

7.2b Instructions for Use - USA

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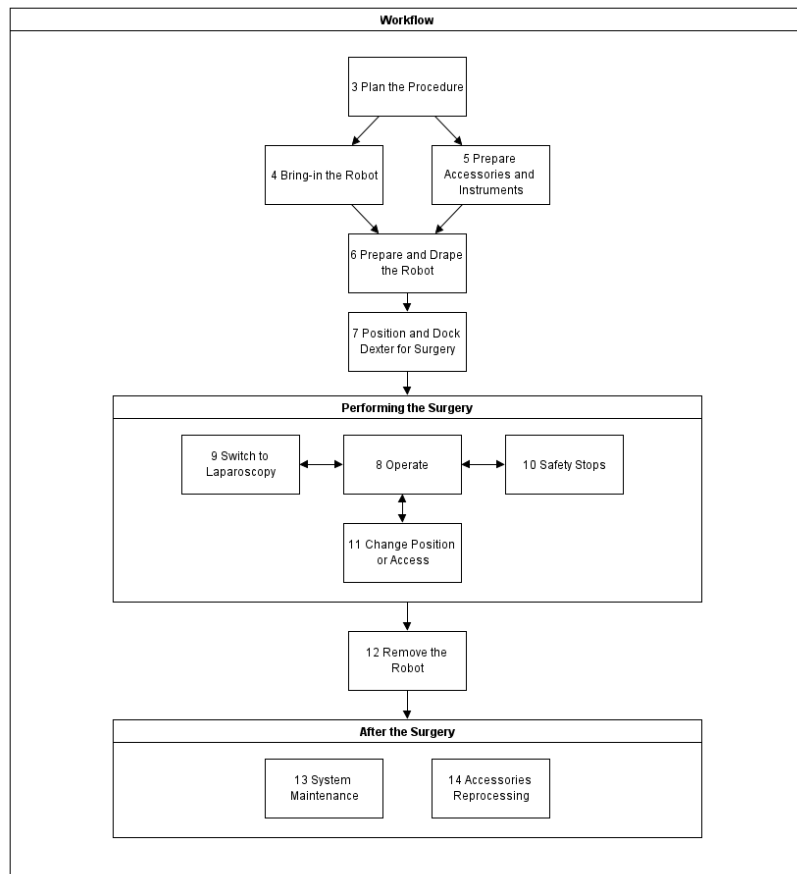
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1 Introduction

This manual provides information specific to the use of the **Distalmotion Endoscopic Instrument Control System** (Dexter Surgical System, Model DM-L6) which is intended to assist in the accurate control of **Distalmotion Endoscopic Instruments**. In addition, the Manual is organized and numbered in chapters following the workflow displayed below.

Note: For visibility of system hardware, this manual usually presents photographs of the Patient Cart and Surgeon Console without sterile drapes, except in Chapter 6.2.2 which explains how to drape Dexter for surgery.



1.1 General Information

1.1.1 Contact Information

For Customer Service and Reporting of Complaints or Adverse Events

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 SA Route de la Corniche 3b 1066 Epalinges Switzerland Phone: +41 21 510 58 90 Email: support@distalmotion.com
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For Technical Support

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

Phone: +41 21 510 58 98

1.1.2 About this Manual

The manual uses the following symbols:

Symbol	Meaning
	Warning: Alerts the reader about a potentially hazardous situation which, if not avoided, may result in injury (including serious injury or death) to the user or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.
	Caution: To indicate that the current situation needs operator awareness or user action in order to avoid undesirable but not critical consequences.

1.2 Professional Instructions for Use

1.2.1 Intended Use and Indications for Use

Intended Use:

The 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, dissecting, coagulating and cutting, with or without high frequency functionality. It is intended for use by trained surgeons in an operating room environment in accordance with the representative and specific procedures set forth in the Instructions for Use

Indications for Use:

Dexter L6 System is intended for use in general laparoscopic surgery. The system is indicated for adult use

1.2.2 Contraindications

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

Please observe: In addition to the general contraindications for the use of conventional endoscopes and endoscopic surgical instruments, the following specific contraindications apply:

- Robotic stapling, advanced energy delivery, ultrasound, cryoablation and microwave energy delivery is excluded.
- Do not use on patients with pacemakers or defibrillators.
- General, non-procedure specific contraindications to endoscopic surgery include bleeding diathesis, morbid obesity, and pregnancy.

1.2.3 Patient Population

The following table describes the characteristics of patients eligible to be operated using Dexter L6:

Category	Definition
Patient age	Adult patients.
Patient sex	Indifferent.
Patient weight	Non-morbid obese.
Nationality / ethnicity	Indifferent.
Patient condition	Patient undergoing a laparoscopic surgery.
Self-application	No.
Possible patient limitations	Same as for laparoscopy.

1.2.4 Intended Users & Training

1.2.4.1 General

Dexter 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 Distalmotion representative. 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. While these messages appear throughout the manual, this chapter provides some general precautions.

 **- WARNING:** Only trained users and those who have developed adequate robotic skills to perform the tasks associated with each procedure should use Dexter. Training provided by Distalmotion is limited to the use of Dexter and does not replace the necessary medical training and experience required to perform laparoscopic surgery.

1.2.4.2 Surgeons

Category	Definition
User age	Indifferent.
User sex	Indifferent.
User weight	Indifferent.
User size	Not restricted. Ergonomics optimized for 10th to 90th percentile of US size.
Professional user or layperson	Laparoscopic surgeon.
Required training / knowledge	Trained general laparoscopic surgeon capable of performing the entire procedure (for which he / she intends to use the device) laparoscopically.
Required language skills	Fluent in English to be able to read the Instructions for Use.
Necessary user training	Successfully completed surgeon training provided by a Distalmotion certified trainer.
Possible user limitations	Surgeons must not be 3D blind.

1.2.4.3 Nurses

Category	Definition
User age	Indifferent.
User sex	Indifferent.
User weight	Indifferent.
User size	Not restricted. Ergonomics optimized for 10th to 90th percentile of US size.
Professional user or layperson	Scrub nurse.
Required training / knowledge	Trained laparoscopic scrub nurse capable of draping and preparing equipment in a laparoscopic operating room, and to handle laparoscopic instruments.
Required language skills	Fluent in English to be able to read the Instructions for Use.
Necessary user training	Successfully completed nurse training provided by a Distalmotion certified trainer.
Possible user limitations	None.

1.3 General Warning and Safety Notices

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

1.3.1 Conversion to Laparoscopy or Open Surgery

-  - **WARNING:** Environmental or equipment failures may cause Dexter to be unavailable. The surgical team should always have all equipment and instrumentation available and be prepared and trained to perform the full procedure using laparoscopy.
-  - **WARNING:** Anatomical characteristics of a patient may preclude using Dexter and minimally invasive techniques. The surgical team should always have all equipment and instrumentation available and be prepared and trained to perform the full procedure using open surgical techniques.
-  - **WARNING:** To ensure a speedy removal of Dexter in case it stops working, consider the physical space required around the patient for the Booms to be pushed away manually.

1.3.2 Operational Hazards

-  - **WARNING:** Make sure that the required Dexter instruments are available and verify that you are able to perform the planned procedure with the available instrument portfolio for Dexter. Otherwise, work laparoscopically.
-  - **WARNING:** To the extent possible, avoid using Dexter when the forward angulation of both patient carts is not similar. Collisions between the two instrument arms may occur.
-  - **WARNING:** The force feedback associated with Dexter 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.
-  - **WARNING:** Once Patient Carts are docked to the patient, the patient **MUST NOT MOVE OR SLIDE** in any way. Serious injury could result. If intraoperative patient movement is necessary, remove all Instruments and the endoscope, undock the Patient Carts, move the patient, and re-dock the Patient Carts.
-  - **WARNING:** Once Patient Carts are docked to the patient, the operating table **MUST NOT BE MOVED** in any way. Serious injury could result. If intraoperative OR table movement is necessary, remove all Instruments and the endoscope, undock the Patient Carts, move the OR table, and re-dock the Patient Carts.
-  - **WARNING:** Once Patient Carts are docked to the patient, the insufflation must not change. Injury could result. If changes to the insufflation are necessary, remove all Instruments, change insufflation, and re-dock the Patient Carts.
-  - **WARNING:** Dexter is only allowed to be used with a 3D endoscope which must have at least HD resolution.
-  - **WARNING:** Do not use Dexter, its Instruments and Accessories for anything else than their intended use.
-  - **WARNING:** Only use Dexter 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 result in improper operation.
-  - **WARNING:** 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.
-  - **WARNING:** Do not clean the Instrument tips with another instrument intra-operatively, as this may damage the Instrument. If an Instrument tip requires cleaning, remove the Instrument from the trocar and gently clean the tip.
-  - **WARNING:** The minimum distance between the Patient Cart and the Surgeon Console shall be at least 10 [cm].
-  - **WARNING:** The minimum distance between Dexter (i.e. the Patient Cart and the Surgeon Console) and other electrical equipment (e.g. surgical table, endoscope tower) shall be at least 10 [cm].
-  - **WARNING:** While Dexter is specified for continuous use, the vertical pillars used for height adjustment 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 seconds. The motor might overheat and stop working for a few minutes.

1.3.3 High Frequency Electrosurgery Precautions

-  - **WARNING:** Due to concerns about the carcinogenic and infectious potential of electrosurgical by-products (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
-  - **WARNING:** Use the lowest power or effect setting possible for the minimum time necessary to achieve the desired effect.
-  - **WARNING:** Dexter monopolar instruments have a rated voltage of **4'000 [Vp]**. Dexter 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 3rd degree burns.
-  - **WARNING:** Using electrosurgical instruments may cause neuromuscular stimulation.

 - **WARNING:** The risk of ignition of flammable gases or other materials generally exists in the surgical application of electrical energy. Precautions must be taken to remove flammable materials and substances from the area of contact (no flammable anaesthetic and nitrous oxide or oxygen use). Otherwise there is a risk of explosion or fire hazard, and may cause serious injury. Dexter is not explosion-proof. Do not use Dexter within areas with an explosion hazard.

 - **WARNING:** Electrosurgery may produce interference with internal or external pacemakers or defibrillators. Electrosurgery may cause these devices to enter an asynchronous mode or may inhibit pacemaker or defibrillator operation entirely. Consult the pacemaker or defibrillator manufacturer for further information when using electrosurgery in patients with cardiac pacemakers or defibrillators.

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

- Use a recent HF surgical equipment with return current and electrode monitoring.
- Ensure that the dispersive electrode is securely affixed to the patient, 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. Maximum power levels to stay below the following limit.
- 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 as possible from the surgical electrodes or the dispersive electrode when HF 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 HF surgical equipment should be positioned in such a way that contact with the patient or other patient leads is avoided.
- Always check the cables, HF surgical equipment, and Instruments for insulation damage and proper function.

 - **WARNING:** Do not use Dexter in or near a strong magnet or in an magnetic resonance imaging (MRI) environment. Dexter has not been evaluated for potential electromagnetic interference when used with MRI where the intensity of electromagnetic disturbances is high. Also, strong magnets might impair the calibration of sensors in the various joints of the Surgeon Console and Patient Carts.

 - **WARNING:** Activate the HF 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.

 - **WARNING:** 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.

1.3.4 Maintenance and Servicing

 - **WARNING:** Dexter may only be serviced by Distalmotion personnel. **DO NOT** attempt to service equipment without Distalmotion personnel. To reduce risk of electric shock, do not open or remove covers.

 - **WARNING:** Do not maintain or service Dexter during use.

 - **WARNING:** No modification of any part of Dexter (including Instruments and Accessories) is allowed. Failure to comply with this warning may result in serious harm to the user or the patient.

1.3.5 Mechanical Hazards

 - **WARNING:** The surgeon and other personnel operating Dexter or working around Dexter shall be mindful of 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 of a Patient Cart with itself (e.g. Instrument with the Boom or the Wheel Base)
- Collisions between Patient Carts
- Collisions of a Patient Cart with a laparoscopic instrument
- Collisions of a Patient Cart with the endoscope

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

CAUTION: Avoid powering-on Dexter while an instrument arm is forcing against an obstacle.

 - **WARNING:** Do not trap a finger in a joint of the Master Arm of the Surgeon Console. Serious injury may occur.

 - **WARNING:** Do not place cables over the Patient Cart or the Surgeon Console. They can limit their range of motion, become pinched or damaged.

 - **WARNING:** Do not trap a finger, hand or arm in the Instrument Arm when the surgeon is operating Dexter. Serious injury may occur.

 - **WARNING:** Do not crush a patient when vertically adjusting the height of a Patient Cart. Serious injury may occur.

 - **WARNING:** Be careful when pushing the Endoscope Cart with the Endoscope Arm mounted to it as it might fall over.

1.3.6 Electrical Hazards

 - **WARNING:** To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

 - **WARNING:** Do not connect Dexter to a multiple socket outlet. The Surgeon Console and both Patient Carts shall be connected to separate, independent sockets.

 - **WARNING:** Do not touch the patient and part of the Surgeon Console or the Patient Cart simultaneously.

 - **WARNING:** As Dexter has type BF applied parts, the applied parts of other medical electric equipment used within Dexter configuration shall be F-type 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.

 - **WARNING:** If Dexter is used together with other medical electronic equipment, leakage currents can be additive. This specifically applies to the so-called robotic surgery configuration in which multiple medical devices (e.g. Dexter, endoscope, Endoscope Arm) are used at the same time.

 - **WARNING:** Do not use Dexter in the vicinity of the heart. Leakage currents flowing through the heart exceeding safety limits may cause ventricular fibrillation.

