

INSTRUCTIONS FOR USE

English



**Caring For Life,
GIVING HOPE**

A partnership with Liger Medical

CURE MEDICAL

Innovation for Better Women's Health

For professional use. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

USER QUALIFICATION

The portable ESU-110 Electrosurgical Generator must be used by personnel who have received sufficient training in clinical procedures under the guidance of a physician. *Cure Medical* does not discuss or provide explanation of clinical procedures.

CAUTION: Read all warnings and cautions provided in these instructions before using the device.

DESCRIPTION

The Cure Medical electrosurgical generator is used to treat human tissue lesions. It is a class II(US)/IIB(EU) electrosurgical generator. It is compact, portable, and battery powered and should be used in professional healthcare locations.

The ESU-110 is designed to provide a source of power and suction for electrosurgical procedures.

INDICATIONS

The ESU-110 Electrosurgical Generator is intended to deliver high frequency electrical current for surgical procedures that can be performed with monopolar cutting and/or coagulation of tissue. One intended use of the ESU-110 Electrosurgical Generator is LLETZ aka LEEP (Large Loop Excision of the Transformation Zone aka Loop Electrosurgical Excision Procedure).



Figure 1: The ESU-110 Electrosurgical Generator.

HOW SUPPLIED

The following components are included with the Cure Medical Electrosurgical Generator:

- ESU-110 Electrosurgical Generator
- Instructions for Use
- Charging Base with A/C adapter
- Two Battery Packs
- Soft Carrying Bag



Figure 2: The ESU-110 is battery operated and is designed to be portable.

COMPATIBLE ACCESSORIES

The following components are compatible but not included with the Cure Medical ESU-110 Electrosurgical Generator:

- Conmed Electrosurgical pencil with Rocker Switch and 10' cable (128115A)
- Conmed Thermogard Single Dispersive Electrode with 10' cable (51-7810)
- Valleylab Handswitching ESU pencil with Rocker Switch and 10' cable (E2350H)
- Valleylab Standard Polyhesive II Patient Return Electrode (E7506)

Be sure to follow all manufacturer's instructions, cautions, warnings, and guidelines for use for any accessories used with the ESU-110 Electrosurgical Generator.

CONTRAINDICATIONS

The user should be familiar with the use of electrical surgical instruments and should take precautions accordingly.

WARNINGS AND PRECAUTIONS:

- **Alternate Site Burns Hazard:** In some circumstances, potential exists for alternate site burns at points of skin contact (e.g., between the arm and the side of the body). This occurs when electrosurgical current seeks a path to the return pad that includes the skin-to-skin contact point. Current passing through small skin-to-skin contact points is concentrated and may cause burns. This is true for grounded, ground referenced, and isolated output generators. To reduce the potential for alternate site burns, do one or more of the following:

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Place 5 to 8cm (2 to 3in.) of dry gauze between contact points to ensure that the contact does not occur.

Position the return pad to provide a direct current route between the surgical site and the pad which avoids skin-to-skin contact areas.

It is important to place the return pad according to the manufacturer's instructions. Potential for alternate site burns increases if the pad is compromised.

- **Danger of Fire/Explosion Hazard:** Do not use the ESU-110 Electrosurgical Generator in the presence of flammable anesthetics.
 - **Electric Shock Hazard:** Always turn the generator off prior to cleaning.
 - **Electrical Output Hazard:** This equipment is for use only by trained, licensed physicians.
 - **Fire/Explosion Hazard:** The following substances may contribute to increased fire and explosion hazards in the operating room:
 - Flammable substances (i.e. alcohol-based skin prepping agents and tinctures).
 - Naturally occurring flammable gases which may accumulate in body cavities such as the bowel.
 - Oxygen enriched atmospheres.
 - Oxidizing agents (i.e. nitrous oxide [N₂O] atmospheres)
- The sparking and heating associated with electrosurgery can provide an ignition source. Observe fire precautions at all times. When using electrosurgery in the same room with any of these substances or gases, prevent their accumulation or pooling under surgical drapes, or within the area where electrosurgery is performed.
- **Implantable Cardioverter Defibrillator Hazard:** If the patient has an implantable Cardioverter Defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgery procedure. Electrosurgery may cause multiple activations of ICDs.
 - **Lithium-Ion Battery Hazards:** The ESU-110 Electrosurgical Generator is used with a separate lithium-ion battery pack. Please observe the following practices:
 - Do not place the ESU-110 on or near fires, heaters, other high temperature locations, or apply heat directly to the unit or battery pack.
 - Do not pierce the unit or battery pack with any sharp objects, strike the unit or battery pack with a hammer, tools, or heavy objects, step on the unit or battery pack, or otherwise damage the unit or battery pack.
 - Do not subject the ESU-110 to strong impacts or shocks.
 - Do not expose the unit or battery to water or any other types of liquid or allow the battery to get wet.
 - Do not leave the unit or battery in direct sunlight, and avoid storing in cars in extreme hot weather. Doing so may cause the battery to generate heat, rupture, or ignite. Using the battery in this manner may result in a loss of performance and short battery life.

