ENTIRE MEDICAL IRE SYSTEM

USER MANUAL

Generator Model Number - ENTIRE001

This user's guide will familiarize you with the controls and output functions available from your ENTire Medical IRE System and instruct you on the proper use of the equipment. Review this manual thoroughly before installation and use of the IRE System. Please also read, understand, and follow all cautions and warnings in this manual and those included in the Instructions for Use included with the IRE System handpieces. Additional information, training and product servicing are available from ENTire Medical. The information contained in this manual is based upon the most current information available at the time of printing. ENTire Medical reserves the right to update the equipment and its operation without notice. The entire content of this manual is the property of ENTire Medical and is protected by all relevant copyright laws.

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1 Introduction

This manual contains important information regarding the IRE System. To ensure the safe use of the system and achieve optimal treatment results, please read this manual before setup and operation. Ensure that you know all safety instructions, guidelines, WARNINGs, and precautions.

Released date:	21/03/2026
Product	ENTire Medical IRE System; ENTire IRE Generator and Handpieces
Hardware Version	V1.0
Software Classification	Class B
GUI Software revision	V1.2
Generator Classification (IEC 60601-1)	Class I
Handpiece Type (IEC 60601-1)	BF
Safety Fuse	12A, 250VAC, Fuse Size: 3AB

Table 1 – User Manual Number, Electrical Medical Device Classification.

1.1 Terms, Abbreviations and Symbols

1.1.1 Terms

Term	Definition
Handpiece (applied part)	The handpiece, also called the applied part, is used by the surgeon to perform the procedure.
Pulse/ Application	Bursts of energy delivered to the tissue. A pulse (or application) is performed by pressing the foot pedal. Treatment is comprised of multiple pulsing sessions (up to 6 per treated site depending on indication- please see instructions for use for each handpiece).

Table 2 – Terms

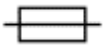
1.1.2 Abbreviation

Term	Definition
ENTire/ENTire Medical	ENTire Medical Ltd.
GUI	Graphical User Interface
HP	Handpiece
IFU	Instructions for Use
IRE	Irreversible Electroporation
MS	Microsoft Software
OS	Operating System
PEF	Pulsed Electric Fields
[A]	Ampere (current)
[V]	Volt
[W]	Watt (power)

Table 3- Abbreviation

1.1.3 Symbols

The following is a list of symbols used on the IRE System and throughout this user manual.

	Batch code		Authorized representative in the European Community/ European Union
	Catalog number		Type BF applied part complying with IEC 60601-1
	Serial number		Medical device
	Manufacturer		Unique device identifier
	Date of manufacture		Electric shock hazard
	Sterilized using steam or dry heat		Do not use if package is damaged and consult instructions for use
	Fuse information		Foot pedal
	Caution		CE mark (Medical)

	WARNING		Consult instructions for use or consult electronic instructions for use
	WEEE compliant		Keep away from sunlight
	Ingress protection mode		Non-ionizing electromagnetic radiation
	Quantity		Double sterile barrier system
	Use-by date		Temperature limit
	Keep dry		Model number
	Single patient use only		Fragile, handle with care
	Do not resterilize		Caution: Federal law restricts this device to sale by or on the order of a physician

Table 4- Symbols

1.2 Instructions for Electrical Safety

Place the product on stable surfaces suitable for this kind of medical device. Do not place the product on or near a heat-generating product. Ensure that there is sufficient clearance between the product and any other system that might block the generator ventilation system. The minimal distance between the generator and any other device or wall shall be at least 25cm. The product is for indoor use only.

⚠ **WARNING** ENTire IRE System needs special precautions regarding EMC and needs to be installed and put into service according to the specific instructions for maintaining basic safety and essential performance with regard to electromagnetic disturbances for the expected service life provided in Section 8 of this user manual.

The following information on electrical safety must be followed. Failing to follow the safety instructions may result in electric shock, fire, and/or serious personal injury or death:

- Always ensure that the product power inlet voltage matches the nominal voltage of the AC supply network.
- This product is supplied with a certified power cable. Never replace the power cable with another cable type or uncertified cable cord.
- Connect the device with a properly grounded electrical network to avoid electrical shock.

- If extension cords are used, they must be checked regularly to ensure that cord insulation is intact.
- DO NOT use the product if the power cable is damaged. Check the power cable regularly to ensure that it is in proper operating condition.
- DO NOT insert the plug into damaged sockets.
- DO NOT remove the cover or any part of the generator. Doing so will expose circuits and components and can lead to injuries, fire, damage to the product, or severe injury to the user or patient.
- Use suitable overvoltage and surge protection elements to protect the system (such as that caused during a lightning storm).
- The product is not liquid proof (IP30); The system must be protected against penetration of liquids to prevent any damage to the system and the user from electric shock.
- Before cleaning the generator, disconnect it from the power source. Use a soft, non-lint cloth to clean the product, as instructed.
- Service procedures or replacement of device parts should be performed only by qualified service personnel.
- DO NOT push any objects or fingers into the air ventilation slots.
- DO NOT leave the system unattended while in power-on mode.