 - **WARNING:** Withdraw instruments and Dexter from the surgical field before using a defibrillator.

 - **WARNING:** Only use one incision pointer at a time to avoid the small residual risk of exceeding patient leakage current limits when both incision pointers are in the trocar and accidentally touch tissue.

 - **WARNING:** Avoid contact between the OR table or the patient with the boom or instrument arm as this could result in loss of electrical safety insulation.

 - **WARNING:** The use of Dexter adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, Dexter and the other equipment should be observed to verify that they are operating normally.

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

 - **WARNING:** Ensure that Dexter is positioned such that the disconnection from supply mains is not difficult.

1.3.7 Sterility Hazards

 - **WARNING:** If the packaging is torn, damaged or open, do not use the instrument, single and reusable accessory as it might not be sterile.

 - **WARNING:** Improper draping of the Surgeon Console or the Patient Carts could result in loss of sterility. Follow the instructions for use and request training when unsure about how to properly drape Dexter.

 - **WARNING:** The surgeon knee area might not be sterile yet touch the Handle, Handle Grip or directly the hand of the surgeon when operating the Surgeon Console in a seated position. This could result in loss of sterility.

 - **WARNING:** The Emergency Release Tool, the Sterile Interface and the Instrument lose sterility when using the Emergency Release Tool. The Sterile Interface shall be replaced after use of the Emergency Release tool.

 - **WARNING:** Do not resterilize nor reuse the Instruments, the Sterile Interfaces or the Sterile Drapes. They are single-use accessories not designed for reprocessing nor reuse. Reuse may lead to infection, loss of performance due to mechanical and electrical integrity impact and physical injury of the patient.

1.3.8 Physical Hazards

 **- WARNING:** Handle accessories such as the Monopolar Scissors or the Emergency Release Tool with caution, as their sharpness could pose a risk to both users and patients.

2 System Overview

2.1 Device Overview

Dexter is designed to enable complex surgery during minimally invasive approach, and is composed of the Robot, the single-use, fully articulated Instruments, compatible with standard single-use laparoscopic trocars of 10 [mm] diameter and larger, as well as reusable Accessories. Please note that the table below list the only items compatible with Dexter.

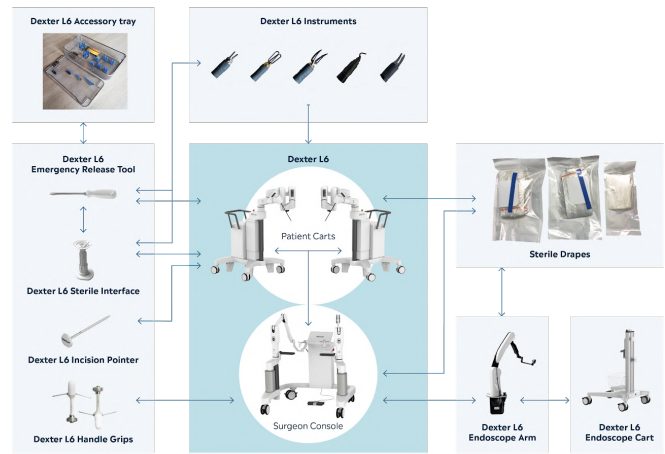
Robot (Dexter L6)	Instruments	Accessories
• Surgeon Console (SC)¹ • Patient Cart 1 (PC-1)¹ • Patient Cart 2 (PC-2)¹	• Needle Holder (IN-N102) • Bipolar Johann Grasper (IN-G101) • Bipolar Maryland Dissector (IN-B101) • Monopolar Scissors (IN-M101, IN-M102)	Single-Use • Sterile Interfaces (AC-SU-SI) • Sterile Drapes (AC-SU-SD) Reusable • Accessory Tray (AC-RU-T) • Handle Grips (AC-RU-HG) • Incision Pointers (AC-RU-IP) • Emergency Release Tool (AC-RU-ERT) Endoscope Control • Dexter Endoscope Arm (SOLO) and its accessories • Endoscope Cart (EC)

Note: The code in brackets refers to the model identification, except for ¹ that not considered as devices.

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). Please find further details of the components in the following subsections.

Surgeon Console	Patient Cart 1	Patient Cart 2	Endoscope Cart
			

The following diagram illustrates the interactions between the different parts of Dexter and how they interact with each other.



2.2 Surgeon Console

The surgeon is seated or stands at the Surgeon Console and controls the movement of the Instruments and of the Endoscope Arm using two Handle Grips, a Clutching Pedal and an Endoscope Pedal.



Figure 1 Surgeon Console

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:** Extremity of the Master Arms connecting to the Handle Grips which the surgeon grabs while operating. Capturing roll, pitch, yaw and open / close movements from the surgeon's hands.
3. **Arms lock button:** The left Master Arm contains a button for Master Arm brake release. When this button is pushed, both Master Arms are blocked on their vertical rotation axis.
4. **Up and Down buttons:** The right Master Arm contains a button for height adjustment. Height can be adjusted to optimize ergonomics for a given surgeon size or to choose between standing or seated working position.
5. **Arm Rest:** Support for the surgeon to rest her/his forearms when operating with Dexter.
6. **Central Pillar:** Contains the electronics and the emergency stop button.
7. **Pedalboard:** Used for clutching the instruments (clutching pedal) and for robotic endoscope control (endoscope pedal).

2.3 Patient Carts

The Patient Carts are positioned at the operating room table and each contains one arm that is positioned with respect to the target patient anatomy. The boom is adjustable and moves the arm horizontally into a position appropriate for the target anatomy and patient position. The vertical column moves the boom up or down to adjust the height of the arm. The patient-side assistant attaches / detaches the Instruments during surgery.

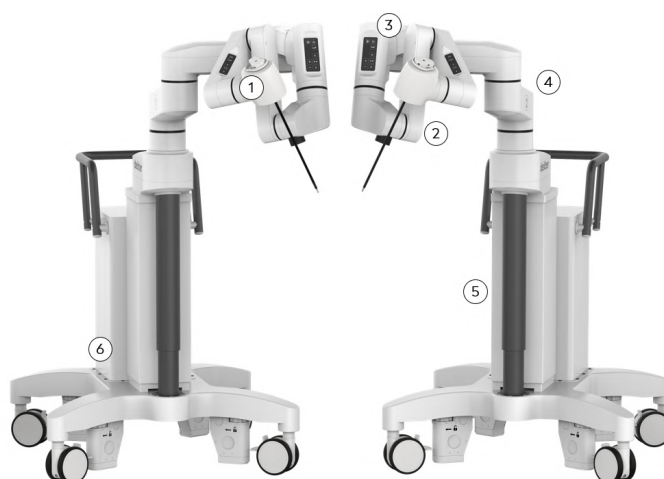


Figure 2 Patient Carts

The Patient Cart is composed of:

1. **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.
2. **Instrument Arm:** Drives the translational degrees of freedom (left / right, up / down, in / out) of the instrument and contains the connector for the incision pointer.
3. **Forward Angulation:** Enables setting the appropriate surgical workspace with regard to the trocars.
4. **Boom:** Enables the horizontal positioning of the instrument arm.
5. **Column:** Enables the vertical positioning of the instrument arm.
6. **Wheel Base:** Contains the electronics rack and has wheels for positioning and transportation of the Patient Cart.

2.4 Single-Use Accessories

The Instruments give surgeons natural dexterity and greater than natural range of motion, compared to unaided human hands, allowing for greater precision when operating in a minimally invasive environment. The Instruments, when used with Dexter, are designed to support rapid and precise suturing and dissection.

The Instruments are single-use and supplied sterile (EtO sterilization). Should the packaging be damaged, then the Instruments are not permitted to be used on patients.

Needle Holder	Bipolar Johann Grasper	Bipolar Maryland Dissector	Monopolar Scissors	Monopolar Hook
REF: 435 (IN-N102)	REF: 437 (IN-G101)	REF: 433 (IN-B101)	REF: 375 (IN-M101)	REF: 216 (IN-M102)
				
	Rated voltage of 770 [Vp]	Rated voltage of 770 [Vp]	Rated voltage of 4'000 [Vp]	Rated voltage of 4'000 [Vp]

The variant of the monopolar scissor (IN-M102) can be also called Monopolar Hook.

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

Note: All bipolar instruments feature a standard rectangular bipolar electrical connector.

Dexter 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 (EtO sterilization). Sterile Drapes are CE-marked, manufactured and supplied by Medline (<https://www.medline.eu>). Should a sterile pouch be damaged, then the corresponding Sterile Interface or Sterile Drape is not permitted to be used.

Sterile Drapes	Sterile Interfaces
AC-SU-SD (REF 141)	AC-SU-SI (REF 140)
	
• 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.	• 2x Inserted into the Hub.

2.5 Electrosurgical Units

Dexter compatibility has been verified with the CE marked electrosurgical generators/units (ESU) listed below, including their accessories (monopolar cables, foot switches, and patient return electrodes). Refer to the instructions for use that accompany the ESU for information about using the equipment and compatible accessories:

Brand	Model
Erbe	VIO 200D
Erbe	VIO 200S
Erbe	VIO 300D
Erbe	VIO 300S
Erbe	ICC 200
Erbe	ICC 300
Erbe	ICC 350
Erbe	VIO 3
Emed	ATOM SMART
Emed	ES350
Emed	ES120

Brand	Model
Emed	Spectrum
Medtronic	Valleylab FT10
Medtronic	Valleylab FX8
Olympus	ESG-300
Olympus	ESG-410
Olympus	ESG-400
KLS Martin	MaXium
KLS Martin	ME MB3

Dexter monopolar instruments have a rated voltage of 4'000 [Vp]. Dexter bipolar instruments have a rated voltage of 770 [Vp]. For more information, please refer to the [L6-56650 - Appendix D: Electrosurgical Units](#)

2.6 Reusable Accessories

Dexter reusable accessories comprise the 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 the instruments from the Patient Carts in case of power loss or system failure.

Dexter reusable accessories are reprocessed using standard washer-disinfector and steam sterilization methods.

Tray	Handle Grips	Incision Pointers	Emergency Release Tool
AC-RU-T (REF 147) 	AC-RU-HG (REF 146) 	AC-RU-IP (REF 413) 	AC-RU-ERT (REF 145) 
1x	2x	2x	1x
To transport, store and reprocess the AC-RU-HG, AC-RU-IP & AC-RU-ERT.	Connected to the Surgeon Console. Held by the surgeon to control Dexter L6.	To dock the Patient Carts to the trocar.	To open instrument blades when Dexter L6 stops working and instruments grab tissue.

2.7 Endoscope Arm & Endoscope Cart

The Endoscope Arm is a CE marked (Class I) product from AKTORmed which can be connected to Dexter. Thereby, the surgeon can control the endoscope via the Surgeon Console. The Endoscope Arm can be attached to the rail of the surgical table, or be used when mounted on the Endoscope Cart.



Figure 3 Endoscope Arm

References is made to the IFU of the Dexter Endoscope Arm from AKTORmed for more information.

The endoscope arm is composed of:

- 1. Control panel
- 2. Cantilever arm
- 3. Releasing slider
- 4. Emergency stop
- 5. Universal joint

6. Endoscope clamp
7. Tension sleeve
8. Tracer pin
9. Quick-fastener for fastening to the operating table
10. Joystick connection
11. Power supply connection

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

Endoscope Cart with Mounted Endoscope Arm	Endoscope Cart
	DM-L6-EC (REF 339)
	

2.8 Function

Motion Capture

The Surgeon Console captures the surgeon's hand movements (7 degrees of freedom or DOF) by means of sensors:

- 3 DOF: Translation (up / down, left / right, in / out) of the surgeon's hand in space - captured by the Master Arm,
- 1 DOF: Roll around the longitudinal axis of the forearm - captured by the Handle,
- 2 DOF: Pitch and yaw of the wrist- captured by the Handle, and
- 1 DOF: Opening and closing the grip of the handle - captured by the Handle.

Instrument Control

When no pedal is pressed, those 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 (7 DOF) by means of electric motors:

- 3 DOF: Translations to move the instrument tip in space - actuated by the Instrument Arm,
- 1 DOF: Roll to rotate the instrument around its main axis - actuated by the Hub,
- 2 DOF: Pitch and yaw of the Instrument tip / end-effector - actuated by the Hub, and
- 1 DOF: Opening and closing the end-effector - actuated by the Hub.

When the clutching pedal is pressed, motion replication pauses. The surgeon can freely reposition the handles (e.g. to improve surgeon comfort and reach). Once the clutching pedal is released, motion replication continues relative to the position prior to clutching.

Note: Compared to other surgical robotic system, Dexter also clutches and scales the roll, pitch and yaw movements.

Endoscope Control

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

Note: Pressing the endoscope pedal also clutches the instruments.

2.9 Power Supply

Dexter is connected to three separate wall power sockets:

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

The optional Dexter 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 an potential equalization conductor to the equipotential

terminals located near the mains inlet on each sub assembly 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. The location of the cables should also facilitate easy movement of the Patient Cart between its 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 separate the Robot from supply mains.



Figure 4 Power Switch location on the Surgeon Console



Figure 5 Power Switch location on the Patient Cart

2.10 Environment

The Surgeon Console (when operated sterile) and the Patient Carts are in the patient environment.

Dexter interfaces with the following items in the operating room:

- Trocars through which the Instruments are inserted into the patient.
- *Optional:* Dexter Endoscope Arm
- *Optional:* Electrosurgical generators which connect to the mono- and bipolar Instruments of Dexter

In order to use Dexter as part of laparoscopic procedures, a 3D endoscope as well as other customary laparoscopy, surgical and anesthesiology equipment is required. However, Dexter doesn't directly interface to or interact with this equipment.

