

Endoscopic Surgical System
(SR-ENS-600)
Technical Description



Medical Device



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Safety Information

Please read this User Manual carefully before using the Endoscopic Surgical System (later referred to as the SHURUI® System, the system, or the product). To ensure the safe operation of this product, please follow the instructions and safety information provided in this manual and keep it in its desired working environment.

This manual contains the following types of safety information.

 CAUTION	CAUTION symbol alerts reader to what needs attention when operating and using the product. Details of relevant scenarios are given in boxes similar to this one.
 WARNING	WARNING symbol alerts reader to a potentially hazardous situation that, if not avoided, may result in minor or moderate injury to user or patient or damage to the product or other property. Details of relevant scenarios are given in boxes similar to this one.
 HAZARD	HAZARD symbol alerts reader to a situation that, if not avoided, could result in serious injury or death to user or patient, or serious damage to the product or other property. Details of relevant scenarios are given in boxes similar to this one.
 PROHIBITION	PROHIBITION symbol alerts reader to actions that are prohibited. Details of relevant scenarios are given in boxes similar to this one.

1 General Information

This Technical Description provides information of Surgerii Robotics' Endoscopic Surgical System (Model SR-ENS-600, later referred to as the SHURUI System, the system, or the product), specifically regarding technical specifications, performances, and requirements. The SHURUI System (Figure 1.1) is intended for use by trained surgeons in an operating room environment in accordance with the representative, specific procedures set forth in the User Manual. The system consists of a Surgeon Console and a Surgical Trolley, and is used with a 3D endoscope, surgical instruments, and accessories.

The expected procedure involves a single-port surgical approach, which requires the use of the trocar incision protector and the sterile drape produced by Surgerii Robotics. The surgeon will operate in a teleoperation manner to perform the surgical procedure.

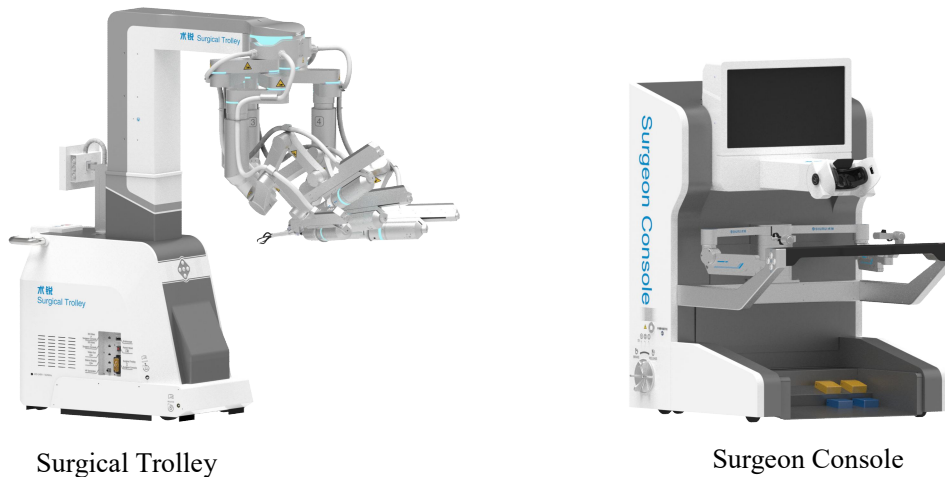


Figure 1.1 Endoscopic Surgical System

1.1 Intended Purpose/Indications for Use

1.1.1 Intended Purpose

The SHURUI System is intended to assist in the accurate control of the SHURUI® instruments during urologic laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general laparoscopic surgical procedures, and

thoroscopic surgical procedures. It is intended for use by trained surgeons in an operating room environment in accordance with the representative, specific procedures set forth in the User Manual.

The SHURUI® Instruments are controlled by the SHURUI System, and include flexible endoscopes, blunt and sharp endoscopic dissectors, scissors, forceps, needle drivers, endoscopic retractors, electrocautery and accessories for endoscopic surgical operations, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, and suturing through a single port. They are intended for use by trained surgeons in an operating room environment in accordance with the representative, specific procedures set forth in the User Manual.

1.1.2 Indications for Use

The system is indicated for adult and pediatric patients eligible for minimally invasive surgeries, indicated for benign or malignant conditions, performed intra-thoracically or intra-abdominally in specialties such as urological, gynecological, general and thoracic surgical procedures.

1.2 Intended Users

The system is intended to be used by trained surgeons in the operating room environment in accordance with the representative, specific procedures set forth in the User Manual.

1.3 Intended Patients

The system is indicated for adult and pediatric use and applicable to people who need laparoscopic or thoroscopic surgery.

1.4 Working Conditions

Temperature: 15°C–35°C

Humidity: 30%–70%

Atmospheric Pressure: 700 hPa–1060 hPa

1.5 Principle of Operation

The system is used to conduct minimally invasive surgery under the control of the surgeon, based on the principle of master-slave teleoperation. During the operation, the operator maneuvers the two haptic masters to control the surgical instruments or the 3D endoscope, while viewing the surgical site from the 3D viewer. The surgeon could also activate electric cutting and coagulation, or switch the control between different surgical instruments or the 3D endoscope, by using the footswitch pedals and buttons.

2 System Structure Composition and Performance

The system software is deployed on each workstation and control board of Surgeon Console and Surgical Trolley. The model specification of this product software is SR-ENS-600-SW, and structure of this product are shown in Table 2.1 and Table 2.2.

Table 2.1 System Components

Surgeon Console	SR-ENS-600-SC
Surgical Trolley	SR-ENS-600-ST

Table 2.2 3D Endoscope, Instruments and Accessories

	3D endoscope	SR-ENP-SP1001
Surgical instruments	Curved bipolar dissector	SR-ENT-SP0801
		SR-ENT-SP0801S
	Maryland bipolar forceps	SR-ENT-SP0802
		SR-ENT-SP0802S
	Monopolar curved scissors	SR-ENT-SP0803
		SR-ENT-SP0803S
	Monopolar cautery hook	SR-ENT-SP0805
		SR-ENT-SP0805S
	Bipolar forceps	SR-ENT-SP0806
		SR-ENT-SP0806S
	Needle driver	SR-ENT-SP0807
		SR-ENT-SP0807S
	Tissue forceps	SR-ENT-SP0808
		SR-ENT-SP0808S
	Large tissue forceps	SR-ENT-SP0809
		SR-ENT-SP0809S
	Large needle driver	SR-ENT-SP0810
		SR-ENT-SP0810S
Accessories	Monopolar energy instrument cord	SR-ENT-MPC1000

	Bipolar energy instrument cord	SR-ENT-BPC1000
	Trocac incision protector	SR-TCIP-4-1
		SR-TCIP-4-2
		SR-TCIP-4-3
		SR-TCIP-4-4
		SR-TCIP-3-2
		SR-TCIP-3-3
	Sterile drape	SR-ENS-600-D1
		SR-ENS-600-D2

2.1 Surgeon Console

The Surgeon Console integrates ergonomic adjustment, image display, status notification, operational input, functional controls, system communication and monitoring functions. During the operation, the surgeon sits in front of the Surgeon Console and controls the surgical instruments and the 3D endoscope by manipulating the left and right haptic masters and footswitch pedals.

The Surgeon Console consists of a 2D display, a 3D viewer, a touchpad, haptic masters (left/ right), a clutch pedal, a swap pedal, an endoscope control pedal, a brake, a footswitch panel, an emergency-stop button, a power button, a multi-functional button, an armrest, a “No Sitting” sign, 3D viewer up/down buttons, a 3D viewer extension lever, a 3D viewer pitch lever, a microphone, a speaker, an UPS, a battery indicator, infrared head sensors, yellow pedals (left/ right), blue pedals (left/ right), armrest up/down buttons, etc. The Surgeon Console components and position are shown in Figure 2.1. For detailed information about the components and usage of the Surgeon Console, please refer to the User Manual.

- **Size and weight**

- Length: 1273mm, width: 1052mm, height: 1537mm (minimum), and weight approximately 390kg.

- **Haptic masters (hand control)**

- Primary input devices for capturing user actions for manipulation of the surgical instruments, adjustment of the field of view by manipulation of the 3D endoscopic, control of the cobra angle of the 3D endoscopic, zoom-in and zoom-out of the field of view, etc.
- Grip: Controls the clamping angle of the end-effector.

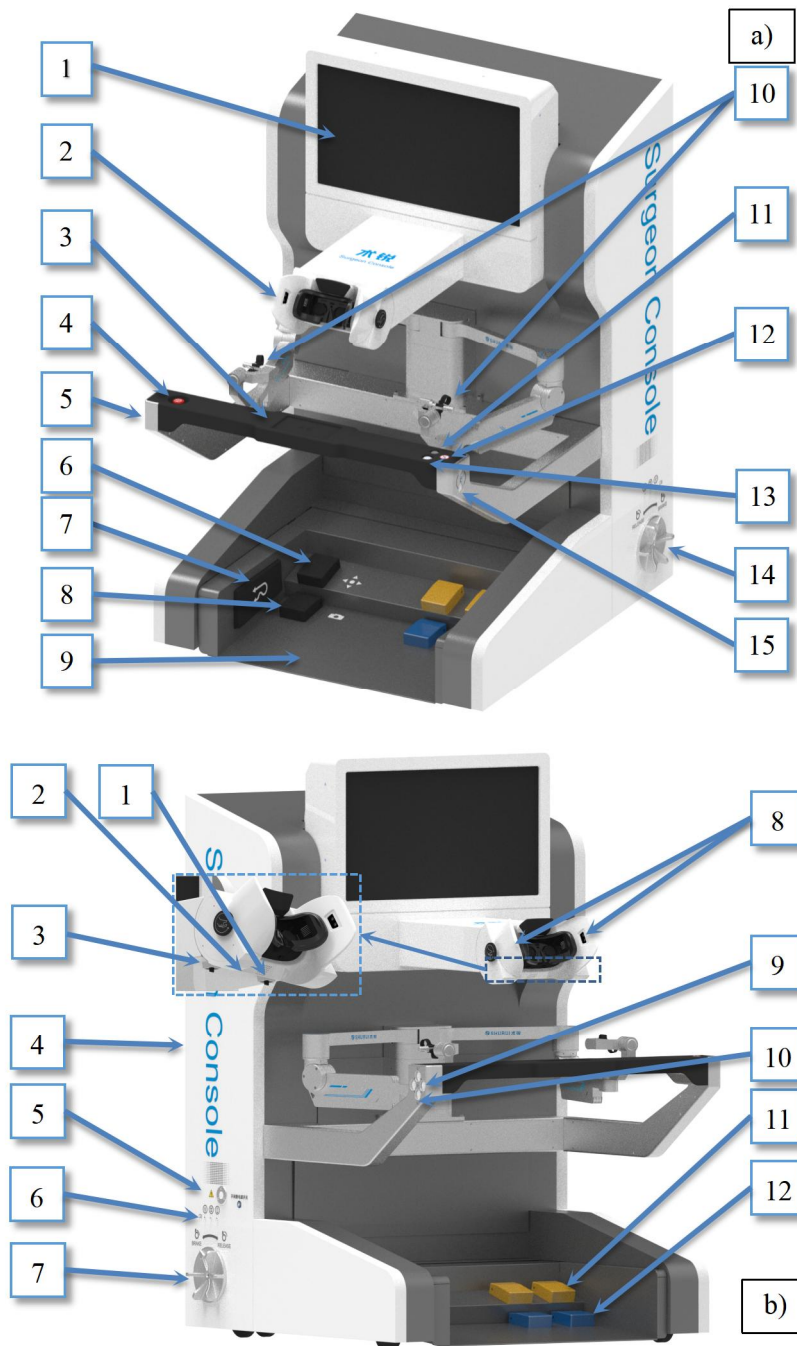


Figure 2.1 Surgeon Console: a) Right view (1-2D display, 2-3D viewer, 3-Touchpad, 4-Emergency-stop button, 5-Armrest, 6-Clutch pedal, 7-Swap pedal, 8-Endoscope control pedal, 9-Footswitch panel,

10-Haptic masters (left/ right), 11-Power button, 12-"No Sitting" sign, 13-Multi-functional button, 14-Brake, 15-3D viewer up/down button); b) Left view (1-3D viewer extension lever, 2-Microphone, 3-3D viewer pitch lever, 4-Speaker (interior), 5-UPS button, 6-Battery indicator, 7-Brake, 8-Infrared head sensors, 9-Footswitch panel move-in / move-out buttons, 10-Armrest up/down button, 11-Left/right yellow pedals, 12-Left/right blue pedals)

- Finger clutch: Trigger to disconnect matching/teleoperation status of haptic master and the surgical instrument, allowing adjustment of each haptic master's comfortable position. Double click to trigger user-defined functions, such as instrument swap.
- Proportional motion scaling: Fast/L3 (1.5:1), medium/L2 (2:1), and slow/L1 (3:1) operation control scales can be selected based on clinical needs.
- Over-speed protection: Teleoperation is interrupted when the haptic master is moving fast to prevent accidental injury.
- Angular mapping adjustment: The angular mapping (i.e., the mapping of pointing direction from the haptic master grip to the surgical instrument end-effector) can be set with a proportional scaling factor or an offset, to facilitate the operation in specific situations.
- **3D Viewer**
 - 1920×1080P at 60 Hz refresh rate.
 - Dual views for each eye, offering direct, naked-eye 3D HD imaging.
 - Supports adjustments for interpupillary distance and diopter.
 - Adjustable brightness of the displayed image.
 - Enables switching between 2D and 3D images.
- **2D Display**
 - Displays a 2D image of the surgical field along with the system status.
 - 1920×1080P at 60 Hz refresh rate.
 - Size: 21.5 inches.
- **Touchpad**
 - Configures the surgical field of view, audio, and system settings.
 - Allows quick allocation of actuation modules corresponding to the left and

right haptic masters via the quick status switch button.

- Surgical field settings: 1x, 2x, 3x zoom, cropping, and image enhancement including adjustment of brightness, sharpness, denoising, contrast, and saturation
- User profile management (up to 10 accounts), personalized parameter settings, and preferred ergonomic seating configuration function.

- **Footswitch Pedals**

- An endoscope control pedal is used to enter the 3D endoscope control mode, enabling field of view adjustment, zoom-in and zoom-out, and camera rotation (refer to Section 3.2.1).
- A clutch pedal is used to temporarily disconnect the matching/teleoperation status of the haptic master and the surgical instruments
- A swap pedal is used to alternate the mapping relationship between the two surgical instruments that are assigned to the same haptic master.
- Two yellow/blue pedals: Activation of high-frequency cutting or coagulation.

- **Ergonomic adjustments**

- The move-in and move-out adjustment of the footswitch panel
- The height of the armrest
- The height of 3D viewer
- The extension of the 3D viewer
- The tilting angle of the 3D viewer

- **UPS**

- In case of emergency, it can provide backup power for at least 15 minutes.

- **Cable Connections**

- One 3D video port: input of 3D images.
- One 2D video port: input of 2D images.

- **Movement and locking**

- Manually moved with four wheels.
- Brakes for lock and unlock.

2.2 Surgical Trolley

The Surgical Trolley is located on the patient's side. The Surgical Trolley can be loaded with surgical instruments and 3D endoscope to perform the operation in response to signals from the Surgeon Console.

As shown in Figure 2.2, the Surgical Trolley includes the stabilization feet, wheels, microphone, speaker, status touchscreen, UPS button, base, helm, front button panel, cable connection panel, positioning indicator, horizontal laser, height indicator, warning laser radiation sign, warning hands pinching sign, column, beam, four robotic arms, and four actuation modules. For detailed information on the structural composition and usage of the Surgical Trolley, please refer to the User Manual.

