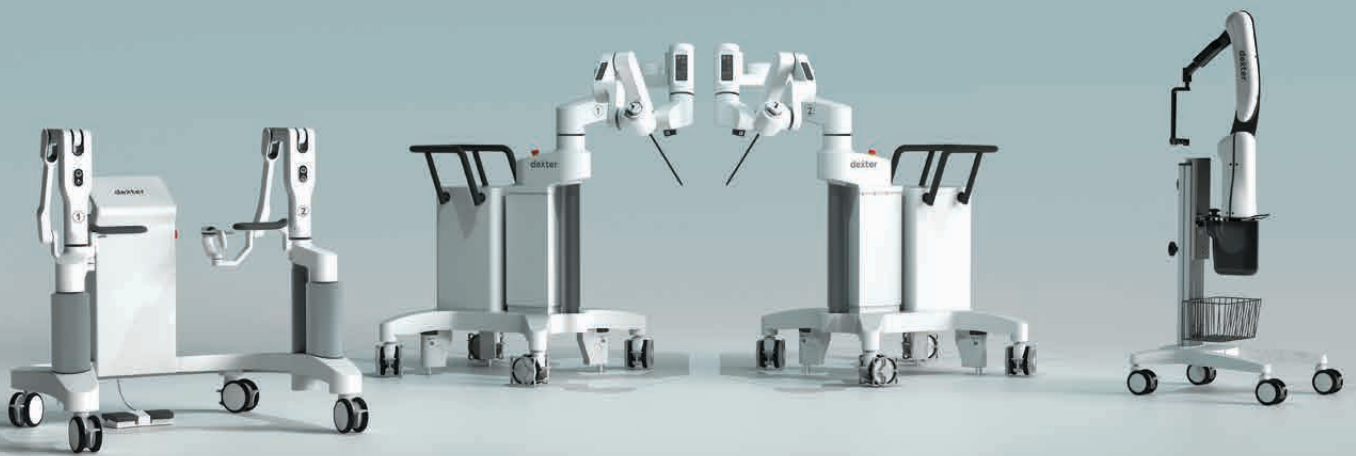


dexter®

THE ASC ROBOT™



DEXTER

Instructions for Use (IFU)



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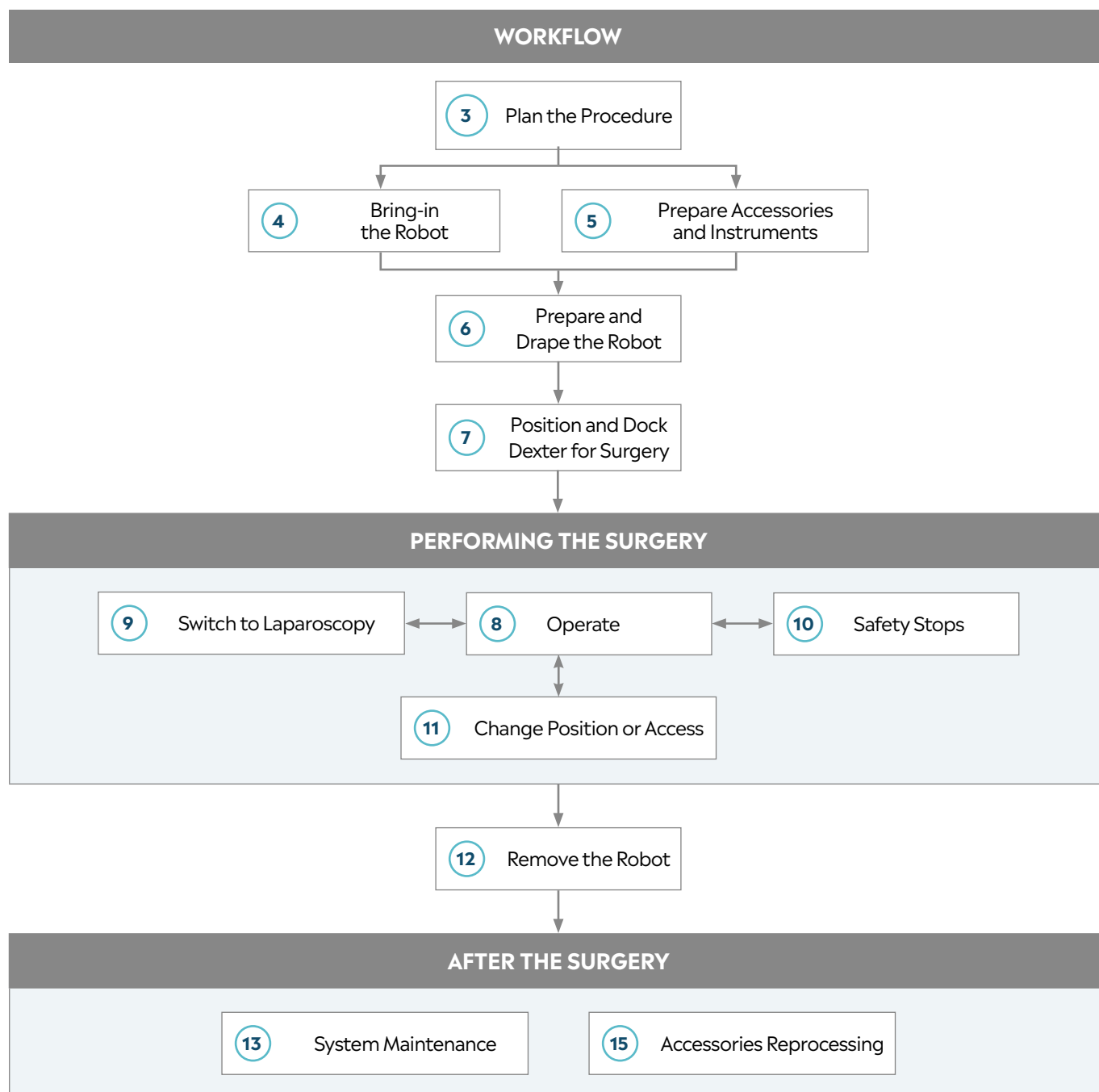
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1 INTRODUCTION

This manual provides information specific to the use of the Dexter L6 System. It is organized in chapters and numbered according to the workflow provided in the Figure below. A glossary of general terms and specific user actions referred to throughout these Instructions for Use is included in Appendix E.



1.1 GENERAL INFORMATION

Rx **Rx only:** Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

1.1.1 Contact Information

For Customer Service

Use the following information for customer service, including ordering, reporting complaints or adverse events, and general information regarding Distalmotion or our products and services.



Address: Distalmotion US Inc. | Customer Service | 200 Park Ave Suite 240 | Orange Village | OH 44122 | USA

Phone: +12167442602

Email: support@distalmotion.com

For Technical Support

Use the following information if the Dexter L6 System requires maintenance or service. Preventive maintenance is required and must be performed by authorized Distalmotion personnel. There are no user-serviceable parts.

Phone number: +12167442602

Cybersecurity

Please call the help line in case of any cybersecurity concerns.

Help line: +12167442602

1.1.2 Patent Information

Distalmotion products are protected by patents, as specified at: <https://www.distalmotion.com/patents>.

1.2 INDICATIONS AND INTENDED USE

1.2.1 Indications for Use

The Distalmotion Dexter L6 System is intended to assist in the accurate control of endoscopes as well as endoscopic instruments for endoscopic manipulation of tissue, including grasping, suturing, dissecting, coagulating and cutting, with or without high frequency functionality. The Distalmotion Dexter L6 System is intended for use in laparoscopic inguinal and ventral hernia repair, cholecystectomy, total benign hysterectomy including salpingo-oophorectomy, and sacrocolpopexy. The system is indicated for adult use, defined as 22 years old and older. It is intended for use by trained laparoscopic or robotic surgeons in an operating room environment in accordance with the representative and specific procedures set forth in the Instructions for Use.

1.2.2 List of Procedures covered by Indications for Use

The representative uses of the Dexter L6 System are indicated for the following procedures:

- Inguinal hernia repair
- Ventral hernia repair
- Femoral hernia repair
- Cholecystectomy
- Total benign hysterectomy with salpingo-oophorectomy
- Total benign hysterectomy with salpingectomy
- Total benign hysterectomy with oophorectomy



- Total benign hysterectomy
- Salpingo-oophorectomy
- Salpingectomy
- Oophorectomy
- Adnexectomy
- Tubal ligation
- Sacrocolpopexy
- Sacrocervicopexy
- Sacrohysteropexy
- Endometriosis resection

1.2.3 Contraindications

Any relative and absolute contraindications for the use of conventional endoscopes and endoscopic surgical instruments apply to the use of the Dexter L6 System.

The Dexter L6 System is not intended for use when endoscopic techniques are contraindicated.

1.2.4 Intended Users & Training

The Dexter L6 System is to be used in accordance with this manual and should not be moved or used by any person who has not been trained by a qualified Distalmotion representative or a certified trainer. Read all instructions carefully. Failure to properly follow instructions and warnings associated with this equipment may lead to serious injury or surgical complications for the patient.



The device is only for distribution to facilities that implement and maintain the device-specific use training program and ensure that users of the device have completed the device-specific use training program. Training provided by Distalmotion is adapted to the surgeon's choice of imaging system, i.e. with a 2D and/or 3D endoscope. Only trained users and those who have developed adequate robotic skills to perform the tasks associated with each procedure should use the Dexter L6 System. Training provided by Distalmotion is limited to the use of the Dexter L6 System and does not replace the necessary medical training and experience required to perform laparoscopic surgery.

1.3 WARNINGS AND PRECAUTIONS

This section lists the general warnings and safety notices for the use of the Dexter L6 System.

The following symbols and definitions are used throughout these Instructions for Use:

SYMBOL	DEFINITION
	Warning: Warning messages alert the reader about a potentially hazardous situation which, if not avoided, may result in injury to the user or patient, or damage to the equipment or other property. Warning messages may also be used to alert against unsafe practices. Warning messages may include information about any special care necessary for the safe and effective use of the device, and any care necessary to avoid damage to the device that may occur as a result of use or misuse.
	Precaution: Precaution messages indicate that the current situation requires operator awareness or user action in order to avoid undesirable effects without critical consequences.

1.3.1 General



The safety and effectiveness for the representative-specific procedures was based on evaluation of the device as a surgical tool and did not include evaluation of outcomes related to the treatment of the patient's underlying disease or condition.



Do not use the Dexter L6 System in or near a strong magnet or in a magnetic resonance imaging environment. The Dexter L6 System has not been evaluated for potential electromagnetic interference when used in proximity to magnetic resonance imaging technology.



Verify that the required Dexter L6 System instruments are available to perform the planned surgical procedure.

1.3.2 Conversion to Laparoscopy or Open Surgery



Environmental or equipment failures may cause the Dexter L6 System to be unavailable. The surgical team should always have all equipment and instruments available and be prepared and trained to perform the procedure using laparoscopy.



Anatomical characteristics of a patient may preclude using the Dexter L6 System and minimally invasive techniques. The surgical team should always have all equipment and instruments available and be prepared and trained to perform the procedure using open surgical techniques.



To ensure quick removal of the Dexter L6 System should it become non-functional, consider the physical space required around the patient and the Patient Carts for the Booms to be pushed aside manually.

1.3.3 Operational Hazards



Once the Patient Carts are docked to the patient, the patient **MUST NOT MOVE OR SLIDE** in any way. Patient movement could result in serious injury. If intraoperative patient movement is necessary, remove all instruments and the endoscope, undock the Patient Carts, move the patient, and redock the Patient Carts.



Once the Patient Carts are docked to the patient, the operating table **MUST NOT BE MOVED** in any way. Movement of the operating table could result in serious injury. If intraoperative table movement is necessary, remove all instruments and the endoscope, undock the Patient Carts, move the operating table, and redock the Patient Carts.



Once the Patient Carts are docked to the patient, the insufflation must not change. Changes to the insufflation could result in injury. If changes to the insufflation are necessary, remove all instruments, change the insufflation, and redock the Patient Carts.



To the extent possible, avoid using the Dexter L6 System when the Forward Angulation of both Patient Carts is not similar. Collision between the two Instrument Arms may occur.



Only use Dexter L6 System instruments and accessories. The use of instruments, accessories, transducers and cables other than those provided by Distalmotion can harm the patient and / or result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and therefore improper operation.



The surgeon must always have both Dexter instrument tips within the field of view of the endoscope. Failure to do so may cause severe harm when moving an instrument that is outside of the field of view.



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



While the Dexter L6 System is specified for continuous use, the pillars used to adjust the height of the Surgeon Console and the Patient Carts are not specified for continuous use. Do not push the Up or Down button continuously for more than 30 s. The motor might overheat and stop working for a few minutes.



Do not use Dexter, its Instruments and Accessories for anything other than their intended use.



The force feedback associated with the Dexter L6 System is different from feedback experienced when using conventional instruments. As with any laparoscopic procedure, the surgeon should rely on visual cues to enhance force feedback.



The minimum distance between the Patient Cart and the Surgeon Console shall be at least 10 cm.



The minimum distance between the Dexter L6 System (i.e., the Patient Cart and the Surgeon Console) and other electrical equipment (e.g., operating table, Endoscope Cart) shall be at least 10 cm.

1.3.4 High Frequency Electrosurgery



Due to concerns about the carcinogenic and infectious potential of electrosurgical by-products (such as tissue smoke plumes and aerosols), protective eyewear, filtration masks, and effective smoke-evacuation equipment should be used in both open and laparoscopic procedures.



Dexter L6 System monopolar instruments have a rated voltage of 4'000 [Vp]. Dexter L6 System bipolar instruments have a rated voltage of 770 [Vp]. Do not attempt to use these instruments with a higher peak voltage, as this could result in failure of the electrical insulation, which can cause severe or third-degree burns.



Do not use energy in the presence of flammable anesthetics or oxidizing gases such as nitrous oxide and oxygen, or in close proximity to volatile solvents (such as ether or alcohol), to reduce the risk of explosion, fire, and serious injury.



To avoid inadvertent thermal damage to surrounding tissue and other hazards, observe the following:

- Use a recent high-frequency surgical equipment with return current and electrode monitoring.
- Ensure that the dispersive electrode is securely affixed to the patient. It must be placed as close as possible to the operating field, and properly connected to the electrosurgical unit.
- For monopolar instruments, always use the lowest output setting that achieves the desired surgical effect while staying within 4'000 [Vp] maximum peak voltage.
- Secure and route the electrosurgical cable to the instrument to prevent cable damage and unintended disconnection.
- Avoid patient contact with grounded metal parts.
- Place any monitoring electrodes as far away as possible from the surgical electrodes or the dispersive electrode when high-frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient.
- Do not deliberately or unintentionally use one instrument to energize other laparoscopic instruments. Energizing other laparoscopic instruments may cause tissue damage inside or outside the field of view. This damage could occur at points near the tip or at the port site (cannula) of the energized instrument.
- The cables to the high-frequency surgical equipment should be positioned in such a way that contact with the patient or other patient leads is avoided.
- Always check the cables, high-frequency surgical equipment, and instruments for insulation damage and proper function.



Verify that the insulation is intact and undamaged by visually inspecting the device for loose, bent, broken or cracked components. Damaged insulation may result in burns or other injuries to the patient or user. Do not use if any defects are observed on the device.



Using electrosurgical instruments may cause neuromuscular stimulation.



Use the lowest power or effect setting possible for the minimum time necessary to achieve the desired effect.



Activate the high-frequency generator only when the distal end (active electrode) is near or touching the target tissue. Activation when not in contact or in position to deliver energy may cause capacitive coupling.



Electrosurgery may produce interference with implantable pacemakers and defibrillators. Electrosurgery may cause these devices to enter an asynchronous mode or may inhibit operation of the implantable pacemaker or defibrillator entirely. Consult the manufacturer for further information when considering electrosurgery in patients with implantable pacemakers or defibrillators.

1.3.5 Maintenance and Servicing



The Dexter L6 System may only be serviced by Distalmotion personnel. DO NOT attempt to service equipment without Distalmotion personnel.



No modification of any part of the Dexter L6 System (including instruments and accessories) by the user is allowed. Failure to comply may result in serious harm to the user or the patient, and/or damage to the equipment.



Do not maintain or service Dexter during use.

1.3.6 Mechanical and Physical Risks



The surgeon and other personnel working with the Dexter L6 System shall be careful to avoid collisions, which could cause serious injury to the patient or the user:

- Collisions between a Patient Cart and the patient during positioning and setup
- Collisions involving the Patient Cart (e.g. instrument colliding with the Boom or the Wheelbase colliding with an obstacle)
- Collisions between Patient Carts
- Collisions involving the Patient Cart and a laparoscopic instrument
- Collisions of a Patient Cart with the endoscope

If a collision is deemed to have potentially displaced the Remote Center of Motion, the surgeon should immediately stop operating and re-dock the Patient Cart that was impacted.



The surgeon and other personnel working with the Dexter L6 System shall be mindful of their extremities (fingers, hands, arms) to avoid entrapment in the joints of the Patient Carts and Master Arms of the Surgeon Console. Serious injury may occur.



Do not place cables over the Patient Cart or the Surgeon Console. This can limit their range of motion and they could also become pinched or damaged.



When adjusting the height of a Patient Cart, be aware of the position of the patient to avoid patient contact and potential injury.



Be careful when pushing the Endoscope Cart with the mounted Endoscope Arm as it might fall over.



Handle with caution the tip of the Monopolar Scissors, the electrical connector of the Bipolar Maryland Dissector and Bipolar Johann Grasper or the Emergency Release Tool, as they contain sharp edges.



Avoid powering on the Dexter L6 System while an Instrument Arm is applying force against an obstacle.



1.3.7 Electrical Hazards



To avoid the risk of electric shock, equipment must only be connected to a mains power supply with protective earth.



Do not connect the Dexter L6 System to a power strip. The Surgeon Console and both Patient Carts shall be connected to separate, independent electrical outlets.



Do not touch the patient and any part of the Surgeon Console or the Patient Cart simultaneously.



As the Dexter L6 System has type BF applied parts, the applied parts of other medical electrical equipment used within the Dexter L6 System configuration shall be type F applied parts. In any case, the biomedical engineers shall perform an installation qualification in which the leakage currents of all devices used in the robotic surgery configuration are measured.



If the Dexter L6 System is used in conjunction with other medical electronic equipment, leakage currents can be additive. This specifically applies to the robotic surgery configuration in which multiple medical devices (e.g. Dexter L6 System, endoscope, Endoscope Arm) are used at the same time.



Remove all instruments and the Dexter L6 System from the surgical field before using an external defibrillator.



Only use one Incision Pointer at a time to avoid the risk of exceeding patient leakage current limits when both Incision Pointers are in the trocar and accidentally touch tissue.



Avoid contact between the operating table or the patient with the Boom or Instrument Arm, as this could result in loss of electrical safety insulation.



The use of the Dexter L6 System adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the Dexter L6 System and the other equipment should be monitored to ensure that they are operating normally.



Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the Dexter L6 System, including cables specified by the manufacturer. Otherwise, degradation in the performance of this equipment could occur.



Ensure that the Dexter L6 System is positioned to facilitate disconnection from the mains power supply.

1.3.8 Sterility Hazards



Tray, Handle Grips, Incision Pointers and Emergency Release Tools – are delivered non-sterile and should only be used after undergoing sterilization according to section 15 - Accessories Reprocessing.



Improper draping of the Surgeon Console or the Patient Carts could result in loss of sterility. Follow the Instructions for Use and request training if in doubt about how to properly drape the Dexter L6 System.



When operating the Surgeon Console in a seated position, and to avoid contact between the surgeon's knees and the Handles, or between the surgeon's hands and the Handle Grips, it is important to properly drape the console all the way down as instructed during user training. The surgeon's knees might not be sterile.



The Emergency Release Tool, the Sterile Interface and the instruments lose sterility when using the Emergency Release Tool. The Sterile Interface shall be replaced after use of the Emergency Release tool.



Do not resterilize or reuse the instruments, the Sterile Interfaces, or the Sterile Drapes. They are single-use accessories that are not designed for reprocessing or reuse. Reuse may lead to infection, loss of performance due impact on mechanical and/or electrical integrity, and physical injury to the patient.



If the packaging of an instrument or a single-use accessory is torn, damaged or open, do not use it, as it might have lost its sterility.



1.4 CLINICAL BENEFIT

The intended clinical benefits of the Dexter L6 System, as a minimally invasive surgical tool, include lower estimated blood loss, lower major complication rates, and a shorter length of hospital stay compared to open surgery, providing clinical benefits comparable to similar robotic systems. These clinical benefits/outcomes may depend on a number of factors, including, but not limited to patient characteristics, disease characteristics, surgeon experience, and hospital/ national patient care and recovery pathways.

1.5 POTENTIAL SIDE EFFECTS

Serious complications may occur in any surgery, including surgery with the Dexter L6 System, up to and including death. Examples of serious or life-threatening complications, which may require prolonged and/or unexpected hospitalization and/or reoperation, include but are not limited to one or more of the following: injury to tissues/organs, bleeding, infection and internal scarring that can cause long-lasting dysfunction/pain. Individual surgical results may vary.

Risks specific to minimally invasive surgery, including surgery with the Dexter L6 System, include but are not limited to, one or more of the following: temporary pain/nerve injury associated with positioning, a longer operative time, the need to convert to an open approach, or the need for additional or larger incision sites.

Converting the procedure could result in a longer operative time, a longer time under anesthesia, and could lead to increased complications.

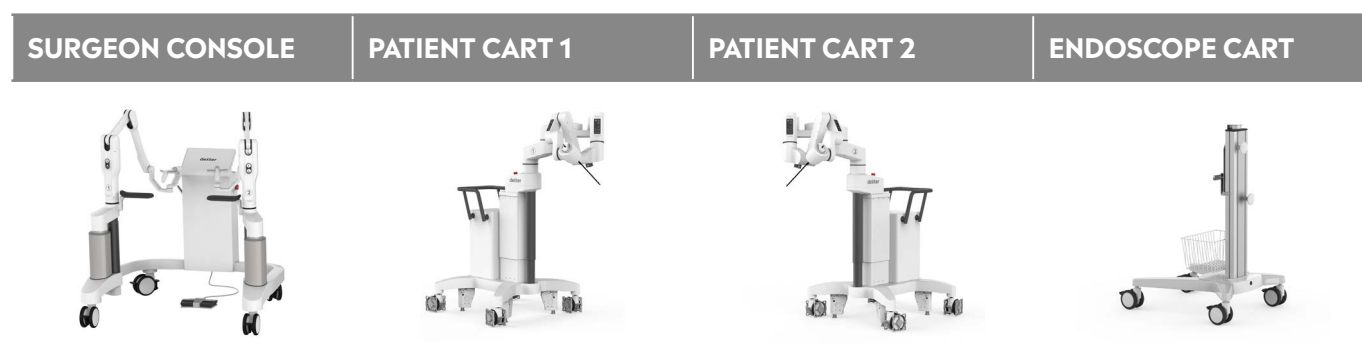
2 SYSTEM OVERVIEW

2.1 DEVICE OVERVIEW

The Dexter L6 System is designed to enable complex surgery using a minimally invasive approach. It is composed of the Robot, the single-use accessories, fully articulated instruments, as well as reusable accessories. The Dexter L6 System is compatible with standard single-use laparoscopic trocars measuring 10 [mm] in diameter and larger, or as otherwise stated in Appendix C of the Instructions for Use. The instruments and accessories compatible with the Dexter L6 System are listed in the Table below. Please note that the table below only lists those items compatible with the Dexter L6 System.

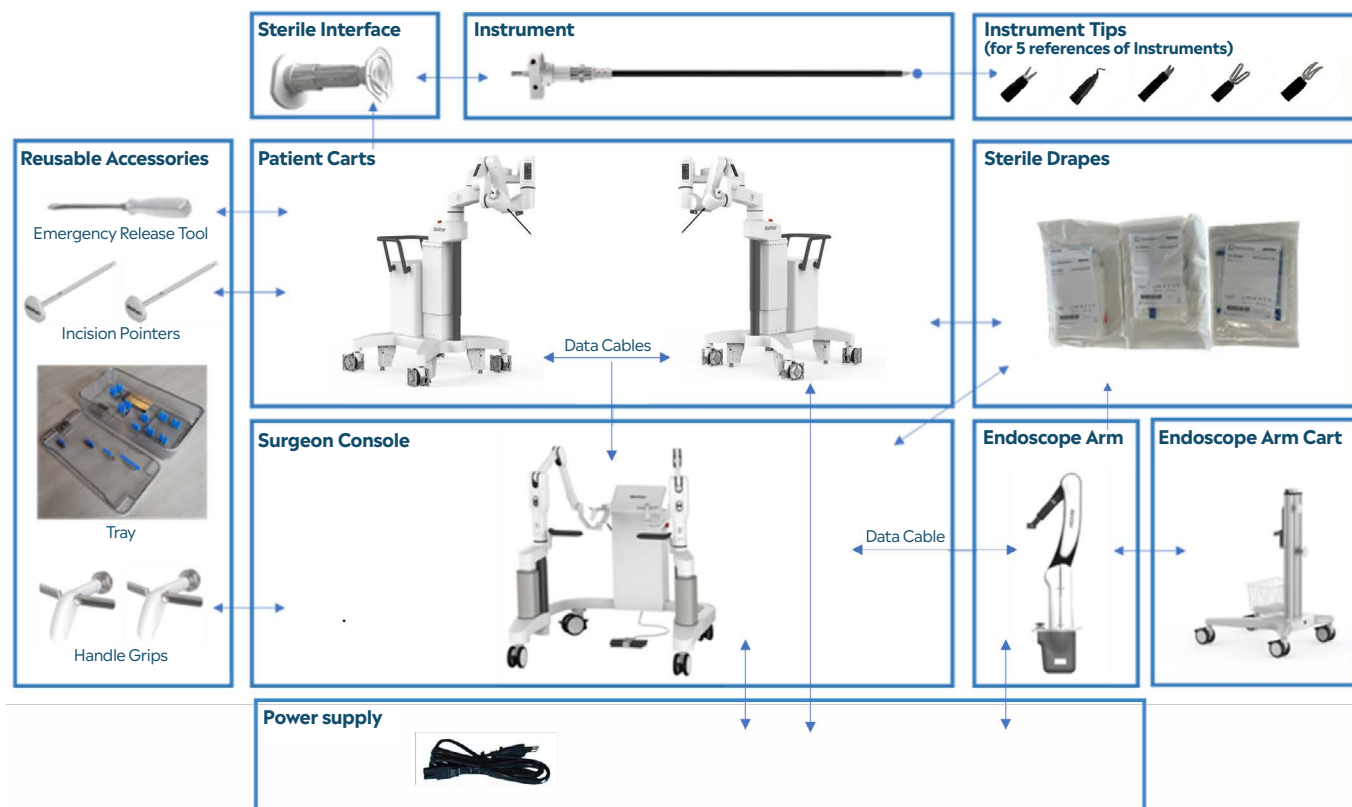
ROBOT	INSTRUMENTS	ACCESSORIES
- Surgeon Console - Patient Cart 1 - Patient Cart 2	- Needle Holder - Bipolar Johann Grasper - Bipolar Maryland Dissector - Monopolar Scissors - Monopolar Hook	Single-Use - Sterile Interfaces - Sterile Drapes Reusable - Accessory Tray - Handle Grips - Incision Pointers - Emergency Release Tool Endoscope Control - Dexter L6 System Endoscope Arm and its accessories - Endoscope Cart

Setup and intraoperative use may require sterile and non-sterile tasks performed by the following users: surgeon, scrub nurse (sterile) and circulating nurse (non-sterile). Further details about the components can be found in the following subsections. The Surgeon Console, Patient Carts and Endoscope Cart are shown below.



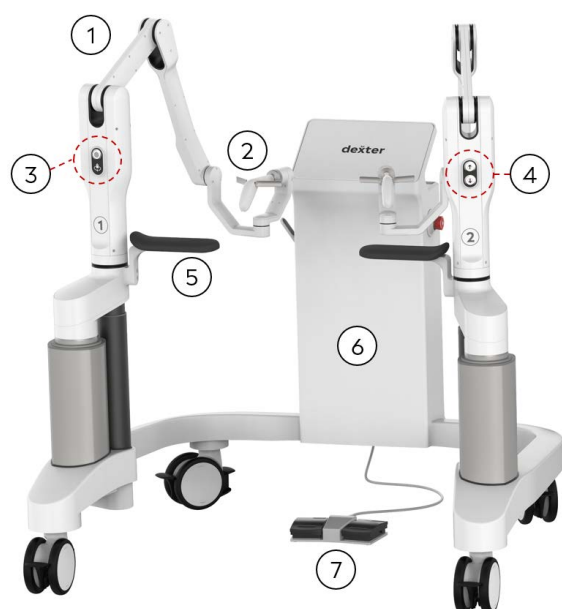


The interactions between the different elements of the Dexter L6 System are shown in the Figure below.



2.2 SURGEON CONSOLE

The surgeon operates from a seated or standing position at the Surgeon Console. The surgeon controls the movement of the instruments and of Endoscope Arm using two Handle Grips, a Clutching Foot Pedal and an Endoscope Foot Pedal.