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.

 - **Select appropriate trocars**

The **surgeon** ensures that translucent trocars of at least 10 [mm] in diameter are used.

 - **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 and in a hybrid or laparoscopy setup (not robotic only).

 - **Select appropriate robotic instruments**

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

 - **Select appropriate laparoscopic instruments**

The surgeon ensures that all laparoscopic and other instruments are in the operating room to perform every task of the procedure manually, that is without the use of the device. This includes stapling, advanced energy delivery, ultrasound, cryoablation and microwave energy delivery instruments which are not part of the portfolio of Dexter.

 - **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).

 - **Select whether surgeon console is sterile or not**

The **surgeon** decides on whether he or she wants to use the surgeon console in a sterile or non-sterile manner.

- **Sterile mode:** Default way of using Dexter.
- **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 delegates all or some of these tasks to a sterile assistant. In any case, it remains the responsibility of the surgeon to ensure that Dexter is used in a safe way.

 - **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 tower, electrosurgical generator & cables, insufflator, screen for surgeon when doing laparoscopy and when using the device, screen for assistant, sterile surface and other potential OR related 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.

- Prepare surgeon console for transportation

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.

- Disengage the wheel brake of the surgeon console

The **circulating nurse** disengages the wheel brake (i.e. the mechanical brakes at each of the four wheels).

- 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 good view onto an endoscope screen when using the robot,
- the **surgeon** movements while operating are not limited by physical constraints (e.g. a wall), and
- the surgeon console doesn't interfere with the surgical workflows, both during laparoscopic and robotic surgical steps

 - **WARNING** - While transporting a component of Dexter, be aware of any object, structure or person that might collide with it

- Engage wheel brakes of the surgeon console

The **circulating nurse** engages the wheel brake (i.e. the mechanical brakes at each of the four wheels).

- Connect the surgeon console to supply mains

The **circulating nurse** checks that the power button on the surgeon console is on "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 supply.

- 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.

- 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 side.

- Prepare the patient cart for transport

The **circulating nurse** ensures that the data and power cords are properly stowed away.

- Disengage the wheel brake of the patient cart

The **circulating nurse** disengages the wheel brake (i.e. the mechanical brakes of the wheels).

- Push the patient cart to the operating room

The **circulating nurse** pushes the patient cart into the operating room into proximity of the location in which it is then docked to the patient, but sufficiently far away from the sterile field so that the patient cart can still be draped. The circulating nurse is mindful of the sterile field of the patient when moving the patient cart.

- Engage wheel brakes of the patient cart

The **circulating nurse** engages the wheel brake (i.e. the mechanical brakes on the wheels). The patient cart can be in proximity of the sterile field which the circulating nurse has to be mindful of.

- Check that the power button on the patient cart is on "off" position

The **circulating nurse** checks that the power button on the patient cart is on "off" position.

- Connect the patient cart to supply mains

Then the **circulating nurse** unwinds the power cable from its storage location at the patient cart and connects it to an appropriate mains supply. In doing this, the **circulating nurse** places the cables in a way that minimizes interference with other equipment or people in the operating room.

- Connect the patient cart to the surgeon console

The **circulating nurse** unwinds the data cable from the patient cart and connects it to the surgeon console. In doing this, the circulating nurse places the 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 & Controller (Optional)

The **circulating nurse** brings in the endoscope cart & endoscope arm into the operating room and sets it up in proximity to the location of use at the patient side.

- Prepare the endoscope cart for transport

The **circulating nurse** ensures that the data and power cords are properly stowed away.

- Disengage the wheel brake of the endoscope cart

The **circulating nurse** disengages the wheel brake (i.e. the mechanical brakes of the wheels).

- Push the endoscope cart to the operating room

The **circulating nurse** pushes the endoscope cart into the operating room in proximity to the location in which it is then 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 and engages the wheel brakes of the endoscope cart when placed at the desired place.

- Engage the endoscope cart wheel break.

The **circulating nurse** engages the endoscope cart wheel break.

 - **Connect the endoscope arm to supply mains**

The **circulating nurse** unwinds the power cable from its storage location at the endoscope cart and connects it to an appropriate supply mains plug as per the instructions for use of the Dexter Endoscope Arm.

 - **If necessary: Mount endoscope arm to surgical table**

In case 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 bed-rail as per the instructions for use of Dexter Endoscope Arm. The endoscope cart is then removed from the patient area.

 - **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 making sure that the Dexter Endoscope Arm joystick is connected to the Dexter Endoscope Arm data cable.

4.4 Power on the Robot

The **circulating nurse** powers on the robot and verifies that the self-tests of the robot pass.

 - **Power on the patient carts**

The **circulating nurse** pushes the Power switches on the Patient Carts and confirms that it is powered by checking that either the "power on" buttons light or the emergency stop buttons light are on.

 - **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.

 - **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, and then releasing the button by rotating it clockwise.



Figure 6 Press the emergency stop button



Figure 7 Release the emergency stop button clockwise

 - **Restart the robot**

Then the **circulating nurse** restarts the robot either pushing the Arms lock button and the Up button on the surgeon console simultaneously during 2 seconds or 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).

 - **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.

 - **Unpack the reusable accessories**

The **circulating nurse** checks the packaging of the accessory tray(s) for integrity and sterility.

 - **Unpack the accessory tray(s)**

The **circulating nurse** and the **scrub nurse** unpack the accessory tray(s) from its sterile packaging. Opening an accessory tray takes place in proximity to the sterile field which the circulating nurse is mindful of.

 - **Place accessory tray(s) or the content**

The **scrub nurse** places the accessories on the sterile surface, keeping them in the accessory tray or putting them directly on the sterile surface.

 - **Inspect the incision pointers**

The **scrub nurse** inspects both incision pointers for damages.

 - **Inspect the handle grips**

The **scrub nurse** grabs both handle grips, inspects them visually for damages.

 - **Test the handle grips**

The **scrub nurse** tests that the handle grips move smoothly by opening and closing the two levers.

 - **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 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).

 - **Bring the single-use accessories to the operating room**

The **circulating nurse** brings the sterile drapes and the sterile interfaces to the operating room.

 - **Inspect the single-use accessories packaging**

The **circulating nurse** inspects the packaging of the sterile drapes and the sterile interfaces for integrity and sterility.

 - **Open the single-use accessories packaging**

The **circulating nurse** opens the packaging in proximity to the sterile field which the circulating nurse is mindful of.

 - **Grab the sterile interfaces**

The **scrub nurse** grabs the sterile interfaces from the single-use accessories packaging



Figure 8 The sterile interface

 - **Inspect the sterile interfaces**

The **scrub nurse** visually inspects the sterile interfaces.

 - **Test the sliders of the sterile interfaces**

The **scrub nurse** moves the sliders of the sterile interfaces to ensure that they work properly.

 - **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 shape.

Note that instruments should be unpacked only when necessary, and at the surgeon's request. Such good practice minimizes instruments' waste.

 - **Bring the instruments to the operating room**

The **circulating nurse** brings the robotic instruments as requested by the surgeon to the operating room.

 - **Check the instrument packaging**

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

 - **Open the instrument packaging**

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

 **- Grab the instrument**

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

 - Inspect the instruments

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

 - 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 Optional: Drape the Surgeon Console

The **scrub nurse** covers both master arms and, optionally, the central pillar with sterile drapes. Upon the **scrub nurse** preference, the **circulating nurse** can be a support for this task.

 - **If necessary: Place the Master Arms at maximum height**

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

 - **If necessary: Prepare the master arms for draping**

For each of the master arms, the **circulating nurse** places the master arms into a position that simplifies draping.

 - **If necessary: Grab the master arm sterile drapes**

For each of the master arms, the **scrub nurse** grabs the corresponding sterile drape for the master arm (1 / 2) from the sterile surface.

 - **If necessary: Cover the master arms**

For each of the master arms, the **scrub nurse** covers the master arm with the drape.

 - **If necessary: Grab the central pillar drape**

The **scrub nurse** grabs the sterile drape for the central pillar from the tray.

 - **If necessary: Cover the central pillar**

The **scrub nurse** covers the central pillar with the drape.

6.1.2 Attach the Handle Grips

The **scrub nurse** attaches the handle grips to each master arm.

 - **Attach the handle grips to the handles**

For each of the master arms, the **scrub nurse** grabs a handle grip from the sterile accessory tray.

 - **Remove the drape cap**

For each of the master arms, the **scrub nurse** removes the drape cap (if applicable).

 - **Attach the handle grip**

For each of the master arms, the **scrub nurse** then attaches the handle grip to the handle gimbal.

 - **Test grip movement to ensure the handle grips work properly**

For each of the master arms, the **scrub nurse** grabs the handle grip (i.e. with the index finger and the thumb) and sequentially tests that all seven degrees of freedom of the master arm run 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 into a predefined position.

 - **Extend the boom**

For each of the patient carts, the **circulating nurse** extends the boom to its most stretched-out 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. The brakes engage once the button is released.

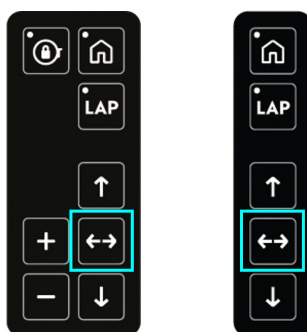


Figure 9 Location of the Lateral Boom Movement buttons. Proximal User Interface on the left, Distal User Interface on the right. When the LEDs are having white blinking pattern, this means the boom is in movement.

 - **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 continuously the Home button until the instrument arm has reached the home position and stops moving.

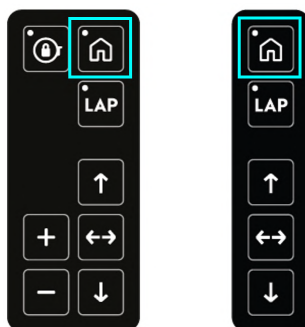


Figure 10 Location of the home buttons. Proximal User Interface on the left, Distal User Interface on the right. When the LEDs are having white blinking pattern, this means either that homing is necessary or that the instrument arm is moving toward the home position. When the LEDs are steady white, this mean the instrument arm is in home position.

6.2.2 Cover the Patient Cart with a Drape

The **scrub nurse** covers both patient carts with sterile drapes. Upon the **scrub nurse** preference, the **circulating nurse** can be a support for this task. Follow the sequential execution of tasks on one Patient Cart and then proceed to the other.

- Grab Patient Cart sterile drape

The **scrub nurse** grabs a patient cart sterile drape from the sterile surface.

- Cover the patient cart with sterile drape

For each of the patient carts, the **scrub nurse** wraps the sterile drape over the patient cart, starting with the hub and then pulling it all the way to the vertical column. Red circular stickers on the Sterile Drapes should be placed on both openings of the Hub, the wider sticker on front.



Figure 11 Patient Carts once draped



Figure 12 Position of the front sticker



Figure 13 Position of the back sticker

- Remove the stickers

The **scrub nurse** then removes the stickers by pulling the flaps, paying attention not to touch the inner section of the stickers, the inside of the drape or the inside of the Hub in the process as those are not sterile.

- Grab the sterile interface

For each of the patient carts, the **scrub nurse** grabs the sterile interface (consisting of two parts).

- Insert the sterile interfaces

For each of the patient carts, the **scrub nurse** inserts the longer part from the proximal end into the lumen of the hub by aligning the Emergency Release Tool circle pictograms printed onto the Sterile Interface with the two holes on the Hub.

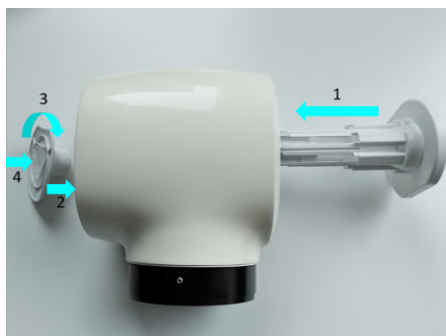


Figure 14 Sterile Interface insertion order



Figure 15 Sterile Interface longer part aligning

CAUTION: During the clockwise rotation (refer to step 3 in the "Sterile Interface Insertion Order" image), if distal part is excessively tightened, the translucent component will not produce a clicking sound upon being pressed down (refer to step 4 in the "Sterile Interface Insertion Order" image), and the user will not receive any haptic feedback. To secure the distal part (refer to step 3 in the "Sterile Interface Insertion Order" image) rotate 45°, no force is needed. If resistance is felt, check that the Sterile cover is fully inserted and that the drape does not prevent full sliding in the Hub (refer to step 1 in the "Sterile Interface Insertion Order" image).

 - **Lock the sterile interfaces**

Then the **scrub nurse** attaches and locks the smaller part from the proximal side so that both parts are attached together. 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 cart into a compact configuration to minimize interference with other equipment or people present in the operating room

 - **Instrument arm in compact configuration**

For each of the patient carts, the **scrub nurse** pushes one of the Boom LAP button until the instrument arm is in transport position.

 - **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. The brakes engage once the button is released.

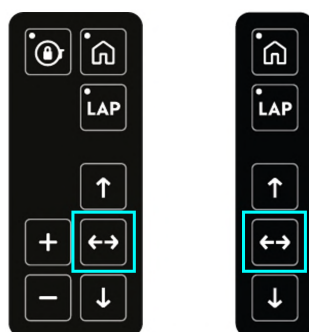


Figure 17 Location of the Lateral Boom Movement buttons. Proximal User Interface on the left, Distal User Interface on the right. When the LEDs are having white blinking pattern, this means the boom is in movement.