- **Size and weight**

- Length: 2286 mm, width: 892 mm, height: 1800 mm (minimum), and weight approximately 1080kg.

- **Column and beam**

- The Surgical Trolley features a boom-type support structure with a height-adjustable column that holds the beam. Four robotic arms are mounted at the distal end of the beam.

- **Status Touchscreen**

- Size: 15 inches.
- Displays system status and guides for arm positioning, pre-operative, intra-operative, and post-operative operations.
- Displays preparation, positioning, and docking guidance for surgical procedures, including recommendations on arm posture, patient positioning, incision locations, and other relevant aspects.
- Rapid positioning: a) Targeted motion, b) Single arm motion, c) Coordinated motion, refer to Section 3.2.3 for details.
- Displays user use errors and system faults with handling suggestions.

- **Helm**

- Emergency-stop button: Cuts off the system power in an emergency.

- Power button: ON/OFF.
- Battery indicator: The green light indicates battery charging, the blue light indicates battery discharging, and the yellow light indicate low battery power.
- Stabilization feet knob: Rotates to deploy or retract the stabilization feet.
- Drive controller: Drive the trolley to move forward, backward, and steer.

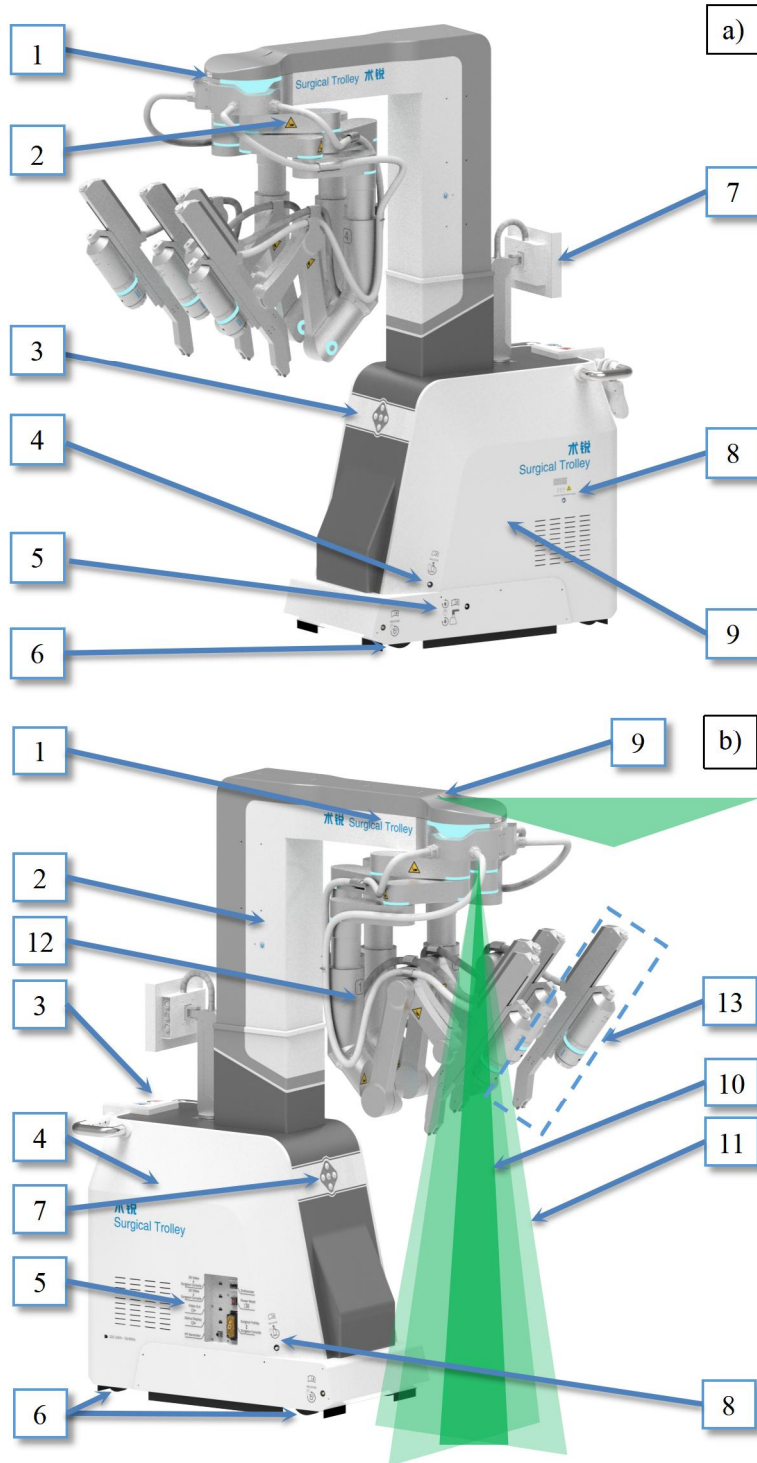


Figure 2.2 Surgical Trolley: a) Left view (1-Warning laser radiation sign, 2-Warning hands pinching sign, 3-Microphone (interior), 4-Left stabilization foot adjustment position, 5-Column adjustment position, 6-Left wheel, 7-Status touchscreen, 8-UPS buttons, 9-Speaker (interior)); b) Right view (1-Beam, 2-Column, 3-Helm, 4-Base, 5-Cable connection panel, 6-Right wheel, 7-Front button panel, 8-Right stabilization feet adjustment position, 9-Horizontal laser, 10-Positioning indicator, 11-Height indicator, 12-Robotic arm, 13-Actuation module)

● **Robotic Arm**

- Integrates four robotic arms, each equipped with multiple joints and an actuation module at the distal end.
- The robotic arms maintain a safe distance during movement via built-in collision detection and avoidance algorithm, and are kept stationary during teleoperation of the instruments and the 3D endoscope; No collisions will happen between the robotic arms.
- Allows for adjustments across 14 directions of trocar movement, enabling versatile and precise orientation adjustment.
- The range of adjustment for overall clockwise and counterclockwise rotation motion can reach up to $180^\circ (\pm 90^\circ)$.

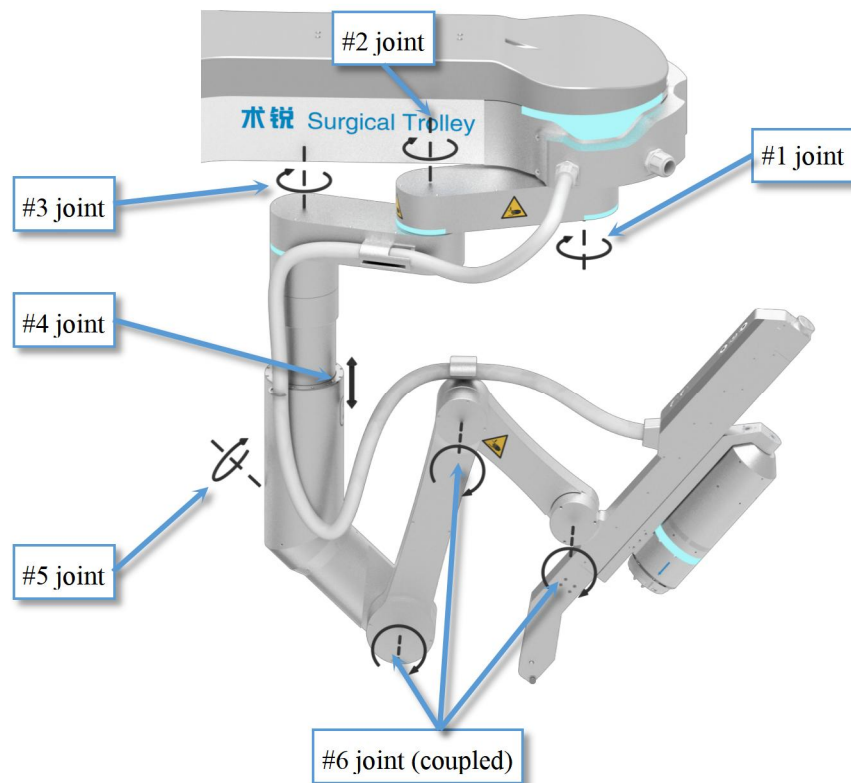


Figure 2.3 Robotic arms structural diagram

- **Actuation Module**

- Upward/downward buttons: Facilitate pitch adjustment for easy draping.
- Status switch button: Switches between robotic arm motion status.
- Move-in / move-out buttons: Facilitate forward/backward movement of the surgical instrument.
- Multi-functional button: Realizes locking and unlocking functions for sterile drape, 3D endoscope and instruments.

- **Imaging System**

- During surgery, the 3D endoscope captures images inside a patient's body, transmitting the images to the Surgical Trolley. The images are processed and then displayed on the Surgeon Console's 3D viewer and other monitors.
- Dual Full HD processing capability.
- Standard HDMI cables can connect to other display or recording devices in the operating room. Zoom, cropping, and image enhancement adjustments are optional, with additional enhancements for brightness, sharpness, denoising,

contrast, and saturation.

- The cold light source is connected to the light guide port on the 3D endoscope via an endoscope illumination fiber.
- Supports external connection to a recorder for real-time image recording.

- **Laser Indicators**

- A horizontal line is projected ahead of the trolley, warning of potential collisions with ceiling structures.
- Circular and cross-shaped laser is projected downwards to indicate the appropriate position and height of the beam relative to the patient.

- **Audio System**

- Two sets of microphones and speakers for communication between operating room personnel and the surgeon.

- **UPS**

- In case of emergency, it can provide backup power for at least 15 minutes.

- **Cable Connections**

- A 3D video port: Output of 3D images to the Surgeon Console.
- A 2D video port: Output of 2D images to the Surgeon Console.
- A 2D video port (External devices): Connect to other display devices or recording devices in the operating room via standard HDMI cables to output 2D image of the field of view.
- A status video port: Connects to other display devices in the operating room via standard HDMI cables to output the system status UI interface.
- A high-frequency generator port: Connects to the high frequency generator through the energy activation cable.
- An endoscope port: Connects to the 3D endoscope.

- **Movement and locking**

- Motorized wheels controlled by the Surgical Trolley drive controller.
- The motorized wheels can be disengaged for manual drive of the Surgical Trolley.
- Stabilization feet can be controlled by the stabilization feet knob to extend

downwards for Surgical Trolley stabilization or retract to release.

- The stabilization feet can be manually released for emergency situation.

2.3 3D Endoscope

3D endoscope is composed of the 3D endoscope housing, endoscope stem, vision module, endoscope cable plug, light guide port, endoscope cable and white balance button. The schematic diagram of 3D endoscope is shown in Figure 2.6. For more information about the 3D endoscope, please refer to the User Manual.

● Structure

- A flexible, snake-like stem body with two distal segments that is capable of bending inside the patient's body.
- The 1st segment (the segment proximal to the endoscope housing) can bend up to 45°, while the 2nd segment (the segment distal to the endoscope housing) can bend up to 90° continuously.
- The 3D Endoscope can be driven by the actuation module to achieve forward and backward feeding and rotation about its own axis.
- The overall length of the 3D endoscope is 759 mm. The overall length with the cleaning cage installed is 822 mm.
- The maximum outer diameter of the part inserted into the body is 10.8 mm.
- Sealed design, IPX 7.

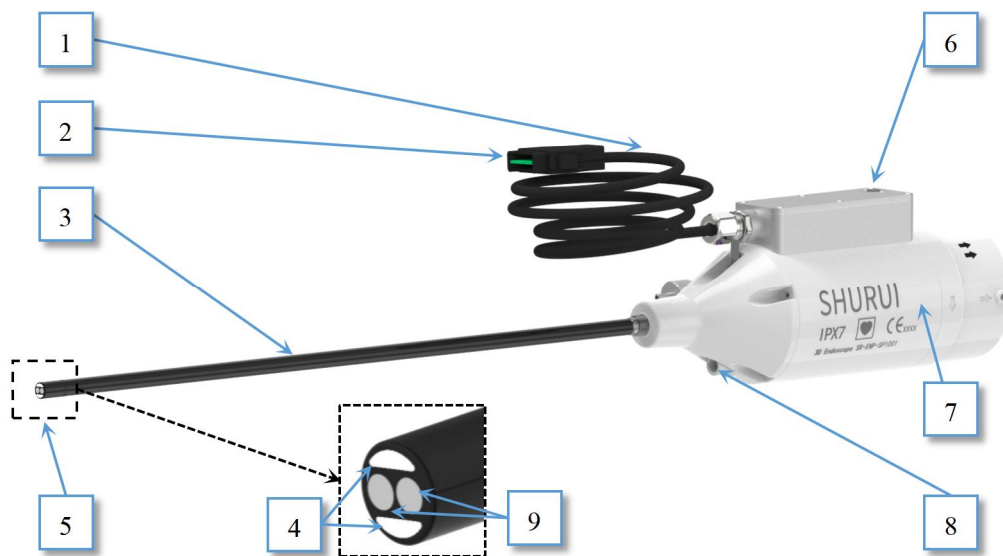


Figure 2.4 Composition of 3D endoscope (1-Endoscope cable, 2-Endoscope cable plug, 3-Stem, 4-Vision module optical fiber, 5-Vision module, 6-White balance button, 7-Endoscope housing, 8-Light guide port, 9-Two groups of imaging chips and lens)

- **Performance Parameters**

- Field of View: 85°.
- Resolution: 1920×1080 at 60 Hz.
- Cobra Mode: Supports both upward and downward (reverse Cobra) orientations, the 1st segment adjustable continuously from -45° to +45°.
- Vision module: Comprises two groups of imaging chips, lenses, and illumination optical fibers.
- White balance button: Aim the vision module at a white object and press the button to correct the color balance.
- Features automatic 3D calibration.
- “Quick wipe” function: Allows the camera to be cleaned and wiped without unloading the endoscope, reducing intraoperative downtime.
- Usage limit: 10 uses.

- **Cable connections**

- Light guide port: Illuminating optical fiber is plugged in to connect the cold light source.
- Endoscope cable: Connect to the Surgical Trolley to transmit the image signal.

- **Reprocessing**

- Compatible with automatic ultrasonic cleaning machine.
- Compatible with high-level disinfection using peracetic acid.
- Compatible with low-temperature hydrogen peroxide plasma sterilization.

2.4 Surgical Instrument

The system has various surgical instruments. Each surgical instrument is composed of the instrument housing, instrument stem, end-effector, pressure valve, energy instrument cord port and grip release knob, as shown in Figure 2.5. For more information about the instruments, please refer to the User Manual.

