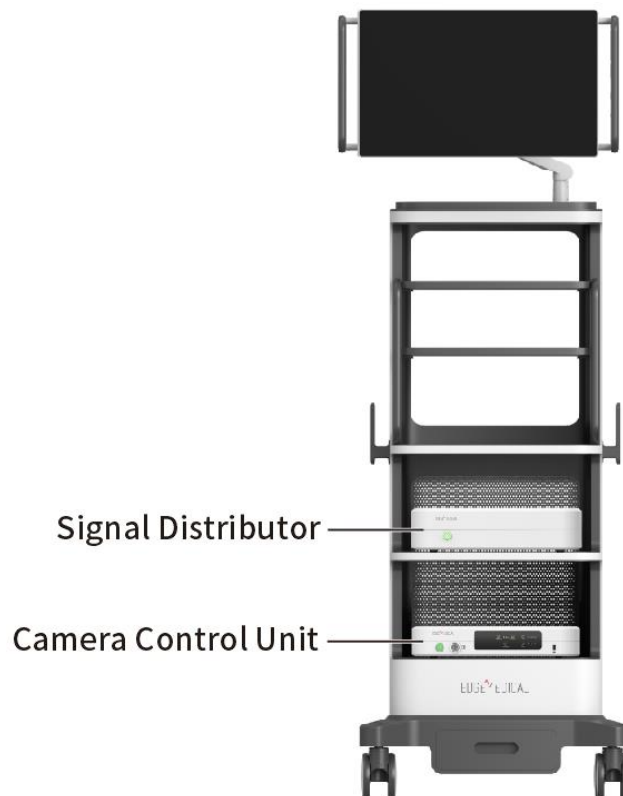


Figure 2.6 Vision Cart

- The Camera Control Unit is located outside the sterile field and operated by a non-sterile user. It is used to process image signals, and communicate with the Surgeon Console, the Patient Cart and auxiliary surgical equipment.



Figure 2.7 Camera Control Unit

- The Signal Distributor is the core electronics of the system. It provides connectors for the connections of the Surgeon Consoles, Patient Cart, Camera Control Unit and energy equipment, which are used for system communication, image processing and energy control.



Figure 2.8 Signal Distributor



Caution: Auxiliary surgical equipment need to be configured separately. The system should be used in conjunction with the equipment specified by the company. The use of unapproved or incompatible equipment may cause patient injury, equipment damage or performance degradation. If you have any questions about compatibility, please contact us.



Note: The monitor, when used with the system, shall be capable of connecting an SDI cable or connecting an SDI cable through a converter. The height, width and depth of the Vision Cart shall be able to accommodate the Camera Control Unit when used with this system.

