English

thermocoagulator®

Instructions For Use

Made in the U.S.A www.ligermedical.com

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

For professional use only. Read all directions, warning, and cautions before use.

LIGER MEDICAL
Innovation for Better Women's Health

050-0014 TC Thermocoagulator Instructions for Use Rev B 04/2024 CN0597

USER QUALIFICATION

The Liger Medical handheld Thermocoagulator (TC) must be used by a physician or medical personnel under the supervision of a physician. The user must have received sufficient training in clinical procedures. Liger Medical does not discuss or provide explanation of clinical procedures.

WARNINGS AND PRECAUTIONS

- Proper surgical procedures and techniques are the responsibility of the medical professional. Each practitioner must determine the appropriate use of this device for each patient based on medical training, experience, the type of procedure employed, and the benefits and risks associated with device use.
- Dispose of TC handle and probes according to national and local regulations and guidelines for electrical medical equipment when it has surpassed its use-life.
- Temperatures at the probe's distal tip may be hot enough to damage tissue.
- Do not use excessive force or in a manner not consistent with normal instrumentation use.
- Although the TC complies with IEC 60601-1-2:2014 standard for electromagnetic compliance (EMC) for the home healthcare environment, the device may emit electromagnetic radiation that may affect the performance of other electrically powered equipment, or the performance of the device may be affected by electromagnetic radiation from other electrically powered equipment in the vicinity.
- The TC batteries should only be connected to the provided battery charger.
- In some circumstances, potential exists for alternate site burns at points of skin contact (e.g. between the legs or on the external labia and inner vagina).
- To avoid burns and prevent damage to the device, remove the probe from the handle prior to cleaning.
- The TC device and accessories have not been tested for magnetic resonance imaging (MRI) safety. Avoid use near MRI equipment.
- The Liger Medical TC device contains a lithium-ion battery pack. Please observe the following practices:
  - Do not place the device on or near fires, heaters, other high temperature locations, or apply heat directly to the device or battery pack.
  - Do not pierce the device or battery pack with any sharp objects, strike the device or battery pack with a hammer, tools, or heavy objects, step on the device or battery pack, or otherwise damage the device or battery pack.
  - Do not subject the device to strong impacts or shocks.
  - Do not expose the device or battery to water or any other types of liquid, or allow the battery to get wet.
  - Do not leave the device or battery in direct sunlight, and avoid storing in vehicles 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.

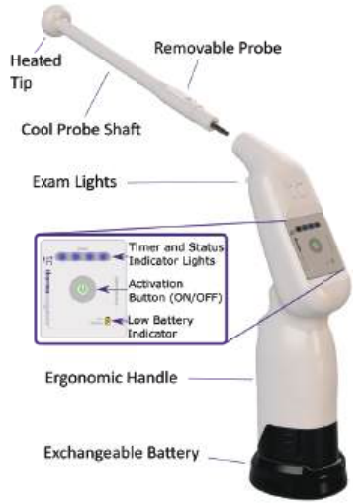

Figure 1: The Thermocoagulator Device Design

DESCRIPTION

The TC Device is used to treat human tissue lesions. It is a type B thermal coagulator which is a compact, portable, battery powered device which can be used in hospital and non-hospital professional healthcare locations.

The TC is reusable and provided non-sterile. It is designed to perform low-power destruction of human tissue (cervical or other) with high temperatures.

The TC probe tip contains a heating element which is heated to approximately 100°C (212°F) for the destruction of human tissue. The probe tip should only be applied to tissue which is intended to be ablated and care should be taken to avoid touching any other tissue with the heated probe tip.

The TC probe shaft is not intended to deliver heat. The probe shaft has a maximum temperature of 43°C (109°F).

INDICATIONS

The Thermocoagulator is intended for the destruction of human tissue with high temperatures by tissue contact with an electrically heated probe.

STANDARD UNIT CONFIGURATION

The following items are included with the Liger Medical Thermocoagulator Unit:

- Liger's Thermocoagulator Device
- Four Probes: 19mm flat, 19mm nipple, or 16mm flat (preference *specified at time of order*)
- Two Removable Lithium Ion Battery Packs with protective battery boots.
- Instructions for Use
- Battery Charger
- Hard Shell Carrying Case

No other accessories are compatible with the TC device.

