MP1000

Endoscopic Instrument Control System

User Manual

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Important Regulatory Information

Contact Information

During the use of the system, if a serious incident has occurred, it shall be reported to the manufacturer and/or its authorized representative and to your national authority.

If the system requires maintenance or service, please use the following contact information.

In China

Manufacturer: Shenzhen Edge Medical Co., Ltd.

Manufacturer Address: 2B 1901, Phase II, Smart Home, No.76, Baohe Avenue, Baolong Community, Baolong Street, Longgang District, 518116, Shenzhen, P.R.China

Manufacturer Site Address: 2B 0401, 1901, 2001, 2101, Phase II, Smart Home, No.76, Baohe Avenue, Baolong Community, Baolong Street, Longgang District, 518116, Shenzhen, P.R.China

E-Mail: contact@edgemed.cn

Web: www.edgemedicalrobotics.com

In Europe

Authorized Representative in the European Community: Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

E-Mail: shholding@hotmail.com

Prescription Information

Rx Only

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Disclaimers

The company reserves the right of final interpretation of this document.

All figures provided in this document are for reference only, and the settings or parameters in the figures may not be exactly same as the products.

The company shall be responsible for the safety, reliability and performance of the products only if all of the following requirements are met:

- 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 European Authorized Representative for a copy.

About This Manual

Thank you for choosing MP1000 Endoscopic Instrument Control 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.
		Click **Restart**.
>	Directs multi-level menus.	Go to **Account** > **User Login**.

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1. Introduction

1.1 System Components

The system consists of one or two Surgeon Consoles, a Patient Cart, a Vision Cart and Accessories.

The vision cart include a camera control unit and a signal distributor.

The accessories include system cables, camera cables, energy activation cables and an illuminator control cable.

1.2 Intended Use/Indication for Use

The Endoscopic Instrument Control System (MP1000) is intended to assist in the accurate control of endoscopic Instruments including rigid endoscopes, scissors, ultrasonic scalpels, forceps, needle drivers, hooks and accessories for endoscopic manipulation, ligation, electrocautery, suturing, and delivery and placement of accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, and thoracoscopic surgical procedures. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the professional instructions for use.

1.3 Intended Users

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

1.4 Intended Patient Population

Adult.

1.5 Training

Warning: Only trained users and those who have developed adequate robotic skills should use the system. Training provided by Edge Medical is limited to the use of MP1000 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 MP1000 have been considered developed.

1.6 Clinical Benefits

The overall benefits of the Edge Medical MP1000 Endoscopic Instrument Control System include an expanded access to minimally invasive surgery for an increasing variety of procedures.

The potential clinical benefits of the Edge Medical MP1000 Endoscopic Instrument Control System as a minimally invasive tool include lower estimated blood loss, fewer complications and lower length of hospital stay when compared with the open approach and lower or similar rates of conversion, when compared to the laparoscopic approach. These clinical benefits/outcomes may depend on a number of factors, including, but not limited to patient characteristics, disease characteristics, surgeon experience, and hospital/national patient care and recovery pathways.

1.7 Clinical Risks

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

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

Individuals' outcomes may depend on a number of factors, including but not limited to patient

characteristics, disease characteristics and/or surgeon experience.

1.8 Safety Information

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

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

Precautions for Use in Smaller Patients

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

1.8.1 Contraindications

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

1.8.2 General Precautions

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

- Check whether the instruments are compatible with the system. Incompatible instruments may result in delayed treatment or even injury to the patient.
- Check for the status, performance and integrity of the system, no rough surfaces, sharp edges or protrusions occurred on the instruments, endoscope, cannulas and obturators. 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, cannulas, obturators and monopolar or bipolar energy instrument cord. Improper operation or ineffective sterilization may cause cross-contamination.
- Check for clearance between the patient and the arms 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 single-use sterile 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: The following safety guidelines should be observed to avoid a pinch or crush hazard:

- When the arms of the Patient Cart preforms a self-test during the startup sequence, keep fingers away from the arms.
- When activating the **Instrument Clutch** buttons, keep fingers away from the joints located on the arms.

Warning: The system is equipped with a laser indicator for auxiliary positioning, which complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to laser notice No. 50 Dated June 24, 2007. Although Class 1 laser products are considered to be “eye-safe” without the need for additional protection, do not look or stare at optical fibers or ports connected to an endoscope illuminator when they are working, reducing the risk of eye injury.

Warning: When using the instruments, do not touch the housings of the instruments because the rising high temperature may result in burns.

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 open 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: Do not remove the cannula and instrument from the body simultaneously because 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: The circulating nurse could push the emergency button to lock the device when there's a potential accident.

Warning: Users should standardize the use of the device. Before docking 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.

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 force feedback associated with the MP1000 is different from feedback experienced when using conventional instruments. As with any endoscopic procedure, the surgeon should rely on visual cues to enhance force feedback.

Caution: The components of the system for use in the patient environment include the Patient Cart, instruments, endoscope, cannulas, cannula seals, obturators, tip covers 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: 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 straight 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 arms, boom or rotating platform of the Patient Cart.

Caution: Do not move the instrument arms 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 User Manuals and Reprocessing Instructions Manuals.

Note: Only items that have been specified as part of the system or that have been specified as being compatible with the system can be connected to the system. Those items that are 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 arms. 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: The system cannot be used for urinary diversion during radical cystectomy. The process shall be carried out as an extracorporeal operation.

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

Note: Consider increasing the distance between the arms 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 arms and surgical bed.

1.8.3 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: High-energy light radiated by the endoscope and endoscope illuminator may cause eye hazards. Only personnel with adequate technical training and rich experience can operate the equipment.

Warning: The highly concentrated light energy can cause the distal end, the light port, adjacent components and tissue in front of the light emission window 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 end, as well as with the light port of the endoscope and the light guide bundles.
- Avoid excessively long continuous direct tissue contact with the shaft.
- Always select the lowest possible light output that still allows optimal illumination of the operating field.
- Avoid resting the endoscope or the light guide cable on the patient or in direct contact with surgical 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: The endoscope can output highly concentrated light energy. When the endoscope is connected to the system and emitting light, never look or stare at the lens of the endoscope. Direct eye exposure to emitted light can cause permanent eye injury.

Warning: To avoid burns or flammation, always turn off the endoscope illuminator when removing the light guide bundles, replacing or stop using the endoscope. Do not contact high-temperature parts of the endoscope with the operator, patient, drapes or flammable materials.

Warning: The laser energy produced by fluorescence imaging may cause injury to the operator or patient. When removing the endoscope from the body, stop using fluorescence imaging.

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

- After disinfection, check and clean the residual liquid before high frequency surgery.
- During cleaning or disinfection, 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.

Warning: When using the system during the procedure, do not allow to establish pneumoperitoneum by suspending the abdominal wall.

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.

Caution: Be careful with the light guide bundles. Serious bends or kinks can

damage the optical materials inside the cable and increase fiber loss.

1.8.4 Energy Surgical Procedure Precautions

Warning: Due to the carcinogenic and infectious potential of by-products such as tissue smoke and suspended solids from energy sources (electrosurgical, laser and ultrasound 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, 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 high frequency generator.
- For electrosurgery where high frequency 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 high frequency 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 high frequency 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 high frequency 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 and disinfecting. If flammable agents are used for cleaning or disinfecting 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 high frequency surgical equipment is used. Attention should be called to the danger of ignition of endogenous gases.

Warning: The rated voltage of the monopolar instruments (monopolar scissors and monopolar electric hooks) 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 (Maryland bipolar forceps and bipolar grasping forceps) and bipolar energy instrument cord should be 375 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: Failure of high frequency surgical equipment can cause unintended increase in output power.

Warning: A thorough understanding of the principles and techniques involved in laser, electrosurgical and ultrasound 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: When the ultrasonic scalpel is used on solid organs, successful hemostasis may require adjunct measures. Do not attempt to transect large masses of tissue or divide large vascular/biliary bundles, as hemostasis may not be predictable.

Warning: During prolonged activation in tissue, the blade, clamp arm and approximately 7 cm of the distal end of the ultrasonic scalpel may become hot. Avoid unintended contact with tissue, drapes, surgical gowns, or other unintended sites at all times.

Warning: Use care when the ultrasonic scalpel is activated, as the surface of the blade and clamp arm may remain hot enough to cause burns.

Warning: Activating an electrosurgical instrument near the ultrasonic scalpel may cause injury to the medical personnel or patient. The aerosols produced by activating the instrument in adipose tissue may be flammable.

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.

Warning: This system requires endoscopic instrument and ultrasonic scalpel to be type CF applied parts, devices connected to endoscopic instruments and ultrasonic

scalpels are at least CF-type devices

Warning: This system requires endoscope to be type BF applied parts.

Warning: Each power supply in the system should be connected to a common ground network power supply, without a common ground may generate static electricity risk.

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

Caution: High frequency electrosurgical procedures may cause interference with pacemakers. If a patient has a pacemaker, please consult the manufacturer of the device.

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

Caution: To avoid damage to the tissue pad, keep the clamp arm open while the blade is active without tissue between the blade and tissue pad.

Caution: The instrument blade, clamp arm, and distal end of the ultrasonic scalpel should not be in contact with any metal instruments or hard objects while in use, or damage (for example, bent, cracked, or broken) to the blade may occur.

Caution: Avoid incidental and prolonged activation against solid surfaces (for example, bone), as this may result in blade heating and subsequent blade failure.

Caution: Avoid introducing or withdrawing the instrument through the cannula or cannula seal with the jaws open, as this may damage the instrument.

Caution: Avoid any intentional or accidental contact with other instruments during use.

Caution: When medical personnel is in contact with the ultrasonic scalpel in a procedure, avoid liquids getting into the instrument and resulting in damage.

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.

Note: If the sound from the blade of the ultrasonic scalpel or hand piece is abnormal while in use, check whether the hand piece is out of service life or connected improperly.

1.8.5 Electrical Safety

Warning: Leakage current to the patient may increase when the system is interconnected to or used with other medical electrical equipment. To ensure safety, only the equipment that meets the requirements of the medical electrical equipment standards IEC 60601-1 can be interconnected with the system.

Warning: Leakage current to the patient may increase when using energy instruments. To ensure safety, only Type BF or CF medical electrical equipment can 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 covers before using instruments to ensure that tip covers are intact. Broken tip covers 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, 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.

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

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

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

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

Note: Portable and mobile communications equipment may produce EMI, which may affect the function of the system. Use the equipment with EMI characteristics proven below recognized limits.

1.8.6 Installation and Maintenance Precautions

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

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 Shenzhen Edge Medical Co., Ltd. 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 Shenzhen Edge Medical Co., Ltd. Read *Installation and Maintenance Guide*, and *Service Manual* carefully before installation, service or maintenance.

1.8.7 Transportation and Storage Precautions

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

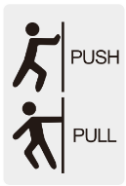
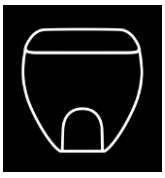
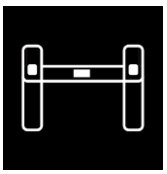
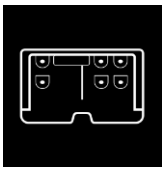
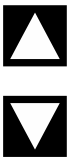
Caution: Handle the instruments and endoscope with care. Avoid mechanical shock or stress that can cause damage to the instruments and endoscope.

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

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

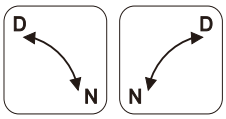
1.9 Symbol Reference Tables

1.9.1 Surgeon Console

Symbol	Meaning	Symbol	Meaning
	“ON” (power)		“OFF” (power)
	Alternating current		Fuse
	Debugging		MS (Master-Slave) communication port
	MV (Master-Video) communication port		Indicates where to push or pull the Surgeon Console
	Do not walk or stand here		Do not push or pull here
	Standby		Emergency stop
	Adjust the viewer height		Adjust the armrest height
	Adjust the footswitch panel depth		Adjust up or down
	Protective earth (ground)		Maximum load

1.9.2 Patient Cart

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

Symbol	Meaning	Symbol	Meaning
	Alternating current		Fuse
	Debugging		Manual movement
	Warning: Laser beam		Brake switch
	Indicates where to open the panel above the base		Adjust the boom position
	Do not walk or stand here		Do not push or pull here
	Pinch/Crush hazard		Maximum load
	Standby		Emergency stop
	MS (Master-Slave) communication port		Type CF applied part
	Protective earth (ground)	EPO	Emergency power off
UPS	Uninterruptible Power Supply	/	/

1.9.3 Camera Control Unit

Symbol	Meaning	Symbol	Meaning
	“ON” (power)		“OFF” (power)
	Alternating current		Fuse

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

1.9.4 Signal Distributor

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

1.9.5 Package Labeling and Other Symbols

Symbol	Meaning	Symbol	Meaning
	This side up		Fragile, handle with care
	Keep dry		Stacking limit by mass
	CE marking	Rx only	Federal (USA) law restricts this device to sale by or on the order of a physician
	Refer to instruction manual		Operating instructions
MD	Medical Device	EC REP	Authorized Representative in the European Community
	Manufacturer		Date of manufacture
	Dispose of in accordance with local regulations—particularly applies to electronic components		Temperature limits
	Humidity limitation		Atmospheric pressure limitation
SN	Serial number		Caution (consult instructions for use)

1.9.6 Laser Safety Labeling

The Patient Cart has laser indicator, which is classified into Class 1 laser products. The Patient Cart has been evaluated IEC 60825-1: 2014 and complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007. The Patient Cart is labeled with the following warning label.

Figure 1.1 Laser Warning Label

1.10 Service Life

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

1.11 Date of Manufacture

See product label for date of manufacture.

1.12 Combination Use

The Endoscopic Instrument Control System is designed for use with the following compatible equipment provided by Edge Medical only:

Product Name		Model
Manufactured by Edge Medical		
Fluorescence Endoscope		MP1212, MP1213
Endoscope Illuminator		HE1003
Disposable Ultrasonic Scalpel		MP1500
Disposable Drape		DR1001, DR1002, DR1003
Endoscopic instruments and accessories	Maryland Bipolar Forceps	MP1302
	Maryland Bipolar Forceps	MP4-BM-P
	Bipolar Forceps	MP1305
	Bipolar Forceps	MP4-BF-P
	Enhanced Bipolar Forceps	MP1316
	Enhanced Bipolar Forceps	MP4-FB-P
	Needle Driver	MP1308
	Needle Driver	MP4-ND-P
	Large Needle Driver	MP1324
	Monopolar Scissors	MP1311

Product Name		Model
	Monopolar Hook	MP1314
	Enhanced Forceps	MP1318
	Enhanced Forceps	MP4-PG-P
	Cadiere Forceps	MP1320
	Cadiere Forceps	MP4-NRG-P
	Tip-up Fenestrated Grasper	MP1322
	Tip cover accessory	MP1402
	Installation tool	MP1801
	Monopolar Energy Instrument Cord	MS1801
	Bipolar Energy Instrument Cord	MS1802
Puncture Kits	Cannula	TR1-A8I, TR1-A8E, TR1-A12, TR1-A15，TR1-A8I-L, TR1-A8E-L, TR1-A12-L, TR1-A15-L
	Obturator	TR2-A8IB, TR2-A8IP, TR2-A8EB, TR2-A8EP, TR2-A12B, TR2-A12P, TR2-A15B, TR2-A15P, TR2-A8IB-L, TR2-A8IP-L, TR2-A8EB-L, TR2-A8EP-L, TR2-A12B-L, TR2-A12P-L, TR2-A15B-L, TR2-A15P-L
	Cannula Seal	TR3-A8, TR3-A8E, TR3-A12, TR3-A15
	Reducer	TR4-A8/5, TR4-A12/8, TR4-A15/8
Manufactured by ERBE		
HF generator		VIO300S
Manufactured by Hocer		
Generator		USG10 Plus

2. System Overview

2.1 System Description

MP1000 Endoscopic Instrument Control System (hereinafter referred to as “MP1000 System” or “the system”) is designed to enable complex surgery using a minimally invasive approach. The system consists of one or two Surgeon Consoles, a Patient Cart, a vision cart (include a camera control unit and a signal distributor) and accessories. Setup and intraoperative use may require sterile and non-sterile tasks performed by the following users: surgeon, circulating nurse (non-sterile user) or scrub nurse (sterile user). The specification of system please refer to appendix A System Specifications.

Figure 2.1 Main Components of the System

2.2 Surgeon Console

The Surgeon Console is the control center of the entire system. The surgeon sits 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 instrumentation along with icons and other user interface features.

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

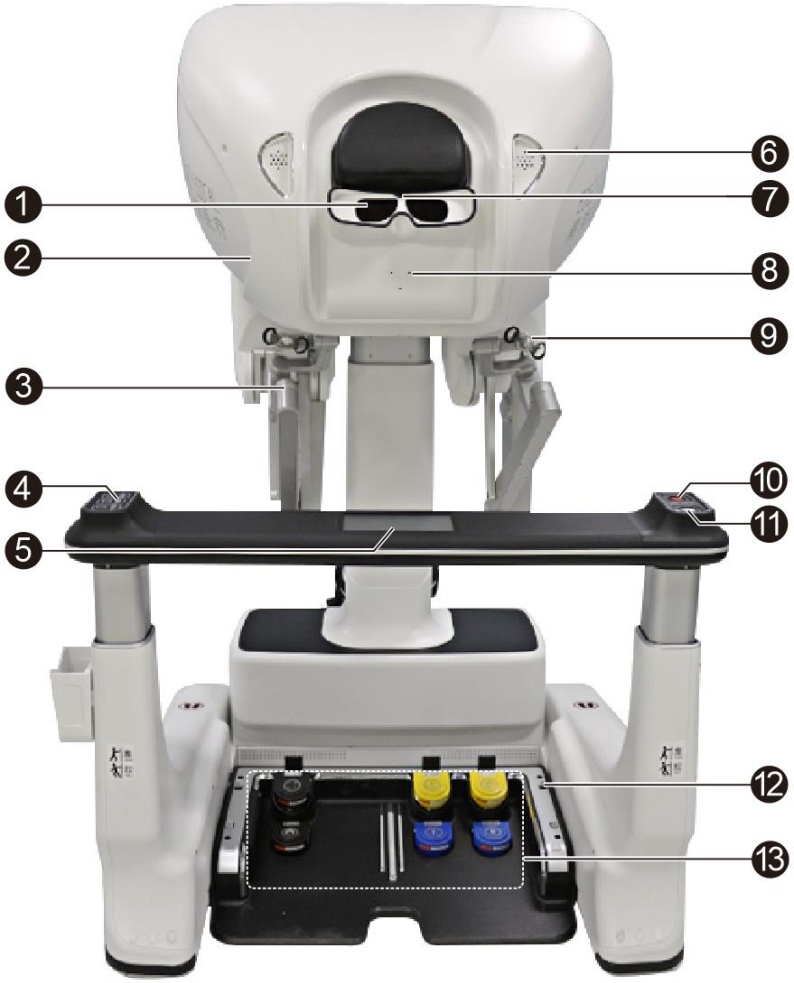
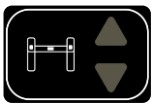
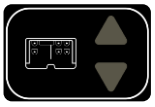


Figure 2.2 Surgeon Console

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

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

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

2.3 Patient Cart

The Patient Cart is positioned at the operating table, and is mainly composed of the base, column, helm, boom, rotating platform and four instrument arms. The instruments and endoscope are attached onto the instrument arms, and all movements are controlled by the surgeon at the Surgeon Console. The Patient Cart can be moved or rotated for positioning based on the patient anatomy and workspace. The patient-side assistant installs and removes the instruments and endoscope intraoperatively.

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

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

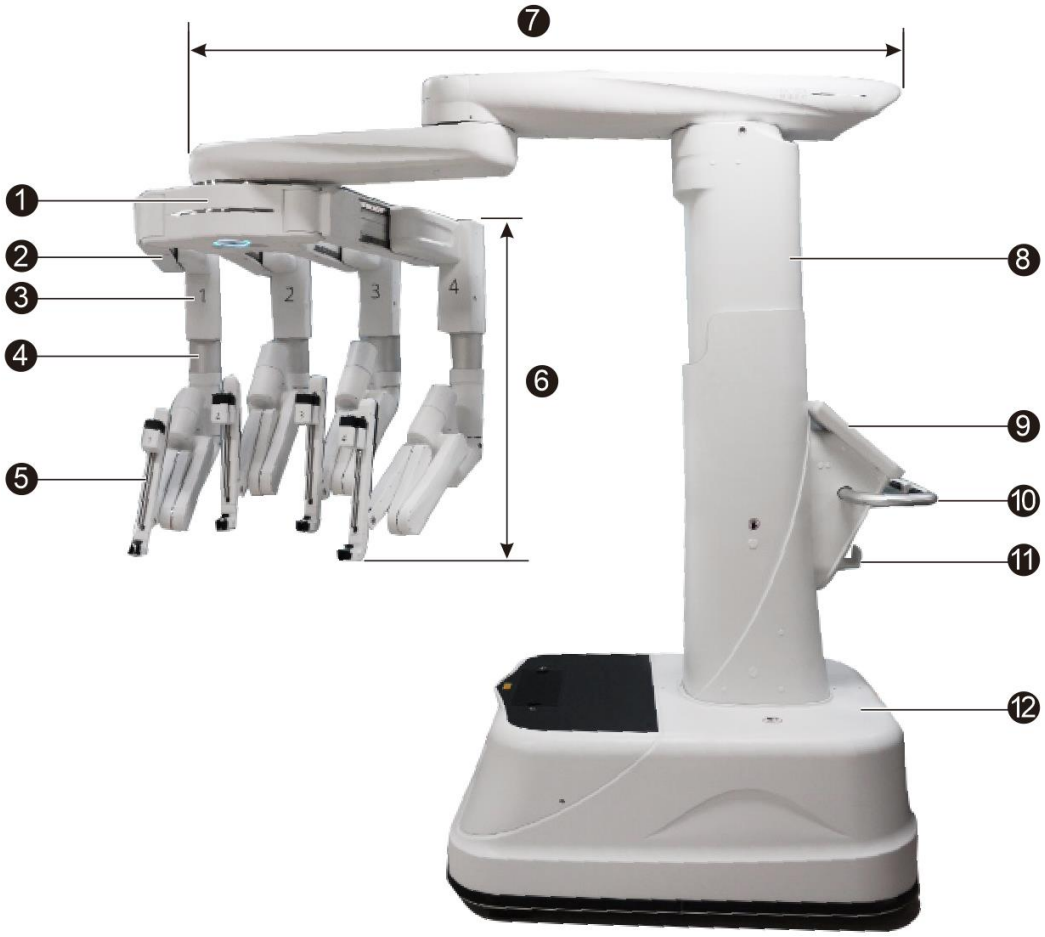


Figure 2.3 Patient Cart

No.	Name	Description
1	Rotating platform	Used to connect four arms, and rotate the boom cluster of arms for the Patient Cart positioning.
2	Horizontal adjustment arms	Used to adjust the position of the arms horizontally.
3	Vertical adjustment arms	Used to adjust the position of the arms vertically.
4	Arm height joints	Used to adjust the height of the arms.
5	Instrument arms	Include instrument carriages, controls, ports and indicator lights for fixing and moving the endoscope and instruments, and indicating working status.

No.	Name	Description
6	Arms	Include instrument arms, vertical adjustment arms, horizontal adjustment arms and arm height joints, four arms in total. The distal end attaches to the cannulas and the proximal end attaches to the rotating platform.
7	Boom	The boom is adjustable, rotating support structures for the arms.
8	Column	Moves the boom up or down.
9	Touchscreen	Provides features for Patient Cart activities including preparing the cart for draping, stowing the cart and enabling boom controls, and also provides a means for system fault notification and recovery.
10	Handlebars	Used for moving the Patient Cart and includes two drive enable switches to maneuver the Patient Cart around the operating room.
11	Hook	Used for hanging the cables.
12	Base	Includes a motorized cart drive for positioning and transportation, and the electronics.

Figure 2.4 Audio System

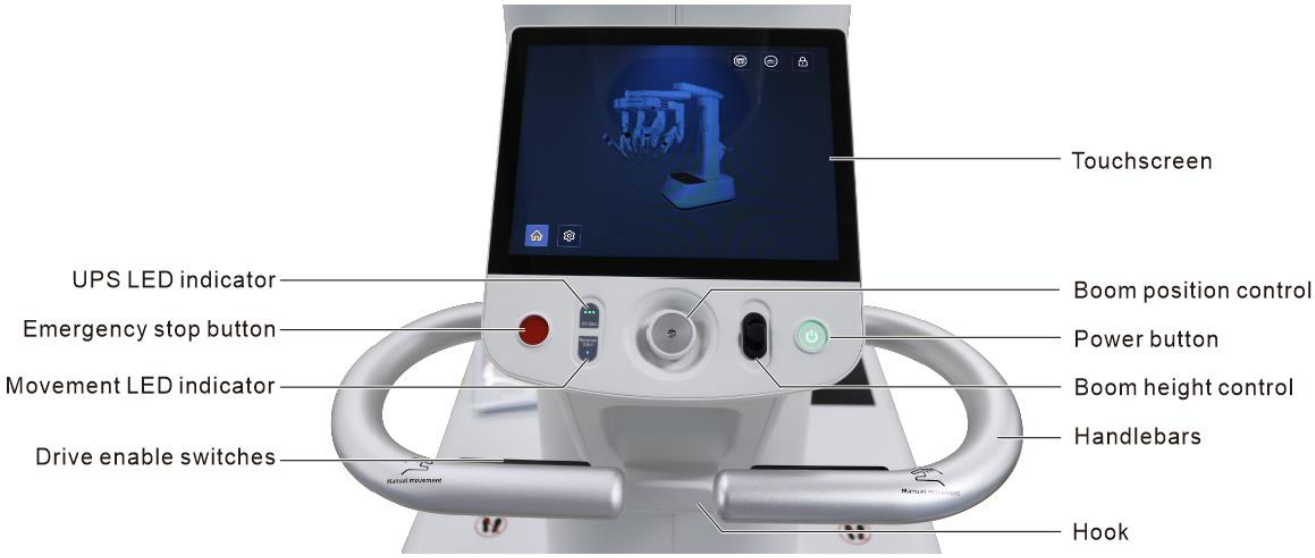


Figure 2.5 Helm

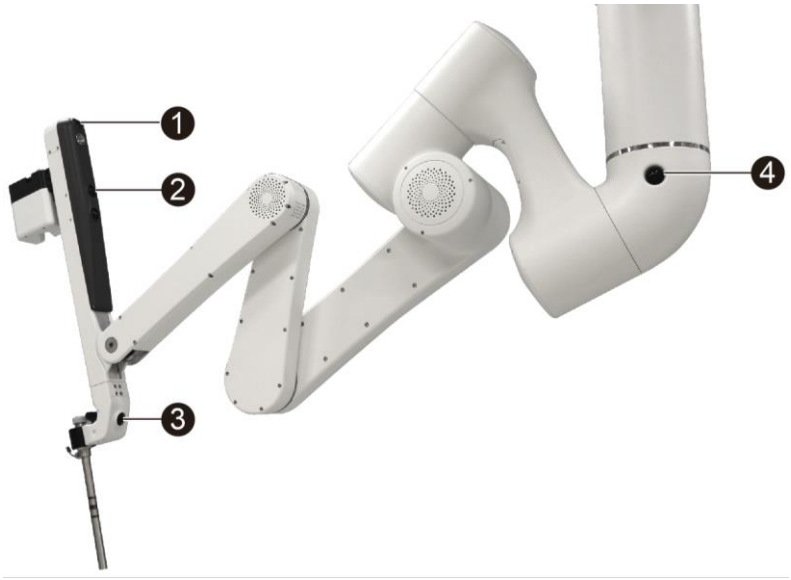


Figure 2.6 Arm controls

No.	Name	Description
1	Instrument clutch button	User initiated movements to advance or retract the endoscope or instrument tip within the surgical site. User initiated movements of the arm about the remote center.
2	Patient clearance button	Used to adjust the arm angle.
3	Port clutch button	Used to reposition the arms to resolve arm collisions and reduce tension at the port site during the procedures.
4	Rotation button	Used to rotate the rotating platform. Only the outer two arms (1 and 4) are equipped with **Rotation** buttons.