Note: the system is used without a neutral electrode

Note: In the event that any serious incident has occurred in relation to the device this should be immediately reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1.3 Environmental Protection

Waste electrical products should not be disposed of with household waste. Please recycle at the appropriate facilities. Check with your local authority for recycling advice or contact your product vendor. The disposal of the IRE System and/or components should be performed according to the WEEE directive 2012/19/EU.

1.4 Applicable Standards and Regulations

Medical Device Regulation - MDR (2017/745):

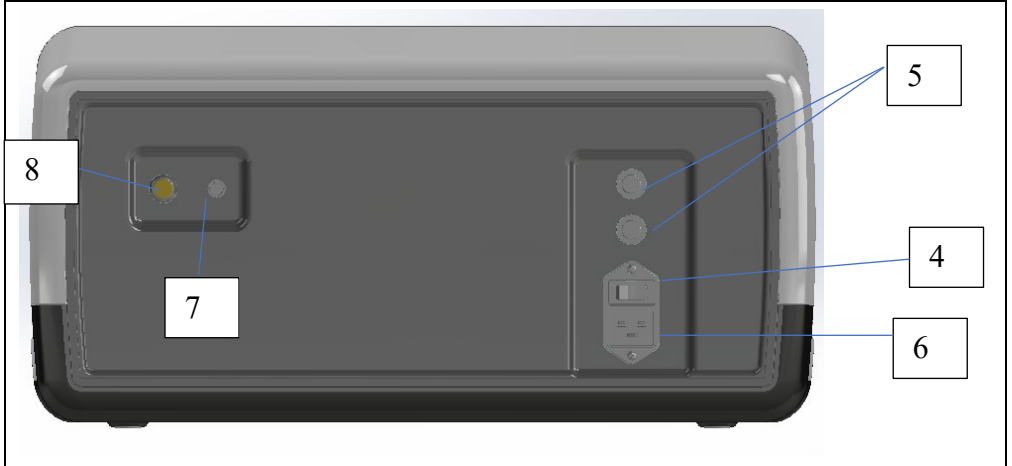
- IEC 60601 – 1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-2-2 - Medical electrical equipment - Part 2-2: Particular requirements for basic safety. and essential performance of high-frequency surgical equipment and high-frequency surgical accessories.
- WEEE Directive 2012/19/EU, Management of Electronic Waste.
- MDCG 2019-16 Guidance on Cybersecurity for medical devices.
- IMDRF - Principles and Practices for Medical Device Cybersecurity (18 March 2020).
- The RoHS (Restriction of Hazardous Substances), Directive 2011/65/EU The radio equipment directive 2014/53/EU (RED) DIRECTIVE 2006/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL: 2006, on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits.
- ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.
- ISO 17665-1:2006 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
- ISO 15223-2:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer.

1.5 System Overview

The ENTire Medical IRE System is an electrosurgical system, comprised of the ENTire IRE Generator and ENTire IRE Handpiece, that delivers controlled non-thermal energy via pulsed electric fields (PEF) to electrodes placed on the target tissue. The system is intended to be used in an operating room, clinic, or other healthcare facility performing such procedures. All procedures will be performed by healthcare professionals. The IRE system comprises a generator that generates electromagnetic applications, dedicated handpieces, and a foot pedal. The user activates the system from the foot pedal. The system may comprise different handpieces (applied parts) that comply with the target organ morphology. All the handpieces are sterile, single-use devices.

1.5.1 System Components

IRE System Generator – Front view



IRE System Generator – Back view

Figure 1 - System Components

Number	Description
1	Power on/off push button
2	Handpiece receptacle
3	GUI touch screen
4	Generator On/Off Switch
5	Fuse (the system includes two fuses)
6	Power inlet
7	BNC connector for an option ECG synchronization device
8	Foot pedal connector

Table 5- Generator components

The Handpieces are sold separately. The IRE Generator is designed to work with the devices listed in the following table. These devices are suitable for use within the patient environment. It is important to note that each handpiece is designed for specific indications, providing targeted functionality based on the intended use.

⚠ **WARNING** DO NOT substitute cables, equipment, or disposables with any cables, equipment, or disposables not provided or specified by ENTire Medical. Doing so could potentially damage the system or cause injury.

Ablation Handpieces	**Manufacturer**	**Model P/N**
ENTire Tonsil Forceps Handpiece	ENTire Medical	ENTTON01

Table 6- Parts to be supplied separately.

The ENTire IRE System uses well-established technology, i.e., Irreversible Electroporation (IRE). IRE is a non-thermal ablation technique that employs electric fields leading to selective tissue ablation by induced apoptosis; it is a developed and utilized ablation technique for soft tissue ablation in other applications.