Figure 2: Standard Unit Configuration

CONTRAINDICATIONS

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

SERVICE AND MAINTENANCE

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

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

REQUIRED EQUIPMENT

Before using the TC, the following equipment should be accessible:

- Battery: Pre-charged. A full charge is recommended but not required.
- TC Device Probes (Sterilized or Disinfected to a High Level)

GENERAL INSPECTION

Before each use, perform the following:

- Inspect for visible damage to the TC handle, battery and probes and all its connections.
- Make sure that no parts are missing or loose.
- Make sure that all connecting elements between instruments function properly.
- Insert a charged battery into the handle of the device. The battery can only be inserted in a single orientation. Push the battery into place until the locking tabs snap.
- Verify that the TC and accessories are in good working order by following the "Using the Device" steps outlined in the following section.

NOTE: *The battery is removed by compressing the two locking tabs on the sides near the battery base releasing the lock and, while firmly holding the device handle, pulling the battery down and out of the handle.*

USING THE DEVICE

Exam Mode Activation

With or without a probe in place, press and hold the activation button for approximately 3 seconds until the front exam lights turn on. The device will automatically shut off after one minute.

NOTE: *If a probe is not in place and the button is not pressed long enough to enter the exam mode, all four blue timer lights will flash and the device will shut off, indicating no probe is inserted into the device.*

Treatment Mode Activation

WARNING: Do not touch the active (heated) probe tip, as it may potentially cause burned tissue damage.

Step 1: Insert the desired treatment probe (19mm flat, 19mm nipple, or 16mm flat) connector into the mating connector at the front of the device. Ensure that the probe is tightly inserted.

Figure 3: Probe Insertion

Step 2: Turn ON the TC by briefly pressing the activation button once, and verify that the green activation light is on. The white illumination lights on the front of the device will turn on, and one blue light will flash showing that the probe is ready for placement (tip not heated yet).

Step 3: TREATMENT

The treatment cycle for the Liger Medical TC is: 1) Short heat-up to setpoint, 2) Treatment at Setpoint, and 3) Cool down and removal.

1. Short heat-up to setpoint (8 – 9 seconds)

Heat-up of the probe occurs while probe is in contact with tissue.

Once the probe has been placed against the tissue needing treatment, press the activation button again to start the procedure. The blue timer lights will rapidly flash from left to right indicating that the probe tip is heating.

2. Treatment

When all four blue timer lights turn on at once and a single audible beep is heard, the treatment cycle has started. One at a time, from right to left, the blue timer lights will turn off, with an audible beep, after each 1/4 of the procedure has finished. When all four (4) blue timer lights are turned off, a long audible beep is heard, indicating that the device is no longer applying heat and has commenced its cool down cycle.

3. Cool down and removal

Once the cool down cycle is complete, the front white lights will turn off, and the probe may then be removed from the treatment area. If a second treatment is needed, repeat the above steps before removing the probe.

Recharging the Batteries

***NOTE:** The Liger Medical TC is capable of performing 30-60 procedures per battery charge. The battery in the device should be replaced with a charged battery soon after the low battery indicator is illuminated. If the indicator illuminates during a procedure, the procedure in process should be completed first. Once completed, replace the battery. If use is continued after the low battery light is illuminated, the device will turn off to protect the battery from being overly discharged. Over-discharge of the battery could reduce the life of the battery.*

» Plug the battery charger into an A/C outlet.

***NOTE:** The charger can be plugged into an A/C power outlet of 100 – 240 VAC, 50/60 Hz, with the proper country adapter. (see TABLE 1)*

» Without a battery connected, the charger light will turn green, indicating the charger is ready.
» Place the battery into the charging adapter, then plug the charger into the charging adapter. The charger light should turn red if the battery needs charging.
» A completely discharged battery should fully recharge in about three (3) hours.
» When the battery is fully charged, the charger light will turn green.
» Remove the battery from the charging adapter and disconnect the charger from the A/C outlet 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.*

The TC batteries are Lithium ion batteries and cannot be charged while connected to the TC handle. The TC handle cannot be connected to supply mains.

PATIENT PREPARATIONS

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

COMPLICATIONS

The following complications may occur during or following use of the device:

» Infection
» Pain
» Tissue burn

CLEANING AND INSPECTION

The TC handle and probes are reusable, and require specialized cleaning. The handle and probes should be cleaned per the following procedures prior to the first use, and immediately after each use thereafter.

Handle and Battery Cleaning Procedure

- Disassemble the TC into three separate parts (handle, battery and probe).
- Thoroughly wipe all surfaces of the TC handle and battery 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 device. Pour/spray the cleaning solution or disinfectant onto a cloth and ensure that the cloth is evenly damp prior to cleaning the device.
- Do not allow fluids to enter the device. Do not sterilize the TC handle or battery.

