edge

MP1000

Endoscopic Instrument Control System

User Manual

www.edgemedicalrobotics.com

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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.

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Prescription Information

Rx Only

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

About This Manual

Thank you for choosing MP1000 Endoscopic Instrument Control System (hereinafter referred to as “MP1000 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

This manual provides instructions for MP1000 Endoscopic Instrument Control System.

Note: Do follow all instructions provided with the applicable user manuals for MP1000 System, instruments and accessories not included in this manual.

Note: Reusable instruments, endoscopes and accessories are shipped non-sterile and should be cleaned and sterilized thoroughly before first use and after every use. Refer to Reprocessing Instruction Manuals for detailed instructions.

1.1 System Components

The system consists of one or two Surgeon Consoles, a Patient Cart, a Signal Distributor, a Vision Cart, instruments and accessories.

See Appendix C List of System Components for more information.

1.2 Intended Use

The Endoscopic Instrument Control System (Model MP1000) is intend to assist in the accurate control of surgical endoscopic instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps, needle drivers, endoscopic retractors, electrocautery and accessories for endoscopic manipulation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories. It 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.

1.3 Training

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

1.4 Safety Information

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

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

1.4.1 Contraindications

The contraindications for the system are the same as those for conventional endoscopic surgery, including severe coagulation abnormalities, morbid obesity and pregnancy.

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



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

- When 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 a light source 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 opened or damaged.

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

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

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

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

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

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

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

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

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

Warning: Failure to establish and maintain proper pneumoperitoneum in abdominal

surgery may reduce available space and injure tissue inside or outside the field of view.

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

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

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

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

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

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

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

Caution: Do not suspend or place any objects over the instrument 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.

Note: Do follow all instructions for use supplied with the system, its components, instruments and accessories, including User Manuals and Reprocessing Instruction Manuals.

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

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

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

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

Note: The remote center is the pivot point around which the system moves the 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 extracorporal operation.

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

1.4.3 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 light source 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, which still allows optimal illumination of the operating field.
- Avoid resting the endoscope or the Light guide bundles 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: When the endoscope is connected to the Endoscope Illuminator and emitting light, the high-intensity light may cause eye discomfort or even injury. Do not look or stare at the lens of the endoscope or the light output surface of the Light guide bundles to avoid eye burns.



Warning: To avoid burns or fires, always turn off the Endoscope Illuminator whenever the Light guide bundles is removed, the endoscope is replaced or the endoscope is not in use.



Warning: Do not contact the lens of the endoscope or light output surfaces of the Light guide bundles 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: Use of third-party components in conjunction with the endoscope presents risk of exposure to laser energy that could result in injury to operator or patient, and could cause improper functioning of the system.



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: The Endoscope Illuminator is a class 3R laser product which may emit invisible laser radiation. Failure to follow the instructions, cautions and warnings related to the product may result in hazardous laser radiation exposure that can cause severe eye injury to the operator or the patient.



Warning: When unplugging the Light guide bundles away from the Endoscope Illuminator after use, do not touch the connector of the Light guide bundles. Otherwise, burns to skin could result.



Caution: Using fluorescence imaging depends on illumination provided by Shenzhen Edge Medical Co., Ltd. Any unauthorized third-party light sources may lead to poor imaging quality.



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.



Caution: When connecting the Light guide bundles, do not turn on the Endoscope

Illuminator, and ensure that there is no debris on the cable connectors and the light output surfaces. Avoid equipment damage or burns.

Caution: When connecting the Light guide bundles to the endoscope, tighten the knurled screw of the cable connector to prevent it from coming off.

Caution: When removing the Light guide bundles, hold the plastic part of the cable connector and pull the cable from the Endoscope Illuminator after cooling. Do not touch the metal part of the cable connector to avoid burns.

Caution: To avoid burns, do not insert or remove the Light guide bundles before disconnecting the power supply.

Caution: The personnel operating or repairing the product, looking or observing it for a long time should wear laser protective spectacles to protect their eyes. Recommend to choose protective spectacles which are reflective, at protective laser wavelength of 808nm, at protective laser power of 2.4W and at the optical density no less than 4.

1.4.4 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 HF electrosurgical procedures, comply with the following requirements:

- Avoid accidental excitation of electrosurgical instruments.
- Ensure the monopolar instruments should be equipped with the neutral electrode. Please configure a suitable neutral electrode and use it correctly according to the manufacturer’s instructions for safety.
- Attach the entire neutral electrode stably to the patient, locate it in the operative field as closely as possible and connect it correctly to HF generator.

- For electrosurgery where HF current may flow through small cross-sectional areas of the body, use bipolar techniques whenever possible to prevent unintended tissue injury.
- Set the minimum output value required to meet the surgical requirements within the shortest time.
- When an output reduction or interruption occurs to HF surgical equipment that runs properly under normal settings, it indicates the neutral electrode in wrong application or poor contact. Check the application and contact of the neutral electrode before selecting higher output power.
- Do not use one instrument to energize the tips of other instruments. This may damage the instruments or injure tissue inside or outside the field of view. Tissue damage could occur at points near the tip or at the port site (cannula) of the energized instrument.
- Secure and route the energy instrument cords to the system to prevent damage and unintended disconnection.
- Avoid the surgical energy cords contact with the patient or other leads. Put the surgical energy cords that are not in use in a place that is isolated from the patient.
- Prevent the patient from coming into contact with grounded metal parts.
- Prevent skin-to-skin contact. For example, wrap the skin contact between the patient’s arm and body with dry gauze.
- When HF surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended. In all cases, monitoring systems incorporating HF current limiting devices are recommended.
- Do not use flammable anesthetics or oxidizing gases such as nitrous oxide and oxygen.
- Do not contact with flammable materials, such as gauze and cotton fabrics, flammable reagents and anesthetics.
- Do not use flammable agents for cleaning 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 HF surgical equipment is used. Attention should be called to the danger of ignition of endogenous gases.



Warning: The rated voltage of the monopolar instruments (monopolar scissors and monopolar electric hooks) and monopolar energy instrument cord should be 3 kV (electric cutting), use the HF 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 HF 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: Maximum HF output voltage must not exceed the rated accessory voltage.



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



Warning: Unless stated, do no use instruments on cartilage, bone or hard objects. Otherwise, the instrument may be damaged and cannot be removed from the cannula.



Warning: Do not grasp tissue with instruments such as needle drivers not intended to grasp tissue, as tissue injury may result.



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



Warning: For HF instrument and associated equipment, requirements for separation between HF patient circuits and the enclosure including signal input/output parts, between HF patient circuits and the intermediate circuit and

between different HF patient circuits are specified by the ME EQUIPMENT standards IEC 60601-1.



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



Warning: A thorough understanding of the principles and techniques involved in 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: Verify the compatibility of the ultrasonic scalpel and generator. The ultrasonic scalpel is compatible with HocerMed Generator (model USG10plus). Please refer to the manufacturer's user manual for operating instructions.



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: The entire exposed blade tip and any exposed blade shaft are active and will cut/coagulate tissue when the instrument blade is activated. Be careful to avoid inadvertent contact between all exposed blade surfaces and surrounding tissue when using the instrument.



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: Blood and tissue buildup between the blade and clamp arm may result in abnormally high temperatures at the distal end of the instrument. For optimum performance and to prevent burn injury, remove any visible tissue buildup at the distal end.



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.



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



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



Caution: 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: Care should be taken not to apply pressure between the blade and clamp arm without having tissue between them. This can result in possible damage to the instrument.



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: Avoid contact with the instrument intraoperatively with liquids getting into the instrument and causing 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.

1.4.5 Electrical Safety

Warning: The system is the type BF applied part. Do not apply it to cardiac surgical procedures. Otherwise, it may cause irreversible injury to the patient.

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

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



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



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



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



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



Warning: Check tip 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.

1.4.6 Installation and Maintenance Precautions

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

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.

1.4.7 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.

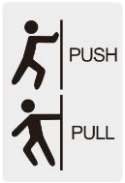
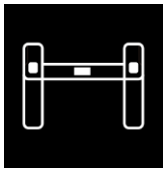
Caution: Handle the instruments and endoscope with care. Avoid mechanical shock or stress that can cause damage to the instruments and endoscope.

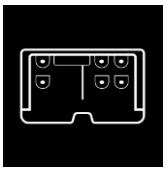
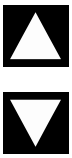
Caution: Do not place endoscope cables or accessory cables over the arms of the Patient Cart. The cables may limit the range of motion of the arms, or become pinched or damaged.

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.

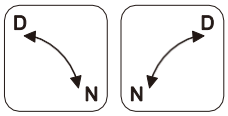
1.5 Symbol Reference Tables

1.5.1 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

Symbol	Meaning	Symbol	Meaning
	Adjust the footswitch panel depth		Adjust up or down
	Protective earth (ground)	/	/

1.5.2 Patient Cart

Symbol	Meaning	Symbol	Meaning
	“ON” (power)		“OFF” (power)
	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		Standby
	Emergency stop		MS (Master-Slave) communication port
	Type BF applied part		Protective earth (ground)
EPO	Emergency power off	UPS	Uninterruptible Power Supply

1.5.3 Camera Control Unit

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

1.5.4 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

Symbol	Meaning	Symbol	Meaning
	Standby		Energy control port

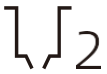
1.5.5 Endoscope Illuminator

Symbol	Meaning	Symbol	Meaning
	“ON” (power)		“OFF” (power)
	Alternating current		Fuse
	Type BF applied part		Warning: Laser beam
	Increase intensity		Decrease intensity
	White light mode		Fluorescence mode
	Standby	/	/

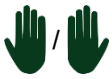
1.5.6 Fluorescence Endoscopes

Symbol	Meaning	Symbol	Meaning
	View direction: 0 degree		View direction: 30 degrees
	30 degrees up arrow		30 degrees down arrow
	Hash mark		Take photo
	Illumination		Left-Right eye swap
	Type BF applied part	IPX7	Protection against the effects of temporary submersion in water

1.5.7 Instruments

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

1.5.8 Accessories

Symbol	Meaning	Symbol	Meaning
	Diameter size indicator of 8 mm		Diameter size indicator of 12 mm
	Diameter size indicator of 15 mm		For endoscopes
	Direction indicator for alignment		Direction indicator for rotation
8-5	Diameter size indicator of 8 mm-5 mm reducer	12-8	Diameter size indicator of 12 mm-8 mm reducer
15-8	Diameter size indicator of 15 mm-8 mm reducer	A/B	Diameter size indicator of gage pin
	Hand symbol		Tear-away tab
	Direction tab	/	/

1.5.9 Package Labeling and Other Symbols

Symbol	Meaning	Symbol	Meaning
	This side up		Fragile, handle with care

Symbol	Meaning	Symbol	Meaning
	Keep dry		Keep away from sunlight
	Stacking limit by mass		Temperature limits
	Humidity limitation		Atmospheric pressure limitation
	Medical Device		Authorized Representative in the European Community
	Manufacturer		Date of manufacture
	Dispose of in accordance with local regulations—particularly applies to electronic components		Use-by date
	Do not use if package is damaged and consult instructions for use		Do not re-use
	Do not re-sterilize		Operating instructions
	Sterilized using ethylene oxide		Caution (consult instructions for use)
	Serial number		Lot number

1.5.10 Laser Safety Labeling

Patient Cart

The Patient Cart has laser indicator, which is classified into Class 1 laser products. The Patient Cart has been evaluated IEC 60825-1 ED. 3 (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

Endoscope Illuminator

The Endoscope Illuminator used with the endoscope can produce laser energy, and it has been evaluated IEC 60825-1 ED. 3 (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 Endoscope Illuminator is labeled with a laser warning label near the Light guide bundles port on the front panel, including the warning symbol and the label text.



Figure 1.2 Laser Warning Label

Fluorescence Endoscopes

The laser aperture label labeled on the housing of the fluorescence endoscope points in the direction that laser light is emitted.



Figure 1.3 Laser Aperture Label

1.6 Service Life

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

See Appendix C List of System Components for more information.

1.7 Date of Manufacture

See product label for date of manufacture.

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, and a Vision Cart and is used with a fluorescence endoscope, instruments and accessories. Setup and intraoperative use may require sterile and non-sterile tasks performed by the following users: surgeon, circulating nurse (non-sterile user) or scrub nurse (sterile user).



Figure 2.1 Main Components of the System

2.2 Surgeon Console

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

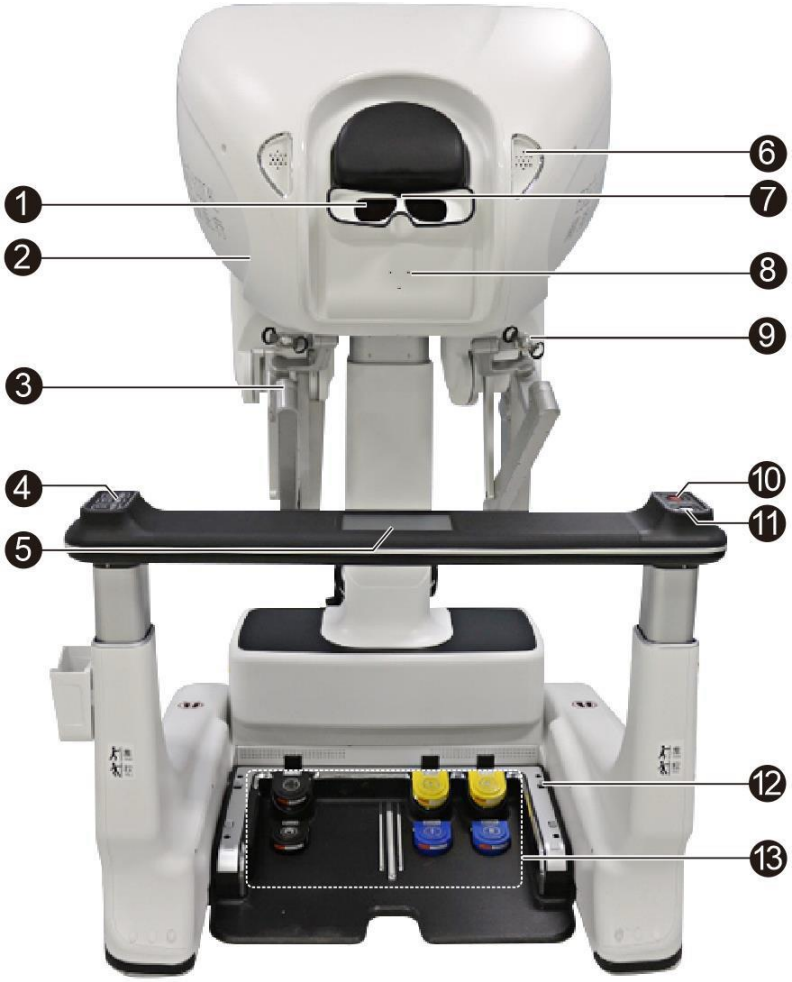
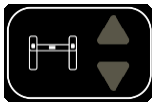
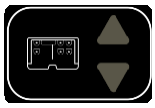


Figure 2.2 Surgeon Console

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

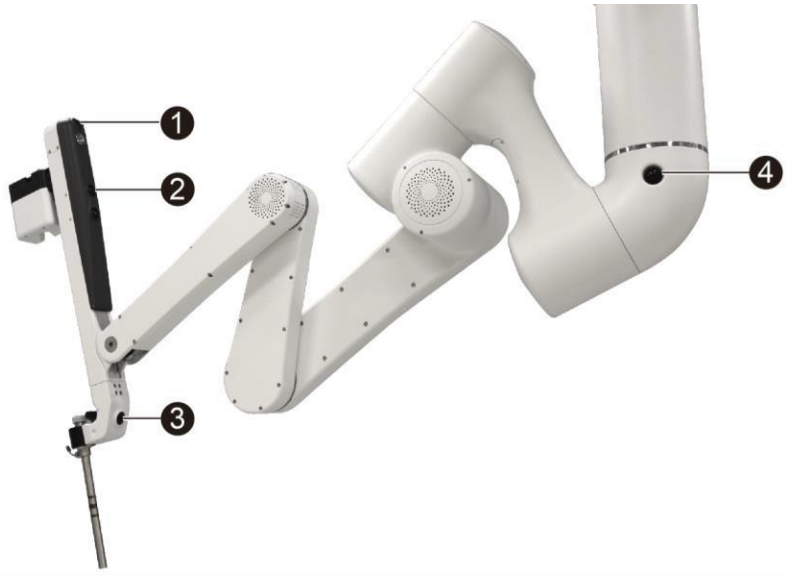


Figure 2.6 Arm controls

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 fluorescence endoscope. 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.
- The fluorescence endoscope provides high resolution 3D HD (high definition) lens, which can magnify the surgical field and display 3D stereo HD images inside the patient's body. It is intended for real-time endoscopic visible and near-infrared fluorescence imaging. The endoscope is available with either a 0° endoscope or 30° tip.

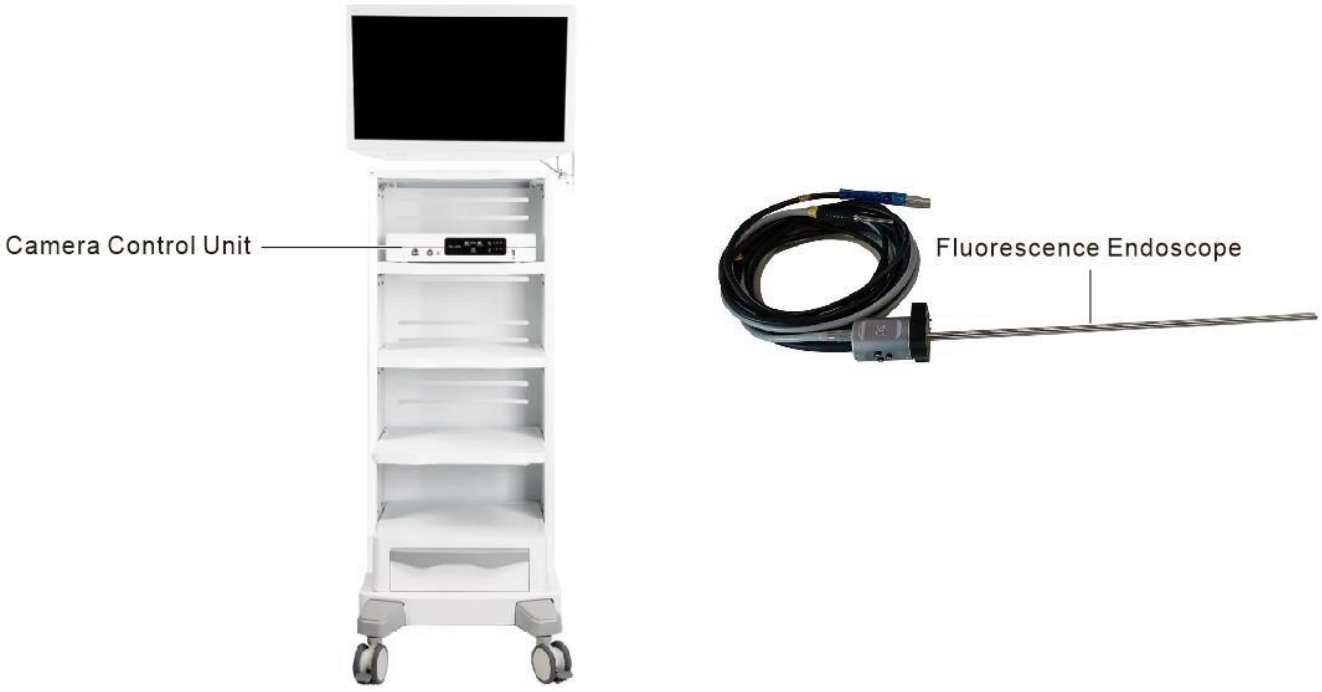


Figure 2.7 Vision Cart

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 Signal Distributor

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

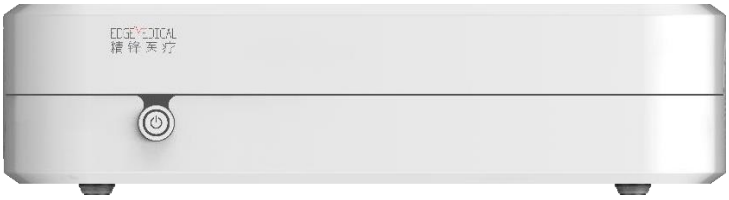


Figure 2.8 Signal Distributor

2.6 Instruments

The instruments include Maryland bipolar forceps, bipolar forceps, enhanced bipolar forceps, needle driver, large needle driver, monopolar scissors, monopolar hook, enhanced forceps, Cadiere forceps, tip-up fenestrated grasper and disposable ultrasonic scalpel.

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 following intended use statements apply to the instruments.

- Maryland bipolar forceps: Used for endoscopic manipulation of blunt dissection, grasping and retraction, coagulation, and manipulating needles and tying suture.
- Bipolar forceps/Enhanced bipolar forceps: Used for endoscopic manipulation of grasping, coagulation, and manipulating needles and tying suture.
- Needle driver: Used for handling and driving needles and handling and tying suture.
- Large needle driver: Used with large needles for handling and manipulating large needles and handling and tying suture.
- Monopolar scissors: Used for endoscopic manipulation of cutting, sharp dissection and coagulation.
- Monopolar hook: Used for endoscopic manipulation of blunt dissection, cutting and coagulation.
- Enhanced forceps: Used for endoscopic manipulation of grasping, manipulating, and retracting tissue.
- Cadiere forceps: Used for endoscopic manipulation of dissecting, grasping, manipulating, and retracting tissue.

- Tip-up fenestrated grasper: Used for grasping, retraction and manipulation of soft tissue.
- Disposable ultrasonic scalpel: Used for soft tissue dissection when bleeding control and minimal thermal injury are required, and ligation of vessels no more than 3mm in diameter.



Figure 2.9 Instruments

2.7 Accessories

The accessories for MP1000 System include reducers, cannulas, obturators, cannula seals, tip cover accessory, installation tool, monopolar energy instrument cord, bipolar energy instrument cord, system cables, camera cables and energy activation cables.

2.7.1 Reducers

A reducer is a sterile, disposable, hollow cylinder with integrated seal. Before inserting a reducer through the cannula, remove the obturator. An instrument cannot be used until a reducer attaches to the cannula.

- Reducer (model TR4-A8/5) is inserted into the 8 mm cannula to make the cannula compatible with 5 mm instruments.
- Reducer (model TR4-A12/8) is inserted into the 12 mm cannula to make the cannula compatible with 8 mm instruments.
- Reducer (model TR4-A15/8) is inserted into the 15 mm cannula to make the cannula compatible with 8 mm instruments.

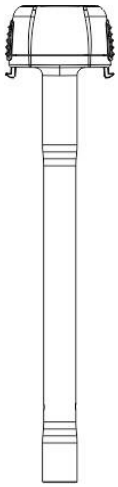


Figure 2.10 Reducer

2.7.2 Cannulas, Obturators and Cannula Seals

The cannulas, obturators and cannula seals are intended to be used to establish a port of entry for instruments and endoscopes. The obturator attaches to the cannula seal, which attaches to the cannula and facilitates the cannula into the body cavity. The cannulas are available in different lengths and diameters, the obturators have various tip configurations for different mechanisms by which to enter the body cavity.

- A cannula is a tube with a lumen which provides a single port of entry into the body cavity for an instrument or an endoscope.

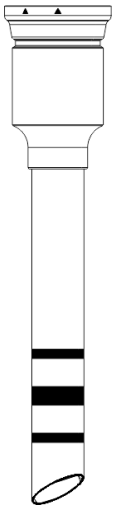
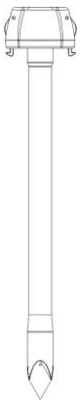


Figure 2.11 Cannula

- An obturator is a cylinder used when inserting the cannula into the patient to avoid coring or tearing of the body wall upon insertion. It should be removed before inserting an instrument or an endoscope through the cannula.

Obturator	Figure	Obturator	Figure
TR2-A8EB, Blunt Obturator TR2-A8EB-L, Long Blunt Obturator		TR2-A8EP, Prismatic Obturator TR2-A8EP-L, Long Prismatic Obturator	
TR2-A8IB, Blunt Obturator TR2-A8IB-L, Long Blunt Obturator		TR2-A8IP, Prismatic Obturator TR2-A8IP-L, Long Prismatic Obturator	
TR2-A12B, Blunt Obturator TR2-A12B-L, Long Blunt Obturator		TR2-A12P, Prismatic Obturator TR2-A12P-L, Long Prismatic Obturator	
TR2-A15B, Blunt Obturator TR2-A15B-L, Long Blunt Obturator		TR2-A15P, Prismatic Obturator TR2-A15P-L, Long Prismatic Obturator	

- A cannula seal is a sterile disposable cap for a cannula. It is used to maintain insufflation before inserting an instrument or an endoscope or during endoscopic surgery.

The cannula seal consists of an insufflation lever and an insufflation port to provide an outlet for insufflation or smoke evacuation. When the lever is straight and in line with the port, the lever is in open position. When the lever is perpendicular with the port, the lever is in closed position.

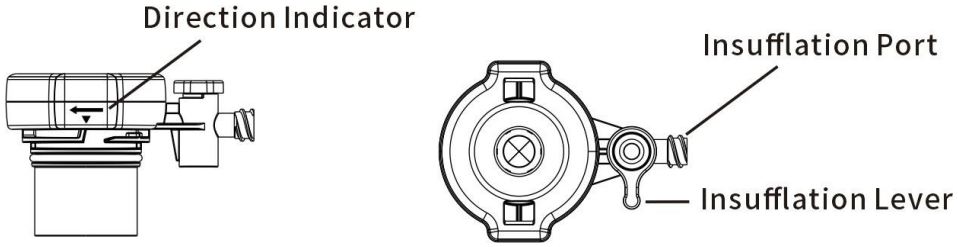


Figure 2.12 Open and Closed Insufflation Port

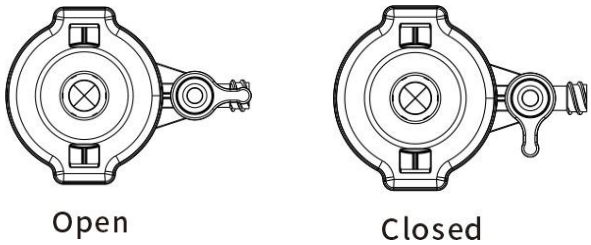


Figure 2.13 Open and Closed Insufflation Port

2.7.3 Tip Cover Accessory and Installation Tool

- The tip cover accessory is used 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 accessory must be always used in conjunction with compatible monopolar scissors (model MP1311).

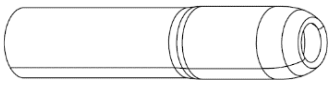


Figure 2.14 Tip Cover Accessory

- The installation tool is used to facilitate installation and removal of the tip cover accessory.

