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ALLY II UPS™

(Uterine Positioning System)
Instructions for Use

REF AU-UPS2

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SECTION 1 INTRODUCTION

The ALLY II UPS™ (Uterine Positioning System) is a non-patient contacting, electromechanical device that consists of a single, multi-segmented, articulated arm that attaches to a standard operating room bed rail, and a separate, sterile, disposable adapter that is used to secure a sterile uterine manipulator to the arm.

Read all information carefully.

Failure to properly follow all instructions, including those supplied with the CooperSurgical manipulator handles and adapters may lead to injury and result in improper functioning of the device.

CAUTION: *U.S. Federal law restricts this device to sale by or on the order of a physician.*

SECTION 2 INTENDED USE

The ALLY II UPS™ is intended to secure uterine manipulator devices for uterine positioning and to assist the surgical staff in mounting, positioning, and holding uterine manipulators during gynecological laparoscopic surgical procedures.

SECTION 3 INDICATIONS FOR USE

The ALLY II UPS™ (Uterine Positioning System) is intended to assist the surgical staff in mounting, positioning, and holding uterine manipulators during gynecological laparoscopic surgical procedures. It is intended for use by trained operating room personnel in an operating room environment.

SECTION 4 INTENDED USERS

Trained operating room personnel in an operating room environment.

SECTION 5 TARGET PATIENT POPULATION

Women who have been assessed suitable by a gynecologist to undergo gynecological laparoscopic surgical procedures.

SECTION 6 PERFORMANCE CHARACTERISTICS

- The segmented design of the arm allows lateral/medial movement from a single point, allowing the system to be attached to one side of the operating room table.
- Foot pedal release facilitates positioning – Lock arm in the desired position by releasing the foot pedal.
- Connects to any operating table.
- Provides static control, consistent cephalad pressure and stability.

SECTION 7 CLINICAL BENEFIT

- Holds the uterus in the desired position and allows for visualization and access.

SECTION 8 CONTRAINDICATIONS

CooperSurgical manipulator handles should not be used in patients who are pregnant or who are suspected of being pregnant, planned gamete intrafallopian transfer procedures, in patients who have an IUD in place, in patients with suspected pelvic infections and in cases where the surgeon deems it inadvisable or finds it difficult to insert the silicone tip into the cervix or uterus.

SECTION 9 WARNINGS AND PRECAUTIONS

WARNINGS:

- *Securely hold arm or manipulator before depressing foot pedal.*
- *To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.*
- *The ALLY II UPS™ is only intended for use with CooperSurgical's family of uterine manipulators. For a complete list of the manipulators compatible with the ALLY II UPS™, please contact CooperSurgical Customer Service. Use of this device in any configuration other than specified is not recommended, and could lead to injury and improper functioning of each device.*
- *Flammable Anesthetics: This device is not suitable for use in the presence of a flammable anesthetic mixture with air, or in the presence of a flammable anesthetic mixture with oxygen or nitrous oxide.*
- *Read all instructions carefully. Failure to properly follow instructions may cause improper functioning of the device.*
- *Use only the rail clamp supplied with the ALLY II UPS™.*

- *Do not install rail clamp across separated rail sections.*
- *Surgical procedures requiring vaginal instrumentation are not sterile. Conventional Operating Room procedures for maintaining sterility must be observed when the ALLY II UPS™ is in use.*
- ***DO NOT USE EXCESSIVE FORCE.** If adequate range of motion is not obtained, reposition the ALLY II UPS™ (reference section 12.2 on proper positioning). If problem persists, discontinue use.*
- ***DO NOT** store the device in direct sunlight, at high temperatures or high humidity.*
- ***DO NOT** store this device in the shipping box.*
- ***ALWAYS** position the patient and the operating room table prior to attaching the ALLY II UPS™ to the manipulator.*
- ***ALWAYS** have patient under general endotracheal anesthesia when ALLY II UPS™ is attached to the manipulator.*
- ***ALWAYS** use caution when attaching and detaching the manipulator from the ALLY II UPS™.*
- ***DO NOT** move the foot end of the Operating Room table while the ALLY II UPS™ is attached to the table.*
- ***ALWAYS** follow all instructions discussed in the Uterine Manipulator Instructions for Use.*
- ***ALWAYS** handle the ALLY II UPS™ with care. Avoid mechanical shock or stress that can cause damage to the device.*
- ***DO NOT** carry the ALLY II UPS™ using anything other than the handle and arm. The foot pedal cover should be used to lift, carry, or reposition the foot pedal.*
- *The ALLY II UPS™ is not designed for use in environments in which strong Electromagnetic interference (EMI) may impact the performance of the equipment.*
  The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as re-locating or re-orienting the equipment.
  If this occurs, the site of use should be surveyed to determine the source of this disruption, and the following actions may be taken to eliminate the source:
  - *Remove, re-orient or re-locate the interfering equipment.*
  - *Increase the separation between the interfering equipment and the ALLY II UPS™.*
  - *Incrementally turn off equipment in the vicinity to identify the interfering device.*

PRECAUTIONS:

