EDGE MEDICAL

SP1000

Endoscopic Instrument Control System

User Manual

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Prescription Information

Rx Only

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- Assembly operation, extensions readjustment, improvement and maintenance are carried out by professionals approved by the company.
- 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: 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, a Patient Cart, a Vision System, endoscopic instruments and accessories.

The Vision System includes a Vision Cart, a Camera Control Unit, a Signal Distributor and an endoscope.

The endoscopic instruments include Maryland bipolar forceps, fenestrated bipolar forceps, needle driver, large needle driver, monopolar curved scissors, monopolar hook, medium-large clip applier, Cadiere forceps, tip-up fenestrated grasper, round tooth retractor and curved needle driver.

The accessories include cannulas, obturators, cannula seals, tip cover accessories, installation tools, disposable drapes, cables, and sterilization trays.

See Appendix C List of System Components for more information.

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 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.

1.5 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.

As single-port surgical robots can be operated through a single multichannel port in laparoscopic surgery, which can also reduce complication rate, decrease intraoperative blood loss and increase surgical success rate, leading clinical benefits to patients. 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.

1.6 Clinical Risks

The main risks to patients associated with the use of system primarily include communication issues, master-slave control errors and image/video problems, resulting in injury to tissues and organs and conversion to other surgical techniques which could result in increased complications complications.

Therefore, to evaluate the clinical safety, complication rate can be used as safety evaluating outcome parameter for the device under evaluation.

1.7 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.

1.7.1 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.

1.7.2 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 robotic arm should be kept at a safe distance of one fist from the patient to avoid excessive pressure on the patient by the robotic 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 overheat 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 carefully 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 manuals 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: 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.

1.7.1 Endoscopic Procedure Precautions

Warning: When using the system with insufflation, only CO_2 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℃). 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.

1.7.2 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 no 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 System, 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.

1.7.3 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.

1.7.4 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.

1.7.5 Transportation and Storage Precautions

Caution: The system components (Surgeon Console, Patient Cart and Vision System) 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.

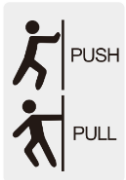
Caution: Handle the instruments and endoscope with care. Avoid mechanical shock or stress that can cause damage to the instruments and endoscope.

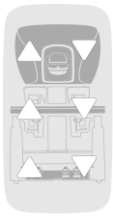
Caution: Do not place endoscope cables or accessory cables over the instrument arm of the Patient Cart. The cables may limit the range of motion of the arm, or become pinched or damaged.

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

1.8 Symbol Reference Tables

1.8.1 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

Symbol	Meaning	Symbol	Meaning
	Do not walk or stand here		Do not push or pull here
	Standby		Emergency stop
	Ergonomic control buttons		Protective earth (ground)
	Maximum load	/	/

1.8.2 Patient Cart

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

Symbol	Meaning	Symbol	Meaning
	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	/	/

1.8.3 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

Symbol	Meaning	Symbol	Meaning
	Type BF applied part		Energy control port
	Protective earth (ground)		MV (Master-Video) communication port

1.8.4 Signal Distributor

Symbol	Meaning	Symbol	Meaning
	“ON” (power)		“OFF” (power)
	Alternating current		Fuse
	Debugging		Protective earth (ground)
	MS (Master-Slave) communication port		MV (Master-Video) communication port
	Standby		Energy control port

1.8.5 Endoscopes

Symbol	Meaning	Symbol	Meaning
	Type BF applied part		Take photo
	Illumination		Left-Right eye swap
	Flush port		MR unsafe
IPX7	Protection against the effects of temporary submersion in water	/	/

1.8.6 Endoscopic Instruments

Symbol	Meaning	Symbol	Meaning
	Type CF applied part		Direction indicator for emergency grip release
	Flush port 1		Flush port 2
	Dangerous voltage	/	/

1.8.7 Accessories

Symbol	Meaning	Symbol	Meaning
	Direction indicator for alignment		Endoscope port indicator
	Hand symbol		Tear-away tab
	Direction tab	/	/

1.8.8 Package Labeling and Other Symbols

Symbol	Meaning	Symbol	Meaning
	This way up		Fragile, handle with care
	Keep dry		Keep away from sunlight
	Stacking limit by number		Temperature limit
	Do not stack		Do not roll
	Humidity limitation		Atmospheric pressure limitation

Symbol	Meaning	Symbol	Meaning
CE 0123	CE mark	Rx only	Federal (USA) law restricts this device to sale by or on the order of a physician
	Refer to instruction manual		Consult instructions for use
MD	Medical device	EU REP	European authorized representative
	Manufacturer		Date of manufacture
	Dispose of in accordance with local regulations—particularly applies to electronic components		Use-by date
	Do not use if package is damaged and consult instructions for use		Do not re-use
	Do not re-sterilize	STERILE EO	Sterilized using ethylene oxide
	Caution	SN	Serial number
LOT	Lot number		Single sterile barrier system with protective packaging inside

1.9 Lifetime

The system has a design lifetime 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.

See Appendix C List of System Components for more information.

1.10 Date of Manufacture

See product label for date of manufacture.

1.11 Combination Use

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

Product Name		Model
Manufactured by Edge Medical		
Surgeon Console		MP1101
Patient Cart		SP1102
Signal Distributor		MP1204
Camera Control Unit		MP1202
Endoscope		SP1207
Vision Cart		CM2101
System Cable		CM1801, CM1802, CM1804,
Camera Cable		CM1806, CM1836, CM1821, CM1805
Energy Activation Cable		CM1807
Disposable Drape		DR1004, DR1006
Sterilization Tray		CM-SFI2, SP1806
Endoscopic instruments and accessories	Maryland Bipolar Forceps	SP1304, SP3-BM
	Fenestrated Bipolar Forceps	SP1303, SP3-BF
	Needle Driver	SP1305, SP3-ND
	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
	Installation Tool	MP1801, SP1802
	Monopolar Energy Instrument Cord	MS1801
	Bipolar Energy Instrument Cord	MS1802

Product Name		Model
Puncture Kits	Cannula	SP1406, TR1-SP
	Obturator	SP1502, TR2-SP
	Cannula Seal	SP0801, TR3-SP
Manufactured by ERBE		
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 System (includes a Vision Cart, a Camera Control Unit, a Signal Distributor and an endoscope), endoscopic instruments 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).

For the specifications of the system, please refer to Appendix A System Specifications.

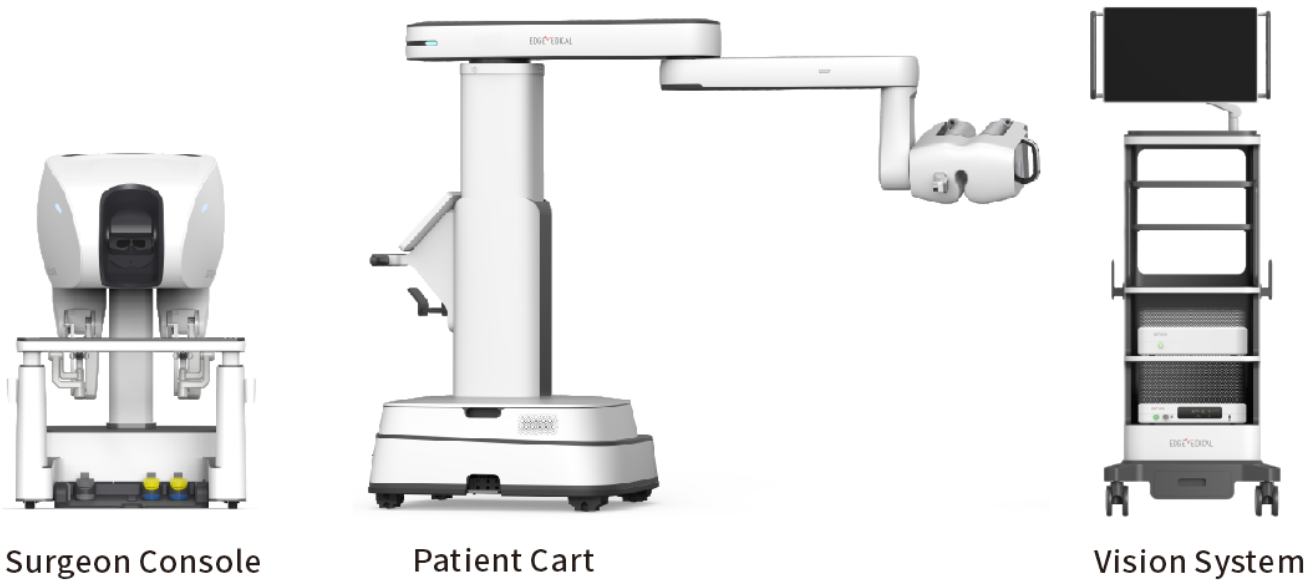


Figure 2.1 Main Components of the System

2.2 Surgeon Console

The Surgeon Console (model MP1101) 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.

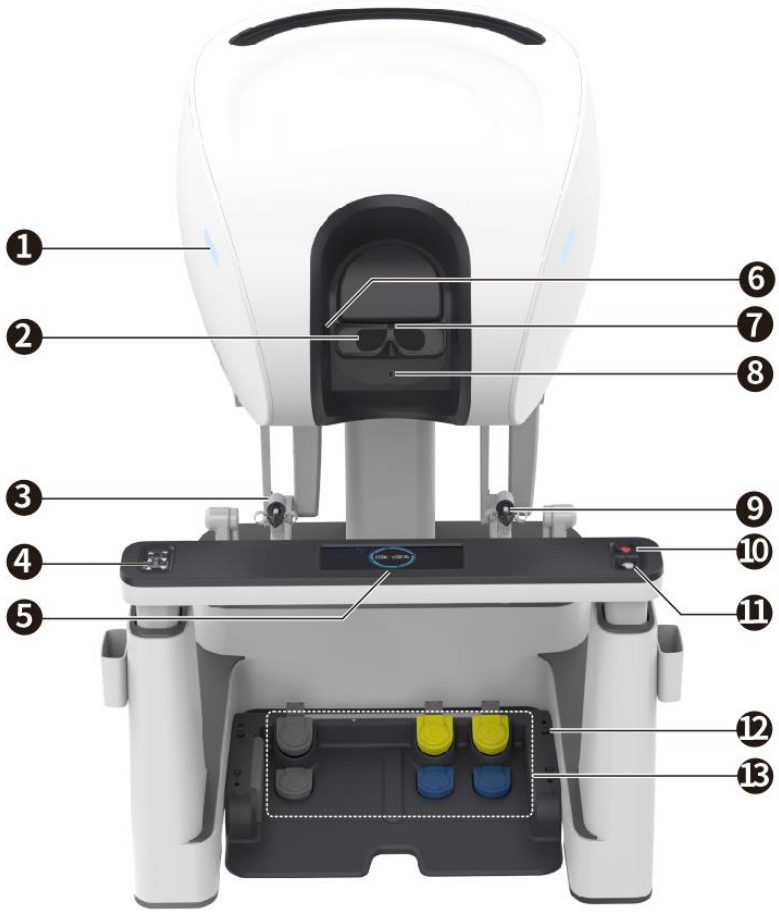
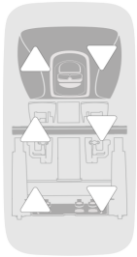


Figure 2.2 Front View of Surgeon Console

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.

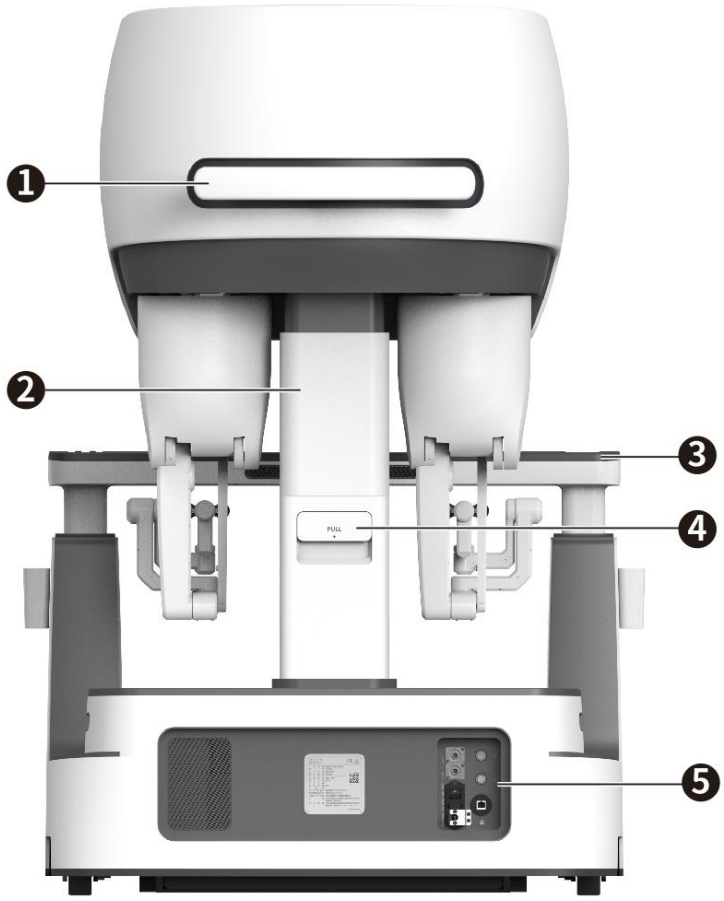


Figure 2.3 Rear View of Surgeon Console

No.	Name	Description
1	Handle	Used for holding the equipment when moving or transporting it.
2	Column	Adjusts the height of the Surgeon Console.
3	Armrest	Contains a touchscreen, **Ergonomic Control**, **Power**, and **Emergency Stop** buttons.
4	Cable hook	Used for cable management. It is necessary to pull out the cable hook for use.
5	Port panel	Ports for the Surgeon Console, including power inlet, SDI ports, and communication ports.

2.3 Patient Cart

The Patient Cart (model SP1102) 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.

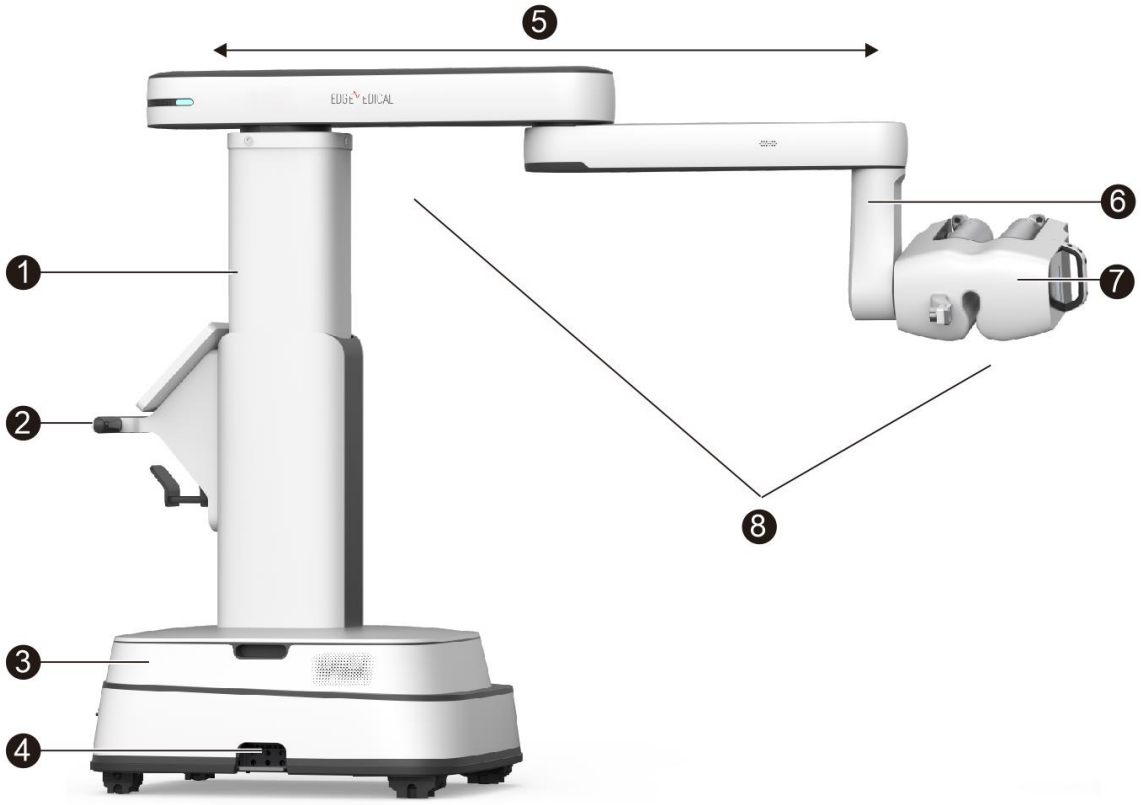


Figure 2.4 Patient Cart

No.	Name	Description
1	Column	Moves the boom up or down.
2	Helm	Used for moving the Patient Cart. Refer to Figure 2.5 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.

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



Figure 2.5 Helm

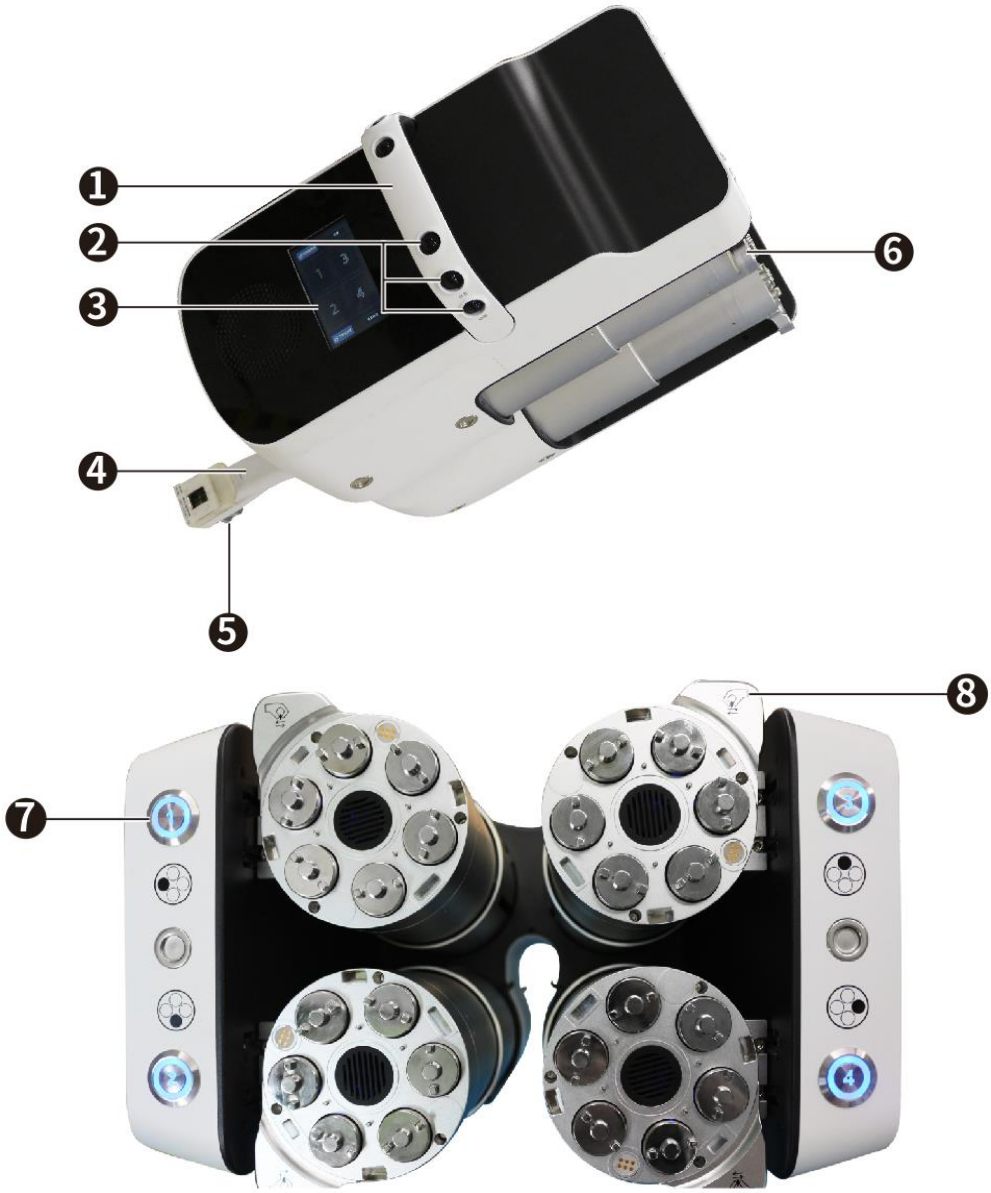


Figure 2.6 Drive box

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. See 9.1.4 Positioning Controls for details.
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.

No.	Name	Description
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 System

The Vision System includes a Vision Cart, a Camera Control Unit, a Signal Distributor and an endoscope. Auxiliary surgical equipment including the monitor, high frequency generator, suction irrigator and pneumoperitoneum apparatus can be also placed on the Vision Cart.

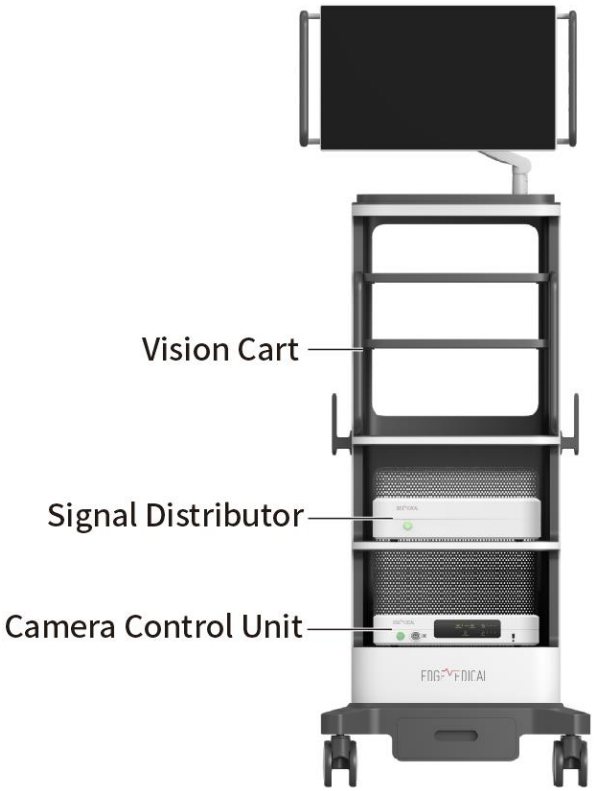


Figure 2.7 Vision System

- The Vision Cart (model CM2101) is a mobile transport cart designed for medical devices and accessories. The cart is located outside the sterile field on either side of anesthesia

or the Patient Cart and operated by a non-sterile user. The cart enables users to clearly visualize the overall process of the surgery.

- The Camera Control Unit (model MP1202) 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 2.8 Camera Control Unit

- The Signal Distributor (model MP1204) 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 2.9 Signal Distributor

- The endoscope (model SP1207) provides high resolution 3D HD (high definition) lens, which can magnify the surgical field and display 3D stereo HD images inside the patient's body.

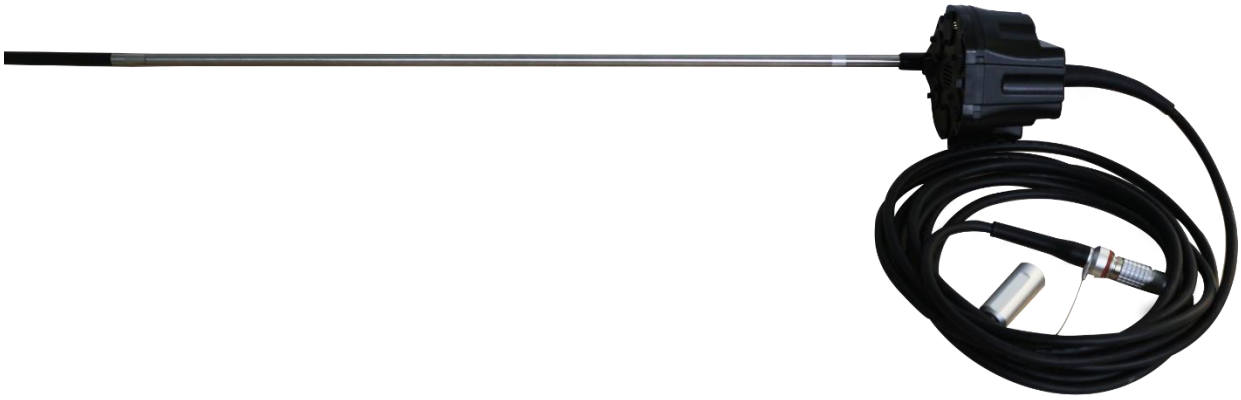


Figure 2.10 Endoscope

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 of the system can be connected to SDI cables or SDI converters.

2.5 Endoscopic Instruments

The endoscopic instruments include Maryland bipolar forceps, fenestrated bipolar forceps, needle driver, large needle driver, monopolar curved scissors, monopolar hook, medium-large clip applier, Cadiere forceps, tip-up fenestrated grasper, round tooth retractor and curved needle driver.

The endoscopic instruments have an articulating design at their distal tips that mimics the human wrist. Each instrument is used to perform a specific surgical task such as grasping, suturing, or tissue manipulation. The instruments enable the surgeon to operate precisely in a minimally invasive surgery.

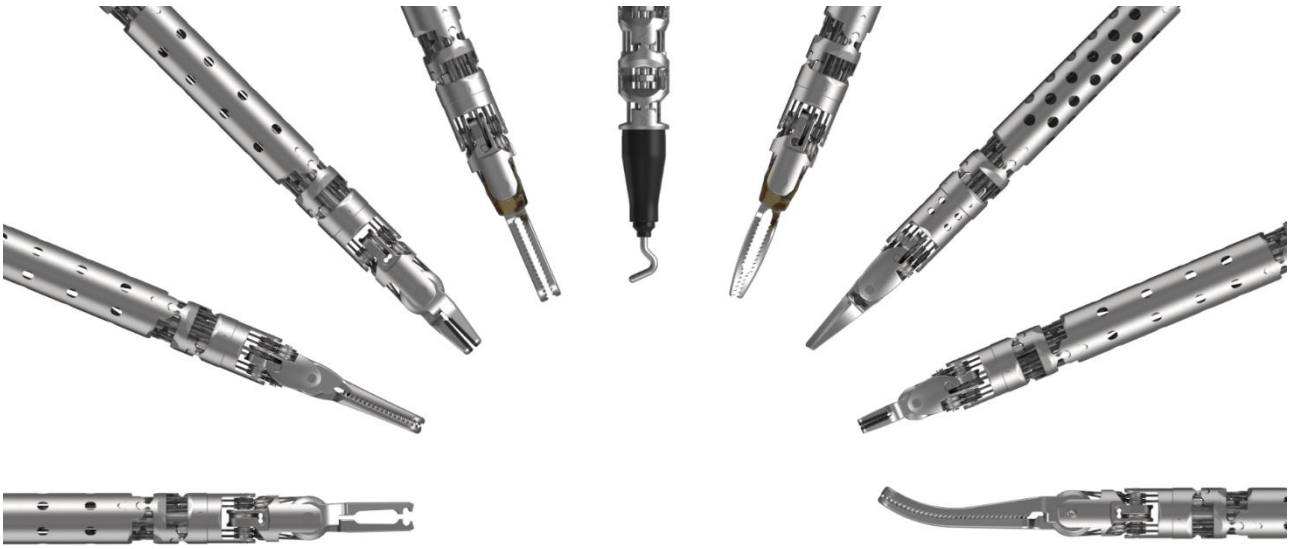


Figure 2.11 Endoscopic Instruments

2.6 Accessories

2.6.1 Tip Cover Accessories

The tip cover accessory (model SP1306/SP4-S/SP1307/SP4-I/SP1403) is specially designed to cover the endoscopic instruments or endoscope and must be installed on the endoscopic instruments or endoscope prior to surgical use. The tip cover accessory is sterilized with verified ethylene oxide (EO) method and parameters. It is supplied sterile and is for single-use only. Do not reuse the tip cover accessory. Always install the tip cover accessory in the sterile

field.



Figure 2.12 Tip Cover Accessories

2.6.2 Installation Tools

The installation tool (model MP1801/SP1802) is used to facilitate installation and removal of tip cover accessories.

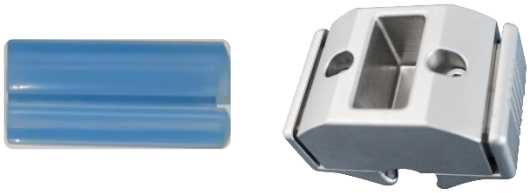


Figure 2.13 Installation Tools

2.6.3 Puncture Kits

The puncture kits for SP1000 System include cannulas, obturators and cannula seals.

The cannulas, obturators and cannula seals are intended to be used to establish a port of entry for instruments and endoscope. The obturator attaches to the cannula seal, which attaches to the cannula and facilitates the cannula into the body cavity.

Cannulas

The cannula (model SP1406/TR1-SP) is a stainless steel component consisting of an insufflation lever, insufflation port and lumen. The lumen provides a single port of entry into the body cavity for instruments and endoscope. The insufflation port is used to allow insufflating through the cannula. The insufflation lever on the port can be opened or closed to control air flow. When the lever is straight and in line with the port, the lever is in open position. When the lever is perpendicular with the port, the lever is in closed position.

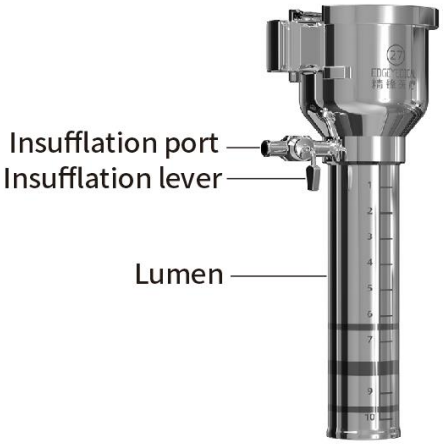


Figure 2.14 Cannula

Obturators

The obturator (model SP1502/TR2-SP) is a cylinder used when inserting the cannula into the patient to avoid coring or tearing of the body wall upon insertion. It should be removed before inserting an instrument or an endoscope through the cannula.



Figure 2.15 Obturator

Cannula Seals

The cannula seal (model SP0801/TR3-SP) is sterile, single-use and disposable and guides instrument and endoscope shafts through the cannula and allows rotation of the instrument drives relative to the cannula. It is used to maintain insufflation before inserting an instrument or an endoscope or during endoscopic surgery. It consists of two 10 mm ports (compatible with endoscopic instruments or endoscope) and two 9 mm ports (compatible with endoscopic instruments).

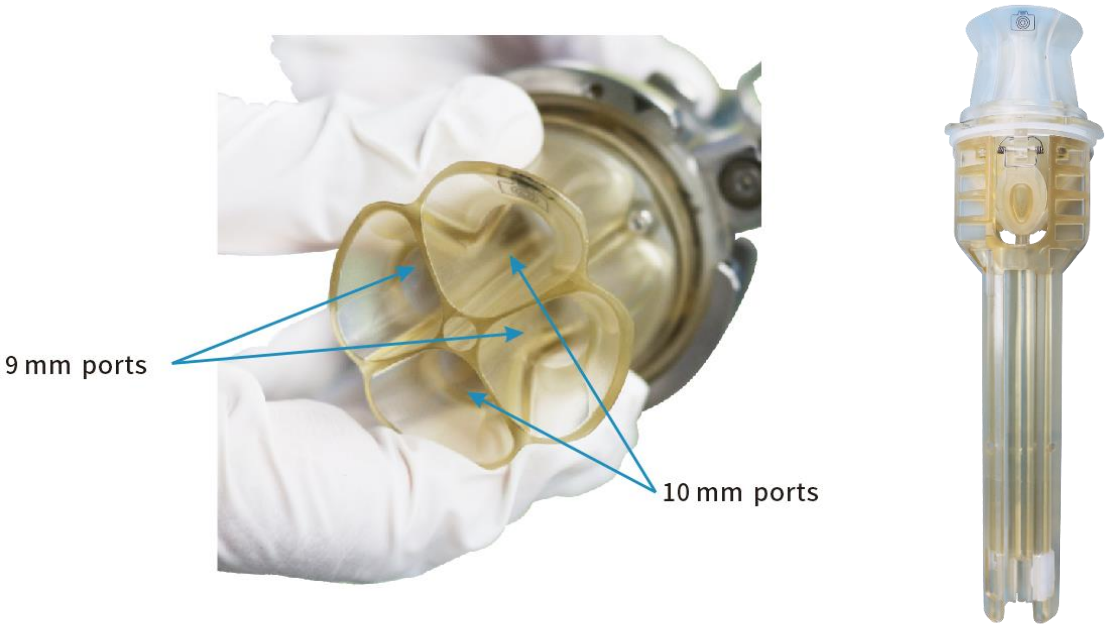


Figure 2.16 Cannula Seal

2.6.4 Cables

- The monopolar energy instrument cord (model MS1801) and bipolar energy instrument cord (model MS1802) are used to connect the corresponding surgical instrument and the high frequency generator.



Monopolar Energy Instrument Cord Bipolar Energy Instrument Cord

Figure 2.17 Energy Instrument Cords

- The system cable of 10 m (model CM1801)/30 m (model CM1802) is used to connect the Patient Cart and Signal Distributor, the Surgeon Console and Signal Distributor. The system cable of 1 m (model CM1804) is used to connect the Camera Control Unit and Signal Distributor.



Figure 2.18 System Cable

- The camera cables of 1 m (model CM1806) and 3.5 m (model CM1836) are used to connect the Camera Control Unit and monitor. The camera cables of 10 m (model CM1821) and 30 m (model CM1805) are used to connect the Surgeon Console and Camera Control Unit.



Figure 2.19 Camera Cable

- The energy activation cable (model CM1807) 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 2.20 Energy Activation Cables

2.6.5 Disposable Drapes

The disposable drape is constructed of a polymer film material that should be impervious and

fluid-resistant to prevent strike-through contamination from microorganisms. It isolates the surgical site from the other areas of the patient's body and non-sterile areas of the OR table in order to contribute to reducing the risk of surgical site infection.

It is for single use only and comes in a sterile package. Ensure that the packaging has no tears that could lead to contamination.

The disposable drape (model DR1004) is used for the instrument arm of the Patient Cart and the disposable drape (model DR1006) is used for the column of the Patient Cart.

2.6.6 Sterilization Trays

The sterilization tray is used to encase and hold medical devices during the sterilization process and subsequent storage and transportation.

The tray does not have direct patient contact. The tray by itself does not maintain sterility. The tray has a rectangular base with a lockable lid. The tray has perforations to allow sterilant penetration. The tray contains instrument holders to hold, organize and protect medical devices within the tray during the sterilization process and subsequent storage and transportation.

The sterilization tray (model SP1806) is used for endoscopes and the sterilization tray (model CM-SFI2) is used for instruments and accessories.