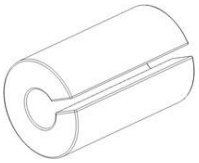


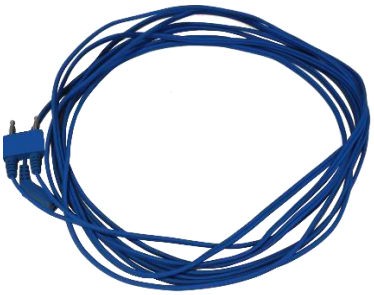
Figure 2.15 Installation Tool

2.7.4 Cables

- The monopolar energy instrument cord and bipolar energy instrument cord are used to connect the corresponding surgical instrument and the high frequency generator.



Monopolar Energy Instrument Cord (Model MS1801)



Bipolar Energy Instrument Cord (Model MS1802)

Figure 2.16 Energy Instrument Cords

- The system cables are used to connect the Patient Cart, Surgeon Console, Camera Control Unit or Signal Distributor for system communication, including 1 m, 10 m and 30 m in length.



Figure 2.17 System Cable

- The camera cables (model CM1806 and CM1820) are used to connect the Camera Control Unit and monitor. The camera cables (model CM1821 and CM1805) are used to connect the Camera Control Unit and Surgeon Console.



Figure 2.18 Camera Cable

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

Distributor. The energy activation cable (CM1835) is used to connect the ultrasonic generator and the Signal Distributor.



Energy Activation Cable (Model CM1807) Energy Activation Cable (ModelCM1835)

Figure 2.19 Energy Activation Cables

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



Figure 2.20 Illuminator Control Cable

- The Light guide bundles is used to connect the Endoscope Illuminator and the endoscope to transmit light.



Figure 2.21 Light guide bundles

2.8 Endoscope Illuminator

The endoscope illuminator is used to illuminate surgical sites in endoscopic diagnostic and therapeutic procedures. When the Endoscope Illuminator is connected to AC power, it can generate light and transmit the light energy through the Light guide bundles to the endoscope.



Figure 2.22 Endoscope Illuminator

3. Operating Room Configuration and System Positioning

3.1 Operating Room Configuration

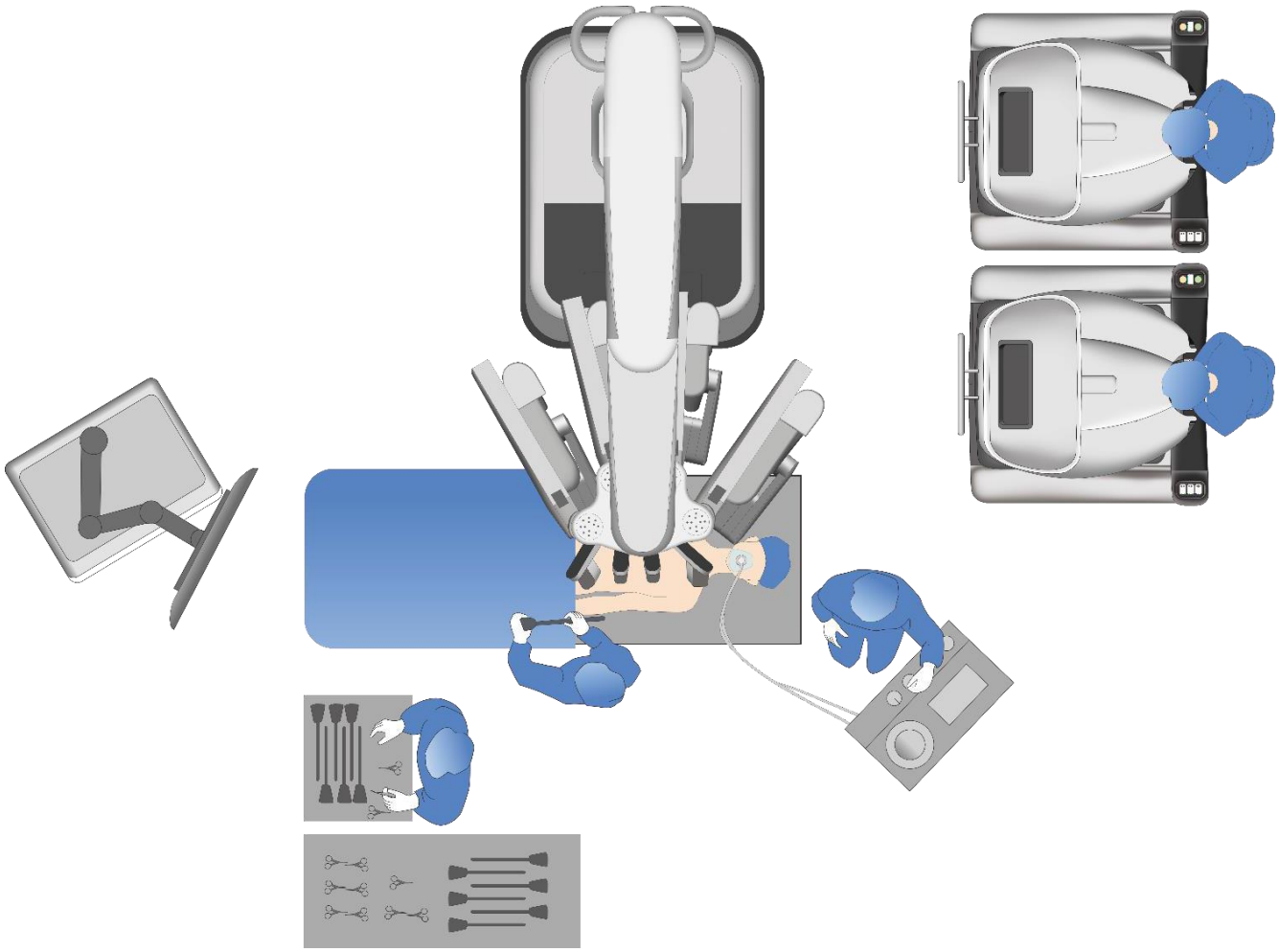


Figure 3.1Example of Operating Room Configuration

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.

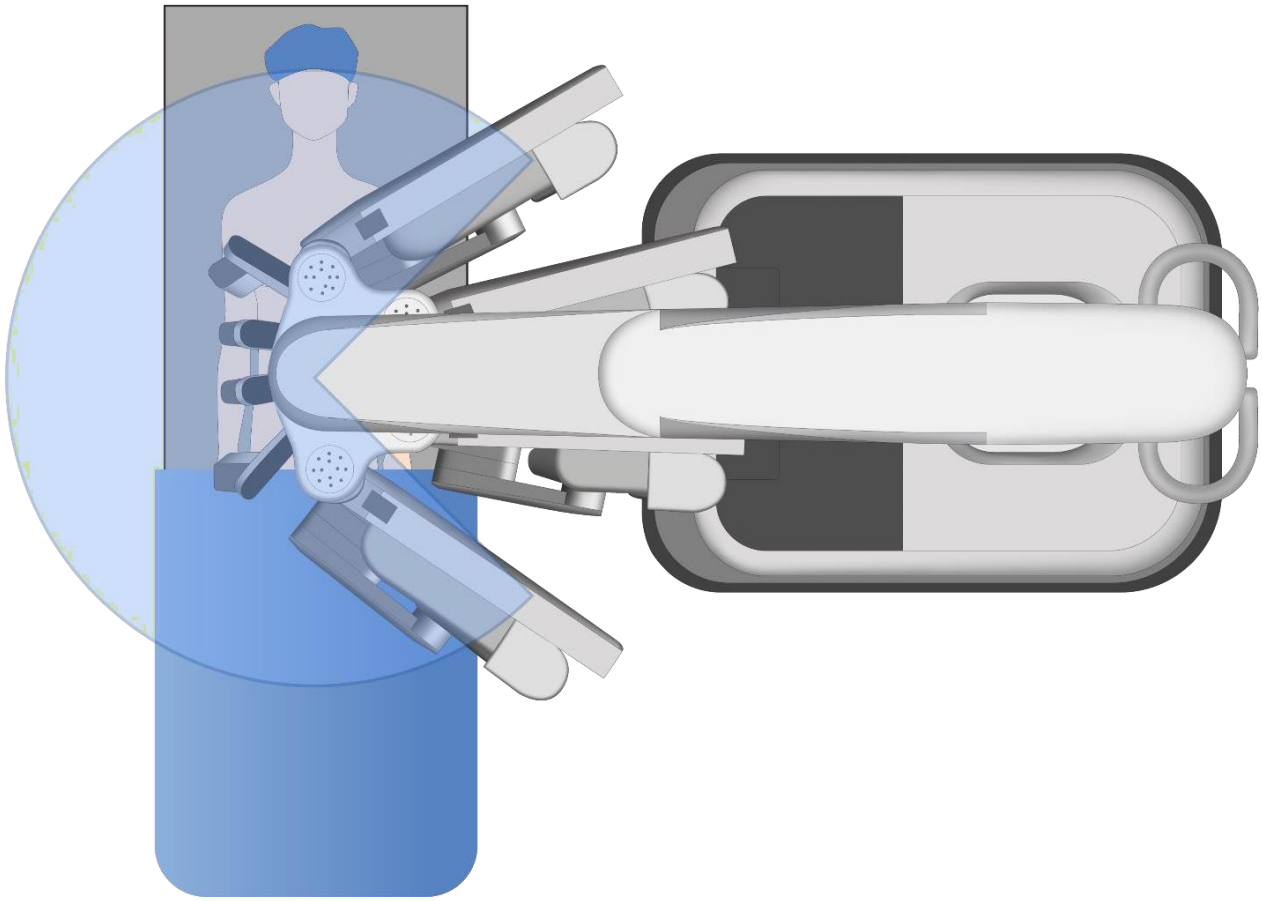


Figure 3.2 270° Patient Access

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

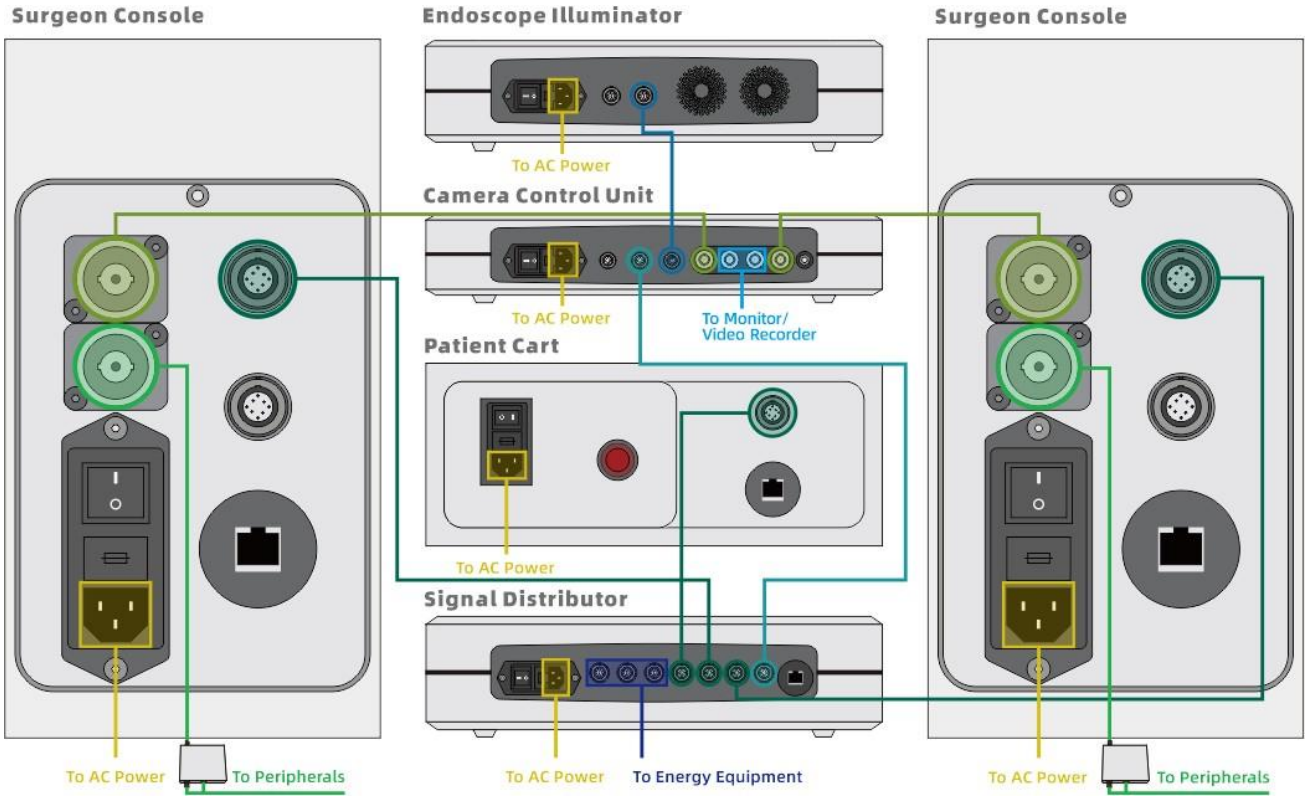


Figure 4.1 System Connections

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 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	Surgeon Console
Power Cord	5 m	1000 VA continuous	Patient Cart
Power Cord	1.8 m	100 VA continuous	Camera Control Unit
Power Cord	1.5 m	135 VA continuous	Monitor
Power Cord	1.8 m	100 VA continuous	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 backup battery 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 cable uses circular connectors and the camera cable uses BNC connectors.

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



Figure 4.2 System Cable

Note: Once the system is connected and powered on, the system cables should not

be removed before the system is completely powered down.

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

4.2.1 Cable Layout

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

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

4.2.2 Cable Connections

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

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

   Align the end of the BNC connector with the matching receptacle, insert the connector, and turn the connector clockwise until it rotates to the limit.
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 no 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 9.5.6 Energy Instrument Cords.

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 or Patient Cart to power on the system.



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

Note: The Camera Control Unit and the Signal Distributor can be started up independently by pressing the **Power** buttons.

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 13 System Troubleshooting.

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

5.2.2 Patient Cart

The power button LED indicator light of the Patient Cart illuminates solid white before the system is connected to AC power. Press the **Power** button to perform the startup sequence, and then the power button LED indicator light flashes white. After the startup sequence is completed, the power button LED indicator light illuminates solid green. After 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 13 System Troubleshooting.

5.3 Power Button LED Indicator

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

Table 5.1 Power Button LED Indicator

Indicator Status	Meaning
Off	Unpowered in any of the following situations:

Indicator Status	Meaning
	● 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. b. The backup battery runs out of battery 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 is connected to the Patient Cart and both of them are connected to AC power, the components are in standby (sleep) mode before startup. The components can be powered on by pressing the **Power** buttons.

Surgeon Console

Disconnect the system cable and then press the **Power** button on the Surgeon Console to power it on independently.

Patient Cart

Disconnect the system cable and then press the **Power** button on the Patient Cart to power it on independently.

5.5 Emergency Power OFF

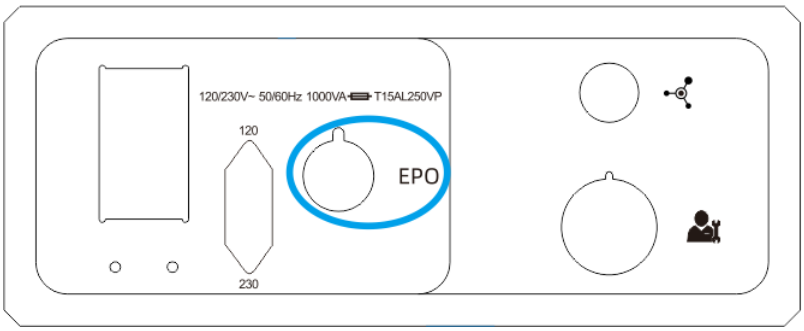


Figure 5.2 **EPO** Button

The **EPO** button is on the base back of the Patient Cart. Press this button to completely remove

power to the Patient Cart. Emergency power off is a non-recoverable fault. The system must be restarted. See 13.2.2 Non-Recoverable Faults.

5.6 Power Switches

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

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

The power switches of all components should be left in the ON position. Use these power switches in special circumstances only; such as those described in 13.6 System Power Problems.

5.7 Power Guidelines

- The backup battery 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 back up battery remains fully charged.
- To operate in dual console mode, the power operations of the second Surgeon Console is the same as the first Surgeon Console.

6. Draping

6.1 Draping Overview

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

6.2 Draping Supplies

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

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

- 4 arm drapes (model DR1001): Includes the sterile adaptor, metal discs, the cannula adaptor and the Velcro
- 1 column drape (model DR1003): Includes the metal discs and the Velcro

6.3 Draping Guidelines

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

6.4 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

6.5 Drape Installation

6.5.1 Draping Column

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

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

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

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

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



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.

6.5.2 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.

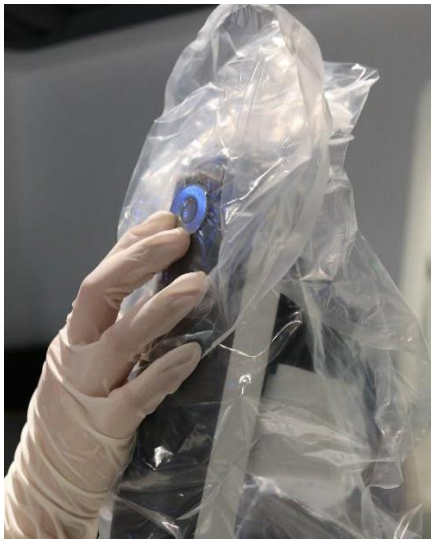


Figure 6.5 Attach the Metal Disc to the Instrument Arm

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.

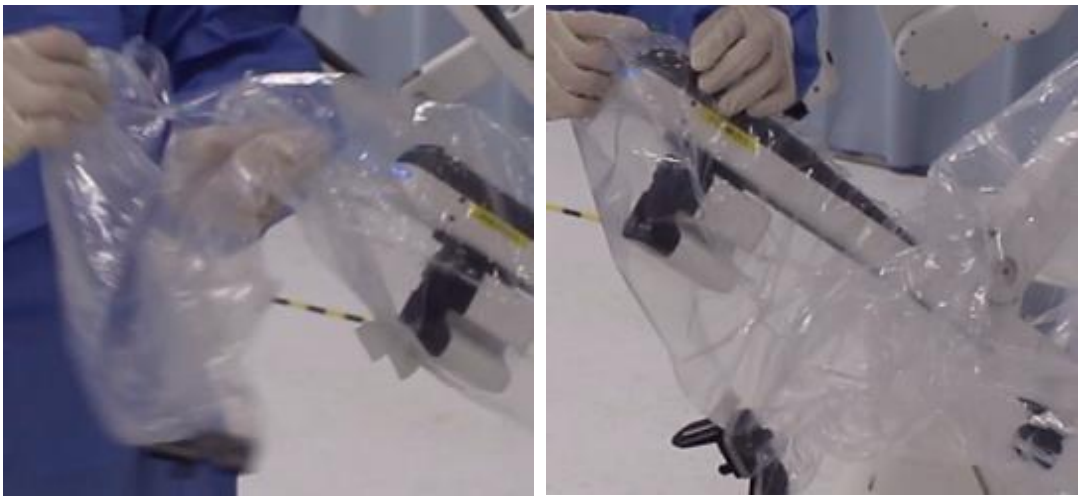


Figure 6.7 Drape the Front of the Instrument Arm

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.

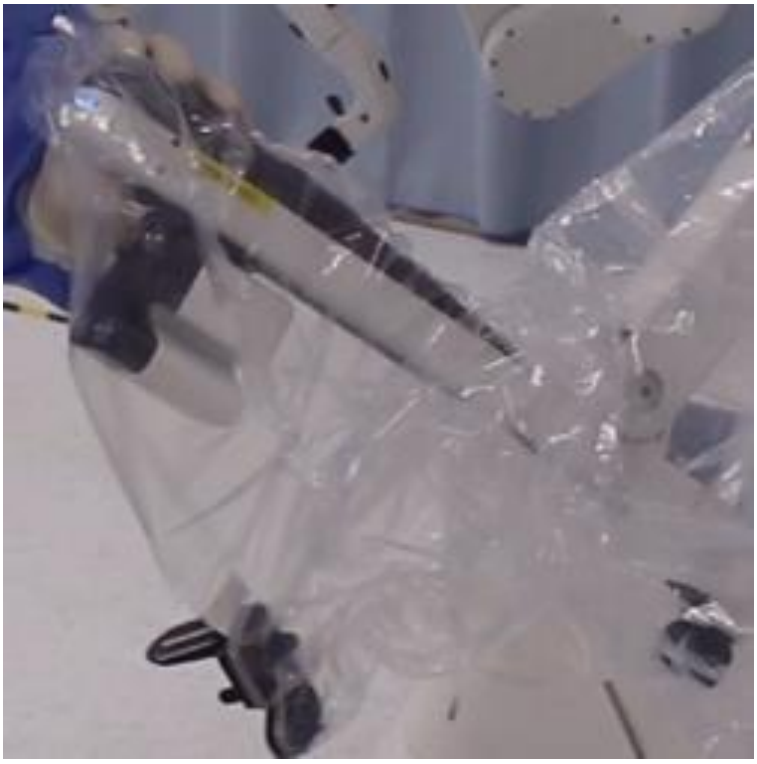


Figure 6.8 Adjust the Position of the Instrument Arm

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.

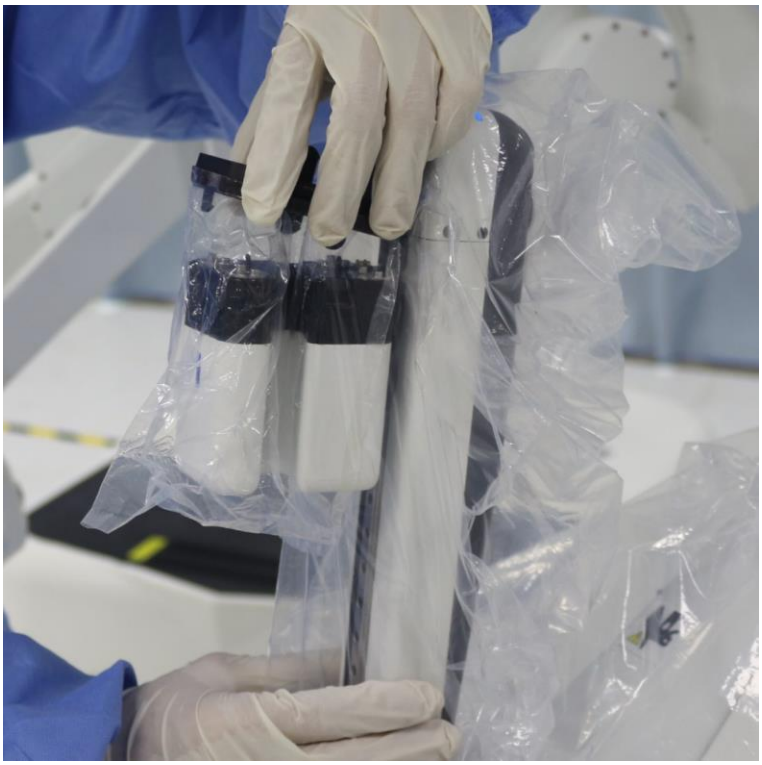


Figure 6.9 Attach the Adaptor to the Instrument Carriage

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.

6.5.3 Sterile Stowing the Draped Patient Cart (Optional)

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

of contamination.

Press and hold **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.

6.6 Drape Removal

The drapes are sterile products designed for single-use. After the procedure, the drapes should be removed and disposed. When removing the drapes, take care to completely remove all adaptors, metal discs and the Velcro.

6.6.1 Removing Column Drape

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

6.6.2 Removing Instrument Arm Drapes

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

7. Vision System Use

7.1 Vision System Overview

The vision system include the components as follows:

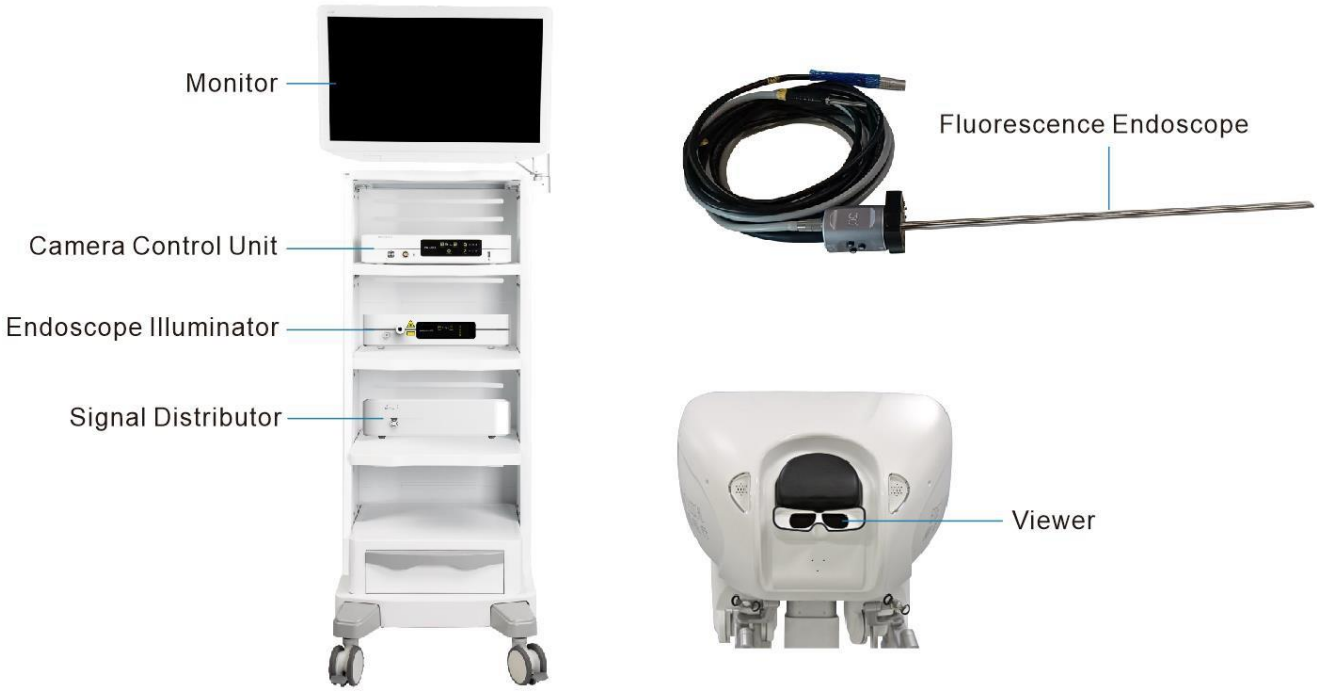


Figure 7.1 Vision System Components

The Vision Cart is mainly composed of the Camera Control Unit, fluorescence endoscope and monitor. The Camera Control Unit provides additional processing of endoscopic video and allows the recording of still images onto a USB flash drive. The endoscope provides high resolution 3D HD (high definition) lens, which can magnify the surgical field and display 3D stereo HD images inside the patient's body. For a complete description of the Vision Cart components, see 2.4 Vision Cart.