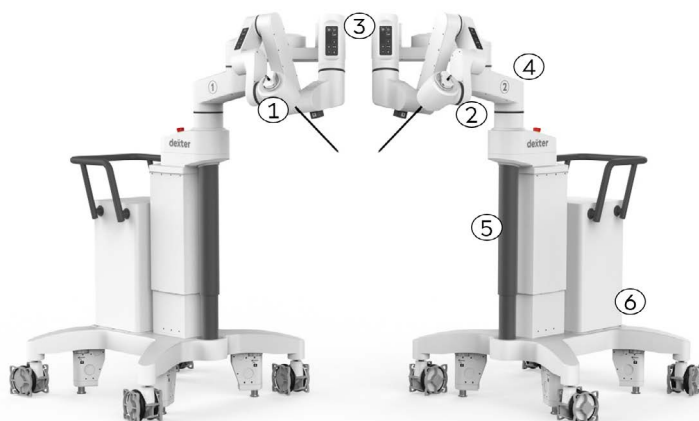
The Surgeon Console is composed of:

- 1 **Master Arms:** Passive structure capturing the translational movements (i.e. up / down, in / out, left / right) of the surgeon's arms.
- 2 **Handles and Handle Grips:** The Handle Grips connect to the Handles at the extremity of the Master Arms. The surgeon grabs the Handle Grips while operating. The Handle Grips capture the roll, pitch, yaw and open/close movements from the surgeon's hands.
- 3 **Arms Lock Button:** The Master Arm 1 features a button that can be used to release the brake of the Master Arm. When the button is pressed, the Master Arms toggle between the locked state and the free state. In addition, the button can be used to check the scaling ratio value when long pressed or adjust the scaling ratio if pressed along with the Master Arm Height Adjustment Up or Down Button.
- 4 **Master Arm Height Adjustment buttons:** The Master Arm 2 features buttons that can be used for height adjustment. The height of the Master Arm can be adjusted to optimize ergonomics for the surgeon, and according to the surgeon's position (seated or standing). In addition, the Master Arm Height Adjustment Buttons can be used to change the scaling ratio by pressing the Up or Down Button along with the Arms lock Button.
- 5 **Armrest:** Support for the surgeon to rest their forearms when operating with the Dexter L6 System.
- 6 **Central Pillar:** Contains the electronics and the emergency stop button.
- 7 **Pedalboard:** Used for clutching the instruments (Clutching Foot Pedal) and for robotic endoscope control (Endoscope Foot Pedal).

Figure 1: Surgeon Console

2.3 PATIENT CARTS

The Patient Carts are positioned at the operating room table in sterile condition. Each Patient Cart contains an Instrument Arm that is positioned with respect to the target patient anatomy. The Boom is adjustable and moves the Instrument Arm horizontally into a position appropriate for the target anatomy and patient position. The Column moves the Boom up or down to adjust the height of the Instrument Arm. The Hub serves as the interface for the instruments and the Instrument Arm. Instruments are inserted and removed through the Hub during surgery.



The Patient Cart is composed of:

- 1 Hub:** Contains a lumen through which the instrument is inserted (through the Sterile Interface). The Hub drives the roll, pitch, yaw and open / close degrees of freedom of the instruments.
- 2 Instrument Arm:** Drives the translational degrees of freedom (left / right, up / down, in / out) of the instruments and contains the connector for the Incision Pointer.
- 3 Forward Angulation:** Enables the appropriate surgical workspace to be established with regard to the trocars and target anatomy.
- 4 Boom:** Enables the horizontal positioning of the Instrument Arm.
- 5 Column:** Enables the vertical positioning of the Instrument Arm.
- 6 Wheelbase:** Contains the electronics rack and has wheels for positioning and transporting the Patient Cart. The Wheelbase also has Floor Locks to secure the Patient Cart in place while operating.

Figure 2: Patient Carts

2.4 INSTRUMENTS

The instruments give surgeons natural dexterity and greater than natural range of motion, allowing for greater precision when operating in a minimally invasive environment. When used with the Dexter L6 System, the instruments are designed to support rapid and precise dissection and suturing.

The instruments are single-use and supplied sterile (ethylene oxide sterilization). If the packaging is damaged, the instruments must not be used on patients under any circumstances.

NEEDLE HOLDER	BIPOLAR JOHANN GRASPER	BIPOLAR MARYLAND DISSECTOR	MONOPOLAR SCISSORS	MONOPOLAR HOOK
				
	Rated voltage of 770 [Vp]	Rated voltage of 770 [Vp]	Rated voltage of 4000 [Vp]	Rated voltage of 4000 [Vp]

NOTE

All monopolar instruments feature a standard 4 mm diameter banana-plug monopolar electrical connector.

NOTE

All bipolar instruments feature a standard rectangular bipolar electrical connector.



2.5 SINGLE-USE ACCESSORIES

The Dexter L6 System single-use accessories are the Sterile Drapes to cover the Surgeon Console and the Patient Carts for sterile use, and the Sterile Interfaces to establish a sterile barrier between the Hub of the Patient Carts and the instruments.

Sterile Interfaces are supplied sterile (ethylene oxide sterilization). Sterile Drapes are manufactured and supplied by Medline. If the primary packaging is damaged, then the corresponding Sterile Interface or Sterile Drape must not be used under any circumstances.

STERILE DRAPES



- 3x Sterile Drapes for the Surgeon Console: Left Master Arm, right Master Arm and Central Pillar.
- 2x Sterile Drapes for the Patient Cart: Left Patient Cart and right Patient Cart.

STERILE INTERFACES



- 2x Inserted into the Hub.

2.6 REUSABLE ACCESSORIES

Dexter L6 System reusable accessories include the Accessory Tray, Incision Pointers for docking the Patient Carts to the patient, the Handle Grips which connect to the Handles of the Surgeon Console, and the Emergency Release Tool for the removal of instruments from the Patient Carts in case of power loss or system failure.

Dexter L6 System reusable accessories are not provided sterile and are reprocessed using standard washer-disinfector and steam sterilization methods.

ACCESSORY TRAY



1x

To transport, store and reprocess the Handle Grips, the Incision Pointers and the Emergency Release Tool.

HANDLE GRIP



2x

Connected to the Surgeon Console. Held by the surgeon to control the Dexter L6 System.

INCISION POINTER



2x

To dock the Patient Carts to the trocars.

EMERGENCY RELEASE TOOL



1x

To open instrument blades when Dexter L6 System stops working and instruments grab tissue.

2.7 ENDOSCOPE ARM & ENDOSCOPE CART

The Endoscope Arm is manufactured by AKTORmed. It can be connected to the Dexter L6 System. The surgeon can control the endoscope via the Surgeon Console. The Endoscope Arm can be attached to the rail of the operating table, or it can be used when mounted on the Endoscope Cart. Please refer to the Endoscope Arm Instructions for Use for all information about using the Endoscope Arm. The Endoscope Arm is shown in the Figure below.



The endoscope arm is composed of:

- 1 Control Panel
- 2 Cantilever Arm
- 3 Releasing Slider
- 4 Emergency Stop Button
- 5 Cantilever
- 6 Joint
- 7 Tension Sleeve
- 8 Probe Pin
- 9 Quick-fastener for fastening to the operating table
- 10 Control Connection
- 11 Power Supply Connection

Figure 3: Endoscope Arm



The Endoscope Cart carries the Endoscope Arm during transport and storage and it can be used to position the Endoscope Arm for use at the bedside. The Endoscope Cart features height adjustment for the Endoscope Arm.

ENDOSCOPE CART WITH MOUNTED ENDOSCOPE ARM



ENDOSCOPE CART



2.8 FUNCTION

The Surgeon Console captures the surgeon's hand movements (seven degrees of freedom) by means of sensors:

- Three degrees of freedom: Translation (up/down, left/right, in/out) of the surgeon's hand in space - captured by the Master Arm, with Alpha, Beta and Gamma joints.
- One degree of freedom: Roll around the longitudinal axis of the forearm - captured by the Handle.
- Two degrees of freedom: Pitch and yaw of the wrist- captured by the Handle.
- One degree of freedom: Opening and closing the grip of the Handle - captured by the Handle.

Instrument Control

If the surgeon does not press either of the Foot Pedals on the Pedalboard (for clutching and endoscope control), their hand movements are transmitted to the corresponding Patient Carts:

- Left hand to Patient Cart 1
- Right hand to Patient Cart 2

Each Patient Cart contains a motion control module that calculates the velocities of each joint in the Instrument Arm and Hub to replicate and scale the surgeon's input. The resulting setpoints are then sent to the corresponding joints on the Patient Cart which move the instrument (seven degrees of freedom) by means of electric motors:

- Three degrees of freedom: Translations to move the instrument tip in space - actuated by the Instrument Arm and its four joints, Alpha, Beta, Gamma and Theta, while keeping the remote center of motion at a fixed location at the fascia level.

- One degree of freedom: Roll to rotate the instrument around its main axis - actuated by the Hub.
- Two degrees of freedom: Pitch and yaw of the Instrument tip/end-effector - actuated by the Hub.
- One degree of freedom: Opening and closing the end-effector - actuated by the Hub.

When the Clutching Foot Pedal is pressed, this pauses the motion replication of all degrees of freedom. The surgeon can reposition the Handles (e.g. to improve comfort and reach). Once the Clutching Foot Pedal has been released, motion replication resumes relative to the position prior to clutching.

Endoscope Control

When the Endoscope Foot Pedal is pressed, the average motion of both hands of the surgeon is forwarded to the attached Dexter L6 System Endoscope Arm which moves the endoscope accordingly.

Pressing the Endoscope Foot Pedal also clutches the instruments.

2.9 ELECTROSURGICAL UNITS

Compatibility of the Dexter L6 System with the commercially available electrosurgical generators/units (ESU) listed below has been verified through documentation - including their accessories (monopolar cables, foot switches, and patient return electrodes). Refer to the Instructions for Use that accompany the electrosurgical unit for information about using the equipment and compatible accessories:

BRAND	MODEL
Erbe	VIO 200D, VIO 200S, VIO 300D, VIO 300S, ICC 200, ICC 300, ICC 350, VIO 3
Emed	ATOM SMART, ES350, ES120, Spectrum
Medtronic	Valleylab FT10, Valleylab FX8
Olympus	ESG-410, ESG-400
KLS Martin	MaXium, ME MB3

Dexter L6 System monopolar instruments have a rated voltage of 4'000 [Vp]. The Dexter L6 System bipolar instruments have a rated voltage of 770 [Vp]. For more information, please refer to the Appendix D: Electrosurgical Units.

2.10 POWER SUPPLY

The Dexter L6 System is connected to three separate electrical outlets (wall sockets):

- Surgeon Console (with a 5-meter power supply cable)
- Patient Carts (each with a separate 5-meter power supply cable)

The optional Dexter L6 System Endoscope Arm is connected to AC mains with a dedicated power supply.

Where required by national laws or local regulations, equipotential bonding of equipment may be accomplished by connecting a potential equalization conductor to the equipotential terminals located near the mains power inlet on each subassembly of the system. See the requirements for medical electrical systems in standard IEC 60601-1.



The cables should be arranged so that they are out of the path of operating room traffic, including other equipment, to avoid damaging the cables or creating an obstacle or hazard for personnel. The location of the cables should also facilitate movement of the Patient Carts between their preoperative (draping) and intraoperative locations.

The Surgeon Console and the Patient Carts have a power switch near the connection of the Power Cord. This Power Switch can be used to safely isolate the Robot from the mains power supply.



Figure 4:
Power Switch location on the Surgeon Console



Figure 5:
Power Switch location on the Patient Cart

2.11 ENVIRONMENT

The Surgeon Console and the Patient Carts are in the patient environment.

The Dexter L6 System interfaces with the following items in the operating room:

- Trocars through which the instruments are inserted into the patient.
- Electrosurgical generators which connect to the monopolar and bipolar instruments of the Dexter L6 System [as needed].

To use the Dexter L6 System as part of laparoscopic procedures, a 2D or 3D endoscope as well as other customary laparoscopy, surgical and anesthesiology equipment is required. However, the Dexter L6 System does not directly interface to or interact with this equipment.

NOTE

When available, it is recommended to use the Dexter L6 System with a 3D endoscope. The Dexter L6 System can also be used with a 2D endoscope at the surgeons' discretion.

3 PLAN THE PROCEDURE

Prior to the decision on whether to use the device for a procedure, the **surgeon** plans the procedure and ensures that the desired use of the device by the surgeon falls within its intended use.

- 1

SELECT APPROPRIATE TROCARS

The **surgeon** ensures that translucent trocars of minimum 10 [mm] in diameter, or as otherwise stated in the Instructions for Use, are used.
- 2

SELECT AN APPROPRIATE PORT PLACEMENT

The **surgeon** plans the port placement to ensure access to the target anatomies, and to avoid collisions between the device, the endoscope, accessories and other laparoscopic instruments. Specifically, the endoscope port and the two robotic instrument ports should be 8 cm apart, along a line perpendicular to the target anatomy.
- 3

SELECT APPROPRIATE ROBOTIC INSTRUMENTS

The **surgeon** selects the robotic instruments required for the procedure so that the **circulating nurse** can prepare them for use.
- 4

SELECT APPROPRIATE LAPAROSCOPIC INSTRUMENTS

The **surgeon** ensures that all laparoscopic instruments and any other instruments necessary are in the operating room. The **surgeon** must have all instruments required to perform every task of the procedure manually, without using the Dexter L6 System. This includes stapling, advanced energy delivery, ultrasound, cryoablation and microwave energy delivery instruments which are not part of the Dexter L6 System.
- 5

SELECT APPROPRIATE ELECTROSURGICAL GENERATOR

The **surgeon** ensures that the electrosurgical generator is compatible with the robotic instruments, including the cable and Electrosurgical Pedalboard (e.g., connector type, operating mode, rated voltage).
- 6

SELECT WHETHER THE SURGEON CONSOLE IS STERILE OR NOT

The **surgeon** decides whether they will use the Surgeon Console in sterile or non-sterile mode.

 - **Sterile mode:** Default way of using the Dexter L6 System.
 - **Non-sterile mode:** Either the **surgeon** scrubs in for activities related to the Patient Cart (e.g. setting Forward Angulation, docking, instrument insertion or removal), or the **surgeon** delegates all or some of these tasks to a sterile assistant. The **surgeon** is responsible for ensuring that the Dexter L6 System is used in a safe manner.
- 7

SELECT APPROPRIATE OPERATING ROOM LAYOUT

The **surgeon** defines the appropriate operating room layout and considers all equipment and people present during surgery:

 - Surgeon Console, Patient Carts, anesthesiology, Endoscope Cart, electrosurgical generator and cables, insufflator, monitor for the **surgeon** when doing laparoscopy and when using the device, monitor for the assistant, sterile surface and other potential operating room equipment.
 - Surgeon, assistant, anesthesiologist, scrub nurse and circulating nurse

4 BRING IN THE ROBOT

4.1 BRING IN THE SURGEON CONSOLE

The **circulating nurse** brings the Surgeon Console into the operating room and positions it at the dedicated location.

- 1 PREPARE THE SURGEON CONSOLE FOR TRANSPORT**
The **circulating nurse** ensures that the Pedalboard and the Power Cord to connect the Surgeon Console are properly stowed away, and that the Surgeon Console is not connected to any other device such as a Patient Cart.

- 2 DISENGAGE THE WHEEL BRAKES OF THE SURGEON CONSOLE**
The **circulating nurse** disengages the Wheel Brakes (i.e., the mechanical brakes at each of the four wheels).

- 3 PUSH THE SURGEON CONSOLE TO THE OPERATING ROOM**
The **circulating nurse** pushes the Surgeon Console into the operating room to the desired location and orients it in the desired direction so that:

- the **surgeon** can easily move between the patient (e.g. for laparoscopy) and the Surgeon Console.
- the **surgeon** has a good view onto an endoscope monitor when using the Robot.
- the **surgeon's** movements while operating are not limited by physical constraints (e.g., a wall).
- the Surgeon Console does not interfere with the surgical workflows, both during laparoscopic and robotic surgical steps.



While transporting any component of the Dexter L6 System, be aware of any objects, structures or persons that may constitute an obstacle and take the necessary precautions to avoid collisions.

- 4 ENGAGE THE WHEEL BRAKES OF THE SURGEON CONSOLE**
The **circulating nurse** engages the Wheel Brakes (i.e., the mechanical brakes at each of the four wheels).

- 5 CONNECT THE SURGEON CONSOLE TO THE MAINS POWER SUPPLY**
The **circulating nurse** checks that the Power Button on the Surgeon Console is in the “off” position. Then, the **circulating nurse** unwinds the power cable from its storage location at the Surgeon Console and connects it to an appropriate mains power supply.

- 6 POSITION THE SURGEON CONSOLE PEDALBOARD**
The **circulating nurse** takes the Pedalboard from its storage location at the Surgeon Console and places it below the base of the Surgeon Console at a location easily accessible by one of the **surgeon's** feet when using the Surgeon Console.

- 7 CONNECT THE PEDALBOARD**
Then the **circulating nurse** connects the Pedalboard to the Surgeon Console.

4.2 BRING IN THE PATIENT CARTS

The **circulating nurse** brings in both Patient Carts and sets them up in proximity to the location of use at the patient's side.

- 1

PREPARE THE PATIENT CARTS FOR TRANSPORT

The **circulating nurse** ensures that the Data Cables and Power Cords are properly stowed away.
- 2

DISENGAGE THE WHEEL BRAKES OF THE PATIENT CARTS

The **circulating nurse** disengages the Wheel Brakes (i.e., the mechanical brakes of the wheels).
- 3

PUSH THE PATIENT CARTS TO THE OPERATING ROOM

The **circulating nurse** pushes the Patient Carts into the operating room in proximity to where it will be docked to the patient, but sufficiently far away from the sterile field so that the Patient Carts can still be draped. The **circulating nurse** is mindful of the sterile field when moving the Patient Carts.
- 4

ENGAGE THE WHEEL BRAKES OF THE PATIENT CARTS

The **circulating nurse** engages the Wheel Brakes (i.e., the mechanical brakes on the wheels). The Patient Carts can be in proximity to the sterile field; however, the **circulating nurse** must be mindful of this.
- 5

CHECK THAT THE POWER BUTTON ON THE PATIENT CARTS IS IN THE “OFF” POSITION

The **circulating nurse** checks that the Power Button on the Patient Carts is in the “off” position.
- 6

CONNECT THE PATIENT CARTS TO THE MAINS POWER SUPPLY

The **circulating nurse** unwinds the Power Cord from its storage location at the Patient Carts and connects it to an appropriate mains power supply. When doing this, the **circulating nurse** places the Power Cords in a way that minimizes interference with other equipment or people in the operating room.
- 7

CONNECT THE PATIENT CARTS TO THE SURGEON CONSOLE

The **circulating nurse** unwinds the Data Cable from the Patient Carts and connects it to the Surgeon Console. In doing this, the **circulating nurse** places the Data Cables in a way that minimizes interference with other equipment or people in the operating room. Both Data Cables can be used with any Patient Cart. They have inverted keyed connections that prevent incorrect connection to the Surgeon Console.



4.3 BRING IN THE ENDOSCOPE CART AND CONTROLLER [AS NEEDED]

The **circulating nurse** brings in the Endoscope Cart and the Endoscope Arm into the operating room and sets them up in proximity to the location of use at the patient's side.

- 1

PREPARE THE ENDOSCOPE CART FOR TRANSPORT

The **circulating nurse** ensures that the Data Cables and Power Cords are properly stowed away.
- 2

DISENGAGE THE WHEEL BRAKES OF THE ENDOSCOPE CART

The **circulating nurse** disengages the Wheel Brakes (i.e., the mechanical brakes of the wheels).
- 3

PUSH THE ENDOSCOPE CART TO THE OPERATING ROOM

The **circulating nurse** pushes the Endoscope Cart into the operating room in proximity to the location where it will be docked to the patient, but sufficiently far away from the sterile field so that the Endoscope Arm can still be draped. The **circulating nurse** is mindful of the sterile field of the patient when moving the Endoscope Cart.
- 4

ENGAGE THE ENDOSCOPE CART WHEEL BREAK.

The **circulating nurse** engages the Endoscope Cart Wheel Brakes.
- 5

CONNECT THE ENDOSCOPE ARM TO THE MAINS POWER SUPPLY

The **circulating nurse** unwinds the power cable from its storage location at the Endoscope Cart and connects it to an appropriate mains power supply plug as per the Instructions for Use of the Dexter L6 System Endoscope Arm.
- 6

MOUNT THE ENDOSCOPE ARM TO THE OPERATING TABLE AS NEEDED

If the **surgeon** wants to operate the Endoscope Arm attached to the bed, it is good practice to first wait for the patient to be properly installed and sedated. Then, the **circulating nurse** removes the Endoscope Arm from the Endoscope Cart and attaches it to the bedrail according to the Instructions for Use of the Dexter L6 System Endoscope Arm. The Endoscope Cart is then removed from the patient area.
- 7

CONNECT THE ENDOSCOPE ARM TO THE SURGEON CONSOLE

The **circulating nurse** unwinds the Data Cable from the Endoscope Cart and connects it to the Surgeon Console and to the Dexter L6 System Endoscope Arm.

4.4 POWER ON THE ROBOT

The **circulating nurse** powers on the Robot and verifies that the self-test sequence is satisfactory.

1

POWER ON THE PATIENT CARTS

The **circulating nurse** pushes the Power Switches on the Patient Carts and confirms that they are powered by checking that either the “Power On” Button light or the Emergency Stop Button light is on.

2

POWER ON THE SURGEON CONSOLE

The **circulating nurse** pushes the Power Switch on the Surgeon Console and confirms that it is powered by checking that either the “Power On” Button light or the Emergency Stop Button light is on.

3

TEST EMERGENCY STOP BUTTON

The **circulating nurse** verifies that the Robot can enter safe state by pushing any of the Emergency Stop Buttons (Patient Carts 1 or 2, Surgeon Console, or Endoscope Arm), i.e., the lights on both Hubs turn red. Then, the **circulating nurse** releases the Emergency Stop Button by turning it clockwise.



Figure 6:
Press the emergency stop button



Figure 7:
Release the emergency stop button clockwise

4

RESTART THE ROBOT

The **circulating nurse** restarts the Robot either pushing the Arms Lock Button and the Up Button on the Surgeon Console simultaneously for two seconds or by manually using the Power Switches.



5 PREPARE ACCESSORIES AND INSTRUMENTS

5.1 REUSABLE ACCESSORIES

The **circulating nurse** and the **scrub nurse** prepare the reusable accessories for the Surgeon Console (i.e., the Handle Grips) and for the Patient Carts (i.e., the Incision Pointers and the Emergency Release Tool).

- 1

BRING THE REUSABLE ACCESSORIES TO THE OPERATING ROOM

The **circulating nurse** brings the reusable accessories for the Surgeon Console and the Patient Carts to the operating room.
- 2

UNPACK THE REUSABLE ACCESSORIES

The **circulating nurse** checks the packaging of the Accessory Tray(s) for integrity and sterility.
- 3

UNPACK THE ACCESSORY TRAY(S)

The **circulating nurse** and the **scrub nurse** unpack the Accessory Tray(s) from their sterile packaging. Opening an Accessory Tray takes place in proximity to the sterile field, and the **circulating nurse** is mindful of this.
- 4

PLACE ACCESSORY TRAY(S) OR THEIR CONTENTS

The **scrub nurse** places the accessories on the sterile surface, keeping them in the Accessory Tray or putting them directly on the sterile surface.
- 5

INSPECT THE INCISION POINTERS

The **scrub nurse** inspects both Incision Pointers visually for damage.
- 6

INSPECT THE HANDLE GRIPS

The **scrub nurse** grabs both Handle Grips and inspects them visually for damage.
- 7

TEST THE HANDLE GRIPS

The **scrub nurse** tests that the Handle Grips move smoothly by opening and closing the two paddles.
- 8

INSPECT THE EMERGENCY RELEASE TOOL

The **scrub nurse** verifies that the Emergency Release Tool is present in the Accessory Tray.

5.2 ENDOSCOPE ARM ACCESSORIES

The **circulating nurse** and the **scrub nurse** prepare the accessories for the Endoscope Arm as per the Instructions for Use of the Dexter L6 System Endoscope Arm.

5.3 SINGLE-USE ACCESSORIES

The **circulating nurse** and the **scrub nurse** prepare the single-use accessories for the Surgeon Console (i.e., Sterile Drapes) and the Patient Carts (i.e., Sterile Drapes, Sterile Interfaces).

- 1 BRING THE SINGLE-USE ACCESSORIES TO THE OPERATING ROOM**
The **circulating nurse** brings the Sterile Drapes and the Sterile Interfaces to the operating room.
- 2 INSPECT THE SINGLE-USE ACCESSORIES PACKAGING**
The **circulating nurse** inspects the packaging of the Sterile Drapes and the Sterile Interfaces for integrity and sterility.
- 3 OPEN THE SINGLE-USE ACCESSORIES PACKAGING**
The **circulating nurse** opens the packaging in proximity to the sterile field and the **circulating nurse** is mindful of this.
- 4 GRAB THE STERILE INTERFACES**
The **scrub nurse** grabs the Sterile Interfaces from the single-use accessories packaging



Figure 8: The sterile interface

- 5 INSPECT THE STERILE INTERFACES**
The **scrub nurse** visually inspects the Sterile Interfaces.
- 6 TEST THE SLIDERS OF THE STERILE INTERFACES**
The **scrub nurse** moves the sliders of the Sterile Interfaces to ensure that they function properly.
- 7 PLACE THE STERILE INTERFACES ON THE STERILE SURFACE**
The **scrub nurse** then places the Sterile Interfaces on the sterile surface.



5.4 INSTRUMENTS

The **circulating nurse** and the **scrub nurse** ensure that all required robotic instruments are present and in good condition.

Please note that instruments should be unpacked only when necessary, and at the surgeon's request. This best practice minimizes waste.

-
- 1

BRING THE INSTRUMENTS TO THE OPERATING ROOM

At the **surgeon's** request, the **circulating nurse** brings the robotic instruments to the operating room.

 - 2

CHECK THE INSTRUMENT PACKAGING

The **circulating nurse** checks the integrity of the packaging for damage.

 - 3

OPEN THE INSTRUMENT PACKAGING

The **circulating nurse** then opens the instrument packaging. Unpacking the instruments takes place in proximity to the sterile field and the **circulating nurse** is mindful of this.

 - 4

GRAB THE INSTRUMENT

The **scrub nurse** grabs the instrument from the single-use packaging.

 - 5

INSPECT THE INSTRUMENTS

The **scrub nurse** visually inspects the instruments for damage to the insulation, unintended rough surfaces, sharp edges, or protrusions

 - 6

PLACE THE INSTRUMENTS ON THE STERILE SURFACE

The **scrub nurse** then places the instruments on the sterile surface.
-

6 PREPARE AND DRAPE THE ROBOT

6.1 PREPARE AND DRAPE THE SURGEON CONSOLE

6.1.1 Drape the Surgeon Console as needed

The **scrub nurse** covers both Master Arms and the central pillar with Sterile Drapes. If the **scrub nurse** prefers, the **circulating nurse** can provide support for this task.

- 1

PLACE THE MASTER ARMS AT MAXIMUM HEIGHT AS NEEDED

The **circulating nurse** moves the Master Arms to maximum height
- 2

PREPARE THE MASTER ARMS FOR DRAPING AS NEEDED

The **circulating nurse** places the Master Arms into a position that facilitates draping.
- 3

GRAB THE MASTER ARM STERILE DRAPES AS NEEDED

The **scrub nurse** grabs the corresponding Sterile Drapes for the Master Arms (1/2) from the sterile surface.
- 4

COVER THE MASTER ARMS AS NEEDED

The **scrub nurse** covers the Master Arms with the Sterile Drapes.
- 5

GRAB THE CENTRAL PILLAR STERILE DRAPE AS NEEDED

The **scrub nurse** grabs the Sterile Drape for the central pillar from the sterile surface.
- 6

COVER THE CENTRAL PILLAR AS NEEDED

The **scrub nurse** covers the central pillar with the Sterile Drape.

6.1.2 Attach the Handle Grips

The **scrub nurse** attaches the Handle Grips to each Master Arm.

- 1

ATTACH THE HANDLE GRIPS TO THE HANDLES

For each of the Master Arms, the **scrub nurse** grabs a Handle Grip from the Accessory Tray.
- 2

REMOVE THE DRAPE CAP

For each of the Master Arms, the **scrub nurse** removes the drape cap (if applicable).
- 3

ATTACH THE HANDLE GRIP

For each of the Master Arms, the **scrub nurse** attaches the Handle Grip to the Handle Gimbal.

4

TEST GRIP MOVEMENT TO ENSURE THE HANDLE GRIPS FUNCTION PROPERLY

For each of the Master Arms, the **scrub nurse** grabs the Handle Grip (i.e., with their index finger and the thumb) and sequentially tests that all seven degrees of freedom of the Master Arm function smoothly (e.g., no pinching or stretching of the drape, no friction):

- Micro-movements: Handle Grip open / close, roll, yaw left / right, pitch up / down
- Macro-movements: Master Arm up / down, left / right, in / out

6.2 PREPARE AND DRAPE THE PATIENT CARTS

6.2.1 Prepare the Patient Cart for Draping

The **circulating nurse** prepares both Patient Carts for draping by positioning them in a predefined position.

1

EXTEND THE BOOM

For each of the Patient Carts, the **circulating nurse** extends the Boom to the fully extended position. To move the Boom, the **circulating nurse** pushes the Lateral Boom Movement Button on either the Proximal User Interface located on the Boom or the Distal User Interface located closer to the Hub. When the LEDs display a white blinking pattern, this indicates that the Boom is in movement. The brakes engage once the button is released.

