OTTAVA™ Robotic System

User Manual

CAUTION: Investigational device. Limited by Federal law to investigational use.

ETHICON

Johnson & Johnson SURGICAL TECHNOLOGIES

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1 About this Manual

This manual contains information about the OTTAVA™ Robotic System, including important prescriptive information about indications for use, warnings and cautions, descriptions of the components of the System, and instructions for using the System with tools and Accessories.

This manual contains information about the following:

- OTTAVA™ Tower
- OTTAVA™ Integrated Table
- OTTAVA™ Physician Console
- OTTAVA™ Endoscope
- OTTAVA™ Arm Sterile Drape
- OTTAVA™ Arm Stowage Covers
- OTTAVA™ Instruments
- OTTAVA™ Accessories

This manual applies to software vX.X.X.

NOTE: Images of the Surgical Arms are shown without Arm Sterile Drapes or Arm Stowage Covers. Images of clinicians are shown without sterile coverings, such as gloves or gowns, except in sections about draping the Surgical Arms.

1.1 Terminology and Abbreviations

The following list includes terminology and definitions used in this manual.

Term	Description
3D	Three dimensional
AC	Alternating current
Arm Sterile Drape	OTTAVA™ Arm Sterile Drape
Arm Stowage Cover	OTTAVA™ Arm Stowage Cover
Attach	To connect an Instrument or Endoscope to a tool driver on the Surgical Arm
Caution	Statement associated with a hazard that, if it happens, can cause minor to moderate injury or damage devices, equipment, or accessories
Cleaning	Mechanical removal of visible surface contaminants and soils through a manual or automated process
Dock	To connect a Surgical Arm to a Cannula that has been placed into the patient's body

Term	Description
DOF	Degrees of freedom
Disinfection	To apply agents to surfaces or objects to kill many or all microorganisms except resistant bacterial spores
Drive	To use the Table Remote to transport or otherwise move the Integrated Table
DVI	Digital video interface
Endoscope	OTTAVA™ Endoscope
GEN11	ETHICON™ Generator G11
Instrument	A tool other than an endoscope used to produce desired tissue effects or to carry out actions during a surgical procedure
Integrated Table	OTTAVA™ Integrated Table
LED	Light emitting diode
ME Equipment	Medical-electrical equipment
MEGEN1	MEGADYNE™ Electrosurgical Generator
OR	Operating room
Physician Console	OTTAVA™ Physician Console
RCM	Remote center of motion
RJ45	A type of connector that is commonly used for Ethernet networking
SDI	Serial digital Interface
Surgical Arm	OTTAVA™ Surgical Arm
System	OTTAVA™ Robotic System
Tool	A general term to indicate an instrument or an endoscope, which attaches to the tool driver on a Surgical Arm and is then controlled by a clinician during a surgical procedure
Tower	OTTAVA™ Tower
USB	Universal serial bus
UI	User interface
Warning	A statement associated with a hazard that, if it happens, can seriously injure or kill a patient or user

2 Prescription and Safety Information

2.1 Indications for Use

The OTTAVA™ Robotic System is intended to assist in the accurate control of endoscopic Instruments, Endoscopes, and Accessories for visualization and manipulation of tissue including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrosurgery, and suturing, and to allow the surgical staff to reposition the patient by adjusting the Table without undocking the Surgical Arms during upper abdominal general laparoscopic surgical procedures in accordance with the representative, specific procedures listed in this manual (page 2-1).

2.1.1 Representative Procedures

The upper abdominal general laparoscopic procedures include:

- Roux-en-Y gastric bypass
- Gastrectomy
- Cholecystectomy
- Splenectomy
- Gastric sleeve
- Small bowel resection
- Appendectomy
- Lysis of adhesions (adhesiolysis in abdomen)
- Fundoplication

2.2 Intended Use

The OTTAVA Robotic System is intended to assist in accurate control of instruments, endoscopes, and accessories in endoscopic surgical procedures and to provide table motion to reposition the patient by adjusting the surgical table without undocking the Surgical Arms.

2.3 User Training

The OTTAVA Robotic System should only be used by medical professionals who have received training in the use of this device. New users should be comfortable and competent with the System before clinical use. The training provided by Auris Health is limited to the use of the OTTAVA Robotic System and does not replace the medical training and experience required to perform surgery.

2.4 Contraindications

Do not use the System when endoscopic techniques are contraindicated.

Any relative and absolute contraindications to endoscopic and laparoscopic surgical techniques applicable to the use of conventional endoscopic surgical Instruments apply to the use of the OTTAVA Robotic System.

2.5 Warnings and Cautions

This section has warnings and cautions for the use of the System. Failure to follow instructions, notes, cautions, and warnings associated with this equipment may lead to serious injury or surgical complications for the patient.

NOTE: Anyone who operates, services, maintains, or is otherwise associated with the System must read, understand, and be thoroughly familiar with the information in this manual, and take precautions to protect themselves, their associates, patients, and the equipment.

System Setup

- Move the Tower, Integrated Table, and Physician Console in a controlled manner to avoid collisions that can lead to surgical staff injury, patient injury, or equipment damage.
- Immobilize the Tower, Integrated Table, and Physician Console after placement in the OR to avoid unexpected movement that can lead to patient or surgical staff injury, or damage to the Physician Console or other equipment.
- Inspect the Tower, Integrated Table, and Physician Console power cords for damage before use. Do not use damaged cords. Damaged power cords may result in patient or surgical team injury or electrical shock.
- When connecting power to the System, use only the Auris-provided cables and plug into the proper electrical circuits to avoid any power loss to the System during a procedure, which could cause injury to the patient.
- Only connect the System to a grounded outlet to avoid the risk of electric shock.
- Do not block access to the System mains disconnect plug.
- The Tower, Integrated Table, and Physician Console must each operate on separate, dedicated branch circuits to avoid circuit overload. Do not connect auxiliary devices, such as energy devices, on the same branch circuit as the Tower. Auxiliary devices must be connected to wall outlets on a separate branch circuit from the Tower, Integrated Table, and Physician Console.
- Inspect Instruments before each patient-use for damage such as rough surfaces, sharp edges, or protrusions that can cause patient injury.
- Do not connect any equipment, including network or data equipment, other than those recommended by Auris Health, to the System.
- Applied parts of other devices used with the System must be Type CF Applied Parts.
- When other medical-electrical equipment is used with the System and energized Instruments, patient leakage currents may be additive.

Prepare for a Procedure

- Do not connect accessories, other medical-electrical equipment, or non-medical-electrical equipment not specified by Auris Health to the mechanical and other interfaces of the System.
- Follow all instructions for Trocar assembly. An improperly assembled Trocar may result in patient injury.
- Level the Integrated Table and stow the Surgical Arms when you transfer the patient to or from the Integrated Table to avoid patient injury.
- Use care when you transfer the patient to or from the Integrated Table to avoid collisions that can lead to patient or surgical staff injury, or equipment damage.

- Fully secure the patient to the Integrated Table before you adjust the Integrated Table position to avoid patient injury.
- Failure to properly position the patient could lead to incision-site tension and patient injury.
- Properly install the Arm Stowage Covers on the Surgical Arms when you transfer the patient to or from the Integrated Table to prevent fluid ingress, which can lead to patient injury or Surgical Arm damage.
- Use caution when you adjust the Integrated Table Tilt or Trendelenburg position, as the patient may shift on the Integrated Table leading to incision-site tension and patient injury.
- Any breach to sterility may lead to injury, illness, or death of the patient.
- Inspect the Arm Sterile Drapes and the Arm Stowage Covers or damage before use. Do not use damaged Arm Sterile Drapes and the Arm Stowage Covers. Damaged Arm Sterile Drapes and the Arm Stowage Covers may breach the sterility; any breach to sterility may lead to patient injury.
- Do not allow a sterile drape to make contact with a non-sterile user, which will breach the sterility; any breach to sterility may lead to patient injury.

Perform a Procedure

- Hazardous optical radiation may be emitted from the System.
- Only use the System with compatible robotic surgical instruments and other applied parts, including those of other medical-electrical equipment.
- Do not service the System during a procedure.
- Use any scanning equipment in a controlled manner to avoid collisions that can lead to surgical staff injury or equipment damage.
- Use care when you are near the System to avoid unintentional System Pause or System Off button activation. This can lead to staff or patient injury. . Patient injury may include, but is not limited to, robotic surgical procedure conversion to open surgery because energy delivery is unavailable.
- Use care to avoid pinch points on the Integrated Table when you position the patient, set up the Table, and move the Surgical Arms to avoid patient or staff injury.
- Do not over insufflate the patient and observe for gas embolism before high-frequency surgery.
- When the Endoscope is used with energized instruments, patient leakage currents may be additive.
- Use caution in the presence of explosive gas concentrations when high-frequency energized devices are in use.
- Use caution around Instruments to avoid collisions. Unintentional movement of Instruments can lead to patient injury.
- Logging in to the wrong surgeon profile can result in errors, which may lead to serious injury.
- Use visualization guidance to insert the Instrument through the Cannula to avoid patient injury.
- Place the Surgical Arms into the proper sequence of positions to prevent delays to the procedure.
- Use care when you move the Surgical Arms to avoid collisions that may cause injury to the surgical staff.
- Make sure you properly dock the Surgical Arm to the Cannula to avoid procedure delays or patient injury.
- Do not move the Surgical Arms away from the patient before you undock from the Cannulas. Any attempt to move a Surgical Arm away from the patient while it is docked to a Cannula could lead to patient injury.
- Use caution during Surgical Arm movement to avoid collisions that can lead to patient or surgical staff injury.
- Fully support the Surgical Arm while you engage the Brake Release to avoid patient injury or Surgical Arm damage.
- Do not allow a Surgical Arm to make contact with patient or staff skin for more than 1 minute, which may result in a burn injury.
- It is important that you react to and resolve all System alerts for proper System function to avoid patient injury.
- Follow the intraoperative System restart procedure to avoid patient injury.
- Do not move the Surgical Arms away from the patient before you undock from the Cannulas. Any attempt to move a Surgical Arm away from the patient while docked to a Cannula may lead to patient injury.

Instruments and Accessories

- The light emission and shaft of the Endoscope can exceed 41°C. Do not touch the light emission portion of the Endoscope to patient tissue to avoid patient injury.

- High energy radiated light may be transmitted from the light emission window of the Endoscope, resulting in high temperatures in front of the light emission window. Maintain a safe distance from patient tissue to avoid patient injury.
- Inspect the Endoscope before each patient-use for damage such as rough surfaces, sharp edges, or protrusions that can cause patient injury.
- Follow all instructions for installing the Endoscope to avoid patient injury. An improperly installed Endoscope may result in patient injury.
- Before each use or after a change to the viewing modes or settings of the Endoscope, make sure that the Endoscope view is a live image and not a stored image, and that the image shows the correct orientation.
- When the Endoscope or energized Instruments are used with laser equipment, wear protective filtering eye coverings to avoid potential clinician eye damage.
-
- Make sure you properly use Instruments within the abdominal cavity to avoid collision with other Instruments, rigid anatomy, or tissue, which may lead to Instrument damage and patient injury.

Emergency Use

- If emergency patient access is required, quickly and safely remove all Instruments and Accessories from the patient before intervention to prevent patient injury.

Cleaning, Storage, Maintenance, and Disposal

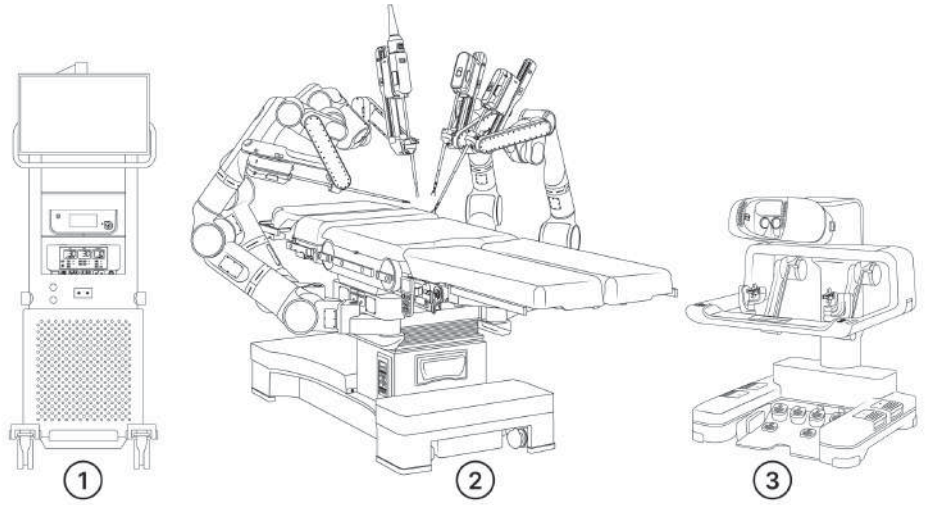
- Make sure you properly wipe down the Tower, Physician Console, Integrated Table, and Table Remote at the end of a procedure to prevent transfer of contaminants to the surgical staff.

3 About the System

The OTTAVA™ Robotic System is a software-controlled, electro-mechanical system designed for surgeons to perform minimally invasive surgery. The System includes:

- OTTAVA™ Tower
- OTTAVA™ Integrated Table
- OTTAVA™ Physician Console

Figure 3-1. The System



1. Tower
2. Integrated Table
3. Physician Console

3.1 Compatible Surgical Instruments and Accessories

The surgical Instruments and Accessories listed are compatible with the OTTAVA Robotic System.

Table 3-1. Instruments and Accessories

Name	Product Code	Use	Reference
MEGADYNE™ Monopolar Curved Scissors	OTT200	Reusable	ETHICON™ Instrument and Accessories User Manual
MEGADYNE™ Monopolar Hook Dissector	OTT201	Reusable	ETHICON™ Instrument and Accessories User Manual

Name	Product Code	Use	Reference
MEGADYNE™ Bipolar Maryland Forceps	OTT210	Reusable	ETHICON™ Instrument and Accessories User Manual
MEGADYNE™ Bipolar Fenestrated Forceps	OTT211	Reusable	ETHICON™ Instrument and Accessories User Manual
ETHICON™ Cadiere Forceps	OTT230	Reusable	ETHICON™ Instrument and Accessories User Manual
ETHICON™ High Force Grasper	OTT231	Reusable	ETHICON™ Instrument and Accessories User Manual
ETHICON™ Needle Driver + Cutting, Large	OTT260	Reusable	ETHICON™ Instrument and Accessories User Manual
ETHICON™ Needle Driver + Cutting, XL	OTT261	Reusable	ETHICON™ Instrument and Accessories User Manual
MEGADYNE™ Disposable Fixed Lead Monopolar Cable, 10 ft (3m)	0075	Reusable	MEGADYNE™ Non-Sterile, Reusable, Monopolar Electrosurgical Cable
MEGADYNE™ Bipolar Cable, 12', single use	4005J	Single use	MEGADYNE™ Electrosurgical Accessories Robotic Bipolar Cable User Manual
MEGADYNE™ Insulation Sheath with Applicator	OTT410	Single use	ETHICON™ Instrument and Accessories User Manual
ENDOPATH XCEL™ Universal Trocar Seal	OTT340	Single use	ETHICON™ Instrument and Accessories User Manual
ENDOPATH XCEL™ Trocar Obturator, 8mm	OTT320	Single use	ETHICON™ Instrument and Accessories User Manual
ENDOPATH XCEL™ Trocar Obturator, 8mm, Long	OTT321	Single use	ETHICON™ Instrument and Accessories User Manual
ENDOPATH XCEL™ Trocar Cannula, 8mm	OTT300	Reusable	ETHICON™ Instrument and Accessories User Manual
ENDOPATH XCEL™ Trocar Cannula, 8mm, Long	OTT301	Reusable	ETHICON™ Instrument and Accessories User Manual
ENDOPATH XCEL™ Cannula Gage Pins, 8mm and 12mm	OTT360 (includes OTT361 and OTT362)	Reusable	ETHICON™ Instrument and Accessories User Manual
ETHICON™ Arm Sterile Drape	OTT420	Single use	Included in this manual
ETHICON™ Arm Stowage Cover	OTT421	Single use	Included in this manual
ETHICON™ Endoscope 0°	OTT600	Reusable	Included in this manual
ETHICON™ Instrument Sterilization Tray	OTT442	Reusable	ETHICON™ Instrument and Accessories Cleaning and Sterilization Instructions
ETHICON™ Accessory Sterilization Tray	OTT440	Reusable	ETHICON™ Instrument and Accessories Cleaning and Sterilization Instructions

Name	Product Code	Use	Reference
ETHICON™ Endoscope Sterilization Tray, Plastic	OTT444	Reusable	ETHICON™ Instrument and Accessories Cleaning and Sterilization Instructions
ETHICON™ Instrument Flush Hose	OTT461	Reusable	ETHICON™ Instrument and Accessories Cleaning and Sterilization Instructions

3.2 OTTAVA™ Tower

The Tower has computers for processing physician-commanded inputs from the Physician Console for robotic-assisted manipulation of the Surgical Arms and Instruments. The computers include a video processor and an Endoscope light source. The Tower also holds two energy generators—ETHICON™ Generator G11 (GEN11) and MEGADYNE™ Electrosurgical Generator (MEGEN1) (page 3-5)—and has space to hold other peripheral equipment.

The touchscreen is the primary source of information for the surgical staff during procedure setup, during a procedure, and during System teardown. Once the Endoscope is attached to the System, the live Endoscope feed is shown. The touchscreen also shows system status notifications and a real-time model of the orientation of Surgical Arms. During a procedure, the live Endoscope feed is shown with procedure information overlaid. Information about the Instruments attached to the Surgical Arms and their status are shown. During system teardown, the touchscreen shows a system teardown guide. See Tower Touchscreen UI (page 4-1).

Use the DVI or SDI ports to replicate the Tower touchscreen image, the console viewer image, and the raw Endoscope feed on an external monitor. The System is not shipped with video cables or converters.

Use the power button on the Tower to power on the Tower. The power button also powers on the Physician Console when it is connected to the Tower. Use the System Pause button to pause System function during a procedure.

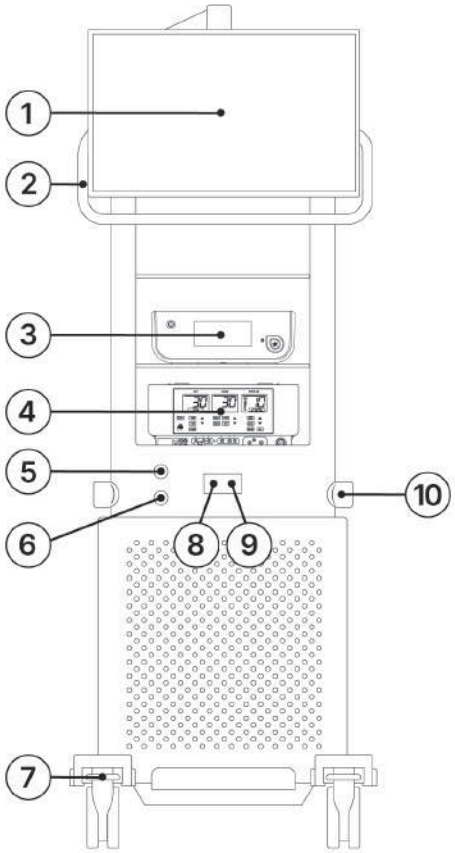
Connect the Endoscope connectors to the camera port and light engine port on the Tower. See Endoscope (page 3-25) for more information.

Connect Monopolar and Bipolar Instruments to the energy generators. See the energy generator manufacturer's user manuals for instructions for use.

The Tower is powered by two separate AC mains ports that must be connected to two separate branch circuits.

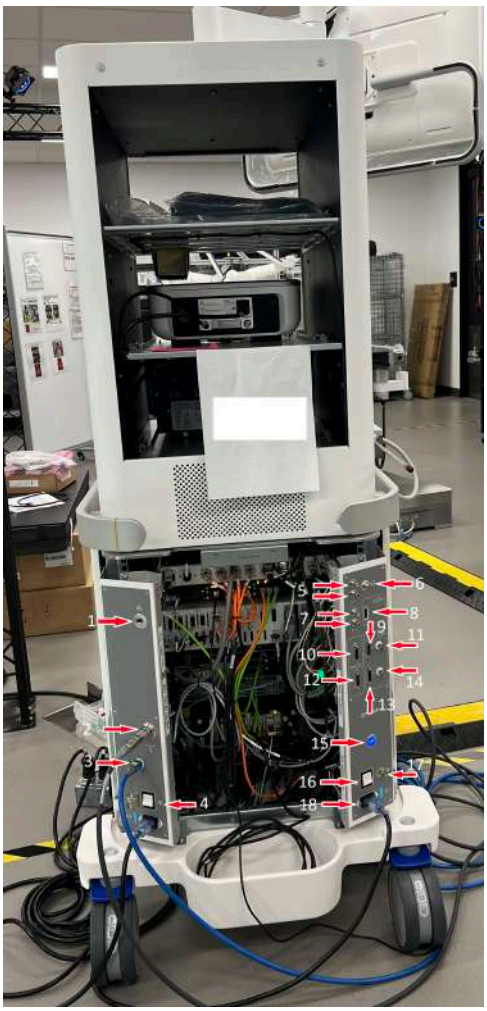
Use the Tower handle to move the Tower. Before you move the Tower, retract the touchscreen position so it is flush with the front of the Tower. See Adjust the Touchscreen Position. You can lock the casters to secure the position of the Tower.

Figure 3-2. Tower, front



1. Touchscreen
2. Touchscreen handle
3. GEN11
4. MEGEN1
5. System pause button
6. Power button
7. Caster lock
8. Endoscope video port
9. Endoscope light port
10. Tower handle

Figure 3-3. Tower, back



1. Network cable port
2. Table umbilical port
3. Physician Console umbilical port
4. Breaker switch
5. Audio in
6. Headset
7. Audio out
8. Tower UI output
9. Physician Console video out, left (DVI)
10. Endoscope video in, left (DVI)
11. Physician Console video out, left (SDI)
12. Endoscope video in, right (DVI)
13. Physician Console video out, right (DVI)
14. Physician Console video out, right (SDI)
15. Power
16. Breaker switch
17. Equipotential lug
18. Power port, right
19. Power port, left (left side bottom, not numbered, will be added)

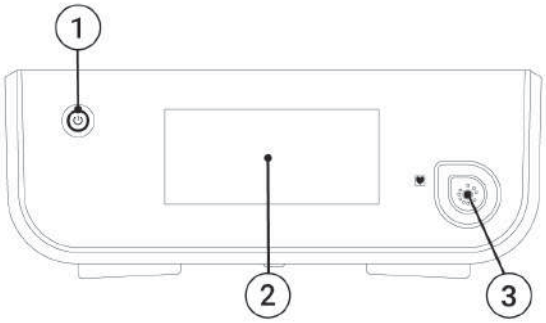
3.2.1 Electrosurgical Generators

The MEGADYNE™ Electrosurgical Generator (MEGEN1) and the ETHICON™ Generator G11 (GEN11) are used with the System. See the manufacturer's instructions for use for warnings, cautions, and other relevant information.