The monitor image duplicates the entire surgical image seen in the Surgeon Console viewer. The Surgeon Console viewer is a pair of high definition screens that provide the surgical video to the surgeon. For a general overview of the Surgeon Console, see 2.2 Surgeon Console.

The Signal Distributor contains the electronics for advanced processing of the video image. For a general overview of the Signal Distributor, see 2.5 Signal Distributor.

The Endoscope Illuminator contains a high-intensity light source to illuminate surgical sites in endoscopic diagnostic and therapeutic procedures. For a general overview of the Signal Distributor, see 2.8 Endoscope Illuminator.

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

7.2 Endoscope Overview

The endoscope acquires 3D video from the surgical field in high definition (HD). The HD video is processed by the Camera Control Unit and displayed on the Surgeon Console viewer and the monitor.

The following endoscopes are available for the system:

Part Name	Part Number	View Direction (Tolerance ±3°)	Visualization Mode
Fluorescence Endoscope	MP1212	0°	Visible light imaging and near-infrared imaging
Fluorescence Endoscope	MP1213	30°	Visible light imaging and near-infrared imaging

The 30° endoscope provides two tip orientations: up and down. When it is installed on an instrument arm, the tip orientations can be selected from the Surgeon Console touchscreen without removing the endoscope from the patient.

Both of two endoscopes are capable of visible light imaging and near-infrared imaging. For near-infrared imaging, the near-infrared light is used in conjunction with the imaging agent Indocyanine Green (ICG).

Note: For specific information of ICG, refer to the manufacturer's instructions.

Note: The imaging agent Indocyanine Green (ICG) is used for near-infrared imaging, in which the excited wavelength is 808nm±10nm, the emitted wavelength is 850nm±30nm and there is enough quantum yield to be detected by the fluorescence endoscope.

Note: Spilled blood or other body fluids containing ICG in the surgical field can maintain their fluorescence for the duration of the procedure.

Caution: The factors such as dosing of the imaging agent, timing of imaging agent administration, working distance, fluorescence mode, etc. are variables that affect image quality. Adjusting these factors can improve image quality. When planning

or providing alternative or additional interventions, it is necessary to combine with clinically relevant information.

7.3 Endoscope Components

The endoscope consists of the tip, shaft, base, housing, cable, connector, and connector cover. It is available with 0° (straight) or 30° (angled) tip, which is marked on the housing.

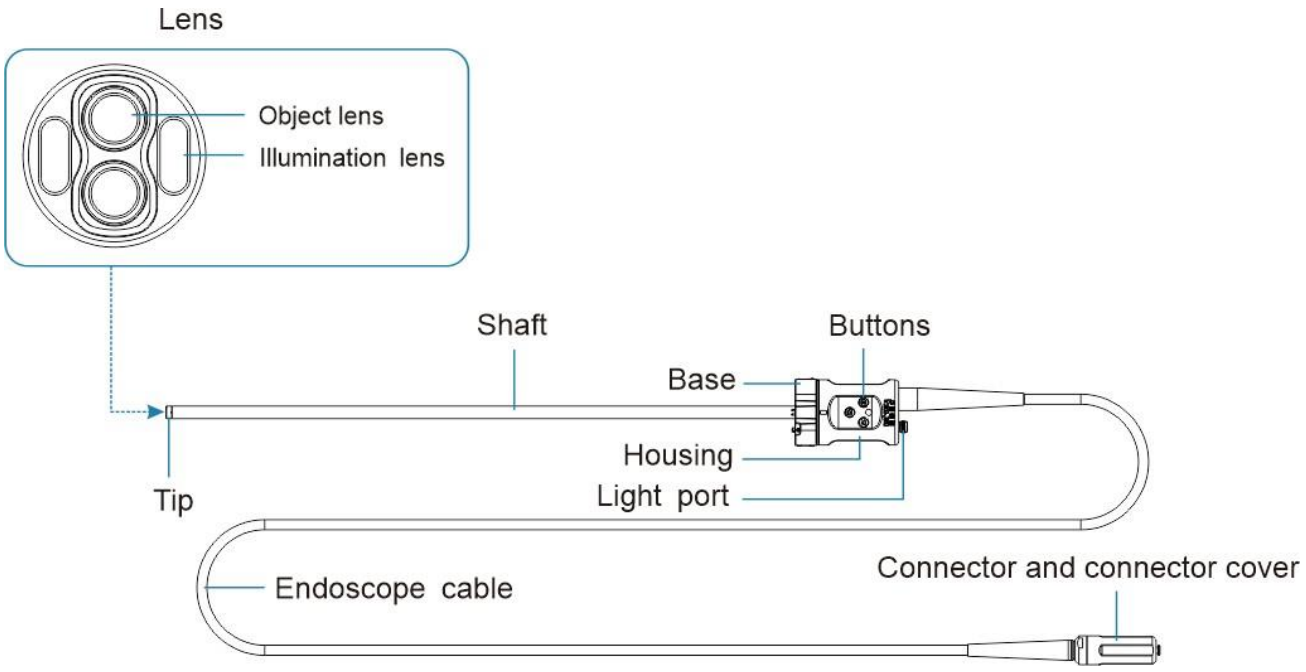


Figure 7.2 Endoscope Components (Model MP1212)

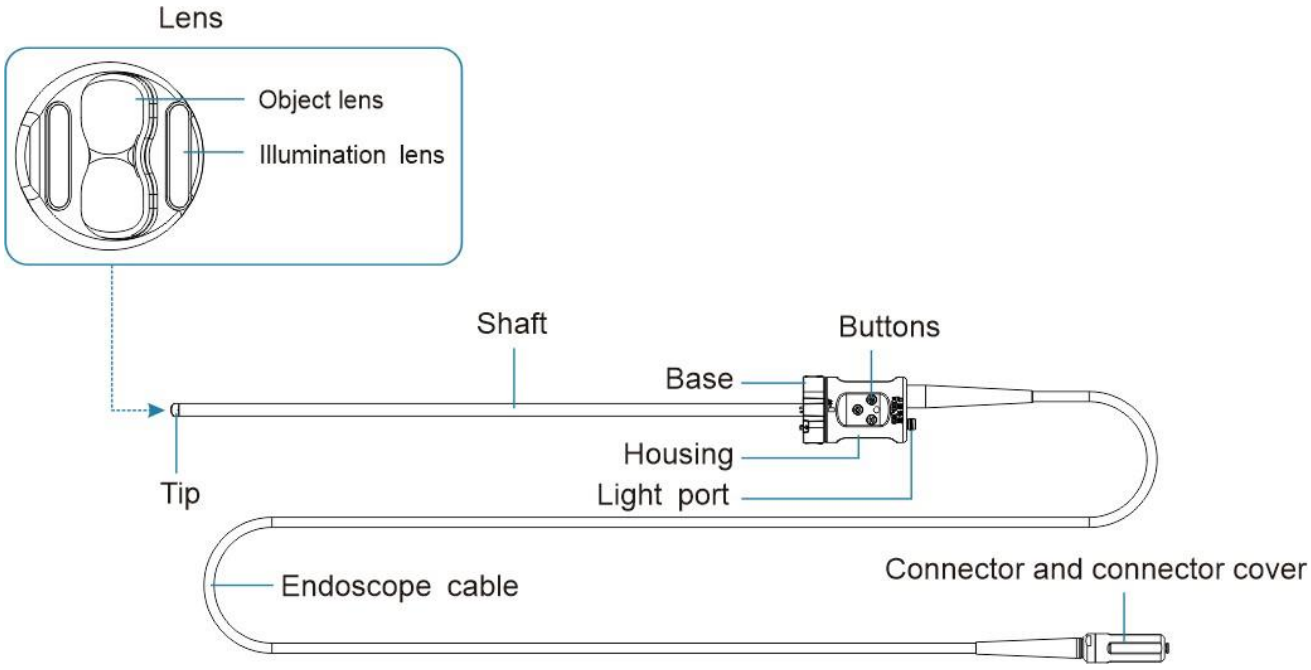


Figure 7.3 Endoscope Components (Model MP1213)

- Connector cover: Protect the connector during cleaning and sterilization, and avoid liquids contact with the connector to prevent endoscope damage. It must be removed before a procedure and reattached when endoscope not in use or before reprocessing.
- Endoscope cable: Connect the endoscope to the Camera Control Unit for signal transmission.
- Light port: Connect the Light guide bundles to the Endoscope Illuminator. After the endoscope is connected to the Endoscope Illuminator, the Endoscope Illuminator will provide light output through illumination lens of the endoscope.
- Base: There are two **Release** buttons on both sides of the base, pins and disc at the bottom of the base, and a hash mark on the base. For further information, see 7.3.1 Endoscope Base.
- Housing: There are three buttons, a LED indicator, and a hash mark on the housing. For further information, see 7.3.2 Endoscope Housing.
- Shaft: After inserted the shaft into the cannula, the endoscope is controlled from the Surgeon Console.
- Tip: Located at the distal end of the endoscope, including two object lens and two illumination lens.

7.3.1 Endoscope Base

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 disc at the bottom of the base, and a hash mark on the base.

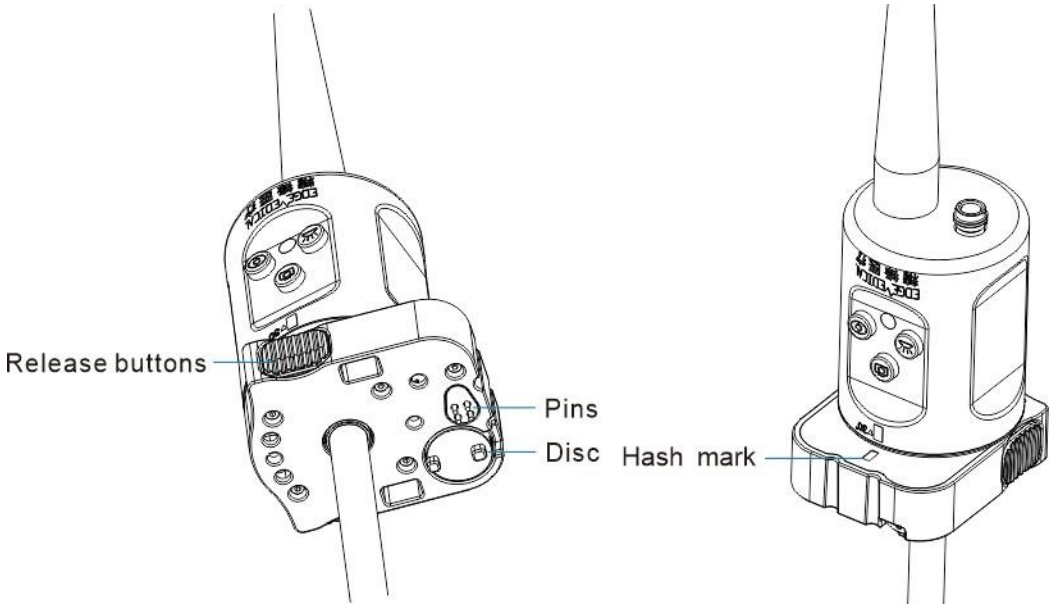


Figure 7.4 Endoscope Base

- **Release** buttons: Used to remove the endoscope from the instrument arm of the Patient Cart by squeezing both **Release** buttons on two sides of the base.
- Pins: Used to communicate with the Patient Cart and for endoscope identification.
- Discs: Used to translate the movements from the Surgeon Console master controls.
- Hash mark: Used to align with the endoscope orientation.

7.3.2 Endoscope Housing

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.

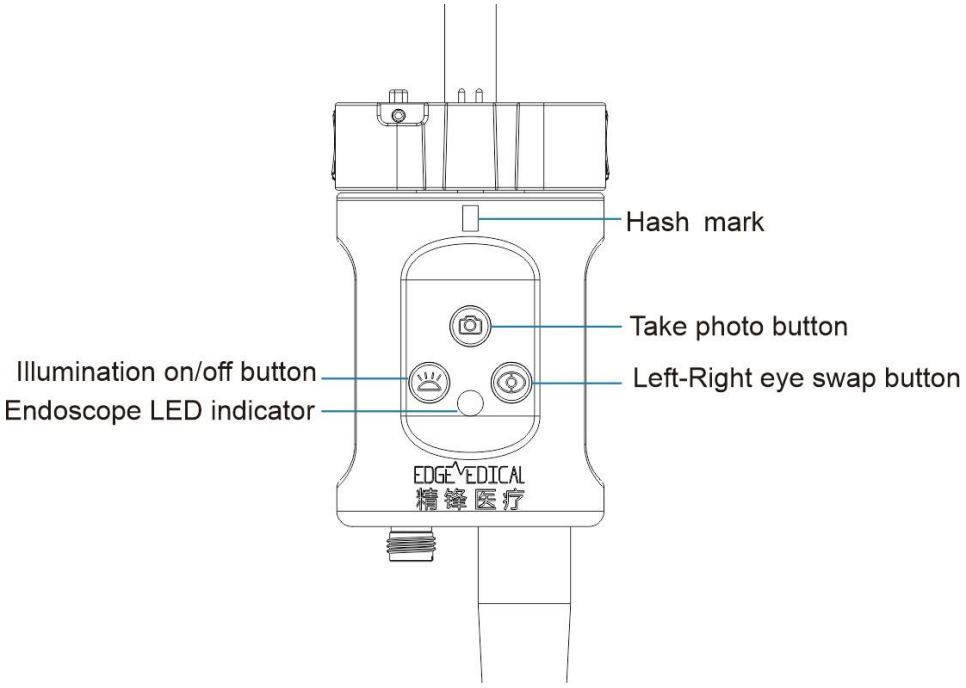


Figure 7.5 Endoscope Housing

7.3.3 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

7.3.4 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 or right endoscope image
	Take photo	Press to capture an image from the endoscope view
	Illumination on/off	Press to turn illumination on or off

7.3.5 Light Apertures

There are three light apertures (openings that emit laser light) in the vision system. The first aperture is on the Endoscope Illuminator. When the Light guide bundles is removed from the Endoscope Illuminator, the laser light will be off. The other apertures are located at the tip of the endoscope.

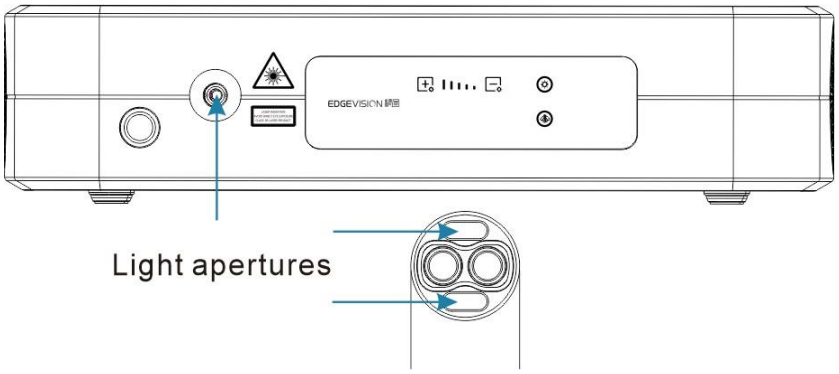


Figure 7.6 Light Apertures of Vision System

7.4 Camera Control Unit Overview

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 a light source and a fluorescence endoscope can provide visible light imaging and near-infrared imaging.

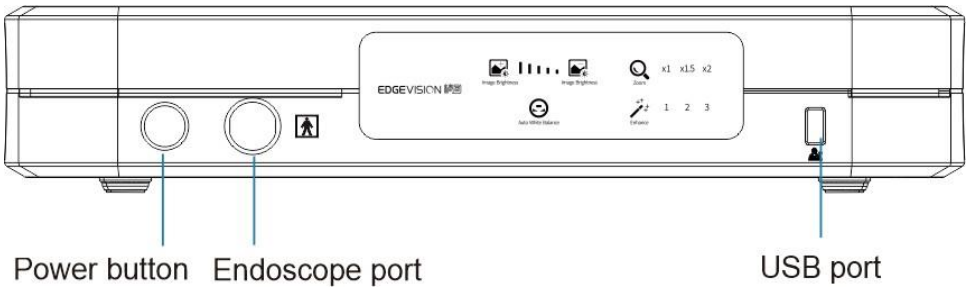


Figure 7.7 Front of Camera Control Unit

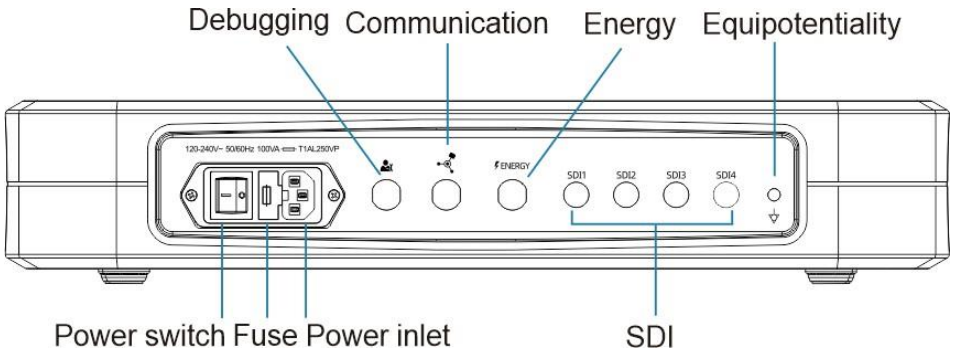


Figure 7.8 Rear of Camera Control Unit

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

7.5 Endoscope Illuminator Overview

The Endoscope Illuminator is used to illuminate surgical sites in endoscopic diagnostic and therapeutic procedures. When the Endoscope Illuminator is connected to AC power, it can generate light and transmit the light energy through the Light guide bundles to the endoscope.

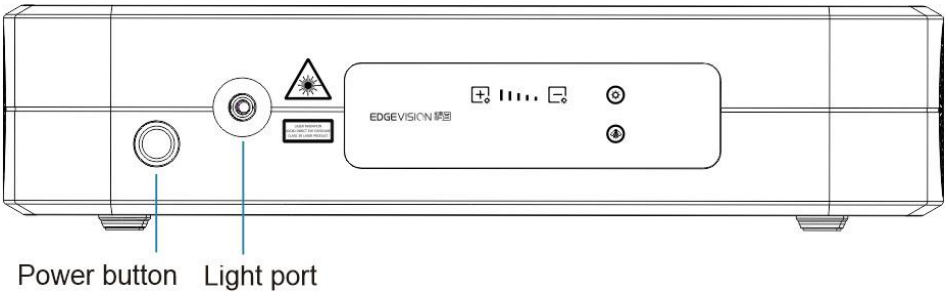


Figure 7.9 Front of Endoscope Illuminator

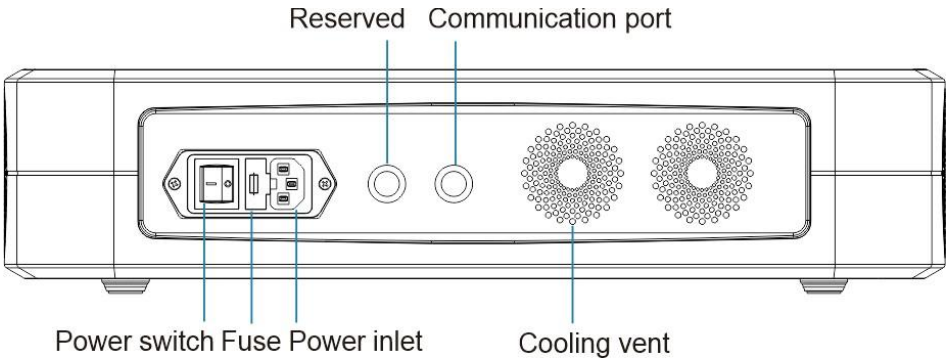


Figure 7.10 Rear of Endoscope Illuminator

The Endoscope Illuminator is equipped with function buttons as shown in following table.

Table 7.4 Endoscope Illuminator Buttons

Buttons		Description
	Increase Intensity	Press to increase light intensity
	Decrease Intensity	Press to decrease light intensity
	White Light Mode	Press to turn white light mode on or off
	Fluorescence Mode	Press to turn fluorescence mode on or off

7.6 Endoscope Use

7.6.1 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 Reprocessing Instruction Manual for detailed instructions.
- Reattach the connector cover to the connector when the endoscope cable is no in use or before reprocessing the endoscope. Failure to secure the connector cover during reprocessing may result in endoscope damage.

7.6.2 Inspection before Use



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

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

7.6.3 Device Connections

Connecting to the Camera Control Unit

The endoscope is connected to the Camera Control Unit through the endoscope cable. The image signals from the endoscope are processed and transmitted by the Camera Control Unit.

1. Remove the connector cover from the endoscope cable.

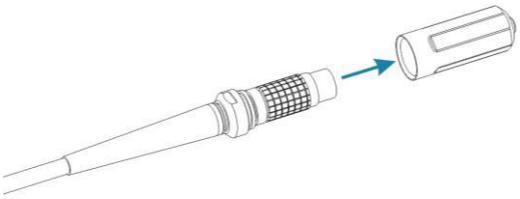


Figure 7.11 Remove the Connector Cover

Note: Reattach the connector cover to the connector when the endoscope cable is no 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.

2. Connect the endoscope cable with the red dot on the connector pointed upwards and ensure alignment with the receptacle on the Camera Control Unit. Gently pull on the connector to verify the cable is fully seated.

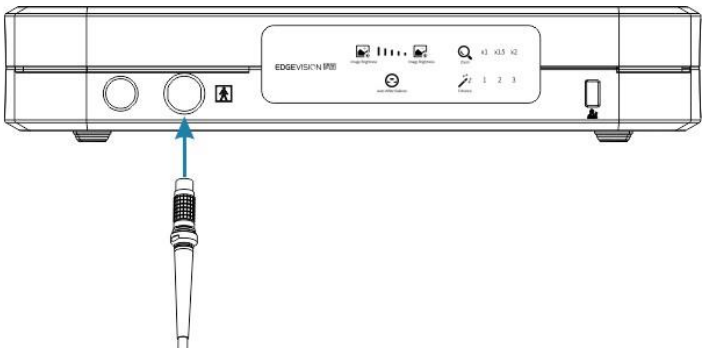


Figure 7.12 Connect to the Camera Control Unit

Connecting the Light guide bundles

The endoscope is connected to the Endoscope Illuminator through the Light guide bundles, which provides illumination for endoscopy and endoscopic surgery.

Warning: Power off the Endoscope Illuminator or deactivate the light output before connecting or removing the Light guide bundles or endoscope.

1. Connect the Light guide bundles by twisting the knurled screw on the endoscope screw base clockwise.

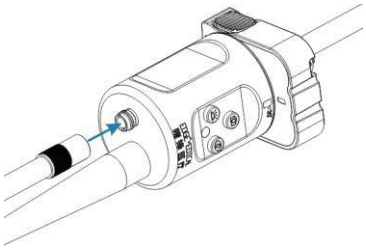


Figure 7.13 Connect to the Light Port

2. Insert the Light guide bundles into the Light guide bundles port of the Endoscope Illuminator until it engages. Note that hold the connector only by the plastic part, never by the metal part.

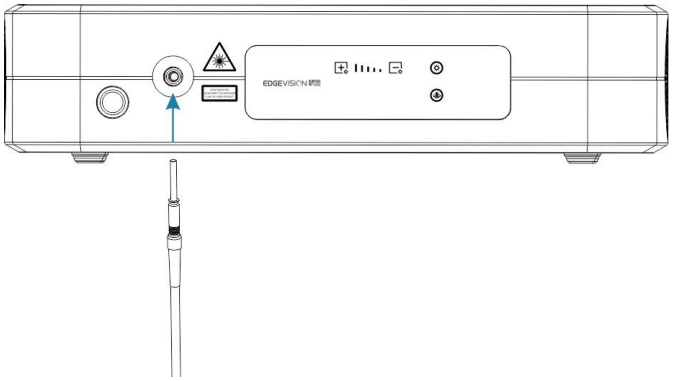


Figure 7.14 Connect to the Endoscope Illuminator

Note: To maintain optimal light transmission, always keep the light input and output surfaces of the Light guide bundles and the endoscope clean.

Caution: Be careful with the Light guide bundles. Serious bends or kinks can damage the optical materials inside the cable and increase fiber loss.

Connecting the Illuminator Control Cable

Connect the illuminator control cable between the Endoscope Illuminator and the Camera Control Unit. An audible click indicates when the cable engages properly.

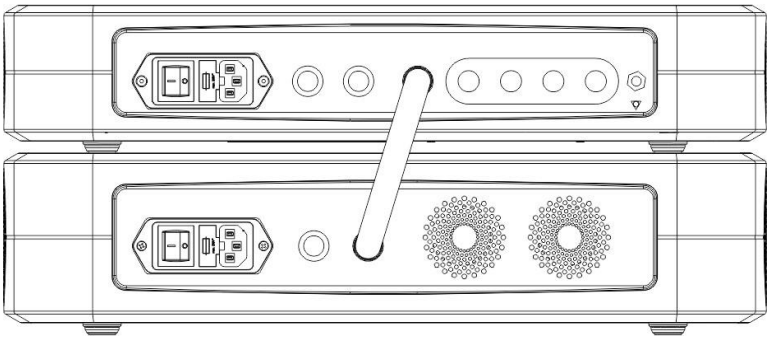


Figure 7.15 Connecting the Endoscope Illuminator and the Camera Control Unit

7.6.4 Power Connection

Caution: The Endoscope Illuminator and Camera Control Unit should be connected to the dedicated power supply separately to avoid circuit overload.

Caution: Do not connect the Endoscope Illuminator or Camera Control Unit to the same AC power wall outlet as the high frequency generator to avoid circuit overload.

Warning: When connecting to AC power, put the Endoscope Illuminator and Camera Control Unit in a place where they can be easily disconnected from the power supply.

Warning: Portable multiple sockets shall not be placed on the floor. Any portable multiple sockets or extension cords shall not be connected to the product.

Warning: To avoid electric shock, the product must only be connected to a power supply with protective earth.

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

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

Warning: Make sure to disconnect the power supply before removing the Light guide bundles and the illuminator control cable.

1. Connect the power cords to the power inlet of the Endoscope Illuminator and Camera Control Unit. Push the power plug fully into the power inlet.
2. Connect the power cords to AC power.

7.6.5 Optimal Light Transmission

The light input and output surfaces of the Light guide bundles and the endoscope must be kept clean to maintain optimal light transmission.

The Light guide bundles must first be removed from the endoscope. Then clean the light input and output surfaces with a clean cotton swab moistened with 75% alcohol.

Caution: Heat from the Endoscope Illuminator can cause chemical residue on the light input and output surfaces to burn, which can damage the optical fibers and

affect the lighting power and the picture quality.

7.6.6 Handheld Endoscope Use

The endoscope can be used handheld after connected to the Camera Control Unit. The endoscopic image displays to aid with visualizing during handheld use. After handheld use, the endoscope is installed on the instrument arm of the Patient Cart.

0° Endoscope

The view direction of the endoscope is 0°. Hold the endoscope with the base and buttons facing up so the image appears upright.