2.4 Vision Cart

The Vision Cart is an important part of the system, mainly composed of the camera control unit and signal distributor. Auxiliary surgical equipment including the monitor, high frequency generator, suction irrigator and pneumoperitoneum apparatus can be placed on the Vision Cart.

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

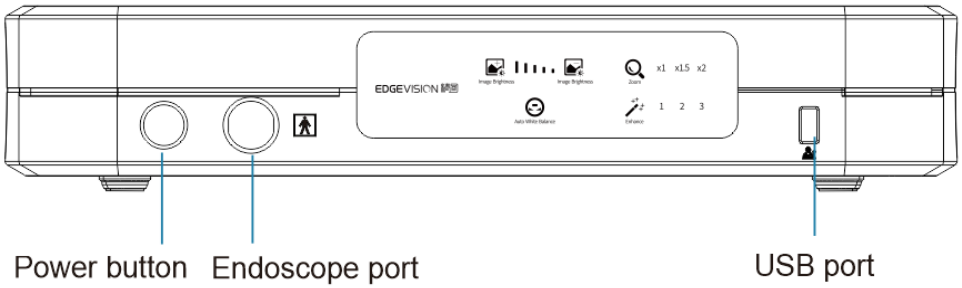


Figure 2.7 Front of Camera Control Unit

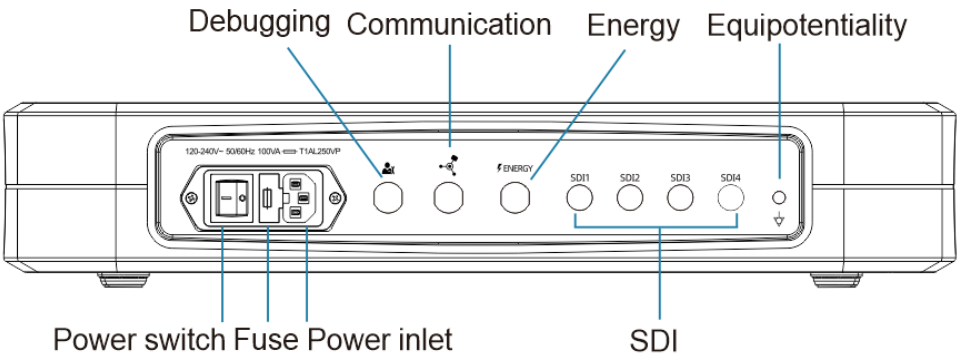


Figure 2.8 Rear of Camera Control Unit

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

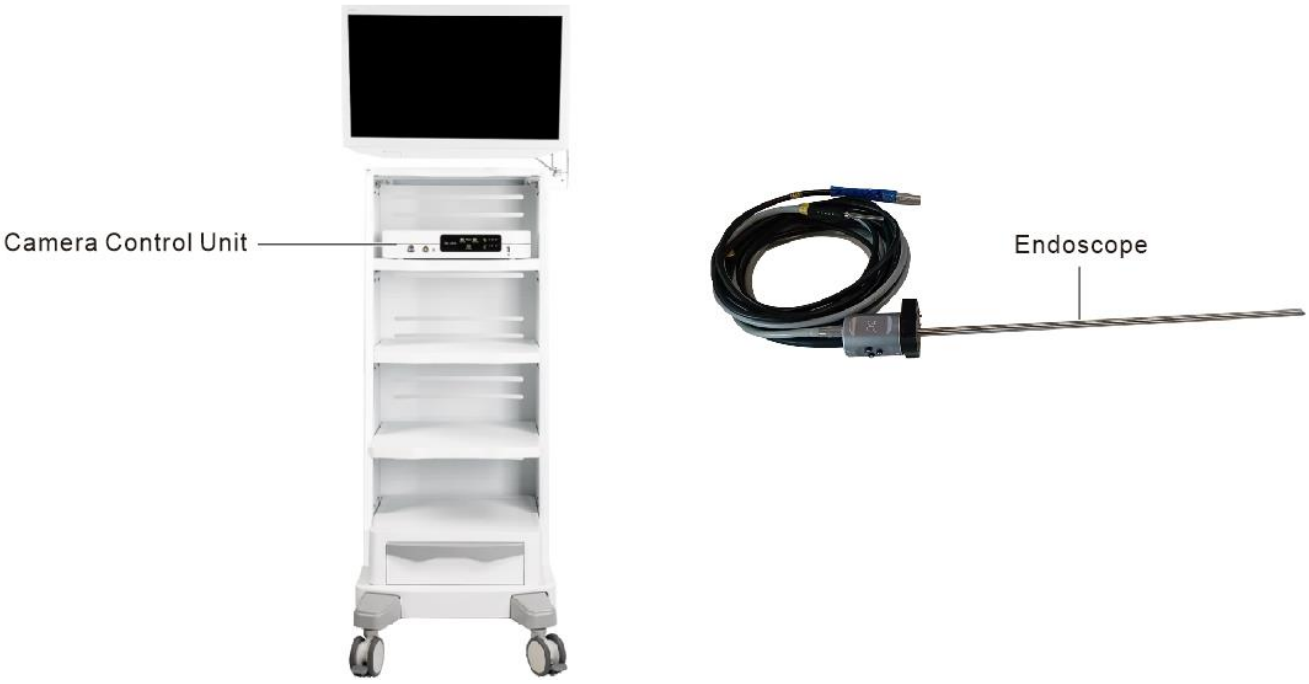


Figure 2.9 Vision Cart

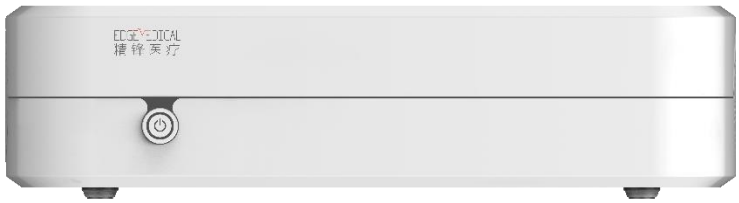


Figure 2.10 Signal Distributor

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

Note: The monitor of the system can be connected to SDI cables or SDI converters.

2.5 Accessories

The accessories for MP1000 System include system cables, camera cables and energy activation cables.

- System cables are used for system communication, including:
  - Two or three system cables, 10m/30m: Used to connect the Patient Cart and Surgeon Console.

- One system cable, 1m: Used to connect the Camera Control Unit and Signal Distributor.

Figure 2.11 System Cable

- Energy activation cables are intended to control the generators providing electrosurgical instruments or ultrasonic scalpels with high frequency energy. The energy activation cable (Model: CM1807) is used to connect HF generator and the Signal Distributor. The energy activation cable (model CM1835) is used to connect the ultrasonic generator and the Signal Distributor.

Figure 2.12 Energy Activation Cables

- The camera cables of 1m and 2m (model: CM1806 and CM1820) are used to connect the Camera Control Unit and monitor. The camera cables of 10m and 30m (model: CM1821 and CM1805) are used to connect the Surgeon Console and Camera Control Unit.

Figure 2.13 Camera Cable

- The illuminator control cable (CM1815) is used to connect the Endoscope Illuminator and the Camera Control Unit on the rear of each equipment.

Figure 2.14 Illuminator Control Cable

3. Operating Room Configuration and System Positioning

3.1 Operating Room Configuration

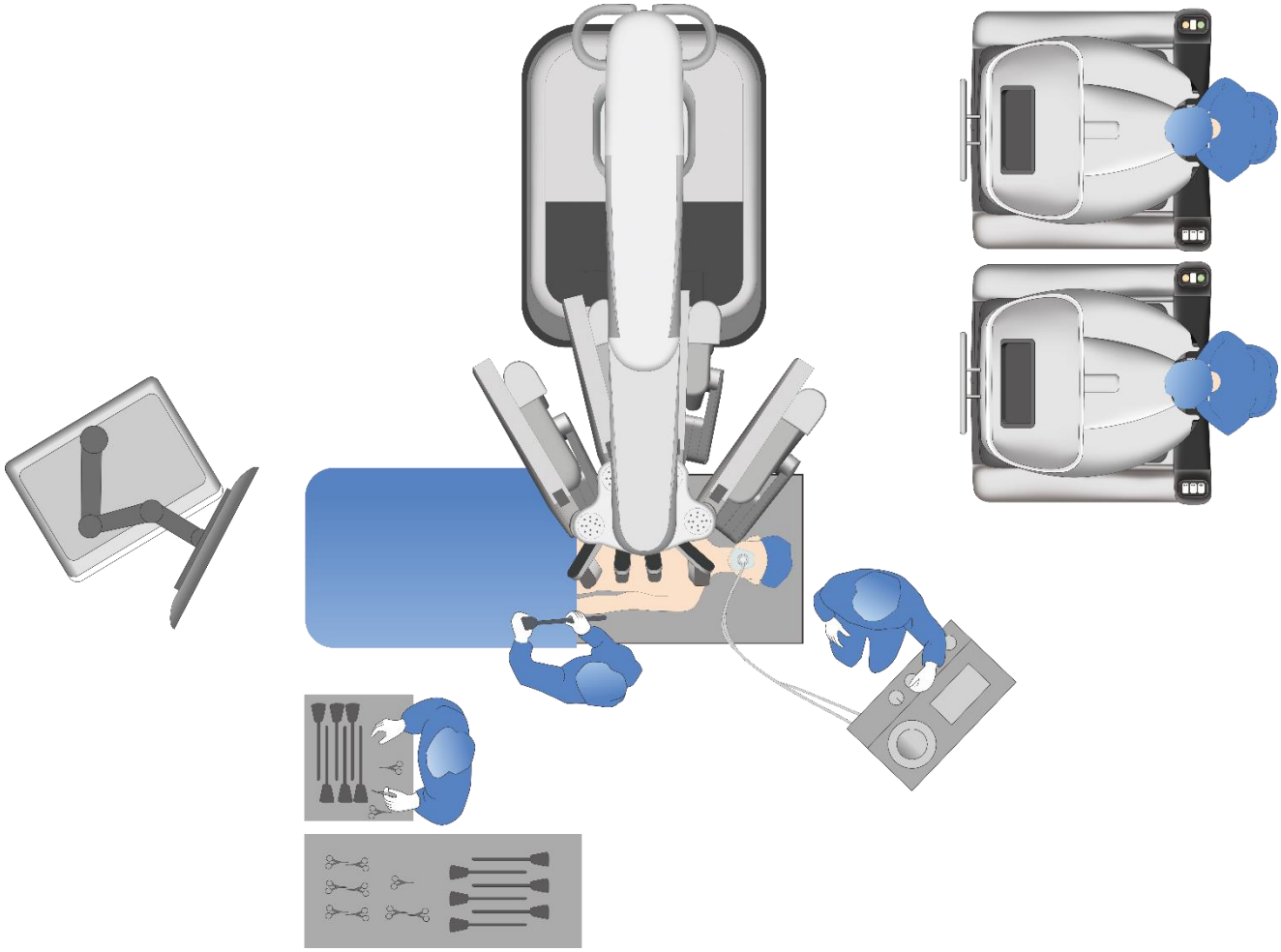


Figure 3.1Example of Operating Room Configuration

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

The system allows up to 270° of patient access. To ensure maximum patient-side access, position the Patient Cart so it is on either side of the patient.

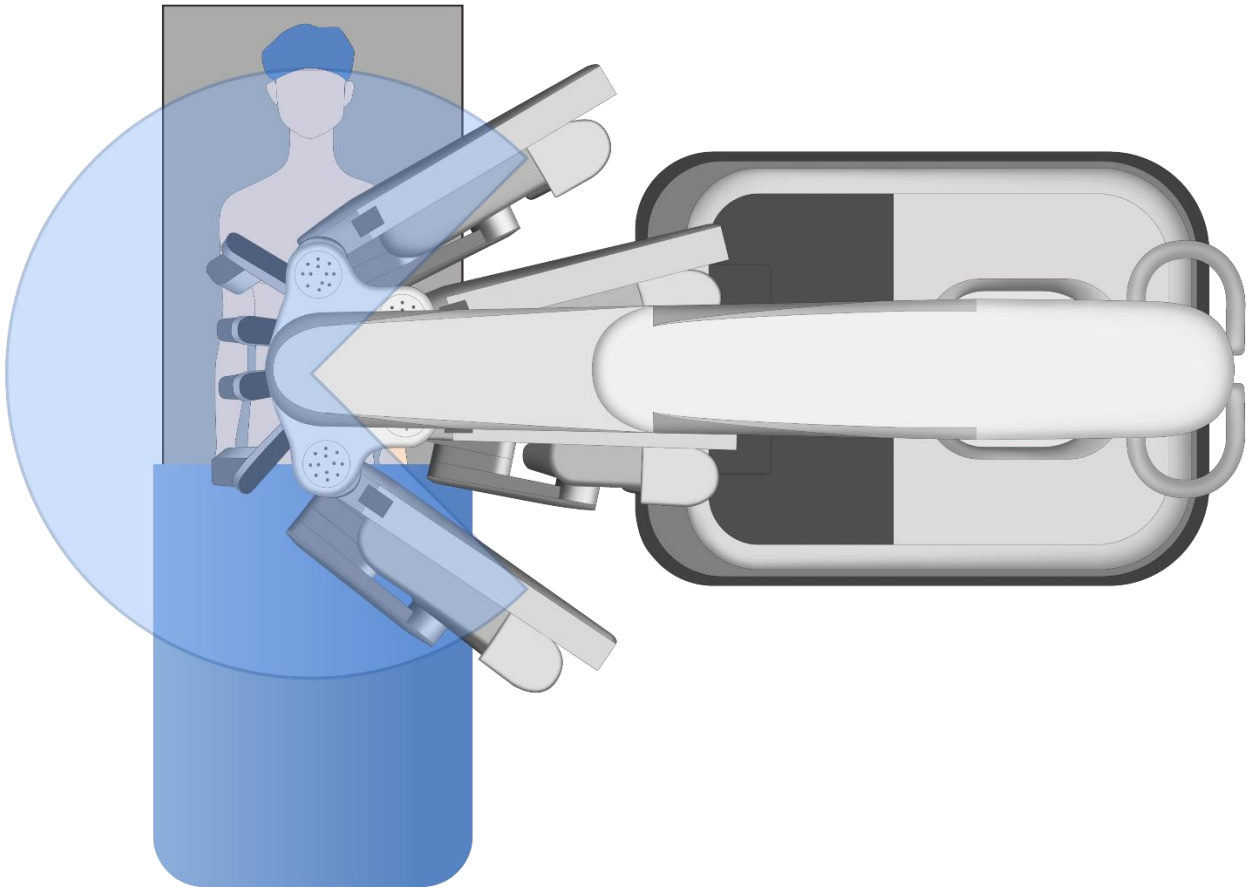


Figure 3.2 270° Patient Access

The Patient Cart can be placed anywhere around the patient. The system provides positioning between the patient's legs or from the side. For procedures where the target anatomy is off midline, place the Patient Cart at the same side of the patient as the target anatomy.

The range of rotation of the boom can be 322°±5°. Avoid rotating the boom to be opposite the base. In this configuration, both patient access and patient-side assistant access are limited, and the assistant is often with his or her back close to the sterile draped column.

- 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 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.

Special considerations for procedures with off midline target anatomies (for example, in the renal and lower abdominal regions):

- Place the Patient Cart on the opposite side of the anesthesia.
- Consider rotating the patient to a certain degree to allow side access to the Patient Cart in order to minimize movement of the anesthesia and Patient Cart and maximize patient-side access.

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.

3.2 Surgeon Console Positioning

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

3.2.1 Pushing or Pulling

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

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

3.2.2 Brakes

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

3.2.3 Footswitch Panel

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

3.3 Patient Cart Positioning

The Patient Cart has a motorized drive that enables to transport the cart. The Patient Cart has three positioning statuses: for power off or standby, draping, and surgery. When moving the Patient Cart, especially getting into the sterile field for surgery, two people are recommended 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 should be an area where it will facilitate the deployment of the instrument arms, 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.
- Brakes: The brakes lock the Patient Cart into place to prevent movement during surgery. The Patient Cart brakes automatically engage when the motor drive is not in use.
- Stabilization devices: To improve the stability of the base, two 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 Cart Positioning

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

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

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

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

4. System Connections

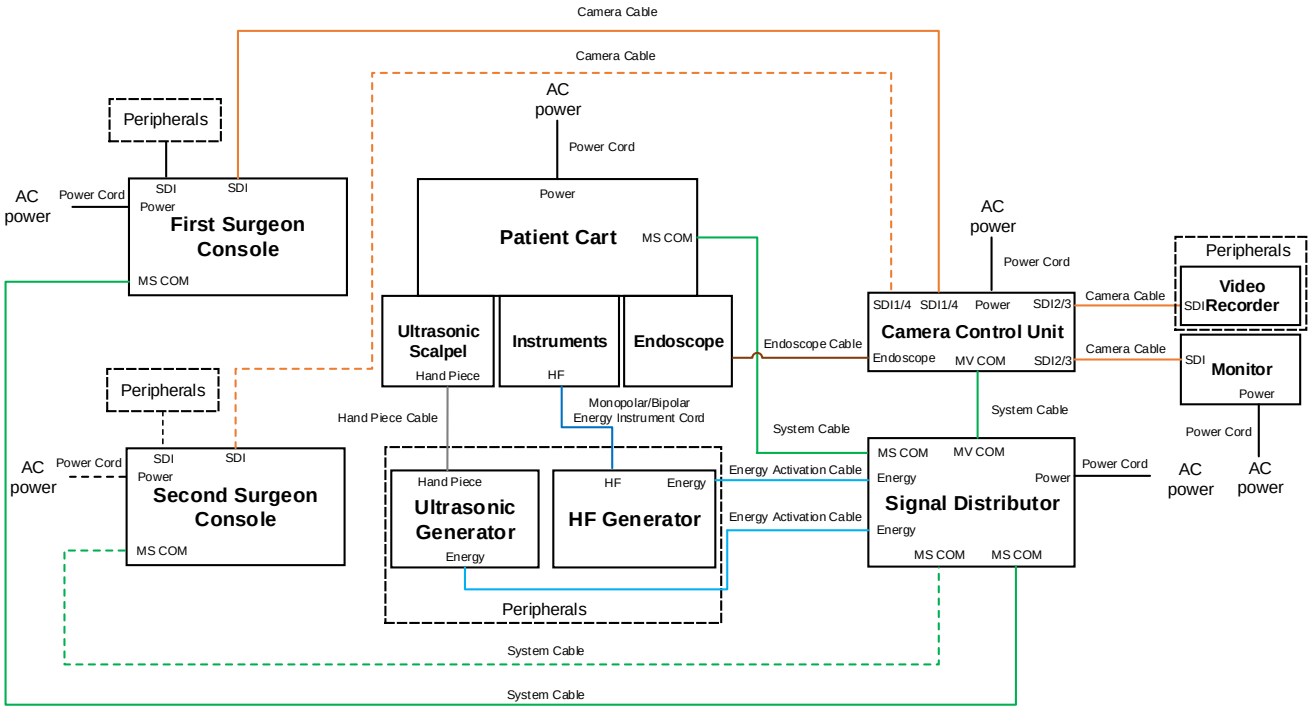


Figure 4.1 System Connections

Note: The cables and cords for system connections are limited to those described in this chapter, which are provided by the company. Other cables should remain connected at all times and should 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	Power Requirement	System Component
Power Cord	5 m	600 VA continuous 5 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	1.5 m	135 VA continuous 1.1 A at 120 V~ 0.55 A at 240 V~	Monitor
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 uninterruptible power supply (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.

4.2 System Connections

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	Used to connect the Surgeon Consoles, Patient Cart, Camera Control Unit or Signal Distributor
System Cable	30 m	
System Cable	1 m	
Camera Cable	1 m	Used to connect the Camera Control Unit and monitor
Camera Cable	2 m	
Camera Cable	10 m	Used to connect the Surgeon Console and Camera Control Unit
Camera Cable	30 m	

The system cables use circular connectors and the camera cables use BNC connectors.

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

Figure 4.2 System Cable

Note: Once the system is connected and powered on, the system cables should not be unplugged until the system has 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.

4. Gently pull on the connector to verify the cable is fully seated.

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

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.

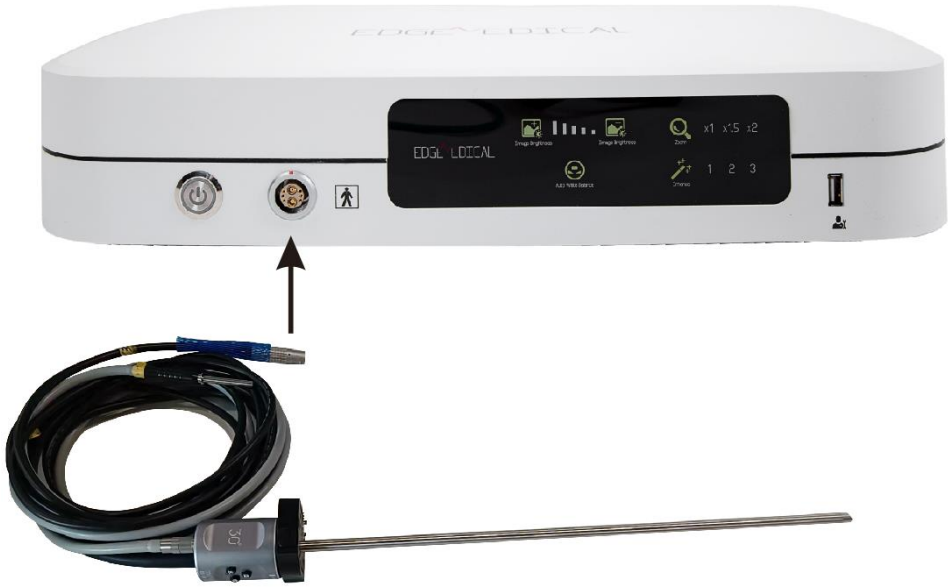


Figure 4.3 Connecting Endoscope Cable

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 of the Vision Cart. 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 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 Energy Instrument Connections

For more instructions of Monopolar energy instrument cord and Bipolar energy instrument cord connected to energy instruments, see 9.5.2 Energy Instrument Cords.

4.6 Network Connections

The MP1000 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 arms of the Patient Cart will perform various movements during this integrity test. When the power button LED indicator illuminates solid green, it indicates that the startup sequence starts. 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 14 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 four instrument arms of the Patient Cart complete the self-test movements and the startup sequence ends, the LED indicators of the instrument arms illuminate solid blue.

- If the system detects mounted adaptors or instruments before startup, the instrument arms 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 14 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: a. The power cord is not connected to AC socket.

Indicator Status	Meaning
	b. 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

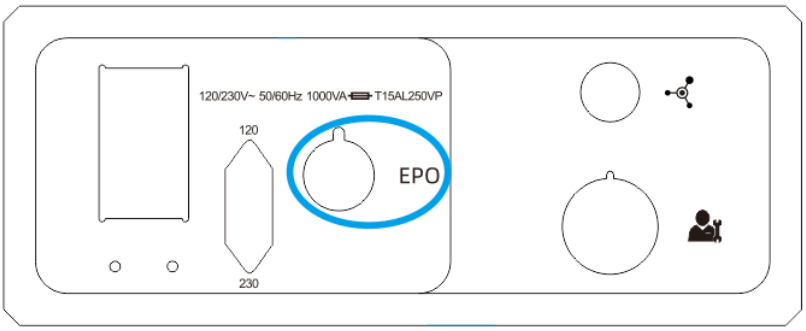


Figure 5.2 **EPO** Button

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 14.2.2 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 14.6 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 Cart is connected to the power supply, the cooling fans running continually is part of normal operation.
- The Patient Cart should be connected to AC power when it is not in use, in order to ensure the UPS remains fully charged.
- To operate in dual console mode, the power operations of the second Surgeon Console is the same as the first Surgeon Console.

6. Draping

6.1 Draping Guidelines

- Ensure there is backup each drape before beginning a procedure.
- 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)
  - A non-sterile person (circulating nurse)

Note: Please refer to Disposable Drape User Manual for the models and specifications of the drapes that are compatible with the system.

6.2 Deploy for Draping

During the deploy step, the boom is extended to allow access to the column for draping while avoiding contamination of the arm drapes. Additionally, the column raises to avoid contamination of the drapes in the sterile field.

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

- Automated deploy for draping

  The circulating nurse presses and holds **Deploy for Draping** on the Patient Cart touchscreen. The system deploys the boom and adjust the arms to prepare the Patient Cart for draping.

- Manual deploy for draping

  The circulating nurse presses and holds **Enable Boom Controls** to position the Patient Cart manually. Use the boom control buttons to raise and deploy the boom and extend the arms outward for enough space to avoid contamination of the arms and column during draping.