Table 3-2. Compatible Instruments

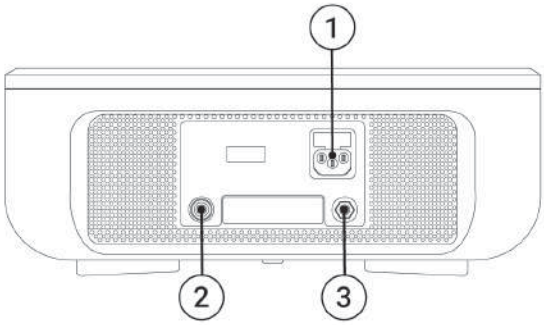
Electrosurgical Generator	Compatible Instruments
MEGEN1	MEGADYNE™ Monopolar Curved Scissors (OTT200) MEGADYNE™ Monopolar Hook Dissector (OTT201) MEGADYNE™ Bipolar Maryland Forceps (OTT210) MEGADYNE™ Bipolar Fenestrated Forceps (OTT211) Any compatible non-robotic monopolar or bipolar energy instruments
GEN11	All ENSEAL™ and HARMONIC™ advanced energy instruments

Figure 3-4. ETHICON™ Generator G11 (GEN11), Front



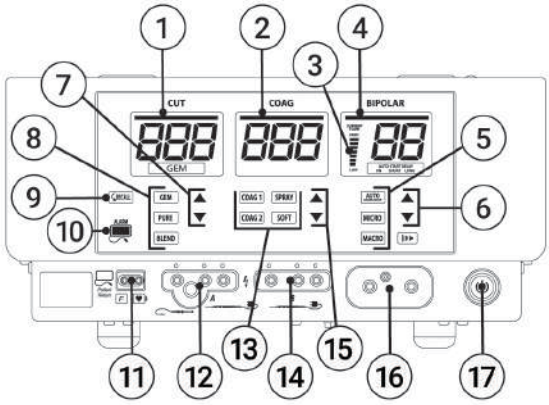
1. Power ON/OFF switch
2. Display/Touch screen
3. Connector/Instrument receptacle

Figure 3-5. ETHICON™ Generator G11 (GEN11), Back



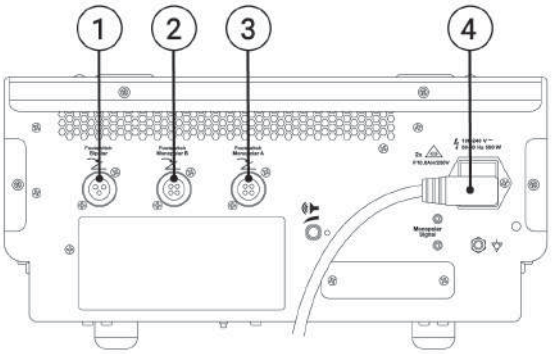
1. Power cord receptacle
2. Footswitch receptacle
3. Potential equalization terminal

Figure 3-6. MEGADYNE™ Electrosurgical Generator (MEGEN1), Front



1. Power settings window "CUT"
2. Power settings window "COAG"
3. Current meter
4. Power settings window "BIPOLAR"
5. "BIPOLAR" mode buttons
6. "BIPOLAR" power adjustment keys
7. "CUT" power adjustment keys
8. "CUT" mode buttons
9. Recall
10. Patient return electrode alarm
11. Patient return electrode port
12. Foot switching cable port
13. "COAG" mode buttons
14. Hand switching cable port
15. "COAG" power adjustment keys
16. Bipolar cable port
17. Power

Figure 3-7. MEGADYNE™ Electrosurgical Generator (MEGEN1), Back



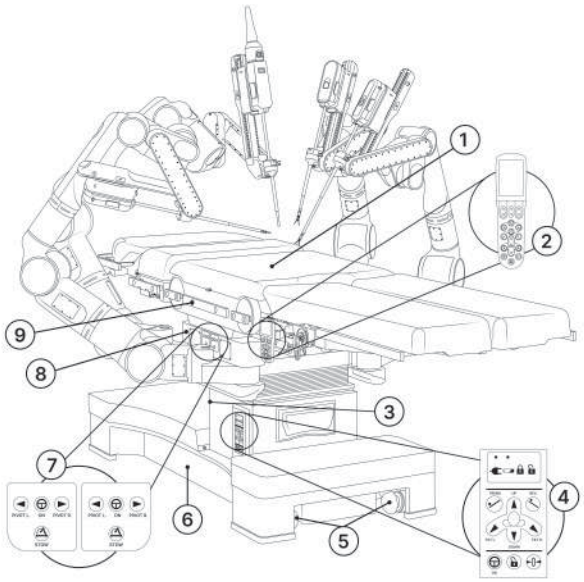
1. Bipolar footswitch cable
2. Monopolar B footswitch cable
3. Monopolar A footswitch cable
4. Power cord

3.3 OTTAVA™ Integrated Table

The Integrated Table is an articulating surgical table with four articulating Surgical Arms attached to the Table. Each Surgical Arm is numbered for identification during the surgical procedure. The Table and Surgical Arms have coordinated motion used during System setup, intraoperative adjustments, and System teardown. The tabletop is adjustable for procedure-specific patient positioning. The table adapter connects the Surgical Arms to the Table. The column raises and lowers the Integrated Table. The base supports the Integrated Table and houses the mains power supply and other connection ports. The Surgical Arms are stowed under the table when not in use. You can lock the casters to secure the Integrated Table position.

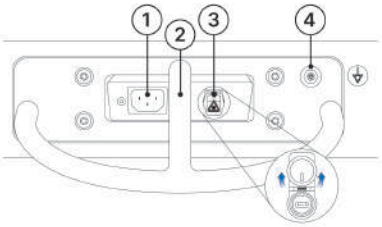
NOTE: The Integrated Table and the Physician Console must be immobilized before you can enter teleoperation.

Figure 3-8. Integrated Table



1. Tabletop
2. Table Remote
3. Table Remote port (2)
4. Secondary Table controls
5. Casters
6. Table base
7. Secondary Arm controls
8. Table adapter
9. Side rails

Figure 3-9. Integrated Table, I/O panel



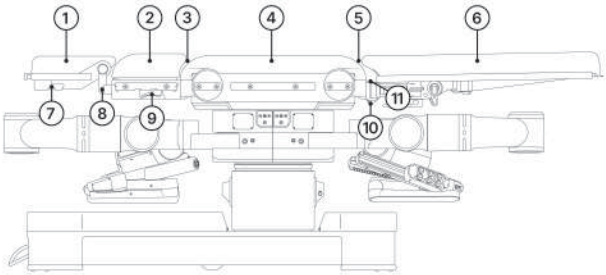
1. Power cable
2. [callout will be removed]
3. Table umbillical port
4. Equipotential lug

3.3.1 Tabletop

The tabletop has adjustable plates that support the patient's head, body, and legs. You can raise and lower the head rest and leg plates with the Table Remote. You can also manually raise and lower the head rest (page 3-8) and leg plates (page 3-9), and move the leg plates laterally (page 3-8).

Optional side rail accessories such as arm boards and width extenders can be attached to the side rails of the tabletop. See Compatible Side Rail Accessories (page 13-3).

Figure 3-10. Tabletop



1. Head rest
2. Extension plate
3. Back joint
4. Seat plate
5. Leg joint
6. Leg plate, left and right
7. Head plate lever and lock
8. Release button, head plate
9. Release lever, extension plate
10. Leg plate release button
11. Leg plate lever

3.3.1.1 Position the Head Rest

1. To unlock the head rest, press the yellow lock buttons.
2. Pull up on the gray controls.
3. Position the head rest and release the gray controls.
4. To lock the head rest, press the yellow lock buttons.

3.3.1.2 Adjust the Extension Plate

1. To unlock the extension plate, press the button on the side of the leg plate.
2. Move the extension plate until you reach the desired position.
3. To lock the extension plate, release the button.

3.3.1.3 Move the Leg Plate Laterally

1. To unlock the leg plate, push down on the leg plate lever.
2. Move the leg plate laterally until you reach the desired position.
3. To lock the leg plate, pull up on the leg plate lever.

3.3.1.4 Raise or Lower the Leg Plate

1. To unlock the lower leg plate, pull up on the leg plate lever.
2. Raise or lower leg plate.
3. To lock the lower leg plate, release the leg plate lever.

3.3.2 Surgical Arms

The four identical Surgical Arms are mounted on the table adapter. The Surgical Arms are used to position and manipulate the Endoscope and Instruments with physician-directed input from the Physician Console.

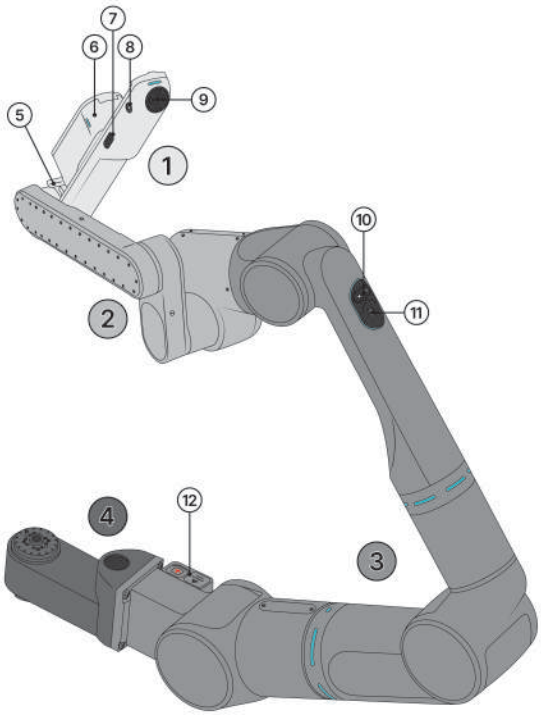
Each Surgical Arm has seven degrees of freedom which aid placement and orientation of the Endoscope and Instruments with respect to patient anatomy, and accommodate patient access for the table-side surgical staff. Each Surgical Arm has an operative arm with a tool driver, setup arm, and Table-Arm connection.

- The operative arm manages the fine movements needed to perform surgical tasks with Instruments. The tool driver guides the insertion and retraction of the Instruments and Endoscope, attached to the carriage, through the Cannula and into the body cavity.
- The setup arm positions the operative arm over the Table for a procedure and moves the Surgical Arm away from the Table for patient access, and when you drape and stow the Surgical Arms.
- The Table-Arm connection joins the Surgical Arm to the Table and pivots the Surgical Arm toward the head or foot of the Integrated Table.

Position the Surgical Arms with the Table Remote (page 3-12), the primary arm controls (page 3-10), or the secondary arm controls (page 3-12).

Use the Arm Brake Release button to release the J1 brake when emergency patient access is needed. See Use the Arm Brake Release (page 9-3).

Figure 3-11. Surgical Arm



1. Tool driver
2. Operative Arm
3. Setup Arm
4. Table-Arm connection
5. Cannula mount
6. Carriage
7. Port clutch buttons
8. Tool clutch buttons
9. Clearance pad
10. Pivot buttons
11. Arm clutch button
12. Arm Brake Release button
13. Cannula latch [needs to be added]

3.3.2.1 Primary Arm Controls

The primary arm controls on the Surgical Arm are used to position the Surgical Arm. The primary arm controls include:

- Clearance pad (page 3-10)
- Tool clutch (page 3-11)
- Port clutch (page 3-11)
- Pivot buttons (page 3-11)
- Arm clutch (page 3-11)

You can also position the Surgical Arms with the Table Remote (page 3-12) and secondary arm controls (page 3-12).

See also, Move a Surgical Arm On Plane (page 3-12).

3.3.2.1.1 Use the Clearance Pad

When the Surgical Arm is docked and before an Endoscope or Instrument is attached to the Surgical Arm, use the clearance pad to create space between the setup Arm and another Surgical Arm, the patient, or tabletop rail accessories while maintaining the remote center around which the Surgical Arm pivots. With the clearance pad engaged, the setup Arm moves as the operative Arm maintains remote center.

To use the clearance pad:

- Press and hold an arrow button to move the Surgical Arm in the corresponding direction. Release the button to stop movement.

  CAUTION: Use caution while making adjustments with the clearance pad while the instrument is near delicate tissue.

3.3.2.1.2 Engage the Arm Clutch

When the Surgical Arm (page 3-9) is docked, the arm clutch is not available.

When the Surgical Arm is undocked, engage the arm clutch for gross movement of the Surgical Arm to the Cannula during docking, and during on-plane alignment of the Surgical Arm. With the arm clutch engaged, the operative Arm is unlocked, the setup Arm is unlocked, and the Table-Arm connection is fixed. During on-plane alignment, joints in the operative Arm and setup Arm that are not on plane are adjustable and the Table-Arm connection is locked.

To engage the arm clutch when the Surgical Arm is undocked and for gross movement of the Surgical Arm:

- Press and release the arm clutch button to engage the arm clutch. Press and release the button again to disengage the arm clutch.

To engage the arm clutch for on-plane alignment:

- Press and hold the arm clutch button to enter on-plane mode. Release the button to disengage on-plane mode.

3.3.2.1.3 Engage the Pivot Buttons

When the Surgical Arm (page 3-9) is docked, the pivot buttons are not available.

When the Surgical Arm is undocked, engage the pivot buttons to create space between Surgical Arms before you drape the Surgical Arms and to move the Surgical Arm on plane and perpendicular to the Integrated Table before you stow the Surgical Arm. With a pivot button engaged, the operative arm is locked, the setup arm is locked, and the Table-Arm connection is adjustable.

To engage the pivot buttons when the Surgical Arm is undocked:

- Press and hold a pivot button to move the Surgical Arm in the corresponding direction. Release the button to stop movement.

3.3.2.1.4 Engage the Port Clutch

When the Surgical Arm (page 3-9) is docked, engage the port clutch to adjust the remote center. The operative Arm is locked, the setup Arm is unlocked, and the Table-Arm connection is locked.

When the Surgical Arm is undocked, engage the port clutch to move the Surgical Arm to the Cannula for docking. With the port clutch engaged, the operative Arm is adjustable, the setup Arm is adjustable, and the Table-Arm connection is locked.

To engage the port clutch when the Surgical Arm is docked:

- Press and release both port clutch buttons to engage the port clutch. Press and release both buttons again to disengage the port clutch.
- Press and hold both port clutch buttons to engage the port clutch. Release both buttons to disengage the port clutch.

3.3.2.1.5 Engage the Tool Clutch

When the Surgical Arm (page 3-9) is docked or undocked, engage the tool clutch for initial instrument insertion. You can also engage the tool clutch to adjust the Cannula mount angle during Surgical Arm docking. With the tool clutch engaged, the operative Arm is adjustable, the setup Arm is locked, and the Table-Arm connection is locked.

To engage the tool clutch when the Surgical Arm is docked or undocked:

- Press and release both tool clutch buttons to engage the tool clutch. Press and release both buttons again to disengage the tool clutch.
- Press and hold both tool clutch buttons to engage the tool clutch. Release both buttons to disengage the tool clutch.

3.3.2.1.6 Move a Surgical Arm On Plane

Use the arm clutch and pivot buttons to unlock the Surgical Arm joints and manually move the Surgical Arm segments on plane. When a Surgical Arm segment is on plane, the Surgical Arm segment LED turns green and a high pitch sound is heard. When the entire Surgical Arm is on plane, all Surgical Arm LEDs are green and a three tone sound is heard.

1. Use the Table Remote to level the Integrated Table.
2. If you want to Stow the arms, use the pivot buttons to move the pivot arm perpendicular to the bed.
3. Press and hold the arm clutch button and rotate the proximal rotational joint.

   The proximal Setup Arm LED turns solid green when the proximal Setup Arm is aligned.
4. Press and hold the arm clutch button and rotate the distal rotational joint.

   The distal Setup Arm LED turns solid green when the distal Setup Arm is aligned.
5. Press and hold the arm clutch button and rotate the Operative Arm joint.

   The carriage LED and Cannula Arm LED turn solid green when the operative arm is aligned.
6. Press and hold the arm clutch button pull back the Surgical Arm so its position is not over the Table.

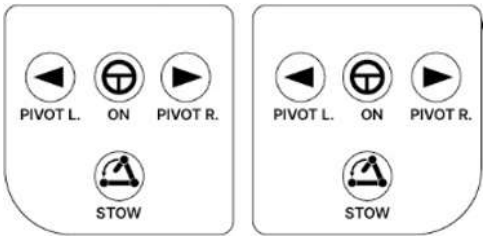
   The LED around the arm clutch and pivot buttons turns solid green when the operative arm is clear of the Table.

3.3.2.2 Secondary Arm Controls

Each Surgical Arm has secondary arm controls on the Table adapter. With the secondary arm controls you can power on and off the Surgical Arm, pivot the Surgical Arm left and right, and stow the Surgical Arm.

You can also use the primary arm controls (page 3-10) and Table Remote (page 3-12) to move the Surgical Arms.

Figure 3-12. Secondary arm controls



1. Pivot left (PIVOT L.)
2. Power (ON)
3. Pivot right (PIVOT R.)
4. Stow (STOW)

3.3.3 Table Remote

The Table Remote is the primary control for the Integrated Table and is used to position the Table before, during, and after a procedure and the Surgical Arms before and after a procedure. From the touchscreen you can access:

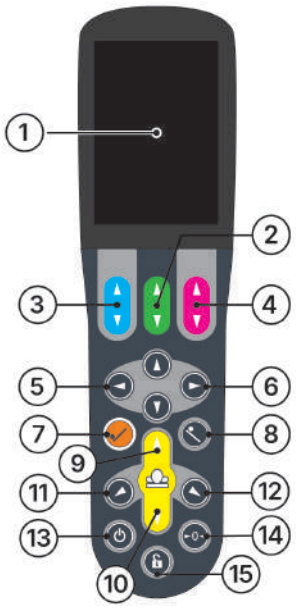
- Controls for patient positioning with the Table Remote
- Table Remote menu
- Surgical Arm positions and controls (page 3-13)

The buttons on the lower half of the Table Remote are used to position the Integrated Table. The Table Remote connects to a port on the Integrated Table column and can be used wired or wireless.

Press and hold a button on the Table Remote until the Table or Surgical Arm is in the desired position.

Press the Table lock button to access the table mobilization controls.

Figure 3-13. Table Remote



1. Touchscreen
2. Surgical Arm controls
3. Upper body plate controls
4. Leg plate controls
5. Translate Table toward the head
6. Translate Table toward the feet
7. Trendelenburg position
8. Reverse Trendelenburg position
9. Tabletop up
10. Tabletop down
11. Lateral Tilt left
12. Lateral Tilt right
13. Power Table Remote on or off
14. Level the Table
15. Table lock menu

NOTE:

- The blue, pink, and yellow buttons on the Table Remote keypad are used for Table adjustments and the button colors correspond to the colors in the Table image in the Table Remote touchscreen.
- The green buttons on the Table Remote keypad are used to move the Surgical Arms.

3.3.3.1 Surgical Arm Adjustments with the Table Remote

Use the Table Remote to:

- Move the Surgical Arms into pre-defined positions

  NOTE: If you are unable to select a Surgical Arm, the Surgical Arm is off plane. See Move a Surgical Arm on Plane (page 3-12).

  NOTE: When the Integrated Table is not connected to the Tower, the Preparation and Procedure positions are not available.

  - Drape position - In the Drape position, the Surgical Arms are away from the Table with space around each Surgical Arm to place the Arm Sterile Drapes without breaching sterility.
  - Preparation position - In the Preparation position, the Surgical Arms are away from the surgery site to allow room for placing the sterile drape over the patient. For example, for a gastric bypass procedure, the Surgical Arms are at the head of the Integrated Table.
  - Procedure position - In the Procedure position, the Surgical Arms are over the patient for docking the Surgical Arms to the Cannulas.
  - Stow position - In the Stow position, the Surgical Arms are beneath the table.
- Pivot a Surgical Arm - Move a Surgical Arm at the Table-Arm connection. You can pivot only one Surgical Arm at a time.
- Transition the System into Standby Mode

3.4 OTTAVA™ Physician Console

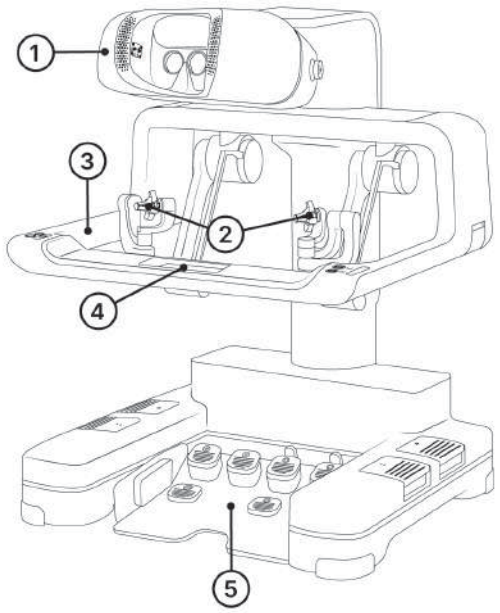
The Physician Console is the part of the System from which the Physician manipulates the Endoscope and Instruments in the surgical field. The Physician Console has casters for transportation.

NOTE: The Integrated Table and the Physician Console must be immobilized before you can enter teleoperation.

The Physician Console has:

- A head-in Viewer (page 3-17) for surgical field visualization
- Hand controls (page 3-15) that translate physician-directed manipulation of the Endoscope and Instruments.
- An armrest (page 3-15) from which you can turn on and off the Physician Console, pause robotic function during a procedure, access ergonomic and other Physician Console settings.
- A footboard (page 3-16) with foot pedals for Endoscope and Instrument control and activation of electrosurgical energy during a procedure.
- Immobilization controls with which you can directionally lock or fully lock the casters.

Figure 3-14. Physician Console



1. Viewer
2. Hand controls
3. Armrest
4. Console touchscreen
5. Footboard
6. Immobilization controls

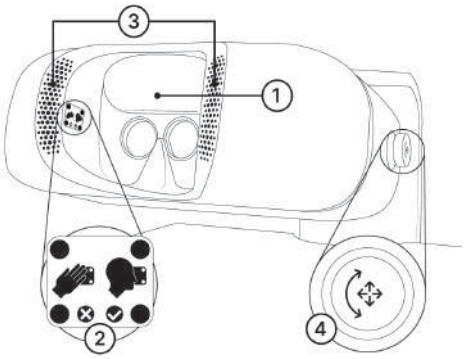
3.4.1 Viewer

The Viewer is the interface used by the physician to see a real-time image of the surgical field. The Viewer has one high-definition screen for each eye and shows the real-time Endoscope image with an overlay of Instrument, Endoscope, System, and procedure information.

The Viewer has left and right sensors that detect when a head is placed into the Viewer. A head must be fully inserted in the Viewer to engage the Hand Controls and teleoperation. This us a safety feature which prevents unintended Instrument motion from the Hand Controls when the surgical field is not actively observed through the Viewer.

The Viewer has speakers that relay System and Electrosurgical generator tones to the physician. You can adjust the position of the viewer with the viewer ergonomics control. (page 3-17).

Figure 3-15. Viewer



1. Headrest
2. Sensors
3. Speakers
4. Viewer ergonomics control

3.4.2 Hand Controls

The Hand Controls are input devices that translate physician-directed motion to the Endoscope and Instruments. Each Hand Control has positioning joints and a distally mounted grasper. The positioning joints provide seven input degrees of freedom to match the seven degrees of freedom available on the Wristed Instruments: three degrees of translation up and down, right and left, in and out, three degrees of orientation—pitch, yaw, and roll, and grasper open and close. Engage the finger clutch on the grasper to reposition the grasper without Instrument motion.

NOTE: The Hand Controls are disabled until the Physician Console is immobilized to prevent unintended motion of the Instruments.

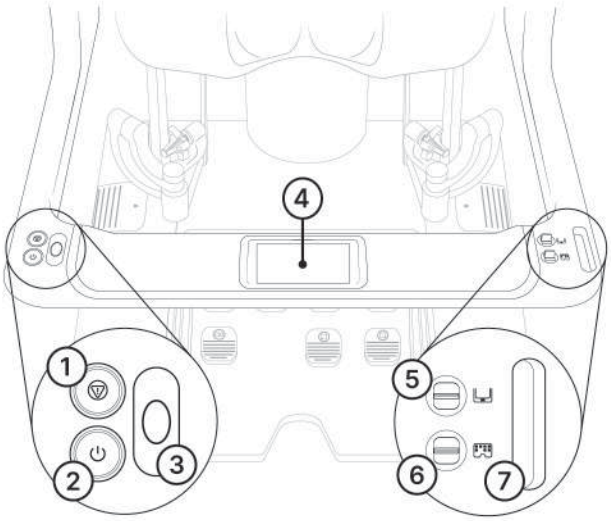
Figure 3-16. Hand Controls

1. Console arm
2. Finger loop
3. Hand Control
4. Finger clutch

3.4.3 Armrest

The armrest has a system pause button, a power button, the console touchscreen, the footboard ergonomics switch, the armrest ergonomics switch, and a phone holder. The system pause button pauses and restarts robotic motion without Instrument removal or a System restart.

Figure 3-17. Armrest



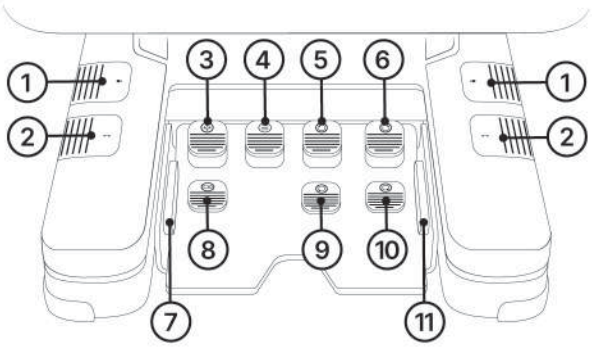
1. System Pause button
2. Power button
3. Fingerprint sensor
4. Console touchscreen
5. Armrest ergonomics switch
6. Footboard ergonomics switch
7. Phone holder

The console touchscreen is embedded in the center of the armrest. From the console touchscreen you can access the Physician Console, Instrument, and Endoscope settings. See Physician Console UI (page 4-8).

3.4.4 Footboard

The Physician Console has a footboard with foot pedals used to control the Endoscope, Instruments, and other System functions while you keep your head in the Viewer. The Instrument pedals have sensors that detect your foot when it hovers over the pedals. This is shown in the tool set (page 4-33) during teleoperation.

Figure 3-18. Physician Console footboard



1. All lock button
2. Directional lock button
3. Clutch pedal
4. Menu pedal (not functional)
5. Instrument pedal, left secondary
6. Instrument pedal, right secondary
7. Instrument swap pedal
8. Endoscope pedal
9. Instrument pedal, left primary
10. Instrument pedal, right primary
11. Instrument swap pedal (not functional)

NOTE: Instrument energy is only active when:

- The Surgical Arm is docked to the Cannula.
- Monopolar or Bipolar Instrument is attached to the Surgical Arm.
- The Instrument is inserted through the Cannula and into the body cavity.
- The Energy Cord is connected to the Instrument and corresponding electrosurgical generator.

Table 3-3. Footboard Actions

Action	Description
Hover	Hold your foot over the pedal, do not touch the pedal
Select	Press and release the pedal
Hold	Press and hold down the pedal
Release	Remove your foot from the pedal

3.4.5 Ergonomic Controls

The Physician Console has ergonomic controls to adjust the position of the armrest (page 3-17), the footboard (page 3-17), and the viewer (page 3-17). Ergonomic adjustment settings can be stored in a user profile.

3.4.5.1 Adjust the Viewer

You can adjust the height, depth, and tilt of the viewer.