- *Always ensure that the ALLY II UPS™ is tightly and securely attached to the table prior to the start of the surgical procedure. Improper or loose mounting of the system can lead to unintended movement and may lead to injury.*
- *Inspect the adapter drape prior to use for damage. Ensure that the packaging of the adapter drape has not been breached. Verify the expiration date.*
- *Operating room personnel should take care not to contaminate the draped ALLY II UPS™ during the remaining patient preparation steps.*
- ***DO NOT** attach the manipulator to the ALLY II UPS™ arm until after the da Vinci® Surgical System patient side cart is in position and the brakes are set.*
- ***DO NOT** attach the manipulator to the ALLY II UPS™ arm until after the patient is in the final position.*
- *Users should check that the adapter is holding the manipulator securely without any extraneous movement prior to operative use. If the manipulator does not securely attach to the manipulator adapter discontinue use immediately.*
- *The ALLY II UPS™ MUST be removed from the table PRIOR to the foot end/pins being returned to the horizontal position.*
- *Damage will result if the flexible arm is cleaned with bleach products.*
- *Damage may result if the rail clamp is cleaned with bleach.*
- *Care should be taken during storage and transportation to avoid drops, falls, mechanical stress, and mechanical shock to the device.*

9.1 REQUIREMENTS APPLICABLE TO THE ALLY II UPS™

The ALLY II UPS™ needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in the tables in Sections 13 through 16.

Portable and mobile RF communications equipment can affect the ALLY II UPS™.

SECTION 10 ADVERSE EVENTS

***PLEASE NOTE:** If a serious incident is suspected from using the ALLY II UPS™, report the details of the incident to CooperSurgical via phone number +1 203-601-5200 Ext 3100 or by email at ProductSurveillance@coopersurgical.com and to the local Health Authority in your area. A serious incident may have caused or contributed to a death, a delay in a procedure which resulted in death or serious injury, or a malfunction that could have caused an adverse event.*

SECTION 11 DEVICE DESCRIPTION

The ALLY II UPS™ attaches to the operating room table and will enable the bed-side assistant to readily mount, hold, and position the manipulator during laparoscopic surgical procedures. The ALLY II UPS™ enables access and provides the ability to maneuver and maintain the manipulator in a desired position.

The ALLY II UPS™ consists of the ALLY II UPS™ and the manipulator adapter with built-in sterile drape (sold separately) known as the adapter drape.

Figure 1 shows the system followed by descriptions of its various parts.

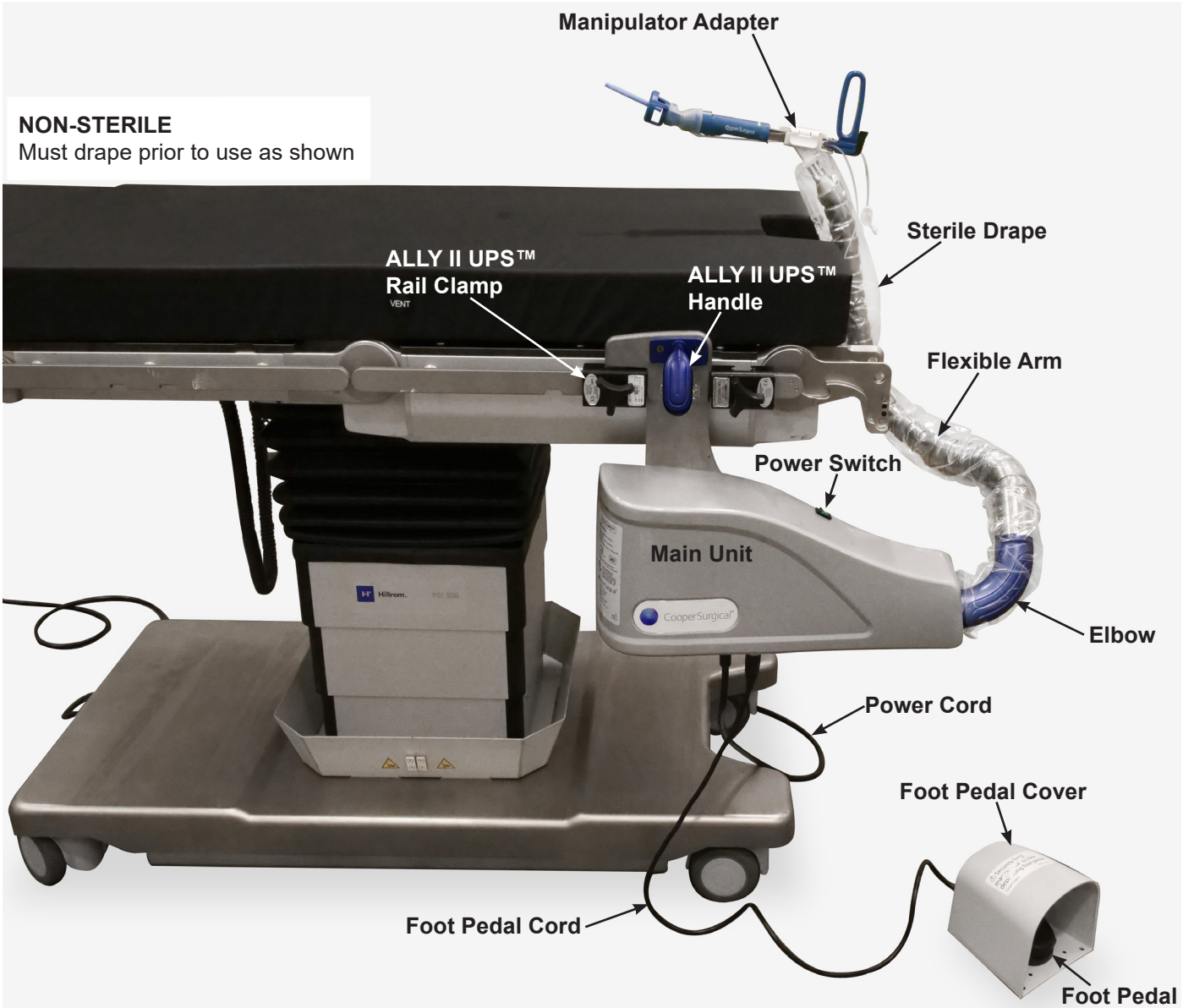
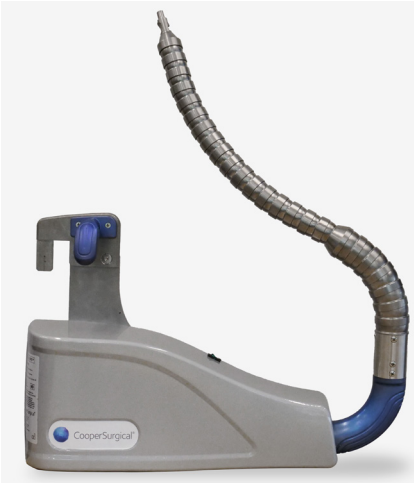


