Doc # 100039 Rev D

ThermiRF+™ System

User Manual

Thermi™
4719 S Congress Ave
Austin, TX 78745 (512) 637-6745

Glossary of Symbols

CAUTION: See Instructions for Use

Dangerous Voltage: Danger of electric shock

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

FRAGILE: Handle with care

This Way Up

Keep Dry

Grounding Pad – Isolated from earth at high frequency

Defibrillator Proof Type BF Equipment

Equipotentiality

Alternating Current

Non-ionizing Electromagnetic Radiation

Protective Earth (ground)

Footswitch

Fuse

Power ON (Connection to the mains)

Power OFF (Disconnection from the mains)

Up and Down buttons

Temperature Range

Humidity

Catalog Number

Serial Number

Date of Manufacture

European Representative

CE Mark

EU: Not for general waste

See Instructions for Use

Preface/Table of Contents

ThermiRF+

Preface

This manual contains information you need to operate and maintain the **ThermiRF+ System**. It is essential that you read and understand all the information in this manual before using or maintaining the system.

U.S. Federal Law restricts this device to sale by or on the order of a physician.

Read these instructions prior to use.

Table of Contents

Contact Thermi

Getting Support and Information

If you have any questions regarding the operation or maintenance of the ThermiRF+ System, please do not hesitate to contact us.

US Distributor

Address: Thermi
4719 S Congress Ave, Austin, TX, 78745

Phone: (512) 637-6745
Fax: (214)-279-0101
Email: orders@thermi.com
Web Page: www.thermi.com

Hotline

If you have a service issue or a technical question, you can reach Technical Support by telephone during normal USA working hours

(8:00 AM to 5:00 PM Central Time Zone) at

Phone: (512) 637-6745
Fax: (214)-279-0101
Email: orders@thermi.com

Before You Call

We can help you faster if you have the following information at hand before you call the hotline:

- Model and serial number of the system, and any accessories that are being used.
- Software version of the device.
- A short description of the problem and the circumstances under which it occurred (such as, beginning of procedure, just turning on machine, etc.)
- Note any error message on the screen, noting any number that follows the message.
- If possible, a photo of the user interface before and after the error.

Returns and Repairs

To contact Thermi for returns or repairs call or email the Service Department to request a RMA (Return Materials Authorization); be sure to clearly mark the outside box with the RMA # provided to you. Also include this number inside with the returned materials. Contact Thermi Service Department for any additional product questions.

Introduction

The **ThermiRF+ System** is designed to provide finely-controlled radiofrequency (RF) energy. The generator is specifically designed for use with Thermi electrodes.

During temperature-controlled procedures, the **ThermiRF+ System** generator monitors temperature and impedance, automatically adjusting energy delivery to maintain Set Temperature.

Thermi is dedicated to providing service and support to its customers. If you have any questions concerning the use of the **ThermiRF+ System**, please contact your authorized representative.

CAUTION: Hazardous electrical output. The ThermiRF+ System and the devices used with it should only be used by qualified physicians who have received training in the use.

Indications for Use

The ThermiRF+ Temperature Controlled RF System is indicated:

- to create lesions in nervous tissue when used in combination with Thermi thermal/coagulation probes
- for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

Contraindications

There are no known absolute contraindications to the use of electro surgery.

The use of the generator and accessories is contraindicated when, in the judgment of the physician, an electrosurgical procedure would be contrary to the best interest of the patient

System Components

The **ThermiRF+ System** is a line-powered, radio-frequency generator capable of delivering up to 50 watts of power. The generator is designed for use with Thermi approved products. The instrument has been designed to meet IEC 60601 safety and performance standards for medical equipment.

The **ThermiRF+ System** provides controls for line power, mode and function changes, starting and stopping RF power delivery, setting temperature, setting treatment time, pausing RF power delivery, resetting elapsed times and treatment profiles, setting Stimulate Output Voltage, setting the frequency of RF power delivery, and for selecting programmed treatment profiles.

An LCD screen displays the Set Temp, impedance, stimulate voltage, actual probe/tissue temperature, elapsed time, set time, mode setting, pause setting, preset selections, and messages.

The system has illuminated indicators for RF Power On, Stim On, and error conditions. When an error occurs the system will also sound a brief alarm tone.

Unpacking and General Inspection

Carefully unpack and inspect all components shipped with the **ThermiRF+ System**. If any parts are missing or damaged, contact your authorized Thermi Service representative. Save the carton and packing materials in the event a component must be returned for repair. You should have received the following:

Description

1 ea. **ThermiRF+ System**
1 ea. Hospital-grade power cord, country-specific
1 ea. Foot switch with attached wiring

⚠**CAUTION:** The **ThermiRF+ System** is designed specifically for use only with RF electrodes provided by Thermi. To prevent RF interference and burn/shock to the patient/user, do not use other electrodes with the **ThermiRF+ System**.

The ThermiRF+ System is compatible with the following Thermi Electrodes:

Model	Mode	Type
RFE-10-D-G3-20w	ThermiSmooth	Non-sterile reusable
RFE-10-D-G2	ThermiSmooth	Non-sterile reusable
RFE-15-D-G3-20w	ThermiSmooth	Non-sterile reusable
RFE-15-D-G2	ThermiSmooth	Non-sterile reusable
RFDE-G3-20w	ThermiVa	Non-sterile single use
RFDE-G3-50w	ThermiVa	Non-sterile single use
V-10-10-18-B-G2	Percutaneous	Single, single use
V-15-10-18-B-G2	Percutaneous	Single, single use
V-20-10-18-B-G2	Percutaneous	Single, single use
V-5-5-20-B-G2	Percutaneous	Single, single use
2130ac or Equivalent	All procedures	Disposable Grounding Pad

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

Controls and Displays

Front Panel Layout

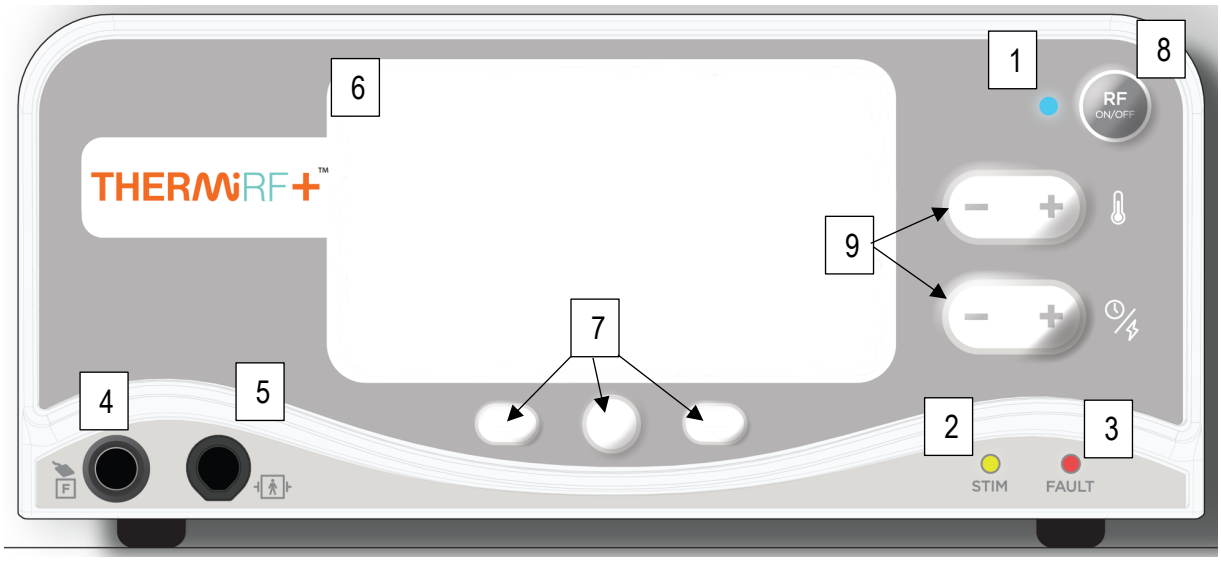


Figure 1. **ThermiRF+ System** front panel.