1. To adjust the viewer position:
   - Tilt the control up to raise the height of the viewer.
   - Tilt the control down to lower the height of the viewer.
   - Tilt the control toward you to move the viewer closer to you.
   - Tilt the control away from you to move the viewer away from you.
   - Rotate the control clockwise to lower the tilt.
   - Rotate the control counter-clockwise to raise the tilt.
2. Select Save to store the settings in your user profile.

   A confirmation message is shown.

   The first time settings are saved, the Destination screen is shown after the confirmation message. For subsequent saves, the previous screen is shown after the confirmation message.

   Select Back to return to the previous screen.

3.4.5.2 Adjust the Armrest

You can adjust the height of the armrest with the armrest ergonomic switch.

1. To adjust the Armrest position:
   - Push the switch away from you to raise the armrest.
   - Pull the switch toward you to lower the armrest.
2. Select Save to store the settings in your user profile.

   A confirmation message is shown.

   The first time settings are saved, the Destination screen is shown after the confirmation message. For subsequent saves, the previous screen is shown after the confirmation message.

   Select Back to return to the previous screen.

3.4.5.3 Adjust the Footboard

You can adjust the depth of the footboard with the footboard ergonomic switch.

1. To adjust the footboard position:
   - Push the switch away from you to move the footboard away from you.
   - Pull the switch toward you to move the footboard toward you.
2. Select Save to store the settings in your user profile.

   A confirmation message is shown.

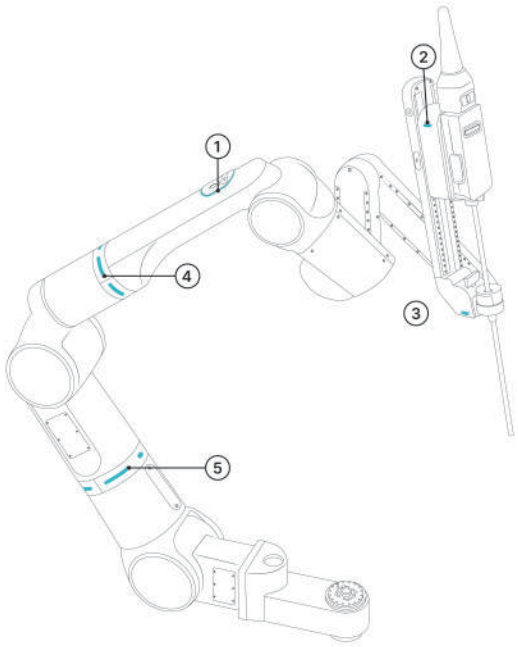
   The first time settings are saved, the Destination screen is shown after the confirmation message. For subsequent saves, the previous screen is shown after the confirmation message.

   Select Back to return to the previous screen.

3.5 System Status Communication

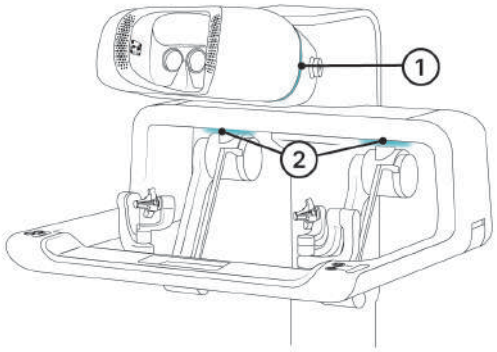
The System uses coordinated colors and sounds to communicate the System status. The Surgical Arm LEDs communicate status with solid, blinking, and pulsing patterns. See System Status LED Colors and Patterns (page 3-19) and System Status Sounds (page 3-20).

Figure 3-19. Surgical Arm LEDs



1. Arm clutch LED
2. Carriage LED
3. Cannula mount LED
4. Upper Setup Arm LED (Distal)
5. Lower Setup Arm LED (Proximal)

Figure 3-20. Physician Console LED



1. Hand Control LED
2. Armrest LED

3.5.1 System Status LED Colors and Patterns

Table 3-4. System Status Colors

Status	Color	
Unavailable	OFF	
Nominal behavior	White	
Active state	Teal	
Successful task completion	Green	
Major or minor fault	Yellow	
Critical fault	Red	

Table 3-5. LED Patterns

State	LED pattern
Solid	
Pulse	
Blink	

Table 3-6. System Status LED colors and patterns

System Status	Description	LED Color and Pattern
System Ready	System and Surgical Arm at rest	
Predefined Surgical Arm positions	Surgical Arm selected	

System Status	Description	LED Color and Pattern
	Surgical Arm in motion	
	Surgical Arm pose reached	
Surgical Arm touchpoints	Surgical Arm Clutch active	
	Port Clutch active	
	Tool Clutch active	
	Surgical Arm docked	
Tool loading	Tool homing	
	Tool homing successful	
	Unable to recognize tool	
On-Plane guidance mode	On-plane guidance mode activated	
	Surgical Arm joint placed on plane	
	All Surgical Arm joints on plane	
	Exit on-plane guidance mode	
Guided Instrument insertion (GIE)	New Instrument attached and homing	
	Homing successful and GIE mode initiated	
	GIE insertion limitation reached	
Fault	Minor or minor fault	
	Critical fault	

3.5.2 System Status Sounds

Table 3-7. Sound Descriptions

Sound Name	When Used	Sound
Instrument clutch engaged	Instrument clutch	A higher-pitch sound. A higher pitch sound that corresponds with the position of the instrument clutch on the Surgical Arm.
	Instrument insertion	
Port clutch unlocked	Port clutch	A higher-pitch sound. A higher pitch sound that corresponds with the position of the port clutch on the Surgical Arm.
Lock	Port clutch exit	A lower-pitch, short sound. A firm, mellow, single note with a decisive end. Lower in pitch than the instrument clutch and port clutch sounds.
	Exit guided insertion	
	Exit Instrument insertion	

Sound Name	When Used	Sound
	An exit action has started or completed	
Homing	Tool homing	A soft sound that loops like a steady pulse. A soft, single note that loops like a steady pulse until the robotic sequence is complete or interrupted.
	System sync ongoing	
Continuous motion	Automated trajectory motion	A four-note sequence that rises and falls. A fluid four-note melody that rises and falls to indicate progression, transition, or robotic motion.
	Surgical Arm pivot motion	
	Movement or a shift within the System such as a transition from one state, mode, or pose to another	
Action successful	Guidance mode	A quick two-note ascending sequence. A short two-note ascending melody that resembles an audible check mark.
	Arm docked successfully	
	Tool homes successfully	
	Instant confirmation that an action taken is successful	
Task complete	Guidance mode	A longer two-note ascending sequence. A prolonged, two-note ascending sequence.
	Automated trajectory motion	
	Insertion limit reached	
	A more significant or long-term task is fully complete	
Full System ready	During System start up when the Tower, Integrated Table, and Physician Console have completed loading and are ready	An ascending 15-note sequence that fades out. An ascending 15-note arpeggio-like sequence, progressively fading out, serving as an auditory conformation of successful System activation.
Successful input	An entry is complete	A three-tone sequence with a rising pitch.
Limit reached	A predefined limit is reached	A two-tone sequence with a consistent pitch; a short first tone and a longer, more pronounced second tone. Two-tone signal with consistent pitch: A short initial note, followed by a longer, more pronounced second note.
Invalid action	An invalid action is attempted	A quick two-tone sequence. A quick, skipping double-tone sound. This faster sequence is similar to the fault sound but more urgent. This serves as an auditory cue for prohibited actions.
Fault	When the fault indicator is activated, immediate user attention is needed. Depending on the situation, the user should acknowledge, dismiss, or directly address the identified fault.	A two-tone sequence. A double-tone sequence, with a distinct negative inflection, is designed to alert users to system errors or issues requiring attention.

3.6 Notifications and Faults

The System uses notifications and faults to convey the System status.

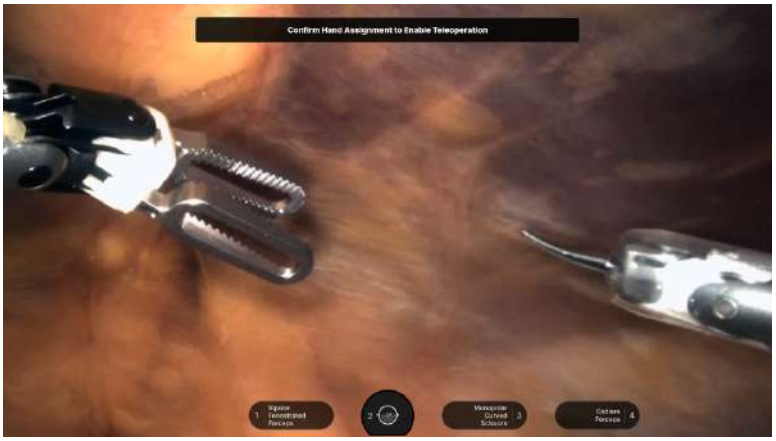
Notifications include information about a change in status, or completion of an action for users to pay attention to; they do not pause or stop robotic motion, and are shown until you dismiss the notification.

Faults include information about issues that need to be addressed and can pause or stop robotic motion. There are three types of faults—minor, major, and critical. The fault level is determined by the impact of the fault on the robotic motion.

When a fault is triggered, the fault is shown on the Tower touchscreen UI, the Console viewer UI, and in the Console touchscreen UI. When a fault is acknowledged, the notification is cleared. When a fault is hidden, the number of hidden faults are shown in the Tower touchscreen UI footer bar and in the Console touchscreen UI footer bar. A fault is shown again if the situation that triggered the fault is not resolved.

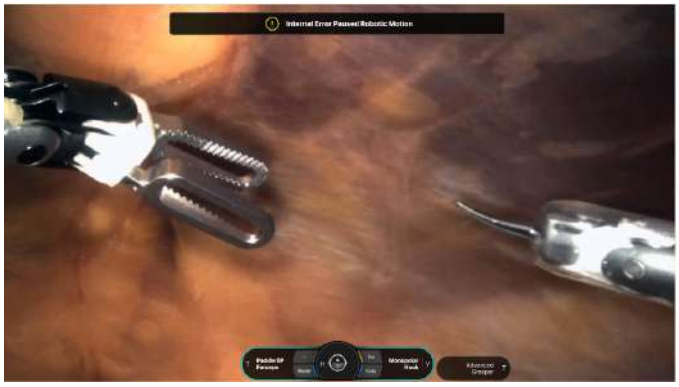
When more than one fault is triggered at the same time, the faults are stacked over each other with pagination controls at the bottom of the fault panel. Faults with the highest severity are shown first. Faults with the same severity are listed in the order they occur.

Table 3-8. Notifications as shown in the System UI locations

System	Notification
Physician Console Viewer	
Console touchscreen	

System	Notification
Tower touchscreen	

Table 3-9. Minor and major faults as shown in the System UI locations

Locations	Screens
Physician Console Viewer	
Console touchscreen	

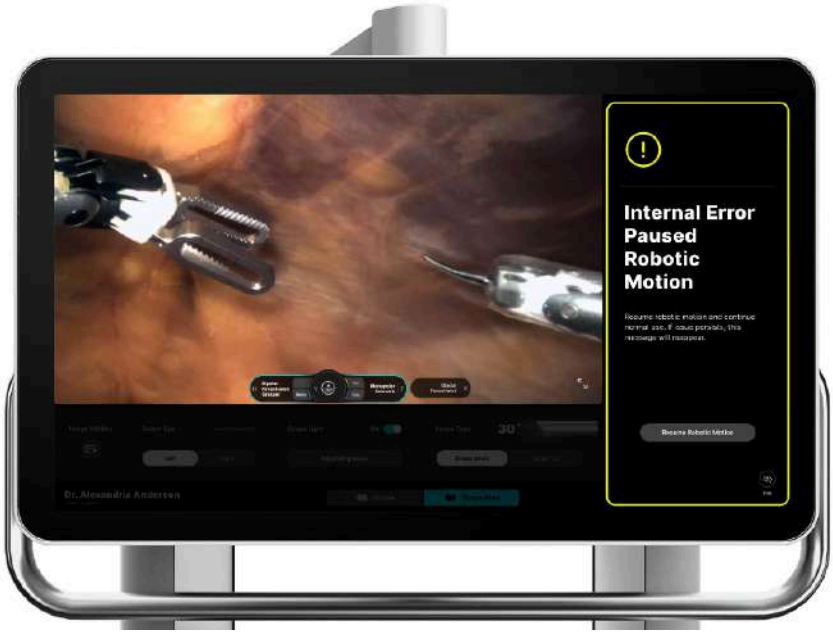
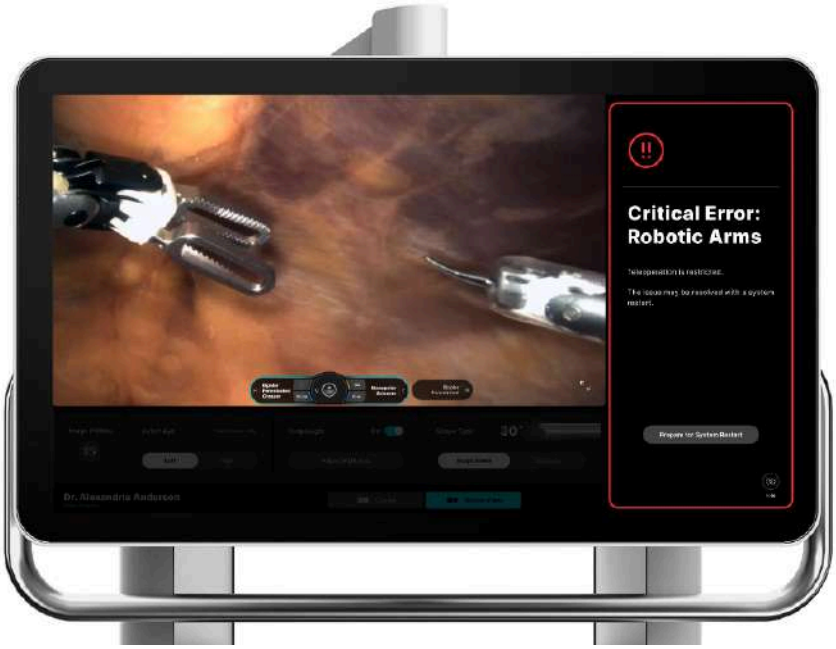
Locations	Screens
Tower touchscreen	

Table 3-10. Critical faults as shown in the System UI locations

Locations	Screen
Viewer	
Console touchscreen	

Locations	Screen
Tower	

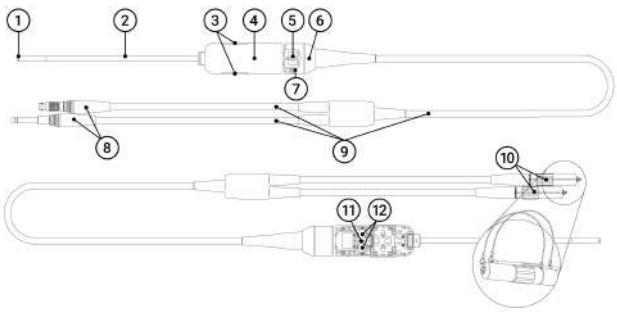
3.7 Endoscope

The Endoscope provides a high-resolution, 3D view of the patient anatomy. Attach the Endoscope to any of the Surgical Arms for a procedure. Once attached to a Surgical Arm, the surgeon controls the Endoscope from the Physician Console.

The optical tip has a light and camera that provide live video to the Tower touchscreen and in the Console viewer. Connect the camera and light engine connectors to the Tower. Insert the shaft through the Cannula and into the body cavity. Use the light button to turn on and off the Endoscope light. Press the release buttons to remove the Endoscope from the Surgical Arm. Cover the camera and light engine connectors during cleaning and sterilization. See the ETHICON™ Instruments and Accessories Cleaning and Sterilization Instructions.

The Endoscope has no user-serviceable parts. See Customer Support and Service (page 12-1).

Figure 3-21. Endoscope



1. Optical tip
2. Shaft
3. Release buttons
4. Handle
5. Button pad with light button
6. Camera head
7. Power light
8. Endoscope video connector and Endoscope light connector
9. Cable
10. Cable connectors, covered

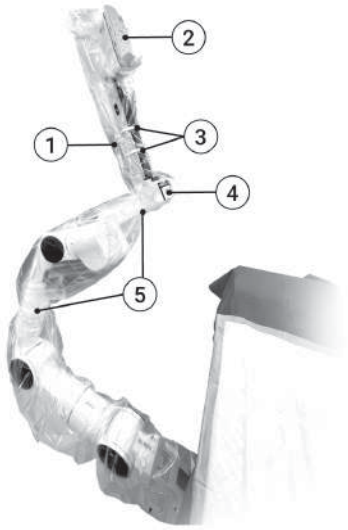
11. Gear box
12. Discs

3.8 Arm Sterile Drape

The Arm Sterile Drape protects the Surgical Arm from debris and provides a sterile barrier between the non-sterile Surgical Arm and the sterile Endoscope, Instrument, and Cannula used in the sterile field during a procedure.

The Arm Sterile Drape has a tool sterile adapter and a Cannula sterile adapter that connect the Endoscope, Instrument, and Cannula to the Surgical Arm. The cinch tape and polyties maintain excess drape material around the Surgical Arm.

Figure 3-22. Arm Sterile Drape



1. Drape
2. Tool sterile adapter
3. Polytie
4. Cannula sterile adapter
5. Cinch tape

3.9 Arm Stowage Cover

The Arm Stowage Cover protects the Surgical Arm from fluid and debris when the Surgical Arms are stowed during patient transfer to and from the Integrated Table and between surgical procedures. The Arm Stowage Cover has an integrated metal disk that connects to the magnet on the Table-Arm connection and polyties near the Table-Arm connection to secure the Arm Stowage Cover.

4 User Interface

The System User Interface, or UI, is the set of digital screens, indicators, messages, and interactive elements that are shown on the System touchscreens.

During System and procedure setup, the UI screens provide information about System startup and general setup. During surgery, they show the Endoscope view and provide ongoing status information about the System, Surgical Arms, Tools, and Tools.

Figure 4-1. Systems UI Displays

1. Tower touchscreen (page 4-1)
2. Physician Console Viewer (page 4-9)
3. Physician Console touchscreen (page 4-9)
4. Integrated Table Remote (page 4-15)

4.1 Tower Touchscreen UI

The Tower touchscreen UI is composed of the main content area and the footer bar. The main content area shows one of the following:

- Guides Dashboard (page 4-2)
- Endoscope View Dashboard (page 4-4)

From the footer bar you can:

- Identify the active surgeon on the System
- Navigate between the Guides Dashboard and Endoscope View Dashboard

- Access the Audio Settings (page 4-11) and general settings (page 4-12)

Figure 4-2. Tower touchscreen UI

1. Footer bar
2. Active surgeon
3. Guides and Endoscope View dashboards tabs
4. Audio settings
5. General settings
6. Main content area

4.1.1 Guides Dashboard

From the Guides Dashboard you can access Procedure Guides (page 4-2) and Robotic Steps Guides (page 4-3). The Guides Dashboard also shows the procedure name and the Endoscope feed when the Endoscope is connected to the Tower.

Figure 4-3. Guides Dashboard

1. Endoscope feed
2. Procedure Guides
3. Robotic Steps Guides
4. Procedure

4.1.1.1 Procedure Guides

A Procedure Guide shows an image with guidance information, a list of optional procedure accessories, the procedure name, and the Endoscope feed when the Endoscope is connected to the Tower. The navigation bar returns you to the Guides screen.

Figure 4-4. An example of a Procedure Guide

1. Endoscope feed
2. Procedure
3. Navigation bar
4. Guidance image
5. Optional procedure accessories

4.1.1.2 Robotic Step Guides

The Robotic Steps Guides show a list of steps to the left of a dynamic 3D model of the Integrated Table with its real-time status.

Work through the steps in the Robotic Steps Guides in the order shown.

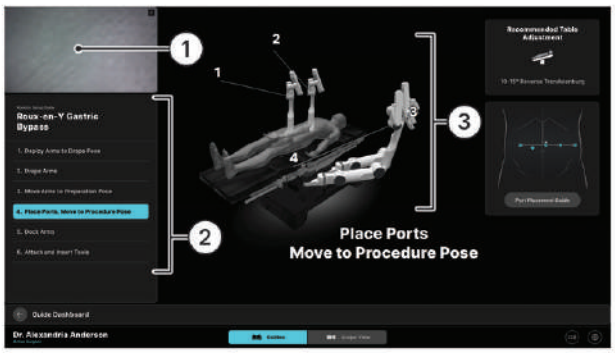
When you select a step in the list, the 3D model of the Integrated Table is shown in its current position. As you complete the tasks in the step, the 3D model updates. For example, when you complete a task on each Surgical Arm, the Surgical Arm is highlighted in green and a check mark is shown next to the Surgical Arm identifier. Once you complete all tasks in a step, select the next step in the list.

As you proceed through the steps, the angle and zoom of the Integrated Table changes to optimize the view for that step.

Some tasks can trigger changes to the System status colors, patterns, and sounds. See System Status Colors and Patterns (page 3-19) and System Status Sounds (page 3-20).

Steps may include guidance information in the upper right corner of the guide.

Figure 4-5. An example of a Robotic Steps Guide



1. Endoscope feed
2. Guide Steps

3. Integrated Table 3D model

4.1.2 Endoscope View Dashboard

The Endoscope View Dashboard shows the Endoscope View with the Tool Set (page 4-33) overlay, the Robotic Status panel (page 4-4), and the Endoscope and image settings and controls (page 4-8). The Endoscope View can be maximized to a full-screen view. System Notifications and Faults (page 3-22) are shown over the Robotic Status panel.

Figure 4-6. Endoscope View dashboard

1. Endoscope feed
2. Endoscope and image settings and controls
3. Maximize the Endoscope feed
4. Robotic panel

Figure 4-7. Endoscope View, maximized

1. Maximized Endoscope feed
2. Minimize feed button

4.1.2.1 Robotic Status Panel

The Robotic Status panel, to the right of the Endoscope View, shows:

- The position of the Integrated Table
- The active Surgical Arms

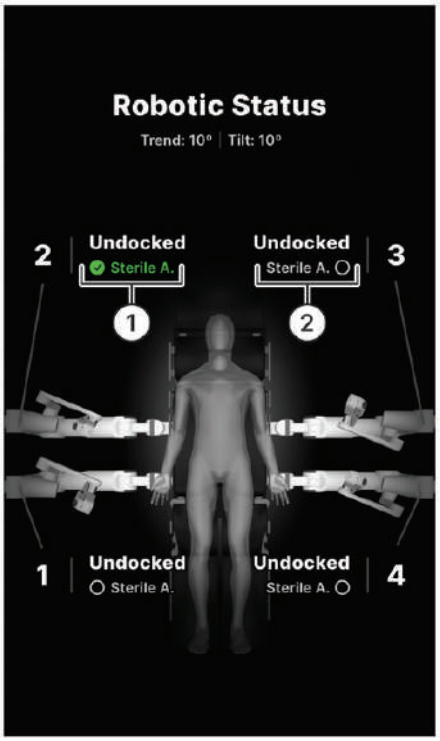
- The Surgical Arm that the Endoscope is attached to
- The Instruments attached to the other Surgical Arms

The Robotic Status panel updates in real time as you proceed through the set up steps. During a procedure, the Robotic Status panel shows the real-time position of the Integrated Table, Instruments, and Endoscope.

Attach Sterile Adapters

Attach the sterile adapters on the Arm Sterile Drape to the Surgical Arm.

Figure 4-8. Attach Sterile Adapters

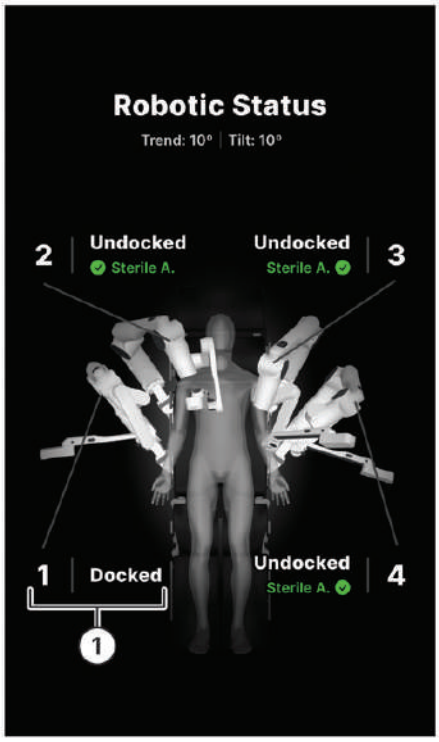


1. Sterile adapters attached
2. Sterile adapters not attached

Dock Surgical Arm

Dock the Surgical Arm to the Cannula.

Figure 4-9. Dock Surgical Arm

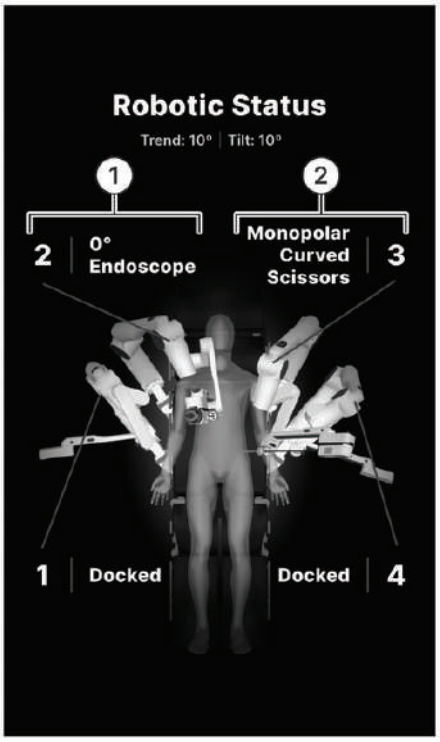


1. Docked Surgical Arm

Attach Tools

Attach the Endoscope and Instruments to the Surgical Arms.