Figure 1: *ALLY II UPS™ (Uterine Positioning System)*

There are three main components to the ALLY II UPS™ System:

(1) MAIN UNIT ASSEMBLY



Main Unit

- The main unit houses the controls of the ALLY II UPS™.

Power Switch

- The power switch must be ON (green light) in order for the system to work.

Foot Pedal

- Controls the locking and unlocking of the arm.
- Depressing the foot pedal releases the arm to allow for maneuvering the manipulator.
- Releasing the foot pedal locks the arm and holds the manipulator in the desired position.

Flexible Arm / Fixed Arm

- Provides desired range-of-motion for positioning the manipulator.
- Holds the manipulator in the desired position.
- Has a mating tip to accommodate engagement with adapter.
- Arm rotates out of the way to provide access between the patient's legs as needed.

ALLY II UPS™ Blue Handle

- This is what is held onto (as well as the arm) when installing or removing the ALLY II UPS™ from the rail. Refer to Section 12.2 for more information.

Power Cord

- A detachable power cord is included which supplies power to both the main unit and the foot pedal.

Grounding Post

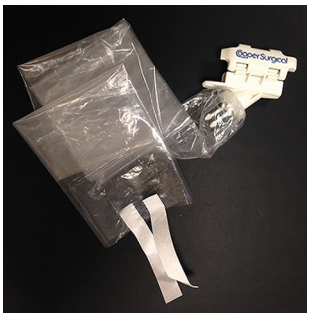
- To access ground connection.

(2) ALLY II UPS™ RAIL CLAMP

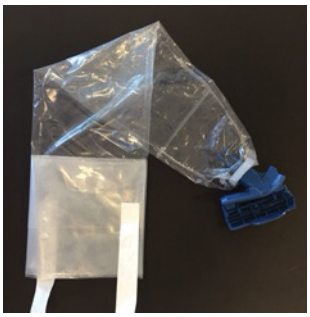
- Used to mount the ALLY II UPS™ to the patient's right side rail of standard operating room tables.
- Secure by tightening the knob.

(3) ADAPTER DRAPE

Sold separately. (Part Numbers AU-AD and AU-AD-DLNTR)



AU-AD



AU-AD-DLNTR

- The adapter drape connects the flexible arm to CooperSurgical manipulators.
- This component is a single-use disposable and comes with drape attached.
- One end of the adapter attaches to the flexible arm via pinch clips.
- The other end of the adapter securely attaches to the manipulator using the latching mechanism.
- The ALLY II UPS™'s arm must be completely draped to ensure that the sterile field is not compromised during the surgical procedure.
- The AU-AD to be used with RUMI and Advincula Arch.
- The AU-AD-DLNTR to be used with the Advincula Delineator

SECTION 12 INSTRUCTIONS FOR USE

WARNING: *Read all instructions carefully. Failure to properly follow instructions may cause improper functioning of the device.*

12.1 INSPECTION PRIOR TO USE

Prior to each use, all components should be inspected for damage or irregularities. The device should not be used if any damage or irregularity is observed. The user should contact CooperSurgical Customer Service if any damage or irregularities are noticed.

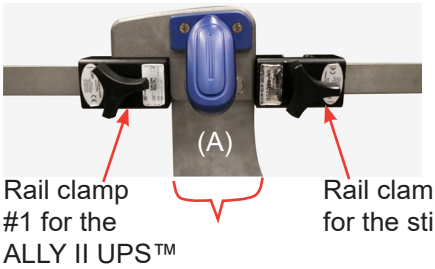
The sequence of operations listed below is recommended to ensure safe and effective functioning of the device.

Surgeon may choose a different order of steps as appropriate.

12.2 RECOMMENDED STEPS FOR MOUNTING THE ALLY II UPS™

(Operating room staff may choose a different method of mounting as appropriate.)

1. Position patient on operating room table in dorsal lithotomy position with legs in stirrups. Refer to leg stirrup manufacturer's instructions for proper use and positioning. Ensure patient is placed such that the buttocks are as close to edge as possible.
2. Lower or remove foot end of the operating room table.
3. Attach the ALLY II UPS™ to the operating room table by placing the rail clamp on the patient's right side near the stirrup. Lower the mounting tab of the ALLY II UPS™ into the rail clamp.
4. Tighten the knob by hand until secure. Check security of hold by trying to slide off the rail. Figure 2a shows how to install the rail clamp over the cutouts in the rail. Figure 2b shows the "final" position of the clamp once it is on the rail.