- **Pacemaker Hazard:** Use electrosurgery with caution in the presence of internal or external pacemakers. Interference produced by the use of electrosurgical devices can cause devices such as a pacemaker to enter an asynchronous mode or can block the pacemaker entirely. Consult the pacemaker manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned for patients with cardiac pacemakers.
- **Trained Only:** Do not use electrosurgical equipment unless properly trained to use it for the specific indicated uses. Use without proper training may result in serious, unintended patient injury.
- **Wrapping Hazard:** Do not wrap the accessory cords around metal objects. This may induce currents that could lead to shocks, fire, or injury to the patient or surgical team.
- **Burn Caution:** At no time should the user touch the active electrode. A burn could result.
- **Grounded Metal Caution:** To avoid the possibility of an electrosurgical burn to either the patient or the physicians, do not allow the patient to come in contact with a grounded metal object during activation.
- **Improper Connection Caution:** Examine all accessories and connections to the electrosurgical generator before use. Ensure that the accessories function as intended. Improper connection may result in arcs, sparks, accessory malfunctions, or unintended surgical effects.
- **Instability Caution:** Do not stack equipment on top of the generator or place the generator on top of other electrical equipment. These configurations may not be stable and may result in inadequate cooling.
- **Interference Caution:** Provide as much distance as possible between the electrosurgical generator and other electronic equipment (such as monitors). An activated electrosurgical generator may cause interference with other electronic or electromagnetic equipment.
- **Jewelry Caution:** Remove any loose-fitting jewelry from the patient before activation.
- **Needle Caution:** Do not use needles as monitoring electrodes during electrosurgical procedures. Inadvertent electrosurgical burns may result.
- **Physiological Monitoring Caution:** When high frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, place any monitoring electrodes as far as possible from the surgical electrodes. Monitoring systems incorporating high frequency current limiting devices are recommended.

SERVICE AND MAINTENANCE

There are no serviceable parts. If any failure has developed, contact Cure Medical to purchase a replacement part or system. No modifications of this equipment are allowed.

The ESU-110 enclosure, charging base, and power supply are reusable and should be routinely cleaned with a clean damp cloth or with an anti-microbial wipe.

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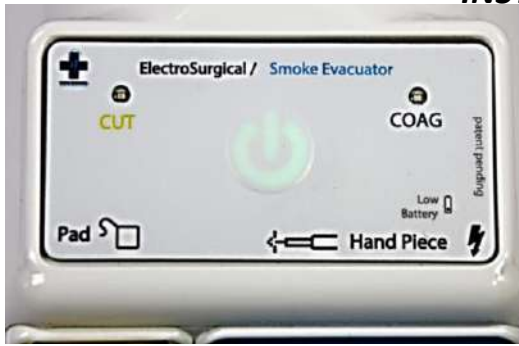


Figure 2: Activation button and front panel detail.

Connecting Accessories:

Plug a compatible hand switch into the connector with the electro-surgical hand switch symbol. The plug can only be properly inserted in a single orientation.

Plug a compatible neutral electrode into the connector with the return pad symbol.

Ensure that a battery has been firmly inserted into the base of the unit. The batteries are charged in the separate battery charger.

NOTE: If present, remove the foam block that was inserted during shipping.

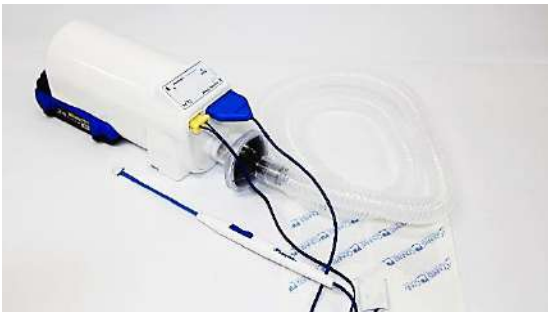


Figure 3: ESU-110 with compatible accessories connected.

Activation (ON/OFF) Button: Press once to turn unit on. The activation button will illuminate green to indicate that the ESU-110 is in standby mode and ready to be activated.

NOTE: There is no need to continuously depress the activation button.