Figure 4-10. Attach Tools

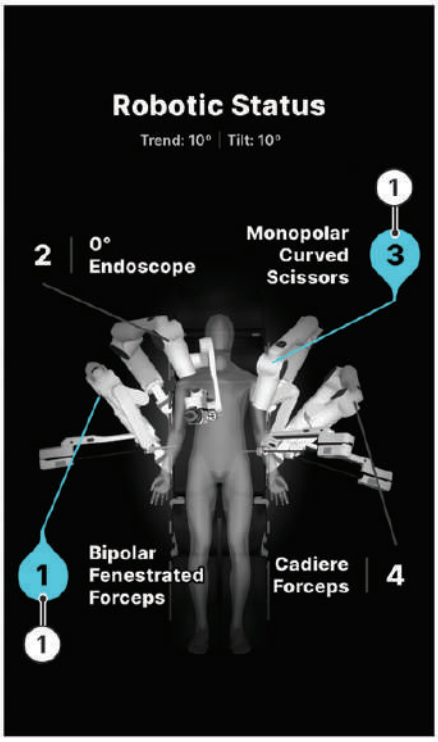


1. Endoscope attached
2. Instrument attached

Confirm Hand Assignment

Once the hand assignments are confirmed, the active Surgical Arm labels are highlighted in teal.

Figure 4-11. Confirm Hand Assignment



1. Hand Assignments confirmed, active Surgical Arm label in teal

4.1.2.2 Endoscope and Image Settings

The Endoscope and image settings shown below the Endoscope View on the Tower touchscreen control only the appearance of the Endoscope View on the Tower. The settings include:

- Image Utilities (page 4-8)
- Primary Eye (page 4-12)
- Endoscope Light (page 4-13)
- View the type of Endoscope in use (page 4-14)

4.1.2.2.1 Image Utilities

The Image Utilities controls on the Tower touchscreen control only the Endoscope View on the Tower. The controls include:

- Adjust Image
- White Balance (page 6-5)
- Turn the color bars on and off.

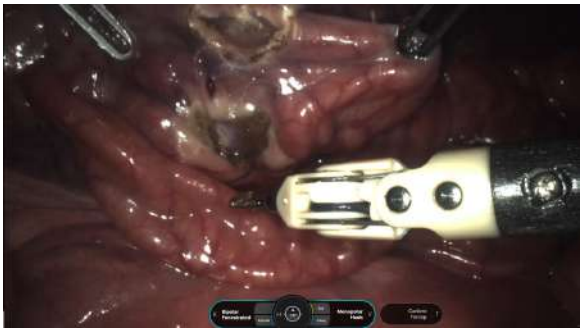
4.2 Physician Console UI

The Physician Console has two UI displays, the viewer Physician Console Viewer (page 4-9) and the touchscreen Physician Console Touchscreen UI (page 4-9) in the armrest.

4.2.1 Physician Console Viewer

The Physician Console viewer shows the live Endoscope feed with the Tool Set (page 4-33). Notifications and Faults (page 3-22) are shown at the top of the screen. Off-screen Instruments are represented by bars with the Surgical Arm number along the edge of the live Endoscope feed closest to the location of the Instrument.

Figure 4-12. Physician Console viewer UI



4.2.2 Physician Console Touchscreen UI

The Physician Console touchscreen UI shows the Procedure Screen (page 4-9) with the Stadium View (page 4-14) and access to the user profile settings , the hand assignment screen (page 4-10), the Physician Console audio settings (page 4-11), and the System settings (page 4-12).

Notifications and Faults (page 3-22) are shown full-screen.

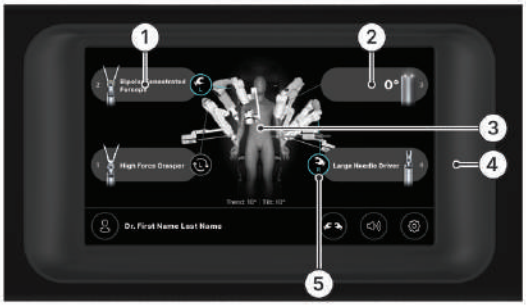
Figure 4-13. Physician Console touchscreen UI

1. Footer bar
2. User profile settings
3. Hand assignment
4. Audio setting
5. System setting
6. Stadium View

4.2.2.1 Procedure Screen

From the Procedure screen, select the Hand assignment you want to adjust the setting.

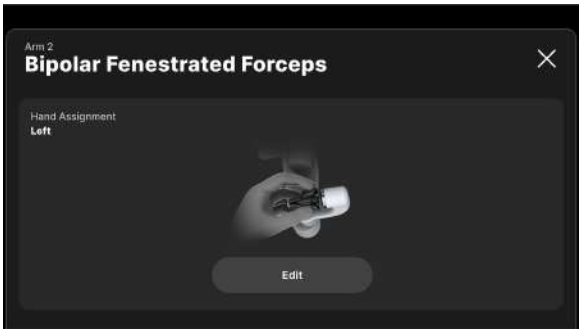
Figure 4-14. Procedure Screen



1. Instrument indicator
2. Endoscope indicator
3. Stadium view
4. Hand assignment indicator
5. Tool Information

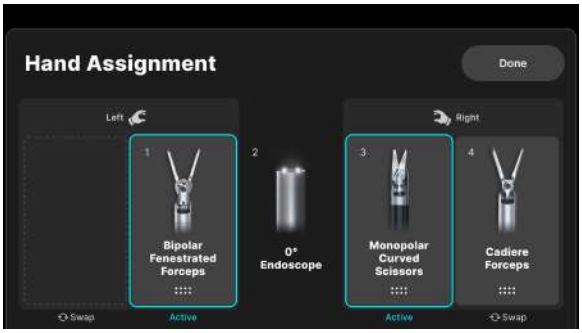
Once you have open the Hand assignment setting, select the Edit.

Figure 4-15. Instrument Setting



This brings you back to the hand assignment where you can make changes. You can swap or change the Instruments.

Figure 4-16. Hand Assignment Setting



4.2.2.2 Hand Assignment

Before you can begin teleoperation, hand-assignment confirmation is required once during or after Tools are attached to the Surgical Arms and loaded on the System. You can complete hand assignment automatically after a Tools are attached to a Surgical Arm (page 3-9), manually (page 4-11), or through System Settings (page 4-12).

NOTE: The hand assignments are shown on the Procedure screen. (page 4-9) When hand assignments change, the 3D model updates to show the new hand assignments.

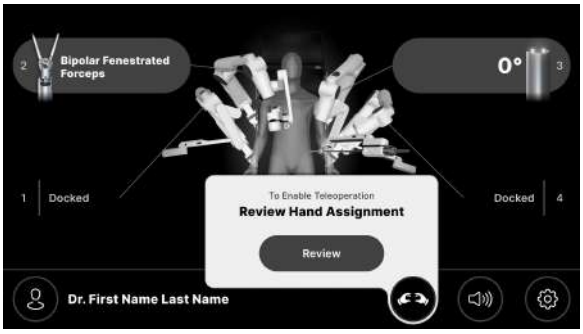
4.2.2.2.1 Automatic Hand Assignment after a Tool is Loaded

Hand assignment is initiated automatically after both the Endoscope and an Instrument are attached to a Surgical Arm and loaded on the System.

Review the automatic hand assignment. If you want to change the hand assignment, drag and drop an instrument card to the hand you want to control that Instrument. Confirm the hand assignment. Hand-assignment confirmation is only required one time before you begin teleoperation.

NOTE: You can skip hand assignment until all Instruments are loaded.

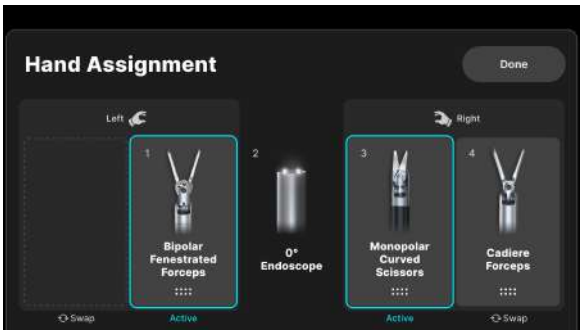
Figure 4-17. Review hand assignment after a Tool is loaded



4.2.2.3 Manual Hand Assignment

Complete manual hand assignments from the Hand Assignment screen. Drag and drop the Instrument card to the hand you want to control that Instrument. Confirm the hand assignment.

Figure 4-18. Manual Hand Assignment screen



4.2.2.4 Audio Settings

From the Audio Settings screen, you can adjust the audio settings for the viewer speaker and lower speaker. See Modify Audio Settings .

Figure 4-19. Audio Settings

4.2.2.5 System Setting

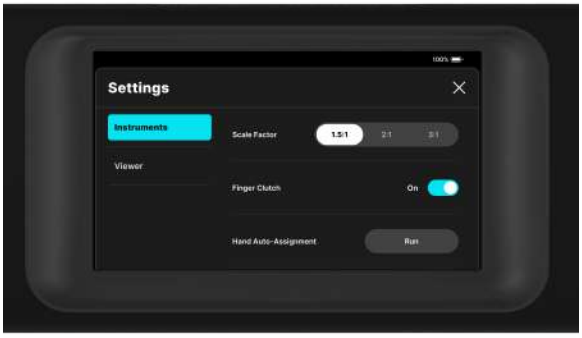
System Settings includes settings for Instruments (page 4-12) and the viewer (page 4-12).

Instruments

From the Instruments, you can:

- Adjust the scale factor, which determines how the surgeon's hand movements translate to the instrument movement.
- Turn on and off the finger clutch for both hand controls; the foot clutch is always available.
- Run hand auto assignment to review and hand assignment settings as necessary.

Figure 4-20. Instrument Setting



Viewer

For Viewer, you can set the view display to 2D or 3D. When 2D is selected, you can switch between the left and right eye as the view shown in the Endoscope View.

Figure 4-21. Viewer Setting Screen, 3D

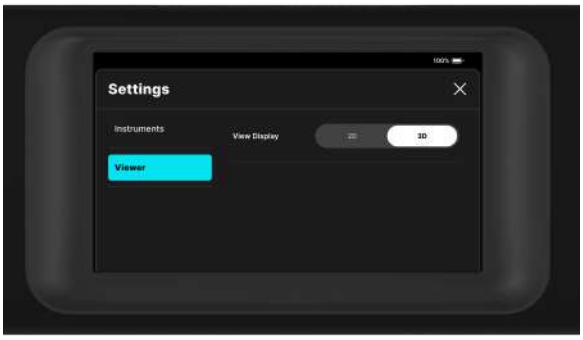
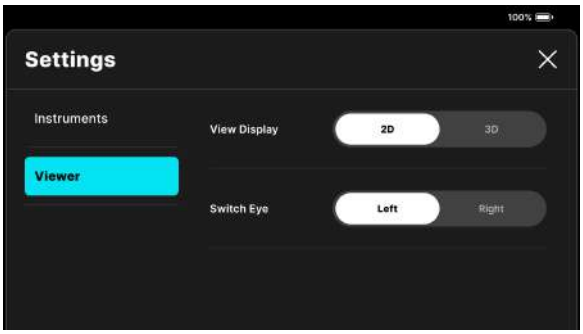


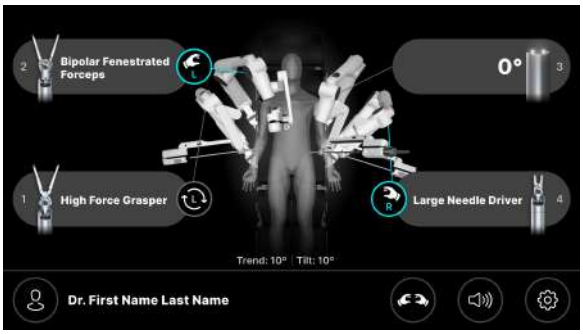
Figure 4-22. Viewer Setting Screen, 2D



4.2.3 Endoscope Settings

From the destination screen, select the Endoscope to adjust the setting.

Figure 4-23. Destination Screen



From the Endoscope Settings screen you can:

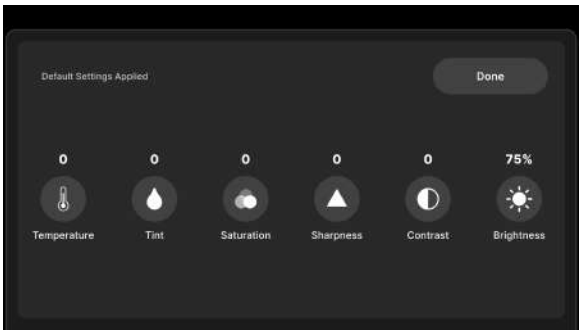
- Access Image Utilities to adjust the appearance of the image and turn the color bars on and off.
- Turn the Endoscope light on and off.

Figure 4-24. Endoscope Settings

Image Utilities

Select the adjust image to adjust the temperature, tint, saturation, sharpness, contrast, and brightness.

Figure 4-25. Adjust Image



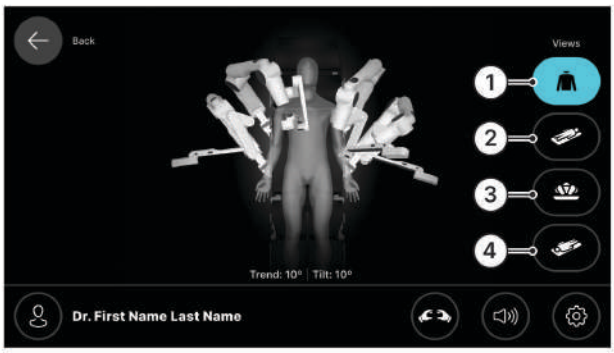
Once completed, select Done.

4.2.4 Stadium View

The Stadium View shows the real-time position of the Integrated Table. You can change the orientation of the Stadium View:

- Port view - shows the Integrated Table from overhead.
- Feet view, isometric - shows the Integrated Table from the feet at an isometric angle.
- Feet view, straight - shows the Integrated Table from the feet straight on from the feet.
- Head view - shows the Integrated Table from the head at an isometric angle.

Figure 4-26. Stadium View screen



1. Port View
2. Feet View isometric
3. Feet View Straight
4. Head View

4.3 Remote UI

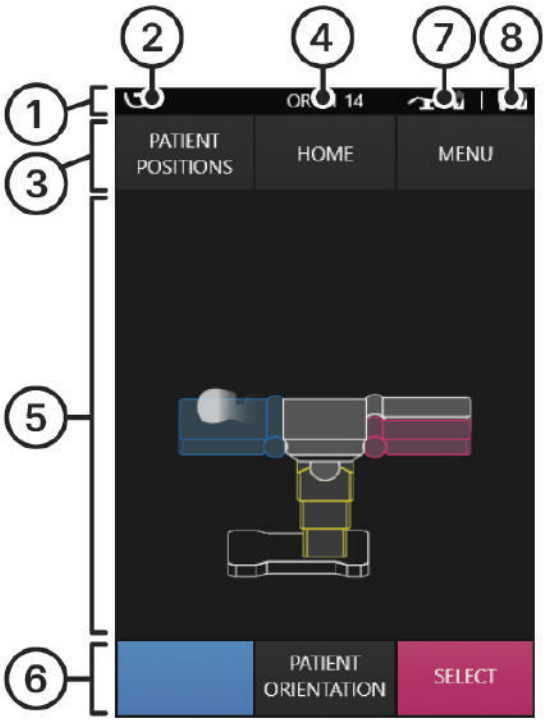
From the Table Remote UI you can access Table and Remote settings (page 4-16), and control the Surgical Arms (page 4-29).

Figure 4-27. Table Remote Home screen

4.3.1 Table and Remote

The Table and Remote screen has a status bar that shows the connection status to the table, table name, and the battery status for both table and remote. The navigation bar has patient positions screen, the home screen, and the menu screen. The table control has a patient orientation screen and a select screen.

Figure 4-28. Table and Remote overlay screen



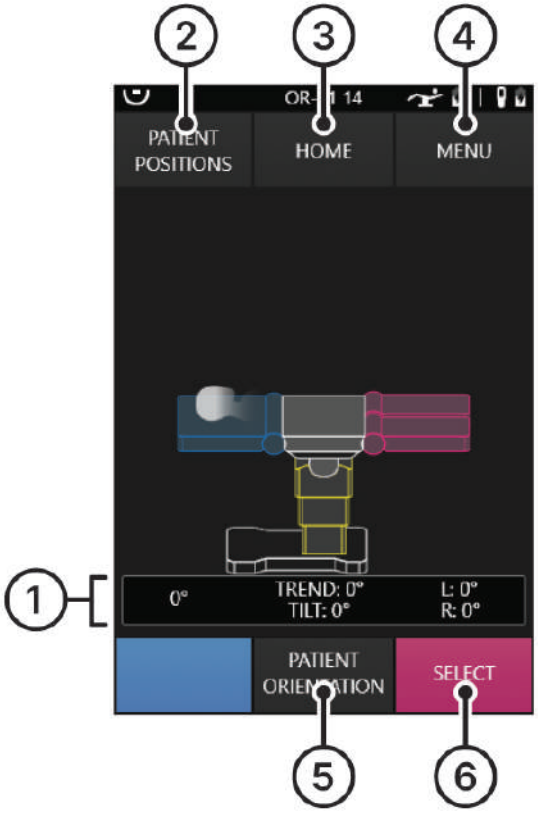
1. Status bar
2. Connection Status
3. Navigation bar
4. Table name
5. Main workspace
6. Table control
7. Battery status, Table
8. Battery status, Remote

Home Screen

From the home screen shows tabletop adjustment angle, then you can navigate to the patient positions screen, menu screen, patient orientation screen and select screen.

When the tabletop is in motion, the adjustment angle is shown on the touchscreen.

Figure 4-29. Home screen



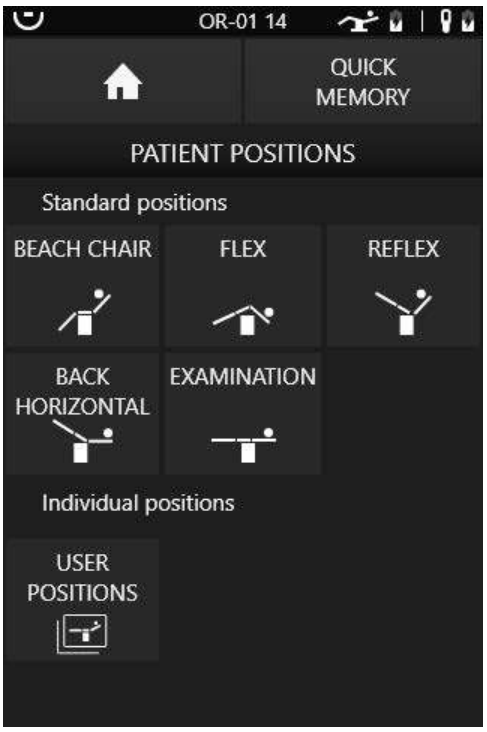
1. Tabletop adjustment angle
2. Patient positions
3. Home
4. Menu
5. Patient orientation
6. Select

WARNING: When adjusting the tabletop, always observe the patient and do not rely on the angle values shown on the touchscreen.

4.3.1.1 Remote Patient Positions

From the patient positions screen, you can positions the patient in these positions beach chair, flex , reflex, beach horizontal, examination, and user positions.

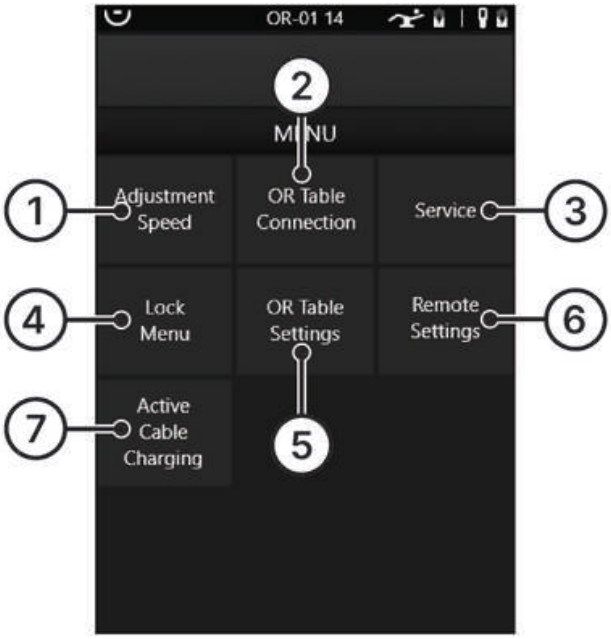
Figure 4-30. Patient positions



4.3.1.2 Table Controls Menu

From the table controls menu you can adjust the speed, connect the OR table connection, lock menu, adjust the OR table setting, adjust the device setting, and see what active cable charging.

Figure 4-31. Main screen

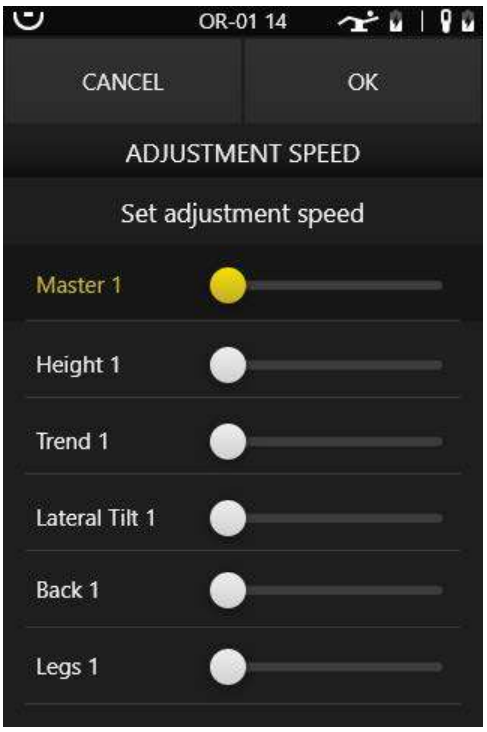


1. Adjustment Speed
2. OR Table Connection
3. Lock Menu
4. OR Table Settings
5. Device Settings
6. Active Cable Charging

4.3.1.2.1 Adjustment Speed

From the adjustment speed screen, you can toggle to the appropriate speeds.

Figure 4-32. Adjustment speed



4.3.1.2.2 OR Table Connection

From the OR table connection screen, you can connect to a OR table, disconnect from an OR table, rename an OR table and view the IR code.

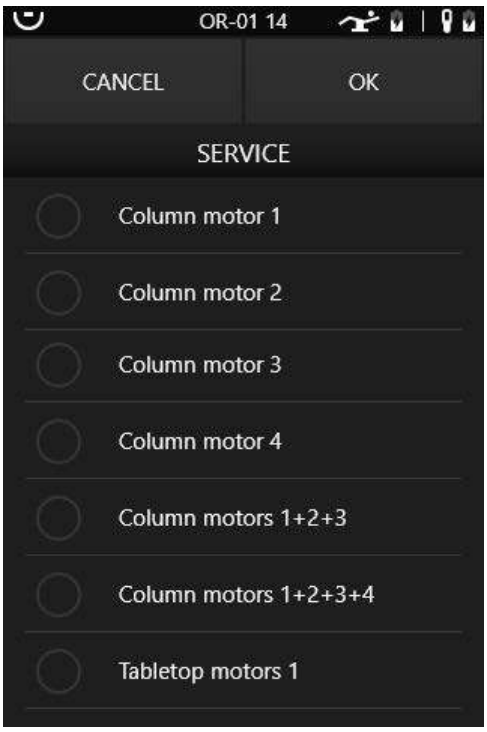
Figure 4-33. OR Table Connection

1. Connect to OR Table
2. Disconnect from OR Table
3. Rename OR Table
4. View IR code

4.3.1.2.3 Service

From the service screen, you can see which motor is in service.

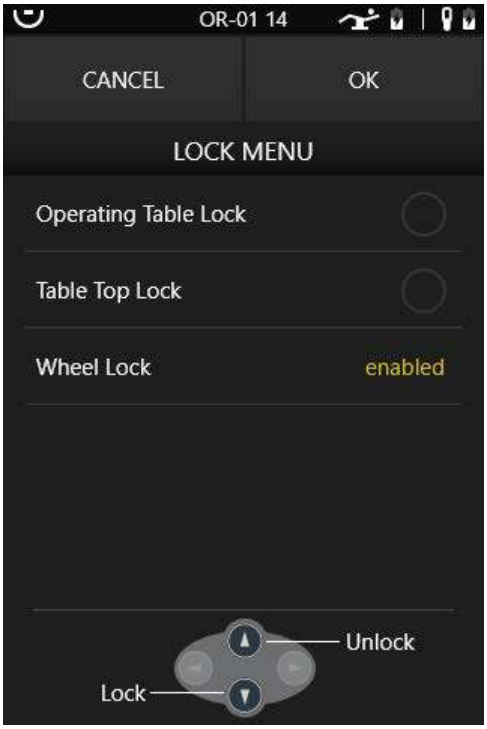
Figure 4-34. Service



4.3.1.2.4 Lock Menu

From the lock menu screen, you can lock and unlock the operating table, table top and wheels.