NOTE: *Leave a minimum gap of 3" (7.6 cm) between rail clamps for the mounting bar (A).*

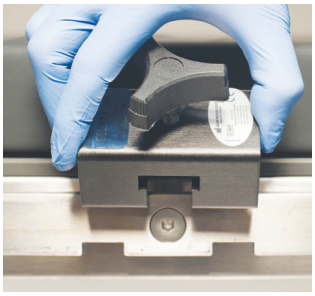


Figure 2a: *Installing the rail clamp*

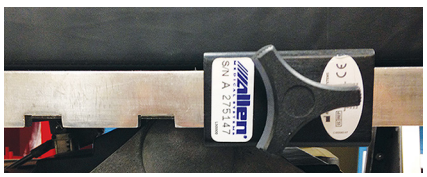


Figure 2b: *Move the clamp to the right, away from the slots in the rail*

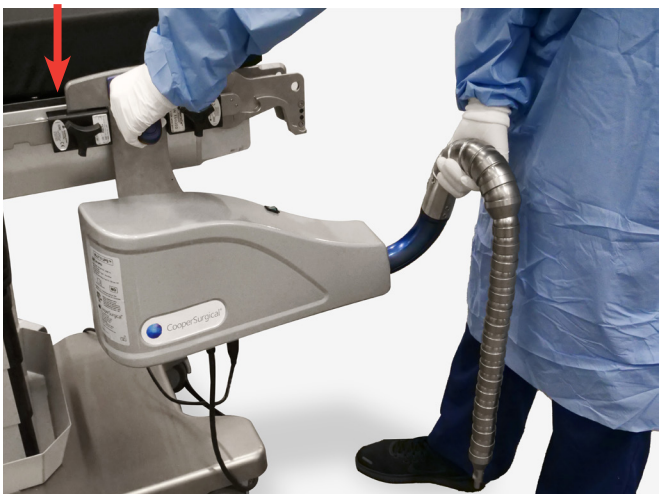
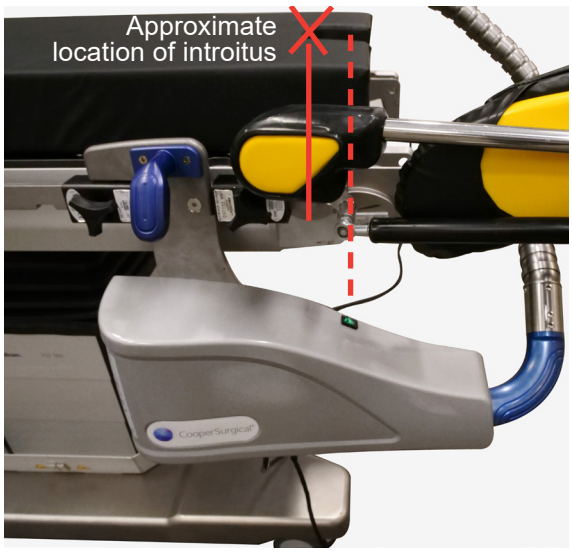


Figure 2c: *Installing the main unit into the ALLY II UPS™ rail clamp*



For optimum position, locate the power switch of ALLY II UPS™ within the area between the introitus and the end of the pad.

WARNING:

- *Use only the rail clamp supplied with the ALLY II UPS™.*
- *Do not install rail clamp across separated rail sections.*

CAUTION: *Always ensure that the ALLY II UPS™ is tightly and securely attached to the table prior to the start of the surgical procedure. Improper or loose mounting of the system can lead to unintended movement and may lead to injury.*