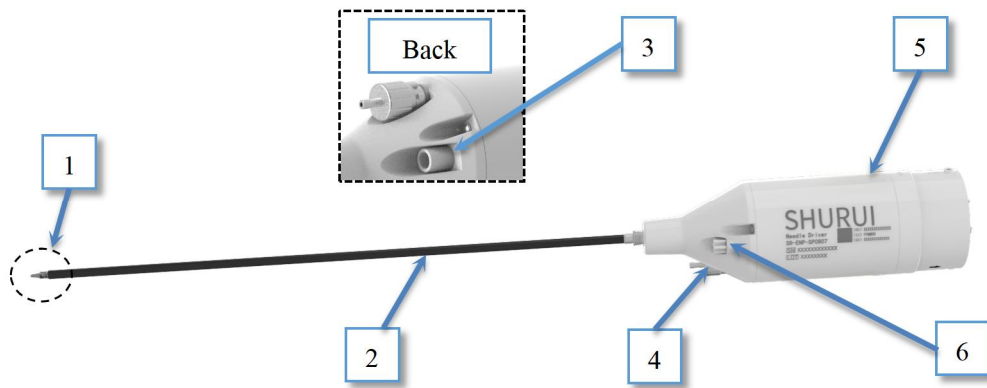


Figure 2.5 Composition of surgical instruments (1-End-effector, 2-Stem, 3-Energy instrument cord port (if it exist), 4-Pressure valve, 5-Instrument housing, 6-Grip release knob)

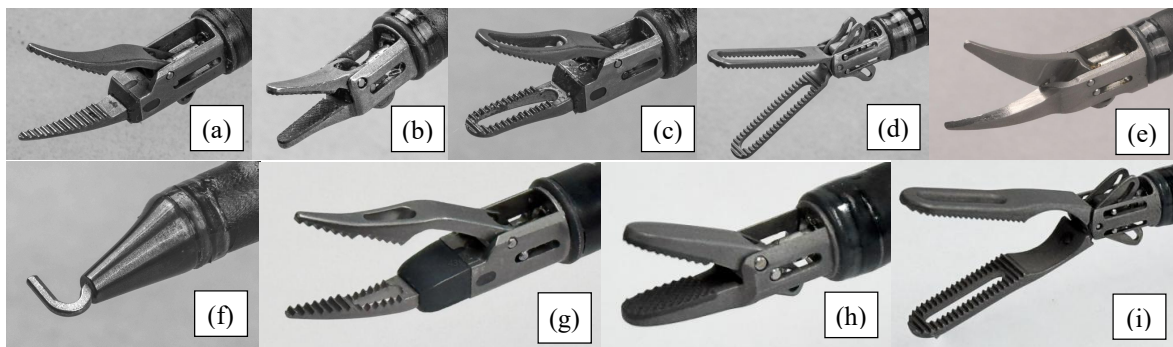


Figure 2.6 Surgical instrument end-effectors: a) curved bipolar dissector, b) needle driver, c) bipolar forceps, d) tissue forceps, e) monopolar curved scissors, f) monopolar cautery hook, g) Maryland bipolar forceps, h) large needle driver, and i) large tissue forceps

● Structure

- A flexible, snake-like stem body with a two distal bendable segments.
- The 1st segment (proximal to the instrument housing) can bend up to 90°, whereas the 2nd segment (distal to the instrument housing) can bend up to 120°
- The surgical instrument can be driven by the actuation module to achieve forward and backward feed and rotation around its own axis.
- The overall length of the instrument is 797–814 mm (depending on the instrument type). The overall length with the cleaning cage installed is 822 mm.
- The maximum outer diameter of the insertion part into the body is 8.0 mm.
- Sealed design, IPX 7.

● Performance Parameters

- Operational force: The maximal operational force is no less than 10 N (the maximal pushing and pulling force is up to 20 N).
- Safe withdrawal/insertion feature: The instrument can be withdrawn or inserted following its shape.
- Pose memory: The system automatically memorize the last pose of the instrument before withdrawal and reload resumes at that pose (slightly short for safety consideration).
- Usage limit: 10 uses.
- Various types of end-effectors: Including curved bipolar dissector, Maryland bipolar forceps, monopolar curved scissors, monopolar cautery hook, bipolar forceps, needle driver, and tissue forceps.
- **Reprocessing**
 - Compatible with automatic ultrasonic cleaning machine.
 - Compatible with high-level disinfection using peracetic acid.
 - Compatible with low-temperature hydrogen peroxide plasma sterilization.
- **Instrument Release Wrench**

The instrument release wrench is used for manually releasing the surgical instruments or 3D endoscope from the actuation module.



Figure 2.7 Instrument release wrench

- **Disposable Tip Cover**

The disposable tip cover is used with the monopolar curved scissors. The tip cover is sleeved over the instrument during operation. The length of the instrument that extends the tip cover is approximately 8mm-10mm. After the operation is finished, the disposable tip cover should be removed and disposed as medical waste.

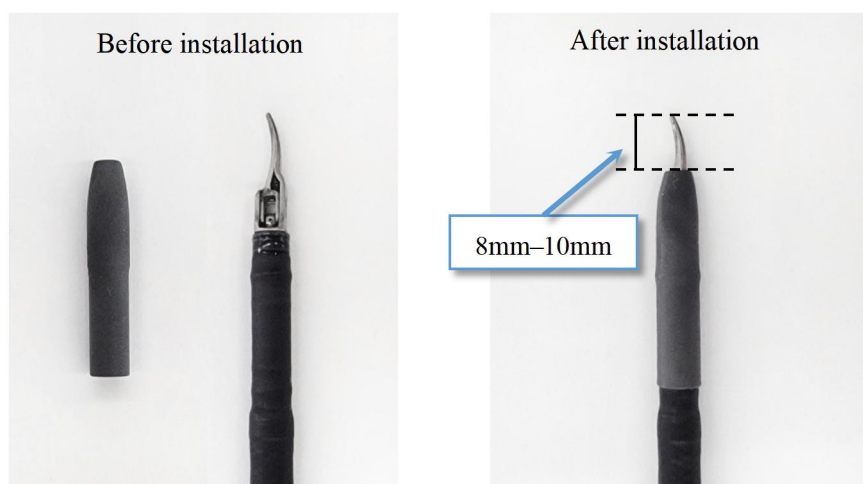


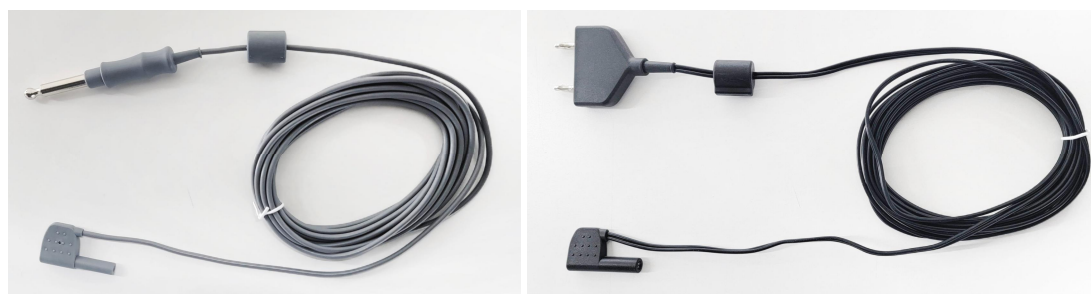
Figure 2.8 Use of disposable tip cover (sleeved over the monopolar curved scissors as an example)

2.5 Accessories

2.5.1 Energy Instrument Cords

The monopolar and bipolar energy instrument cord and bipolar energy instrument cord are used to connect high-frequency surgical instruments and high-frequency generators to transmit electrical energy for electric cutting and coagulation.

The monopolar energy instrument cord has a single plug connector. The bipolar energy instrument cord has a dual plug connector.



Monopolar energy instrument cord

Bipolar energy instrument cord

Figure 2.9 Energy instrument cords

2.5.2 Sterile Drape

Sterile drape is used to wrap around the robotic arm and column of the SHURUI System, to prevent surgical team members from directly coming into contact with these parts and then later with the patient's surgical site during surgery, thus avoiding potential infections. Please refer to the Sterile Drape User Manual for further information.

Model	Description
SR-ENS-600-D1	Used to wrap around the robotic arm
SR-ENS-600-D2	Used to wrap around the column

2.5.3 Trocar Incision Protector

Trocar incision protector is provided sterile for single use. It is intended for use with the SHURUI System. The trocar incision protector is composed of a trocar and an incision protector. It is used to establish channels for endoscope and surgical instruments during surgery, protecting the incision from damage (without puncturing function). The models of trocar incision protectors are listed in the table below. Please refer to the Trocar Incision Protector User Manual for further information.

Model	Description
SR-TCIP-4-1	Composed of a standard 4-channel trocar (SR-TC-4-2) and an incision protector without auxiliary ports (SR-IP-1).
SR-TCIP-4-2	Composed of a standard 4-channel trocar (SR-TC-4-2) and an incision protector with an auxiliary port (SR-IP-2).
SR-TCIP-4-3	Composed of a short 4-channel trocar (SR-TC-4-3) and an incision protector without auxiliary ports (SR-IP-1).
SR-TCIP-4-4	Composed of a short 4-channel trocar (SR-TC-4-3) and an incision protector with an auxiliary port (SR-IP-2).
SR-TCIP-3-2	Composed of a standard 3-channel trocar (SR-TC-3-1) and an incision protector with an auxiliary port (SR-IP-2).
SR-TCIP-3-3	Composed of a compactly arranged 3-channel trocar (SR-TC-3-2) and an incision protector without auxiliary port (SR-IP-1).



Figure 2.10 Example of a trocar incision protector

- **4-channel trocar (SR-TC-4-2)**
 - 1 endoscope channel and 3 instrument channels.
 - Insertion part diameter 2.6 cm.
- **4-channel trocar (SR-TC-4-3)**
 - 1 endoscope channel and 3 instrument channels.
 - Insertion part diameter 2.6 cm.
 - 30 mm longer in insertion part than SR-TC-4-2. Suitable for patients with thicker adipose tissue.

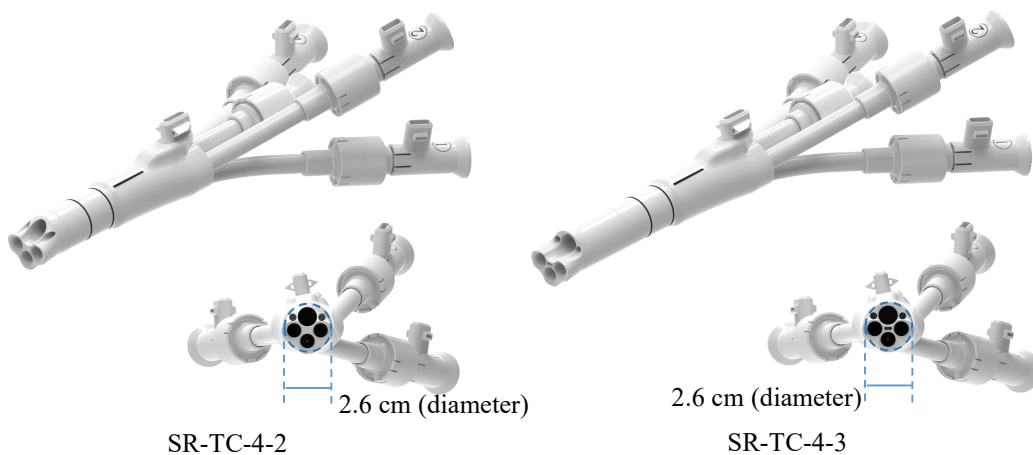


Figure 2.11 4-channel trocar SR-TC-4-2 and SR-TC-4-3

- **3-channel trocar (SR-TC-3-1)**
 - 1 endoscope channel and 2 instrument channels.
 - Insertion part width 2.6 cm, height 2.1 cm.
- **3-channel trocar (SR-TC-3-2)**

- 1 endoscope channel and 2 instrument channels.
- Insertion part width 2.1 cm, height 2.5 cm.
- 30 mm longer in insertion part than SR-TC-3-1. Suitable for patients with thicker adipose tissue.

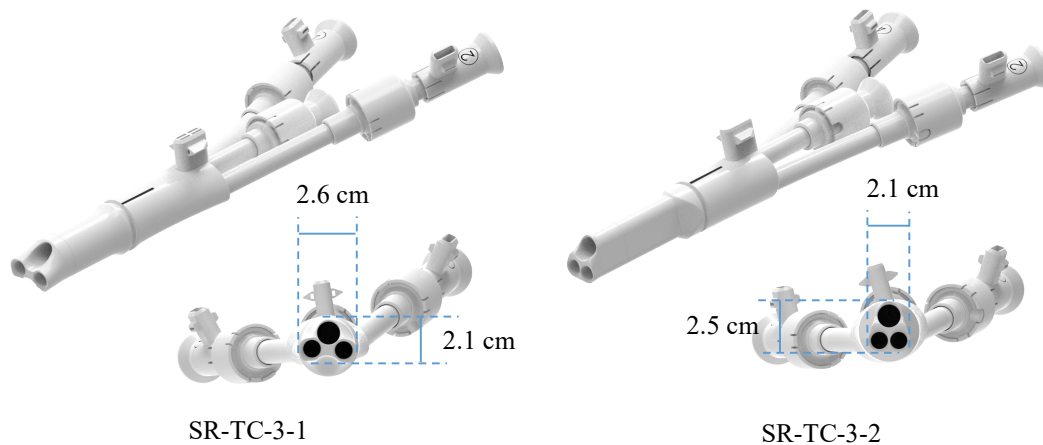


Figure 2.12 3-channel trocar SR-TC-3-1 and SR-TC-3-2

- **Incision protector (SR-IP-1)**
 - One main channel for the trocar
 - Gas inlet and outlet ports for the connection to the insufflator.
- **Incision protector (SR-IP-2)**
 - One main channel for the trocar and one additional channel for auxiliary instruments with diameters ranging from 3 to 12 mm.
 - Gas inlet and outlet ports for the connection to the insufflator.

2.5.4 Sheath Connector

The sheath connector is intended to connect and fix with the trocar adapter on the sterile drape with the trocar incision protector. Each sheath connector is provided with a sheath connector wrench.

Model	Description
SR-ENS-600-TCH1	Used on robotic arms 1, 2, and 4
SR-ENS-600-TCH2	Used on robotic arm 3

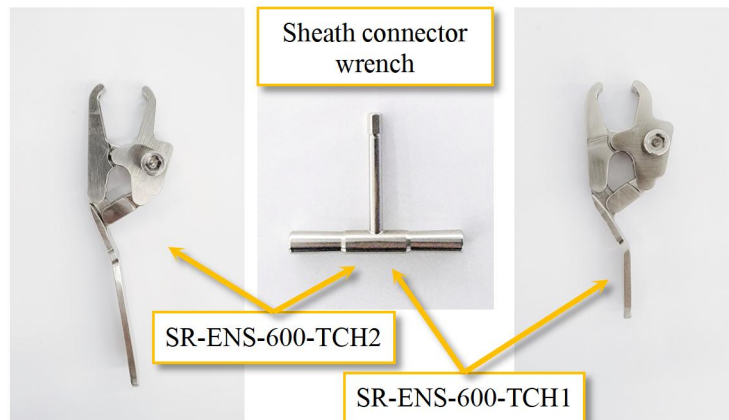


Figure 2.13 Sheath connector

2.6 Audio System

The audio system consists of two sets of microphones and speakers installed on the Surgical Trolley and the Surgeon Console respectively, used for voice communication between operating room personnel and the surgeon.

The audio system can also produce a variety of prompt tones. The Surgical Trolley speaker volume can be adjusted in the settings.

3 System Performance

The SHURUI System is an electro-mechanical system designed for assisting surgeons to perform safe and precise operations in single-port minimally invasive surgery. The Endo-system consists of a Surgeon Console and a Surgical Trolley and is used with 3D endoscope, surgical instruments, and accessories.

3.1 Principle of single-port surgery

The SHURUI System accomplishes minimally invasive procedures via the single-port surgical approach, as shown in Figure 3.1. After the positioning of the patient, a 2–5 cm skin incision can be introduced. Then an incision protector can be used to spread apart and protect the incision. A multi-channel trocar is then inserted through the main channel of the incision protector. The draped Surgical Trolley can then be driven to the patient side and the robotic arms can be controlled to connect to the channels of the trocar, positioning into a single port configuration. The 3D endoscope can then be installed on the actuation module of the robotic arm #3 and surgical instruments can be installed on the actuation modules of the other three robotic arms. The 3D endoscope and surgical instruments could bend to pass the curved channels of the trocar. The multi-channel trocar hence introduces all surgical instruments and the 3D endoscope to access human body via one skin incision. When used with the 4-channel trocars (SR-TC-4-2, SR-TC-4-3), one 3D endoscope and up to three surgical instruments can be deployed. When used with the 3-channel trocars (SR-TC-3-1, SR-TC-3-2), one 3D endoscope and up to two surgical instruments can be deployed.

