LIGER MEDICAL ECU-110 ELECTROSURGICAL GENERATOR

INSTRUCTIONS FOR USE

EQUIPMENT COVERED BY THESE INSTRUCTIONS:

Liger Medical ECU-110 Electrosurgical Generator

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℞: These instructions and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure indicated for use. These instructions are intended as a guide for using the Liger Medical ECU-110 Electrosurgical Generator only.

Made in the USA

Printed in the USA

Revision B.

CONVENTIONS USED IN THESE INSTRUCTIONS:

WARNING:
Indicates a potentially hazardous situation. Ignoring warnings could result in death or serious injury.

CAUTION:
Indicates a potentially moderately hazardous situation. Ignoring cautions could results in injury.

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WARNINGS

CAUTION:

Read all warnings and cautions provided in these instructions before using the generator.

Read all warnings, cautions, and instructions for the approved electrosurgical accessories before using.

WARNINGS:

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:

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 Liger Medical ECU-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 [N_2O] 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 activation of ICDs.

Lithium-Ion Battery Hazards: The Liger Medical ECU-110 Electrosurgical Generator contains a lithium-ion battery pack. Please observe the following practices:

- Do not place the Liger Medical ECU-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 Liger Medical ECU-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 by physicians 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.

CAUTIONS

Burn Caution: At no time should you 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 malfunction, 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.

COMPONENTS, OPERATION, AND SAFETY

Components and Accessories

The following components are included with the Liger Medical ECU-110 Electrosurgical Generator:

- Liger ECU-110 Electrosurgical Generator
- Instructions for Use
- Wall Wart for charging the unit

The following accessories are compatible and recommended, but not included:

Conmed Accessories:

- Conmed Electrosurgical pencil with Rocker Switch and 10’ cable (128115A)
- Conmed Thermogard Single Dispersive Electrode with 10’ cable (51-7810)

Valleylab Accessories:

- 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 Liger Medical ECU-110.

Indications for Use

The Liger Medical ECU 110 Electrosurgical Unit is intended deliver high frequency electrical current for surgical procedures that can be performed with monopolar cutting of tissue. The primary intended use of the Liger Medical ECU-110 Electrosurgical Unit is adult male circumcision for which the unit has been specifically designed and tuned.

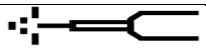
Contraindications

Electrosurgery should only be performed by a physician with proper training in the electrosurgical procedure to be performed.

INDICATORS AND CONNECTORS

Front Panel Labels and Description:

Indicators	
	Defibrillator-proof type BF equipment
	RF Isolated: Patient connections are isolated from earth
	Read instructions prior to use
	Caution: High Voltage

Connectors	
	Electrosurgical Hand Switch
	Neutral Electrode Return Pad
	Battery Charger

Rear Panel Labels and Description:

Back Panel Symbols	
	Non-Ionizing Radiation
	Lithium-Ion Battery Enclosed
	Danger: Explosion Risk If Used With Flammable Anesthetics
	Risk of Electric Shock: Do Not Open the Unit
	See Instructions for Use Prior to Operating Unit

INSTRUCTIONS FOR USE

Prior to Use

Inspecting the Generator and Accessories:

Before each use of the Liger Medical ECU-110 Electrosurgical Generator, verify that the unit and all accessories are in good working order. Inspect for visible damage to the generator and all its connections. Verify that the appropriate accessories and adapters are present. Inspect all cords and connectors for signs of wear, damage, and abrasion.

Connecting Accessories:

Plug the hand switch into the connector with the electrosurgical hand switch symbol. The plug can only be properly inserted in one direction.

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

Ensure the battery charging cable is not connected. The unit will not activate if the battery charger is connected.

Activating the Unit

Turn on the generator by pressing the ON side of the ON/OFF switch located on the front panel and verify that the green 'active' LED illuminates.

Activate the unit by pressing the activation button on the hand switch. When the unit is activated, the 'active' audible tone sounds and the 'active' LED (amber) will illuminate.

The duty cycle for the Liger Medical ECU-110 Electrosurgical Generator is 10 seconds of active followed by 20 seconds of inactive use. A ratio of 1:2 active to inactive time must be maintained to avoid damaging the generator.

NOTE: When fully charged, the Liger Medical ECU-110 Electrosurgical Generator can run for 24 minutes of accumulated activation before the low battery indicator will illuminate. The unit should be recharged when the low battery indicator is illuminated.

When the procedure is complete, turn off the generator by pressing the OFF side of the ON/OFF switch located on the front panel and verify that the green 'active' LED is no longer illuminated.

Ensure that the hand switch and return pad are unplugged from the unit.