Probe Cleaning Procedure

The probes require specialized cleaning after each use to remove all visible soil. After cleaning, additional sterilization or high level disinfection (HLD) processing must be completed before each individual use of the probe, see below for directions.

- Allow the probe tip to cool to room temperature before cleaning.
- Clean instrument within 30 minutes of completing a treatment.
- **Place silicone cap on probe connector to prevent liquid ingress to the connector.**

CAUTION: Never use abrasive materials to clean as they may damage the probes.

Manual Cleaning

Equipment: Personal protective equipment, enzymatic detergent, brush/cloth, running water

- **Place silicone cap on probe connector.**
- Rinse probe shaft using cool running water to remove gross soil. A soft bristled brush or cloth may be used to aid in the removal of soil. Run water over shaft, crevices, hard to reach areas until water runs clear.
- Prepare an enzymatic detergent such as Enzol® per manufacturer's recommendations. Vertically immerse the distal end of the probe in the prepared detergent up to the silicone cap. Do not allow the proximal end covered by the silicon cap to be immersed. Allow probe to soak for a minimum of one (1) minute.
- Following the soak time, while still immersed, use a soft bristled brush or cloth to thoroughly clean the probe. Pay particular attention to hard-to-reach areas.
- Remove the probe from the detergent solution and rinse with running water.
- Visually inspect each probe for visible soil. If soil remains, repeat the cleaning procedure outlined above.

** Liger Medical validated the manual cleaning method using an independent accredited test laboratory and has the data on file. The validation was accomplished using Enzol®* as the enzymatic detergent. *Use of an automated cleaning system was not validated by Liger Medical and use of such a system is at the risk and discretion of the user.*

Drying

Ensure the probes are free from residual moisture prior to sterilization. If moisture remains on the probe, dry using a clean lint-free cloth and/or filtered pressurized air.

WARNING: Failure to properly clean and dry the probes may lead to inadequate sterilization or a reduction in instrument life.

PROBE HIGH-LEVEL DISINFECTION (HLD)

Liger Medical has validated the following HLD methods (Glutaraldehyde, Boiling/ Pasteurization, and Tristel DUO Foam) with an independent accredited test laboratory and has the data on file.

In global regions where the above mentioned methods are not available/feasible there may be other HLDs available (e.g. Cidex OPA, Perasafe, etc.) in these cases follow the manufacturer's recommendations for processing. These HLD methods have not been validated by Liger Medical. Individuals or hospitals not using the recommended method are advised to validate an alternative method using appropriate laboratory techniques.

A 20 minute soak in a 0.5% Strong Chlorine Solution is not an HLD method. It is a Mid-Level Disinfection (MLD) method. The Center for Disease Control (US CDC) has instructions for preparing a 0.5% Strong Chlorine Solution. This MLD method has not been validated by Liger Medical for use on the probes.

WARNING: Failure to properly disinfect the probes per these instruction may lead to inadequate disinfection and/or reduction in instrument use-life.

Glutaraldehyde

Materials (not provided):

- Cidex®, in a basin deep enough for vertically immersing the distal end of the probe.
- Tongs
- Pure water (boiled or Reverse Osmosis/ De-ionized (RO/DI) water) at room temperature.
- Sterile cloths for drying and storage.

Disinfection Procedure:

1. Ensure minimum effective concentration (MEC) of the HLD following manufacture's guidelines.
2. **Place silicone cap firmly on probe connector.**
3. Vertically immerse the distal end of the heating tip of the probe into a basin of glutaraldehyde approximately 5 to 6 inches (12 to 13 cm) deep. Keep probes upright. Do not immerse the connector end in the solution.
4. Allow the probe to soak in Glutaraldehyde for 20 minutes.
5. Thoroughly rinse the probe(s) in pure water by agitating then allowing them to set for a minimum of 5 minutes.
6. Repeat the previous rinsing step (5) two more times for a total of 3 rinses using a fresh batch of pure water each time.
7. Dry with sterile lint-free cloth.
8. Store the probe in a sterile lint-free cloth until next use.

Boiling (Pausterization)

Materials (not provided):

- Hot plate, gas burner, or other means of supplying heat to a container
- A water container that is over 6 inches (15 cm) in height and can withstand the heat of the boiling process.
- Tap water
- Sterile cloths for drying and storage.

Disinfection Procedure:

1. Fill container with water to 4.5" to 5" (11.5 cm to 13 cm) high
2. **Place silicone cap firmly on probe connector.**
3. Immerse ~4.5 inches (11.5 cm) of the device in room temperature tap water. Ensure that the distal heating tip is pointed downward and the connector end is pointed upward. DO NOT immerse the connector end.
4. Begin to heat the tap water with the probe immersed until the water is boiling.
5. Once the water has reached boiling, allow the probe to remain in the boiling water for five (5) minutes.
6. Remove the probe from the water and allow the probe to air dry
7. Store the probe in a sterile lint-free cloth until next use.