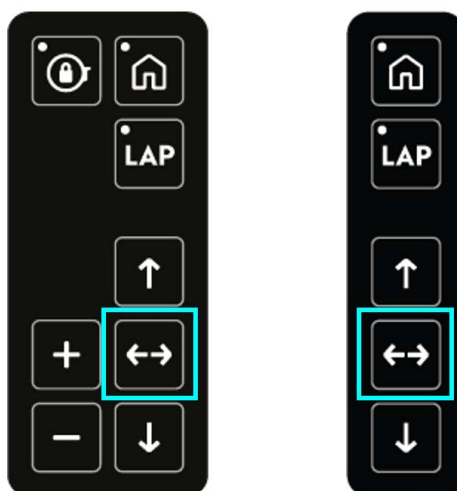


Figure 9: Proximal User Interface (left), Distal User Interface (right).

2

PLACE THE INSTRUMENT ARM INTO THE HOME POSITION

For each of the Patient Carts, the **circulating nurse** places the Instrument Arm into the home position by pushing the Home button continuously until the Instrument Arm has reached the home position and stops moving. When the LEDs display a white blinking pattern, this indicates either that homing is necessary, or that the Instrument Arm is moving toward the home position. When the LEDs are steady white, this indicates that the Instrument Arm is in home position.

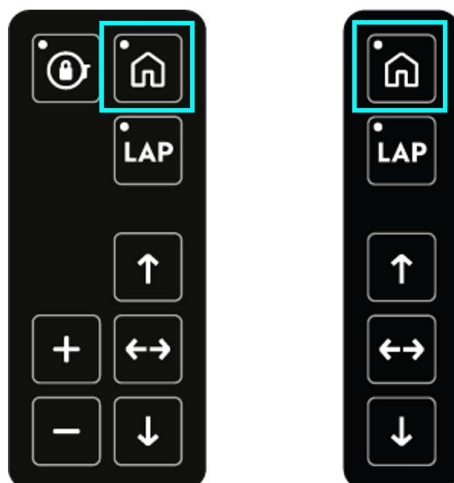


Figure 10: Proximal User Interface (left), Distal User Interface (right).

6.2.2 Cover the Patient Cart with a Drape

The **scrub nurse** covers both Patient Carts with Sterile Drapes. If the scrub nurse prefers, the circulating nurse can provide support for this task. Follow the sequence of tasks for one Patient Cart and then proceed to the other.

1

GRAB THE PATIENT CART STERILE DRAPE

The **scrub nurse** grabs a Patient Cart Sterile Drape from the sterile surface.

2

COVER THE PATIENT CART WITH STERILE DRAPE

The **scrub nurse** wraps the Sterile Drape over the Patient Carts, starting with the Hub and then pulling it all the way to the column. Red circular stickers on the Sterile Drapes should be placed on both openings of the Hub, with the wider sticker on front.

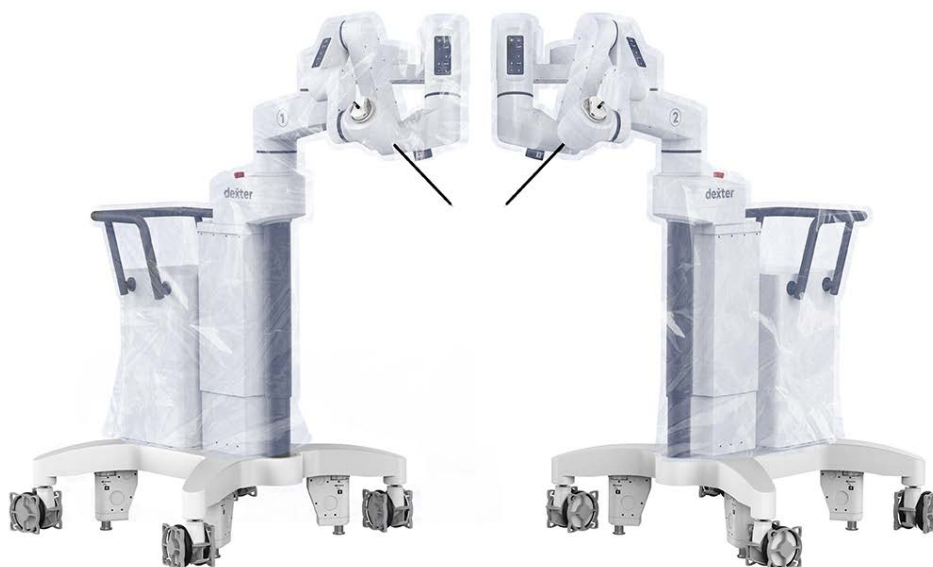


Figure 11: Draped Patient Carts



Figure 12: Front sticker



Figure 13: Rear sticker

3

REMOVE THE STICKERS

The **scrub nurse** pulls the flaps to remove the stickers, taking care not to touch the inner section of the stickers, the inside of the Sterile Drape or the inside of the Hub, as those are not sterile.

4

GRAB THE STERILE INTERFACE

For each of the Patient Carts, the **scrub nurse** grabs the Sterile Interface (consisting of two parts).

5

INSERT THE STERILE INTERFACES

To insert the Sterile Interfaces, the **scrub nurse** first inserts the longer part (1) into the lumen of the Hub on the proximal end. The circle pictograms printed on the Sterile Interface must align with the two corresponding holes on the Hub. Once the longer part is correctly inserted, the **scrub nurse** can insert the shorter part (2) on the distal end. Then, the **scrub nurse** will turn the shorter part clockwise (3). Finally, the **scrub nurse** will push the shorter part again (4).

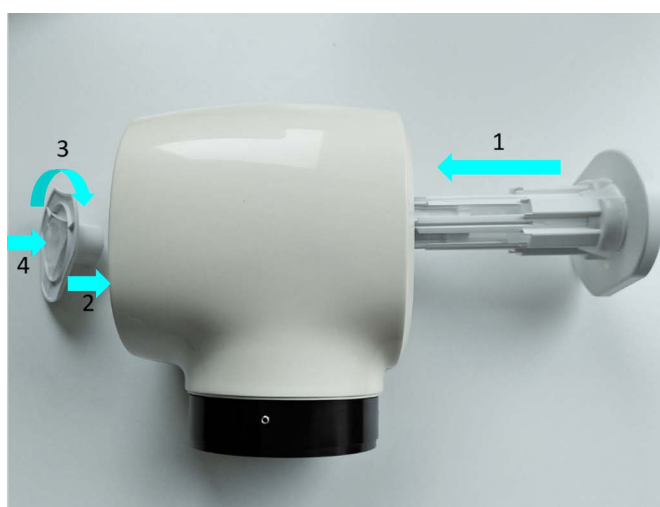


Figure 14: Sterile Interface Insertion Sequence



Figure 15: Sterile Interface Longer Part Alignment



During the clockwise rotation, if the distal part is excessively tightened, the translucent component will not produce a clicking sound when it is pressed down (refer to step 4 in the “Sterile Interface Insertion Sequence” image), and the user will not receive any haptic feedback. To secure the distal part (refer to step 3 in the “Sterile Interface Insertion Sequence” image) rotate by 45° but do not apply force. If resistance is felt, check that the sterile cover is fully inserted and that the Sterile Drape does not prevent full sliding in the Hub (refer to step 1 in the “Sterile Interface Insertion Sequence” image).

6

LOCK THE STERILE INTERFACES

Then the **scrub nurse** attaches and locks the smaller part from the proximal side so that both parts are attached to one another. The smaller part is locked by inserting it inside the Hub, rotating it clockwise and then pushing on the transparent part at the center until it clicks in place.



Figure 16: Sterile Interface Smaller Part Locking

6.2.3 Place the Patient Cart into Standby Position

The **scrub nurse** folds both Patient Carts into a compact configuration to minimize interference with other equipment or people present in the operating room

1

INSTRUMENT ARM IN COMPACT CONFIGURATION

For each of the Patient Carts, the **scrub nurse** pushes one of the Boom LAP Buttons until the Instrument Arm is in transport position.

2

BOOM IN COMPACT CONFIGURATION

For each of the Patient Carts, the **scrub nurse** then folds the Boom into a compact configuration. To move the Boom, the **scrub nurse** pushes the Lateral Boom Movement Button. When the LEDs display a white blinking pattern, this indicates that the Boom is in movement. The Lateral Boom Movement Buttons on the Proximal User Interface and the Distal User Interface and the compact Boom configuration are shown in the Figures below.

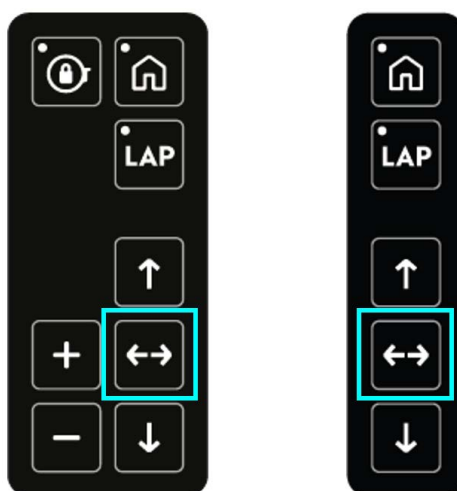


Figure 17: Lateral Boom Movement buttons on the Proximal User Interface (left) and on the Distal User Interface (right).



Figure 18: Compact Boom Configuration

6.3 PREPARE AND DRAPE THE ENDOSCOPE ARM [AS NEEDED]

The **scrub nurse** prepares the Endoscope Arm.

1

COVER THE ENDOSCOPE ARM

The **scrub nurse** covers the Endoscope Arm (and the Endoscope Cart if the Endoscope Arm is mounted on it) with the dedicated Sterile Drape.

The Endoscope Arm Sterile Drape is long enough to cover both the Endoscope Arm and the Endoscope Cart when the Endoscope Arm is mounted on the Endoscope Cart.

2

ATTACH THE ACCESSORIES

The **scrub nurse** attaches the accessories as per the Instructions for Use of the Dexter L6 System Endoscope Arm. If the **scrub nurse** prefers, the **circulating nurse** can provide support for this task.

7 POSITION AND DOCK THE DEXTER L6 SYSTEM FOR SURGERY

7.1 MOVE THE PATIENT CART TO THE PATIENT

The **surgeon** and the **scrub nurse** (or the **assistant**) move the Patient Carts to the patient to prepare docking.

- 1 INCREASE THE HEIGHT OF THE PATIENT CART AS NEEDED**

The **surgeon** increases the height of the Patient Carts to avoid collision of the Hub or the Instrument Arm with the patient. To increase the height of the Patient Carts, the **surgeon** pushes one of the Up Buttons and releases it when the desired height is reached.

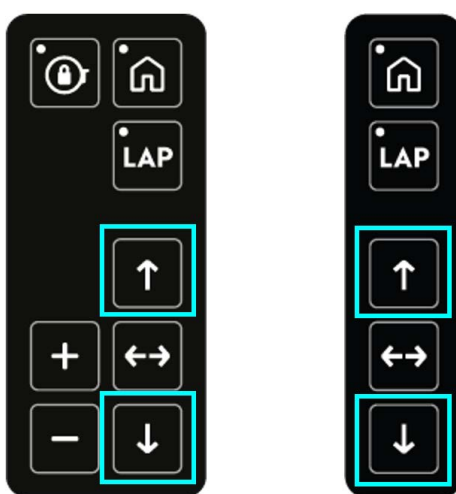


Figure 19: Up and Down Buttons on the Proximal User Interface (left) and the Distal User Interface (right).

- 2 DISENGAGE THE WHEEL BRAKES**

The **scrub nurse** (or the **assistant**) disengages the Wheel Brakes on the wheels of the Patient Carts.
- 3 MOVE THE PATIENT CARTS TO THE DESIRED LOCATION**

The **scrub nurse** pushes the Patient Carts to the intended location at the operating table, while being mindful of the cables between the Patient Carts and the Surgeon Console, as well as any other equipment and people in the operating room.
- 4 SUPERVISE THE PATIENT CARTS POSITIONING**

The **surgeon** supervises the positioning of the Patient Carts at the operating table, while being mindful of the cables between the Patient Carts and the Surgeon Console, as well as any other equipment and people in the operating room.
- 5 DEPLOY THE FLOOR LOCKS**

For each of the Patient Carts, the **scrub nurse** deploys the Floor Locks using the dedicated button located on the Proximal User Interface. When the Floor Lock Button light is blinking white, this indicates that either the Floor Lock is retracted or that it is in the process of moving to the fully deployed or fully retracted position. When the Floor Lock light is steady white, this indicates that the Floor Lock is deployed.



Figure 20: Floor Lock Button

NOTE

If the Floor Lock Button light turns yellow during deployment, check for any obstructions (e.g., cables) or uneven floors beneath the Patient Cart. Once the area is clear, press the Floor Lock button again to redeploy the Floor Locks.

6

UNFOLD THE BOOMS AND INSTRUMENT ARMS

The **surgeon** uses the Lateral Boom Movement, Up and Down Buttons to unfold the Instrument Arms.

7.2 SET THE FORWARD ANGULATION

The **surgeon** adjusts the Forward Angulation of the Instrument Arms to align the vertical workspace with the target anatomy.

1

SET THE FORWARD ANGULATION

The **surgeon** pushes the Forward Angulation Buttons to set the desired Forward Angulation.

NOTE

If needed, the Forward Angulation can be set before homing the Instrument Arms.

7.3 DOCK THE PATIENT CARTS TO THE TROCARS

The **surgeon** docks each Patient Cart to the corresponding trocar. Docking involves aligning the remote center of motion of the Patient Cart Instrument Arms with the trocars. Docking is achieved when the Incision Pointer is inside the translucent trocar in such a way that the tip of the Incision Pointer is just barely visible when looking at the trocar from the inside of the abdomen using an endoscope. Follow the sequence of tasks on one Patient Cart and then proceed to the other.

1

PLACE THE INCISION POINTER IN THE TROCAR

The **surgeon** places the Incision Pointer in the trocar, holding it with one hand. Their other hand is free to manipulate the Boom and Instrument Arm.

2

ALIGN THE INCISION POINTER WITH THE INSTRUMENT ARM MAGNET

The **surgeon** grabs the Boom and actuates the Lateral Boom Movement Button and the Patient Cart Up and Down Buttons in order to align the Instrument Arm Magnet with the Incision Pointer. Once the plate of the Incision Pointer and the Magnet of the Instrument Arm are parallel and connected to each other, they are considered aligned.

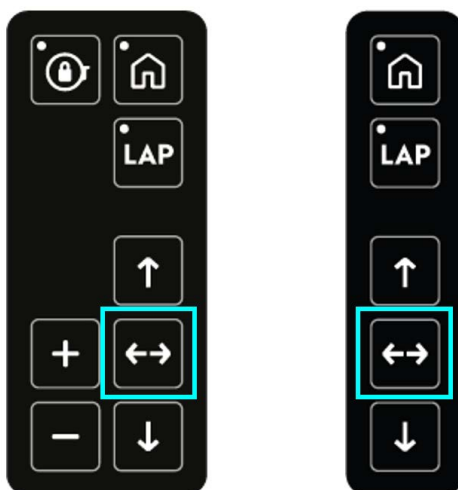


Figure 21: Lateral Boom Movement Buttons on the Proximal User Interface(left) and on the Distal User Interface (right)



If you notice any unexpected movement from Dexter, quickly press the emergency stop button.

3

INSERT THE INCISION POINTER INTO THE TROCAR

The **surgeon** actuates the Patient Cart Up and Down Buttons to insert the Incision Pointer into the trocar until the tip of the Incision Pointer becomes barely visible to the endoscope (i.e., the tip of the Incision Pointer ends up as close as possible to the fascia).

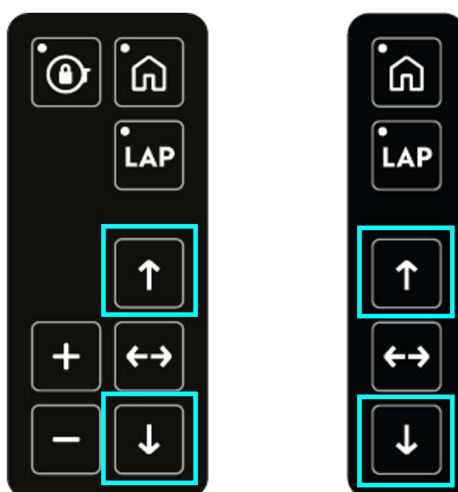


Figure 22: Up and Down Buttons on the Proximal User Interface (left) and the Distal User Interface (right)

-
- 4 **MONITORING THE DISTAL END OF THE TROCAR**
The **scrub nurse** assists the **surgeon** in this process by monitoring the distal end of the trocar with the endoscope.
 - 5 **REMOVE THE INCISION POINTER AFTER DOCKING**
The **surgeon** removes the Incision Pointer from the Instrument Arm and gives it to the **scrub nurse** who places it on the Accessory Tray.
 - 6 **PLACE THE INCISION POINTER ON THE STERILE SURFACE**
The **scrub nurse** places the Incision Pointer on the sterile surface.
-

7.4 POSITION AND DOCK THE ENDOSCOPE ARM

The **scrub nurse** and the **surgeon** position and dock the Endoscope Arm to the trocar. Then, the surgeon inserts the endoscope. All user actions involving the Endoscope Arm are carried out as per the Instructions for Use of the Dexter L6 System Endoscope Arm.

-
- 1 **POSITION THE ENDOSCOPE ARM**
In case the **surgeon** wants to operate the endoscope arm on the endoscope cart, the **scrub nurse** moves the endoscope cart to the desired position, engages the wheel brakes and sets the height of the cart so that the endoscope arm is about on the same height as if it was attached to the bed-rail.
-



Engage the Wheel Brakes of the Endoscope Cart once positioned for use.

-
- 2 **DOCK THE ENDOSCOPE ARM**
The **surgeon** docks the Endoscope Arm to the trocar using the Probe Pin.
 - 3 **INSERT THE ENDOSCOPE**
The **surgeon** inserts the endoscope into the trocar and attaches it to the Endoscope Arm.
-



8 OPERATE

8.1 INSERT AN INSTRUMENT

The **surgeon** inserts and locks the desired instrument in the Patient Cart. The surgeon can choose to insert and lock an instrument in just one Patient Cart or in each of the Patient Carts.



Monitor the instrument tip with the endoscope upon instrument insertion to avoid damaging tissue.

- 1 ENSURE THE PATIENT CART IS IN THE HOME POSITION FOR INSTRUMENT INSERTION**

Before inserting an instrument, the **surgeon** ensures that Patient Cart is in home position by pushing one of the Home Buttons on the Patient Cart until the Home Button turns steady white. Once the Patient Cart has reached the home position, the Hub light starts blinking.
- 2 ADJUST INSTRUMENT INSERTION POSITION ON THE INSERTION ZONE**

Once the home position is reached, the **surgeon** can press the LAP or Home Button to adjust the position of the Hub along a predefined insertion zone, as needed. When the Hub is on the insertion zone, the Home button is steady white and the Hub light is blinking white (i.e. instrument insertion is allowed).
- 3 HAND OVER THE INSTRUMENT**

At the **surgeon's** request, the **scrub nurse** gives the instrument to the **surgeon**.
- 4 ENSURE THAT THE INSTRUMENT TIP IS STRAIGHT**

When the **surgeon** has the instrument, it is important to ensure that the instrument tip is straight. The instrument must be straight in order to pass through the Hub and the trocar.
- 5 ENSURE THAT THE INSTRUMENT KNOB IS IN THE INSERTION POSITION**

Prior to inserting the instrument, the **surgeon** verifies that the instrument knob is in the insertion position, i.e., turned counterclockwise without any freedom to rotate.
- 6 PLACE IN THE INSERTION POSITION AS NEEDED**

If the insertion position has been lost, a maneuver should be performed to put it back into the insertion position, holding the shaft with one hand and rotating the knob counterclockwise until it makes a clicking sound.

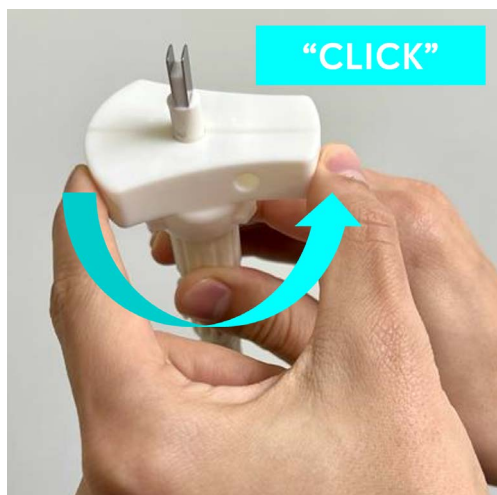


Figure 23: Instrument Knob Insertion Position

7

INSERT THE INSTRUMENT THROUGH THE HUB AND THE TROCAR

The **surgeon** carefully inserts the instrument through the Hub and the trocar, while making sure not to apply radial or flexural tension to the body wall or to the instrument.



Figure 24: Instrument Knob Instrument Insertion

8

MONITOR THE INSTRUMENT TIP

During instrument exchange, the **scrub nurse** shall monitor the instrument tip with the endoscope to avoid tissue damage.

9

LOCK INSTRUMENT IN HUB

The **surgeon** locks the instrument into the Hub by rotating the instrument clockwise while simultaneously holding the Sterile Interface and checking the endoscope monitor for any unintended instrument movement.



Figure 25: Instrument Locking

NOTE

A blinking white pattern on the Hub indicates that the instrument is authorized and can be locked. The instrument identifier in the RFID tag is checked by the Hub's RFID reader. A steady white pattern indicates that the instrument is locked and accepted, ready for instrument control. If the instrument is not accepted or recognized, a user warning will be displayed on the Hub via a steady yellow pattern. Refer to Appendix - Status Lights, for more detailed information.



If the instrument is bent or if it penetrates through the trocar into the abdomen during insertion, this indicates that the Patient Cart is not properly docked. Remove the instrument and verify docking with the Incision Pointer.

10

CONNECT ELECTROSURGICAL GENERATOR AS NEEDED

For those instruments requiring connection (e.g. monopolar and bipolar instruments) to an electrosurgical generator, the **surgeon** connects the proximal end of the instrument to the electrosurgical cabling.

11

INSTRUCT ELECTROSURGICAL GENERATOR MODE AND POWER AS NEEDED

For those instruments requiring connection (e.g., monopolar and bipolar instruments) to an electrosurgical generator, the **surgeon** instructs the **circulating nurse** to set the mode and power of the electrosurgical generator. The mode and power settings must comply with the Instructions for Use of the electrosurgical generator, and with the rated voltage limitations of the Dexter L6 System instruments.

12

SET MODE AND POWER OF THE ELECTROSURGICAL GENERATOR AS NEEDED

The **circulating nurse** sets the mode and power of the electrosurgical generator.



Use of bipolar techniques may be preferable in order to avoid unwanted tissue damage during surgical procedures where high-frequency current could flow through a relatively small cross-sectional area of body.



If any flammable agent is used (e.g., for cleaning, for disinfecting, or as solvents of adhesives) it must be allowed to fully evaporate before applying high-frequency surgical techniques.



If any flammable agent is used, there is a risk of pooling under the patient or in body depressions such as the umbilicus, or in body cavities such as the vagina.



If any fluids have pooled in body depressions and/or cavities, the fluids must first be removed before any high-frequency instruments can be used.



Endogenous gases are dangerous and pose an ignition hazard (e.g., cotton and gauze saturated with oxygen may be ignited by sparks produced during normal use of a high-frequency instrument).



8.2 ASSUME THE WORKING POSITION

The **surgeon** assumes the working position at the Surgeon Console and carries out the following adjustments and checks.

-
- 1

ADJUST THE HEIGHT OF THE STOOL AS NEEDED

The **surgeon** adjusts the height of the stool to ensure a comfortable working posture, as needed.

 - 2

ADJUST THE HEIGHT OF THE SURGEON CONSOLE

The **surgeon** adjusts the height of the Surgeon Console by pushing the Up or Down Button on Surgeon Console.

 - 3

ADJUST THE ORIENTATION OF THE SURGEON CONSOLE

The **surgeon** adjusts the orientation of the Surgeon Console to ensure an optimal view of the monitor and optimal use of the limited space in the operating room. To adjust the orientation, the **surgeon** disengages the Wheel Brakes, moves the Surgeon Console, and then reengages the Wheel Brakes.

 - 4

ENSURE THAT THE SURGEON CONSOLE PEDALBOARD IS POSITIONED

The **surgeon** ensures that the Pedalboard is positioned within comfortable reach when operating the Surgeon Console.

 - 5

HELP WITH PEDALBOARD POSITIONING

The **circulating nurse** may assist the **surgeon** in positioning the Pedalboard.

 - 6

ENSURE THAT THE ELECTROSURGICAL PEDALBOARD IS POSITIONED

The **surgeon** ensures that the Pedalboard to operate the electrosurgical instruments is positioned within reach when using the Surgeon Console.

 - 7

HELP WITH ELECTROSURGICAL PEDALBOARD POSITIONING

The **circulating nurse** may help the **surgeon** in positioning the Electrosurgical Pedalboard.
-

8.3 INSTRUMENT CONTROL

To begin replicating the movements made at the Surgeon Console, at least one of the Patient Carts must have an instrument locked. Then, the **surgeon** performs the following sequence of events.

- 1

GRAB THE HANDLE GRIP
The **surgeon** grabs the Handle Grip with their fingers.
- 2

ADJUST THE SCALING RATIO
The **surgeon** adjusts the scaling ratio according to their preference.

To adjust the scaling ratio, the surgeon presses and holds the Arms Lock Button while using the Height Adjustment Up or Down Button to increase or decrease the hand controls' sensitivity relative to the instruments. Three scaling ratios are available: Quick (1.5:1), Normal (2:1) and Fine (3:1). When the Arms Lock Button is held, the selected scaling ratio is displayed through a light pattern on the Height Adjustment Up and Down Buttons: 1 blink for Fine, 2 blinks for Normal and 3 blinks for Quick. By default (i.e., at each start of the system or restart from the Surgeon Console), the scaling ratio is set to "Normal".



- 3

INSTRUMENT CONTROL: GRAB THE HANDLE GRIPS AND PRESS THE CLUTCHING PEDAL
If the hub displays an active pattern (i.e. steady white light), the instrument control sequence can be performed: the **surgeon** presses and releases the clutching pedal while holding the Handle Grips.



4

PASS THE INSTRUMENTS THROUGH THE TROCAR

The **surgeon** carefully pushes the instrument into the patient while the assistant monitors the instrument tip with the endoscope using manual control.



If the Sterile Drape is getting trapped under the Sterile Interface in a way it affects the rotation of the Instrument, the Sterile Drape should be promptly replaced to avoid any unwanted emergency stops.

5

VERIFY THAT THE INSTRUMENTS MOVE AS EXPECTED

The **surgeon** verifies that the instruments move as expected by applying macro- and micro-movements to the Handle Grips and verifying that the instrument tips replicate those movements.

8.4 PERFORM THE SURGICAL TASKS

Once the instrument control sequence is completed, the **surgeon** can perform the surgical tasks.

1 OPERATE THE DEXTER L6 SYSTEM

Holding the Handles, the **surgeon** performs the surgical tasks.



If any of the Handle Grips are jammed in the closed position, the surgeon or scrub nurse should immediately press the Emergency Stop Button to prevent any unintended movement inside the patient. After the Emergency Stop has been triggered, the scrub nurse should proceed to replace the affected Handle Grip.



Ensure that the instrument tip remains clean, as eschar accumulation can diminish the instrument's performance and effectiveness.



To better grasp the needle during suturing, it is preferable to use the most distal part of the Needle Holder, i.e., 1 and 2, rather than 3 as shown in the Figure below.

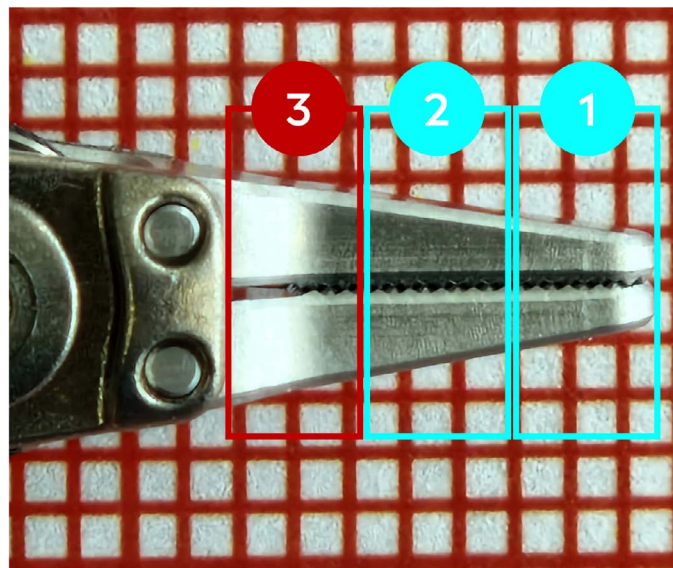


Figure 26: Needle Holder

2 MONITORS THE INSTRUMENT TIPS WITH THE ENDOSCOPE

While performing the surgical tasks, the **surgeon** monitors the tips of the instruments with the endoscope.

3 CLUTCHING AS NEEDED

When the Handles are not in an ergonomic position, the **surgeon** can perform clutching which temporarily pauses the motion replication, thus allowing the **surgeon** to place the Handles to a more ergonomic position. The detailed use case for clutching is described in its dedicated section.