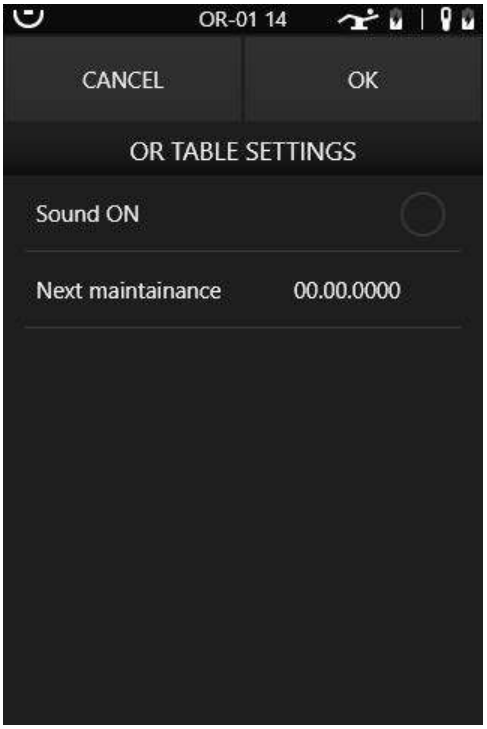
Figure 4-35. Lock Menu



4.3.1.2.5 OR Table Setting

From the OR table setting screen, you can turn sound ON and see when the next maintenance is due.

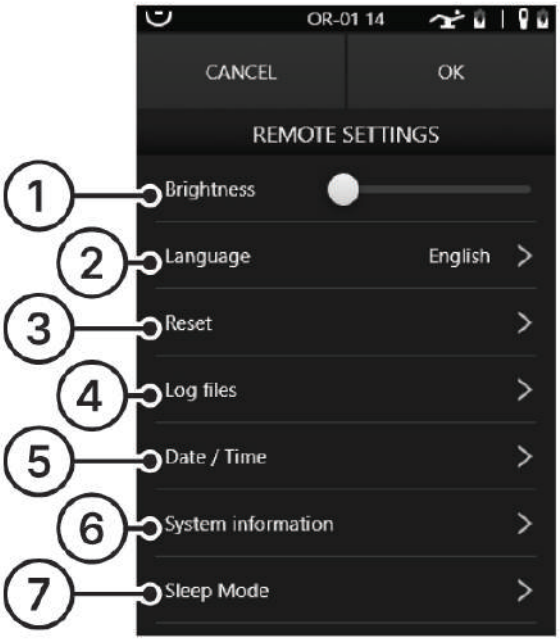
Figure 4-36. OR Table setting



4.3.1.2.6 Remote Settings

From the Device setting screen you can change the brightness, language, reset, log files, date and time, system information and sleep mode.

Figure 4-37. Device Settings screen



1. Brightness
2. Language
3. Reset
4. Log files
5. Date and time
6. System information
7. Sleep mode

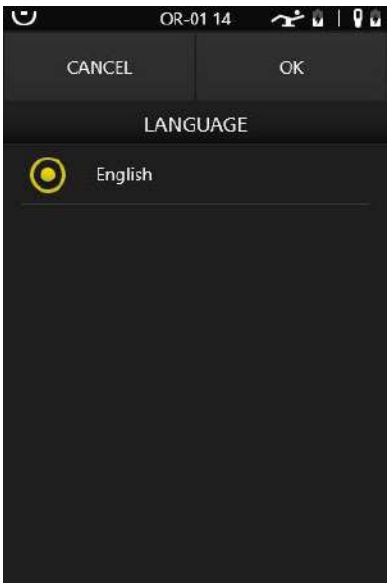
Brightness toggle screen

1. Slide the toggle to the right to increase, or to the left to reduce the brightness.
2. Select the OK button to save.

Language screen

Select the desired language.

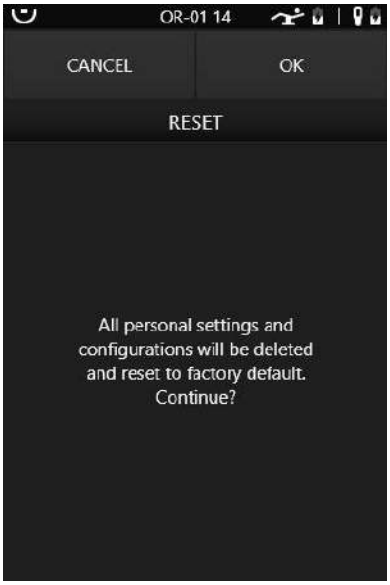
Figure 4-38. Language screen



Reset screen

Reset will return to factory default setting.

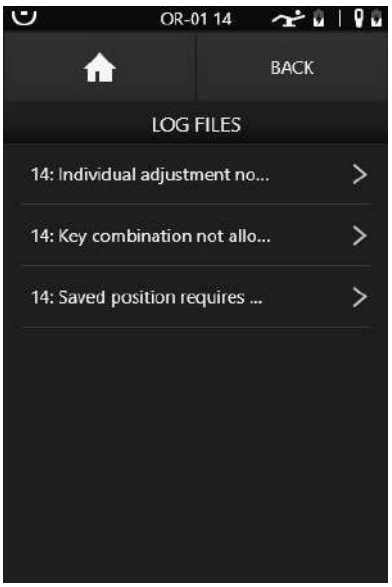
Figure 4-39. Reset screen



Log Files screen

From the log files screen, you can review the log files.

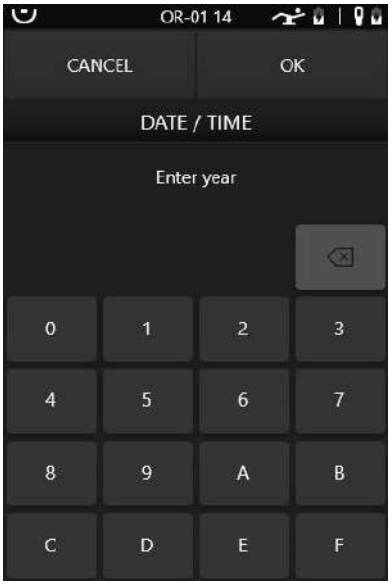
Figure 4-40. Log files screen



Date and Time screen

From the date and time screen you can enter year, month, day, hour, and minute.

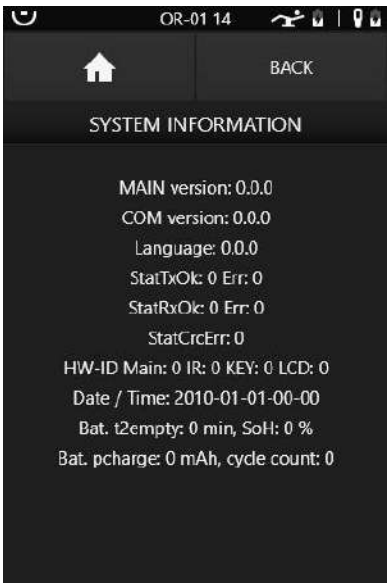
Figure 4-41. Date and time screen



System Information screen

From the system information screen, you can view the systems information.

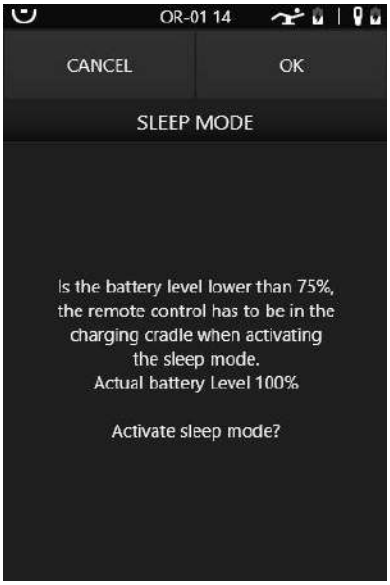
Figure 4-42. System information screen



Sleep mode screen

From the sleep mode screen, you can switch the remote to sleep mode.

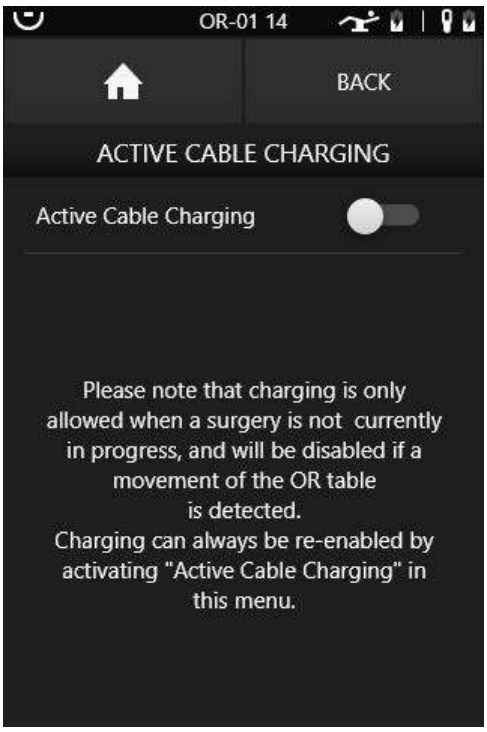
Figure 4-43. Sleep mode screen



4.3.1.2.7 Active Cable Charging

From the active cable charging screen, you can activate the cable charging from this screen.

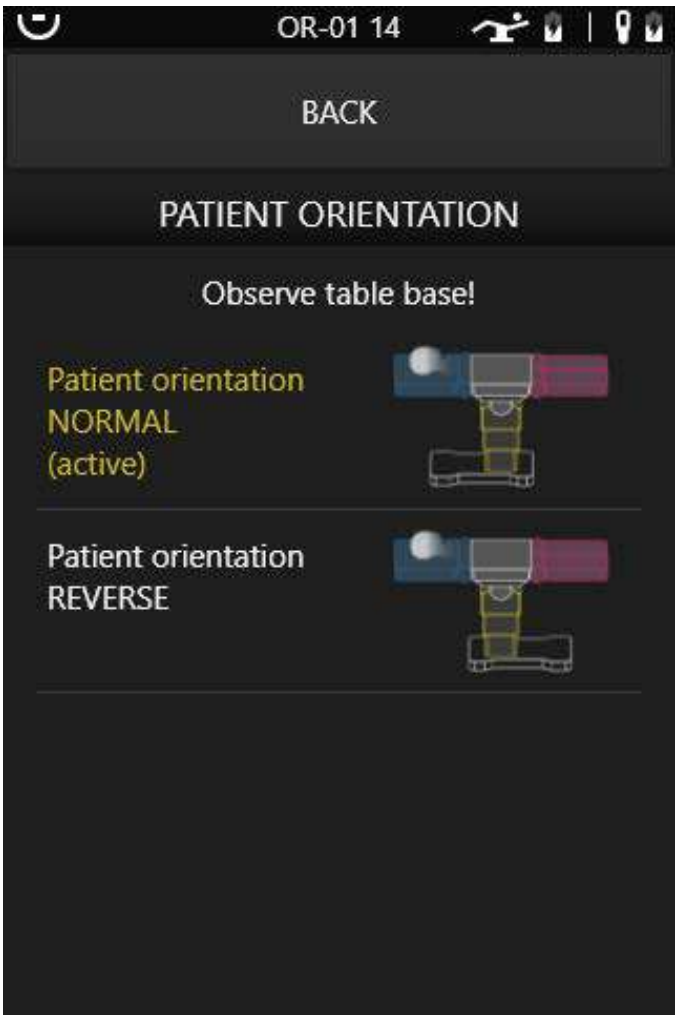
Figure 4-44. Active cable charging



4.3.1.3 Patient Orientation

From the patient orientation screen, you can change the orientation of the table base.

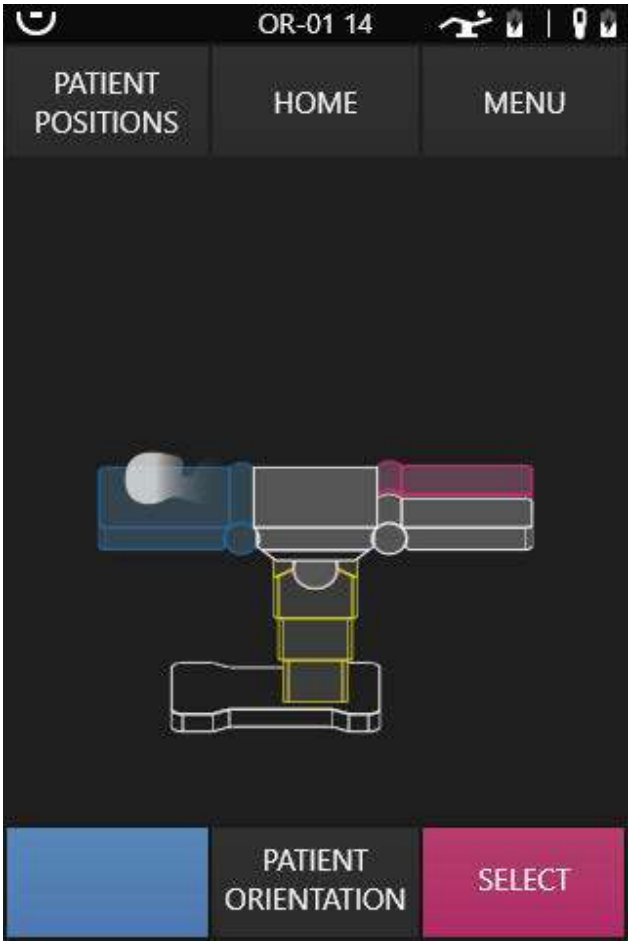
Figure 4-45. Patient Orientation



4.3.1.4 Select

From the select screen, you can move the left or right legs up or down.

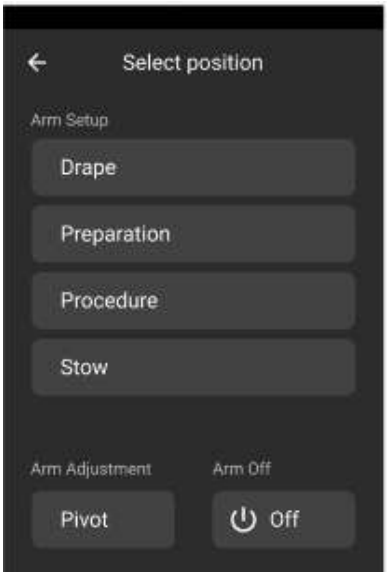
Figure 4-46. Select



4.3.2 Arms

Select the Arms button to access the Select Position screen from which you can select predetermination Surgical Arm positions, pivot a Surgical Arm, or turn a Surgical Arm on or off.

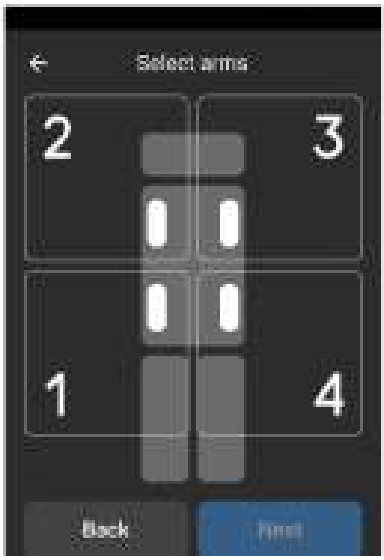
Figure 4-47. Select Position Screen



4.3.2.1 Select Surgical Arm

From the select Surgical Arm screen, you can touch the single Surgical Arm quadrants to select individual Surgical Arms. Then you can touch single Surgical Arm quadrants to deselect individual Surgical Arms.

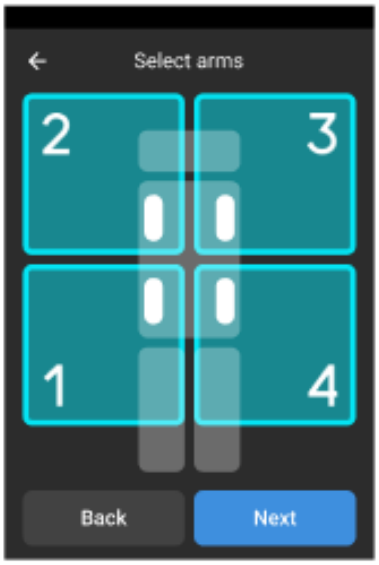
Figure 4-48. Select arm screen



4.3.2.2 Arms All Selected

From the Arms All Selected, you can see all the arms are selected and then touch next to proceed.

Figure 4-49. Arms All Selected.



4.3.2.3 Deploy Arms

From the deploy arms screen, you can select the up green arrow to proceed directly to the progress screens.

Figure 4-50. Arm movable screen

From the arm deploy screen, you can see the progress screens in process until complete. The arm pose represents the final position of the arm.

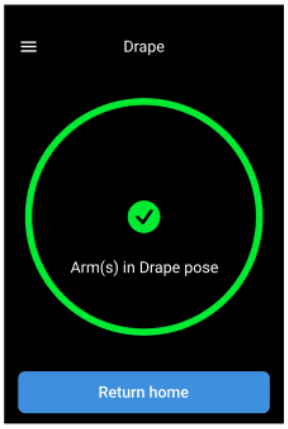
NOTE: The progress indicator is an estimate of the time remaining to deploy the arms to the selected position.

Figure 4-51. Arm deploy progress screens

4.3.2.4 Arms Process Finished

From the arms process finished screen, once finished you can touch return home.

Figure 4-54. Arms process finished



4.4 Tool Set

The Tool Set is an overlay on the Endoscope View that shows Instrument and Endoscope information. The Endoscope information is shown in the center and includes the Surgical Arm that the Endoscope is attached to, the type of Endoscope, and the horizon indicator. When you engage the Camera pedal, the outline around the Endoscope indicator is highlighted in teal. .

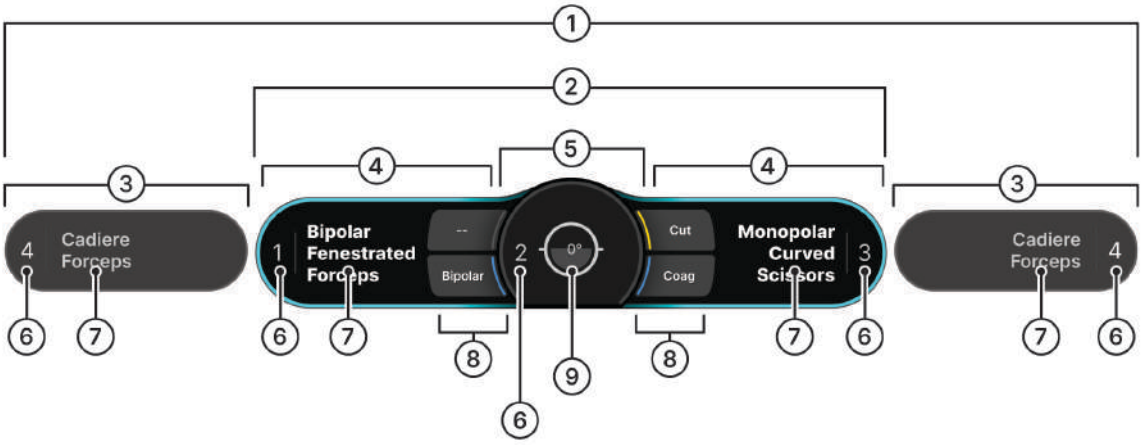
To the left of center, the Instruments assigned to the left hand are shown and to the right of center, the Instruments assigned to the right hand are shown.

The Active Instrument Indicator are to the left and right of the Endoscope Indicator and the Swap Instrument Indicator is shown to the left or right of the Active Instrument Indicator on the same side as its hand assignment.

The Active Instrument Indicator shows which Surgical Arm the Instrument is attached to, the name of the Instrument, and the foot pedal modes available for the Instrument.

See Tool Set Status Elements (page 4-34) for information on other Instrument status elements.

Figure 4-55. Tool Set



1. Tool Set
2. Active Zone

3. Swap Instrument
4. Active Instrument Indicator
5. Endoscope Indicator
6. Arm Indicator
7. Instrument Name
8. Pedal Mode Indicator
9. Endoscope Horizon Indicator

4.4.1 Tool Set Status Elements

The Tool Set includes status elements in the UI that convey information consistently across the different UI locations.

Loading

The Loading status indicator is shown above the Endoscope or Instrument indicator when a Tool is attached to a Surgical Arm. Information about the Tool is being read by the system. The message is dismissed when the Tool is loaded.

No sound is played.

Figure 4-56. Loading status

Insert

The Insert status indicator is shown above the Endoscope or Instrument indicator when a Tool is attached to the Surgical Arm but has not been inserted into the Cannula.

No sound is played.

Figure 4-57. Insert status

Disengaged

Instruments are assigned to hands and teleoperation is disengaged. Reconfirm hand assignment on the Console touchscreen to re-engage the instruments.

No sound is played.

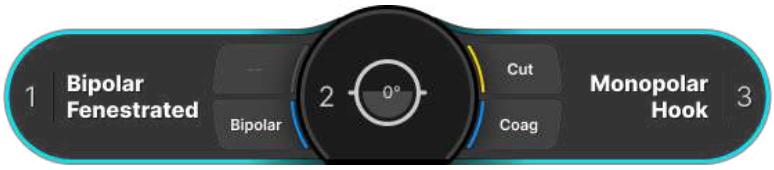
Figure 4-58. Disengaged status

Active

The hand assignment is confirmed and the right and left Instruments are active and can be controlled by the surgeon.

No sound is played.

Figure 4-59. Active status



Active Cut - Non-Energy Instrument

The cut pedal is engaged.

The sound plays continuously while the cut pedal is pressed.

Right finger clutch

The right flinger clutch is engaged. The Instrument controlled by the right hand can be repositioned.

No sound is played.

Figure 4-60. Right finger clutch status

Left finger clutch

The left finger clutch is engaged. The Instrument controlled by the right hand can be repositioned.

No sound is played.

Figure 4-61. Left finger clutch status

Foot clutch

The foot clutch is engaged. The Instruments controlled by the left and right hands can be repositioned.

No sound is played.

Figure 4-62. Foot clutch status

Match Grips

Match the grips to reengage the Instruments.

The sound plays when the grips are matched.

Figure 4-63. Match Grips status

Clutched at Bedside

The Clutched at Bedside status indicator is shown above the Endoscope or Instrument indicator when a tool clutch on the Surgical Arm is engaged.

No sound is played.

Figure 4-64. Clutched at Bedside status

Camera Clutch

The camera pedal is engaged.

No sound is played.

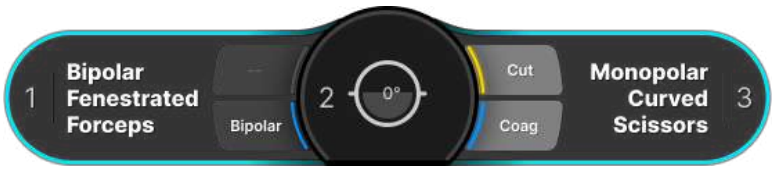
Figure 4-65. Camera clutch status

Right Pedal Hover

The surgeon's foot hovers over the right Instrument pedals.

No sound is played.

Figure 4-66. Pedal Hover Right status

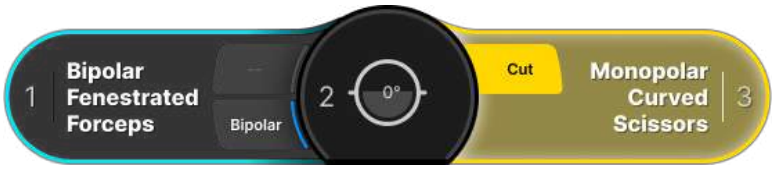


Energy Instrument Active Cut

The surgeon has engaged the cut energy pedal.

The sound audio cue plays continuously while the energy mode pedal is pressed.

Figure 4-67. Energy Instrument active cut statusstatus



Left Pedal Hover

The surgeon's foot hovers over the left Instrument pedals.

Energy Instrument Active Bipolar

The bipolar energy pedal is engaged.

The sound audio cue plays continuously while the energy pedal is engaged.

Figure 4-68. Energy Instrument active bipolar status

Instrument swap

The swap pedal is engaged. The active and inactive Instrument indicators switch place.

The sound audio cue plays continuously while the energy pedal is engaged.

5 System Setup

System setup is the responsibility of Auris Health as described. Users can change between on and standby mode.

1. Place the following components in the OR and lock the casters on each to immobilize.
   - Physician Console
   - Integrated Table
   - Tower
2. Install optional tabletop accessories.
3. Adjust the Tower touchscreen for use.

Power and umbilical connections:

4. Connect the power cord to the power cable port on the back of the Tower and to an electrical outlet on a dedicated circuit.

   Make sure that the power LED on the Tower I/O panel turns blue.
5. Connect the power cord from the Electrosurgical generators to a separate circuit from the System.
6. Connect the power cord from the Integrated Table and to an electrical outlet on a dedicated circuit.
   a) Connect the blue mesh umbilical cable to the umbilical port on the Integrated Table and to the umbilical port on the back of the Tower.

      Make sure that the data LED on the Tower I/O panel turns blue.
   b) Connect the power cord to the rightmost power port on the back of the Physician Console and to an electrical outlet on a dedicated circuit.

      Make sure that the power LED on the Physician Console I/O panel turns blue.
   c) Connect the black smooth umbilical cable to the umbilical port on the Physician Console and to the umbilical port on the back of the Tower.

      Make sure that the data LED on the Physician Console I/O panel turns blue.
7. Once the power and umbilical cables are connected to the Physician Console I/O panel, make sure that both cable connections are secure.