Tristel Duo ULT Foam

Materials (not provided):

- Tristel Duo ULT Foam
- Tristel Duo Wipe
- Sterile cloths for drying and storage.

Disinfection Procedure:

1. **Place silicone cap firmly on probe connector.**
2. Prime the Tristel Duo ULT by depressing the pump 2-4 times
3. Dispense two pumps of the Tristel Duo ULT foam onto the the Tristel Duo Wipe.
4. Allow the foam to dwell for 10 seconds on the wipe.
5. Apply the Tristel Duo ULT onto the distal 4.5 inches (11.5 cm) of the probes tip end.
6. Use the wipe to spread the foam evenly on the distal end of the probe. Ensure that the foam is spread through the joints crevices of the probe.
    1. Apply new additional foam with new wipes as necessary so that the surfaces of the probe remain visibly wet for the entire two (2) minute contact time. Contact time is the amount of time that the probe surfaces appear visibly wet with the foam.
    2. Do NOT continuously wipe during the two (2) minute contact time.
7. Allow the probe to air dry.
8. Store the probe in a sterile lint-free cloth until next use.

Probe Sterilization

- Sterilize probes in sterilization trays/pouch and containers. Disposable sterilization packages may also be used.
- Place silicone cap on probe connector.
- Insert probe(s) into sterilization tray/pouch following sterilizer manufacturer guidelines for appropriate tray/pouch and packaging instructions.
- Ensure that all surfaces will be exposed to the sterilizing agent. Ensure that probes do not contact each other if multiple probes are packaged together.
- Control the water purity dedicated to steam production to prevent damage to the instruments.
- Sterilization temperatures higher than 121°C (250°F) may damage the instruments.

To achieve a sterility assurance level of 10^{-6}, use of the following sterilization parameters is recommended:

Gravity Steam Sterilization Method*	Temperature	Time	Drying time**
Gravity Steam	121 °C (250 °F)	30 min	30 min

** Liger Medical validated this sterilization cycle using an independent accredited test laboratory and has the data on file. The validation was accomplished with probes individually double pouched and placed on edge in the sterilizer. Other sterilization cycles may be suitable; however, individuals or hospitals not using the recommended method are advised to validate an alternative method using appropriate laboratory techniques. Steam sterilization will significantly reduce the useful life of the probe.*

*** Liger Medical validated this dry time using probes individually double pouched, weighing approximately 17g (0.6 oz.). Longer dry times may be required for instrument trays exceeding this weight.*

INSPECTION

Liger Medical recommends that the TC handle and probes be regularly inspected every month for visible damage.

The following concerns should be immediately addressed:

- Signs of deterioration or obvious damage to the device
- Signs of damage to any connector
- Accumulation of lint or debris on or around the device

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

CAUTION: Life of the probes is determined by disinfection or sterilization cycles. Do NOT reuse probes for more than two hundred and fourty (240) disinfection cycles. Do NOT reuse probes for more than six (6) sterilization cycles by steam autoclave.

DEVICE DISPOSAL

When the TC handle, probe, battery, or power supply no longer are functional, or show signs of wear and damage, they should be disposed of in the same manner as electrical waste.

TECHNICAL ASSISTANCE

For Technical Assistance, please call Liger Medical Technical Support at the following telephone number: +1 801-256-6576, email to sales@ligermedical.com, or visit us at www.ligermedical.com

TROUBLESHOOOTING

The Liger Medical TC has no user-adjustable controls or diagnostic tests. If the device fails to respond as expected, refer to the following information before contacting Liger Medical.

Issue	Cause(s)	Solution(s)
The TC is completely unresponsive when pushing the activation (on/off) button.	» The battery is not inserted properly or is not fully charged. » (If a probe is inserted) Liquid has ingressed the connector, either of the probe or the device. » (If a probe is inserted) The probe has reached the end of its use life.	» Verify the battery is fully charged and inserted properly. » Try a different battery. » Try activating the device without a probe inserted. » Try a different probe » Allow the device/ probe to dry, then try the above suggestions again. If problem persists, contact Liger Medical.
With a probe inserted, the device powers on briefly, all blue lights flash three times, then device shuts off. OR After the treatment cycle has started, all blue lights flash three times, then device shuts off.	» The probe is not properly inserted » The probe has reached the end of its use life.	» Ensure the probe is securely connected and inserted properly. » Try a different probe. If a different probe works, try the initial probe again. If the same error occurs again, the initial probe has reached the end of its use life. Contact Liger Medical to purchase a replacement probe. If problem persists, contact Liger Medical.