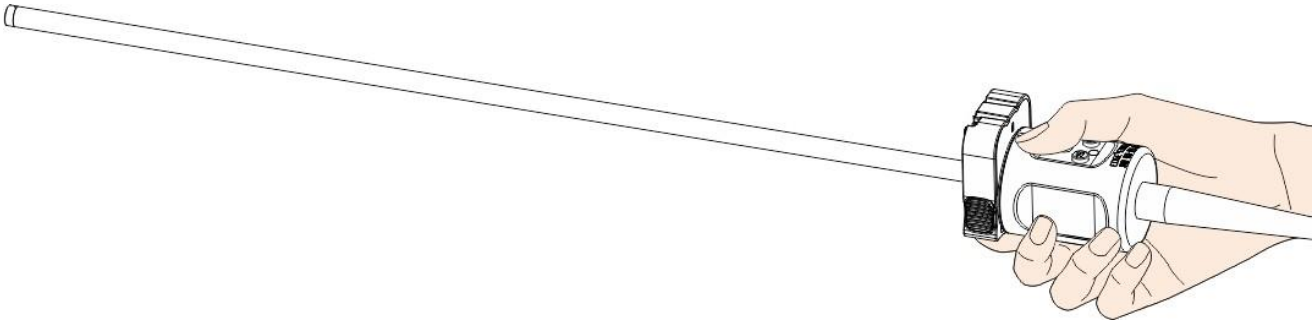


Figure 7.16 Handheld Orientation of 0° Endoscope

30° Endoscope

The view direction of the endoscope is 30°. The endoscope provides two tip orientations: up and down. If the base faces down, the image appears upside-down.

- When selecting the 30° down orientation, hold the endoscope with the base and buttons facing up, and the hash mark on the base aligning with the 30° down marking on the housing.

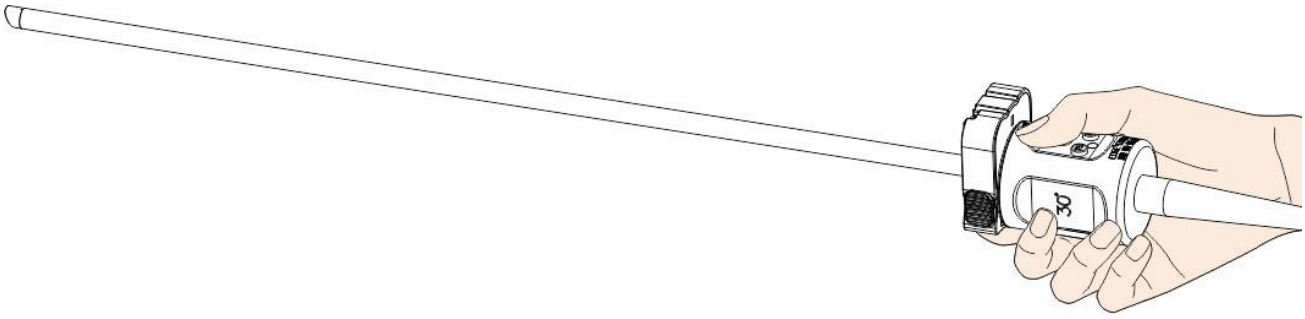


Figure 7.17 Down Orientation of 30° Endoscope

- When selecting the 30° up orientation, hold the endoscope with the base and buttons facing down, and the hash mark on the base aligning with the 30° up marking on the housing.

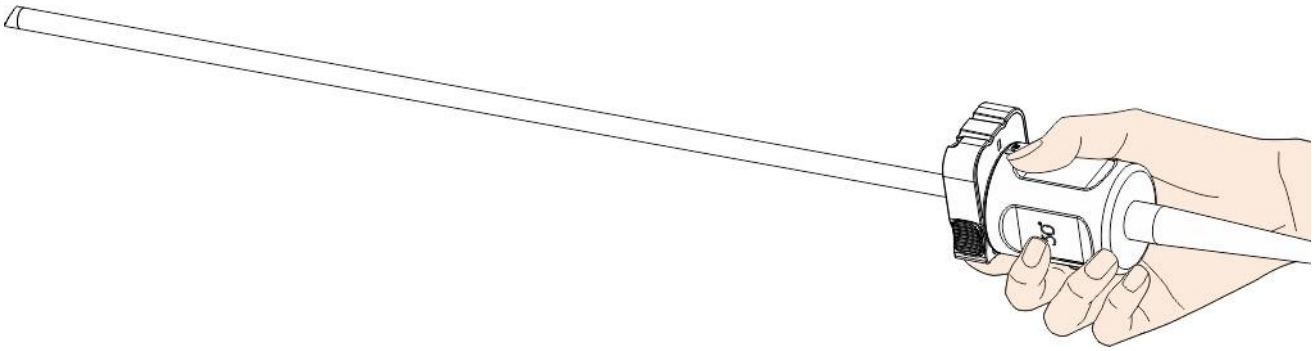


Figure 7.18 Up Orientation of 30° Endoscope

7.7 Endoscope Installation and Removal

7.7.1 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.

7.7.2 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.

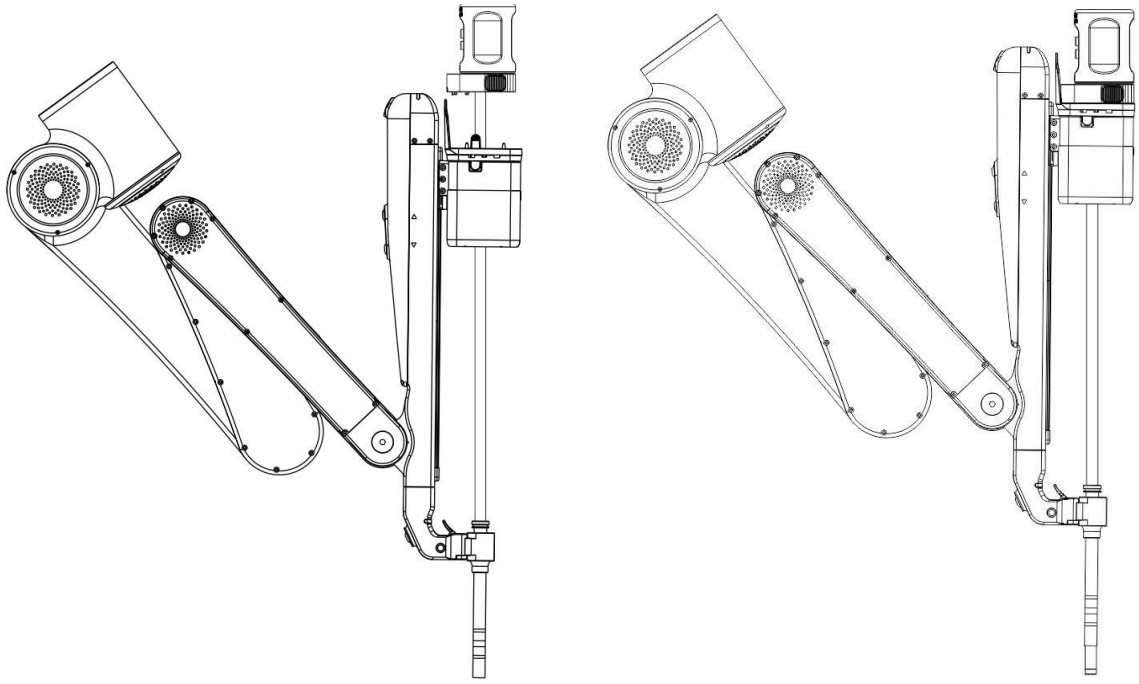


Figure 7.19 Insert the Endoscope into the Cannula and Adaptor

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.

7.7.3 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.
   e. Unplug the Light guide bundles from the Endoscope Illuminator and endoscope.
2. Install a new endoscope:
   a. Connect the endoscope cable to the Camera Control Unit.
   b. Connect the Light guide bundles to the Endoscope Illuminator and endoscope.
   c. Attach the endoscope to the instrument arm. See 7.7.2 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.

7.8 Feature Settings

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

7.8.1 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.

7.8.2 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.

7.8.3 Take Photo

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

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

7.8.4 Illumination

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

- When near-infrared imaging is activated, press the button to turn off visible light and near-infrared light.
- When visible light imaging is activated, press the button to turn 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 activated by the Surgeon Console.

7.8.5 3D Calibration and White Balance

The endoscope is calibrated and white balanced at the factory. Usually no special treatment is required. If it is necessary to adjust the perception of white and the ability to display colors properly, set white balance by the following method:

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.

7.8.6 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.

7.8.7 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.

7.8.8 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.

7.8.9 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.

7.8.10 Light Intensity

Light intensity is used to adjust the light output for illumination of the operating field. The system provides two methods for light intensity:

- Press the  button on the Endoscope Illuminator to increase light intensity and press the  button on the Endoscope Illuminator to decrease light intensity.

- Select **Settings** > **Fluor** > **Light Intensity** on the Surgeon Console touchscreen.

Note: Always select the lowest possible light output which still allows optimal illumination of the operating field.

Note: To ensure safety, high-intensity light cannot be used for a long time.

7.8.11 Imaging Toggling

Users can toggle between white light mode and fluorescence mode for the endoscope.

When white light mode is activated, the Endoscope Illuminator illuminates white light and displays the images in real color. When fluorescence mode is activated, the Endoscope Illuminator uses near-infrared light in conjunction with the imaging agent Indocyanine Green (ICG), to create fluorescent images of tissue.

The system provides following methods for imaging toggling:

- Press the button on the Endoscope Illuminator to enable or disable white light mode and press the button on the Endoscope Illuminator to enable or disable fluorescence mode. The button LED is on when illumination mode is enabled.
- Use the master control finger clutches of the Surgeon Console, tap the **Fluorescence** button or select **Settings** > **Fluor** > **Visible Light Mode**/**Fluorescence Mode** on the Surgeon Console touchscreen.

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: The near-infrared laser light generated in fluorescence mode is invisible. Avoid look directly at the emitting light.

Note: Before delivering the ICG into the patient, locate the target anatomy in white light mode and then activate fluorescence imaging.

7.8.12 Laser Protection

The Endoscope Illuminator provides laser protection during use, and can sense whether the Light guide bundles is inserted into the matching port.

- If the Light guide bundles is not inserted into the port, press the  or  button on the Endoscope Illuminator, and the lamp will not work.
- If the Light guide bundles is unplugged from the port during use, both the laser light and the  button LED will be off.

7.8.13 Temperature Monitoring

The Endoscope Illuminator has the function of temperature monitoring, and provides audible and visual prompts in the conditions of exceeding standard temperature.

- If the temperature of the Endoscope Illuminator exceeds 45℃ in white light mode, the  button LED flashes and an audible sound appears.
- If the temperature of the Endoscope Illuminator exceeds 40℃ in fluorescence mode, the  button LED flashes and an audible sound appears.

If the temperature of the Endoscope Illuminator is too high, stop using the device and resume use until the temperature returns to normal. If the prompts persist, contact the company for technical support.

7.8.14 Replacement Prompt

The Endoscope Illuminator provides a fail-safe safety function. When the Endoscope Illuminator reaches its service life, an audible sound prompts to place the module.

7.8.15 Parameter Memory

The Endoscope Illuminator has the function of parameter memory. After powering on the Endoscope Illuminator and adjusting the brightness level, power off the Endoscope Illuminator. When the Endoscope Illuminator is powered on again, its intensity remains at the level set last time.

7.8.16 Version

The software version of the Camera Control Unit and Endoscope Illuminator is V1.

7.9 Endoscope Fogging and Cleaning

7.9.1 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 to the maximum flow rate.
- Activate smoke evacuator before activating energy and deactivate after use.

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

7.9.2 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.

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.

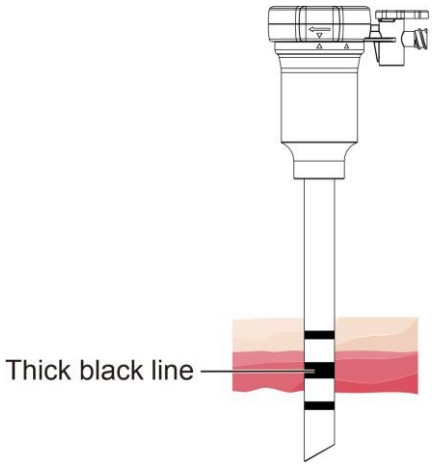


Figure 8.1 Mark of Cannula Remote Center

- 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, viewing remaining uses, Patient Cart audio setting, power protection, force sensor reset and system height limit. 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 the Home tab 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 : The feature is associated with the boom controls switch on the Settings tab. When the boom controls switch is on, 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 the Settings tab to access a variety of the Patient Cart settings.

- View remaining uses: Tap the button and the remaining uses for instruments or endoscopes appears. The number on the left represents the uses it has been used, and the number on the right represents its maximum uses.
- Patient Cart audio: Turn the Patient Cart microphone, audible sounds and voice annunciation messages on or off. Adjust the volume on the Patient Cart speakers, audible sounds and voice annunciation messages.
- Power protection: Turn power protection on or off. When the power protection is ON, the motor drive is disabled to ensure that backup battery power is adequate for removing the instruments safely from the patient when the Patient Cart is disconnected to AC power.
- Boom controls switch: Turn boom controls on or off. For details, see Enable boom controls on the Home tab.
- Force sensor: Tap **Reset** to reset the force sensor on the helm of the Patient Cart. Do not touch the cart during the process.
- System height limit: The system height limit (the height of the Patient Cart from the maximum height to the ground) is set for the use of the Patient Cart in environments with low overhead clearance. Selecting ON restricts the system to the set height. Selecting OFF allows the system to extend to its maximum height.

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 the backup battery power status. The battery percentage displays on the Surgeon Console touchscreen.

Table 9.2 UPS LED Indicator

Indicator Status	Meaning
Off	Unpowered
Flashing	Loss of AC power, running on backup battery 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
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
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.

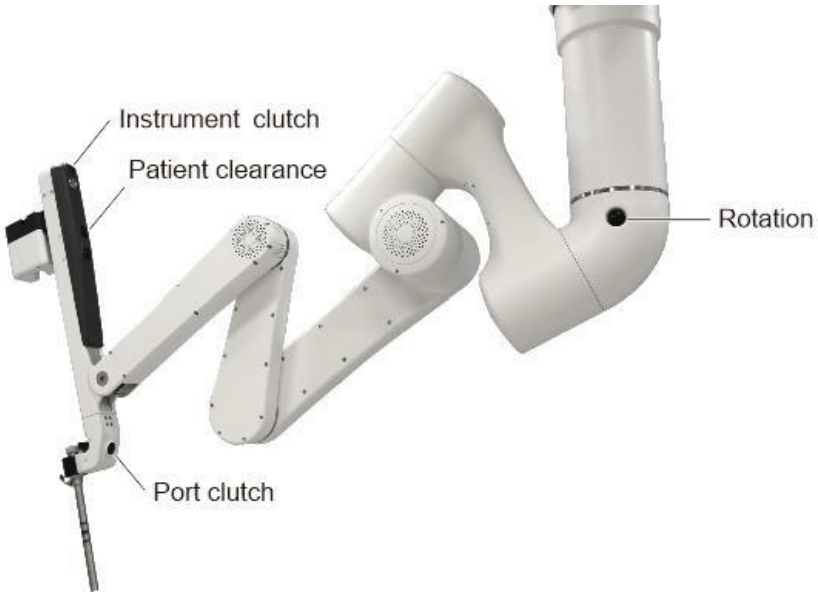


Figure 9.5 Controls on Patient Cart Instrument Arms

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.

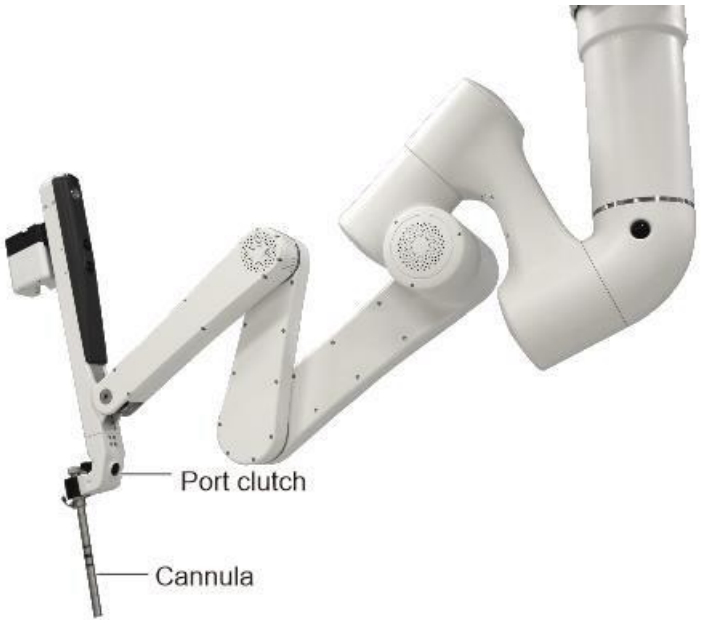


Figure 9.6 Example Where to Support the Arm and Cannula

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.

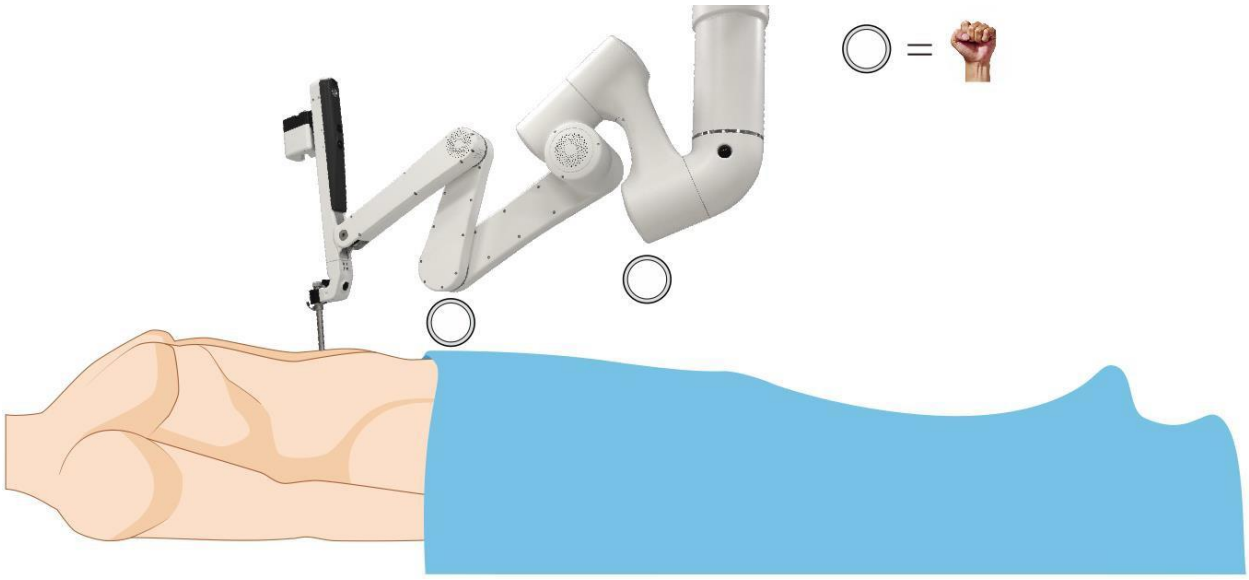


Figure 9.10 Patient Clearance Adjustment with a Fist's Space

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 6.5.2 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 Disposable Ultrasonic Scalpel

9.4.1 Product Overview

The disposable ultrasonic scalpel a single-use, sterile instrument used to deliver ultrasonic energy to enable transection and coagulation of tissue. The movement and function of the instrument are controlled by the surgeon from the endoscopic instrument control system. The instrument is compatible with the HocerMed Hand Piece (model HP25), HocerMed Pedal (model GP210) and HocerMed Generator (model USG10plus).

The instrument consists of the blade, tissue pad, clamp arm, instrument housing, release buttons, discs and shaft. It is shipped sterile and has been sterilized using Ethylene Oxide and it is provided in sterile packaging that contains a sterile, single-use torque wrench. The torque wrench should not be discarded until the completion of assembly and disassembly. Do not attempt to sterilize the instrument or torque wrench.

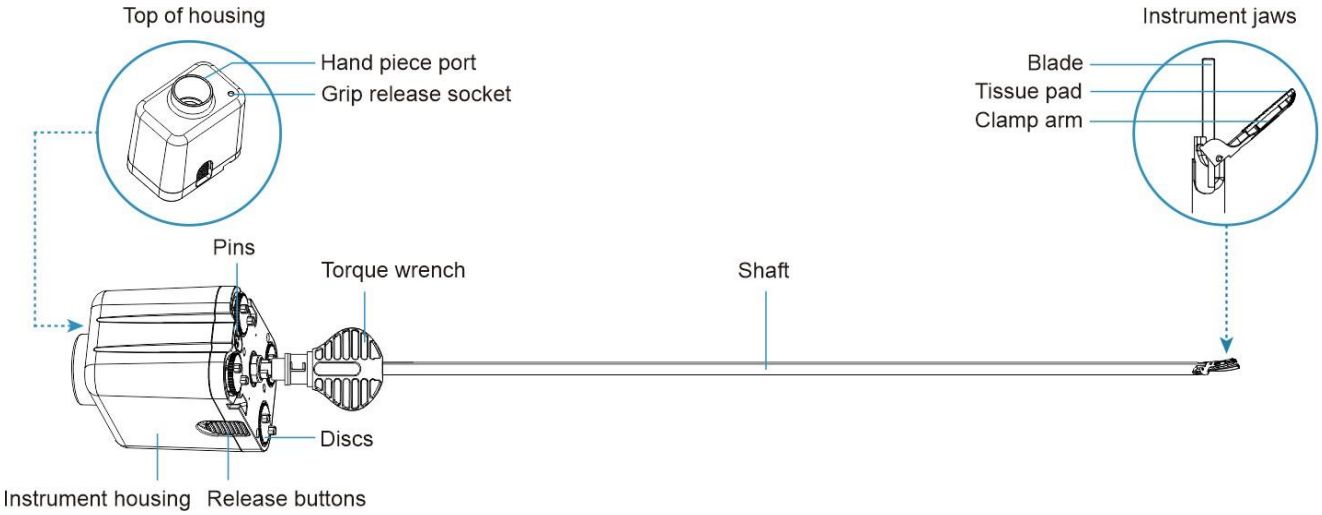


Figure 9.11 Disposable Ultrasonic Scalpel

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.

9.4.2 Compatibility Information

The disposable ultrasonic scalpel is designed for use with the following compatible equipment only:

- Endoscopic Instrument Control System (model MP1000)
- Energy Activation Cable (modelCM1835)
- HocerMed Hand Piece (model HP25)
- HocerMed Pedal (model GP210)
- HocerMed Generator (model USG10plus)

The instrument is compatible with the 5 mm reducer, 8 mm cannula, obturator and cannula seal.

9.4.3 Inspection before Use

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

- Inspect the packaging and do not use if damaged.
- Confirm the date of manufacture and the shelf life and do not use any expired instruments.
- Inspect the instruments for damage or abnormalities. Examples of damage or abnormalities include:
  - Blade is scratched, bent, cracked or broken.
  - Clamp arm is bent, cracked or broken.
  - Tissue pad is damaged or loose.
  - Shaft is bent, flawed, dented or cracked.
  - Instrument housing has cracks or flaws.

9.4.4 Instrument Assembly

Caution: Avoid using any means other than the supplied torque wrench to assemble the ultrasonic scalpel. Otherwise, damage may occur on the instrument.

Caution: Failure to close the instrument jaws before inserting or removing the torque wrench may cause damage to the jaws. Take care when sliding the wrench to avoid damage.

1. Open the package of the ultrasonic scalpel, and prepare the instrument.
2. Gently insert the hand piece into the instrument housing.

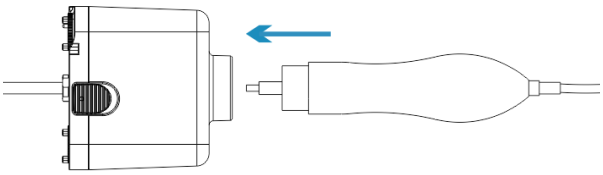


Figure 9.12 Insert the Hand Piece

3. Rotate the shaft in a clockwise direction until there is large resistance.

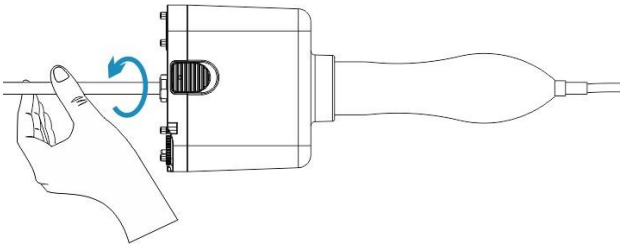


Figure 9.13 Rotate the Shaft

4. Rotate the disc at the bottom of the housing in a counter-clockwise direction to close the instrument jaws.

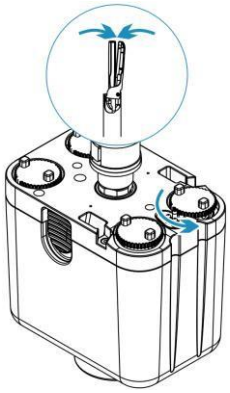


Figure 9.14 Close the Instrument Jaws

5. Tighten with the torque wrench.

   a. Insert the torque wrench onto the shaft and slide it to the bottom.



Figure 9.15 Insert the Torque Wrench

   b. Rotate the torque wrench in a clockwise direction until you hear loud clicks, which indicate a tight connection.

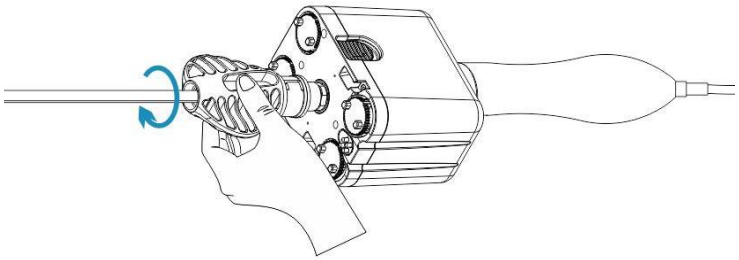


Figure 9.16 Rotate the Torque Wrench

   c. Remove and keep the torque wrench for post-operative disassembly.



Figure 9.17 Remove the Torque Wrench

9.4.5 Generator Self-Test

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: Do not perform generator self-test in patient's body and/or with the instrument installed on the system, as unintended injury or instrument damage may occur.

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.

Note: The instrument jaws must be open during self-test. Otherwise, an error may occur.