Control/Connections	Function
1. RF ON (blue light)	Illuminated when generator is delivering RF power.
2. STIM ON (yellow light)	Illuminated when generator is delivering Stimulate power.
3. Fault (red light)	Illuminated when an error condition is detected.
4. Grounding Pad connection port	Used to connect a grounding pad to the generator. Applied Part
5. Device connection port	Used to connect Thermi devices to the generator. Applied Part
6. Display window	Displays generator information, modes, and operating parameters.
7. Soft keys	Soft key options vary based on generator mode. Soft keys include: Stim: Motor, ThermiTight, ThermiRase, ThermiSmooth, Help/Exit Help, Start, Reset, and OK.
8. RF ON button	Starts or stops RF power delivery.
9. Up/Down buttons	Used to increase or decrease function settings.

Rear Panel Layout

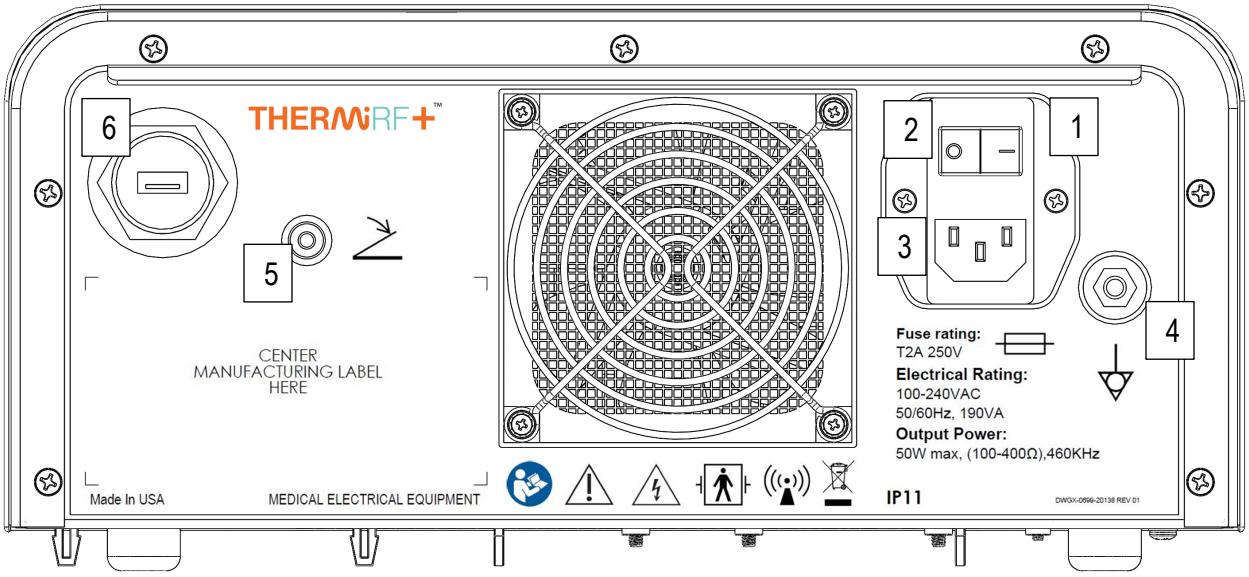


Figure 2. **ThermiRF+ System** rear panel.

Control/Connections	Function
1. On/Off rocker switch	Turns the generator main power on and off.
2. Fuse access door	Provides user access for fuse replacement. Use appropriate fuses to avoid hazards.
3. Power cord connector	This receptacle is an integral part of the power input module and accommodates the hospital-grade power cord accessory.
4. Equipotential compensator	Used to bring other equipment into the same case potential as the terminal (case ground) generator.
5. Footswitch connector	Used to connect the footswitch to the generator.
6. USB Connector	Used to download historical date to USB

Front Panel Displays

Actual Temp (°C)
Displays the temperature, in degrees Celsius (+/- 3°C), measured by the device. Not active in Stim: Motor mode.

Elapsed Time
Displays current elapsed time during a procedure. Not active in Stim: Motor mode.

Frequency (Hz)
Displays the power delivery frequency, in hertz (Hz). This display is only active in Stim: Motor mode. In Stim: Motor mode the frequency is fixed at 2 Hz.

Impedance (Ω)
Displays impedance, in ohms (Ω), of the connected device. This is the device to grounding pad impedance for the monopolar devices.

Mode
Displays the current mode of the generator as determined by the attached device.

PAUSED
Displayed when RF power delivery is paused. RF power delivery may be paused by pressing the footswitch or the RF ON button during power delivery. Power delivery will cease and the timer will pause, but all other functions will continue to monitor and display the device parameters. Pressing the footswitch or RF On button again resumes power delivery and the elapsed time counter.

Set Temp (°C)
Displays the target temperature, in degrees Celsius. Not active in Stim: Motor mode.

Set Time
Displays the RF power delivery time, in minutes. This display is only active in ThermiTight, ThermiRase, ThermiVa, and ThermiSmooth modes.

Stim Volts (V)
Displays the Stimulate Voltage, in volts. This display is only active in Stim: Motor mode.

Width (MS)
Displays the pulse width of the Stimulate Pulse, in milliseconds. This display is only active in Stim: Motor mode.

Front Panel Controls

RF On Button/Footswitch

Starts or stops RF Power delivery. Press and release the footswitch or RF On button to start RF power delivery. Press and release the footswitch or RF On button a second time to cease RF power delivery. Stopping RF power delivery during a procedure will “pause” the procedure. The generator will display the “PAUSED” message and the elapsed time counter will pause, but all other functions will continue to monitor and display the device parameters.

Set Temp (°C) Up/Down buttons

Used to set the target tissue temperature, in degrees Celsius. Press the Up/Down buttons to the right of the Set Temp display to increase or decrease the Set Temp value. Not active in the Stim: Motor mode.

Set Time Up/Down buttons

Used to set the RF power delivery time. Press the Up/Down buttons to the right of the display to increase or decrease the Set Time value.

Reset

The Reset soft key control will appear when the generator has been paused or at the completion of a procedure. Pressing the Reset soft key while a procedure is paused resets the Elapsed Time to 0:00. This control is not active in the Stim: Motor mode.

Width (ms)

Displays the pulse width of the Stimulate Pulse, in milliseconds (ms), set using the Up/Down buttons to the right of the display. Width may be adjusted to 0.1, 0.5, 1, 2, or 3ms. This control is only active in the Stim: Motor mode.

Back button

Click to return to the previous screen.

Front Panel Indicators

RF On (blue light)

Illuminated when **ThermiRF+ System** is delivering RF power. When the generator is idle and a mode has been selected, the RF On light will blink, indicating a continuous impedance check.