WARRANTY AND RETURN POLICY

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, 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 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:

- TC Thermocoagulator: Two (2) years from date of shipment.
- Thermocoagulation Probes: 240 Disinfection Cycles or Two (2) years from date of shipment, whichever comes first.

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.

TECHNICAL SPECIFICATIONS

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.

TABLE 1: Device Parameters

Power Parameters	
Power Supply:	12.6 VDC
Battery Pack:	Rechargeable Lithium-Ion 3-cell 2AH Battery Pack BMS overcharge protection
Battery Charger:	100 – 240 VAC, 0.4A, 50-60Hz Input 12.6VDC, 1.0 amp, Output Charge Time: Three (3) hours
Power Output:	30 Watts
Transport and Storage	
Ambient Temperature:	-12° to 60°C
Relative Humidity:	0% to 90% non-condensing

Dimensions and Weight	
Width:	1.5 inches (4 cm)
Height:	8 inches (20 cm)
Depth:	2 inches (5 cm)
Weight:	11 oz (240 g)
Operating Conditions	
Ambient Temperature:	16° to 45°C
Relative Humidity:	0% to 80% non-condensing
General Info	
Type B Applied Parts	
IP21 Rating	Solid particle protection: Level 2 (>12.5mm) Liquid ingress protection: Level 1 (dripping water)

TABLE 2: Manufacturer’s Declaration – Electromagnetic Emissions

The TC 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.

Emissions Test	Compliance	EMC Environment Compliance
RF Emission CISPR 11	Group 1	The TC uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF Emission CISPR 11	Group 1	The TC uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF Emission CISPR 11	Class B	The TC is suitable for use in all establishments, including domestic establishments 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	Not Applicable	
Voltage Fluctuation & Flicker – IEC 61000-3-3	Not Applicable	

TABLE 3: Manufacturer's Declaration – Electromagnetic Immunity			
The TC 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)	±8kV contact ±2,±4,±8,±15kV air	±8kV contact ±2,±4,±8,±15kV 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 61000-4-8 – Power frequency (50/60Hz) magenetic field	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

NOTE: *U_T is the a.c. mains voltage prior to application of the test level.*

TABLE 4: Manufacturer's Declaration – Electromagnetic Immunity			
The TC is intended for use in the electromagnetic environment specified below. The customer or the user of the TC 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 TC 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 $d = 2.33\sqrt{P}$
Radiated RF EM Fields IEC 61000-4-3	3 V/m 80 MHz to 2.7GHz 80% AM at 1kHz	3 V/m	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 surveya, should be less than the compliance level in each frequency rangeb. Interference may occur in the vicinity of equipment marked with the symbol IEC 60417 – 5140.

TABLE 5: Enclosure Port Immunity to RF wireless communication equipment						
Test Frequency (MHz)	***Band (MHz)***	***Service***	***Modulation***	***Maximum Power (W)***	***Distance (m)***	***Immunity Test Level (V/m)***
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900,TETRA 800,iDEN820,CDMA 850,LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM1800,CDMA 1900,GSM1900,DECT,LTE Band 1,3,4,25, UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n. RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

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

The TC is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TC can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TC 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 150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz 80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz 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.*

Symbol	Description	Symbol	Description
	Attention, See Instructions for Use		Temperature Limitation: -5°C to 45°C
SN	Serial Number		Humidity Limitation: 0% to 80%
REF	Catalogue Number: HTU-110 Thermocoagulator		Manufacturer & date of manufacturing
	CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician.		Type B Applied Parts
EC REP	Authorized Representative in the European Community	IP21	Solid particle protection: Level 2 (>12.5mm) Liquid ingress protection: Level 1 (dripping water)
	Direct Current: 12 Volts DC, 49 Watt Max		MRI Unsafe: Keep away from magnetic resonance imaging (MRI) equipment

The handheld HTU-110 Thermocoagulator device products are protected by U.S. Patent No. 10849675B2 and other pending patents. Please direct any inquires to Liger Medical.

To order additional devices, probes, or accessories go to www.ligermedical.com email us at sales@ligermedical.com or call us at +1 801-256-6576

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3300 North Running Creek Way
Building G, Basement Suite G20
Lehi, UT, 84043, USA

www.ligermedical.com

EC REP

MEDNET
EC-REP GmbH
Borkstrasse 10,
48163 Münster,
Germany

CE
2797