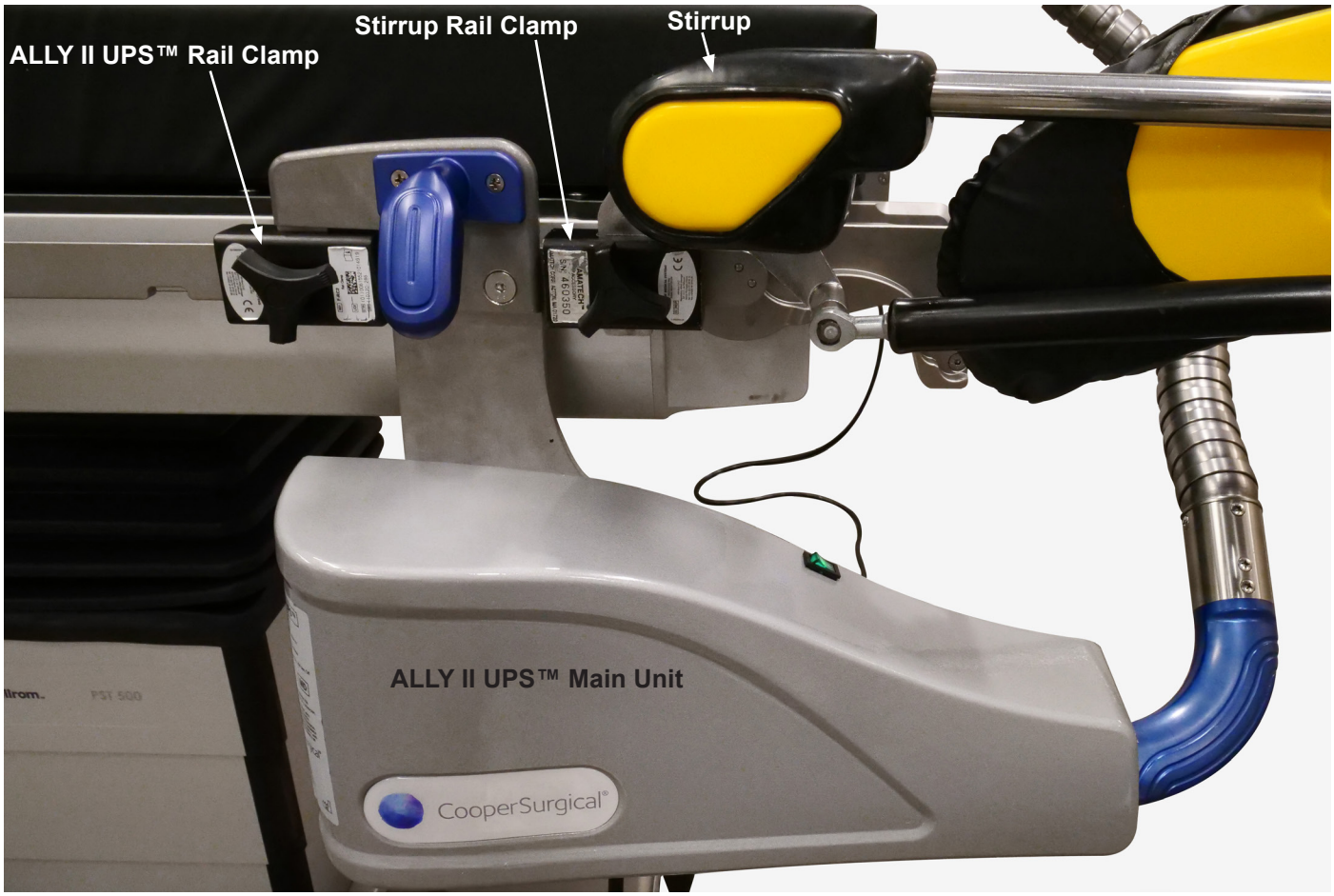


Figure 2d: *ALLY II UPS™ in position in the ALLY II UPS™ rail clamp (shown to the left of the stirrup clamp. Operating room staff may choose a different configuration or placement as appropriate).*

5. Attach the foot pedal cable to the main unit. Ensure the connector locks in place.
6. Attach the power cord to the main unit (making sure it is firmly in place) and attach it to the nearest outlet. If an extension cord is needed, make sure it is a medical grade cord suitable to withstand 125VAC/10 amps.

   Note: Position foot pedal within reach of operating room personnel actuating the ALLY II UPS™. It is recommended to position the ALLY II UPS™ foot pedal separately from other foot pedals.

   CAUTION: *Securely hold arm or manipulator before depressing foot pedal.*

7. Turn the power on and verify that the green light indicator is lit. Press and hold the foot pedal once. Release to initialize the ALLY II UPS™. The ALLY II UPS™ arm can be moved by grasping the flexible arm and depressing the foot pedal. Releasing the foot pedal locks the ALLY II UPS™ in place, holding the arm in a static position.
8. Position the ALLY II UPS™ flexible arm out of the way prior to patient preparation. It is recommended to cover the arm while prepping the patient.

12.3 ATTACHING THE ADAPTER DRAPE

WARNING: *Surgical procedures requiring vaginal instrumentation are not sterile. Conventional Operating Room procedures for maintaining sterility must be observed when the ALLY II UPS™ is in use.*

CAUTION: *Inspect the adapter drape prior to use for damage. Ensure that the packaging of the adapter drape has not been breached. Verify the expiration date.*

NOTE: It is recommended to have spare adapter drapes ready at the start of a case.

1. Once patient prep is complete, and prior to draping the patient, it is time to connect the adapter drape to the ALLY II UPS™.
2. The sterile personnel should connect the adapter drape. Align the pinch clips as shown and press them onto the end of the flexible arm. Make sure the adapter drape snaps fully into place. Slide the attached adapter drape around the elbow of the ALLY II UPS™ until you get to the main unit.

Figure 3a: *Holding the sterile adapter drape*

Figure 3b: *Final position of the adapter drape in the connector*

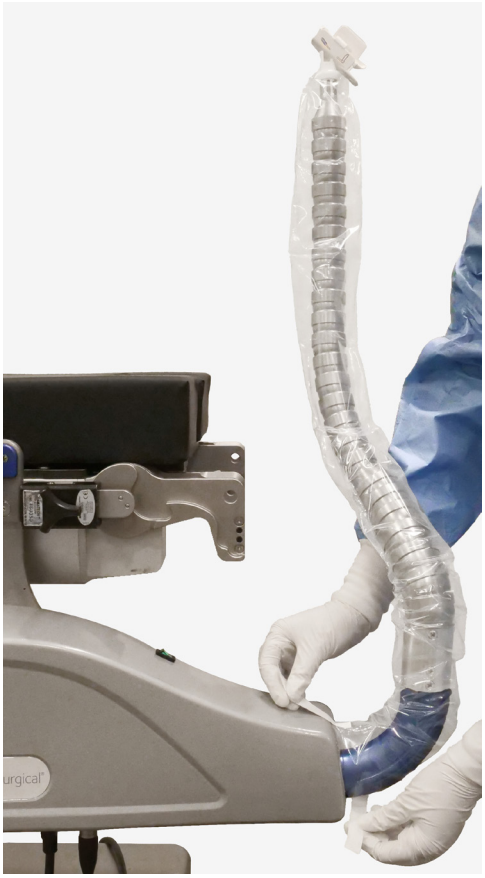


Figure 3c: *Fully extended adapter drape*

CAUTION: *Operating room personnel should take care not to contaminate the draped ALLY II UPS™ flexible arm during the remaining patient preparation steps.*

3. It is recommended to drape the patient's legs at this step in the process.
   NOTE: Continue with necessary patient preparation steps.