Figure 18 Example of compact boom configuration

6.3 Prepare and Drape the Endoscope Arm (Optional)

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

- 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 onto the Endoscope Cart.

- Attach accessories

The **scrub nurse** attaches the accessories as per the instructions for use of the Dexter Endoscope Arm. Upon the scrub nurse preference, the circulating nurse can be a support for this task.

7 Position and Dock Dexter for Surgery

7.1 Move the Patient Cart to the Patient

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

- If necessary: Increase the height of the patient cart

For each of the patient carts, the **surgeon** increases the height of the patient cart to avoid collision of the hub or the instrument arm with the patient. To increase the height of the patient cart, the **surgeon** pushes one of the Up buttons and releases it when desired height is reached.

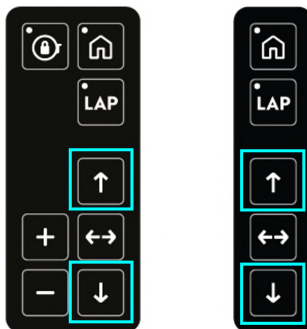


Figure 19 Location of the patient cart up and down buttons. Proximal User Interface on the left, Distal User Interface on the right. When the LEDs are having white blinking pattern, this means the patient cart is either raising or lower its height.

- Disengage the wheel brakes

For each of the patient carts, the **scrub nurse** (or the **assistant**) disengages the wheel brakes on the wheels of the patient carts.

- Move the patient cart to the desired location

For each of the patient carts the **scrub nurse** (or the **assistant**) pushes the patient cart to the intended location at the surgical table being mindful of the cabling between the patient cart and the surgeon console, as well as other equipment and people in the operating room.

- Supervises the patient cart positioning

Surgeon supervises the patient cart positioning at the surgical table, being mindful of the cabling between the patient cart and the surgeon console, as well as other equipment and people in the operating room.

- Deploy the floor locks

For each of the patient carts, the **scrub nurse** (or the **assistant**) deploys the floor locks using the dedicated button located on the Proximal User Interface. When the floor lock button light is blinking white, it means that either the floor lock is retracted or that is moving to be deployed or fully retracted. When the floor lock light is steady white, it means the floor lock is deployed.



Figure 20 Location of the floor locks button. Only on the Proximal User Interface. When the LEDs are having white blinking pattern, this means either that the floor lock step is necessary or that the floor locks are either on the process of being deployed or retracted. When the LEDs are steady white, the floor locks deployed.

- Unfold the boom and instrument arm

The **surgeon** use the Lateral Boom Movement, Up and Down buttons to unfold the instrument arm.

7.2 Set the Forward Angulation

The **surgeon** adjusts the forward angulation of the instrument arm to align the vertical workspace with the target anatomy.

- Home the instrument arm

The **surgeon** pushes the "home" button until the instrument arm reaches the home position.

- 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 arm.

7.3 Dock the Patient Cart to the Trocar

The **surgeon** docks each patient cart to the corresponding trocar. Docking means aligning the remote center of motion of the patient cart instrument arm with the trocar. 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 with the help of an endoscope. Follow the sequential execution of tasks on one Patient Cart and then proceed to the other.

- Place the incision pointer in the trocar

The **surgeon** places the incision pointer in the trocar, holding it with one hand. His other hand is free to manipulate the Boom and Instrument Arm.

- 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 to the Incision Pointer. Once the plate of the Incision Pointer and the magnet of the Instrument Arm are exactly parallel and connected to each other, they are considered aligned.

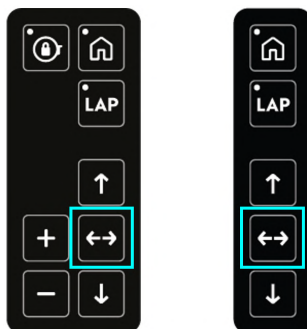


Figure 21 Location of the Lateral Boom Movement buttons. Proximal User Interface on the left, Distal User Interface on the right. When the LEDs are having white blinking pattern, this means the boom is in movement.

- 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).

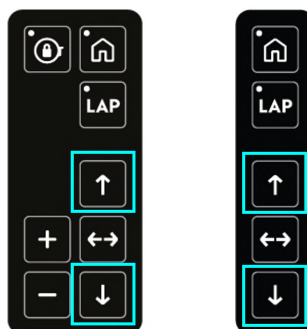


Figure 22 Location of the patient cart up and down buttons. Proximal User Interface on the left, Instrument Distal User Interface on the right. When the LEDs are having white blinking pattern, this means the patient cart is either raising or lower its height.

- 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.

- Remove the incision pointer after docking

The **surgeon** removes the incision pointer from the instrument arm and hands it to the **scrub nurse** who places it on the tray.

- 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 **circulating nurse** and the **surgeon** position and dock the endoscope arm to the trocar and inserts the endoscope. All user actions involving the endoscope arm are done as per the instructions for use of the Dexter Endoscope Arm.

- If necessary: Position the endoscope arm

The **surgeon** push the endoscope arm mounted on the endoscope cart to the intended location at the surgical table

 **- WARNING:** Engage the wheel brakes of the endoscope cart once positioned for use.

- Dock the endoscope arm

The **surgeon** docks the endoscope arm to the trocar using the probe pin.

- 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

For both patient carts, the **surgeon** inserts the desired instrument.

 - **WARNING:** Monitor the instrument tip with the endoscope upon instrument insertion to avoid damaging tissue.

 - **Ensure the patient cart is in home position for instrument insertion**

Before inserting an instrument, the **surgeon** ensures that the patient cart is in the home position by pushing one of the Home button on the Patient Cart until the Hub lights turn solid white. Once both Hubs have reached home position and the Home button is released, the Hub lights start blinking.

 - **Hand instrument**

The scrub nurse hands instrument to surgeon as requested.

 - **Ensure that the Instrument tip is straight**

Upon getting the instrument from the **scrub nurse**, the **surgeon** ensures that the instrument tip is straight. This is required for the instrument to pass through the hub and the trocar.

 - **Ensure the Instrument Knob is in the insertion position**

Prior to inserting the instrument, the **surgeon** verifies that the instrument knob is in insertion position, i.e. turned anticlockwise without any freedom to rotate.

 - **If necessary: place in insertion position**

If insertion position has been lost, a maneuver should be performed to put it back to insertion position, holding the shaft with one hand and rotating the knob anticlockwise until hearing a click.



Figure 23 Maneuver to put instrument knob back to insertion position

 - **Insert instrument through hub and trocar**

The **surgeon** carefully inserts the instrument through the hub and the trocar ensuring not applying radial nor flexural tension to body wall nor instrument.



Figure 24 Instrument insertion

 - **Monitor the instrument tip**

If an instrument is inserted when the Hub is not in home position, then the **scrub nurse** shall monitor the instrument tip with the endoscope to avoid tissue damage.

 - **Lock instrument in hub**

The **surgeon** locks the instrument into the hub by rotating the instrument clockwise while holding the sterile interface and checking on the endoscope screen any unintended instrument movement.



Figure 25 Instrument locking

Note: If it is a blinking white pattern, the instrument is locked and requires the surgeon's grip verification for final acceptance. If it is a solid white pattern, the instrument is locked and accepted, ready to be synchronized.

 **- WARNING:** If the instrument is bent or penetrates through the trocar into the abdomen when being inserted, then this is an indication that the Patient Cart is not properly docked. Remove the Instrument and verify docking with the Incision Pointer.

 **- If necessary: Connect electro-surgical generator**

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

 **- If necessary: Instruct electro-surgical generator mode & power**

For those instrument requiring connection (e.g. monopolar and bipolar instruments) to the electro-surgical generator, the **surgeon** instructs the circulating nurse to set the mode and power of the electro-surgical generator (as per the IFU of the electro-surgical generator, and while following the rated voltage limitations of the Dexter Instruments).

 **- If necessary: Set mode and power of the electro-surgical generator**

The **circulating nurse** sets mode and power of the electro-surgical generator.

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

 **- WARNING -** If any flammable agent is used for cleaning, disinfecting, or as solvents of adhesives, it should be allowed to evaporate before application of high-frequency surgery

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

 **- WARNING -** If fluids are pooled in the body depressions and cavities should be mopped up before high-frequency instrument is used.

 **- WARNING -** Beware the danger of ignition of endogenous gases (e.g., cotton and gauze saturated with oxygen may be ignited by sparks produced during normal use of high-frequency instrument).

8.2 Assume Working Position

The **surgeon** assumes the working position at the surgeon console and gets ready to use the robot.

 **- If necessary: Adjust the height of the stool**

The **surgeon** adjusts the height of the stool for best comfort.

 **- If necessary: 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.

Height shall be adjusted in less than 2 minutes, followed by a pause of 5 minutes.

 **- If necessary: Adjust the orientation of the surgeon console**

The **surgeon** adjusts the orientation of the surgeon console for optimal view onto the screen and optimal use of the limited space in the operation room. To adjust the orientation, the **surgeon** disengages the wheel brake, moves the surgeon console, and then reengages the wheel brake.

 **- If necessary: Ensure that the surgeon console pedalboard is positioned**

The **surgeon** ensures that the pedalboard is positioned within comfortable reach when operating the surgeon console.

 **- If necessary: Help with pedalboard positioning**

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

 **- If necessary: Ensure that the electro-surgical pedalboard is positioned**

The **surgeon** ensures that the pedalboard to operate the electro-surgical instruments is positioned within reach when using the surgeon console.

 **- If necessary: Help with electro-surgical pedalboard positioning**

The **circulating nurse** may help the surgeon in positioning the pedalboard.

8.3 Handle Grip verification and Synchronization

For the patient carts to start replicating the movements applied to the surgeon console, both need to synchronize. The **surgeon** performs the following sequence of events for each handle / instrument pair.

 - **Grab the handle grip**

The **surgeon** grabs the handle grip with his / her fingers.

 - **Verify handle Grip**

If the hub displays a blinking white light pattern, grip verification is required: the **surgeon** fully opens and closes the handle grip twice within 5 seconds. Note: Grip verification should be done only once. In case of Emergency Stop requiring a restart, Grip verification should be performed again.

 - **Macro-Sync: Grab handle and press the clutching pedal**

If the hub displays a steady white light pattern, macro-sync can be performed: the **surgeon** presses and releases the clutching pedal while holding the handle grip. This starts to synchronize the macro movements.

CAUTION: When operating the clutch pedal for the first time, make certain to apply a firm and decisive amount of force with your feet.

 - **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.

 - **Micro-Sync: Open and close the handle grip twice**

The **surgeon** opens and closes the handle grips twice to synchronize the micro movements.

 - **WARNING:** If the drape remains stuck to the sterile interface after micro synchronization and affect roll movement, it should be promptly replaced to avoid any unwanted emergency stops.

 - **Verify that the instruments move as expected**

Once the instruments are micro- and macro-synchronized, 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.

 - **WARNING:** If the handle grip is replaced after the verification step, either the surgeon or the scrub nurse must perform a manual restart of Dexter after changing the handle grip.

8.4 Perform the Surgical Tasks

Once the handles are synchronized to the instruments, the **surgeon** can perform the surgical tasks with the device.

 - **Operate Dexter**

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

 - **WARNING:** 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.

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

CAUTION: Avoid from using the needle holder's most proximal part (third part) to grasp the needle while suturing.

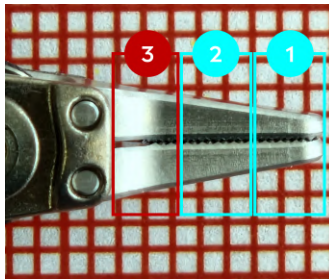


Figure 26 The third area of the Needle Holder should be avoided.

 - **Monitors both instrument tips with the endoscope**

While performing the surgical tasks, the surgeon monitors both instrument tips with the endoscope.

 - **If necessary: Clutching**

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.

 - **If necessary: Adjust the Surgical Workspace**

When approaching a workspace limitation of Dexter, 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 Dexter is reached, the **surgeon** has the option to adjust the forward angulation. This requires wrapping-up the surgical tasks and removing the instrument, and then adjusting the forward angulation, docking the patient cart again, and then resuming operations.

 - **WARNING:** Regularly monitor the Instrument shaft to ensure that it is not bent when operating with Dexter. If the shaft of the Instrument is bent, then the Patient Cart might not be properly docked anymore. Remove the Instrument and repeat the docking procedure.

 - **WARNING:** 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.

 - **If necessary: Adjust the Endoscope Workspace**

When reaching a workspace limitation with the endoscope, the **surgeon** has the option to reposition and redock the endoscope arm. This doesn't require redocking the instruments.

CAUTION: 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.

8.5 Clutching

To place the handles into an ergonomic working position, the surgeon has the option to temporarily stop the macro movement replication while moving the handle into an ergonomic position.

- Press the Clutching Pedal

The **surgeon** presses and keeps pressing the Clutching Pedal. The clutching pedal applies to both handles simultaneously.



Figure 27 Clutching pedal

- Reposition the Handles

The **surgeon** positions the handles to a more ergonomic position.

- Release the Clutching Pedal

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

8.6 Endoscope Control

To move the endoscope, and assuming the endoscope arm is installed, the surgeon has the option to temporarily stop the movement of Instruments so that the movement of the Handles moves the endoscope approximately proportionally.

 - **WARNING:** Do not move the endoscope cart (incl. pushing it around on its wheels, and adjusting the height of the vertical pillar) when an endoscope is attached to the endoscope arm.

 - **WARNING:** The endoscope arm must be redocked when the patient or the endoscope cart move after initial docking. Movement includes horizontal displacement with regards to the floor as well as height adjustments.