Cut Light: When the yellow button of the hand switch is pressed, a yellow light indicates that the device is outputting power to the active electrode for cut procedures. The device will also emit a distinct “cut” tone.

Coag Light: When the blue button of the hand switch is pressed, a blue light indicates that the device is outputting power to the active electrode for coag procedures. The device will also emit a distinct “coag” tone.

Low Battery Indicator: When the battery reaches its low threshold, this indicator will illuminate. Replace the battery with a fully charged battery after completing the current procedure.

REQUIRED EQUIPMENT

Before using the ESU-110, the following equipment should be accessible:

- Battery Pre-charged, full charge is recommended but not required.
- Compatible ESU pencil
- Compatible ESU Neutral Electrode
- Compatible suction tubing

HANDLING AND PREPARATION

Inspection Before Each Use

Before each use, perform the following:


General Inspection.

- Inspect for visible damage to the ESU-110 Electro-surgical Generator, battery and all connections.
- Make sure that no parts are missing or loose.
- Make sure that connecting elements between instruments function properly.
- Verify that the ESU-110 Electro-surgical Generator and accessories are in good working order by visually inspecting for signs of deterioration, including wear, damage, or abrasion.
- If the battery is not already installed, insert a charged battery into the handle of the unit. The battery can only be inserted in a single orientation. Push the battery into place until the locking tabs snap; these tabs lock the battery into the bottom of the unit..
- If there are any signs of damage to the ESU-110, any connectors, or deterioration, discontinue use and contact Cure Medical.

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- Read all instructions before use.

Activating the Unit

Step 1: Turn on the generator by pressing the ON/OFF  switch located on the front panel and verify that the green ‘active’ LED under the switch illuminates.

Activate the unit by pressing either the CUT (yellow and closest to electrode end of the pencil) or COAG (blue and closest to the operator end of the pencil) button on the hand switch, appropriate for the procedure being performed. When the unit is activated, the CUT or COAG audible tone sounds and the CUT (yellow) or COAG (blue) LED will illuminate. The smoke evacuation fan will also spin.

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Figure 4: ESU-110 with CUT active

Duty Cycle: The duty cycle for the ESU-110 Electrosurgical Generator is a ratio of 1:3 active to inactive time.

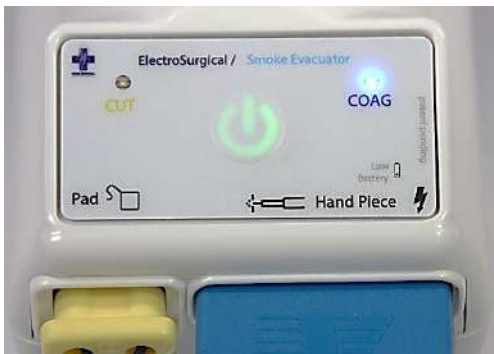



Figure 5: ESU-110 with COAG active

NOTE: When fully charged, the ESU-110 can run for 24 minutes of accumulated activation before the low battery indicator will illuminate. The battery should be removed and recharged when the low battery indicator is illuminated. Any in-progress procedure should be completed before removing and charging the battery. If necessary, a second, charged battery can be quickly swapped for the low charge battery. The battery packs have a charge indicator, which is activated by pressing the button on the battery pack.

Step 2: When the procedure is complete, turn off the generator by pressing the the ON/OFF  button located on the front panel. Verify that the green LED is no longer illuminated. This indicates that the ESU-110 is turned completely off and cannot be activated for output power.

NOTE: To conserve battery power, the ESU-110 will turn itself off after 10 minutes of inactivity.

Recharging the Batteries

- The batteries should only be recharged when the battery and charger are dry.
- Plug the charger into an A/C outlet with a voltage of 90-120VAC.
- Place the battery into the charging base. The 'charging' indicators on the charging base will activate as indicated on the base.

- A completely discharged battery should fully recharge in about six (6) hours.
- Remove the battery from the charger base once the battery has been fully charged.

NOTE: The battery will not be damaged by leaving the battery in the charger after the battery is fully charged making overnight charging convenient.

NOTE: The battery is removed by pinching the two buttons on each side at the back of the battery (see Figure 6) and pulling. The buttons are on each side of the charge indication panel.

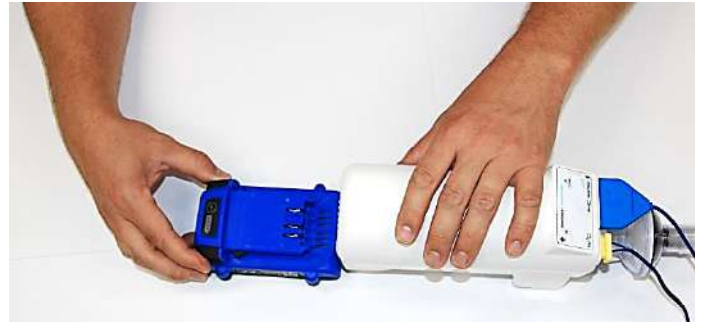


Figure 6: Battery removal.