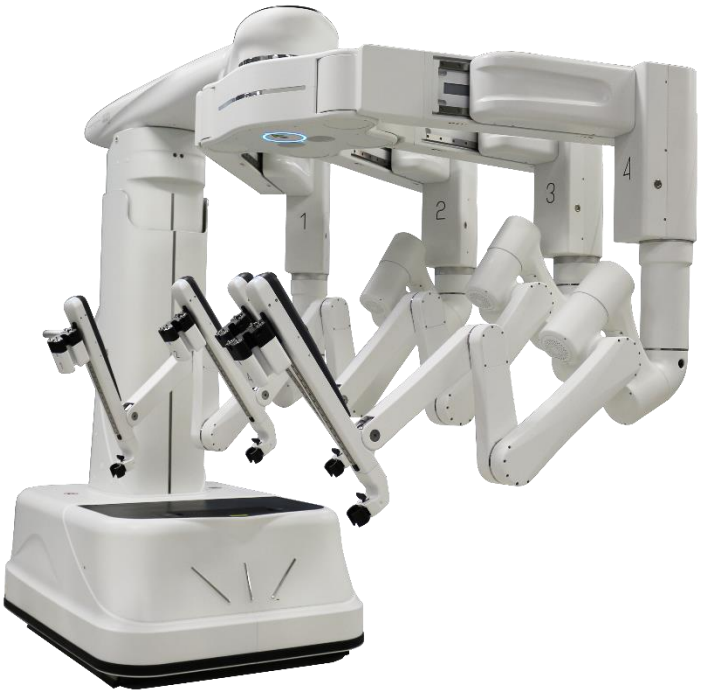


Figure 6.1 Deploy for Draping

6.3 Drape Installation

6.3.1 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.

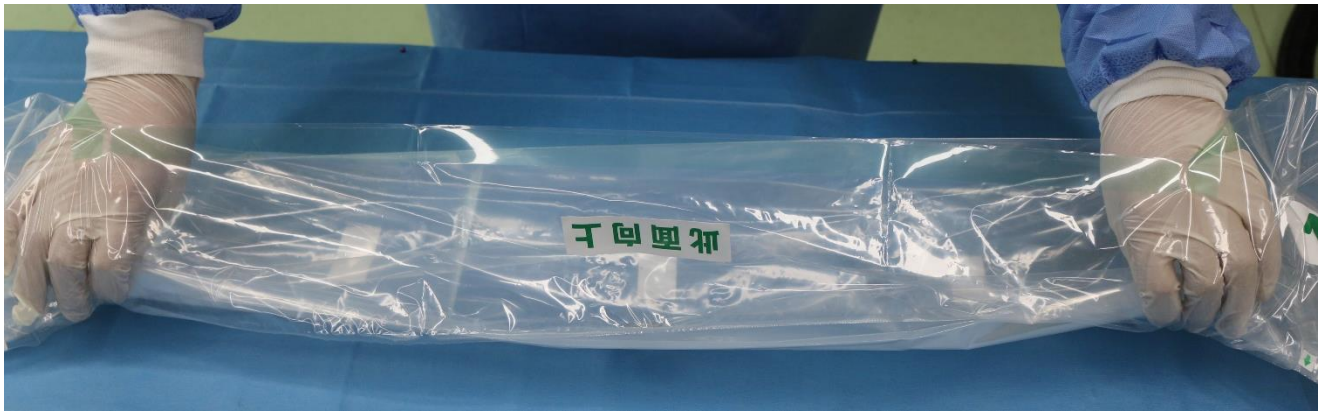


Figure 6.2 Pick Up the Drape

c. Attach two 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.

Figure 6.3 Snap the Tabs

3. The circulating nurse fastens the end of the strap 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.

6.3.2 Draping Instrument Arms

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 arms, ensure that there is no excess drape material either between the adaptor and the instrument carriage or between the cannula adaptor and the cannula mount that can block the connection.

Note: When draping the instrument arms, it is recommended to drape in order from arm 1 to arm 4 or arm 4 to arm 1. In this process, the scrub nurse should face away from the undraped instrument arms.

1. The circulating nurse does the following:
   a. Press the buttons on the instrument arms to move each arm as needed to make sure there is enough space to maneuver between each arm to maintain sterility while draping. If necessary, use the boom control buttons on the helm to adjust the boom.
   b. Open the paper-plastic package and deliver 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.
   b. Grab the tab “Open from Here” and spread apart to expose the center opening of the drape.

Figure 6.4 Spread Apart to Expose the Center Opening of the Drape

   c. Carefully lower the drape over the instrument arm.
   d. Attach the metal disc on the drape to the magnetic socket at the front of the instrument arm temporarily to protect the drape from contamination.

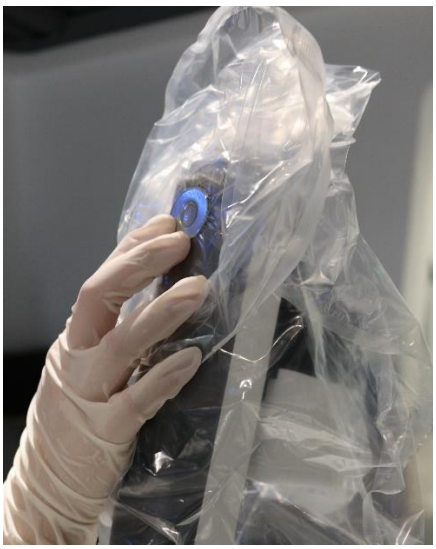


Figure 6.5 Attach the Metal Disc to the Instrument Arm

e. Snap the tear-away tab identified by arrow icon .

f. Place two hands inside the drape cuffs on both sides of the drape identified by the hand icons , and attach two metal discs on the drape to the magnetic sockets on the column.

Figure 6.6 Attach Metal Discs to the Column

g. Take down the metal disc attached at the front of the instrument arm, snap the tear-away tab at the front of the drape, lower the drape over the instrument arm, and reattach the metal disc to the corresponding magnetic socket.

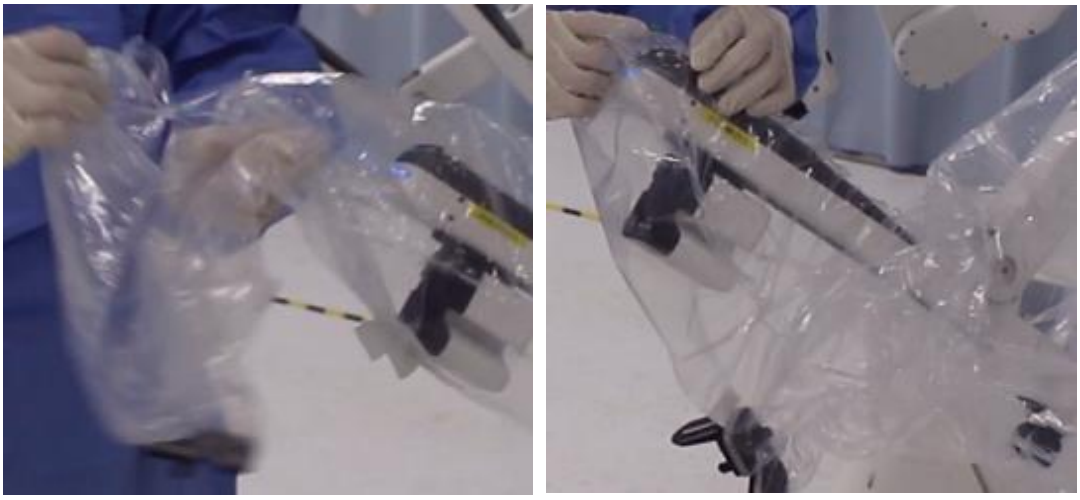


Figure 6.7 Drape the Front of the Instrument Arm

h. Press the **Instrument Clutch** button on the instrument arm to advance or retract the front end of the arm into proper position for adaptor installation.

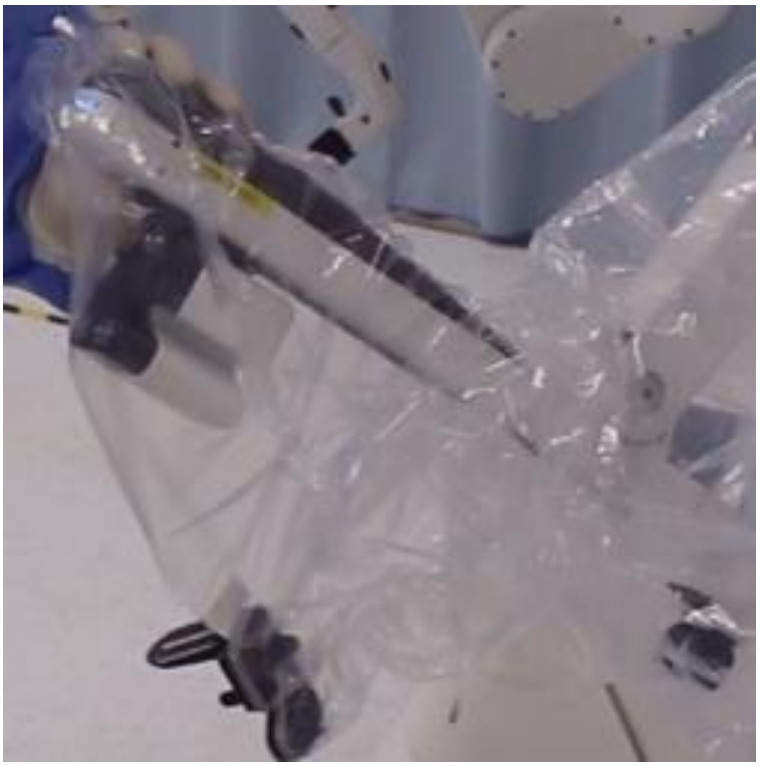


Figure 6.8 Adjust the Position of the Instrument Arm

i. Gently straighten the excess drape material downward, and use both thumbs to press the adaptor into the instrument carriage.

   Ensure the adaptor clicks into place and each disc at the top of the adaptor spins. If not, the adaptor does not engage, remove and re-seat the adaptor.

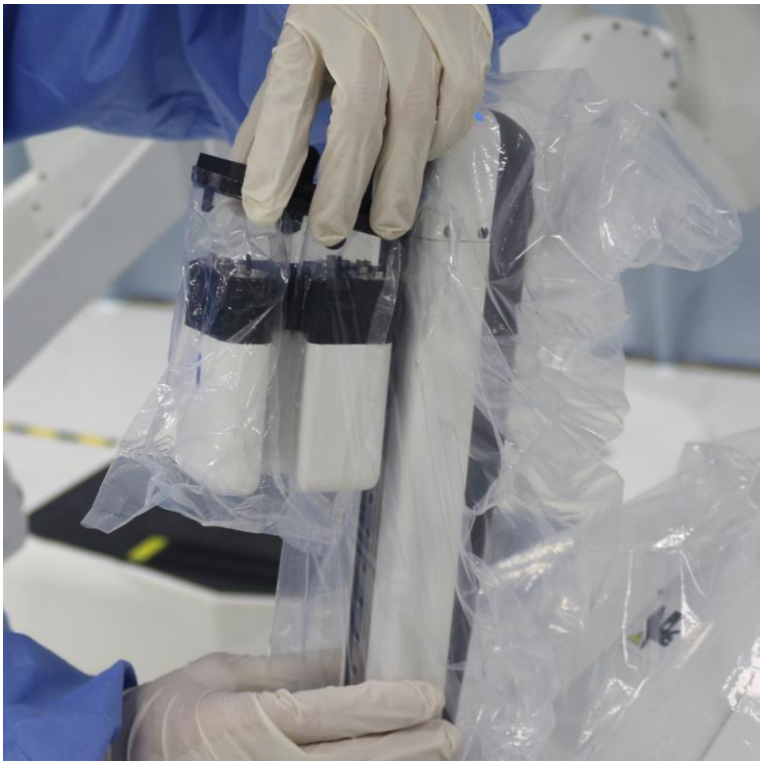


Figure 6.9 Attach the Adaptor to the Instrument Carriage

j. Straighten the drape material around the cannula adaptor, hold both ends of the cannula adaptor, and press the cannula adaptor straight into the cannula mount to engage.

Figure 6.10 Attach the Cannula Adaptor to the Cannula Mount

k. Fasten the Velcro and adjust the drape properly.

l. Move the draped arm away from the undraped arms to avoid cross-contamination. Repeat the above steps to drape the remaining instrument arms until all arms are draped.

6.3.3 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 **Sterile Stow**  on the Patient Cart touchscreen. The Patient Cart moves to the sterile stow position where the arms are folded out of the way with enough space from the column to ensure that sterility is not breached.

6.4 Drape Removal

The drapes are sterile products designed for single-use. After the procedure, the drapes should be removed and disposed. Please dispose 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 the Velcro.

6.4.1 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.
4. Dispose the drape into the designated location.

6.4.2 Removing Instrument Arm Drapes

1. Remove the adaptor, metal discs and the cannula adaptor of one instrument arm.
2. Remove the drape.
3. Repeat the above steps to remove the drapes of the remaining instrument arms.
4. Dispose the drape into the designated location.

7. Vision Cart Use

7.1 Vision Cart Overview

The Vision Cart is mainly composed of the Camera Control Unit and signal distributor. For a complete description of the Vision Cart components, see 2.4 Vision Cart.

7.2 Endoscope Use

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 viewer of the Surgeon Console and the monitor.

For further information on endoscopes, see the Fluorescence Endoscopes User Manual for MP1000 System.

7.2.1 Endoscope Components

The endoscope has two **Release** buttons on both sides of the base for removing the endoscope from the instrument arm of the Patient Cart. There are pins and a drive chuck at the bottom of the base, and a hash mark on the base.

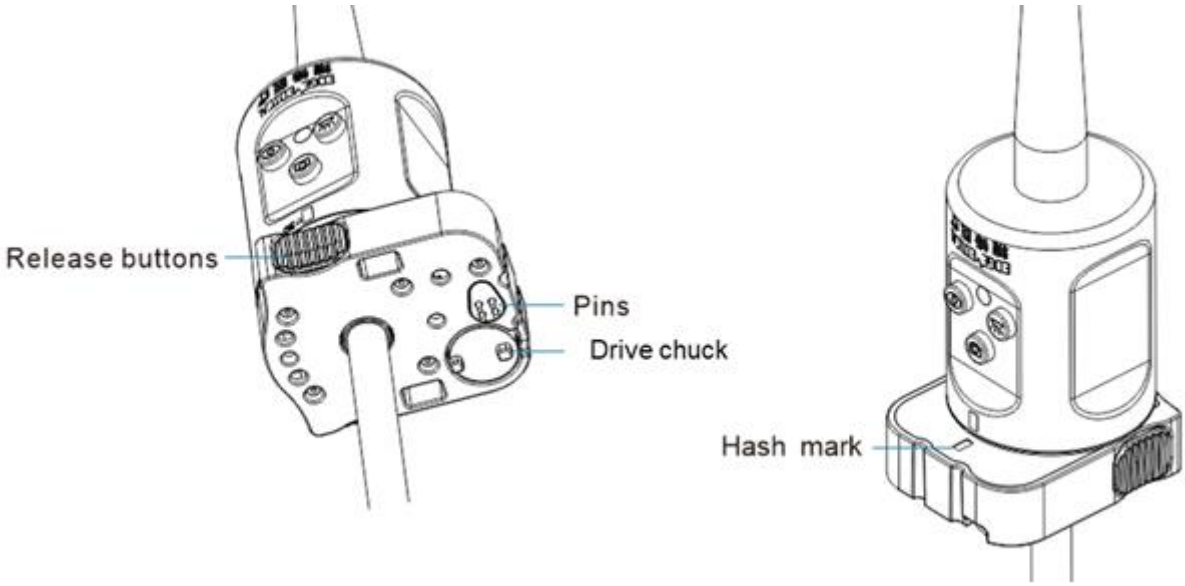


Figure 7.1 Endoscope Base

There are three buttons, a LED indicator, view direction, and up/down arrow on the housing. The buttons are designed for illumination on/off, take photo, and left-right eye swap.

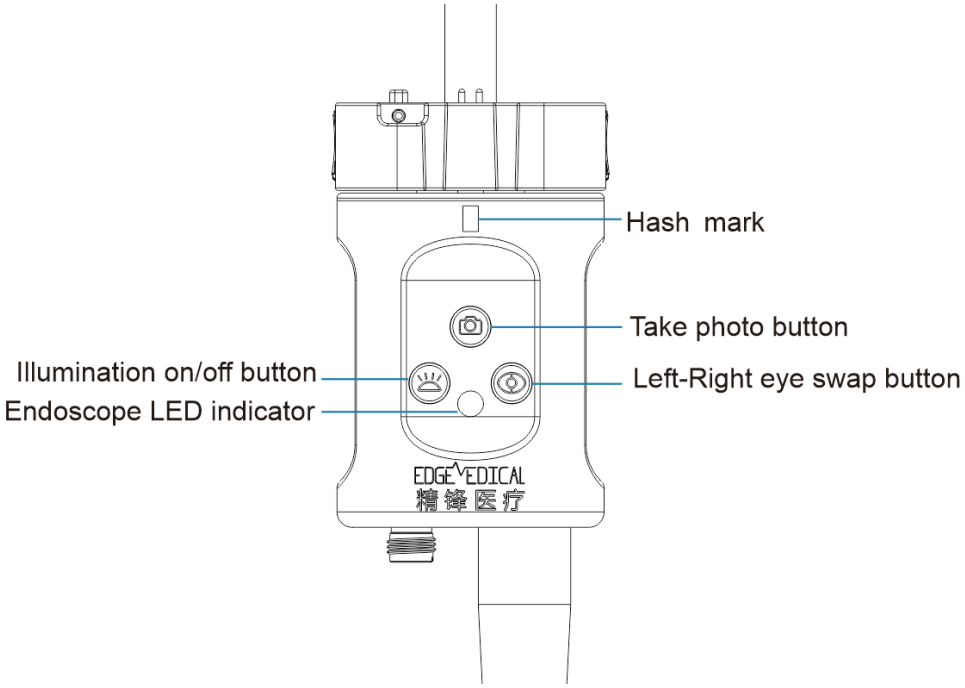


Figure 7.2 Endoscope Housing

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 Endoscope Buttons

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

Table 7.2 Endoscope Buttons

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

7.2.4 Endoscope Guidelines

- To avoid permanent eye injury, observe the following cautions:
  - Do not look directly at light emitted directly from the endoscope or the light guide bundles when the laser light is being emitted.
  - Do not use an optical instrument (magnifying glass or similar) to examine the optical fibers at the tip of the endoscope when the endoscope is connected.
  - Adjustments, settings and maintenance other than those specified and allowed herein and on the rating plate and in the user manual may result in eye injury.
  - Do not attempt to perform any repair or maintenance on any of the optical components in the system.
- In order to avoid excessive heating of the cannula, do not leave the endoscope tip inside the cannula for a prolonged period of time while the endoscope illuminator is on.
- Ensure the vision system can provide the ability of adequate visualization to complete operative tasks safely.
- Avoid excessively long continuous direct tissue contact with the shaft during procedures, which may cause permanent tissue injury or burns.
- Be careful with the light guide bundles. Serious bends or kinks can damage the optical materials inside the cable and increase fiber loss.
- 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 Fluorescence Endoscopes Reprocessing Instructions Manual for detailed instructions.
- Reattach the connector cover to the connector when the endoscope cable is not in use or before reprocessing the endoscope. Failure to secure the connector cover during reprocessing may result in endoscope damage.

7.2.5 Inspection before Use

- Inspect the endoscope for any defects or damage, including breaks, bends, cracks, rough surfaces, sharp edges, burrs, protrusions, etc.
- Inspect the endoscope for mechanical or optical 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 sheath for any cuts, damage or defects.
- Inspect the cable fiber surfaces for any deposits or residues.

7.3 Camera Control Unit Use

The Camera Control Unit is used to process the images from the endoscope and then transmit to the system. The Camera Control Unit in conjunction with an endoscope illuminator and a fluorescence endoscope can provide visible light imaging and near-infrared imaging.

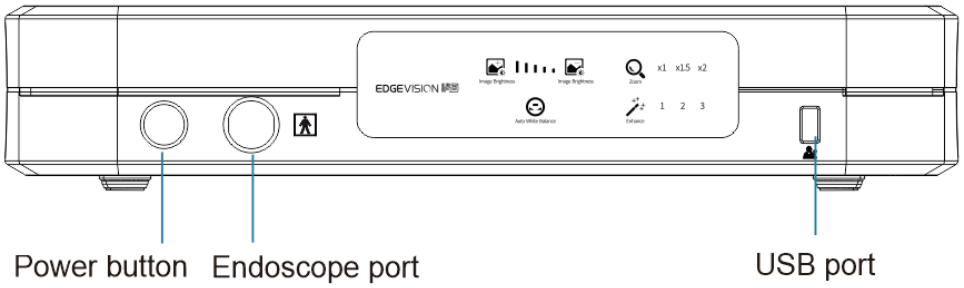


Figure 7.3 Front of Camera Control Unit

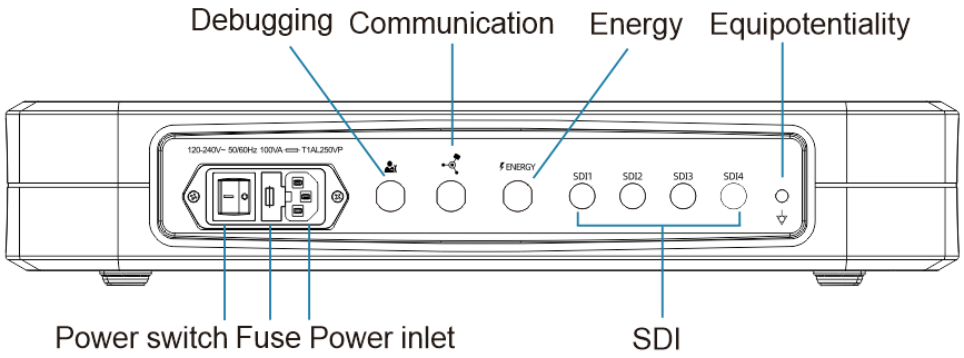


Figure 7.4 Rear of Camera Control Unit

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

7.4 Image Settings

The image is displayed on the Surgeon Console viewer and the Vision Cart monitor. The image settings are available with the Surgeon Console touchscreen, the Camera Control Unit, and the endoscope. For the instructions of the Surgeon Console touchscreen, see 10.2.9 Settings Tab.

7.4.1 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.

7.4.2 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.

7.4.3 Take Photo

Press the  button on the housing of the endoscope, images can be captured from the endoscopic view. 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.

7.4.4 Illumination

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

When near-infrared imaging is activated and only the fluorescence endoscope is removed from the instrument arm, press the button to turn off near-infrared light or turn on/off visible light.

When visible light imaging is activated with the near-infrared imaging inactivated, regardless of removal of the fluorescence endoscope from the instrument arm, press the button to turn on/off visible light.

After turning off illumination, press the button again to turn on illumination and activate visible light imaging. Instead of being activated by the button, near-infrared imaging can only be turned on and activated by the Surgeon Console.

7.4.5 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. Select **Settings** > **Image** > **White Balance** on the touchscreen.

7.4.6 Image Brightness

The system provides two methods for setting image brightness:

- Press the button or the button on the Camera Control Unit.
- Select **Settings** > **Image** > **Brightness** on the Surgeon Console touchscreen.

7.4.7 Image Enhancement

The system provides two methods for enhancing image sharpness:

- Press the button on the Camera Control Unit.
- Select **Settings** > **Image** > **Image Enhancement** on the Surgeon Console touchscreen.

7.4.8 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.
- Select **Settings** > **Viewer** > **Digital Zoom** on the Surgeon Console touchscreen.

7.4.9 Dynamic Illumination

The system automatically adjusts the light output based on the endoscopic image. During the procedure, when the endoscope is positioned closer to tissue, less light is needed to maintain a bright image and the system will reduce the light output. This reduces the ability of the light to affect tissue at close working distances.

7.5 Endoscope Installation and Removal

7.5.1 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.

7.5.2 Endoscope Installation

Endoscope Port

The endoscope can be installed on any of the instrument arms (where cannula diameters permit). The system recognizes the arm on which the endoscope is installed, and provides

auxiliary UI information displayed on the Surgeon Console viewer and the Vision Cart 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 instrument arm properly before endoscope installation.

1. Confirm the orientation.
   - Install 0° endoscope with the buttons facing the instrument arm.
   - Install 30° endoscope with the buttons facing the instrument arm for the down orientation, and the buttons facing away from the instrument arm for the up orientation.
2. Hold the endoscope base, and place the cable between the endoscope shaft and the instrument arm and the hash mark on the inside of the instrument arm.
3. Insert the endoscope tip into the cannula and press the endoscope into the adaptor.

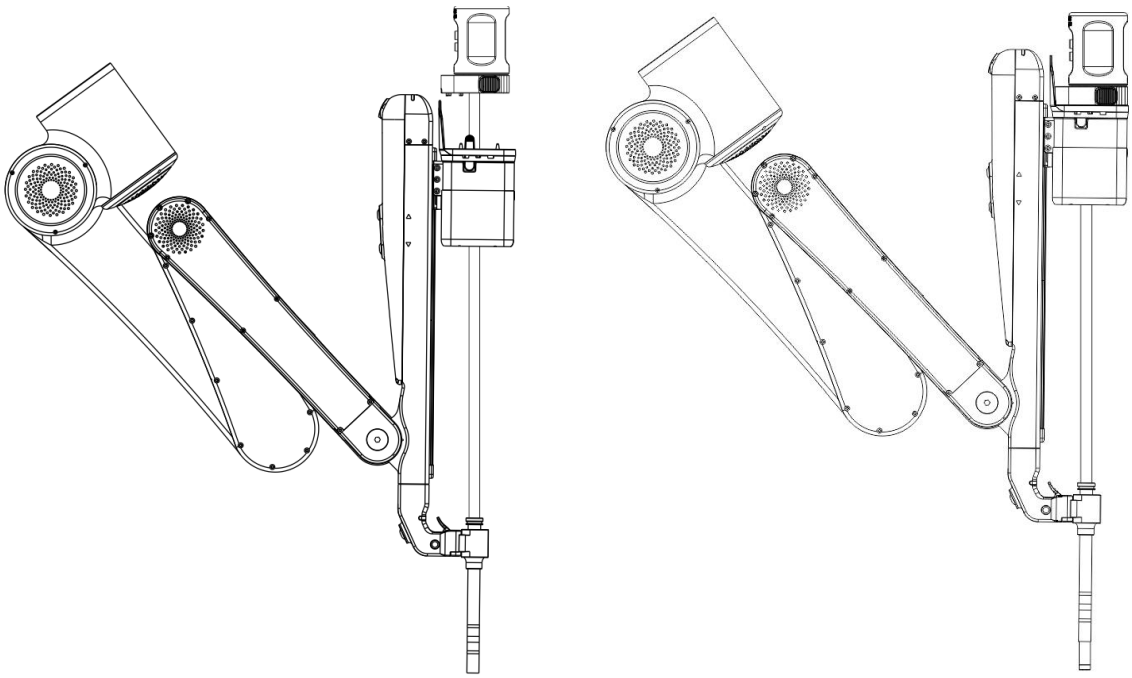


Figure 7.5 Insert the Endoscope into the Cannula and Adaptor

4. After the endoscope is installed on the instrument arm, the system will identify endoscope information, which can be displayed on the Surgeon Console viewer and the Vision Cart monitor.
5. Use the **Instrument Clutch** button to manually advance the endoscope. Position the endoscope to view the operative field and the target anatomy.