3. Operating Room Configuration and System Positioning

3.1 Operating Room Configuration

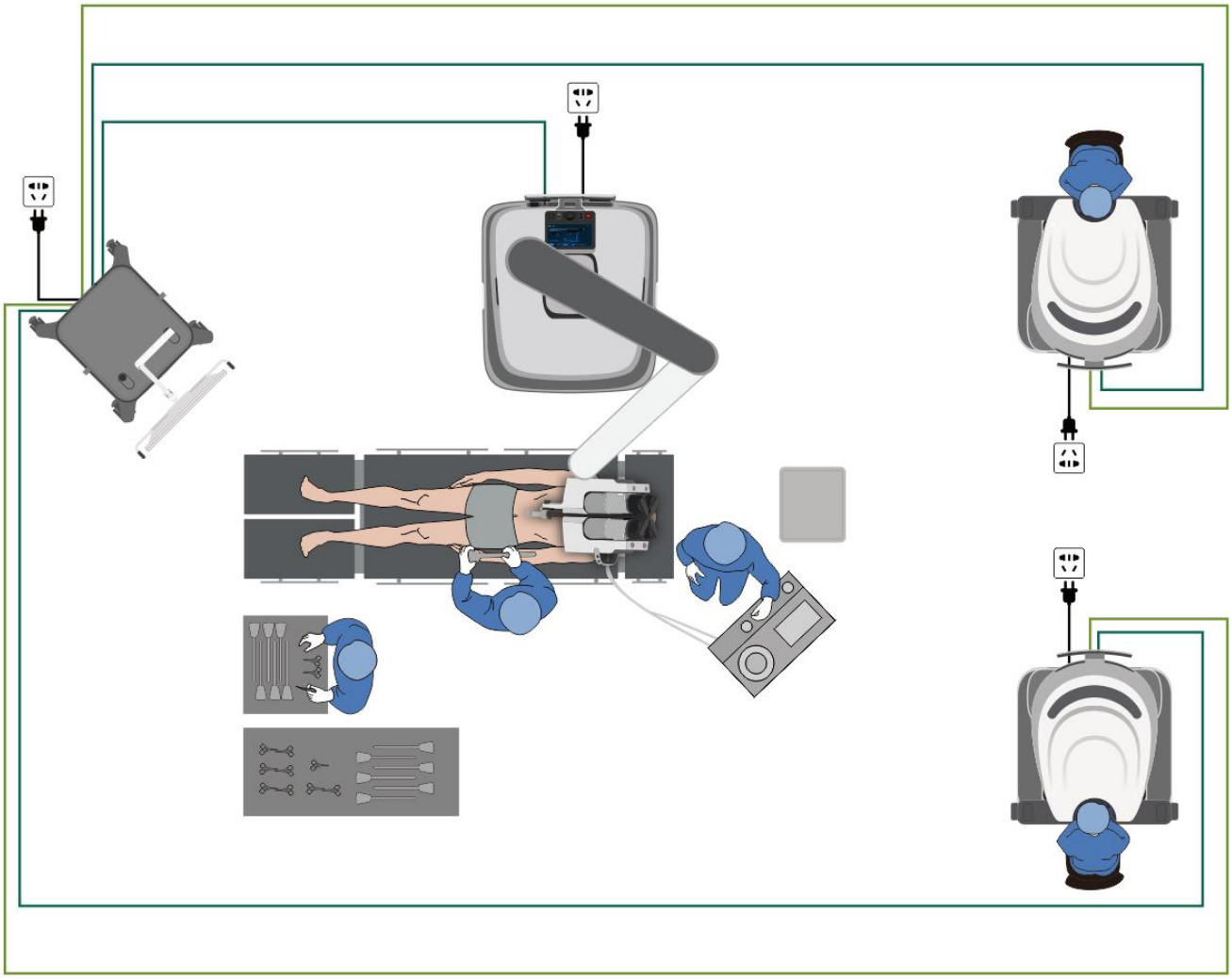


Figure 3.1 Example of Operating Room Configuration

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 rear wheel is equipped with 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 2.5 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 System Positioning

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

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

The Vision System 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

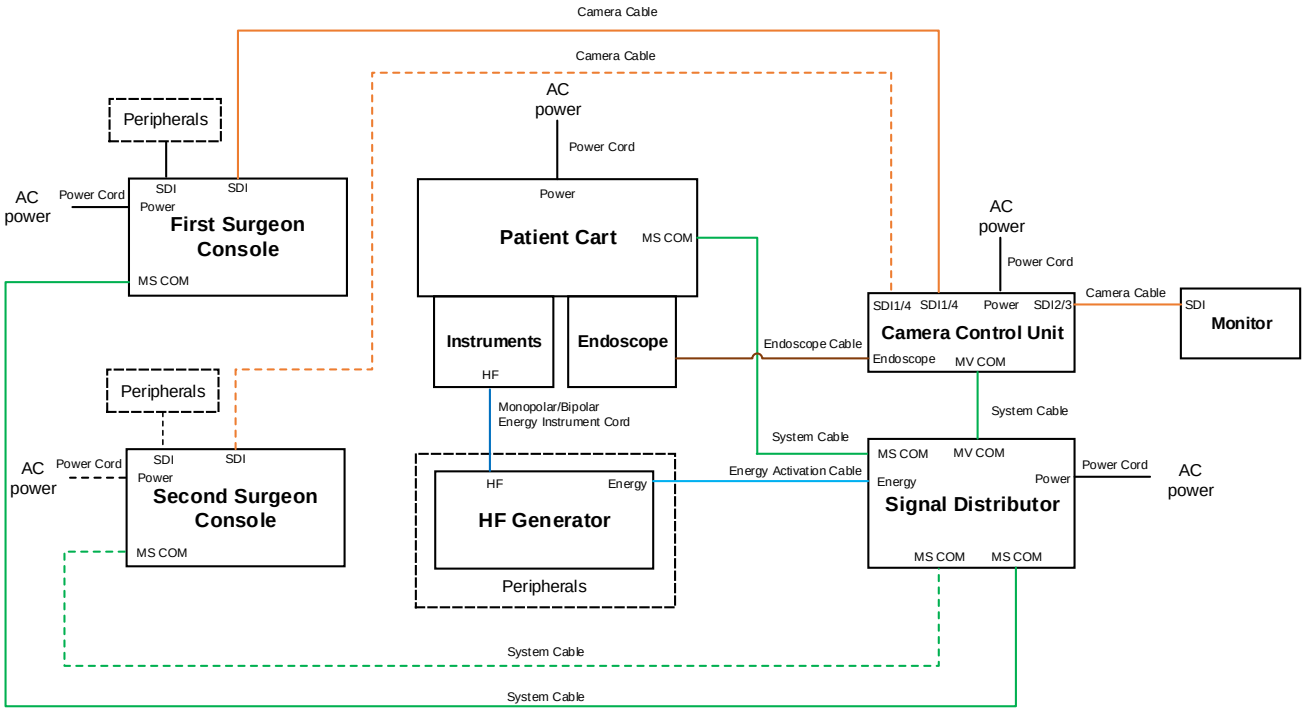


Figure 4.1 System Connections (Dual Console)

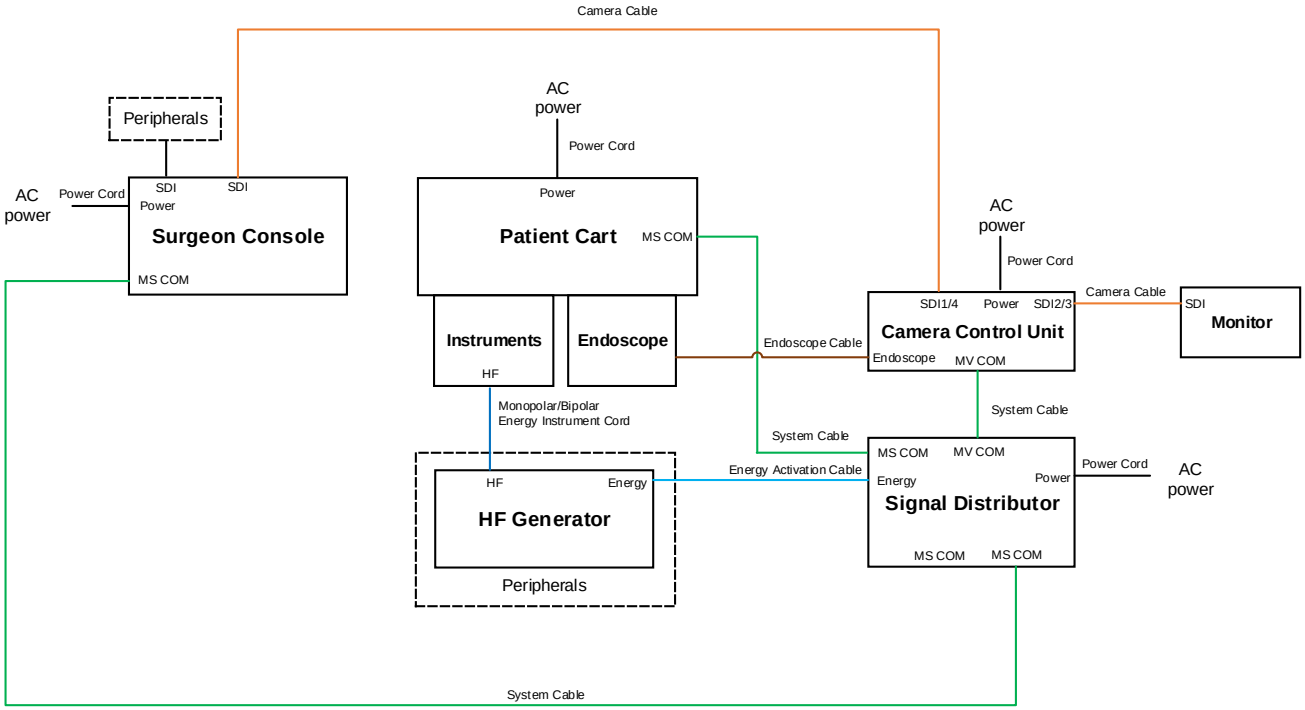


Figure 4.2 System Connections (Single Console)

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 System 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
System Cable	10 m, CM1801	Connect the Patient Cart and Signal Distributor, the Surgeon Console and Signal Distributor
	30 m, CM1802	
	1 m, CM1804	Connect the Camera Control Unit and the Signal Distributor

Cable Name	Length	Note
Camera Cable	10 m, CM1821	Connect the Surgeon Console and the Camera Control Unit
	30 m, CM1805	
Camera Cable	1 m, CM1806	Connect the Camera Control Unit and the monitor
	3.5 m, CM1836	

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 System. 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.

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 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.

4.5 Network Connections

SP1000 Endoscopic Instrument Control System is designed to have no access to the internet.

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. For more information about fault types and troubleshooting, see 13 System Troubleshooting.

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. For more information about fault types and troubleshooting, see 13 System Troubleshooting.

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.

Indicator Status	Meaning
	➢ The UPS exhaustion or the component is in EPO mode.
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

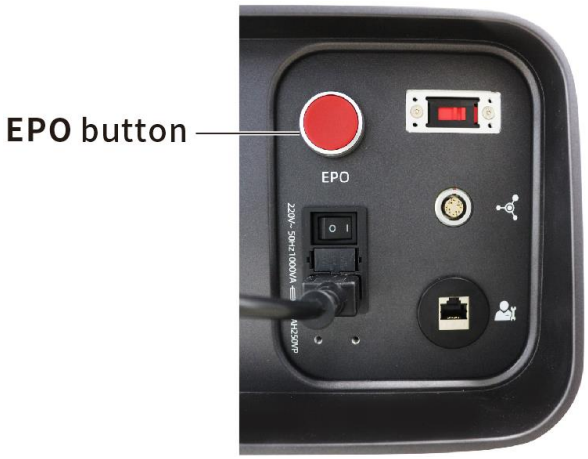


Figure 5.2 **EPO** Button

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. See 13.2.2 Non-Recoverable Faults.

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; such as those described in 13.6 System Power Problems.

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 System 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. Draping

6.1 Draping Overview

The drapes are constructed of polymer film materials and other parts for fixing and marking. The drapes should be impervious and fluid-resistant to prevent strike-through contamination from microorganisms. It isolates the surgical site from the other areas of the patient's body and non-sterile areas of the OR table in order to contribute to reducing the risk of surgical site infection.

6.2 Draping Supplies

The drapes are for single use only and come in a sterile package. Ensure that the packaging has no tears that could lead to contamination of the drapes.

Before beginning a procedure, ensure that there is at least one backup of each drape to account for inadvertent contamination while setting up the system.

- 1 disposable drape for the instrument arm (model DR1004): Includes the sterile adaptor, metal discs, the cannula adaptor and the Velcro
- 1 disposable drape for the column (model DR1006): Includes the metal discs and the Velcro

6.3 Draping Guidelines

- The Patient Cart should be positioned to ensure there is enough space to drape the system outside of the sterile field.
- For speed, sterility and safety, draping should be done by a two-person team:
  - A sterile person (scrub nurse or surgical assistant) who can work within the sterile surgical field
  - A non-sterile person (circulating nurse) who can handle non-sterile components
- Drape the instrument arm by following the draping guidance. For detailed steps, see 9.1.2 Touchscreen of Helm.

6.4 Deploy for Draping

During the deploy step, the system deploys the boom and adjusts the instrument arm to prepare for draping. Additionally, the column raises to avoid contamination of the drapes in the sterile field.

There are two ways to deploy for draping: automated and manual.

- Automated deploy for draping

  The circulating nurse pushes down the **Boom Position Control** button on the Patient Cart helm. The system will automatically deploy the boom and adjust the instrument arm to prepare the Patient Cart for the draping position. Hold and push the button down until the instrument arm stops moving and the system emits a completion tone.

- Manual deploy for draping

  The circulating nurse presses and holds **Enable Boom Controls** on the Patient Cart touchscreen to position the Patient Cart manually. Use the boom control buttons on the Patient Cart helm to raise and deploy the boom and extend the instrument arm outward for enough space to avoid contamination of the arm and column during draping. Ensure that the instrument drives are rotated and retracted to the draping position by using the function buttons on the drive box helm.



Figure 6.1 Deploy for Draping

6.5 Drape Installation

6.5.1 Draping Column

Note: If a non-sterile person is assisting in installation of the drape, he/she must not grasp the labeled sterile area of the drape.

Note: A sterile person must not touch the non-sterile area when operating.

1. The circulating nurse opens the paper-plastic package and delivers it to the scrub nurse.



2. The scrub nurse does the following:

   a. Take out the drape from the paper-plastic package and unfold the drape on a sterile table, with the tab “This Side Up” facing the ceiling.



   b. Place two hands inside the drape cuffs on both sides of the drape identified by the hand icons, pick up the drape and move towards the column, being careful to prevent cross-contamination.



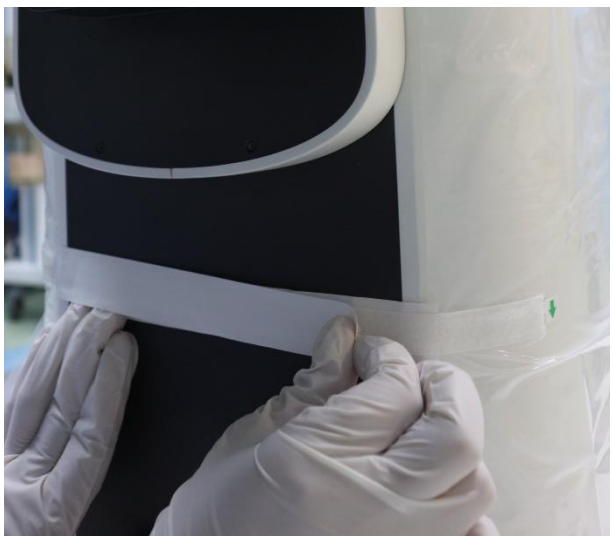
   c. Attach three metal discs on the drape to the magnetic sockets at the top of the column.



d. Snap the tear-away tabs identified by arrow icons, and unroll the remainder of the drape.



3. The circulating nurse fastens the end of the dividing strip to the Velcro at the back of the drape, being careful that the arrow indicates above the helm and the arrow indicates below the helm.



4. The scrub nurse adjusts the drape around the column as needed.

6.5.2 Draping Instrument Arm

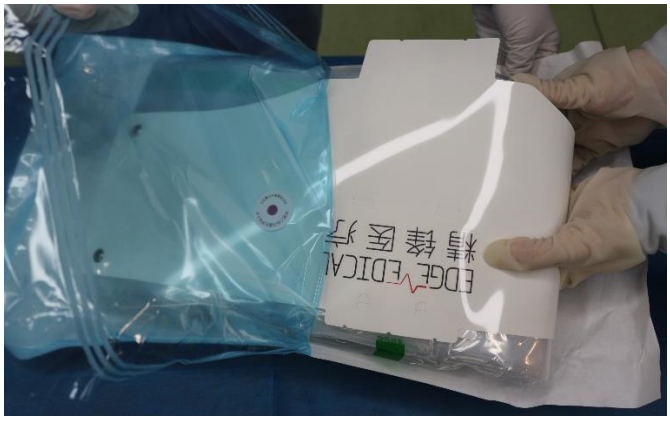
Note: If a non-sterile person is assisting in installation of the drape, he/she must not grasp the labeled sterile area of the drape.

Note: A sterile person must not touch the non-sterile area when operating.

Note: When draping the instrument arm, ensure that there is no excess drape material either between the adaptor and the instrument drive that can block the connection.

Circulating Nurse:

The circulating nurse opens the paper-plastic package and delivers it to the scrub nurse.



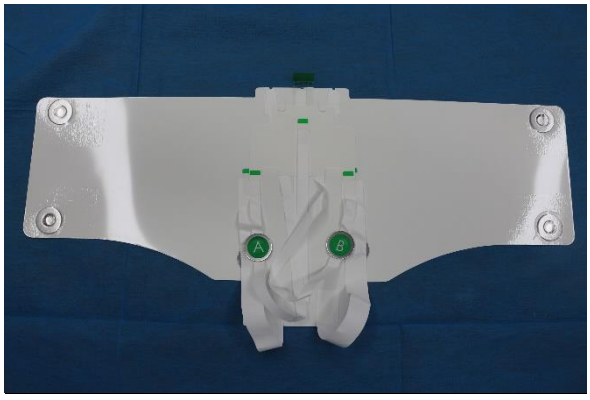
Scrub Nurse:

The scrub nurse does the following:

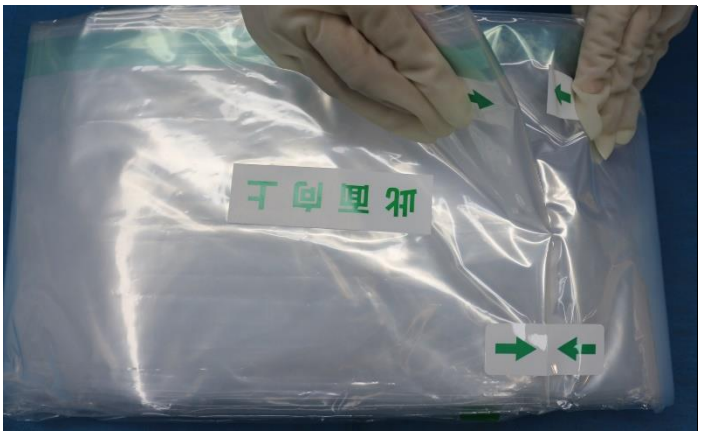
1. Prepare the drape.

   a. Take out the drape from the paper-plastic package and a flap and put them on a sterile table, with the tab “This Side Up” facing the ceiling.





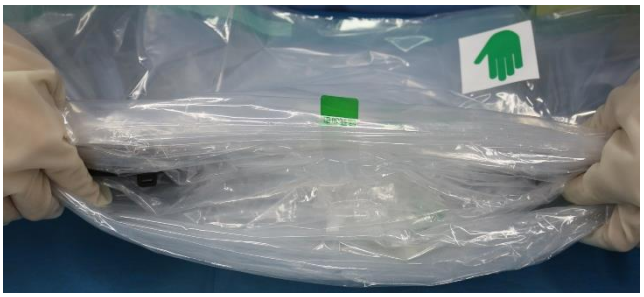
b. Snap the tear-away tabs identified by arrow icons, and unroll the remainder of the drape.





c. Grab the tab “Open from Here”, grasp the drape material on both sides of the opening, and spread apart to expose the center opening of the drape.





d. Pick up the drape and move towards the instrument arm, being careful to prevent cross-contamination.



2. Install the adaptors.

   a. Carefully attach the drape over the drive box and place the adaptors over the corresponding instrument drive. Take care that the external surface of the drape does not come into contact with the Patient Cart.

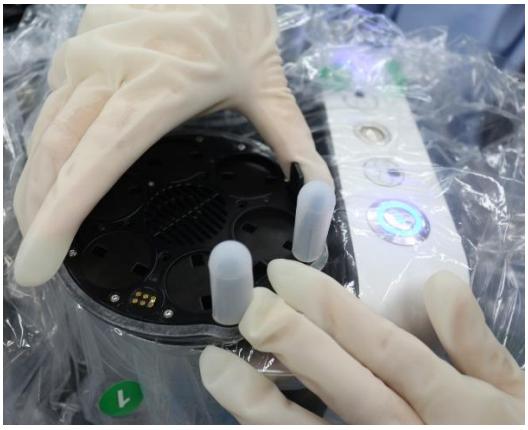


   b. Place two hands inside the drape cuffs on both sides of the drape identified by the hand symbols. Gently guide the drape along the top of the instrument arm and up toward the boom.



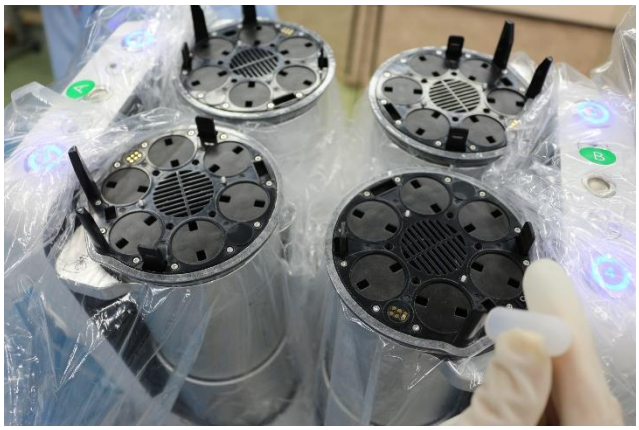
   c. Gently straighten the excess drape material around the adaptors, and press the four adaptors into the instrument drives.

      Ensure the adaptors click into place and each drive chuck at the top of the adaptor spins. If not, the adaptors do not engage, remove and re-seat the adaptors.



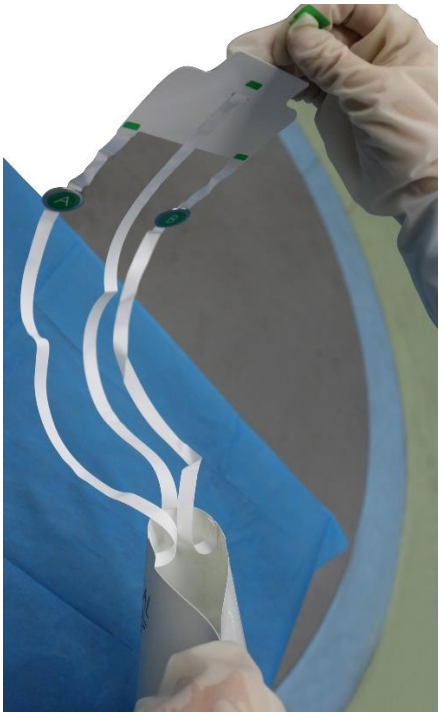
d. Stack the excess drape material in the middle of the adaptors among the instrument drives, and remove the protective covers on the adaptors.





3. Install the flap.

a. Lift the dividing strip located in the middle of the flap from the tab “Open from Here” with one hand, and hold the flap with the other hand in a slight curve.



b. Pull the dividing strip up through the middle of instrument drives, insert the flap into the connectors and ensure it is in place.

Confirm that the flap is attached to the drives at four connectors by pulling it gently.

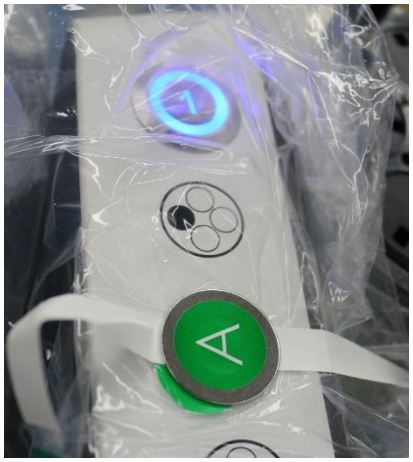


c. Attach the metal discs on the drape to the magnetic sockets on the drive box.



d. Pull two dividing strips below the flap up, remove the tape from the dividing strips, straighten and attach the two dividing strips to the left and right as shown below (that is, A and B letters align with each other).







e. Attach the dividing strip above the flap to the drape below.



4. Install the cannula adaptor.

a. Press the function button on the helm with one hand and hold the clamping handle with the other hand to adjust the drive box to a horizontal orientation.



b. Gently straighten the excess drape material around the cannula adaptor, rotate the fixing knob towards the OPEN direction into place (that is, the solid black dot on the knob lines up with the solid black arrow on the handle), snap the cannula adaptor into the cannula mount and press gently with fingers to ensure that it is in place, and finally rotate the fixing knob towards the CLOSE direction into place (that is, the solid black dots on the knob and handle line up).





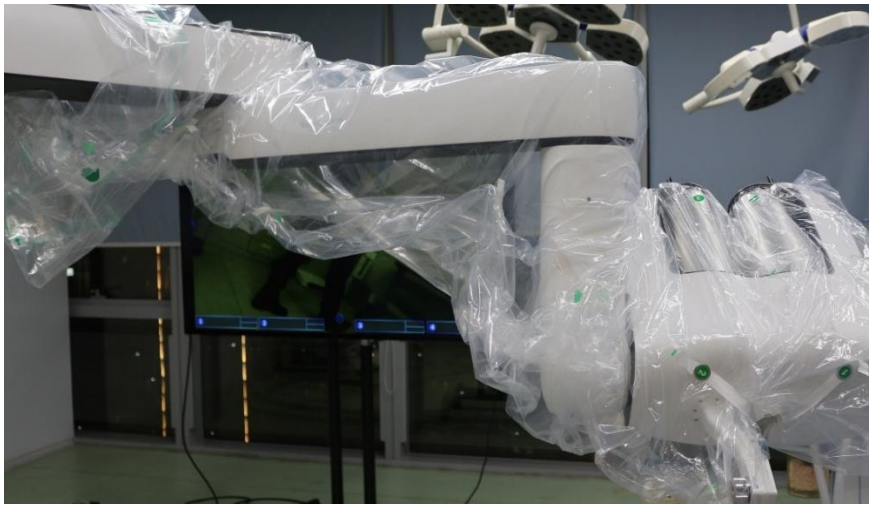
c. Align and attach metal discs 1 and 2 on the drape with the magnetic sockets on the drive box. Take care not to cross-fix the metal discs.



d. Remove the protective film on the cannula adaptor.



5. Fasten the Velcro on the boom, attach the metal discs and adjust the drape properly.



6.5.3 Sterile Stowing the Draped Patient Cart (Optional)

The draped Patient Cart may be sterile stowed, so that it is out of the path of operating room personnel and equipment before the surgical procedure, and its sterile components are free of contamination.

Press and hold **Enable Boom Controls** on the Patient Cart touchscreen, and simultaneously push the **Boom Position Control** button up. The Patient Cart will retract the column and instrument arm. Hold and push the button up until the instrument arm and column are fully retracted and the system emits a completion tone.

If desired, cover the Patient Cart in a sterile manner until the system is ready for docking to the patient.



Figure 6.2 Patient Cart in Sterile Stowed Position

6.6 Drape Removal

The drapes are sterile products designed for single-use. After the procedure, the drapes should be removed and disposed. Please dispose of the expired drapes as medical waste in accordance with local regulations instead of recycling the drapes as household waste.

When removing the drapes, take care to completely remove all adaptors, metal discs and other parts for fixing.

6.6.1 Removing Column Drape

1. Remove all the metal discs from the magnetic sockets at the top of the column.
2. Detach the Velcro at the back of the column.
3. Remove the drape from the column.
4. Dispose of the drape into the designated location.

6.6.2 Removing Instrument Arm Drape

1. Release the Velcro, cannula adaptor, adaptors, dividing strips, flap and metal discs.
2. Remove the drape from the instrument arm.
3. Dispose of the drape into the designated location.

7. Vision System Use

7.1 Vision System Overview

The Vision System is an important part of the system, mainly composed of the Camera Control Unit, Signal Distributor, endoscope, and is used with the monitor and Surgeon Console viewer. For a general overview of the Vision System, see 2.4 Vision System.

The endoscope acquires 3D video from the surgical field in high definition (HD). The HD video is processed by the Camera Control Unit and displayed on the Surgeon Console viewer and the monitor. The Surgeon Console viewer is a pair of high definition screens that provide the surgical video to the surgeon while the monitor provides a view of the surgical site from the patient-side.

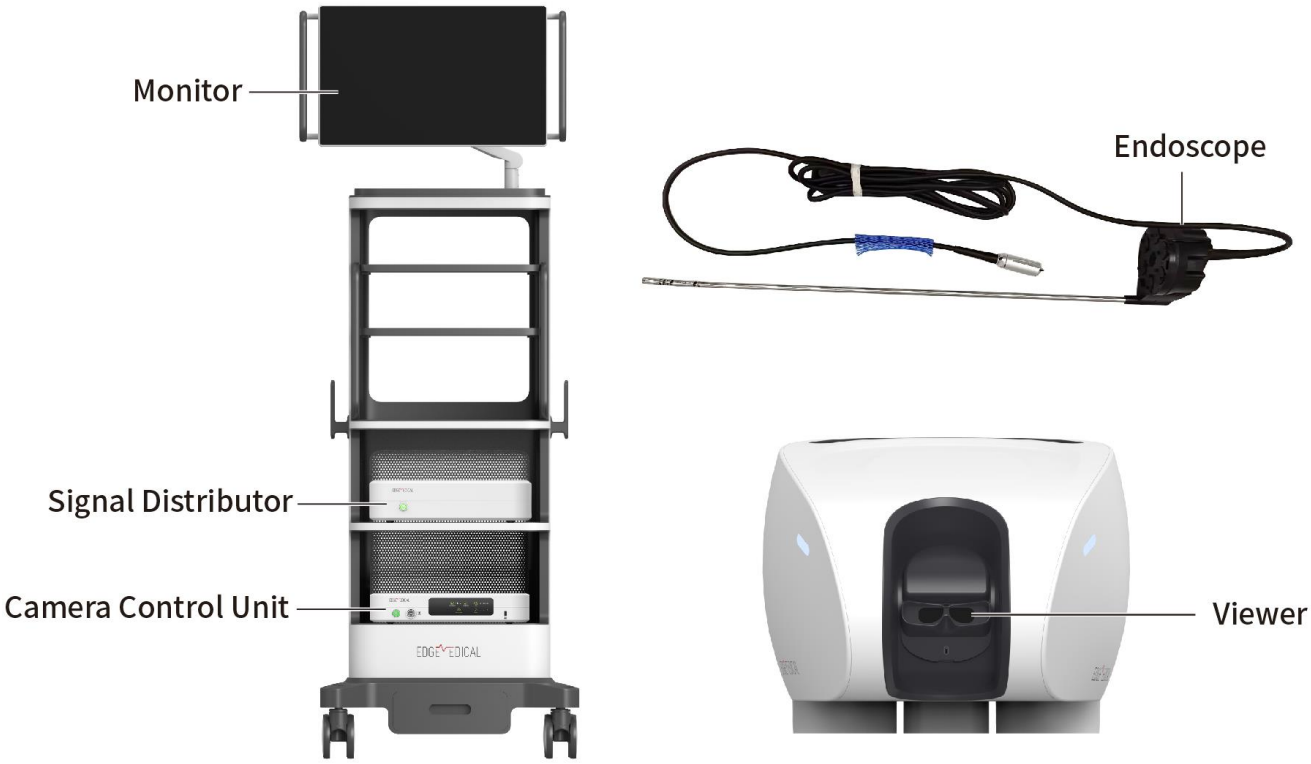


Figure 7.1 Vision System Components

Note: Only use approved or supplied vision system components with the system. This requirement ensures optimal image quality and system performance.

7.2 Endoscope Components

7.2.1 Endoscope

The endoscope mainly consists of the instrument housing, cable, connector cover, shaft and

tip. Refer to the endoscope user manual and the reprocessing instructions manual for detailed instructions.

Refer to the reprocessing instructions manual for cleaning instructions.

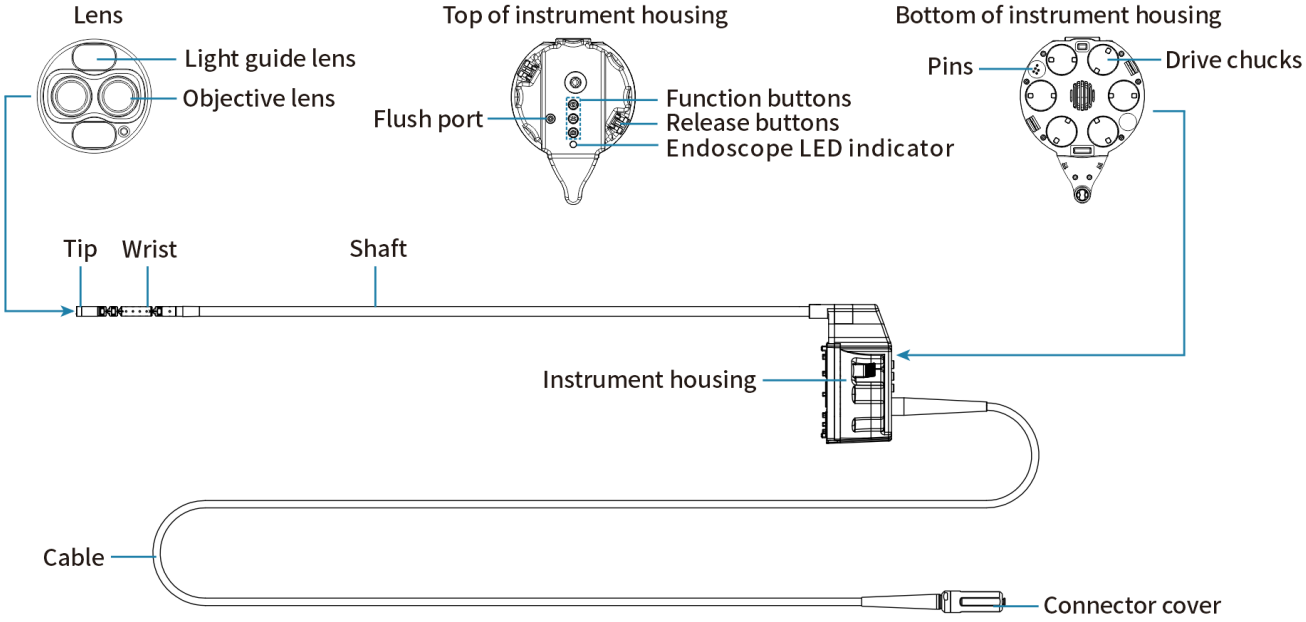


Figure 7.2 Endoscope Components

- Instrument housing: Three function buttons, a LED indicator and a flush port are located on the top of the instrument housing, two **Release** buttons are located on both sides, and the drive chucks and pins are located on the bottom.
  - **Release** buttons: Used to release the endoscope from the adaptor on the instrument drive of the Patient Cart.
  - Flush port: Used for endoscope cleaning.
  - Endoscope LED indicator: Indicates the current status of the endoscope.
  - Function buttons: Used to swap left/right eye, take photo and turn illumination on/off.
  - Pins: Used to communicate with the Patient Cart and for endoscope identification.
  - Drive chucks: Connect to the endoscope wrist and translate the movements of the master controls from the Surgeon Console.
- Cable: Connects the endoscope to the Camera Control Unit for signal transmission.
- Connector cover: Protects the connector during cleaning and sterilization, and avoid liquids contact with the connector to prevent endoscope damage. It must be removed before a procedure and reattached when endoscope not in use or before reprocessing.
- Shaft: Inserts through the cannula, and rotates as controlled by the movements of the master controls from the Surgeon Console.

- Wrist: Provides a wide range of movements of the endoscope tip and improves the flexibility.
- Tip: Located at the distal end of the endoscope, including two objective lens and two light guide lens.

7.2.2 Endoscope LED Indicator

The LED indicator indicates the current status of the endoscope.

Table 7.1 Endoscope LED Indicator

Indicator Status	Meaning
Off	Not connected
Flashing blue	Restoring
Solid blue	Connected and ready

7.2.3 Function Buttons

The function buttons can be used after the endoscope is connected to the system.

Table 7.2 Function Buttons

Buttons		Description
	Left-Right eye swap	Press to swap the left or right endoscope image
	Take photo	Press to capture an image from the endoscope view
	Illumination on/off	Press to turn illumination on or off

7.3 Endoscope Use

7.3.1 Endoscope Guidelines

- To avoid permanent eye injury, observe the following cautions:
  - Do not look directly at light when the endoscope is connected to the system and emitting light.
  - Do not attempt to perform any repair or maintenance on any of the optical components in the system.
- The highly concentrated light energy can cause the distal tip and the shaft to heat up (may exceed 41℃). 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.

- Ensure the vision system can provide the ability of adequate visualization to complete operative tasks safely.
- Care should be taken to avoid sharply bending or kinking the cable, as it can damage the cable. Do not step on the cable, since this can damage it.
- The endoscope is delicate and can be broken if dropped or struck. Adhere to the sterilization, inspection, and connection requirements.
- Prior to each procedure, the endoscope should be cleaned and sterilized, and only can be used by personnel in sterile field. Refer to the reprocessing instructions manual for detailed instructions.
- The endoscope must be used with the tip cover accessory. Install the tip cover accessory on the endoscope in the sterile field prior to installing the endoscope on the instrument arm.
- Do not dip or submerge the sheathed endoscope in liquid. To clean the tip, wipe it with warm, moistened sterile gauze.
- Reattach the connector cover to the connector when the endoscope cable is no in use or before reprocessing the endoscope. Failure to secure the connector cover during reprocessing may result in endoscope damage.

7.3.2 Inspection before Use



Warning: Do not use endoscopes with any defects or signs of damage, including damage to the glass surfaces or cables. Otherwise, serious injury or surgical complications may occur to the patient.

- Inspect the endoscope for any defects or damage, including breaks, bends, cracks, rough surfaces, sharp edges, burrs, protrusions, etc.

- Inspect the endoscope for mechanical defects.
- Inspect the exterior of the endoscope for cleanliness, paying special attention to the tip. There should be no visual contamination.
- Inspect the glass surfaces at the distal tip. There should be no deposits, residues or haze.
- Inspect the endoscope cable for any cuts, damage or defects.
- Inspect the cable surfaces for any deposits or residues.
- Inspect the port and connector for loosening, distortion, damage, smudges or soiling that can affect connections, and there should be no debris in the port.
- Ensure that only compatible equipment and accessories are connected to the endoscope.

7.4 Endoscope Installation and Removal

7.4.1 Endoscope Cable Management

For improved cable management throughout the procedure, place the cable between the endoscope shaft and the arm before inserting the endoscope into the cannula. This minimizes the length of cable that is free to swing around during the procedure. Do not hang the endoscope cable over the arm as it may get caught or damaged and limit the arm's range of motion.

Caution: If pulls or swings occur on the endoscope cable, in some severe cases, it may cause abnormal image display or even cable damage.

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.

7.4.2 Endoscope Installation

Endoscope Port

In combination with cannula, endoscope can be installed on instrument drive 2 or instrument drive 3. The system recognizes the corresponding drive on which the endoscope is installed, and provides auxiliary UI information displayed on the Surgeon Console viewer and the Vision System monitor, facilitating getting the installation state of the endoscope.

Note: The endoscope is usually installed by a patient-side assistant. He or she should confirm the endoscope port with the surgeon before installation.

Installation Guidelines

Note: Ensure the instrument arm has been draped properly before endoscope installation.

Note: Ensure the cannula has been connected to the drive box properly before endoscope installation.

Before installing the endoscope onto the Patient Cart, make sure the surgeon is ready. The endoscope must be installed before any instrument can be controlled from the Surgeon Console.

The endoscope installation is the same with the instrument installation. For more detailed information, see 9.4.4 Instrument Installation.



Figure 7.3 Install the Endoscope

7.4.3 Endoscope Removal and Replacement

Before removing the endoscope from the Patient Cart, ensure that the surgeon is ready. When changing from one endoscope to another, it is necessary to disconnect one endoscope from the Camera Control Unit and then connect the other endoscope.

1. The sterile operator removes the endoscope from the instrument drive and places it on the sterile table. The non-sterile operator removes the cable connector from the Camera Control Unit.
2. The non-sterile operator connects the cable connector of the to-be-installed endoscope to the Camera Control Unit. After connecting successfully, the real-time image acquired by the endoscope can be viewed from the Surgeon Console viewer and monitor.

3. The sterile operator mounts the endoscope to the corresponding instrument drive and advances the endoscope to the appropriate position.

To remove the endoscope:

1. Press and hold the corresponding **Drive Function** button of the endoscope or the **Drive Hold** button. Retract the endoscope to the loading position. The system automatically straightens the endoscope joints to allow for full retraction.
2. Squeeze the **Release** buttons on both sides of the instrument housing and slide the endoscope up and out through the instrument drive.

Note: When the endoscope is re-installed or replaced, the memory function may be activated automatically. At this time, the endoscope can be advanced into memory position.

Note: In order to prevent tissue hardening and deposits caused by high temperature, wipe the tip and lens immediately after removing the endoscope from the instrument drive.

7.5 Camera Control Unit Use

The Camera Control Unit is used to process the images from the endoscope and then transmit to the system.