3. Operating Room Configuration and System Positioning

3.1 Operating Room Configuration

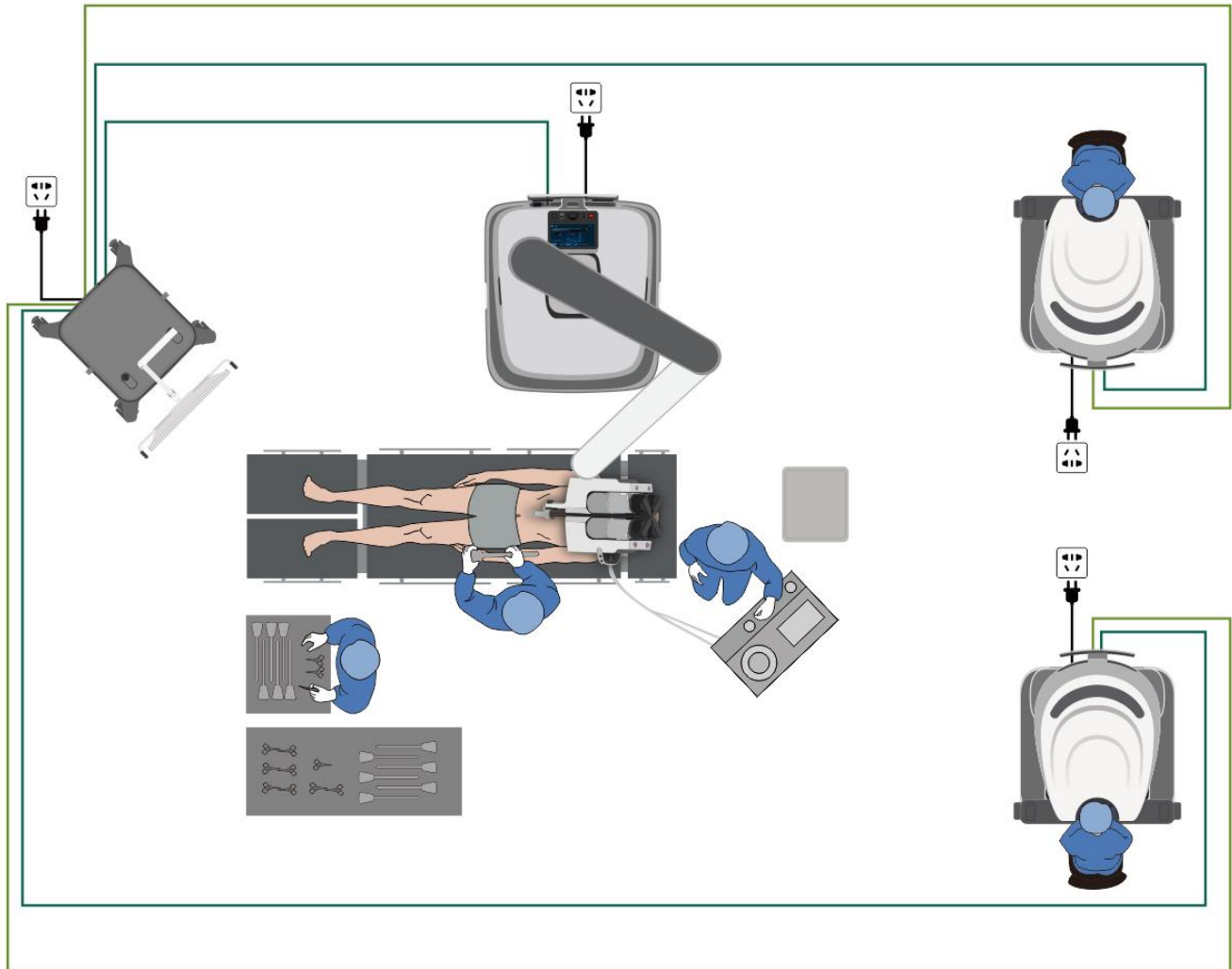


Figure 3.1 Example of Operating Room Configuration



Note: The figure above is a typical example of operating room configuration. For reference only, please refer to the actual situations.

3.1.1 Operating Room

- Operating rooms may vary in size and shape. Consider access to doors, outlets and overhead structures.
- Room restrictions may necessitate an alternate setup.
- Consider cables and power cords connections.

3.1.2 System Components

- Surgeon Console
 - Position in the non-sterile field.
 - Ensure that the surgeon can have direct line of sight to the operative field.
 - Ensure that the surgeon can communicate with the patient-side assistant.
- Patient Cart
 - Consider that there is sufficient room for instrument arm to be fully deployed for draping.
 - Consider the path to drive the cart.
 - Consider the position of the anesthesia to minimize its movement.
- Camera Control Unit
 - Consider monitor visibility. The operating room staff should have direct line of sight to the monitor to view messages.
 - Consider system connections.

3.2 Surgeon Console Positioning

The Surgeon Console is placed outside the sterile field. When possible, adjust the orientation of the Surgeon Console so that the surgeon has direct line of sight to the operative field and easily communicates with the patient-side assistant.

3.2.1 Pushing or Pulling

Push or pull the Surgeon Console from the lower columns on both sides of the armrest or the handle on the back for moving or positioning. Pay attention to the operating warning labels on the Surgeon Console when pushing or pulling. To avoid damage, do not directly push or pull the Surgeon Console by other means.



Note: Take care when moving heavy and large equipment. It is recommended to move the equipment after lowering it to the minimum height. Make sure to transport on a level floor, away from uneven floor, steps and steep slopes.

3.2.2 Brakes

The base of the Surgeon Console has four wheels, each of which has an independent brake. Before moving the console, make sure that the brakes are all released and the wheels can move freely. After confirming the positioning of the Surgeon Console, operate the brakes to

lock the wheels, and ensure positioning stability.