Stim On (yellow light)

Illuminated when **ThermiRF+ System** is delivering Stim power.

Error (Red Light)

Illuminated when an error condition is detected.

Other Indicators

Alarm Tone and Error Display

The alarm tone is sounded briefly during generator start-up, and in the event of an error condition. In the rare event of an error, a numerical code is displayed. Please make note of the numerical code. Compare the numerical value to those in the appropriate Tables 1 or 2.

Back Button Soft Key

The Back button soft key option appears when a warning is detected (Figure 11). After resolving the error, pressing

the Back button soft key will clear the warning display and move the generator into the paused state

Preoperative Setup

⚠**CAUTION:** Prior to use, examine the device for possible damage to assure proper functioning. If damaged, do not use.

⚠**WARNING:** Risk of explosion if used in the presence of flammable anesthetics, skin preparation agents, or bio-intestinal gases. Do not use in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N20) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.

1. Plug the generator power cord into the rear panel power cord connector and a grounded AC power source. Make sure not to position the generator so it is difficult to operate the disconnection device (plug).

⚠**WARNING:** Hazardous electrical output. To prevent patient burns and incorrect lesioning, this equipment is for use only by qualified medical personnel trained in the use of electro surgery.

⚠**WARNING:** Check that the electrical equipment is properly grounded (i.e., plugs contain a ground prong), to prevent shock. The generator must be plugged into a hospital-grade AC outlet.

⚠**WARNING:** Excessive risk (leakage) current may result if this equipment is connected to other than the manufacturer's recommended power distribution system.

2. Connect the footswitch into back panel footswitch connector.

Note: Footswitch use is optional. The RF Button on the front panel performs the same functions as the footswitch.

⚠ ⚠**WARNING:** Inspect the footswitch for any obvious defects. **WARNING:** Do not place the footswitch or hose where any liquids could ingress into the components and do not get electrode contacts wet; patient or user burns are possible.

⚠**WARNING:** Before attaching any accessory to the ThermiRF+ generator, please read and understand the instruction for use for that accessory.

3. Plug the Grounding Pad cord into the front panel Grounding Pad Connection Port. For monopolar devices such as the RF Electrodes, a disposable grounding pad such as a Thermi RF Disposable Grounding Pads (2130ac) or equivalent is required. To attach a grounding pad, insert the plug into the grounding pad connector port on the front panel. Assure the plug is fully seated with no metal exposed.

⚠**WARNING:** Safe use of monopolar electro surgery demands proper grounding of the patient. A disposable grounding pad with a banana plug such as a Thermi RF Disposable Grounding Pads (2130ac) or equivalent is required. Improper pad selection, improper pad placement, or improper probe usage may result in patient or operator burns at the return pad. To avoid this, follow the manufacturer's Instructions for Use.

Prepare the patient using standard technique for monopolar electrosurgical procedures. Proper grounding pad placement is essential (follow the manufacturer's instructions).

⚠**WARNING:** to prevent burns to the patient / user, the patient's entire body, including extremities, must be insulated against contact with grounded metal parts. The operating table itself should be grounded, and sufficient layers of electrically insulating sheets should be placed underneath the patient.

⚠**WARNING:** RISK OF BURNS OR FIRE. Do not use near conductive materials such as metal bed parts, inner-spring mattresses, etc.

⚠**WARNING:** To prevent shock to patient/user a waterproof cover should be placed over the insulating sheets, with absorbent sheets placed between the patient and the waterproof cover to absorb any moisture. Make sure that fluids cannot or do not pool under the patient or in body depressions (such as the umbilicus) or in body cavities (such as the vagina) before or during the procedure. Any fluid pooled in these areas should be mopped up before the generator is used.

Preoperative Setup (continued)

⚠**WARNING:** This device has been tested and verified to comply with the IEC 60601-1-2. This exceeds the requirements specified by FCC Part 18 for ISM equipment. This device is intended for operation in a medical facility

only. Usage in a residential environment will likely cause unacceptable RF interference for which the user is held responsible.

⚠**WARNING:** Do not place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.

⚠**WARNING**: Over treatment of patient may cause burns.

⚠**WARNING**: Skin-to-skin contact (for example between the arms and body of the PATIENT) should be avoided, for example by insertion of dry gauze.

Operation

⚠**WARNING** Not indicated for treating patients with implanted electronic devices, such as cardiac devices (AICD, defibrillators, mechanical valves, etc.), Cochlear implants, and patient's active dermatological conditions such as collagen vascular disease and autoimmune diseases

⚠ **WARNING** Stop procedure if at any time the patient reports heat is felt at site of the grounding

⚠**WARNING** Patient should be aware and monitored during the procedure for any unexpected symptoms (pain, numbness, etc.).

Start Up

1. **Turn the ThermiRF+ System on** using the rocker switch on the rear panel. The generator performs a system self-test to determine if it is performing properly.

During the self-test the generator will emit a long beep and all three front panel LEDs will illuminate. The software version number is displayed after power-up tests are complete. The version number is displayed transiently.

Note: If any of the tests fail, the error indicator on the front panel is illuminated and a three-second continuous tone sounds. The generator will display a flashing "Error" message with an associated error code and the Help soft key. Pressing the Help soft key displays a message regarding the fault. If this happens, please note the Error number and contact your Thermi Service Representative.

Standby Mode

Immediately after power-up, the system enters Standby Mode and cannot deliver RF power. A cable with an attached device must be connected to the device connection port to exit this mode (Figure 4). While in Standby Mode, the ThermiRF+ splash screen appears in the display.

Figure 4: Display screen in Standby Mode before probe is attached.

⚠**WARNING:** Before attaching any accessory to the ThermiRF+ generator, please read and understand the instruction for use for that accessory.

2. **Connect an electrode device to the front panel Device Connection Port.** ThermiRF+ Electrodes (Applied Part) connect directly to the front panel of the generator.
   NOTE: The ThermiRF+ device provides auto recognition of the connected treatment probes and sets the maximum power level. Specifically:

Probe	Mode	Power limit
RFE-10-D-G3-20w	ThermiSmooth	22 watts
RFE-10-D-G2	ThermiSmooth	50 watts
RFE-15-D-G3-20w	ThermiSmooth	22 watts
RFE-15-D-G2	ThermiSmooth	50 watts
RFDE-G3-20w	ThermiVa	22 watts
RFDE-G3-50w	ThermiVa	50 watts
V-10-10-18-B-G2	ThermiTight ThermiRase	50 watts
V-15-10-18-B-G2	ThermiTight ThermiRase	50 watts
V-20-10-18-B-G2	ThermiTight ThermiRase	50 watts
V-5-5-20-B-G2	ThermiTight ThermiRase	50 watts
2130ac or Equivalent	Transcutaneous	50 watts

Operation (continued)

⚠WARNING**:** When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns. The cables to the surgical electrodes should be positioned in such a way that contact with the patient or other leads is avoided. Probes not in use should be stored isolated from the patient.

⚠WARNING: Burns to the surgeon's hands are possible if the probe comes into contact with a metal instrument or surface.

⚠**CAUTION:** Inspect the probe and extension cable connections for the presence of liquid before use or whenever a probe is connected or disconnected during a procedure. Liquid may enter the connection during a procedure. ANY liquid can cause the connections to short, resulting in erroneous probe recognition, temperature readings, or damage to the probe, cable, or generator.