CAUTION: If the orange LED labeled 'Service' (with a wrench symbol) remains on after powering up the Endoscope Arm or during operation, restart the device by unplugging and then replugging the power supply cord. After the restart, redock the endoscope arm.



Figure 28 Wrench symbol

CAUTION: If the red LED labeled 'Service' (with a wrench symbol) of the endoscope arm is on, the emergency stop button becomes unresponsive. If necessary, use the other emergency stop buttons on both patient carts or on the surgeon console as they are still functioning.

CAUTION: If the white LED labeled 'Target' (with a Target symbol) is blinking instead of being steady and suddenly the Endoscope Arm stops moving while in operation, take the manual control of the endoscope arm and re-dock it.



Figure 29 Target symbol

- Press the Endoscope Pedal

The **surgeon** presses and keeps pressing the Endoscope Pedal. This stops the movement both Instruments.



Figure 30 Endoscope pedal

 - **Move the Handles**

The **surgeon** moves both handles to move the endoscope arm.

 - **Release the Endoscope Pedal**

Once the endoscope is in the desired position, the **surgeon** releases the Endoscope Pedal, briefly activates the Clutching 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 below sequence of actions.

 - **WARNING:** if no homing is performed, make sure before releasing handle grips to place the instrument tips away from each other and away from any anatomical structure.

 - **Return to the Patient**

The **surgeon** leaves the surgeon console and returns to the patient.

 - **If necessary: Disconnect the Electrosurgical Cable**

For those instruments connected to the electrosurgical generator, the **surgeon** removes the cable.

 - **Unlock the Instrument**

The **surgeon** unlocks the instrument by rotating the instrument anti-clockwise while holding the sterile interface and checking on the endoscope screen any unintended instrument movement.

 - **Retract the Instrument**

The **surgeon** carefully retracts the instrument and hands it to the scrub nurse who places it on the sterile surface.

 - **Take the instrument**

The **scrub nurse** takes the instrument and places it on the sterile surface.

9 Switch to Laparoscopy

9.1 Simple: Fold an Instrument Arm to Laparoscopy Mode

The "Laparoscopy Mode" switch to laparoscopy is rapid and keeps the patient cart docked to the trocar.

- Remove the instruments

The **surgeon** removes the instruments as described in Wrap-Up and Remove Instruments.

- Fold the instrument arm

The **surgeon** pushes one of the LAP Mode button 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 arm doesn't collide with the patient or other instruments.

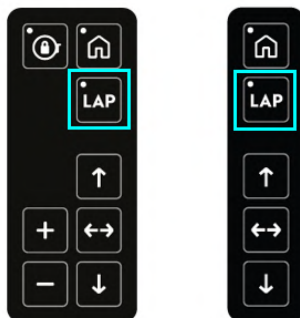


Figure 31 Location of the LAP Mode buttons. Proximal User Interface on the left, Distal User Interface on the right. When the LEDs are having a white blinking pattern, this means that the instrument arm is moving toward the laparoscopic position.

- Use Laparoscopic Instruments

Once the instrument arms are in the "LAP" position, the **surgeon** can access the trocars using laparoscopic instruments.

- Return to Robotics Mode

To return to robotics mode, the **surgeon** removes the laparoscopic instrument, places the instrument arms into home position, and then resumes operating Dexter.

9.2 Advanced: Undocking

When the "Fold Instrument Arm" is not sufficient to gain sufficient access for the surgeon to work in laparoscopy mode, the surgeon can undock the patient cart and move it to the side.

- Remove the Instruments for Undocking

The **surgeon** removes the instruments as described in Wrap-Up and Removed Instruments.

- Fold the instrument arm

The **surgeon** folds the instrument arm as described in Switch to Laparoscopy, Simple: Fold Instrument Arm to Laparoscopy Mode.

- Move Instrument Arm Away

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

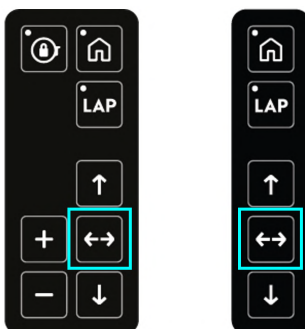


Figure 32 Location of the Lateral Boom Movement buttons. Proximal User Interface on the left, Distal User Interface on the right. When the LEDs are having white blinking pattern, this means the boom is in movement.

- Use Laparoscopic Instruments

Once the instrument arms are moved away, the **surgeon** can access the trocars using laparoscopic instruments.

- Return to Robotics

To return to robotics mode, the **surgeon** removes the laparoscopic instrument and places it on the tray, putting the instrument arms back in robotic mode.

- Re-dock the instrument arm

The Surgeon docks the patient cart to the trocar and then resumes operation of Dexter.

10 Safety Stops

10.1 Resume Use after Protective Stops

Dexter enters into a Protective Stop when a temporary system issue occurs or that the system judged the user behavior as 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.

- Resume Use after Protective Stop

To restart the use of Dexter after a Protective Stop, the **surgeon** grabs both Handle Grips and presses on the Clutching Pedal.

10.2 Resume Use after Emergency Stops

Dexter 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.

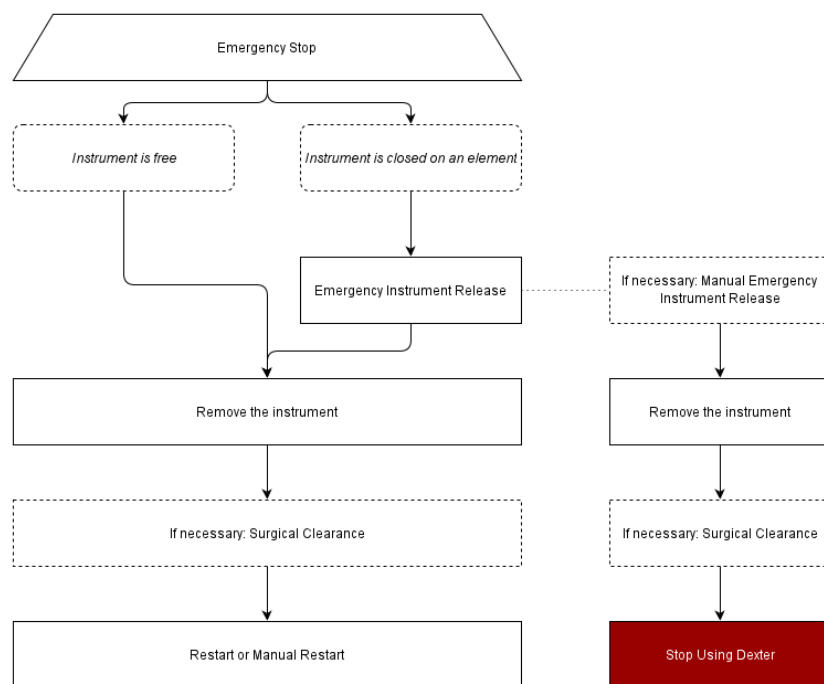


Figure 33 Diagram on the process to follow after the occurrence of an emergency stop

- Verify if instrument is free from any tissue, suture, needle or other surgical tool

The **surgeon** verifies if the instrument is free from any tissue, suture, needle or other surgical tool in such a way that the instrument rotation and/or removal would not harm the patient.

- If instrument is free: Remove the Instrument

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

- If instrument is closed on an element: Emergency Instrument Release

In the event that the instrument is closed, entrapping tissue, a suture, needle, or any other surgical implement between its blades, in a manner that could potentially cause harm during the instrument's removal, the surgeon, at their discretion, may 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 the system being successfully restarted
3. Verify that yellow steady light are on hubs
4. Take the handle grip and close the handle grip's 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 and,
7. Clutch to block the actuation replication.
8. The Instrument can be then retracted from the patient

- If necessary: Manual Emergency Instrument Release

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

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

Following the use of the Emergency Release Tool, Dexter should no longer be employed.



Figure 34 Emergency Release Tool and Sterile Interface

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

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

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

 - If necessary: Surgical Space Clearance

If immediate access to the patient is necessary and Dexter is either powered off or in Emergency Stop mode, the surgeon or nurse can push the instrument arm aside to access the surgical site. However, this requires applying significant force onto the Instrument Arm Distal Segment 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 instrument arm safely. Additionally, it is essential for both the surgeon and nurse to coordinate and communicate effectively to avoid any potential harm to the patient.

11 Change Position or Access

During a more complex surgery, Dexter might have to be docked first to one 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 adjusting the height of the surgical table). In both of those scenarios, the following sequence of Use Cases shall be performed:

1. Remove the instruments and the endoscope
2. If necessary, reposition the patient or the surgical table, or prepare the new set of trocars
3. If necessary, 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 & Cart (Optional)

When no longer used, 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 Endoscope Arm.

- Remove the endoscope

The **surgeon** removes the endoscope from the endoscope arm.

- Remove the endoscope arm

The **scrub nurse** unmounts, undrapes, unplugs and removes the endoscope arm from the patient.

- If necessary: Place the endoscope arm onto the endoscope cart

When it is attached to the bedrail, the **scrub nurse** places the endoscope arm onto the endoscope cart.

- Remove the accessories of the endoscope arm

Then, the **scrub nurse** removes the accessories of the endoscope arm and brings them back to the tray.

- 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 Dexter is no longer used, the **surgeon**, the **scrub nurse** and the **circulating nurse** put the patient cart into Compact Configuration.

- Release and/or Retract the floor locks and disengage the wheel brakes

The **surgeon** retracts the floor locks using the dedicated button and disengages the wheel brakes. If the floor lock light is off, the floor lock is released or fully retracted.



Figure 35 Location of the floor locks button. Only on the Proximal User Interface. When the LEDs are having white blinking pattern, this means either that the floor lock step is necessary or that the floor locks are either on the process of being deployed or retracted. When the LEDs are steady white, the floor locks deployed.

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.

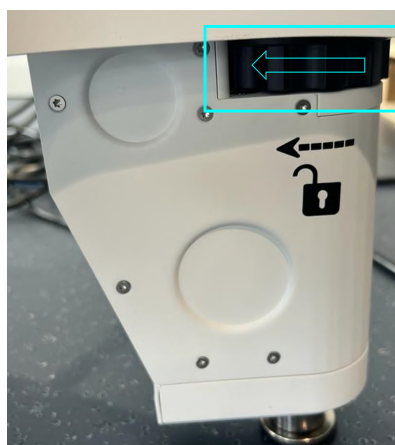


Figure 36 Rotate the Manual Floor Lock Wheel clockwise to perform the Manual Floor Lock Release

CAUTION: 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 necessary to move the Patient Cart.

- If necessary: Increase the height of the Patient Cart

The **surgeon** increases the height of the patient cart to avoid collisions of the Instrument Arm with the patient during the removal of the Patient Cart.

- Move the Patient Cart away from the patient

The **surgeon** carefully moves the patient cart away from the patient.

- Remove and Discard the Sterile Interface

The **scrub nurse** unmounts the sterile interface by:

- Beginning to compress 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.

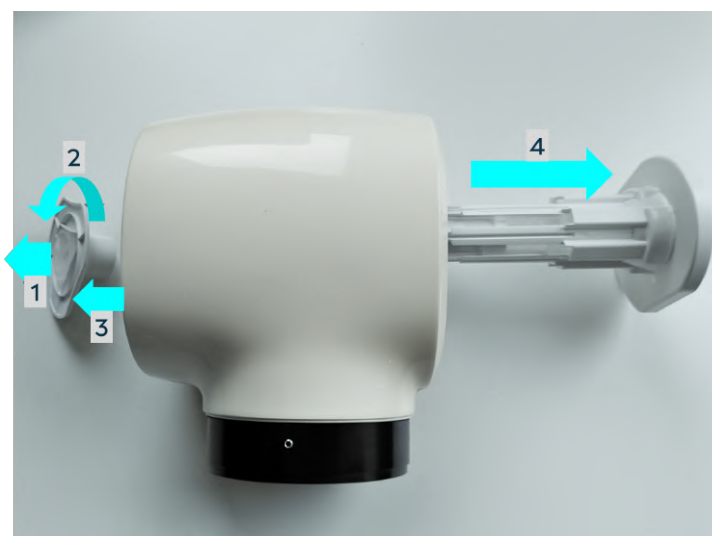


Figure 37 Steps to remove the Sterile Interface

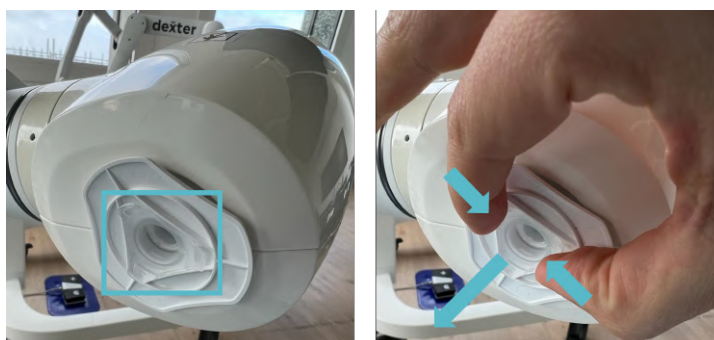


Figure 38 How to pull the Sterile Interface Lock away (Step 1 on the image above)

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

 - **Inspect sterile interface exterior for any fluid infiltration**

Once the sterile interface is detached, the **scrub nurse** should inspect it for fluid infiltration.

 - **Dispose the sterile interface**

Then the **scrub nurse** safely disposes the sterile interface following proper protocol.

 - **Check Hubs for fluids infiltration**

The **scrub nurse** inspects both hubs for fluids infiltration.