7.5.3 Endoscope Removal and Replacement

Remove the endoscope from the instrument arm by squeezing both **Release** buttons on the endoscope base and pulling the endoscope up and away from the instrument arm.

If the endoscope needs to be replaced during the procedure, do as follows:

1. Remove the endoscope:
   a. Squeeze both **Release** buttons on the endoscope base.
   b. Pull the endoscope up and away from the instrument arm.
   c. Put the endoscope on a sterile table.
   d. Unplug the endoscope cable from the Camera Control Unit.
2. Install a new endoscope:
   a. Connect the endoscope cable to the Camera Control Unit.
   b. Attach the endoscope to the instrument arm. See 7.5.2 Endoscope Installation.

Note: When the endoscope is re-installed or replaced, the memory function may be activated automatically. At this time, the LED indicator of the instrument arm flashes green, indicating 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 arm.

Warning: To avoid burns or flammation, always turn off the endoscope illuminator when removing the light guide bundles, replacing or stop using the endoscope. Do not contact high-temperature parts of the endoscope with the operator, patient, drapes or flammable materials.

7.6 Endoscope Fogging and Cleaning

7.6.1 Endoscope Fogging

Caution: When the endoscope is connected to the endoscope illuminator, 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 endoscope illuminator 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.
- 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.

7.6.2 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.

7.7 Image Quality Troubleshooting

Note: If the following methods cannot be available for troubleshooting, replace the damaged endoscope with a backup. If the problem persists, contact the company for technical support.

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

7.7.1 Image Too Bright or Dark

- According to the methods described in 7.4.6 Image Brightness, adjust image brightness as required.
- If the image is too dark, remove the endoscope from the instrument arm, turn off illumination, check whether the glass surfaces on the endoscope are smudged or soiled, and clean the glass surfaces if necessary.

7.7.2 Image Flickering

Check for high frequency interference.

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

7.7.3 Image Blurring

- According to the methods described in 7.4.8 Digital Zoom, adjust zoom setting to **X1**.
- Remove the endoscope from the instrument arm, turn off illumination, check whether the glass surfaces on the endoscope are smudged or soiled, and clean the glass surfaces if necessary.

7.7.4 Color Cast

After connecting to the Camera Control Unit, the endoscope is white balanced automatically

by the system. If color cast still occurs, activate white balance according the methods described in 7.4.5 3D Calibration and White Balance.

8. Patient Preparation and Port Placement

8.1 Patient Preparation

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

The Patient Cart arms 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

Note: The initial endoscope port can be used to provide endoscope visualization for placement of the other cannulas. All port placement should be performed within endoscopic vision. The obturator tips should remain in view at all times during cannula insertion.

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.

Straight line port placement allows the arms to work in parallel, maximizing surgical space and minimizing arm interference. If necessary, the ports are kept in a straight line. A triangulated port placement can also be used.

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.

Note: Inspect the cannulas and obturators before use, following the instructions in the Accessories User Manual for MP1000 System.

1. Insufflate the abdomen before measuring port placement. Following insufflation, mark the locations of instrument and assistant ports.
2. Identify the surgical workspace.
3. Place the initial endoscope port 10 cm～20 cm from the target anatomy.
   - Use the compatible obturator for port placement.
   - Ensure the surgical workspace is adequate for the endoscope and instruments.
   - Place the initial endoscope port at the edge or beyond the edge of the surgical workspace so as not to lose perspective over the surgical workspace.
4. Place remaining ports 6 cm～10 cm apart (8 cm recommended) in a perpendicular line relative to the target anatomy.
   - Before placing ports, visually confirm target anatomy with initial endoscope port.
   - If space is limited, minimize distance between ports to 6 cm.
   - If space is not limited, distance between ports can be up to 10 cm.
   - Ports can be a minimum of 4 cm apart in certain cases (small surgical workspace, requiring minimal external arm motion).
   - Maintain 2 cm or more between ports and bony prominences.
   - Consider port hopping potential during port placement.
   - Consider placing four ports to switch between two right hands and two left hands
5. Place assistant ports as far away from robotic ports as needed (at least 7 cm).
   - Place in a straight line or triangle with the robotic ports to maximize access and minimize instrument arm interference.
   - Do not place an assistant port between a robotic port and the target anatomy.
   - Consider assistant ports are easily accessible. Ensure the assistant ports face the target anatomy and allows for instrument exchange and intraoperative endoscope cleaning.

- Use longer length laparoscopic instruments to increase the distance between the assistant port and the instrument arm.

After the cannulas are inserted into the patient, a non-sterile person should move the Patient Cart into the sterile field for docking with the operating table.

Docking is the process of moving the Patient Cart to the operating table and connecting the cannulas to the instrument arms. See 9 Patient Cart Use for details.

8.2.2 Remote Center

The instrument arms of the Patient Cart control the endoscope and instruments by remote center technology, which enables the system to precisely maneuver 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 arms 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.

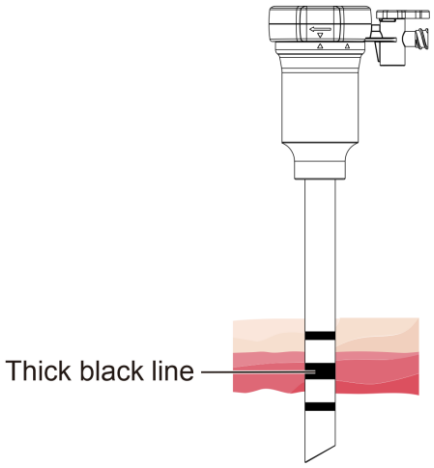


Figure 8.1 Mark of Cannula Remote Center

- 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 through an endoscope.
  - 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 arms with the remote center placed incorrectly increases friction, reduces precision, and increases tissue trauma at the port site.

- The surgeon cannot move the remote center at the Surgeon Console. The patient-side assistant can adjust the remote center by repositioning the instrument arms using the port clutches. It is recommended to check the position of the instrument arms throughout the procedure to ensure there is no tension at the port site. For instructions to release tension, see 9.2.5 Instrument Clutch and Port Clutch Buttons.

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 arms under the control of the Surgeon Console by a surgeon. A patient-side assistant in the sterile field helps the surgeon replace the instruments and endoscope on the arms. For a complete description of the Patient Cart components, see 2.3 Patient Cart.

9.1.1 Positioning Laser Indicator

The positioning laser indicator is mounted in the center of the boom and projects downward to assist positioning of the Patient Cart at the patient. In addition, the positioning laser indicator is activated during draping, providing a reference line for adjusting arm position.

Figure 9.1 Positioning Laser Indicator

9.1.2 Patient Cart Helm

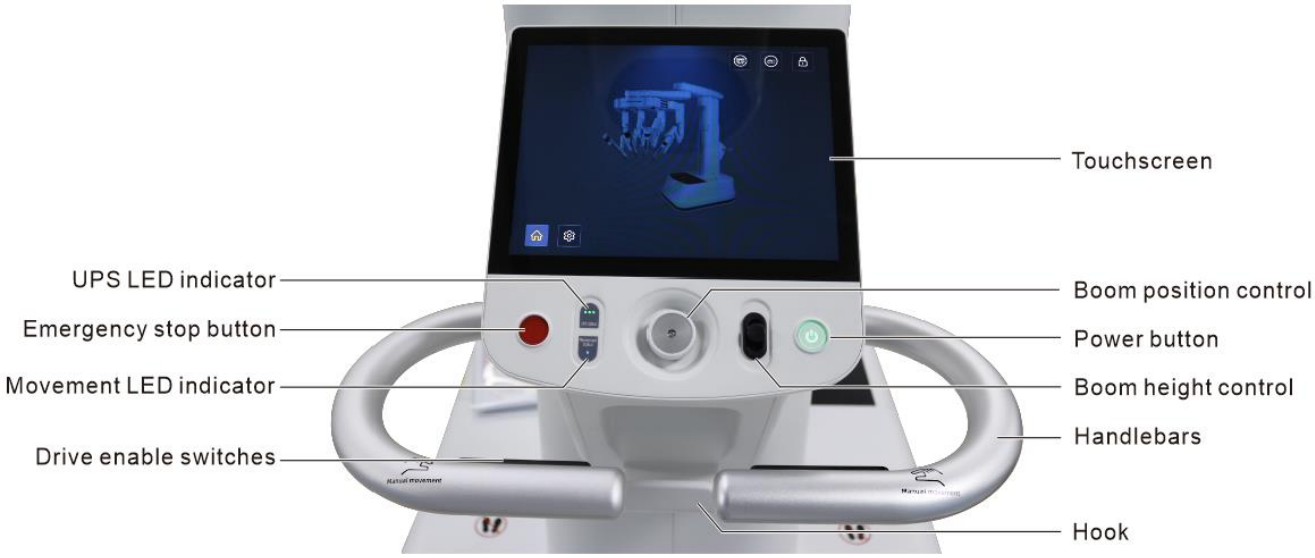


Figure 9.2 Patient Cart Helm

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

Use the control buttons on the helm:

- Raise/Lower the boom: Push the boom height control button up to raise the boom. Push down to lower the boom.
- Extend/Retract: Push the boom position control up to extend the boom. Push down to retract the boom.
- Rotate boom: Rotate the boom position control to rotate the boom.
- Move boom left/right: Push the boom position control left or right to move the boom to the left or to the right.

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.

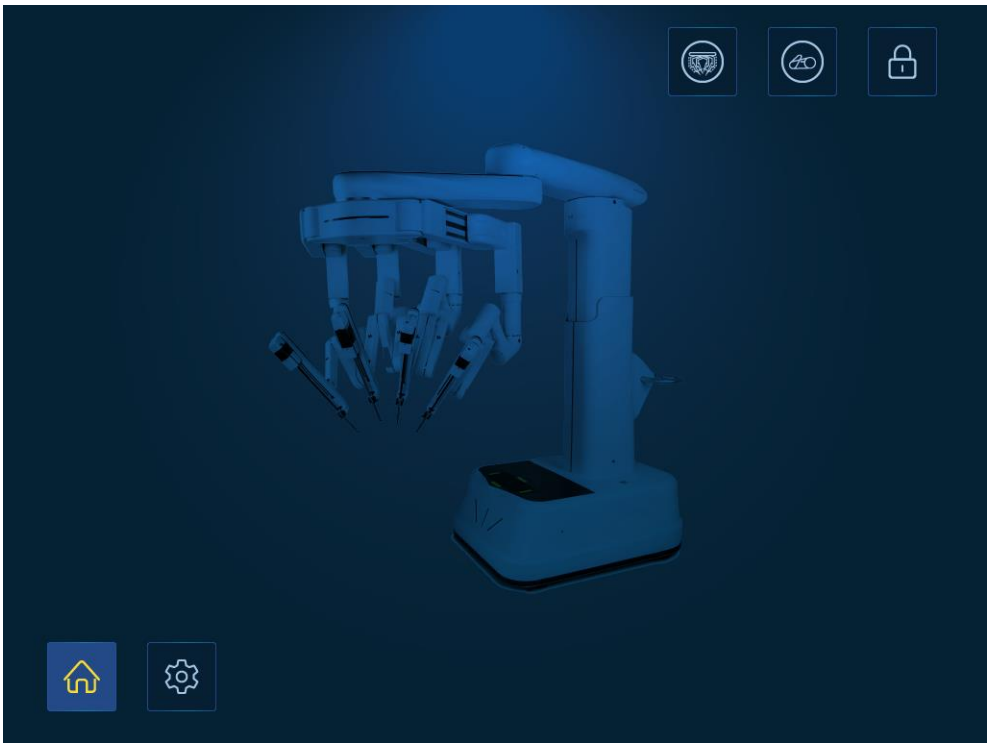
9.1.3 Touchscreen

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 and drive force sensor reset. 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

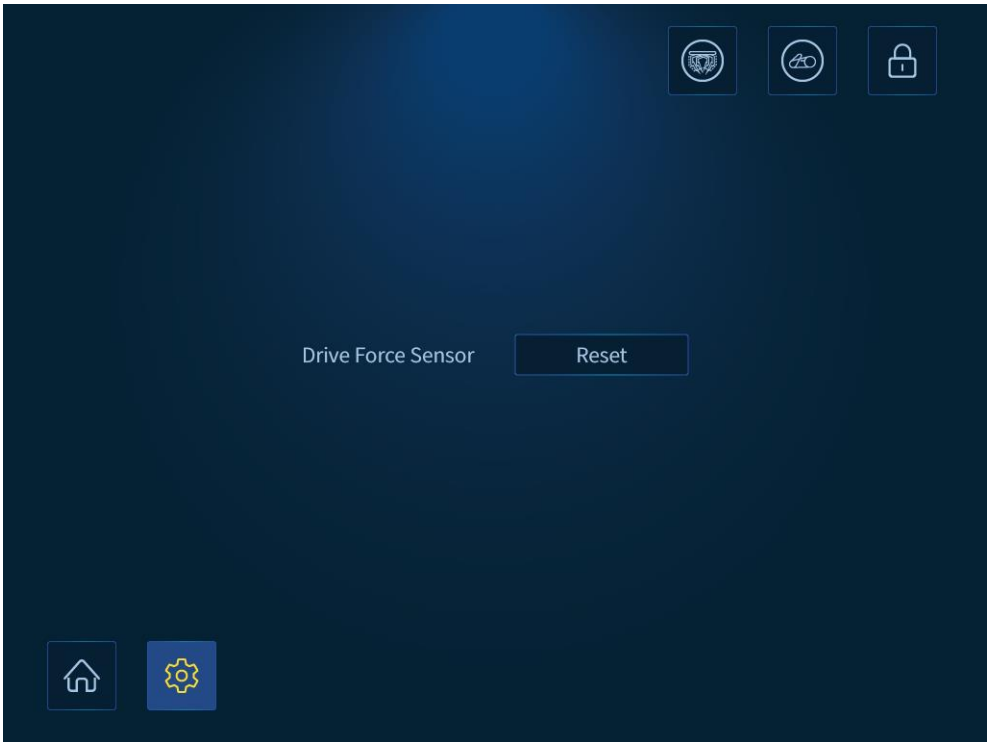
Settings tab, tap  back to the Home tab.



- Deploy for draping  : Press and hold the button. The boom rises, extends and rotates. The arms move to the proper position in preparation for draping.
- Stow  : If the drapes are installed on the Patient Cart, press and hold the button to move the arms into a sterile stow position to ensure the sterility is not breached. If the drapes are removed from the Patient Cart, press and hold the button to stow the Patient Cart for transporting and storage.
- Enable boom controls  : Press and hold the button and use the boom position control button and the boom height control button to move the boom.

Settings Tab

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



- Drive force sensor: Tap **Reset** to reset the drive force sensor on the helm of the Patient Cart. Do not touch the cart during the process.

9.1.4 LED Indicators

Movement LED Indicator

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

Table 9.1 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

UPS LED Indicator

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

Table 9.2 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

Instrument Arm LED Indicator

A LED indicator is located on the top of the instrument arm as shown below to communicate system status and conditions. Corresponding icons and graphics depicting system status appear simultaneously on the monitor of the Vision Cart and viewer of the Surgeon Console.

Figure 9.3 Instrument Arm LED Indicator

The meanings of instrument arm LED indicator are defined in the table below.

Table 9.3 Instrument Arm LED Indicator

Indicator Status	Meaning
Off	Unpowered
Solid blue	• Adaptors or instruments complete self-test • Arms are operating normally

Indicator Status	Meaning
Flashing blue	• Adaptors or instruments are self-testing • Arms in motion
Flashing green	Instruments or endoscope replaced in memory mode
Solid white	• Being powered on • Being initialized
Flashing yellow	• Disengagement of adaptors • Recoverable fault occurred on instruments or arms (including emergency stop)
Flashing red	Non-recoverable fault occurred on instruments or arms

Boom LED Indicator

A LED indicator is located at the bottom of the rotating platform to communicate system status and conditions. Corresponding icons and graphics depicting system status appear simultaneously on the monitor of the Vision Cart and viewer of the Surgeon Console.

Figure 9.4 Boom LED Indicator

The meanings of boom LED indicator are defined in the table below.

Table 9.4 Boom LED Indicator

Indicator Status	Meaning
Off	Unpowered
Solid blue	The column, boom and rotating platform are operating normally

Indicator Status	Meaning
Flashing blue	The column, boom and rotating platform are moving

9.2 Patient Cart Positioning and Docking

Position the Patient Cart for docking, deploy the drapes, adjust instrument arms, 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 arms flex (a joint that allows spacing of the arms from each other) and 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”.

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 arms. Prolonged pressure on the patient could result in serious injury.

Warning: When moving the arms or instruments, keep fingers clear of the joints located on the arms to avoid injury.

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

9.2.2 Positioning Overview

The instrument arms have a series of clutch buttons and joints that allow the arms to be

attached to the cannulas during installation. The Patient Cart arms are locked unless specific movements are made from the patient side or controlled by the Surgeon Console.

There are control buttons on the instrument arms, as shown in Figure 9.5.

After installing an instrument, the patient-side assistant can no longer adjust the boom and rotating platform. Only **Instrument Clutch**, **Patient Clearance** and **Port Clutch** buttons are available.

In addition to the controls available on all of the instrument arms, the outer two instrument arms (1 and 4) are equipped with **Rotation** buttons.

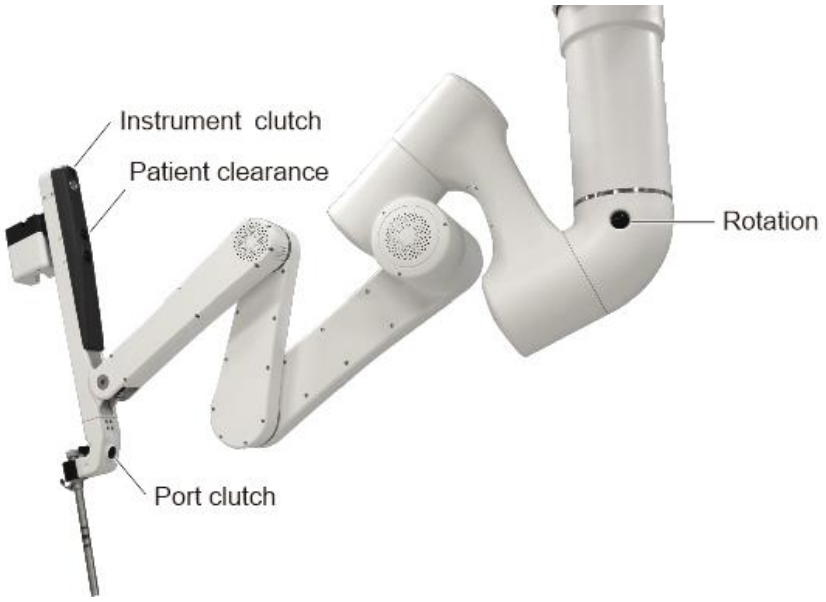


Figure 9.5 Controls on Patient Cart Instrument Arms

9.2.3 Automated Deploy Guided Setup

The system provides the feature of location selection guided setup, the Patient Cart deploys to a preset position for docking based on the anatomy and cart location selections. Follow these steps:

1. Select the target anatomy on the touchscreen of the Patient Cart.
2. Select the cart location (the side of the patient the Patient Cart will be positioned) on the touchscreen of the Patient Cart.
3. Press and hold **Deploy for Docking** until the arms move to the proper orientation for the selected approach.

9.2.4 Instrument Selection Guided Setup

The system provides the feature of instrument selection guided setup based on the anatomy

and surgical procedures. Follow these steps:

1. Select the target anatomy on the touchscreen of the Patient Cart.
2. Select the surgical procedure on the touchscreen of the Patient Cart.
3. The system recommends the instruments used in the procedure.

9.2.5 Instrument Clutch and Port Clutch Buttons

The **Instrument Clutch** and **Port Clutch** buttons allow users to reposition instrument arms at the Patient Cart.

Note: To prevent a change in the endoscope or instrument insertion depth, hold the instrument arm steady by grasping the top of the instrument whenever you press the **Instrument Clutch** button.

Note: Pay special attention to avoid collisions when using the **Port Clutch** button.

Note: Hold the **Port Clutch** button with one hand and support the cannula with the other.

Note: When using the **Port Clutch** button, take care to prevent sliding the cannula out of the port site.

Instrument Clutch Button

What Instrument Clutch button does:

- Initiate movements of the arm about the remote center.
- Initiate movements to advance or retract the endoscope or instrument tip within the surgical site.

How to use Instrument Clutch button:

When the instrument engages with the adaptor, press and release for ON, then press for OFF.

When the instrument does not engage or is not installed, press and hold for ON, then release for OFF.

Port Clutch Button

When no instruments or endoscopes are installed:

- Press and hold to reposition the arms.

- Press and hold to raise or lower the boom: Press and hold the **Port Clutch** button to move the arm up or down. When the arm reaches its upper limit, the system starts a 3-second countdown. After the countdown, the system enters extension mode. Continue to move the arm up or down, and the boom will be raised or lowered. During the process, the remote centers of other arms do not follow motions.

When instruments or endoscopes are installed:

- Space the arms together or apart.
- Resolve and avoid potential arm collisions during the procedure.
- Reposition the remote center to release tension at the port site.

9.2.6 Patient Clearance Buttons

Patient clearance is a pair of buttons that allows users to adjust the arm to a steep or shallow angle. Steep angles are used to make more room under the arm (patient clearance), whereas shallow angles are used to achieve the maximum working range of motion (instrument reach).

Note: Be careful to avoid collisions when using the **Patient Clearance** button to adjust the arm angle.

What patient clearance buttons do:

The buttons can adjust the arm angle, and the remote center does not move.

How to use patient clearance buttons:

Press and hold the up or down arrow to adjust the angle “up” for improved patient clearance, or “down” for improved instrument access.

Note: Take care of collisions with objects in the operating room. Remove overhead obstacles.

9.2.7 Rotation Button

The outer two arms (1 and 4) provide **Rotation** buttons, which allow the user to rotate the boom clockwise or counterclockwise.

Note: When rotating the boom manually, take care to avoid collision of the arms with the patient, user or external equipment.

What Rotation buttons do:

- Located on arm 1 or 4 only.
- The boom can be only rotated when there are no instruments installed.

How to use Rotation buttons:

Press and hold the **Rotation** button on arm 1 or 4 while rotating the boom in the required direction.

9.2.8 Horizontal Adjustment Arm

The horizontal adjustment arm can be extended and adjusted for appropriate remote center placement and arm position management during surgery. If adjustment of the horizontal adjustment arm is required, and instruments are installed on the system:

1. Ensure that the instruments are not grasping tissue.
2. Remove all instruments.
3. Use one hand to support the instrument arm and cannula while adjusting the horizontal adjustment arm.
4. Use the other hand to press the **Port Clutch** button, and carefully move the horizontal adjustment arm closer to or further from the adjacent arm.

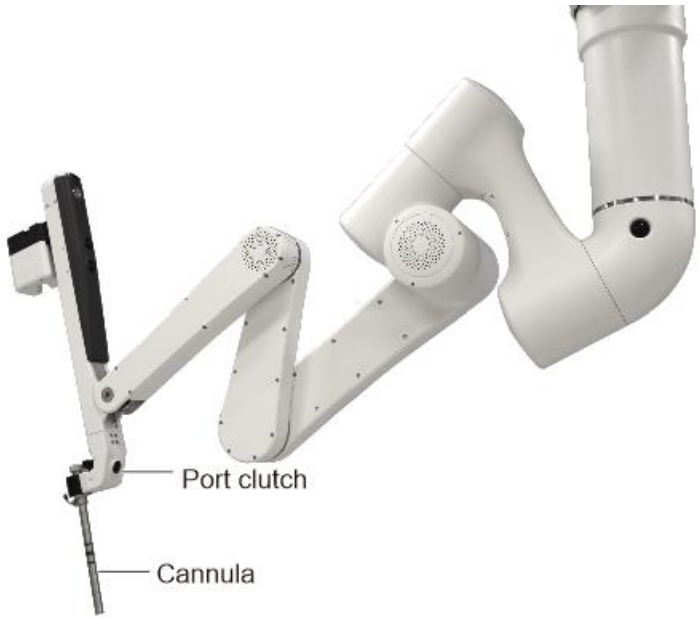


Figure 9.6 Example Where to Support the Arm and Cannula

9.2.9 Patient Cart Positioning

After deploying the Patient Cart, drive the Patient Cart to the operating table.

1. Squeeze drive enable switches on the helm of the Patient Cart to start the drive. The green positioning laser is projected from the boom toward the floor. It may be necessary to adjust the arms to see the laser and/or avoid collisions.
2. Confirm that the positioning laser is visible on the floor before positioning the Patient Cart. If the laser is not visible, push all arms behind the laser lines.

Figure 9.7 Positioning Laser Lines

3. Slowly drive the Patient Cart to the operating table. Position the Patient Cart base next to the operating table where patient-side access is not required.
4. Watch for potential collisions with the non-sterile field. Ensure there is sufficient clearance between the patient and the lowest point of the instrument arms.

   The following adjustments can be made during Patient Cart positioning to increase patient clearance and avoid contamination:

   - A sterile person can grab and move the arms to reposition the arms individually.
   - A sterile person can use the **Port Clutch** button to raise the entire boom.
   - A non-sterile person can adjust boom height and position using the control buttons at the Patient Cart helm.
5. Slowly drive the Patient Cart to position the laser lines within 5 cm of the initial endoscope port. The orientation of the Patient Cart with respect to the operating table is not critical. Make further adjustments using the controls on the Patient Cart helm.

Note: Before moving the Patient Cart towards the operating table, make sure there is enough clearance between patient and lowest point of arms. If necessary, use the **Port Clutch** button to raise the arms.

9.2.10 Patient Cart Docking

Docking is the process of moving the Patient Cart to the operating table and connecting the instrument arms to the cannulas. Once cannulas are inserted in the patient, a non-sterile person moves the Patient Cart into the sterile field.