3.2.3 Footswitch Panel

Make sure to raise the footswitch panel before moving the Surgeon Console. Lifting controls are located on both sides of the footswitch panel to raise or lower the footswitch panel.

3.3 Patient Cart Positioning

The Patient Cart has a motorized drive that enables to transport the cart. The Patient Cart has three positioning states: for power off or standby, draping, and surgery. When moving the Patient Cart, especially getting into the sterile field for surgery, it is recommended that two people to move the Patient Cart. One pushes or pulls the cart by the helm on the back, while the other positioned in the front or on the side of the cart guides to ensure the cart do not collide with any obstacles.

The Patient Cart is equipped with detection sensor feature: After an endoscope or instrument is installed, the Patient Cart locks automatically and cannot be moved.

- For draping: Dedicate a space in the room where the Patient Cart can be draped before moving it into place for surgery. This is an area where it will facilitate the deployment of the instrument arm, and not easily contact non-sterile objects or impede traffic.
- For surgery: After the Patient Cart is draped, the patient is positioned and prepared, and the port is placed, drive the Patient Cart into the sterile field for instrument arm positioning and cannula connection.
- Unlock pedals: Unlocks and moves the Patient Cart in abnormal situations.
- Stabilization devices: To improve the stability of the base, the stabilization devices automatically deploy at the base of the cart when a port is docked.

Movement



Note: Take care when moving heavy and large equipment. It is recommended to move the equipment after lowering it to the minimum height. Make sure to transport on a level floor, away from uneven floor, steps and steep slopes.

For more information on the helm, see Figure 2.4 Helm. By holding the handlebars with hands and pressing the drive enable switches, the movement function of the motor drive can be activated. Pushing or pulling by hands implement the positioning of the Patient Cart. The motor drive adjusts its speed to how hard you push. Considering the safety in the operating room, the Patient Cart is limited to the maximum speed.

3.4 Vision Cart Positioning



Note: To avoid collision hazards, stow the monitor and close storage box before moving the Vision Cart.



Note: Unlock wheels manually before moving the cart, and lock wheels into place after confirming positioning.

The Vision Cart is positioned outside the sterile field. Follow the positioning guidelines:

- Ensure that the patient-side assistant should have direct line of sight to system components to view states and perform settings.
- Consider cable connections of the instruments, endoscope and other equipment.

4. System Connections



Note: The cables and cords for system connections are limited to those described in this chapter, which are provided by the company. Other cables should remain connected at all times and only be accessed by authorized personnel.



Note: The system can operate in single console mode or dual console mode. The peripherals need to be configured separately.

4.1 Power Connections

The power cords of the system are shown in the following table:

Table 4.1 List of Power Cords

Cable Name	Length	Requirement	System Component
Power Cord	5 m	600 VA continuous 5.0 A at 120 V~ 2.5 A at 240 V~	Surgeon Console
Power Cord	5 m	1000 VA continuous 8.4 A at 120 V~ 4.4 A at 230 V~	Patient Cart
Power Cord	1.8 m	100 VA continuous 0.8 A at 120 V~ 0.4 A at 240 V~	Camera Control Unit
Power Cord	1.8 m	100 VA continuous 0.8 A at 120 V~ 0.4 A at 240 V~	Signal Distributor

Connect the AC power cords to the wall outlets. To support continued use of the system in case of a site power failure, it is recommended to use wall outlets supported by backup power, and ensure that each wall outlet can meet the power requirements of system components.



Note: Before first use, connect the Patient Cart to a wall outlet for at least 5 to 6 hours to allow the UPS to fully charge.



Note: When using AC power, place the system components where it is easy to disconnect the power supply.



Caution: Any additional multiple socket outlets or extension cords shall not be connected to the system.



Caution: The system components should be connected to the dedicated power supply separately.



Caution: Do not connect the high frequency generator to the same AC power wall outlet as the pneumoperitoneum apparatus and additional equipment to avoid circuit overload.



Warning: When connecting the power supply, avoid the power cords getting wet. Otherwise, an electric shock may occur.



Warning: Avoid bending, pulling or kinking the power cords. Otherwise, an electric shock, equipment damage or fire may occur.

Power guidance

- It is normal for the cooling fan to run continuously when the Patient Cart or Vision Cart is connected to AC power.
- The Patient Cart should also be connected to AC power when not in use to ensure that the UPS remains fully charged at all times.