The novelty of the IRE System lies in its specific application for tonsillotomies, addressing clinical needs by providing reduced or eliminated intra and post-operative bleeding/hemorrhage and pain, reduced operative time and improved patient recovery time.

1.6 Principle of Operation

The IRE handpieces are used to perform the treatment by delivering energy generated by the generator to the treated organ. The handpieces are connected to the generator, and the generator generates the applications controlled by the system operating parameters, which are automatically set when connecting the handpiece. Dedicated, indication-specific, electrodes are located at the distal end of the handpiece. Handpieces are single-use and are provided sterile by ENTire Medical Ltd. Only one handpiece may be connected to the generator at a time. The system automatically detects the type of handpiece connected and automatically determines parameter settings. After the handpieces are attached to the generator, the handpiece can be used for a limited time (up to 90 minutes). When the System is activated from the foot pedal, the system generates high-frequency and high-voltage applications delivered in multiple bursts, through the handpiece, leading to selective tissue apoptosis in the region in between the electrodes.

1.7 The Operating Screen (GUI)

The Generator GUI is designed to allow the user to view operation parameters: number of applications, handpiece type, etc. The figure below provides a detailed explanation of the GUI operation:

GUI

1. **Device Type** - Indicates to the user which HP is connected to the generator.
2. **Ablation counter** – counts the number of applications used from the treatment beginning.
3. **Reset** – resets ablation (operation) counter.
4. **Message Bar** – a green checkmark indicates proper conditions for use. If a red x appears the error number will be displayed to the right of the red x.

Figure 2 - GUI Screen

2 System Usage

The IRE System is intended for use in a professional healthcare facility environment (such as Physician offices, clinics, limited care facilities, freestanding surgical centers, multiple treatment facilities, hospitals (emergency rooms, patient rooms, intensive care, surgery rooms except near HF SURGICAL EQUIPMENT, outside the RF shielded room of an ME SYSTEM for magnetic resonance imaging)).

2.1 Intended Use

The IRE System is intended for the surgical ablation of soft tissue for Otorhinolaryngology (ENT) indications.

The ENTire IRE Generator is intended to deliver energy to tissue and utilize Irreversible Electroporation technology to induce controlled cell death (apoptosis) in target tissues.

The Generator delivers energy through the compatible handpiece for ablation of soft tissue in surgical procedures within the field of Otorhinolaryngology (ENT).

The ENTire Handpiece is a sterile, single-use handpiece intended to be used in conjunction with the ENTire IRE Generator and is indicated for ablation of soft tissue in otorhinolaryngology (ENT) surgery.

2.2 Indication For Use

Indication for use can be obtained in the Information for Use (IFU) provided with each indication specific handpiece.

2.3 Intended User

The operation of the system is restricted to trained, qualified physicians only.

⚠ **WARNING** The operator should be experienced in electrosurgical techniques. The user should also be familiar with advances in otorhinolaryngology (ENT) procedures. Additional training in the use of the IRE System from a company representative is recommended.

2.4 Treated Organ

The system using the dedicated handpieces should only be used for treating the specific indication mentioned in the handpiece-specific instructions for use (IFU).

2.5 Contraindications

- Patients with a pacemaker or similar electro stimulator.
- Patients for whom the anesthesia involves high risk or known or suspected complications for any general or local anesthetic agents.
- Epilepsy or other conditions involving convulsions.
- Severe heart disease.
- Pregnancy or breastfeeding.
- Significant systemic illness (e.g., cancer, severe autoimmune disease, neurological disease).

2.6 Determination of treatment parameters

The system automatically sets system operation parameters based on the connected handpiece.

2.7 Expected Possible Complications and Adverse Events:

Potential risks associated with the use of the IRE System include risks associated with general or local anesthetics. Additional risks associated with the system are listed below.

Possible adverse events may include, but are not limited to:

- Inflammation/ generalized redness in the treated area.
- Swelling.
- Pain or burning sensation.
- Local burns.
- Hematoma.
- Allergic reaction (itching, redness, or rash).
- Scar formation.
- Arrhythmia.
- Reactions to anesthetics.
- Temporary numbness/tingling.
- Severe muscle contraction during procedure.
- Sensory changes at treatment sites.
- Charring.
- Procedural Complication.
- Infection.
- Patients do not receive benefits of therapy.
- Bleeding (other than bleeding greater than anticipated).
- Injury to anatomical structure.
- Fever.
- Shock.
- Ablative Injury.
- Venous Thrombosis.
- Death

2.8 Expected Benefits

- Non-thermal ablation
- Non-invasive – no bleeding
- Minimal pain post procedure
- Quick procedure –1-2 minutes per tonsil
- Minimal inflammation, swelling and scarring
- Minimal mucosal damage

- Fast recovery

The benefits are supported by clinical data, including studies carried out with the ENTire IRE System. Based on those studies, no adverse events or device related complications were reported during the procedure and in the follow-up period of up to 3 months. No primary or secondary bleeding was observed in any of the subjects. In addition, reported pain levels at 1-week post-procedure were below non-inferiority threshold for all participants.