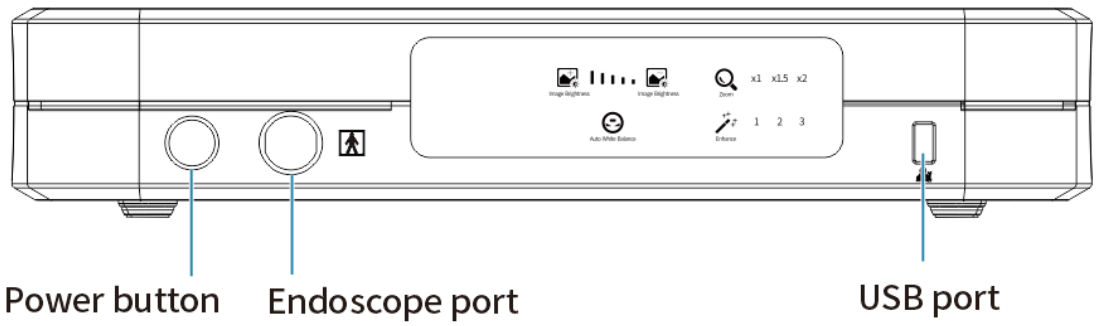


Figure 7.4 Front of Camera Control Unit

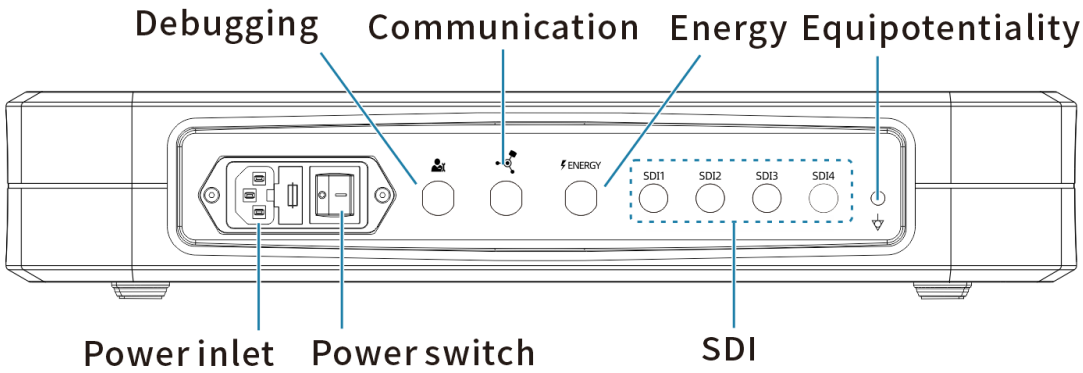


Figure 7.5 Rear of Camera Control Unit

The Camera Control Unit is equipped with function buttons as shown in following table.

Table 7.3 Camera Control Unit Buttons

Buttons		Description
	Image Brightness+	Press to increase image brightness
	Image Brightness-	Press to decrease image brightness
	Digital Zoom	Press to zoom in on the image
	Auto White Balance	Press to set white balance on the endoscope
	Image Enhancement	Press to adjust image enhancement

For the instructions on the ports of the Camera Control Unit, see A.5.3 Camera Control Unit in A.5 Ports.

Note: To eliminate the ground potential difference among different devices and ensure safety, connect the potential equalization line to the connectors for potential equalization on the Camera Control Unit and the power supply when the Camera Control Unit is used in conjunction with the system.

7.6 Feature Settings

The image is displayed on the Surgeon Console viewer and the Vision System monitor. The feature settings are available with the Surgeon Console touchscreen, Camera Control Unit and endoscope. For the instructions of the Surgeon Console touchscreen, see 10.2.8 Settings Tab.

Before the feature setting operation, ensure that the endoscope and the Camera Control Unit

are correctly connected. All cables have been connected correctly, please refer to 4 System Connections.

7.6.1 Live Image and Orientation

Each time an endoscope is installed, and after changing visualization modes or settings during a procedure, look in the viewer to confirm a live image and a desired orientation. Adjust endoscope orientation by the Surgeon Console as necessary.

7.6.2 Left-Right Eye Swap

Press the button on the housing of the endoscope. Then the endoscope can swap the left or right eye video image displayed on the monitor or in the viewer.

7.6.3 Take Photo

Press the button on the housing of the endoscope. The system can capture an image from the endoscope view and save the image into a specified USB flash drive connected to the Camera Control Unit. The system records the left or right image based on which image is currently displayed on the touchscreen.

Note: Use the USB flash drive specified or allowed by the company. Otherwise, the system may be unable to identify it.

7.6.4 Illumination

Press the button on the housing of the endoscope to turn illumination on or off.

7.6.5 3D Calibration and White Balance

The endoscope is calibrated at the factory. Usually no special treatment is required.

Before each surgical procedure, it is necessary to perform white balance to adjust the perception of white and the ability to display colors properly. Follow the steps to perform white balance:

1. Turn illumination on.
2. Point the tip of the endoscope at any clean white surface (such as white gauze).
3. Press the button on the Camera Control Unit.

White balance can be also set on the Surgeon Console touchscreen. See Image in 10.2.8 Settings Tab for more information.

7.6.6 Image Brightness

The system provides two methods for setting image brightness:

- Press the  button or the  button on the Camera Control Unit.
- Image brightness can be also set on the Surgeon Console touchscreen. See Image in 10.2.8 Settings Tab for more information.

7.6.7 Image Enhancement

The system provides two methods for enhancing image sharpness:

- Press the  button on the Camera Control Unit.
- Image enhancement can be also set on the Surgeon Console touchscreen. See Image in 10.2.8 Settings Tab for more information.

7.6.8 Digital Zoom

Digital zoom increases the magnification of the image. The normal zoom setting is **X1** magnification, but **X1.5** and **X2** are also available. When **X1.5** or **X2** digital zoom is active, the image resolution decreases, which can impact image quality. **X1** zoom setting provides the maximum resolution.

The system provides two methods for digital zoom:

- Press the  button on the Camera Control Unit.
- Digital zoom can be also set on the Surgeon Console touchscreen. See Image in 10.2.8 Settings Tab for more information.

7.7 Endoscope Fogging and Cleaning

7.7.1 Endoscope Fogging



Caution: When the endoscope is connected to the Camera Control Unit, do not use methods that heat the endoscope for a long time, which may cause overheating and damage to the endoscope.

When the endoscope tip is inserted into the body, the lens may appear fogging due to temperature difference between inside and outside the body. This affects the endoscope view. The electronics in the distal tip of the endoscope generate heat, which should reduce fogging.

The following methods can be used to prevent fogging before a procedure:

- Avoid connecting insufflation or smoke evacuation to the endoscope cannula.
- Clean any residual detergent solution.
- Connect the endoscope to the Camera Control Unit 30 minutes (no need to turn on illumination) before advancing the endoscope into the patient, so that the internal electronics in the distal tip of the endoscope generate enough heat.
- When the endoscope is outside the patient and waiting to be used, it can be placed in an endoscope warming device (the temperature inside less than 55℃).
- Apply antifogging agent evenly to the endoscope tip.
- Set the CO_2 inflow speed of the insufflator to the maximum flow rate.
- Activate smoke evacuator before activating energy and deactivate after use.

If endoscope fogging appears during a procedure, it needs to remove the endoscope and carefully wipe the tip and lens with moistened sterile gauze. If necessary, briefly (less than 15 seconds) submerge the tip of the endoscope in sterile warm water for injection (the temperature less than 55℃) and dry with sterile gauze.

7.7.2 Endoscope Cleaning

If endoscope contamination appears during a procedure, it needs to remove the endoscope and carefully wipe the tip and lens with moistened sterile gauze. The following methods can be used to confirm cleanliness:

- Point the tip of the endoscope at an object, and check whether the image on the monitor is clear.
- Turn off illumination, observe the tip directly to confirm cleanliness, and then turn on illumination.

7.8 Image Quality Troubleshooting

Note: If image quality cannot be restored by the following methods, a backup endoscope can be provided for replacement. If the problem persists after replacement, contact our company.

Warning: Do not use the endoscope if any part of the vision system is damaged or functioning abnormally. Failure to follow this warning may result in injury to the operator or patient.

7.8.1 Image Too Bright or Dark

- Adjust the image brightness in accordance with the method in 7.6.6 Image Brightness.
- If the image is too dark, remove the endoscope from the instrument drive, turn off the light by using the button on the housing, and check the front of the tip end for smudges or soiling adhering to the lens that may block the light. If necessary, clean the tip end.

7.8.2 Flickering Image

Check for high frequency interference.

- If flickering only happens during cautery, move high frequency generator away from the Vision System and move all of the cautery cords away from the Vision System cables.
- Use a high frequency generator verified by the company.
- Restart the Camera Control Unit.

7.8.3 Blurry Image

- Set the digital zoom to **X1** according to the method in 7.6.8 Digital Zoom.
- Remove the endoscope from the instrument drive, and check the front of the tip end for smudges or soiling. If necessary, clean the tip end.

7.8.4 White Balance Deviation

After the endoscope is connected to the Camera Control Unit, the white balance is set automatically by the system. If for any reason white balancing is needed, follow these steps described in 7.6.5 3D Calibration and White Balance.

7.9 Vision Cart Use

7.9.1 Vision Cart Overview

The Vision Cart is a mobile transport cart designed for medical devices and accessories.

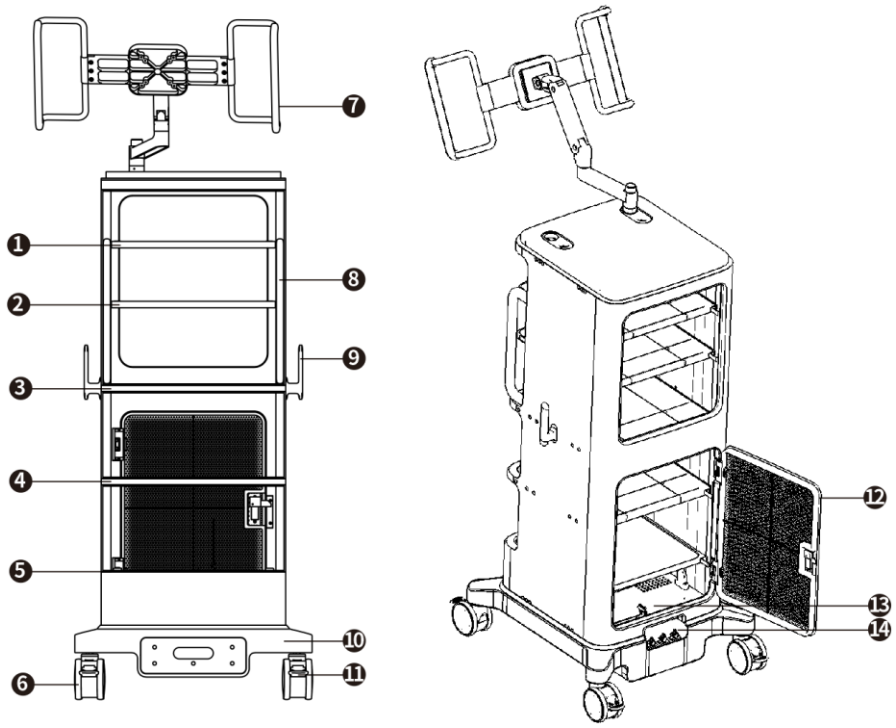


Figure 7.6 Vision Cart Components

No.	Component	No.	Component
1	6th shelf	8	Handles
2	5th shelf	9	Hooks
3	4th shelf	10	Base
4	3rd shelf	11	Brakes
5	2nd shelf	12	Rear door
6	Wheels	13	1st shelf
7	Monitor mounting bracket	14	Cable clamps

7.9.2 Use Guidelines

- The cart is heavy and may present a hazard (for example, tipping) if control is lost when moving. Only trained personnel should attempt to move the cart.
- Do not convert or modify the cart. Unauthorized repairs and modifications may result in loss of function and void warranty.
- Make sure that medical devices do not slide around on the cart and fall off.
- In order to protect persons from falling devices, secure the devices on the cart with the stabilizing elements.

- Unlock wheels manually before moving the cart, and lock wheels into place after confirming positioning.
- When moving the cart, look out for medical devices and accessories as the cart could collide with them or they could cause it to tip over.
- When moving the cart, make sure the movable devices do not slide around and the cart does not collide with any obstacles.
- Position the cart appropriately so that the power cords of medical devices can be unplugged at any time.
- Always use caution when moving the Vision Cart to prevent injury to the user or patient.
- Do not use abrasive cleaning tools, corrosive gases or liquids to clean the cart.
- The cart can only be installed and serviced by authorized personnel from Edge Medical. Do not attempt to install or service the cart without authorized personnel.

7.9.3 Monitor Installation

1. Assemble the parts of the monitor armrest by 6 M5*8M hexagon socket head cap screws.

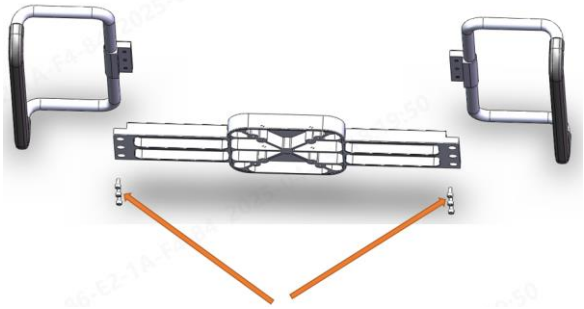


Figure 7.7 Assemble Monitor Armrest

2. Attach the monitor to the monitor armrest by 4 M4*10 hexagon socket head cap screws.

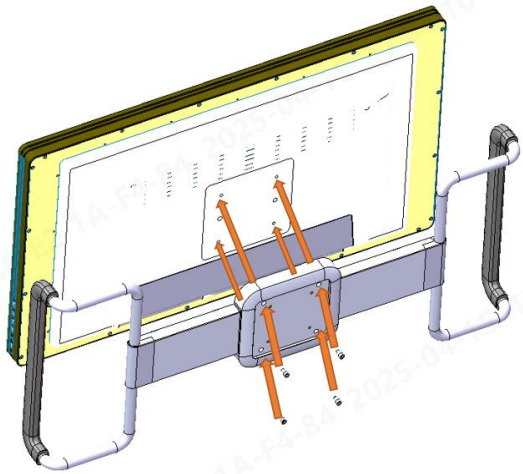


Figure 7.8 Attach Monitor to Monitor Armrest

3. Connect the monitor armrest to the monitor mounting plate by 4 M4*10 hexagon socket head cap screws.

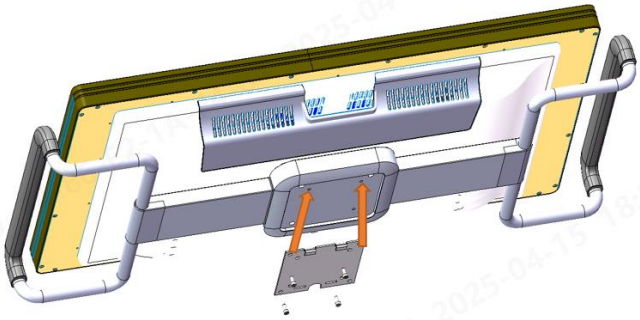


Figure 7.9 Connect Monitor Armrest to Monitor Mounting Plate

4. Connect the monitor mount assembly to the column mount and then fix the locking screw.

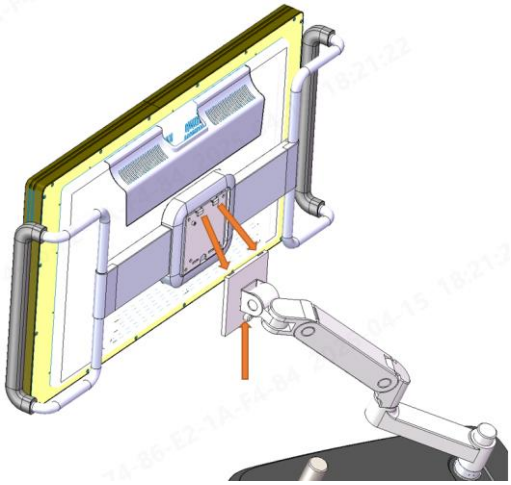


Figure 7.10 Connect Monitor Mount Assembly to Column Mount

5. Adjust the joints of the monitor mount according to the user's habits.

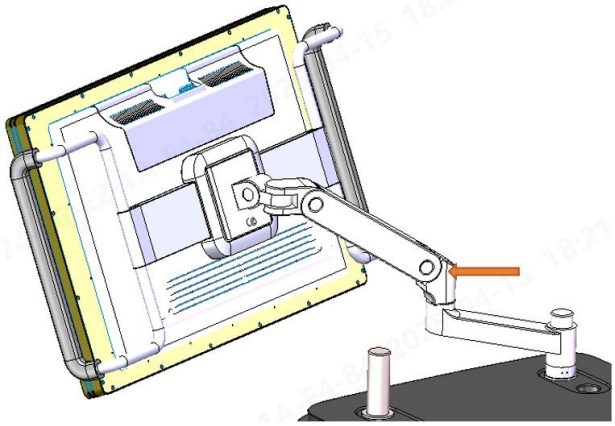


Figure 7.11 Adjust Monitor Mount Joints

7.9.4 Network Security Device Installation

1. Unlock and open the rear door of the cart.

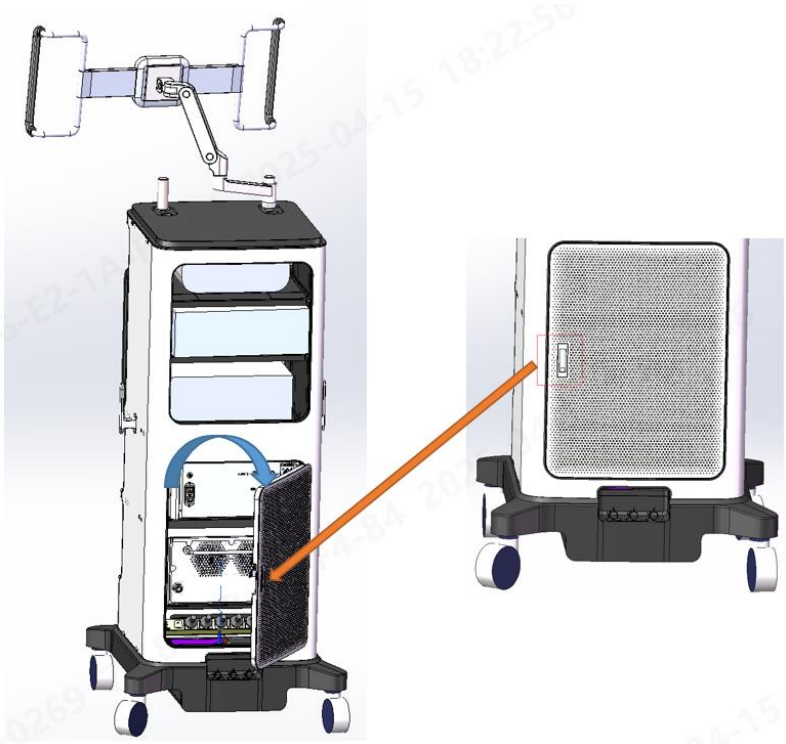


Figure 7.12 Open Rear Door

2. Align the network security device with the snap, press the device vertically down until it is secured in place. Pay attention to the installation direction: the arrow faces out the door.

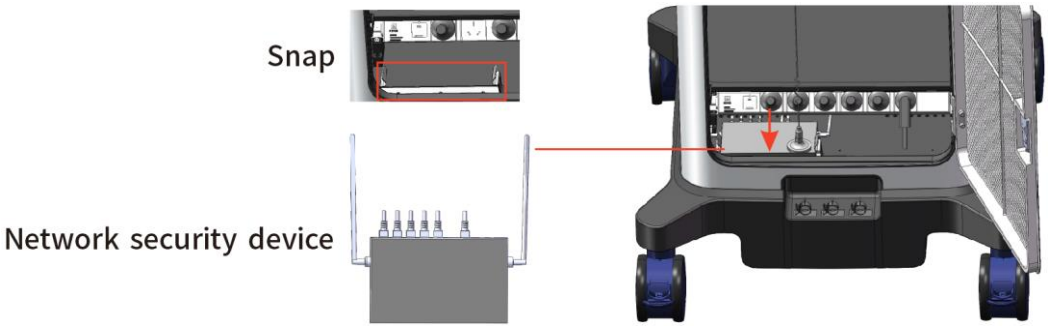


Figure 7.13 Install Network Security Device

3. Attach the antenna to the housing of the network security device after connection.
4. Use a M5 allen wrench to remove the mounting screws of the socket.
5. Connect the network port of the network security device to the communication port of the Signal Distributor.



Figure 7.14 Connect Network Security Device to Signal Distributor

6. Reinstall the socket after network cable connection.
7. Plug the power cord of the network security device into the first port on the left of the socket.

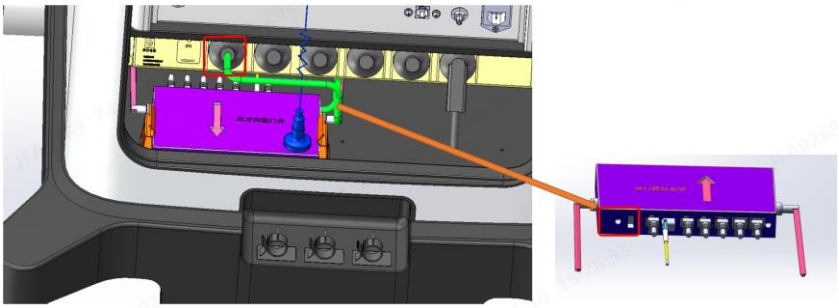


Figure 7.15 Connect Power Cord

8. Close and lock the rear door of the cart.

7.9.5 Lock and Unlock Wheels

Lower the brakes on four wheels with your toe to lock the cart; lift the brakes on four wheels with your toe to unlock the cart.

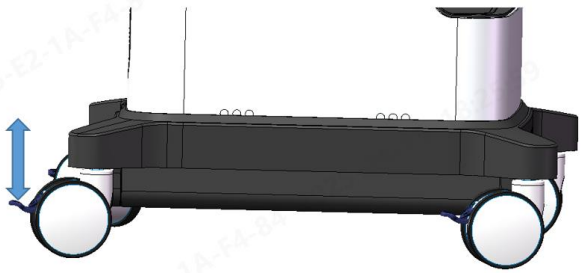


Figure 7.16 Lock and Unlock Wheels

7.9.6 Move Cart

1. Unlock all cart wheels.
2. Position the cart for surgery (on either side of anesthesia or the Patient Cart). Consider monitor visibility, cable and cord connections.
3. Lock all cart wheels.

8. Patient Preparation and Port Placement

8.1 Patient Preparation

Patient positioning is procedure-specific and is at the discretion of the surgeon.

The instrument arm of the Patient Cart should be arranged to avoid contact with the patient.

Warning: Once the system is connected to the patient, the Patient Cart must be not moved in any way. Serious injury could result. If the operating table needs to be moved during the procedure, remove all instruments and the endoscope, undock the system, move the operating table, and re-dock the system.

Note: The patient should be positioned prior to docking. Adjust the operating table height and positon before driving the Patient Cart into place.

8.2 Port Placement

8.2.1 Port Placement Guidelines

- Port placement is key to a successful procedure, as it enables the instruments to achieve the maximum and available working range.
- Port placement varies by procedure and patient and should be thoroughly discussed with an experienced surgeon.
- Anatomical restriction may necessitate an alternate setup.

Note: The target anatomy is the center of the surgical workspace boundary, but not necessarily the location of the pathology.

The general guidelines for port placement:

- Place port so it is in a straight line with the instrument base and the target anatomy.
- If possible, place the endoscope port 8 cm～10 cm from the target anatomy.
- Place assistant ports as far away from robotic ports at least 8 cm～10 cm, while avoiding the orientation of the instrument arm as much as possible.

8.2.2 Cannula and Cannula Seal Preparation

Before using the cannula, the cannula seal should be properly attached to the cannula.

Using a standard surgical technique, make a skin incision large enough to introduce the

cannula. Introduce the port through the incision and apply continuous, controlled pressure with a deliberate rotating motion until the cannula passes through the body wall. The depth should be appropriate that the remote center is within the body wall.

Considering the anatomical site of the surgery and the type of combined accessories, initially select the position of the surgical port.

Position the patient by a standard surgical technique, carry out draping and the Patient Cart positioning. After insufflation using a CO_2 pneumoperitoneum machine, mark the target location of the surgical port.

During surgery, it is necessary to remove the instruments from the patient first, then move the Patient Cart, and finally re-dock the system.

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.

8.2.3 Remote Center

The instrument arm of the Patient Cart controls the endoscope and instruments by remote center technology, which enables the system to precisely maneuver the endoscope and instruments in the surgical site while exerting minimal force on the patient's body wall. The remote center is the pivot point around which the endoscope and instruments move.

If the remote center is correctly placed in the patient's body wall, moving the instrument arm exerts minimal pull and tug at the port site. The remote center can not only improve the precision of the instrument motion, but also reduce tissue injuries at the incisions.

The remote center is marked on the cannula as a thick, center black line.

- To correctly place the remote center, the thick black line on the cannula should be inserted into the patient's body wall.
- Correct placement of the cannula should be verified by viewing the cannula tip with visual inspection.
  - The first thin line at the distal cannula tip should be visible, indicating that the remote center is placed correctly within the boundaries of the patient's body wall.
  - The thick black line on the cannula is visible, indicating that the remote center is inserted too deeply. Moving the arm with the remote center placed incorrectly increases friction, reduces precision, and increases tissue trauma at the port site.

- The system supports adjust the remote center by repositioning the instrument arm. It is recommended to check the position of the instrument arm throughout the procedure to ensure there is no tension at the port site.



Figure 8.1 Remote Center

Remote Center Setting

The system supports the feature of remote center setting, enabling the setting of a new fulcrum to replace the depth of the system default remote center location. The depth of the system default remote center is 8 cm while the feature can set the remote center from 1 cm to 20 cm.

Remote center setting should be used when using a port, or when the thick black line on the cannula cannot be aligned with the body wall. The feature may reduce interference between the incision and the endoscope and instruments shafts, reduce the need for intraoperative port clutching and provide the best instrument motion performance.

Warning: While using remote center setting, instrument arm and joint motion could cause collisions with external devices or personnel, which may lead to pressure injury.

Warning: Set the remote center relative to the body wall under sufficient visualization from the Surgeon Console or patient side to prevent body wall injury.

Remote center setting can be set any time during the procedure after the endoscope and instruments have been installed and the system is out of following mode.

Set remote center on the touchscreen of drive box. Select **Setting** > **Remote Center Setting** to set remote center.



Figure 8.2 Remote Center Setting

9. Patient Cart Use

9.1 Patient Cart Overview

The Patient Cart is the operative component of the system. Its main function is to move the instruments and endoscope using four instrument dives under the control of the Surgeon Console by a surgeon. A patient-side assistant in the sterile field helps the surgeon install and move the instruments and endoscope on instrument drives. For a complete description of the Patient Cart components, see 2.3 Patient Cart.

9.1.1 Patient Cart Helm



Figure 9.1 Patient Cart Helm

Note: Press both drive enable switches on the helm to drive the Patient Cart.

Buttons

To enable the following operations, use the control buttons on the Patient Cart helm:

- Boom Position Control:
  - Push the **Boom Position Control** button down, and the Patient Cart will automatically deploy the boom and adjust the arm. Hold and push the button down until the instrument arm moves to the draping position and the system emits a completion tone.

- Push the **Boom Position Control** button up, and the Patient Cart will retract the column and arm. Hold and push the button up until the instrument arm and column are fully retracted and the system emits a completion tone.
- Push the **Boom Position Control** button left/right, and the Patient Cart will move to left/right deployment.
- Rotate the **Boom Position Control** button clockwise, and the Patient Cart will move to right deployment.

- Boom Height Control: Push the **Boom Height Control** button up to raise the boom. Push the button down to lower the boom.
- **Emergency Stop** button: Stop the system at any time by pressing the **Emergency Stop** button on the helm of the Patient Cart. Restart the system by tapping the **Recover** button on the Surgeon Console touchscreen.
- **Power** button: Press the **Power** button to power on the Patient Cart.

UPS LED Indicator

The UPS LED indicator located on the helm of the Patient Cart indicates the UPS power status. The UPS power displays on the Patient Cart touchscreen.

Table 9.1 UPS LED Indicator

Indicator Status	Meaning
Off	Unpowered
Flashing	Loss of AC power, running on UPS power
Three Solid green	High power
Two solid yellow	Medium power
One solid red	Low power

Movement LED Indicator

The movement LED indicator located on the helm of the Patient Cart indicates the current status of the Patient Cart.

Table 9.2 Movement LED Indicator

Indicator Status	Meaning
Off	Unpowered
Flashing blue	The Patient Cart is moving

Solid blue	The Patient Cart can move after powered on
Solid yellow	The Patient Cart cannot move after powered on
Flashing red	Drive fault occurred, emergency stop

9.1.2 Touchscreen of Helm

The touchscreen, located on the helm of the Patient Cart, provides features for Patient Cart activities including preparing the cart for draping, stowing the cart, enabling boom controls, selecting anatomy and approach, and settings. The touchscreen also provides a means for system fault notification and recovery.

Home Tab

After the Patient Cart is powered on, the Home tab appears on the touchscreen. On the Settings tab, tap  back to the Home tab.

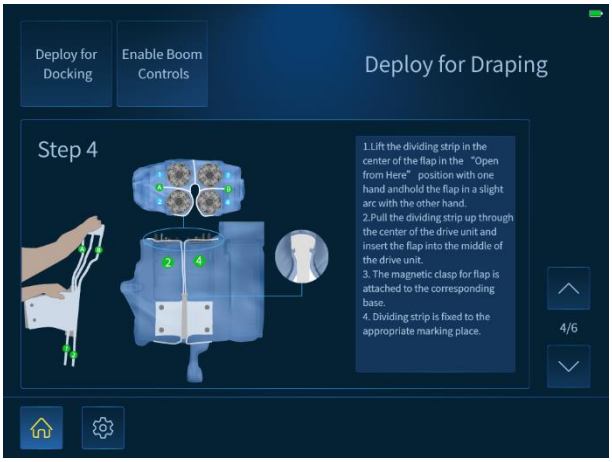


- Draping guidance: Tap **Draping guidance** to view the step-by-step images and instructions for the draping process.





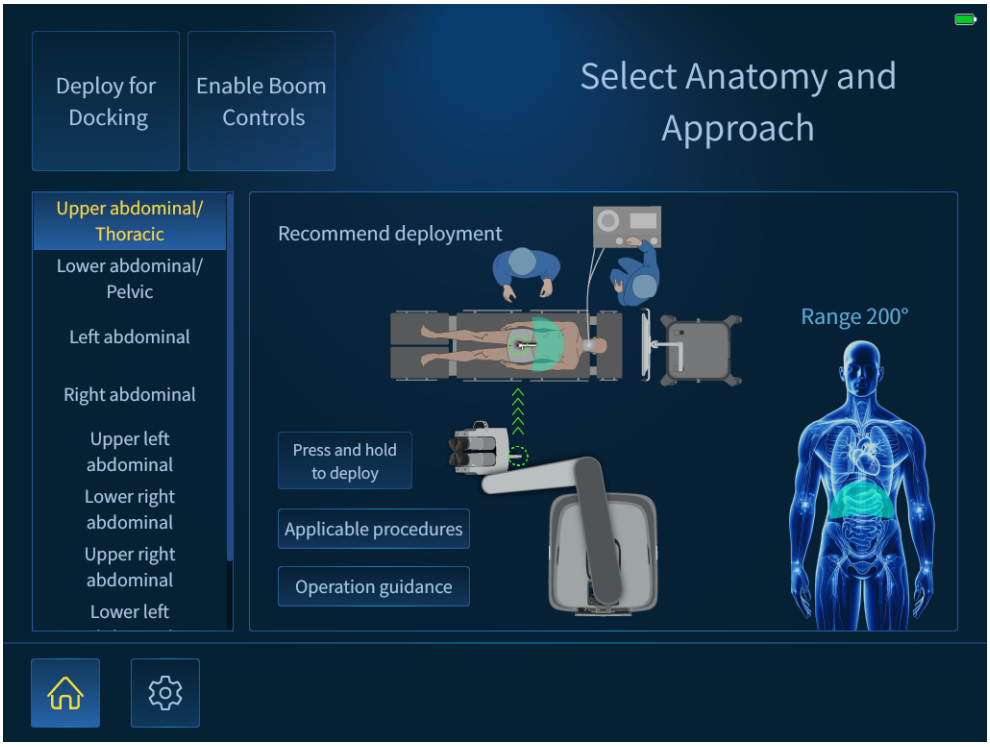








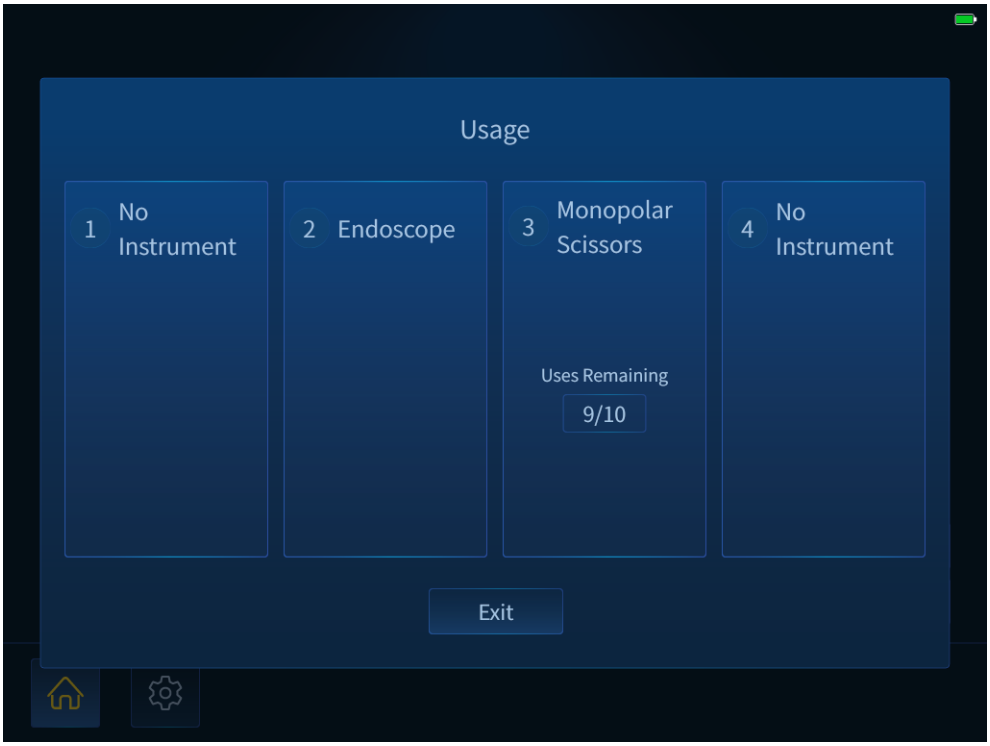
- Deploy for Docking: After the Patient Cart is fully draped, select the desired anatomy and approach. When ready to move towards the patient, press and hold **Deploy for Docking**. The instrument arm will move for the selected approach.



- Enable Boom Controls: After the feature of boom controls switch is enabled in the Settings tab, press and hold **Enable Boom Controls**, you can use the **Boom Position Control** button and the **Boom Height Control** button to move the boom.
- Beeps: When a fault occurs, the system will sound a series of error beeps and alert to eliminate the fault condition. If the fault condition remains, the system allows the user to turn off the beeps temporarily on the touchscreen by tapping .



- Usage: On the Surgery in Progress interface, tap **Usage** to view the uses remaining summary. The number on the left represents the number of uses remaining, and the number on the right represents its maximum uses. The number of uses remaining does not include the current use. Tap **Exit** and return to the Surgery in Progress interface.



- Limit Setting: On the Surgery in Progress interface, tap **Limit Setting** to set whether to unlock limit settings on the helm side, the arm side and the bottom of drive box. Tap **Exit** and return to the Surgery in Progress interface.



Settings Tab

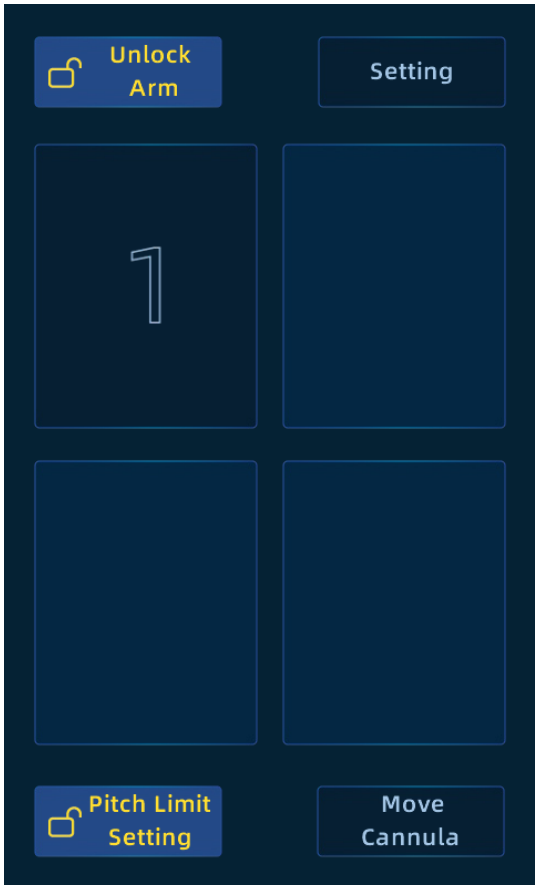
On the Home tab, tap  to access a variety of the Patient Cart settings.



- Patient Cart Voice: Drag the sliders to adjust the microphone and audio volume of the Patient Cart.
- Power Protection: Select **ON** or **OFF** to turn power protection on or off. When the power protection is **ON**, the motor drive is disabled to ensure that UPS power is adequate for removing the instruments safely from the patient when the Patient Cart is disconnected to AC power.
- Boom Controls Switch: When the boom controls switch is **OFF**, operate the **Boom Position Control** button and the **Boom Height Control** button to move the boom. When the boom controls switch is **ON**, move the boom by the **Enable Boom Controls** button on the Home tab.
- Force Reset: Tap **Reset** to reset the drive force sensor on the helm of the Patient Cart. Do not touch the cart during the process.
- Left-right Limit: Select **ON** or **OFF** to turn left-right limit on or off. When the left-right limit is **ON**, the limit settings on the helm side and the arm side can be locked or unlocked.
- More Settings: Tap **More Settings**, and then enter the admin password. The pop-up window of the Engineering Settings appears. The user can reset the router of the Patient Cart, and disable drives, instrument arm, wheels or stabilization devices.