3. **Device Recognition:** The software recognizes which type of Thermi device is connected to the generator by reading a sensor in the connector of the device. (Figure 6), and only allows selection available treatment options for the attached probe.

Figure 6: Main Selection Screen Display

The default settings may be changed from their preset values using the appropriate Up/Down buttons. Once a mode is selected, the generator begins a continuous impedance check by emitting short bursts of low-level RF power. The blue RF indicator light blinks during the impedance check. This check occurs only when the generator is idle.

Operational Mode

Percutaneous Electrode Procedures

- **WARNING:** It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- **WARNING:** To prevent injury to patients and damage to the device, please thoroughly read and understand all accessories manuals before use.

There are three operational modes of the **ThermiRF+ System** for percutaneous electrodes: ThermiTight, ThermiRase and Stim: Motor. These modes deliver RF energy controlled by Set Temp and limited by Set Time. One operational mode is reserved for the electrical stimulation of nerves, the Stim: Motor mode. It is available only from the ThermiRase mode screen. The Stim: Motor mode allows the user to control pulse width (Width) and pulse amplitude (Stim Volts). These Operational Modes are described below.

⚠ WARNING: Prior to increasing the intensity, check the adherence of the grounding pad and its connections. Apparent low output or failure of the device to function correctly at the normal operating settings may indicate faulty application of the grounding pad or poor contact in its connections.

⚠ WARNING: Failure of the radiofrequency surgical equipment could result in unintended increase of output power.

⚠**WARNING:** Expected side effects may include pain, erythema, edema, headache or nausea. Other possible side effects of RF treatments include blistering, temporary tingling and/or numbness, burn, scarring, bruising, cutaneous depressions, dyspigmentation, hyperpigmentation, ecchymosis, urticaria, altered sensation, focal linear depressions, nerve damage, purpura, platysmal ridging, induration. Also, transcient Homers syndrome, pre-vertebral hematoma, sensory loss; psoriatic rash (Kobner phenomenon), dropped head syndrome (cervical nerve treatment), spasms, disturbed balance.

⚠ WARNING: Failure to follow electrode instructions for use; or use of excessive force or torque when placing electrodes may result in tip breakage.

ThermiTight Mode

Set Temp will default to 40°C; Set Time will default to zero (display will show 0:00). In this mode (Figure 7), the **ThermiRF+ System** will automatically control power to reach and maintain the target temperature according to the selected Set Temp.

In ThermiTight Mode, the Set Temp can be set between 35 - 70°C. The Set Time can be set between 0:00 and

Operational Mode (continued)

10:00 minutes in increments of 15 seconds (0:15). The timer will begin immediately upon application of RF Power.

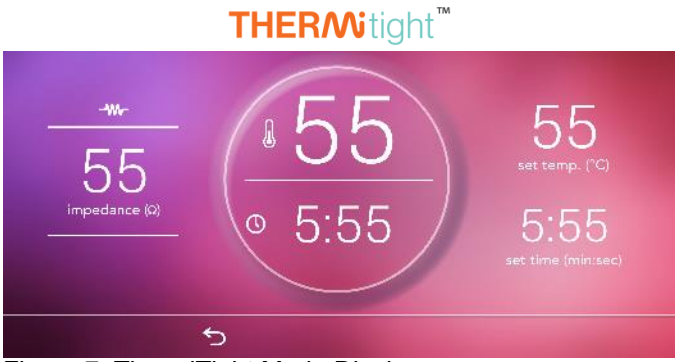


Figure 7: ThermiTight Mode Display

Note: Once a procedure is complete, the generator must be reset using the Back button soft key before a new procedure can be started.

ThermiRase Mode

Set Temp will default to 80°C; Set Time will default to 1 minute (display will show 1:00). In this mode (Figure 8), the **ThermiRF+ System** will automatically control power to reach and maintain the target temperature according to the selected Set Temp.

In ThermiRase Mode, the Set Temp can be set between 35 - 90°C. The Set Time can be set between 0:00 and 2:00 minutes in increments of 15 seconds (0:15).

Figure 8: ThermiRase Mode Display

Stim: Motor Mode

The Stim: Motor mode (Figure 9) is used for the electrical stimulation of nerves. The Stim: Motor mode is selected using the soft key under the Stim: Motor option at the bottom of the display (Figures8). This option is only available from the ThermiRase screens. Frequency will default to 2 Hz; Width will default to 1 msec; Stim Volts (V) will default to display OFF. Once the Stim: Motor Mode is activated, the output voltage always starts at 0.0.

Figure 9: Stim: Motor Mode Display

Operational Mode (continued)

Transcutaneous Electrode Procedures

⚠WARNING It is the surgeon's responsibility to be familiar with the appropriate surgical techniques prior to use of this device.

There are two Operational Modes for use with **ThermiRF+** Transcutaneous Electrodes:
ThermiVa and ThermiSmooth.

⚠WARNING Do not activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling.

⚠WARNING: Expected side effects may include pain, erythema, edema, blistering, numbness, burn. Other possible side effects of RF treatments may include blistering, temporary tingling and/or numbness, scarring, bruising, cutaneous depressions, dyspigmentation, hyperpigmentation, ecchymosis, urticarial, altered sensation, focal linear depressions, nerve damage, pupura, platysmal ridging, induration.

1. Ensure the patient grounding pad is properly positioned on the patient according to the instructions for use.
2. Plug a Transcutaneous Thermi electrode (such as the ThermiSmooth Handpiece (RFE-10-D-G3-20w, or RFDE-VA-G3-50w) into the device connection port on the front of the generator.

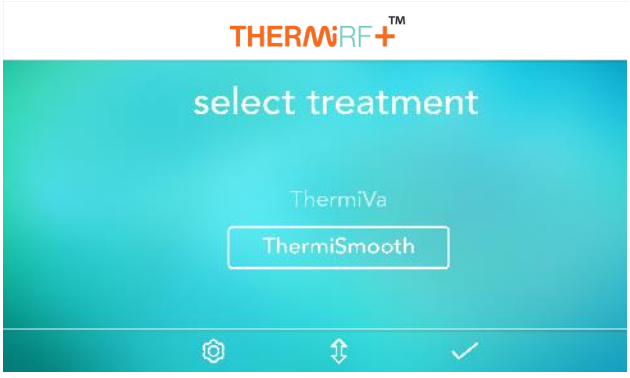


Figure 10

3. Press index down arrow softkey to select “ThermiSmooth” or “ThermiVa” to select checkbox
4. Verify that the tissue temperature is measured correctly. Check that the displayed Actual Temperature is the approximate room temperature if the probe is in free air, or surface body temperature if the probe is placed on the patient’s skin. If the actual temperature reading is incorrect see the “Troubleshooting” section.

ThermiSmooth Mode

Figure 11: ThermiSmooth Mode Display using RFE-10-D-G3-50w or RFE-15-D-G3-50w probe

Figure 12: ThermiSmooth Mode Display using RFE-10-D-G3-20w or RFE-15-D-G3-20w probe

⚠CAUTION: Incorrect Actual Temperature readings may result in improper treatment or patient burns. Verify that the Act Temp display reads the expected value (room temperature or skin surface temperature) prior to treatment. If the Act Temp reading is not accurate, check the device and connectors for damage, moisture, or contamination. Use of damaged electrode can result in burns. Clean or replace as needed, see “Cleaning and Sterilization.”