The IRE procedure was well tolerated in all cases, and the results indicate that the subject device is not associated with any increased or different intra and post-treatment risks or complications as compared to standard treatments.

3 General Safety Information

3.1 ⚠ WARNINGs

WARNINGs are safety instructions indicating a hazardous situation, which, if not avoided, might lead to serious injury to the patient or user.

3.1.1. Before using the IRE System read this user manual and the IRE System's instructions for use provided with the handpiece. Failure to follow instructions or failure to comply with WARNINGs or precautions may result in harm to the patient.

3.1.2. The IRE System is for use only by qualified ENT medical personnel trained in electrosurgical devices.

3.1.3. Use only ENTire Medical handpieces compatible with the system's Generator. Non-compatible handpieces might cause patient injury or procedure failure.

3.1.4. DO NOT use in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.

3.1.5. DO NOT use the system if there are any signs of damage to its components. Visually inspect all components before use and verify cable insolation integrity.

3.1.6. Ensure that Generator vents are not obstructed to prevent system failure.

3.1.7. DO NOT connect the handpieces to the Generator when powering on and preparing the Generator for use. This could result in injury to the user or the patient.

3.1.8. DO NOT place the handpiece electrodes on any metal parts when activating the device.

3.1.9. DO NOT reuse, reprocess, or re-sterilize the handpieces. Handpieces are intended for single use only. Any reuse, reprocessing, or re-sterilization could result in device failure causing patient or user injury. Reuse, reprocessing, or re-sterilization could cause contamination of the device, which may result in patient infection.

3.1.10. Always connect the system to an AC mains supply outlet with a protective earth-ground connection, to prevent the risk of electric shock.
3.1.11. DO NOT disassemble the generator or any of its components. Modification of this equipment might result in injury to the operator or damage to the unit equipment. In case service is required contact company representatives.
3.1.12. DO NOT touch the handpiece's electrodes. Doing so may lead to injury.
3.1.13. DO NOT place the Generator near or in contact with flammable materials. Instruments that are activated or hot from use may cause a fire.
3.1.14. When not using the handpiece, place it in a clean, dry area, not in contact with the patient.
3.1.15. DO NOT activate the system when not in contact with the target tissue.
3.1.16. Only activate the system when the indicator light is green and the check mark appears on the GUI screen.
3.1.17. AVOID placing the handpieces on or near any metal implants (i.e. dental implants). If a patient has any metal implants, place the handpieces on the away from the implant.
3.1.18. DO NOT use in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N2O) and pure oxygen) or in close proximity to volatile solvents (such as ether or alcohol).
3.1.19. DO NOT place the IRE System near or in contact with flammable materials (such as gauze or surgical drapes).

3.2 Precautions

Precautions are safety instructions that must be followed to prevent minor or moderate injury to the patient or user.

3.2.1 The IRE System is intended for use by ENT healthcare professionals only.
3.2.2 Use caution when transporting the components of the IRE System. Some components may be heavy for some users. Dropping a component may result in harm to the user or the component.
3.2.3 Use caution when walking around the foot pedal and foot pedal cable to avoid injury.
3.2.4 Equipment or cables connected to the Generator's external connections must comply with applicable standards. Connecting cables or devices (e.g., a foot pedal) to the Generator may affect the medical device system, and therefore should be used only if such connection was verified to comply (together with the device) with the requirements of IEC/EN 60601-1.

4 Contents and Inspection

4.1 Contents

The IRE System is supplied in packaging within a transportation case, this case is intended to protect the items during storage and transportation (handpieces are supplied separately).

Gently open the box and place all components on a dry, stable, clean surface. The content of the package is described in the table below:

Number	Description	Quantity
1	IRE Generator	1
2	Power cord	1
3	Foot pedal	1
4	Handpieces (optional)	1

Table 7- Package Content

⚠ **Caution**: The packed product may be heavy and should be handled carefully.
The system installer may require suitable means of lifting and/or moving the product to avoid physical injury.

Note: the single-use handpieces are provided separately and should be connected to the dedicated receptacle located on the device's front panel

4.2 Inspection

4.2.1 Visually inspect the system components' integrity.
4.2.2 For sterile components, ensure that the sterile packaging is intact.
4.2.3 In case of any damage, do not use the system and contact your local vendor.

5 Instructions for Use

5.1 Pre-Treatment Patient Preparation

Any metallic components, e.g., jewelry, should be removed from the patient's ears, neck, and face.

5.2 Instructions on Product Positioning

Place the product on stable surfaces suitable for this kind of medical device. Do not place the product on or near a heat-generating product. Ensure that there is sufficient clearance between the product and any other system that might block the generator ventilation system. The minimal distance between the generator and any other device or wall shall be at least 25cm. The product is for indoor use only.