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

 - **Remove the sterile drapes**

The **scrub nurse** removes the sterile drape.

 - **Discard the sterile drapes**

The **scrub nurse** discards the sterile drape.

 - **Put the Patient Cart 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" button and then, by pushing one of the Lateral Boom Movement buttons until the instrument arm is in transport position, folds the boom into transport position and puts it to minimum height. Note that the Patient Cart is not switched off at this step, because all units have to be switched off at the same time. It will be switched off, unplugged and stowed away at the same time as the Surgeon console.



Figure 39 Example of compact boom configuration

12.3 Put the Surgeon Console into Transport Position

When Dexter is no longer used, the scrub nurse and the circulating nurse put the surgeon console into transport position.

- Remove the Handle Grips

The **scrub nurse** removes the handle grips and places it on the tray.

L6-57808 - Work Item does not exist.

- Remove the Sterile Drapes

The **scrub nurse** removes the sterile drapes covering the master arms and the central pillar.

- Discard the sterile drapes

The **scrub nurse** discards the sterile drapes covering the master arms and the central pillar.

- Position both Master Arms within the Wheelbase Volume

The **scrub nurse** positions both master arms within the wheelbase volume, protecting them from collisions.

- If necessary: Position Master Arms at minimum height

The **scrub nurse** puts the master arms at minimum height using the Up or Down button on the surgeon console.

- Power off the Surgeon Console

The **circulating nurse** turns off the surgeon console.

- Unplug Patient Carts from the Surgeon Console

The **circulating nurse** unplugs the patient carts from the surgeon console and stows-away the connecting cables.

- Unplug the Surgeon Console from Supply Mains

The **circulating nurse** unplugs the surgeon console from supply mains and Potential Equalization plug and stows away the power cable.

- Stow away the Surgeon Console Pedalboard

The **circulating nurse** stows away the surgeon console pedalboard.

- Disengage wheel brakes

The **circulating nurse** disengages the wheel brakes of the surgeon console.

- If necessary: Power on Surgeon Console in standalone mode to enable Up, Down and Arm Locks Buttons.

The **circulating nurse** checks that the patient carts are not connected and powered on before using the Power Switch on the Surgeon Console. Then, 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 reusable accessories in the accessory tray.

- Place Handle Grips in the Accessory Tray

The **circulating nurse** places the contaminated handle grips in the accessory tray.

- Place Incision Pointers in the Accessory Tray

The **circulating nurse** places the contaminated incision pointers in the accessory tray.

- Place Emergency Release Tool in the Accessory Tray

The **circulating nurse** places the potentially contaminated emergency release tool in the accessory tray.

- Close the Accessory Tray

The **circulating nurse** closes the accessory tray and makes it ready 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.

- 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.

- Disengages the wheel brake of the Surgeon Console

The **circulating nurse** disengages the wheel brake of the Surgeon Console.

- Pushes the Surgeon Console into the storage location

The **circulating nurse** pushes the Surgeon Console into the storage location.

- 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).

- 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.

- 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).

- Push the Patient Carts into storage location

The **circulating nurse** pushes the Patient Carts from the operating room into storage location.

- 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

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

Examples include Envirocide®, CaviCide® and 70% isopropyl alcohol or the corresponding pre-moistened disinfectant wipe product. Allow components to dry before use. If any liquids or bodily fluids get inside Dexter, contact Distalmotion.

If unable to clean Dexter properly, contact Distalmotion.

WARNING: The Surgeon Console and the Patient Carts are not designed for exposure to liquids. Do not spray liquids while disinfecting the Robot nor add disinfectant product on pre-moist cloth. Care should be taken to ensure liquids do not contact electronic equipment on the system components.

 - **WARNING:** Use non-flammable agents for cleaning and disinfections wherever possible

13.2 Preventive Maintenance

Preventive maintenance is required and must be performed at least after every 2 months (after the first six months) by Distalmotion service personnel pursuant to the Dexter L6 Service Manual. Do not perform servicing or maintenance work on your own.

For Technical Support

If the system requires maintenance or service, contact Distalmotion Technical Support on:

 +41 21 510 58 98
 support@distalmotion.com

14 Accessories Reprocessing

 - **WARNING:** Don't use washer-disinfector not compliant with ISO 15883.

 - **WARNING:** The accessory tray is packaged with sterilization wrap. Only use validated sterilization wrap and follow the manufacturer's instruction.

 - **WARNING:** The accessory tray should be used only for the reprocessing of Dexter's reusable accessories. Do not load the tray with additional accessories or instruments.

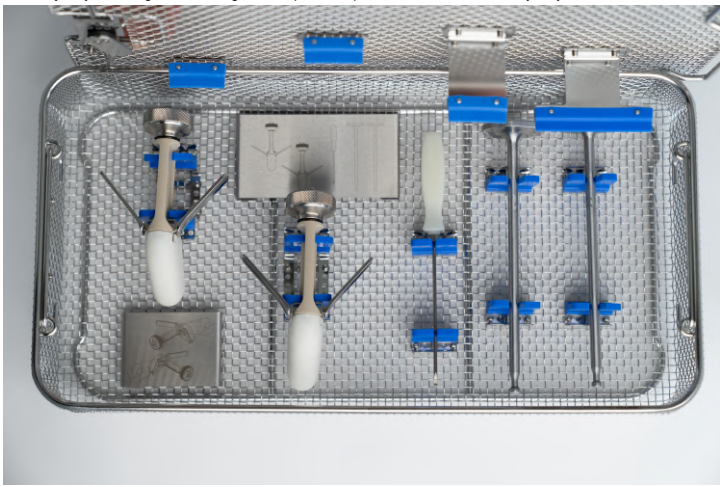
WARNING: The accessories should be handled and operated by trained personnel. Handle with care. Avoid mechanical shock or stress that can cause damage to the device!

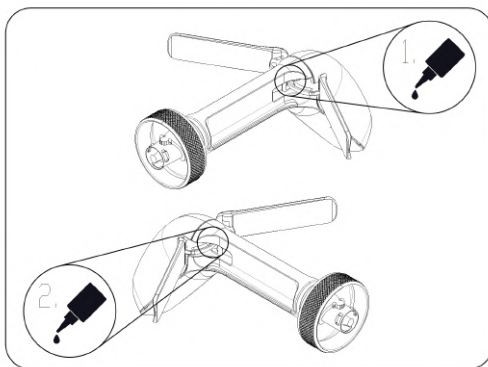
WARNING: The reprocessing of the accessories has been tested for 300 cycles for the handle grips and 100 cycles for the rest of the accessories.

WARNING: The reprocessing of the accessories must start within 60 minutes after the procedure. It is recommended that accessories are reprocessed as soon as is reasonably practical following use. Do not allow blood or residual tissue to dry on the device. Rinse or soak with sterile deionized water as necessary.

WARNING: The instructions have been validated by Distalmotion as being capable of preparing a Dexter L6 accessories 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.

14.1 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 transportation: 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. 
Preparation before cleaning:	No preparation such as disassembly, gross debris removal or testing procedures is required prior to cleaning.

STEP	INSTRUCTIONS																														
Cleaning:	Automated cleaning: With a washer-disinfector meeting the requirements of the ISO 15883 series, using enzymatic solution, and followed by rinsing with water. The table below provides the minimum settings for the washer-disinfector: <table><tr><th>Phase</th><th>Time</th><th>Water Temp/Temp*</th><th>Cleaning Agent</th><th>Comments</th></tr><tr><td>Pre-rinse</td><td>2 minutes</td><td>Cold tap water</td><td>N/A</td><td>N/A</td></tr><tr><td>Wash</td><td>10 minutes</td><td>Hot tap water (set point 40°C)</td><td>Neodisher® MediClean Forte 0.2% (2 ml/L)</td><td>N/A</td></tr><tr><td>Rinse</td><td>2 minutes</td><td>Cold tap water</td><td>N/A</td><td>N/A</td></tr><tr><td>Thermal disinfection</td><td>5 minutes</td><td>90°C</td><td>N/A</td><td>N/A</td></tr><tr><td>Dry time</td><td>20 minutes</td><td>100°C</td><td>N/A</td><td>N/A</td></tr></table> Figure 40 Suitable alternative cleaning agents are: - Prozyme Alka-x from Borer Chemie - Any cleaning agent with similar properties	Phase	Time	Water Temp/Temp*	Cleaning Agent	Comments	Pre-rinse	2 minutes	Cold tap water	N/A	N/A	Wash	10 minutes	Hot tap water (set point 40°C)	Neodisher® MediClean Forte 0.2% (2 ml/L)	N/A	Rinse	2 minutes	Cold tap water	N/A	N/A	Thermal disinfection	5 minutes	90°C	N/A	N/A	Dry time	20 minutes	100°C	N/A	N/A
Phase	Time	Water Temp/Temp*	Cleaning Agent	Comments																											
Pre-rinse	2 minutes	Cold tap water	N/A	N/A																											
Wash	10 minutes	Hot tap water (set point 40°C)	Neodisher® MediClean Forte 0.2% (2 ml/L)	N/A																											
Rinse	2 minutes	Cold tap water	N/A	N/A																											
Thermal disinfection	5 minutes	90°C	N/A	N/A																											
Dry time	20 minutes	100°C	N/A	N/A																											
Disinfection:	No additional disinfection required.																														
Drying:	Handle Grips: To speed-up reprocessing, the handle grips may be dried using pressurized air.																														
Visual Inspection	All the accessories below are limited to 50 sterilization cycles. Furthermore, the following criteria should be taken in account while inspecting the accessories listed below: Incision Pointer: Verify there is no deformation or surface alteration (corrosion, stains, degraded marking). Tray: Verify 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. Emergency Release Tool: Verify there is no deformation, damaged part, surface alteration (corrosion on metal part, cracks on plastic part or degraded marking). Color modification of the plastic part is an expected aging reaction of the polymer and is therefore acceptable. If the criteria above are not met, the accessory should be discarded following the related instructions in Disposal Information section.																														
Lubrication:	Lubricate the Handle Grip actuation mechanism with a silicone-free, steam permeable and pH-neutral lubrication product (for example, instrument care oil or an equivalent lubricant intended for surgical instruments that are sterilized). Place one drop on each side of the mechanism:  No lubrication required for the other accessories.																														
Packaging:	Wrapping: The accessory tray is packaged with sterilization wrap.																														
Sterilization:	Moist heat: 3x prevacuum, Temperature 270°F (132°C) , Holding time minimum 4 minutes, Dry time minimum 20 minutes.																														
Storage:	No special storage requirements.																														
Additional information:	No additional information.																														

Manufacturer contact:**Distalmotion SA**

📍 Route de la Corniche 3b
1066 Epalinges
Switzerland

✉️ reprocessing@distalmotion.com

🌐 www.distalmotion.com/

15 Appendix A: Technical Information

15.1 Status Lights

The software system shall use the following visual patterns:

Name	Pattern	Light Intensity	Color	Blinking Period
Off		0%	n/a	n/a
Active		100%	White	Not blinking
Blinking		0% to 100%	White	600 milliseconds
User Warning		100%	Yellow	Not blinking
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 check re presents the default display pattern for the state (when all other conditions in the column are not met).

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

Display Pattern	Power Staging	Preparation	Ready for Instrument	Ready for Operation	Operating	Service	Emergency Stop
Off							
Active							

The software system shall manage the display according to the following table :

Display Pattern	Power Staging	Preparation	Ready for Instrument	Ready for Operation	Operating	Service	Emergency Stop
Off							
Blinking		When instrument arm moves (*)	If no instrument is locked	If handle grips not verified			
Active		When home position reached					
User Warning		When instrument is locked or protective stop	If locked instrument is not authorized or protective stop	If protective stop(**)			
Error							
Service							

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

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

The software system shall manage the display according to the following table :

Display Pattern	Power Staging	Preparation	Ready for Instrument	Ready for Operation	Operating	Service	Emergency Stop
Off							
Error (*)							

(*) 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.

15.2 Technical System Information

15.2.1 Compliance and Classifications

Compliance and classification:



The Distalmotion Endoscopic Instrument Control System (Dexter Surgical System, Model DM-L6) is in conformance with the Medical Device Regulation, (EU) 2017/745.

Dexter 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 foot pedal which is IPx6.



The Distalmotion Dexter Surgical System accessories (see table below) are in conformance with the Medical Device Regulation, 2017/745.