During operation, the surgeon at the Surgeon Console can view the 3D image of the surgical field acquired by the 3D endoscope, observing the patient anatomy and the surgical instruments, and can use haptic masters, foot pedals and buttons to control the 3D endoscope and surgical instruments installed on the Surgical Trolley to accomplish surgical operations. The robotic arms stay stationary during the teleoperation of the 3D endoscope and surgical instruments, totally avoiding the collision risks of the robotic arms.

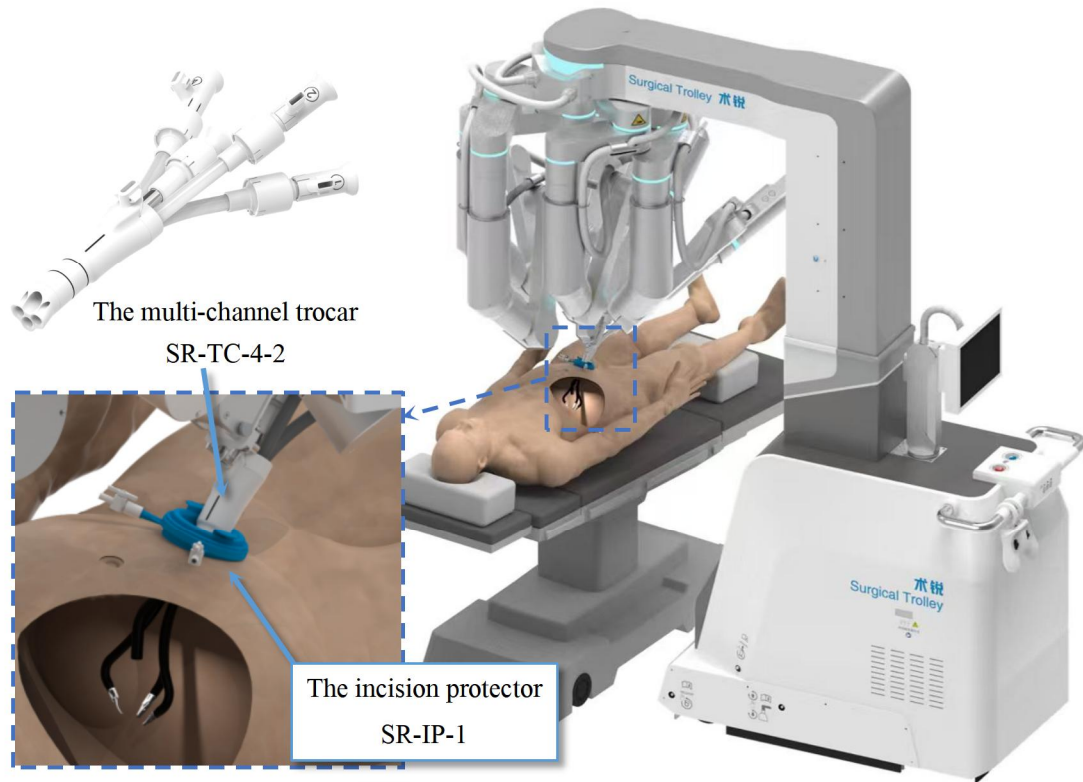


Figure 3.1 The single-port configuration of the Endoscopic System

3.2 Operational functions and specifications

3.2.1 Operation of the 3D endoscope

- **Motion degrees of freedom (DoFs) for the 3D endoscope**

The stem of the 3D endoscope consists of two bendable flexible segments. These two segments can independently change their bending angle and bending direction, as shown in Figure 3.2. Each continuum segment has two degrees of freedom: 1) The segment can bend in a plane (the bending plane shown in the figure) with a certain angle, and 2) The bending plane can be rotated, changing the bending direction in arbitrary directions. In addition, the 3D endoscope can achieve overall linear advancement driven by the linear module, as well as overall rotation driven by the rotational module. Therefore, **the 3D endoscope has a total of six degrees of freedom.**

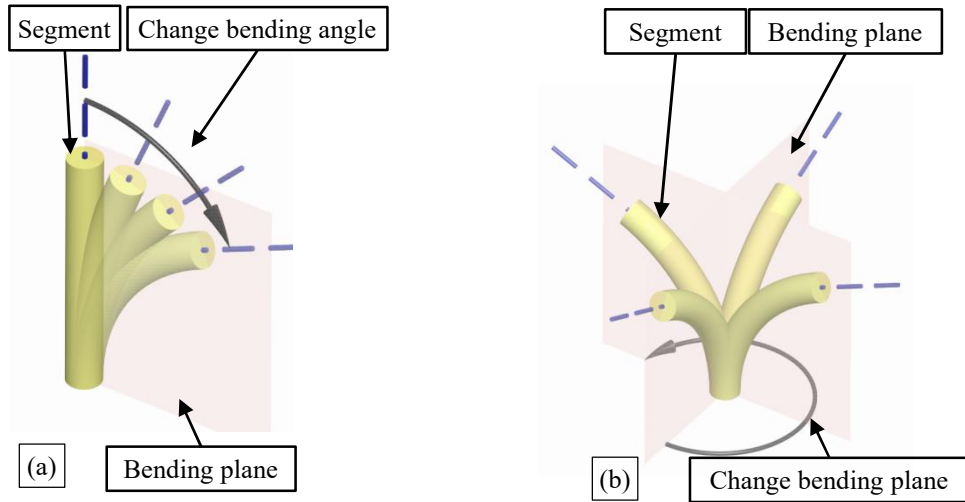


Figure 3.2 The 2-DoFs of a bending segment: a) change bending angle, and b) change bending plane

After the 3D endoscope is installed to the actuation module, it must first be advanced through the trocar into patient's body before teleoperation control. During teleoperation, the user can control the 3D endoscope to adjust the view, or adjust the cobra angle.

● Adjusting endoscopic view

During view adjustment, the user can: 1) steer the endoscope to adjust the endoscopic field of view in all directions (up, down, left, right); 2) zoom the endoscope in or out for a close view or a wide view; 3) rotate the camera to level the view. These motion modes are respectively realized by: 1) bending the 2nd segment toward arbitrary directions, 2) overall linear translation of the 3D endoscope, and 3) rotation of the vision module about its own axis (which is achieved by the overall axial rotation of the 3D endoscope and the change in the bending directions of the 1st and the 2nd segment), as demonstrated in Figure 3.3. Detailed operation instructions can be referred to Section 10.4.4.2 in the User Manual.

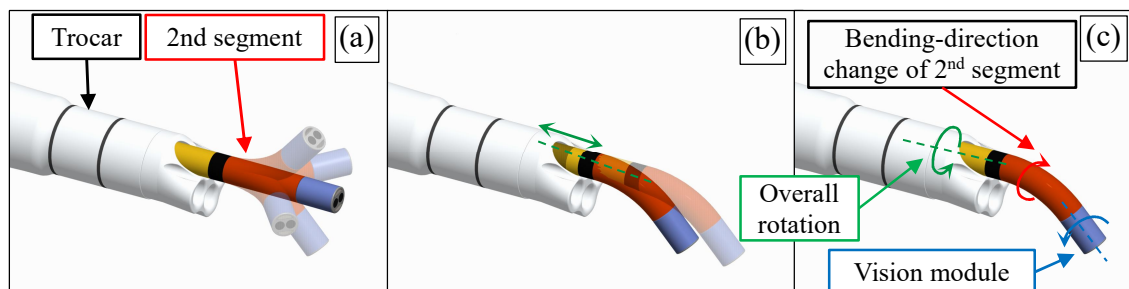


Figure 3.3 Adjusting endoscopic view (when the 1st segment is straight): a) adjust the field of view in arbitrary directions, b) zoom in or zoom out, c) rotating about the vision module's axis.

● Cobra mode (and reverse cobra mode)

After the first segment of the 3D endoscope passes through the trocar, the 1st segment of the 3D endoscope can be adjusted to bend up or down during teleoperation, forming a cobra or reverse cobra shape, as shown in Figure 3.4. After the cobra angle adjustment, teleoperation of the 3D endoscope can be continued to adjust the field of view. The view adjustment under a cobra shape (or reverse cobra shape) is similar to that in a flat shape (i.e., when the 1st segment is straight, as those in Figure 3.3). The user can still steer the endoscope for different field-of-view orientations, zoom in and out, or rotate the camera, as demonstrated in Figure 3.5.



Figure 3.4 3D endoscope cobra mode: a) cobra angle adjustment, b1) a cobra configuration and b2) a reverse cobra configuration

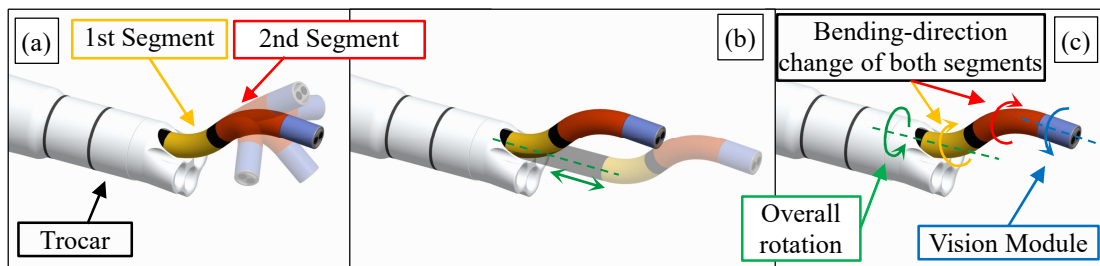


Figure 3.5 Adjusting endoscopic view under a cobra shape: a) adjust the field of view in arbitrary directions, b) zoom in or zoom out, and c) rotating about the vision module's axis.

● Motion limits

The ranges of motion for each degree of freedom of the 3D endoscope are described as follows. The bending direction of both the first and second segments can be oriented arbitrarily within 0–360°. The bending-angle range of the first segment is

0–45°, whereas that of the second segment is 0–90°. The overall linear feeding range of the 3D endoscope is 394 mm, and the overall rotation ranges from –50° to 60°.

As shown in Figure 3.6, after installation, the 3D endoscope can move in to pass the trocar channel for operation. It can also move out to form the wiping pose for cleaning. The receding length from the install position to the wiping pose is 14 mm, whereas the maximum feeding length is 380 mm. When the vision module is aligned with the front end of the trocar outlet, the 3D endoscope reaches its minimum feeding length required for operation. Taking the trocar SR-TC-4-2 as an example, the maximum feeding length of the 3D endoscope is 380 mm, and its minimum feeding length required for entering teleoperation is 220 mm, resulting in a 160-mm feeding range during teleoperation.

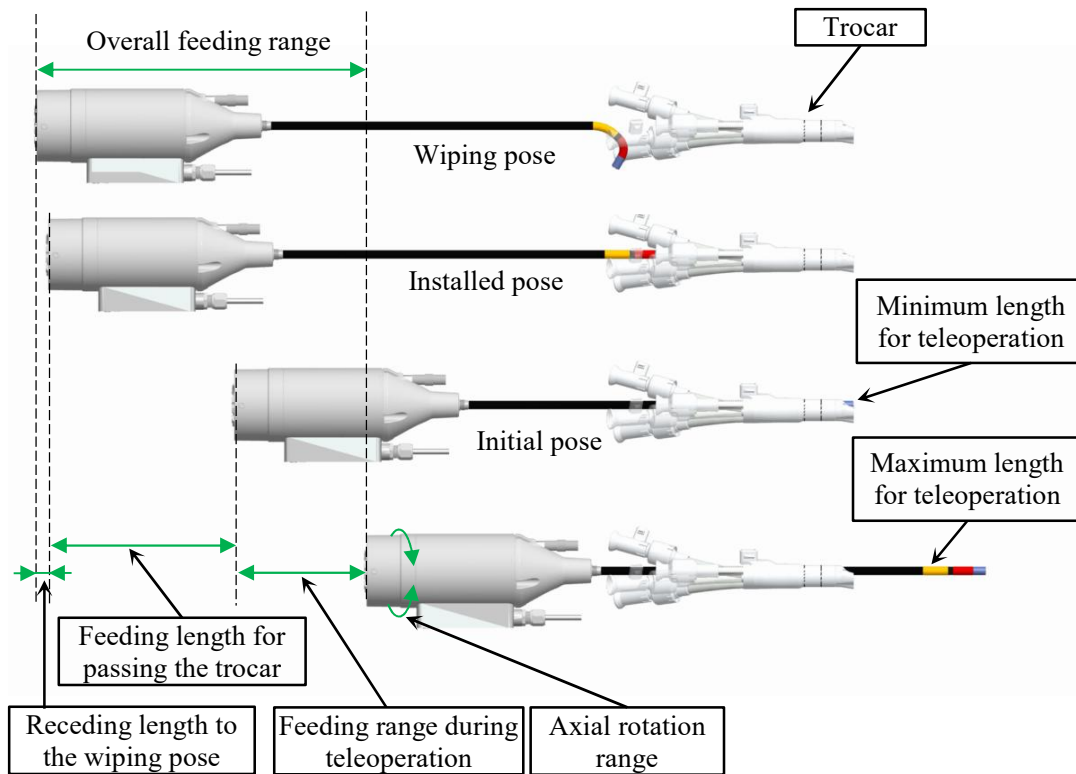


Figure 3.6 Feeding and axial rotation ranges for the 3D endoscope

● Cleaning pose

The 3D endoscope can be moved out to reach the cleaning pose for quick cleaning of the lens, without reloading the 3D endoscope from the actuation module. In the

cleaning pose, the 3D endoscope moves out of the trocar channel's entry port and its segments bend backwards to facilitate wiping and cleaning. Detailed operation instructions can be referred to Section 9.4.2 in the User Manual.

- **3D endoscope target pose**

When the 3D endoscope is moved in, it will finally stop in the target pose. For a new surgery, the target pose of the 3D endoscope is a default pose in which the both the first and second segment bend to form a cobra mode configuration. When the 3D endoscope has been moved by teleoperation control, the target pose of the 3D endoscope will be updated to its current pose. This ensures the 3D endoscope can more conveniently get back to its former operated pose after it is moved out.

3.2.2 Operation of the surgical instruments

- **Motion degrees of freedom for surgical instruments**

The stem of the surgical instruments also consists of two bendable flexible segments. Similar to the 3D endoscope, each segment has two DoFs: 1) change the bending angle in its bending plane, and 2) change the bending direction by rotating its bending plane. The surgical instrument can also achieve overall linear advancement and overall rotation. Therefore, **the surgical instrument has a total of six degrees of freedom**, as shown in Figure 3.7. Most of the surgical instruments have the seventh degrees of freedom: open and close of its end effector.

The operation of surgical instruments can be performed in the normal mode and the short mode.

- **Normal mode operation**

In the normal operation mode, all six DoFs of the surgical instrument is employed, which means both segments must extend out of the trocar to bend. Hence, a shortest feeding length of the surgical instrument is required for the normal mode operation, where the length of the 1st segment extending out of trocar is set to 10 mm. In the normal mode, the pose surgical instrument end-effector fully follows that of the haptic master grip, with a defined scaling factor for translational movement. For surgical instruments with grippers, the instrument grip opening angle follows the haptic master grip's angle.