   If the cables are not secure, reconnect the cables.
8. Press and hold the power button on the Physician Console armrest or I/O panel.

Integrated Table:

9. Toggle the breaker switches to the ON position.
10. Press the power button on the Table Remote.

    Make sure that the LEDs on the Surgical Arms pulse white.

Tower:

11. Press and hold the power button on the Tower.

    Make sure that the power button starts pulsing.
12. Power on the Electrosurgical generators (page 3-5).

System Connectivity:

13. Make sure that the power button on the Physician Console has changed from pulsing to solid.

14. Make sure that the power button on the Tower has changed from pulsing to solid.
15. Make sure that the LEDs on the Surgical Arms have changed from pulsing to solid.
16. Make sure that the data LED on the Tower I/O panel and the data LED on the Physician Console I/O panel is blue.

6 Prepare for a Procedure

This section provides general workflows and instructions for OR Prep and Setup for the procedure using the System. The information in this section covers activities that occur the day of the procedure before any incision is made.

To prepare for the procedure:

- Prepare and Set Up the OR (page 6-1)
- Transfer and Position the Patient (page 6-3)
- Set Up and Test the Endoscope (page 6-4)
- Establish the Sterile Environment (page 6-5)
- Prepare the Patient for the Procedure (page 6-8)
- Set Up the System for the Procedure (page 6-9)

6.1 Prepare and Set Up the OR

Prepare and place the tools, accessories, and equipment in dedicated locations in the OR.

1. Set Up Auxiliary Equipment (page 6-1).
2. Obtain Tools and Accessories Needed for the Procedure (page 6-1).
3. Install the Insulation Sheath on the Monopolar Curved Scissors (page 6-2).
4. Assemble the Trocars (page 6-2).
5. Establish External Video Connections from the Tower (page 6-3).

6.1.1 Set Up Auxiliary Equipment

1. Set up auxiliary medical equipment in the OR such as an insufflator, a suction-irrigator pump, and a patient warming system
2. If needed, connect the insufflator to the power outlet and place the insufflator on the Tower shelf.
3. Make sure that CO_2 is connected to the insufflator.
4. If needed, bring patient positioning equipment into the OR and pre-install the footplates and arm boards on the non-gurney side of the Integrated Table.

6.1.2 Obtain Tools and Accessories Needed for the Procedure

Use aseptic technique to:

1. Unpack the Instruments, Endoscope, Cannulas, and reusable cables from the Sterilization Trays.
2. Transfer the Instruments, Endoscope, Cannulas, and reusable cables into the sterile field.
3. Open and transfer the sterile Obturators, and Universal Seal Packs into the sterile field.
4. Open and transfer four Arm Sterile Drapes into the sterile field.

6.1.3 Install the Insulation Sheath on the Monopolar Curved Scissors

NOTE:

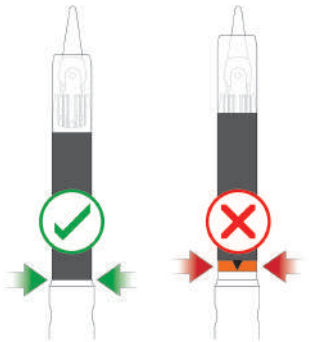
- The Insulation Sheath and the Monopolar Curved Scissors are packaged separately.
- The Monopolar Curved Scissors is provided NON-STERILE and must be cleaned and sterilized before the first use and between subsequent uses. See the ETHICON™ Instruments and Accessories Cleaning and Sterilization instructions.
- The Insulation Sheath with Applicator is provided STERILE for SINGLE-PATIENT USE. Install the Insulation Sheath onto the Instrument in a sterile field.
- The Insulation Sheath with Applicator is provided fully assembled and includes the applicator, an Insulation Sheath, and a blade barrier.

WARNING: Failure to properly install the Insulation Sheath may result in improper scissor opening, the Insulation Sheath falling off, electrical arcs and alternate site burns, and difficulty attaching the Instrument on the Surgical Arm.

To install the Insulation Sheath:

1. Manually close the scissor blades and straighten the wrist.
2. Grasp the insertion grip on the Sheath Applicator and align the tabs with the notches on the Instrument shaft.
3. Slide the Sheath Applicator with Insulation Sheath over the distal end of the Instrument. Push the Sheath Applicator onto the shaft until it stops.
4. Retract the Sheath Applicator and set it aside for use at the end of the procedure to remove the Insulation Sheath.

   Dispose of the blade barrier.
5. The Insulation Sheath is properly installed when the orange band between the Insulation Sheath and the shaft is no longer visible.



6. Before and during use, inspect the installed Insulation Sheath for visible punctures or scrapes.

6.1.4 Assemble the Trocar

WARNING:

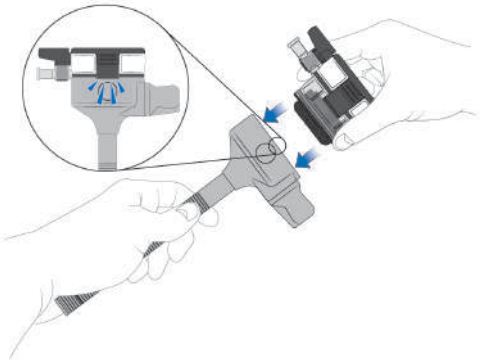
- If a Device is dropped outside the sterile field, replace it. Failure to do so will result in compromised sterility and potential for transmission of infection and disease.

CAUTION:

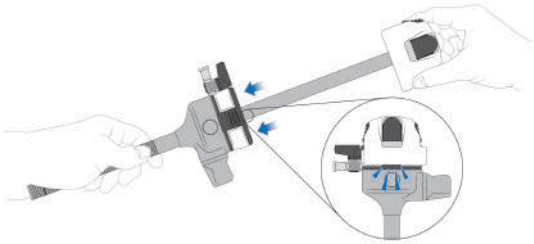
- To avoid Device damage, do not flip the Device into the sterile field.

To assemble the Trocar:

1. Use aseptic technique to remove the Obturator, Universal Seal, and Cannula from their packages.
2. Insert the Universal Seal into the Cannula.
   Push down on the Universal Seal until the latches snap into the Cannula with an audible click.



3. Close the Universal Seal stopcock valve, which is shipped in the open position.
   The stopcock valve is closed when the stopcock lever is perpendicular to the stopcock valve.
4. Remove the protective tip cover from the Obturator.
   Discard the tip cover.
5. Insert the Obturator into the Universal Seal.
6. Push down on the Obturator until the latches snap into the Universal Seal with an audible click.



6.1.5 Establish External Video Connections from the Tower

1. Connect a cable to the video output port on the Tower.
2. Connect the other end of the cable to a video device such as a wall-mounted display.

6.2 Transfer and Position the Patient

When you bring the patient into the OR before the procedure, follow the recommended steps to safely transfer the patient to the Integrated Table and then position and secure the patient on the Integrated Table.

1. Access the Procedure Guides (page 6-4).
2. Transfer the Patient to the Integrated Table (page 6-4).
3. Intubate and Establish Physiological Monitoring.
4. Position the Patient on the Integrated Table (page 6-4).
5. Secure the Patient to the Tabletop.
6. Preoperative Patient Preparation.

6.2.1 Access the Procedure Guides

The Procedure Guides on the Tower touchscreen show information to help with patient positioning and accessory positioning.

1. Select Guides.
2. Select the applicable procedure guide.

6.2.2 Transfer the Patient to the Integrated Table

When you transfer the patient from the gurney to the Integrated Table, make sure the Integrated Table casters are locked. It is recommended to match the height of the Integrated table and gurney for patient transfer. It is recommended to stow all Surgical Arms during patient transfer.

1. Use the Table Remote to adjust the tabletop height to the gurney height.
   a) Press the Power button on the Remote to turn it on.
   b) Press the up and down yellow arrow buttons on the Remote to increase or decrease the height of the tabletop to match the height of the gurney.
2. Follow hospital procedures to safely transfer the patient from the gurney to the Integrated Table.

6.2.3 Position the Patient on the Integrated Table

Adjust the position of the patient and tabletop plates for the procedure.

WARNING: When moving parts of the tabletop, make sure that the patient is secure to prevent a patient fall from the tabletop or other injury.

CAUTION: Be aware of any parts of the patient's body that can be pinched or bruised by parts of the Integrated Table when you position the tabletop and tabletop plates. Labels on the Table show high-risk areas.

Use the Integrated Table Remote and manual buttons and levers on the tabletop to change the angle and position of the tabletop plates. General guidelines for patient positioning are listed below.

6.2.4 Secure the Patient to the Tabletop

After initial patient positioning is complete and before the procedure, secure the patient to the tabletop for their comfort and safety. The patient positioning guide on the Tower touchscreen shows guidance for accessories used in the procedure and where to place them on the tabletop.

It is recommended to follow the steps described to secure the patient to the tabletop:

- Use positioning aids as necessary.
- Make sure positioning aids, body straps and restraints, and all side rail accessories will not obstruct the Table controls or interfere with Integrated Table movement.
- Keep the patient's arms parallel to the tabletop until the Surgical Arms are docked to the Cannulas.

6.3 Set Up and Test the Endoscope

Confirm that the Endoscope or Endoscopes for use in the procedure are functional before you start a procedure to avoid a prolonged procedure. If an Endoscope is not functional, replace it.

1. Connect the Endoscope to the Tower (page 6-5).
2. White Balance the Endoscope (page 6-5).

6.3.1 Connect the Endoscope to the Tower

To maintain the sterility of the Endoscope for the procedure, two members of the surgical staff—one within the sterile environment and one outside of it—are needed to connect the Endoscope to the Tower and to test that it is functional.

CAUTION: After you connect the Endoscope to the Tower:

- Keep the Endoscope tip pointed away from your and others' eyes to avoid injury.
- Do not touch the optical tip of the Endoscope to avoid damage to the Endoscope tip.

1. Hand off the Endoscope connectors to the non-sterile circulating nurse.
2. From outside the sterile environment, remove the Endoscope connector covers.

   The connector covers are tethered to the cables.
3. Connect the Endoscope connectors to the Endoscope ports on the Tower.

   Make sure the live Endoscope feed is shown on the Tower touchscreen and on the Physician Console viewer.

6.3.2 White Balance the Endoscope

White balance the Endoscope image at the beginning of every procedure and during a procedure, if you change Endoscopes, to establish the baseline for white from which all other colors are measured.

1. Point the endoscope tip at a white surface, such as a piece of paper, to fill the field of view with a white color.
2. With the Endoscope connected to the Tower, turn on the Endoscope light.
3. On the Tower touchscreen, select Image Utilities.

   The Image Utilities screen is shown.
4. Select White Balance.

   The White Balance icon is shown in the center of the Endoscope View.
5. Select Set to start the white balance process.

   When the process is complete, the white balance icon is shown with a green checkmark and a confirmation tone is played.

   If the process is unsuccessful, the white balance icon is shown with a yellow unsuccessful symbol and an error tone is played.
6. To attempt the white balance process again, point the endoscope tip at a white surface to fill the field of view with a white color and select Retry.

6.4 Establish the Sterile Environment

1. Deploy the Surgical Arms to the Drape Position (page 6-6).
2. Remove the Arm Stowage Covers (page 6-6).
3. Drape the Surgical Arms (page 6-6).
4. Deploy the Surgical Arms to the Preparation Position (page 6-7).
5. Connect Auxiliary Equipment (page 6-8).

6.4.1 Deploy the Surgical Arms to the Drape Position

The drape position moves the Surgical Arms to a height and spacing to make it easier to apply the Arm Sterile Drapes. Although you can put the Surgical Arms in a drape position using many different methods, the recommended method is to move the Surgical Arms with the Table Remote.

To move the Surgical Arms to the drape position with the Table Remote:

NOTE: The Deploy Arms screen shows progress toward deployment, but it does not represent a real-time estimate of the time remaining in the process.

1. Press the power button on the Table Remote to turn on the Table Remote.
   The Home screen is shown.
2. Select Arms.
   The Select Position screen is shown.
3. Select Drape.
   The Select Arms screen is shown.
4. Select the Surgical Arms that you want to drape.
   As you select the Surgical Arms on the Select Arms screen, the LEDs on the selected Surgical Arms turn solid teal.
5. Select Next.
   The Deploy Arms screen is shown.
6. Press and hold the green UP button until the Surgical Arms are in the drape position.

   Monitor the area around the Integrated Table as the Surgical Arms deploy to the position for potential collision with the surgical staff or equipment. You can also use the green DOWN button to reverse the Surgical Arm movement.

   As the Surgical Arms move to the drape position, the LEDs on the Surgical Arms pulse white. When the drape position is reached, the LEDs on the Surgical Arms turn solid white.

6.4.2 Remove the Arm Stowage Covers

Arm Stowage Covers protect the Surgical Arms from environmental damage during patient transfer to and from the Integrated Table, between procedures, and when the Integrated Table is in storage. Remove the Arm Stowage Covers before you drape the Surgical Arms for a procedure.

Deploy the Surgical Arms to the Drape position (page 6-6). To remove the Arm Stowage Covers the Surgical Arms in the drape position:

1. Release the cinch tape used to secure the Arm Stowage Cover.
2. Detach the metal disc from the magnet the Table-Arm connection.
3. Carefully remove the Arm Stowage Cover from the Surgical Arm, start from the cover opening around the pivot arm and work your way up the rest of the Surgical Arm.

   CAUTION: Do not pull or hang on parts of the Surgical Arm as you remove the Arm Stowage Covers to avoid damage to the Surgical Arm.
4. Dispose of the used Arm Stowage Cover as biohazardous waste.

6.4.3 Drape the Surgical Arms

The Arm Sterile Drapes must be applied to the Surgical Arms by someone in the sterile field. A surgical team member outside the sterile field will extend the Arm Sterile Drapes below the sterile field.

CAUTION:

- As you extend the Arm Sterile Drape along a Surgical Arm, make sure that the Arm Sterile Drapes does not snag or tear on any part of the Surgical Arm.
- When you connect the tool sterile adapter and cannula sterile adapter into place, make sure that Arm Sterile Drape material does not get caught underneath an adapter. If the Arm Sterile Drape material gets caught underneath an adapter, remove the adapter, straighten the Arm Sterile Drape, and continue to drape the Surgical Arm.

1. Break the tape on the folded Arm Sterile Drape.
2. Position the hand plates of the Arm Sterile Drape, so the arrows point toward the floor.
3. Align and carefully extend the Arm Sterile Drape along the operative arm.
4. Adjust the Arm Sterile Drape so the tool sterile adapter is over the carriage and the cannula sterile adapter is over the cannula latch.
5. Grasp the hand plates on either side of the opening at the end of the Arm Sterile Drape.
6. Use the hand plates to extend the Arm Sterile Drape over the Surgical Arm.
7. Carefully extend the rest of Arm Sterile Drape along the setup arm.
8. Press the tool sterile adapter onto the carriage until it snaps in place.

   Hook the top of the tool sterile adapter on the carriage and then press the tool sterile adapter into place.

   The carriage discs rotate when the tool sterile adapter is properly connected.
9. Press the cannula sterile adapter firmly and fully into the cannula mount.
10. Secure the excess drape to the stage using the polyties and to the arm joints using cinch tape.

6.4.4 Deploy the Surgical Arms to the Preparation Position

The preparation position moves the Surgical Arms away from the Integrated Table to make it easier to access the patient. Although you can put the Surgical Arms in the preparation position using many different methods, the recommended method is to move the Surgical Arms with the Table Remote.

To move the Surgical Arms to the preparation position with the Table Remote:

NOTE: The Deploy Arms screen shows progress toward deployment, but it does not represent a real-time estimate of the time remaining in the process.

1. Press the power button on the Table Remote to turn on the Table Remote.
   The Home screen is shown.
2. Select Arms.
   The Select Position screen is shown.
3. Select Preparation.
   The Select Arms screen is shown.
4. Select the Surgical Arms you want to move.
   As you select the Surgical Arms on the Select Arms screen, the LEDs on the selected Surgical Arms turn solid teal.
5. Select Next.
   The Deploy Arms screen is shown.
6. Press and hold the green UP button to move the Surgical Arms into the preparation position.

   Monitor the area around the Integrated Table as the Surgical Arms deploy to the position for potential collision with the surgical staff or equipment. You can also use the green DOWN button to reverse the Surgical Arm movement.

   As the Surgical Arms move to the preparation position, the LEDs on the Surgical Arms pulse white. When preparation position is reached, the LEDs on the Surgical Arms turn solid white.

   At this point in the procedure, it is recommended to drape the patient.

6.4.5 Connect Auxiliary Equipment

1. Maintain sterility and hand off the MEGEN1 connectors on the energy cables to the non-sterile circulating nurse.
2. Set aside the energy cables for later connection to the Energy Instruments.
3. Connect the energy cables to the MEGEN1 ESU.
4. Set the ESU energy settings for the procedure.
5. Maintain sterility and hand off the insufflator tubing to the non-sterile circulating nurse.
6. Set aside the insufflation tubing for later connection to the indufflation port on the Universal Seal.
7. Connect the insufflation tubing to the insufflator.
8. Set the insufflator pressure for the procedure.

6.5 Prepare the Patient for the Procedure

1. Place the Cannulas and Insufflate (page 6-8).
2. Transpose the Tabletop to Align the Patient with the Table Column.
3. Move the Tabletop to Orient the Patient for the Procedure (page 6-9).
4. Place Laparoscopic Accessories (page 6-9).

6.5.1 Place the Cannulas and Insufflate

Review the Port Placement Guide on the Tower touchscreen. See Procedure Guides (page 4-2).

WARNING:

- An inadequate incision may cause increased resistance to insertion, increase the required penetration force, and possibly result in a loss of control during entry.
- Although the Trocar has a blunt tip, use care to avoid damage to major vessels and other anatomic structures such as bowel or mesentery. To minimize the risk of such injury:
  - Establish adequate pneumoperitoneum
  - Properly position the patient to help displace organs out of the area of penetration
  - Note important anatomical landmarks
  - Direct the Trocar tip away from major vessels and structures
  - Do not use excessive force

To place the Trocars and insufflate:

1. Use a standard surgical procedure to create an incision for Trocar insertion.
2. Insert the Trocar through the incision. Apply light, continuous, and controlled downward pressure on the Trocar with 30° to 90° rotation.
3. When the Trocar is in the abdominal cavity, remove the Obturator from the Trocar and leave the Cannula with the installed Universal Seal in place.
4. Adjust the depth of the Cannula so the RCM is centered in the abdominal wall.
5. Attach an insufflation line to the Universal Seal insufflation port and open the stopcock valve.

   The stopcock valve is open when the stopcock lever is inline with the stopcock valve.
6. Insert the Endoscope through the Cannula with installed Universal Seal.
7. Survey the patient's internal anatomy and plan the placement of additional Trocars as needed for the procedure.

8. Repeat these steps to place additional Trocars.

6.5.2 Move the Tabletop to Orient the Patient for the Procedure

Use the Table Remote to move the tabletop to orient the patient for the procedure. See Integrated Table Adjustments with the Table Remote.

6.5.3 Place Laparoscopic Accessories

Place laparoscopic accessories, as needed.

6.6 Set Up the System for the Procedure

1. Deploy the Surgical Arms to the Procedure Position (page 6-9).
2. Dock the Surgical Arms to the Cannulas (page 6-10).
3. Attach and Insert the Endoscope (page 6-10).
4. Attach and Insert the Instruments (page 6-11).
5. Sign in to the System (page 6-11).
6. Customize Ergonomic Settings.
7. Apply Ergonomic Settings
8. Confirm Hand Assignment (page 6-12).
9. Adjust Physician Console Ergonomic Settings (page 6-12).

6.6.1 Deploy the Surgical Arms to the Procedure Position

The procedure position moves the Surgical Arms closer to the patient's body for docking to the Cannulas. Although you can put the Surgical Arms in the procedure position using many different methods, the recommended method is to move the Surgical Arms with the Table Remote and then use the manual touchpoints on each Surgical Arm to fine tune the position.

To move the Surgical Arms into the procedure position with the Table Remote:

NOTE: The Deploy Arms screen shows progress toward deployment, but it does not represent a real-time estimate of the time remaining in the process.

1. Press the power button on the Table Remote to turn on the Table Remote.
   The Home screen is shown.
2. Select Arms.
   The Select Position screen is shown.
3. Select Procedure.
   The Select Arms screen is shown.
4. Select the Surgical Arms you want to move.
   As you select the Surgical Arms on the Select Arms screen, the LEDs on the selected Surgical Arms turn solid teal.
5. Select Next.
   The Deploy Arms screen is shown.

6. Press and hold the Surgical Arms UP (green) button to move the Surgical Arms into the Procedure position.

   Monitor the area around the Integrated Table as the Surgical Arms deploy to the position for potential collision with the surgical staff or equipment. You can also use the green DOWN button to reverse the Surgical Arm movement.

   As the Surgical Arms move to the Procedure position, the LEDs on the Surgical Arms pulse white. When Procedure position is reached, the LEDs on the Surgical Arms turn solid white.

6.6.2 Dock the Surgical Arms to the Cannulas

With the Surgical Arms in the procedure position, dock the Surgical Arms to the Cannulas. To effectively dock the Surgical Arms, use the port clutch to manually move the Surgical Arm to the Cannula. To add control while you move the Surgical Arm, use both hands—one on the operative arm and the other on the setup arm.

CAUTION: Do not excessively manipulate the Cannula as you dock the Surgical Arm to prevent patient injury at the incision site and to maintain correct placement of the Cannula.

To dock a Surgical Arm to a Cannula:

1. Fully retract the release lever on the Cannula latch.
2. Activate the port clutch mode.
3. Dock the Surgical Arm to the Cannula.
   a) Seat the opening of the Cannula mount firmly over the Cannula fin until you hear and feel the Cannula latch click.

      The guide on the Tower touchscreen shows when the Surgical Arm successfully docks to the Cannula and the carriage fully retracts.
   b) If the cannula latch has not fully engaged, reseat the opening of the Cannula latch over the Cannula fin.

      Manually pull the Cannula latch forward to engage the Cannula fin.
   c) To make sure that the Surgical Arm is successfully docked to the Cannula, test for RCM activation and brake engagement on the Surgical Arm.
   d) Release the port clutch buttons to deactivate port clutch mode.
4. Repeat the previous steps to dock the other Surgical Arms.
5. Once all Surgical Arms are docked, adjust the arm boards as necessary for patient comfort.

   Limit adduction of the arm plates to 45° to prevent collisions with the Surgical Arms when they are deployed.

6.6.3 Attach and Insert the Endoscope

Attach the Endoscope to a Surgical Arm and insert the Endoscope through the Cannula into the body cavity before you attach the Instruments to the other Surgical Arms. The live Endoscope feed provides visualization for Instrument insertion.

CAUTION: Use care while you advance the tip of the Endoscope through the Cannula to avoid damage to the Endoscope, compromise of the sterile field with a tear in the Arm Sterile Drape, or injury to the patient.

To attach and insert the Endoscope:

1. Route the Endoscope cable to prevent a trip hazard and damage from Surgical Arm movement.
2. Guide the Endoscope tip through the Universal Seal and into the Cannula.
3. Slide the back of the Endoscope flush onto the carriage.

   The tool drive adapter latches click when attachment is complete and the gears on the tool driver turn during Endoscope homing and the guide on the Tower touchscreen confirms correct attachment.
4. Press the tool clutch buttons to activate tool clutch mode.

5. Carefully advance the Endoscope tip through the Cannula until the camera fully clears the Cannula opening.

   Confirm visualization of the body cavity on the Tower touchscreen.
6. Visualize the Cannula and confirm nominal placement of the RCM.

6.6.4 Attach and Insert the Instruments

It is recommended to insert the Instruments under visualization.

WARNING:

- When you attach or advance an Instrument, use care to avoid a puncture of the Arm Sterile Drape with the Instrument tip.
- Confirm visualization of the Instrument to prevent instrument collisions or tissue damage upon entry into the body cavity.

1. Identify the Surgical Arm for Instrument attachment.
2. As needed, close the Instrument jaws or straighten the wrist.
3. Guide the Instrument tip through the Universal Seal and into the Cannula.
4. Slide the back of the Instrument flush onto the carriage.

   The tool drive adapter latches click when attachment is complete and the tool driver discs turn during Instrument homing and the guide on the Tower touchscreen confirms correct attachment.
5. Verify the Instrument and Surgical Arm information on the Tower touchscreen.
6. Visualize the Cannula and confirm the placement of the RCM.

   If necessary, press and hold the port clutch buttons to adjust the RCM position.
7. Press the tool clutch buttons to activate tool clutch mode.
8. Use visualization from the live Endoscope view on the Tower touchscreen to carefully advance the Instrument tip through the Cannula until the Instrument is in the target workspace.
9. For an Energy Instrument, connect the energy cable to the Instrument.
10. Route the energy cable to prevent a trip hazard and damage from Surgical Arm movement.
11. Repeat these steps for each Instrument.

6.6.5 Insert the Instruments Through the Cannulas

1. Verify the Instrument and Surgical Arm information on the Tower touchscreen.
2. Visualize the Cannula and confirm nominal placement of the RCM.
3. Press the tool clutch buttons to activate tool clutch mode.
4. Use visualization from the live Endoscope view on the Tower touchscreen to carefully advance the Instrument tip through the Cannula until the Instrument is in the target workspace.
5. For Energy Instruments, connect the energy cable to the Instrument.
6. Route the energy cable to prevent a trip hazard and damage from Surgical Arm movement.
7. Repeat these steps for each Instrument.