PATIENT PREPARATIONS

The patient should be prepared according to clinic protocol for the appropriate type of procedure.

CLEANING AND INSPECTION

The ESU-110 Electrosurgical Generator must be cleaned after every use per the following procedure:

Enclosure Cleaning Procedure:

- Ensure all accessories are completely disconnected from the ESU-110.
- Thoroughly wipe all surfaces of the ESU-110 with a mild cleaning solution (i.e. 70% isopropyl alcohol) or disinfectant and damp cloth. The cleaning solution or disinfectant should not be applied directly to the unit. Pour/spray the cleaning solution or disinfectant onto a cloth and ensure that the cloth is evenly damp and not wet prior to cleaning the unit.
- Follow any procedures required by your institution or use a ventilated infection control procedure.
- Do not allow fluids to enter the device. Do not attempt to sterilize the device.
- The listed compatible accessories are sterile and disposable. Do not reuse accessories. Do not attempt to reprocess, via disinfection or sterilization, accessories.

CAUTION: Only use a soft brush or cloth to manually remove impurities; never use abrasive materials as they may damage the enclosure.

TROUBLESHOOTING

The ESU-110 Electrosurgical Generator has no user-adjustable controls or diagnostic tests. If the unit fails to respond as

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expected, try the following steps before contacting Cure Medical.

- 1- If the ESU-110 Electrosurgical Generator will not turn on, please verify that the battery is charged by pressing the charge indicator button on the battery pack.
Replace the battery if necessary.

DEVICE DISPOSAL:

When ESU-110 Electrosurgical Generator, including the battery, is no longer are functional, or show signs of wear and damage, they should be disposed of in the same manner as electrical waste.

To order additional devices/ accessories, or replacement accessories go to www.curemedicalglobal.com.

WARRANTY AND RETURN POLICY

Cure Medical warrants each product manufactured by it to be free from defects in material and workmanship under normal use and service for the period(s) set forth below.

Cure Medical's obligation under this warranty is limited to the repair or replacement, as its sole option, of any product, or part thereof, which has been returned to it or its Distributor within the applicable time period shown below, after delivery of the product to the original purchaser, and which examination discloses, to Cure Medical's satisfaction, that the product is indeed, defective.

This warranty does not apply to any product, or part thereof, which has been repaired or altered outside Cure Medical's factory in a way so as, in Cure Medical's judgment, to affect its stability or reliability, or which has been subjected to misuse, neglect, or accident.

The warranty periods for Cure Medical products are as follows:

- The ESU-110 Electrosurgical Generator: :
Two (2) years from date of shipment

This warranty is in lieu of all other warranties, express or implied, including without limitation, the warranties of merchantability and fitness for a particular purpose, and of all other obligations or liabilities on the part of Cure Medical.

Cure Medical neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of Cure Medical's products.

Notwithstanding any other provision herein or in any other document or communication, Cure Medical's liability with respect to this agreement and products sold hereunder shall be limited to the aggregate purchase price for the goods sold by Cure Medical to the customer.

Cure Medical disclaims any liability hereunder or elsewhere in connection with the sale of this product, for indirect or consequential damages.

This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of Utah, United States of America (USA). The sole forum for resolving disputes arising under or relating in any way to this warranty is the 3rd District Court of Utah, USA.

Cure Medical, its dealers, and representatives reserve the right to make changes in equipment built and/or sold by them at any time without incurring any obligation to make the same or similar changes on equipment previously built and/or sold by them.

TECHNICAL ASSISTANCE:

For Technical Assistance, please call Cure Medical Technical Support at the following telephone number: (1)801-256-6576, email to sales@Curemedicalglobal.com, or visit us at www.curemedicalglobal.com

TECHNICAL SPECIFICATIONS

All specifications are nominal and subject to change without notice. A specification referred to as "typical" is within $\pm 20\%$ of a stated value at room temperature (25°C/77°F) and utilizing a sufficiently charged battery pack.