4.2 System Connections

The system cables are used to connect the Surgeon Consoles, Patient Cart, Camera Control Unit or Signal Distributor for master-slave control operation and image processing.

The camera cables are used to connect the Camera Control Unit and monitor, the Camera Control Unit and Surgeon Console for image processing.

The system cables and camera cables are shown in the following table:

Table 4.2 List of System Cables and Camera Cables

Cable Name	Length	Note
	10 m	

Cable Name	Length	Note
System Cable	30 m	Used to connect the Patient Cart and Signal Distributor, the Surgeon Console and Signal Distributor
	1 m	Connect the Camera Control Unit and the Signal Distributor
Camera Cable	10 m	Connect the Surgeon Console and the Camera Control Unit
	30 m	
Camera Cable	1 m	Connect the Camera Control Unit and the monitor
	3.5 m	

The system cable uses circular connectors and the camera cable uses BNC connectors.

The system cable is always connected to the Patient Cart, and the system cable and the camera cable are always connected to the Vision Cart. It is recommended to hang the cables on the cable hook at the bottom of the helm of the Patient Cart or at the back of the Surgeon Console.



Figure 4.1 System Cable



Figure 4.2 Camera Cable



Note: Once the system is connected and powered on, the system cables should not be removed before the system is completely powered down.



Caution: Care should be taken to avoid bending the cable, as kinks can damage the cable and may prevent system operation. The minimum safe bend radius is 1 inch (2.54 cm).

4.2.1 Cable Layout

The principle of cable layout should be out the path of operating room personnel and equipment, to avoid cable damage or operation interruption caused by trampling. The location of the cables should be convenient for draping before the procedure and movement during the procedure of the Patient Cart.



Note: If the cable layout cannot avoid the path of operating room personnel and equipment, it needs to be laid on the path, and provides appropriate protection for the cables.

4.2.2 Cable Connections

1. Inspect the cable connectors and the system receptacle for debris or bent pins.
2. Connect the system cables.

Align the red dot on the cable connector with the red dot on the matching receptacle, insert the connector, and turn the connector clockwise until it rotates to the limit.

3. Connect the camera cables.

Align the end of the BNC connector with the matching receptacle, insert the connector, and turn the connector clockwise until it rotates to the limit.



Note: When connecting the system cables, pay attention to the text indications near the ports.



Note: After the cables are connected, gently pull on the connector to check that the connection is in place.

4.3 Endoscope Connection

Remove the connector cover of the endoscope before use, and then attach the connector to the Camera Control Unit. The endoscope cable uses circular connectors. Connect the endoscope cable with the red dot on the connector pointed upwards and ensure alignment with the receptacle on the Camera Control Unit.



Figure 4.3 Connecting Endoscope Cable

After the cable is connected, confirm the real-time images and auxiliary UI information in the viewer of the Surgeon Console or on the monitor. If no real-time images, inspect whether the camera cables and the endoscope cable are connected correctly. If no auxiliary UI information, inspect whether the camera cables are connected correctly.



Note: Reattach the connector cover to the connector when the endoscope cable is not in use or before reprocessing the endoscope.



Note: The part of the connector under the cover is not sterile. Sterile users should not handle the end of the connector once the cover has been removed.



Caution: Handle the endoscope cable carefully. If bent sharply or kinked, especially at the connectors and handles on both sides of the cable, the cable can be damaged.

4.4 Electrosurgical Connection

The energy activation cable is used to connect the HF generator and the Camera Control Unit, or the HF generator and the Signal Distributor for controlling the operation of the HF generator's functions such as cutting and coagulation.



Figure 4.4 Energy Activation Cable

The compatible high frequency generator can be used with the system to provide high frequency current for the instruments to cut and/or coagulate tissue. Attach one connector of the energy activation cable to the corresponding receptacle on the high frequency generator, and the other connector to the energy port of the Camera Control Unit or the Signal Distributor.



Note: The system does not allow energy activation if two electrosurgical generators of the same energy type are connected to the system.



Note: Only compatible high frequency generators can be used with the system. The compatibility of unauthorized high frequency generators and cables cannot be guaranteed. Any damage to the system resulting from using incompatible high frequency generators and cables will not be covered under warranty.