1. Connect the hand piece and foot pedal.
   a. Connect the hand piece to the generator.

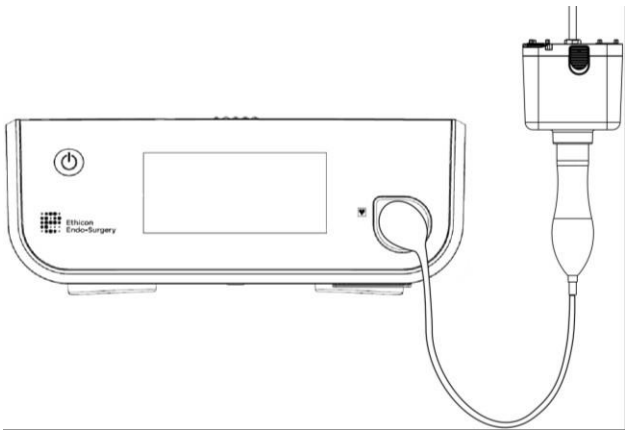


Figure 9.18 Connect the Hand Piece

   b. Connect the foot pedal to the generator.

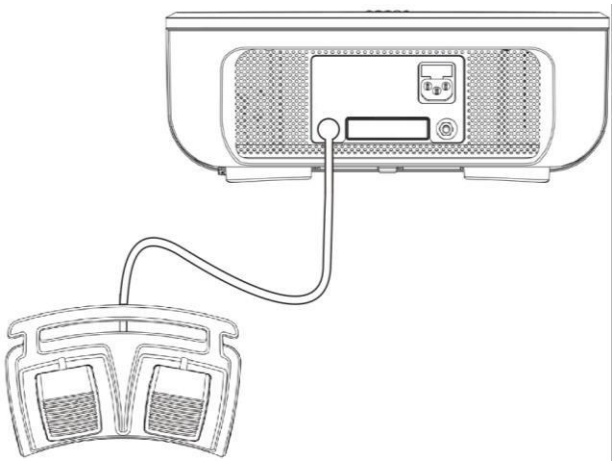


Figure 9.19 Connect the Foot Pedal

2. Connect the generator to AC power.

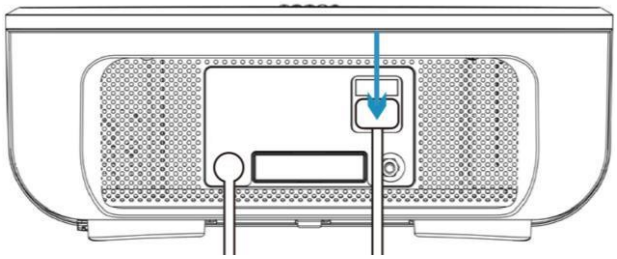


Figure 9.20 Connect to AC power

3. Press the **Power** button on the generator.

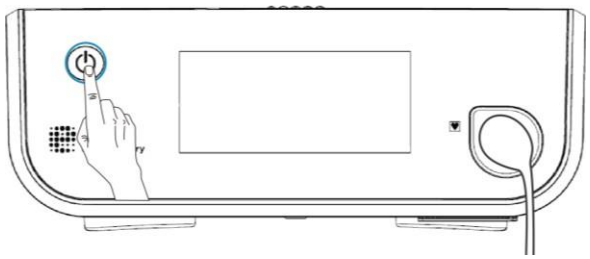


Figure 9.21 Generator Startup

4. Rotate the disc at the bottom of the housing in a clockwise direction to open the instrument jaws.

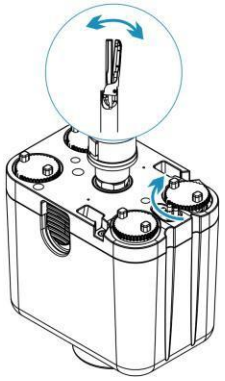


Figure 9.22 Open the Instrument Jaws

5. Hold and press either pedal until the generator displays ready, and then release the pedal.
   - If any error is identified, the generator will prompt to correct it.
   - If no error is identified, the generator will indicate the self-test is completed.

9.4.6 System Connections

1. Disconnect the foot pedal from the back of the generator.

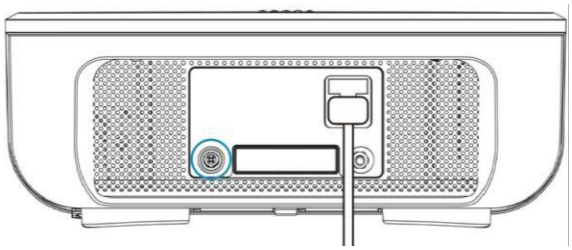


Figure 9.23 Disconnect the Foot Pedal

2. Connect the energy activation cable to the back of the generator.
3. Connect the energy activation cable to the energy port of the Signal Distributor.
4. Install the ultrasonic scalpel onto the instrument arm of the Patient Cart.

9.4.7 Intraoperative Operation

Warning: Keep the surgical site in the field of view when inserting, advancing or removing the instrument.

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

1. Inspect the instrument and do not use the instrument if it is damaged.
2. Rotate the disc at the bottom of the housing in a counter-clockwise direction to close the instrument jaws.

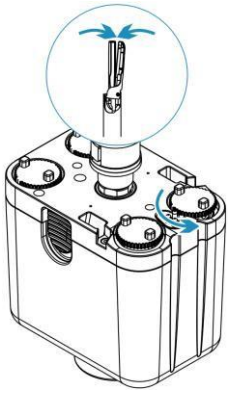


Figure 9.24 Close the Instrument Jaws

3. Insert the instrument tip into the cannula and press the instrument housing into the adaptor. Audible sounds indicate that the instrument is engaged.
4. Select the desired minimum power level on the generator for appropriate tissue cutting speed and coagulation.

   There are 5 adjustable power levels for the ultrasonic scalpel controlled by the generator. The maximum power level is Level 5. The recommended minimum starting power level is Level 3. For greater tissue cutting speed, use a higher generator power level (for example, Level 5). For greater coagulation, use a lower generator power level (for example, Level 3). Use the lowest power setting possible for the minimum time necessary to achieve the desired effect.

Note: The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors, including the power level selected, blade characteristics, grip force, tissue tension, tissue type, pathology, and surgical technique.

5. Activate the instrument by pressing the associated foot pedals in the Surgeon Console.
6. Once tissue manipulation including dissection, grasping, coagulation and cutting between the blade and clamp arm is complete, remove the instrument from the surgical site and visually inspect adequate hemostasis is achieved.

9.4.8 Intraoperative Cleaning

Caution: Do not intraoperatively use an instrument to clean debris from another instrument. This may result in damage to the instrument or other unintended consequences.

Caution: Do not use metal instruments or abrasives to clean the blade, as this may cause damage to the blade.

Warning: Blood and tissue buildup between the blade and clamp arm may result in abnormally high temperatures at the distal end of the instrument. For optimum performance and to prevent burn injury, it is necessary to remove any visible tissue buildup at the distal end.

Blood and tissue buildup between the blade and clamp arm may result in abnormally high temperatures at the distal end of the instrument. For optimum performance and to prevent burn injury, it is necessary to remove any visible tissue buildup at the distal end by following

the guidelines:

1. Remove the instrument safely from the cannula.
2. It requires a non-sterile user to reconnect the auxiliary HocerMed pedal by swapping the energy activation cable for the footswitch cable.
3. Activate the distal end of the instrument in saline.
4. Wipe the instrument with a moist gauze sponge to remove tissue.

   If tissue is still visible in the clamp arm, use hemostats to remove residue, taking care not to actuate the hand piece. If desired, the instrument may be unplugged.
5. After cleaning, it requires a non-sterile user to reconnect the energy activation cable to the generator.

9.4.9 Instrument Disassembly



Caution: Avoid using any means other than the supplied torque wrench to assemble the ultrasonic scalpel. Otherwise, damage may occur on the instrument.



Caution: Failure to close the instrument jaws before inserting or removing the torque wrench may cause damage to the jaws. Take care when sliding the wrench to avoid damage.

1. Power off the generator, and then remove the hand piece from the generator.
2. Remove the ultrasonic scalpel from the instrument arm of the Patient Cart.
3. Loosen with the torque wrench.
   a. Insert the torque wrench onto the shaft and slide it to the bottom.
   b. Rotate the torque wrench in a counter-clockwise direction until the connection is loose.
   c. Remove the torque wrench.
4. Loosen and remove the hand piece from the instrument housing.
5. Dispose of the instrument into the designated location.

9.5 Accessories

9.5.1 Product Overview

The accessories consists of reducers, cannulas, obturators, cannula seals, tip cover accessory and installation tool. For detailed instructions, see 2.7 Accessories.

9.5.2 Compatibility Information

8 mm Cannulas, Obturators and Cannula Seals

Cannula	Obturator	Cannula Seal	Compatible Laparoscopic Instruments
TR1-A8I, Cannula	TR2-A8IB, Blunt Obturator TR2-A8IP, Prismatic Obturator	TR3-A8, Cannula Seal	8 mm Instruments
TR1-A8I-L, Long Cannula	TR2-A8IB-L, Long Blunt Obturator TR2-A8IP-L, Long Prismatic Obturator		
TR1-A8E, Cannula	TR2-A8EB, Blunt Obturator TR2-A8EP, Prismatic Obturator	TR3-A8E, Cannula Seal	Endoscopes
TR1-A8E-L, Long Cannula	TR2-A8EB-L, Long Blunt Obturator TR2-A8EP-L, Long Prismatic Obturator		

12 mm Cannulas, Obturators and Cannula Seals

Cannula	Obturator	Cannula Seal
TR1-A12, Cannula	TR2-A12B, Blunt Obturator TR2-A12P, Prismatic Obturator	TR3-A12, Cannula Seal
TR1-A12-L, Long Cannula	TR2-A12B-L, Long Blunt Obturator TR2-A12P-L, Long Prismatic Obturator	

15 mm Cannulas, Obturators and Cannula Seals

Cannula	Obturator	Cannula Seal
TR1-A15, Cannula	TR2-A15B, Blunt Obturator TR2-A15P, Prismatic Obturator	TR3-A15, Cannula Seal

Cannula	Obturator	Cannula Seal
TR1-A15-L, Long Cannula	TR2-A15B-L, Long Blunt Obturator TR2-A15P-L, Long Prismatic Obturator	

Reducers

Reducer	Cannula	Cannula Seal	Compatible Laparoscopic Instruments
TR4-A8/5, Reducer	TR1-A8I, Cannula TR1-A8I-L, Long Cannula	TR3-A8, Cannula Seal	5 mm Instruments
TR4-A12/8, Reducer	TR1-A12, Cannula TR1-A12-L, Long Cannula	TR3-A12, Cannula Seal	8 mm Instruments
TR4-A15/8, Reducer	TR1-A15, Cannula TR1-A15-L, Long Cannula	TR3-A15, Cannula Seal	8 mm Instruments

9.5.3 Cannulas, Obturators and Cannula Seals

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

Inspection before Use

- Cannula seals are for single use only and comes in a sterile package. Inspect the packaging and ensure it has no tears. Do not use if the packaging is damaged or not intact.
- Confirm the date of manufacture and the shelf life and do not use any expired accessories.
- Inspect cannulas and obturators for cleanliness. If there is residual soil on the device, clean and sterilize the device in accordance with Reprocessing Instruction Manual.
- Inspect the integrity of cannulas, obturators and cannula seals. If any damage or abnormalities are observed, do not use the accessories.
- Hold the device up close and inspect for damage. Examples of damage include rough edges, dents, cracks, corrosions or a noncircular shape that may interfere with the smooth insertion of an instrument.
- Hold the cannula upright, drop the gage pin through the cannula with one hand and catch the gage pin with the other hand at the cannula tip. If the gage pin gets stuck, it indicates

the cannula is damaged. There are 8 mm, 12 mm and 15 mm gage pins available for 8 mm, 12 mm and 15 mm cannula inspection.

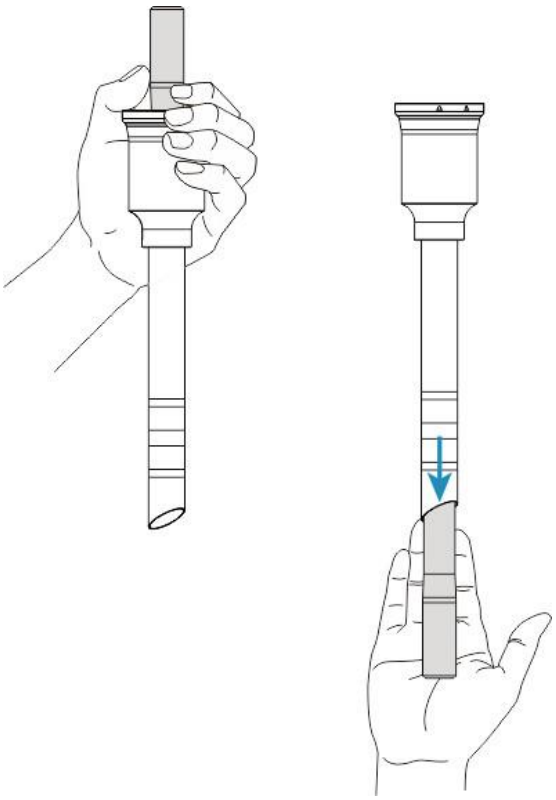


Figure 9.25 Use Gage Pin for Cannula Inspection

Intraoperative Operation

1. Remove the product from the package using sterile technique and ensure the reusable accessories have been appropriately reprocessed according to the Reprocessing Instruction Manual.
2. Using sterile technique, attach the compatible cannula seal to the cannula.
   Attach the cannula seal to the cannula by aligning the direction indicators as shown in Step ①and ② , and then rotate the cannula seal until the direction indicators are aligned as shown in Step ③.

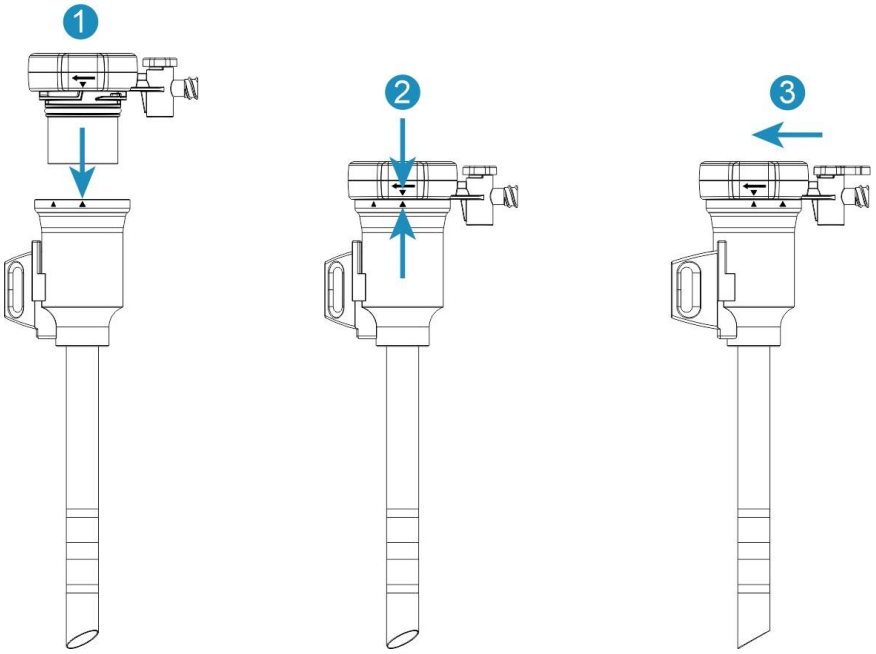


Figure 9.26 Cannula Seal and Cannula Assembly

3. Insert the obturator completely into the cannula seal and cannula until latched. Make sure it is fully engaged with an audible click.

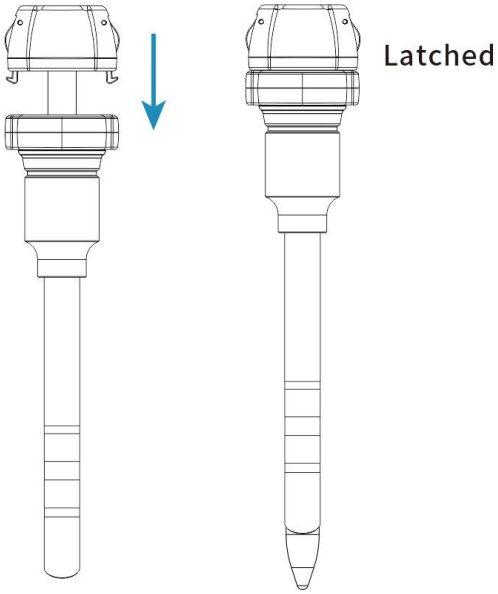


Figure 9.27 Obturator, Cannula Seal and Cannula Assembly

Warning: Follow the instructions to completely attach an obturator to a cannula and seal assembly. Failure to observe the instructions may result in incomplete attachment and unexpected detachment from the cannula.

4. Using standard surgical technique, make a skin incision to introduce the cannula and obturator. Note that the incision should match the cannula and obturator.

5. Hold the top of the cannula and obturator, and apply continuous, controlled pressure with a delicate rotating motion of approximately 180° until the cannula and obturator tip passes through the body wall.
6. When the cannula and obturator enter the body cavity, remove the obturator, leaving the cannula and cannula seal assembly in place.

Note: Do not remove the cannula seal to avoid unexpected loss of insufflation.

7. According to the specific procedure being performed, the remote center of the cannula marked in a thick black line should be placed within the boundaries of the body wall. If a patient has thicker body wall, use a long cannula.

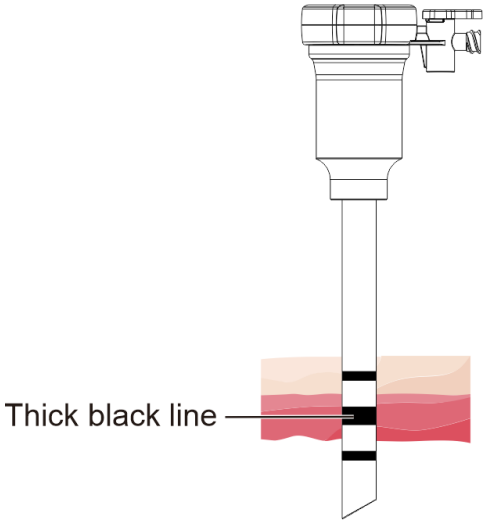


Figure 9.28 Remote Center Placement

8. Once all ports are placed, attach cannulas to the Patient Cart arms by pressing and holding the cannula mount lever, inserting the cannula, and releasing the lever. Note that the insufflation port is not facing the arm.
9. Insert and remove the instrument and endoscope through the cannula and cannula seal intraoperatively.
10. If the cannula seal is soiled intraoperatively, gently wipe with sterile gauze moistened with sterile saline or water as needed.
11. To remove the cannula, first detach the cannula and cannula seal assembly from the system, and then remove the cannula and cannula seal assembly from the body cavity.

9.5.4 Reducers

Inspection before Use

- Reducers are for single use only and comes in a sterile package. Inspect the packaging and ensure it has no tears. Do not use if the packaging is damaged or not intact.
- Confirm the date of manufacture and the shelf life and do not use any expired accessories.
- Inspect accessories for damage or abnormalities. Examples of damage or abnormalities include cracked or broken latches on the reducer cap. Do not use the accessories with any defects or signs of damage.

Attaching a Reducer

1. After removing the obturator, insert the reducer completely into the cannula seal and cannula using sterile technique. Make sure the reducer is latched with an audible click.
2. Insert a compatible instrument through the reducer. See 9.5.2 Compatibility Information for details.

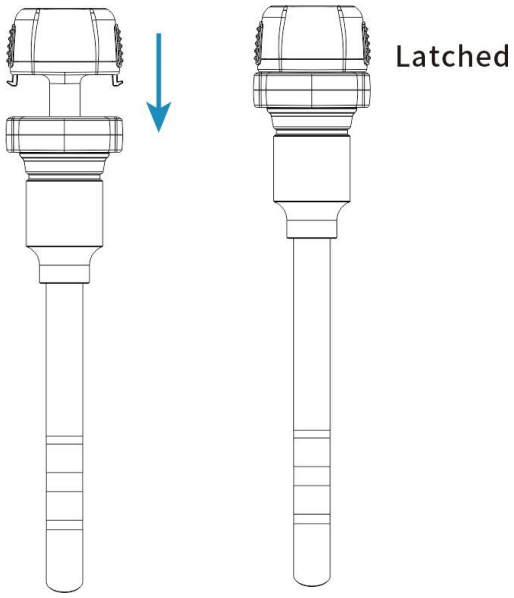


Figure 9.29 Attaching a Reducer

Removing a Reducer

To remove the reducer, firmly squeeze the reducer latches toward each other and then pull the reducer out of the cannula and cannula seal assembly.

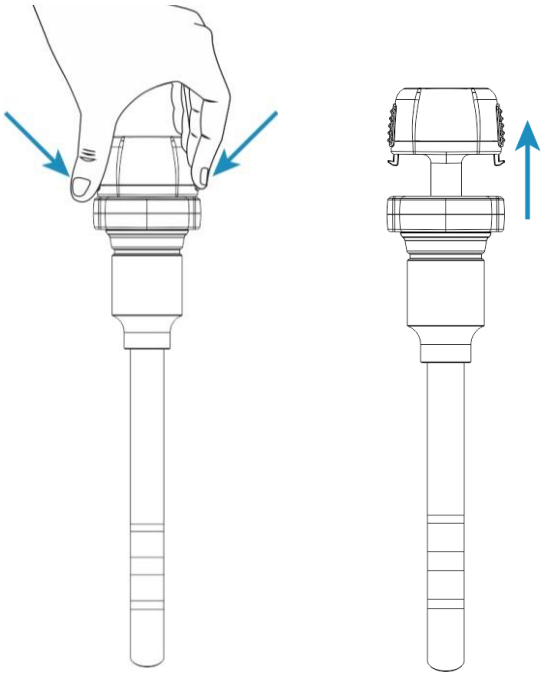


Figure 9.30 Removing a Reducer

Note: Do not remove the cannula seal to avoid unexpected loss of insufflation.

9.5.5 Tip Cover Accessory

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

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

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

Inspection before Use

- Tip cover accessory and installation tool are for single use only and comes in a sterile package. Inspect the packaging and ensure it has no tears. Do not use if the packaging is damaged or not intact.
- Confirm the date of manufacture and the shelf life and do not use any expired accessories.
- Inspect accessories for damage or abnormalities. Examples of damage or abnormalities include punctures, cuts, scratches, tears, unusual bumps or significant discoloration. Do not use the accessories with any defects or signs of damage.

Tip Cover Accessory Installation

1. Close the blades of the monopolar scissors.
2. Straighten the wrist of the instrument.
3. Install the installation tool onto the tip cover accessory.

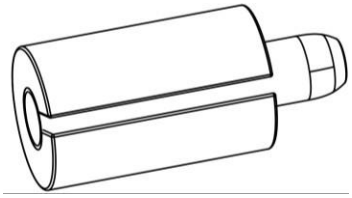


Figure 9.31 Install the Installation Tool

4. Grasp the tip cover accessory, and slide it onto the distal end of the instrument until it comes to the stop.

   Ensure that the tip cover accessory is installed in place.

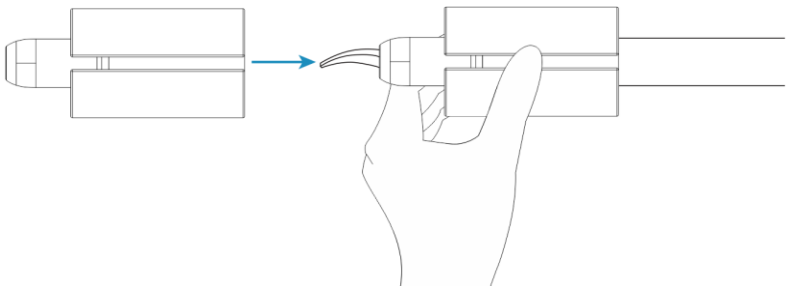


Figure 9.32 Slide the Tip Cover Accessory onto the Instrument

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

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

Tip Cover Accessory Removal

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

9.5.6 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 9.33 Connect the Monopolar Energy Instrument Cord



Figure 9.34 Connect the Bipolar Energy Instrument Cord

3. Connect the energy instrument cord to the instrument.

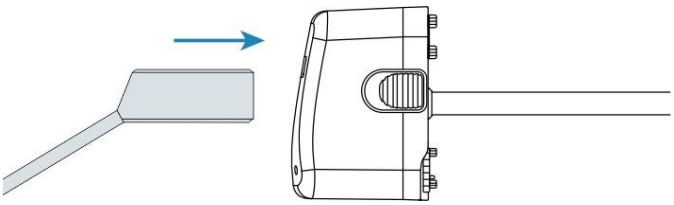


Figure 9.35 Connect the Instrument

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 Instruments

9.6.1 Product Overview

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

The instruments are mainly composed of instrument housings, release buttons, discs, grip release sockets, shafts and tips. The overall structure of these instruments is the same except for slight differences in the structure of the tips. The following figures are examples of instruments. For reference only, please refer to the actual situations.

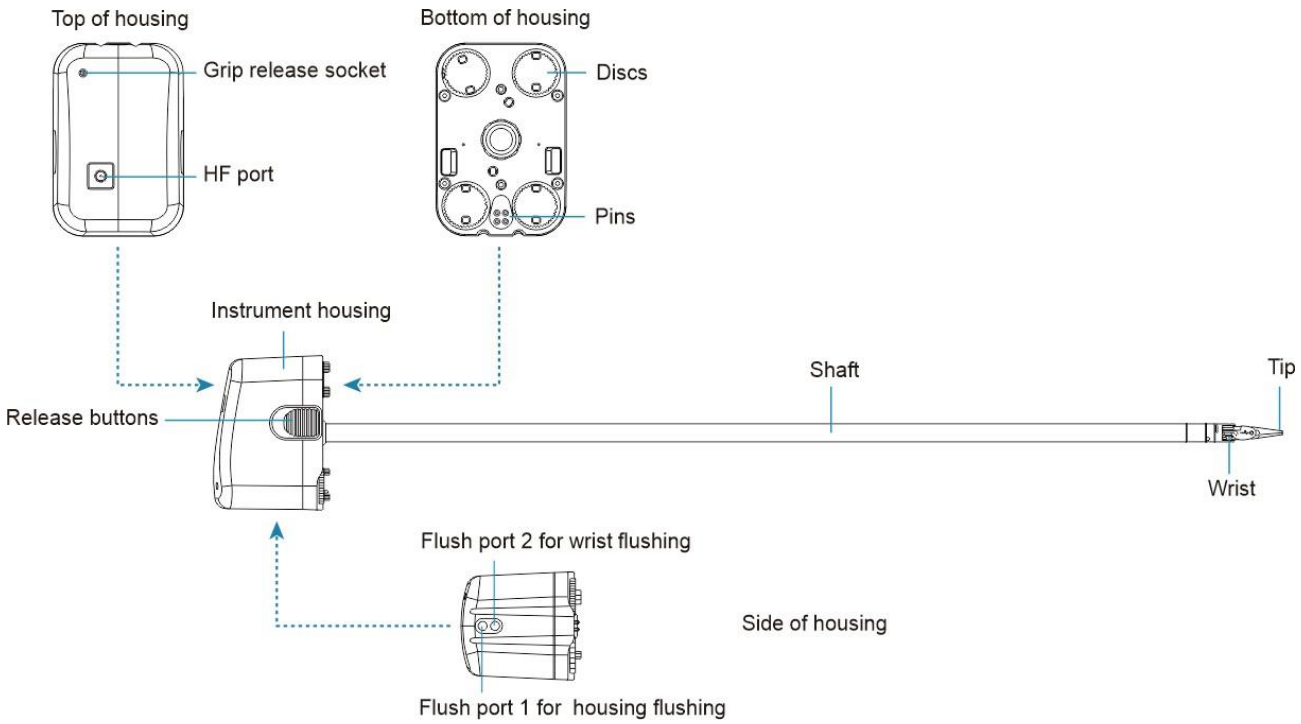


Figure 9.36 Instrument Components

- 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.
- Discs: The discs 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 port is used to connect monopolar energy instrument cord or bipolar energy instrument cord to high frequency generator.