5. Verify that the impedance is being measured correctly. The device impedance should display a value between 80 - 599Ω when the RF Electrode is placed on the patient’s skin. If the device impedance does not fall in this range see the “Troubleshooting” section.

Operational Mode (continued)

6. Set the treatment temperature. The Set Temperature default is 35°C for ThermiSmooth Mode, and can be adjusted up to 47°C. The timer will begin immediately upon application of RF Power. The treatment temperature can be reduced based on patient feedback.

   Set the duration of the treatment. The default Set Time value for the ThermiSmooth Mode is Continuous (display will show 0:00). The timer can be set between 0:00 and 10:00 minutes in increments of 15 seconds (0:15).

7. To begin delivery of RF power to the probe, press the RF button or press the footswitch.

   ▲ **CAUTION:** For patient comfort and safety, while RF power is being delivered from the hand piece tip, keep the hand piece tip in motion and do not linger in any one spot too long.

   ▲ **CAUTION:** Always use a coupling gel, such as (Aquasonic Ultrasound Gel, Parker Laboratories, Inc.) on the area to be treated.

   ⚠**Warning:** ThermiSmooth operational mode allows for maximum temperature of 47°C. High temperatures may cause burn.

RF power delivery ceases when the Elapsed Time reaches the Set Time. If set to 0:00, the system is in continuous mode and will not time out. The RF power delivery can be stopped by either pressing the foot switch or pressing the RF Button.

ThermiVa® Mode

Verify that the impedance is being measured correctly. The device impedance should display a value between 80 - 599Ω when the RF Electrode is placed on the patient's skin. If the device impedance does not fall in this range see the "Troubleshooting" section.

Set Temp will default to 35°C; Set Time will default to zero (display will show 0:00). In this mode (Figure 9), the THERMI RF+™ Temperature Controlled RF System will automatically control power to reach and maintain the target temperature according to the selected Set Temp.

In ThermiVa® Mode, the Set Temp can be set between 35- 47°C. The Set Time can be set between 0:00 and 10:00 minutes in increments of 15 seconds (0:15). The timer will begin immediately upon application of RF Power.

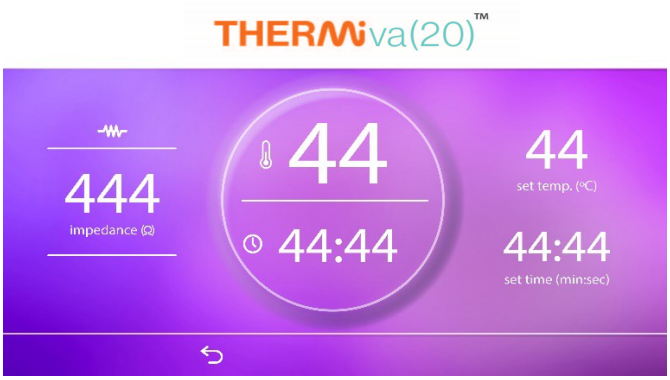


Figure 13: ThermiVa® Mode Display using RFDE-VA-G3-20w probe. This limits the output power to 20 watts

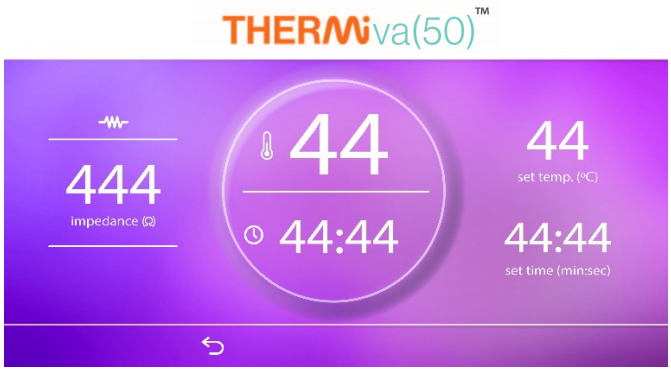


Figure 14: ThermiVa® Mode Display using RFDE-VA-G3-50w probe. This limits the output power to 50 watts

⚠**CAUTION: I**ncorrect Actual Temperature readings may result in improper treatment or patient burns. Verify that the Act Temp display reads the expected value (room temperature or skin surface temperature) prior to treatment. If the Act Temp reading is not accurate, check the device and connectors for damage, moisture, or contamination. Use of damaged electrode can result in burns. Clean or replace as needed, see "Cleaning and Sterilization."

Cleaning and Sterilization

ThermiRF+ System Generator

The ThermiRF+ system generator has no sterilization requirements. The exterior surface of the **ThermiRF+ System** generator may be wiped down with an alcohol wipe or equivalent. The unit should be disconnected from the grounded AC outlet when being cleaned. Care must be taken not to allow any liquid to pass into any electrical connections or the interior of the unit. Let the surfaces dry thoroughly before plugging in the instrument. DO NOT steam to sterilize the generator. DO NOT submerge generator for any reason.

⚠**CAUTION:** Care must be taken to avoid having moisture enter the connector, as this may affect temperature readings.

Footswitch

The footswitch may be wiped with an alcohol wipe or equivalent.

Electrode Cleaning and Disposal

Cleaning and disposal of electrodes and grounding pads according to the Instructions For Use.

Troubleshooting

Troubleshooting

If a problem is encountered while using the generator, review this section for possible solutions. If the problem cannot be solved using the information here, contact your authorized Thermi service representative.

Alarm on Power-Up

If the alarm sounds but no error code is displayed or if a non-numeric error code is displayed during generator power-up, a significant hardware failure that requires factory repair has occurred. Contact Thermi for instructions on returning the generator for repair.

If a numeric error code is displayed (Figure 11), see the “Error Codes” section for more information.

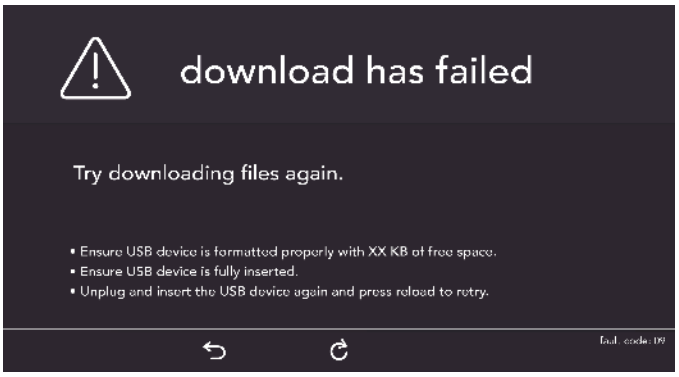


Figure 15: Numeric Error Code Example

Error Codes

The generator may display a numeric error code in the LCD screen when an error is detected. See Table 1: Error Codes for a list of codes, an explanation of the problem, and corrective actions. If the suggested action does not correct the problem or if the error code signifies a factory-serviceable problem, make note of the error code and contact your authorized Thermi service representative.

Note: Disconnecting and reconnecting a device will reset the generator to the default settings for that device.