5. Startup

5.1 System Startup

1. Ensure that the cables of the system are connected to each component.
2. Ensure that system components are connected to AC power and their power switches are in the ON position.
3. Press any individual **Power** button on the Surgeon Console, Patient Cart or Signal Distributor to power on the system.



Figure 5.1 **Power** Buttons (from Left to Right: Surgeon Console, Patient Cart, Signal Distributor)

5.2 Startup Sequence

During the startup sequence, the system performs an integrity test. The master controls of the Surgeon Console and the instrument drives of the Patient Cart will perform various movements during this integrity test. The startup sequence of the Surgeon Console and the Patient Cart starts at the same time but runs independently. After the system integrity test is successfully complete, the startup sequence ends.

5.2.1 Surgeon Console

The master controls will move to the initial position after a self-test is completed, and then the system can work.

During the startup sequence, if a fault is detected, the master control self-test will stop, depending on the type of fault. If the fault is recoverable, self-test can be continued to complete the startup sequence after the fault is eliminated.

Press the **Emergency Stop** button in case of emergency during startup if needed. At this time,

the master controls will lose power and stop moving, entering into a mechanical natural state. If the fault is eliminated, this state can be cleared on the touchscreen and the master controls can restore to normal automatically. If the system cables are connected, pressing the **Emergency Stop** button on the Surgeon Console will trigger the self-test stop of the Patient Cart at the same time. Similarly, after the fault is eliminated and the state is cleared, the Patient Cart resumes and starts the self-test.

5.2.2 Patient Cart

The power button LED indicator light of the Patient Cart illuminates solid white before the system is connected to AC power. Press the **Power** button to perform the startup sequence, and then the power button LED indicator light flashes white. After the startup sequence is completed, the power button LED indicator light illuminates solid green. After the instrument drives of the Patient Cart complete the self-test movements and the startup sequence ends, the corresponding drive function buttons illuminate solid blue.

- If the system detects mounted adaptors, instruments or cannula before startup, the instrument arm will not move during startup. This allows the system to stay connected to a patient safely during the startup sequence.
- Instruments should be removed when starting the system.
- During the startup sequence, if a fault is detected, the instrument arm self-test will stop totally or partially, depending on the type of fault. If the fault is recoverable, self-test can be continued to complete the startup sequence after the fault is eliminated.

5.3 Power Button LED Indicator

The power button LED indicators illuminate specific colors depending on the mode.

Table 5.1 Power Button LED Indicator

Indicator Status	Meaning
Off	Unpowered in any of the following situations: • Surgeon Console: The power cord is not connected to AC socket or the power switch is in the OFF position. • Patient Cart: ➤ The power cord is not connected to AC socket. ➤ The UPS exhaustion or the component is in EPO mode.

Indicator Status	Meaning
Solid green	Powered up
Flashing green	Shutdown confirmation
Flashing white	Powering up or down
Solid white	Standby (sleep) mode

5.4 Component Startup

If the Surgeon Console, Patient Cart, Signal Distributor or Camera Control Unit is connected to AC power, the components are in standby (sleep) mode before startup. The components can be powered on by pressing the **Power** buttons.

The Camera Control Unit can be started up independently by pressing the **Power** button. When the system cable is disconnected, the components can be powered on independently by pressing the **Power** buttons.

5.5 Emergency Power OFF

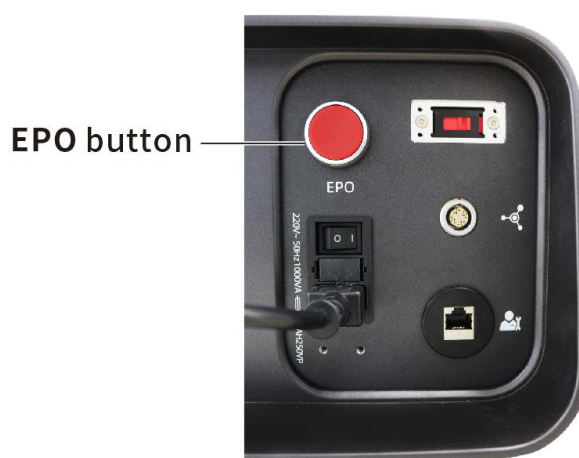


Figure 5.2 **EPO** Button

The **EPO** button is on the base back of the Patient Cart. Press this button to completely remove power to the Patient Cart. Emergency power off is a non-recoverable fault. The system must be restarted.