4

ADJUST THE SURGICAL WORKSPACE AS NEEDED

When approaching a workspace limitation of the Dexter L6 System, the movement replication speed will gradually scale down. On the contrary, it will scale up while going away from the workspace limitation until reaching standard movement replication speed.

However, if a workspace limitation of the Dexter L6 System is reached, the **surgeon** has the option to adjust the Forward Angulation. This requires completing the surgical tasks and removing the instrument, and then adjusting the Forward Angulation, docking the Patient Cart again, and then resuming operations.



Regularly monitor the instrument shaft to ensure that it is not bent when operating with the Dexter L6 System. If the instrument shaft is bent, then the Patient Cart might not be properly docked anymore. Remove the instrument and repeat the docking procedure.



If any of the User Interfaces, hubs, or other sources from Dexter provide visual feedback with an unknown or inappropriate color or no color in the wrong context, the user must stop using Dexter immediately and contact a Distalmotion representative for assistance.

5

ADJUST THE ENDOSCOPE WORKSPACE AS NEEDED

When reaching a workspace limitation with the endoscope, the **surgeon** has the option to reposition and redock the Endoscope Arm. This does not require redocking the instruments.



Whenever feasible, avoid setups where the Hub is positioned below the horizontal level, and prevent instruments from being overly immersed in blood or other bodily fluids throughout the procedure.



Sterile Drape tears due to interactions between Instrument Arms or Endoscope Arm could cause breach of sterility.

8.5 CLUTCHING

To place the Handles into an ergonomic working position, the surgeon can temporarily stop the macro movement replication.

1

PRESS THE CLUTCHING FOOT PEDAL

The **surgeon** presses and keeps pressing the Clutching Foot Pedal. The Clutching Pedal applies to both Handles simultaneously.



Figure 27: Clutching Foot Pedal

2

REPOSITION THE HANDLES

The **surgeon** positions the Handles into a more ergonomic position.

3

RELEASE THE CLUTCHING FOOT PEDAL

Once the Handles are in an ergonomic position, the **surgeon** releases the Clutching Foot Pedal and continues performing the surgical tasks.

8.6 ENDOSCOPE CONTROL

To move the endoscope, and assuming the Endoscope Arm is installed, the surgeon can temporarily stop the movement of instruments so that the movement of the Handles moves the endoscope approximately proportionally.



Do not move the Endoscope Cart (this includes pushing it around on its wheels, and adjusting the height of the pillar) when an endoscope is attached to the Endoscope Arm.



The Endoscope Arm must be redocked when the patient or the Endoscope Cart moves after initial docking. Movement includes horizontal displacement with respect to the floor as well as height adjustments.

1

PRESS THE ENDOSCOPE FOOT PEDAL

The **surgeon** presses and keeps pressing the Endoscope Foot Pedal. This stops the movement of both instruments.

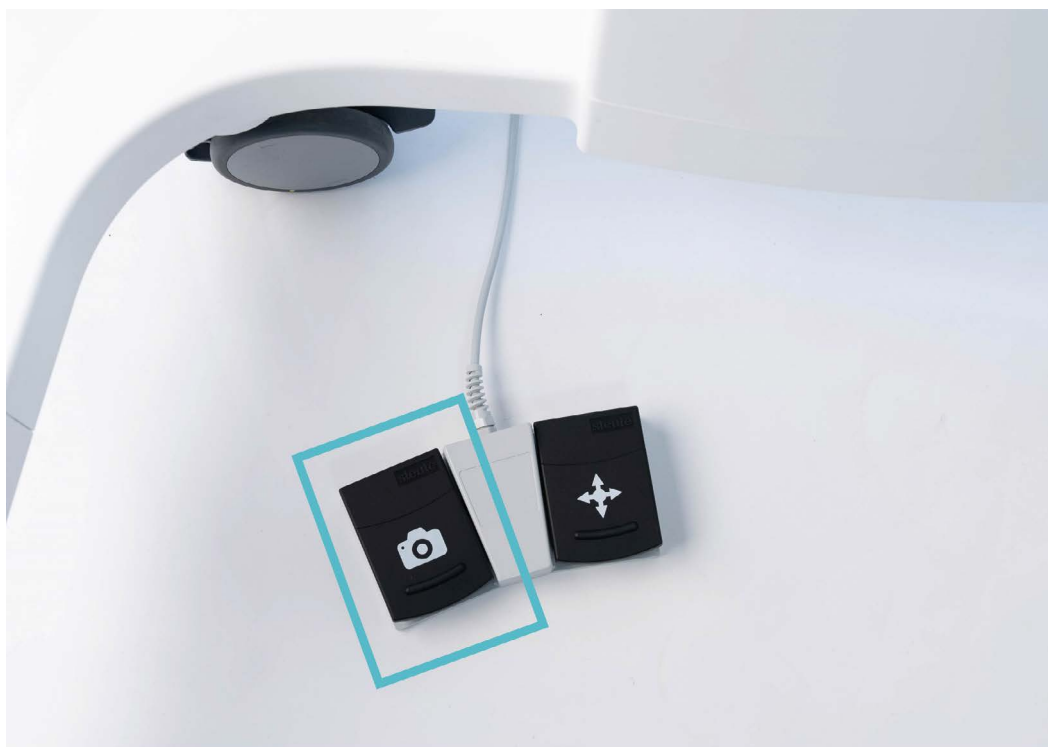


Figure 28: Endoscope Foot Pedal

2

MOVE THE HANDLES

The **surgeon** moves both Handles to move the Endoscope Arm.

3

RELEASE THE ENDOSCOPE FOOT PEDAL

Once the endoscope is in the desired position, the **surgeon** releases the Endoscope Foot Pedal and continues performing the surgical tasks.

8.7 WRAP-UP AND REMOVE (OR CHANGE) INSTRUMENTS

Once the surgical task is completed or when an instrument change is required, the surgeon follows the following sequence of actions.



if no homing is performed, before releasing the Handle Grips, make sure to place the instrument tips away from each other and away from any anatomical structure.

- 1 RETURN TO THE PATIENT**
The **surgeon** leaves the Surgeon Console and returns to the patient.
- 2 DISCONNECT THE ELECTROSURGICAL CABLE AS NEEDED**
For those instruments connected to the electrosurgical generator, the **surgeon** removes the cable.
- 3 UNLOCK THE INSTRUMENT**
The **surgeon** unlocks the instrument by rotating the instrument counterclockwise while holding the Sterile Interface and checking the endoscope monitor for any unintended instrument movement.
- 4 RETRACT THE INSTRUMENT**
The **surgeon** carefully retracts the instrument and gives it to the **scrub nurse** who places it on the sterile surface.
- 5 TAKE THE INSTRUMENT**
The **scrub nurse** takes the instrument and places it on the sterile surface.

8.8 SINGLE INSTRUMENT CONTROL

When needed for specific surgical tasks (e.g., suturing), the surgeon may choose to lock a single instrument in one Patient Cart and control only that Patient Cart with the locked instrument.

- 1 OPERATE THE DEXTER L6 SYSTEM IN SINGLE INSTRUMENT CONTROL**
Holding the two Handle Grips, the **surgeon** performs the surgical tasks in Single Instrument Control.
- 2 ENDOSCOPE CONTROL IN SINGLE INSTRUMENT CONTROL**
The **surgeon** takes the control of the Endoscope Arm (i.e. presses and keeps pressing the Endoscope Foot Pedal) while only one instrument is locked (i.e. Single Instrument Control). Once the endoscope is in the desired position, the **surgeon** releases the Endoscope Foot Pedal and continues performing the surgical tasks.

9 SWITCH TO LAPAROSCOPY

9.1 SIMPLE METHOD: FOLD AN INSTRUMENT ARM TO LAPAROSCOPY MODE

The switch to laparoscopy mode is rapid and keeps the Patient Carts docked to the trocars.

- 1

REMOVE THE INSTRUMENTS

The **surgeon** removes the instruments as described in section 8.7 - Wrap-Up and Remove (or Change) Instruments.
- 2

FOLD THE INSTRUMENT ARMS

The **surgeon** pushes one of the LAP Mode Buttons to free-up space for the **surgeon** to access the trocars using standard laparoscopic instruments. While pushing the LAP Mode Button, the **surgeon** monitors the patient and ensures that the Instrument Arms do not come into contact with the patient or other instruments. When the LEDs display a white blinking pattern, this indicates that the Instrument Arms are moving toward the laparoscopic position. The LAP Mode Buttons on the Proximal User Interface and the Distal User Interface are shown in the Figure below.

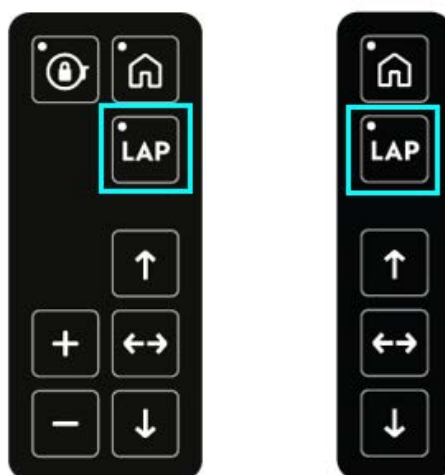


Figure 29: LAP Mode Buttons on the Proximal User Interface (left) and the Distal User Interface (right)

- 3

USE LAPAROSCOPIC INSTRUMENTS

Once the Instrument Arms are in the “LAP” position, the **surgeon** can access the trocars using laparoscopic instruments.
- 4

RETURN TO ROBOTICS MODE

To return to robotics mode, the **surgeon** removes the laparoscopic instrument, presses the Home button continuously until the Instrument Arm stops moving. Then, the **surgeon** resumes operating the Dexter L6 System following the related instructions in section 8 - Operate.

9.2 ADVANCED METHOD: UNDOCKING

When the “Fold Instrument Arm” function is not sufficient for the surgeon to operate in laparoscopy mode, the surgeon can undock the Patient Carts and move them to the side.

- 1

REMOVE THE INSTRUMENTS FOR UNDOCKING

The **surgeon** removes the instruments as described section 8.7 - Wrap-Up and Remove (or Change) Instruments.
- 2

FOLD THE INSTRUMENT ARMS

The **surgeon** folds the Instrument Arms as described in “Simple Method: Fold an Instrument Arm to Laparoscopy Mode”.
- 3

MOVE THE INSTRUMENT ARMS AWAY

The **surgeon** grabs the Instrument Arms or the Booms and moves the Instrument Arms away from the surgical field using one of the Lateral Boom Movement Buttons.

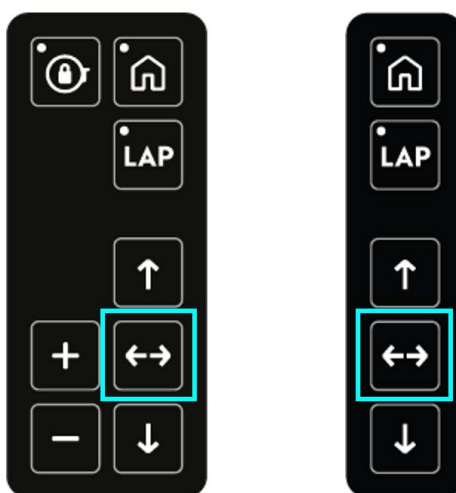


Figure 30: Lateral Boom Movement Buttons on the Proximal User Interface (left) and on the Distal User Interface (right)

- 4

USE LAPAROSCOPIC INSTRUMENTS

Once the Instrument Arms have been moved away, the **surgeon** can access the trocars using laparoscopic instruments.
- 5

RETURN TO ROBOTICS MODE

To return to robotics mode, the **surgeon** removes the laparoscopic instrument and places it on the sterile surface, putting the Instrument Arms back in robotic mode.
- 6

REDOCK THE INSTRUMENT ARMS

The **surgeon** docks the Patient Carts to the trocars and then resumes operation of the Dexter L6 System.

10 SAFETY STOPS

10.1 RESUME USE AFTER PROTECTIVE STOPS

The Dexter L6 System enters into a Protective Stop when a temporary system issue occurs or when the system determines that the user behavior is potentially harmful. All movements stop to avoid potential harm to the patient or the operator. A Protective Stop is indicated by the lights of the Hubs turning steady yellow for a few seconds.

1

RESUME USE AFTER PROTECTIVE STOP

To resume using the Dexter L6 System after a Protective Stop, the **surgeon** grabs both Handle Grips and presses on the Clutching Foot Pedal.

10.2 RESUME USE AFTER EMERGENCY STOPS

The Dexter L6 System enters into an Emergency Stop when a permanent system issue occurs or when an Emergency Stop Button is pressed. All movements stop to avoid potential harm to the patient or the operator. An Emergency Stop is indicated by the lights of the Patient Carts blinking red.

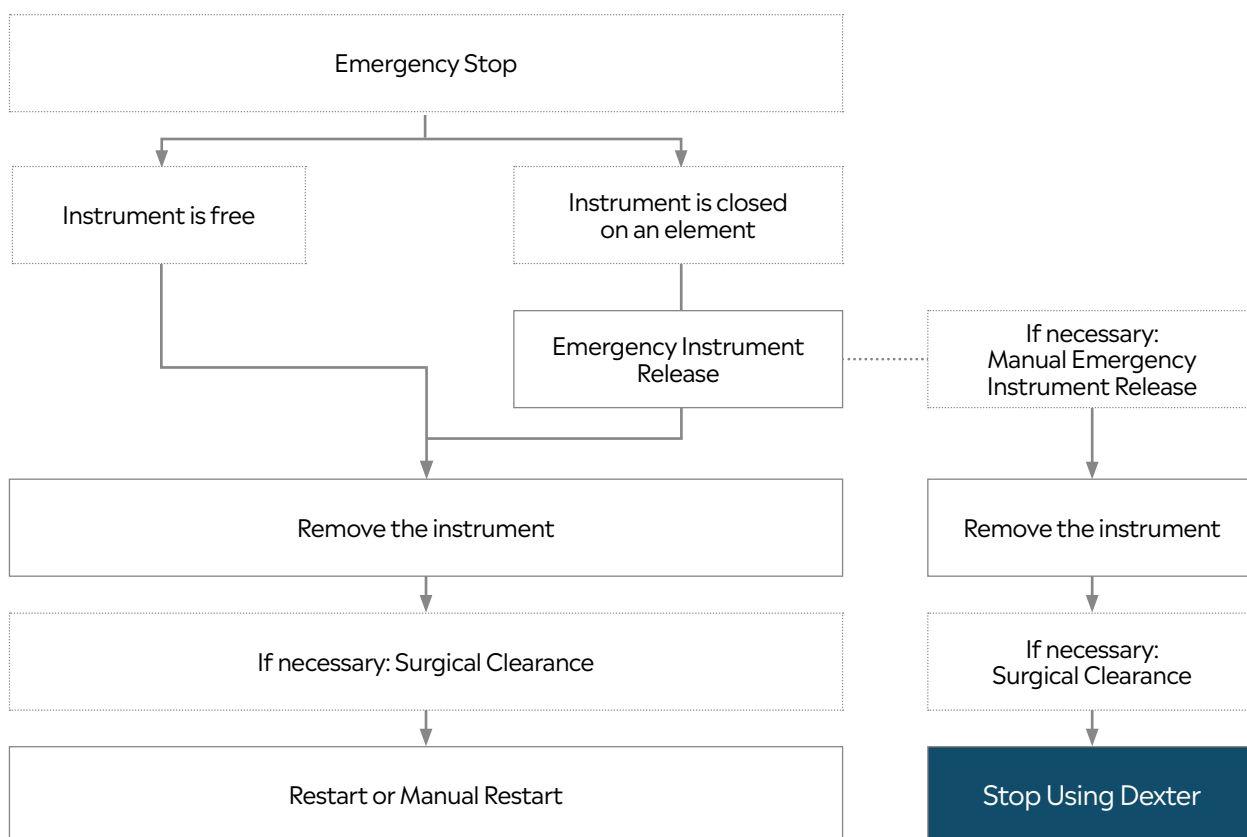


Figure 31: Emergency Stop Procedure

1 VERIFY THAT THE INSTRUMENT IS FREE FROM ANY TISSUE, SUTURES, NEEDLES OR OTHER SURGICAL TOOLS

The **surgeon** verifies that the instrument is unobstructed (with no tissue, sutures, needles or any other surgical tools between its blades). This is to ensure that instrument rotation and/or removal would not harm the patient.

2 IF THE INSTRUMENT IS FREE: REMOVE THE INSTRUMENT

The **surgeon** removes the instrument as described for normal use.

3 IF THE INSTRUMENT IS CLOSED ON AN ELEMENT: EMERGENCY INSTRUMENT RELEASE

If the instrument is closed, with tissue, sutures, needles, or any other surgical tools between its blades, then the instrument removal could cause harm to the patient. To prevent harm to the patient, the **surgeon** must execute the following steps:

1. Restart the system from the Surgeon Console by pressing the Arms Lock Button and the Up Button on the Surgeon Console simultaneously during 2 seconds.
2. Wait while the system successfully restarts.
3. Verify that there are yellow steady lights on the Hubs.
4. Take the Handle Grips and close their paddles.
5. Clutch to initiate actuation replication.
6. Gradually open the paddles to open the blades of the instrument so that the tissue is released.
7. Clutch to block the actuation replication.
8. The instrument can then be retracted from the patient.

4 MANUAL EMERGENCY INSTRUMENT RELEASE AS NEEDED

Should the **surgeon** be unable to execute the Emergency Instrument Release, the Emergency Release Tool may be used. This tool manually expands the instrument's blades, thereby liberating the trapped element, and allowing the instrument to be safely withdrawn from the patient.

For the correct use of the Emergency Release Tool, the **surgeon** should firmly hold the Hub with one hand while maneuvering the Emergency Release Tool with the other hand. Subsequently, the **surgeon** will puncture the designated circular area marked with a screwdriver symbol. Finally, the **surgeon** will rotate the Emergency Release Tool clockwise until the entrapped element is successfully dislodged.

Following the use of the Emergency Release Tool, the Dexter L6 System should no longer be used.



Figure 32: Emergency Release Tool and Sterile Interface

**NOTE**

In the event that the surgeon chooses to proceed with the operation after using the Emergency Release Tool (ERT), another sterile Emergency Release Tool shall be available. To maintain the sterility of the device, replace any disposables that have been affected by the Manual Emergency Instrument Release.



While performing the Manual Emergency Instrument Release, avoid applying excessive force that might damage the Hub during the Sterile Interface puncture.



Avoid manually rotating the Hub while manipulating the instrument. Always hold the Sterile Interface to avoid instrument rotation.

5

SURGICAL SPACE CLEARANCE

If immediate access to the patient is required and the Dexter L6 System is either powered off or in an Emergency Stop state, the **surgeon** or the nurse can push the boom aside to get access to the surgical site. However, this requires applying significant force to the distal segment of the boom in order to override the mechanical brakes. Before doing so, it is important to ensure that there is sufficient space available next to the patient to move the boom safely.

11 CHANGE POSITION OR ACCESS

During a more complex surgery, the Dexter L6 System might have to be docked to a first set of trocars, and then to a second set of trocars. In other situations, the patient position might have to be changed (e.g. from forward to reverse Trendelenburg, or the height of the operating table might have to be adjusted). The following sequence of actions can be adapted to each of these scenarios:

1. Remove the instruments and the endoscope.
2. If, as needed, reposition the patient or the operating table, and prepare the new set of trocars.
3. If, as needed, move the Patient Carts and, if used, the Endoscope Arm.
4. Dock the Patient Carts and, if used, the Endoscope Arm.
5. Resume operation.

12 REMOVE THE ROBOT

12.1 REMOVE THE ENDOSCOPE ARM AND CART

After use, the **surgeon**, the **scrub nurse** and the **circulating nurse** remove the Endoscope Arm and the Endoscope Cart from the patient, thereby following the Instructions for Use of the Dexter L6 System Endoscope Arm.

- 1 REMOVE THE ENDOSCOPE**
The **surgeon** removes the endoscope from the Endoscope Arm.
- 2 REMOVE THE ENDOSCOPE ARM**
The **scrub nurse** unmounts, undrapes, unplugs and moves the Endoscope Arm away from the patient.
- 3 PLACE THE ENDOSCOPE ARM ONTO THE ENDOSCOPE CART AS NEEDED**
When it is attached to the bedrail, the **scrub nurse** places the Endoscope Arm onto the Endoscope Cart.
- 4 REMOVE THE ACCESSORIES FROM THE ENDOSCOPE ARM**
Then, the **scrub nurse** removes the accessories from the Endoscope Arm and puts them back on the Accessory Tray.
- 5 REMOVE THE ENDOSCOPE CART**
The **circulating nurse** removes the Endoscope Cart by disengaging the Wheel Brakes and moving the Endoscope Cart to storage.

12.2 PUT THE PATIENT CARTS INTO COMPACT CONFIGURATION

When the Dexter L6 System is no longer used, the **surgeon**, the **scrub nurse** and the **circulating nurse** put the Patient Carts into Compact Configuration.

- 1 RELEASE AND/OR RETRACT THE FLOOR LOCKS AND DISENGAGE THE WHEEL BRAKES**
The **surgeon** retracts the Floor Locks using the Floor Lock Button and disengages the Wheel Brakes. If the Floor Lock light is off, the Floor Lock is released or fully retracted.



Figure 33: Floor Lock Button

IMPORTANT

If the **surgeon** cannot retract the Floor Locks using the dedicated button, he / she can use the manual wheel located on the Floor Lock to release it manually.

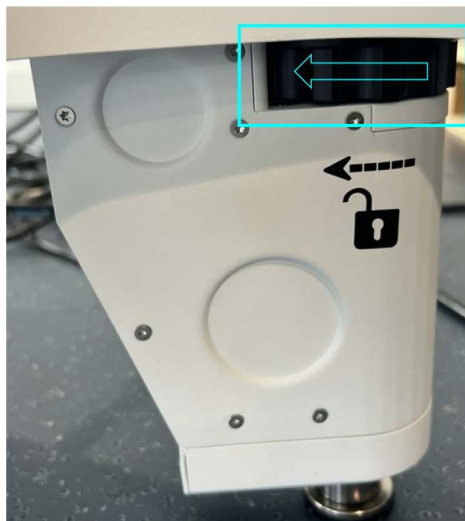


Figure 34: Manual Floor Lock Wheel



While using the Manual Floor Lock Wheel during a manual Floor Lock release, do not fully retract the Floor Lock, but only retract it a few millimeters from the ground, as needed to move the Patient Cart.

- 1 INCREASE THE HEIGHT OF THE PATIENT CART AS NEEDED**
The **surgeon** increases the height of the Patient Cart to avoid contact between the Instrument Arm and the patient during removal of the Patient Cart.
- 2 MOVE THE PATIENT CARTS AWAY FROM THE PATIENT**
The **surgeon** carefully moves the Patient Carts away from the patient.
- 3 REMOVE AND DISCARD THE STERILE INTERFACES**
The **scrub nurse** unmounts the Sterile Interface by:
 - Compressing the lock mechanism to release its grip.
 - Gently pulling the lock away from the Sterile Interface.
 - Rotating the far end (distal part) of the Sterile Interface counterclockwise to disengage it.
 - Carefully pulling the distal part away from the device.
 - Finally, removing the near end (proximal part) by pulling it away as well.

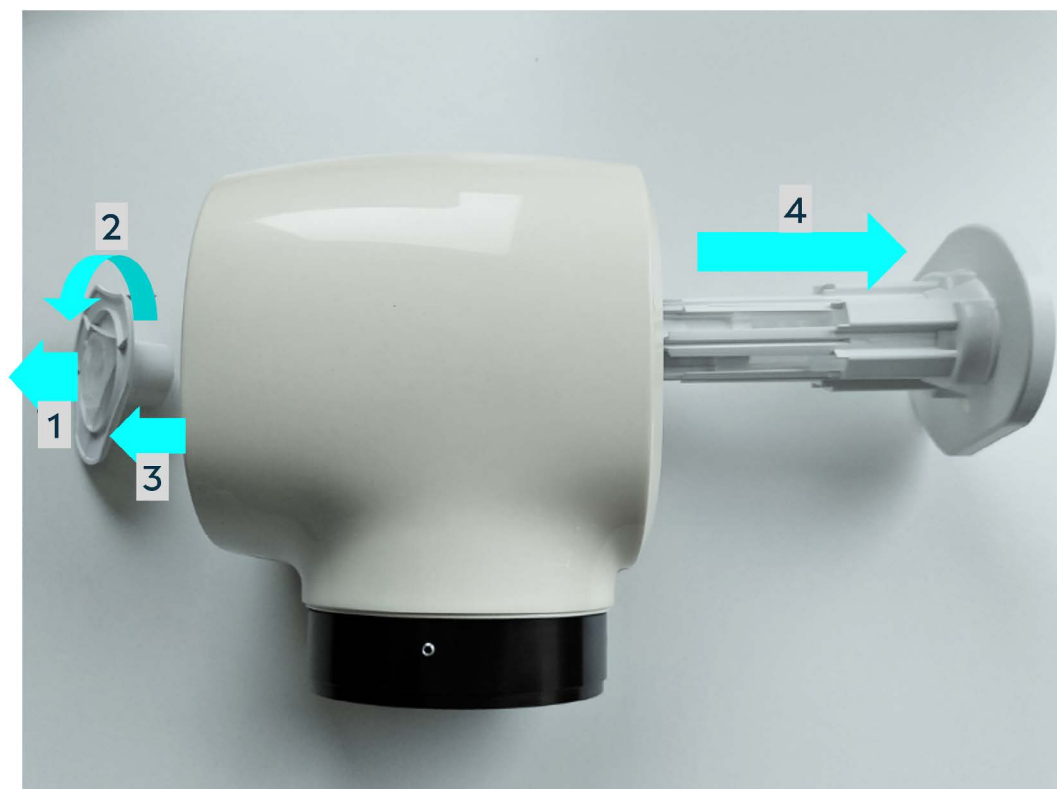


Figure 35: Removing the Sterile Interface



Figure 36: Step 1 of removing the Sterile Interface



If needed the scrub nurse or the circulating nurse can cautiously use a tool (e.g. the Emergency Release Tool) to facilitate Sterile Interface removal.

4

INSPECT THE STERILE INTERFACE EXTERIOR FOR ANY FLUID INFILTRATION

Once the Sterile Interface is detached, the **scrub nurse** should inspect it for fluid infiltration.

5

DISPOSE OF THE STERILE INTERFACES

Then the **scrub nurse** safely disposes of the Sterile Interfaces in accordance with protocol.

6

CHECK THE HUBS FOR FLUID INFILTRATION

The **scrub nurse** inspects both Hubs for fluid infiltration.

7

REMOVE THE STERILE DRAPES

The **scrub nurse** removes the Sterile Drapes.

If any liquids or bodily fluids get inside the Dexter L6 System, contact Distalmotion.

8

DISCARD THE STERILE DRAPES

The **scrub nurse** discards the Sterile Drapes.

9

PUT THE PATIENT CARTS INTO COMPACT CONFIGURATION

The **scrub nurse** places the Patient Cart into compact configuration by putting the Forward Angulation at 0°, by pushing one of the “LAP” Mode Buttons and then, by pushing one of the Lateral Boom Movement Buttons until the Instrument Arm is in the transport position. The **scrub nurse** then folds the Boom into the transport position and puts it to minimum height. Note: the Patient Cart is not switched off at this step, because all units have to be switched off at the same time. The Patient Cart will be switched off, unplugged and stowed away at the same time as the Surgeon Console.



Figure 37: Example of compact boom configuration



12.3 PUT THE SURGEON CONSOLE INTO TRANSPORT POSITION

When the Dexter L6 System is no longer used, the scrub nurse and the circulating nurse put the Surgeon Console into the transport position.

- 1

REMOVE THE HANDLE GRIPS

The **scrub nurse** removes the Handle Grips and places them on the Accessory Tray.
- 2

REMOVE THE STERILE DRAPES

The **scrub nurse** removes the Sterile Drapes covering the Master Arms and the central pillar.
- 3

DISCARD THE STERILE DRAPES

The **scrub nurse** discards the Sterile Drapes covering the Master Arms and the central pillar.
- 4

POSITION BOTH MASTER ARMS WITHIN THE WHEELBASE PERIMETER

The **scrub nurse** positions both Master Arms within the Wheelbase perimeter, protecting them during transport.
- 5

POSITION THE MASTER ARMS AT MINIMUM HEIGHT AS NEEDED

The **scrub nurse** puts the Master Arms at minimum height using the Up or Down Button on the Surgeon Console.
- 6

POWER OFF THE SURGEON CONSOLE

The **circulating nurse** turns off the Surgeon Console.
- 7

UNPLUG THE PATIENT CARTS FROM THE SURGEON CONSOLE

The **circulating nurse** unplugs the Patient Carts from the Surgeon Console and stows-away the connecting cables.
- 8

UNPLUG THE SURGEON CONSOLE FROM THE MAINS POWER SUPPLY

The **circulating nurse** unplugs the Surgeon Console from the mains power supply and the potential equalization plug and stows away the power cable.
- 9

STOW AWAY THE SURGEON CONSOLE PEDALBOARD

The **circulating nurse** stows away the Surgeon Console Pedalboard.
- 10

DISENGAGE THE WHEEL BRAKES

The **circulating nurse** disengages the Wheel Brakes of the Surgeon Console.
- 11

POWER ON THE SURGEON CONSOLE IN STANDALONE MODE TO ENABLE UP, DOWN AND ARM LOCK BUTTONS AS NEEDED

The **circulating nurse** checks that the Patient Carts are not connected and powered on before using the Power Switch on the Surgeon Console. Then, the **circulating nurse** confirms that it is powered on by checking that either the Power Switch light or the Emergency Stop Button light is on.