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”.

Note: To avoid excessive heating of the cannula, do not leave the endoscope tip in the cannula for a prolonged period of time when the endoscope illuminator is turned on.

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

Note: Pay attention to avoid collisions.

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

Note: If the master controls are moved during operation, but no instrument motion occurs, there may be interference between the instruments or arms, or between an arm and the patient. Resolve the interference before surgery.

Note: If there are collisions between the arms, it may be possible to slightly adjust the position of the joints using the **Port Clutch** button to create more space between arms. Remove the instruments before pressing the **Port Clutch** button and take care to prevent the cannula from sliding out of the port site.

Note: If collisions between the arms occur, make sure the instruments are still fully engaged on the arms.

Once the Patient Cart is in place (see 9.2.9 Patient Cart Positioning), the arms and boom must be positioned to connect to the cannulas.

1. If needed, manually adjust the positioning of the arm by using the **Instrument Clutch** and **Port Clutch** buttons to hold the endoscope. The arm needs to be docked with the cannula first.

Note: Arms that are not docked to cannulas can be positioned by grabbing the arms and moving as desired.

Note: If collisions between the arms occur, make sure the instruments are still fully engaged on the arms.

2. Make sure the sterile adaptor on the drape is aligned with the cannula mount.
3. Press and hold the cannula mount lever, insert the cannula, and release the lever.

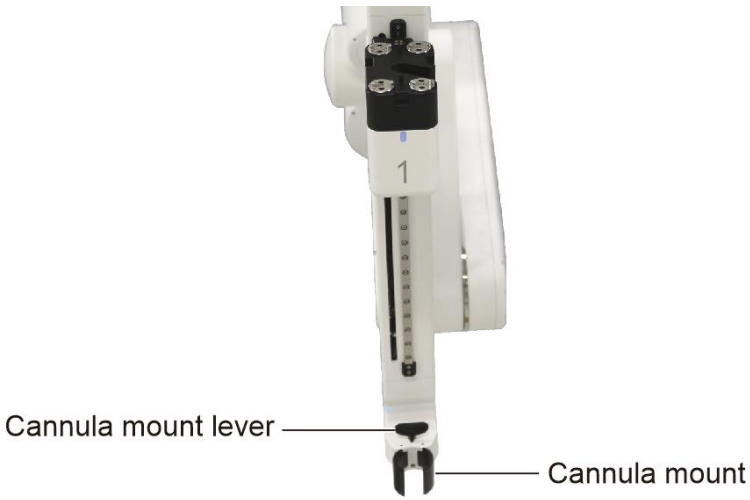


Figure 9.8 Cannula Mount Lever and Cannula Mount

4. Insert the endoscope tip into the cannula and press the endoscope onto the adaptor until it clicks into place.
5. Use the **Instrument Clutch** button and manually advance the endoscope.

9.2.11 Instrument Arm Docking

The guidelines for complete instrument arm docking are following:

1. Use the **Port Clutch** button to adjust the joint of the endoscope arm to be in line with the target anatomy. This centers that arm so the rest of the arms can be adjusted. Ensure the joint is not at a range of motion limit.
2. Dock the remaining arms: align each cannula mount to a cannula and connect.
   - If needed, use the **Port Clutch** button to space the arms (about a fist's space). This helps resolve and avoid potential arm collisions during a procedure. It is recommended to position the arms as close together as possible while still allowing each axis to move without interference.
   - If needed, use the **Patient Clearance** button on each arm to adjust the arm angle. Adjust the angle "up" for increased patient clearance, or "down" for increased instrument access.
3. Starting with the arms closest to the endoscope arm, use the **Port Clutch** buttons to bring arms together, using one hand to measure about the fist's space between the arms. This ensures sufficient space for the arms to work in parallel, and for patient clearance adjustment.

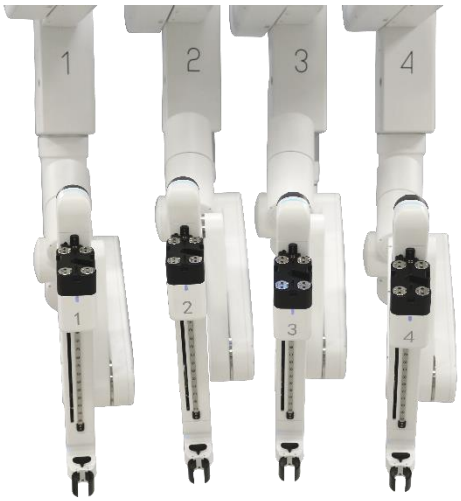


Figure 9.9 Example of Fist's Space

4. After the arms are spaced, lower the patient clearance joints with about a fist's space to the patient or other sterile obstacles. This ensures maximum instrument reach.

Note: Patient clearance adjustment is optional. Consider patient access and instrument reach needs and adjust patient clearance joints accordingly

Note: The relative position of each patient clearance can vary from arm to arm.

Note: Patient clearance and adjustment for remote center placement and arm position management may result in cannula and/or instrument tip movement.

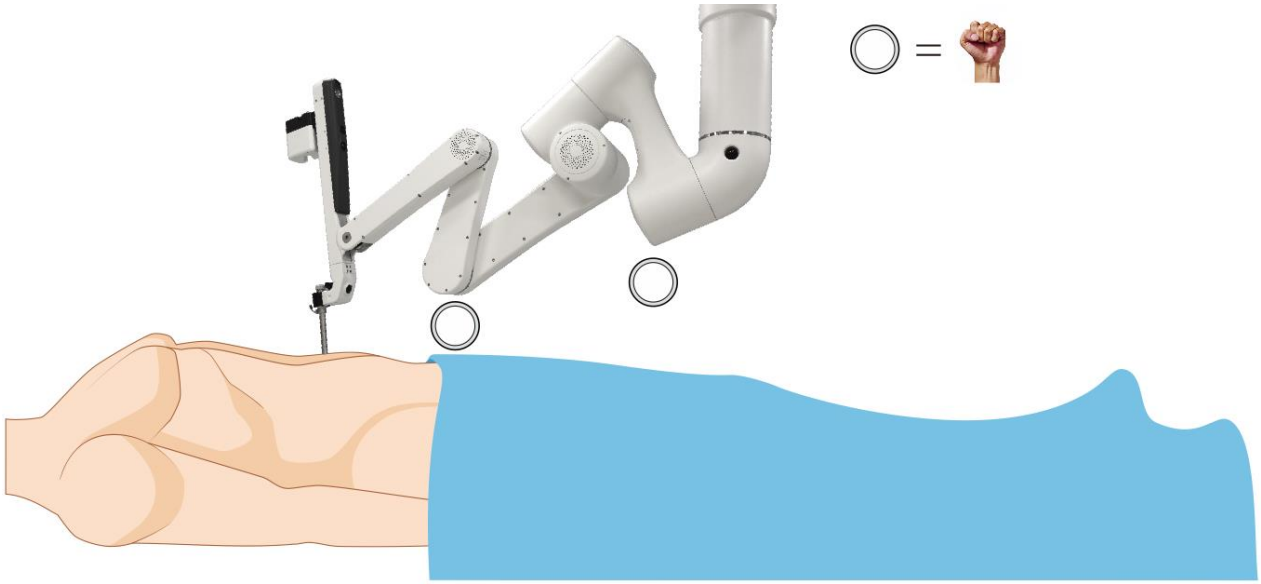


Figure 9.10 Patient Clearance Adjustment with a Fist's Space

9.3 Three-Arm Procedure

To stow an arm not required for use in surgery:

Note: It is recommended to stow an outer arm. If an inner arm needs to be stowed, perform step 3 (below) before docking.

1. Drape the arms to be stowed. See 6.3.2 Draping Instrument Arms for details.
2. Once the arms are docked, use the **Instrument Clutch** buttons to stow the arms.
3. Use the **Port Clutch** buttons to rotate and move the arms away from the surgical field.

Note: The system will detect the position of the stowed arm during boom movement; however, it is up to the patient-side assistant to ensure that the arm is placed out of the way of the other arms during the procedure.

9.4 Instruments 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 include Maryland bipolar forceps, bipolar forceps, enhanced bipolar forceps, needle driver, large needle driver, monopolar scissors, monopolar hook, enhanced forceps, Cadiere forceps, and tip-up fenestrated grasper. The instruments are mainly composed of instrument housings, release buttons, flush ports, drive chuck, grip release sockets, shafts, wrists and tips. The overall structure of these instruments is the same except for slight differences in the structure of the tips. See the Endoscopic Instruments and Accessories User Manual for MP1000 System for details.

The following figure is an example of instruments. For reference only, please refer to the actual situations.

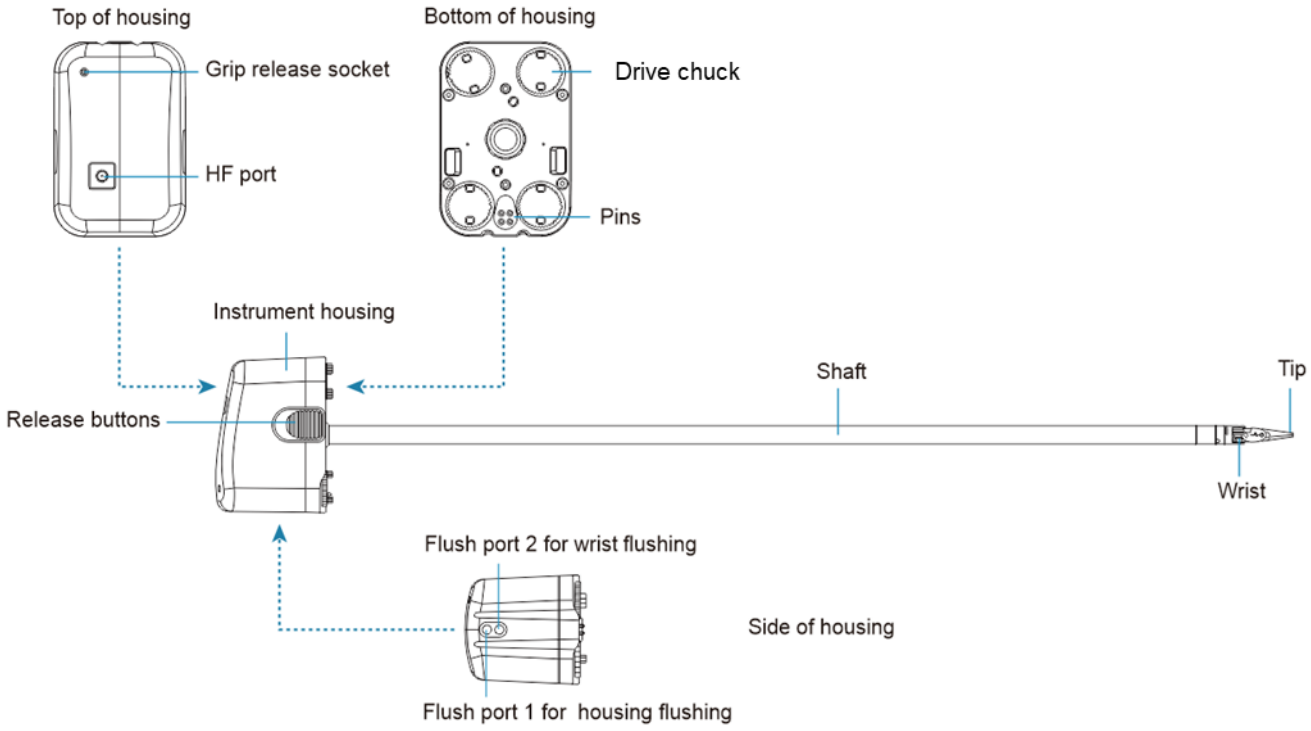


Figure 9.11 Instrument Components

- Instrument housing: The instrument housing engages with the adaptor on the Patient Cart arm, 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 housing, are used to disengage the instrument from the Patient Cart arm for removal.
- Flush ports: The two flush ports are used for instrument reprocessing.
- Drive Chuck: 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).
- Grip release socket: Mechanism for manual grip release.
- HF port: The high frequency port is used to connect monopolar energy instrument cord or bipolar energy instrument cord.

Note: Use only the instruments and accessories approved by the company. System compatibility with non-approved instrumentation 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: Except the ultrasonic scalpel, other instruments are supplied non-sterile and should be cleaned and sterilized thoroughly before first use and after every use. Refer to the Instruments Reprocessing Instructions Manual for detailed instructions.

Warning: The ultrasonic scalpel is provided in sterile packaging and is intended for a single-use. Reprocessing and/or reuse may result in degraded instrument performance or loss of functionality, and in exposure to viral, bacterial, fungal, or prion pathogens.

Warning: Verify the compatibility of the ultrasonic scalpel and ultrasound surgical equipment. The instrument should be only used in conjunction with ultrasound surgical equipment verified by the company. Please refer to the manufacturer's user manual for operating instructions.

9.5 Accessories Use

9.5.1 Tip Cover Accessory

The tip cover is only installed on the tip of monopolar scissors to protect the instrument from high frequency energy leakage through the bypass, while protect excessive tissue from entering the instrument wrist and avoid tissue damage caused by the wrist.

The tip cover must be always used in conjunction with compatible instruments, the

compatibility as shown in the following table.

Tip Cover & Part Number	Compatible Instrument & Part Number
Tip Cover Accessory, MP1402	Monopolar Scissors, MP1311

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

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

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

Tip Cover Installation

1. Close the jaws of the instrument.
2. Straighten the wrist of the instrument.
3. Install the installation tool onto the tip cover.

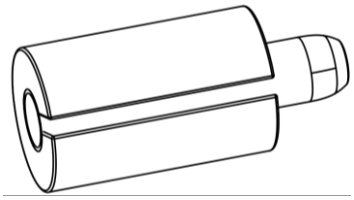


Figure 9.12 Install the Installation Tool

4. Grasp the tip cover, and slide it onto the distal end of the instrument.

   Ensure that the tip cover is installed in place.

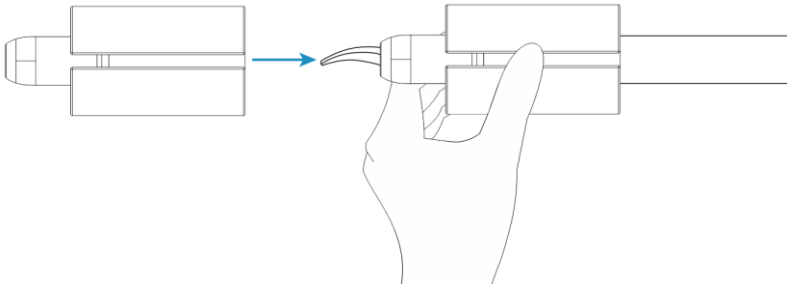


Figure 9.13 Install the Tip Cover

Warning: Failure to install the tip cover may cause:

- Jaws opening improperly.

- Tip cover falling off in the body.
- Electrical arcs and alternate site burns.
- Difficult instrument installation.

Tip Cover Removal

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

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

9.5.2 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 the Monopolar Energy Instrument Cord

Figure 9.15 Connect the Bipolar Energy Instrument Cord

3. Connect the energy instrument cord to the instrument.

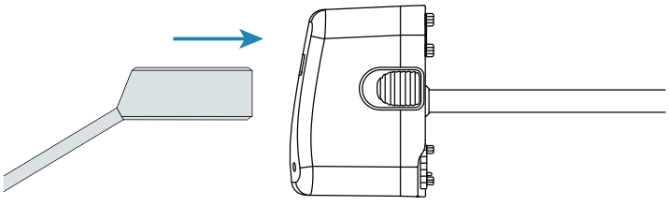


Figure 9.16 Connect the Instrument

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

Warning: The rated voltage of the monopolar instruments (monopolar scissors and monopolar electric hooks) and monopolar energy instrument cord should be 3 kV (electric cutting), use the high frequency generators (ERBE VIO300S) 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 (Maryland bipolar forceps and bipolar grasping forceps) and bipolar energy instrument cord should be 375 V (coagulation), use the high frequency generators (ERBE VIO300S) 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 dedicated power supply 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 supply before removing the energy instrument cords.

9.6 Instrument Installation

1. Inspect the instruments for breaks, cracks, chips, or wear. Do not use an instrument if it is damaged.
2. Straighten the instrument wrist and close the jaws to ensure easy insertion of the cannula to avoid damage to the instrument.

Caution: Straighten the instrument wrist by rotating the drive chuck at the bottom of the instrument housing or manipulating the instrument tip.

3. Insert the instrument tip into the cannula and press the instrument housing into the adaptor. Audible sounds indicate that the instrument is engaged.

Figure 9.17 Install the Instrument

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

Note: When inserting the instrument tip into the cannula, be careful not to puncture the drapes.

Note: Ensure that the surgeon is ready to resume control of the instrument before inserting the instrument into the sterile field.

Note: The endoscope can be installed on any of the instrument arms.

Note: Pressing the **Release** buttons once an instrument is installed can lead to unintended consequences such as disengagement of the instrument from the arm.

Manual Insertion of Instruments

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.

1. After installing instruments, the system performs a self-test first. After the self-test is completed, the arm LED indicator will illuminate solid blue.
2. When pressing and holding the **Instrument Clutch** buttons to manually adjust the positioning of the arm, the arm LED indicator flashes blue.
3. When locking the instrument by pressing the **Instrument Clutch** button after the instrument reaches the desired position, the arm LED indicator illuminates solid blue.
4. During the entire instrument installation process, the Surgeon Console operator cannot control the instruments.
5. The Surgeon Console operator can control the instruments in conditions of the endoscope installed, at least one instrument locked, the operator's head in the viewer, matching grips succeeded, and out of other motion states (such as cart movement).

9.7 Intraoperative Arm Management

The following are guidelines for intraoperative arm management:

- Arm management varies by procedure and patient. Anatomical restrictions may require alternate adjustments.
- To ensure maximum reach and minimum arm-to-arm interference, set up the arms in parallel (using the flex joints) and lower the patient clearance joints.

Arm-to-arm Interference

Identify the interference (for example, on the front end or back end of the arm).

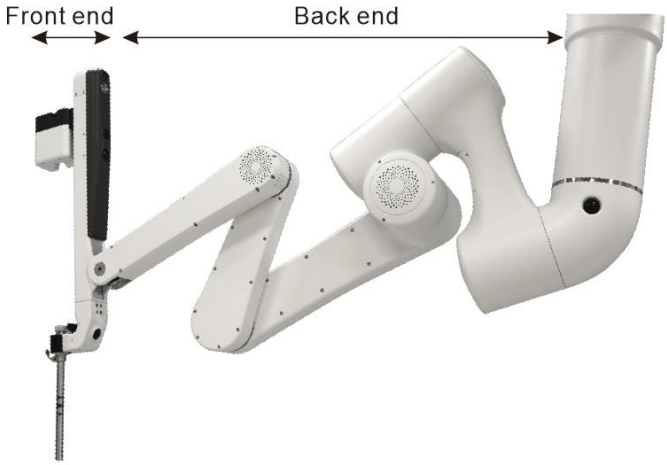


Figure 9.18 Front End and Back End of the Arm

- If the interference is on the front end of the arm: Use the **Port Clutch** button to space the arms. This allows the arm to work in parallel to minimize interference.

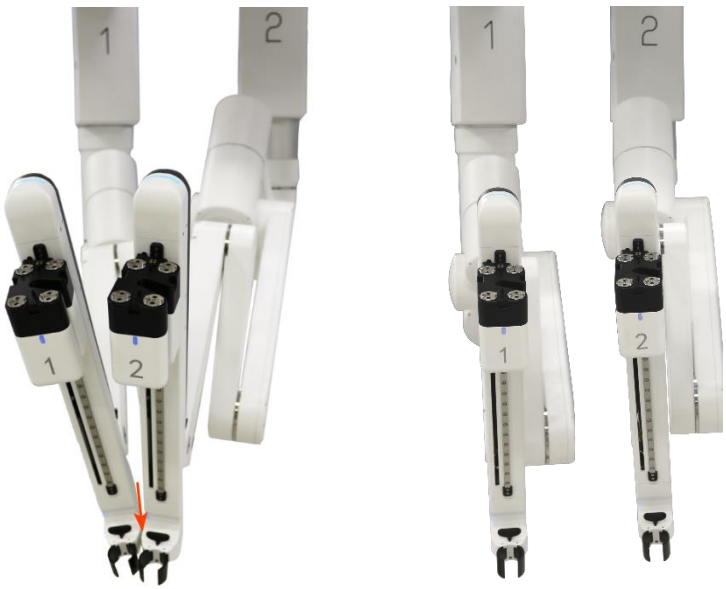


Figure 9.19 Horizontal Adjustment to Resolve Interference

- If interference is on the back end of the arm: Use the **Patient Clearance** button to adjust the arms away from each other (up or down). This increases the space between the joints and minimizes interference.

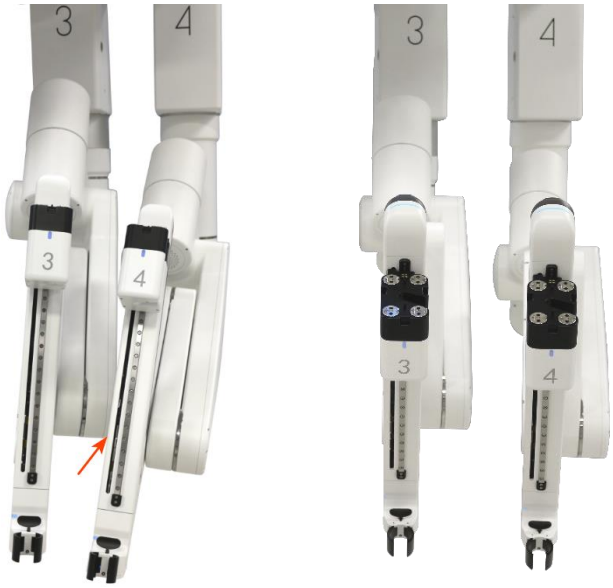


Figure 9.20 Patient Clearance Adjustment to Resolve Interference

Note: The patient-side assistant should always pay attention to the operating state of the arms, estimate the possibility of arm interference in advance, or prompt the surgeon in time after a collision.

9.8 Instrument Removal

Before removing an instrument, make sure the surgeon is ready.

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: 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.

Before removing an instrument, the surgeon should:

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

To remove an instrument:

1. Make sure the instrument is free and away from the patient's anatomy.
2. Squeeze both **Release** buttons on the instrument housing to slide the instrument up and out through the cannula.

Figure 9.21 Remove the Instrument

Note: The Patient Cart automatically retracts the instrument carriage when the instrument is disconnected. If the instrument is not removed in time, the adaptor may re-engage the instrument during the retraction. If the instrument re-engages, repeat the instrument removal steps.

Note: To avoid damage to the instrument arm drapes, be careful not to scrape instruments against Patient Cart arms during instrument removal.

Note: Be careful not to inadvertently breach the sterility barrier when removing an instrument or endoscope from the draped Patient Cart arm. If necessary, clutch the arm to adjust its angle such that the instrument or endoscope clears the sterility barrier upon removal.

9.9 Emergency Grip Release

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

Caution: In the event of a system failure when the instrument is grasping tissue, the grip can be opened manually by inserting the grip release wrench. Use visualization of the surgical site when inserting the grip release wrench, opening jaws, clearing tissue from jaws, and removing instruments from the system.

Caution: Rotating the grip release wrench in the incorrect direction may cause unintended instrument motion or damage to the grip release mechanism.

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

The grip release mechanism facilitates removal of an instrument when a system is fault, or when Surgeon Console control of the instrument is not practical. If the instrument tips are holding tissue, the grip release wrench contained on the instrument release kit allows the patient-side operator to manually release the grips.

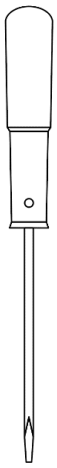


Figure 9.22 Grip Release Wrench

Note: It is recommended that the grip release wrench should be individually sterile-wrapped, labeled, and placed in the Vision Cart drawer. Surgeon and operating room staff should always know its location in case it is needed to manually release an instrument.

To release the instrument grips manually, perform these steps while visualizing the surgical site:

1. Prepare the grip release wrench.
2. Press the **Emergency Stop** button on the Surgeon Console.

3. Insert the long straight end of the wrench into the grip release socket on the instrument housing. Push to make sure the wrench engages with the socket. Once engaged, a slight resistance will be felt when rotating the wrench gently.
4. Rotate the wrench in the direction indicated by the arrow on the instrument housing to open the instrument grip. Support the instrument carriage to prevent accidental advancement of the instrument.
5. Confirm that the grip is not grasping tissue.
6. Once the tissue is released from the grip, remove the wrench from the instrument.
7. Squeeze the **Release** buttons on the instrument housing to remove the instrument.
8. Operate on the touchscreen to clear the fault, or restart the system as needed. Do not reuse the instrument.

Warning: Do not re-use an instrument that has had its grip released with the grip release wrench. Re-using an instrument after emergency grip release could result in critical failure of the instrument and injury to the patient.

After emergency grip release, return the affected instrument to the company by contacting technical support.

9.10 Intraoperative Instrument Cleaning

If an instrument needs to be cleaned during a procedure, remove the instrument from the patient and carefully wipe the instrument tip with a piece of soft gauze moistened in saline or sterile water.

To ensure satisfactory performance of the instruments, follow the guidelines for cleaning:

- Clean instrument tips when changing instruments.
- Do not use one instrument to clean other instruments inside the body.
- A non-sterile user needs to reconnect the foot pedal by swapping the energy activation cable for the footswitch cable. After cleaning, reconnect the energy activation cable to the generator.

Caution: Do not use an instrument to clean debris from another instrument inside the patient. This may result in damage to the instruments. To clean an instrument intraoperatively, remove the instrument from the body and wipe the instrument tip.

9.11 Instrument Service Life

Instruments are programmed 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.

9.12 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 drapes or adaptors during the procedure, do the following:

1. Remove the instrument from the arm 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 Instruments Reprocessing Instructions Manual.

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

9.13 Stowing the Patient Cart

Stowing retracts the boom and arms from their current positions to a predefined default stow or sterile stow position. The Patient Cart is stowed when the structure is in its most compact state.

The Patient Cart has two stow positions:

Stow

If all drapes have been removed and no adaptors are installed, stow the Patient Cart for transport through the hospital or within the operating room and for storage when not in use.

1. Press and hold **Sterile Stow** on the Patient Cart touchscreen to retract until the column and boom are in most compact state.
2. Use the clutch buttons on the Patient Cart arms to get the arms compact enough to fit comfortably through a doorway.