Recharging the Unit

- The unit should only be recharged when both the unit and charger are dry.
- Ensure the unit is turned OFF. The unit will not charge if in the ON position.
- Plug the wall wart charger into an A/C plug and plug the connector end into the battery charger located on the front panel.
- The white 'charging' LED should illuminate. There may be a very slight delay before the LED illuminates.
- A completely discharged battery should fully recharge in less than six (6) hours.
- When the battery is fully charged, the white 'charging' LED will blink for 15 minutes.
- After 15 minutes, the 'charging' LED will no longer be illuminated.
- Disconnect the charger once the battery has been fully charged.
- Neither the Liger Medical ECU-110 nor the battery will be damaged by leaving the charger connected after the battery is fully charged. The ECU-110 is designed to be unable to overcharge thus making overnight charging convenient.

MAINTENANCE

Cleaning and Inspection

Liger Medical recommends that the ECU-110 Electrosurgical Generator be cleaned after every use using the following procedure:

- Turn generator to OFF position
- Ensure battery charger is not connected
- Ensure hand switch and return pad are disconnected
- Thoroughly wipe all surfaces of the generator with a mild cleaning solution 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 prior to cleaning the unit.
- Follow any procedures approved by your institution or use a ventilated infection control procedure. Do not allow fluids to enter the chassis. Do not sterilize the generator.
- The standard accessories compatible with the ECU-110 are disposable. Do not attempt to re-sterilize or re-use the standard accessories compatible with the ECU-110.

Liger Medical recommends that the ECU-110 Electrosurgical Generator be periodically inspected every six months for visible damage. The following concerns should be immediately addressed:

- Obvious damage to the unit
- Damage to any connector
- Accumulation of lint or debris on or around the unit

In each case, discontinue using the unit. If the unit is damaged externally or has a damaged connector, please contact Liger Medical for service. If the unit has accumulated dust or debris follow the cleaning procedure to remove the debris.

TROUBLESHOOTING

The Liger Medical ECU-110 Electrosurgical Generator has no user-adjustable controls or diagnostic tests. If the unit fails to respond as expected, please contact Liger Medical for service.

If the Liger Medical ECU-110 Electrosurgical Generator will not turn on, please verify that the battery charger is not connected. The unit is designed to not operate while recharging or with the charger connected. Always disconnect the charger before attempting to activate the unit.

WARRANTY AND RETURN POLICY

Warranty

Liger 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.

Liger Medical's obligation under this warranty is limited to the repair or replacement, at 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 Liger 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 Liger Medical's factory in a way so as, in Liger Medical's judgment, to affect its stability or reliability, or which has been subjected to misuse, neglect, or accident.

The warranty periods for Liger Medical products are as follows:

- ECU-110: Two 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 Liger Medical.

Liger 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 Liger Medical's products.

Notwithstanding any other provision herein or in any other document or communication, Liger 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 Liger Medical to the customer.

Liger 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.

Liger 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.

Returning Unit for Service

- Obtain a Returned Merchandize Authorization (RMA) number from your Liger Medical representative
- Have the following information ready when contacting your Liger Medical representative:
    - Hospital/clinic name/customer number
    - Telephone number
    - Department, address, city, state, and postal code
    - Model number
    - Serial number
    - Description of the problem
- Clean the generator (see instructions for cleaning)
- Ship the generator
    - Attach a tag to the generator that includes the Returned Merchandize Authorization (RMA) number and the information (hospital, phone number, etc.) listed above. Also include the name of the Liger Medical representative which you contacted along with the date and time of contact.
    - Be sure the generator is completely dry before packing it for shipment. Package the unit in its original shipping container, if possible.
    - Ship the generator to the address given to you by your Liger Medical representative.

TECHNICAL SPECIFICATIONS AND PERFORMANCE CHARACTERISTICS

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

Power Parameters:

Power Supply:	21VDC
Battery Pack:	Rechargeable Lithium-Ion 5-cell 2600mAH Battery Pack BMS overcharge protection Inaccessible to user: Factory replacement only
Battery Charger:	230VAC, 0.60A, 50-60Hz Input 24VDC, 0.75A, Output Charge Time: Six (6) hours
Full-Charge Activation:	24 minutes until low-battery indicator illuminates
Power Output:	45 Watts @ 300 Ω load
Duty Cycle:	10 seconds active followed by 20 seconds inactive. If active time is shorter, the inactive time can be reduced proportionately as long as the ratio is always 1:2 active: inactive.

Dimensions and Weight:

Width:	26.42cm
Height:	9.14cm
Depth:	17cm
Weight:	1.36kg

Operating Conditions:

Ambient Temperature:	10° to 40°C
Relative Humidity:	0% to 90% non-condensing

Transport and Storage:

Ambient Temperature:	-30° to 85°C
Relative Humidity:	0% to 80% non-condensing

Activation Tone:	65dB
Frequency:	2kHz

080-0014: ECU-110 Instructions for Use/User Manual
Release: 07/26/14
Revision: B

Revision History

Revision	Section	ECN	Description of Change	Date	Revised By
A	All	0002	Initial Release	07/17/12	JF
B	All	0005	Formatted to meet FDA requirements	07/09/13	JF
C	All	0006	Removed waveform graph and waveform results for test units	07/24/14	JF
D	All	0007	Revised change block format	07/26/14	JF

Approval:

Approval _____ Date _____

Approval _____ Date _____

Approval _____ Date _____