12.4 INTRA-OPERATIVE USE

1. Grasp the handle of the manipulator or the ALLY II UPS™ flexible arm.
2. Depressing the foot pedal allows for dynamic manipulation of the flexible arm.
3. Maneuver to the desired position.
4. Releasing the foot pedal locks the ALLY II UPS™ in place, holding the manipulator in a static position.

WARNING: ***DO NOT USE EXCESSIVE FORCE.*** *If adequate range of motion is not obtained, reposition the ALLY II UPS™ (reference section 12.2 on proper positioning). If problem persists, discontinue use.*

CAUTION: ***DO NOT*** *attach the manipulator to the ALLY II UPS™ arm until after the patient is in the final position.*

CAUTION: *Users should check that the adapter is holding the manipulator securely without any extraneous movement prior to operative use. If the manipulator does not securely attach to the manipulator adapter discontinue use immediately.*

12.5 REMOVING THE ALLY II UPS™

1. Detach the manipulator from the adapter drape by opening the latch per the Instructions for Use provided with the adapter. Detach the manipulator from the adapter drape prior to extracting the uterus during a hysterectomy procedure.
2. If used, undock the da Vinci® Surgical System and move patient side cart away from the operating room table.
3. Detach the adapter by squeezing the pinch clips together.
4. Remove the used sterile adapter drape and dispose of properly.

NOTE: Refer to the adapter drape's Instructions for Use for complete instructions.

CAUTION: *The flexible arm must be rotated out of the way or the ALLY II UPS™ MUST be removed from the table PRIOR to the foot end/pins being returned to the horizontal position.*

12.6 POWERING DOWN THE ALLY II UPS™

1. Press the foot pedal while powering down so that the arm remains in its flexible state when dismounting and storing. Operating room staff may choose to store the flexible arm in a rigid position as appropriate.
2. Turn off the power switch and unplug from the wall outlet.
3. Fully loosen the knob on the operating room table rail camp until the ALLY II UPS™ is no longer firmly secured to the operating room table. The ALLY II UPS™ can be lifted off the rail clamp. Figure 4 shows how to remove the ALLY II UPS™ main unit from the rail.
4. Remove the rail clamp and store it with the ALLY II UPS™.

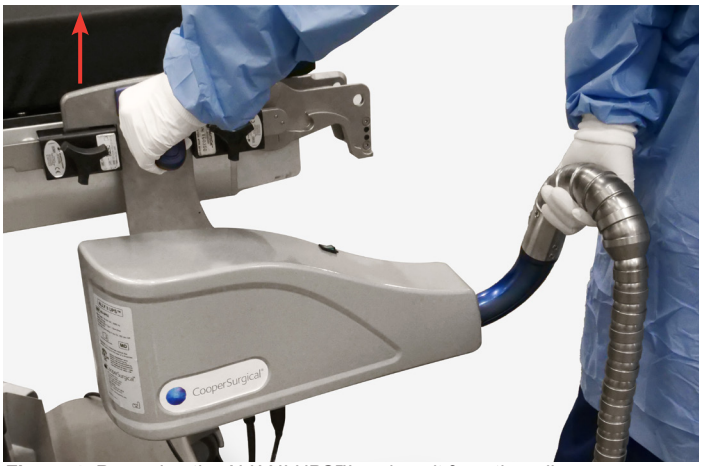


Figure 4: *Removing the ALLY II UPS™ main unit from the rail*

12.7 CLEANING AND STORAGE

1. The ALLY II UPS™ system including main unit, fixed arm, handle and foot pedal should be cleaned after each use. Only use Isopropyl Alcohol 70 percent (70% or higher) or CaviWipes™ (or equivalent) not to exceed .28% ammonium chloride. Wipe all surfaces free of debris. Do not spray flexible arm. Ensure flexible arm is locked in upright orientation during cleaning application. Ensure flexible arm is thoroughly dry before powering on.
2. After each use clean the rail clamp; clean and disinfect using a quaternary ammonium disinfecting/cleaning solution, read the cleaning product's directions and follow the instructions on the label for recommendation for achieving low-level disinfection; use caution around the knob where fluid migration may occur. Wipe device with a clean, dry cloth; make certain the product is dry prior to reinstalling to avoid damage.

CAUTION: *Damage will result if the flexible arm is cleaned with bleach products.*

CAUTION: *Damage may result if the rail clamp is cleaned with bleach.*

CAUTION: *Care should be taken during storage and transportation to avoid drops, falls, mechanical stress, and mechanical shock to the device.*

3. The foot pedal cover should be used to lift, carry or reposition the foot pedal.
4. Store this device in a clean, dry and well-ventilated environment.

WARNING: ***DO NOT*** *store the device in direct sunlight, at high temperatures or high humidity.*

WARNING: ***DO NOT*** *store this device in the shipping box.*

SECTION 13 GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS (for all Medical Equipment and Medical Equipment Systems)

The ALLY II UPS™ is intended for use in the electromagnetic environment specified below. The customer or the user of the ALLY II UPS™ should assure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
RF emissions CISPR 11	Group 1	The ALLY II UPS™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The ALLY II UPS™ is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

SECTION 14 GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY (for all Medical Equipment and Medical Equipment Systems)

The ALLY II UPS™ is intended for use in the electromagnetic environment specified below. The customer or the user of the ALLY II UPS™ should assure that it is used in such an environment.