12.4 REMOVE THE ACCESSORIES

The circulating nurse places the following reusable accessories in the Accessory Tray.

- 1 **PLACE HANDLE GRIPS IN THE ACCESSORY TRAY**
The **circulating nurse** places the contaminated Handle Grips in the Accessory Tray.
- 2 **PLACE INCISION POINTERS IN THE ACCESSORY TRAY**
The **circulating nurse** places the contaminated Incision Pointers in the Accessory Tray.
- 3 **PLACE EMERGENCY RELEASE TOOL IN THE ACCESSORY TRAY**
The **circulating nurse** places the potentially contaminated Emergency Release Tool in the Accessory Tray.
- 4 **CLOSE THE ACCESSORY TRAY**
The **circulating nurse** closes the Accessory Tray and prepares it for reprocessing.

12.5 REMOVE THE ROBOT FROM THE OPERATING ROOM

Remove the robot from the operating room.

The **circulating nurse** removes the robot from the operating room.

- 1 **STOW AWAY CABLES OF THE SURGEON CONSOLE**
The **circulating nurse** ensures that the Clutching Pedal and the power cord to connect the SC are properly stowed away, and that the **surgeon** console is not connected to any other device such as a patient cart.
- 2 **DISENGAGES THE WHEEL BRAKE OF THE SURGEON CONSOLE**
The **circulating nurse** disengages the wheel brake of the Surgeon Console.
- 3 **PUSHES THE SURGEON CONSOLE INTO THE STORAGE LOCATION**
The **circulating nurse** pushes the Surgeon Console into the storage location.
- 4 **ENGAGE WHEEL BRAKES OF THE SURGEON CONSOLE**
The **circulating nurse** engages the wheel brake of the Surgeon Console (i.e. the mechanical brakes at each of the four wheels).
- 5 **STOW AWAY CABLES OF THE PATIENT CARTS**
The **circulating nurse** ensures that the data and power cords of the Patient Carts are properly stowed away.
- 6 **DISENGAGE THE WHEEL BRAKE OF THE PATIENT CARTS**
The **circulating nurse** disengages the wheel brake of the Patient Carts (i.e. the mechanical brakes of the wheels).
- 7 **PUSH THE PATIENT CARTS INTO STORAGE LOCATION**
The **circulating nurse** pushes the Patient Carts from the operating room into storage location.
- 8 **ENGAGE THE WHEEL BRAKE OF THE PATIENT CARTS**
The **circulating nurse** engages the wheel brake of the Patient Carts (i.e. the mechanical brakes on the wheels).



13 SYSTEM MAINTENANCE

13.1 CLEANING THE ROBOT

Surgeon Console, Patient Carts, Endoscope Cart and System Cables

Use a soft, lint-free cloth and a surface disinfectant product (or a disinfectant wipe) to wipe the exterior surfaces of the system components and cables at the frequency required by individual hospital policy.

The following disinfectants may be used: Envirocide®, CaviCide® and 70% isopropyl alcohol. Consult the manufacturer's Instructions for Use to ensure that the agent is compatible.

Allow components to fully dry before use.

Follow your facility's protocol for appropriate cleaning of non-critical medical equipment.

Wipe all exterior surfaces of the Patient Carts, Surgeon Console and Endoscope Cart until visually clean.

Pay special attention to areas where the operator comes into contact with the system, such as the Handles of the Surgeon Console and the Armrests and to areas that are not covered by the Sterile Drapes such as the Patient Cart Wheelbase, the Floor Locks, the cables and the Pedalboard.

If it is not possible to clean the Dexter L6 System properly or if any liquids, including bodily fluids, get inside the system, follow your facility's protocol for the handling of blood and bodily fluids and contact Distalmotion Technical Support at:



+12167442602



support@distalmotion.com



The Surgeon Console and the Patient Carts are not designed for exposure to liquids. Do not spray liquids while disinfecting the Robot or add disinfectant products to disinfectant wipes. Special care should be taken to ensure that liquids do not come in contact with electronic equipment on the system components (specifically the internal surface of the Hubs).

13.2 PREVENTIVE MAINTENANCE

Preventive maintenance is required and must be performed at least after every 12 months by Distalmotion service personnel pursuant to the Dexter L6 System Service Manual. Do not perform servicing or maintenance work on your own.

For Technical Support

If the Dexter L6 System requires maintenance or service, contact Distalmotion Technical Support at:



+12167442602



support@distalmotion.com

14 TRANSPORT OF THE DEXTER L6 SYSTEM



In these Instructions for use, the term transport refers to the process of relocating all or some system components within the hospital premises. Do not transport the Dexter L6 System outside hospital premises.

If you need to relocate the Dexter L6 System outside hospital premises, contact Distalmotion Technical Support at:



+12167442602



support@distalmotion.com

15 ACCESSORIES REPROCESSING



Do not use washer-disinfectors that are not compliant with ISO 15883.



Enclose the Accessory Tray in standard sterilization wrap according to the manufacturer's instructions.



The Handle Grips, Incision Pointers and Emergency Release Tool should only be reprocessed by using the dedicated Accessory Tray and by respecting the designated location for each accessory. No other accessories, aside from those specified, should be reprocessed using the Accessory Tray.



The accessories should be handled and operated by trained personnel. Handle with care. Avoid any mechanical shocks or stress that can cause damage to the device!



The reprocessing of the reusable accessories must start within 60 minutes after the procedure. It is recommended that the accessories are reprocessed as soon as possible after use. Do not allow blood or residual tissue to dry on the accessories.



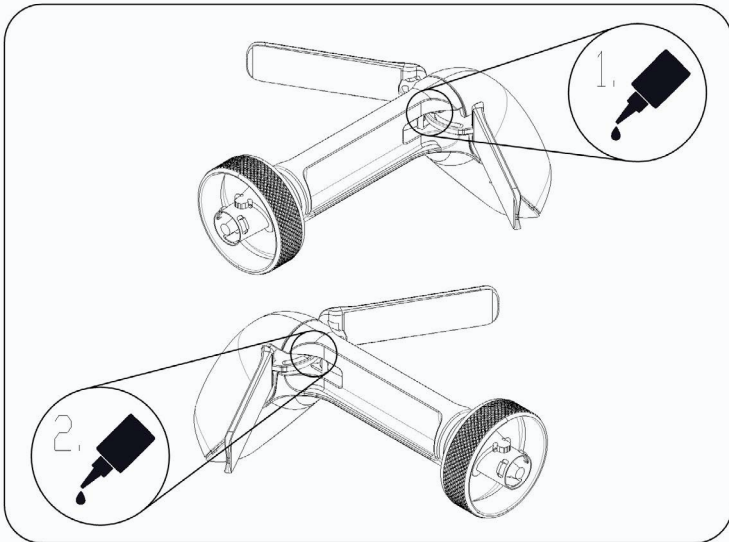
The instructions have been validated by Distalmotion as being capable of preparing the reusable accessories of the Dexter L6 System for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

15.1 DETAILED INSTRUCTIONS

STEP	INSTRUCTIONS
Initial treatment at the point of use:	Remove contamination: Wipe or rinse with water to remove visible blood or other bodily liquids/substances. Prepare for transport: Place the Handle Grips with open paddles, the Incision Pointers and the Emergency Release Tool at the appropriate place in the Accessory Tray according to the drawing on the top metallic plate, and close the Accessory Tray.
	
	Note: Handle Grips should be placed with open paddles in the Accessory Tray.
Preparation for automated cleaning:	● Rinse the accessories with cold tap water. ● Remove the accessories from the Accessory Tray and remove any visible stains and debris with a soft brush. Take special care to remove any soiling substances that could be on the support system of the Accessory Tray (blue silicone parts). ● Inspect the accessories for any residue. If there is residue, remove the debris and rinse again. ● Place the pre-cleaned accessories on the Accessory Tray and then close it. No disassembly or testing procedures are required prior to cleaning.



STEP	INSTRUCTIONS																														
Automated cleaning:	Automated cleaning must be performed with a washer-disinfector compliant with the ISO 15883 standard. The table below provides the minimum settings recommended for the washer-disinfector: <table><tr><th>Steps</th><th>Time</th><th>Temperature</th><th>Chemical</th><th>Water</th></tr><tr><td>Pre-Rinse</td><td>2 min</td><td>68°F (20°C)</td><td>-</td><td>Tap Water</td></tr><tr><td>Wash</td><td>10 min</td><td>104°F (40°C)</td><td>Mildly-alkaline, enzymatic, detergent diluted per the manufacturer's instructions (neodisher® MediClean Forte)</td><td>Tap Water</td></tr><tr><td>Rinse</td><td>2 min</td><td>68°F (20°C)</td><td>-</td><td>Tap Water</td></tr><tr><td>Thermal Disinfection</td><td>5 min</td><td>194°F (90°C)</td><td>Optional: Rinse aid, diluted per the manufacturer's instructions (neodisher® Mediklar)</td><td>Deionized</td></tr><tr><td>Drying</td><td>20 min</td><td>212°F (100°C)</td><td>-</td><td>-</td></tr></table> Other solutions or rinse aids can be used in the following pH range: 5.7-10.8.	Steps	Time	Temperature	Chemical	Water	Pre-Rinse	2 min	68°F (20°C)	-	Tap Water	Wash	10 min	104°F (40°C)	Mildly-alkaline, enzymatic, detergent diluted per the manufacturer's instructions (neodisher® MediClean Forte)	Tap Water	Rinse	2 min	68°F (20°C)	-	Tap Water	Thermal Disinfection	5 min	194°F (90°C)	Optional: Rinse aid, diluted per the manufacturer's instructions (neodisher® Mediklar)	Deionized	Drying	20 min	212°F (100°C)	-	-
Steps	Time	Temperature	Chemical	Water																											
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Drying	20 min	212°F (100°C)	-	-																											
Disinfection:	No additional disinfection is required.																														
Drying:	To speed up reprocessing, the Handle Grips may be dried using pressurized air.																														
Visual Inspection:	The following criteria should be taken into consideration when inspecting the accessories listed below: - Incision Pointer: verify that there is no deformation or surface alteration (corrosion, stains, degraded marking). - Accessory Tray: verify that there is no deformation or surface alteration (corrosion, stains, degraded marking). - Handle Grip: verify there is no deformation, damaged part, surface alteration (corrosion on metal part or degraded marking). Color modification of the plastic part is an expected aging reaction of the polymer and is therefore acceptable. This accessory is limited to 300 sterilization cycles. - Emergency Release Tool: verify that there is no deformation or surface alteration (corrosion, stains, degraded marking). If the criteria above are not met, the accessory should be discarded following the related instructions in Disposal Information section.																														

STEP	INSTRUCTIONS									
Lubrication:	Lubricate the Handle Grip actuation mechanism with a silicone-free, steam-permeable and pH-neutral lubrication product (e.g., instrument care oil or an equivalent lubricant intended for surgical instruments that are sterilized). Lubrication is mandatory on both sides to ensure proper functioning of the Handle Grips. Place one drop on each side of the mechanism:  No lubricification required for the other accessories.									
Packaging:	The accessories are placed back in the Accessory Tray and the tray is closed. The Accessory Tray is packaged with an FDA cleared and marketed sterilization wrap. Note: it is recommended to double wrap the Accessory Tray with an FDA cleared or legally marketed H200 wraps grade.									
Sterilization:	The minimum settings for steam sterilization are: <table><tr><th>Phase</th><th>Time</th><th>Temperature</th></tr><tr><td>Sterilization</td><td>4 min</td><td>270°F (132°C)</td></tr><tr><td>Drying</td><td>40 min</td><td>N/A</td></tr></table> Note: it is recommended to have a cool down time of 30 minutes at the end of the steam sterilization.	Phase	Time	Temperature	Sterilization	4 min	270°F (132°C)	Drying	40 min	N/A
Phase	Time	Temperature								
Sterilization	4 min	270°F (132°C)								
Drying	40 min	N/A								
Storage:	No special storage requirements.									
Additional information:	No additional information.									



STEP	INSTRUCTIONS
Manufacturer contact:	Distalmotion SA  Distalmotion US Inc. Customer Service 200 Park Ave Suite 240 Orange Village OH 44122 USA  +12167442602  reprocessing@distalmotion.com  www.distalmotion.com/

16 DEXTER L6 SYSTEM CLINICAL STUDY SUMMARY

16.1 GENERAL SURGERY PROCEDURES

16.1.1 Inguinal Hernia Repair

A prospective, single-arm, multicenter study (NCT05873582) was performed at three centers in France, Germany, and Switzerland, to confirm the perioperative and early postoperative safety and effectiveness of the Dexter Robotic System (Dexter L6 System) in patients undergoing primary transperitoneal unilateral or bilateral inguinal hernia repair. Fifty adult patients underwent robot-assisted inguinal hernia repair (33 unilateral, 17 bilateral) and were followed up for 30 days after the surgery.

Demographics

Amongst the 50 subjects, the mean age was 60.1 ± 15.2 years. Most subjects were male (94.0%). The mean BMI was 25.7 ± 3.3 kg/m².

Study Results

- Out of the 50 procedures, there was one conversion to conventional laparoscopy (2.0%).
- There were no postoperative major (Clavien-Dindo grades III-V), device-related, adverse events perioperatively up to 30 days.
- The mean duration of docking time was 4.2 ± 2.0 min.
- The mean operative time was 54.5 ± 14.2 min for unilateral and 94.6 ± 22.2 min for bilateral inguinal hernia repair.
- The mean intraoperative blood loss was 5.5 ± 7.3 mL. No intraoperative blood transfusion was needed.
- 26 of 50 subjects (52.0%) were discharged on the day of the procedure. The remaining subjects were discharged after a mean of 1.1 ± 0.3 days.
- None of the subjects required a reoperation following discharge after the index procedure.
- There were no intraoperative adverse events.
- There were 12 (18.0%) postoperative adverse events up to the 30 days follow-up, all were anticipated for this type of procedure and were not device-related:
 - 11 (16.0%) were Clavien-Dindo grade I events (e.g. hematomas, seromas, anesthesia complications, persistent groin pain, trocar specific complication);
 - One subject (2.0%) was re-hospitalized after being discharged after the index procedure. The rehospitalization was due to a small intestine occlusion (Clavien-Dindo grade II). The event started 3 days post-procedure and was resolved without any sequelae at the time of the 30 days follow-up visit.

Study Conclusion

The results of the study demonstrate the Dexter L6 System is safe and effective for subjects undergoing primary unilateral or bilateral inguinal hernia repair.

16.1.2 Cholecystectomy

A prospective, single-arm, multicenter study (NCT06473688) was performed at four centers in France, Germany, and Switzerland, to confirm the perioperative and early postoperative safety and effectiveness of the Dexter Robotic System (Dexter L6 System) in patients undergoing cholecystectomy. Fifty-one adult patients underwent robot-assisted cholecystectomy and were followed up for 30 days after the surgery.



Demographics

Amongst the 51 subjects, the mean age was 55.1 ± 14.7 years. Female subjects accounted for 62.7%. The mean BMI was 27.7 ± 4.2 kg/m².

The patients were operated predominantly for the following indications: symptomatic cholelithiasis (62.7%), cholecystitis (19.6%) and choledocholithiasis (11.8%). Other indications included biliary pancreatitis, gallbladder polyps, and gallbladder hydrops. All patients were followed up for 30 days after the surgery.

Study Results

- Out of the 51 procedures, there was one conversion to conventional laparoscopy (2.0%).
- There was one postoperative major Clavien–Dindo grade IIIa event perioperatively up to 30 days (patient requiring an Endoscopic Retrograde Cholangiopancreatography for postoperative Choledocholithiasis, which was resolved without the need for reoperation).
- The mean duration of docking time was 3.5 ± 1.9 min.
- The mean operative time was 67.5 ± 32.2 min for robotic-assisted and laparoscopic cholecystectomy.
- The mean intraoperative blood loss was 12.5 ± 29.5 mL. No intraoperative blood transfusion was needed.
- 12 of 51 subjects (23.5%) were discharged on the day of the procedure. The remaining 39 subjects were discharged after a mean of 1.7 ± 1.0 days.
- No bile duct injury nor bile leaks were reported.
- None of the subjects required reoperation following discharge after the index procedure.
- There were two intraoperative adverse events (4.0%) categorized as Class Intra grade 2 that were not related to the device:
 - Gallbladder perforation; the event was treated with prophylactic antibiotics. The event was resolved at the time of study completion.
 - Injury of the posterior wall of the gallbladder; the event was treated with prophylactic antibiotics. The event was resolved at the time of study completion.
- There were 8 (14.0%) postoperative adverse events up to the 30 day follow-up in 7 subjects, thereof four (8.0%) were Clavien-Dindo grade I, three (6.0%) were Clavien-Dindo grade II, and one (2.0%) was Clavien-Dindo grade IIIa. Among these, two (4.0%) required re-hospitalization:
 - Re-hospitalization due to post-operative agranulocytosis and pancytopenia as an adverse reaction to metamizole therapy. The event was resolved at the time of study completion, not related to the procedure and not related to the device.
 - Re-hospitalization due to the migration of a pre-existing choledocholithiasis (already described above). The event was resolved at the time of study completion and classified as Clavien-Dindo IIIa, not related to the procedure and not related to the device.

Study Conclusion

The results of the study demonstrate the Dexter L6 System is safe and effective for subjects undergoing cholecystectomy.

16.1.3 Ventral Hernia Repair

A prospective, single-arm, multicenter study (NCT07071740) was performed at five centers in France, Germany, Austria and Switzerland, to confirm the perioperative and early postoperative safety and clinical performance/efficacy of the Dexter Robotic System (Dexter L6 System) in patients undergoing ventral hernia repair. The thirty-three adult patients were followed up for 30 days after the surgery.

Demographics

Amongst the 33 patients, the mean age was 56.5 ± 14.5 years. Male patients accounted for 63.6%. The mean BMI was 27.0 ± 4.6 kg/m². The patients were operated predominantly for the following indications: symptomatic hernia (84.8%), cosmetic concerns (27.3%), painful bulge (9.1%), enlarged hernia (6.1%) and bowel obstructions (3.0%). As multiple indications could be reported for a single patient, percentages may exceed 100%.

Hernia Characteristics and defect dimensions:

A total of 47 hernia defects were treated, including 3 defects that were identified intraoperatively. For the 44 pre-operatively documented hernias, the types were primary (56.8%), incisional (34.1%), and recurrent (9.1%); this classification data was not collected for the 3 hernias identified during surgery. The majority of defects were classified as M3 (65.2%), while M2 locations accounted for 34.0%. The mean hernia width was 2.3 ± 1.5 cm and mean length was 2.2 ± 1.5 cm. Most hernias were reducible (70.2%), while non-reducible (incarcerated) hernias accounted for 29.8%.

Surgical Procedures performed (N=33):

Different surgical procedure techniques were utilized across the 33 subjects. 60.6% Transabdominal Preperitoneal (TAPP), 27.3% Transabdominal Retromuscular Umbilical Prosthetic Hernia Repair (TARUP), 6.1% Total Extraperitoneal (eTEP), and 6.1% Intraperitoneal Onlay Mesh (IPOM+). A single hernia was treated in 60.6% of procedures, two hernias in 36.4%, and three hernias in 3.0%.

Study Results

- Out of the 33 procedures, there was one conversion to conventional laparoscopy (3.0%).
- There was one major Clavien-Dindo grade IIIa event perioperatively up to 30 days: On postoperative day 2, delayed arterial bleeding in the retromuscular space was identified. A coil embolization of the left inferior epigastric artery successfully controlled the bleeding.
- The mean duration of docking time was 2.4 ± 1.5 min.
- The mean operative time (skin-to-skin) was 96.8 ± 47.0 min for robotic-assisted ventral hernia repair.
- The mean intraoperative blood loss was 5.3 ± 6.0 mL. No intraoperative blood transfusion was needed.
- The mean overall time to discharge was 1.6 ± 1.2 days; 6 of 33 patients (18.2%) were discharged on the day of the procedure.
- None of the patients required reoperation following discharge after the index procedure.
- There were no intraoperative adverse events.
- None of the patients required rehospitalization following discharge after the index procedure.
- No recurrence of hernia within 30 days postoperatively was recorded.
- There were 8 (24.2%) postoperative adverse events up to the 30-day follow-up in 8 out of 33 subjects. Thereof six (18.2%) were categorized as Clavien-Dindo grade I (hematoma (2), persistent abdominal wall pain, dysesthesia in the right upper quadrant, glue allergy, and surgical site infection); one (3.0%) was categorized as Clavien-Dindo grade II (seroma), and one (3.0%) was categorized as Clavien-Dindo grade IIIa (bleeding).

Study Conclusion

The results of the study demonstrate the Dexter L6 System is safe and effective for subjects undergoing ventral hernia repair.

16.2 GYNECOLOGY PROCEDURES

16.2.1 Benign Hysterectomy

A prospective, single-arm, multicenter study (NCT06473675) was performed at four centers in France, Germany, and Switzerland, to confirm the perioperative and early postoperative safety and effectiveness of the Dexter Robotic System (Dexter L6 System) in patients undergoing hysterectomy with adnexal surgery for benign disease. Fifty two adult patients underwent robot-assisted hysterectomy and were followed for 42 days postoperatively. Total hysterectomy was performed in 100% of the procedures. Salpingectomy was the most common type of adnexal surgery (80.8%), followed by salpingo-oophorectomy (17.3%), and oophorectomy (1.9%). Almost all procedures, 98.1%, were bilateral.

Demographics

Amongst the 52 subjects, the mean age was 43 ± 11.7 years. The mean BMI was 24.5 ± 4.3 kg/m².

32.7% (17/52) of subjects had abnormal uterine bleeding as an indication for surgery whereas fibroids, adenomyosis or pelvic pain or inflammation - each reported in 10 subjects (19.2%) - were the second most common indication for surgery. Other indications included endometriosis, premalignant lesion of the endometrium and the cervix, and menstrual disorders.

Study Results

- Out of the 52 procedures, there was no conversion to an open or fully laparoscopic surgical approach (0%).
- There was one (1.9%) postoperative major Clavien-Dindo grade IIIb event perioperatively up to 42 days (active bleeding from the vaginal cuff, requiring reoperation and re-hospitalization). At the 42-day follow-up visit, the cervical stump was confirmed to have healed, and the event had resolved without any sequelae.
- The mean duration of docking time was 3.8 ± 1.3 min.
- The mean operative time was 121.9 ± 42.7 min for robotic-assisted laparoscopic hysterectomy with adnexal surgery for benign disease.
- The mean intraoperative blood loss was 87.8 ± 93.8 mL. No intraoperative blood transfusion was needed.
- The overall mean time to discharge was 2.1 ± 0.9 days.
- There were no intraoperative adverse events.
- There were 25 postoperative adverse events up to 42 days follow-up in 19 subjects (36.5%), all were anticipated for this type of procedure and were not device-related:
 - 11 (21.2%) Clavien-Dindo grade I (e.g., bleeding, hematoma, postoperative subileus, abdominal pain with cough, infection, nausea and vomiting, gastroenteritis, discovery of endometrial adenocarcinoma, vaginal cuff dehiscence - not requiring a reoperation),
 - 13 (21.6%) Clavien Dindo Grade II (e.g., bleeding, mild anemia, wound infection, infected hematoma, genitourinary tract infection, abdominal pain with diarrhea and nausea, allergic reaction); and
 - One (1.9%) Clavien-Dindo grade IIIb (already described above).
- Three subjects out of fifty-two (5.8%) required re-hospitalization following discharge from the index procedure:
 - One subject (already described above) reported active bleeding from the vaginal cuff.
 - One subject was re-hospitalized due to elevated blood infection markers and the presence of fever. The subject was subsequently re-admitted and treated with medication. The event resolved within one week and without sequelae.
 - One subject was re-hospitalized for postoperative vaginal bleeding. The bleeding was resolved at the time of the 42-day follow-up visit.

Study Conclusion

The results of the study demonstrate the Dexter L6 System is safe and effective for subjects undergoing benign hysterectomy.

16.2.2 Sacrocolpopexy

A prospective, single-arm, multicenter study (NCT07031050) was performed at five centers in Germany and Switzerland, to confirm the perioperative and early postoperative safety and clinical performance/efficacy of the Dexter Robotic System (Dexter L6 System) in patients undergoing robotic-assisted laparoscopic sacrocolpopexy or sacrocervicopexy. All subjects were followed for 42 days postoperatively.

Demographics

Amongst the 35 subjects, the mean age was 65 ± 11.4 years. The mean BMI was 27.1 ± 4.4 kg/m². The mean value for the POP-Q Point C measurement was -1.3 ± 2.1 cm. POP-Q stage III was the most prevalent: 40.0% (14/35), followed by stage II: 34.3% (12/35).

88.6% (31/35) of subjects had cystocele as an indication for surgery whereas uterine prolapse was the second most common indication for surgery (74.3%, 26/35). Other indications included rectocele (48.6%, 17/35), vaginal prolapse (42.9%, 15/35), enterocele (25.7%, 9/35), descensus urethrae (17.1%, 6/35), and bladder emptying disorder (8.6%, 3/35).

60.0% (21/35) of subjects underwent at least one concomitant urogynecological procedure.

Study Results

- Out of the 35 procedures, there was one conversion to conventional laparoscopy (2.9%).
- There were three (8.6%) Clavien-Dindo grades III-V events perioperatively up to 42 days, in three subjects with: hematoma (Grade IIIb), lower compartment leg syndrome (Grade IIIb) and genitourinary tract infection (Grade IIIa). All three events were resolved at the time of the 42-day follow-up visit.
- Anatomical cure defined as any simplified POP-Q point < 2 at 42-day follow-up was confirmed in 100% of the patients treated. No apical prolapse recurrence was reported at the time of the follow-up assessment.
- The mean duration of docking time was 5.8 ± 1.8 min.
- The mean operative time was 206.6 ± 63.5 min for robotic-assisted laparoscopic sacrocolpopexy and sacrocervicopexy.
- The mean intraoperative blood loss was 84.6 ± 101.2 mL. No intraoperative blood transfusion was needed.
- The overall mean time to discharge was 4.0 ± 4.3 days.
- There were three intraoperative adverse events (8.6%) that were not related to the device:
 - Two patients presented a subcutaneous emphysema. The events were resolved spontaneously without the need for any treatment (both categorized as ClassIntra grade 1);
 - The third event refers to a malposition of the mesh that perforated the vaginal cuff. The mesh had to be repositioned and re-attached (categorized as ClassIntra grade 2). The event was corrected intraoperatively (including the closure of the vaginal defect) without further sequelae.
- There were 9 postoperative complications up to 42 days follow-up in 8 subjects (22.9%), all were anticipated for this type of procedure and were not device-related:
 - 6 (14.3%) Clavien-Dindo grade I (e.g., lower abdominal pain, constipation, urinary stress incontinence, hematoma – not requiring a reoperation);
 - One (2.9%) Clavien Dindo grade IIIa (already described above); and
 - Two (5.7%) Clavien-Dindo grade IIIb (already described above).
- One subject out of thirty-five required re-hospitalization (2.9%) following discharge from the index procedure for the treatment of a genitourinary tract infection (Clavien-Dindo grade IIIa event already described above).

Study Conclusion

The results of the study demonstrate the Dexter L6 System is safe and effective for subjects undergoing sacrocolpopexy or sacrocervicopexy.



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17 APPENDIX A: TECHNICAL INFORMATION

17.1 STATUS LIGHTS

Visual Feedback - Patterns Definition

The following visual patterns are used:

NAME	PATTERN	LIGHT INTENSITY	COLOR	BLINKING PERIOD
Off		0%	n/a	n/a
Active		100%	White	Not blinking
User Request		0% to 100%	White	600 milliseconds
Scaling Indication		0% to 100%	White	1 blink for Fine 2 blinks for Normal 3 blinks for Quick Blink duration 150 milliseconds ON and 250 milliseconds OFF
User Warning		100%	Yellow	Not blinking
Caution		100%	Yellow	600 milliseconds
Error		100%	Red	480 milliseconds
Service		100%	Blue	Not blinking



In the following sections, each visual feedback element is described by a table. It indicates the pattern that the software system shall display for each functional state. The "X" sign represents the default display pattern for the state (when all other conditions in the column are not met).

Visual Feedback - Surgeon Console - Height Adjustment Buttons

The software system manages the height buttons adjustment backlight according to the following table:

DISPLAY PATTERN	POWER STAGING	PREPARATION	READY FOR INSTRUMENT	READY FOR OPERATION	OPERATING	SERVICE	SAFE STATE	INSTRUMENT RELEASE
Off	X	X	X	X	X	X	X	X
Active		When the button is pressed and the corresponding end-stop is reached	When the button is pressed and the corresponding end-stop is reached	When the button is pressed and the corresponding end-stop is reached				
User Request		When the button is pressed and the height adjustment is moving	When the button is pressed and the height adjustment is moving	When the button is pressed and the height adjustment is moving			Up Button, when reset is allowed	Up Button, when reset is allowed
Scaling indication		When the Arms Lock Button is pressed for more than 1 second	When the Arms Lock Button is pressed for more than 1 second	When the Arms Lock Button is pressed for more than 1 second				
User Warning								
Caution								
Error								
Service								

Visual Feedback - Patient Cart - Hub - Status LED Ring

The software system manages the display according to the following table:

DISPLAY PATTERN	POWER STAGING	PREPARATION	READY FOR INSTRUMENT	READY FOR OPERATION	OPERATING	SERVICE	SAFE STATE	INSTRUMENT RELEASE
Off		X						
Active		When home position reached	X	X	X			
User Request	X	When instrument arm moves (*)	If no instrument is locked					
Scaling indication								

DISPLAY PATTERN	POWER STAGING	PREPARATION	READY FOR INSTRUMENT	READY FOR OPERATION	OPERATING	SERVICE	SAFE STATE	INSTRUMENT RELEASE
User Warning		When instrument is locked or protective stop	If locked instrument is not authorized or protective stop	If protective stop(**)				When instrument is locked
Caution		While collision detected (***)	While collision detected (***)	While collision detected (***)	While collision detected (***)			
Error							×	
Service						×		

(*) This applies to any movement: Floor Lock moving, Boom brakes released, Forward Angulation moving, pillar moving, Homing, Going to Lap Mode.