9.1.3 Touchscreen of Drive Box

The touchscreen of the drive box of the Patient Cart provides the features of arm lock, setting, pitch limit setting and cannula movement, as well as instrument drive display for the four instrument drives and system status.



- Lock Arm: When the patient-side assistant taps **Lock Arm**, the master-slave control operation interrupts and the patient-side assistant takes control of the instrument drives.
- Setting: Includes force reset and C-point set.
  - Force Reset: Resets the drive force sensor of the Patient Cart. If the cannula, instruments or endoscope are installed on the Patient Cart, the force reset cannot be activated.
  - C-Point Set: Sets the position of the remote center on the cannula.
- Pitch Limit Setting: Sets the lowest position of the drive box.
- Move Cannula: Adjusts the position of the drive box around the remote center and along the axis of the cannula. Movement toward the cannula is forward, movement toward the drive box is backward.

See the following table for the status and meaning of the instrument drive display indicator.

Table 9.3 The status and meaning of the instrument drive display indicator

Indicator Status	Meaning
Off	Unpowered
	Self-test complete, no adaptor installed
	Install the adaptor and start the self-test process
	Adaptor/instrument/endoscope installation and self-test complete
	Instrument/endoscope self-test
	Instrument drive can move on the guide rail
	Recoverable fault occurred during adaptor self-test
	Non-recoverable fault occurred during adaptor self-test
	Recoverable fault occurred during instrument/endoscope self-test
	Non-recoverable fault occurred during instrument/endoscope self-test
	Other non-recoverable faults
	Other faults
	Endoscope installed on Arm 1 or 4

9.1.4 Positioning Controls

There are two groups of six function buttons on the drive box of the Patient Cart. Button 1 can be used to move the instrument arm for repositioning the Patient Cart, button 2 can be used to adjust the position of the Patient Cart around the remote center, and button 3 can be used

to move the instrument arm as well as adjust the position of the Patient Cart around the remote center.



Figure 9.2 Positioning Controls

9.2 Patient Cart Positioning and Docking

Position the Patient Cart for docking, deploy the drapes, adjust the instrument arm, and position the Patient Cart next to the operating table in preparation for surgery. The height of the boom, extension (closer or farther from the base) and rotation are adjustable. The arm flex can be extended and adjusted for appropriate placement and range of motion for surgery.

9.2.1 Preparation for Positioning

- Non-sterile personnel push the Patient Cart into the sterile field.
- Communication is critical when moving and docking the Patient Cart. Only one person should give directions to the Patient Cart operator about potential collisions and for positioning when approaching the patient.
- When moving the Patient Cart, the person providing directions should use anatomical or room references (such as “toward the head” or “away from the Camera Control Unit”) to direct the Patient Cart movements. The person providing directions should avoid using relative terms such as “left” or “right”.
- There may be elevated barriers in the operating room. Consider placing the patient in a position where the obstacle will not get in the way.
- Due to room constraints, it may be necessary to develop an alternative program.

Under normal circumstances, surgical port positioning is the easiest and most accurate method to position the Patient Cart, and manual positioning can be used.

Warning: Check for clearance between the patient and the Patient Cart arm. Prolonged pressure on the patient could result in serious injury.

Warning: When using function buttons, keep your fingers clear of the joints located on the instrument arm and instrument drive insertion axis to avoid injury.

Caution: To avoid damage to the Patient Cart, be careful when moving or positioning the Patient Cart to ensure the instrument arm out of collisions with any objects.

9.2.2 Deploy for Docking

The Patient Cart can be positioned for docking using preset deployment and manual deployment that controls column up/down, arm extension/retraction, and drive box rotation.

Preset Deployment

The Patient Cart touchscreen enables preset deployment of the instrument arm. The Patient Cart allows for deployment of the anatomy and the cart positioning to the preset docking position. Follow the steps below:

1. Tap **Deploy for Docking** on the touchscreen.
2. Select the desired anatomical region on the Select Anatomy and Approach interface.
3. Confirm the peripheral instruments and adjust the position to reserve space for the Patient Cart according to the recommended deployment.
4. Press and hold the deploy button to deploy until the instrument arm is fully deployed.

Note: Ensure that there is sufficient space for the arm during deploy to avoid mechanical interference with the equipment.

Manual Deployment

If the preset deployment can not meet the deployment requirements, the Patient Cart can be deployed manually to the target position.

After the Patient Cart is normally activated, press the function buttons on the helm with one hand, hold the clamping handle with the other hand, and move the drive box with slight force.



Figure 9.3 Move the Drive Box

Note: The system has an assist function so the operator does not have to apply large force when moving the drive box.

9.2.3 Patient Cart Docking

Docking is the process of moving the Patient Cart to the operating table and connecting the instrument arm to the cannula.

Note: Before docking, it is recommended to detect the patient's internal condition through a hand-held endoscope to determine whether there are conditions for surgical operation before deciding whether to proceed with docking.

Movement

Once cannula is inserted in the patient, a non-sterile person moves the Patient Cart into the sterile field.

When moving the Patient Cart, the Patient Cart should be moved slowly in the expected direction of movement by holding the drive enable switches on the handlebars with both hands simultaneously. The person providing directions should use anatomical or room references (such as “toward the head” or “away from the Camera Control Unit”) to direct the Patient Cart movements. The person providing directions should avoid using relative terms such as “left” or “right”.

Note: Before moving the Patient Cart to the sterile area, ensure that the Patient Cart has been draped.

Note: The system has an assist function so the operator does not have to apply

large force when moving the Patient Cart.

Note: Move the Patient Cart by holding the drive enable switches with both hands simultaneously. One-hand operation can only move the Patient Cart forward or backward.

Note: To prevent movement during surgery, the Patient Cart automatically activates the motor drive brake after docking.

Warning: Ensure that the cannula is reliably attached, as failure to do so may result in incomplete cannula attachment or accidental detachment of the cannula during the procedure.

Warning: Make sure there is adequate room for the arm to move without contacting the patient. Ensure that the patient-side assistant can see the arm during the procedure and can alert the surgeon when the arm is close to contacting the patient.

Caution: Unexpected motion can occur when instruments collide. Ensure there is adequate room for instruments to move inside the patient.

Caution: Pay attention to avoid collisions.

Cannula Connection

Insert the cannula into the patient and position the patient.

When the connection between the cannula and the arm is completed, the system automatically locks and allows only forward and backward movement by moving the drive box around the remote center and along the axis of the cannula, and limits the speed of movement.

9.3 Puncture Kits

9.3.1 Product Overview

The puncture kits include cannulas, obturators and cannula seals. For detailed instructions, see 2.6.3 Puncture Kits. Refer to the reprocessing instructions manual for cleaning instructions.

Only a physician or medical personnel under the supervision of a physician should use cannulas, obturators and cannula seals.

9.3.2 Compatibility Information

The puncture kits are compatible with the instruments and endoscope. The cannulas, obturators and cannula seals are available in different lengths. The following table presents

compatibility information of cannulas, obturators, and cannula seals.

No.	Cannula	Obturator	Cannula Seal
1	SP1406, Cannula	SP1502, Obturator	SP0801, Cannula Seal
2	TR1-SP, Cannula	TR2-SP, Obturator	TR3-SP, Cannula Seal

9.3.3 Inspection before Use

Warning: Follow instructions to properly inspect the cannula before use. Do not use a damaged cannula as this may lead to parts falling into the patient or tissue injury.

Warning: Do not use an obturator with visible cracks or other damage, as this may lead to tissue injury.

Warning: Do not use the reprocessed cannula with the cannula seal installed. Inadequate sterilization may occur when the single-use cannula seal is installed during reprocessing, resulting in infection.

- Cannula seals are for single use only and comes in a sterile package. Inspect the packaging and ensure it has no tears. Do not use if the packaging is damaged or not intact.
- Confirm the date of manufacture and the shelf life and do not use any expired accessories.
- Inspect cannulas and obturators for cleanliness. If there is residual soil on the device, clean and sterilize the device in accordance with the reprocessing instructions manual.
- Inspect the integrity of cannulas, obturators and cannula seals. If any damage or abnormalities are observed, do not use the accessories.
- Hold the device up close and inspect for damage. Examples of damage include rough edges, dents, cracks, corrosions or a noncircular shape that may interfere with the smooth insertion of an instrument.
- Insert the obturator into the cannula to inspect the inner diameter of the cannula. If the obturator cannot be inserted smoothly or fully, it indicates the cannula is damaged.

9.3.4 Intraoperative Operation

Warning: Follow instructions for proper insertion of the cannula, including correct attachment of the obturator, to prevent tissue injury.

Warning: Follow instructions for proper attachment of the cannula seal to prevent loss of insufflation.

Warning: The cannula must be used with the cannula seal. Do not insert an endoscope or instruments through a cannula without a cannula seal installed, as this may result in device damage resulting in parts falling into the patient.

Warning: Follow instructions for proper use and safe handling of port accessories, to prevent device damage leading to parts falling into the patient.

Note: If the cannula and cannula seal are soiled intraoperatively, gently wipe with sterile gauze moistened with sterile saline or water as needed.

1. Carefully inspect the cannula, obturator and cannula seal prior to use. See 9.3.3 Inspection before Use for details.
2. Using standard surgical technique, make a skin incision to introduce the cannula and obturator. Note that the incision should match the cannula and obturator.
3. Attach the obturator to the cannula.

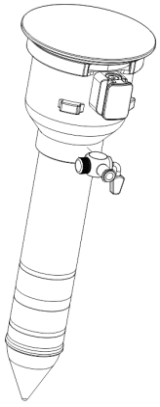


Figure 9.4 Insert the Obturator into the Cannula

4. Make the tip of the obturator pass through the wound protector.
5. Insert the wound protector with the obturator and cannula assembly into the incision and install the protector.
6. Remove the obturator, leaving the cannula in place.
7. Install the cannula seal.
   a. Align the top of the cannula seal with the cannula by alignment marks and then insert the cannula seal into the cannula.

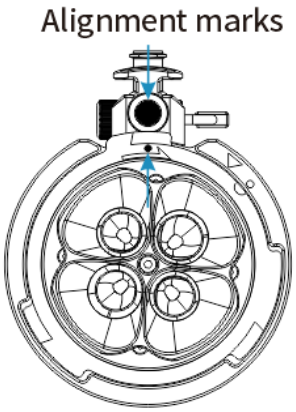


Figure 9.5 Insert the Cannula Seal into the Cannula

b. Rotate the top of the cannula seal clockwise until the alignment marks line up.

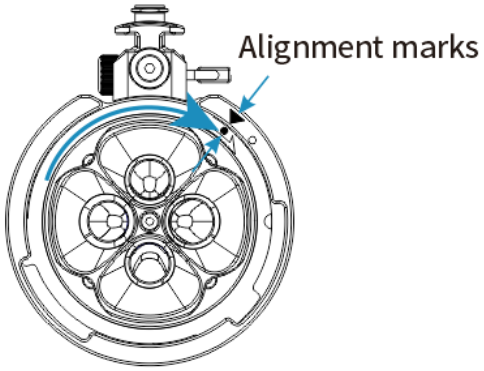


Figure 9.6 Lock the Cannula Seal into Place

8. According to the specific procedure being performed, the remote center of the cannula marked in a thick black line should be placed within the boundaries of the body wall.

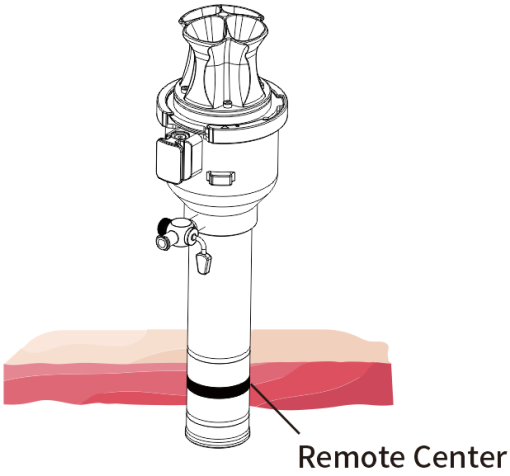


Figure 9.7 Remote Center on Cannula

9. Once port accessories are placed, attach the cannula to the drive box of the Patient Cart.



Figure 9.8 Attach the Cannula to the Drive Box

a. Rotate the fixing knob towards the OPEN direction into place (that is, the solid black dot on the knob lines up with the solid black arrow on the handle).
b. Snap the cannula adaptor into the cannula mount and press gently with fingers to ensure that it is in place.
c. Rotate the fixing knob towards the CLOSE direction into place (that is, the solid black dots on the knob and handle line up).

10. Insert and remove the instruments and endoscope through the cannula and cannula seal intraoperatively.

The cannula seal consists of four ports. The port identified by a symbol is the common endoscope port and another port opposite can be also used as an endoscope port. Except the endoscope port, the remaining three ports can be used as instrument ports.

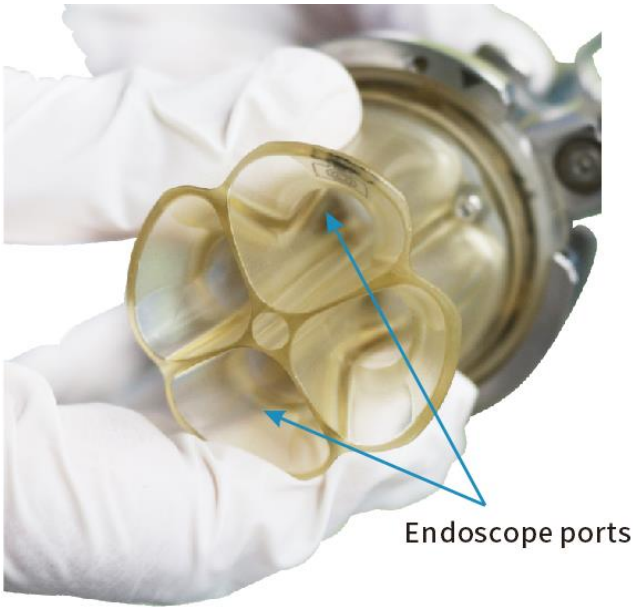


Figure 9.9 Ports on the Cannula Seal

11. To remove the cannula, first detach the cannula and cannula seal assembly from the system, and then remove the cannula and cannula seal assembly from the body cavity.

9.4 Endoscopic Instruments and Accessories

9.4.1 Instrument Overview

The instruments have an articulating design at their distal tips that mimics the human wrist. Each instrument is used to perform a specific surgical task such as grasping, suturing, or tissue manipulation. The instruments enable the surgeon to operate precisely in a minimally invasive surgery.

The instruments are mainly composed of instrument housing, flush ports, release buttons, emergency button, pins, drive chucks, shaft, wrist and tip. The overall structure of these instruments is the same except for slight differences in the structure of the tips.

The following figures are examples of instruments. For reference only, please refer to the actual situations.

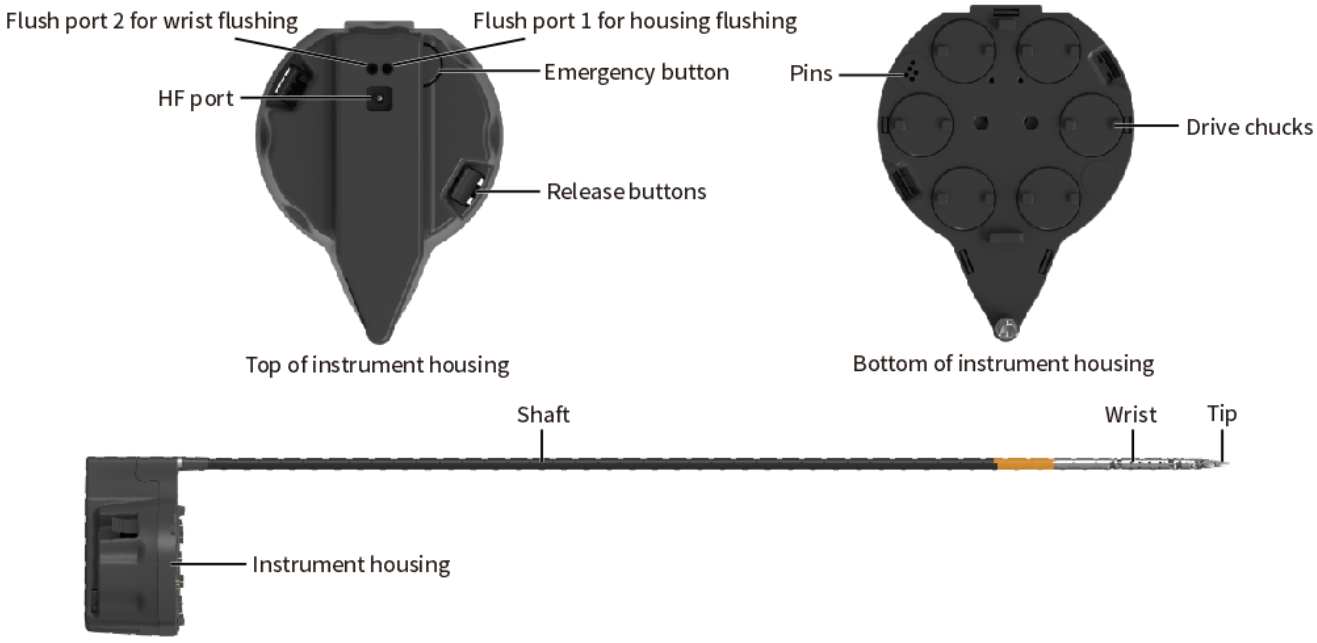


Figure 9.10 Instrument Components

- Instrument housing: The instrument housing engages with the adaptor on the instrument drive, and can be used as a handle, for instrument identification and reprocessing.
- Release buttons: The two release buttons, one release button on each side of the instrument housing, are used to disengage the instrument from the instrument drive for removal.
- Flush ports: The two flush ports are used for instrument reprocessing.

- Drive chucks: The drive chucks are connected to the instrument wrist and can be used to translate the movements from the Surgeon Console master controls.
- Pins: The pins are used to communicate with the Patient Cart and for instrument identification.
- Shaft: The shaft inserts through the cannula and rotates as controlled by the Surgeon Console.
- Wrist: The articulating wrist provides a wide range of movements and improves the flexibility of movements.
- Tip: The instrument's end effector (for example, grasping, suturing, or tissue manipulation).
- Emergency button: In case of emergency, the button is rotated to manually release the instrument grips.
- HF port: The port is used to connect monopolar energy instrument cord or bipolar energy instrument cord to high frequency generator.

Refer to the reprocessing instructions manual for cleaning instructions.

Note: Use only the instruments and accessories approved by the company. System compatibility with non-approved instruments and accessories cannot be guaranteed. The warranty does not cover damage to the system that occurs as a result of using non-approved instruments and accessories.

Note: The instruments are supplied non-sterile and should be cleaned and sterilized thoroughly before first use and after every use. Refer to the reprocessing instructions manual for detailed instructions.

General Warnings and Cautions

Warning: The instruments are designed and manufactured for a specific surgical function. Using an instrument for a task other than that for which it is intended may result in injury, damage to instruments or equipment.

Warning: Operate instruments with care. Avoid contact between instruments inside the patient and do not apply excessive force with the instruments, especially during instrument insertion motions to prevent instrument damage leading to parts falling into the patient or tissue injury.

Warning: Avoid collisions between the instruments and endoscope to prevent unintended instrument motion leading to tissue injury.

Warning: Do not use the reprocessed instruments with single-use accessories (for example, tip cover accessory) installed. Inadequate sterilization may occur when these single-use accessories are installed during reprocessing, resulting in infection.

Warning: Unless it is stated, do not use the instruments on cartilage, bone or hard objects. Doing so may cause damage to the instruments and difficulty in removing 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: 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.

Warning: Instruments and accessories contain metal components. To prevent immunological or bio-incompatibility reaction, ensure that patients do not have metal allergies.

Caution: After the lifetime has been expired, the functionality of the device will deteriorate, which may result in a risk of use.

Note: Only instruments specified by our company may be used, and our company shall not be responsible for any risks arising from the use of other instruments.

Note: Before inserting instruments, make sure that the pneumoperitoneum pressure is in the target range so that there is enough room to place the instruments.

Inspection before Use

Warning: Inspect the instruments prior to use and be careful when using the instruments, to prevent use of damaged instruments resulting in parts falling into the patient or tissue injury.

Warning: Inspect instruments and cables for damage prior to use, especially the insulation of the instruments. This may be done visually under magnification.

Warning: Do not use the instruments and associated accessories with any defects or signs of damage. Otherwise, serious injury or surgical complications may occur to the patient.

Visually inspect the instruments for damage or abnormalities. Examples of damage or abnormalities include:

- Scratches, cracks or broken parts on the instrument housing or shaft
- Cracks or missing pieces where the grip attaches to the shaft
- Broken, bent, misaligned or gouged instrument tip or grip
- Broken wrist or elbow joint segments
- Loose tip or grips
- Broken or frayed cables or wires, or broken away from location

9.4.2 Tip Cover Accessories

The tip cover accessory is used to cover the shaft and joints of the instrument or endoscope to reduce ingress of biological material into the instrument or endoscope, allow smooth insertion and retraction through the cannula seal, and provide electrical insulation during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, and thoracoscopic surgical procedures. For detailed instructions, see 2.6 Accessories.

Compatibility Information

The tip cover accessory is only compatible with the instrument or endoscope provided by Shenzhen Edge Medical Co., Ltd. as shown in the following table.

Tip Cover Accessory	Compatible Instrument or Endoscope
Tip Cover Accessory, SP1306	Monopolar Curved Scissors, SP1301
Tip Cover Accessory, SP4-S	Monopolar Curved Scissors, SP3-MS
	Monopolar Curved Scissors, SP1301
Tip Cover Accessory, SP1307	Maryland Bipolar Forceps, SP1304
	Fenestrated Bipolar Forceps, SP1303

Tip Cover Accessory	Compatible Instrument or Endoscope
	Needle Driver, SP1305
	Large Needle Driver, SP1335
	Monopolar Hook, SP1302
	Medium-Large Clip Applier, SP1332
	Cadiere Forceps, SP1334
	Tip-up Fenestrated Grasper, SP1337
	Round Tooth Retractor, SP1333
	Curved Needle Driver, SP1309
Tip Cover Accessory, SP4-I	Maryland Bipolar Forceps, SP3-BM
	Fenestrated Bipolar Forceps, SP3-BF
	Needle Driver, SP3-ND
	Large Needle Driver, SP3-LND
	Medium-Large Clip Applier, SP3-CA
	Cadiere Forceps, SP3-CF
	Tip-up Fenestrated Grasper, SP3-TG
Tip Cover Accessory, SP1403	Endoscope, SP1207

Warning: The tip cover accessories must be used with the compatible instruments. Using with unauthorized instruments cannot achieve the desired effect.

Warning: Remove the tip cover accessories before reprocessing. Failure to remove may result in incomplete cleaning and sterilization.

Warning: To prevent energy delivery to unintended tissue resulting in patient injury, do not use a torn tip cover accessory.

Inspection before Use

- Tip cover accessories are for single use only and comes in a sterile package. Inspect the packaging and ensure it has no tears. Do not use if the packaging is damaged or not intact.

- Confirm the date of manufacture and the shelf life and do not use any expired tip cover accessories.
- Visually inspect tip cover accessories and installation tool for damage or abnormalities. Examples of damage or abnormalities include punctures, cuts, scratches, tears, unusual bumps or significant discoloration. Do not use the accessories with any defects or signs of damage.

Installation

Follow the steps below to install the tip cover accessory onto the instrument or endoscope.

1. Close the blades of the instrument. If the instrument has no blades, skip this step.
2. Straighten the wrist of the instrument.
3. Grasp the tip cover accessory, and slide it onto the distal end of the instrument.



Figure 9.11 Slide Tip Cover Accessory onto Instrument

4. Aligning the clamps of the installation tool with the rings on the metal part of the tip cover accessory, squeeze the buttons on both sides of the tool and pull the tip cover accessory until the tip cover accessory locked in place.

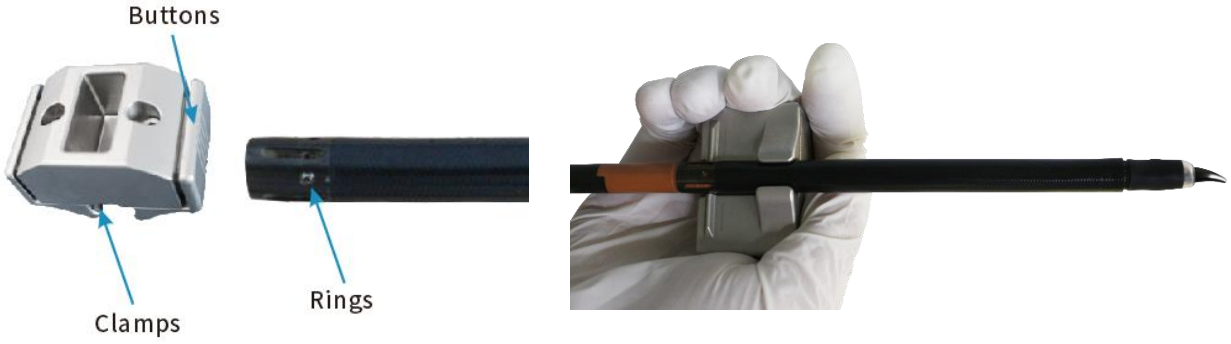


Figure 9.12 Install Tip Cover Accessory with Installation Tool



Figure 9.13 Tip Cover Accessory Properly Installed

5. Remove the installation tool and retain it to aid in removing the tip cover accessory.

Warning: Failure to install the tip cover accessory may cause:

- Blades opening improperly.
- Tip cover accessory falling off.
- Electrical arcs and alternate site burns.
- Difficult instrument installation.

Removal

After each procedure, remove the tip cover accessory from the instrument. The installation tool is also used to facilitate removal. Always inspect instruments for any defects or damage after tip cover accessory removal. If any abnormality is detected, do not use the instrument.

Discard the tip cover accessory in compliance with institution biohazard protocol and all applicable national and local laws and guidelines.

9.4.3 Energy Instrument Cords

The monopolar or bipolar instruments are equipped with high frequency ports, and are connected to the high frequency generator to deliver energy through monopolar energy instrument cord or bipolar energy instrument cord.

1. Prepare a compatible high frequency generator.
2. Connect the energy instrument cord to the generator.



Figure 9.14 Connect Monopolar Energy Instrument Cord to Generator



Figure 9.15 Connect Bipolar Energy Instrument Cord to Generator

3. Connect the energy instrument cord to the instrument.

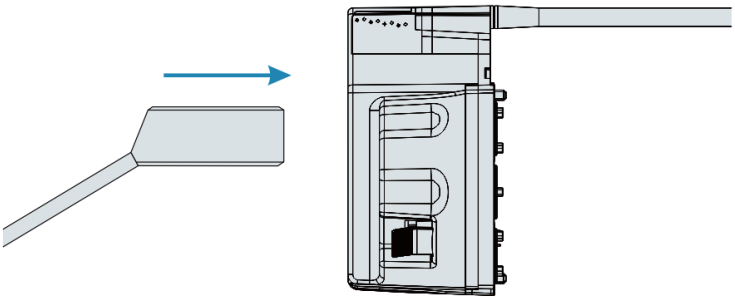


Figure 9.16 Connect Energy Instrument Cord to Instrument

Warning: Improper installation of the energy instrument cords may result in energy delivery being unavailable.

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

Warning: For patient safety, do not connect the energy instrument cords when not in use.

Caution: Monopolar energy instrument cords may only be connected to monopolar ports, and bipolar cords to bipolar ports.

Caution: The high frequency generator should be connected to the AC power wall outlet separately to avoid circuit overload.

Caution: Do not connect the high frequency generator to the same AC power wall outlet as the Vision System to avoid circuit overload.

Note: Disconnect the high frequency generator from power switch before removing the energy instrument cords.

9.4.4 Instrument Installation

1. Inspect instruments for damage, cracks, chips or wear. Do not use the instrument if it is damaged. See Inspection before Use in 9.4.1 Instrument Overview for details.
2. Straighten the instrument joints manually, and close the jaws by rotating the drive chuck at the bottom of the instrument housing to ensure easy insertion of the cannula to avoid damage to the instrument.

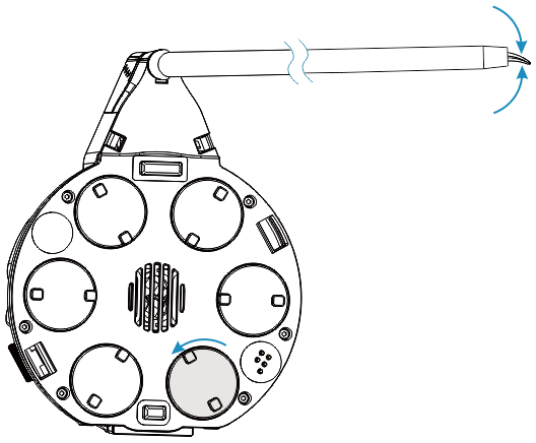


Figure 9.17 Rotate the Drive Chuck to Close the Jaws

3. Ensure that the instrument drive is fully retracted to the loading position. If it is not, press the **Drive Function** button of the instrument drive.

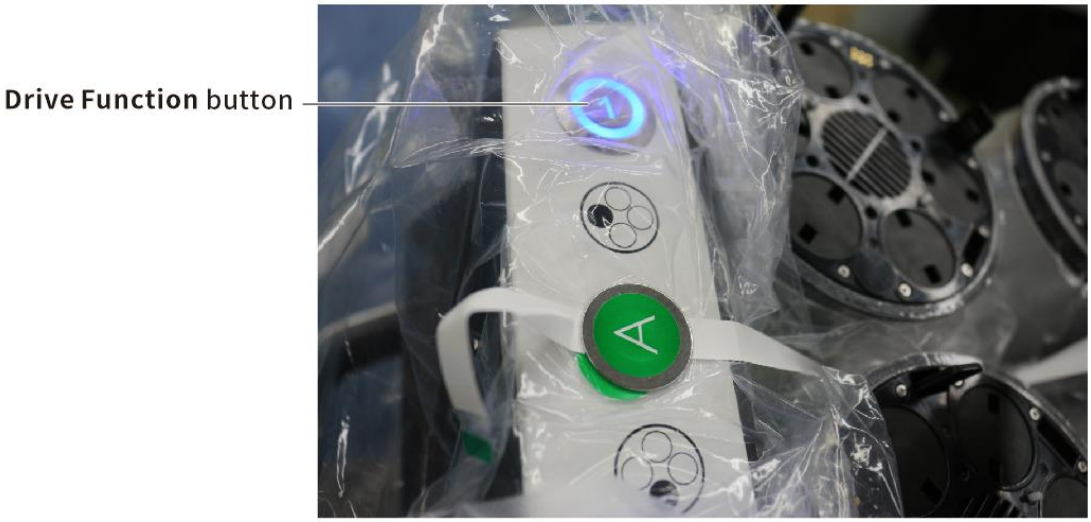


Figure 9.18 **Drive Function** Button

4. Facing the function buttons, insert the instrument tip past the corresponding instrument port and through the cannula seal according to the instrument port indicator (indicating by a solid black circle) on the drive box.

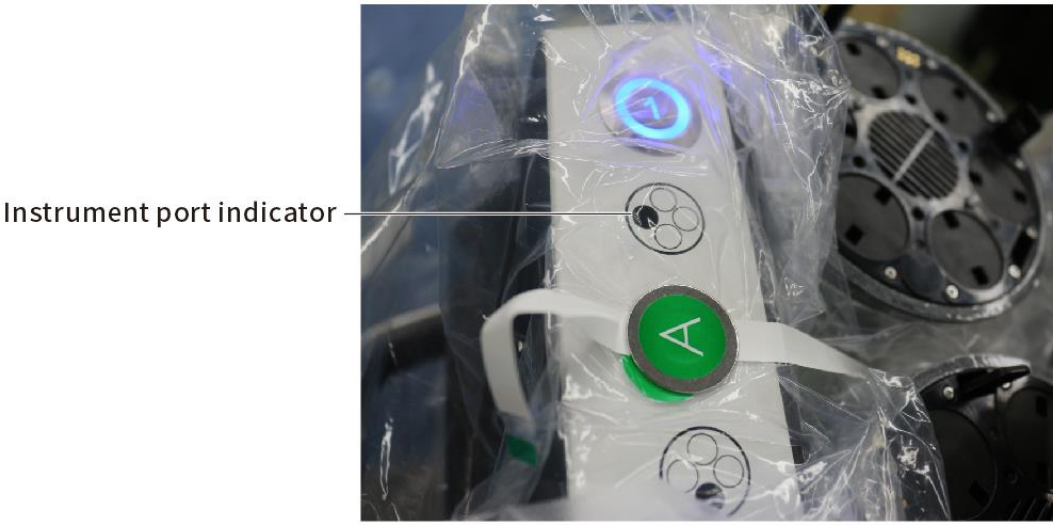


Figure 9.19 Instrument Port Indicator

5. Align the instrument housing with the installation position and press in the adaptor.

   By the following means of alignment:

   - The metal contacts of the instrument housing and the adaptor are aligned for installation.
   - The concave and convex structures of the instrument housing and the adaptor are aligned for installation.



Figure 9.20 Install the Instrument

6. After self-test, press the corresponding **Drive Function** button of the instrument or press and hold the **Drive Hold** button to advance the instrument to the desired position. Press the **Drive Function** button again or release the **Drive Hold** button to lock the instrument.
   - When the progress bar at the bottom of the instrument and endoscope information area displayed on the monitor passes the marking point, indicating that the end joint of the instrument is fully extended out of the cannula, press the **Drive Function** button to lock the instrument.
   - When the progress bar at the bottom of the instrument and endoscope information area displayed on the monitor does not reach the marking point yet, it indicates that the end joint of the endoscope is still within the cannula. Press the **Drive Function** button to lock the endoscope. At this time, the end joint is in a state of straightening, and the angle of the endoscope cannot be switched.
   - When the progress bar at the bottom of the instrument and endoscope information area displayed on the monitor passes the marking point, it indicates that the end joint of the endoscope fully extends the cannula. Press the **Drive Function** button to lock the endoscope. At this time, the end joint is in a bending state, and the angle of the endoscope can be switched.

Note: Install the endoscope before instrument installation and ensure that there is appropriate space, so as to reduce accidental damage.

Note: To prevent puncturing the drape, instruments should be handled carefully when inserted.

Note: The endoscope can only be mounted on instrument drive 2 or instrument drive 3.

Note: Before each insertion, instruments need to be checked for sterilization status markings.

Note: To prevent malfunctions, spare instruments must always be available to complete the procedure.

Caution: Do not operate the **Release** buttons once an instrument is installed to prevent unintended consequences such as disengagement of the instrument from the instrument drive.

Warning: Follow proper instrument installation and removal including ensuring that instrument tips are not positioned near tissue, to prevent tissue injury, instrument damage, or parts falling into the patient.

Warning: The instrument may not be immediately visible when being moved from the cannula into the patient. Move the endoscope to visualize the instrument and use caution when inserting the instrument into the patient.

Warning: After inserting instruments, ensure that all installed instruments are visible in the Surgeon Console before proceeding. This visual inspection prevents inadvertent harm to the patient.

Warning: Before inserting the instruments, ensure that the surgeon is in position at the Surgeon Console.

Warning: In case of system failure while the instrument is grasping tissue, manually open the grips by rotating **Emergency** button on the instrument housing to release the grips and then squeezing both **Release** buttons to remove the instrument.

After the system is turned on, for the instrument drive that inserts the instrument for the first time, the initial attitude after the instrument is inserted into the pneumoperitoneum is an extended pose.

9.4.5 Intraoperative Operation

1. Contact the tissue to be manipulated with the instrument tips. Make sure that the tips do not contact with non-target tissue.

2. Activate the instrument energy functions by pressing the associated foot pedals in the Surgeon Console. If energy activation is not necessary, skip this step.
3. Once tissue manipulation including grasping, cutting, coagulating and suturing is complete, remove the instruments from the surgical workspace and visually inspect adequate hemostasis is achieved.



Warning: Do not use one instrument to energize the tips of another instrument to prevent instrument damage, or unintended application of energy leading to tissue injury. Energy may flow to the patient from places other than the tip, inside or outside the field of view. Avoid close proximity to other instrument tips when energizing monopolar instruments.



Warning: Thermal spread adjacent to target tissue may result in unintended burns to surrounding tissue.



Warning: It is possible for energy to discharge in an area other than the instrument tip. Exercise caution when using an energized monopolar instrument to avoid unintended contact with tissue adjacent to the area to be cauterized.



Warning: Exercise caution when using monopolar instruments close to other instruments. Unintended energy may be delivered from the active monopolar instrument to a second instrument. This could cause burns to tissue in contact with the metal parts or cannula of the second instrument. Ensure that monopolar instrument tip should be closer to the tissue than the second instrument.



Warning: While activating monopolar energy, be careful with the anatomy that is in contact with the instrument wrist or shaft. Do not use the instrument as a retractor while applying energy.



Warning: While activating or using the instruments, do not place them near or in contact with flammable materials, such as gauze or drapes.



Warning: When not using the instruments, do not place them in contact with the patient, fabrics, hard objects or flammable materials. Inadvertent contact may result in injury or damage.



Warning: Aspirate fluid from the surgical workspace before activating the

instrument. Conductive fluids (such as blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat from target tissue and may cause unintended burns to the patient.

Warning: After the RF current is deactivated, some heat may remain on the surface of the active electrode, which may cause burns.

Warning: Due to the carcinogenic and infectious potential of by-products such as tissue smoke and suspended solids from energy sources (electrosurgical procedures), 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 high frequency electrosurgical procedures, ensure the monopolar instruments should be equipped with the neutral electrode.

- 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 high frequency generator.

Warning: To avoid inadvertent electrical arcs from monopolar instruments, do not fire the instrument if the tip is not in contact with target tissue.

Warning: Do not touch the instrument tips while energized. Otherwise, it may cause serious injury.

Caution: Do not place the instrument tips in contact with any staplers, clips or sutures while energized. Otherwise, it may cause damage to the tips.

Note: Use caution when activating monopolar energy during procedures in which contact between the endoscope cannula and the body wall is not assured.