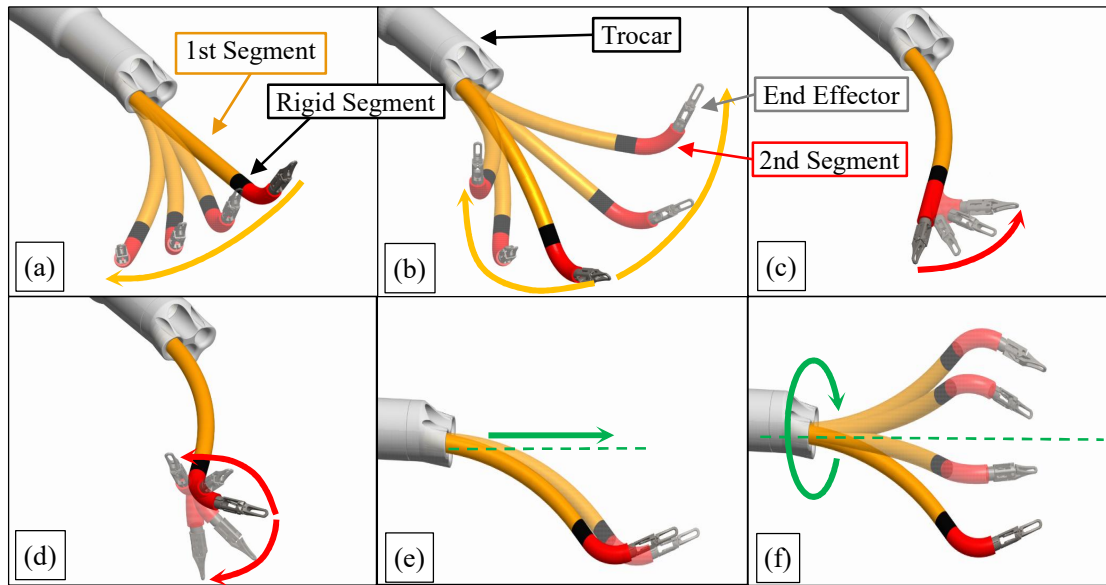


Figure 3.7 Diagram of the degrees of freedom of the surgical instrument: a) bending-angle adjustment of the first segment, b) bending-direction adjustment of the first segment, c) bending-angle adjustment of the second segment, d) bending-direction adjustment of the second segment, e) overall linear advancement, and f) overall axial rotation.

● Short mode operation

Short mode operation is performed only when the first segment is inside the trocar channel. And a short mode operation can be started as soon as the surgical instrument's 2nd segment gets out of the trocar outlet port. In the short mode, 4 DoFs are available: 2-DoF bending of the second segment, and the overall advancement and rotation of the surgical instrument. Because the 4-DoF movement of the surgical instrument in the short mode can not fully follow the 6-DoF movement of the haptic master, the position of the surgical instrument end-effector follows that of the haptic master grip; And the rotation about the end-effector axis (which is realized by the combined rotations of the surgical instrument and the 2nd segment bending plane) follows the rotation of the haptic master grip's own axis.

● Motion Limit

As shown in Figure 3.8, for both the first and second segments of the surgical instrument, the bending directions can be oriented arbitrarily within 0–360°. The ranges of bending angles for the first segment and second segment are 0–90° and

0–120°, respectively. The overall rotation range of the surgical instrument correspond to the rotation module’s motion range, which is -270° to 270° .

The range of the surgical instrument for linear feeding is 490 mm. The linear feeding range of the surgical instrument during teleoperation depends on the trocar type. Taking the trocar SR-TC-4-2 as an example, the overall linear advancement stroke of the surgical instrument is 490 mm, and the minimum insertion length required for entering teleoperation is 296 mm (which corresponds to the shortest length in the short mode), resulting in a 194-mm feeding range during teleoperation, as shown in Figure 3.9.

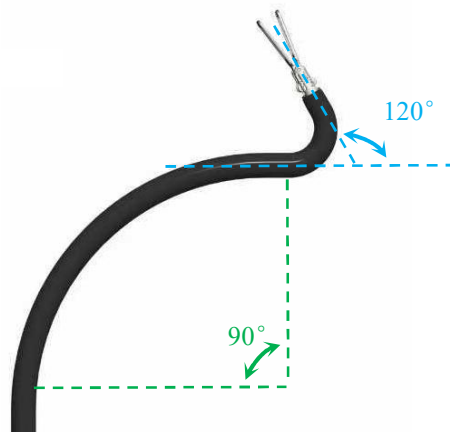


Figure 3.8 Motion limits of the surgical instrument

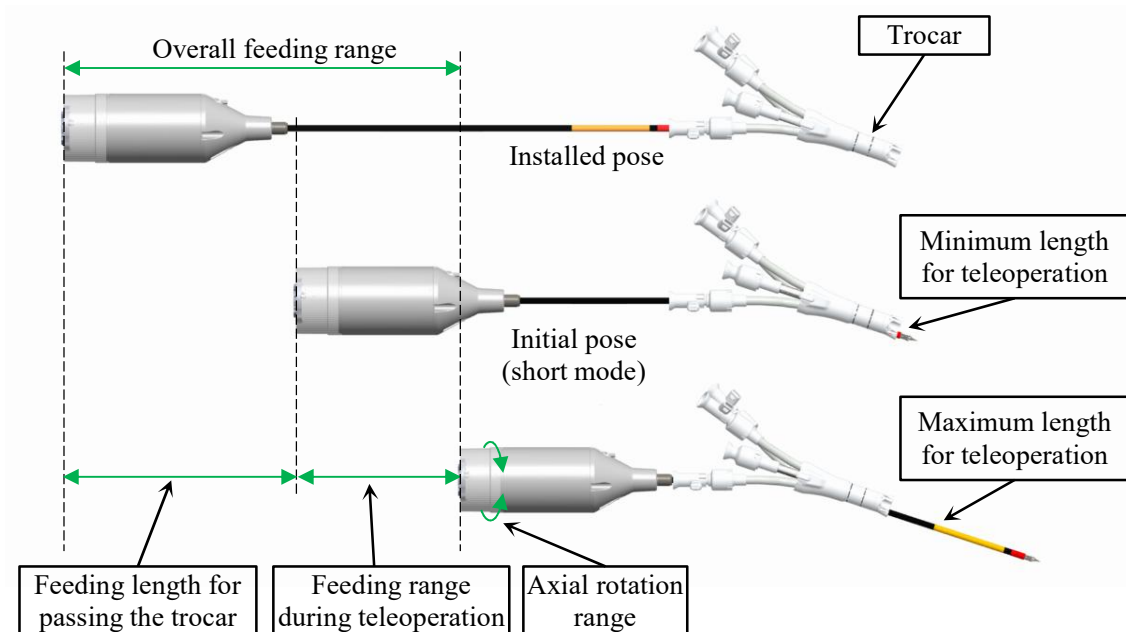


Figure 3.9 Feeding and axial rotation ranges for the surgical instrument

- **Surgical instrument target pose**

After moved in, the surgical instrument will finally stop at its target pose. For a new surgery, the instrument has a default target pose. The default target pose of the surgical instrument has a shape in which both the 1st and the 2nd segments bend and the end-effector is pointing toward the central axis of the trocar. After teleoperation, the instrument's target pose is updated with its current pose. This ensures the instrument can more conveniently get back to its former operated pose after it is moved out.

- **Swap the control between instruments**

Surgical instruments can be swapped by a short press on the switching pedal. A long press on the switching pedal switches assignment of the surgical instrument installed on actuation module 1 between two haptic masters. Refer to Section 10.4.3 in the User Manual for detailed information.

- **Limited bending mode**

As described earlier, the default maximum bending angles of the first and second segments are 90° and 120°, respectively. However, when operating in confined spaces, the user may manually set the maximum bending angles of both segments (0–90° for the 1st segment and 0–120° for the 2nd segment) to restrict the instrument's motion range and prevent unintended contact with surrounding tissues.

3.2.3 Adjustment of the robotic arms

- **Motion capabilities of the robotic arms**

The Surgical Trolley integrates four robotic arms. Each robotic arm contains 6 joints, consisting of five rotational joints (the six joint consists of three coupled joints) and one translational joint, as shown in Figure 2.3. These 6 joints combined, making it possible for the robotic arm to realize 6-DoF movement (e.g., 3-DoF translation and 3-DoF rotation of the actuation module).

Based on the motion capability, the robotic arms can be controlled to realize different motion modes.

- **Target arm pose adjustment mode**

In the target arm pose adjustment mode, the robotic arms each move to their

predefined target arm poses. The predefined target arm poses are specially designed to facilitate preoperative preparations, maintenance, docking, etc., accommodating different surgical scenarios. The target arm poses and their functional descriptions is listed in Table 3.1.

Table 3.1 List of target arm poses

Target arm pose	Functional description
Shipping pose	Fully compact configuration for transport
Cleaning pose	Fully unfolded configuration for surface cleaning
Stowed pose	Standard storage configuration
Draping pose	Arm-separated configuration for drape installation
Folded pose	Pre-operation ready configuration for bedside positioning
Adjusting pose	For trocar docking of the robotic arm 3 and the trocar
Docking pose	For trocar docking of all robotic arms and the trocar

● Single-arm adjustment mode

The single-arm adjustment mode allows the user to adjust the pose of a single robotic arm in different motion directions. When the robotic arms are in the target arm poses "initial trocar docking", as shown in Figure 3.10, the user can choose the motion direction and fine-tune the position and orientation of robotic arm 3, in order to accomplish docking between robotic arm 3 and the trocar.



Figure 3.10 Single-arm adjustment menu in the page of "initial trocar docking"

- **Coordinated adjustment mode**

In the coordinated adjustment mode, all robotic arms are moved in a coordinated manner such that the relative poses of the actuation modules with respect to each other maintain the same. After the robotic arms have been docked to the trocar, the motion of the robotic arms follows the coordinated adjustment mode. In this mode, the robotic arms are moving together to adjust the trocar in the direction selected by the user, as shown in Figure 3.11.

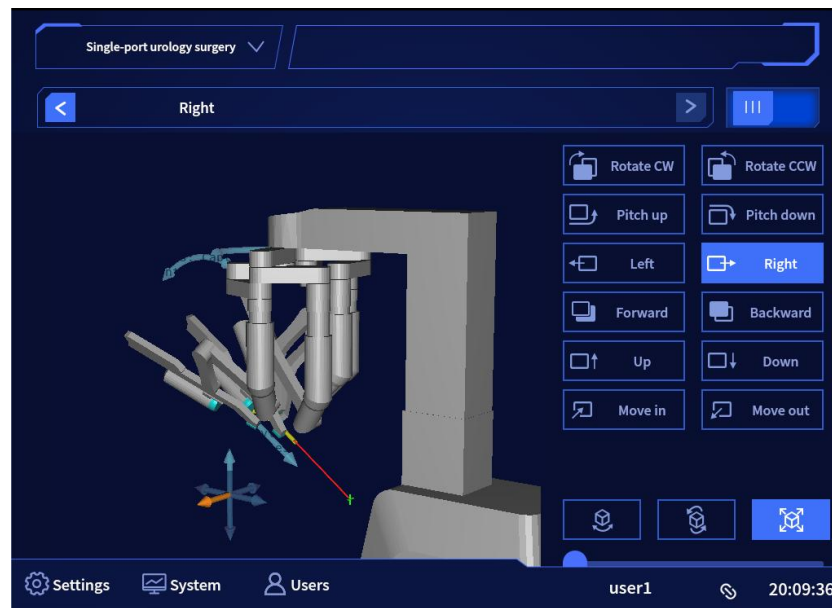


Figure 3.11 Coordinated adjustment menu

3.3 Range of operation

The system has the capability of accessing all quadrants of one's abdomen. This capability is achieved through the range of motion of the surgical instruments and endoscope and the coordinated adjustment mode of the robotic arms.

3.3.1 The range of motion of surgical instruments and endoscope

- **Lateral motion range of surgical instruments**

The lateral motion range of the surgical instruments is up to 22 cm (11 cm at each side), as demonstrated in Figure 3.12.

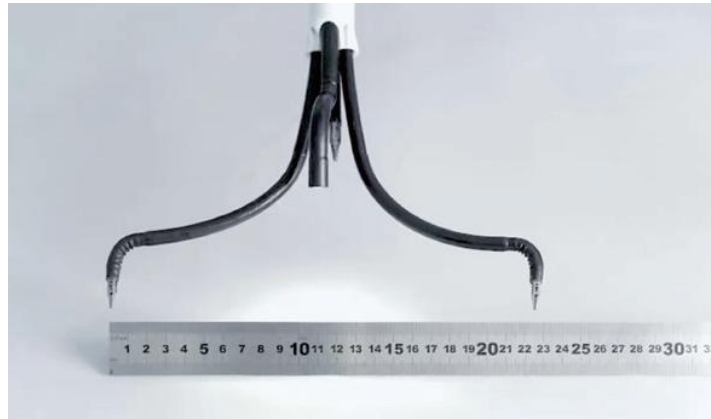


Figure 3.12 Demonstration of the surgical instrument's lateral span.

● Longitudinal operational distance

The minimum longitudinal length (from the trocar channel outlet port to the surgical instrument's end-effector tip) in the normal operation mode is about 5 cm. For the short mode operation, the minimum longitudinal length is about 3 cm. The maximum longitudinal length is up to 22 cm, as shown in Figure 3.13.

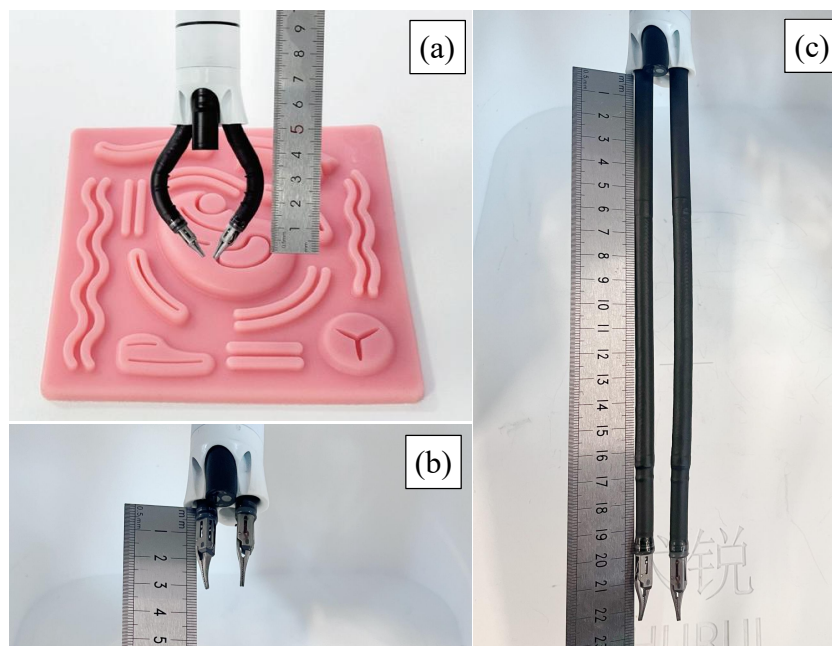


Figure 3.13 Longitudinal operation range: a) the minimum distance for normal operation mode, b) the minimum distance for short operation mode, and c) the maximum longitudinal distance.

With the aforementioned lateral and longitudinal ranges of motion, the surgical instruments and 3D endoscope can reach different locations in the work space (with an illustrative fixed trocar placement), as illustratively shown in Figure 3.14.