(**) The user warning display pattern in case of protective stop is displayed for 5 seconds even if the stop condition is resolved.

(***) The Caution display pattern in case of detected collision is displayed for 1.5 seconds even if the collision is resolved.

Visual Feedback - Patient Cart - Hub - Error LED Ring

The software system manages the display according to the following table:

DISPLAY PATTERN	POWER STAGING	PREPARATION	READY FOR INSTRUMENT	READY FOR OPERATION	OPERATING	SERVICE	SAFE STATE	INSTRUMENT RELEASE
Off	×	×	×	×	×	×		×
Active								
User Request								
Scaling Indication								
User Warning								
Caution								
Error (*)							×	
Service								

(*) For Hub Error LED Ring, all display patterns shall be steady lights, not blinking.

This is to avoid un-synchronized blinking effect with the Status LED ring.



17.2 TECHNICAL SYSTEM INFORMATION

17.2.1 Compliance and Classifications

Compliance and classifications:

The Dexter L6 System is designed to be in compliance with IEC 60601-1, with the following mode of operation, and type and degree of protection against electric shock:

- Mode of operation: Continuous.
- Type of Protection: Class I.
- Degree of Protection: BF for all patient applied parts (inserted portion of instruments).
- Ingress Protection: IPx0, except for the Pedalboard which is IPx8.

ITEM NAME	ITEM ID	ARTICLE (REF)	TYPE OF USE
Dexter L6	DM-L6	105	Reusable
Dexter L6 Needle Holder	IN-N102	516	Single Use
Dexter L6 Bipolar Johann Grasper	IN-G101	514	Single Use
Dexter L6 Bipolar Maryland Dissector	IN-B101	512	Single Use
Dexter L6 Monopolar Scissors	IN-M101	518	Single Use
Dexter L6 Monopolar Hook	IN-M102	520	Single Use
Dexter L6 Sterile Interface	AC-SU-SI	140	Single Use

ITEM NAME	ITEM ID	ARTICLE (REF)	CLASSIFICATION (MEDICAL DEVICE DIRECTIVE)	TYPE OF USE
Dexter L6 Drapes set	AC-SU-D	711	Distalmotion acts as distributor. Manufactured by Medline US.	Single Use

ITEM NAME	ITEM ID	ARTICLE (REF)	TYPE OF USE
Dexter L6 Handle Grip	AC-RU-HG	146	Reusable
Dexter L6 Incision Pointer	AC-RU-IP	413	Reusable
Dexter L6 Emergency Release Tool	AC-RU-ERT	487	Reusable
Dexter L6 Accessory Tray	AC-RU-T	147	Reusable
Dexter L6 Endoscope Cart	DM-L6-EC	339	Reusable

ITEM NAME	ITEM ID	ARTICLE (REF)	CLASSIFICATION (MEDICAL DEVICE DIRECTIVE)	TYPE OF USE
Dexter Endoscope Arm (incl. its accessories)	SOLO	212499	Distalmotion acts as distributor. Manufactured by AKTORmed.	Reusable

17.2.2 Essential Performance

The following essential performance statements are in compliance with IEC 60601-1.

Except when clutched or when the hand control is released, the Instruments move only in response to motions of the hand control initiated by the operating surgeon. The motions of the Instrument tips are approximately proportional to the surgeon-initiated motions of the hand control. The Instruments always pass through the Remote Center of Motion. There are no uncontrolled or unexpected motions of the Instruments.

Except when the Endoscope Pedal is released or a Handle Grip is released, and for as long as the Endoscope Holder is connected to the Robotic system and ready to operate, the endoscope tip moves approximately proportionally to the surgeon-initiated motions of the hand control.

The Robotic system transitions into a safe state (i.e. motors stopped, brakes engaged and instruments stopped) upon user input (e.g. pushing one of the E-Stop buttons), when RASS detects an abnormal condition, or when the RASS or one of its subsystems loses power.

17.2.3 Key Physical Characteristics

ITEM	SIZE	WEIGHT	POWER SUPPLY
Surgeon Console	1090 x 1035 x 1200 mm	86 kg	350 VA, 100-240V~, 50/60Hz
Patient Cart	1425 x 850 x 815 mm	230 kg	700 VA, 100-240V~, 50/60Hz
Endoscope Cart	700 x 600 x 1300 mm	32 kg	n/a
Needle Holder	575 x 63 x 45 mm	99 g	n/a
Bipolar Johann Grasper	611 x 63 x 45 mm	107 g	≤770 Vp
Bipolar Maryland Dissector	610 x 63 x 45 mm	106 g	≤770 Vp
Monopolar Scissors	604 x 63 x 45 mm	105 g	≤4 kVpeak
Monopolar Hook	606 x 63 x 45 mm	99 g	≤4 kVpeak
Sterile interface	ø74 x 134 mm	35 g	n/a
Surgeon Console Master Arm Drapes	2350 x 1400 x 0.4 mm	150 g	n/a
Surgeon Console Central Pillar drape	905 x 700 x 0.4 mm	80 g	n/a
Patient Cart Drape	3300 x 1300 x 0.6 mm	220 g	n/a
Accessories Tray	480 x 250 x 110 mm	2.25 kg	n/a
Handle Grip	140 x 120 x 80 mm	224 g	n/a
Incision Pointer	ø50 x 207 mm	165 g	n/a
Emergency Release Tool	165 x 14 x 14 mm	62 g	n/a
Endoscope Arm	291 x 167 x 1059 mm	11.5 kg	100-240 V



17.2.4 Applied and Accessible Parts

The applied parts of the Robotic system are:

	APPLIED PART CLASSIFICATION	TYPE	RATIONALE	CONTACT DURATION
IN	Instrument	BF	Direct contact with patient during use (surgery)	> 1 min
AC-RU-IP	Incision Pointer	BF	Direct contact with patient during use (setup / docking)	1 s < t < 10 s

As both instruments are inserted in the patient for the purpose of robotic surgery at the same location in the patient's body, they shall be considered as a **single applied part** during surgery. Consequently, patient and patient auxiliary leakage currents are cumulative.

The accessible parts which could come in contact with the patient accidentally are:

	ACCESSIBLE PART	EQUIVALENT APPLIED PART CLASSIFICATION	RATIONALE	CONTACT DURATION
AC-SU-SD	Sterile Drape	BF	Direct contact with patient during use (docking, surgery)	1 s < t < 10 s
AC-SU-SI	Sterile Interface	BF	Subclause §4.6: Foreseeable accidental short duration contact with patient during normal use (setup) Subclause §7.2.10: Marking with relevant symbols. This requirement does not apply to parts that have been identified according to Subclause §4.6	1 s < t < 10 s
PC-H	Hub	BF	Subclause §4.6: Foreseeable accidental short duration contact with patient during normal use (surgery) Subclause §7.2.10: Marking with relevant symbols. This requirement does not apply to parts that have been identified according to Subclause §4.6	1 s < t < 10 s
PC-IA	Instrument Arm	BF	Subclause §4.6: Foreseeable accidental short duration contact with patient during normal use (setup) Remark: PC-IA under sterile drape, patient under blanket in laparoscopy setup, no risk of electric shock. Subclause §7.2.10: Marking with relevant symbols. This requirement does not apply to parts that have been identified according to Subclause §4.6	1 s < t < 10 s

	ACCESSIBLE PART	EQUIVALENT APPLIED PART CLASSIFICATION	RATIONALE	CONTACT DURATION
PC-B	Boom	BF	Subclause §4.6: Foreseeable accidental short duration contact with patient during normal use (setup) Remark: PC-IA under sterile drape, patient under blanket in laparoscopy setup, no risk of electric shock. Subclause §7.2.10: Marking with relevant symbols. This requirement does not apply to parts that have been identified according to Subclause §4.6	$1\text{ s} < t < 10\text{ s}$
PC-WB	Wheel Base (Vertical Column, Tube)	BF	Subclause §4.6: Foreseeable accidental short duration contact with patient during normal use (setup) Remark: PC-IA under sterile drape, patient under blanket in laparoscopy setup, no risk of electric shock.	$1\text{ s} < t < 10\text{ s}$
EC	Endoscope Cart	N/A	Subclause §4.6: Foreseeable accidental short duration contact with patient during normal use (setup) Subclause §7.2.10: Marking with relevant symbols. This requirement does not apply to parts that have been identified according to Subclause §4.6	$1\text{ s} < t < 10\text{ s}$

NOTE

As Surgeon Console only provides Means of Operator Protection (MOOP), the Patient Cart is separated from the Surgeon Console with 1x MOPP (working voltage: 250VAC). The minimum distance between the Patient Cart and the Surgeon Console is defined to be $> 0.1\text{ [m]}$.

NOTE

Applied parts are not defibrillation-proof.



The accessible parts of the Dexter L6 System are:

	ACCESSIBLE PART	COMMENT	CONTACT DURATION
AC-RU-HG	Handle Grip	Accessible to the Operator during Setup, Transport and Surgery	> 1 min
PC	Rest of Patient Cart (everything which is not an applied part)	Accessible to the Operator during Setup, Transport and Surgery	10 s < t < 1 min
SC	Surgeon Console	Accessible to the Operator during Setup, Transport and Surgery	10 s < t < 1 min



Before you operate the Dexter L6 System, ensure that it is compatible with all robotic surgical instruments and other components you plan to use, including those not manufactured by Distalmotion. Carefully follow the safety guidance detailed in this document to verify this compatibility.

17.2.5 Disposal Information



At the time of their disposal, the following components of the Dexter L6 System shall be disposed of as Waste Electrical and Electronic Equipment:

- Patients Carts
- Surgeon Console
- Cables

Please return them to Distalmotion SA.

Contaminated single use instruments, single-use accessories, and reusable accessories are disposable biohazards, they shall be disposed in accordance with local regulations and following the same procedure as other consumables in the operating room.

If uncontaminated, single-use instruments (Dexter L6 Needle Holder, Dexter L6 Bipolar Johann Grasper, Dexter L6 Bipolar Maryland Dissector, Dexter L6 Monopolar Hook, Dexter L6 Monopolar Scissors) shall be disposed of as Waste Electronic and Electrical Equipment.

Please return them to Distalmotion SA.

Waste Electronic and Electrical Equipment shipments, for recycling purposes, are free of charge to the customer.

Dispose of all remaining components in accordance with local regulations.

17.3 SYMBOLS AND ICONS

Please find below the list of symbols and icons:

SYMBOL OR ICON	MEANING	WHERE FOUND
	Prescription device	Product label
	Nationally Recognized Test Laboratory number	Product label
	Warning	Instructions for Use
	Warning - Crushing of hands	Product
	Information	Instructions for Use
	Precaution	Product label
	Mains power supply	Product label
	Fuse rating	Product label
	Weight	Product label
	Consult Instructions for Use or consult electronic Instructions for Use	Product label
	Read Instructions for Use	Product label
	Type BF Applied Part	Product label Patient Carts
	Protective earth (ground)	Instructions for use
	Potential Equalization Conductor	Instructions for Use Patient Carts Surgeon Console
	Emergency stop	Surgeon Console
	Dispose of in accordance with local regulations—particularly applies to electronic components	Product label Instructions for Use
	Use-by date	Product label
	Sterilized using ethylene oxide	Product label
	Indicates a single sterile barrier system	Product label



SYMBOL OR ICON	MEANING	WHERE FOUND
	Indicates a single sterile barrier system with protective packaging outside	Product label
	Indicates the number of items in the package	Product label
	Ethylene oxide exposed	Product label
	Ethylene oxide unexposed	Product label
	Do not reuse.	Product label
	Do not use if package is damaged	Product label
	Batch code	Product label
	Serial number	Product label
	Catalogue number	Product label
	Unique device identifier	Product label
	Manufacturing date and country of manufacture. CC is the two or three letter country code.	Product label
	Manufacturer	Product label Instructions for use
	CE Mark	Product label Instructions for use
	CE mark with notified body notification number	Product label Instructions for use
	Medical device	Product label
	Address	Instructions for Use
	Phone number	Instructions for Use
	Email	Instructions for Use
	Website address	Instructions for Use
	Floor Lock Button to deploy or disengage the Patient Cart Floor Lock	Instructions for use Patient Carts

SYMBOL OR ICON	MEANING	WHERE FOUND
	Down Button for height adjustment of the Patient Cart	Instructions for use Patient Carts
	Up Button for height adjustment of the Patient Cart	Instructions for use Patient Carts
	Lateral Boom Movement Button to release the Boom brakes	Instructions for use Patient Carts
	Fold Instrument Arm to Laparoscopy Mode	Instructions for use Patient Carts
	Extend Instrument Arm to Home Position	Instructions for use Patient Carts
	Decrease Forward Angulation	Instructions for use Patient Carts
	Increase Forward Angulation	Instructions for use Patient Carts
	Master Arm Lock. It can also be used to check the scaling ratio value when long pressed or adjust the scaling ratio if pressed along with the Master Arm Up or Down Button	Instructions for use Surgeon Console
	Identification of Patient Cart 1 and Master Arm 1	Instructions for use Patient cart Left
	Identification of Patient Cart 2 and Master Arm 2	Instructions for use Patient cart Right
SC	Connection of the Data Cable on the Patient Cart to the Surgeon Console	Instructions for use Patient cart
PC-1	Connection of the Data Cable on the Surgeon Console to Patient Cart 1	Instructions for use Surgeon Console
PC-2	Connection of the Data Cable on the Surgeon Console to Patient Cart 2	Instructions for use Surgeon Console
	Master Arm Height Adjustment Buttons for height adjustment of the Master Arms. It can also be used to change the scaling ratio if the Up or Down Button is pressed along with the Arms lock Button	Instructions for use Surgeon Console
	Manual Floor Lock Release in case of emergency	Instructions for use Patient cart
	Connection of the Pedalboard on the Surgeon Console	Instructions for use Surgeon Console
	High voltage parts	Patient cart
	Left Pedal: Endoscope Foot Pedal Right Pedal: Clutching Foot Pedal	Surgeon Console

SYMBOL OR ICON	MEANING	WHERE FOUND
	Temperature limit	Product label
	Humidity limit	Product label
	Atmospheric pressure limit	Product label
	Non-pyrogenic	Product label
	European Authorized Representative	Product label
	Indicates the entity distributing the medical device into the locale	Instructions for Use
	Indicates the entity importing the medical device into the locale	Product label
	Pushing prohibited: To indicate that pushing against an object is prohibited	Endoscope Cart
	Visual inspection	Reprocessing sheet
	Removal of stains and debris	Reprocessing sheet
	Cleaning step	Reprocessing sheet
	Cleaning agent	Reprocessing sheet
	To discard	Reprocessing sheet
	Lubrication product	Reprocessing sheet

17.4 SYSTEM SPECIFICATIONS

17.4.1 Service Life

The expected service life is defined as follows:

Surgeon Console & Patient Carts	Expected service life of 7 years or up to 2912 surgeries.
Endoscope Arm	Expected service life of 10 years or up to 3000 surgeries.
Instruments	Shelf-life of 18 months. Single-use (do not reuse).
Sterile Interfaces	Shelf-life of 36 months. Single-use (do not reuse).
Sterile Drapes	Shelf-life of 5 years. Single-use (do not reuse).
Accessory Tray	Can be used as long as the visual inspection criteria of the accessories reprocessing instructions are met. To cover the service life of the system, this accessory needs to be replaced by a new one.
Handle Grips	Can be used for up to 300 uses (including reprocessing). To cover the service life of the system, this accessory needs to be replaced by a new one.
Incision Pointers	Can be used as long as the visual inspection criteria of the accessories reprocessing instructions are met. To cover the service life of the system, this accessory needs to be replaced by a new one.
Emergency Release Tool	Can be used as long as the visual inspection criteria of the accessories reprocessing instructions are met. To cover the service life of the system, this accessory needs to be replaced by a new one.

17.4.2 Environmental Specifications

Operating Conditions	The Dexter L6 System can withstand the following environmental operating conditions: • Temperature range: 15° to 25° [C] • Relative humidity range: 10 to 85 [%] non-condensing • Pressure range: 86 to 106 [kPa]
Transport and Storage Conditions	The Dexter L6 System can withstand the following environmental transport and storage conditions: • Temperature range: 10° to 35° [C] • Relative humidity range: 10 to 85 [%] non-condensing • Pressure range: 50 to 106 [kPa]

17.4.3 Electromagnetic Compatibility

Electromagnetic Emissions

The Dexter L6 System is intended for use in the electromagnetic environment specified below. The customer or user of the Dexter L6 System should ensure that the device is used in such an environment.

EMISSION TEST	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
RF emissions CISPR 11	Group 1	The Dexter L6 System uses energy from radiofrequency currents for its internal functions. The Dexter L6 System contains a radio frequency identification (RFID) module with the following characteristics: - Frequency band of transmission: 13.56 MHz (ISM band) - Type and frequency characteristics of the modulation: amplitude shift modulation (ASK), load modulation - Effective radiated power: 1.4 W (estimated) The Dexter L6 System may be interfaced with high-frequency (HF) generators, provided that they comply with the national regulations. Please refer to the Instructions for Use of the high-frequency generators for guidance on separation distance.
	Class A	
Harmonic current emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Passed	

NOTE

The Dexter L6 System is suitable for use in industrial areas and hospitals (CISPR 11 class A). If the device is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection with respect to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Electromagnetic Immunity

The Dexter L6 System is intended for use in the electromagnetic environment specified below. The customer or user of the Dexter L6 System should ensure that the device is used in such an environment.

IMMUNITY TEST STANDARD	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	- Contact: $\pm 8\text{kV}$ - Air: $\pm 15\text{kV}$	- Contact: $\pm 8\text{kV}$ - Air: $\pm 15\text{kV}$	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic fast transient / burst IEC 61000-4-4	5/50 ns, 100 kHz, $\pm 2\text{kV}$	5/50 ns, 100 kHz, $\pm 2\text{kV}$	Quality of the mains power supply should be similar to that of a hospital environment.

IMMUNITY TEST STANDARD	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Surge IEC 61000-4-5	1.2/50 (8/20) μs - LtL: ± 1 kV - LtG: ± 2 kV	1.2/50 (8/20) μs - LtL: ± 1 kV - LtG: ± 2 kV	Quality of the mains power supply should be similar to that of a hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	0 % UT for 0.5 cycle (1 phase) 0 % UT for 1 cycle 70 % UT for 25/30 cycles (50 Hz) 0 % UT for 250/300 cycles (50 Hz)	0 % UT for 0.5 cycle (1 phase) 0 % UT for 1 cycle 70 % UT for 25/30 cycles (50 Hz) 0 % UT for 250/300 cycles (50 Hz)	Quality of the mains power supply should be similar to that of a hospital environment. When the user of the device requires continuous operation in the event of disruption of the service, it is recommended that the device is operated from an uninterruptible power supply or battery.

NOTE

UT is the AC mains voltage prior to application of the test level

Power frequency [50 Hz] magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a hospital environment.
Proximity magnetic fields IEC 61000-4-39	30 kHz: CW 134.2 kHz: Pulse modulation 2.1 kHz 13.56 MHz: Pulse modulation 50 kHz	30 kHz: 8 A/m 134.2 kHz: 65 A/m 13.56 MHz: 7.5 A/m	

IMMUNITY TEST STANDARD	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
			Portable and mobile radiofrequency communications equipment should only be used in proximity to any part of the Dexter L6 system, including cables, in accordance with the recommended separation distance as calculated using the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	150 kHz – 80 MHz 3 V - ISM and amateur radio bands 6 V	150 kHz – 80 MHz 3 V - ISM and amateur radio bands 6 V	$d = 1.2 * \sqrt[3]{P}$ from 80 MHz to 800 MHz $d = 2.3 * \sqrt[3]{P}$ from 800 MHz to 2.5 GHz



IMMUNITY TEST STANDARD	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Radiated RF IEC 610004-3	80 MHz - 2.7 GHz 3 V/m	80 MHz - 2.7 GHz 3 V/m	$d = 1.2 * \sqrt[3]{P}$

Where P is the maximum output power of the transmitter in Watts (W), according to the transmitter manufacturer and distance (d) is the recommended separation distance in meters (m).

NOTE 1

At 80MHz and 800MHz, 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

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER W	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2 * \sqrt[3]{P}$ (meters)	$d = 1.2 * \sqrt[3]{P}$ (meters)	$d = 2.3 * \sqrt[3]{P}$ (meters)
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

NOTE 1

At 80 MHz 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.

NOTE 3

If the System detects an abnormal condition due to an EM disturbance, it will transition to Safe state, a mode that maintains BASIC SAFETY, stops moving and allows the release of the patient.

17.4.4 RFID Tag and RFID Reader Specifications

Radio Frequency Identification (RFID) system refers to a wireless system comprised of two components: tag and reader. The RFID reader is a device that has one antenna that emit radio waves and receive signals back from the RFID tag. The RFID reader, located in the Hub, is used to read the instrument's RFID tag via a short range communication.

The RFID tag embedded in each instrument's knob contains the following information:

- The instrument's identifier for the correct acceptance of the instrument by the Robot via the RFID reader;
- Control parameters and characterization data related to the instrument's tip movement.

RFID Tag Specifications:

- Protocol: ISO/IEC 15693
- Type: NXP ICODE SLI-X2
- RFID system frequency range: 13.553 - 13.567 MHz

RFID Reader Specifications:

- Operating frequency range: From 13.110 MHz to 14.010 MHz
- Number of channels: 1
- Antenna type: Integrated PCB antenna
- Modulation: ASK
- Power source: 100-240 Vac - 50/60 Hz
- Maximum radio-frequency power transmitted: 45.91 dBμV/m at 13.56 MHz at 10m

FCC Compliance:

NOTE 1

The Dexter L6 System has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC (Federal Communications Commission) Rules. These limits are designed to provide reasonable protection against harmful interference when the system is operated in a commercial environment. This system generates, uses, and can radiate radio-frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this system in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at their expense.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the Dexter L6 System.

NOTE 2

"Harmful interference" is defined in 47 CFR Part 15 by the FCC as follows: Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radiocommunications service operating in accordance with this regulation.



The Dexter L6 System with its antenna complies with the Federal Communications Commission's radiation exposure limits set forth for an uncontrolled environment.

To maintain compliance, follow the instructions below:

1. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. Avoid direct contact with the antenna, or keep contact to a minimum while using this equipment.

18 APPENDIX B: TROUBLESHOOTING

18.1 SETUP

Endoscope Connection - Audio Feedback

Incomplete insertion of the Data Cable is possible and may occur inadvertently.

Listen for a “clicking” sound when inserting the Endoscope Arm Data Cable, as it may appear visually connected without being securely in place.

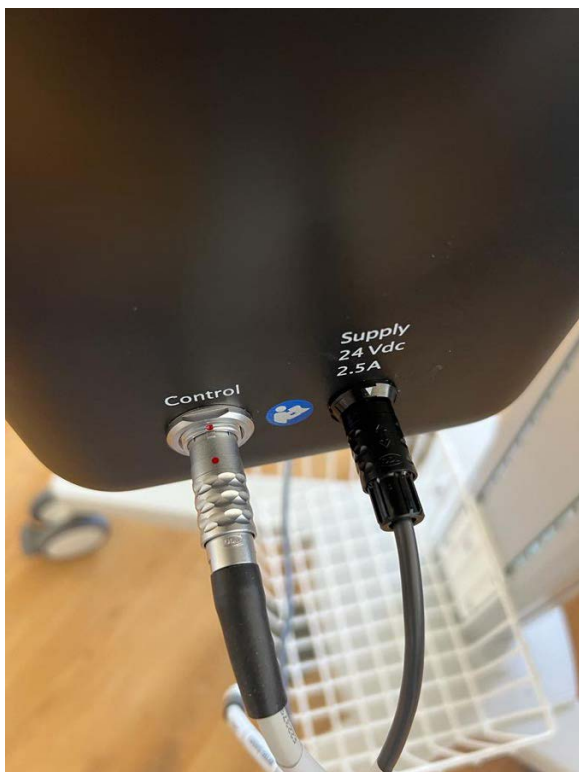


Figure 38: Example of a Data Cable incorrectly connected



Figure 39: Example of a Data Cable correctly connected

18.2 WHILE OPERATING

Instrument not recognized

If the instrument is not recognized by the Dexter L6 System, remove the instrument and replace it with another one.

Difficult instrument insertion

If you encounter difficulties during instrument insertion, follow these steps:

1. Verify that the instrument is in the correct insertion position.
2. Ensure that the Instrument Arm is in the home position.
3. If instrument insertion remains challenging, confirm that the docking position has not been lost.

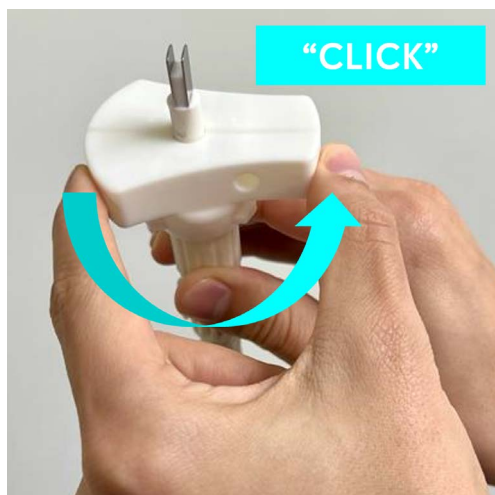


Figure 40: Maneuver to put instrument knob back to insertion position

Failing to home

If the Home Button and Hub remain yellow after completing the homing, take the following actions:

1. Retract the instruments.
2. Press the Home Button until the Instrument Arms stops moving.
3. Reinsert the instruments.
4. Check if the visual feedback is still steady white.
5. Repeat the previous steps if the visual feedback is still yellow.

If after multiple attempts, the visual feedback remains yellow, perform the following actions:

1. Retract the instruments.
2. Manually restart the Dexter L6 System.
3. Press the Home Button until the Instrument Arms stops moving.
4. Reinsert the instruments.

Suboptimal energy delivery

If energy delivery appears weaker than anticipated, inspect the cable's integrity before considering an instrument change.

Collision applying pressure on the patient

If a collision exerts pressure on the patient and triggers an emergency stop, carefully remove the instruments, restart the system and use the Patient Cart's Up and Down Buttons and/or Lateral Boom Movement button to alleviate pressure on the patient by moving the Booms up and/or left/right. Always redock the Patient Carts to the corresponding trocars.

Refrain from using the LAP or Home Button to reposition the Booms, as this may inadvertently increase pressure on the patient.

In emergency situations, such as pressure on a critical area, execute the surgical clearance space procedure by gently but firmly moving the Instrument Arms aside to gain access to the surgical site.

All of these maneuvers should be assessed by the surgeon, who ultimately serves as the final decision-maker in determining the most appropriate course of action.

19 APPENDIX C: TROCARS

These Instructions for Use provide a list of trocars that are compatible with the Dexter L6 System. This list is not exhaustive. Users are welcome to utilize other third-party trocars, provided that they are at least 10 [mm] in diameter and translucent or as otherwise listed in the table below.

Please refer to the trocar manufacturer's Instructions for Use for additional information.