PHENOMENON	BASIC EMC STANDARD OR TEST METHOD	IMMUNITY TEST LEVELS	
		PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT	HOME HEALTHCARE ENVIRONMENT
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	
Radiated RF EM fields [a]	IEC 61000-4-3	3 V/m [f] 80 MHz - 2,7 GHz [b] 80 % AM at 1 kHz [c]	10 V/m [f] 80 MHz - 2,7 GHz [b] 80 % AM at 1 kHz [c]
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See 8.10 IEC 60601-1-2	
Rated power frequency magnetic fields [d] [e]	IEC 61000-4-8	30 A/m [g] 50 Hz or 60 Hz	

[a] The interface between the patient physiological signal simulation, if used, and the ME equipment or ME system shall be located within 0,1 m of the vertical plane of the uniform field area in one orientation of the ME equipment or ME system.
[b] ME equipment and ME systems that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the risk management process. This test assesses the basic safety and essential performance of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.
[c] Testing may be performed at other modulation frequencies identified by the risk management process.
[d] Applies only to ME equipment and ME systems with magnetically sensitive components or circuitry.
[e] During the test, the ME equipment or ME system may be powered at any nominal input voltage, but with the same frequency as the test signal (see Table 1 in IEC 60601-1-2).
[f] Before modulation is applied.
[g] This test level assumes a minimum distance between the ME equipment or ME system and sources of power frequency magnetic field of at least 15 cm. If the risk analysis shows that the ME equipment or ME system will be used closer than 15 cm to sources of power frequency magnetic field, the immunity test level shall be adjusted as appropriate for the minimum expected distance.

SECTION 15 GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY(for all Medical Equipment and Medical Equipment Systems that are not Life-Supporting)

The ALLY II UPS™ is intended for use in the electromagnetic environment specified below. The customer or the user of the ALLY II UPS™ should assure that it is used in such an environment.

PHENOMENON	BASIC EMC STANDARD	IMMUNITY TEST LEVELS	
		PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT	HOME HEALTHCARE ENVIRONMENT
Electrical fast transients / bursts [a) l) o)]	IEC 61000-4-4	± 2 kV 100kHz repetition frequency	
Surges [a) b) j) o)] Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	
Surges [a) b) j) k) o)] Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	
Conducted disturbances induced by RF fields [c) d) o)]	IEC 61000-4-6	3 V [m)] 0,15 MHz - 80 MHz 6 V [m)] in ISM bands between 0,15 MHz and 80 MHz [n)] 80 % AM at 1 kHz [e)]	3 V [m)] 0,15 MHz - 80 MHz 6 V [m)] in ISM and amateur radio bands between 0,15 MHz and 80 MHz [n)] 80 % AM at 1 kHz [e)]
Voltage dips [f) p) r)]	IEC 61000-4-11	0 % U_T; 0,5 cycle [g)] At 0º, 45º, 90º, 135º, 180º, 225º, 270º and 315º [q)]	
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles [h)] Single phase: at 0º	
Voltage interruptions [f) i) o) r)]	IEC 61000-4-11	0 % U_T; 250/300 cycle [h)]	

[a)] The test may be performed at any one power input voltage within the ME equipment or ME system rated voltage range. If the ME equipment or ME system is tested at one power input voltage, it is not necessary to re-test at additional voltages.
[b)] All ME equipment and ME system cables are attached during the test.
[c)] Calibration for current injection clamps shall be performed in a 150 Ω system.
[d)] If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
[e)] Testing may be performed at other modulation frequencies identified by the risk management process.
[f)] ME equipment and ME systems with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the manufacturer of the ME equipment or ME system. The immunity test levels are applied to the a.c. power input of the converter.
[g)] Applicable only to ME equipment and ME systems connected to single-phase a.c. mains.
[h)] E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.
[i)] ME equipment and ME systems with rated input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). ME equipment and ME systems with battery backup shall resume line power operation after the test. For ME equipment and ME systems with rated input current not exceeding 16 A, all phases shall be interrupted simultaneously.
[j)] ME equipment and ME systems that do not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV line
[k)] Not applicable to Class II ME equipment and ME systems.
[l)] Direct coupling shall be used.
[m)] r.m.s., before modulation is applied.
[n)] The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
[o)] Applicable to ME equipment and ME systems with rated input current less than or equal to 16 A / phase and ME equipment and ME systems with rated input current greater than 16 A / phase.
[p)] Applicable to ME equipment and ME systems with rated input current less than or equal to 16 A / phase.
[q)] At some phase angles, applying this test to ME equipment with transformer mains power input might cause an overcurrent protection device to open. This can occur due to magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME equipment or ME system shall provide basic safety during and after the test.
[r)] For ME equipment and ME systems that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the minimum and maximum rated input voltage. ME equipment and ME systems with a rated input voltage range of less than 25 % of the highest rated input voltage shall be tested at one rated input voltage within the range. See Table 1 Note c) in IEC 60601-1-2 for examples calculations.

SECTION 16 RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND ALLY II UPS™

(for all Medical Equipment and Medical Equipment Systems that are not Life Supporting)

The ALLY II UPS™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ALLY II UPS™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ALLY II UPS™ as recommended below, according to the maximum output power of the communications equipment.

Test Frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**Immunity test level** (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse Modulation [b] 18 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation [b] 217 Hz	2	0,3	28
870						
930						
1 720	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation [b] 217 Hz	2	0,3	28
5 240	5 100 - 5 800	WLAN 802.11 a/n	Pulse Modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE: If necessary to achieve the immunity test level, the distance between the transmitting antenna and the ME equipment or ME system may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

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

WARNING: *Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.*

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 the ALLY II UPS™ system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.*

SECTION 17 DISPOSAL

Dispose of in accordance with all applicable Federal, State, and Local Medical/Hazardous waste practices.