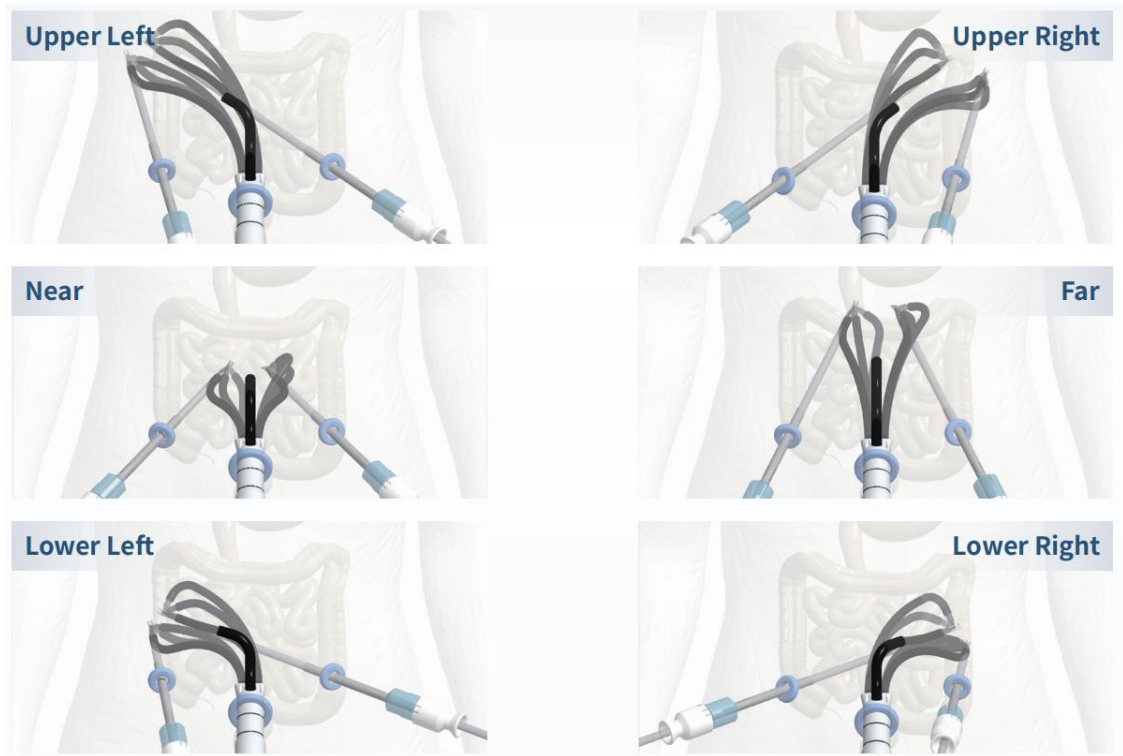


Figure 3.14 Range of motion of surgical instruments and 3D endoscope with a fixed trocar placement

3.3.2 Coordinated adjustment of the robotic arms

In the coordinated adjustment mode, the robotic arms are moving to adjust the pose of the trocar about the entry point or along the trocar axis, as shown in Figure 3.15.

The motion ranges of the adjustment are:

- Up-down adjustment: ± 50 mm
- Forward-backward adjustment: ± 50 mm
- Left-right adjustment: ± 50 mm
- Clockwise and counter-clockwise rotation: $\pm 90^\circ$
- Pitch up and pitch down rotation: $+10^\circ$ (up), -45° (down)
- Move in and move out along the trocar axis: ± 30 mm

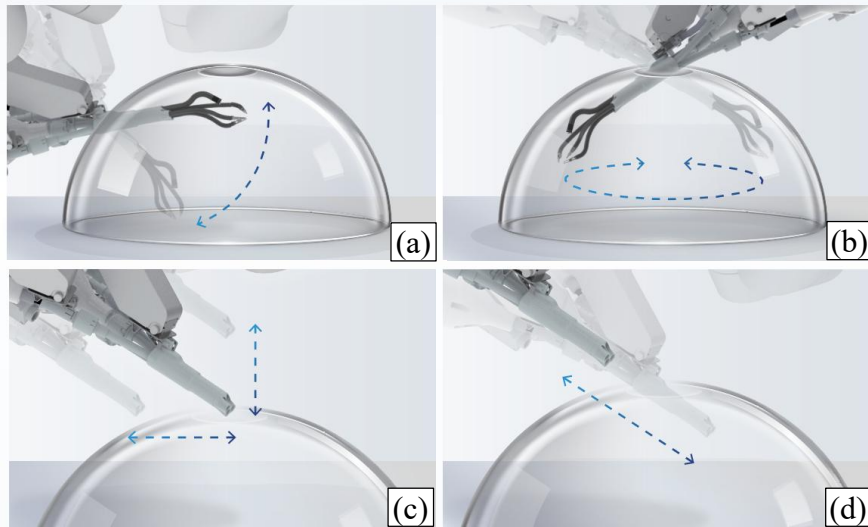


Figure 3.15 Coordinate moving of robotic arms: (a) pitch up and pitch down rotation, (b) clockwise and counter-clockwise rotation, (c) up-down move and forward-backward move, (d) move in and move out.

3.3.3 Float docking technology

Float docking is an approach to place the trocar away from the incision. Under float docking, only the surgical instruments reach the target anatomy. Figure 3.16 demonstrates the float docking trocar placement and instrument configurations in different applications. Because the surgical instruments and the 3D endoscope has a smaller overall circumference compared to the trocar, and because they are compliant, a small incision (less than 2 cm) is needed to accommodate these instruments.

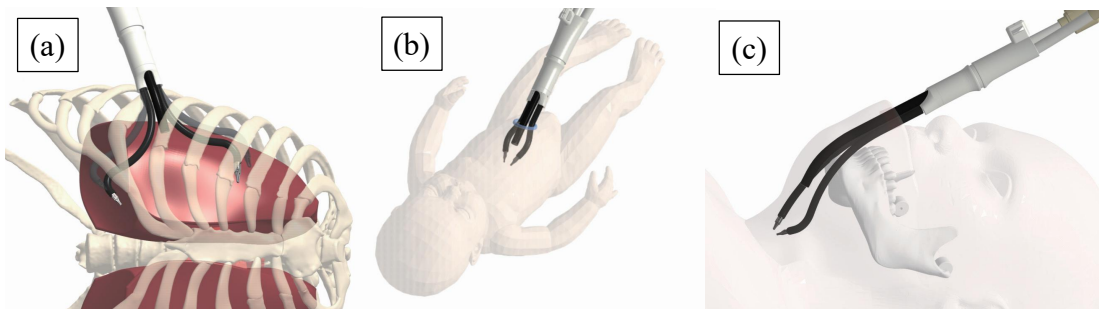


Figure 3.16 Potential applications of the float docking technology: a) transcostal thoracic surgery, b) pediatric surgery, and c) transoral thyroid surgery.

3.4 The 3D viewer display

The Surgeon Console 3D viewer displays the stereo image of the surgical field and provides extended system information using icons and text messages.

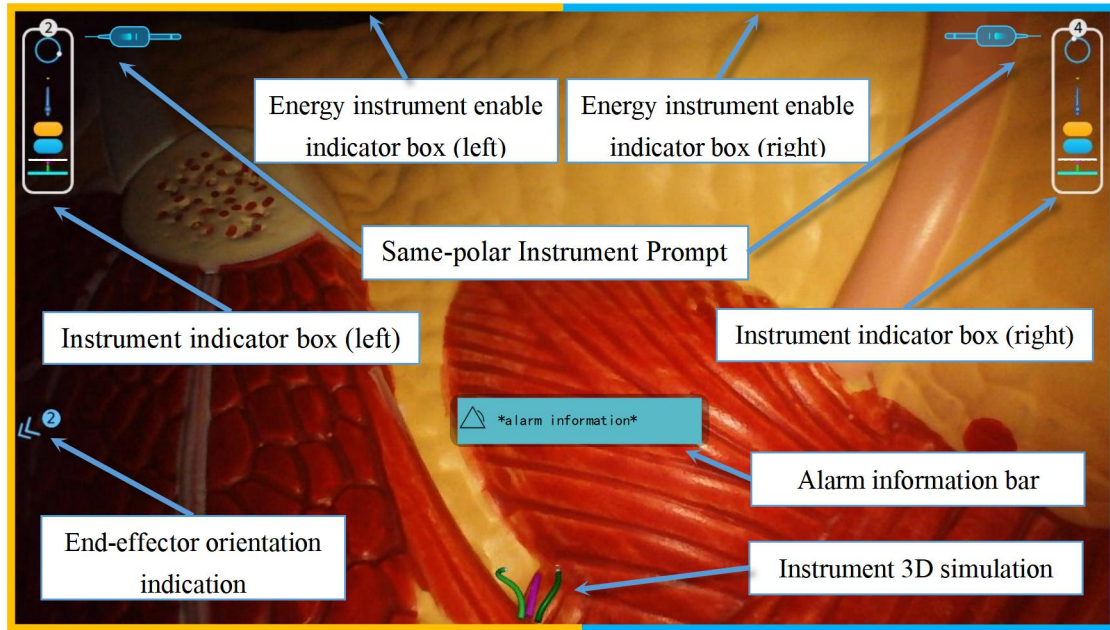


Figure 3.17 Surgeon Console 3D viewer interface

- **Energy instrument enable indicator box**
 - Indicates the activation status of electric cutting and electric coagulation of left and right hand controlled instruments.
- **Alarm information bar**
 - Display the alarm information that needs to be read by the surgeon during the operation.
- **Instrument 3D simulation**
 - Real-time simulation of the 3D endoscope and surgical instruments out of trocar channel during surgery.
 - Notification when joint of the 3D endoscope and surgical instruments reaches limit.
 - Different color indicates the insertion length of the 3D endoscope and surgical instruments.
- **End-effector position indication**
 - Indicates the orientation of the end-effector out of the field of view.
- **Instrument indicator box indicates:**
 - Actuation module number
 - Matching status of the surgical instruments

- Instrument rotation angle limit
- Grip opening angle
- High-frequency energy mode supported
- The vertical and lateral position of the haptic master
- Same-polar instrument installation

3.5 Safety Features

The SHURUI System is designed with multiple safety features, including human-in-operation detection, collision detection, over-speed operation protection, safe instrument insertion and withdrawal, etc.. Some are introduced as follows.

● Detection of user presence

To use the haptic master for teleoperation of the instruments, the surgeon must first place his/her head into the 3D viewer. A pair of infrared sensors on the distal sides of the 3D viewer will detect whether a user is present. If the infrared sensor does not detect a user, the system will not allow the establishment of matching for teleoperation.

● Automatic locking the electric wheels when connect to the trocar

Once a robotic arm is connected to the trocar, the system will disable the driving function of the Surgical Trolley's base. This function will remain disabled until all sheath connectors are disconnected, preventing inadvertently driving the electric wheels during surgical operation. In addition, the electric wheel of the Surgical Trolley is self-locking, preventing external forces from moving the trolley when the driving power is turned off.

● Shape-following insertion and withdrawal of surgical instruments

When withdrawing the surgical instrument, it will move out along its snake-like shape, reducing the risks of interfering with tissues or other instruments during surgery. When a surgical instrument is moved in again on the same actuation module (e.g., when the surgical instrument is replaced by another one, or cleaned), it also follows the path of the same shape to the target pose of the instrument. The surgical instrument will stop feeding 10 mm before the target pose is reached to prevent damage to the tissue

(in case that a surgical instrument with a sharp end-effector is inserted).

- **Collision detection of the robotic arms**

The software system continuously monitors the gap between the robotic arms during movement. Upon detecting a potential collision, it automatically stops motion and triggers an alarm.

- **Redundant hardware design**

Two encoders are employed for each joint of the haptic masters, robotic arms and each motor in the actuation modules. Hence, if one of the encoders malfunctions, mutual verification between the two encoders enables fault detection, and the other encoder can serve as a backup. Also, when a button or a pedal is pushed to execute a movement or an energy function, it is triggered only when two separate electric contacts are activated, improving the safety of these interfaces.

4 Transportation and Storage

4.1 Transportation

4.1.1 Unloading Area Requirements

The product is initially delivered to the hospital's unloading area, where it will be unpacked and the parts disassembled for transportation will be restored by authorized technical engineer. Subsequently, it will be moved to the operating room. The unloading area should meet the following specifications for space, pathways, and environment.

- **Minimum dimensions for unloading:** Minimum dimensions of the entrance/exit of the unloading area are 230 cm in height and 150 cm in width.
- **Preferred dimensions for unpacking:** The unloading area should have a minimum space of 500 cm × 500 cm for unpacking. If the unloading area is outdoors, it should be covered with a canopy to protect against rain.

4.1.2 Transport Pathway Requirements

After completing the unpacking and basic assembly of the equipment in the unloading area, the Surgical Trolley and the Surgeon Console will be transferred one by one to the final installation site. The requirements for the transport pathway are as follows.

- **Transport surface:** The surface of the transport pathway from the unloading area to the final installation site should be level, without steps or steep ramps.
- **Straight pathway dimensions:** Minimum dimensions for straight entrances/exits of the transport pathway are 190 cm in height and 120 cm in width.
- **Turning pathway dimensions:** Minimum dimensions for transport pathway with a right angle turn are 190 cm in height and 150 cm in width.
- **Elevator:** If the final installation site is on a different level than the unloading area, an elevator with a minimum load capacity of 1600 kg and minimum dimensions of 200 cm in height, 120 cm in width, and 250 cm in depth is required.

4.1.3 Surgical Trolley Transportation Status

Schematic diagram of the Surgical Trolley in the transportation status is provided in Figure 4.1.

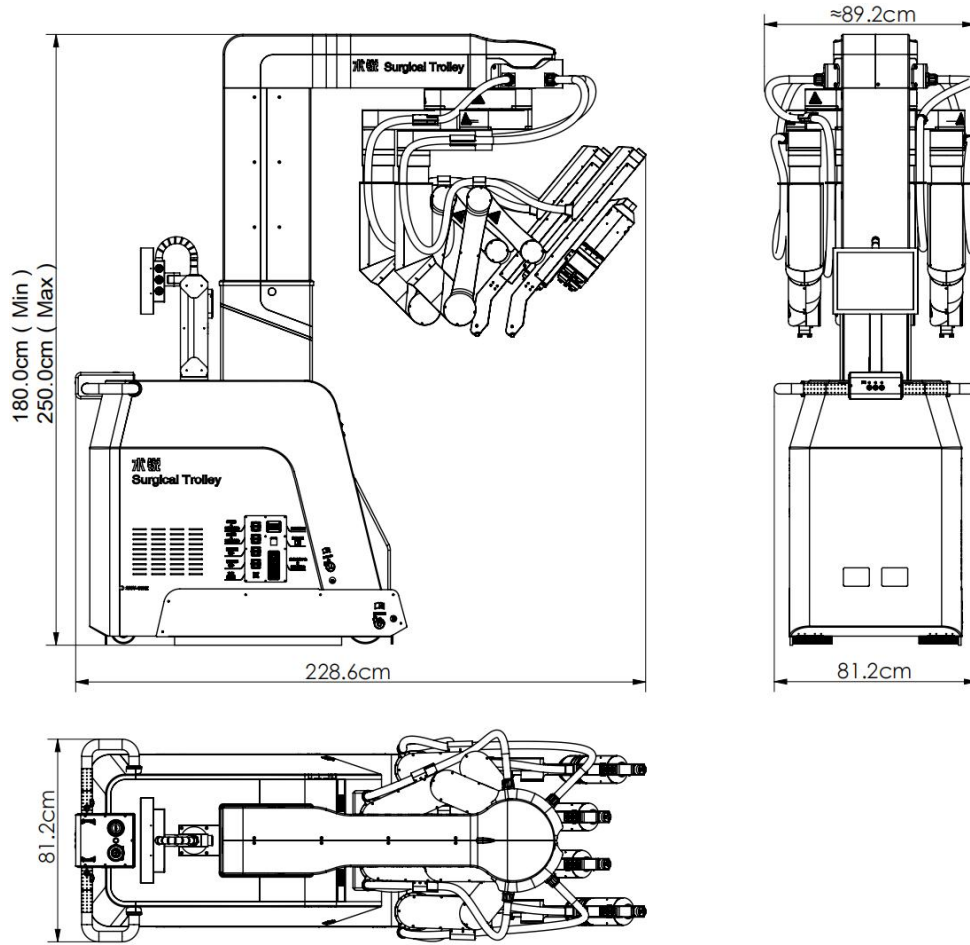


Figure 4.1 Schematic diagram of Surgical Trolley after unpacking and during transportation

4.1.4 Surgeon Console Transportation Status

Schematic diagram of the Surgeon Console in the transportation status is provided in Figure 4.2.