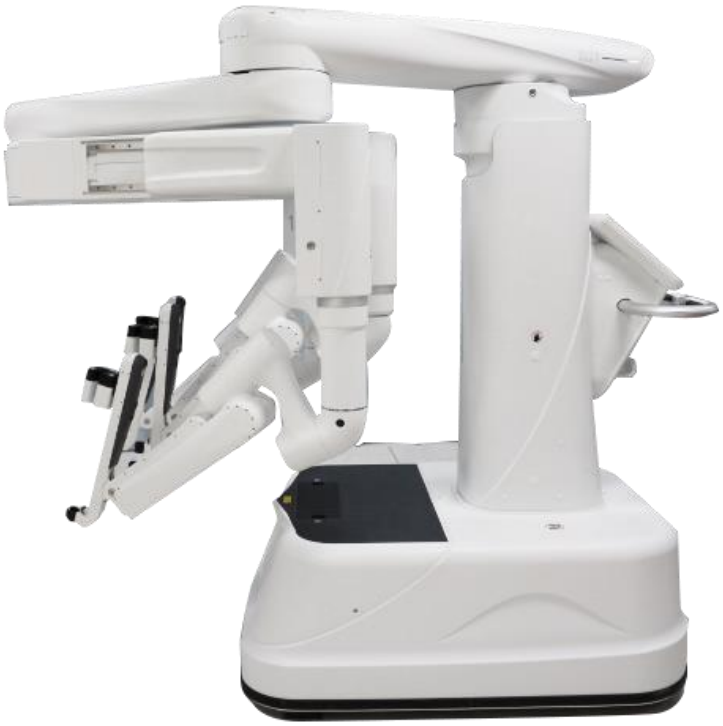


Figure 9.23 Stow Position of the Patient Cart

Sterile Stow

If one or more adaptors are installed, 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. See 6.3.3 Sterile Stowing the Draped Patient Cart (Optional) for more information.

The Patient Cart moves to the sterile stow position where the arms are folded out of the way

with enough space from the column to ensure that sterility is not breached.

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.

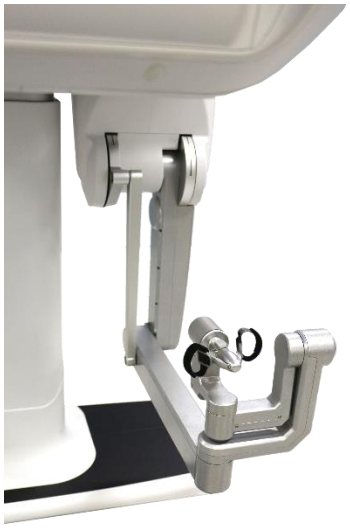


Figure 10.1 Master Controls

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.

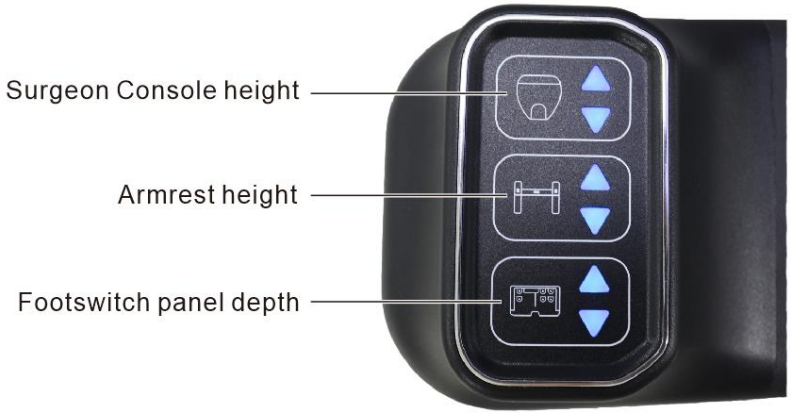


Figure 10.3 **Ergonomic Control** Buttons

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.

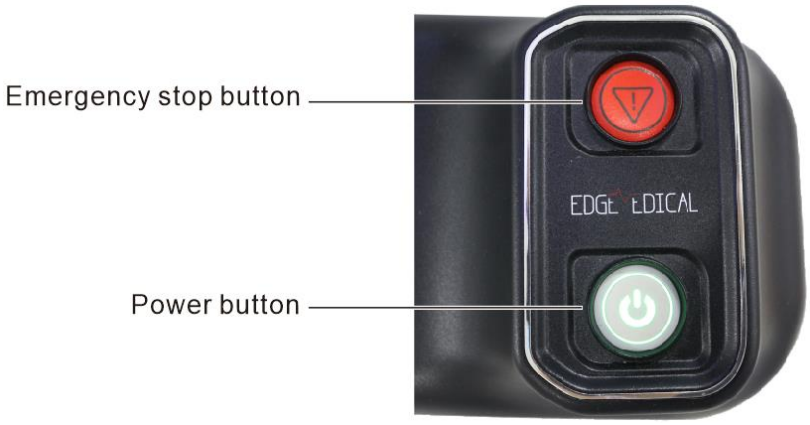


Figure 10.4 **Emergency Stop** Button and **Power** Button

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 14.3 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.

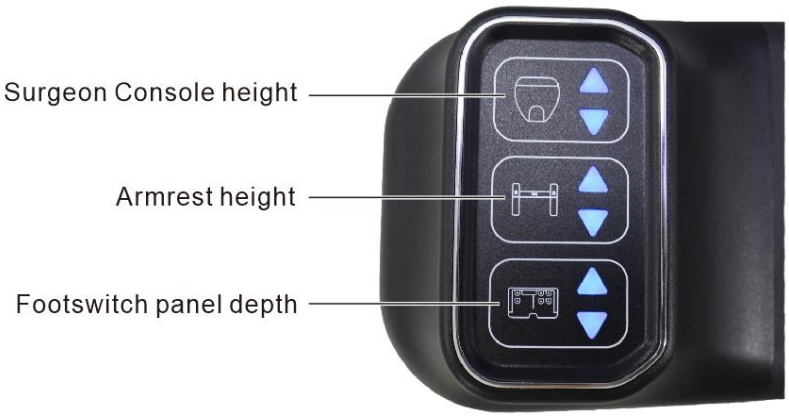


Figure 10.6 **Ergonomic Control** Buttons

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:

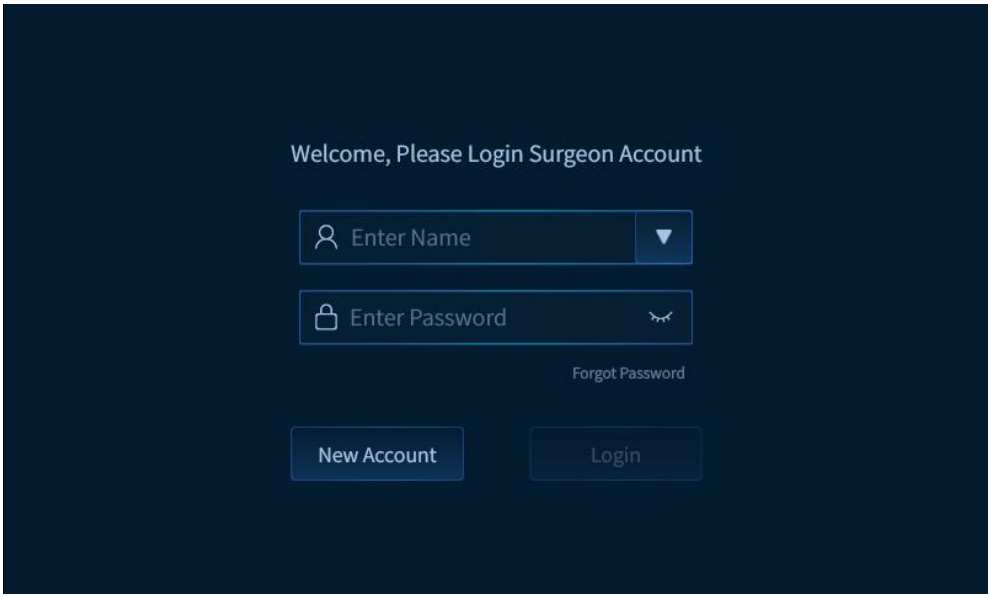
- Account Tab
  - Surgeon account: After logging in to surgeon account, surgeon can restore ergonomic, edit account, change password, logout and delete account.
  - Admin account: After logging in to admin account, surgeon can restore ergonomic, logout and delete surgeon account.
- Instrument Tab

  The Instrument tab allows surgeons to view the status for all four arms, give or take control of arms, quick-adjust audio, take photo, rotate the endoscope angle, etc.
- Settings Tab

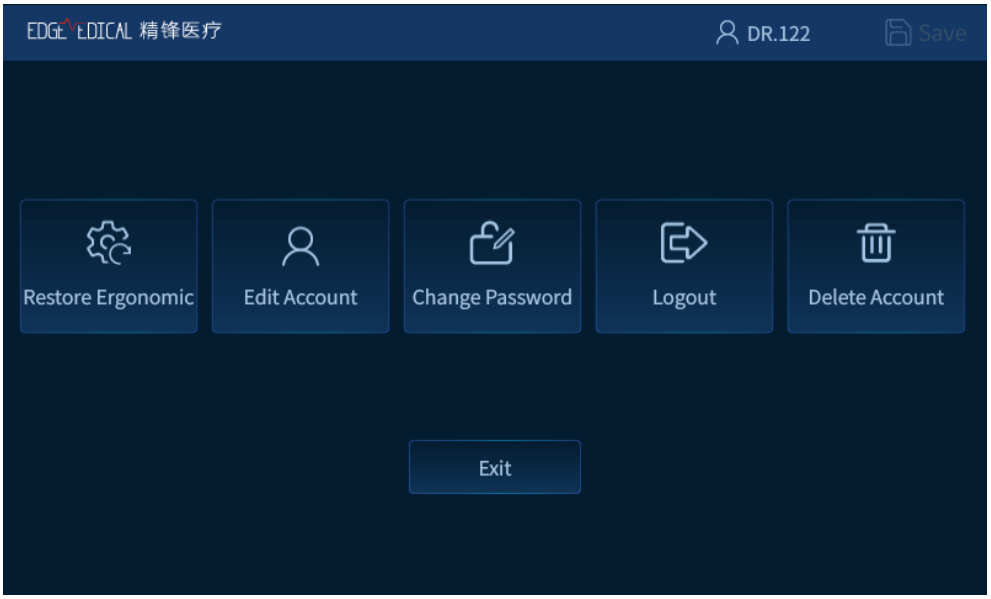
The Settings tab allows surgeons to configure system settings, including image, viewer, controls, Picture in Picture, fluorescence, account, general settings, etc. and acquire the software version. Besides, admin account lists more detail on software information.

Logging In to Surgeon Account

1. Enter the name and password of surgeon account.



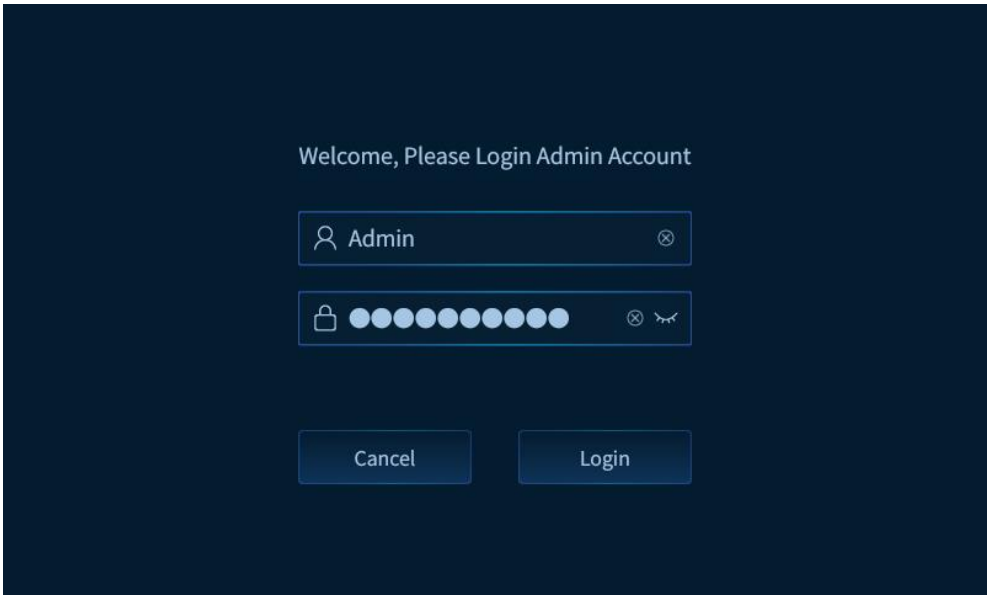
2. Tap the **Login** button and the Account tab appears.



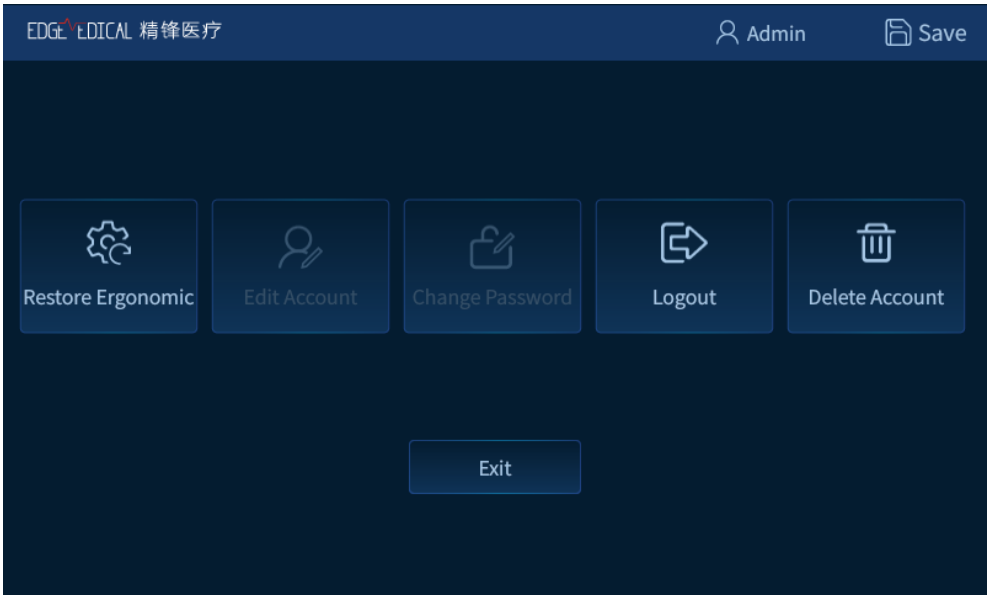
Logging In to Admin Account

1. Enter the name and password of admin account.

The default name is Admin and the password is Edgemp1000.

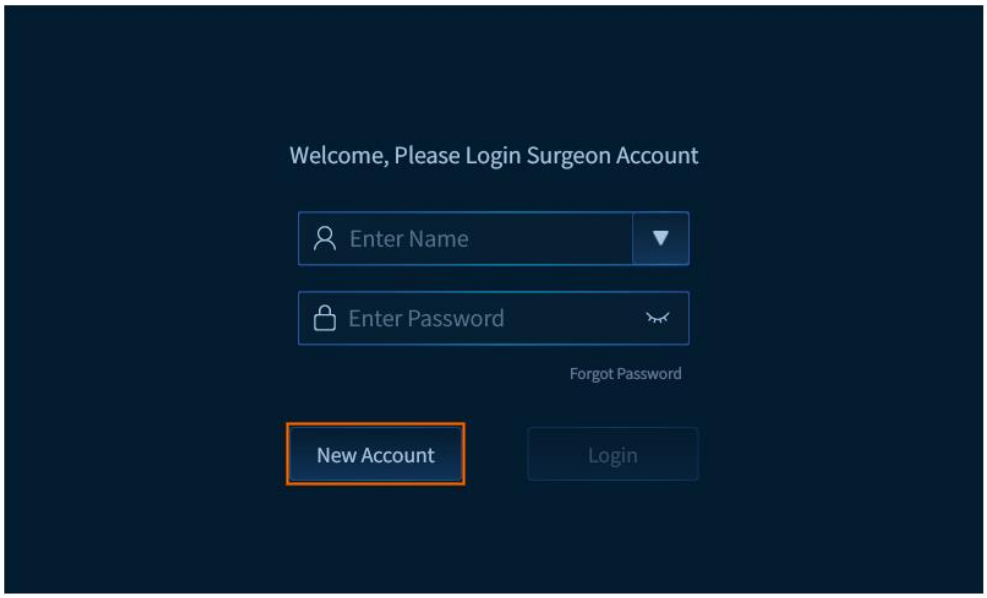


2. Tap the **Login** button and the Account tab appears.

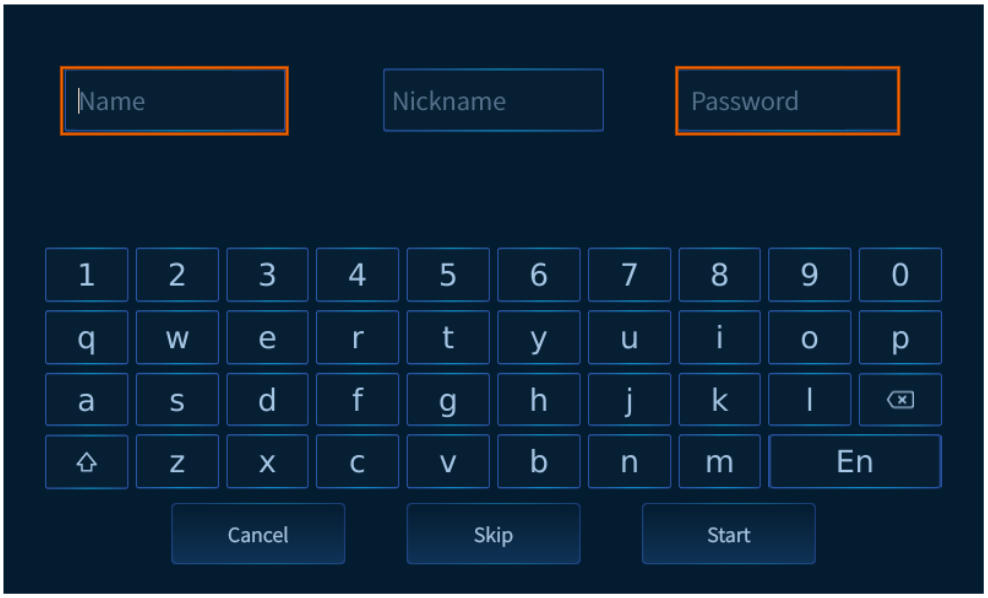


10.2.3 New Accounts

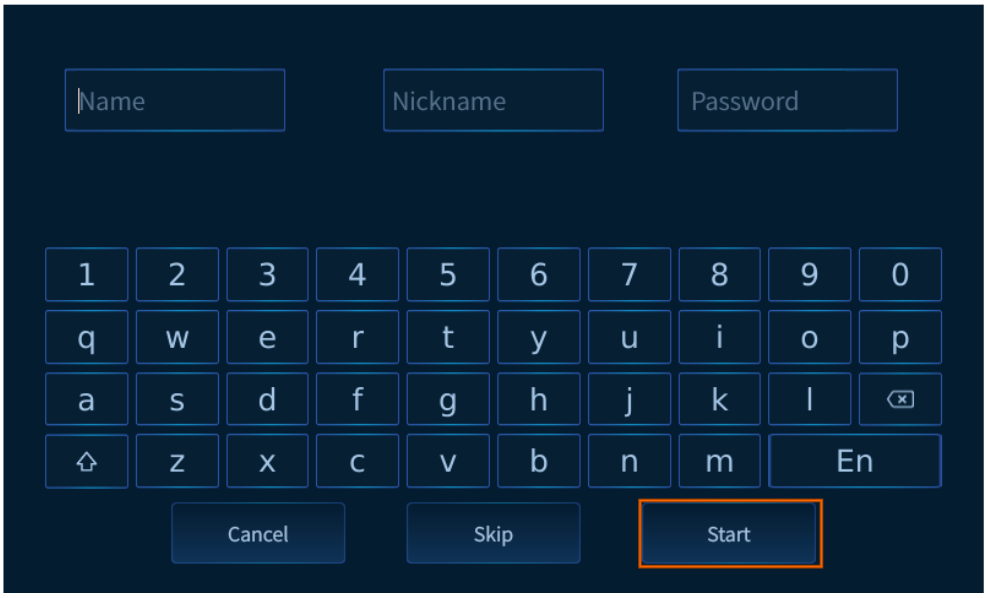
1. When logging in a surgeon account, tap **New Account**.



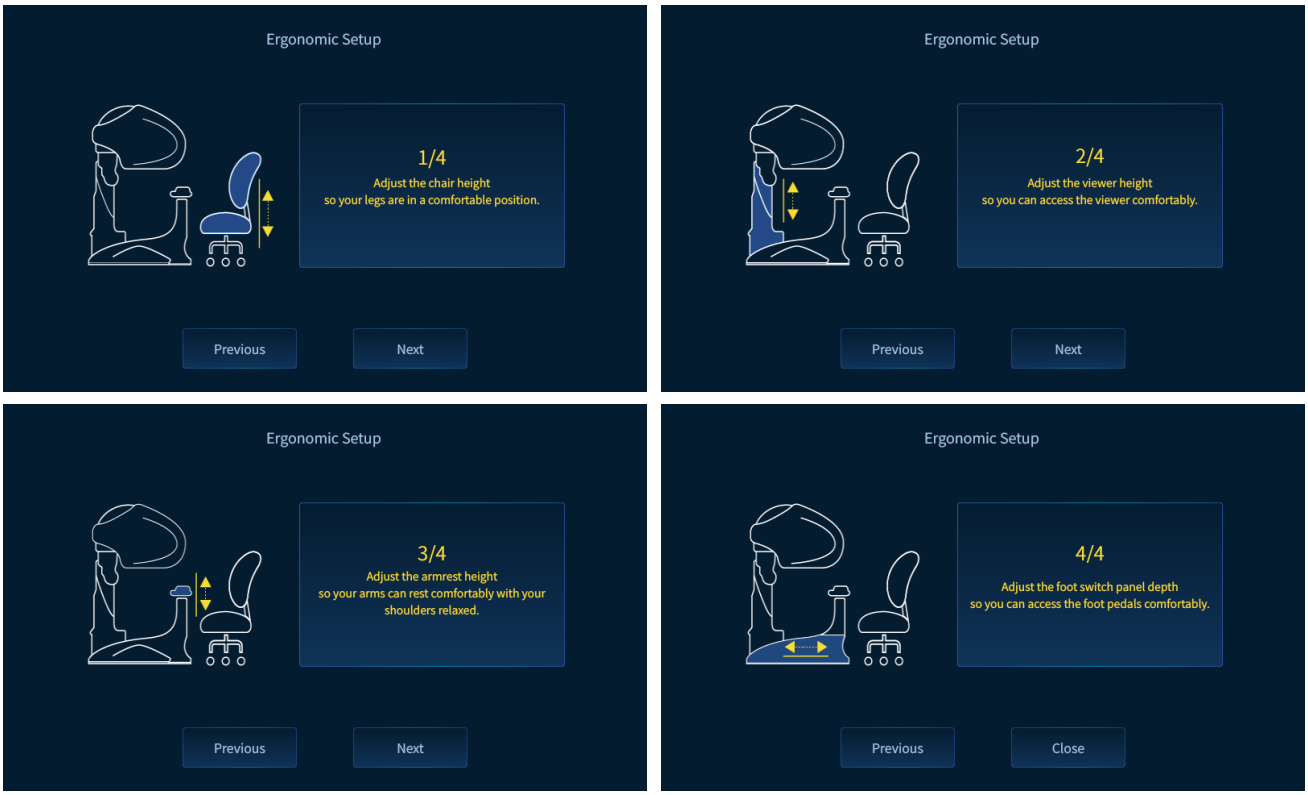
2. Enter the name and password of a new account.



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.

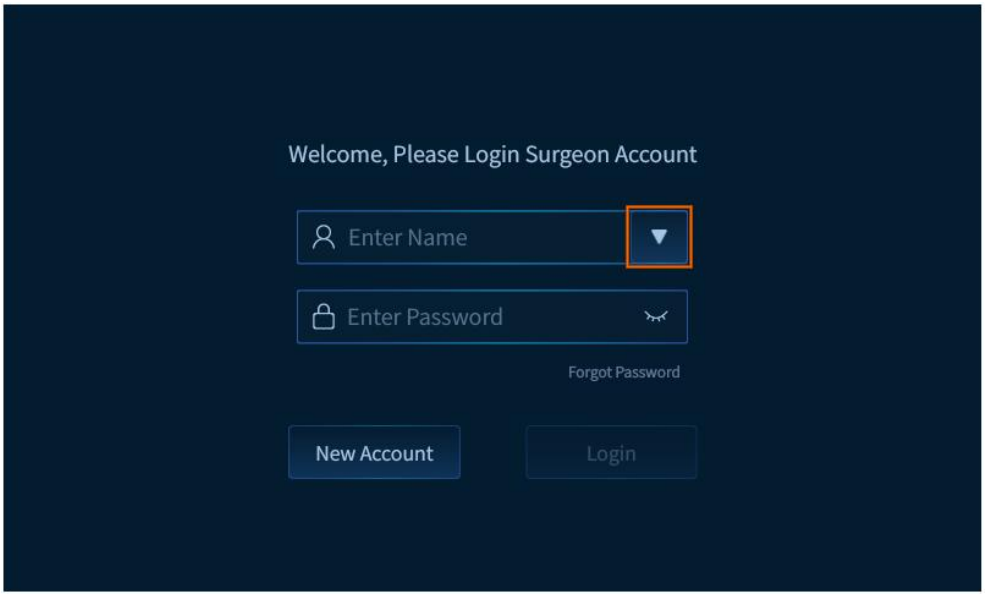
10.2.4 Save Settings

The Surgeon Console allows the surgeon who have previously created a surgeon account to

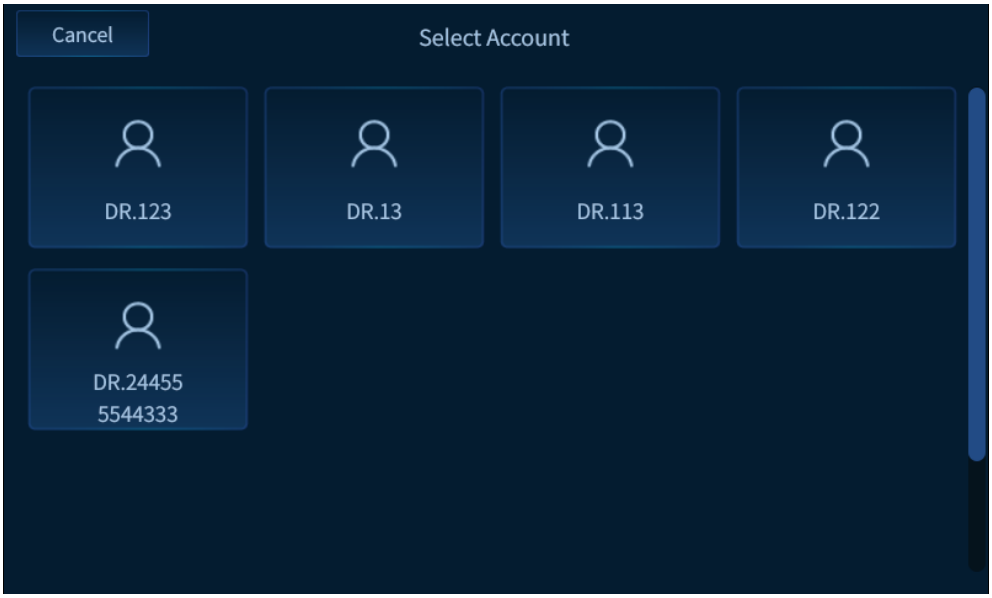
save the last set of adjustable settings. When there are some changes, tap the **Save** button to save the changes. When the system asks for confirmation, select **Yes** to save or **No** to cancel.