5.3 Installation (System Assembly)

5.3.1 Ensure that the I/O switch of the power inlet on the back panel is on the "O"position.
5.3.2 Connect the power cord to the power inlet.
5.3.3 Connect the power cord to the mains (power source).

⚠ **Caution**: Refer to the general safety information section and the technical specification in Appendix I of this user manual)

5.4 Operation Instructions:

5.4.1 Turning the Device On:
5.4.2 Turn the I/O switch on the back panel to the "I" position.
5.4.3 Push on the on/off pushbutton located on the front panel to turn the system on.
5.4.4 Push the on button on the top of the IRE System to turn on the GUI system. The panel will turn on, and the operation screen will be displayed.
5.4.5 Unpack the handpiece in a sterile environment.
5.4.6 Connect the handpiece connector to the receptacle the front of the Generator.
5.4.7 The Generator is suitable for continuous operation.

5.5 Treatment Instructions:

Please refer to indication-specific Instructions for Use (Nasal or Tonsil).

⚠ **WARNING** Failure to follow the limit of the number of applications or operation parameters, as presented in this manual, might lead to patient injury.

⚠**WARNING** The IRE System is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

5.6 Turning Off The System

Press the push button to turn off the GUI system. Then press the power on/off switch to turn off the system and finally switch off the generator's power switch on the back of the generator.

6 Troubleshooting, Cleaning, Maintenance, and Storage

6.1 Troubleshooting

6.1.1 The system won't activate when the foot pedal is pressed:

- Ensure the mechanical connection between the foot pedal connector and the generator receptacle. Ensure that nothing blocks the mechanical movement of the pedal during the operation.

6.1.2 The system won't work, no valid contact is displayed:

- Ensure the mechanical connection between the handpiece connector and the generator receptacle. Ensure that nothing blocks the mechanical movement of the handpiece during operation.

6.1.3 In case of fatal error (i.e., communication loss error) the system must be turned off and reloaded by the user.

The table below provides the notification/error codes that might be displayed during the system operation:

Displayed Error	**Explanation and Instructions:**
Error message 1	Voltage error- The system is loading voltage parameters. 1. Wait for up to 3 minutes and see if loading is complete. 2. Restart the system and see if the error persists.
Error message 2	Current error – Over or under current during ablation which causes the system to stop the ablation process. 1. Verify the integrity of the handpiece and connections. 2. Restart the system and see if the error persists.

Displayed Error	Explanation and Instructions:
Error message 3	EEPROM (Handpiece Memory) Error: The system was unable to recognize the ablation tool. 1. Disconnect the handpiece from the system. 2. Carefully reconnect the handpiece, ensuring it is properly connected and secure. 3. Restart the system and check if the error message clears. 4. If the error persists, try using different handpiece to determine if the issue is with the specific tool.
Error message 4	Communication Error: The system has encountered a communication error and is unable to restore normal operation. 1. Check all communication connections between system components, such as cables and connectors. Ensure they are properly connected and not damaged. 2. Restart the system to attempt to restore normal communication.
Error message 5	Insufficient contact of tissue between electrodes resulting in insufficient energy delivery for desired effect. 1. Ensure that electrodes are in full contact with the tissue and no part of the electrode is exposed to the air. 2. Disconnect the handpiece from the system. 3. Carefully reconnect the handpiece, ensuring it is properly connected and secure and try again.
Error message 7	Generator is in Start Up Mode running through processes of checking connections, warming up, and loading voltage. 1. Wait for approximately 2 minutes. 2. Wait for Green check mark to appear and error number to disappear. 3. No action required.

Table 8- GUI Error Message

6.2 Device Cleaning

⚠ **Caution**: Device cleaning should be performed using disposable gloves.

⚠ **Caution**: Handpieces are single-use components. Do not re-sterilize the single-use components. Single-use components should be processed/disposed of following local regulations.

6.2.1 Generator

Use Alcohol (Ethanol) 70% with fiber-free fabric and gently wipe the generator after the operation.

6.3 Maintenance

6.3.1 The system does not require any specific maintenance during normal use.
6.3.2 The IRE Generator is designed to provide consistent power output (voltage and current). There are no internal adjustments in the system. In case of any component malfunction, call your local vendor.
6.3.3 Once a month, inspect the generator to ensure that the system and system components, such as cords (power, foot pedal) are not damaged.
6.3.4 In case of any damage or malfunction, the device shall be sent back to the manufacturer for servicing.
6.3.5 After the first 5 years, the device shall be sent back to the manufacturer.

Note: in some countries, local regulations may require periodic safety tests. Contact your local vendor for any information regarding the issue.

⚠ **WARNING** In case of any damage, stop using the system immediately and contact the local vendor. Damaged equipment should not be used in any situation.

6.4 Fuse Replacement:

Fuse replacement will be performed by a qualified technician only.