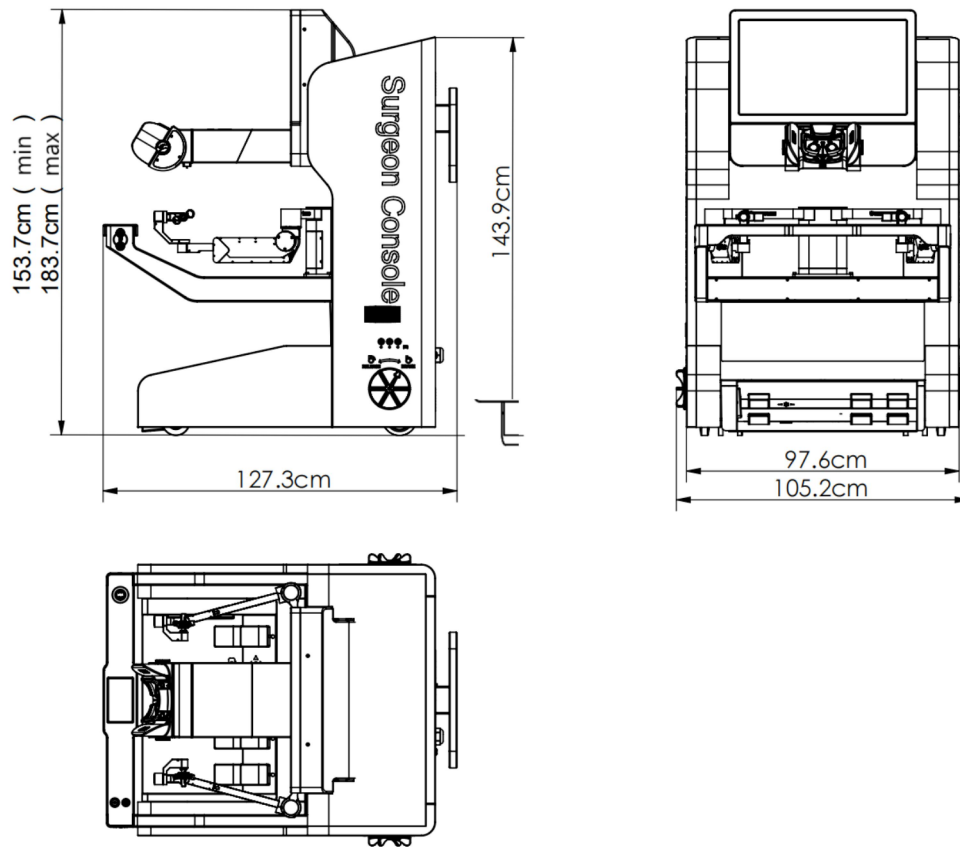


Figure 4.2 Schematic diagram of Surgeon Console after unpacking and during transportation

4.2 Transportation and Storage Conditions

The transportation and storage conditions of the Surgeon Console, Surgical Trolley, 3D endoscope, surgical instruments, and reusable accessories are as follows:

Temperature: $-10^{\circ}\text{C} - 50^{\circ}\text{C}$

Relative humidity: 20% – 95%

Atmospheric pressure: 651 hPa – 1060 hPa

The minimum footprint of the main body of the product is as follows:

Table 3.1 Footprint of system components (in square meters)

Component name	Surgeon Console	Surgical Trolley
Footprint area	1.34	2.04

During the period when the equipment is not in use, the following requirements are mandatory:

The Surgeon Console and Surgical Trolley integrate UPS batteries, and they are

required to perform a system check every six months.

Prevent dust and moisture during equipment storage.

No corrosive gas is allowed in the environment where the Surgeon Console and the Surgical Trolley is located.

The Surgeon Console and the Surgical Trolley should be placed on a flat ground with a slope of no more than 10°.

5 Installation

 WARNING	1) No modification of this equipment by unauthorized personnel is allowed. 2) To avoid risk of electric shock, this equipment must be connected to power supply with protective ground only.
 CAUTION	1) This product may only be installed and serviced by Surgerii Robotics personnel. DO NOT attempt to install or service equipment without Surgerii Robotics personnel. To reduce the risk of electric shock, DO NOT open or remove covers. 2) Intense environmental vibrations in buildings can have an impact on the operation and use of this product, so it is important to avoid this possibility when deciding where and when to use it. 3) Accessories of this product should be used in combination. Using accessories that are not provided by Surgerii Robotics may result in improper use, damage of this product and even cause danger.

The room and transfer pathway used for equipment installation or storage need to withstand a local ground pressure of approximately 19.2 kg/cm² from the equipment's wheels to avoid floor damage.

The layout of the operating room for this product can be referred to in Figure 4.1.

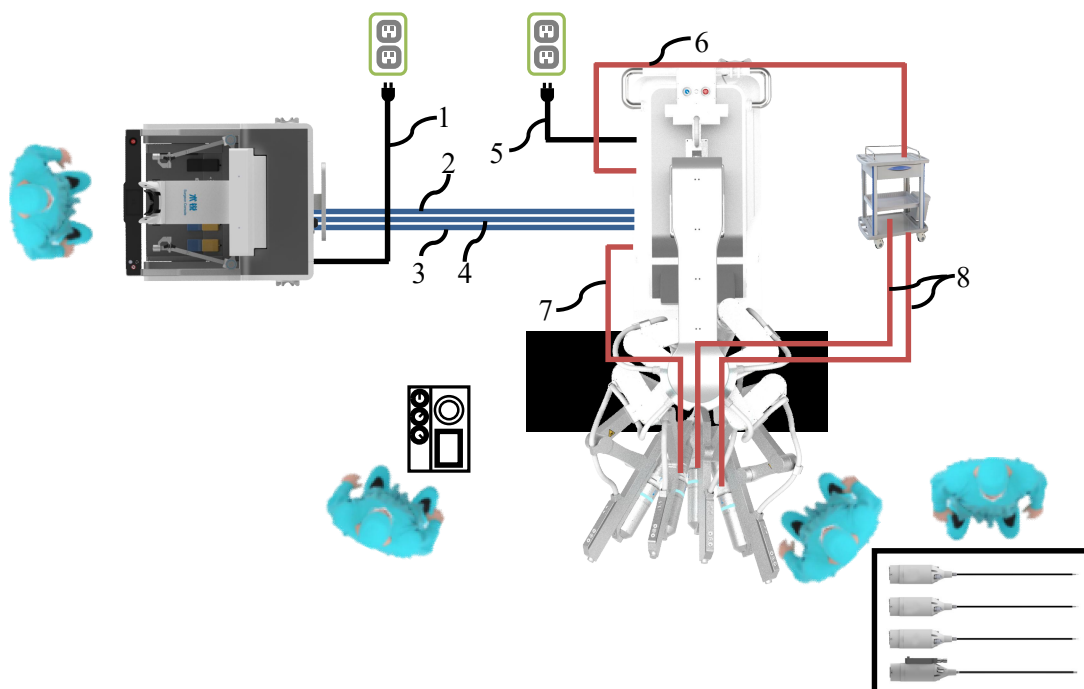


Figure 5.1 System cable connection diagram (1-Surgeon Console power cable, 2-System connection cable, 3-2D video cable, 4-3D video cable, 5-Surgical Trolley power cable, 6-Energy activation cable, 7-Endoscope cable, 8-Monopolar and bipolar energy instrument cord)

During the use of this product, depending on the surgical procedure, the Surgical Trolley may be placed in different positions next to the operating table. Considering the presence of various other devices in the operating room and for the convenience of moving the equipment, it is recommended that the operating room has an area greater than 42 m².

The height of the Surgical Trolley column can be adjusted up to 2.5 m. When in use, care should be taken to avoid collisions with the ceiling, surgical lights, medical booms, or other equipment.

The components of this product are connected to each other by cables and cords to transmit energy and data. The bending radius of the cables and cords should not be too small to prevent them from breaking or getting damaged. During surgery, the cables and cords should not be run over by the operating table or other carts.

Power configuration: At least three independent, grounded power sources are required, and the outlet panels should have air switches on the power supply line. The positioning of outlets should be distributed reasonably to meet the requirements of equipment placement according to different surgical positions. Both the Surgeon Console and the Surgical Trolley are equipped with transformers to provide electrical isolation. When performing system maintenance, it is necessary to unplug the Surgeon Console power cable and Surgical Trolley power cable from the power outlets.

The power cord for this product is 7.0 m in length. The power requirements of the components are as listed in Table 4.1.

Table 5.1 Power requirements of system components

Component name	Surgeon Console	Surgical Trolley
Power requirements	1000 VA, 220-240V~, 50/60Hz or 110-120V~, 60Hz	2000 VA, 220-240V~, 50/60Hz or 110-120V~, 60Hz

The batteries can provide up to 15 minutes of emergency power, allowing the removal of surgical instruments and endoscope from the patient's body and the undocking of system from the operating table in case of an external power outage.

In addition to the status touchscreen on the Surgical Trolley and the 2D display on the Surgeon Console, users can connect external image display screens via the 2D video port (External Devices) on the Surgical Trolley to display endoscopic images using standard HDMI connections. If an external status display is required, it can be connected to the status video port on Surgical Trolley to display system status using standard HDMI connections.

Compatible high-frequency generator (also referred to as electrosurgical units, ESU) can be used after connecting the energy activation cable to the Surgical Trolley and connecting monopolar/bipolar energy instrument cords to corresponding instruments. Information on compatibility and the conditions of the intended use during surgery is referred to as the following tables.

Table 5.2 Compatible high-frequency generator

Device Name	Manufacturer	Model Name	CE Mark
Electrosurgical Generator	Covidien Ilc.	VLFX8GEN	CE2797

Table 4.3 Rated high frequency repetitive peak voltage for the operating modes of high frequency surgical instruments

Instrument name	Working mode	Rated high-frequency repetitive peak voltage	Maximum power
Monopolar curved scissors, Monopolar cautery hook	PURE CUT	1287V	300W
	BLEND CUT	2187V	200W
	SOFT COAG	264V	120W
	FULGURATE COAG	3448V	120W
	SPRAY COAG	3448V	60W
Curved bipolar dissector, Maryland bipolar	PRECISE	284V	70W
	STANDARD	415V	70W

forceps, Bipolar forceps	MACRO	530V	70W
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Table 5.4 Rated high frequency repetitive peak voltage of the energy instrument cords and the 3D endoscope used in high-frequency surgical applications' interconnection conditions

Name	Working mode	Rated high-frequency repetitive peak voltage
3D endoscope, Monopolar energy instrument cord, Bipolar energy instrument cord	Monopolar	3448V
	Bipolar	530V

6 Maintenance and Troubleshooting

The maintenance of the system can be mainly divided into the following parts: i) reprocessing of the surgical instruments, 3D endoscope and reusable accessories; ii) cleaning of trolley, console and their connecting cables; iii) system preventive maintenance and troubleshooting.

For reprocessing instructions of surgical instruments, 3D endoscope, and reusable accessories, please refer to the Instrument Reprocessing Instructions, 3D Endoscope Reprocessing Instructions, and Accessories Reprocessing Instructions.

For information on the cleaning of the trolley, console, and their connecting cables, as well as preventive maintenance and system alarms, please refer to the User Manual.

6.1 Customer Service

If the system requires maintenance or service, call the Customer Service line: +31-850643988.

6.2 Convert to Open Surgery

If conversion to open surgery is required, please follow the steps to remove the system from the patient:

1. Remove all surgical instruments from the Surgical Trolley. If semi-electric exit or manual exit of the surgical instrument is required, please follow the instructions in the User Manual.
2. Remove the 3D endoscope from the Surgical Trolley.
3. Open the latches of all sheath connectors to separate the trocar from the linear modules.
4. Raise the beam of the Surgical Trolley appropriately according to the actual needs.
5. Release the stabilization feet and drive the Surgical Trolley away from the operating table.

6.3 Access to Logs

The user can view logs via the “log” option in the “system” menu in the Surgical Trolley status touchscreen or the Surgeon Console touchpad. The log information can be filtered by date, log, error, warning, and notification. The logs are saved for 90 days. Users cannot delete or modify the logs.

6.4 Surgical Trolley Drive Troubleshooting

In circumstances where the drive controller malfunctions or power supply is not accessible, the Surgical Trolley can be moved manually. Use the trolley adjustment tool to release the stabilization feet and wheels via the left/right wheel locking release sockets and the stabilization feet release sockets (refer to Section 3.4.1 in the User Manual), then manually push or pull the surgical trolley to move.

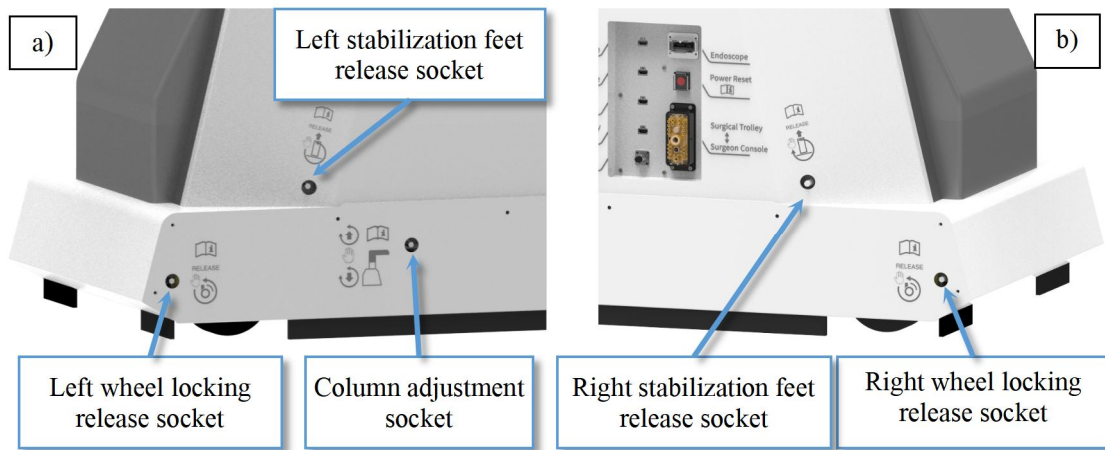


Figure 6.1 Wheel locking release socket and stabilization feet release socket for the Surgical Trolley

6.5 Alarms

This system has a distributed alarm system. During its operation, should any faults occur, the system will alert users through both visual and auditory means.

If an alarm is related to both the Surgical Trolley and the Surgeon Console, it will also be transmitted to the Surgeon Console when the alarm is sourced from the Surgical Trolley. The Surgical Trolley will display the alarm information in the system information bar, show corresponding visual alarm signals with the alarm light, and play the corresponding alarm sound through the speaker. Meanwhile, the Surgeon Console will display the alarm information in the system information bar and play the

corresponding alarm sound via its speaker as well.

If the Surgeon Console is the source of the alarm, it will transmit the alarm information to the Surgical Trolley, and the alarm methods will be identical to those described above.

The Surgical Trolley and the Surgeon Console will each trigger their own alarm to alert the user when the alarm is not related to both the Surgical Trolley and the Surgeon Console.

The system performs a self-test on the alarm system during the power-on process: the alarm light first flashes yellow, then red, followed by two start-up prompt tones. It is also possible to trigger an alarm during use to check whether the alarm system is functioning properly (for example, by pressing the emergency-stop button).

The “system information bar” displays current alarm information along with corresponding alarm icons. Alarm messages are categorized into high, medium, and low priority levels, each represented by different colors. Red indicates high priority, yellow indicates medium priority, and cyan-green indicates low priority.