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 Reprocessing Instruction Manual for detailed instructions.

9.6.2 Inspection before Use

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

Before use, inspect the instruments for damage or abnormalities. Examples of damage or abnormalities include:

- Scratches, cracks or broken parts on the instrument housing or shaft
- Cracks or missing pieces where the grip attaches to the shaft
- Broken, bent, misaligned or gouged instrument tip or grip
- Cracked or broken pulley near instrument tip
- Cracks or missing pieces on the outer components surrounding the pulley
- Broken insulated cables
- Frayed or cracked steel wires, or broken away from location

9.6.3 Instrument Installation

1. 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 discs at the bottom of the instrument housing or manipulating the instrument tip.

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



Figure 9.37 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).

9.6.4 Intraoperative Operation

1. Contact the tissue to be manipulated with the instrument tips. Make sure that the tips do not contact with non-target tissue.
2. Activate the instrument energy functions by pressing the associated foot pedals in the Surgeon Console. If energy activation is not necessary, skip this step.
3. Once tissue manipulation including grasping, cutting, coagulating and suturing is complete, remove the instruments from the surgical workspace and visually inspect adequate hemostasis is achieved.



Warning: Do not use one instrument to energize the tips of 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.



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



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



Warning: Exercise caution when using monopolar instruments close to other instruments. Unintended energy may be delivered from the active monopolar

instrument to a second instrument. This could cause burns to tissue in contact with the metal parts or cannula of the second instrument. Ensure that monopolar instrument tip should be closer to the tissue than the second instrument.

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

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

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

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

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

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

- Configure a suitable neutral electrode and use it correctly according to the manufacturer’s instructions for safety.
- Attach the entire neutral electrode stably to the patient, locate it in the operative field as closely as possible and connect it correctly to high frequency generator.

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

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

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

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

9.6.5 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).

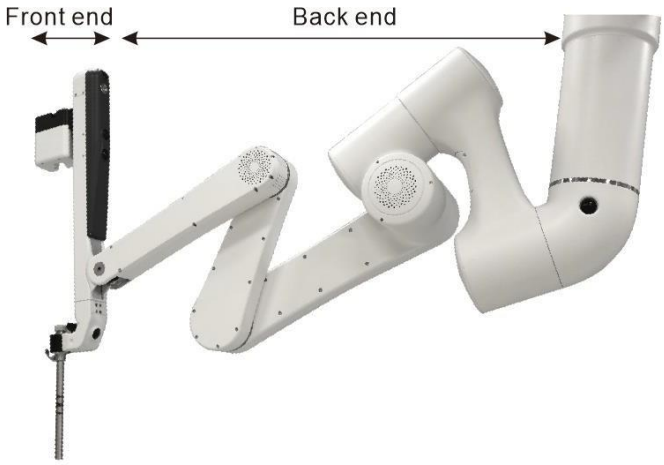


Figure 9.38 Front End and Back End of the Arm

- 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.

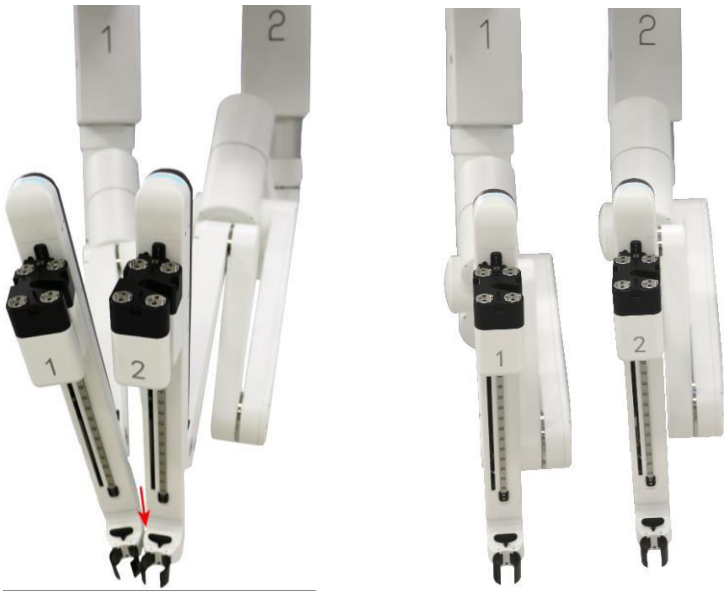


Figure 9.39 Horizontal Adjustment to Resolve Interference

- 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 9.40 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.

9.6.6 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.

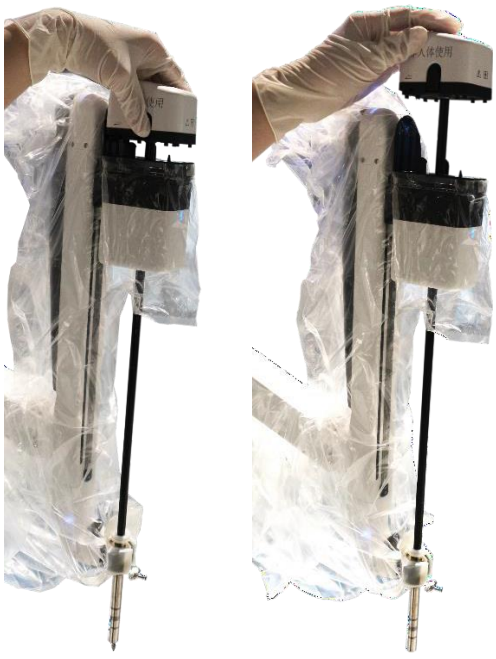


Figure 9.41 Remove the Instrument

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.

9.6.7 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 in the event of a system 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 9.42 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.

9.6.8 Intraoperative 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.

9.6.9 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.

9.6.10 Fluid Leakage Precautions

The instruments are designed so that they can be positioned horizontally or inclined upwards as needed during a procedure. As with any laparoscopic instrument, these positions allow blood or other fluid to migrate through the instrument shaft towards its proximal end. The instruments are designed to resist fluid migration and minimize fluid leakage from the proximal end. However, if blood or other fluid is noticed leaking out of the instrument and onto the arm 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 Reprocessing Instruction 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.

9.7 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 9.43 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 6.5.3 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.

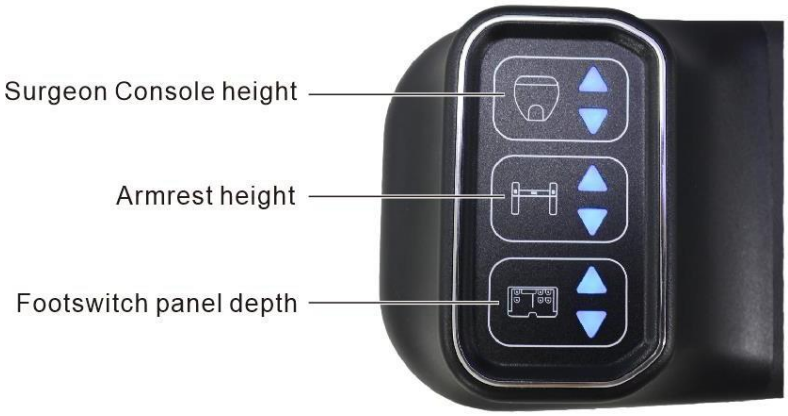


Figure 10.3 **Ergonomic Control** Buttons

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.

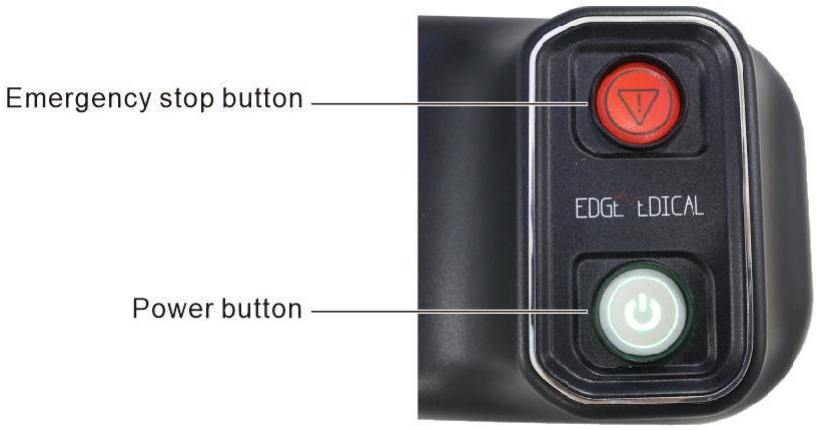


Figure 10.4 **Emergency Stop** Button and **Power** Button

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 13.3 Emergency Stop for details.

10.1.7 Footswitch Panel

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



Figure 10.5 Footswitch Panel

10.2 Surgeon Console Settings

10.2.1 Ergonomic Settings

Note: Before adjusting the **Ergonomic Control** buttons of the Surgeon Console, make sure there is adequate room for the components to move.

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

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

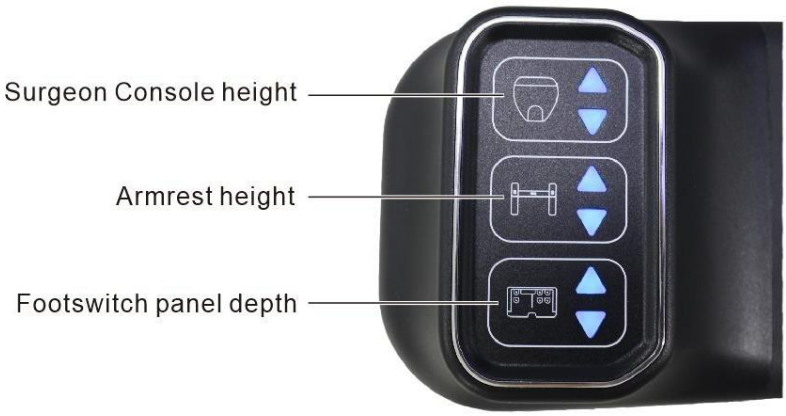


Figure 10.6 **Ergonomic Control** Buttons

10.2.2 Account Authority

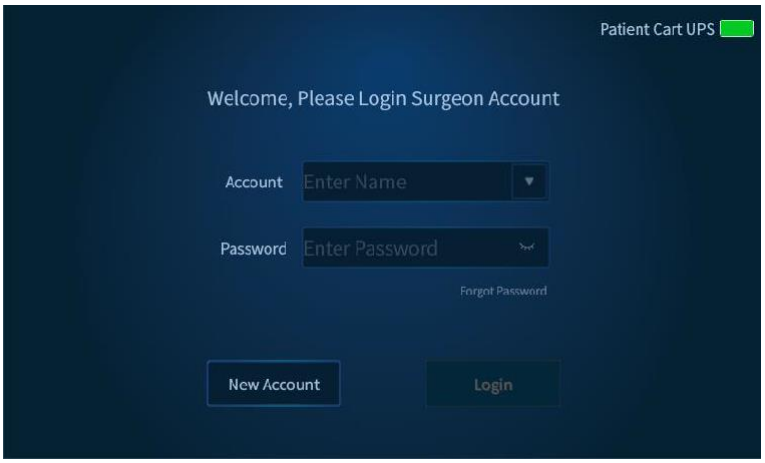
The feature of account authority allows a surgeon to operate the system after he or she log in to an applicable account, which can prevent the account information from being modified or the system from being operated improperly by any unauthorized individual.

There are two types of accounts, surgeon account and admin account:

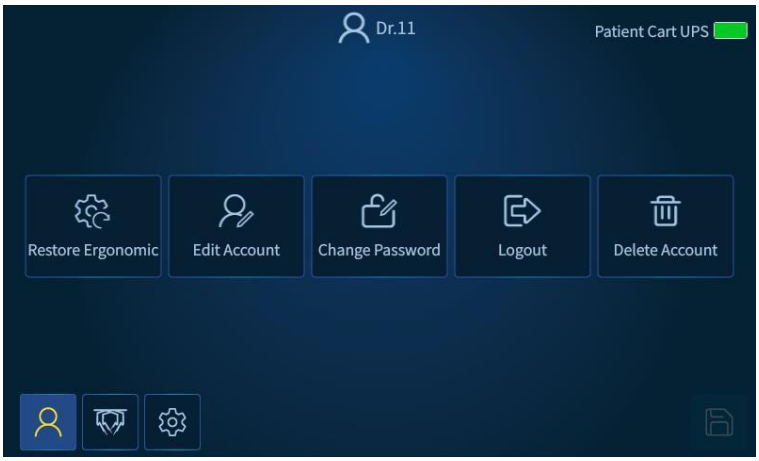
- Surgeon account: At login, surgeons can restore ergonomic, edit account, change password, logout and delete account. Logging in surgeon accounts also allows surgeons to configure image, viewer, master controls, Picture in Picture, fluorescence, account and general settings, give or take control of instrument arms, quick-adjust audio, take photo, and acquire the software version.
- Admin account: After logging in admin account, surgeons can restore ergonomic, logout and delete surgeon account. Admin account also allows surgeons to configure system settings and control instruments the same as surgeon accounts. Besides, the account lists more software information of the Surgeon Console, Patient Cart, Camera Control Unit and Signal Distributor.

Logging In to Surgeon Account

1. Enter the name and password of surgeon account.



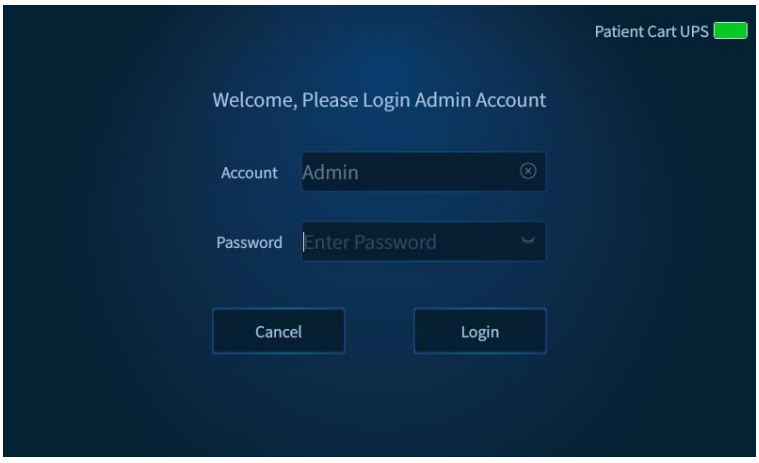
2. Tap the **Login** button and the Account tab appears.



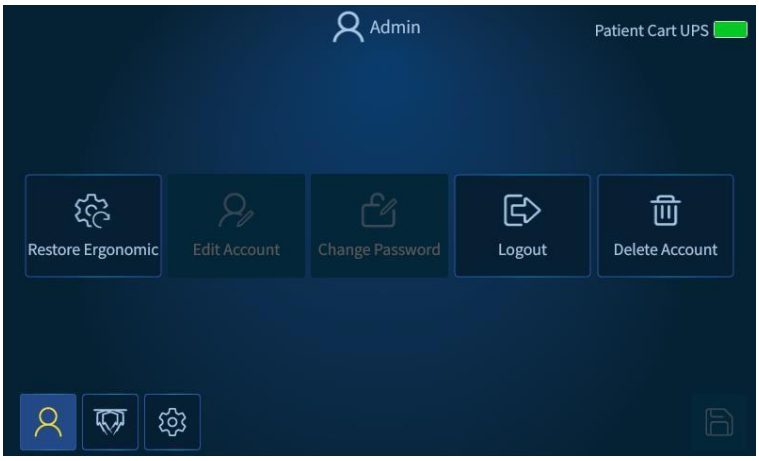
Logging In to Admin Account

1. Enter the name and password of admin account.

   The default name is Admin and the password is edgemp1000.

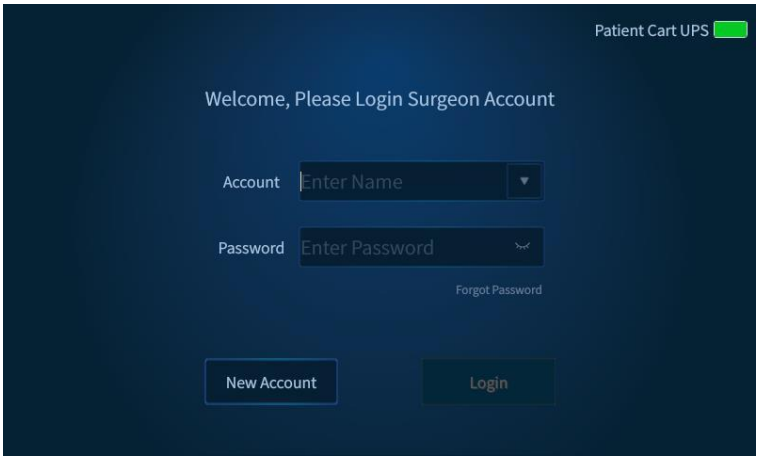


2. Tap the **Login** button and the Account tab appears.

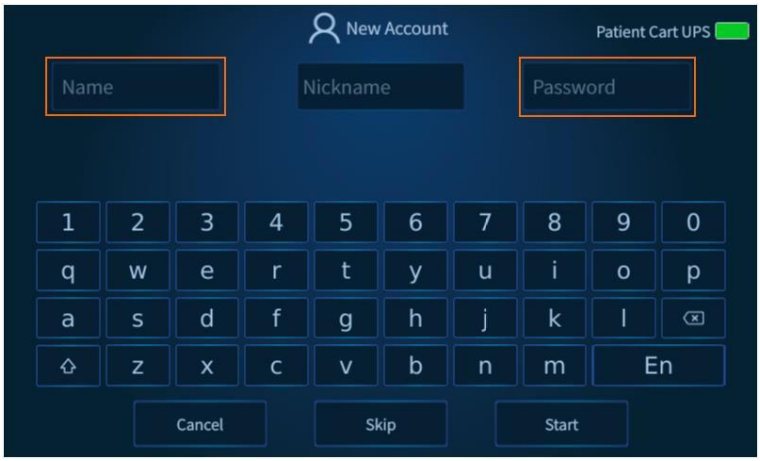


10.2.3 New Accounts

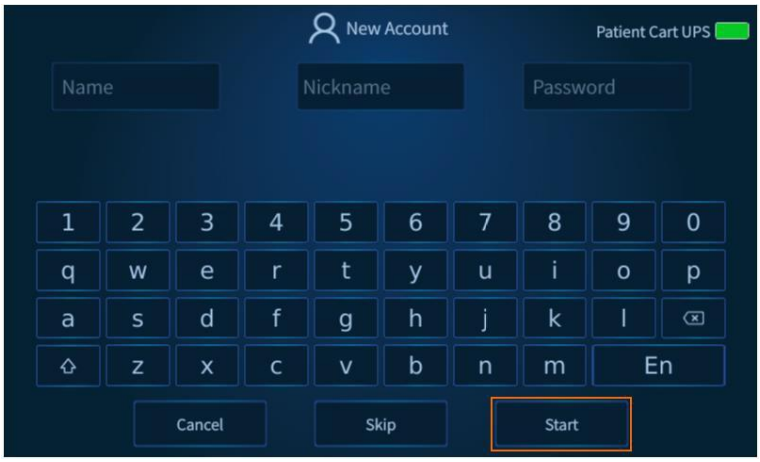
1. When logging in a surgeon account, tap **New Account**.



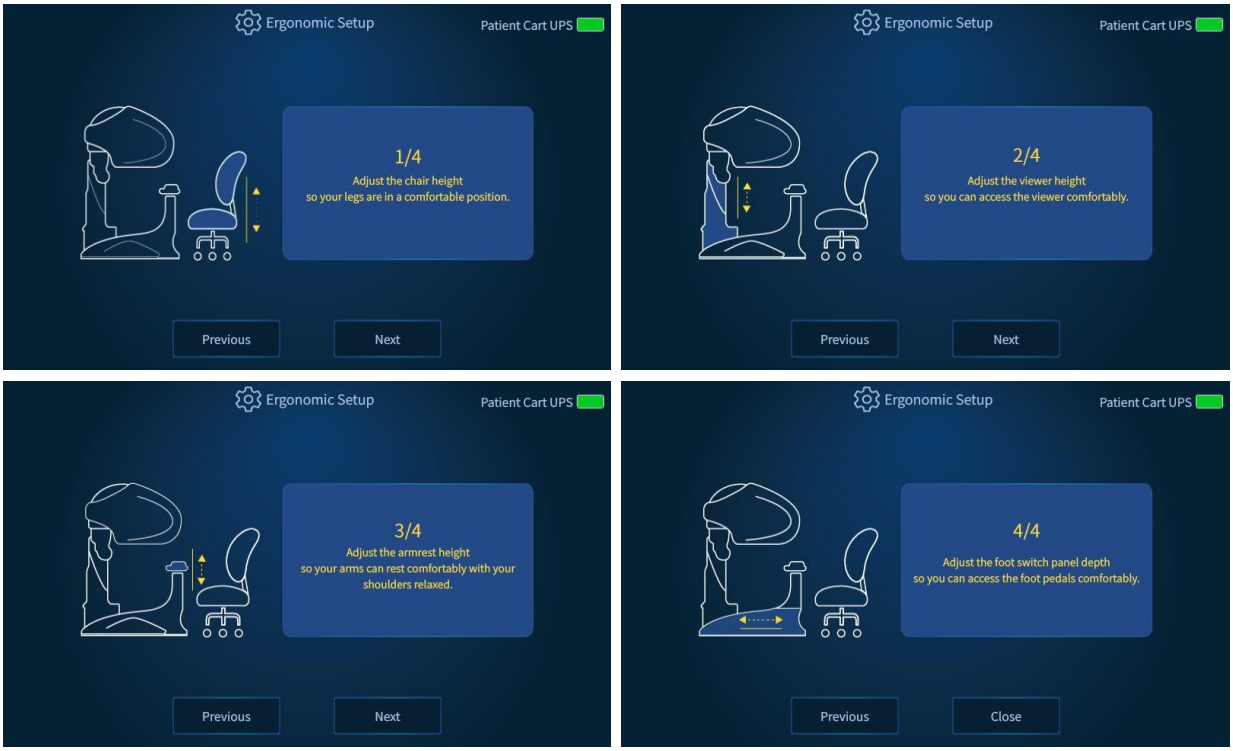
2. Enter the name and password of a new account.



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.

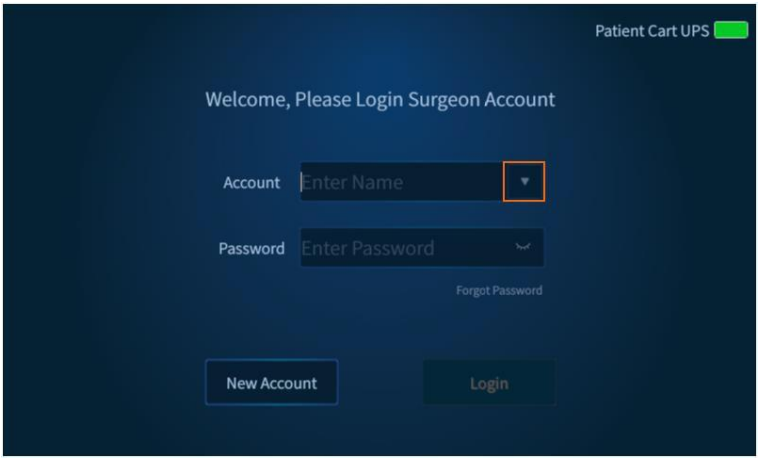
10.2.4 Save Settings

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.

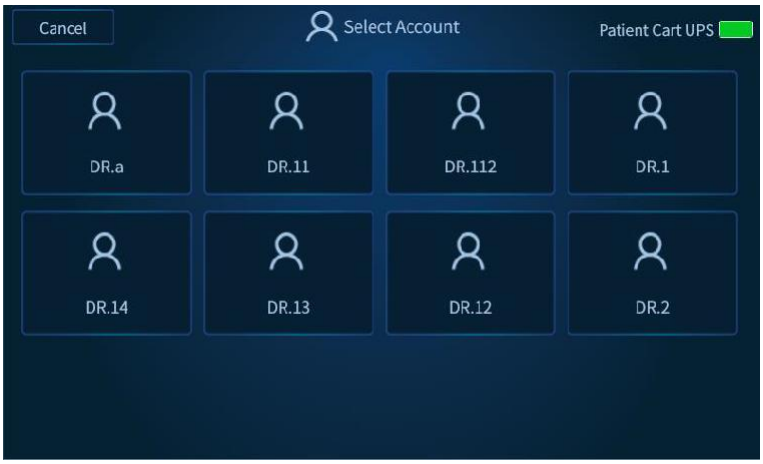


10.2.5 Select Accounts

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



2. Select an account from the user list.



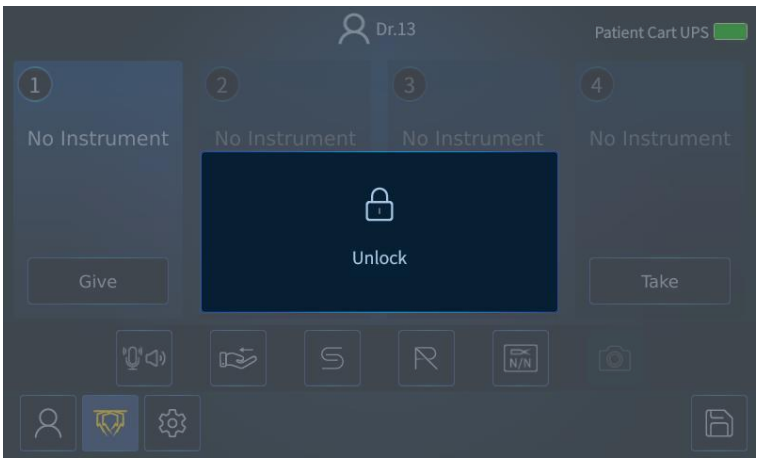
3. Enter the password to log in to the account.