9.4.6 Medium-Large Clip Applier Use

The medium-large clip appliers are made to hold and apply plastic clips for procedures involving ligation of vessels or tissue structures. The surgeon should apply the appropriate clip size for the size of the vessel or tissue structure to be ligated such that the clip completely

encompasses the vessel or tissue structure.

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: Do not use the clip applier as a fallopian contraceptive tubal occlusion device or in ligating the renal artery during laparoscopic donor nephrectomies.

Warning: In procedures other than laparoscopic donor nephrectomy, it is recommended to use more than one clip on the patient side with a minimum distal artery cuff of 2-3 mm beyond the distal clip. Application of a second clip on all other vessels should be dictated by the surgeon's judgment.

Warning: The clip applier is not designated for use as a tissue marker.

Note: The clip applier should be used with compatible plastic clips. The green ligation clips manufactured by Pride Medical Device Technology Jiangsu Co., Ltd are recommended. Use the clips correctly according to the manufacturer's instructions for safety.

Before use, inspect the clip applier for damage, bent components or misalignment and verify the proper clip size for the vessel or tissue structure. Ensure correct operation of the clip applier during use or processing. After application, inspect the ligation site to confirm proper closure of the clip.

1. Fully open the jaws of the clip applier by rotating the drive chucks at the bottom of the instrument housing.
2. Rest the instrument housing on a sterile table. Lift the instrument shaft 45 degree from the table top, straighten and stabilize the instrument wrist.
3. Holding the instrument wrist completely straight, firmly press the plastic clip into the instrument jaws. Ensure that the clip is properly loaded.
   - Pressing too hard with the instrument or the clip may damage the instrument jaws.
   - Touching or squeezing the instrument jaws may result in the clip falling out.

Warning: Only compatible plastic clips can be used. It is the user's responsibility to use any clips not compatible with the clip applier.

Warning: Do not attempt to close the jaws down on a vessel or anatomic structure without a clip properly loaded into the jaws. Closure of empty jaws on a vessel or structure may result in patient injury.

Warning: If excessive motion of the wrist or jaws occurs during loading the clip or inserting the instrument, it may affect grip action and the clip may become slightly compressed, resulting in the clip falling out of the jaws and into the patient during insertion or engagement. Once it happens, remove the clip and insert a new clip.

4. Rotating the drive chucks to make the instrument jaws in half-open position, ensure the instrument tip can be inserted smoothly through the cannula.
5. Install the instrument on the Patient Cart. See 9.4.4 Instrument Installation.

Note: To enter the following mode during clip application, first ensure the corresponding master control is at least 90 percent open. Roll the master control slightly to enter the following mode. Do not move the master control closed in any way to activate the following mode to avoid the clip being compressed or falling out of the instrument.

6. When closing the clip by the Surgeon Console, ensure the master control is completely closed. If the master control is not adequately closed, there may be a larger clip gap than required.

9.4.7 Instrument Removal

Before retracting and removing an instrument, the surgeon should do the following:

1. Make sure the instrument is free and away from the patient’s anatomy.
2. Clearly communication with the patient-side assistant about which instrument to remove. Identify the instrument name and the function button number (1, 2, 3, 4).

To remove an instrument, the patient-side assistant should do the following:

1. Make sure the instrument is free and away from the patient’s anatomy.
2. Press and hold the corresponding **Drive Function** button of the instrument or the **Drive Hold** button. Retract the instrument to the loading position. The system automatically straightens the instrument joints to allow for full retraction.

3. Squeeze the **Release** buttons on both sides of the instrument housing and slide the instrument up and out through the instrument drive.



Figure 9.21 Remove the Instrument

Warning: Ensure that instrument tips are not positioned near tissue and always visualize instrument tips when inserting and removing the instruments. If the instrument is not visible, retract endoscope to visualize entrance of the instrument into the surgical field.

Note: Removing an instrument during a procedure should be performed with care and only when the surgeon is informed of the removal and has the instrument in full view. Do not remove the instrument when it is not in view.

Note: Removing an instrument during a procedure should be performed with care to avoid damage to the instrument arm drape.

Note: Make sure the tip of the instrument is not grasping tissue before removal.

Note: Any lateral pressure on the instrument during removal may damage the instrument.

Note: Ensure that the instrument is retracted to the top of the instrument drive before removing it.

9.4.8 Intraoperative Cleaning

If the tip of an instrument is contaminated by carbonized tissue intraoperatively, remove the instrument from the patient and carefully wipe the instrument tip with a piece of soft sterile gauze moistened in saline or sterile water.

Warning: Do not use one instrument to clean another instrument inside the patient. Otherwise, it may result in instrument damage, leading to parts falling into the patient or tissue injury.

Warning: Take care not to twist the tip cover accessory when cleaning the instrument tip intraoperatively. Otherwise, it may cause the tip cover accessory to loosen and fall into the patient, leading to tissue injury.

Caution: Keep the active electrodes clean. Build-up of eschar may reduce the instrument's effectiveness. Do not activate the instrument while cleaning. Injury to user may result.

9.4.9 Instrument Lifetime

Instruments are designed for a predetermined number of uses to ensure reliable and consistent performance throughout the life of the instruments. The system decrements one use from an instrument the first time it is installed and taken into following mode during a procedure. If an installed instrument is not controlled by the Surgeon Console, it can be removed without reducing the number of remaining uses.

When the instrument is used for the last time during a procedure, the system displays the message to remind that the instrument will expire. The instrument can be used in the current procedure, but will not be available for the next procedure.

Viewing Remaining Uses

The remaining number of uses (expiration information) for all instruments used in the current procedure can be viewed on the touchscreen of the Surgeon Console or the Patient Cart. The remaining uses of instruments will be displayed.

Expiration and Disposal

When an instrument expires, it can no longer be used. Expired instruments must be properly disposed of in accordance with all applicable national and local laws and regulations.

Caution: Using expired instruments may cause hazards to patient safety.

9.4.10 Fluid Leakage Precautions

The instruments are designed so that they can be positioned horizontally or inclined upwards as needed during a procedure. As with any laparoscopic instrument, these positions allow

blood or other fluid to migrate through the instrument shaft towards its proximal end. The instruments are designed to resist fluid migration and minimize fluid leakage from the proximal end. However, if blood or other fluid is noticed leaking out of the instrument and onto the arm drape or adaptors during the procedure, do the following:

1. Remove the instrument from the instrument drive and hold it vertically (tip down) to drain the fluid.
2. Before inserting other instruments, thoroughly wipe any fluid off the adaptor and drape.
3. After a procedure, thoroughly clean the instruments following the cleaning instructions in the reprocessing instructions manual.

In addition, if any blood or other fluid is observed inside the drape (on instrument drives), stop use and contact the company for technical support as soon as possible.

9.5 Emergency Management

9.5.1 Emergency Stop

The **Emergency Stop** button is located on the helm of the Patient Cart. Pressing the **Emergency Stop** button will stop system operation. The instruments and endoscope will pause in motion and the excitation signal from the high frequency generator will stop.

Emergency stop initiates a recoverable fault, which can be overridden on the Patient Cart or Surgeon Console touchscreen.

Note: When pressing the **Emergency Stop** button, not only the Patient Cart functions but also the Surgeon Console functions are disabled. After the system is restored, the surgeon needs to match grips again before controlling the instruments.

9.5.2 Emergency Grip Release

Warning: In case of system failure while the instrument is grasping tissue, manually open the grips by rotating the **Emergency** button on the instrument housing to release the grips and then squeezing both **Release** buttons to remove the instrument.

Caution: Do not use the emergency grip release in a non-fault situation without pressing the **Emergency Stop** button. Otherwise, it may result in unintended instrument motion.

Caution: Rotating the **Emergency** button in the incorrect direction may cause unintended instrument motion.

Note: Whenever possible, use the Surgeon Console controls to release the instrument grips.

In the event of a system fault or the instruments out control of the Surgeon Console, when the instrument is grasping tissue, the patient-side assistant will be allowed to manually release the instrument grips. Perform the following steps under surgical visualization:

1. Press the **Emergency Stop** button.
2. Rotate the **Emergency** button in the direction indicated by the arrow on the instrument housing to open the instrument grip.
3. Confirm that the grips are not grasping tissue under the endoscopic view or direct visualization.
4. Once the tissue is released from the grip, squeeze the **Release** buttons on both sides of the instrument housing to remove the instrument.
5. Override the fault on the touchscreen or restart the system if necessary.

9.5.3 Emergency Power Off

During emergency power off, the system will get into a braking state. In the event of such emergency, do the following:

1. Perform emergency grip release according to 9.5.2 Emergency Grip Release.
2. Remove the instrument.
3. Disconnect the cannula from the instrument arm.
4. Activate the unlock pedals on the Patient Cart.
5. Remove the Patient Cart from the patient.
6. The surgeon performs emergency surgical treatment on the patient.

9.6 Stowing the Patient Cart

If all drapes have been removed, stow the Patient Cart for transport through the hospital or within the operating room and for storage when not in use. Retract the column and instrument arm from their current positions to a predefined default stow position. The Patient Cart is stowed when the structure is in its most compact state.

Press and hold **Enable Boom Controls** on the Patient Cart touchscreen, and simultaneously push the **Boom Position Control** button up. The Patient Cart will retract the column and instrument arm. Hold and push the button up until the instrument arm and column are fully retracted and the system emits a completion tone.

For sterile stowing the draped Patient Cart, see 6.5.3 Sterile Stowing the Draped Patient Cart (Optional).

10. Surgeon Console Use

10.1 Surgeon Console Overview

The Surgeon Console is the control center of the entire system. The surgeon can observe image of the surgical site through the viewer, and control the instruments and endoscope through two master controls. For a complete description of the Surgeon Console components, see 2.2 Surgeon Console.

10.1.1 Master Controls

The master controls are located below the magnified three-dimensional image of the surgical site. The surgeon grasps the master controls while viewing the surgical site.

The instrument tips as seen in the viewer appear aligned with the surgeon's hands at the master controls.



Figure 10.1 Master Controls

Caution: If instruments cannot be manipulated in a precise and controlled manner, contact the company for technical support.

For more details on the use of master controls, see 10.3.1 Matching Grips and 10.3.2 Finger Clutch Use.

10.1.2 Viewer

The viewer is a high resolution screen that provides the surgeon with video images. Icons and text messages are overlaid on top of the video, providing extended information for the surgeon. With his or her head in the viewer, the surgeon can view the 3D image in full screen mode.



Figure 10.2 Viewer

10.1.3 Armrest

The armrest contains **Ergonomic Control** buttons for ergonomics settings, a touchscreen for settings, a **Power** button, and an **Emergency Stop** button.

10.1.4 Touchscreen

The touchscreen is the primary control interface for the Surgeon Console. For detailed functional descriptions, see 10.2 Surgeon Console Settings.

10.1.5 Ergonomic Control Buttons

As shown below, the **Ergonomic Control** buttons on the left side of the armrest provides ergonomic adjustment control to the Surgeon Console.

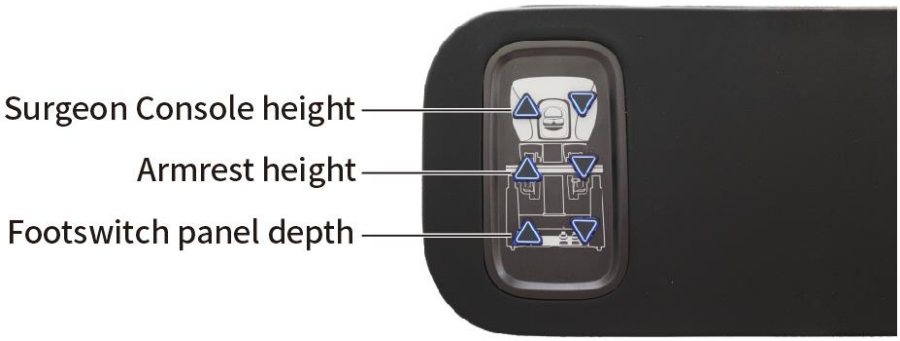


Figure 10.3 **Ergonomic Control** Buttons

For more details on ergonomic adjustment, see 10.2.1 Ergonomic Settings.

10.1.6 Emergency Stop and Power Buttons

The control buttons on the right side of the armrest consist of an **Emergency Stop** button and a **Power** button.

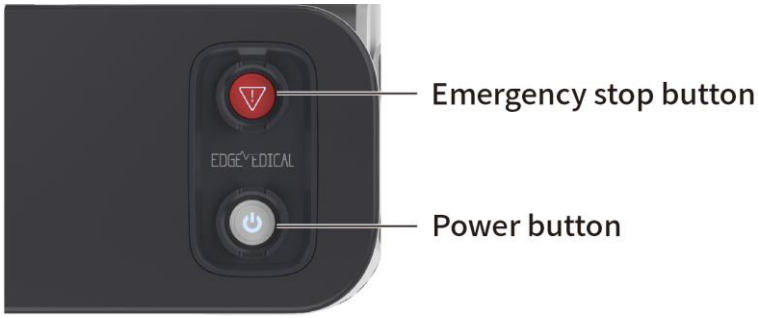


Figure 10.4 **Emergency Stop** Button and **Power** Button

To stop system operation, press the red **Emergency Stop** button. The **Emergency Stop** button ceases the system control of the instruments and endoscope. The instruments and endoscope remain in the last commanded position.

If the instrument grips are closed when the **Emergency Stop** button is pressed, the grips remain closed, but the gripping force may be reduced.

Pressing the **Emergency Stop** button initiates a recoverable fault and can be overridden by tapping **Resume Use** on the touchscreen. See 13.3 Emergency Stop for details.

10.1.7 Footswitch Panel

The footswitch panel allows the surgeon to control the endoscope, instruments, and instrument functions (such as cutting, coagulation) without removing his or her head from the viewer. For more details about the footswitch panel, see 10.3.3 Footswitch Panel Use.



Figure 10.5 Footswitch Panel

10.2 Surgeon Console Settings

10.2.1 Ergonomic Settings

Note: Before adjusting the **Ergonomic Control** buttons of the Surgeon Console,

make sure there is adequate room for the components to move.

Perform the following steps to adjust the **Ergonomic Control** buttons of the Surgeon Console:

1. Adjust the chair height so the surgeon's legs are in a comfortable position.
2. Adjust the viewer height so the surgeon can access the viewer comfortably.
3. Adjust the armrest height so the surgeon's arms can rest comfortably with his or her shoulders relaxed.
4. Adjust the footswitch panel depth so the surgeon can access the foot pedals comfortably.

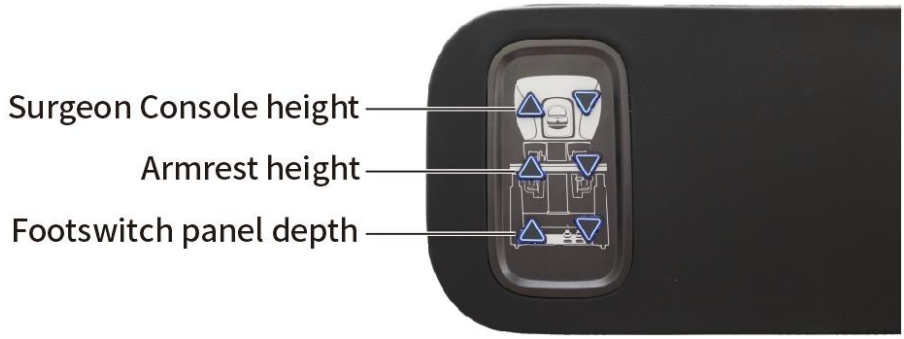


Figure 10.6 **Ergonomic Control** Buttons

10.2.2 Account Authority

The feature of account authority allows a surgeon to operate the system after he or she log in to an applicable account, which can prevent the account information from being modified or the system from being operated improperly by any unauthorized individual.

There are two types of accounts, surgeon account and admin account. Specific access control functions are as follows:

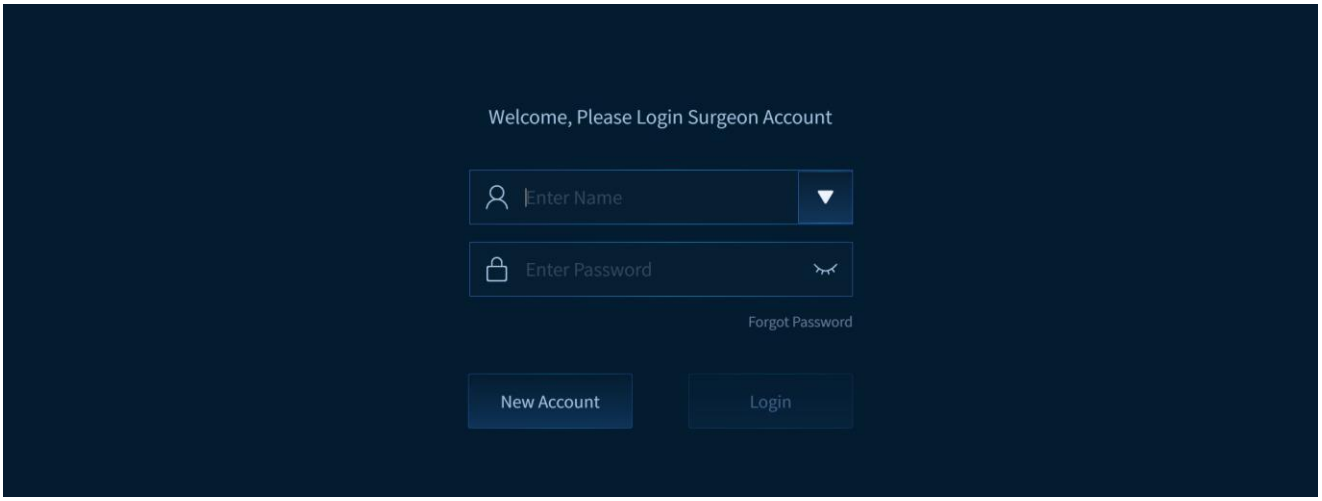
- Account Tab
  - Surgeon account: After logging in to surgeon account, surgeon can restore ergonomic, edit account, change password, logout and delete account.
  - Admin account: After logging in to admin account, surgeon can restore ergonomic, logout and delete surgeon account.
- Instrument Tab

  The Instrument tab allows surgeons to view the status for instruments and endoscope, take photo, endoscope angle, quick-adjust audio, usage, limit UI, etc.
- Settings Tab

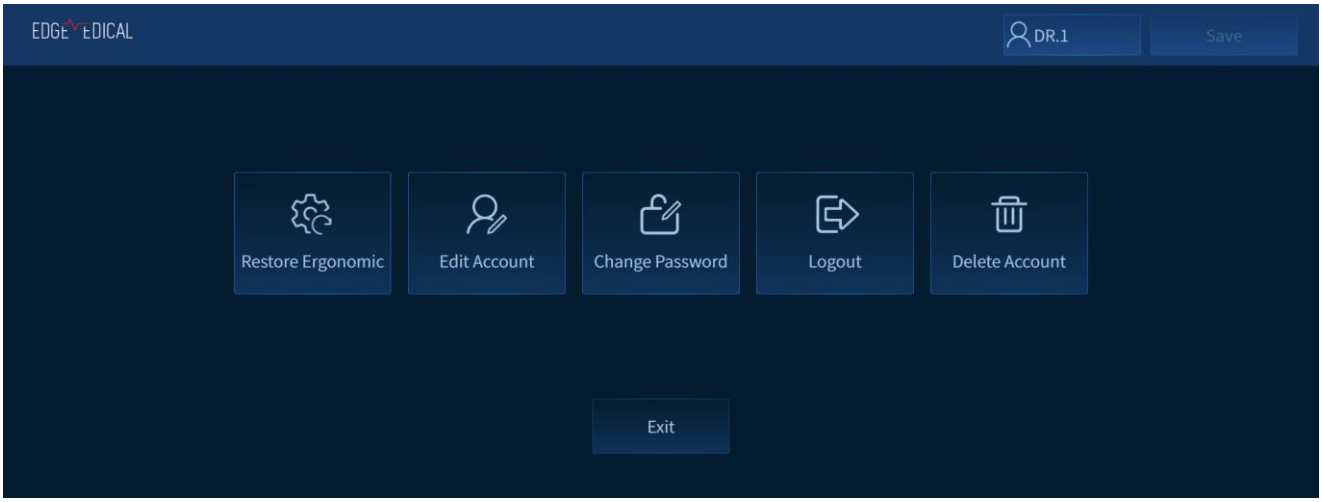
The Settings tab allows surgeons to configure system settings, including image, viewer, PiP, controls, account, general settings, etc. and acquire the software version. Besides, admin account lists more detail on software information.

Logging In to Surgeon Account

1. Enter the name and password of surgeon account.



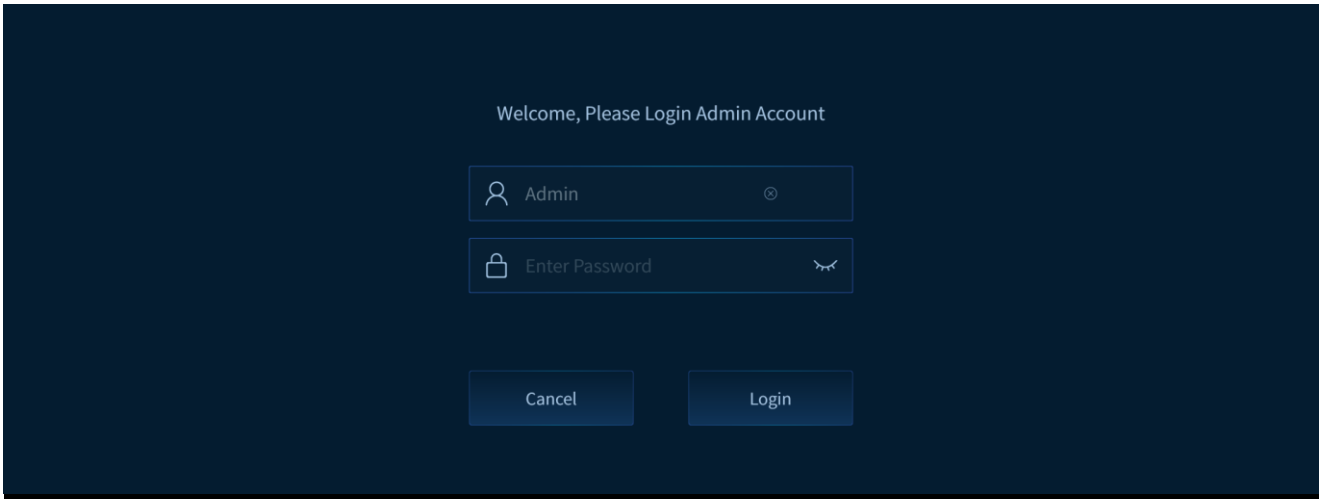
2. Tap the **Login** button and the Account tab appears.



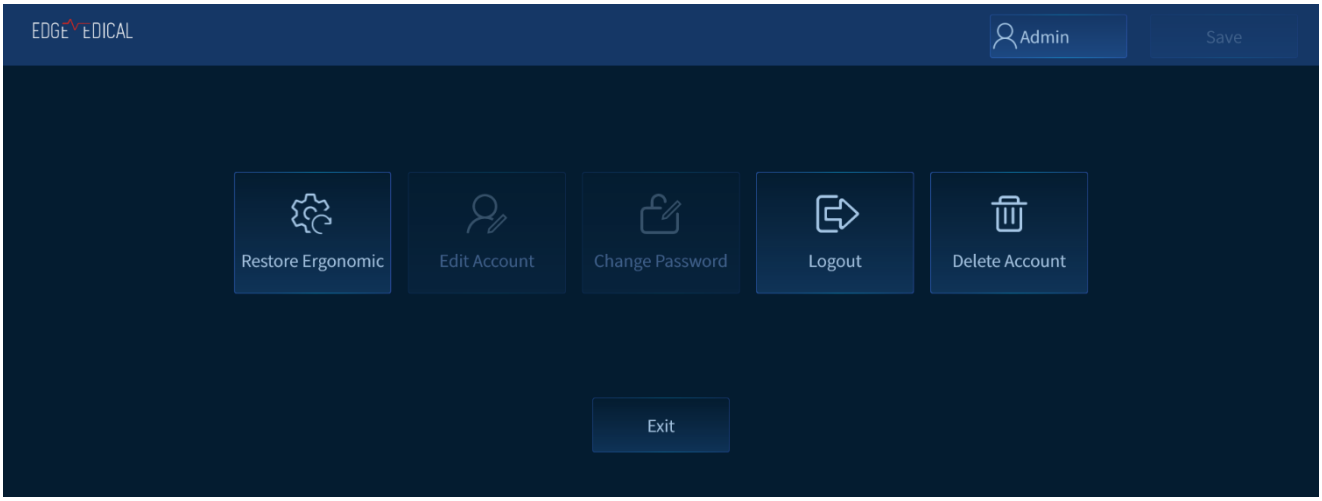
Logging In to Admin Account

1. Enter the name and password of admin account.

   The default name is Admin and the password is edgemp1000.

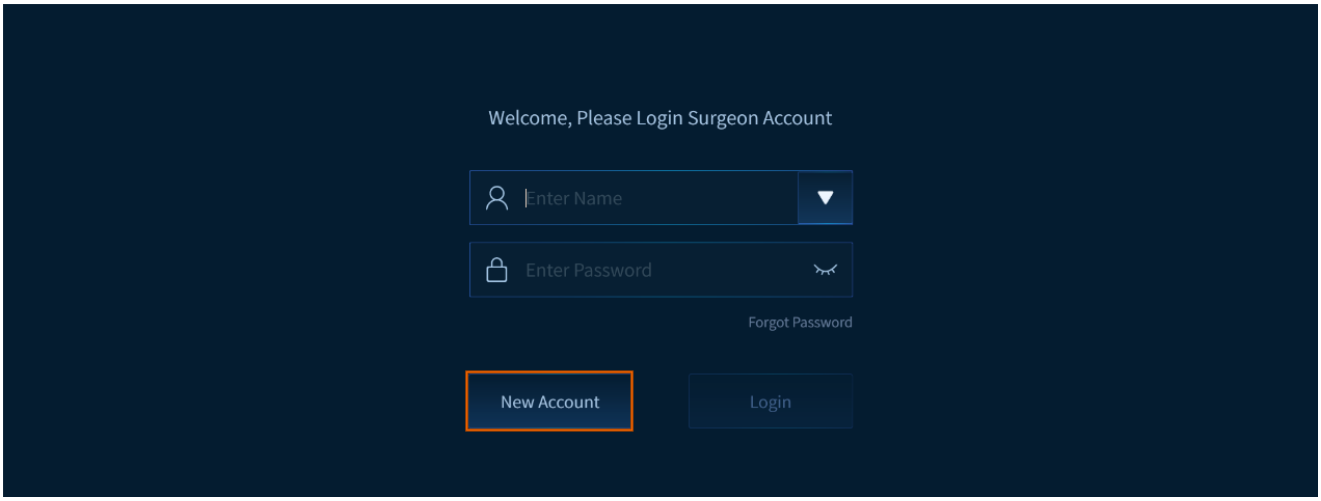


2. Tap the **Login** button and the Account tab appears.

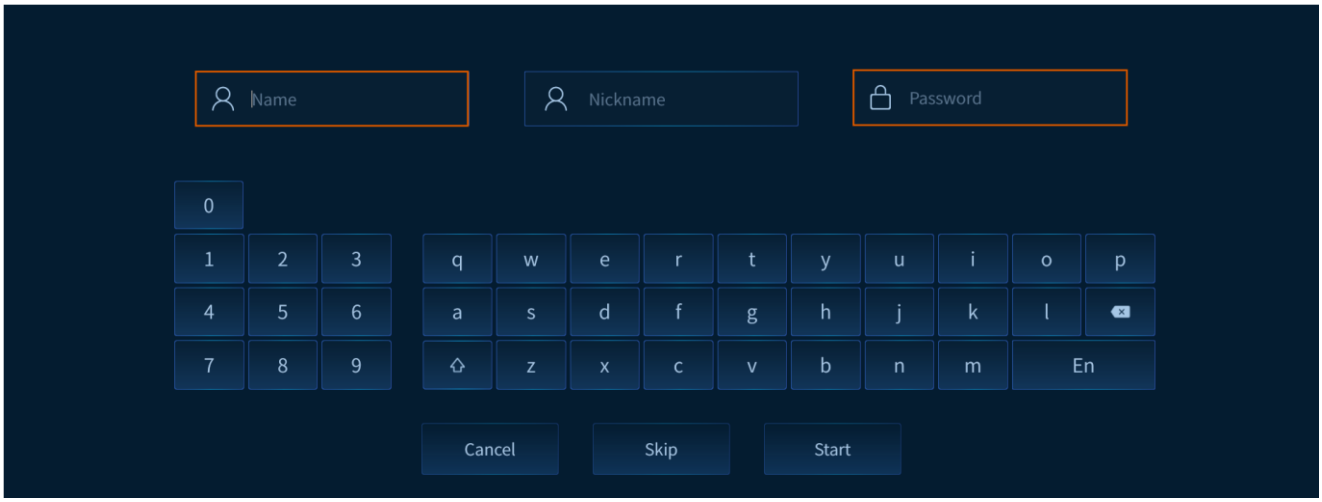


10.2.3 New Accounts

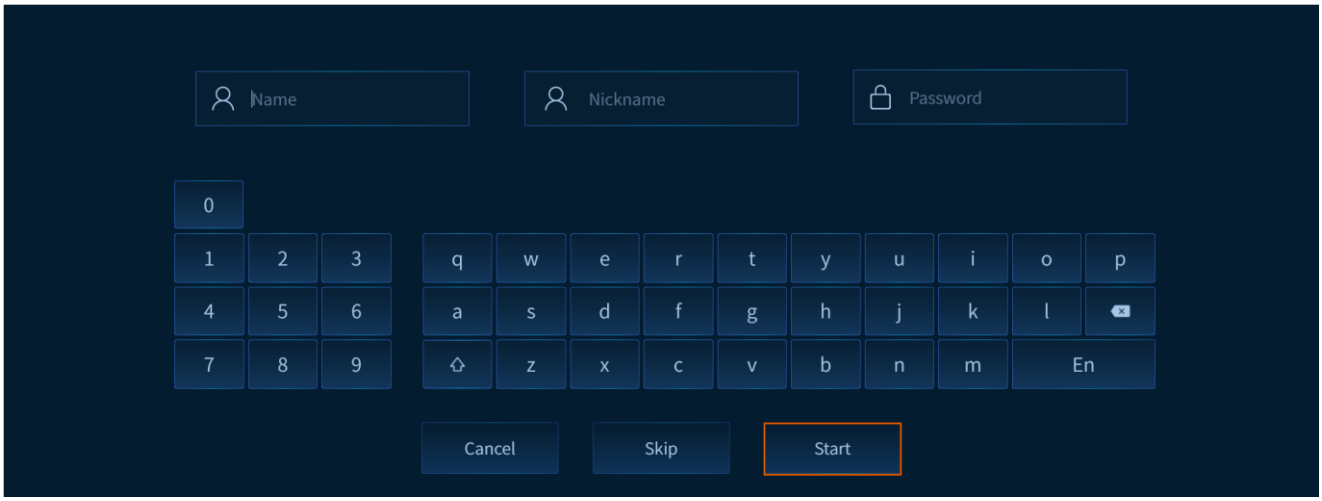
1. When logging in a surgeon account, tap **New Account**.



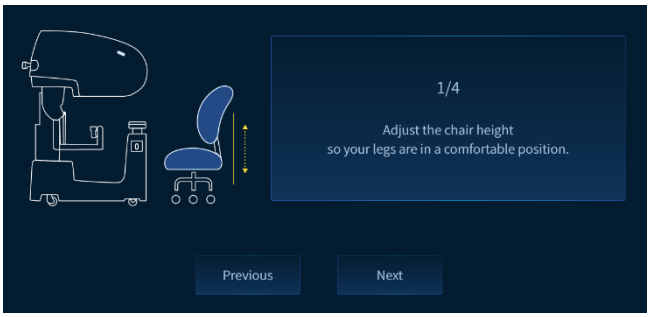
2. Enter the name and password of a new account.

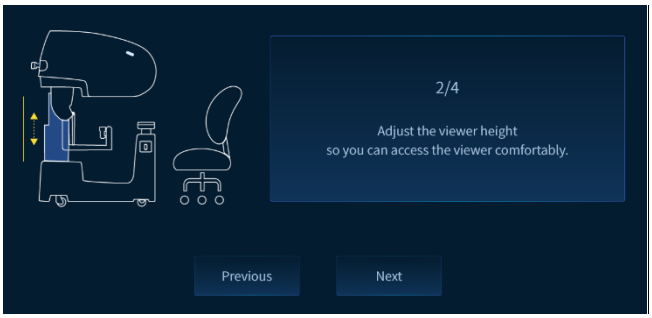


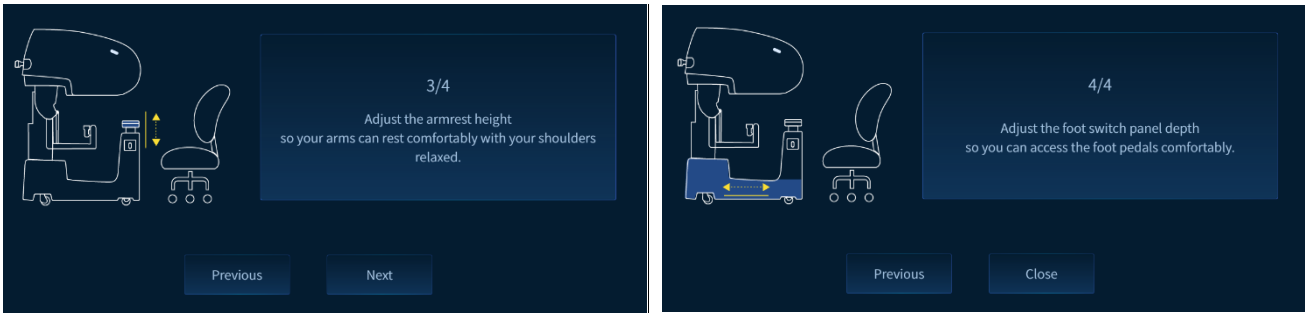
3. Tap the **Start** button.



4. Complete the personalized settings according to the guidance of ergonomic settings: According to the instructions on the touchscreen, press the **Ergonomic Control** buttons on the left side of the armrest to adjust the chair height, viewer height, armrest height and footswitch panel depth in sequence.







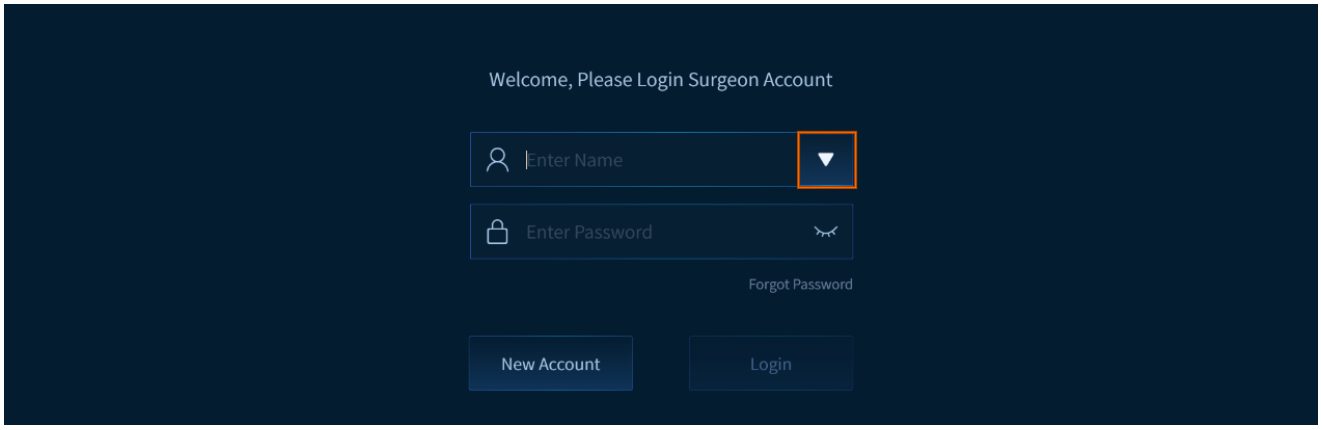
5. When ergonomic settings complete, tap the **Close** button.

10.2.4 Save Settings

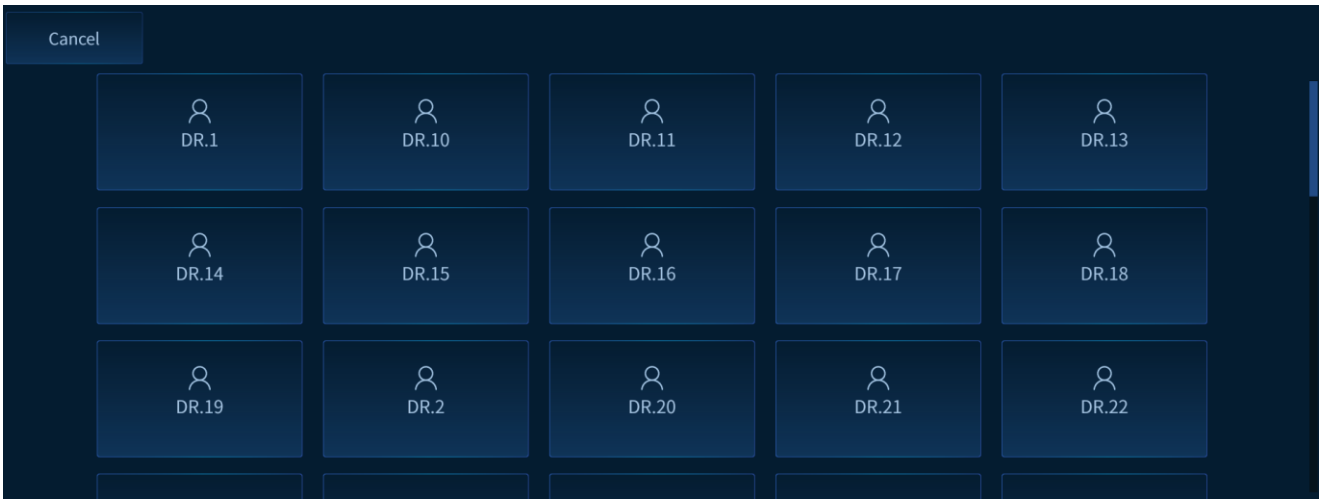
The Surgeon Console allows the surgeon who have previously created a surgeon account to save the last set of adjustable settings. When there are some changes, tap the **Save** button to save the changes. When the system asks for confirmation, select **Yes** to save or **No** to cancel.