5.6 Power Switches

Each component of the Patient Cart, Surgeon Console, Camera Control Unit and Signal Distributor has a rear power switch, which must be in the ON position for the component to power on.

- Power on: Press the power switch and set it to the ON position (indicated by “|”)
- Power off: Press the power switch and set it to the OFF position (indicated by “○”)

The power switches of all components should be left in the ON position. Use these power switches in special circumstances only.

5.7 Power Guidelines

- The UPS of the Patient Cart should be adequately charged, at least 1 hour of AC power charge.
- Once the cables are connected, they must not be disconnected until the system has been completely powered down.
- After the Patient Cart or Vision Cart is connected to the power supply, the cooling fans running continually is part of normal operation.
- The Patient Cart should be connected to AC power when it is not in use, in order to ensure the UPS remains fully charged.
- To operate in dual console mode, the power operations of the second Surgeon Console is the same as the first Surgeon Console.

6. Shutdown and Storage

6.1 Preparation for Shutdown

1. Remove the instruments and endoscope from the Patient Cart.
2. Rotate the fixing knob on the drive box of the Patient Cart to unlock the cannula and remove the cannula from the clamping handle.
3. Use the function buttons on the drive box to move the instrument arm away from the patient.
4. Move the Patient Cart away from the operating table.
5. Remove the drapes from the system.
 - a. Remove the column drape.
 - b. Remove the drape of the instrument arm.
6. Dispose of the drapes into the designated location.
7. Remove the instruments and endoscope for cleaning and sterilization.
8. Clean the Patient Cart, Surgeon Console, Camera Control Unit, and Signal Distributor.
9. Retract the instrument arm and stow the Patient Cart.

6.2 System Shutdown

Press the **Power** button of the Patient Cart, Surgeon Console, or Signal Distributor. The power button LED indicator flashes green while the system confirms to perform the shutdown process.

- If there are no operations within 10 seconds, the power button LED indicator flashes white while the system begins the shutdown process. After system shutdown, the power button LED indicator illuminates solid white.
- Press the **Power** button again within 10 seconds to cancel shutdown. The power button LED indicator illuminates solid green.



Note: System power supply is required for stowing and moving the Patient Cart. Please power down the system after the movement is completed.



Note: If possible, it is recommended to keep system cables connected to minimize exposure to contaminants and cable damage.

6.3 System Storage

1. Hang the cables on the cable hook at the bottom of the Patient Cart helm, at the back of the Surgeon Console or on the side of the Vision Cart.
2. Store the system according to the requirements of environmental specifications.
 - Relative humidity: 5%~90% (non-condensing)
 - Temperature: -40°C~55°C
 - Atmospheric pressure: 700hPa~1060hPa
3. Place the Patient Cart near a wall outlet and connect it to AC power.

7. System Maintenance

7.1 Cleaning

Clean the Patient Cart, Surgeon Console, Camera Control Unit, and Signal Distributor at the frequency required by individual hospital protocol. Before cleaning, inspect the equipment for broken, cracked, chipped, or worn parts. Do not use the equipment and contact the company for technical support if there are signs of damage.

Perform cleaning as follows:

1. Power off the system and unplug to AC power.
2. Wear protective gloves.
3. Use a sterile, lint-free cloth moistened with a diluted mixture of neutral detergent and water, or 75% alcohol to wipe the exterior surfaces of the system components to be cleaned.
4. After cleaning, use a new sterile lint-free cloth to absorb an appropriate amount of sterile water to wipe the residual detergent solution until no obvious remains.
5. Wipe off the surfaces with a dry sterile lint-free cloth.
6. Dry and store the system components in a well-ventilated and cool place.



Warning: To avoid electric shock and potential risk of personal injury or even death, make sure to disconnect the power supply before cleaning.



Caution: Avoid the electronic equipment and observable metal parts of the system components to contact with liquids. If any liquid enters the system accidentally, contact the company for technical support in time.



Caution: Spilling or spraying liquids on or into the equipment or immersing the equipment in any liquid may result in damage and creates a risk of shock or fire.



Caution: Do not use abrasive cleaning tools, corrosive gases or liquids to clean the system components.



Note: After cleaning, visually inspect the external surfaces of the equipment for cleanliness. If visible soil remains, repeat cleaning until all visible soil is removed.