BRAND	MODEL	DIAMETER	LENGTH
Afs-medical, Austria	X-ONE Trokar 300-V11	11 mm	100 mm
Afs-medical, Austria	X-ONE Trokar 300-V12	12 mm	100 mm
Applied Medical, USA	Kii Optical Access System CFR33	11 mm	100 mm
Applied Medical, USA	Kii Optical Access System CFR73	12 mm	100 mm
B.Braun, Germany	AESCU LAP® Optical Trocar	11 mm	100 mm
B.Braun, Germany	AESCU LAP® Optical Trocar	12 mm	100 mm
CAK, China	Disposable Thoracoscopic Trocar AKYCCA-10 (10mm)	10 mm	100 mm
CAK, China	Disposable Thoracoscopic Trocar AKYCCA-12 (12mm)	12 mm	100 mm
Changzhou Lookmed Medical, China	Disposable Optical Trocar 10 mm (LMTC-10/100) and 12	10 mm	100 mm
Changzhou Lookmed Medical, China	Changzhou Lookmed Medical Disposable Optical Trocar 12 mm (LMTC-12/100)	12 mm	100 mm
Channel Med, China	Disposable Abdominal Trocar 10 mm (CN-TCI-10N, CN-TCI-10L)	10 mm	110 mm
Channel Med, China	Disposable Abdominal Trocar 12mm (CN-TCI-12N, CN-TCI-12L)	12 mm	110 mm
CONMED, USA	BluView™ Optical Trocar 11 mm (BV-11x100)	11 mm	100 mm
CONMED, USA	BluView™ Optical Trocar 11 mm (BV-11x100)	11 mm	100 mm
CONMED, USA	BluView Optical Trocar, BV-12x100	12 mm	100 mm
Covidien, USA	VersaOne™ Bladeless Trocar (NONB8STF)	8 mm	100 mm
Ethicon, USA	Endopath Xcel® Trocars	11 mm	100 mm
Ethicon, USA	Endopath Xcel® Trocars	12 mm	100 mm
Genicon, USA	Laparoscopic trocar Sleeve 10/100	10 mm	100 mm
Genicon, USA	Laparoscopic trocar Sleeve 12/100	12 mm	100 mm
Geyi, China	Disposable Optical Trocar GYTR-IV 10 mm	10 mm	110 mm
Golden Stapler, China	Single Use Abdominal Trocar, L10 (NKTL10)	10 mm	100 mm
Golden Stapler, China	Single Use Abdominal Trocar, L12 (NKTL12)	12 mm	100 mm
Hangzhou Kangji Medical, China	Disposable Optical Trocar 101Y.605 (10x100 mm)	10 mm	100 mm
Hangzhou Kangji Medical, China	Disposable Optical Trocar 101Y.607 (12x100)	12 mm	100 mm
Jiangsu Coopwin Med, China	Disposable Trocar KHCC-Bladeless type KHCC-10/100: 10 mm	10 mm	100 mm



BRAND	MODEL	DIAMETER	LENGTH
Katsanas, Turkey	Lapafix® Trocar 10mm	10 mm	100 mm
Katsanas, Turkey	Lapafix® Trocar 11mm	11 mm	100 mm
Katsanas, Turkey	Lapafix® Trocar 12mm	12 mm	100 mm
Lagis, Taiwan	Lagis FineSeal™ Optical Trocar (TRC-11V1, 10 mm)	11 mm	108 mm
Lagis, Taiwan	Lagis FineSeal™ Optical Trocar (TRC-12V1, 12mm)	12 mm	108 mm
LaproSurge, UK	Optical, Bladed and Bladeless Trocar 10/11 mm (EC10SL-O Auto)	10 mm	100 mm
LaproSurge, UK	Optical, Bladed and Bladeless Trocar 12mm (EC12SL-O Auto)	12 mm	100 mm
LocaMed, UK	Optical Trocar 10 mm (LM510V, LM10S, LM510HSN, LM510D)	10 mm	100 mm
LocaMed, UK	Optical Trocar 12 mm (LM512V, LM12S, LM512HSN, LM512D)	12 mm	100 mm
Medtronic, USA	VersaOne™ Access system Trocars	11 mm	100 mm
Medtronic, USA	VersaOne™ Access system Trocars	12 mm	100 mm
Meril Life Sciences, India	Eliro Trocars 10 mm (ELR10)	10 mm	100 mm
Meril Life Sciences, India	Eliro Trocars 12 mm (ELR12)	12 mm	100 mm
Purple Surgical, UK	Ultimate Trocars 10 mm PS3560ULT	10 mm	100 mm
Purple Surgical, UK	Ultimate Trocars 12 mm	12 mm	100 mm
Sejong Medical, Korea	Laport-MU, Laport-L, Laport-U and Laport	10 mm	100 mm
Sejong Medical, Korea	Laport-MU, Laport-L, Laport-U and Laport	11 mm	100 mm
Sejong Medical, Korea	Laport-MU, Laport-L, Laport-U and Laport	12 mm	100 mm
T.K. Medical, China	Disposable Trocars Model CT compatible with 5mm to 12 mm instruments		100 mm
Taiwan Surgical Corporation (Twsc), Taiwan	Inno-Port™ Disposable Trocar Access	11 mm	100 mm
Taiwan Surgical Corporation (Twsc), Taiwan	Inno-Port™ Disposable Trocar Access	12 mm	100 mm
Unimax, Taiwan	Disposable trocars	10 mm	100 mm
Unimax, Taiwan	Disposable trocars	11 mm	100 mm
Unimax, Taiwan	Disposable trocars	12 mm	100 mm
Vaxon BNR, Korea	Bladeless trocars	10 mm	100 mm
Vaxon BNR, Korea	Bladeless trocars	12 mm	100 mm
Watson Medical, China	Disposable trocars	10 mm	100 mm
Watson Medical, China	Disposable trocars	12 mm	100 mm
Weck Vista, USA	Weck Vista® Bladeless Access Port 10x100 mm	10 mm	100 mm
Weck Vista, USA	Weck Vista® Bladeless Access Port 12x100 mm	12 mm	100 mm

20 APPENDIX D: ELECTROSURGICAL UNITS

These Instructions for Use provide a compilation of electrosurgical units (ESU) compatible with the Dexter L6 System. The list is not exhaustive. Users can utilize other third-party electrosurgical units, provided that they adhere to the specified requirements outlined in these Instructions for Use and provided that they are deemed compatible with the Dexter L6 System.

The tables below provide electrosurgical unit settings that have been deemed safe for use with the Dexter L6 System depending on the brand and the model. As a reminder the rated peak voltage for Dexter monopolar instruments is at 4'000 [Vp] and 770 [Vp] for bipolar instruments.

For instructions on using and configuring each electrosurgery unit, refer to the instruction manual provided with the electrosurgical unit

20.1 ERBE

Erbe Vio 3

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
autoCUT	360 Watts / Effect 0.1 to 10	360 Watts / Effect 0.1 to 10	100 Watts / Effect 0.1 to 8	100 Watts / Effect 0.1 to 8
highCUT	400 Watts / Effect 0.1 to 10	400 Watts / Effect 0.1 to 10	N/A	N/A
DryCUT	240 Watts / Effect 0.1 to 10	240 Watts / Effect 0.1 to 10	N/A	N/A
endoCUT	110 Watts / Effect 1 to 4	110 Watts / Effect 1 to 4	N/A	N/A
endoCUT Q	330 Watts / Effect 1 to 4	330 Watts / Effect 1 to 4	N/A	N/A
softCOAG	200 Watts / Effect 0.1 to 10	200 Watts / Effect 0.1 to 10	120 Watts / Effects 0.1 to 10	120 Watts / Effects 0.1 to 10
forcedCOAG	120 Watts / Effects 0.1 to 10	120 Watts / Effects 0.1 to 10	120 Watts / Effects 0.1 to 5.5	120 Watts / Effects 0.1 to 5.5
swiftCOAG	240 Watts / Effect 0.1 to 10	240 Watts / Effect 0.1 to 10	N/A	N/A
sprayCOAG	Must not be used	Must not be used	Must not be used	Must not be used
preciseSECT	144 Watts / Effect 0.1 to 10	144 Watts / Effect 0.1 to 10	N/A	N/A
twinCOAG	240 Watts / Effect 0.1 to 10	240 Watts / Effect 0.1 to 10	N/A	N/A
Thermoseal	N/A	N/A	360 W / Effects 1 to 2	360 W / Effects 1 to 2

**Erbe Vio 300D**

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
AUTO CUT	300 Watts / Effects 1 to 8	300 Watts / Effects 1 to 8	N/A	N/A
HIGH CUT	300 Watts / Effects 1 to 8	300 Watts / Effects 1 to 8	N/A	N/A
DRY CUT	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	N/A	N/A
DRY CUT ^o	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	N/A	N/A
SOFT COAG	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	120 Watts / Effects 1 to 8	120 Watts / Effects 1 to 8
SWIFT COAG	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	N/A	N/A
FORCED COAG	120 Watts / Effects 1 to 4	120 Watts / Effects 1 to 4	20 Watts / Effect 1	20 Watts / Effect 1
SPRAY COAG	Must not be used	Must not be used	N/A	N/A
PRECISE CUT	50 Watts / Effects 1 to 8	50 Watts / Effects 1 to 8	50 Watts / Effects 1 to 8	50 Watts / Effects 1 to 8
ENDO CUT Q	400 Watts / Effects 1 to 4	400 Watts / Effects 1 to 4	N/A	N/A
ENDO CUT I	155 Watts / Effects 1 to 4	155 Watts / Effects 1 to 4	N/A	N/A
PRECISE COAG	50 Watts / Effects 1 to 8	50 Watts / Effects 1 to 8	50 Watts / Effects 1 to 8	50 Watts / Effects 1 to 8
TWIN COAG	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	N/A	N/A
Bipolar cut	N/A	N/A	100 Watts / Effects 1 to 4	100 Watts / Effects 1 to 4
BiClamp	N/A	N/A	225 Watts / Effects 1 to 4	225 Watts / Effects 1 to 4

Erbe Vio 300S

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
AUTO CUT	300 Watts / Effects 1 to 8	300 Watts / Effects 1 to 8	N/A	N/A
HIGH CUT	300 Watts / Effects 1 to 8	300 Watts / Effects 1 to 8	N/A	N/A
DRY CUT	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	N/A	N/A
DRY CUT ^o	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	N/A	N/A
ENDO CUT Q	400 Watts / Effects 1 to 4	400 Watts / Effects 1 to 4	N/A	N/A
ENDO CUT I	170 Watts / Effects 1 to 4	170 Watts / Effects 1 to 4	N/A	N/A
SOFT COAG	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	120 Watts / Effects 1 to 8	120 Watts / Effects 1 to 8
SWIFT COAG	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	N/A	N/A
SWIFT COAG ^o	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	N/A	N/A
FORCED COAG	120 Watts / Effects 1 to 4	120 Watts / Effects 1 to 4	N/A	N/A
SPRAY COAG	Must not be used	Must not be used	N/A	N/A
TWIN COAG	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	N/A	N/A
CLASSIC COAG	60 Watts / Effects 1 to 2	60 Watts / Effects 1 to 2	N/A	N/A
Bipolar Cut	N/A	N/A	100 Watts / Effects 1 to 4	120 Watts / Effects 1 to 4

**Erbe Vio dV**

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
AUTO CUT	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	N/A	N/A
DRY CUT	150 Watts / Effects 1 to 8	150 Watts / Effects 1 to 8	N/A	N/A
SWIFT COAG	150 Watts / Effects 1 to 8	150 Watts / Effects 1 to 8	N/A	N/A
FORCED COAG	120 Watts / Effects 1 to 4	120 Watts / Effects 1 to 4	N/A	N/A
CLASSIC COAG	60 Watts / Effects 1 to 2	60 Watts / Effects 1 to 2	N/A	N/A
Bipolar cut	N/A	N/A	100 Watts / Effects 1 to 4	100 Watts / Effects 1 to 4
Bipolar Soft Coag	N/A	N/A	120 Watts / Effects 1 to 8	120 Watts / Effects 1 to 8
BiClamp	N/A	N/A	260 Watts / Effects 1 to 4	260 Watts / Effects 1 to 4

Erbe Vio 200 D

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
AUTO CUT	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	N/A	N/A
SOFT COAG	120 Watts / Effects 1 to 8	120 Watts / Effects 1 to 8	120 Watts / Effects 1 to 8	120 Watts / Effects 1 to 8
SWIFT COAG	120 Watts / Effects 1 to 8	120 Watts / Effects 1 to 8	N/A	N/A
FORCED COAG	120 Watts / Effects 1 to 4	120 Watts / Effects 1 to 4	20 Watts / Effect 1	20 Watts / Effect 1
DRY CUT	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	N/A	N/A
PRECISE CUT	50 Watts / Effects 1 to 8	50 Watts / Effects 1 to 8	50 Watts / Effects 1 to 8	50 Watts / Effects 1 to 8
ENDO CUT Q	400 Watts / Effects 1 to 4	400 Watts / Effects 1 to 4	N/A	N/A

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
ENDO CUT I	170 Watts / Effects 1 to 4	170 Watts / Effects 1 to 4	N/A	N/A
PRECISE COAG	50 Watts / Effects 1 to 8	50 Watts / Effects 1 to 8	50 Watts / Effects 1 to 8	50 Watts / Effects 1 to 8
Bipolar cut	N/A	N/A	100 Watts / Effects 1 to 4	100 Watts / Effects 1 to 4

Erbe Vio 200S

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
AUTO CUT	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	N/A	N/A
ENDO CUT Q	400 Watts / Effects 1 to 4	400 Watts / Effects 1 to 4	N/A	N/A
ENDO CUT I	155 Watts / Effects 1 to 4	155 Watts / Effects 1 to 4	N/A	N/A
SOFT COAG	120 Watts / Effects 1 to 8	120 Watts / Effects 1 to 8	120 Watts / Effects 1 to 8	120 Watts / Effects 1 to 8
FORCED COAG	120 Watts / Effects 1 to 4	120 Watts / Effects 1 to 4	N/A	N/A

Erbe Vio ICC 200

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
AUTO CUT	200 Watts / Effects 1 to 4	200 Watts / Effects 1 to 4	N/A	N/A
SOFT Coagulation	120 Watts / Effects N/A	120 Watts / Effects N/A	N/A	N/A
Forced coagulation	120 Watts / Effects N/A	120 Watts / Effects N/A	N/A	N/A
Bipolar coagulation	N/A	N/A	120 Watts / Effects N/A	120 Watts / Effects N/A

**Erbe Vio ICC 300**

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
AUTO CUT	300 Watts / Effects 1 to 4	300 Watts / Effects 1 to 4	N/A	N/A
HIGH CUT	300 Watts / Effects 1 to 4	300 Watts / Effects 1 to 4	N/A	N/A
SOFT COAG	120 Watts / Effects N/A	120 Watts / Effects N/A	N/A	N/A
FORCED COAG	120 Watts / Effects N/A	120 Watts / Effects N/A	N/A	N/A
SPRAY COAG	120 Watts / Effects N/A	120 Watts / Effects N/A	N/A	N/A
AUTO BIPOlar	N/A	N/A	120 Watts / Effects N/A	120 Watts / Effects N/A

Erbe Vio ICC 350

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
AUTO CUT	300 Watts / Effects 1 to 4	300 Watts / Effects 1 to 4	N/A	N/A
HIGH CUT	300 Watts / Effects 1 to 4	300 Watts / Effects 1 to 4	N/A	N/A
Program 'b'	120 Watts / Effects 1 to 4	120 Watts / Effects 1 to 4	N/A	N/A
SOFT COAG	120 Watts / Effects N/A	120 Watts / Effects N/A	N/A	N/A
FORCED COAG	120 Watts / Effects 1 to 8	120 Watts / Effects 1 to 8	N/A	N/A
SPRAY COAG	120 Watts / Effects N/A	120 Watts / Effects N/A	N/A	N/A
AUTO BIPOlar	N/A	N/A	120 Watts / Effects N/A	120 Watts / Effects N/A

20.2 EMED

Emed Atom Smart

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
Monopolar Pure cut	200 Watts / Effects N/A	200 Watts / Effects N/A	N/A	N/A
Monopolar Blend cut	200 Watts / Effects N/A	200 Watts / Effects N/A	N/A	N/A
Monopolar Soft coag	200 Watts / Effects N/A	200 Watts / Effects N/A	N/A	N/A
Monopolar Forced coag	200 Watts / Effects N/A	200 Watts / Effects N/A	N/A	N/A
Bipolar. Soft Bi-coag	N/A	N/A	120 Watts / Effects N/A	120 Watts / Effects N/A

Emed ES120

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
Monopolar PURE CUT	120 Watts / Levels 1 to 9	120 Watts / Levels 1 to 9	N/A	N/A
Monopolar BLEND CUT	120 Watts / Levels 1 to 9	120 Watts / Levels 1 to 9	N/A	N/A
Monopolar FORCED COAG	120 Watts / Levels 1 to 9	120 Watts / Levels 1 to 9	N/A	N/A
Monopolar SOFT COAG	120 Watts / Levels 1 to 9	120 Watts / Levels 1 to 9	N/A	N/A
Bipolar, SOFT BI-COAG	N/A	N/A	120 Watts / Levels 1 to 9	120 Watts / Levels 1 to 9

**Emed ES350**

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
PURE CUT	400 Watts / Effects N/A	400 Watts / Effects N/A	N/A	N/A
BLEND CUT I	180 Watts / Effects N/A	180 Watts / Effects N/A	N/A	N/A
BLEND CUT II	150 Watts / Effects N/A	150 Watts / Effects N/A	N/A	N/A
BLEND CUT III	150 Watts / Effects N/A	150 Watts / Effects N/A	N/A	N/A
URO CUT	400 Watts / Levels 1 to 9	400 Watts / Levels 1 to 9	N/A	N/A
POLIPO CUT	400 Watts / Levels 1 to 9	400 Watts / Levels 1 to 9	N/A	N/A
SOFT COAG	180 Watts / Effects N/A	180 Watts / Effects N/A	N/A	N/A
FORCED COAG	180 Watts / Effects N/A	180 Watts / Effects N/A	N/A	N/A
SPRAY COAG	Do not use	Do not use	N/A	N/A
HYBRID COAG	180 Watts / Effects N/A	180 Watts / Effects N/A	N/A	N/A
Thermostapler	300 Watts / Effects N/A	300 Watts / Effects N/A	N/A	N/A
BI-PURE CUT	N/A	N/A	150 Watts / Effects N/A	150 Watts / Effects N/A
BI BLEND CUT I	N/A	N/A	150 Watts / Effects N/A	150 Watts / Effects N/A
BI BLEND CUT II	N/A	N/A	150 Watts / Effects N/A	150 Watts / Effects N/A
BI BLEND CUT III	N/A	N/A	150 Watts / Effects N/A	150 Watts / Effects N/A
URO BI-CUT	N/A	N/A	400 Watts / Effects N/A	400 Watts / Effects N/A
SOFT BI-COAG	N/A	N/A	120 Watts / Effects N/A	120 Watts / Effects N/A

Emed Spectrum

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
MONO CUT	400 Watts / Effects 1 to 9	400 Watts / Effects 1 to 9	N/A	N/A
PRECISE CUT	50 Watts / Effects 1 to 9	50 Watts / Effects 1 to 9	N/A	N/A
MIXED CUT	150 Watts / Effects 1 to 9	150 Watts / Effects 1 to 9	N/A	N/A
MUCO CUT	400 Watts / Effects 1 to 9	400 Watts / Effects 1 to 9	N/A	N/A
POLIPO CUT	400 Watts / Effects 1 to 9	400 Watts / Effects 1 to 9	N/A	N/A
PAPILO CUT	400 Watts / Effects 1 to 9	400 Watts / Effects 1 to 9	N/A	N/A
ARTRO CUT	400 Watts / Effects 1 to 9	400 Watts / Effects 1 to 9	N/A	N/A
URO CUT	400 Watts / Effects 1 to 9	400 Watts / Effects 1 to 9	N/A	N/A
HYSTERO CUT	400 Watts / Effects 1 to 9	400 Watts / Effects 1 to 9	N/A	N/A
SOFT COAG	200 Watts / Effects 1 to 9	200 Watts / Effects 1 to 9	N/A	N/A
FORCED COAG	200 Watts / Effects 1 to 9	200 Watts / Effects 1 to 9	N/A	N/A
HYBRID COAG	200 Watts / Effects 1 to 9	200 Watts / Effects 1 to 9	N/A	N/A
SPRAY COAG	Do not use	Do not use	N/A	N/A
ENDO SPRAY	30 Watts / Effects N/A	30 Watts / Effects N/A	N/A	N/A
URO COAG	200 Watts / Effects 1 to 9	200 Watts / Effects 1 to 9	N/A	N/A
ARTRO COAG	200 Watts / Effects 1 to 9	200 Watts / Effects 1 to 9	N/A	N/A
HYSTERO COAG	200 Watts / Effects 1 to 9	200 Watts / Effects 1 to 9	N/A	N/A
DUAL COAG	200 Watts / Effects 1 to 9	200 Watts / Effects 1 to 9	N/A	N/A
Thermostapler®	N/A	N/A	300 Watts / Effects 1 to 9	300 Watts / Effects 1 to 9



ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
Thermostapler® LAP	N/A	N/A	60 Watts / Effects 1 to 9	60 Watts / Effects 1 to 9
BI-CUT	N/A	N/A	Do not use	Do not use
URO BI-CUT	N/A	N/A	400 Watts / Effects 1 to 9	400 Watts / Effects 1 to 9
URO BI-VAPOR	N/A	N/A	400 Watts / Effects 1 to 9	400 Watts / Effects 1 to 9
ARTRO BI-CUT	N/A	N/A	400 Watts / Effects 1 to 9	400 Watts / Effects 1 to 9
HYSTERO BI-CUT	N/A	N/A	400 Watts / Effects 1 to 9	400 Watts / Effects 1 to 9
SOFT BI-COAG	N/A	N/A	120 Watts / Effects 1 to 9	120 Watts / Effects 1 to 9
FORCED BI-COAG	N/A	N/A	Do not use	Do not use
URO BI-COAG	N/A	N/A	400 Watts / Effects 1 to 9	400 Watts / Effects 1 to 9
HYSTERO BI-COAG	N/A	N/A	400 Watts / Effects 1 to 9	400 Watts / Effects 1 to 9
ARTRO BI-COAG	N/A	N/A	400 Watts / Effects 1 to 9	400 Watts / Effects 1 to 9
SCICC BI-COAG	N/A	N/A	350 Watts / Effects 1 to 9	350 Watts / Effects 1 to 9

20.3 MEDTRONIC

Covidien Valleylab FT10

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
Monopolar CUT PURE	300 Watts/ Effects N/A	300 Watts/ Effects N/A	N/A	N/A
Monopolar CUT BLEND	200 Watts/ Effects N/A	200 Watts/ Effects N/A	N/A	N/A
Monopolar CUT VALLEYLAB	200 Watts/ Effects N/A	200 Watts/ Effects N/A	N/A	N/A
Monopolar COAG SOFT	120 Watts/ Effects N/A	120 Watts/ Effects N/A	N/A	N/A
Monopolar COAG FULGURATE	120 Watts/ Effects N/A	120 Watts/ Effects N/A	N/A	N/A
Monopolar COAG SPRAY	120 Watts/ Effects N/A	120 Watts/ Effects N/A	N/A	N/A
Bipolar LOW	N/A	N/A	1 to 15 Watts/ Effects N/A	1 to 15 Watts/ Effects N/A
Bipolar MEDIUM	N/A	N/A	16 to 40 Watts/ Effects N/A	16 to 40 Watts/ Effects N/A
Bipolar HIGH	N/A	N/A	45 to 90 Watts/ Effects N/A	45 to 90 Watts/ Effects N/A
Bipolar Resection CUT	N/A	N/A	Do not use	Do not use
Bipolar Resection COAG	N/A	N/A	175 Watts/ Effects 1 to 6	175 Watts/ Effects 1 to 6

**Covidien Valleylab FX8**

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
Monopolar CUT PURE	300 Watts/ Effects N/A	300 Watts/ Effects N/A	N/A	N/A
Monopolar CUT BLEND	200 Watts/ Effects N/A	200 Watts/ Effects N/A	N/A	N/A
Monopolar CUT VALLEYLAB	200 Watts/ Effects N/A	200 Watts/ Effects N/A	N/A	N/A
Monopolar COAG SOFT	120 Watts/ Effects N/A	120 Watts/ Effects N/A	N/A	N/A
Monopolar COAG FULGURATE	120 Watts/ Effects N/A	120 Watts/ Effects N/A	N/A	N/A
Monopolar COAG SHARED FULGURATE	120 Watts/ Effects N/A	120 Watts/ Effects N/A	N/A	N/A
Monopolar COAG SPRAY	120 Watts/ Effects N/A	120 Watts/ Effects N/A	N/A	N/A
Bipolar PRECISE	N/A	N/A	70 Watts/ Effects N/A	70 Watts/ Effects N/A
Bipolar STANDARD	N/A	N/A	70 Watts/ Effects N/A	70 Watts/ Effects N/A
Bipolar MACRO	N/A	N/A	70 Watts/ Effects N/A	70 Watts/ Effects N/A
Bipolar LOW Effect	N/A	N/A	1 to 15 Watts/ Effects N/A	1 to 15 Watts/ Effects N/A
Bipolar MEDIUM Effect	N/A	N/A	16 to 40 Watts/ Effects N/A	16 to 40 Watts/ Effects N/A
Bipolar HIGH Effect	N/A	N/A	45 to 90 Watts/ Effects N/A	45 to 90 Watts/ Effects N/A

20.4 OLYMPUS

Olympus ESG-400

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
BlendCut	200 Watts / Effects 1 to 3	200 Watts / Effects 1 to 3	N/A	N/A
PulseCut Fast	150 Watts / Effects 1 to 3	150 Watts / Effects 1 to 3	N/A	N/A
PulseCut Slow	150 Watts / Effects 1 to 3	150 Watts / Effects 1 to 3	N/A	N/A
PureCut	300 Watts / Effects 1 to 3	300 Watts / Effects 1 to 3	N/A	N/A
ForcedCoag	120 Watts / Effects 1 to 3	120 Watts / Effects 1 to 3	N/A	N/A
PowerCoag	120 Watts / Effects 1 to 3	120 Watts / Effects 1 to 3	N/A	N/A
SoftCoag	200 Watts / Effects 1 to 3	200 Watts / Effects 1 to 3	N/A	N/A
SprayCoag	Do not use	Do not use	N/A	N/A
BipolarCut	N/A	N/A	100 Watts / Effects 1 to 2	100 Watts / Effects 1 to 2
AutoCoag	N/A	N/A	120 Watts / Effects 1 to 3	120 Watts / Effects 1 to 3
BISoftCoag	N/A	N/A	120 Watts / Effects 1 to 3	120 Watts / Effects 1 to 3
HardCoag	N/A	N/A	120 Watts / Effects 1 to 3	120 Watts / Effects 1 to 3
RF Coag	N/A	N/A	50 Watts	50 Watts
FineCoag	N/A	N/A	40 Watts / Effect 1	40Watts / Effect 1

**Olympus ESG-410**

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
Blend	200 Watts / Effect 1	200 Watts / Effect 1	N/A	N/A
BlendCut	200 Watts / Effects 1 to 3	200 Watts / Effects 1 to 3	N/A	N/A
FineCut	120 Watts / Effect 1	120 Watts / Effect 1	N/A	N/A
PowerCut	120 Watts / Effects 1 to 3	120 Watts / Effects 1 to 3	N/A	N/A
PulseCut Fast	150 Watts / Effects 1 to 3	150 Watts / Effects 1 to 3	N/A	N/A
PulseCut Slow	150 Watts / Effects 1 to 3	150 Watts / Effects 1 to 3	N/A	N/A
Pure	300 Watts / Effect 1	300 Watts / Effect 1	N/A	N/A
PureCut	300 Watts / Effects 1 to 3	300 Watts / Effects 1 to 3	N/A	N/A
Fulgurate	120 Watts / Effect 1	120 Watts / Effect 1	N/A	N/A
ForcedCoag	120 Watts / Effects 1 to 3	120 Watts / Effects 1 to 3	N/A	N/A
PowerCoag	120 Watts / Effects 1 to 3	120 Watts / Effects 1 to 3	N/A	N/A
SoftCoag	200 Watts / Effects 1 to 5	200 Watts / Effects 1 to 5	N/A	N/A
Spray	Do not use	Do not use	N/A	N/A
SprayCoag	Do not use	Do not use	N/A	N/A
BipolarCut	N/A	N/A	100 Watts / Effects 1 to 2	100 Watts / Effects 1 to 2
PK LoopCut	N/A	N/A	200 Watts / Effect 1	200 Watts / Effect 1
PK MoreCut	N/A	N/A	300 Watts / Effects 1 to 2	300 Watts / Effects 1 to 2
PK PureCut	N/A	N/A	200 Watts / Effects 1 to 2	200 Watts / Effects 1 to 2
PK SoftCut	N/A	N/A	200 Watts / Effect 1	200 Watts / Effect 1
AutoCoag	N/A	N/A	120 Watts / Effects 1 to 3	120 Watts / Effects 1 to 3
BISoftCoag	N/A	N/A	120 Watts / Effects 1 to 3	120 Watts / Effects 1 to 3
HardCoag	N/A	N/A	120 Watts / Effects 1 to 3	120 Watts / Effects 1 to 3

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
PK Coag	N/A	N/A	120 Watts / Effects 1 to 3	120 Watts / Effects 1 to 3
PK SoftCoag	N/A	N/A	120 Watts / Effects 1 to 3	120 Watts / Effects 1 to 3

20.5 KLS MARTIN

KLS Martin MaXium

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
Monopolar Pure Cut	360 Watts / Effects N/A	360 Watts / Effects N/A	N/A	N/A
Monopolar Blend Cut	250 Watts / Effects N/A	250 Watts / Effects N/A	N/A	N/A
Monopolar Super Blend	150 Watts / Effects N/A	150 Watts / Effects N/A	N/A	N/A
Monopolar Uro Pure Cut	360 Watts / Effects N/A	360 Watts / Effects N/A	N/A	N/A
Monopolar Uro Blend Cut	320 Watts / Effects N/A	320 Watts / Effects N/A	N/A	N/A
Monopolar Polyp I	350 Watts / Effects G1 to G5	350 Watts / Effects G1 to G5	N/A	N/A
Monopolar Polyp II	350 Watts / Effects G1 to G5	350 Watts / Effects G1 to G5	N/A	N/A
Monopolar Papilla I	180 Watts / Effects G1 to G5	180 Watts / Effects G1 to G5	N/A	N/A
Monopolar Papilla II	180 Watts / Effects G1 to G5	180 Watts / Effects G1 to G5	N/A	N/A
Monopolar Papilla III	180 Watts / Effects G1 to G5	180 Watts / Effects G1 to G5	N/A	N/A
Monopolar ESD	180 Watts / Effects G1 to G5	180 Watts / Effects G1 to G5	N/A	N/A
Monopolar Soft Cut	360 Watts / Effects N/A	360 Watts / Effects N/A	N/A	N/A
Monopolar Clamp Coag	250 Watts / Effects N/A	250 Watts / Effects N/A	N/A	N/A



ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
Monopolar Forced Clamp	150 Watts / Effects N/A	150 Watts / Effects N/A	N/A	N/A
Monopolar Forced Prep	150 Watts / Effects N/A	150 Watts / Effects N/A	N/A	N/A
Monopolar Contact Coag	250 Watts / Effects N/A	250 Watts / Effects N/A	N/A	N/A
Monopolar Forced Coag	150 Watts / Effects N/A	150 Watts / Effects N/A	N/A	N/A
Monopolar Uro Coag	150 Watts / Effects N/A	150 Watts / Effects N/A	N/A	N/A
Monopolar Forced Uro Coag	150 Watts / Effects N/A	150 Watts / Effects N/A	N/A	N/A
Monopolar Spray	Do not use	Do not use	N/A	N/A
Monopolar Air Beam	Do not use	Do not use	N/A	N/A
Monopolar Endo Spray	100 Watts / Effects N/A	100 Watts / Effects N/A	N/A	N/A
Monopolar Duo Prep	150 Watts / Effects N/A	150 Watts / Effects N/A	N/A	N/A
Monopolar Duo Spray	Do not use	Do not use	N/A	N/A
Bipolar Bipol Pure Cut	N/A	N/A	120 Watts / Effects N/A	120 Watts / Effects N/A
Bipolar Bipol Blend Cut	N/A	N/A	120 Watts / Effects N/A	120 Watts / Effects N/A
Bipolar Forfex	N/A	N/A	120 Watts / Effects N/A	120 Watts / Effects N/A
Bipolar Uro Bip Pure Cut	N/A	N/A	350 Watts / Effects G1 to G5	350 Watts / Effects G1 to G5
Bipolar Uro Bip Pure Cut - without Booster	N/A	N/A	350 Watts / Effects G1 to G5	350 Watts / Effects G1 to G5
Bipolar Uro Bip Pure Cut - with Booster	N/A	N/A	350 Watts / Effects G1 to G5	350 Watts / Effects G1 to G5
Bipolar Uro Bip BlendCut - without Booster	N/A	N/A	350 Watts / Effects G1 to G5	350 Watts / Effects G1 to G5

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
Bipolar coagulation:	N/A	N/A	50 Watts / Effects N/A	50 Watts / Effects N/A
• Micro coag				
• Micro Auto Stop				
• Micro Auto Start				
• Auto Micro				
Bipolar coagulation:	N/A	N/A	120 Watts / Effects N/A	120 Watts / Effects N/A
• Macro coag				
• Macro Auto Stop				
• Macro Auto Start				
• Auto Macro				
Bipolar SealSafe	N/A	N/A	320 Watts / Effects N/A	320 Watts / Effects N/A
Bipolar SealSafe®IQ	N/A	N/A	320 Watts / Effects G1 to G5	320 Watts / Effects G1 to G5
Bipolar Bipol TUR Coag	N/A	N/A	200 Watts / Effects N/A	200 Watts / Effects N/A

**KLS Martin MaXium Smart C**

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
Pure Cut	400 Watts / Effects 1 to 7	400 Watts / Effects 1 to 7	N/A	N/A
Blend Cut	150 Watts / Effects 1 to 7	150 Watts / Effects 1 to 7	N/A	N/A
Uro Pure Cut	400 Watts / Effects 1 to 7	400 Watts / Effects 1 to 7	N/A	N/A
Uro Blend Cut	150 Watts / Effects 1 to 5	150 Watts / Effects 1 to 5	N/A	N/A
Soft Cut	80 Watts / Effects 1 to 7	80 Watts / Effects 1 to 7	N/A	N/A
Forced Clamp	100 Watts / Effects 1 to 5	100 Watts / Effects 1 to 5	N/A	N/A
Forced Prep	150 Watts / Effects 1 to 7	150 Watts / Effects 1 to 7	N/A	N/A
Contact Coag	200 Watts / Effects 1 to 7	200 Watts / Effects 1 to 7	N/A	N/A
Forced Coag	150 Watts / Effects 1 to 9	150 Watts / Effects 1 to 9	N/A	N/A
Uro Coag	Do not use	Do not use	N/A	N/A
Spray	Do not use	Do not use	N/A	N/A
Duo Prep	150 Watts / Effects 1 to 7	150 Watts / Effects 1 to 7	N/A	N/A
Duo Spray	Do not use	Do not use	N/A	N/A
Bipol Pure Cut	N/A	N/A	120 Watts / Effects 1 to 7	120 Watts / Effects 1 to 7
Forfex	N/A	N/A	120 Watts / Effects 1 to 3	120 Watts / Effects 1 to 3
BiCoag	N/A	N/A	120 Watts / Effects 1 to 5	120 Watts / Effects 1 to 5

KLS Martin ME MB 3

ESU MODE	MONOPOLAR SCISSORS (RATED VOLTAGE = 4000 VPEAK)	MONOPOLAR HOOK (RATED VOLTAGE = 4000 VPEAK)	BIPOLAR JOHANN GRASPER (RATED VOLTAGE = 770VPEAK)	BIPOLAR MARYLAND (RATED VOLTAGE = 770VPEAK)
Cut 1 (pure)	400 Watts / Effects N/A	400 Watts / Effects N/A	N/A	N/A
Cut 2 (blend)	300 Watts / Effects N/A	300 Watts / Effects N/A	N/A	N/A
Cut 3 (super blend)	200 Watts / Effects N/A	200 Watts / Effects N/A	N/A	N/A
Forced Prep	120 Watts / Effects N/A	120 Watts / Effects N/A	N/A	N/A
Endo Mode	100 Watts / Effects N/A	100 Watts / Effects N/A	N/A	N/A
Contact coagulation	250 Watts / Effects N/A	250 Watts / Effects N/A	N/A	N/A
Spray coagulation	Do not use	Do not use	N/A	N/A
Bipolar coagulation	N/A	N/A	350 Watts / Effects N/A	350 Watts / Effects N/A



21 APPENDIX E: GLOSSARY

21.1 GENERAL TERMS

Endoscope Cart

Cart on which the Endoscope Arm is mounted



Emergency Release Tool

Used to open instrument blades in the event that the Dexter L6 System stops working and the instruments grab tissue or hold a needle or suture (Manual Emergency Instrument Release)



Surgeon Console - Up Button

Button to elevate the Surgeon Console Master Arms or to change the scaling ratio if pressed along with Surgeon Console - Arms lock Button

**Surgeon Console - Down Button**

Button to lower the Surgeon Console Master Arms or to change the scaling ratio if pressed along with Surgeon Console - Arms lock Button

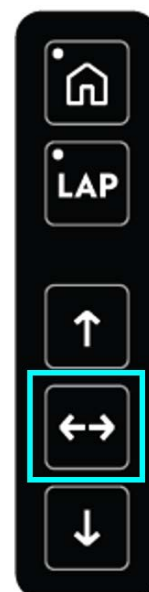
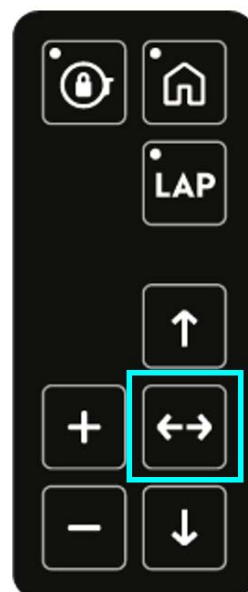
**Surgeon Console - Arms lock Button**

Button that can be used to toggle between the blocked state and the free state of the Master Arm of the Surgeon Console. It can also be used to check the scaling ratio value when long pressed or adjust the scaling ratio if pressed along with Surgeon Console - Down Button or Surgeon Console - Up Button



**Lateral Boom Movement Button**

Button that can be used to release or lock the Boom brakes

**Patient Cart - Up Button**

Button to elevate the Patient Cart

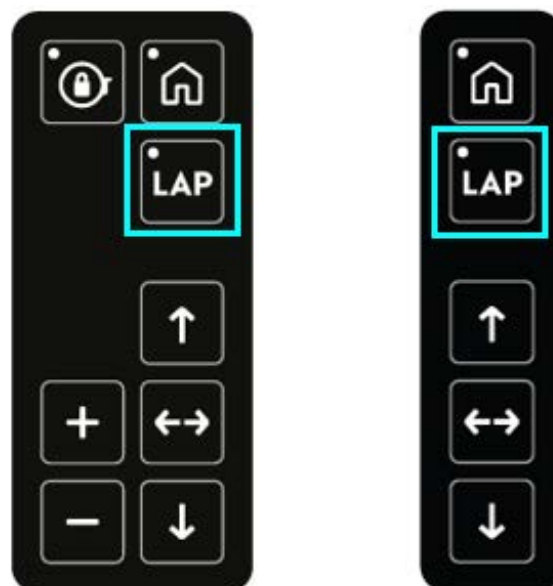
**Patient Cart - Down Button**

Button to lower the Patient Cart

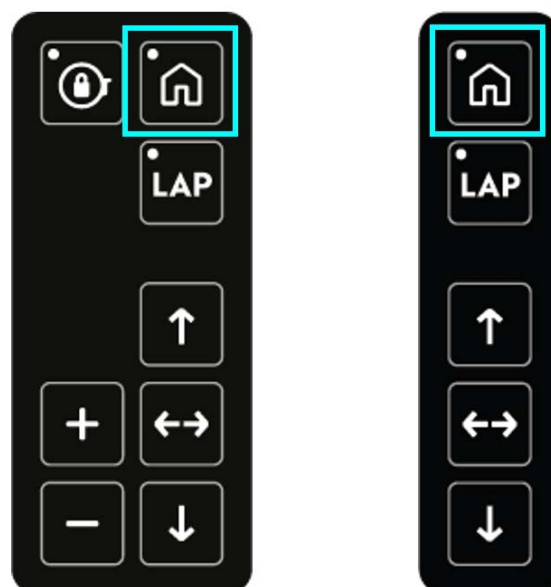


Patient Cart - LAP Mode Button

Button to contract the Instrument Arm to allow the surgeon to perform the surgical step in laparoscopy

**Patient Cart - Home Button**

Button to position the Instrument Arm in the Home position

**Patient Cart - Floor Lock Button**

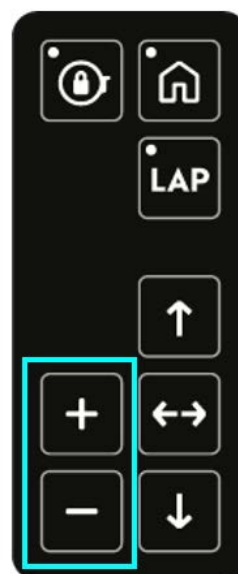
Button to deploy or retract the Floor Locks





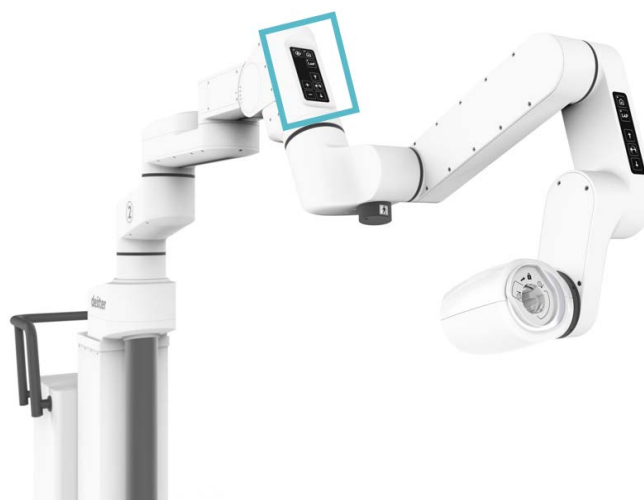
Patient Cart - Forward Angulation Buttons

Buttons to increase or decrease the Forward Angulation



Proximal User Interface

User interface located on the proximal part of the Instrument Arm



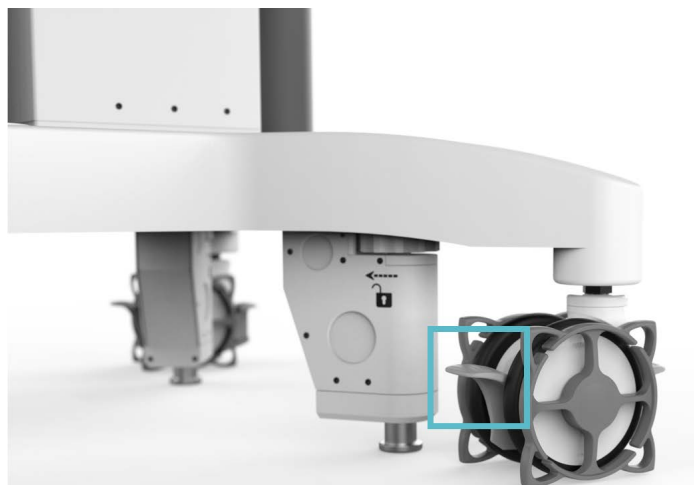
Distal User Interface

User interface located on the distal part of the Instrument Arm



Patient Cart - Wheel Brake

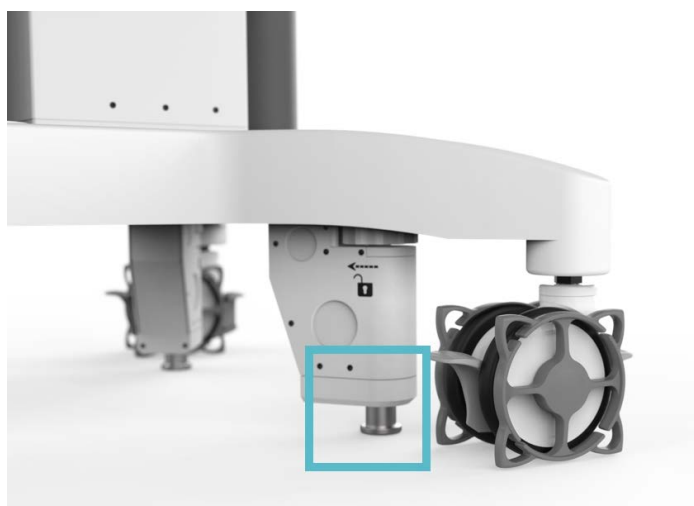
Brakes on the wheel of the Patient Carts

**Surgeon Console - Wheel brake**

Brakes on the wheel of the Surgeon Console

**Floor Lock**

Pillar stabilizing the Patient Carts





Pedalboard

Pedalboard containing the Endoscope Foot Pedal and the Clutching Foot Pedal



Endoscope Pedal

Left pedal on the Surgeon Console Pedalboard used for robotic endoscope control



Clutch Pedal

Right pedal on the Surgeon Console Pedalboard used for clutching instruments.



Electrosurgical Pedalboard

Pedalboard connected to the electrosurgical unit to deliver either monopolar or bipolar energy



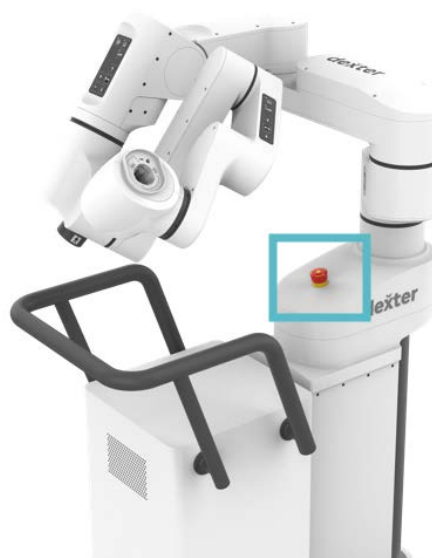
Power Switch

Switch located on the Patient Carts and Surgeon Console that can be used to power on or off the device.



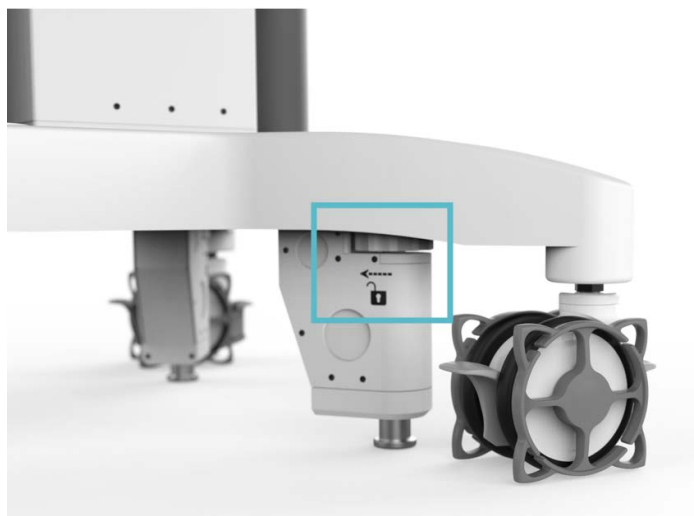
Emergency Stop Button

Red buttons located on the Patient Carts and Surgeon Console to trigger an emergency stop



**Manual Floor Lock Wheel**

Wheel located at the bottom of the Patient Cart to manually release the Floor Lock in case of emergency

**Incision Pointer**

To dock the Patient Carts to the trocars

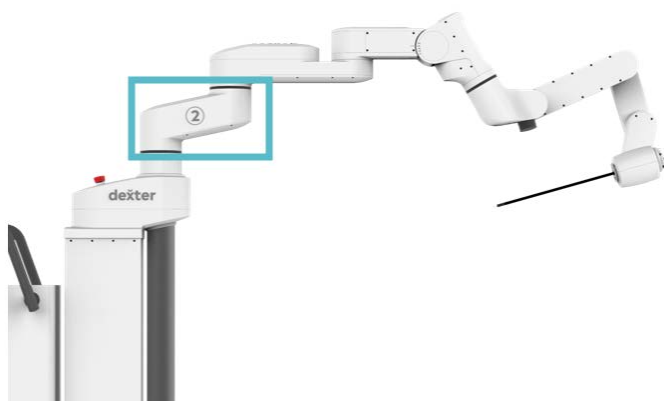
**Handle Grips**

Connected to the Surgeon Console. The surgeon grabs the Handle Grips while operating, which capture the roll, pitch, yaw and open/close movements from the surgeon's hands.

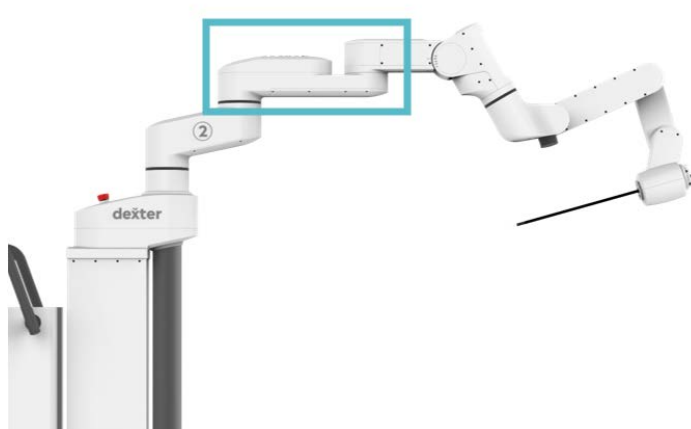


Boom Proximal Segment

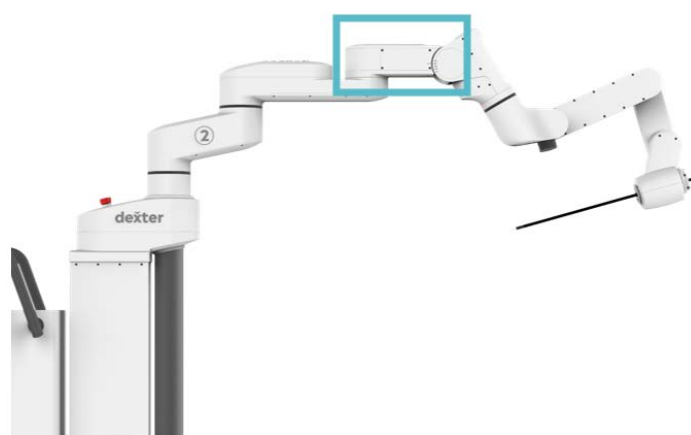
Proximal Segment of the Boom

**Boom Mid Segment**

Central Segment of the Boom

**Boom Distal Segment**

Distal Segment of the Boom



Instrument Arm Proximal Segment

Proximal Segment of the Instrument Arm

**Instrument Arm Mid Segment**

Central segment of the Instrument Arm

**Instrument Arm Distal Segment**

Distal segment of the Instrument Arm



Hub

Contains a lumen through which the instrument is inserted and drives the roll, pitch, yaw and open / close degrees of freedom of the instruments

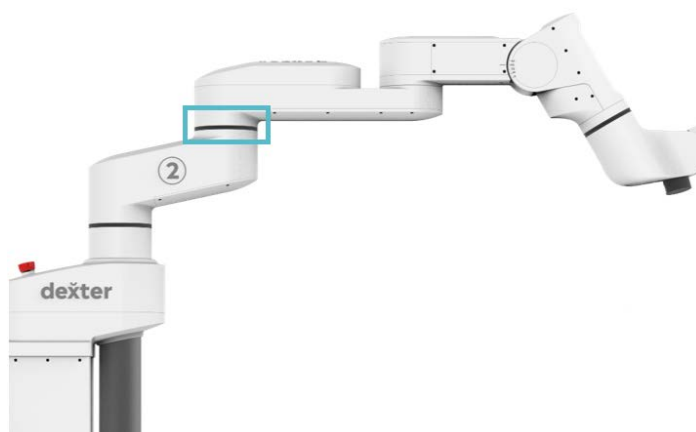
**Instrument Arm Magnet**

Magnet that secures the Incision Pointer to the Instrument Arm for docking

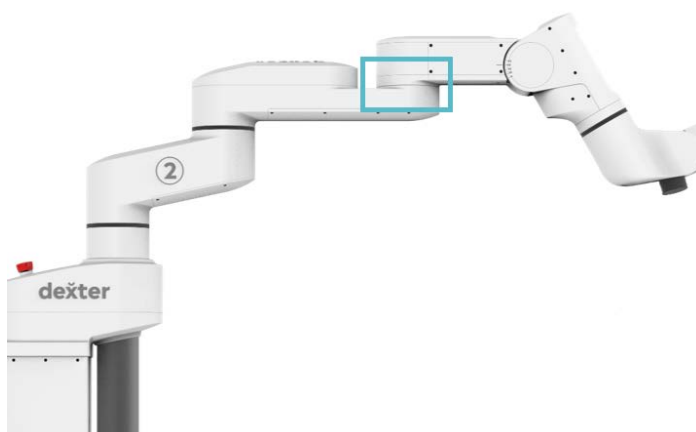
**Patient Cart - Epsilon Joint**



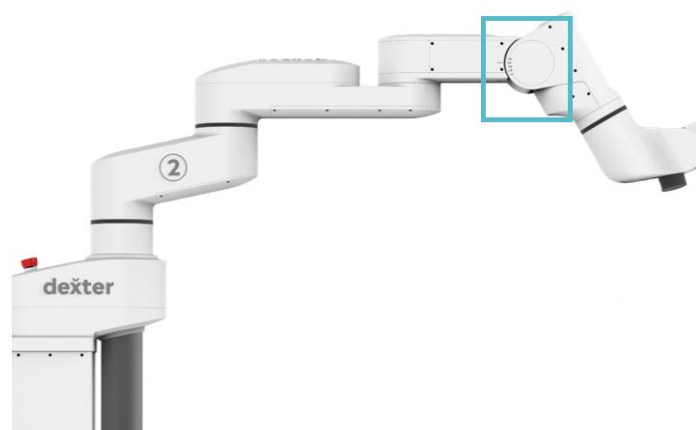
Patient Cart - Eta Joint



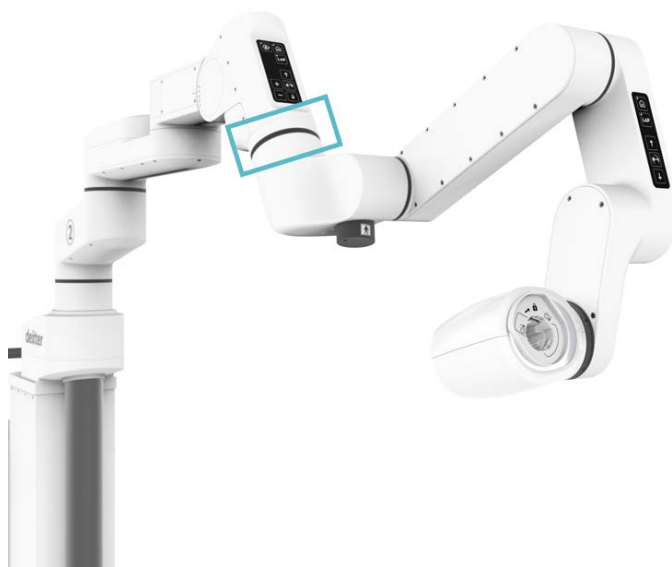
Patient Cart - Phi Joint



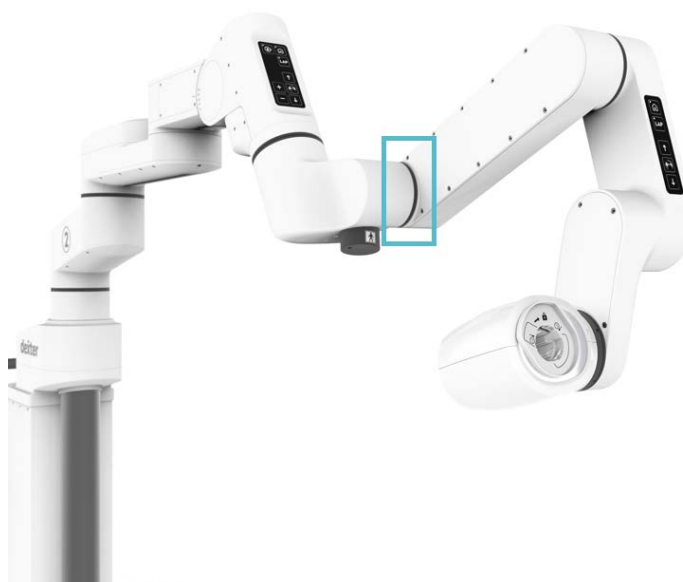
Patient Cart - Forward Angulation



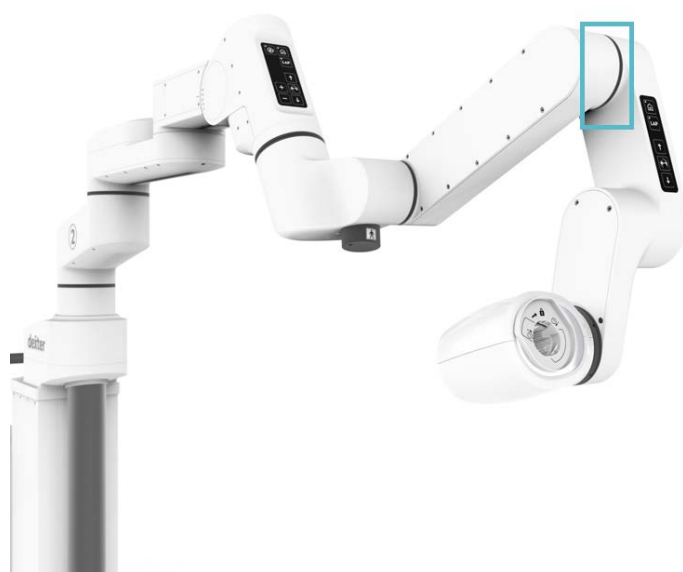
Patient Cart - Alpha Joint



Patient Cart - Beta Joint



Patient Cart - Gamma Joint





Patient Cart - Theta Joint



Surgeon Console - Alpha Joint



Surgeon Console - Beta Joint



Surgeon Console - Gamma Joint



Scaling Adjustment

Scales the sensitivity of the hand controls in relation to the instruments. Quick (1.5:1), Normal (2:1) and Fine (3:1) ratios. The camera movements are not affected.



21.2 SPECIFIC USER ACTIONS

Power on

Switching on the Patient Carts and/or the Surgeon Console

Power off

Switching off the Patient Carts and/or the Surgeon Console

Restart

Dexter L6 System reboot performed from the Surgeon Console

Manual Restart

Dexter L6 System reboot performed by power off and on the Patient Carts and the Surgeon Console

Emergency Instrument Release

Opening instrument blades from the Surgeon Console

Manual Emergency Instrument Release

Opening instrument blades using the Emergency Release Tool

Insertion Zone

Area where the instrument can be inserted and locked. The user can adjust the position of the hub using the Home or LAP buttons to either place the tip of the instrument within the trocar or to return it to the position where the instrument was removed.

Deploy Floor Lock

Deploy Floor Locks using the primary Human Machine Interface (user interface)

Retract Floor lock

Retract Floor Locks using the primary Human Machine Interface (user interface)

Manual Floor lock Release

Unlocking Floor Lock using the wheel located on Patient Carts

Roll

Rotation movement of the instrument

Engage / Disengage Wheel brake

Allowing the wheels to move or preventing the wheels from moving on the Patient Carts or Surgeon Console



Distalmotion