10.2.5 Select Accounts

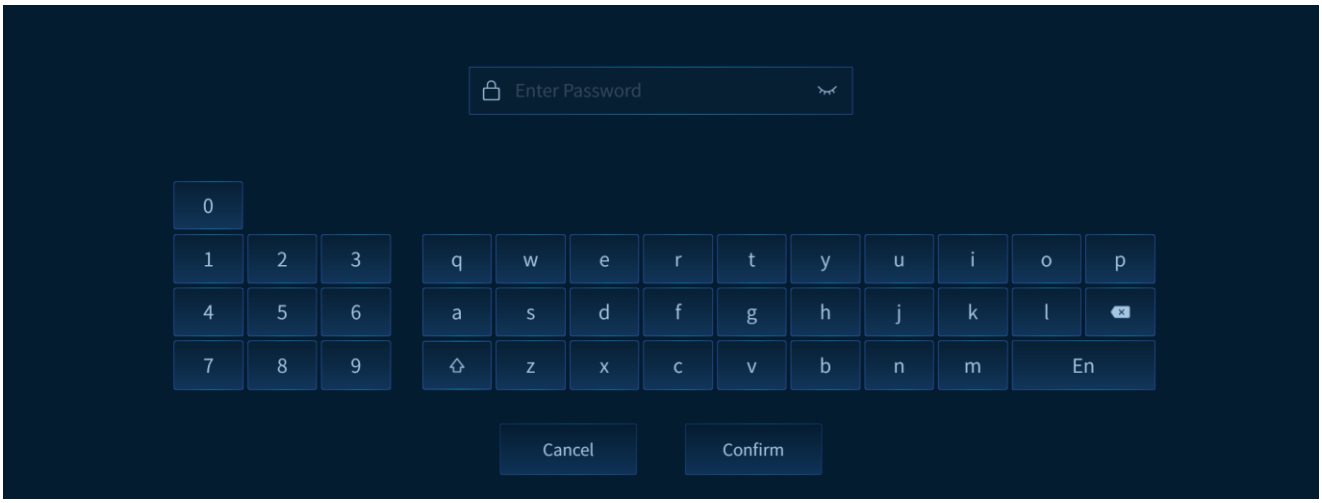
1. When logging in a surgeon account, tap the pull down icon.



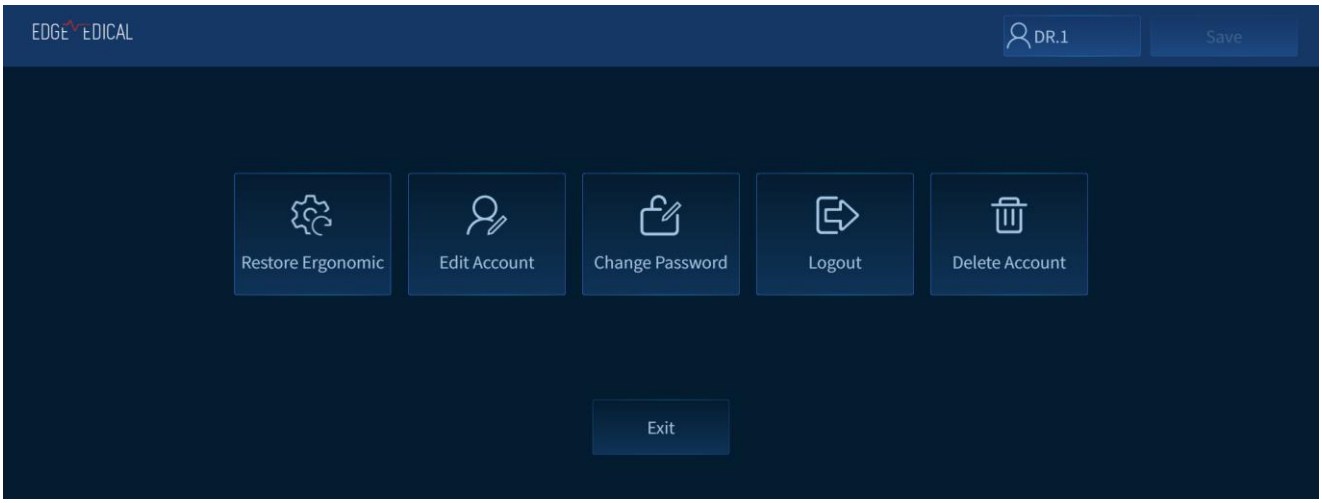
2. Select an account from the user list.



3. Enter the password to log in to the account.



10.2.6 Account Tab



After logging in to an account, the following settings are available:

- Restore Ergonomic: Restore the ergonomic settings, including the chair height, viewer height, armrest height and footswitch panel depth.
- Edit Account: Edit the name and nickname of the surgeon account.
- Change Password: Edit the password of the surgeon account. If a surgeon forgets his or her password, reset the password by admin account.

  Note that the password policy is as follows: 1) Length should be at least higher than 8 digits; 2) Passwords should include uppercase letters, lowercase letters, and numbers; 3) Avoid passwords that are the same as usernames.
- Logout: Log out the current account.
- Delete Account: Delete a surgeon account.

10.2.7 Instrument Tab

The Instrument tab provides instrument status and enables quick settings. The status and controls associated with each instrument or endoscope is displayed on the Instrument tab as instrument status boxes arranged horizontally across the screen.



Instrument/Endoscope Status Box

After an instrument or an endoscope is installed on the Patient Cart arm, its status will be displayed on the corresponding instrument or endoscope status box.

Instrument Status Box

- Instrument name.
- The number of the instrument drive.
- The installation status icon of the adaptor.
- The energy activation status icon of monopolar or bipolar surgical instruments, including no activation available, CUT activated and COAG activated.
- When the instrument is installed on instrument drive 2, appears on the second instrument status box. Tap the button to reassign the master control association from the left master control to the right master control.
- When the instrument is installed on instrument drive 3, appears on the third instrument status box. Tap the button to reassign the master control association from the right master control to the left master control.

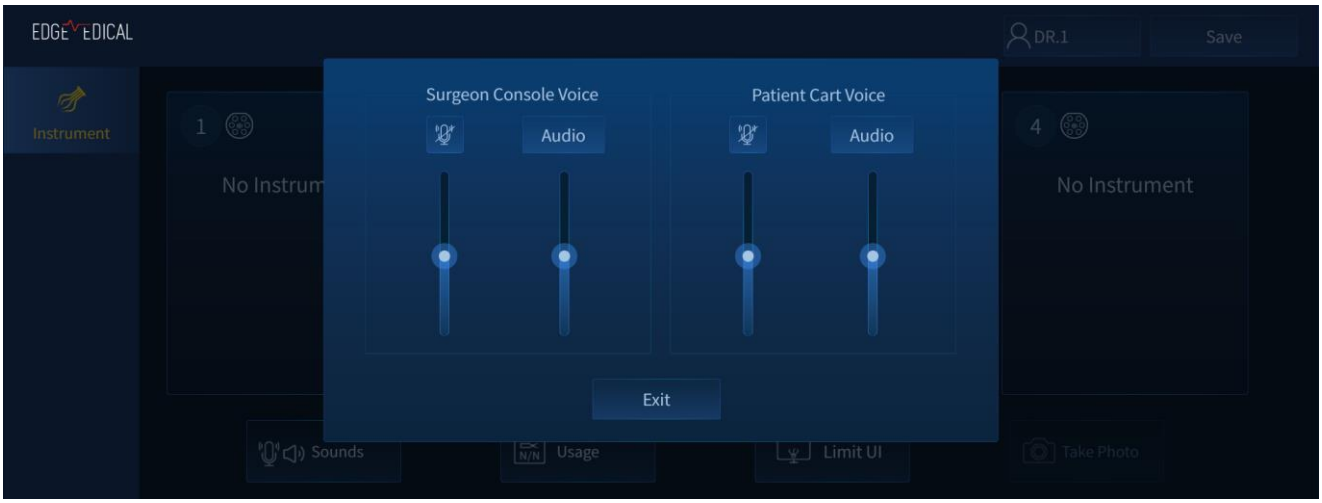
Endoscope Status Box

- Endoscope name.
- The number of the instrument drive.
- The installation status icon of the adaptor.

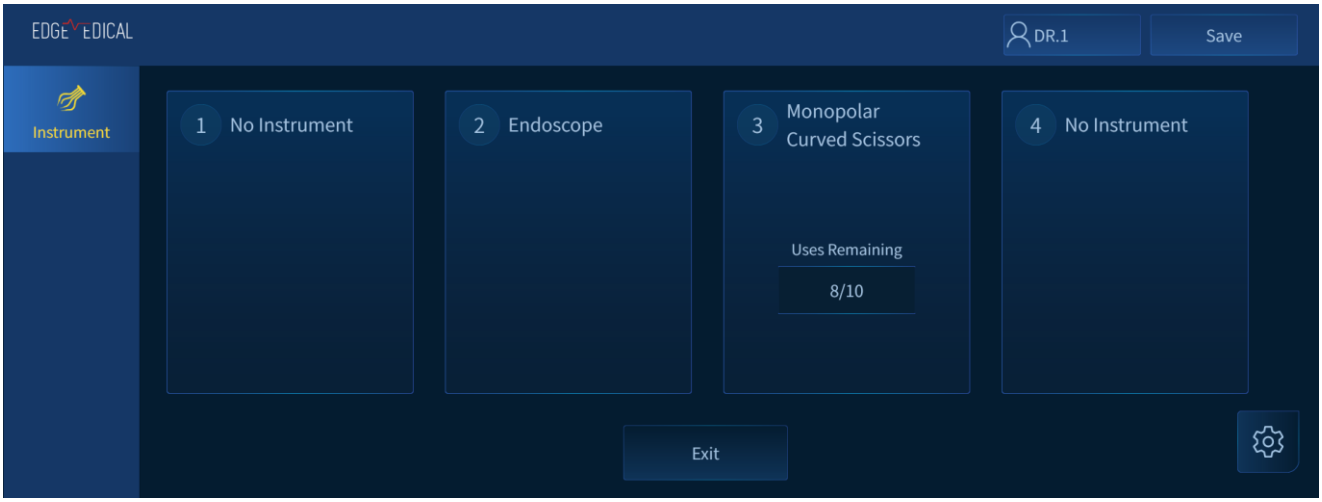
- When the endoscope is installed on the instrument drive, the system detects and displays the endoscope angle. The angled endoscope can be set to the rotation angle of 0° (Straight), 15° (UP), 15° (DOWN), 30° (UP) and 30° (DOWN).
- The magnification of the image (Digital Zoom).
- Press and hold the / button to continuously adjust the endoscope angle, and release the button to stop adjustment. The system automatically identifies to adjust the endoscope angle up or down according to the position of the endoscope.
- Press and hold the / button to straighten the endoscope, and release the button to stop adjustment.

Quick Settings

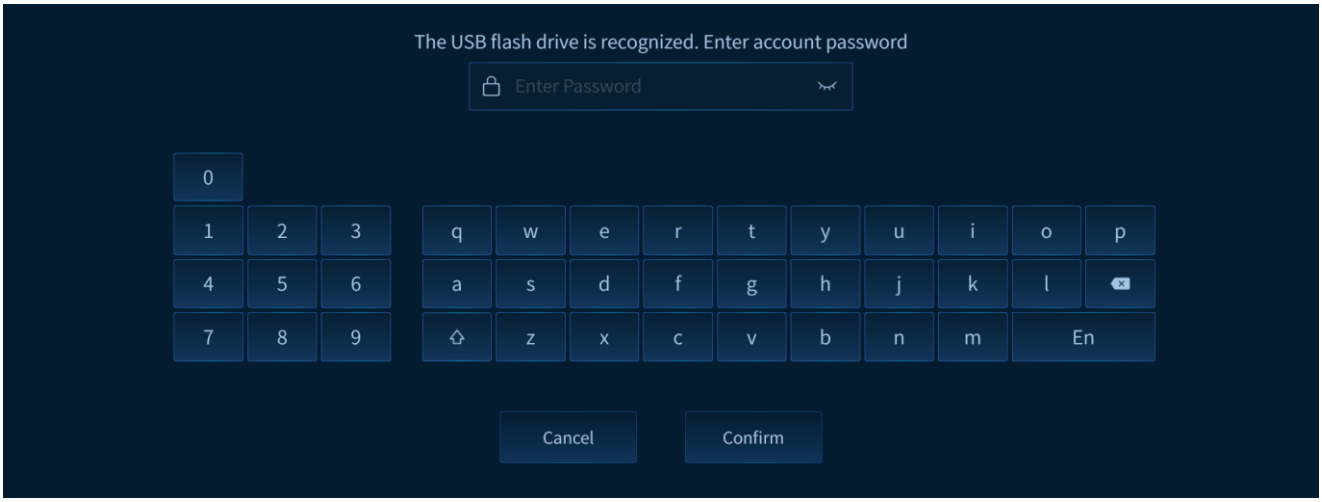
- **Sounds** : It is the button for audio settings. Tap the button to open the dialog to adjust voice of the Surgeon Console and Patient Cart. Drag the slider down to decrease volume or drag up to increase volume.



- **Usage** N/N: It is the button for viewing the uses remaining summary. The number on the left represents the number of uses remaining, and the number on the right represents its maximum uses.

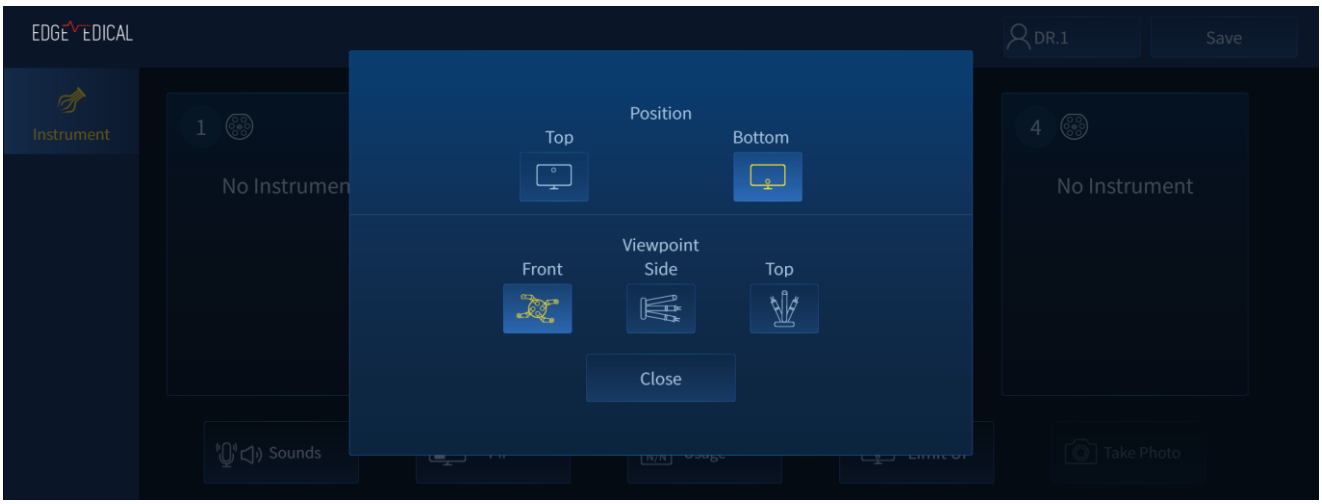


- **Take Photo** : It is the button for capturing the current image of the endoscope and save it to the USB flash drive inserted in the Camera Control Unit. When there is no USB flash drive, the button becomes unavailable. Once the USB flash drive is recognized, enter the account password and tap **Confirm**. Then the **Take Photo** button becomes available.

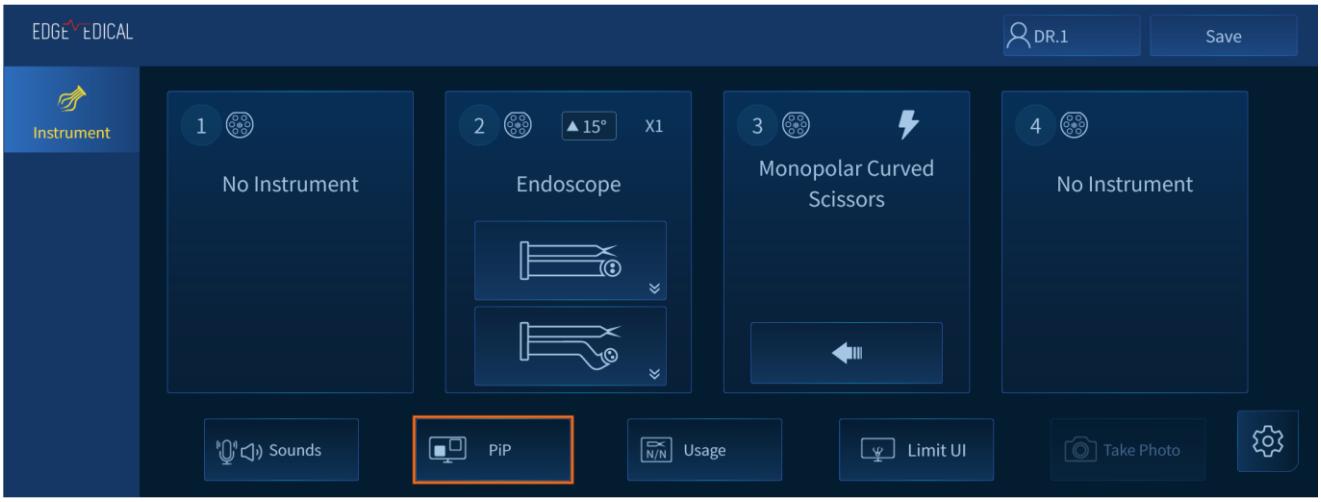


- **Navigator** : Tap the **Navigator** button to open the panel to adjust the navigator position and navigator viewpoint.
  - Position: Allows the user to select between top and bottom screen position of the navigator. The navigator is a graphical representation of the configuration of the instruments and endoscope that appears overlaid on the surgical image near the bottom or top of the surgeon's view.
  - Viewpoint: Provides a front viewpoint, side viewpoint or top viewpoint.
    - Front viewpoint: When set to front view, the upper graphic represents instrument 3 (usually endoscope), the lower graphic represents instrument 2, the left graphic represents instrument 1, and the right graphic represents instrument 4.

- Side viewpoint: When set to side view, the upper graphic represents instrument 3 (usually endoscope), the lower graphic represents instrument 2, the graphic near the screen represents instrument 4, and the one away from the screen represents instrument 1.
- Top viewpoint: When set to the top view, the top graphic represents instrument 3 (usually endoscope), the lower graphic represents instrument 2, the left graphic represents instrument 1, and the right graphic represents instrument 4.

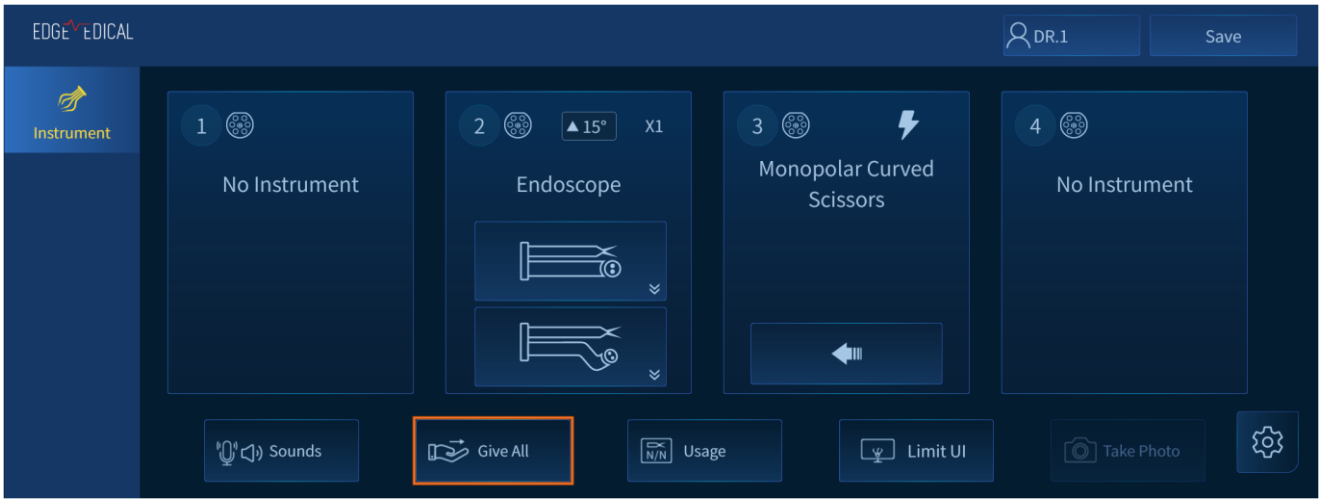


- **PiP** : Select **Settings** > **PiP** > **Shortcuts** > **Show** on the Surgeon Console touchscreen to enable the **PiP** button on the Instrument tab. Tap the button to turn picture in picture on or off.



- indicates **Give All** (Dual Console); indicates **Take All** (Dual Console).

  Toggle to assign control (that is, **Give** or **Take**) of all instruments from one Surgeon Console to another. Tapping either of the buttons will affect control of all instruments. All instruments go out of following until the surgeon matches grips once again.



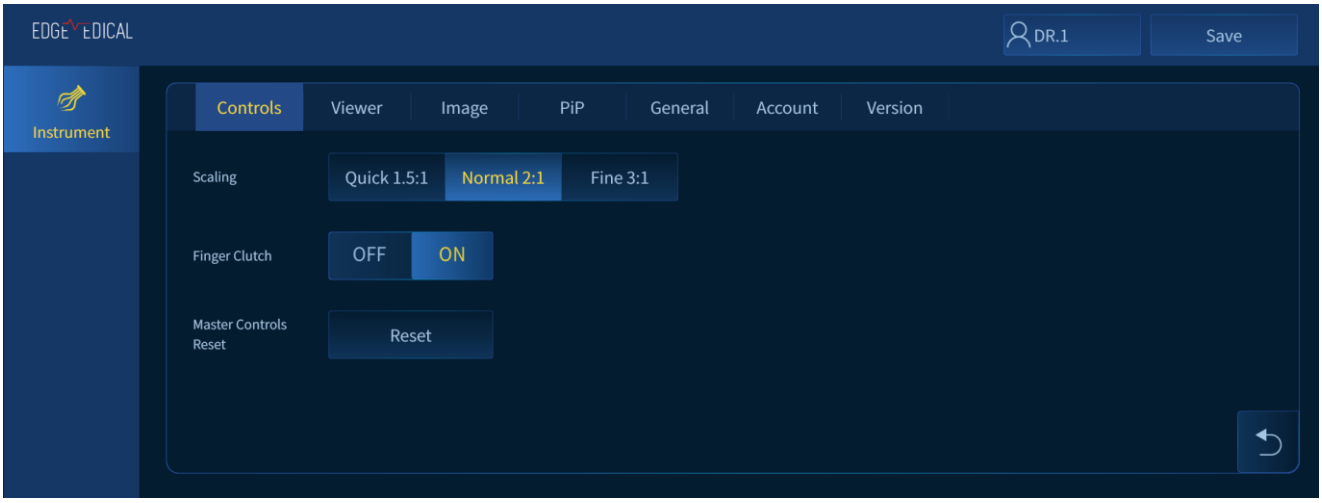
10.2.8 Settings Tab

The Settings tab allows the surgeon to configure a variety of system settings. The available settings are grouped in the following sections:

- Controls
- Viewer
- Image
- Dual Console
- PiP
- General
- Account
- Version

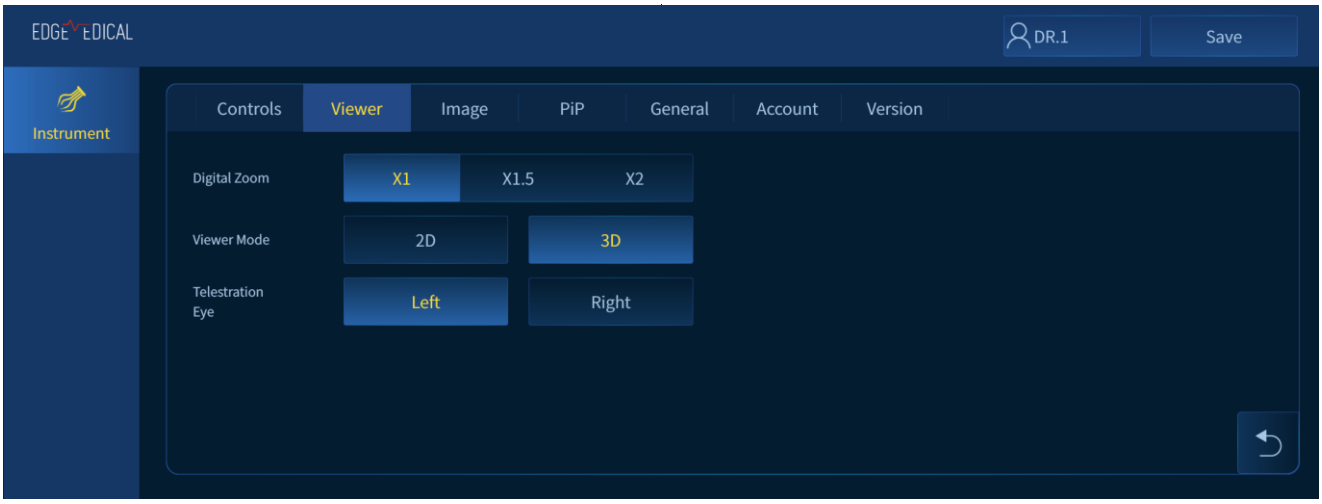
Controls

Tap the **Controls** button to view the controls settings section.



- Scaling: Scale the sensitivity of the master controls in relation to the instruments. Scaling has three settings (**Quick 1.5:1**, **Normal 2:1** and **Fine 3:1**).
- Finger Clutch: Select **ON** or **OFF** to turn finger clutches on or off. When the finger clutches are **OFF**, the surgeon can slide the finger clutches but cannot activate clutching.
- Master Controls Reset: Tap the **Reset** button to reset the master controls.

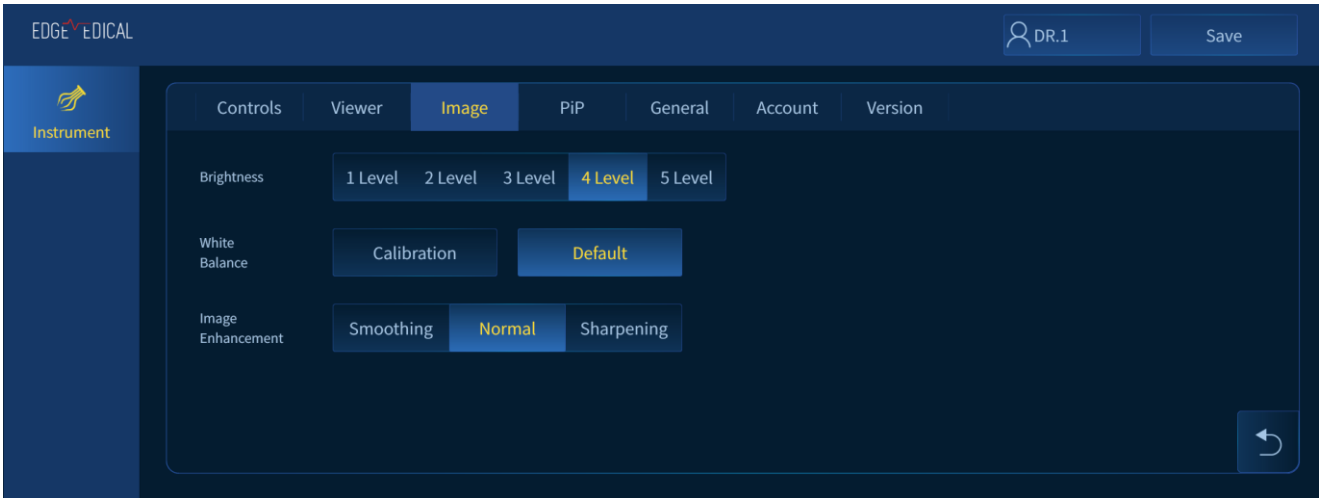
Viewer



- Digital Zoom: Zoom in on the image without changing the position of the endoscope tip. Zoom setting increases the magnification of the image. Zoom has three settings (**X1**, **X1.5**, **X2**).
- Viewer Mode: Toggle the viewer of the Surgeon Console between **3D** and **2D** mode. The viewer displays 3D images by default, and it displays the same images in 2D mode as the monitor.
- Telestration Eye: Toggle the image displayed on the monitor of the Vision System between the left-eye (**Left**) and right-eye (**Right**) image.

Image

Tap the **Image** button to view the image settings section.

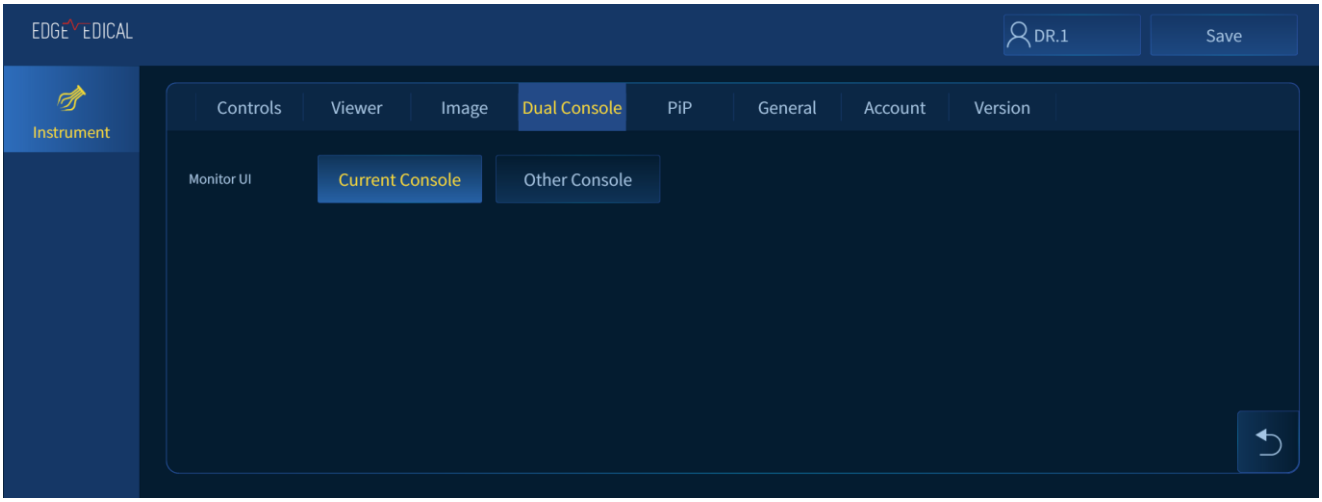


- Brightness: Select five settings (**1 Level**, **2 Level**, **3 Level**, **4 Level**, **5 Level**) to set image brightness, but this will not change the actual light output of the endoscope.
- White Balance: If it is necessary to adjust the perception of white and the ability to display colors properly, point the tip of the endoscope at any clean white surface (such as white gauze), and tap **Calibration** to enable white balance. Tap **Default** to restore white balance to factory default value.
- Image Enhancement: Select three settings (**Smoothing**, **Normal**, **Sharpening**) to enhance image sharpness.

Dual Console

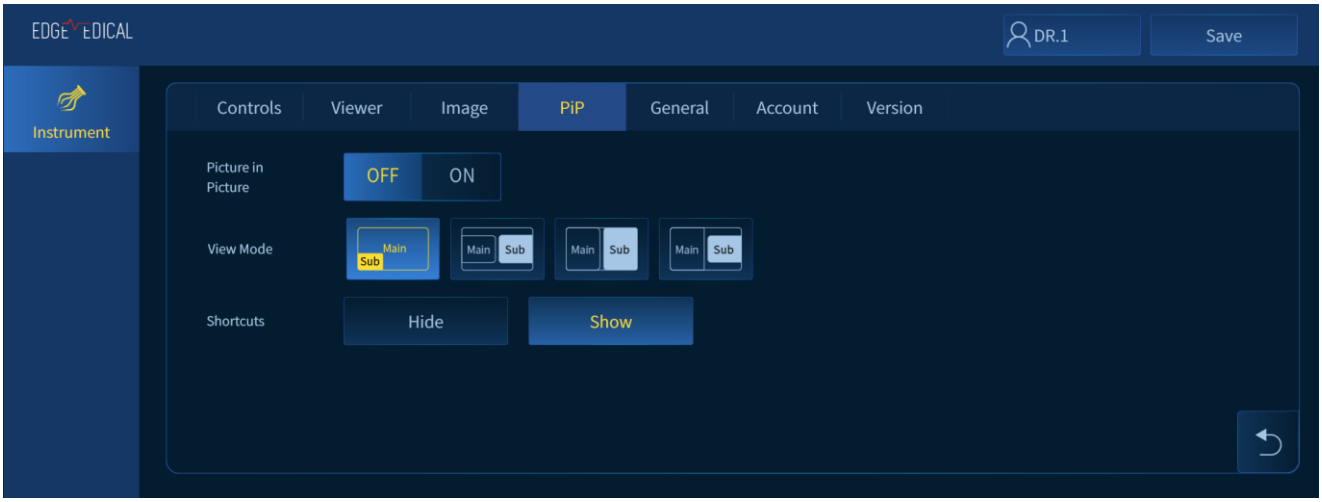
In dual console mode, tap the **Dual Console** button to view the dual console settings.

Monitor UI: The monitor UI can be set to keep consistent with the console UI.



PiP

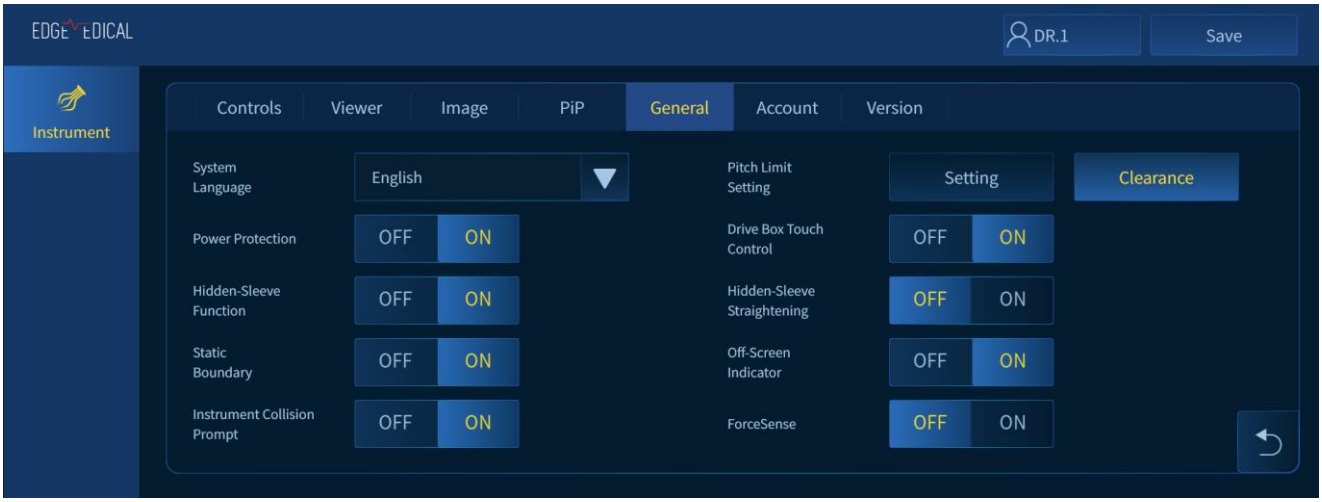
Tap the **PiP** button to view the picture in picture settings section.



- Picture in Picture: The system allows auxiliary video sources, including digital imaging and communications in medical viewer, ECG, ultrasound, endoscope and room camera. The viewer display the live endoscopic image along with the auxiliary images. When connecting an auxiliary video source to the Surgeon Console, tap **ON** or **OFF** to turn picture in picture on or off.
- View Mode: Set the image layout in the display area after connecting an auxiliary video source. There are four view modes. The main image is the endoscopic image while the sub image is the auxiliary image.
- Shortcuts: Hide or show the shortcut key of Picture in Picture on the Instrument tab.

General

Tap the **General** button to view the general settings section.



- System Language: Switch system language to **Chinese** or **English**. After selecting the language displayed on the Surgeon Console, the equipment connected with the Surgeon Console such as the Patient Cart or Other Console changes language synchronously.

- Pitch limit setting: The patient-side assistant can set a pitch limit to control how low the drive box of the instrument arm is allowed to move. When the lowest limit of the instrument arm is set, the drive box cannot move down in the lowest limit. Otherwise, there will be a force in the opposite direction to stop this intended movement.

  This function can be cleared as follows:

  - Clear the lowest limit of the instrument arm in the General settings.
  - Disconnect the cannula from the Patient Cart.
- Power Protection: Select **ON** or **OFF** to turn power protection on or off. When the power protection is **ON**, the motor drive is disabled to ensure that UPS power is adequate for removing the instruments safely from the patient when the Patient Cart is disconnected to AC power.