TABLE 1: Device Parameters	
Power Parameters	
Power Supply:	24 VDC
Battery Pack:	Rechargeable Lithium-Ion 12-cell 2AH Battery Pack BMS overcharge protection
Battery Charger:	90 – 120 VAC, 1.0A, 47-63Hz Input 24VDC, 1.25 amp, Output Charge Time: Six (6) hours
Full-Charge Activation:	24 minutes until low-battery indicator illuminates
Power Output:	49 Watts @ 300Ω load
Treatment (Duty) Cycle	10 seconds active followed by 30 seconds inactive. The active and inactive duration ratio must always be 1:3 active:inactive.
Dimensions and Weight	
Width:	3.2 inches (8 cm)
Height:	4.3 inches (11 cm)
Depth:	9.6 inches (24.5 cm)
Weight:	22 oz (630 g) (without battery); 15.9 oz (450 g) (battery)
Operating Conditions	
Ambient Temperature:	10° to 40°C
Relative Humidity:	0% to 80% non-condensing
Transport and Storage	
Ambient Temperature:	-30° to 85°C
Relative Humidity:	0% to 90% non-condensing
General Info	
Type BF Applied Parts	
IP21 Rating	Solid particle protection: Level 2 (>12.5mm) Liquid ingress protection: Level 1 (dripping water)
Activation Tone	

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Volume:	65dB
Frequency (Cut):	700Hz

Frequency (Coag):	1200Hz
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Electromagnetic Compatibility Guidance (in accordance with EN/IEC 60601-1-2:2007)

TABLE 2: Manufacturer's Declaration – Electromagnetic Emissions		
The ESU-110 Electrosurgical Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the ESU-110 Electrosurgical Generator should ensure that it is used in such an environment.		
Emissions Test	Compliance	EMC Environment Compliance
RF Emission CISPR 11	Group 1	The ESU-110 uses RF energy only for its internal function when in standby mode. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment when in standby mode. The ESU-110 emits non-ionizing high frequency radiation when activated. This radiation is likely to cause interference in nearby electronic equipment that is not specifically designed for use with electrosurgical generators. The ESU-110 is suitable for use in professional healthcare environments.
RF Emission CISPR 11	Class A	
Harmonic Emissions -IEC 61000-3-2	Not Applicable	
Voltage Fluctuation & Flicker – IEC 61000-3-3	Not Applicable	

TABLE 3: Manufacturer's Declaration – Electromagnetic Immunity			
The ESU-110 Electrosurgical Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the TC should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
IEC 61000-4-2 - Electrostatic discharge (ESD)	±6kV contact ±8kV air	±6kV contact ±8kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with a synthetic material, the relative humidity should be at least 30%.
IEC 61000-4-4 - Electrical fast transient/burst	Not Applicable	Not Applicable	Not applicable
IEC 61000-4-5 - Surge	Not Applicable	Not Applicable	Not applicable
IEC 61000-4-11 - Voltage dips, short interruptions and voltage variations on power supply input lines	Not Applicable	Not Applicable	Not applicable
Power frequency (50/60Hz) magnetic field	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

TABLE 4: Manufacturer's Declaration – Electromagnetic Immunity			
The ESU-110 Electrosurgical Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the ESU-110 Electrosurgical Generator should assure that it is used in such an environment.			
IMMUNITY Test	IEC 60601 test level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	Not applicable	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the ESU-110 Electrosurgical Generator, including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Recommended separation distance For 80 MHz to 800 MHz $d = 1.17\sqrt{P}$ For 800 MHz to 2.3 GHz $d = 2.33\sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF			

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transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TC is used exceeds the applicable RF compliance level above, the TC should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TC.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

TABLE 5: Recommended separation distanced between portable and mobile RF communications equipment and the TC

The ESU-110 Electrosurgical Generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ESU-110 Electrosurgical Generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ESU-110 Electrosurgical Generator as recommended below, according to the maximum output power of the communications equipment











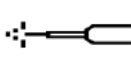


Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	N/A	0.117m	0.233m
0.1	N/A	0.37m	0.74m
1	N/A	1.17m	2.33m
10	N/A	3.70m	7.37m
100	N/A	11.7m	23.3m

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.

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Symbol	English
	Device Serial Number
	Serial Number
	Manufacturer Information
	Attention, See Instructions for Use
	Type BF Defibrillator-Proof Applied Parts
	CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician.
	Solid particle protection: Level 2 (>12.5mm) Liquid ingress protection: Level 1 (dripping water)
	Non-ionizing Radiation
	Warning: High Voltage. Do not open enclosure.
	HF Isolated Patient Circuit: Patient connections are isolated from earth
	Electrosurgical Hand Switch
	Neutral Electrode Return Pad
	Lithium-Ion Battery Connection

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The portable ESU-110 Electrosurgical Generator products are protected by U.S. patents and patents pending. Please direct any inquiries to Cure Medical, LLC.



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