Troubleshooting (continued)

Table 1: Error Codes

Fault #	Description
1	Remove the USB drive and reinsert. If the fault recurs, note the fault number and contact customer service.
2	Remove the USB drive and reinsert. If the fault recurs, note the fault number and contact customer service.
3	Remove the USB drive and reinsert. If the fault recurs, note the fault number and contact customer service.
4	Remove the USB drive and reinsert. If the fault recurs, note the fault number and contact customer service.
5	USB Drive is full. Remove and insert a new USB drive. If the fault recurs, note the fault number and contact customer service.
6	Low Impedance Warning. Confirm system is set up properly. If the fault recurs, note the fault number and contact customer service.
7	Electrode Expired. Electrode has already been used. Remove and insert a new electrode. If the fault recurs, note the fault number and contact customer service.
8	Electrode has bad data on it (Probe ID, Date/Time, or Cypher text). Remove and insert a new electrode. If the fault recurs, note the fault number and contact customer service.
100-150	Restart generator. If the fault recurs, note the fault number and contact customer service.

Service

Service Philosophy

There are no user-serviceable components inside the **ThermiRF+ System**. Repairs and adjustments are to be performed only by Thermi authorized service centers.

⚠**WARNING:** Do not attempt to open the back panel of the generator. This may cause serious injury and damage to the unit. It will void your warranty. If any problems are not resolved by the directions in the Troubleshooting section, please contact your authorized Thermi service representative for further assistance.

If service becomes necessary, call your authorized Thermi Customer Service representative prior to returning the device and request a Return Material Authorization (RMA) number. Your representative can also explain the available Service Replacement and Repair Programs.

Service items should be carefully repackaged and returned post-paid to Thermi. Pre-shipment pictures of the faulty device are recommended.

Note: Product returned that is found to have been serviced by an unauthorized third party repair facility and/or sterilized with a sterilization method other than one approved by Thermi will incur additional costs, regardless of warranty status.

It is not necessary to include accessory items (i.e., power cords, footswitches, etc.) when returning a device for service unless informed by Thermi Service Representative.

Electrical Interference

CAUTION: This equipment is designed and tested to minimize interference with other electrical equipment over the expected service life of this equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:

- **Reorient or relocate this equipment, the other equipment, or both.**
- **Increase the separation between the pieces of equipment.**
- **Connect the pieces of equipment into different outlets or circuits.**
- **Consult a biomedical engineer.**

Environmental Protection

CAUTION: This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

Replacing Fuses

⚠**WARNING:** To prevent electric shock, unplug the unit from the electrical outlet before attempting to replace the fuses.

⚠**WARNING:** To avoid fire hazard, use only fuses of the correct type, voltage rating, and current rating.

To inspect and/or replace fuses:

1. Unplug the power cord from the power outlet and from the generator.
2. Use a screwdriver to open the fuse compartment door on the AC receptacle and slide out the two fuse carriers (Figure 13).
3. Replace fuses. See “Technical Specifications” for replacement fuse types.
4. Reinsert fuse carriers using the arrows on the inside of the fuse compartment door as a guide.
5. Snap the fuse compartment door closed.

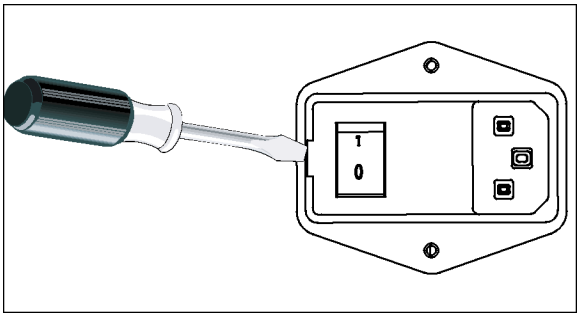


Figure 14: Rear panel fuse location

Maintenance

Generator Verification

Thermi recommends yearly verification of the calibration of the temperature and power measurement function of the generator.

⚠**WARNING:** Electrical safety testing should be performed by a biomedical engineer or other qualified person.

Replacing / Returning Worn or Defective Equipment or Parts

Contact Thermi to order a replacement footswitch, or any accessories, and for instructions on disinfection and return of worn or defective equipment or parts.

Other than fuses, the **ThermiRF+ System** has no user-serviceable parts. For service, please contact your authorized Thermi service representative.

WARNING: No modification of this equipment is allowed.

Specifications

Input Power	100 - 240V ± 10%, 50/60 Hz
Rated Power Input	190 VA
Output Power	50 watts (maximum) 100–400 Ω (RFE-10-D-G2, RFE-15-D-G2, RFDE-G3-50w) 22 watts (maximum) 40–600 Ω (RFE-10-D-G3-20w, RFE-15-D-G3-20w, RFDE-G3-20w)
Maximum Output Voltage	140Vrms RF 0-10 V Stimulate
Operating Frequency	460 kHz (±10%)
Power Delivery Modes	Stimulate, RF
Set Temperature Range	35–90°C; (+/- 3°C) this range varies for each Power Delivery Mode
Fuses	Dual fuses: T2AH 250V
Waveform	Sine wave for RF Modes Square wave for Stimulate Modes
Dimensions	5.75" H X 12.5" W X 13.0" D (146 mm X 318 mm X 330 mm)
Service Life	5 years
Weight	12.6 lbs.(5.7 kg)
Protection	Class I, Type BF Applied Part – defibrillator proof, IP11, continuous operation. This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
Controls	Line Power ON/OFF, RF On/Off, Stimulate Output, Front Panel soft keys (Start, Set Temp, Set Profile, Reset, Width, Frequency, and Mode selection).
Displays	Impedance, Actual Temp, Set Temp, Elapsed Time, Paused, Volts, Frequency
Connections	Footswitch connector, power cord connector, device connection port, grounding pad connection port.

Environmental Conditions		
	Transport and/or Storage	Use
Temperature	-20° to +60°C	20° to 35°C (+/- 2^0C)
Humidity	20–90% (no condensation allowed)	30–70%
Atmospheric Pressure	500–1060 hPa	700–1060 hPa

Specifications (continued)

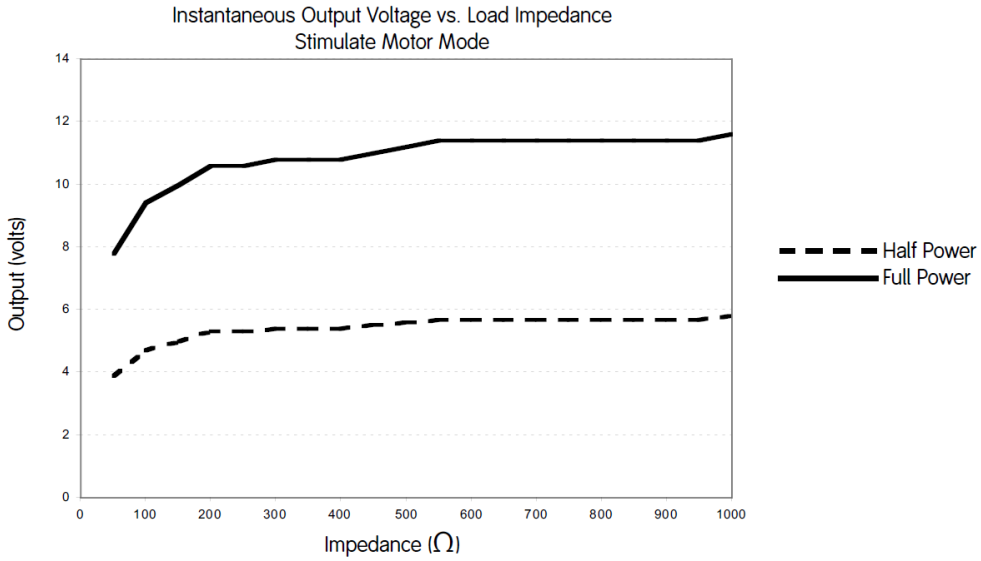
CAUTION: Inspect all components regularly for wear, to prevent burn and shock to the patient/user. Pay particular attention to potential damage to insulation, especially with universal extension cables.