Device Description - List of Items & Classification (Class IIb)

Item Name	Item ID	Article (REF)	EMDN	Classification (MDR)	Type of use
Dexter L6	DM-L6	104	Z120201	Class IIb (rule 9)	Reusable
Dexter L6 Needle Holder	IN-N102	435	K010202	Class IIa sterile (rule 7)	Single Use
Dexter L6 Bipolar Johann Grasper	IN-G101	437	K010202	Class IIb sterile (rule 9)	Single Use
Dexter L6 Bipolar Maryland Dissector	IN-B101	433	K010202	Class IIb sterile (rule 9)	Single Use
Dexter L6 Monopolar Scissors	IN-M101	375	K010202	Class IIb sterile (rule 9)	Single Use
Dexter L6 Monopolar Hook	IN-M102	216	K010202	Class IIb sterile (rule 9)	Single Use
Dexter L6 Sterile Interface	AC-SU-SI	140	K010202	Class I sterile (rule 1)	Single Use

Device Description - List of Items & Classification (Class Is)

Item Name	Item ID	Article (REF)	Classification (MDR)	Rule	Type of use
Dexter L6 Drapes set	AC-SU-SD	141	Class I sterile Distalmotion acts as distributor. Manufactured and CE marked by Medline. Medline article number KITDPC.	Rule 1	Single Use

Device Description - List of Items & Classification (Class I)

Item Name	Item ID	Article (REF)	EMDN	Classification (MDR)	Type of use
Dexter L6 Handle Grip	AC-RU-HG	146	Z120201	Class I (rule 1)	Reusable
Dexter L6 Incision Pointer	AC-RU-IP	413	Z120201	Class I (rule 1)	Reusable
Dexter L6 Emergency Release Tool	AC-RU-ERT	145	Z120201	Class I (rule 1)	Reusable
Dexter L6 Accessory Tray	AC-RU-T	147	S010401	Class I (rule 1)	Reusable
Dexter L6 Endoscope Cart	DM-L6-EC	339	Z120290	Class I (rules 1)	Reusable

Device Description - Endoscope Arm Items & Classification

Item Name	Item ID	Article (REF)	Classification (MDR)	Rule	Type of use
Dexter Endoscope Arm (incl. its accessories)	SOLO	N/A	Class I / Class Is / Class Ir Distalmotion acts as distributor. Manufactured and CE marked by AKTORmed.	N/A	Reusable

EC Representative:



The EC representative is:

Qarad EC-REP BV
Pas 257
2440 Geel
Belgium

15.2.2 Essential Performance

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.

15.2.3 Key Physical Characteristics

Item	Size	Weight	Power Supply
Surgeon Console	1'090 x 1035 x 1'200 mm	86 kg	350 VA, 100-240V~, 50/60Hz
Patient Cart	1'425 x 850 x 815 mm	230 kg	700 VA, 100-240V~, 50/60Hz
Endoscope Cart	700 x 600 x 1'300 mm	32 kg	n/a
Needle Holder	506x63x45 mm	83 g	n/a
Bipolar Johann Grasper	541x63x45 mm	87 g	≤770 Vp
Bipolar Maryland	540x63x45 mm	87 g	≤770 Vp
Monopolar Scissors	534x63x45 mm	86 g	≤4 kVpeak
Monopolar Hook	536x63x45 mm	84 g	≤4 kVpeak
Sterile interface	ø74x134 mm	35 g	n/a
Surgeon Console Master Arm Drapes	2350x1400x0.4 mm	150 g	n/a
Surgeon Console Central Pillar drape	905x700x0.4 mm	80 g	n/a
Patient Cart Drape	3300x1300x0.6 mm	220 g	n/a
Accessories Tray	480x250x110 mm	2.25 kg	n/a
Handle Grip	140x120x80 mm	224 g	n/a
Incision Pointer	ø50x207 mm	165 g	n/a
Emergency Release Tool	183x18x18 mm	30 g	n/a
Endoscope Arm	291x167x1059 mm	11.5 kg	100-240 V

15.2.4 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 body, they shall be considered as a **single applied part** during surgery. Consequently, patient and patient auxiliary leakage currents add up.

The accessible parts which could be accidental contact with the patient 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
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 s < t < 10 s

	Accessible Part	Equivalent Applied Part Classification	Rationale	Contact duration
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 s < t < 10 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 s < t < 10 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 [m].

Note: Applied parts are not defibrillation-proof.

The accessible parts of the Robotic 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

 - **WARNING:** Before you operate Dexter, 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.

15.2.5 Disposal Information



At the time of their disposal, the following components of the Dexter System shall be disposed 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 bio-hazard, they shall be disposed in accordance with local regulation 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 as Waste Electronic and Electrical Equipments. Please return them to Distalmotion SA.

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

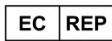
Dispose of all remaining components in accordance with local regulations.

15.3 Symbols and Icons

Please find below the list of symbols and icons:

Symbol or Icon	Meaning	Where Found
	Warning	Instructions for use
	Warning - Crushing of hands	Product
	Information	Instructions for use
	Caution	Product label
	Supply mains	Product label
	Fuse rating	Product label
	Weight	Product label
	Consult instruction 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

Symbol or Icon	Meaning	Where Found
	Potential Equalization Conductor	Instructions for use Patient Carts Surgeon Console
	E-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
	Indicates a single sterile barrier system with protective packaging outside	Product label
	To indicate the number of pieces 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 Internet Address	Instructions for use
	Floor lock button to deploy or disengage the patient cart floor lock	Instructions for use Patient Carts
	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 by release Boom brakes	Instructions for use Patient Carts

Symbol or Icon	Meaning	Where Found
	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	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 the Patient cart 1	Instructions for use Surgeon Console
PC-2	Connection of the data cable on the Surgeon Console to the Patient cart 2	Instructions for use Surgeon Console
	Up and Down buttons for height adjustment of the Master Arms	Instructions for use Surgeon Console
	Manual Floor Lock Release in case of emergency	Instructions for use Patient cart
	Connection of the Foot pedal on the Surgeon Console	Instructions for use Surgeon Console
	High voltage parts	Patient cart
	Left Pedal: Camera Control Right Pedal: Instrument Clutching	Surgeon Console
	Temperature limit	Product label
	Humidity limit	Product label
	Non-pyrogenic	Product label
	EC 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

Symbol or Icon	Meaning	Where Found
	No Pushing: To prohibit pushing against an object	Endoscope Cart

15.4 System Specifications

15.4.1 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 36 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 use for up to 300 uses. 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 use for up to 100 uses. To cover the service life of the system, this accessory needs to be replaced by a new one.

15.4.2 Environmental Specifications

Operating Conditions	Dexter withstands the following environmental operating conditions: • Temperature range: 10° to 25° [C] • Relative humidity range: 10 to 85 [%] non-condensing • Pressure range: 645 to 795 [mmHg] Deviation for Instruments and Incision Pointers (invasive parts of Dexter): • Temperature range: 10° to 38° [C] • Relative humidity range: 10 to 100 [%] • Pressure range: 645 to 815 [mmHg] (pneumoperitoneum over-pressure)
Transport and Storage Conditions	Dexter withstands the following environmental transport and storage conditions: • Temperature range: 10° to 35° [C] (a peak temperature of up to 50°C during two days is permitted) • Relative humidity range: 10 to 85 [%] non-condensing • Pressure range: 645 to 795 [mmHg]

15.4.3 Electromagnetic Compatibility

Electromagnetic Emissions

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

Emission test	Compliance level	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	Dexter uses RF energy for its internal function. Dexter contains a 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) Dexter may be interfaced with HF generators, which complies with the national regulations. Please refer to the HF general's instructions for use 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: Dexter is suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.		

Electromagnetic Immunity

Dexter is intended for use in the electromagnetic environment specified below. The customer or user of Dexter should ensure that it 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, $\pm 2\text{ kV}$	Mains power quality should be similar to that of a hospital environment.
Surge IEC 61000-4-5	1.2/50 (8/20) μs - LtL: $\pm 1\text{ kV}$ - LtG: $\pm 2\text{ kV}$	1.2/50 (8/20) μs - LtL: $\pm 1\text{ kV}$ - LtG: $\pm 2\text{ kV}$	Mains power quality 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)	Mains power quality should be similar to that of a hospital environment. When the user of the device requires continuous function in the event of disruption of the service, it is recommended 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 RF communications equipment should be used no closer to any part of the Dexter system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:	
Conducted RF IEC 61000-4-6	150 kHz – 80MHz 3 V - ISM and amateur radio bands 6V	150 kHz – 80MHz 3 V - ISM and amateur radio bands 6V	$d = 1.2 * \sqrt[3]{P}$	from 80 MHz to 800 MHz
			$d = 2.3 * \sqrt[3]{P}$	from 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	80 MHz – 2.7GHz 3 V/m	80 MHz – 2.7GHz 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 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 $d = 1.2 * \sqrt[3]{P}$ (meters)	80 MHz to 800 MHz $d = 1.2 * \sqrt[3]{P}$ (meters)	800 MHz to 2.5 GHz $d = 2.3 * \sqrt[3]{P}$ (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

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter
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.	

15.4.4 Operating Frequency and Power

Dexter includes a RFID transceiver which operates with the following characteristics:

Free range	Maximum Output Power
NFC 13.56 MHz	5.6 dBuA/m at 10m

This Dexter L6 and all of its accessories having radio equipment are compliant with the European Directive 2014/53/EU (RED – Radio Equipment Directive) , and with the following standard EN 300 330 V2.1.1.

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

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment 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 equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

⚠ - WARNING - This portable equipment with it's antenna complies with FCC'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 to the antenna, or keep contact to a minimum while using this equipment.

16 Appendix B: Troubleshooting

16.1 Setup

Surgeon Console Positioning

If possible, avoid placing the surgeon console in the corner of a room, i.e. with two sides of it against a wall. Such positioning generate the following constraints:

- Draping and manual restart made more difficult
- No or lack of room for 3D monitor

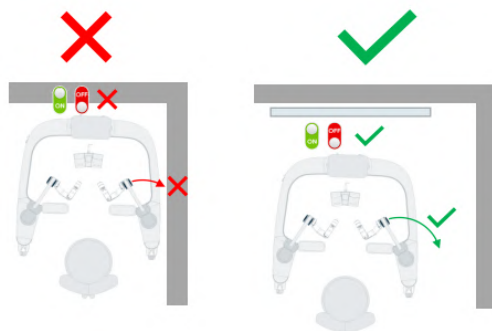


Figure 41 Suboptimal Surgeon Console positioning. Ideal positioning on the right.

Patient Carts Draping - Elastic Backlash

When removing the red stickers on the Patient Cart Sterile Drapes, be careful of the "elastic backlash" from the sticker, as it may make the glove lose sterility by sticking on it.

Consider bending the stick into the other direction to avoid such behavior while removing the sticker.

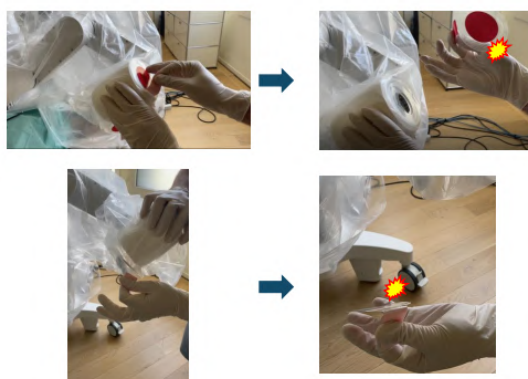


Figure 42 On the top, illustration of the "elastic backlash". On the bottom, illustration of the good practice.

Patient Bed Preparation

Position the patient bed at its lowest possible height to minimize the risk of collision. Prior to initiating the docking process, ensure that the Trendelenburg angle is correctly set to prevent the need for redocking should the values change.



Figure 43 Patient Bed Height and Trendelenburg

Endoscope Cable Management

Secure the endoscope cable to the drape, ensuring sufficient cable slack for the Endoscope Arm, using either clamps or sterile Velcro straps. Refrain from allowing the endoscope cable to hang freely, as this may increase the likelihood of unintended roll movement of the endoscope arm. If appropriate, consider combining the endoscope cable with monopolar and/or bipolar energy cables for convenience.



Figure 44 On the left, wrong management of the endoscope cable. On the right, suggested placement.

Data and Power Cables Management

To reduce the risk of bumping into cables or obstructing the OR staff's movement, consider the following best practices:

1. Bundle the cables together using Velcro straps.
2. Position the cables along the walls.
3. When cables cross a walking path in the OR, cover them with a tissue drape or a similar protective material.



Figure 45 On the left, bundling cable. On the right, covering them.

Endoscope Connection - Audio Feedback

An incomplete insertion of the cable might be inadvertently performed.

Make certain to listen for a "click" when inserting the endoscope arm cables, as it may appear visually connected without being securely in place.

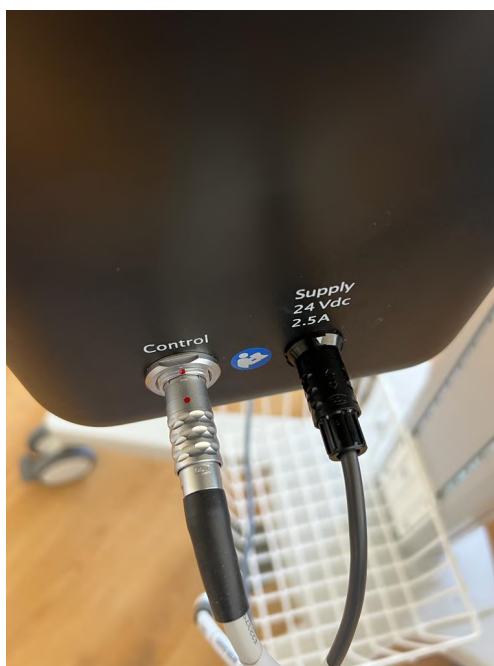


Figure 46 Example of a cable wrongly plugged



Figure 47 Example of a cable rightly plugged

3D Endoscope Connection

To prevent technical issues during setup, always plan for the connection between the endoscope module and the 3D monitor, as compatibility may differ across brands.

Endoscope Universal Joint Positioning

Always keep the endoscope Universal Joint 45° in direction of the trocar to reduce probability of collision.



Endoscope Cantilever Positioning

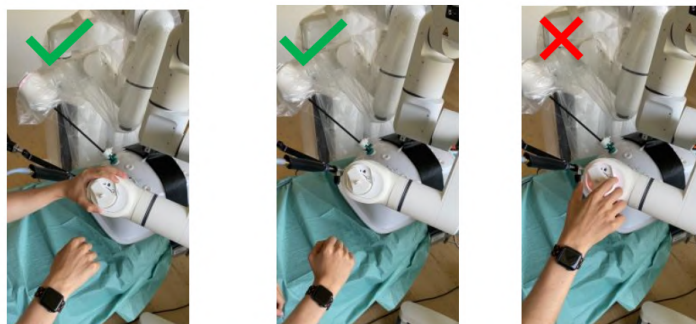
Start with a 90° lateral positioning. If needed, move around while communicating with the assistant surgeon.