10.2.5 Select Accounts

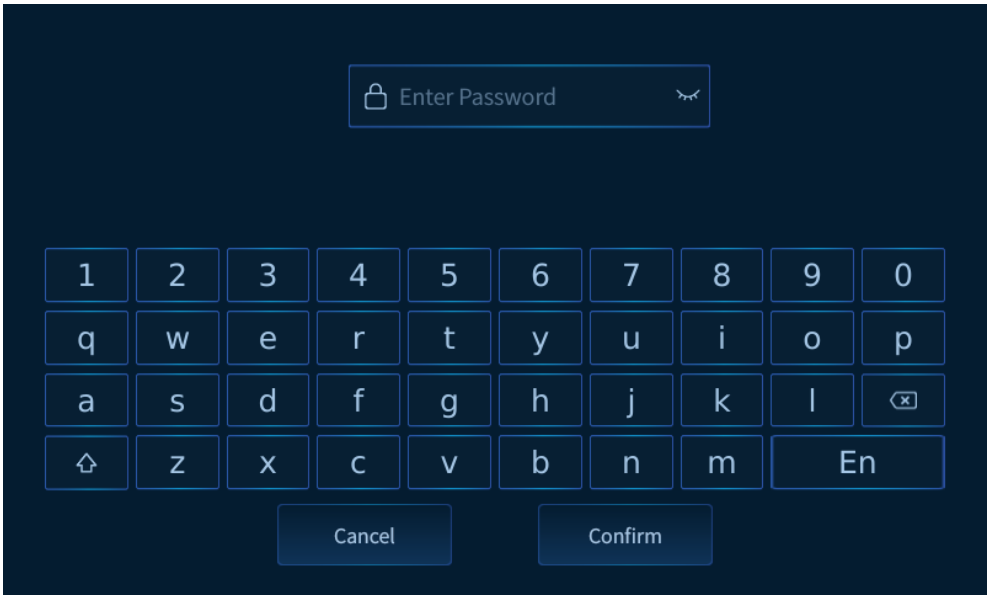
1. When logging in a surgeon account, tap the pull down icon.



2. Select an account from the user list.



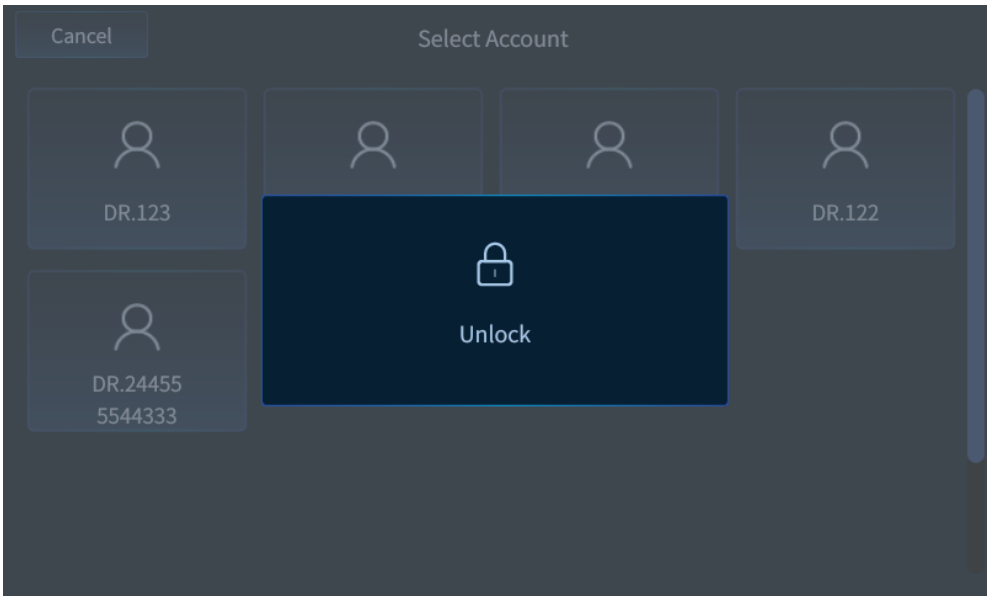
3. Enter the password to log in to the account.



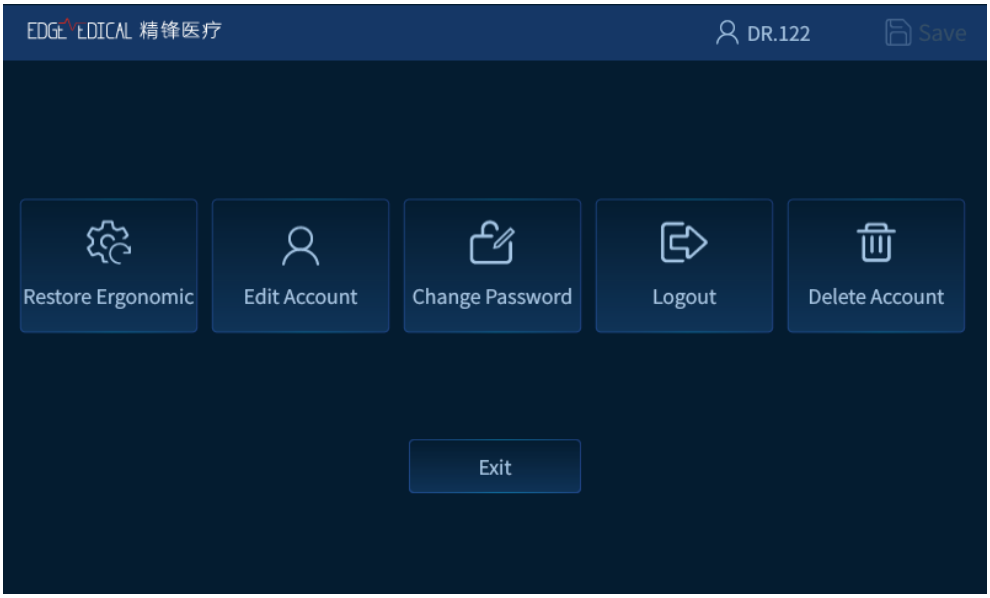
10.2.6 Lock Touchscreen

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.



10.2.7 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.

10.2.8 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

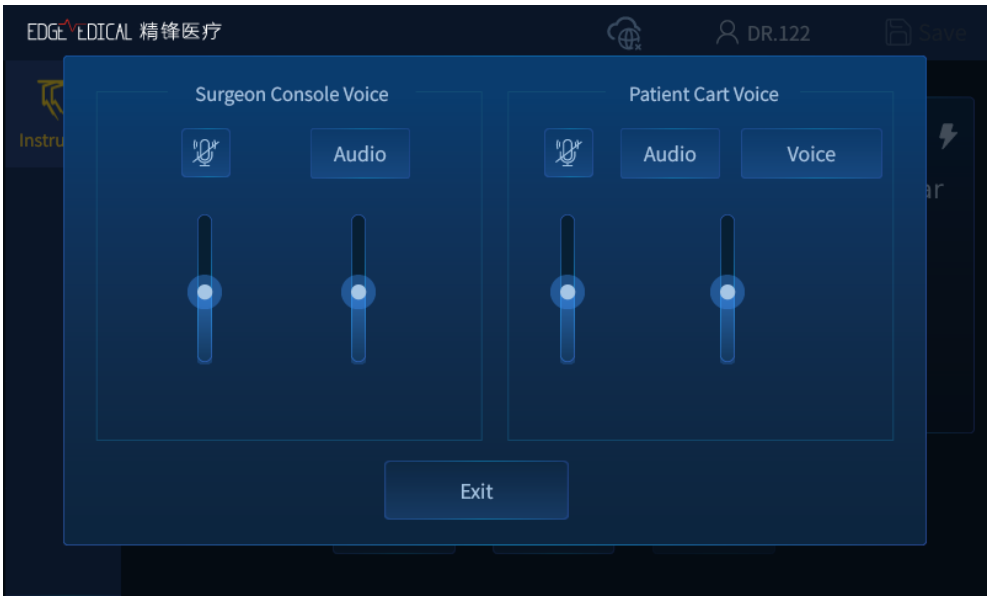
After an instrument or an endoscope is installed on the Patient Cart arm, its status will be displayed on the corresponding instrument or endoscope status box.

- Instrument status box
  - Instrument name.
  - The number of the Patient Cart arm.
  - 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.
  - **Give**/**Take** Button (Dual Console): The **Give** button indicates that you have control and the **Take** button indicates you do not have control at your console. Either surgeon can give or take control of a specific instrument arm by tapping **Give** or **Take**. When control is transferred by tapping **Give** or **Take**, the instrument goes out of following until the surgeon assuming control matches grips in the usual way.
- Endoscope status box
  - Endoscope name.
  - The number of the Patient Cart arm.
  - The installation status icon of the adaptor.
  - The magnification of the image (Digital Zoom).
  - Brightness Button: Adjust image brightness when a white light endoscope is connected; adjust background brightness and fluorescence intensity when a fluorescence endoscope is connected and the fluorescence mode is activated.

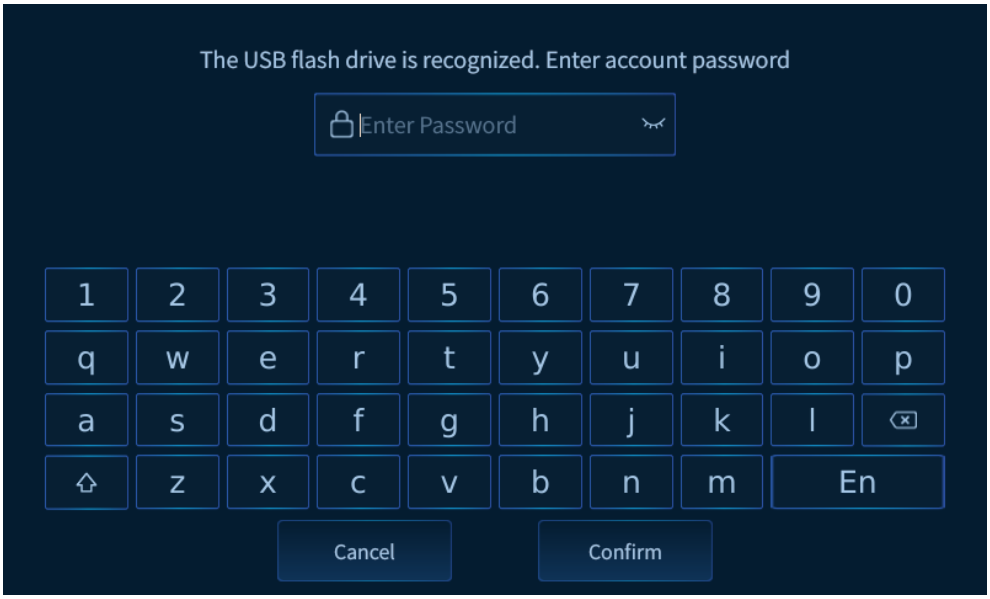
- Fluorescence Button: Tap to cycle among OFF (turn fluorescence mode off), Standard mode and FL-Only mode when a fluorescence endoscope is connected.
- Angle Button: When the endoscope is installed on the arm, the system detects and displays the endoscope angle. The angled endoscope can be set to the rotation angle of 0° (Straight), 30° (UP) and 30° (DOWN).

Quick Settings

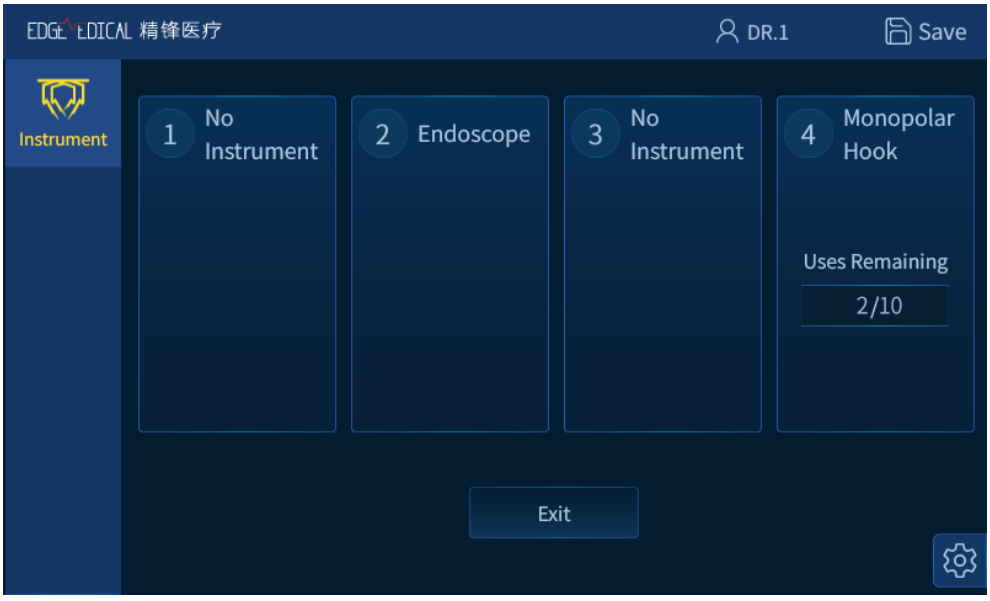
- **Sounds** : It is the button for audio settings. Tap the button to open the dialog to adjust voice of the Surgeon Console and Patient Cart. Drag the slider down to decrease volume or drag up to increase volume.



- **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.



- **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.



- **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 instrument arms. All instruments go out of following until the surgeon matches grips once again.

10.2.9 Settings Tab

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

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

Image

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

- Brightness: Drag the slider right to increase image brightness, but this will not change the actual light output of the endoscope.
- Background Brightness: Drag the slider to adjust the image background brightness.
- 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 (**1 Level**, **2 Level**, **3 Level**) to enhance image sharpness.
- Vessel Enhancement: Tap **ON** to turn Vessel Enhancement on to enhance the vessel image display, but affect tissue imaging except vessels.
- Image Denoising: Tap **ON** to remove noise from a noisy image, so as to restore the true image.

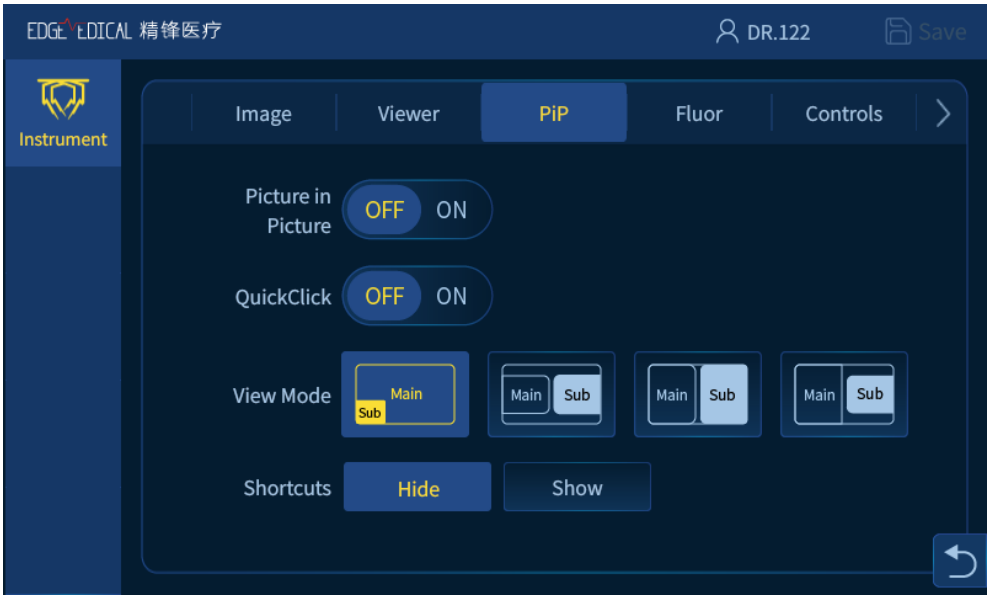
Viewer

- 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 Cart between the left-eye (**Left**) and right-eye (**Right**) image.
- Instrument Icon: The instrument icon displayed on the monitor of the Vision Cart and viewer of the Surgeon Console provides visual cues to identify instruments controlled by the Surgeon Console.
- 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.

PiP

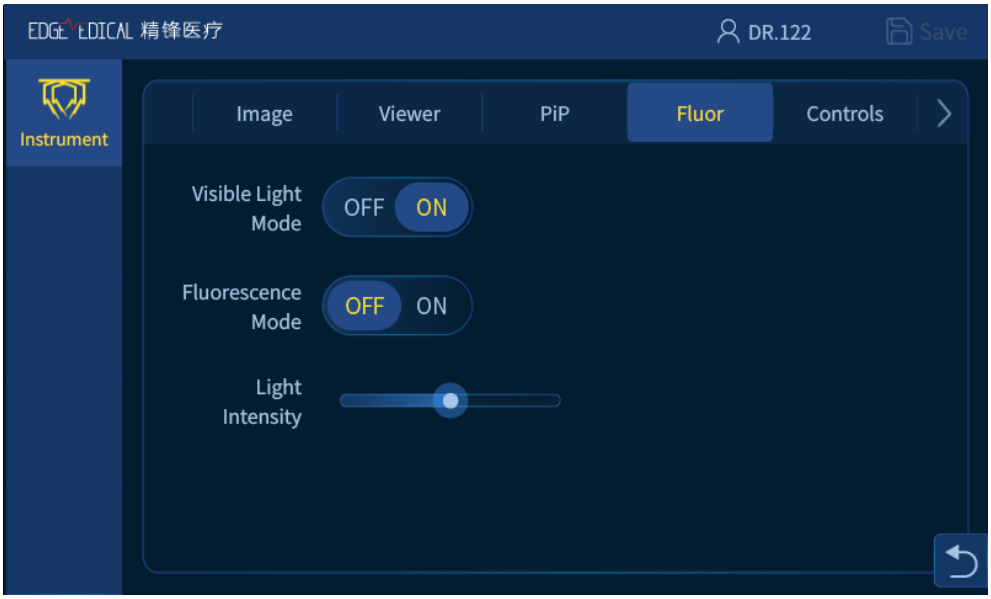
Tap the **PiP** button to view the picture in picture settings section.



- 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.
- QuickClick: When the QuickClick is **ON**, the user can switch to picture in picture with a quick press of the endoscope control pedal.
- 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.

Fluor

Tap the **Fluor** button to view the fluorescence settings section.



- Visible Light Mode: Select **ON** or **OFF** to turn visible light mode on or off. When the visible light mode is activated, the system illuminates white light.
- Fluorescence Mode: Select **ON** or **OFF** to turn fluorescence mode on or off. When the fluorescence mode is activated, the system uses near-infrared light in conjunction with the imaging agent Indocyanine Green (ICG), to create fluorescent images of tissue. Tap **OFF** to switch back to visible light mode and manipulate the tissue.
- Light Intensity: Adjust the light output for illumination of the operating field. Drag the slider left to decrease intensity or right to increase intensity.

Controls

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

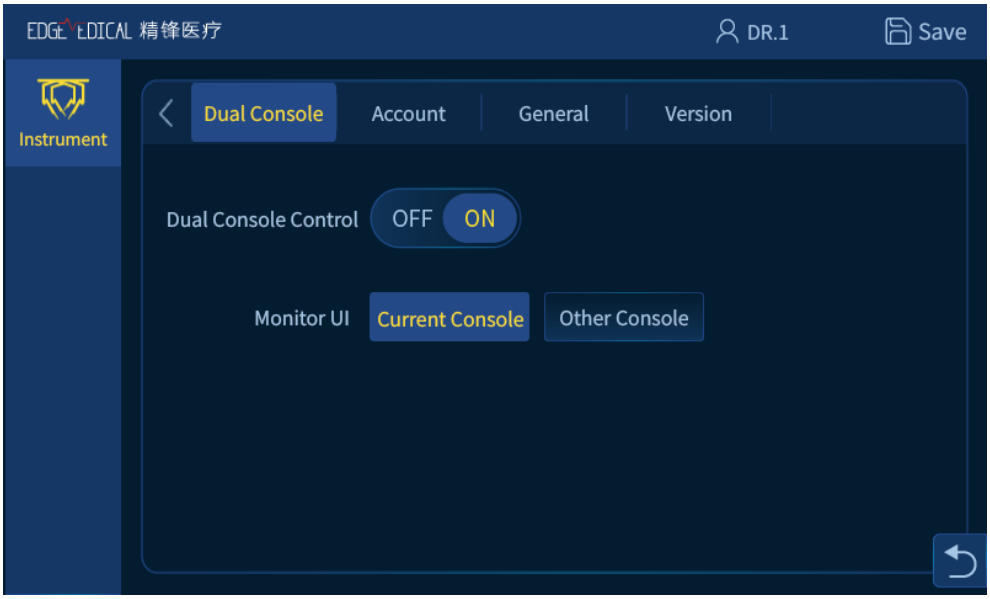
- Scaling: Scale the sensitivity of the master controls in relation to the instruments. Scaling has three settings (**Quick 1.5:1**, **Normal 2:1** and **Fine 3:1**).
- Finger Clutch: Select **ON** or **OFF** to turn finger clutches on or off. When the finger clutches are **OFF**, the surgeon can slide the finger clutches but cannot activate clutching.
- Master Controls Reset: Tap the **Reset** button to reset the master controls.
- Master Control Assignments: Enable surgeons to manually associate either master control with any instrument arm. Tap **Auto** to apply Master Control Assignments automatically, while tap **Manual** to switch assignments manually by arm. When arms are reassigned, the system takes the instrument arms out of following, and prompts the user to press the instrument swap pedal to control the arm.

Note: More than two arms cannot be associated with one master control.

Note: In dual console mode, either surgeon can use the Master Control Assignments to reassign instruments to different master controls, even while the other surgeon has control of the instruments. The new instrument assignment applies on both consoles and persists when instruments are swapped.

Dual Console

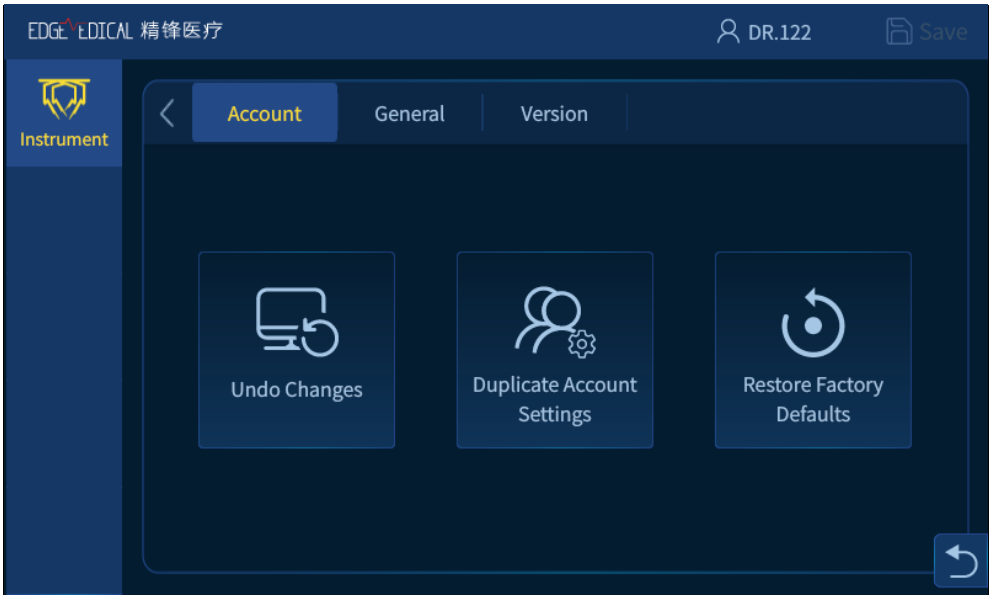
In dual console mode, tap the **Dual Console** button to view the dual console settings.



- Dual Console Control: When the Dual Console Control is **OFF**, the dual console features become limited. Tap **ON** to cancel limitations.
- Monitor UI: The monitor UI can be set to keep consistent with the console UI.

Account

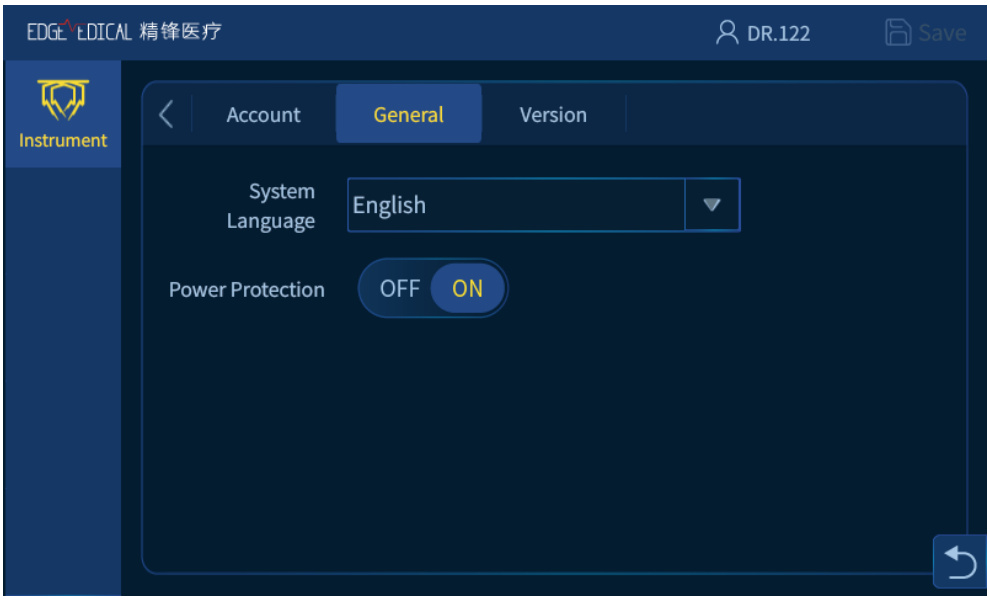
Tap the **Account** button to view the account settings. The section can be shown only after logging in to an account.