CAUTION: Use only Thermi electrodes, cannulas and cables with the ThermiRF+ System generator.

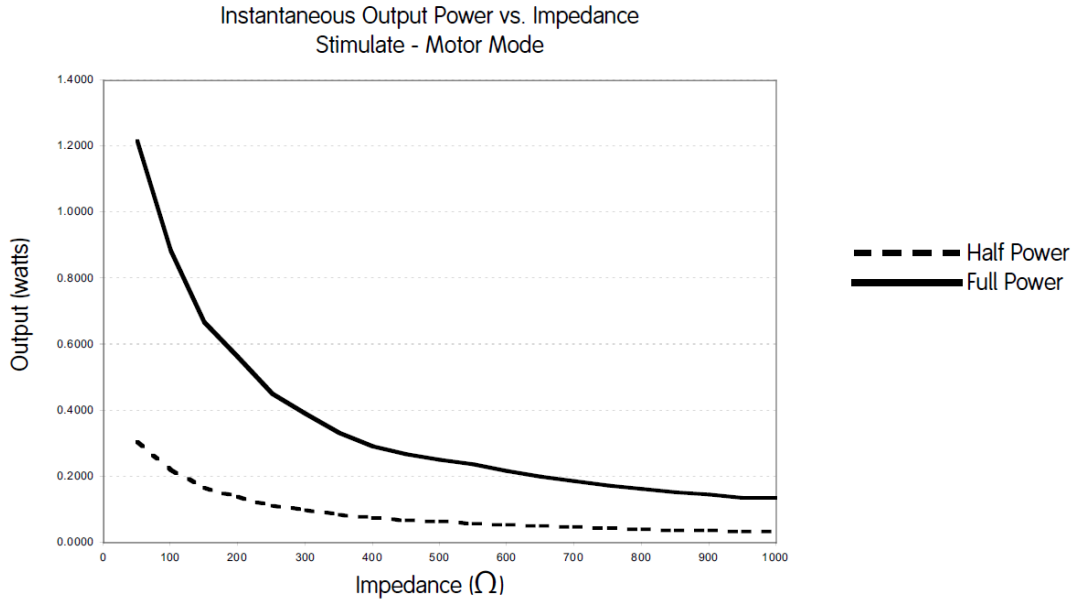
Note: Thermi devices must be used in a manner consistent with the Instructions for Use packaged with the Instructions for Use.

* Contact Thermi or visit our web site for the most current list of available products.