The fuse holder is located on the back wall of the generator. To replace the fuse, turn off the generator power (both from the front panel button and the fuse holder) and remove the cable cord after waiting for at least 10 seconds. Use a flat-head screwdriver to remove the fuse holder by depressing the locking tab. Replace **both fuses** with Littelfuse part number 0326012MXP, 12A 250V. Reinstall the fuse holder until the locking tabs snap into place. Reconnect the power cable and turn on the system. If the fuse fails again, contact your local vendor.

6.5 Technical Device Servicing

Should service or repair be necessary, contact an ENTire Medical representative.

In any case of system malfunction, the system should be serviced only by qualified trained and certified service personnel. For any service issue, please contact your local vendor.

6.6 Storage conditions

The Device should be stored in a cool dry place, avoiding exposure to sunlight and extreme temperatures. System components may be safely stored and transported at an ambient temperature range of -20°C to 50°C.

7 Appendix I - General Guidance And Manufacturer's Declaration: Essential Performances and Electromagnetic Emissions and Immunity

7.1 Essential Performances:

The system shall be capable of delivering the IRE ablation with output voltage in a bipolar mode with the following specifications: Bipolar voltage up to 1500V over an impedance of 50 Ohm. The delivered voltage accuracy shall be a maximum of +-20% from the target voltage at the generator output connector.

7.2 Product Specifications:

Maximum Energy Output	Maximum of 80 Bursts per activation (i.e., foot pedal press). Fundamental Frequency of up to 1000kHz. Peak Voltage rating of up to 1500V	
Operating Temperature	up to 40°C	
Input Power	100-240 VAC, 50 Hz - 60 Hz universal power supply. Fuse rating 250V: 12A	
Dimensions	Generator: 47.6 cm wide x 26.3cm high x 37.0cm length	
Weight	Generator (Max): 20 Kg	
Rear Controls	Line Power On/Off	
Display	Touch screen display: Microsoft Surface Go 3 - 10.5"; Screen Resolution, 1920x1280 Pixels. Capable of displaying graphics, messages and activation information.	
Environmental Conditions		
	Transport or Storage	**Operating**
Temperature	-20 °C to 50 °C	10°C to 40°C
Classifications	Class 1. Applicable general test and electrical safety requirements for Class 1 protection of ANSI AAMI ES60601-1, EN 60601-1, and CAN/CSA C22.2 No. 60601-1. Safety requirements of high-frequency surgical equipment of ANSI AAMI IEC 60601-2-2 and EN 60601-2-2. Electromagnetic compatibility (EMC) requirements of ANSI AAMI IEC 60601-1-2 and EN 60601-1-2. BF Applied Part Foot Pedal IXP8 Hazard Class: Class IIb	

Table 9 - Product Specification

7.3 System Output Charts:

Average output power delivered over the specified impedance range during device activation (per IEC 60601-2-2, subclause 6.8.3) is given in the graph below:

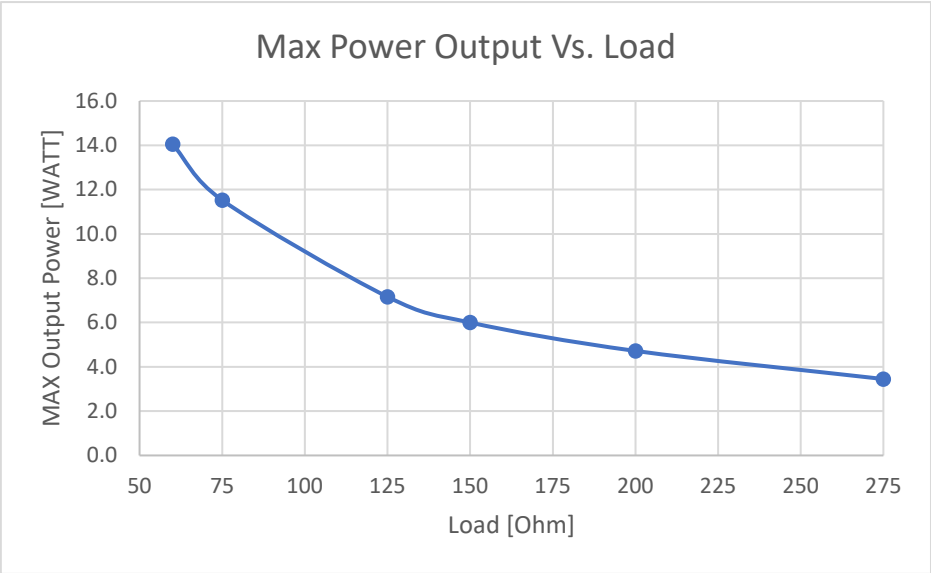


Figure 3 - Average Power Output Over a single pulse.

7.4 Guidance and Manufacturer's Declaration – Electromagnetic Emissions and Immunity

The IRE System is designed for use in the specified electromagnetic environment. Users must ensure that the device is used within this environment.