6.6.6 Sign in to the System

To sign in to the System:

1. On the Physician Console touchscreen, enter your username.
2. Enter your passphrase.

3. Select Login .

   When sign in is successful, a green checkmark is shown on the Physician Console touchscreen and a confirmation tone is played.

   When sign in fails, a message is shown on the Physician Console touchscreen indicating that incorrect credentials were used and an error tone is played. Attempt to sign in again. After ten failed attempts your account is locked for 30 minutes. Contact your administrator to confirm your credentials.

6.6.7 Restore Settings from the User Profile

1. Restore the Physician Console ergonomic settings from your user profile.
2. The Endoscope image settings are automatically applied.

6.6.8 Confirm Hand Assignment

You can confirm hand assignment in different ways. Hand assignment confirmation is part of the workflow when you attach the Endoscope or Instruments to the Surgical Arm. You can also select Hand Assignment on the Procedure screen (page 4-9).

1. On the Physician Console touchscreen, select Hand Assignment.
2. Confirm or adjust hand assignments, as necessary.
3. Select Done to return to the previous screen.

6.6.9 Adjust Physician Console Ergonomic Settings

1. Adjust the ergonomic settings for the viewer.
2. Adjust the ergonomic settings for the armrest.
3. Adjust the ergonomic settings for the footboard.

7 Perform a Procedure

7.1 Drive from the Physician Console

To drive the System from the Physician Console during a procedure:

- Place your head in the viewer and match grips
- Control the Endoscope (page 7-1)
- Use the Instruments (page 7-2)
  - Energy Instruments
  - Non-Energy Instruments
  - Cadiere Forceps and High Force Grasper
  - Needle Driver + Cutting
- Locate off-screen Instruments
- Use the swap pedal to switch the active Instrument
- Adjust the hand controls with the finger clutch or foot clutch

7.1.1 Place Your Head in the Viewer and Match Grips

To insert your head in the viewer:

1. Lean forward toward the viewer.
2. Place your forehead against the headrest and look through the left and right lenses.

   The Match Grips (page 4-36)status indicator is shown above the Tool Set.

With your head in the viewer, look at the Tool Set to identify which Instruments are ready to match grips. An

To match grips:

3. Grasp the left- and right-hand controls and insert your fingers into the finger loops.

   Tighten the finger loops if desired.
4. Partially open or close the left- and right-hand controls at the same time and match the grip angle of the Instruments.

   When grips are matched, a sound is played, the Match Grips status indicators are removed, and the Tool Set is updated.

7.1.2 Control the Endoscope

To control of the Endoscope:

1. Press and hold the camera pedal.

2. While you press the camera pedal, move both hand controls together to move the Endoscope.

   Table 7-1. Hand control movement for Endoscope movement

Direction	Hand control motion
Zoom in	Move the hand controls away from you.
Zoom out	Move the hand controls toward you.
Move left	Move the hand controls to the left.
Move right	Move the hand controls to the right.
Rotate the Endoscope horizon	Rotate the hand controls left or right like a steering wheel.

   Hand control movement translates to the Endoscope:

3. While you press the camera pedal, move both hand controls together to move the Endoscope.
   - Zoom in - move the hand controls away from you.
   - Zoom out - move the hand controls toward you.
   - Move left - move the hand controls to the left.
   - Move right - move the hand controls to the right.
   - Rotate the Endoscope horizon - rotate the hand control left or right like a steering wheel.
4. Release the camera pedal to stop Endoscope control.

7.1.3 Activate Instrument Functions

Activate Instrument functions with the left- and right-Instrument mode pedal pairs on the footboard. The Instrument mode pedal pairs on the left control the functionality of the Instrument controlled by the left-hand control. Likewise, the Instrument mode pedal pairs on the right control the functionality of the Instrument controlled by the right-hand control.

Sensors below the Instrument mode pedal pairs detect the presence of a foot. Before you activate an Instrument mode pedal, hover over the food pedal pairs. The Instrument mode pedal pair being hovered over is show highlighted in light gray in the Tool Set. If the wrong pedal pair is being hovered over, hover your foot over the other Instrument mode pedal pair. Once you see in the active zone that your foot is over the desired pedal pair, press and hold the foot pedal to apply the Instrument mode.

Each Instrument mode pedal pair has a primary and secondary pedal. The primary pedal is blue and controls the primary function of the Instrument. The secondary pedal is yellow and controls the primary function of the Instrument. For example, for a Monopolar Instrument, the primary pedal delivers coag energy and the secondary pedal delivers cut energy.

To use the Instruments during a procedure, you must understand the controls used for the different Instrument types:

- monopolar and bipolar instrument pedalsEnergy Instruments
- Non-Energy Instruments
- Cadiere Forceps and High Force Grasper
- Needle Driver + Cutting

7.1.4 Locate Off-Screen Instruments

An Instrument located beyond the field of view is identified by a bar with the Surgical Arm number on the perimeter of the Endoscope View. When hand assignment is confirmed, the bar is teal. When hand assignment is not confirmed, the bar is gray.

To locate an Instrument outside the Endoscope View, do one of the following:

- Press and hold the camera pedal and move the Endoscope toward the off-screen Instrument indicator.
- Move the Instrument into the field of view.

7.1.5 Reposition the Hand Controls

To reposition the hand controls without Instrument movement, use the finger clutch (page 7-3) or clutch pedal (page 7-3).

7.1.5.1 Use the Finger Clutch

Retract and keep the finger clutch of a hand control retracted to reposition the hand control without moving the instrument that the hand control is controlling. Release the finger clutch and match grips to take control of the instrument controlled by that hand control again.

7.1.5.2 Use the Foot Clutch

Press and hold the clutch pedal to reposition both hand controls at the same time without moving the instruments assigned to those hand controls. Release clutch pedal and match grips of instruments to regain control of the tools.

7.1.6 Use the Swap Pedal to Switch Instruments

Press the swap pedal to take control of the Instrument that is not actively controlled by a hand control. When you press the swap pedal the Instrument names in the active zone change. The Instrument that was not actively controlled by the hand controls is shown in the active zone. Match grips with that Instrument to take control of that Instrument.

7.2 Intra-operative Settings at the Physician Console

You can modify settings from the Physician Console during teleoperation:

- Confirm or modify Instrument-Arm assignments.
- Turn ON and OFF the Endoscope light from the Physician Console.
- Modify the Endoscope image settings.
- Enable 2D visualization.
- Enable 3D visualization.
- Modify image utilities—Adjust Image and Color Bars .
- Modify audio settings— Physician Console volume and Tower volume .
- Modify Instrument motion scaling.

7.3 Intra-operative Tools and Accessories Handling

To handle Tools and Accessories during teleoperation:

- Insert an Instrument under direct visualization.
- Insert an Instrument with Guided Instrument Exchange Enabled.
- Replace a Universal Seal.

- Clean an Instrument.
- Clean a Cannula.
- Clean the Endoscope.
- Turn ON and OFF the Endoscope light from the Endoscope.
- Move the Surgical Arms with the Tool Clutch or Port Clutch.

7.3.1 Instrument Exchange

Use two-way communication when you exchange an instrument. Below is an example of two-way communication:

- Surgeon: "Remove the Monopolar Curved Scissors from Arm 1."
- Bedside Assist: "Removing the Monopolar Curved Scissors from Arm 1."
- Bedside Assist: "The Monopolar Curved Scissors has been removed from Arm 1."

To remove an Instrument from a Surgical Arm:

1. Press and hold the release buttons on the Instrument handle.
2. Pull the Instrument handle away from the tool driver.
3. Withdraw the Instrument from the Cannula.
4. Insert the next Instrument.

7.3.2 Guided Instrument Exchange

Install desired instrument on Arm where an instrument was removed. Once the system has recognized the instrument as the name is shown on the user interface, advance the tool into the endoscope view watching the instrument come into the field of view.

7.3.3 Clean and Defog the Endoscope

The light source in the optical tip of the Endoscope generates heat during use, which can reduce the amount of fogging on the camera lens that may naturally occur during a procedure. However, if the Endoscope live feed becomes fogged or impaired by bodily fluids, the tip must be cleaned before you continue the procedure.

WARNING: Do not continue a procedure without proper visualization of the Instruments or target anatomy to avoid serious patient injury.

To clean or defog the endoscope during a procedure:

1. The physician communicates with table-side team to remove and clean or defog the Endoscope.
2. The table-side staff confirms request to remove the Endoscope by repeating the instructions back to the surgeon.
3. Press and hold the tool clutch on the Surgical Arm to activate the instrument clutch mode and pause teleoperation.
4. Move the tool driver back to retract the Endoscope from the Cannula.
5. Release the tool clutch on the Surgical Arm to exit tool clutch mode.
6. Remove the endoscope by pressing and holding the release buttons on the tool drive adapter and sliding the endoscope off the arm.
7. Use sterile, nontoxic agents and supplies to gently wipe any debris from the Endoscope tip.
8. Reattach the Endoscope to the Surgical Arm.

   If the guided instrument exchange mode is active, the Endoscope will automatically advance to its original position. Otherwise, press the tool clutch buttons to activate the instrument clutch mode and advance the Endoscope tip through the Cannula shaft.

9. The table-side staff announces when the Endoscope is reattached and reinserted.
10. The physician confirms visualization of all Instrument, reengages the hand controls, and continues the procedure.

7.4 Intra-operative Instrument Exchange

During a procedure, an Instrument attached to a Surgical Arm may need to be exchanged with Instrument. Remove an Instrument during a procedure very carefully and with clear two-way communication between the physician and the surgical staff throughout the exchange.

CAUTION:

- Other Surgical Arms may be active while you are exchange an Instrument on another Surgical Arm. To prevent injury or equipment damage, avoid bumping or being bumped by the Surgical Arms or other attached Instruments.
- Even though the guided tool exchange feature will return the tip of a tool to its previous position, the System has no way to detect any obstacles that may have entered the path of the Instrument during the exchange. Visualize the Instrument tip as it enters the body cavity.

To exchange an Instrument during a procedure:

1. Physician requests which Instrument needs to be removed using the name of the Instrument and the Surgical Arm number.
   For example, "Remove the monopolar curved scissors from Arm 3".
2. Confirm the Instrument to remove; repeat the instruction back to the physician.
3. Make sure the Instrument is not grasping tissue.
4. If needed, ask the physician to place the Instrument in view and move the end-effector away from tissue with the hand controls.
5. Press and hold the tool clutch buttons on the Surgical Arm to activate tool clutch mode and pause teleoperation.
6. Withdraw the tool driver to retract the Instrument from the Cannula opening.
7. Release the tool clutch buttons to exit tool clutch mode.
8. To remove the Instrument from the tool drive adapter, press and hold the release buttons on the Instrument housing and lift the Instrument off the tool driver.
9. Set the Instrument aside.

   Make sure to maintain sterility if the Instrument will be used again during the procedure.
10. Retrieve the new Instrument and attach it to the available Surgical Arm.
11. Confirm or modify the hand assignment from the Physician Console touchscreen.
12. The physician confirms visualization of all Instruments, reengages the hand controls, and continues the procedure.

7.5 Intraoperative Coordinated Table Motion

Intraoperative Table motion allows for the operating room bed to be repositioned once at least one Surgical Arm is docked to a Cannula. If Instruments are installed on the Surgical Arms, they must be actively controlled at the Surgeon Console during the intraoperative Table motion. You can make the following interoperative Table adjustments:

- Trendelenberg and Reverse Trendelenberg
- Raise and lower height
- Tilt

To adjust the table intraoperatively, press the desired Table position button on the Table Remote and follow the prompts remote touchscreen. Adjustments to Trendelenberg, reverse Trendelenberg, and Tilt are shown above the Tool Set while the Table movement is ongoing.

7.6 Intra-operative Surgical Arm Adjustment

Use the patient clearance button to adjust the "no go zone" of the instruments and resolve Arm interferences intraoperatively. The direction of the sphere indicates where instruments can't reach. Press and hold the patient clearance button to move the Arm joints in the direction of the arrow. The remote center of the Arm will not move.

8 Finish a Procedure

1. Sign out of the System (page 8-1).
2. Unload and Remove the Tools (page 8-1).
3. Undock the Surgical Arms (page 8-2).
4. Remove the Cannulas and Close the Incisions (page 8-2).
5. Prepare the Patient for Transfer (page 8-2).
6. Stow the Gurney-Side Surgical Arms (page 8-2).
7. Transfer the Patient to the Gurney.
8. Prepare for Surgical Arm Disinfection (page 8-3).
9. Apply the Arm Stowage Covers to the Surgical Arms (page 8-3).
10. Stow the Surgical Arms (page 8-4).
11. Prepare the Tools for Cleaning and Sterilization (page 8-5).
12. Prepare the OR for the Next Procedure (page 8-5).
13. Stow the Surgeon Console (page 8-5).
14. Stow the Tower (page 8-5).

8.1 Sign out of the System

Work in progress

8.2 Unload and Remove the Tools

1. Disconnect the energy cables from the Instruments.
2. Dispose of single-use monopolar cables according to hospital procedure.
3. Wipe down the monopolar cables and set aside for cleaning and sterilization prep.
4. Make sure the Instrument end effector free of tissue.
5. Press the release buttons on the sides of the Instrument and withdraw the Instrument from the Cannula and away from the tool sterile adapter.
6. Set the Instruments aside for cleaning and sterilization prep.
7. Press the release buttons on the side of the Endoscope and withdraw the Endoscope from the Cannula and away from the tool sterile adapter.
8. Disconnect the Endoscope cable connectors from the Tower.
9. Set the Endoscope aside for cleaning and sterilization prep.

8.3 Undock the Surgical Arms

After you detach all tools from the Surgical Arms, undock all Surgical Arms from the Cannulas, and detach the insufflation line.

1. Press the port clutch buttons once to activate arm clutch mode.
2. Pull back the Cannula latch and carefully move the Surgical Arm away from the Cannula fin.

   Minimize any movement of the Cannula with installed Universal Seal.
3. Move the Surgical Arm away from the Cannula site and into a position to provide enough room to undock any other Surgical Arms.
4. Press the port clutch buttons once to deactivate arm clutch mode.
5. Repeat the previous steps to undock the other Surgical Arms.
6. Once all Surgical Arms are undocked, use the Table Remote to level the table.
7. Stop insufflation and open the Universal Seal insufflation port to rapidly deflate the abdominal cavity.
8. Detatch the insufflation line from the Universal Seal.

8.4 Remove the Cannulas and Close the Incisions

1. Remove the Cannulas from the patient.
2. Dispose of the single-use Universal Seals according to hospital procedure.
3. Set the Cannulas aside for cleaning and sterilization prep.
4. Remove the specimen and close the incisions.
5. Clean and dress the surgical site.
6. Undrape the patient.

8.5 Prepare the Patient for Transfer

1. Extubate the patient.
2. Remove tubing and lines from the patient.
3. Remove the arm boards, footplates, and other Integrated Table accessories as applicable.

8.6 Stow the Gurney-Side Surgical Arms

1. Press the power button on the Table Remote to turn it on.

   The Home screen is shown.
2. Select Arms.

   The Select Position screen is shown.

3. Select Stow.

   The Select Arms screen is shown.
4. Select the Surgical Arms you want to stow.

   As you select the Surgical Arms on the Select Arms screen, the LEDs on the selected Surgical Arms are solid teal.
5. Select Next.

   The Deploy Arms screen is shown.
6. Press and hold the Surgical Arms UP button to move the Surgical Arms into the Stow position.

   Monitor the area around the Integrated Table as the Surgical Arms deploy to the Stow position for potential collision with the surgical staff or equipment. As the Surgical Arms move to the Stow position, the LEDs on the Surgical Arms pulse teal. When Stow position is reached, the LEDs on the Surgical Arms are solid green.

   NOTE: The Deploy Arms screen shows progress toward deployment, but it does not represent a real-time estimate of the time remaining in the process.
7. Apply a Stow Cover to the stowed Surgical Arms.

8.7 Prepare for Surgical Arm Disinfection

1. Press the power button on the Table Remote to turn it on.
   The Home screen is shown.
2. Select Arms.
   The Select Position screen is shown.
3. Select Drape.
   The Select Arms screen is shown.
4. Select the gurney-side Surgical Arms.
   As you select the Surgical Arms on the Select Arms screen, the LEDs on the selected Surgical Arms are solid teal.
5. Select Next.
   The Deploy Arms screen is shown.
6. Press and hold the Surgical Arms UP (green) button to move the Surgical Arms into the Drape position.

   Monitor the area around the Integrated Table as the Surgical Arms deploy to the Drape position for potential collision with the surgical staff or equipment.

   As the Surgical Arms move to the Drape position, the LEDs on the Surgical Arms pulse white. When Drape position is reached, the LEDs on the Surgical Arms are solid white.

   NOTE: The Deploy Arms screen shows progress toward deployment, but it does not represent a real-time estimate of the time remaining in the process.
7. Remove the Arm Stowage Covers from the gurney-side Surgical Arms.
8. Remove the Arm Sterile Drapes from the non-gurney-side Surgical Arms.
9. Disinfect the Surgical Arms. See Cleaning, Storage, Maintenance, and Disposal (page 11-1).

8.8 Apply the Arm Stowage Covers to the Surgical Arms

Apply the Arm Stowage Covers to the Surgical Arms for protection from fluid and debris when the Surgical Arms are stowed during patient transfer to and from the Integrated Table, and when the System is not in use.

CAUTION: When extending the Arm Stowage Cover along a Surgical Arm, make sure the Arm Stowage Cover does not snag or tear on any part of the Surgical Arm.

1. Make sure each Surgical Arm is on plane.

   The Surgical Arms must be on plane before you can use the Table Remote to deploy the Surgical Arms to a predetermined position.
2. Press the power button on the Table Remote to turn it on.

   The Home screen is shown.
3. Select Arms.

   The Select Position screen is shown.
4. Select Drape.

   The Select Arms screen is shown.
5. Select the Surgical Arms you want to drape.

   As you select the Surgical Arms on the Select Arms screen, the LEDs on the selected Surgical Arms are solid teal.
6. Select Next.

   The Deploy Arms screen is shown.
7. Press and hold the Surgical Arms UP (green) button to move the Surgical Arms into the Drape position.

   Monitor the area around the Integrated Table as the Surgical Arms deploy to the Drape position for potential collision with the surgical staff or equipment.

   As the Surgical Arms move to the Drape position, the LEDs on the Surgical Arms pulse white. When Drape position is reached, the LEDs on the Surgical Arms are solid white.

   NOTE: The Deploy Arms screen shows progress toward deployment, but it does not represent a real-time estimate of the time remaining in the process.
8. Retrieve Arm Stowage Covers.
9. Place the Arm Stowage Covers on the Surgical Arms. .
10. Orient the open end of the Arm Stowage Cover over the tool driver.
11. Carefully extend the Arm Stowage Cover along the Operative Arm.
12. Carefully extend the rest of Arm Stowage Cover along the Setup Arm and down to the Table-Arm connection.
13. Connect the metal disk near the opening of the Arm Stowage Cover to the magnet in the Table-Arm connection.

8.9 Stow the Surgical Arms

1. Press the power button on the Table Remote to turn it on.
   The Home screen is shown.
2. Select Arms.
   The Select Position screen is shown.
3. Select Stow.
   The Select Arms screen is shown.
4. Select the Surgical Arms you want to stow.
   As you select the Surgical Arms on the Select Arms screen, the LEDs on the selected Surgical Arms are solid teal.
5. Select Next.
   The Deploy Arms screen is shown.

6. Press and hold the Surgical Arms UP (green) button to move the Surgical Arms into the Stow position.

   Monitor the area around the Integrated Table as the Surgical Arms deploy to the Stow position for potential collision with the surgical staff or equipment.

   As the Surgical Arms move to the Drape position, the LEDs on the Surgical Arms pulse white. When Drape position is reached, the LEDs on the Surgical Arms are solid white.

   NOTE: The Deploy Arms screen shows progress toward deployment, but it does not represent a real-time estimate of the time remaining in the process.

8.10 Prepare the Tools for Cleaning and Sterilization

See the ETHICON™ Instruments and Accessories User Manual for OR cleaning and sterilization preparation instructions.

8.11 Prepare the OR for the Next Procedure

Disinfect the Tower, Table, Physician Console. See Cleaning (page 11-1).

8.12 Stow the Surgeon Console

1. Use the Stow button to lower the viewer and arm rest.
2. Power off the Surgeon Console.
3. Disconnect the power cable from the wall outlet and Surgeon Console.
4. Disconnect the data cable from the Tower and Physician Console.
5. Loosely coil the power cable and data cable.
6. Store the cables on the cable hooks.

8.13 Stow the Tower

1. Fully retract the Tower touchscreen display.
2. Power off the Tower.
3. Disconnect the power cables from the wall outlets and Tower.
4. Disconnect the data cables from the Tower, Integrated Table, and Physician Console.
5. Loosely coil the power cables and data cables.
6. Store the cables on the cable hooks.

9 Immediate Access and Troubleshooting

9.1 Emergency Patient Access

9.1.1 A Non-Faulted Nominal System

1. Unplug the energy cables from Energy Instruments.
2. Unload and remove the Tools (page 8-1).
3. Undock the Surgical Arms (page 8-2).
4. Move the Surgical Arms away from the patient and the Table.
5. Press and hold the pivot buttons on a Surgical Arm to reposition the Table-Arm connection.
6. If necessary, use the Table Remote to level the Integrated Table.

9.1.2 A Faulted Surgical Arm

1. Unplug the energy cables from Energy Instruments.
2. Unload and remove the Tools (page 8-1).
3. Undock the Surgical Arms (page 8-2).
4. Press and hold the arm clutch button on a faulted Surgical Arm to reposition all joints that are not faulted.
5. Press and hold the pivot buttons on a faulted Surgical Arm to reposition the Table-Arm connection.
6. If necessary, use the Table Remote to level the Integrated Table.

9.1.3 Loss of Surgical Arm Power or Control

1. Unplug the energy cables from Energy Instruments.
2. Unload and remove the Tools (page 8-1).
3. Undock the Surgical Arms (page 8-2).
4. Use the Arm Brake Release (page 3-9) to release the J1 brake on the Surgical Arm and move the Surgical Arm away from the patient and the Table.
5. If necessary, use the Table Remote to level the Integrated Table.

9.2 User-Initiated System Pause

Use the System Pause button to temporarily pause all patient-side robotic-controlled motion to stop instrument energy delivery, and prevent new Instrument energy activation to avoid patient harm or prevent a Surgical Arm collision with other equipment or the surgical staff that may lead to equipment damage or surgical staff injury.

Manual Surgical Arm motion and Table motion is available while the System is paused for patient accessibility without the need to exit the System Pause.

A System Pause button is available on the Tower and Physician Console armrest.

Figure 9-1. System Pause buttons

Initiate System Pause

Press the System Pause button on the Tower or Physician Console to initiate a System Pause.

When a System Pause is initiated, a message is shown on the Tower touchscreen and the Physician Console touchscreen; the Surgical Arm LEDs and Physician Console LEDs pulse teal ; the System Pause button on the Tower and on Physician Console pulse white, and the limit reached sound is played.

Exit System Pause

Acknowledge the notification on the Tower touchscreen or the Console touchscreen to return to teleoperation after a user-initiated System Pause. The LEDs are solid white.

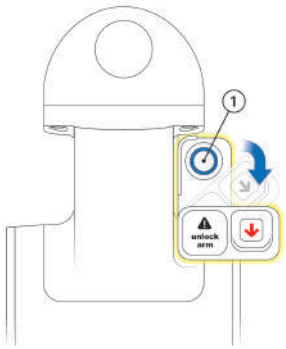
9.3 Use the Arm Brake Release

The Arm Brake Release button releases the J1 brake.

NOTE: Only use the Surgical Arm brake release in an emergency situation.

WARNING: Before you press the Arm Brake Release button, firmly support the entire Surgical Arm to prevent the Surgical Arm from falling and becoming damaged, and to avoid potential injury to the patient or surgical staff.

1. Firmly support the entire Surgical Arm.
2. Slide the Arm Brake Release door to the side.
3. Press the Arm Brake Release button.



a. Arm Brake Release button

4. Move the Surgical Arm away from the patient and Table.
5. Press the Arm Brake Release button again to lock the Surgical Arm in place.

9.4 Notification and Fault Recovery

9.4.1 Troubleshoot a Critical Fault

To troubleshoot a critical fault:

1. Identify fault notification on Tower Monitor, Physician Console Touchpad, or Physician Console Viewer.
   You may choose to hide the fault via the Tower Monitor or Physician Console.
2. Perform procedure conversion.
3. Perform an intra-operative System restart (page 9-4).

9.4.2 Troubleshoot a Persistent Fault

A major or minor fault has occurred. If the loss of functionality is acceptable, continue with the following steps.

1. Hide the notification from the Tower touchscreen or Physician Console touchscreen.
2. Do one of the following:
   a) Continue teleoperation with a faulted Surgical Arm and keep the Instrument in place.
   b) Remove the Instrument from the faulted Surgical Arm (page 8-1) and undock the Surgical Arm from the Cannula (page 8-2).
3. Press the arm clutch button and reposition the faulted Surgical Arm.

   If the degraded touchpoints are not available, use the Arm Brake Release button to move the faulted Surgical Arm away from the Table (page 9-3).