  The motor drive can be enabled by following means:

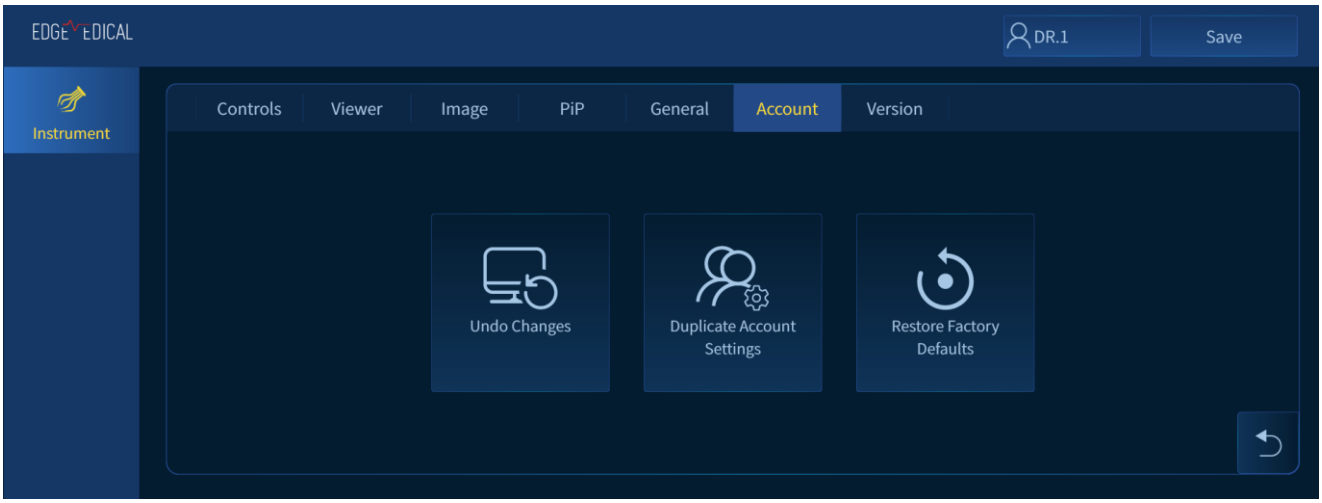
  - Select **OFF** to turn off power protection.
  - When UPS power drops below power protection preset, the motor drive is disabled, and the screen prompts the user to tap **Restore Drive** to enable the motor drive.
- Drive box touch control: Tap **ON** or **OFF** to turn drive box touch control on or off.
- Hidden-sleeve function: Select **ON** or **OFF** to turn hidden-sleeve function on or off. When the hidden-sleeve function is **ON**, the instrument forearm forced straightening can enter into the cannula and separate master-slave movements are available for the instrument wrist. In hidden-sleeve mode, the operator feels resistance feedback when the instrument forearm reaches the cannula opening during wrist deployment.
- Hidden-sleeve straightening: Select **ON** or **OFF** to turn hidden-sleeve straightening on or off. When the hidden-sleeve straightening is **ON**, the operator feels resistance feedback when the instrument forearm reaches the cannula opening during wrist deployment. The instrument wrist needs to be straightened.
- Static boundary: Select **ON** or **OFF** to turn static boundary on or off. When the static boundary is **ON**, the operator will feel resistance from the direction of the boundary when the position or pose of the instrument is outside the boundary. Turn off the static boundary if it is not required.
- Instrument collision prompt: When the instrument collision prompt is **ON**, the screen will prompt to avoid collision before instrument collision.
- Off-Screen Indicator: Tap **ON** to turn Off-Screen Indicator on. When an instrument controlled by master controls is out of view, the off-screen indicator appears on the screen.

Adjust the endoscope view so that it points towards the indicator until the instrument is in the field of view.

- ForceSense: When the ForceSense is **ON**, the drive box can detect forces from outside. If the external force exceeds limit, the drive box will stop movement.

Account

Tap the **Account** button to view the account settings. The section can be shown only after logging in to an account.



- Undo Changes: Restore the settings to the last saved settings by the user, excluding ergonomic settings. To restore ergonomic settings, go to the Account tab and tap the **Restore Ergonomic** button.
- Duplicate Account Settings: Allow a user to import settings (including ergonomics) from another user profile. Select another user name and log in to apply the settings of this user.
- Restore Factory Defaults: Restore the settings to factory defaults, including brightness, white balance, image enhancement, digital zoom, telestration eye and working distance, etc.

Version

Tap the **Version** button to view the version information section.

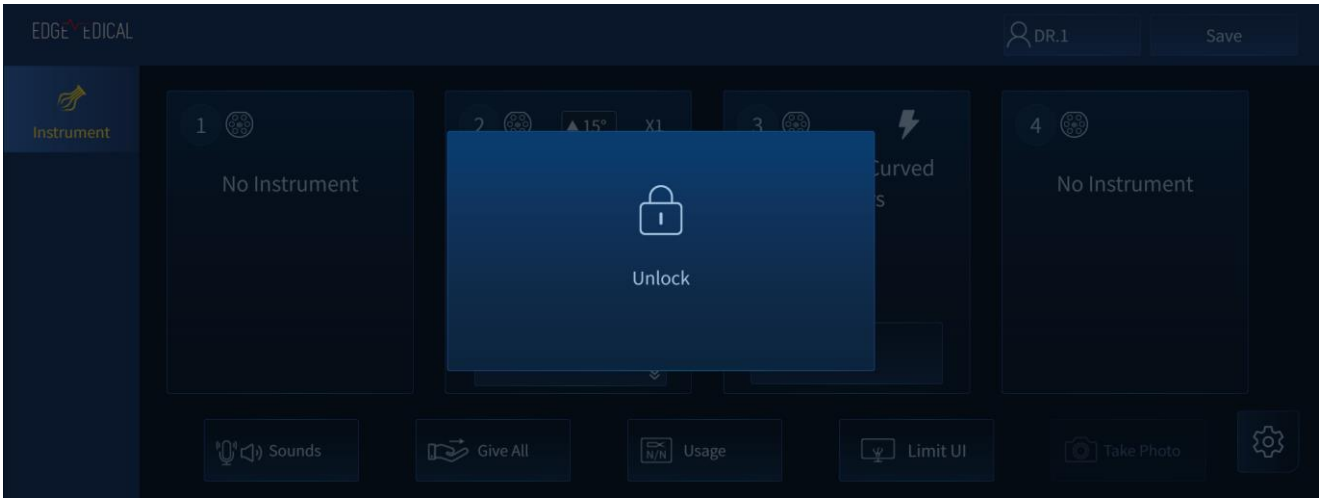
- Software Name: Endoscopic Instrument Control System Software
- Release Version: V1

10.2.9 Lock Touchscreen

To prevent the touchscreen from misoperation during procedures, when the surgeon matches grips and the system goes into the following mode, the touchscreen will automatically lock after the preset time. Unlock the touchscreen to resume use. Touchscreen locking does not

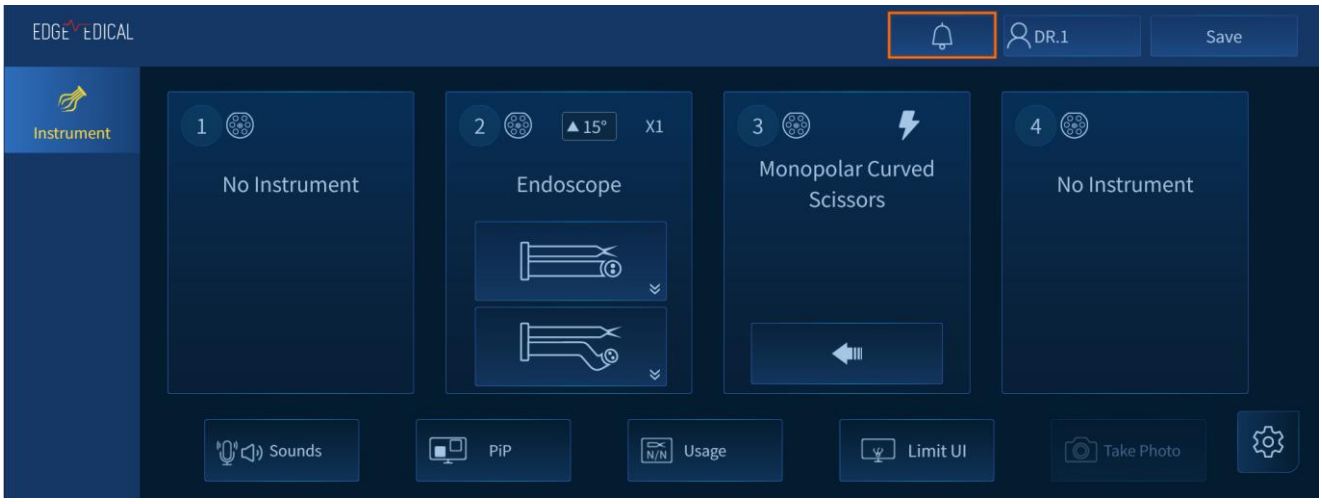
affect other functions of the Surgeon Console.

Tap to unlock the touchscreen, the system takes the instrument arms out of the following mode.



10.2.10 Beeps

When a fault occurs, the system will sound a series of error beeps and alert to eliminate the fault condition. If the fault condition remains, the system allows the user to turn off the beeps temporarily on the touchscreen by tapping .



10.3 Surgical Controls

Before using the master controls, the surgeon’s head must be in the viewer, which uses infrared head sensors to determine if the system is in use or not. If the surgeon’s head is out of the viewer, he or she cannot be able to control the instruments or endoscope.

Warning: The infrared head sensors have a safety feature to prevent the surgeon from controlling the instruments or endoscope when his or her head is not in the

viewer. Do not intentionally block the sensors.

10.3.1 Matching Grips

Before controlling the instruments, the surgeon must first match grips. Matching grips is a safety feature designed to prevent inadvertent activation of instruments. It also ensures that items being held by inactive instruments are not accidentally dropped when activated.

Meet either of the following two requirements to match grips:

- Match the master control grip angle to the instrument grip angle.
- When matching the master control grip angle to the instrument grip angle, use the master controls to slightly rotate the grips.

The surgeon can control the instruments after matching grips. Maintain a light grip on the master controls when taking or re-taking control (for example, when a new instrument is installed or the patient-side assistant moves the arm). This allows the system to align the master controls relative to the tips of the instruments in the viewer.

Warning: For patient safety, the surgeon must not match grips for instruments whose tips are not visible in the viewer. Otherwise it may cause serious injury to the patient.

Warning: Once in surgeon control mode (that is, the surgeon can control the instruments and endoscope with his or her head in the viewer), the surgeon must not remove his or her hands from the master controls. Otherwise it may cause uncontrolled movement of the master controls, thereby resulting in serious injury to the patient.

Note: To avoid electrical hazards, the surgeon should never touch the patient while using the master controls.

10.3.2 Finger Clutch Use



Figure 10.7 Finger Clutch

- While you slide the finger clutch, you can move the master control and the instrument does not move. Applying the finger clutch enables you to reposition the master controls for comfort, and to reclaim space to maneuver when the master control reaches its limits.
- Unlike the master clutch on the footswitch panel, the finger clutch applies only to the hand using the clutch. For example, when you apply the right-hand finger clutch, the instrument assigned to the left hand remains in surgeon control mode.
- To resume instrument control, release the finger clutch and match grips as usual (see 10.3.1 Matching Grips).

10.3.3 Footswitch Panel Use

The footswitch panel has two groups of foot pedals. There are three function pedals on the left side, including master clutch, instrument swap pedal and endoscope control. There are four function pedals on the right side which are used to control the energy activation of the instruments.



Figure 10.8 Footswitch Panel

Endoscope Control

Pressing the endoscope control pedal can enable endoscope control mode. In endoscope control mode, the motion of the endoscope will be achieved while the surgeon simultaneous moves two master controls (such as moving in or out, moving from side to side, or rotating).

To move the endoscope toward the target anatomy, pull both master controls toward the eyes. To rotate the endoscope clockwise, turn both master controls clockwise at the same time, similar to a steering wheel. Press and hold the endoscope control pedal while performing these actions.

Note: Always confirm that all instrument tips are in the surgical view.

Continue to press the endoscope control pedal to enter the endoscope control state, the Endoscope Control menu appears in the viewer of the Surgeon Console, including three control modes: quick adjust, endoscope and relocate. The system enters into the quick adjust mode by default. Roll the right master control clockwise and turn past the resistance on the master control to select the endoscope control mode. Roll the right master control counter-clockwise and turn past the resistance on the master control to select the relocate mode.

When a control mode is selected in the Endoscope Control menu, the icon color of the selected mode illuminates to indicate the mode is activated, and the icon color of the unselected mode displays gray. When the endoscope control mode is activated, only the icon corresponding to that mode is displayed in the endoscope view, and other icons disappear. To switch to another mode, continue to press the endoscope control pedal again to pop up the Endoscope Control menu and select it again. To exit the current mode, release the endoscope control pedal.

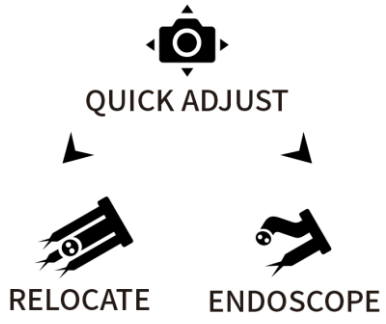


Figure 10.9 Endoscope Control Menu

- Quick adjust mode: Users can adjust the view and workspace, rotate the endoscope, and retract and straighten the endoscope.

- When adjusting the view and the workspace of the instrument, the endoscope joints pose remains unchanged, move the master controls together to the left, right, up, down or rolling around the remote center, and the tip of the instrument stays in place.
- When rotating the endoscope, the endoscope image produces a rotational motion, the endoscope joints pose remains unchanged, and the tip and joints of the instrument stay in place.
- While retracting and straightening the endoscope, the tip and joints of the instrument stay in place. When the elbow and wrist joints of the endoscope are outside the cannula, the pose of the joints of the endoscope remains unchanged, and the endoscope can be only retracted and straightened. When the elbow and wrist joints of the endoscope are inside the cannula, the endoscope appears to be straightened. The resistance may generate on the master control during the process of straightening, and it disappears until the endoscope is fully straightened. The endoscope remains in the entry state when it extends from the cannula after straightening.

- Endoscope control mode: Users can control endoscope joints motion and adjust endoscope pose. This mode limits the endoscope in self-rotating, retracting and straightening movements.
- Relocate mode: Users can control the drive box to perform a rotational motion around the remote center for repositioning. This mode limits endoscope and instrument movements.

Master Clutch

Pressing the master clutch decouples both hands from the instrument movement and enables the surgeon to adjust the master controls while all instruments remain immobile. You cannot use the master clutch to decouple hands independently. Pressing the master clutch pedal allows the surgeon to reposition his or her hands for ergonomic comfort, and to reclaim space to maneuver the master controls when they run out of workspace. All instruments remain immobile until the surgeon resumes control by releasing the pedal and then matching grips as usual.

Instrument Swap

Pressing the instrument swap pedal allows the surgeon to select which of the instruments is actively controlled by the master controls.

Note: When operating the instrument swap pedal, the instrument tips should be always within the surgical view.

Instrument Activation

The instrument activation pedals include two pairs of pedals, left and right, for activating the special instrument energy functions of the instruments being controlled by the master controls.

The instrument activation pedals are automatically associated with instruments. The left pair of pedals activate the instrument associated with the left master control and the right pair of pedals activate the instrument associated with the right master control.

At the bottom of the viewer, the system displays instrument information on each arm. In the scenario below, the surgeon presses the associated blue pedal to activate the Bipolar Forceps's primary energy mode (COAG). The surgeon presses the associated yellow pedal to activate the Bipolar Forceps's secondary energy mode (CONV).





Figure 10.10 Instrument Activation Pedals

The functions of instrument activation pedals are as follows:

- **Left Secondary Pedal** (yellow): Activates the secondary function of the instrument controlled by the left master control (for example, cutting for monopolar instruments).
- **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).

For the user interface related to pedal activation, see 10.4 Viewer Display.

10.4 Viewer Display

When the Surgeon Console is in use, the viewer displays the endoscopic video image, and provides extended system, instrument and endoscope information through icons and text messages.

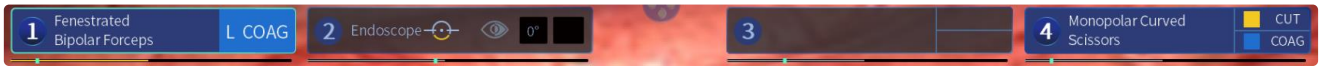


Figure 10.11 Viewer Display

- System status information area: Displays system status and text messages, including basic information and fault information.
- Endoscopic video image area: Displays the live endoscopic video image of the system.
- Instrument and endoscope information area: Displays the status information of the instruments, endoscope and master control.
- Activation status bar: The activation status bar appears on the left or right side of the viewer display. The yellow bar is associated secondary pedals color (yellow) and the blue bar is associated primary pedals color (blue).
- Instrument and endoscope navigator: Indicates the motion limits, potential collisions, and endoscope field of view.

10.4.1 Instrument and Endoscope Information of One Console

When one Surgeon Console is in use, the viewer displays the status information of the instruments, endoscope and master control.



10.4.2 Endoscope Status

When the endoscope is installed on the instrument drive, the corresponding status box in the instrument and endoscope information area displays all of the associated endoscope information including instrument drive number, endoscope name, rotation angle, telestration eye, view direction and digital zoom.

- Endoscope Status:
  - Endoscope not available: Displays gray



  - Endoscope available: Illuminates background and highlights borders



- ②: Indicates the number of the Patient Cart instrument drive.
- Endoscope: Indicates the name of the endoscope.
- : Indicates the rotation angle of the endoscope.
- : Indicates the endoscope displays the left eye video image.

  : Indicates the endoscope displays the right eye video image.
- 0°: Indicates the view direction of the endoscope.
- X1: Indicates the digital zoom of the endoscope.

10.4.3 Instrument Status

When the instruments are installed on the instrument drives, the corresponding status boxes in the instrument and endoscope information area display all of the associated instrument information including instrument drive number, instrument name, activation status, lifetime and energy mode.

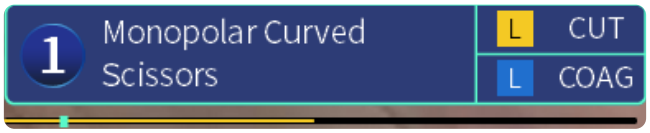
- Instrument Status:
  - Instrument not in use: Displays gray



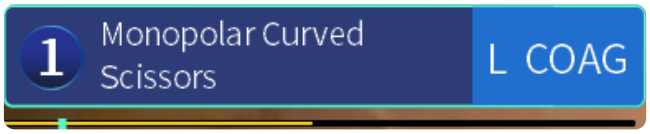
- Instrument to be activated: Illuminates background



- Instrument activated: Illuminates background and highlights borders



- ①: Indicates the number of the Patient Cart instrument drive.
- Monopolar Curved Scissors: Indicates the name of the instrument.
- CUT COAG: Functions are shown on the right edge.
  - Non-functions: Just the name of the instrument appears; for instruments with no special functions.
  - Special functions: Special functions available are shown at right edge of its field, such as CUT and COAG. When the function is activated, the associated pedal color is highlighted.



10.4.4 Motion Status Bar

A motion status bar appears at the bottom of instrument and endoscope information area to indicate the position of an instrument or an endoscope. The motion status bar will change while an operator moves the instrument or the endoscope on the arm.



- When the instrument or the endoscope is not available, the motion status bar is gray.
- When the instrument or the endoscope is available, the motion status bar is yellow.
- When the instrument or the endoscope reaches motion limit, the motion status bar is red.

10.4.5 Instrument and Endoscope Information of Second Console

While in dual console mode, the viewer provides the instrument and endoscope status for the other console, including the associated drive number, instrument name, activation status, energy mode, etc.

10.4.6 Arm Popup Information

If the surgeon requires action to control the instruments or endoscope, the system generates a popup message with information about the required action. When the operation is completed, the popup message disappears.

10.4.7 Instrument and Endoscope Navigator

Instrument and endoscope navigator contains the distal edge of the cannula, the endoscope or instrument elbow and wrist joints past the distal edge, displayed in the bottom center or top center of the viewer and providing a front viewpoint, side viewpoint or top viewpoint for the endoscope and instrument information.

The instrument and endoscope navigator displays the tips of the endoscope and instruments, which consist of three areas: instrument shaft area, forearm area (elbow to wrist joints section), and wrist area (wrist to tip section). Each area displays different colors that indicate the status of the endoscope and instruments.

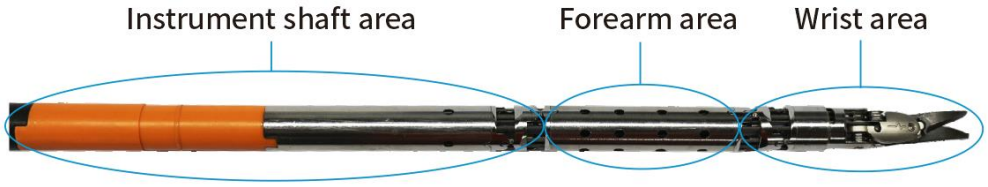


Figure 10.12 Displayed Areas in Navigator

- Display white by default.
- The three areas change to blue when the insertion depth of the endoscope or instrument reaches its limit or when all joints movements are restricted.
- The forearm area turns blue when the elbow joints of the endoscope or instrument are restricted in movements.
- The wrist area turns blue when the wrist joints of the endoscope or instrument are restricted in movements.

10.5 Dual Console Use

10.5.1 Dual Console Overview

The system supports dual console surgery. Two Surgeon Consoles communicate with the Patient Cart through the Signal Distributor, which can share the endoscopic video source and video settings to meet the requirements of surgical training, intraoperative assistance and dual console surgery.

The power operations of the second Surgeon Console is the same with the first Surgeon Console, and two consoles need to be connected to dedicated power supply separately.

10.5.2 Dual Console Connection

Perform the following steps to connect the second Surgeon Console:

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

   One connector is connected to MS (Master-Slave) communication port of the Surgeon Console, and the other connector is connected to MS (Master-Slave) communication port of the Signal Distributor.
3. Connect the camera cable.

   One connector is connected to SDI port of the Surgeon Console, and the other connector is connected to SDI1 or SDI4 port of the Camera Control Unit.

10.5.3 Instrument Control

When the system detects two Surgeon Consoles in use, the **Give All/Take All** buttons on the Instrument Tab of the touchscreen appear. “Give All” and “Take All” indicate to assign control (give or take) of all instruments. Either surgeon can give or take control of all installed instruments by tapping the **Give All/Take All** buttons.

When the actions of a surgeon at one console causes master control assignments to change at the other console, the surgeon whose master control assignments are affected receives a notification and is not allowed to move any instruments until acknowledging the notification (by pressing the instrument swap pedal).

When tapping the **Give All** or **Take All** buttons, the instruments go out of surgeon control until the surgeon assuming satisfies the normal conditions for taking control of instruments. The surgeon can control the instruments after matching grips.

10.5.4 Image Control and Display

In dual console mode, either Surgeon Console can take control of the endoscope by pressing the endoscope control pedal. The first one to do so has endoscope control.

The Surgeon Console viewer and the Vision System monitor share the endoscopic source and display the same image information. When the endoscopic image changes, the viewer and the monitor follow in real time.

10.5.5 Dual Console Settings

In dual console mode, the Surgeon Consoles allow surgeons to configure dual console settings on the touchscreen. For details, see Dual Console in 10.2.8 Settings Tab.

The monitor can be set to display the current console or the other console. Video output from the monitor keeps consistent with the set Surgeon Console viewer.

10.5.6 Instrument and Endoscope Status

Dual Console instruments/endoscope status is highlighted through the background color of the instrument status bar. A diagram of the different states of the instruments/endoscope under the dual console mode.

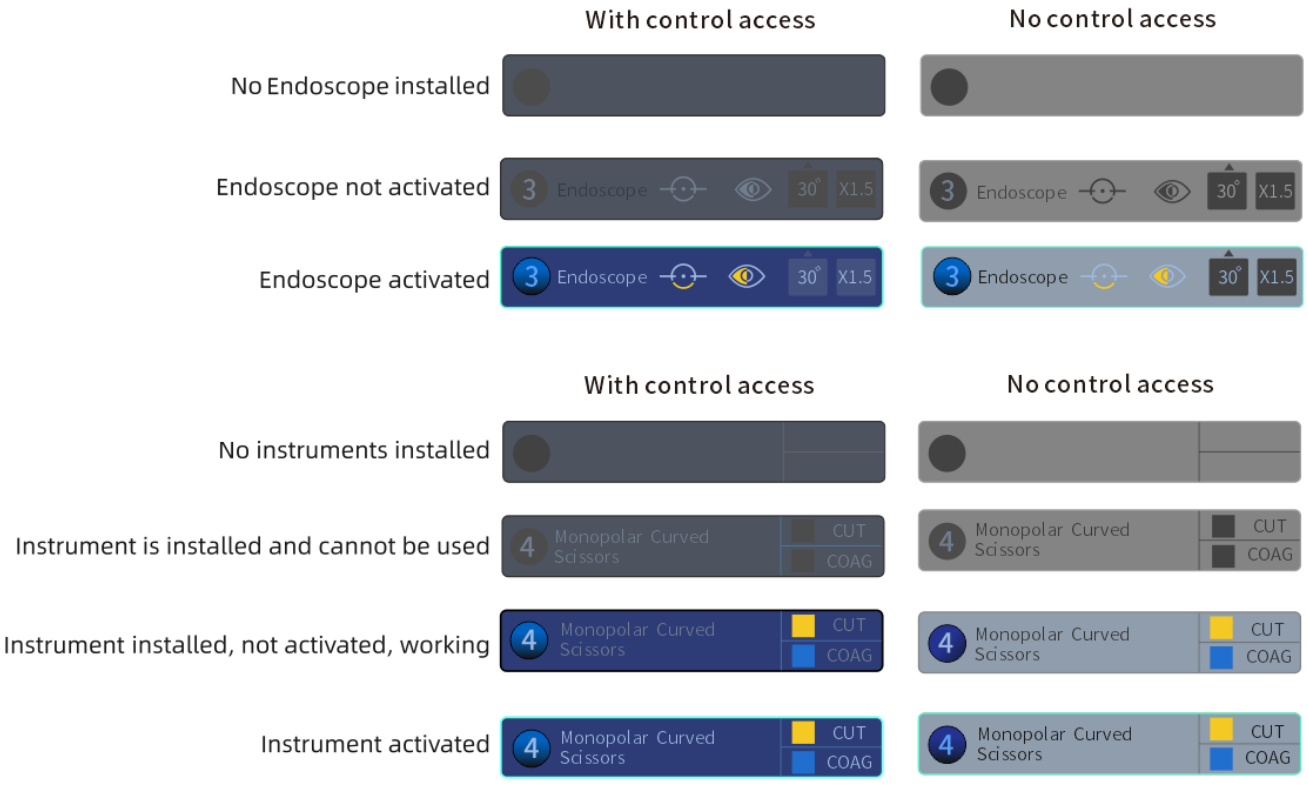


Figure 10.13 Diagram of Instruments/Endoscope Status

10.5.7 Virtual Pointer (Dual Console Teaching Aid)

The virtual pointer is a software tool designed as an instructional aid, typically for use during dual console operation. The pointer is conical in shape, which appears overlaid on the live video image when activated. It enables a surgeon to point and refer to specific anatomical region on the live video image intraoperatively. The surgeon can activate and control one pointer with each master control that is not associated with an arm.



Figure 10.14 Virtual Pointer

Guidelines for Using Virtual Pointer

- By closing the grips of an unassociated master control, the surgeon activates a virtual pointer. The surgeon can activate two pointers simultaneously by closing the grips of both master controls while surgeons can activate four pointers in dual console mode.
- After a virtual pointer is activating, the surgeon can manipulate the position and orientation of the pointer with the master control.
- The virtual pointer disappears when the surgeon releases the grips, operates in single console mode, associates a master control with an instrument or presses the endoscope control pedal to enter endoscope control mode.
- The surgeon can clutch the master control while the virtual pointer is activating to reposition the master control without moving the pointer. The clutch feature can be activated by pressing the master clutch pedal or sliding the finger clutch of the master control that controls the pointer.

11. Shutdown and Storage

11.1 Preparation for Shutdown

1. Remove the instruments and endoscope from the Patient Cart. See 9.4.7 Instrument Removal and 7.4.3 Endoscope Removal and Replacement for details.
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. See 6.6 Drape Removal for details.
   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. See the reprocessing instructions manuals for details.
8. Clean the Patient Cart, Surgeon Console, Camera Control Unit, and Signal Distributor. See 12.1 Cleaning for details.
9. Retract the instrument arm and stow the Patient Cart.

11.2 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.

11.3 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 System.
2. Store the system according to the requirements of environmental specifications.
   - Relative humidity: 5%～90% (non-condensing)
   - Temperature: -40℃～55℃
   - Atmospheric pressure: 700 hPa～1060 hPa
3. Place the Patient Cart near a wall outlet and connect it to AC power.

12. System Maintenance

12.1 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.

12.2 Reprocessing

The reusable instruments, endoscopes and accessories are shipped non-sterile and should be cleaned and sterilized thoroughly before first use and after every use.

For complete reprocessing information, refer to the reprocessing instructions manuals.

Warning: Prior to use, after use or reprocessing, always inspect devices for any defects or damage. Failure to inspect may result in patient harm and/or additional device damage.

Note: Carefully remove all accessories, including disposable attachments, such as tip cover accessory or cannula seal before reprocessing.

Note: Check the remaining number of uses for instruments on the Surgeon Console touchscreen. When instruments expire, they can no longer be used. Expired instruments must be properly disposed of.

12.3 Sterilization Methods and Parameters

The following tables list the sterilization information for reusable and disposable parts of the system.

Warning: Only sterilization machines, methods, parameters and cycles verified by the company can be used, and follow instructions in entirety. Unverified sterilization machines, sterilization methods (such as chemical sterilization), parameters (such as too high or too low sterilization temperature) or cycles may cause instruments damage or incomplete sterilization.

Caution: Following steam sterilization, allow all components to cool to room temperature. Sudden changes in temperature may damage the components.

Note: Dry time depends on the packing materials and load capacity of the sterilizer.

Note: Please refer to sterilization system manufacturers' instructions for proper use of the system and recommendations for sterilization.

12.3.1 Reusable Parts

Reusable parts of the system are shipped non-sterile. Clean and sterilize thoroughly before first use and after every use.

Table 12.1 Validated Sterilizers

Validated Sterilizer			
Sterilization Method	**Manufacturer**	**Model**	**Compatible Device**
Pre-vacuum steam sterilization	SHINVA	BIST-A-D	● Endoscopes ● Endoscopic instruments
Pre-vacuum steam sterilization	STERIS	AMSCO Century	Accessories
Hydrogen peroxide low temperature sterilization	STERIS	V-PRO MAX2	Endoscopes
	SHINVA	PS-200X	

Table 12.2 Sterilization Methods and Parameters

Part Name	Model	Sterilization Method	Sterilization Parameter
Maryland Bipolar Forceps	SP1304	Pre-vacuum steam sterilization	● Temperature and exposure time: 132℃, for 4 minutes; 134℃, for 3 minutes ● Dry time: 30 minutes Based on the packing system, steam quality, load capacity of the sterilizer and environment conditions, the dry time may be different, 30 minutes recommended by the company. Dry time should be determined according to hospital policy.
	SP3-BM		
Fenestrated Bipolar Forceps	SP1303		
	SP3-BF		
Needle Driver	SP1305		
	SP3-ND		
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		
	SP1337		

Part Name	Model	Sterilization Method	Sterilization Parameter
Tip-up Fenestrated Grasper	SP3-TG		
Round Tooth Retractor	SP1333		
Curved Needle Driver	SP1309		
Monopolar Energy Instrument Cord	MS1801		
Bipolar Energy Instrument Cord	MS1802		
Installation Tool	SP1802		
Cannula	SP1406		
	TR1-SP		
Obturator	SP1502		
	TR2-SP		
Endoscope	SP1207	Hydrogen peroxide low temperature sterilization	• STERIS V-PRO MAX2, Lumen Cycle • SHINVA PS-200X, Standard Cycle
		Pre-vacuum steam sterilization	• Temperature and exposure time: 132℃, for 4 minutes; 134℃, for 3 minutes • Dry time: 30 minutes

Part Name	Model	Sterilization Method	Sterilization Parameter
			Based on the packing system, steam quality, load capacity of the sterilizer and environment conditions, the dry time may be different, 30 minutes recommended by the company. Dry time should be determined according to hospital policy.

12.3.2 Disposable Parts

Disposable parts of the system are shipped sterile and are for single use only.

Table 12.3 Sterilization Methods

Part Name	Model	Sterilization Method
Tip Cover Accessory	SP1306	Ethylene oxide sterilization
Tip Cover Accessory	SP4-S	Ethylene oxide sterilization
Tip Cover Accessory	SP1307	Ethylene oxide sterilization
Tip Cover Accessory	SP4-I	Ethylene oxide sterilization
Tip Cover Accessory	SP1403	Ethylene oxide sterilization
Cannula Seal	SP0801	Ethylene oxide sterilization
Cannula Seal	TR3-SP	Ethylene oxide sterilization
Disposable Drape	DR1004	Ethylene oxide sterilization
Disposable Drape	DR1006	Ethylene oxide sterilization
Installation Tool	MP1801	Ethylene oxide sterilization

12.4 Replacing Accessories

12.4.1 Fuse Replacement

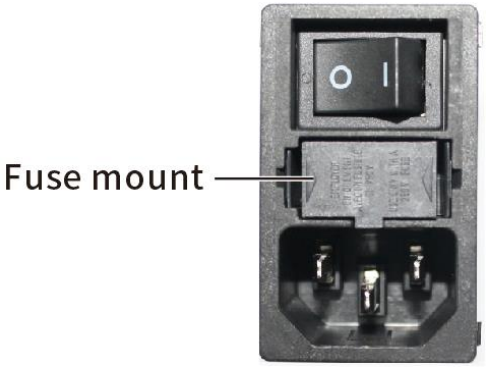
The fuse type of each component has been marked on the corresponding power switch, and the hospital can replace the same type of the fuse by itself.

Table 12.4 Fuse Parameters

Model	Specification	System Component
0215010.MXP	T10AH250VP	Surgeon Console
0215015.MXP	T15AH250VP	Patient Cart
0215002.MXP	T2AH250VP	Camera Control Unit
0215002.MXP	T2AH250VP	Signal Distributor

Warning: Only authorized personnel is allowed to replace the blown fuse. Make sure the fuse is consistent with the fuse specification marked on the power switch.

Perform the replacing steps as follows:



1. Remove the fuse mount from the power switch with a screwdriver.
2. Take out the blown fuse.
3. Install a new specified fuse.
4. Insert the fuse mount into the power switch.

Fuse blow usually means that some faults may have occurred. Even if the equipment operates normally after replacement, please contact technical support for system inspection.

12.4.2 Instrument and Endoscope Replacement

After each procedure, the system counts down one use for the instruments and endoscope will reduce. When the instruments and endoscope have reached the maximum uses, to ensure the system can be used safely, the expired instruments and endoscope can no longer be used.

Replace the components in time.



Warning: Using the expired instruments and endoscope could result in injury to the patient.

12.5 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.

To maximize lifetime of the system, perform proper routine maintenance or service as follows:

- Avoid sharply bending or kinking the cables during storage or use.
- When connecting cables, especially power cords, make sure that the connectors are completely dry and free of any debris. If needed, use a clean low-lint cloth to dry off any residual moisture or residue before using.
- Place the cables and endoscope properly on the Vision System to avoid potential collisions with other objects and reduce the risk of connector contamination and cable damage.
- Handle with care to avoid mechanical shock or stress on the instruments.
- Do not touch the tip of the endoscope and avoid the tip colliding with other objects. Otherwise roughness or damage may cause blurred images.
- After the system is in normal operation, it is not advisable to move, disassemble or change its position frequently.
- Regularly inspect lifetime of the instruments and endoscope, and replace them once they run out of lifetime.
- When the system is not used for a long time, system maintenance should be performed by authorized personnel at least every 2 years.

Brake Maintenance

To maintain the use-safety of the system, it is necessary to perform brake maintenance by authorized personnel at least every 12 months. Refer to the following maintenance instructions.

When pressing the **Emergency Stop** button on the Surgeon Console or Patient Cart, the system displays the message informing emergency stop, the audible brake control tones

sound, and the Patient Cart arm does not move due to gravity or external forces.

UPS Maintenance

There is a UPS in the Patient Cart. During UPS maintenance, observe the following cautions:

- The UPS is not user-serviceable, and must be replaced by authorized personnel only.
- Take care of the danger of electric shock during safety inspection of the UPS.
  - Tools must be dealt with insulation.
  - Wear appropriate personal protective equipment, such as rubber gloves, eyewear, to protect from electrolyte leakage.
  - Do not place the UPS upside down when transporting the Patient Cart.
  - Make sure that the power switch of the Patient Cart is in the OFF position.
- Do not use or store the UPS near heat or open flame.
- After the UPS is discharged, charge the UPS fully in time (at least no more than 24 hours) to avoid affecting the lifetime.
- Avoid overdischarge, or it may affect the capacity of the UPS.
- When the UPS is not used for a long time, it is required to charge the UPS for activation at least once every 3 months, and the time for charging is no less than 4 hours.
- Generally, it is required to charge the UPS at least once every 4～6 months, and the time for charging is no less than 4 hours.

12.6 Technical Support

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

12.7 Disposal

12.7.1 System Components

Do not use system parts once they exceed lifetime. Using expired devices may cause hazards to patient safety.

When disposing of the Surgeon Consoles, Patient Cart, Signal Distributor, Camera Control Unit, or any reusable parts of the system, follow all applicable national and local laws and guidelines.

Discard all disposable parts as biological hazardous waste and according to all applicable national and local laws and guidelines.

12.7.2 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.

13. System Troubleshooting

13.1 Conversion to Open Surgery

If it is required to convert to open surgery during a procedure, perform the following steps to remove the system from the patient:

1. Remove the instruments from the patient.
   a. If necessary, release the instrument grips with the master controls of the Surgeon Console.
   b. If the instrument grips cannot be released, see 9.5.2 Emergency Grip Release.
2. Remove the endoscope from the patient.
3. Disconnect the cannula from the arm.
4. Move the arm away from the patient.
5. If necessary, move the Patient Cart away from the operating table.
6. The surgeon performs the procedure according to open surgical process.

Caution: Do not perform grip release on a non-faulted system without pressing the **Emergency Stop** button. Failure to observe this warning may result in unintended instrument motion or damage to the grip release mechanism.

13.2 Recoverable Faults and Non-Recoverable Faults

When a fault occurs, the system determines whether the fault is recoverable or non-recoverable. The system takes these actions when a fault occurs:

- All instrument drives will be locked.
- The status of the instrument drive display indicator will change. See 9.1.3 Touchscreen of Drive Box.
- A recoverable or non-recoverable fault text message will display on the monitor or the Surgeon Console viewer.
- The touchscreen of the Surgeon Console or Patient Cart will display a recoverable fault prompt.

13.2.1 Recoverable Faults

If the fault is recoverable, resume use by following means:

- Tap the **Recover** button on the touchscreen of the Surgeon Console or Patient Cart for recoverable faults.
- Press the **Drive Function** buttons of instrument drives for recoverable faults of instrument drives or instruments.

If the system cannot be recovered, the fault becomes unrecoverable.

Note: Using fault recover does not diminish the system's fault detection capability. If the fault condition remains, the system immediately faults again. If the fault condition is removed, then the system is fully functional.

Caution: Before using the **Recover** button, you should find the cause of the fault. Correcting a malfunction without understanding its cause may result in uncontrolled movement of the instruments or master controls.

13.2.2 Non-Recoverable Faults

If a fault is non-recoverable, it is necessary to restart the system. The fault still exists after restart and then the system will display a non-recoverable text message.