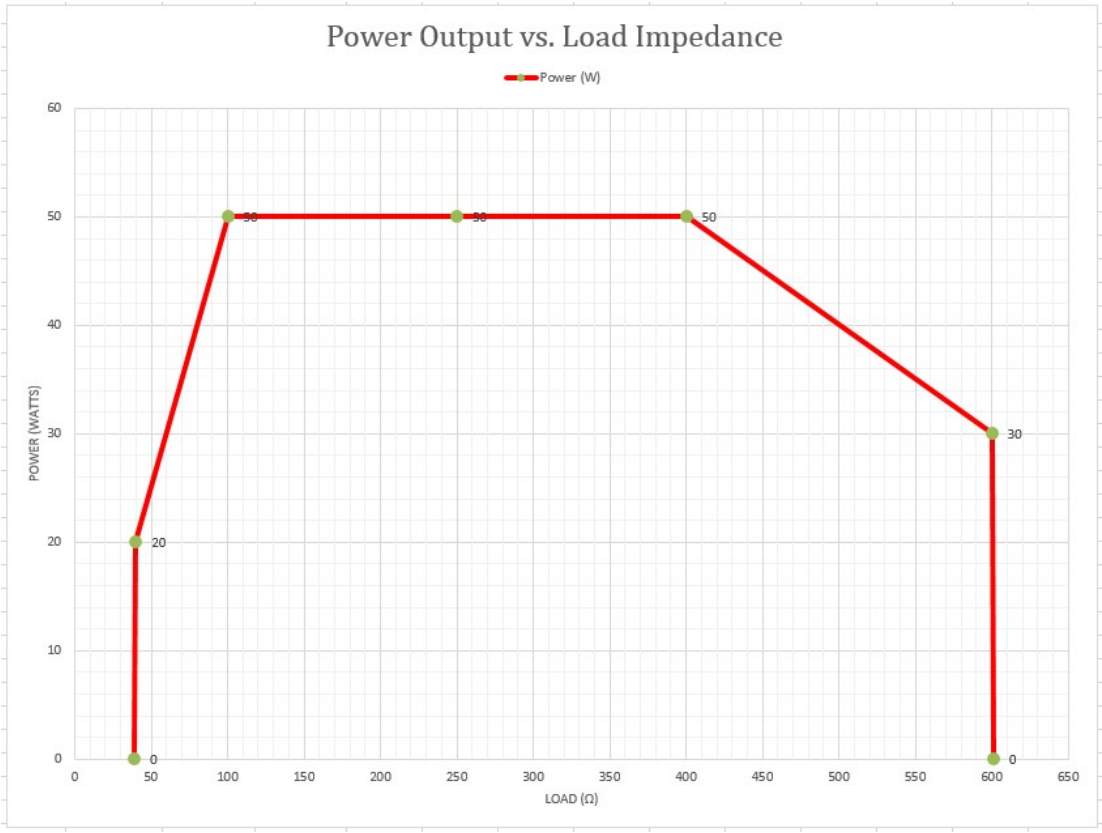
Instantaneous Output Voltage Charts



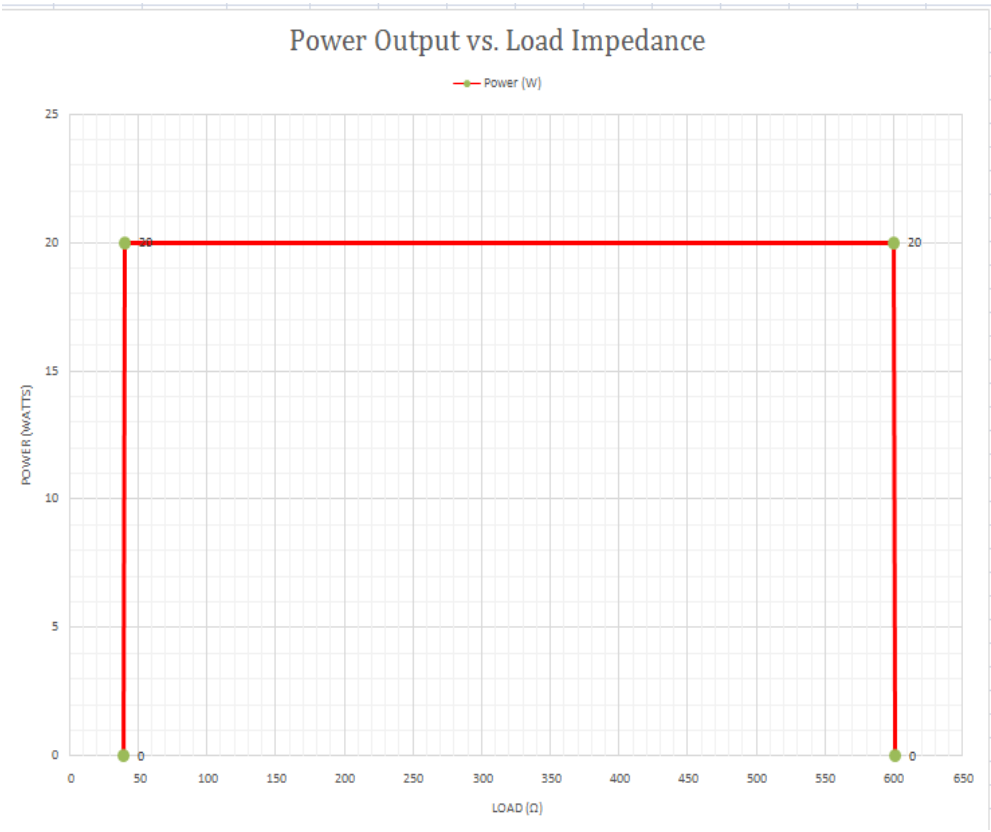
Instantaneous Output Power Charts



Instantaneous Output Charts

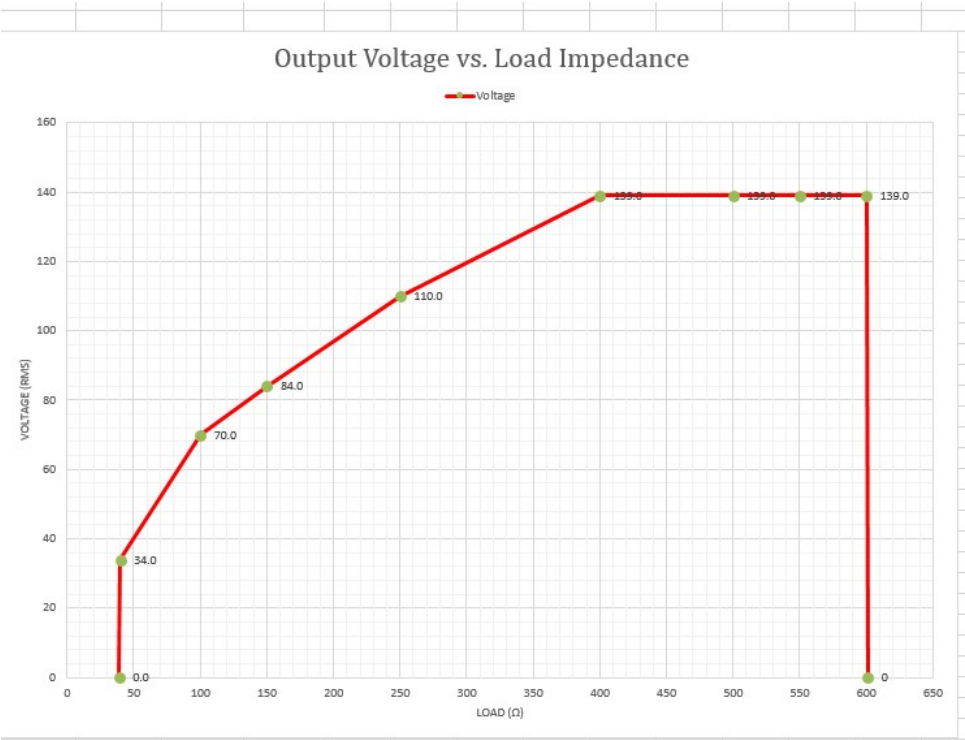


Power Output vs. Load Impedance (50-watt mode)



Power Output vs. Load Impedance (22-watt mode)

Instantaneous Output Charts (continued)



Note: Output is sinusoidal and maximum output voltage is 140 RMS (198Vpk).

Guidance and Manufacturer's Declaration – Electromagnetic Emissions and Guidance for Separation Distances

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.

The **ThermiRF+ System** is intended for use in the electromagnetic environment specified below. The customer or the user of the **ThermiRF+ System** should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
Conducted and radiated RF EMISSIONS **CISPR11**	Group 2 Class A	The **ThermiRF+ System** must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Harmonic emissions **IEC 61000-3-2**	Not applicable	The **ThermiRF+ System** is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions **IEC 61000-3-3**	Not applicable	

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

The ThermiRF+ System generator monitors temperature and impedance, automatically adjusting energy delivery to maintain Set Temperature. Because the ThermiRF+ System generator delivers high frequency energy at 460KHz up to 50W, it has been designed to operate with a high degree of immunity to EM self-Disturbances. In the presence of external EM Disturbance degradation of the performance of this equipment could result; therefore, Thermi recommends the separation distances to other equipment as follows:

Guidance and Manufacturer's Declaration Guidance for Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the **ThermiRF+ System**.

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

Rated Maximum Output Power of Transmitter W	Separation distance according to frequency of transmitter M		
	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3

100	12	12	23

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.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The **ThermiRF+ System** is intended for use in the electromagnetic environment specified below. The customer or the user of the **ThermiRF+ System** should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge(ESD) **IEC 61000-4-2**	+/- 8kV contact +/- 15kV air	+/- 8kV contact +/- 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst **IEC 61000-4-4**	+/- 2kV for power supply lines +/- 1kV for input/output lines	+/- 2kV for power supply lines +/- 1kV for input /output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge **IEC 61000-4-5**	+/- 1kV differential mode +/- 2kV common mode	+/- 1kV differential mode +/- 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field **IEC 61000-4-8**	30 A/m	30 A/m	The power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines **IEC 61000-4-11**	0 % *U*T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0° 0 % *U*T; 250/300 cycle	0 % *U*T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles Single phase: at 0° 0 % *U*T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **ThermiRF+ System** requires continued operation during power mains interruptions, it is recommended that the **ThermiRF+ System** be powered from an uninterruptible power supply or a battery.

Note: *U*T is the a.c. mains voltage prior to application of the test level.

⚠ **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 [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The **ThermiRF+ System** is intended for use in the electromagnetic environment specified below. The customer or the user of the **ThermiRF+ System** 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**	3 Vrms 150 KHz to 80 MHz 6 V ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 150 KHz to 80 MHz 6 V ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the **ThermiRF+ System**, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz 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).
Radiated RF **IEC 61000-4-3**	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	
Radiated RF Proximity fields from RF wireless communications equipment **IEC 61000-4-3**	28 V/m at 0.3 m 2 W max 380 MHz to 5.8 GHz	28 V/m at 0.3 m 2 W max 380 MHz to 5.8 GHz	Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, [a]should be less than the compliance level in each frequency range Interference may occur in the vicinity of equipment marked with the following symbol: 

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.

[a]Field strengths from fixed transmitters, such as base stations for radio, (cellular/cordless) telephones, land mobile radios, amateur radios, 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 in which the **ThermiRF+ System** is used exceeds the applicable RF compliance level above, the **ThermiRF+ System** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **ThermiRF+ System**.

[b]Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

⚠**CAUTION**: This device has been tested and verified to comply with IEC 60601-1-2 (EN 55011). This exceeds the requirements specified by FCC Part 18 for ISM equipment. This device is intended for operation in a medical facility only. Usage in a residential environment will likely cause unacceptable RF interference for which the user is held responsible.

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