- Undo Changes: Restore the settings to user-saved values of Image Brightness, Image Enhancement, and Digital Zoom.
- 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. To restore ergonomic settings, go to the Account tab and tap the **Restore Ergonomic** button.

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.
- 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.

Version

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

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

More

Tap the **More** button to view more version information regarding the system components. The section can be shown only after logging in to the admin account.

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 arms). 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.

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 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 10.9 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, arm and instrument information through icons and text messages.

Figure 10.10 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.
- Arm and instrument information area: Displays the information on the arms and associated the instruments and endoscope.
- 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).

10.4.1 Arm, endoscope, instrument information

When one Surgeon Console is in use, the 3D viewer shows hand control, instrument status, and endoscope status.

10.4.2 Endoscope Status

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

- Endoscope Status:
  - Endoscope not available: Displays gray

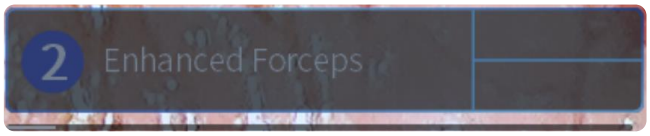
  - Endoscope available: Illuminates background and highlights borders

- ②: Indicates the number of the Patient Cart arm.
- 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.

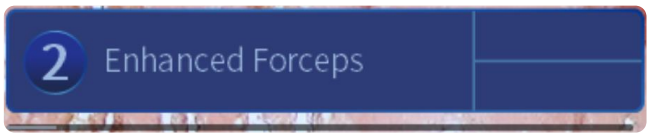
10.4.3 Instrument Status

When the instruments are installed on the arms, the corresponding status boxes in the arm and instrument information area display all of the associated instrument information including arm number, instrument name, activation status, service life and energy mode.

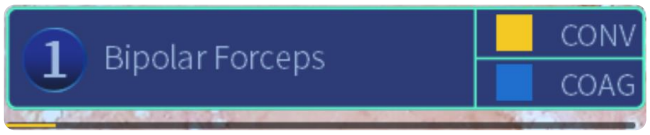
- Instrument Status:
  - Instrument not in use: Displays gray



- Instrument to be activated: Illuminates background



- Instrument activated: Illuminates background and highlights borders



- ②: Indicates the number of the Patient Cart arm.
- Bipolar Forceps: Indicates the name of the instrument.
- CONV / 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 arm and instrument 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 Second Console Instrument Status

While in dual console mode, the 3D viewer provides the instrument status for the other console, including the associated arm number, instrument name, activation status and energy mode.

10.4.6 Arm Popup Information

If the surgeon requires action to control the arm, including handling arm-specific error or fault condition, the system generates a popup message with information about the required action. When the operation is completed, the popup message disappears.

10.5 Dual Console Use

10.5.1 Dual Console Overview

The system does not supports dual console surgery or intraoperative assistance, the system are intended to use in the skill training. 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.

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/Take** buttons on the Instrument Tab of the touchscreen appear. For each arm, “Give” indicates that has control of the arm while “Take” indicates that does not have control of the arm. Either surgeon can give

or take control of a specific arm by tapping the **Give/Take** 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 control is transferred by tapping **Give** or **Take**, the instrument goes out of following until the surgeon assuming control matches grips in the usual way. 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 Cart 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 10.2.9 Settings Tab.

When the Dual Console is OFF, toggle to assign control of all instruments and the endoscope to the Surgeon Console in primary control. The surgeon cannot give or take control of a specific instrument arm but give or take control of all arms. When the Dual Console is ON, the dual console limitations will be cancelled.

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 Arm, endoscope, instrument Status

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

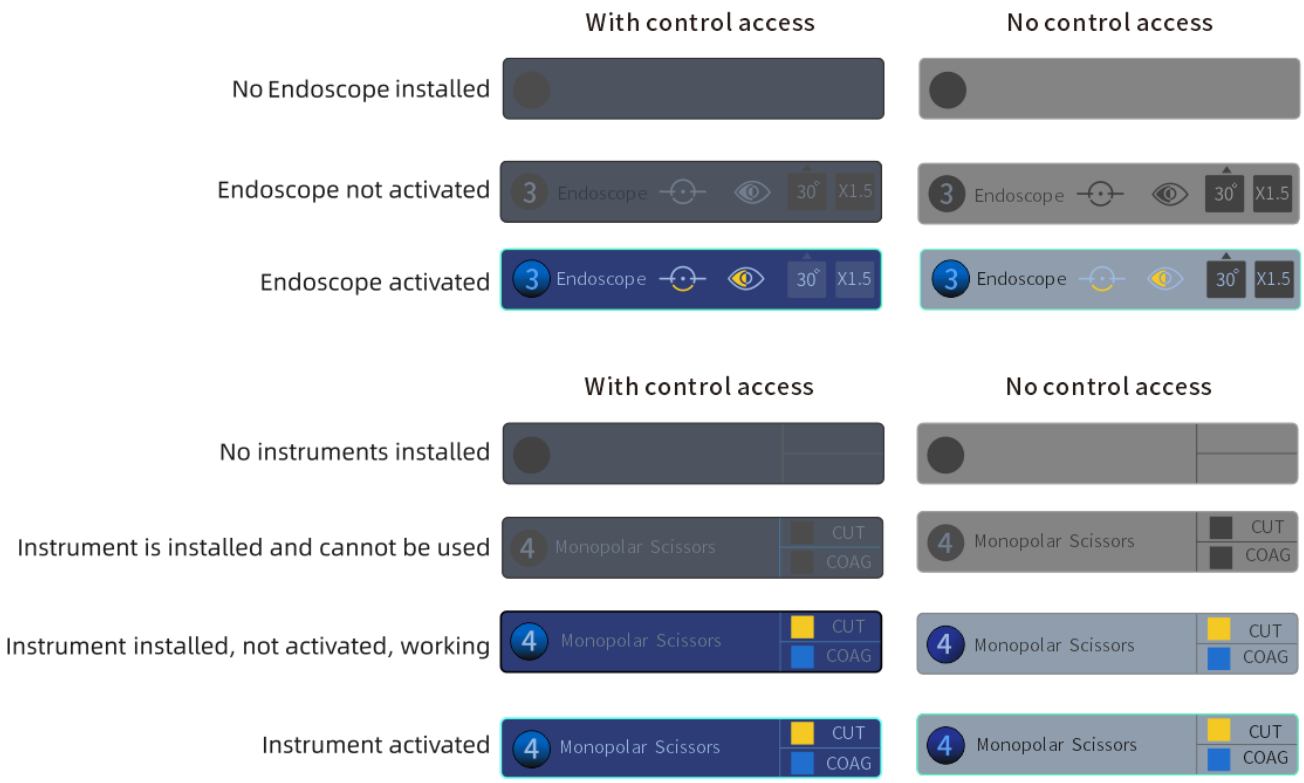


Figure 10.11 Schematic design of arm bar status

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 10.12 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. Insufflator Use

11.1 Insufflator Overview

The insufflator is used in conjunction with Endoscopic Instrument Control System, creates and maintains pneumoperitoneum through the cannula seal.

The insufflator is indicated for use in minimally invasive endoscopic procedures by filling the patient cavity with appropriate amount of gas. The settings of the insufflator including gas volume, flow rate and pressure can be adjusted according to the patient's conditions and surgical needs.

Warning: Only medical grade pure CO_2 can be used for Endoscopic Instrument Control System. Insufflation should be performed by personnel with adequate technical training and rich experience, otherwise hazards may exist with over-insufflation, such as gas embolism.

11.2 Compatibility Information

The insufflator is connected to the insufflation port of the cannula seal by a insufflation tube set with a standard 5/16 inch Luer fitting.

11.3 Inspection before Use

Before use, all parts and accessories should be visually inspected for damage or irregularities.

- Inspect the gas supply for no or low gas supply.
- Inspect the insufflator for any defects or damage.
- Inspect the Luer fitting and insufflation port for any scratches, cracks or broken parts.
- Ensure the insufflation tube and port are dry.

11.4 Operation Steps

1. Connect the insufflator to the power supply.
2. Prepare the gas supply with an appropriate amount of gas and connect the insufflator and the gas supply.
3. Open the gas supply and check for possible leakage.
4. Power on the insufflator and select insufflation operating modes.
5. Connect the insufflator and the cannula seal.

Ensure complete attachment of a Luer fitting to the cannula seal without gas leakage by following methods.

- Whether there is sound of leakage at the connections;
- Whether the pressure of the insufflator drops quickly.

The insufflator can be used with the system when there is no sound of leakage and the pressure of the insufflator remains stably.

6. Set the gas volume, flow rate and pressure according to the patient's conditions and surgical needs. The insufflator can start insufflation.
7. After the procedure, stop insufflation and then power off the insufflator.

12. Shutdown and Storage

12.1 Preparation for Shutdown

1. Remove the instruments and endoscope from the Patient Cart. See 9.8 Instrument Removal for details.
2. Disconnect the cannulas from the instrument arms.
3. Use the **Port Clutch** buttons to move the instrument arms away from the patient.
4. Move the Patient Cart away from the operating table.
5. Remove the drapes from the system. See 6.4 Drape Removal for details.
   a. Remove the drapes of four instrument arms in sequence.
   b. Remove the column drape.
6. Dispose the drapes into the designated location.
7. Remove the instruments and endoscope for cleaning and sterilization.
8. Clean the Patient Cart, Surgeon Console and Vision Cart. See 13.1 Cleaning for details.
9. Stow the instrument arms and the Patient Cart. See 9.13 Stowing the Patient Cart for details.

12.2 System Shutdown

Press the **Power** button. 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: The Camera Control Unit can be shut down independently by pressing the **Power** buttons.

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.

12.3 System Storage

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

13. System Maintenance

13.1 Cleaning

Clean the Patient Cart, the Surgeon Console, the Vision Cart and the Signal Distributor at the frequency required by individual hospital policy. Perform the cleaning steps 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: Do not use abrasive cleaning tools, corrosive gases or liquids to clean the system components.

13.2 Replacing Accessories

13.2.1 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 13.1 Fuse Parameters

Part Number	Specification	System Component
0215010.MXP	T10AH250VP	Surgeon Console
0215015.MXP	T15AH250VP	Patient Cart

Part Number	Specification	System Component
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.

13.2.2 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.

13.3 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 service life 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 service life 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 Cart 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 service life of the instruments and endoscope, and replace them once they run out of service life.
- 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 arms do 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 service life.
- Avoid over discharge, 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.

13.4 Technical Support

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

13.5 Disposal

13.5.1 System Components

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

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

13.5.2 UPS

The Patient Cart contains a UPS. If the UPS exceeds its service life, 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.

14. System Troubleshooting

14.1 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 9.9 Emergency Grip Release.
2. Remove the endoscope from the patient.
3. Disconnect the cannulas from the arms.
4. Move the arms away from the patient.
5. If necessary, move the Patient Cart away from the operating table. If the Patient Cart drive fails to work, see 14.8.1 Drive Fault.
6. The surgeon performs the procedure according to open surgical process.

Note: If the system is in a fault state while converting to open surgery, the Patient Cart still allows assistant to use the **Port Clutch** buttons. When the system loses all power, assistant can still apply small force to move the arms and joints if necessary.

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.

14.2 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:

- The corresponding arm will be locked and not allow taking control of the instrument.
- When a recoverable fault occurs on an arm or instrument, the corresponding instrument arm LED indicator flashes yellow. When a non-recoverable fault occurs on an arm or instrument, the corresponding instrument arm LED indicator flashes red.

- 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.

14.2.1 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.
- Press the **Instrument Clutch** or **Port Clutch** button on the instrument arm.

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 arms or master controls.

14.2.2 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 cannulas 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.

14.3 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 9.9 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 9.9 Emergency Grip Release.

- Non-Recoverable faults

  The system must be restarted. See 14.2.2 Non-Recoverable Faults.

14.4 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.

14.5 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.

14.6 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 of 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.

14.6.1 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 14.6.2 Hard-Cycle Power on System for details.

14.6.2 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.

14.7 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.

14.8 Patient Cart Faults

14.8.1 Drive Fault

Caution: Do not move the Patient Cart when the arms are docked to the patient.

Caution: Do not disengage the drive while the Patient Cart is on a slope.

Caution: To ensure safety, the Patient Cart cannot be moved if the arms have been installed with cannulas or instruments.

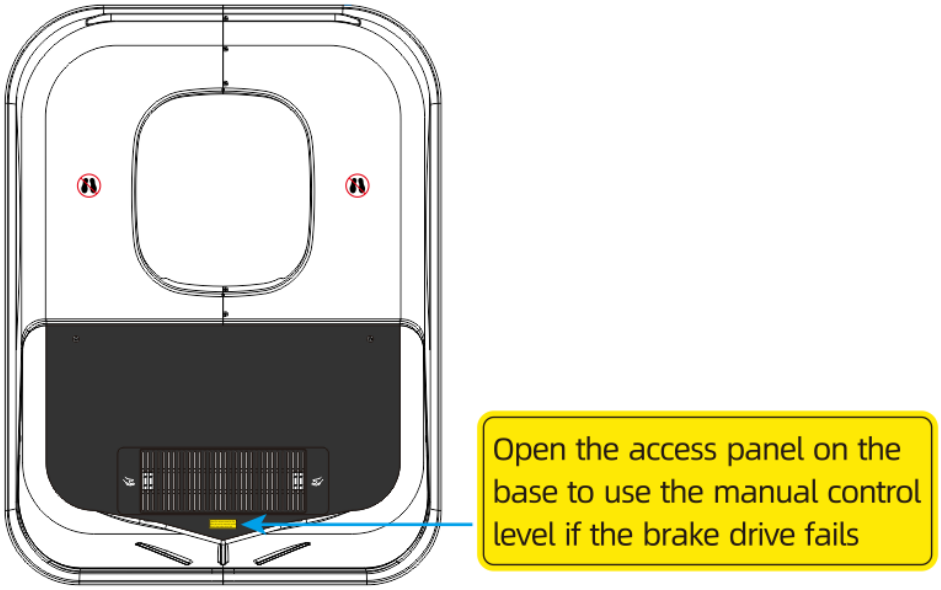
Note: It is recommended that two people move the Patient Cart manually due to the high force required.

The Patient Cart provides the manual drive feature, allowing moving the Patient Cart manually

without motor drive. In the event of a drive failure on the Patient Cart, perform the following steps:

1. On the base of the Patient Cart, open the access panel designed for repair.

   Pay attention to the label on the interior of the access panel. This label provides instructions for manual drive control of the Patient Cart.



2. Push the lever to the N position.
3. Two people manually transport or position the Patient Cart.
4. To restore the drive of the Patient Cart, push the lever to the D position.

Note: Make sure to push the lever back to D position once manual drive control is no longer required.

14.8.2 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 9.1.4 LED Indicators 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.

14.8.3 Arm-to-Arm Interference

If there is an interference between two arms, a fault message will display on the on the monitor or the Surgeon Console viewer.

1. Identify the interference is at the front end or back end of the arm, do as follows:
   - Front end interference: Adjust the arms to an appropriate position through the **Port Clutch** button.
   - Back end interference: Adjust the arms to an appropriate position through the **Patient Clearance** button.
2. Operate on the touchscreen to resume use.

14.8.4 Adaptor Disengagement

If an adaptor disengages from an arm abnormally, the corresponding instrument arm LED indicator flashes yellow, and a fault message will display on the monitor or the Surgeon Console viewer.

1. Remove the instrument and the adaptor.
2. Reset the instrument carriage on the Surgeon Console touchscreen.
3. Reinstall the instrument and the adaptor.

14.9 Vision Cart Faults

Table 14.1 Vision Cart 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 illumination.
	The image brightness set too high or low.	Adjust brightness setting. See 7.4.6 Image Brightness.
Image flickering	Flickering happens during cautery	Keep away from or replace high frequency equipment, and restart the system.

Fault	Possible Cause	Solution
Image blurring	The glass surfaces on the endoscope are smudged or soiled.	Clean the glass surfaces after removing the endoscope and turning off illumination.
	The image is zoomed out too much.	Adjust zoom setting to zoom in to the image. See 7.4.8 Digital Zoom.
Color cast	The system needs white balancing manually.	Perform manual white balance. See 7.4.5 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 endoscope illuminator.
	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.
No or weak fluorescence image in the expected time after ICG injection	Clinical factors related to ICG dosage and administration.	Use ICG properly according to the manufacturer's instructions while in combination with clinically relevant information.
	The fluorescence intensity needs adjustment.	Adjust light intensity. See Fluor in 10.2.9 Settings Tab.
No light is emitting from the endoscope when it is connected to the endoscope illuminator	The light guide bundles is not connected properly.	Connect the light guide bundles to its matching receptacle and confirm that the endoscope and the endoscope illuminator are connected correctly.

Fault	Possible Cause	Solution
Surgical image appears dark or there are too many image artifacts	The administration of ICG is inadequate or is completed incorrectly.	Confirm that the administration of ICG is completed correctly.

Note: If the above solutions cannot clear the faults, the endoscope may be damaged. The system is equipped with backup endoscope for replacement. If any fault still exists after endoscope replacement, contact the company for technical support.

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

14.10 Other Faults

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

15. System Alarm

15.1 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
Position overlimit of arms	The arms reach motion limit during operation.	Surgeon Console
Position deviation of arms	When the arms collide with obstacles during operation, the desired position deviates from the actual position.	Surgeon Console
Unexpected motion of arms	When operating in non-following mode, unexpected motion occurs to the arms due to external interference.	Surgeon Console
Adaptors drop abnormally	When operating in following mode, the adaptors 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

15.2 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
Position overlimit of arms	Technical alarm
Position deviation of arms	Technical alarm
Unexpected motion of arms	Technical alarm
Adaptors drop abnormally	Technical alarm
Abnormal system communication	Technical alarm
Invalid instrument use	Technical alarm

15.3 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.

Users are not allowed to change any alarm settings, including alarm information, presets and priorities.

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.	
Position overlimit of arms	Arms reach motion limit and the preset is FALSE.	
Position deviation of arms	Position deviation of arms is preset to FALSE.	Medium priority

Alarm Name	Preset	Priority
Unexpected motion of arms	Unexpected motion of arms is preset to FALSE.	
Adaptors drop abnormally	Adaptors 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

15.4 Alarm Signal

When an alarm occurs, the monitor will display alarm icons, text messages and LED indicator, all alarm signal delay time not more than 1 second.

Priority	Alarm Icon	Text message	LED indicator
Low priority		Desired position deviation of master controls, tap **Recover** on the touchscreen.	No
		Unexpected motion of master controls, tap **Recover** on the touchscreen.	No
		Position overlimit of arms, tap **Recover** on the touchscreen.	No
Medium priority		Position deviation of arms, tap **Recover** on the touchscreen.	No
		Unexpected motion of arms, tap **Recover** on the touchscreen.	No
		Abnormal system communication, check connections of system cables	No

Priority	Alarm Icon	Text message	LED indicator
		Adaptor dropped abnormally, reinstall the adaptor.	The instrument arm LED indicator flashes yellow at 0.5 Hz.
High priority		Invalid instrument use, change a validated instrument.	No

15.5 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 15.4 Alarm Signal for the alarm signals (including icons and text messages) when alarm triggering and see 15.6 Alarm Elimination for operation methods.

15.6 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 signal clearing delay of no more than 1 second.

Alarm Name	Operation Method	Alarm style
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.	Latching alarm
Unexpected motion of master controls	Tap **Recover** on the touchscreen after resolving the external interference.	Latching alarm
Position overlimit of arms	Adjust the position of the arms, and then tap **Recover** on the touchscreen.	Latching alarm

Alarm Name	Operation Method	Alarm style
Position deviation of arms	Remove the obstacles at the range of motion or arrange the arms, and then tap **Recover** on the touchscreen.	Latching alarm
Unexpected motion of arms	Prevent the external interference, and then tap **Recover** on the touchscreen.	Latching alarm
Adaptors drop abnormally	Reset on the touchscreen after removing the instrument and the adaptor, and then reinstall the instrument and the adaptor.	Latching alarm
Abnormal system communication	Re-connect the system cables.	Latching alarm
Invalid instrument use	Replace the instrument and use the specified instrument during its service life.	Non-latching alarm

15.7 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.
Position overlimit of arms	When operating in following mode, make an arm reach motion limit. The result meets the alarm requirements.
Position deviation of arms	Based on the manufacturer’s methods, make an arm deviate abnormally. The result meets the alarm requirements.
Unexpected motion of arms	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.
Abnormal system communication	After connecting the system cables correctly, disconnect the cables. 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.

15.8 Alarm Log

Only the maintenance personnel of Shenzhen EDGE 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	6 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 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.4 Laser Specifications

The table below provides laser specifications of the Patient Cart:

Complies with 21 CFR 1040.10 and 1040.11
Except for deviations pursuant to laser notice No. 50
Dated June 24, 2007

Laser Class	Wavelength	Power	Specification
Class 1	525 nm±20 nm	No more than 1000 μW	As per IEC 60825-1

A.5 Physical Dimensions

Surgeon Console

Height (Min)	Height (Max)	Width	Depth	Weight	Ground Clearance
1440 mm	1630 mm	1000 mm	1000 mm	Approx. 291 kg	36 mm

Patient Cart

Height (Min)	Height (Max)	Width	Depth	Weight	Ground Clearance
1758 mm	2488 mm	910 mm	2065 mm	Approx. 1055 kg	50 mm

Camera Control Unit

L×W×H	Weight
450 mm×290 mm×87 mm	Approx. 8.5 kg

Signal Distributor

L×W×H	Weight
450 mm×278 mm×112 mm	Approx. 10.6 kg

A.6 Ports

A.6.1 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.6.2 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.
3	Communication port	Connected to the devices with equivalent transmission protocols, e.g. debugging tools.

A.6.3 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 or an illuminator.
3	MV (Master-Video) communication port	Connected to MV communication port of the Signal Distributor for image processing.
4	Energy control	Connected to an illuminator.
		Connected to energy equipment, such as ultrasonic generator or 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.6.4 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 ultrasonic generator or high frequency generator.
3	MS (Master-Slave) communication	Connected to MS communication port of one Surgeon Console or two Surgeon Consoles for master-slave control operation.
4		Connected to MS communication port of the Patient Cart for master-slave control operation.

No.	Port Name	Description
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.

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 use 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 surgeon grasps the master controls of the Surgeon Console to perform accurate motion control over the instruments and endoscope on the Patient Cart arms, and observes the real-time endoscopic image through the viewer of the Surgeon Console.
- The instruments can be manipulated in a precise and controlled manner and there is no significant delay in motions or images.
- The maximum distance after emergency stop activity is within 5mm;
- Error for belt angle is $\leqslant 3^{\circ}$;
- Error for movement distance of operation accessories is ≤ 3mm.

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
5	Power cord	1.8 m	No	Power supply for the Signal Distributor
6	System cable	10 m	Yes	Used for the connection of the Surgeon Console, the Patient Cart, the Camera Control Unit or the Signal Distributor
7	System cable	30 m	Yes	Used for the connection of the Surgeon Console, the Patient Cart, the Camera Control Unit or the Signal Distributor

No.	Cable Name	Cable Length	Shield	Note
8	System cable	1 m	Yes	Used for the connection of the Surgeon Console, the Patient Cart, the Camera Control Unit or the Signal Distributor
9	Energy activation cable	1 m	No	Used for the connection of the high frequency generator and the Camera Control Unit or the Signal Distributor
10	Monopolar energy instrument cord	4 m	No	Used for the connection of the monopolar instruments and the high frequency generator
11	Bipolar energy instrument cord	5 m	No	Used for the connection of the bipolar instruments and the high frequency generator
12	Camera cable	1 m	Yes	Used for the connection of the Camera Control Unit and the monitor
13	Camera cable	2 m	Yes	Used for the connection of the Camera Control Unit and the monitor
14	Camera cable	10 m	Yes	Used for the connection of the Surgeon Console and the Camera Control Unit
15	Camera cable	30 m	Yes	Used for the connection of the Surgeon Console and the Camera Control Unit
16	Energy activation cable	1.5 m	Yes	Used for the connection of the ultrasonic generator and the Signal Distributor

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

Guidance and manufacturer’s declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions	Class A

Guidance and manufacturer's declaration - electromagnetic emissions	
CISPR 11	
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 50Hz/60Hz	30 A/m 50Hz/60Hz
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	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5 100 – 5 800	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				
Radiated RF IEC61000-4-39	**Test Frequency**	**Modulation**	**IEC 60601-1-2 Test Level** (A/m)	**Compliance level** (A/m)

Guidance and manufacturer’s declaration - electromagnetic Immunity				
(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 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.
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 cannulas to the Patient Cart at the start of a surgery.
EPO	Emergency Power Off. A button is used to power off the Patient Cart.
Fluor	Fluorescence Settings.
HD	High Definition.
HF	High Frequency.
ICG	Indocyanine Green. A cyanine dye is used for near-infrared imaging in medical diagnostics
LED	Light Emitting Diode. A light-emitting diode is a semiconductor device that emits light when current flows through it.
ME	Medical Electrical Equipment.
MS	Master-Slave
MV	Master-Video

Term	Meaning
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 endoscopes 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.
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.

Shenzhen Edge Medical Co., Ltd.
Manufacturer Address: 2B 1901, Phase II, Smart Home, No.76, Baohe Avenue, Baolong Community, Baolong Street, Longgang District, 518116, Shenzhen, P.R.China
Manufacturer Site Address: 2B 0401, 1901, 2001, 2101, Phase II, Smart Home, No.76, Baohe Avenue, Baolong Community, Baolong Street, Longgang District, 518116, Shenzhen, P.R.China
E-Mail: contact@edgemed.cn
Web: www.edgemedicalrobotics.com

EC REP
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
E-Mail: shholding@hotmail.com

CE 0123

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