Intraoperative Restart

If an unrecoverable fault occurs during the procedure, the instruments and endoscope need to be removed from the patient and the cannula need to be disconnected. After that, power off the system and then restart it.

Note: If the fault cannot be cleared by a system restart, contact the company for technical support.

13.3 Emergency Stop

Surgeon Console

1. If necessary, press the **Emergency Stop** button on the Surgeon Console to stop the system. The system identifies this operation as a recoverable fault.
2. Tap the **Recover** button on the touchscreen to clear the fault.

Regarding the **Emergency Stop** button while the instruments are grasping tissue, see 9.5.2 Emergency Grip Release.

Patient Cart

- Recoverable faults

a. If necessary, press the **Emergency Stop** button on the Patient Cart to stop the system. The system identifies this operation as a recoverable fault.

b. Tap the **Recover** button on the touchscreen to clear the fault.

Regarding the **Emergency Stop** button while the instruments are grasping tissue, see 9.5.2 Emergency Grip Release.

- Non-Recoverable faults

  The system must be restarted. See 13.2.2 Non-Recoverable Faults.

13.4 No Response to System

If the system is non-responsive or otherwise not functioning as desired:

1. Check the messages on the monitor or the Surgeon Console viewer to ensure whether the system is performing an action.
2. Press the **Emergency Stop** button on the Patient Cart or Surgeon Console.
3. Tap the **Recover** button on the touchscreen, and confirm that the system is functioning normally.

If the fault still exists, restart the system by pressing the **Power** button on the Patient Cart, Surgeon Console or Signal Distributor.

13.5 Abnormal System Connection

If the screen prompts to check the system cable connection, ensure that the system cables are correctly connected to the Signal Distributor, Camera Control Unit, Patient Cart, and Surgeon Console. See 4 System Connections.

13.6 System Power Problems

The system may experience anomalous behavior when the system or an individual component (Surgeon Console, Patient Cart, Signal Distributor and Camera Control Unit) fails to power on normally or fails to undergo an automatic, controlled power-down sequence. For instance, faulty power connections might create power-on problems. A system component overheating problem might cause power-down problems.

Note: Incorrect system connection may cause the system or components to fail to power on normally, and overheating of system components may cause the system to enter power-down sequence during operation.

13.6.1 Checking Connections

In all cases of inconsistent power behavior, AC power connections should be checked first:

1. Confirm that the power cords of the Surgeon Console, the Patient Cart, the Signal Distributor and the Camera Control Unit are properly connected to AC power outlet.
2. Confirm that the power switches of the Surgeon Console, the Patient Cart, the Signal Distributor and the Camera Control Unit are set to the ON position (represented by "|" near each switch).
3. Ensure that the **Emergency Power OFF** (**EPO**) button on the Patient Cart is not pressed. After pressing the **EPO** button, you need to press it again to reset. See 13.6.2 Hard-Cycle Power on System for details.

13.6.2 Hard-Cycle Power on System

Use this troubleshooting procedure if the entire system or either of the Surgeon Console and the Patient Cart fails to power on normally after pressing the **Power** button.

Check AC power connections as described above. If AC power is properly connected, follow the steps below:

1. Press the **Emergency Power OFF** (**EPO**) button on the Patient Cart to disconnect the power supply. The button remains partially pressed in.
2. Turn off the power switches of the system components (represented by "O" near each switch).
3. Wait until a series of error beeps stop sounding, and then press the **EPO** button to reset the system. The button will rebound to its fully extended ready position.



Note: The Patient Cart continues to operate on UPS power temporarily even after powered off. Use the **EPO** button to disconnect the Patient Cart from AC power and exit the default standby (sleep) mode.

4. Turn on the power switches of the system components.
5. Verify that the power switches are in the ON position (if not, turn on). After 30 seconds, the Patient Cart and the Surgeon Console return to their default standby mode. Their power button LED indicators will illuminate white.
6. Start the system normally by pressing the **Power** button on Surgeon Console and the Patient Cart.

13.7 System Overheating

If the system powers down within a short time after it starts normally, a component or subsystem overheats.

When the system detects overheating, it automatically initiates a power-down sequence. This controlled power-down prevents system damage.

Note: If a shutdown caused by overheating of components occurs, it is advisable to wait 5 minutes for the overheated system component to cool.

Note: Move the system to a location with adequate ventilation and check whether the cooling vents are blocked.

Note: Follow the steps for standby restart properly.

Note: If overheating reoccurs, contact the company for technical support.

13.8 Patient Cart Faults

13.8.1 UPS

The Patient Cart must not be powered off. Otherwise, the system will alert that it is running on UPS power and advises to plug-in the Patient Cart to avoid loss of power. The system will allow to continue operation on UPS. The UPS LED indicator shows the power of the UPS, flashing indicates loss of AC power and running on UPS power, and solid red indicates that the UPS power is low. See 9.1.1 Patient Cart Helm for details.

Note: The UPS is only intended for safe removal of the system components from the patient and is not intended for continuing the procedure.

Note: If the UPS cannot be used, it must be replaced by authorized personnel only. Please contact the company for technical support.

13.8.2 Adaptor Disengagement

If an adaptor of the instrument drive disengages from an arm abnormally, the status of the instrument drive display indicator changes. See 9.1.3 Touchscreen of Drive Box. A fault message will display on the monitor or the Surgeon Console viewer.

1. Remove the instrument and the adaptor.
2. Reset the instrument adaptor on the touchscreen.
3. Press the **Drive Function** button of the instrument drive, and reinstall the instrument and the adaptor.

13.9 Vision System Faults

13.9.1 Endoscope Faults

Fault	Possible Cause	Solution
Image too bright or dark	The glass surfaces on the endoscope are smudged or soiled.	Clean the glass surfaces after removing the endoscope and turning off the illumination.
	The image brightness set too high or low.	Set image brightness at the system.
Image flickering	Flickering happens during cautery.	Keep away from or replace high frequency equipment, and restart the system.
Image blurring	The glass surfaces on the endoscope are smudged or soiled.	Clean the glass surfaces after removing the endoscope and turning off the illumination.
	The image is zoomed out too much.	Set digital zoom at the system.
Color cast	The system needs white balancing manually.	Perform manual white balance. See 7.6.5 3D Calibration and White Balance.
3D images displayed improperly	The system needs manual 3D calibration.	Perform manual 3D calibration by technical support.
No image	No illumination.	Connect the endoscope to the Camera Control Unit.

Fault	Possible Cause	Solution
	The endoscope cable connector or the matching receptacle of the Camera Control Unit has dirt or moisture.	Clean the connector and the matching receptacle after disconnecting the endoscope cable.

13.9.2 Camera Control Unit Faults

Problem	Possible Cause	Possible Solution
Cannot power on	The Camera Control Unit is not connected to the power supply.	Connect to the power supply.
	The power cord is not connected properly.	Ensure the power cord is properly connected.
	The fuse is blown.	Replace the fuse.
	The power switch is set to the off position.	Set the power switch to the on position.
Image too bright or dark	The image brightness set too high or low.	Set image brightness via the / button on the Camera Control Unit or via the Surgeon Console. See 7.6.6 Image Brightness.
Image flickering	Flickering happens during cautery.	Connect to the dedicated power supply separately and keep away from high frequency equipment. If necessary, replace the endoscope and restart the system.
Image blurring	The image is zoomed out too much.	Set digital zoom via the button on the Camera Control Unit or via the Surgeon Console. See 7.6.8 Digital Zoom.

Problem	Possible Cause	Possible Solution
Color cast	The system needs white balancing manually.	Activate white balance via the button on the Camera Control Unit or via the Surgeon Console. See 7.6.5 3D Calibration and White Balance.

Note: If the above solutions cannot clear the faults, the vision system components may be damaged. Contact the company for technical support.

Warning: Do not use the endoscope if any part of the vision system is damaged. Failure to follow the warning may cause injury to the operator or patient.

13.10 Other Faults

If other faults occur, contact the company for technical support.

14. System Alarm

14.1 Alarm Overview

When the system fails in the process of operation, an alarm is intended to notify the operator of the existence of an alarm condition.

The alarm list contained in the system is as follows:

Alarm name	Description	Position
Position deviation of master controls	When the master controls match the instruments, the desired position deviates from the actual position.	Surgeon Console
Unexpected motion of master controls	When operating in non-following mode, unexpected motion occurs to the master controls due to external interference.	Surgeon Console
Unexpected motion of arm	When operating in non-following mode, unexpected motion occurs to the arm due to external interference.	Patient Cart
Unexpected motion of instrument drive	When operating in non-following mode, unexpected motion occurs to the instrument drive due to external interference.	Patient Cart
Adaptors drop abnormally	When operating in following mode, the adaptors drop abnormally due to external interference.	Patient Cart
Instruments drop abnormally	When operating in following mode, the instruments drop abnormally due to external interference.	Patient Cart
Abnormal system communication	Abnormal system communication occurs when the system cables are disconnected unintendedly.	Patient Cart
Invalid instrument use	When using an instrument not supplied by the company, the system prompts invalid instrument use.	Patient Cart

14.2 Alarm Type

The alarm system comes from the equipment itself. Due to the technical obstacles in use or the equipment faults, the system cannot operate normally. This is a technical alarm.

Alarm name	Alarm type
Position deviation of master controls	Technical alarm
Unexpected motion of master controls	Technical alarm
Unexpected motion of arm	Technical alarm
Unexpected motion of instrument drive	Technical alarm
Adaptors drop abnormally	Technical alarm
Instruments drop abnormally	Technical alarm
Abnormal system communication	Technical alarm
Invalid instrument use	Technical alarm

14.3 Priority and Preset

Each alarm status has a level characteristic, divided into three by priority: low priority, medium priority, and high priority. The higher the level, the higher the potential risk.

The default alarm preset is consistent with the manufacturer’s setting, provided with only one preset that cannot be set by users.

The alarm presets are restored by default when the system is powered off.

Alarm name	Preset	Priority
Position deviation of master controls	Position deviation of master controls is preset to FALSE.	Low priority
Unexpected motion of master controls	Unexpected motion of master controls is preset to FALSE.	
Unexpected motion of instrument drive	Unexpected motion of instrument drive is preset to FALSE.	Medium priority
Unexpected motion of arm	Unexpected motion of arm is preset to FALSE.	

Alarm name	Preset	Priority
Adaptors drop abnormally	Adaptors drop abnormally and the preset is FALSE.	
Instruments drop abnormally	Instruments drop abnormally and the preset is FALSE.	
Abnormal system communication	Abnormal system communication is preset to FALSE.	
Invalid instrument use	Invalid instrument identification is preset to FALSE.	High priority

14.4 Alarm Signal

When an alarm occurs, the monitor will display alarm icons and text messages.

Priority	Alarm icon	Text message
Low priority		Desired position deviation of master controls, tap **Recover** on the touchscreen.
		Unexpected motion of master controls, tap **Recover** on the touchscreen.
Medium priority		Abnormal MS (Master-Slave) communication, check connections of system cables.
		Unexpected motion of arm, please tap **Recover** button.
		Instrument on instrument drive 1/2/3/4 dropped abnormally, reinstall the instrument.
		Unexpected motion of instrument drive, please tap **Recover** button.
		Adaptor on instrument drive 1/2/3/4 dropped abnormally, reinstall the adaptor.

Priority	Alarm icon	Text message
High priority		Invalid instrument installed on instrument drive 1/2/3/4, change a validated instrument.
Note: When high, medium and low priority alarms are triggered at the same time, the system will not display low priority alarms, and only two alarms can be displayed at the same time.		

14.5 Alarm Condition

The alarm condition of the system includes:

- Alarm Triggering: Indicates the existence of an alarm condition.
- Alarm Eliminating: Indicates the elimination of an alarm condition.

When the system starts running, all alarms are in the elimination of an alarm condition. In the subsequent time, if an alarm meets the conditions, the system enters into alarm triggering. See 14.4 Alarm Signal for the alarm signals (including icons and text messages) when alarm triggering and see 14.6 Alarm Elimination for operation methods.

14.6 Alarm Elimination

An alarm can be eliminated by the corresponding operation methods, and then the alarm signals disappear. Unless retriggered, the alarm will be not repeated. When multiple alarms occur simultaneously, they are independent from each other.

Alarm name	Operation method
Position deviation of master controls	Adjust the position of the master controls, be careful not to disengage completely, and then tap **Recover** on the touchscreen.
Unexpected motion of master controls	Tap **Recover** on the touchscreen after resolving the external interference.
Unexpected motion of instrument drive	Prevent the external interference, and then tap **Recover** on the touchscreen.
Unexpected motion of arm	Prevent the external interference, and then tap **Recover** on the touchscreen.
Adaptors drop abnormally	Reset on the touchscreen after removing the instrument and the adaptor, and then reinstall the instrument and the adaptor.

Alarm name	Operation method
Instruments drop abnormally	Remove the instruments, and then tap the function button to reinstall the instruments.
Abnormal system communication	Re-connect the system cable to at least one Surgeon Console or the system cable to the Patient Cart.
Invalid instrument use	Replace the instrument and use the specified instrument during its lifetime.

14.7 Alarm Setting

The alarm type of the system is technical alarm, and the parameters about the alarms including alarm information, trigger conditions and priorities are not allowed to be changed by the user.

All alarm-related settings of the system are specified into the software code, which cannot be accessed and changed by the user through tool software, advanced user passwords, etc., and can only be changed by the manufacturer through software upgrades.

14.8 Alarm Verification

The following methods are used to verify whether the alarms are effective.

Alarm name	Verification method
Position deviation of master controls	Based on the manufacturer’s methods, make the master controls deviate abnormally. The result meets the alarm requirements.
Unexpected motion of master controls	Based on the manufacturer’s methods, make the master controls stop abnormally. The result meets the alarm requirements.
Unexpected motion of instrument drive	Based on the manufacturer’s methods, make the instrument drive stop abnormally. The result meets the alarm requirements.
Unexpected motion of arm	Based on the manufacturer’s methods, make an arm stop abnormally. The result meets the alarm requirements.
Adaptors drop abnormally	When operating in following mode, make an adaptor disengage from an arm. The result meets the alarm requirements.
Instruments drop abnormally	When operating in following mode, make an instrument drop. The result meets the alarm requirements.
Abnormal system communication	After connecting the system cables correctly, disconnect the system cables from both Surgeon Consoles or the system cable from the

	Patient Cart. The result meets the alarm requirements.
Invalid instrument use	Install an expired instrument or an instrument not supplied by the company. The result meets the alarm requirements.

Note: Only trained professionals can perform alarm verification.

Note: Alarm verification may cause damage to the equipment. If you are unsure, contact the company for technical support.

14.9 Distributed Alarm System

The alarm system of the system involves a multiple components comprising a Surgeon Console, a Patient Cart, and a monitor, with the Surgeon Console and monitor allowing for placement outside of the patient environment, where multiple operator locations exist, and which is a distributed alarm system.

This distributed alarm system is a permitted form of alarm system. Data is sent or received between the system components that include the information signals and the indications of the alarm status. And data is transmitted via system cables.

In this distributed alarm system, the timed communication (heartbeat packet) between the Surgeon Console and the Patient Cart is 100 ms. The sum of the maximum alarm state delay and the maximum alarm signal generation delay of this system is less than 1 s, which means that the alarm delays of both the Surgeon Console and the Patient Cart are less than 1 s.

14.10 Alarm Log

Only the maintenance personnel of Edge Medical can use the tool to view the system’s historical alarm log, which contains information such as the date the alarm appeared, the content of the alarm, preset time, etc.

Appendix A System Specifications

A.1 Power Specifications

System Component	Voltage	Rating and Typical Current	Fuse	Backup Power
Surgeon Console	120-240 VAC 50/60 Hz	600 VA Continuous 5.0 A at 120 V~ 2.5 A at 240 V~	T10AH250VP	No
Patient Cart	120/230 VAC 50/60 Hz	1000 VA continuous 8.4 A at 120 V~ 4.4 A at 230 V~	T15AH250VP	15 minutes
Camera Control Unit	120-240 VAC 50/60 Hz	100 VA continuous 0.8 A at 120 V~ 0.4 A at 240 V~	T2AH250VP	No
Signal Distributor	120-240 VAC 50/60 Hz	100 VA continuous 0.8 A at 120 V~ 0.4 A at 240 V~	T2AH250VP	No

A.2 Environmental Specifications

Operating Conditions	
Temperature	10℃～30℃
Relative humidity	30%～70%
Atmospheric pressure	700 hPa～1060 hPa
Storage and Transport Conditions	
Temperature	-40℃～55℃
Relative humidity	5%～90%, non-condensing
Atmospheric pressure	700 hPa～1060 hPa

A.3 Electrical Safety Classification

A.3.1 Surgeon Console

- Type of protection against electric shock: Class Ⅰ
- Degree of protection against electric shock: No applied part
- Ingress protection: IPX0 (except footswitch rated IPX8)
- Safety classification when using in environments with flammable anesthetic mixture of air, oxygen and/or nitrous oxide: Non-AP/APG equipment
- Mode of operation: Continuous
- Power supply and operating frequency: 120-240 VAC, 50/60 Hz
- Power input: 600 VA
- Degree of protection against defibrillation discharge effect: No applied part
- Equipped with signal output or input part
- Non-permanently installed equipment

A.3.2 Patient Cart

- Type of protection against electric shock: Class Ⅰ
- Degree of protection against electric shock: BF and CF applied part
- Ingress protection: IPX0
- Safety classification when using in environments with flammable anesthetic mixture of air, oxygen and/or nitrous oxide: Non-AP/APG equipment
- Mode of operation: Continuous
- Power supply and operating frequency: 120/230 VAC, 50/60 Hz
- Power input: 1000 VA
- No defibrillation-proof applied part
- Equipped with signal output or input part
- Non-permanently installed equipment

A.3.3 Camera Control Unit

- Type of protection against electric shock: Class Ⅰ
- Degree of protection against electric shock: BF applied part
- Ingress protection: IPX0

- Safety classification when using in environments with flammable anesthetic mixture of air, oxygen and/or nitrous oxide: Non-AP/APG equipment
- Mode of operation: Continuous
- Power supply and operating frequency: 120-240 VAC, 50/60 Hz
- Power input: 100 VA
- No defibrillation-proof applied part
- Equipped with signal output or input part
- Non-permanently installed equipment

A.3.4 Signal Distributor

- Type of protection against electric shock: Class Ⅰ
- Degree of protection against electric shock: No applied part
- Ingress protection: IPX0
- Safety classification when using in environments with flammable anesthetic mixture of air, oxygen and/or nitrous oxide: Non-AP/APG equipment
- Mode of operation: Continuous
- Power supply and operating frequency: 120-240 VAC, 50/60 Hz
- Power input: 100 VA
- No defibrillation-proof applied part
- Equipped with signal output or input part
- Non-permanently installed equipment

A.3.5 Instruments

- Type of protection against electric shock: Not applicable
- Degree of protection against electric shock: CF applied part
- Ingress protection: IPX0
- Safety classification when using in environments with flammable anesthetic mixture of air, oxygen and/or nitrous oxide: Not applicable
- Mode of operation: Continuous
- Power supply and operating frequency: Not applicable
- Power input: Not applicable
- No defibrillation-proof applied part

- Equipped with signal output or input part
- Non-permanently installed equipment

A.3.6 Endoscopes

- Type of protection against electric shock: Not applicable
- Degree of protection against electric shock: BF applied part
- Ingress protection: IPX7 (endoscope tip)
- Safety classification when using in environments with flammable anesthetic mixture of air, oxygen and/or nitrous oxide: Not applicable
- Mode of operation: Continuous
- Power supply and operating frequency: Not applicable
- Power input: Not applicable
- No defibrillation-proof applied part
- Equipped with signal output or input part
- Non-permanently installed equipment

A.4 Physical Specifications

A.4.1 Surgeon Console

Height (Min)	Height (Max)	Width	Depth	Weight	Ground Clearance
147 cm	167 cm	101 cm	105 cm	Approx. 322 kg	2 cm

A.4.2 Patient Cart

Height (Min)	Height (Max)	Width	Depth	Weight	Ground Clearance
149 cm	202 cm	96 cm	267 cm	Approx. 798 kg	4.3 cm

A.4.3 Camera Control Unit

L×W×H	Weight
45 cm×29 cm×8.7 cm	Approx. 8.5 kg

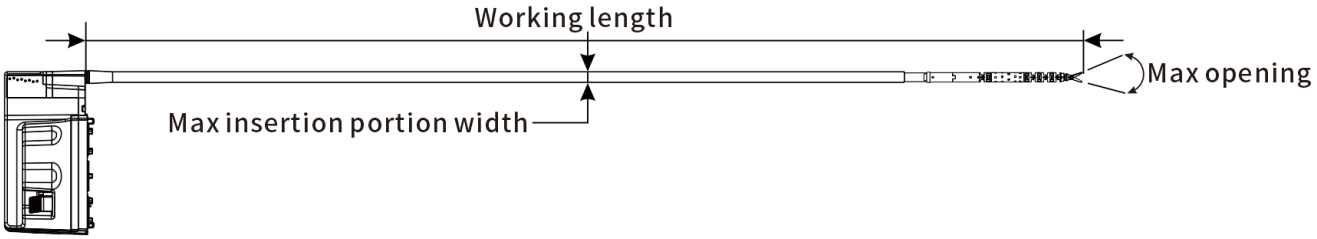
A.4.4 Signal Distributor

L×W×H	Weight
45 cm×27.8 cm×11.2 cm	Approx. 10.6 kg

A.4.5 Vision Cart

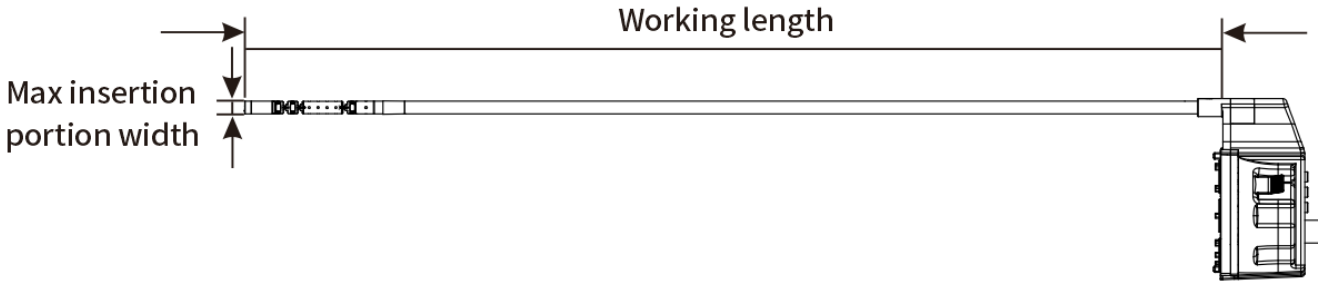
Net weight	Approx. 210 kg
Physical dimensions (L×W×H)	783 mm×733 mm×1729 mm
Gross weight	Approx. 285 kg
Packaging dimensions (L×W×H)	1040 mm×900 mm×1865 mm
Total load capacity	100 kg～130 kg
Load capacity of each shelf	● 1st shelf: 30 kg ● 2nd shelf: 20 kg ● 3rd shelf: 30 kg ● 4th/5th/6th shelf: 25 kg
Height of each shelf	● 1st shelf: 130 mm ● 2nd/3rd shelf: 260 mm ● 4th shelf: 235 mm ● 5th shelf: 165 mm ● 6th shelf: 155 mm

A.4.6 Endoscopic Instruments



Part Name	Model	Max Insertion Portion Width (Tolerance -0.5 mm~0)	Working Length (Tolerance ±3%)	Maximum Opening (Tolerance ±20%)
Maryland Bipolar Forceps	SP1304	8.8 mm	819 mm	40°
	SP3-BM	8.8 mm	819 mm	45°
Fenestrated Bipolar Forceps	SP1303	8.8 mm	819 mm	40°
	SP3-BF	8.8 mm	819 mm	45°
Needle Driver	SP1305	8.8 mm	800 mm	45°
	SP3-ND	8.8 mm	809 mm	45°
Large Needle Driver	SP1335	8.8 mm	808 mm	50°
	SP3-LND	8.8 mm	814 mm	45°
Monopolar Curved Scissors	SP1301	8.8 mm	819 mm	32°
	SP3-MS	8.8 mm	819 mm	32°
Monopolar Hook	SP1302	8.8 mm	816 mm	N/A
Medium-Large Clip Applier	SP1332	8.8 mm	813 mm	34°
	SP3-CA	8.8 mm	819 mm	25°
Cadiere Forceps	SP1334	8.8 mm	815 mm	47°
	SP3-CF	8.8 mm	819 mm	45°
Tip-up Fenestrated Grasper	SP1337	8.8 mm	825 mm	48°
	SP3-TG	8.8 mm	831 mm	45°
Round Tooth Retractor	SP1333	8.8 mm	818 mm	47°
Curved Needle Driver	SP1309	8.8 mm	806 mm	45°

A.4.7 Endoscope



Part Name	Model	Max Insertion Portion Width	Working Length (Tolerance ±3%)	Weight
Endoscope	SP1207	≤12 mm	780 mm	Approx. 600 g

A.4.8 Disposable Drapes

Part Name	Model	Length and Tolerance	Width and Tolerance	Thickness
Disposable Drape	DR1004	300 cm±30 cm	100 cm±10 cm	≥0.03 mm
Disposable Drape	DR1006	150 cm±15 cm	100 cm±10 cm	≥0.03 mm

A.4.9 Cannulas

Part Name	Model	Min Inner Diameter	Working Length
Cannula	SP1406	27.1 mm	107.5 mm
Cannula	TR1-SP	27.1 mm	50 mm

A.4.10 Obturators

Part Name	Model	Top Diameter	Working Length
Blunt Obturator	SP1502	27 mm	198.5 mm
Blunt Obturator	TR2-SP	27 mm	141 mm

A.4.11 Cannula Seals

Part Name	Model	Inner Diameter	
Cannula Seal	SP0801	8 mm	9 mm
Cannula Seal	TR3-SP	8 mm	9 mm

A.4.12 Tip Cover Accessories

Part Name	Model	Effective Length (Tolerance ±10%)	Max Outer Diameter (Tolerance ±1)
Tip Cover Accessory	SP1306	142 mm	9.5 mm
Tip Cover Accessory	SP4-S	151 mm	9.5 mm
Tip Cover Accessory	SP1307	100 mm	9.5 mm
Tip Cover Accessory	SP4-I	100 mm	9.5 mm
Tip Cover Accessory	SP1403	108 mm	10.7 mm

A.4.13 Installation Tools

Part Name	Model	Max Thickness (Tolerance ±0.5)	Working Inner Diameter (Tolerance ±1)
Installation Tool	MP1801	3.5 mm	9.0 mm
Installation Tool	SP1802	/	9.0 mm

A.4.14 Sterilization Trays

Part Name	Model	Dimensions (L×W×H)
Sterilization Tray	SP1806	805 mm×420 mm×370 mm
Sterilization Tray	CM-SFI2	805 mm×420 mm×370 mm

A.4.15 Cables

Part Name	Model	Length
System cable	CM1801	10 m
System cable	CM1802	30 m
System cable	CM1804	1 m
Camera cable	CM1821	10 m
Camera cable	CM1805	30 m
Camera cable	CM1806	1 m
Camera cable	CM1836	3.5 m

Part Name	Model	Length
Energy activation cable	CM1807	1 m
Monopolar energy instrument cord	MS1801	4 m
Bipolar energy instrument cord	MS1802	5 m

A.5 Ports

A.5.1 Surgeon Console

No.	Port Name	Description
1	MS (Master-Slave) communication	Connected to MS communication port of the Signal Distributor for master-slave control operation.
		Connected to the simulator for skills and techniques exercises.
2	MV (Master-Video) communication	Reserved.
3	SDI	Connected to SDI1 or SDI4 of the Camera Control Unit for image transmission.
4		Connected to auxiliary devices which have standard SDI inputs.
5	Power inlet	Connected to the power cord for power supply.
6	Communication port	Connected to the devices with equivalent transmission protocols, e.g. debugging tools.

A.5.2 Patient Cart

No.	Port Name	Description
1	Power inlet	Connected to the power cord for power supply.
2	MS (Master-Slave) communication	Connected to MS communication port of the Signal Distributor for master-slave control operation.

No.	Port Name	Description
3	Communication port	Connected to the devices with equivalent transmission protocols, e.g. debugging tools.

A.5.3 Camera Control Unit

Front Panel

No.	Port Name	Description
1	Endoscope port	Connected to the endoscope for receiving image signals from the endoscope.
2	USB port	Connected to a USB flash drive to save the captured images.

Rear Panel

No.	Port Name	Description
1	Power inlet	Connected to the power cord for power supply.
2	Communication port	Connected to the devices with equivalent transmission protocols, e.g. debugging tools.
3	MV (Master-Video) communication port	Connected to MV communication port of the Signal Distributor for image processing.
4	Energy control	Connected to energy equipment, such as high frequency generator.
5	SDI1	Connected to SDI port of the Surgeon Console or other devices for image transmission.
6	SDI2	Connected to a monitor, a video recorder or other devices for image transmission.
7	SDI3	Connected to a monitor, a video recorder or other devices for image transmission.
8	SDI4	Connected to SDI port of the Surgeon Console or other devices for image transmission.
9	Equipotential ground plug	Connected to a potential equalization conductor.

A.5.4 Signal Distributor

No.	Port Name	Description
1	Power inlet	Connected to the power cord for power supply.
2	Energy control	Connected to energy equipment, such as high frequency generator.
3	MS (Master-Slave) communication	Connected to MS communication port of one or two Surgeon Consoles for master-slave control operation.
4		Connected to MS communication port of the Patient Cart for master-slave control operation.
5	MV (Master-Video) communication	Connected to MV communication port of the Camera Control Unit for image processing.
6	Communication port	Connected to the devices with equivalent transmission protocols, e.g. debugging tools or an insufflator.

A.6 HF Output Characteristics

Part Name	Model	Rated Voltage
Maryland Bipolar Forceps	SP1304	Coagulation, 740 V
	SP3-BM	Coagulation, 740 V
Fenestrated Bipolar Forceps	SP1303	Coagulation, 740 V
	SP3-BF	Coagulation, 740 V
Bipolar Energy Instrument Cord	MS1802	Coagulation, 740 V
Monopolar Curved Scissors	SP1301	Cutting, 3 kV
	SP3-MS	Cutting, 3 kV
Monopolar Hook	SP1302	Cutting, 3 kV
Monopolar Energy Instrument Cord	MS1801	Cutting, 3 kV

A.7 Optical and Illumination Properties

Parameter	Value
View field (2 W)	80°, tolerance ±15%

Parameter	Value
View direction	0°, tolerance ±10°
IL_{eR}(Relative self-effect of illumination light luminosity)	At the working distance of 5 cm, the nominal value of IL_{eR} at 90% of view field is 0.56, and the measured value is not less than the nominal value
Brightness response characteristic	The linear fitting coefficient of EOTF (Electro-optical Transfer Function) is not less than 0.98
SFR (Spatial frequency response)	At the working distance of 5cm, the corresponding objective spatial angular frequency is 3.0 C/(°) and 4.0 C/(°) when the SFR is 50% and 30%, tolerance -20%, no upper limit
Static image tolerance	120, tolerance -20%, no upper limit
Effective luminosity rate	The image surface of the endoscope displays that the minimum surface brightness of critical noticeable grayscale difference is 30 cd/m^2
Image resolution (frames per second)	No less than 60 fps
Color rendering index	No less than 70

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.2, B.3, B.4, and B.5, 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.

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 $\leqslant$ 5 mm
- Master-slave distance accuracy $\leqslant$ 6 mm
- Instrument angle deviation $\leqslant$ 5°
- Image delay time $\leqslant$ 50 ms

Table B.1 Table of Cables

No.	Cable Name	Cable Length	Shield	Note
1	Power cord	5 m	No	Power supply for the Surgeon Console
2	Power cord	5 m	No	Power supply for the Patient Cart
3	Power cord	1.8 m	No	Power supply for the Camera Control Unit
4	Power cord	1.8 m	No	Power supply for the Signal Distributor

No.	Cable Name	Cable Length	Shield	Note
5	System cable	10 m	Yes	Used to connect the Patient Cart and Signal Distributor, the Surgeon Console and Signal Distributor
6	System cable	30 m	Yes	
7	System cable	1 m	Yes	Connect the Camera Control Unit and the Signal Distributor
8	Camera cable	10 m	Yes	Used for the connection of the Surgeon Console and the Camera Control Unit
9	Camera cable	30 m	Yes	
10	Camera cable	1 m	Yes	Used for the connection of the Camera Control Unit and the monitor
11	Camera cable	3.5 m	Yes	
12	Energy activation cable	1 m	No	Used for the connection of the high frequency generator and the Camera Control Unit or the Signal Distributor
13	Monopolar energy instrument cord	4 m	No	Used for the connection of the monopolar instruments and the high frequency generator
14	Bipolar energy instrument cord	5 m	No	Used for the connection of the bipolar instruments and the high frequency generator
15	Endoscope cable	5 m	Yes	Used for the connection of the endoscope and the Camera Control Unit.

Table B.2 Guidance and Manufacturer’s Declaration - Electromagnetic Emissions

Guidance and Manufacturer’s Declaration - Electromagnetic Emissions	
Emissions Test	Compliance

Guidance and Manufacturer’s Declaration - Electromagnetic Emissions	
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.3 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

Immunity Test	IEC 60601 Test Level	Compliance Level
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.4 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity						
	Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**IEC 60601-1-2 Test Level (V/m)**	**Compliance Level (V/m)**
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	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;	Pulse modulation 217 Hz	28	28
	1845					
	1970					

Guidance and Manufacturer's Declaration - Electromagnetic Immunity						
			LTE Band 1, 3, 4, 25; UMTS			
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500					
	5785					

Table B.5 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

Appendix C List of System Components

No.	Part Name	Model	Lifetime/Shelf Life
1	Surgeon Console	MP1101	10 years
2	Patient Cart	SP1102	10 years
3	Signal Distributor	MP1204	10 years
4	Camera Control Unit	MP1202	10 years
5	Vision Cart	CM2101	10 years
6	System Cable	CM1801	N/A
7	System Cable	CM1802	N/A
8	System Cable	CM1804	N/A
9	Energy Activation Cable	CM1807	N/A
10	Camera Cable	CM1806	N/A
11	Camera Cable	CM1836	N/A
12	Camera Cable	CM1821	N/A
13	Camera Cable	CM1805	N/A
14	Endoscope	SP1207	100 uses
15	Maryland Bipolar Forceps	SP1304	10 uses
16		SP3-BM	10 uses
17	Fenestrated Bipolar Forceps	SP1303	10 uses
18		SP3-BF	10 uses
19	Needle Driver	SP1305	10 uses
20		SP3-ND	10 uses
21	Large Needle Driver	SP1335	10 uses
22		SP3-LND	10 uses
23	Monopolar Curved Scissors	SP1301	10 uses
24		SP3-MS	10 uses

No.	Part Name	Model	Lifetime/Shelf Life
25	Monopolar Hook	SP1302	10 uses
26	Medium-Large Clip Applier	SP1332	150 closures
27		SP3-CA	150 closures
28	Cadiere Forceps	SP1334	10 uses
29		SP3-CF	10 uses
30	Tip-up Fenestrated Grasper	SP1337	10 uses
31		SP3-TG	10 uses
32	Round Tooth Retractor	SP1333	10 uses
33	Curved Needle Driver	SP1309	10 uses
34	Cannula	SP1406	500 uses
35		TR1-SP	500 uses
36	Obturator	SP1502	500 uses
37		TR2-SP	500 uses
38	Cannula Seal	SP0801	1 use/2 years
39		TR3-SP	1 use/2 years
40	Disposable Drape	DR1004	1 use/2 years
41		DR1006	1 use/2 years
42	Tip Cover Accessory	SP1306	1 use/2 years
43		SP4-S	1 use/2 years
44		SP1307	1 use/2 years
45		SP4-I	1 use/2 years
46		SP1403	1 use/2 years
47	Installation Tool	MP1801	1 use/2 years
48		SP1802	500 uses
49	Monopolar Energy Instrument Cord	MS1801	50 uses

No.	Part Name	Model	Lifetime/Shelf Life
50	Bipolar Energy Instrument Cord	MS1802	50 uses
51	Sterilization Tray	SP1806	500 uses
52		CM-SFI2	500 uses

Appendix D Glossary

Term	Meaning
2D	Two-dimensional.
3D	Three-dimensional.
AC	Alternating Current, also represented by the AC symbol ～.
AP/APG	ME equipment or parts described in the accompanying documents for use with flammable anaesthetics (category AP) or flammable anaesthetics with oxidants (category APG) shall comply with IEC 60601-1.
BF	An IEC 60601-1 classification for patient applied parts, which is protectively earthed, connected to earth but not protectively earthed, or floating but not isolated from earth to the degree that would be required for a type BF applied part, but is not suitable for direct cardiac application.
CF	An IEC 60601-1 classification for patient applied parts. Type CF is the most stringent classification, being required for those applications where the applied part is in direct conductive contact with the heart or other applications as considered necessary.
Circulating nurse	A nurse who prepares for an operation and continually monitors the patient and staff in the operating room outside the sterile field.
COM	A communication port.
Docking	Attaching the cannula to the Patient Cart at the start of a surgery.
EPO	Emergency Power Off. A button is used to power off the Patient Cart.
EOTF	Electro-optical Transfer Function.
HD	High Definition.
HF	High Frequency.
LED	Light Emitting Diode. A light-emitting diode is a semiconductor device that emits light when current flows through it.
ME	Medical Electrical Equipment.

Term	Meaning
MS	Master-Slave
MV	Master-Video
OR table	Operating table.
PiP	Picture in Picture, a feature that allows display of the image of the operative field and up to two additional images provided by auxiliary inputs.
Remote center	A pivot point around which the endoscope and instruments move, indicated by the thick, center black line on the cannula. Remote center technology enables the system to maneuver instruments and endoscope in the surgical site while exerting minimal force on the patient’s body wall.
Scrub nurse	A nurse who assists a surgeon by performing certain specialized duties in the operating room inside the sterile field.
SDI	Serial Digital Interface.
SFR	Spatial frequency response.
Surgical workspace	The area within the patient that the instruments will be required to reach to complete all surgical tasks throughout the procedure.
Target anatomy	The center of the surgical workspace boundary.
UPS	Uninterruptible Power Supply.
USB	Universal Serial Bus. An industry standard that specifies the physical interfaces and protocols for connecting, data transferring and powering of hosts.

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