NOTE: 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 relocating or re-orienting the equipment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11 (EN55011)	Group 1	When the generator is in standby mode, radiofrequency (RF) energy is only used for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment. When the generator is activated and delivering energy, the device must emit electromagnetic energy to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11 (EN55011)	Class A	The IRE System is suitable for use in all establishments other than domestic (i.e.,

Emissions Test	Compliance	Electromagnetic Environment - Guidance
Harmonic emissions EN 61000-3-2	Class A	residential) and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	

Immunity Test	IEC60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
EN 61000-4-3 Radiated, radio-frequency, electromagnetic field immunity	80 MHz - 2700 MHz, 3 V/m, 80 % 1 kHz AM Various per Table 9 of ANSI AAMI IEC 60601-1-2 and EN 60601-1-2.	80 MHz - 2700 MHz, 3 V/m, 80 % 1 kHz AM Various per Table 9 of ANSI AAMI IEC 60601-1-2 and EN 60601-1-2.	Radio frequency and electromagnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
EN 61000-4-4 Electrical fast Transient/burst	For AC / DC power ports: ±2 kV ±1 kV for signal ports	For AC power ports: ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
EN 61000-4-5 Surge	For AC / DC power ports: ±1 kV differential mode ±2 kV common mode 1.2/50 µs	For AC power ports: ±1 kV differential mode ±2 kV common mode 1.2/50 µs	Mains power quality should be that of a typical commercial or hospital environment.
EN 61000-4-6 Conducted, radio-frequency immunity	3 Vrms, 150 kHz to 80 MHz 6 Vrms in ISM bands (6.765 MHz to 6.795 MHz, 13.553MHz to 13.567 MHz 26.957 MHz o 27.283 MHz And 40.66 MHz to 40.70 MHz)	3 Vrms, 150 kHz to 80 MHz 6 Vrms in ISM bands (6.765 MHz to 6.795 MHz, 13.553MHz to 13.567 MHz 26.957 MHz o 27.283 MHz And 40.66 MHz to 40.70 MHz)	Radio frequency and electromagnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Interference may occur in the vicinity of equipment marked with the following symbol: 

Emissions Test		Compliance	Electromagnetic Environment - Guidance
EN 61000-4-8 Power frequency magnetic field	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
EN 61000-4-11 Voltage dips, short interruptions, and voltage variations on power supply input lines, UT = AC 230V/50Hz	>95 % dip in UT for 0.5 cycle 60 % dip in UT for 5 cycles 30 % dip in UT for 25 cycles >95 % dip in UT for 250 cycles	>95 % dip in UT for 0.5 cycle 60 % dip in UT for 5 cycles 30 % dip in UT for 25 cycles >95 % dip in UT for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the IRE System requires continued operation during mains power interruptions, it is recommended that the IRE System is powered from an uninterruptible power supply.
IEC 61000-4-39 Immunity to magnetic field inclose proximity	65 A/m 134.2kHz 75 A/m 13.56 MHz	65 A/m 134.2kHz 75 A/m 13.56 MHz	

Table 10- Electromagnetic Emission

⚠ **WARNING** Use of this device adjacent to or stacked with other equipment should be avoided as it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to ensure that they operate normally.

⚠ **WARNING** The use of accessories other than those specified for the device is prohibited. They may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device.

The IRE System has been verified and found to comply with specified immunity standards and is designed for use in the specified electromagnetic environment. To ensure the device's Essential Performance in the presence of electromagnetic disturbances, it is essential for users to operate it within the recommended environment and follow the provided EMC information.

<table>
<tr><th>Immunity Test</th><th colspan="5">IEC60601-1-2 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td rowspan="13">Immunity to proximity fields from RF wireless communication equipment as defined in Table 9 of IEC 60601-1-2 Proximity Fields</td><td>Test Frequency (MHz)</td><td>Band (MHz)</td><td>Service</td><td>Modulation</td><td>Immunity Test level (V/m)</td><td rowspan="13">Compliance level is the same as test level – may be referred to test level column</td><td rowspan="13">Portable and mobile RF communications equipment should be used no closer to the device, than the recommended separation distance of 30 cm.</td></tr>
<tr><td>385</td><td>380 – 390</td><td>TETRA 400</td><td>Pulse Modulation 18 Hz</td><td>27</td></tr>
<tr><td>450</td><td>430 – 470</td><td>GMRS 460, FRS 460</td><td>FM ±5 kHz deviation
1 kHz sine</td><td>28</td></tr>
<tr><td>710</td><td rowspan="3">704 – 787</td><td rowspan="3">LTE Band 13, 17</td><td rowspan="3">Pulse modulation 217 Hz</td><td rowspan="3">9</td></tr>
<tr><td>745</td></tr>
<tr><td>780</td></tr>
<tr><td>810</td><td rowspan="3">800 – 960</td><td rowspan="3">GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5</td><td rowspan="3">Pulse modulation 18 Hz</td><td rowspan="3">28</td></tr>
<tr><td>870</td></tr>
<tr><td>930</td></tr>
<tr><td>1720</td><td rowspan="3">1700 – 1990</td><td rowspan="3">GSM 1800, CDMA 1900, GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS</td><td rowspan="3">Pulse modulation 217 Hz</td><td rowspan="3">28</td></tr>
<tr><td>1845</td></tr>
<tr><td>1970</td></tr>
<tr><td>2450</td><td>2400 – 2570</td><td>Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7</td><td>Pulse modulation 217 Hz</td><td>28</td></tr>
<tr><td>5240</td><td rowspan="3">5100 – 5800</td><td rowspan="3">WLAN 802.11 a/n</td><td rowspan="3">Pulse modulation 217 Hz</td><td rowspan="3">9</td></tr>
<tr><td>5500</td></tr>
<tr><td>5785</td></tr>
</table>