7.2 Preventive Maintenance

Preventive maintenance is necessary and should be performed at least every 2 years. System maintenance includes wear inspection of the moving parts, insulation inspection of the cables (such as monopolar energy instrument cord or bipolar energy instrument cord) and the endoscope, inspection of lifetime of the components, and safety inspection of the UPS, etc.

There are no user-serviceable parts on the main system components, with the exception of system accessories.

7.3 Technical Support

If the system requires maintenance or service, please contact the company. Refer to the user manual for company contact information.

7.4 Disposal

7.4.1 System Components

The system mainly consists of one or two Surgeon Consoles, a Patient Cart, a Signal Distributor and a Camera Control Unit. Do not use system components once they exceed the lifetime.

Recycling system components as electronic waste facilitates saving resources, and protecting the environment and human health.

When disposing of system components, follow all applicable national and local laws and guidelines.

7.4.2 UPS

The Patient Cart contains a UPS. If the UPS exceeds its lifetime, or any crack, leakage, rust and bulge occurs, stop using it immediately. Accidentally contacting with the electrolyte may cause chemical burns to skin. Contact the company to replace the UPS.

The Patient Cart and its UPS must be recycled separately to prevent environmental pollution.

When disposing of the UPS, follow all applicable national and local laws and guidelines.

Appendix A System Specifications

A.1 Essential Performance

The essential performance for the system is defined as follows:

- The system displays a real-time image of the surgical site.
- Except when clutched and under the control of the patient-side assistant, the instrument tip, shaft, and arm moves only in response to motions of the master control initiated by the operating surgeon. The motions of the instrument tip are approximately proportional to the surgeon-initiated motions of the master control and are approximately in the same direction relative to the endoscope/viewer frames of reference. There should be no uncontrolled or unexpected motions of the instrument tip.
- The motion will stop upon user input by pressing one of the **Emergency Stop** buttons or when real-time system monitoring detects a potential problem that necessitates stopping all motion of the system or subsystem. Error messages will display to alert the user.
- Emergency stop distance ≤ 5 mm
- Master-slave distance accuracy ≤ 6 mm
- Instrument angle deviation $\leq 5^\circ$
- Image delay time ≤ 50 ms

Appendix B Electromagnetic Compatibility

The system was tested according to the recommendations of Technical Report IEC TR 60601-4-2: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

Note:

- The customer or the user should use the system in the electromagnetic environment as specified in Tables B.1, B.2, B.3, and B.4, otherwise the system may not work properly.
- Portable and mobile RF communications equipment may affect the use of the system, so the system should be used in the recommended electromagnetic environment.
- The system is suitable for professional healthcare facility environment (such as hospital).
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). this equipment 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 equipment.

Warning:

- Due to the intended purpose in the electromagnetic environment, the system is Class A equipment. The system cannot provide sufficient protection for radio communications when the equipment is operated in a residential area.
- Except the accessories and cables provided by the company (see the table below for details), the use of unspecified accessories and cables can lead to an increase in radiated emissions or a decrease in immunity of the system.
- The system should not be used adjacent to or stacked with other equipment. However, if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it is used.
- Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- 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 equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The system is not life-supporting equipment of CISPR 11 Group 1 Class A.

Table B.1 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Guidance and Manufacturer's Declaration - Electromagnetic Emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class A
Harmonic emissions IEC 61000-3-2	Not Applicable
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable

Table B.2 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle	0 % UT; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % UT; 1 cycle and 70 % UT; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz/60 Hz	30 A/m 50 Hz/60 Hz
Conducted RF IEC61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
NOTE: UT is the AC mains voltage prior to application of the test level.		

Table B.3 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC 60601-1-2 Test Level (V/m)	Compliance Level (V/m)
	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430 – 470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	28	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	870					
	930					
	1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5100 –	WLAN 802.11	Pulse modulation	9	9
	5500					

Guidance and Manufacturer's Declaration - Electromagnetic Immunity						
	5785	5800	a/n	217 Hz		

Table B.4 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity				
	Test Frequency	Modulation	IEC 60601-1-2 Test Level (A/m)	Compliance Level (A/m)
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	30 kHz	CW	8	Not applicable
	134.2 kHz	Pulse modulation 2.1 kHz	65	65
	13.56 MHz	Pulse modulation 50 kHz	7.5	7.5



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