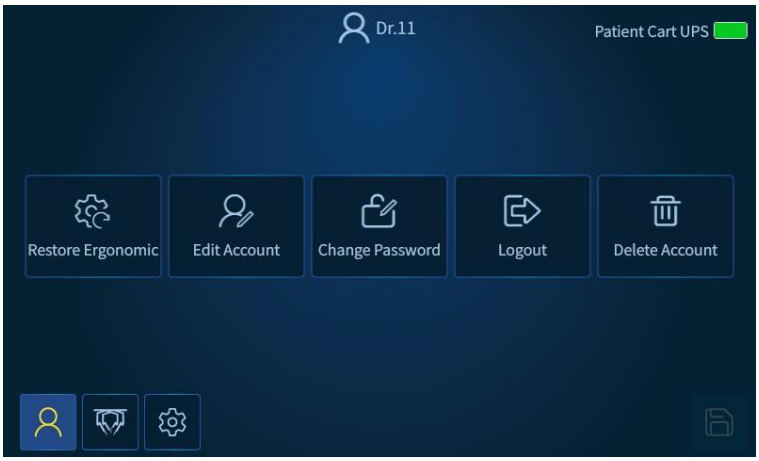
10.2.6 Lock Touchscreen

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



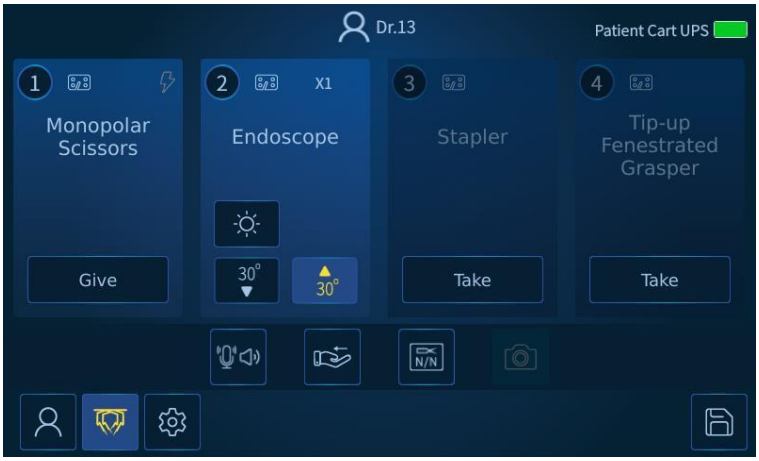
After logging in to an account, the following settings are available:

- 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 must be 1～16 characters, including letters or numbers, case-sensitive, and no spaces, Chinese character or other special characters.
- 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.



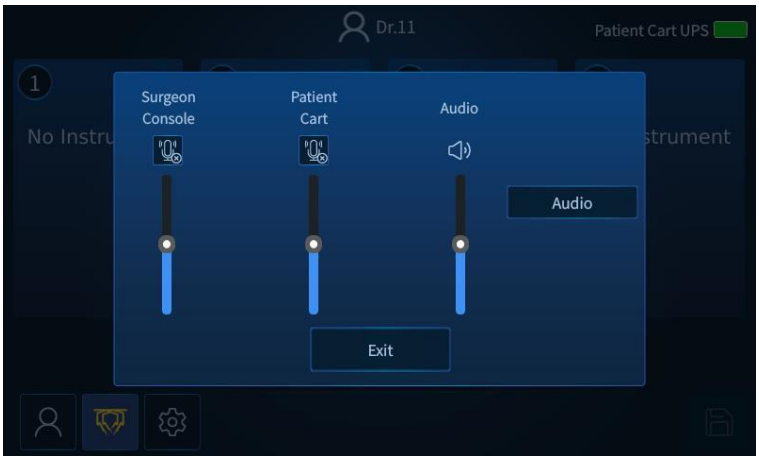
Instrument/Endoscope Status Box

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: Used to adjust visible light in the Surgeon Console viewer.
  - Fluorescence Button: Used to toggle between fluorescence imaging and visible light imaging.
  - 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

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



- : 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.



- 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.
- : It is the button for viewing the uses remaining summary. The number on the left represents the uses it has been used, and the number on the right represents its maximum uses.

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

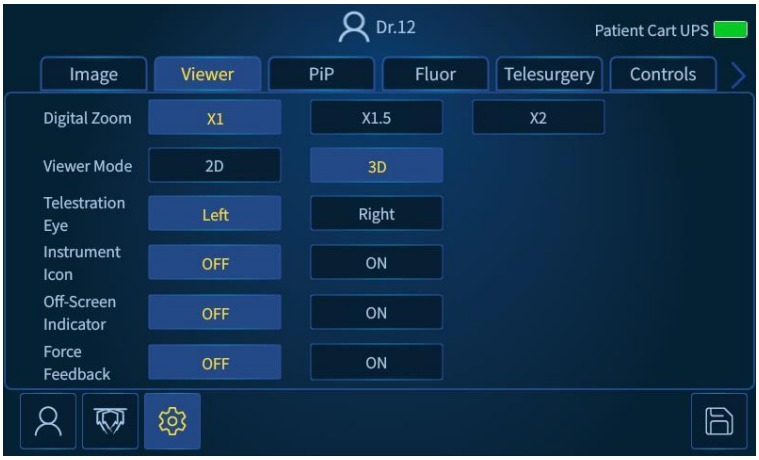
Image

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 brightness of the image during fluorescence imaging.
- 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 the settings to enhance image sharpness.
- Vessel Enhancement: The feature is OFF by default. Tap **ON** to turn Vessel Enhancement on to enhance the vessel image display, but affect tissue imaging except vessels.
- Image Denoising: 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.
- 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 and right-eye.
- Instrument Icon: The instrument icon provides visual cues to see which an instrument is controlled from 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 message appears on the screen. Adjust the endoscope view so that it points towards the indictor until the instrument is in the field of view.
- Force Feedback: When the Force Feedback is ON, the instrument force feedback appears on the screen. During the process of closing the instrument grip, the status indicators change.
- Working Distance: Enhances the ability to see a fused 3D image when the endoscope works at **Normal** or **Close Up** distances.

PiP

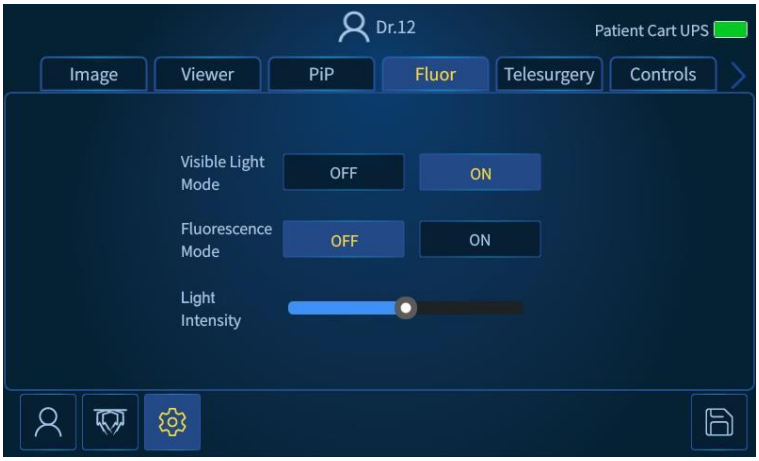
Tap the **PiP** button to view the picture in picture settings section.



- 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 quickly switch to picture in picture by pressing 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.
- PiP Shortcut: Hide or show the shortcut key of Picture in Picture.

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 and displays the images in real color.

- 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.
- Fluorescence Fingerswitch: When the Fluorescence Fingerswitch is on, the finger clutch can be used to toggle between visible light and fluorescence imaging.

Controls

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



- Scaling: Scale the sensitivity of the master controls in relation to the instruments. **Quick** (1.5:1), **Normal** (2:1) and **Fine** (3:1) ratios.
- 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.

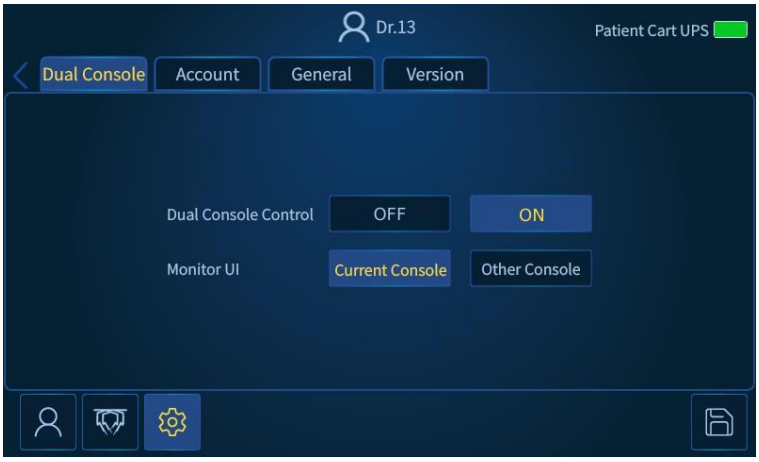
Note: In dual console mode, either surgeon can use the Master Control Assignments to reassign instruments to different master controls, even while the

other surgeon has control of the instruments. The new instrument assignment applies on both consoles and persists when instruments are swapped.

- Console Router/Cart Router/Signal Distributor Router: Tap the **Reset** button to reset the router of the Surgeon Console, the Patient Cart or the Signal Distributor to factory defaults. The settings can be shown only after logging in to the admin account.

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: Select system language. The components connected with the Surgeon Console change 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 backup battery 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 backup battery 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 being controlled by the master controls.

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

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

to activate the Bipolar Forceps's secondary energy mode (CONV).



Figure 10.9 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.

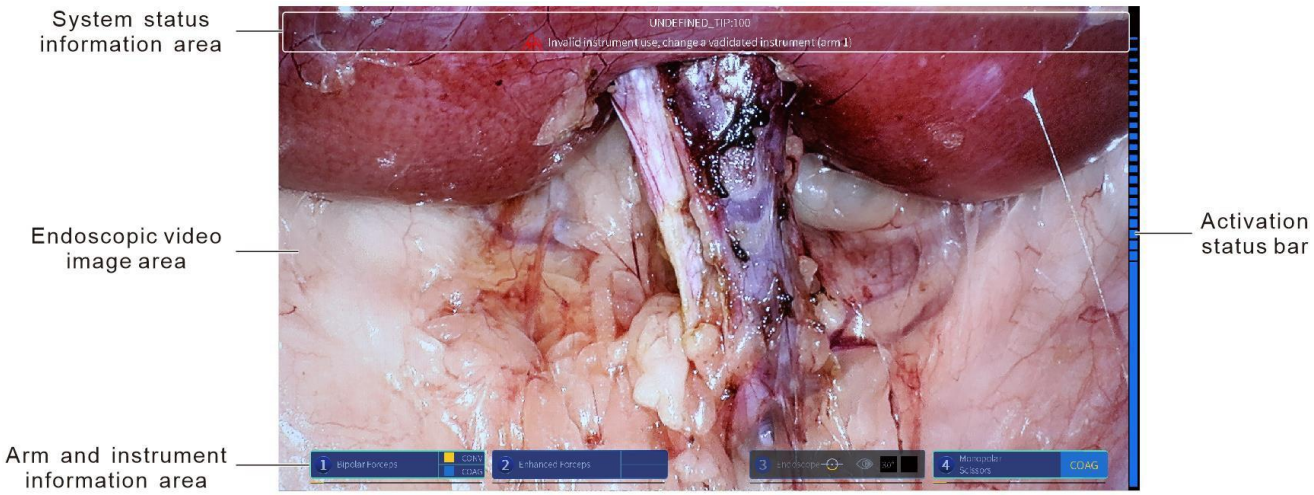


Figure 10.10 Viewer Display

- 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 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



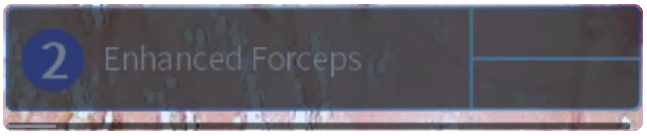
-  : Indicates the number of the Patient Cart arm.
-  : Indicates the name of the endoscope.

-  : 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.
-  : Indicates the view direction of the endoscope.
-  : Indicates the digital zoom of the endoscope.

10.4.2 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.

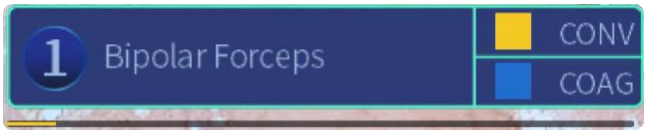
- Instrument Status:
  - Instrument not in use: Displays gray



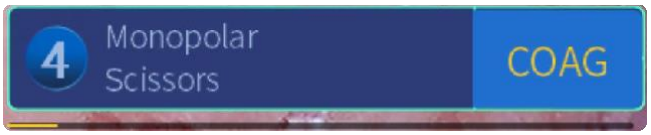
  - Instrument to be activated: Illuminates background



  - Instrument activated: Illuminates background and highlights borders



-  : Indicates the number of the Patient Cart arm.
-  : Indicates the name of the instrument.
-  : 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.



10.4.3 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.

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

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

10.5.2 Dual Console Connection

Perform the following steps to connect the second Surgeon Console:

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

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

3. Connect the camera cable.

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

10.5.3 Instrument Control

When the system detects two Surgeon Consoles in use, the **Give/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.

10.6 Insufflator Use

10.6.1 Insufflator Overview

An insufflator in conjunction with the system is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with medical grade CO_2 gas, to create and maintain a gas-sealed obstruction-free path of entry for endoscopic instruments and to evacuate surgical smoke.

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.

10.6.2 Insufflator Connection

The communicator port of the insufflator is a network port. The insufflator is connected to the system through the debugging port of the Camera Control Unit or the Signal Distributor.

10.6.3 Insufflator Operation

Power On/Off

After the insufflator is connected to the system, press any individual **Power** button on the Surgeon Console or Patient Cart to power on the insufflator. The system cannot be powered on/off by pressing the **Power** button on the insufflator.

Insufflator Tab

After the insufflator is connected to the system, the Insufflator tab appears on the Surgeon Console touchscreen. Tap the button to enter into the Insufflator tab, which dynamically displays the gas flow rate, pressure, smoke evacuation level, gas supply volume and method, etc.

Operating Mode Selection

The insufflator can be used with three different insufflation operating modes: AirSeal Mode, Smoke Evacuation Mode and Standard Insufflation Mode. Select the desired operating mode prior to a procedure.

Configuring Settings:

The user can configure the following settings:

- Standard Insufflation Mode: Flow Rate, Pressure, Supply Volume, Supply Method
- Smoke Evacuation Mode: Flow Rate, Pressure, Smoke Evacuation, Supply Volume, Supply Method
- AirSeal Mode: Flow Rate, Pressure, Smoke Evacuation, Supply Volume, Supply Method

11. Shutdown and Storage

11.1 Preparation for Shutdown

1. Remove the instruments and endoscope from the Patient Cart. See 9.6.6 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 6.6 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. See the Reprocessing Instruction Manuals for details.
8. Clean the Patient Cart, Surgeon Console, Camera Control Unit, Signal Distributor and Endoscope Illuminator. See 12.1 Cleaning for details.
9. Stow the instrument arms and the Patient Cart. See 9.7 Stowing the Patient Cart for details.

11.2 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 and the Signal Distributor 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.

11.3 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.

12. System Maintenance

12.1 Cleaning

Clean the Patient Cart, Surgeon Console, Camera Control Unit, Signal Distributor and Endoscope Illuminator at the frequency required by individual hospital policy. When cleaning, inspect the equipment for broken, cracked, chipped, or worn parts. Do not use the equipment and contact the company for technical support if it is damaged.

Perform the cleaning steps as follows:

1. Power off the system and unplug to AC power.
2. Wear protective gloves.
3. Moisten a sterile lint-free cloth with a diluted mixture of mild, neutral pH detergent and water and wipe the external surfaces of the system components that need to be cleaned.
4. After cleaning, use a new sterile lint-free cloth to absorb an appropriate amount of tap 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 and disinfection.



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 or disinfect the system components.

12.2 Disinfection

Disinfecting the Patient Cart, Surgeon Console, Camera Control Unit, Signal Distributor and Endoscope Illuminator ensures safety. Perform the disinfection steps as follows:

1. Power off the system and unplug to AC power.
2. Wear protective gloves.

3. Use a sterile lint-free cloth soaked in 75% alcohol to wipe clean the external surfaces of the system components that need 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 disinfection 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 and disinfection.



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 or disinfect the system components.

12.3 Reprocessing

For complete reprocessing information, refer to the Reprocessing Instruction Manuals.

Fluorescence endoscopes, Maryland bipolar forceps, bipolar forceps, enhanced bipolar forceps, needle driver, large needle driver, monopolar scissors, monopolar hook, enhanced forceps, Cadiere forceps, tip-up fenestrated grasper, cannulas, obturators, Light guide bundless, monopolar energy instrument cord and bipolar energy instrument cord are shipped non-sterile and should be cleaned and sterilized thoroughly before first use and after every use.



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



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



Note: The wet step in the operating room should begin within 60 minutes and it is recommended to begin reprocessing steps immediately after the procedure to avoid residual soil drying out on devices.

12.4 Sterilization Methods and Parameters

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

Warning: Only sterilization methods and parameters verified by the company can be used. Unverified sterilization methods (such as chemical sterilization) or parameters (such as too high or too low sterilization temperature) may cause damage or incomplete sterilization.

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

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

Note: All endoscopes must be properly aerated following ethylene oxide sterilization to remove toxic ethylene oxide residuals.

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

12.4.1 Reusable Parts

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

Table 12.1 Sterilization Methods and Parameters

Part Name	Part Number	Sterilization Method	Sterilization Parameter
Maryland Bipolar Forceps	MP1302	Pre-vacuum steam sterilization	• Temperature: 132℃ • Exposure time: 4 minutes • Dry time: 30 minutes Based on the packing system, steam quality, load capacity of the sterilizer and environment conditions, the dry time may be different, 30 minutes recommended by the company. Dry time
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		

Part Name	Part Number	Sterilization Method	Sterilization Parameter
Large Needle Driver	MP1324		should be determined according to hospital policy.
Monopolar Scissors	MP1311		
Monopolar Hook	MP1314		
Enhanced Forceps	MP1318		
Enhanced forceps	MP4-PG-P		
Cadiere Forceps	MP1320		
Cadiere Forceps	MP4-NRG-P		
Tip-up Fenestrated Grasper	MP1322		
Cannula	TR1-A8I		
Cannula	TR1-A8E		
Cannula	TR1-A12		
Cannula	TR1-A15		
Long Cannula	TR1-A8I-L		
Long Cannula	TR1-A8E-L		
Long Cannula	TR1-A12-L		
Long Cannula	TR1-A15-L		
Blunt Obturator	TR2-A8IB		
Blunt Obturator	TR2-A8EB		
Blunt Obturator	TR2-A12B		
Blunt Obturator	TR2-A15B		
Prismatic Obturator	TR2-A8IP		

Part Name	Part Number	Sterilization Method	Sterilization Parameter
Prismatic Obturator	TR2-A8EP		
Prismatic Obturator	TR2-A12P		
Prismatic Obturator	TR2-A15P		
Long Blunt Obturator	TR2-A8IB-L		
Long Blunt Obturator	TR2-A8EB-L		
Long Blunt Obturator	TR2-A12B-L		
Long Blunt Obturator	TR2-A15B-L		
Long Prismatic Obturator	TR2-A8IP-L		
Long Prismatic Obturator	TR2-A8EP-L		
Long Prismatic Obturator	TR2-A12P-L		
Long Prismatic Obturator	TR2-A15P-L		
Monopolar Energy Instrument Cord	MS1801		
Bipolar Energy Instrument Cord	MS1802		
Light guide bundles	CM1810		
	CM1811		
Fluorescence Endoscope	MP1212/ MP1213	Low temperature hydrogen peroxide plasma sterilization	• Sterilization mode: Full cycle mode (Full cycle) • Injection volume: 4.5 mL*2 times • Temperature: 55℃±5℃ • Cabin pressure: ≤65 Pa • Main component and content: H_2O_2

Part Name	Part Number	Sterilization Method	Sterilization Parameter
			concentration (2800～3200 mg)*s/L (56%～63%)

12.4.2 Disposable Parts

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

Table 12.2 Sterilization Methods

Part Name	Part Number	Sterilization Method
Disposable Ultrasonic Scalpel	MP1500	Ethylene oxide sterilization
Reducer	TR4-A8/5	Ethylene oxide sterilization
Reducer	TR4-A12/8	Ethylene oxide sterilization
Reducer	TR4-A15/8	Ethylene oxide sterilization
Cannula Seal	TR3-A8	Ethylene oxide sterilization
Cannula Seal	TR3-A8E	Ethylene oxide sterilization
Cannula Seal	TR3-A12	Ethylene oxide sterilization
Cannula Seal	TR3-A15	Ethylene oxide sterilization
Tip Cover Accessory	MP1402	Ethylene oxide sterilization
Installation Tool	MP1801	Ethylene oxide sterilization
Disposable Drape	DR1001	Ethylene oxide sterilization
Disposable Drape	DR1003	Ethylene oxide sterilization

12.5 Replacing Accessories

12.5.1 Fuse Replacement

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

Table 12.3 Fuse Parameters

Part Number	Specification	System Component
0218005.MXP	T5AL250VP	Surgeon Console
0218015.MXP	T15AL250VP	Patient Cart
0218001.MXP	T1AL250VP	Camera Control Unit
0218001.MXP	T1AL250VP	Signal Distributor
0218002.MXP	T2AL250VP	Endoscope Illuminator

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

Perform the replacing steps as follows:



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

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

12.5.2 Instrument and Endoscope Replacement

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

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

12.6 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 backup battery, 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 the authorized personnel at least 2 years.

Battery Maintenance

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

- The backup battery 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 backup battery.
  - 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 battery 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 battery near heat or open flame.
- After the battery is discharged, charge the battery fully in time (at least no more than 24 hours) to avoid affecting the service life.
- Avoid overdischarge, or it may affect the capacity of the battery.
- When the battery is not used for a long time, it is required to charge the battery 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 battery at least once every 4～6 months, and the time for charging is no less than 4 hours.

12.7 Technical Support

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

12.8 Disposal

12.8.1 System Components

Do not use system components once they exceed the service life.

When disposing of all components, including the Surgeon Consoles, Patient Cart, Signal Distributor, Endoscope Illuminator, instruments, accessories, or any of their components, follow all applicable national and local laws and guidelines.

Discard all disposable instruments and accessories after each use and/or expiration in accordance with the laws and regulations of medical waste.

12.8.2 Battery

The Patient Cart contains a backup battery. If the battery 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 battery.

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

13. System Troubleshooting

13.1 Conversion to Open Surgery

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

1. Remove the instruments from the patient.
   a. If necessary, release the instrument grips with the master controls of the Surgeon Console.
   b. If the instrument grips cannot be released, see 9.6.7 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 13.8.1 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.

13.2 Recoverable Faults and Non-Recoverable Faults

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

- 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.

13.2.1 Recoverable Faults

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

- Tap the **Recover** button on the touchscreen of the Surgeon Console or Patient Cart.
- 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.

13.2.2 Non-Recoverable Faults

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

Intraoperative Restart

If an unrecoverable fault occurs during the procedure, the instruments and endoscope need to be removed from the patient and the 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.

13.3 Emergency Stop

Surgeon Console

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

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

Regarding the **Emergency Stop** button while the instruments are grasping tissue, see 9.6.7 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 9.6.7 Emergency Grip Release.

- Non-Recoverable faults

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

13.4 No Response to System

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

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

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

13.5 Abnormal System Connection

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

13.6 System Power Problems

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

problem might cause power-down problems.

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

13.6.1 Checking Connections

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

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

13.6.2 Hard-Cycle Power on System

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

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

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

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

4. Turn on the power switches of the system components.

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

13.7 System Overheating

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

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

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

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

Note: Follow the steps for standby restart properly.

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

13.8 Patient Cart Faults

13.8.1 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.

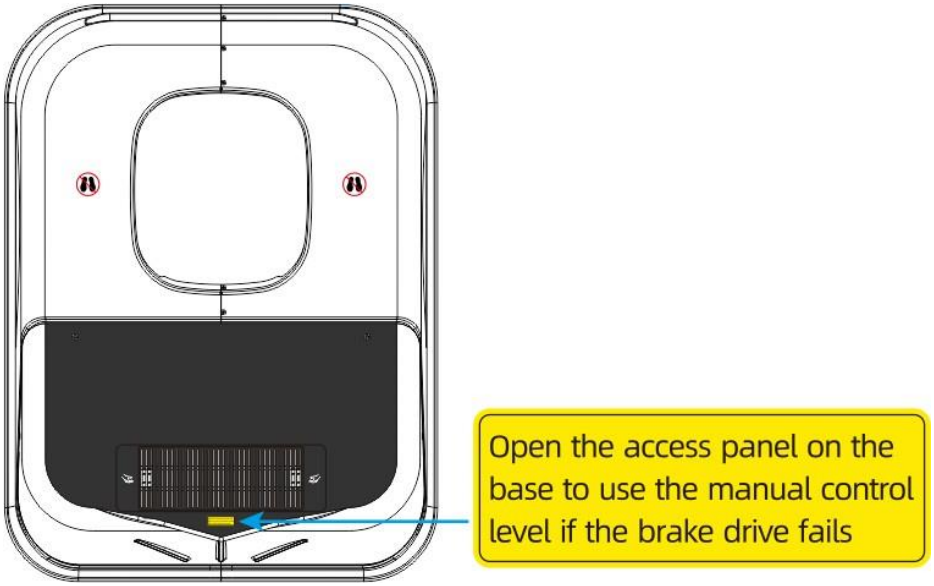
Note: It is recommended that two people move the Patient Cart manually due to the high force required.

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.

13.8.2 Backup Battery

The Patient Cart must not be powered off. Otherwise, the system will alert that it is running on battery power and advises to plug-in the Patient Cart to avoid loss of power. The system will allow to continue operation on backup battery. The UPS LED indicator shows the power of the backup battery, flashing indicates loss of AC power and running on backup battery power, and solid red indicates that the battery power is low. See 9.1.4 LED Indicators for details.

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

Note: If the backup battery cannot be used, it must be replaced by authorized

personnel only. Please contact the company for technical support.

13.8.3 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.

13.8.4 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.

13.9 Vision System Faults

Table 13.1 Endoscope Faults

Fault	Possible Cause	Solution
Image too bright or dark	The glass surfaces on the endoscope are smudged or soiled.	Clean the glass surfaces after removing the endoscope and turning off the illumination.
Image blurring	The glass surfaces on the endoscope are smudged or soiled.	Clean the glass surfaces after removing the endoscope and turning off the illumination.
No image	No illumination.	Connect the endoscope to the Endoscope Illuminator.

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

Table 13.2 Camera Control Unit Faults

Problem	Possible Cause	Possible Solution
Cannot power on	The Camera Control Unit is not connected to the power supply.	Connect to the power supply.
	The power cord is not connected properly.	Ensure the power cord is properly connected.
	The fuse is blown.	Replace the fuse.
	The power switch is set to the off position.	Set the power switch to the on position.