Click “system information bar” to display the current alarm information list. When there are multiple alarms with different priority levels in the “system information bar,” the alarm system displays visual alarm signals and plays alarm tones according to those with the highest priority level in the list; When there are multiple alarms with the same highest priority level in the “system information bar”, the alarm system will alternately display the alarm information with the highest alarm priority. The number in the upper right corner represents the total number of alarm messages. Click the number to expand the alarm message list and view each alarm message.

Click any alarm message in the list to pop up the alarm detail message box.

Click the “Alarm OFF” button to close the current alarm information. Click the “Alarm reset” button, the alarm information is to be cleared if the alarm event ceases. The alarm will repeat if the alarm event continues to occur. Click the “Sound OFF” button to close the alarm sound of the current alarm information. At this time, the “Sound OFF” icon is updated to “Sound ON”. Click the “Sound ON” button to restore the Alarm prompt tone.

After clicking “Alarm OFF” and “Sound OFF”, you can view the corresponding prompt signal in the “system information bar.”

Detailed information regarding the alarms can be referred to the User Manual.

6.6 Reboot the System

If the user is advised to restart the system in the alarm information, click the “system” menu in the Surgical Trolley status touchscreen or the Surgeon Console touchpad, and choose “reboot” option. Click “Confirm”, the Surgical Trolley or the Surgeon Console will reboot in seconds.

If the system experience power issues (e.g., fails to power on/off normally) and power reset is required, long press the emergency power reset button on the Surgical Trolley or the Surgeon Console for more than 5 seconds to reset the power supply.

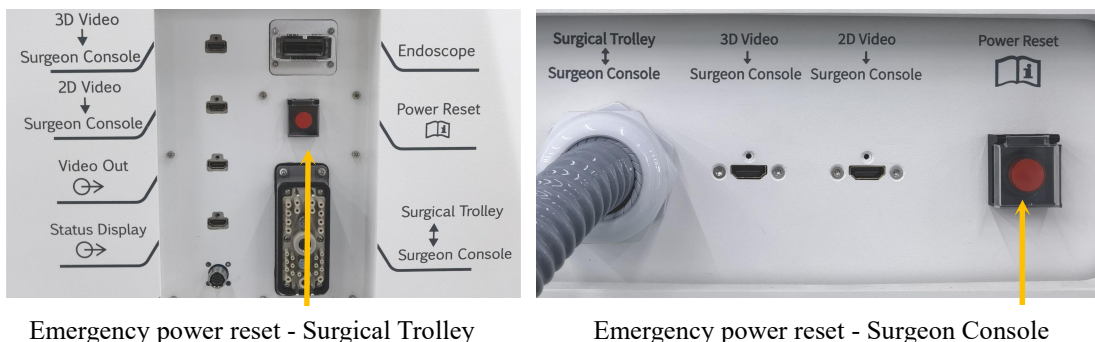


Figure 6.2 Emergency power reset buttons

6.7 Software Update

The upgrade of the software for this product can only be carried out by professional maintenance engineers authorized by Surgerii Robotics.

7 Service Life

For the service life of each system component, please refer to the User Manual.

Appendix A Symbols and Identifications

Table A.1 Attentions

Number	Symbol	Description
1	 Caution	CAUTION symbol alerts reader what needs attention when operating and using. Details of relevant scenarios are given in boxes similar to this box.
2	 Warning	WARNING symbol alerts reader about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. Details of relevant scenarios are given in boxes similar to this box.
3	 Hazard	HAZARD symbol alerts reader about a situation which, if not avoided, could result in death or serious injury or serious damage to the equipment or other property. Details of relevant scenarios are given in boxes similar to this box.
4	 Prohibition	PROHIBITION symbol alerts reader about actions that are absolutely forbidden or prohibited. Details of relevant scenarios are given in boxes similar to this box.
5		Operating instructions
6		Read the User Manual before use
7		Caution

Table A.2 Current

Number	Symbol	Description
1		Alternating current

Table A.3 Grounding

Number	Symbol	Description
1		Protective earth (ground)
2		Earth (ground)

Table A.4 Other symbols

Number	Symbol	Description
1		Type CF Applied Part
2		Country of manufacture
3		Use by Date
4		Serial Number
5	IPN₁N₂	Ingress Protection (IP) Rating
6		Non-sterile
7		Do not use if package is damaged
8		Do not re-use
9		Unique Device Identifier

Number	Symbol	Description
10		Medical Device
11		Dispose in accordance with local regulations—particularly applies to electronic components
12		Batch code
13		Model number
14		Sterilized using ethylene oxide
15		Do not re-sterilize
16		Manufacturer
17		Authorized representative in the European Union
18		Catalogue number
19		In conformity with Regulation (EU) 2017/745 European Medical Devices Regulation (MDR)

Table A.5 Warning signs

Number	Sign	Description
1		Hands pinching warning
2		No sitting

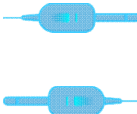
Table A.6 Outer packaging symbols

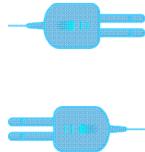
Number	Symbol	Symbol Name
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Number	Symbol	Symbol Name
1		Keep dry
2		Keep away from sunlight
3		Fragile, handle with care
4		Temperature limit
5		Humidity limit
6		Atmospheric pressure limit
7		This way up
8		Do not roll
9		Do not stack
10		Stacking limit by number

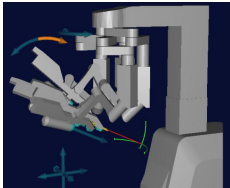
Table A.7 Symbols or icons on UI

Number	Symbol or icon	Description
1		Menu: Settings

2		Menu: System
3		Menu: Users
4		Electric coagulation of the instrument assigned to the left haptic master is activated
5		Electric cutting of the instrument assigned to the left haptic master is activated
6		Electric coagulation of the instrument assigned to the right haptic master is activated
7		Electric cutting of the instrument assigned to the right haptic master is activated
8		Haptic master and surgical instrument are not matched
9		Haptic master and surgical instrument are matched
10		Indicates the endoscope is in control and the tilting angle of the endoscope
11		The surgical instrument supports electric coagulation
12		The surgical instrument supports electric cutting
13		Actuation module index number
14		Symbol of 3D endoscope
15		Appears when both the left and right hand-assigned instruments are monopolar energy instruments.

16		Appears when both the left and right hand-assigned instruments are bipolar energy instruments.
17		Appears on the left when the swap pedal is pressed and held to indicate that the actuation module 1 is swapped between two haptic masters
18		Appears on the right when the swap pedal is pressed and held to indicate that the actuation module 1 is swapped between two haptic masters
19		Screen locked
20		Screen unlocked
21		Switch this instrument to the right hand
22		Switch this instrument to the left hand
23		UPS charging
24		UPS NOT charging
25		Switch language
26		Voice enabled
27		Voice disabled
28		Microphone enabled
29		Microphone disabled
30		Login password is invisible
31		Login password is visible

32		Connected to grid power
33		NOT connected to grid power.
34		Teleoperation connection is established
35		Teleoperation connection is not established
36		View switch: switch views between status of the actuation modules and the pose simulation of the robotic arms
37		Instrument exit
38		“Wiping” function for 3D endoscope
39		Coordinated adjustment mode: Rotate clockwise
40		Coordinated adjustment mode: Rotate counterclockwise
41		Coordinated adjustment mode: Pitch down
42		Coordinated adjustment mode: Pitch up
43		Coordinated adjustment mode: Move left
44		Coordinated adjustment mode: Move right
45		Coordinated adjustment mode: Move backward
46		Coordinated adjustment mode: Move forward
47		Coordinated adjustment mode: Move down
48		Coordinated adjustment mode: Move up

49		Coordinated adjustment mode: Move in
50		Coordinated adjustment mode: Move out
51		Left-right rotation of the robotic arm simulation
52		Up-down rotation of the robotic arm simulation
53		Zoom in-out of the robotic arm simulation
54		Actuation module assigned to left haptic master
55		Actuation module assigned to right haptic master
56		The pose simulation of the robotic arms

Appendix B Terminology and Abbreviations

Table B.1 Terminology and Abbreviations

Number	Terminology and abbreviations	Meaning
1	BPC	Bipolar Energy Instrument Cord
2	ENP	3D Endoscope
3	ENS	Endoscopic Surgical System
4	ENT	Surgical instrument
5	MPC	Monopolar Energy Instrument Cord
6	SC	Surgeon Console
7	SP	Single-Port
8	SR	Beijing Surgerii Robotics Company Limited
9	ST	Surgical Trolley
10	SW	Software
11	UI	User Interface
12	UPS	Uninterruptible Power Supply

Appendix C Compliance and Classifications

1. Classification by type of protection against electric shock: Class I.
2. Classification by degree of protection against electric shock: CF for all patient applied parts (the surgical instruments that in contact with patient and 3D endoscope).
3. Classification by degree of protection against ingress of liquid:
 - 1) Surgeon Console: IPX0
 - 2) Surgeon Console footswitch pedals: IPX8
 - 3) Surgical Trolley: IPX0
 - 4) Surgical instrument: IPX7
 - 5) 3D endoscope: IPX7
4. Classification by the safety when using in the presence of flammable anaesthetic mixture with air or flammable anaesthetic mixture with oxygen or nitrous oxide: Equipment that cannot be used in the presence of flammable anaesthetic mixture with air or flammable anaesthetic mixture with oxygen or nitrous oxide.
5. Classification by mode of operation: Continuous operation.
6. Rated voltage and frequency of equipment: 220–240V~, 50/60Hz or 110–120V~, 60Hz.
7. Input power of equipment:
 - 1) Surgeon Console: 1000VA;
 - 2) Surgical Trolley: 2000VA.
8. Application part of equipment that provides protection against defibrillation discharge effect: Not applicable.
9. Signal output or input part of equipment: Yes.
10. Transportable equipment: No. This product is a stationary equipment.

Essential Performance of the SHURUI System:

The following essential performance information is in compliance with IEC

60601-1.

- The Endoscopic Surgical System allows real-time acquisition of surgical field images on the side of surgical instruments through a 3D endoscope. Surgical field can be displayed normally on 2D display and 3D viewer with no interruption or blackout in image transmission.
- The Endoscopic Surgical System provides motion control of the surgical instruments and 3D endoscope loaded on the Surgical Trolley through the Surgeon Console with master-slave teleoperation accuracy and master-slave teleoperation time delay within the claimed range: master-slave teleoperation distance accuracy $\leq 2\text{mm}$, master-slave teleoperation distance repeatability $\leq 2\text{mm}$, master-slave teleoperation time delay $\leq 200\text{ms}$.
- The Endoscopic Surgical System have no unintended motion during preoperative preparation and intraoperative manipulation.

Appendix D Electromagnetic Compatibility Description

D.1 Instructions

1. This product requires specific guidance on electromagnetic compatibility and instructions for installation and use based on the electromagnetic compatibility information provided in this appendix.
2. Portable and mobile RF communication devices may affect the product.

This product complies with IEC 60601-1-2:2014 + A1:2020. During immunity testing, the basic safety and essential performance criteria in Appendix C were satisfied.

Equipment in the operating room, including the system and other portable or mobile communications equipment, can produce Electromagnetic Interference (EMI), which may affect the function of these devices. Such effects are prevented by use of equipment with EMI characteristics proven below recognized limits, as identified in the following tables.

 WARNING	1) In the event of suspected interference from other equipment which prevents the proper functioning of the SHURUI Endoscopic Surgical System, contact Surgerii Robotics and discontinue use of the system until the problem can be remedied, to prevent procedure delay and potential patient harm. Symptoms of interference could include repeated faults, unintentional movement of the robotic arms, instruments, or 3D endoscope, and lost or frozen video.
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D.2 Cables Used

Name	Quantity used	Length(meter)	Shielding Layer
Surgeon Console Power Cable	1	7	No
Surgical Trolley Power Cable	1	7	No
System Connection Cable	1	10	Yes
2D Video Cable	1	10	Yes

3D Video Cable	1	10	Yes
Energy Activation Cable	1	5	Yes
Monopolar Energy Instrument Cord	1	5	No
Bipolar Energy Instrument Cord	1	5	No

The use of accessories and cables other than those specified by the manufacturer of this product may lead to an increase in the emission of this product or a decrease in the degree of perturbation.

D.3 Electromagnetic Emission Statement

Table D.1 IEC 60601-1-2:2014+A1:2020, Manufacturer's Declaration - Electromagnetic Emissions

IEC 60601-1-2:2014+A1:2020, Manufacturer's Declaration - Electromagnetic Emissions		
This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	This product does not use RF energy for its function. Therefore, its RF emissions are very low and are not likely to cause any interference for nearby electronic environment.
RF emissions CISPR 11	Class A	This product 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	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might

not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

D.4 Warning

This product should not be placed near or stacked with other devices. If it is necessary to place it near or stack it with other devices, you should observe and verify that it operates properly in the given configuration.

Table D.2 IEC 60601-1-2:2014+A1:2020, Manufacturer's Declaration - Electromagnetic Immunity

IEC 60601-1-2:2014+A1:2020, Manufacturer's Declaration - Electromagnetic Immunity			
This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV ±4 kV ±8 kV ±15kV air	±8 kV contact ±2 kV ±4 kV ±8 kV ±15kV air	NA
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	The network power supply should have the quality used in typical commercial or hospital environments
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	The network power supply should have the quality used in typical commercial or hospital environments
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 250 cycles.	<5% UT (>95% dip in UT) for 0.5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 250 cycles.	The network power supply should have the quality used in typical commercial or hospital environments. The uninterruptible power supply (UPS) can support the system to run

			continuously during a power interruption.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	The network power supply should have the quality used in typical commercial or hospital environments
Note: UT is the AC mains voltage before application of the test level.			

Table D.3 IEC 60601-1-2:2014+A1:2020, Manufacturer's Declaration - Electromagnetic Immunity

IEC 60601-1-2:2014+A1:2020, Manufacturer’s Declaration - Electromagnetic Immunity			
This product is intended for use in the electromagnetic environment specified below. The customer or the user of this product should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM/Amateur band	3 Vrms 6 Vrms	Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 9 V/m to 28 V/m Proximity fields	3 V/m 9 V/m to 28 V/m	
Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Note 2: In all cases, 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.

Table D.4 IEC 60601-1-2:2014+A1:2020, Recommended separation distances between portable and mobile RF communications equipment and this product

IEC 60601-1-2:2014+A1:2020, Recommended separation distances between portable and mobile RF communications equipment and this product			
This product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this product can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this product as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter watts (W)	Separation distance according to frequency of transmitter meters (m)		
	150kHz–80MHz $d=1.2\sqrt{P}$	80MHz–800MHz $d=1.2\sqrt{P}$	800MHz–2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters 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.			

Table D.4 IEC 60601-1-2:2015, Recommended separation distances between portable and mobile RF communications equipment and this product

IEC 60601-1-2:2015, Recommended separation distances between portable and mobile RF communications equipment and this product			
This product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this product can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this product as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter watts (W)	Separation distance according to frequency of transmitter meters(m)		
	150kHz~80MHz $d=1.2\sqrt{P}$	80MHz~800MHz $d=1.2\sqrt{P}$	800MHz~2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters 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 E Manufacturer Information

Manufacturer information

Manufacturer Name: Beijing Surgerii Robotics Company Limited

Manufacturer Address:

102, Floor 1, Building 7, Tiandilinfeng, No. 1 Yongtaizhuang North Road,
Haidian District, Beijing 100192, China

Production Address:

1F West, Building 6, No. 38 Yongda Road, Daxing District, Beijing 102629,
China

1F, 2F, Building 9, No. 69 Qingfeng West Road, Daxing District, Beijing 102629,
China

EU Representative Information

Name: Surgerii Robotics (Netherlands) B.V

Address: Herengracht 449A, 1017 BR, Amsterdam, Netherlands

Contact: +31-850643988