SECTION 18 WARRANTY

CooperSurgical warrants that the ALLY II UPS™ will be free from defects in materials and workmanship for one year from the date of purchase. If CooperSurgical, Inc. determines that the ALLY II UPS™ fails to perform within that one year, as the sole remedy for that failure to perform, at CooperSurgical's discretion, we will repair or replace the ALLY II UPS™ free of charge.

SECTION 19 SERVICE

Annual service by authorized CooperSurgical personnel is required to ensure proper device operation. Please contact CooperSurgical Representative or CooperSurgical service team: ServiceandRepair@coopersurgical.com

SECTION 20 SPECIFICATIONS

Dimensions (H x W x D): ..... 15.4 inches x 22.3 inches x 7.5 inches (39.0 cm x 56.5 cm x 19 cm)
Depth of the Main Unit: .....4.5 inches (11.4 cm)
Weight: .....approximately 30 pounds (13.6 kg)
Power Requirement
Main Supply: 100-240VAC, 50/60Hz
Rating: ..... 1.6 Amps
Fuse: .....250 V / 2.0 A, Type T, Slow Blow
Classification: I
IP Rating:
Main Unit: IP30
Foot Pedal: IPX6
Average Duty Cycle Rating: .....5 seconds ON, 300 seconds OFF
No customer-replaceable components inside the main unit assembly
Environmental Conditions
Operational:
Temperature: .....68 °F to 75 °F (20 °C to 24 °C)
Humidity: ..... 20% RH to 60% RH
Shipping and Storage:
Temperature: ..... 14 °F to 122 °F (-10 °C to 50 °C)
Humidity: ..... 10% RH to 85% RH

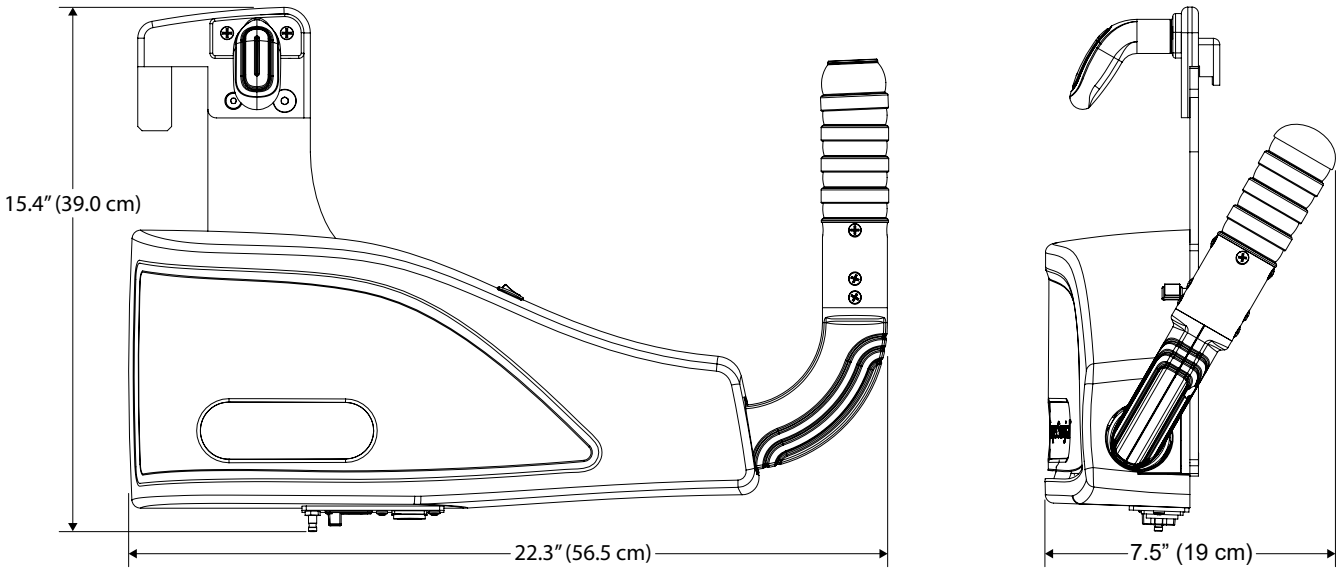


Figure 5: *Front and side views of main unit and arm*

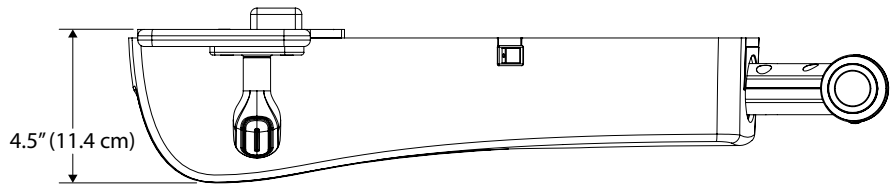


Figure 6: *Top view of main unit*

SECTION 21 GLOSSARY OF SYMBOLS

ISO 15223-1, ISO 7000, and ISO 60417

Symbol	Title
	Manufacturer
	Caution
	Catalogue number
	Serial number
	Country of manufacture Date of manufacture
	Consult instructions for use
	UL Rating/Approved MEDICAL EQUIPMENT WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARD ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1:2005, C1:2009, A2:2010 and CAN/CSA-C22.2 No. 60601-1 2008
R_x Only	Prescription Device
MD	Medical device
	Non-sterile
	Equipotentiality
	Packaging Unit

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