Problem	Possible Cause	Possible Solution
Image too bright or dark	The image brightness set too high or low.	Set image brightness via the  button on the Camera Control Unit or via the Surgeon Console. See 7.8.6 Image Brightness.
Image flickering	Flickering happens during cautery	Connect to the dedicated power supply separately and keep away from high frequency equipment. If necessary, replace the endoscope and restart the system.
Image blurring	The image is zoomed out too much.	Set digital zoom via the  button on the Camera Control Unit or via the Surgeon Console. See 7.8.8 Digital Zoom.
Color cast	The system needs white balancing manually.	Activate white balance via the  button on the Camera Control Unit or via the Surgeon Console. See 7.8.5 3D Calibration and White Balance.

Table 13.3 Endoscope Illuminator Faults

Problem	Possible Cause	Possible Solution
Cannot power on	The Endoscope Illuminator is not connected to the power supply.	Connect to the power supply.
	The power cord is not connected properly.	Ensure the power cord is properly connected.
	The fuse is blown.	Replace the fuse.
	The power switch is set to the off position.	Set the power switch to the on position.

Problem	Possible Cause	Possible Solution
No light output	The Light guide bundles is not connected properly.	Ensure the Light guide bundles is properly connected.
	The Light guide bundles is damaged	Replace the Light guide bundles.
	Soiling or residues remain inside the connectors of the endoscope or the Light guide bundles.	Clean the connectors of the endoscope or the Light guide bundles with a clean cotton swab moistened with 75% alcohol.
	Endoscope Illuminator failure	Check the power supply, the fuse and operating status. Restart required and contact the company if the problem persists.
Flickering image	Flickering happens during cautery.	Connect to the dedicated power supply separately and keep away from high frequency equipment.
	The Light guide bundles is not connected properly.	Connect the Light guide bundles properly after removing the endoscope and powering off the Endoscope Illuminator.

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

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

13.10 Other Faults

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

14. System Alarm

14.1 Alarm Overview

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

The alarm list contained in the system is as follows:

Alarm Name	Description	Position
Position deviation of master controls	When the master controls match the instruments, the desired position deviates from the actual position.	Surgeon Console
Unexpected motion of master controls	When operating in non-following mode, unexpected motion occurs to the master controls due to external interference.	Surgeon Console
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 expired instrument or an instrument not supplied by the company, the system prompts invalid instrument use.	Patient Cart

14.2 Alarm Type

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

Alarm Name	Alarm Type
Position deviation of master controls	Technical alarm
Unexpected motion of master controls	Technical alarm
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

14.3 Priority and Preset

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

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

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

14.4 Alarm Signal

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

When a medium or high priority alarm tone sounds, the system allows the user to temporarily mute or unmute the alarm tone on the touchscreen if the fault is not resolved.

Priority	Alarm Icon	Text message	Alarm Tone	LED indicator
Low priority		Desired position deviation of master controls, tap **Recover** on the touchscreen.	Only 1 group of alarm tones sounds and each group contains 2 beeps.	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

Priority	Alarm Icon	Text message	Alarm Tone	LED indicator
		Unexpected motion of arms, tap **Recover** on the touchscreen.	The alarm tones repeat in groups, each group contains 3 beeps and the interval between 2 groups is 10 seconds.	No
		Abnormal system communication, check connections of system cables		No
		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.	The alarm tones repeat in groups, each group contains 10 beeps and the interval between 2 groups is 5 seconds.	No

14.5 Alarm Condition

The alarm condition of the system includes:

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

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

14.6 Alarm Elimination

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

Alarm Name	Operation Method
Position deviation of master controls	Adjust the position of the master controls, be careful not to disengage completely, and then tap **Recover** on the touchscreen.
Unexpected motion of master controls	Tap **Recover** on the touchscreen after resolving the external interference.
Position overlimit of arms	Adjust the position of the arms, and then tap **Recover** on the touchscreen.
Position deviation of arms	Remove the obstacles at the range of motion or arrange the arms, and then tap **Recover** on the touchscreen.
Unexpected motion of arms	Prevent the external interference, and then tap **Recover** on the touchscreen.
Adaptors drop abnormally	Reset on the touchscreen after removing the instrument and the adaptor, and then reinstall the instrument and the adaptor.
Abnormal system communication	Re-connect the system cables.
Invalid instrument use	Replace the instrument and use the specified instrument during its service life.

14.7 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.

Appendix A System Specifications

A.1 Power Specifications

System Component	Voltage	Rating and Typical Current	Fuse	Backup Power
Surgeon Console	220 VAC 50 Hz	600 VA Continuous	T5AL250VP	No
Patient Cart	220 VAC 50 Hz	1000 VA continuous	T15AL250VP	6 minutes
Camera Control Unit	220 VAC 50 Hz	100 VA continuous	T1AL250VP	No
Signal Distributor	220 VAC 50 Hz	100 VA continuous	T1AL250VP	No
Endoscope Illuminator	220 VAC 50 Hz	200 VA continuous	T2AL250VP	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: 220 VAC, 50 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: 220 VAC, 50 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: 220 VAC, 50 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: 220 VAC, 50 Hz
- Power input: 100 VA
- No defibrillation-proof applied part
- Equipped with signal output or input part
- Non-permanently installed equipment

A.3.5 Endoscope Illuminator

- Continuous operation
- Power supply and operating frequency: 220 VAC, 50 Hz
- Power input: 200 VA
- Class Ⅰ equipment
- Type BF applied part
- IPX0 ingress protection

- Safety classification when using in environments with flammable anesthetic mixture of air, oxygen and/or nitrous oxide: Not compliant
- No defibrillation-proof applied part
- Equipped with signal output or input part
- Non-permanently installed equipment

A.3.6 Instruments

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

A.3.7 Ultrasonic Scalpel

- Type of protection against electric shock: Provided by the generator
- Degree of protection against electric shock: CF applied part
- Ingress protection: Not applicable
- Safety classification when using in environments with flammable anesthetic mixture of air, oxygen and/or nitrous oxide: Not applicable
- Mode of operation: Non-continuous, the maximum activation (on) time is 10 seconds and the minimum deactivation (off) time is 2 seconds
- Power supply, operating frequency and power input: Provided by the generator
- Defibrillation-proof applied part and signal output or input part: Not applicable
- Non-permanently installed equipment

A.3.8 Fluorescence Endoscopes

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

A.4 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 and Weights

A.5.1 Surgeon Console

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

A.5.2 Patient Cart

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

A.5.3 Camera Control Unit

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

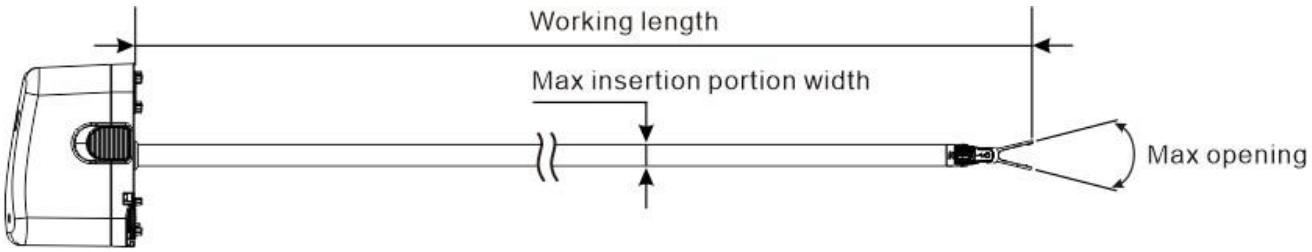
A.5.4 Signal Distributor

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

A.5.5 Endoscope Illuminator

L×W×H	Weight
450 mm×300 mm×110 mm	Approx. 11 kg

A.6 Instrument Specifications



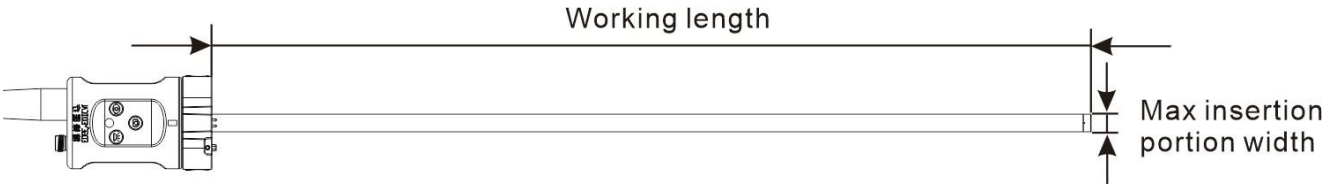
Part Name	Part Number	Max Insertion Portion Width	Working Length (Tolerance ±3%)	Maximum Opening (Tolerance ±20%)
Maryland Bipolar Forceps	MP1302	≤9.5 mm	580 mm	45°
Maryland Bipolar Forceps	MP4-BM-P	≤9.5 mm	580 mm	45°

Part Name	Part Number	Max Insertion Portion Width	Working Length (Tolerance ±3%)	Maximum Opening (Tolerance ±20%)
Bipolar Forceps	MP1305	≤9.5 mm	580 mm	45°
Bipolar forceps	MP4-BF-P	≤9.5 mm	580 mm	45°
Enhanced Bipolar Forceps	MP1316	≤9.5 mm	590 mm	40°
Enhanced Bipolar forceps	MP4-FB-P	≤9.5 mm	590 mm	40°
Enhanced Forceps	MP1318	≤9.5 mm	590 mm	40°
Enhanced forceps	MP4-PG-P	≤9.5 mm	590 mm	40°
Cadiere Forceps	MP1320	≤9.5 mm	580 mm	45°
Cadiere Forceps	MP4-NRG-P	≤9.5 mm	580 mm	45°
Tip-up Fenestrated Grasper	MP1322	≤9.5 mm	590 mm	45°
Needle Driver	MP1308	≤9.5 mm	570 mm	40°
Needle Driver	MP4-ND-P	≤9.5 mm	570 mm	40°
Large Needle Driver	MP1324	≤9.5 mm	575 mm	40°

Part Name	Part Number	Shaft Diameter	Working Length (Tolerance ±3%)	Maximum Opening (Tolerance ±20%)
Monopolar Scissors	MP1311	≤9.5 mm	570 mm	45°

Part Name	Part Number	Max Insertion Portion Width	Working Length (Tolerance ±3%)
Monopolar Hook	MP1314	≤9.5 mm	580 mm

A.7 Endoscope Specifications



Part Name	Part Number	Max Insertion Portion Width	Working Length (Tolerance ±3%)	Weight
Fluorescence endoscope	MP1212	≤10.5 mm	500 mm	Approx. 855 g
Fluorescence endoscope	MP1213	≤10.5 mm	500 mm	Approx. 855 g

A.8 Drape Specifications

Part Name	Part Number	Length and Tolerance	Width and Tolerance	Thickness
Arm drape	DR1001	240 cm±20 cm	70 cm±5 cm	≥0.03 mm
Column drape	DR1003	180 cm±15 cm	100 cm±10 cm	≥0.03 mm

A.9 Cannula Specifications

Part Name	Part Number	Min Inner Diameter		Working Length	
		Diameter	Tolerance	Diameter	Tolerance
Cannula	TR1-A8I	9.5 mm	±0.3	108.0 mm	±2

Part Name	Part Number	Min Inner Diameter		Working Length	
		Diameter	Tolerance	Diameter	Tolerance
Cannula	TR1-A8E	10.6 mm	0	108.0 mm	
Cannula	TR1-A12	14.4 mm		108.0 mm	
Cannula	TR1-A15	15.6 mm		108.0 mm	
Long Cannula	TR1-A8I-L	9.5 mm		158.0 mm	±2%
Long Cannula	TR1-A8E-L	10.6 mm		158.0 mm	
Long Cannula	TR1-A12-L	14.4 mm		158.0 mm	
Long Cannula	TR1-A15-L	15.6 mm		158.0 mm	

A.10 Obturator Specifications

Part Name	Part Number	Top Diameter		Working Length	
		Diameter	Tolerance	Diameter	Tolerance
Blunt Obturator	TR2-A8IB	9.4 mm	±0.3 0	190.0 mm	±2%
Blunt Obturator	TR2-A8EB	10.5 mm		192.0 mm	
Blunt Obturator	TR2-A12B	14.3 mm		196.0 mm	
Blunt Obturator	TR2-A15B	15.5 mm		198.0 mm	
Prismatic Obturator	TR2-A8IP	9.4 mm		189.0 mm	
Prismatic Obturator	TR2-A8EP	10.5 mm		191.0 mm	
Prismatic Obturator	TR2-A12P	14.3 mm		197.0 mm	
Prismatic Obturator	TR2-A15P	15.5 mm		199.0 mm	
Long Blunt Obturator	TR2-A8IB-L	9.4 mm		240.0 mm	
Long Blunt Obturator	TR2-A8EB-L	10.5 mm		242.0 mm	
Long Blunt Obturator	TR2-A12B-L	14.3 mm		246.0 mm	
Long Blunt Obturator	TR2-A15B-L	15.5 mm		248.0 mm	
Long Prismatic Obturator	TR2-A8IP-L	9.4 mm		239.0 mm	
Long Prismatic Obturator	TR2-A8EP-L	10.5 mm		241.0 mm	

Part Name	Part Number	Top Diameter		Working Length	
		Diameter	Tolerance	Diameter	Tolerance
Long Prismatic Obturator	TR2-A12P-L	14.3 mm		247.0 mm	
Long Prismatic Obturator	TR2-A15P-L	15.5 mm		249.0 mm	

A.11 Cannula Seal Specifications

Part Name	Part Number	Inner Diameter		Outer Diameter	
		Diameter	Tolerance	Diameter	Tolerance
Cannula Seal	TR3-A8	7.5 mm	±0.5	44.0 mm	±5.0
Cannula Seal	TR3-A8E	7.5 mm		44.0 mm	
Cannula Seal	TR3-A12	10.0 mm		44.0 mm	
Cannula Seal	TR3-A15	10.0 mm		44.0 mm	

A.12 Reducer Specifications

Part Name	Part Number	Min Inner Diameter		Working Length	
		Diameter	Tolerance	Diameter	Tolerance
Reducer	TR4-A8/5	5.7 mm	±0.3 0	154.0 mm	±2%
Reducer	TR4-A12/8	9.5 mm		154.0 mm	
Reducer	TR4-A15/8	9.5 mm		154.0 mm	

A.13 Tip Cover Accessory Specifications

Part Name	Part Number	Effective Length (Tolerance ±10%)	Max Outer Diameter (Tolerance ±1)
Tip Cover Accessory	MP1402	45.0 mm	8.9 mm

A.14 Installation Tool Specifications

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

A.15 Ports

A.15.1 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	Connects to the power cord for power supply.
6	Debugging port	Used for equipment debugging by technicians.

A.15.2 Patient Cart

No.	Port Name	Description
1	Power inlet	Connects 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	Debugging port	Used for equipment debugging by technicians.

A.15.3 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	Connects to the power cord for power supply.
2	Debugging port	Used for equipment debugging by technicians.
3	MV (Master-Video) communication port	Connected to MV communication port of the Signal Distributor for image processing.
4	Energy control	Connected to energy equipment, such as ultrasonic generator or high frequency generator, and illuminator
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.15.4 Signal Distributor

No.	Port Name	Description
1	Power inlet	Connects 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.
5	MV (Master-Video) communication	Connected to MV communication port of the Camera Control Unit for image processing.

No.	Port Name	Description
6	Debugging port	Used for equipment debugging by technicians.

A.16 HF Output Characteristics

Part Name	Part Number	Rated Voltage
Maryland Bipolar Forceps	MP1302	Coagulation, 375 V
Maryland Bipolar Forceps	MP4-BM-P	Coagulation, 375 V
Bipolar Forceps	MP1305	Coagulation, 375 V
Bipolar forceps	MP4-BF-P	Coagulation, 375 V
Enhanced Bipolar Forceps	MP1316	Coagulation, 375 V
Enhanced Bipolar forceps	MP4-FB-P	Coagulation, 375 V
Bipolar energy instrument cord	MS1802	Coagulation, 375 V
Monopolar Scissors	MP1311	Cutting, 3 kV
Monopolar Hook	MP1314	Cutting, 3 kV
Monopolar energy instrument cord	MS1801	Cutting, 3 kV

A.17 Ultrasonic Scalpel Properties

- Primary tip vibration excursion: 30 μm～100 μm
- Primary acoustic output area less than 2.5 mm^2, secondary acoustic output area less than 25 mm^2
- At reference primary tip vibration excursion, the derived output acoustic power less than 30 W
- Primary tip vibration excursion modulation: 100%
- Tip vibration frequency/Drive frequency: 55.5 kHz±1 kHz

A.18 Endoscope Illuminator Properties

Parameter	Value
Laser product classification	Class 3R laser product, complies with IEC 60825-1
Laser wavelength	808 nm±10 nm

Parameter	Value
Laser power	≤ 2.4 W
Pulse width and repetition frequency	Continuous laser energy
Divergence angle	60°
Service life of lamp	20000 hours
Maximum noise emission	Less than 55 dB
Correlated color temperature	In the range of 3000 K～7000 K
Light guide bundles port	Φ7.1 mm × 48.8 mm (D × L) , tolerance ±0.5 mm
Light guide bundles	Model CM1810, 3 m length, tolerance ±5%
	Model CM1811, 5 m length, tolerance ±5%

A.19 Optical and Illumination Properties

Parameter	Value
View field (2 W)	80°, tolerance ±15%
View direction	MP1212: 0°, tolerance ±3°
	MP1213: 30°, tolerance ±3°
IL_{eR}(Relative self-effect of illumination light luminosity)	At the working distance of 5 cm, the nominal value of IL_{eR} at 90% of view field is 0.56, and the measured value is not less than the nominal value
Brightness response characteristic	The linear fitting coefficient of EOTF (Electro-optical Transfer Function) is not less than 0.98
Signal-to-noise ratio	50 dB, tolerance -20%, no upper limit
SFR (Spatial frequency response)	At the working distance of 5cm, the corresponding objective spatial angular frequency is 3.0 C/(°) and 4.0 C/(°) when the SFR is 50% and 30%, tolerance -20%, no upper limit

Parameter	Value
Static image tolerance	180, tolerance -20%, no upper limit
Effective luminosity rate	The image surface of the endoscope displays that the minimum surface brightness of critical noticeable grayscale difference is 30 cd/m^2
Image resolution (frames per second)	No less than 60 fps
Color rendering index	No less than 70
Correlated color temperature	In the range of 5000 K～7000 K
Radiation flux ratio of red, green and blue light	Based on the green radiation flux φ_{eg} in the wavelength range of 515 nm～545 nm, the ratio of the red radiation flux φ_{er} and φ_{eg} in the wavelength range of 630 nm～660 nm is 0.35, tolerance ±20% And the nominal value of the ratio of the blue radiation flux φ_{eb} and φ_{eg} in the wavelength range of 435 nm～465 nm is 1.70, tolerance ±20%
Infrared cut properties	The ratio of radiation and luminous flux in the wavelength range of 300 nm～1700 nm is not more than 6 mW/lm
Radiation properties	The nominal value of total luminous flux is 12 lm, tolerance -10%, no upper limit
Lux	No less than 4500 lx

Appendix B Electromagnetic Compatibility

The system has been tested and found to be in compliance with IEC 60601-1-2 for electromagnetic compatibility requirements.

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.

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.

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

The essential performance for the system is defined as follows:

The system can perform accurate motion control over the instruments through the Surgeon Console, provide real-time image feedback to motions of the instruments through the Vision Cart, and ensure the accuracy of master-slave operation distance and attitude, master-slave control delay within the specified range, and no malfunction occurs.

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

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

No.	Cable Name	Cable Length	Shield	Note
17	Energy activation cable	1.5 m	Yes	Used for the connection of the ultrasonic generator and the Signal Distributor
18	Endoscope cable	5 m	Yes	Used for the connection of the Camera Control Unit and the endoscope
19	Illuminator Control Cable	1 m	Yes	Used for the connection of the Endoscope Illuminator and the Camera Control Unit

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

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic environment.
RF emissions CISPR 11	Class A	The system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliant	

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

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD (Electrostatic discharge) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment with highly reliable service.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment with highly reliable service.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment with highly reliable service. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply.
Power frequency (50 Hz/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer’s Declaration - Electromagnetic Immunity
Note: U_T is the AC mains voltage before application of the test level.

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

Guidance and Manufacturer’s Declaration - Electromagnetic Immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz～80 MHz 3 V/m 80 MHz～2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz～800 MHz $d = 2.3\sqrt{P}$ 800 MHz～2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 

Guidance and Manufacturer's Declaration - Electromagnetic Immunity
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the system. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table B.5 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the System

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the System			
The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz～80 MHz $d = 1.2\sqrt{P}$	80 MHz～800 MHz $d = 1.2\sqrt{P}$	800 MHz～2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the System
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz to 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix C List of System Components

No.	Part Name		Part Number	Service Life/Shelf Life
1	Surgeon Console		MP1101	10 years
2	Patient Cart		MP1102	10 years
3	Signal Distributor		MP1204	10 years
4	Vision Cart	Camera Control Unit	MP1202	10 years
5		Fluorescence Endoscope	MP1212	500 uses
6		Fluorescence Endoscope	MP1213	500 uses
7	Instruments	Maryland Bipolar Forceps	MP1302	10 uses
8		Maryland Bipolar Forceps	MP4-BM-P	14 uses
9		Bipolar Forceps	MP1305	10 uses
10		Bipolar forceps	MP4-BF-P	14 uses
11		Enhanced Bipolar Forceps	MP1316	10 uses
12		Enhanced Bipolar forceps	MP4-FB-P	12 uses
13		Needle Driver	MP1308	10 uses
14		Needle Driver	MP4-ND-P	15 uses
15		Large Needle Driver	MP1324	10 uses
16		Monopolar Scissors	MP1311	10 uses
17		Monopolar Hook	MP1314	10 uses
18		Enhanced Forceps	MP1318	10 uses
19		Enhanced forceps	MP4-PG-P	18 uses
20		Cadiere Forceps	MP1320	10 uses
21		Cadiere Forceps	MP4-NRG-P	18 uses
22		Tip-up Fenestrated Grasper	MP1322	10 uses
23		Disposable Ultrasonic Scalpel	MP1500	1 use/2 years
24	Accessories	Reducer	TR4-A8/5	1 use/2 years

No.	Part Name		Part Number	Service Life/Shelf Life
25		Reducer	TR4-A12/8	1 use/2 years
26		Reducer	TR4-A15/8	1 use/2 years
27		Cannula	TR1-A8I	500 uses
28		Cannula	TR1-A8E	500 uses
29		Cannula	TR1-A12	500 uses
30		Cannula	TR1-A15	500 uses
31		Long Cannula	TR1-A8I-L	500 uses
32		Long Cannula	TR1-A8E-L	500 uses
33		Long Cannula	TR1-A12-L	500 uses
34		Long Cannula	TR1-A15-L	500 uses
35		Blunt Obturator	TR2-A8IB	500 uses
36		Blunt Obturator	TR2-A8EB	500 uses
37		Blunt Obturator	TR2-A12B	500 uses
38		Blunt Obturator	TR2-A15B	500 uses
39		Prismatic Obturator	TR2-A8IP	500 uses
40		Prismatic Obturator	TR2-A8EP	500 uses
41		Prismatic Obturator	TR2-A12P	500 uses
42		Prismatic Obturator	TR2-A15P	500 uses
43		Long Blunt Obturator	TR2-A8IB-L	500 uses
44		Long Blunt Obturator	TR2-A8EB-L	500 uses
45		Long Blunt Obturator	TR2-A12B-L	500 uses
46		Long Blunt Obturator	TR2-A15B-L	500 uses
47		Long Prismatic Obturator	TR2-A8IP-L	500 uses
48		Long Prismatic Obturator	TR2-A8EP-L	500 uses
49		Long Prismatic Obturator	TR2-A12P-L	500 uses

No.	Part Name		Part Number	Service Life/Shelf Life
50		Long Prismatic Obturator	TR2-A15P-L	500 uses
51		Cannula Seal	TR3-A8	1 use/2 years
52		Cannula Seal	TR3-A8E	1 use/2 years
53		Cannula Seal	TR3-A12	1 use/2 years
54		Cannula Seal	TR3-A15	1 use/2 years
55		Tip Cover Accessory	MP1402	1 use/2 years
56		Installation Tool	MP1801	1 use/2 years
57		Monopolar Energy Instrument Cord	MS1801	50 uses
58		Bipolar Energy Instrument Cord	MS1802	50 uses
59		System Cable	CM1801	/
60		System Cable	CM1802	/
61		System Cable	CM1804	/
62		Camera Cable	CM1806	/
63		Camera Cable	CM1820	/
64		Camera Cable	CM1821	/
65		Camera Cable	CM1805	/
66		Energy Activation Cable	CM1807	/
67		Energy Activation Cable	CM1835	/
68	Disposable Drape		DR1001	1 use/2 years
69	Disposable Drape		DR1003	1 use/2 years
70	Endoscope Illuminator		HE1003	5 years
71	Light Guide Bundles		CM1810	100 uses
72	Light Guide Bundles		CM1811	100 uses
73	Illuminator Control Cable		CM1815	/

Appendix D Glossary

Term	Meaning
2D	Two-dimensional.
3D	Three-dimensional.
AC	Alternating Current, also represented by the AC symbol ～.
AP/APG	ME equipment or parts described in the accompanying documents for use with flammable anaesthetics (category AP) or flammable anaesthetics with oxidants (category APG) shall comply with IEC 60601-1.
BF	An IEC 60601-1 classification for patient applied parts, which is protectively earthed, connected to earth but not protectively earthed, or floating but not isolated from earth to the degree that would be required for a type BF applied part, but is not suitable for direct cardiac application.
CF	An IEC 60601-1 classification for patient applied parts. Type CF is the most stringent classification, being required for those applications where the applied part is in direct conductive contact with the heart or other applications as considered necessary.
Circulating nurse	A nurse who prepares for an operation and continually monitors the patient and staff in the operating room outside the sterile field.
COM	A communication port.
Docking	Attaching 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.
EOTF	Electro-optical Transfer Function.
FLUOR	Fluorescence Settings
HD	High Definition.
HF	High Frequency.
ICG	Indocyanine Green. A cyanine dye is used for near-infrared imaging in medical diagnostics

Term	Meaning
Laser Aperture	A symbol is used to point in the direction where laser light is emitted.
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
OR table	Operating table.
PiP	Picture in Picture, a feature that allows display of the image of the operative field and up to two additional images provided by auxiliary inputs.
Remote center	A pivot point around which the endoscope and instruments move, indicated by the thick, center black line on the cannula. Remote center technology enables the system to maneuver instruments and 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.
SFR	Spatial frequency response.
Surgical workspace	The area within the patient that the instruments will be required to reach to complete all surgical tasks throughout the procedure.
Target anatomy	The center of the surgical workspace boundary.
UPS	Uninterruptible Power Supply.
USB	Universal Serial Bus. An industry standard that specifies the physical interfaces and protocols for connecting, data transferring and powering of hosts.

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