9.4.3 Troubleshoot a Recoverable Fault

To resolve a recoverable fault:

1. Review the fault notification on Tower touchscreen, Physician Console viewer, or Physician Console touchscreen.
2. Disengage from teleoperation.
3. Select the acknowledge button to resolve the fault.
4. Remove faulted Tool from the Surgical Arm.
5. Make sure the Surgical Arm is docked securely to the Cannula.
6. Press the port clutch to release external force on the abdominal wall from the Cannula.

9.4.4 Resolve an Informational Notification

1. Review the informational notification on Tower touchscreen, Physician Console viewer, or Physician Console touchscreen.
2. Perform the recommended steps shown in the notification.
3. Select the acknowledge button to resolve the fault.

9.5 Intraoperative System Restart

A System restart during a procedure may be required to recover System functionality.

To perform an intraoperative System restart:

1. Prepare for Intraoperative System Restart (page 9-4).
2. Turn Off the System (page 9-5).
3. Turn On the System (page 9-6).
4. Teleoperation Setup (page 9-6).

9.5.1 Prepare for Intraoperative System Restart

Before you perform an intraoperative System restart:

1. Remove all Instruments from the Surgical Arms.

   As needed, use the manual jaw slider on the handle to release tissue from the jaws.
2. Remove the Endoscope from the Surgical Arm.
3. Undock all Surgical Arms from the Cannulas.

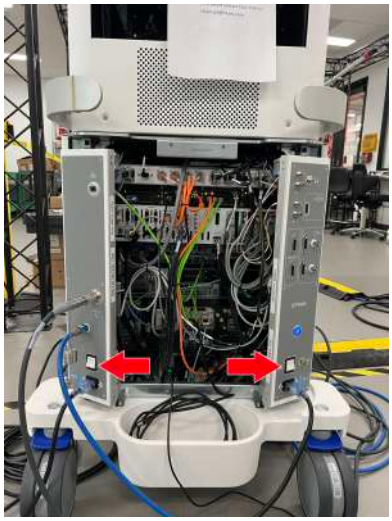
4. Move any faulted Surgical Arms so they are not over the Table.
   A faulted Surgical Arm has solid yellow LEDs.

9.5.2 Turn Off the System

To turn off the System:

1. Press the power button on either the Tower or the Physician Console for 5–10 seconds but no longer.

2. Acknowledge the shutdown message on the Tower touchscreen or the Console touchscreen.
3. On the Tower, turn off the left and right breaker switches.



4. Unplug the Integrated Table power cord from the wall outlet.
5. Make sure the Tower is off.
   The Tower touchscreen will show no image.

6. Turn off the Integrated Table with the Table Remote.

   NOTE: You can not turn off the Integrated Table when the Surgical Arms or Table are in motion or the Surgical Arms are clutched.

   a) On the Table Remote, press the power button.

      The Home screen is shown.

   b) Select Arms.
   c) Select Off.
   d) Select Power Off on the confirmation message.
7. Unplug the Physician Console power cord from the wall outlet.
8. Make sure the umbilical cable between the Tower and the Integrated Table is properly connected.
9. Make sure the umbilical cable between the Tower and the Physician Console is properly connected.

9.5.3 Turn On the System

To turn on the System:

1. Plug in the Physician Console power cord to an electrical outlet.
2. On the Tower, turn on the left and right breaker switches.
3. Press the power button on the Tower or Physician Console to turn on the Tower and Physician Console.
4. Plug in the Integrated Table power cord to the wall outlet.

   The Table starts up automatically.

   The System is ready for Teleoperation Setup (page 9-6).
5. If you hear a loud tone from the Tower as the System starts up, a fault is shown on the Tower touchscreen. Acknowledge the fault to continue.

   Once the power-on self-test is completed, the action successful sound is played.

9.5.4 Teleoperation Setup

Before you can resume teleoperation:

1. Make sure the markers on the hand controls are aligned.

If the markers are not aligned, this is an unrecoverable critical fault and you must restart the System or convert to open surgery.

2. Dock the Surgical Arms to the Cannulas.
3. Attach and insert the Endoscope.
4. Attach and insert the Instruments.
5. Sign in to the System.
6. Change or confirm hand assignment.
   The System is ready for teleoperation.

9.6 Instrument Manual Override

9.6.1 Release Tissue from a Faulted Instrument

The manual jaw slider manually opens the Instrument jaws when an Instrument is faulted, or when Physician Console control of the Instrument is not practical.

To release tissue from a faulted Instrument:

1. Press the System Pause button.
2. Move the manual jaw slider away from the proximal end of the Instrument to release tissue from the jaws.
3. Under visualization, clear the tissue from the jaws.
   If needed, adjust the Surgical Arm to position the Instrument away from tissue.
4. After the tissue is cleared from the jaws, press the release buttons on the Instrument handle and remove the Instrument from the Cannula.

9.7 Loss of Connection Between the Integrated Table and the Tower

When the Integrated Table loses connection to the Tower, teleoperation is not available but the Table and Surgical Arms are fully accessible with the table remote, secondary table controls, primary arm controls, secondary arm controls, and

9.8 Power Loss

In the event of Integrated Table power loss, teleoperation and Integrated Table functions are supported by battery power for a short period of time.

In the event of operating room power loss, teleoperation is not supported but the Integrated Table functions are supported by battery power for a short period of time.

10 System Shutdown

System shutdown is the responsibility of Auris Health as described. There are no user shutdown steps.

1. On the Tower single press the button.
2. On the Physician Console single press the button, locate the left side of the Armrest.

10.1 Tower Shutdown

1. Disconnect the AC Main Power Cord from the electrical power outlet.
2. Disconnect end of the AC Main Power Cord from the rear I/O panel of the Tower.
3. Mobilize the Tower by pressing all four Lock pedals located along the base of the Tower.

10.2 Integrated Table Shutdown

1. Disconnect Table Remote from the base of the Integrated Table.
2. Disconnect the electrical power outlet.
3. Disconnect the AC Power Cable to the Integrated Table.

10.3 Physician Console Shutdown

1. Disconnect both umbilical and AC cables from the Physician Console I/O panel.
2. Disconnect the end of the Physician Console's AC main power cord from the rightmost port on the I/O panel at the back and bottom of the Physician Console.
3. Disconnect the AC power.
4. Disconnect the end of the umbilical cable to the rear I/O panel of the Tower.
5. Mobilize Physician Console by pressing all four Lock pedals located along the base of the Physician Console.

11 Cleaning, Storage, Maintenance, and Disposal

11.1 Cleaning

Use a soft, lint-free cloth and a surface disinfectant, or a pre-moistened disinfectant wipe, to wipe down the exterior surfaces of the Physician Console, Tower, and cables according to your hospital's policy or protocol. Examples of these products include, a 70% isopropyl alcohol solution, 96% ethanol or the corresponding pre-moistened disinfectant wipe product. Allow equipment to dry before use. If any liquids—including bodily fluids—get inside the System, contact Customer Support and Service (page 12-1).

CAUTION: The Physician Console and Tower are not designed for exposure to liquids. Do not spray or pour liquids directly on the Physician Console or Tower while cleaning. Care should be taken to make sure liquids do not contact electronic equipment on the system components.

11.2 Preventative Maintenance

Preventative maintenance, if required, will be performed by an authorized representative.

When a device reaches the end of its useful life and your facility desires to remove the device, contact Customer Support (page 12-1) to uninstall and appropriately dispose of the components. For disposal of Instruments, Accessories, or any of their components, follow all applicable national and local laws and guidelines.

11.3 Backup Batteries

The System has lithium-ion UPS batteries that can hold a charge for up to 3 months. Unpowered storage of the System for an extended period of time—longer than 3 months—will result in degradation of the batteries. The batteries are not user-serviceable and can only be replaced by an authorized representative.

11.4 Disposal

When the System or a component of the System reaches the end of its usable life, contact Auris Health for disposal or dispose of the System or component of the System according to local regulations.

When a reusable Instrument or Accessory reaches the end of its usable life, contact Auris Health for disposal or dispose of the Instrument or Accessory according to local regulations.

Dispose of single-use Devices according to local regulations.

12 Customer Support and Service

Installation of this system is to be performed only by an authorized Auris Health representative. There are no user serviceable components. Unauthorized modifications of any Auris products may void any and all warranties. Auris Health does not assume any responsibility or liability with respect to unauthorized modification or substitution of subsystems or components.

For customer support or service, contact Customer Support +1.888.888.1000 or OttavaSupport@its.jnj.com.

13 Technical Specifications and Environmental Conditions

13.1 Expected Life

With proper care and maintenance, the expected service life of the System is 2 years.

13.2 Technical Specifications

13.2.1 Environmental Conditions: System

Table 13-1. Environmental Conditions: System

Specification	Use	Transportation	Storage
Temperature	10–24°C	-15–60°C	-15–60°C
Humidity	20–60%	15–85%	15–85%
Pressure	Up to 600 mmHg	Up to 600 mmHg	Up to 600 mmHg

13.2.2 Tower Specifications

Table 13-2. Tower Specifications

Specification	Value
Ingress protection	IPX0
Applied part	Instruments, Energy: Type CF
	Endoscope: Type CF

Table 13-3. Dimensions, Weight, and Power Requirements

Specification	Tower
Height, maximum with touchscreen fully raised	2238 mm
Width	727 mm

Specification	Tower
Depth	901 mm
Weight (maximum)	330 kg
Power Requirement	(1) 120 VAC 60 Hz, 1200 W
	(2) 120 VAC 60 Hz, 1200 W

13.2.3 Integrated Table Specifications

Table 13-4. Integrated Table Specifications

Specification	Value
Ingress protection rating - Table with Surgical Arms	With Surgical Arms stowed with Arm Stowage Covers installed: IPX4
	With Surgical Arms deployed with Arm Sterile Drape installed: IPX0
Applied part	Tabletop: Type B
	Instruments, Energy and Non-Energy: Type CF

Table 13-5. Dimensions, Weight, and Power Requirements

Specification	Integrated Table
Height	1220 mm
Width	760 mm
Length	2135 mm
Mass (maximum)	66o kg
Power Requirement	120 VAC 60 Hz, 1200 W

13.2.4 Physician Console Specifications

Table 13-6. Physician Console Specifications

Specification	Value
Ingress protection rating	Console: IPX0
	Footboard: IPX8
Applied part	Not applicable, no patient contact

Table 13-7. Dimensions, Weight, and Power Requirements

Specification	Physician Console
Height	1080 mm
Width	975 mm
Depth	875 mm

Specification	Physician Console
Weight (maximum)	234.5 kg
Power requirement	120 VAC, 60 Hz, 800 W

13.3 Compatible Tabletop Accessories

Compatible tabletop accessories connect to the tabletop. See the manufacturer's instructions for use and safety information.

NOTE:

- Use only compatible tabletop accessories.
- Make sure that the surface of the plate is level with the surface of the back-seat plate.

Table 13-8. Compatible Tabletop Accessories

Accessory	Reorder Number
Head plate	Getinge™ Head Plate
Extension plate	Getinge™ Extension Plate
Leg plate	Getinge™ Head Plate

13.4 Compatible Side Rail Accessories

Accessories can be attached to the Integrated Table side rails.

- Follow the accessory instructions for use.
- Do not use accessories that hang below the tabletop to minimize interference with Table or Surgical Arm movement.
- Do not over tighten the accessory mounting clamps.

Table 13-9. Side rail accessories requirements:

Description	Measurement
Mass	20 kg, total mass for all side rail accessories together
Rail size	Maximum width: 9.525 mm (0.375 in) Maximum height: 28.575 mm (1.125 in)

13.5 Transport Position

The Tower, Integrated Table, and Physician Console must be properly positioned before transportation:

- Tower - Retract the Tower Touchscreen and remove the insufflation tanks from the storage compartment.

- Integrated Table - Stow the Surgical Arms.
- Physician Console - Lower the viewer.

13.6 Essential Performance

Endoscope Live Image

The System displays a real-time image of the surgical site. If the displayed image is not live, such as when displaying a recorded image or in the event of system malfunction, it is apparent to the user that the displayed image is not a live image.

Endoscope Sufficient Illumination

Insufficient endoscopic illumination intensity, nonuniform light levels across the frequency spectrum, or other imperfections in image quality are readily apparent to the operating surgeon.

Instrument Control No Uncontrolled or Unexpected Motions

The Instrument tip, shaft, and Instrument Surgical Arm, move only in response to motions of the Hand Controls initiated by the operating surgeon or when under the control of a patient-side staff member, excluding effects of external loads. There should be no uncontrolled or unexpected motions of the Instrument tip that could lead to an unacceptable risk.

Instrument Control Motion Reflective of Inputs

The motions of the Instrument tip are approximately reflective of the surgeon-initiated motions of the Hand Control relative to the displayed image, when under the control of the operating surgeon and excluding the effects of external loads, unless otherwise indicated to the user.

Integrated Table Patient Support and No Uncommanded Motion

The Integrated Table supports the patient without uncommanded motion that could lead to an unacceptable risk.

13.7 Electromagnetic Compatibility

The System has been tested and found to be in compliance with IEC 60601-1-2; Edition 4.1, International standard for Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. The system is classified as an Industrial, Scientific, and Medical (ISM) device for use specifically in an operating room environment.

The essential performance of the system is unaffected when exposed to the electromagnetic environmental conditions as described in the IEC 60601-1-2 EMC standard. The system shows a real-time image of the surgical site with acceptable clinical performance. If the image shown is not live, such as when a recorded image is shown or in the event of system malfunction, it shall be obvious to the user that the displayed image is not a live image. There shall be no uncontrolled or unexpected motions of the Endoscope or Instrument tips. The operator can expect no degradation of functional performance and therefore no risks to the patient or other devices due to Electromagnetic Interference (EMI) when used within the electromagnetic environment as specified in Table 1 to 4 within the following sections.

WARNING: The use of Instruments, cables, or Accessories other than those specified or provided by Ethicon as replacement parts for the System could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Use of such components could result in improper operation or degraded performance and compromised EMC Compliance.

WARNING: Symptoms of interference could include repeated faults, unintentional movement of arms, loss of Instruments or Endoscope, frozen or loss of video. If the System does not properly function and interference from other equipment is suspected, discontinue use of the system, and contact Ethicon.

WARNING: The System should not be used adjacent to or stacked with other equipment as this could result in improper operation. If such a configuration is required, observe the System to verify normal operation.

WARNING: Portable RF communications equipment, including peripheral equipment such as antenna cables and external antennas, should be used no closer than 30 cm (12 inches) to any part of the System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

NOTE: The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If the System 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 to relocate or reorient the equipment.

NOTE: The wireless coexistence testing conducted does not cover use in the presence of MRI, electrocautery devices, or diathermy devices/machines.

13.8 FCC Compliance

This ISM equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to 47 CFR Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference to and from the equipment, when the equipment is operated in a commercial environment. This equipment requires "Hospital Grade" power receptacles and utilizes "Hospital Grade" power plugs to achieve reliable grounding. This equipment generates, uses, and can radiate radio frequency energy that may cause harmful interference to radio communications when not installed and used in accordance with the user manual.

13.9 Electromagnetic Emissions and Immunity Specifications

The System includes three subsystems: the Tower for central control, the Physician Console for control input, and the Integrated Table for patient bed and robotic Surgical Arms. All subsystem interfaces are provided through electrical and optical fiber cables. Software is also a component of the System.

The following tables list the electromagnetic emissions and immunity specifications for the System and the applicable standards to which these specifications comply.

The System is intended for use in the electromagnetic environment specified. The customer or user of the System should make sure it is used in such an environment.

Table 13-10. Electromagnetic Emissions

Emission Test	Compliance	Electromagnetic Environment
RF Emissions CISPR 11	Group 1[a]	Integrated Table and Physician Console use RF energy only for internal function. RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class A[c]	

Emission Test	Compliance	Electromagnetic Environment
	Group 2[b]	The Tower used with the ETHICON MEGADYNE ESU must emit electromagnetic energy in order to perform its intended function.
	Class A[c]	
RF Emissions CISPR 11	Group 1[a]	The System is suitable for use in all establishments other than domestic, and may be used connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **WARNING**: This equipment is intended for use by healthcare professionals only. This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as to reorient or relocate the System or shielding the location. **NOTE**: High-frequency (HF) surgical equipment shall meet the limits specified for group 1, class A equipment, in stand-by mode of operation. For high-frequency (HF) surgical equipment operating at frequencies outside designated ISM bands, these limits also apply at the operating frequency and inside the designated frequency bands. The related measurements shall be performed in a test arrangement in accordance with IEC 60601-2-2.
	Group 2[b]	
	Class A[c]	
Harmonic Emissions IEC 61000-3-2	Class A[c]	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	
a. Group 1 Equipment contains all ISM equipment in which there is intentionally generated or used conductivity-coupled radiofrequency (RF) energy that is necessary for the internal functioning of the equipment itself. b. Group 2 Equipment contains all ISM equipment in which radiofrequency (RF) energy, in the frequency range 9 kHz to 400 GHz, is intentionally generated and used or only used locally, in the form of electromagnetic radiation, inductive and/or capacitive coupling, for the treatment of material, for inspection/analysis purposes, or for transfer of electromagnetic energy. c. Class A equipment is ISM equipment suitable for use in all establishments other than domestic and those directly connected to a low-voltage power supply network which supplies buildings used for domestic purposes. ISM equipment is intended for use in an industrial, scientific, or medical environment.		

The System is intended for use in the electromagnetic environment specified. The customer or user of the System should make sure it is used in such an environment.

Table 13-11. Electromagnetic Immunity

Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	Contact discharge: ±2, 4, 8 kV Air discharge: ±2, 4, 8, 15 kV Class 4[d]	±8 kV Contact Discharges ±15 kV Air Discharges	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 AC Mains ± 1 kV I/O Lines 5/50 100 kHz Bursts PRF	± 2 kV AC Mains Lines ± 1 kV Input/output Lines	Mains power quality should be that of a typical commercial or hospital environment. Sharing Mains Power lines with large motors or noisy equipment must be avoided.
AC Power Surges IEC 61000-4-5	±.5, 1 kV Line to Line ± .5, 1, 2kV L & N to P.E. 1.2us rise / 50us decay 5 Bursts / 20 sec Delay 0, 90 and 270 Degrees	± 1 kV Differential Mode ± 2 kV Common Mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment
Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (4th Ed.) Class 4[e]	30 A/m	Power frequency magnetic fields should be at levels characteristic of atypical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% drop for 0.5 cycle at 8 Angles 0 100% drop for 1 period 30% dip in 25/30 periods 100% drop in 5 seconds	100% drop UT for 0.5 cycle at eight 45^0 Phase Angles 100% drop UT for 1 period 30% dip UT in 25/30 periods 100% drop UT in 5 seconds[f]	Mains power quality should be that of a typical commercial or hospital environment. The OTTAVA Tower and Integrated Table include an uninterruptible power supply.

d. Class 4 immunity environment with humidity as low as 10%, not antistatic and uses synthetic material.
e. Class 4 immunity environment is defined as a typical industrial environment. The environment is characterized by the following attributes:

- Short branch power lines as busbars, etc.
- High power electrical equipment that may give rise to leakage fluxes
- Ground conductors of protection system
- M.V. circuits and H.V. busbars at relative distance (a few tens of meters) from equipment concerned.

f. UT is the AC mains voltage before application of the test level. The OTTAVA Tower and Integrated Table provide emergency backup power to allow for a safety power down of the system during a loss of power condition. The available backup time is clearly displayed for the operator.

The System is intended for use in the electromagnetic environment specified. The customer or user of the System should make sure it is used in such an environment.

Table 13-12. Electromagnetic RF Immunity

Immunity Test	EN 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment
Radiated RF EM Fields IEC 61000-4-3	3 V/m for 80 MHz to 2.7 GHz at 1KHz modulation. Class 2[g]	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: $d = [\frac{3,5}{V_1}]\sqrt{P}$ 150 KHz to 80 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 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[h] should be less than the compliance level in each frequency range.[i] Interference may occur in the vicinity of equipment marked with the following symbol: Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than 12 in. (30 cm).
Proximity Fields from RF Wireless Communications Equipment IEC 61000-4-3	380 MHz to 6.0 GHz in V/m per 4th Edition levels	9 V/m to 28 V/m	
Conducted Disturbances Induced by RF Fields IEC 61000-4-6	6 V_{RMS} from 150 kHz to 80 MHz Class 2[g]	6 V_{RMS}	
Proximity Magnetic Fields tested per IEC 61000-4-39	30 kHz: CW Modulation	8 A/m	The magnetic field is applied to those surfaces of the enclosure or attached accessories that are accessible during intended use.
	134.2 kHz: Pulse Modulation 2.1 kHz	65 A/m	
	13.56 MHz: Pulse Modulation 50 kHz	7.5 A/m	

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.

g. Class 2 immunity environment with Low power portable transceivers (typically less than 1 W rating) are in use, but with restrictions on use in close proximity to the System.
h. 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-orienting or relocating the System.
i. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 6 V/m.

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 interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended, according to the maximum output power of the communications equipment.

Table 13-13. Recommended separation distances between portable and mobile RF communications equipment and the System

Radiated maximum output power of transmitter W	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
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 and 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.			

14 Symbols

These symbols may be found on the product or product package.

Symbol	Description	Reference
0°	Endoscope tip angle, 0 degree	Proprietary
	Instrument swap	Proprietary
	Audio in	ISO 60417: 6249
	Audio out	ISO 60417: 6250
	Cable hook	Proprietary
	Remote center of motion with depth guides	Proprietary
	Foot clutch	Proprietary
	Armrest ergonomic switch	Proprietary
	Stand-by	IEC 60417: 5009
	Footboard ergonomic switch	Proprietary

Symbol	Description	Reference
	Console ready	Proprietary
	Console stowed for transport	Proprietary
	Console casters, directional lock	Proprietary
	Console casters, total lock	Proprietary
	Console viewer, ergonomic control	Proprietary
	Do not intervene; do not operate	ISO 7000: 1627
S-Video	S-Video	Proprietary
	Eye swap	Proprietary
NON STERILE	Non-sterile	ISO 7000: 2609
	Do not reuse	ISO 7000: 1051
	Camera pedal	Proprietary
	Image flip	Proprietary
	Left primary instrument	Proprietary

Symbol	Description	Reference
	Right primary instrument	Proprietary
	Left secondary instrument	Proprietary
	Right secondary instrument	Proprietary
	Lamp; lighting; illumination	IEC 60417: 5012
12	12 mm diameter	Proprietary
8	8 mm diameter	Proprietary
	Equipotentiality	IEC 60417: 5021
	Pedal lock	Proprietary
	Warning; Crushing of hands	ISO 7010: W024
	Data transfer	Proprietary
	Power plug	IEC 60417: 5534
RAW	RAW video output	Proprietary
	Sterile drape installation direction	Proprietary

Symbol	Description	Reference
	Peel here	Proprietary
	Tower control panel data connection	Proprietary
	Headphone connector	Proprietary
	Endoscope ports; camera	Proprietary
	Tower stowing monitor label	Proprietary
UI	User interface output	Proprietary
	Video output	Proprietary
	Physician head in sensor	Proprietary
SN	Serial number	ISO 7000: 2498
	Manufacturer	ISO 7000: 3082
	Emergency stop	IEC 60417: 5638

Symbol	Description	Reference
	Refer to instruction manual	ISO 7010: M002
REF	Catalog number	ISO 7000: 2493
	Temperature limit	ISO 7000: 0632
	Use by date	ISO 7000: 2607
STERILE EO	Sterilized using ethylene oxide	ISO 7000: 2501
STERILIZE	Do not resterilize	ISO 7000: 2608
	Caution	ISO 7000: 0434A
	Do not use if package is damaged	ISO 7000: 2606
	Manufacture date	ISO 7000: 2497
	Packaging unit	ISO 7000: 2794
LOT	Batch code	ISO 7000: 2492
	Operator's manual	ISO 7000: 1641
	Alternating Current	IEC 60417: 5032
	Type B Applied Part	IEC 60417: 5840
	Type CF Applied Part	ISO 7000: 5335

Symbol	Description	Reference
	Protective Earth	IEC 60417: 5019
	Compliance with the WEEE Directive	WEEE-EC Directive 2012.19.EU
	Menu	Proprietary
	On (power)	IEC 60417: 5007
	Off (power)	IEC 60417: 5008
	Dangerous voltage	IEC 60417: 5036
IPX4	Ingress protection: foreign particle protection level not formally tested, protected against water splashed at any angle	IEC 60529

This device complies with Innovation, Science and Economic Development Canada's licence-exempt RSSs. Operation is subject to the following two conditions:

(1) This device may not cause interference; and
(2) This device must accept any interference, including interference that may cause undesired operation of the device.

Cet appareil est conforme aux flux RSS exemptés de licence d'Innovation, Science et Développement économique Canada. L'opération est soumise aux deux conditions suivantes:

(1) Cet appareil ne doit pas provoquer d'interférence; et
(2) Cet appareil doit accepter toute interférence, y compris les interférences susceptibles de provoquer un fonctionnement indésirable de l'appareil.

This equipment complies with the IC RSS-102 radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 cm between the radiator and your body.

Cet équipement est conforme aux limites d'exposition aux rayonnements ioniques RSS-102 Pour un environnement incontrôlé. Cet équipement doit être installé et utilisé avec un Distance minimale de 20 cm entre le radiateur et votre corps.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications made to this device that are not expressly approved by Auris Health, Inc. could void the user's authority to operate the equipment.

REF

OTT101, OTT420, OTT421, OTT600

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ETHICON

Johnson & Johnson SURGICAL TECHNOLOGIES

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