16.2 While Operating

Instrument lock/unlock

Ensure a firm grip on the sterile interface to prevent any movement while locking or unlocking the instrument. This precaution helps avoid unintended rotation of the instrument, which could potentially trigger an emergency stop for safety reasons.



Instrument not recognized

In case the instrument is not recognized by the system, replace directly the instrument by another one.

Difficult Instrument insertion

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

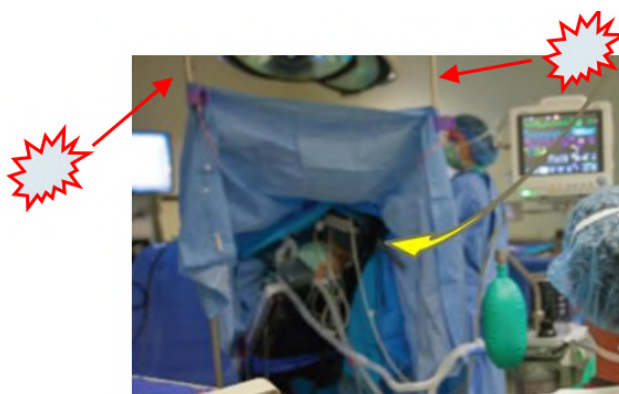
1. Verify that the instrument is in the correct insertion position.
2. Ensure that the instrument arm is in the Home position.
3. If insertion remains challenging, confirm that the docking position has not been lost.



Figure 48 Maneuver to put instrument knob back to insertion position

Instrument Retraction

Be cautious of the metallic bars on the patient's sterile drape, as accidentally touching them while retracting the instrument may compromise sterility. To mitigate this risk, proactively coordinate with the anesthesia team during setup.



Instruments Cleanliness

Maintain clean instruments, as accumulated eschar can diminish their effectiveness. You might for example:

- Clean the instrument with a sterile, wet gauze
- Cover with sterile, wet gauze when not used



Manual Emergency Instrument Release - Puncturing Force

To facilitate the puncturing maneuver of the Sterile interface, perform clockwise and anti-clockwise rotation with the Emergency Release Tool while perforating it.

Endoscope Arm Collision

To prevent endoscope arm collisions, it is preferable to place the endoscope arm on the endoscope cart rather than the patient bed.



Loss of docking

Continuously monitor that the following elements do not move once the docking has been performed:

- Table (height, inclination, etc.)
- Patient positioning
- Insufflation parameters such as the pressure
- Patient Carts due to, for example, a collision

If you have any doubts of loss of docking, perform the following actions:

- Remove the instruments
- Use the incision point to redock the patient carts

Falling to home

If the home button and hub remain yellow after completing the home movement, take the following steps:

1. Retract instrument
2. Press Home button until the instrument arm stops moving
3. Reinsert the instrument
4. Check if the visual feedback is still steady white
5. Perform previous steps if the color is still yellow

If after multiple attempts, the visual feedback remains yellow, take the following steps:

1. Retract instruments
2. Manual Restart Dexter
3. Press Home button until the instrument arm stops moving
4. Reinsert instruments

Suboptimal Energy Delivery

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

Foot Pedal Connection while operating

Generally, refrain from connecting the pedalboard while the robot is powered on. If necessary, reconnect the pedalboard when the surgeon is not holding the handle grips.

Collision applying pressure on the patient

If a collision exerts pressure on the patient and triggers an emergency stop, carefully remove the instrument, restart the system and utilize the Patient Cart's Up and Down buttons and/or Lateral Boom Movement button to alleviate the pressure on the patient by moving the Boom up and/or left/right. Always re-dock the patient cart to the corresponding trocar.

Refrain from using the LAP or Home button to reposition the boom, 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 arm 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.

17 Appendix C: Trocars

This IFU offers a compilation of trocars verified for compatibility with Dexter. Be aware that this list is not all-inclusive. Users are welcome to utilize other third-party trocars, as long as they adhere to the specified requirements outlined in this IFU and are deemed compatible with Dexter: at least 10 [mm] in diameter and being translucent.

Please refer to the manufacturer's IFU 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	AESCULAP® Optical Trocar	11 mm	100 mm
B.Braun, Germany	AESCULAP® 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
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
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

Brand	Model	Diameter	Length
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

Disposable Abdominal Trocar VIO 3 (CN-TCI-10N, CN-TCI-10L) and 12 mm (CN-TCI-12N, CN-TCI-12L)

18 Appendix D: Electrosurgical Units

This IFU offers a compilation of ESU verified for compatibility with Dexter. Be aware that this list is not all-inclusive. Users are welcome to utilize other third-party ESU, as long as they adhere to the specified requirements outlined in this IFU and are deemed compatible with Dexter.

The tables below provide ESU settings that have been deemed safe for use with Dexter 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

18.1.1 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

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)
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*	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
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*	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	100 Watts / Effects 1 to 4	100 Watts / Effects 1 to 4
SWIFT COAG	200 Watts / Effects 1 to 8	200 Watts / Effects 1 to 8	N/A	N/A
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	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	120 Watts / Effects 1 to 8	120 Watts / Effects 1 to 8

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
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

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)
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

18.1.2 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	Do not use	Do not use	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
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

18.1.3 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	Do not use	Do not use	N/A	N/A
Monopolar COAG SPRAY	Do not use	Do not use	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	Do not use	Do not use	N/A	N/A
Monopolar COAG SHARED FULGURATE	Do not use	Do not use	N/A	N/A
Monopolar COAG SPRAY	Do not use	Do not use	N/A	N/A
Monopolar COAG SHARED FULGURATE	Do not use	Do not use	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

18.1.4 Olympus

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	Do not use	Do not use	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
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

18.1.5 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
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	Do not use	Do not use	N/A	N/A
Monopolar Duo Prep	Do not use	Do not use	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
Bipolar coagulation: • Micro coag • Micro Auto Stop • Micro Auto Start • Auto Micro	N/A	N/A	50 Watts / Effects N/A	50 Watts / Effects N/A
Bipolar coagulation: • Macro coag • Macro Auto Stop • Macro Auto Start • Auto Macro	N/A	N/A	120 Watts / Effects N/A	120 Watts / Effects N/A
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	150 Watts / Effects 1 to 4	150 Watts / Effects 1 to 4	N/A	N/A
Spray	Do not use	Do not use	N/A	N/A
Duo Prep	Do not use	Do not use	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
Forflex	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

19 Appendix E: Glossary**19.1.1 General Terms****Endoscope Cart**

Cart where the endoscope arm is mounted on

**Emergency Release Tool**

White screwdriver to be used for Manual Emergency Instrument Release

**Surgeon Console - Up Button**

Button to elevate the surgeon console master arms



Surgeon Console - Down Button

Button to lower the surgeon console master arms



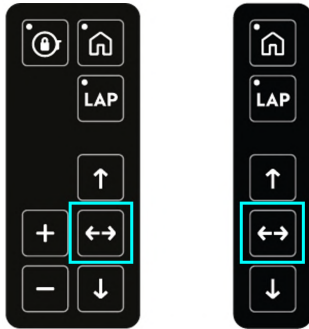
Surgeon Console - Arms lock Button

Button allowing to un/lock the master arms of the surgeon console



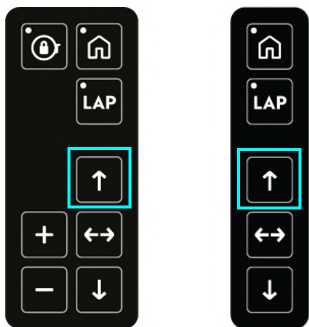
Lateral Boom Movement Button

Button releasing or locking the Boom brakes



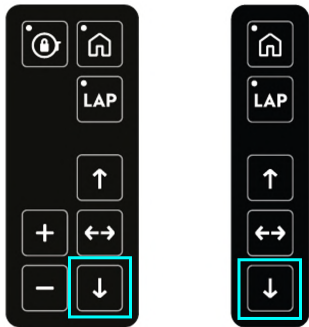
Patient Cart - Up Button

Button to elevate the patient cart



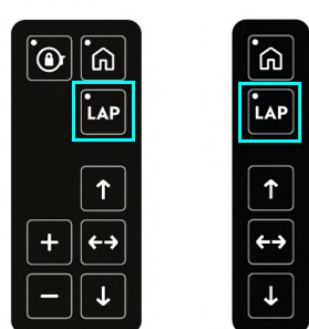
Patient Cart - Down Button

Button to lower the patient cart



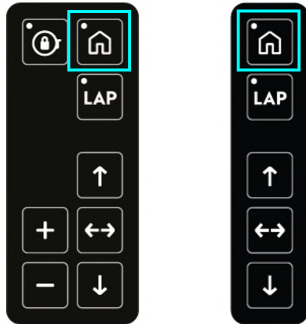
Patient Cart - LAP Mode Button

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 at Home position



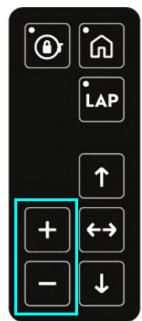
Patient Cart - Floor Lock Button

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 the distal part of the instrument arm



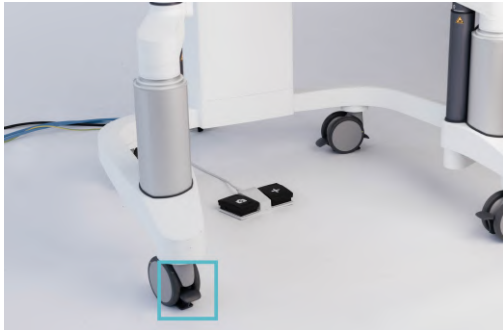
Patient Cart - Wheel Brake

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



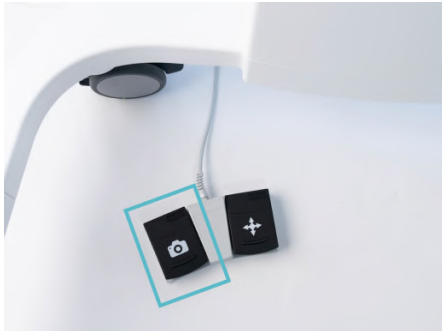
Pedalboard

Foot pedal panel containing the endoscope pedal and the clutch pedal



Endoscope Pedal

Left pedal in the surgeon console pedalboard



Clutch Pedal

Right pedal in the surgeon console pedalboard



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 consoles allowing to power on or off the devices.



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 release manually the floor lock in case of emergency



Incision Pointer

To dock the Patient Carts to the trocar



Handle Grips

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



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.



Incision Pointer Magnet

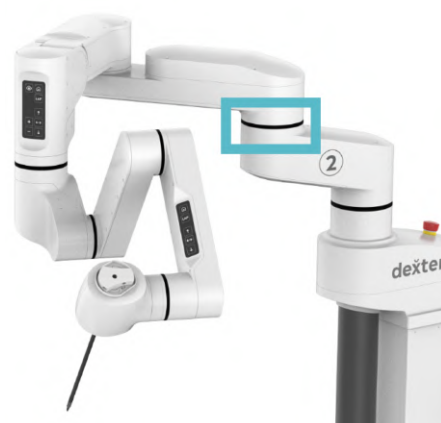
Magnet able to fix the Incision Pointer to the Instrument Arm for docking



Patient Cart - Epsilon Joint



Patient Cart - Eta Joint



Patient Cart - Phi Joint



Patient Cart - Forward Angulation



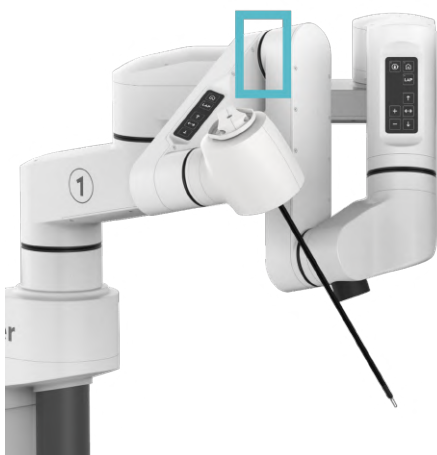
Patient Cart - Alpha Joint



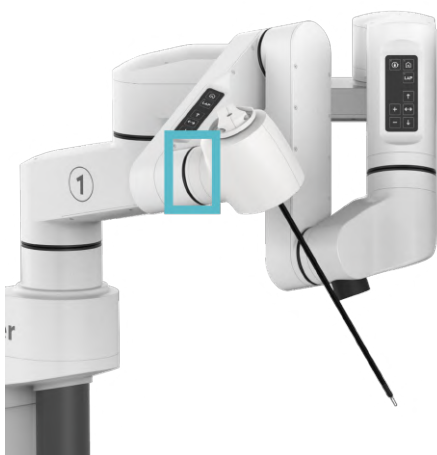
Patient Cart - Beta Joint



Patient Cart - Gamma Joint



Patient Cart - Theta Joint



Surgeon Console - Alpha Joint



Surgeon Console - Beta Joint



Surgeon Console - Gamma Joint



19.1.2 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 reboot performed from the surgeon console

Manual Restart

Dexter 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

Deploy Floor Lock

Deploy floor locks using the primary HMI (user interface)

Retract Floor lock

Retract floor locks using the primary HMI (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 or prohibiting the wheels to roll on the patient carts or surgeon console