Table 11- Electromagnetic Environment Specified.

- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts, and TV broadcasts 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 where the device is used exceeds the applicable RF compliance level above, the device should be observed to ensure normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

- **Notes:**
  - It is the AC mains voltage prior application of the test level.
  - At 80 MHz and 800 MHz, the higher frequency range applies.
  - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Device

These devices are intended for use in an environment in which radiated RF disturbances are controlled. The device operator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device according to the maximum output power of the communications equipment.

⚠ **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 IRE System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

8 Appendix II Guidance on Cyber Security

This section complies with the regulatory requirements presented by the EU as presented in the applicable documents: MDCG 2019-16 and IMDRF - Principles and Practices for Medical Device Cybersecurity (18 March 2020).

⚠ **WARNING** Users should strictly follow the instructions and technical notes listed in this section to reduce any cyber security risk to the system.

8.1 Product installation

8.1.1 The device does not require any installation before use.

8.2 Recommended cybersecurity controls appropriate for the intended use environment.

8.2.1 The device does not interface with other devices.

8.2.2 Device does not interface with peripherals (i.e., PC, Cell phone). Never try to connect the device with any external device.

8.2.3 The generator is sealed with a warranty label to ensure that the unit was not serviced/opened by uncertified personnel. If warranty labels are not in place or the device seal has been broken, do not use the device and report immediately to your local vendor that the seal was broken.

8.3 High-Level Summary Of The Risk Profile Of The Medical Device And The Corresponding IT Security Objectives

The IRE System is not connected to the IT system during normal operation.

8.3.1 The IRE System does not store any user/patient data.

8.3.2 Cases of penetration into your system firmware might cause damage and potentially harm the system, causing the system not to work properly not work at all.

8.4 IRE System features that protect critical functionality, even when device cybersecurity has been compromised. (IT security controls included in the medical device)

The system is designed to provide several features that protect the system against cyber threats:

8.4.1 Device firmware is encrypted to prevent any changes in firmware by uncertified personnel.
8.4.2 IRE System generator consists of seal labels to indicate if uncertified personnel attempt to engage device hardware.
8.4.3 The IRE System consists of dedicated propriety operation modified MS OS windows to protect the system from uncertified system modification.

8.5 System backup and restore features

The IRE System provides several means of device data backup.

Note: None of the system components store personal data, and only device data is stored in the system.

8.5.1 System firmware is always backed up by the company.
8.5.2 Your System configuration, when applicable, is kept in the company records in case a firmware restore is required.

8.6 Supporting infrastructure requirements so that the device can operate as intended.

The IRE System does not require IT infrastructure to allow system usage. The system is ready to use and does not require any installation. The system should be used only in indoor clinics or hospitals under controlled environmental conditions as specified in the system user manual. EMC safe environment conditions are also specified in the system user manual.

8.7 Does the user require any IT skills?

The IRE System does not require any user knowledge of IT systems of systems operation. The system is ready for use. No system settings are required either for system operation.

8.8 Does the device require any cyber hardening configuration?

There is no way to connect a USB or any wireless device to the system. Wireless connection is blocked in the system so no anti-malware is required.

8.9 Initial configuration guidelines

The IRE System does not require any login during normal operation.

8.10 In case IRE System is subjected to anomalous conditions you should follow the instructions below:

In case IRE System OS or firmware were affected by anomalous conditions, the device will prompt a series of text lines instead of the standard GUI screen, indicating that someone is trying to make changes in the system. In such a case, do not use the System and contact your local vendor immediately for servicing.

8.11 Does the IRE System store log files?

The IRE System firmware is not accessible for the user; therefore, no access to any system log files is permitted for the user.

8.12 Security risks and consequences of changes to the security configuration, or to the use environment.

IRE System security configurations are not accessible to system users.

8.13 In case your device was affected by cyber-attack, and device configuration has been changed, you should act as presented below:

Any change in IRE System configuration should be done solely by an ENTire Medical qualified technician. Unqualified personnel should never be allowed access to the system.

8.14 Minimum platform requirements for the connected IRE System

Not applicable for the IRE System.

8.15 User roles and respective access privileges/permissions on the device

Not applicable for the IRE System.

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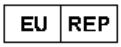

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