thermage®

Thermage CPT™ System
Model TG-2B

TECHNICAL USER'S MANUAL

SOLTA MEDICAL®

P/N P009240-06

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CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a licensed health care professional only.

Refer to page 1 for applicability of this Technical User's Manual.

LIMITED WARRANTY

The Seller warrants to the original purchaser of this product that the product substantially conforms to its written specifications current at the date of delivery of such product, and shall perform for a period of one year from such date of delivery substantially in accordance with those specifications. The obligations of the Seller and any affiliate of the Seller under this warranty shall be limited to repair or replacement of a non-conforming product, at the option of the Seller. The above warranty is contingent upon use of the product in accordance with its intended use and pursuant to operating instructions contained in the specifications. This warranty does not cover products that have been modified without the Seller's prior approval or which have been subject to unusual physical or electrical stress. EXCEPT AS STATED ABOVE, THERE ARE NO OTHER WARRANTIES. THE SELLER EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, WRITTEN OR ORAL, WITH RESPECT TO PRODUCTS, INCLUDING WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANT-ABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE AND NON-INFRINGEMENT.

NOTICES

TRADEMARKS

Thermage is a registered trademark of Solta Medical, Inc.

PATENTS

Patents that cover the Thermage CPT System can be found at:
www.thermage.com/patents

CE 0197 (CE marking excludes the CPT system console)

Devices compliant with the European Communities Council Directive 93/42/EEC, Medical Device Directive.

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1. Introduction

1.1 Thermage CPT System Components

The Thermage CPT System described in this Technical User's Manual consists of the following:

Table 1.1 System Components and Accessories

Description	Model #
Thermage CPT Generator with Cooling System	TG-2B
Thermage CPT Standard Handpiece with Vibration	TH-4
Thermage CPT 16.0 Handpiece	TH-3
Thermage Treatment Tips (0.25 cm², 3.0 cm² and 16.0 cm²)	TTNS series
Electronic Footswitch (optional)	TW-1
Return Pad	TR-2
Return Pad Cable	TP-2
Cryogen Canister	TC-1-4 / TC-2-4
Coupling Fluid	TF Series
Skin Marking Paper	TK Series

- Software Version: Please verify software version on system home screen under the Thermage logo.
- The Thermage CPT System ('System') consists of the RF Generator / Cooling System, 16.00 cm² Handpiece ('Body Handpiece'), Standard Handpiece with Vibration ('Face Handpiece'), optional electric Footswitch, accessory cables, Return Pad, Return Pad Cable, and Treatment Tips. The components and accessories listed in Table 1.1 will also be referred to in this User's Manual as the 'System'.
- The Thermage CPT RF Generator will also be referred to in this User's Manual as the 'Generator'.
- The Thermage CPT Body Handpiece or Face Handpiece with Vibration with attached Treatment Tips will also be referred to in this User's Manual as the 'Handpieces' and / or 'Handpiece Assemblies'. They have a lifespan of 100,000 pulses.
- The Thermage Cryogen Canister will also be referred to as 'coolant canister' in this User's Manual.

This Technical User's Manual provides a description of the System, its controls and displays, and a sequence for its proper operation. This manual also supplies other information of importance to the operator (user) and is intended as a user's manual only. Do not operate the Thermage CPT System before thoroughly reading and understanding this manual.

2. Indicated Use

The radiofrequency (RF) energy delivery components of the Thermage CPT System and Accessories are indicated for use in:

- Dermatologic and general surgical procedures for electrocoagulation and hemostasis;
- Non-invasive treatment of periorbital wrinkles and rhytids including upper and lower eyelids;
- Non-invasive treatment of wrinkles and rhytids.

The simultaneous application of radiofrequency energy and skin vibration by the Thermage CPT System and Accessories are indicated for use in:

- Dermatologic and general surgical procedures for electrocoagulation and hemostasis;
- Non-invasive treatment of periorbital wrinkles and rhytids;
- Non-invasive treatment of wrinkles and rhytids;
- Temporary improvement in the appearance of cellulite;
- Relief of minor muscle aches and pains;
- Relief of muscle spasms;
- Temporary improvement of local circulation (i.e., blood circulation).

The Thermage CPT system must be operated only by trained and accredited users. Training to be performed by Solta Medical authorized personnel only.

3. Contraindications

The Thermage CPT System is contraindicated for use in patients with either an implantable pacemaker, an Automatic Implantable Cardioverter / Defibrillator (AICD), or any other implantable electrical device, as these devices may be adversely affected by radiofrequency (RF) field or current.

4. Warnings and Precautions

The safe and effective use of RF energy is highly dependent upon factors under the control of the operator. It is important that all warnings, precautions, and the supplied operating instructions be read, understood, and followed before and during use.

4.1 Warnings

4.1.1 The Thermage RF system has been studied in US clinical trials for the treatment of wrinkles and rhytids. Use of the System for indications other than those expressed in this manual are considered "off-label".

4.1.2 The user must be aware that failure of the System could result in an unintended increase in output power.

4.1.3 Remove all of the anesthetic material and / or other substances (cosmetics, lotions, etc.) from the surface of the skin at the treatment site. During the treatment process there must be no material, other than Thermage Coupling Fluid between the surface of the Treatment Tip and the patient's skin.

4.1.4 Thoroughly remove beard stubble prior to treatment.

4.1.5 Treatment in areas containing superficial and / or other facial nerves may be more sensitive and susceptible to irritation. The operator should pay special attention to patient heat feedback and consider reducing the Generator Treatment Level setting when treating these areas.

4.1.6 Caution should be used when treating skin directly over metal dental work. In particular, when treating over metal dental work of large surface areas (such as crowns, braces, implants, etc.) consideration should be given to inserting dry absorbent cotton roll(s) between the dental work and the inner cheek area to prevent radiofrequency heating of the metal materials. Such heating may result in burns to the skin, dental pain, and / or damage to the dental work.

4.1.7 Do not use the System near critical life-support equipment. Radiofrequency electromagnetic emissions can interfere with the operation of electronic equipment.

4.1.8 Caution should be used when selecting treatment levels. The risks of adverse outcomes may be associated with elevated treatment levels.

4.1.9 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.

4.1.10 The use of accessories, transducers and cables other than those specified could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Thermage CPT system and result in improper operation.

4.1.11 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 Thermage CPT system, including cables specified by Solta. Otherwise, degradation of the performance of this equipment could result.

4.2 Precautions

General

4.2.1 Solta has not studied the use of the Thermage CPT system in humans over dermal fillers.

4.2.2 The use of the Thermage CPT System on the following patient populations is unstudied and unknown:

- Pregnant and breast-feeding
- Diabetic
- Auto-immune disease (e.g. lupus)
- Herpes simplex
- Children
- Epilepsy

4.2.3 An Eyes by Thermage™ treatment requires use of PLASTIC ocular shields. DO NOT use metal shields. Follow standard precautions for the placement and use of the eye shields.

4.2.4 The Thermage CPT system does not allow for vibration during an Eyes by Thermage™ treatment. The System disables vibration when the 0.25 cm² treatment tip is attached to the Standard Handpiece. Do not attempt to use the 3.0 cm² treatment tips around the eye or on the eyelid with vibration. Vibration may cause displacement of the ocular shields; resulting in increased risk of corneal abrasions or ocular damage.

4.2.5 Allow the System to equilibrate to room temperature for a minimum of four (4) hours if the System has been stored at temperatures outside the operational temperature range—below 15°C (59°F) or above 25°C (77°F).

4.2.6 Use only Solta-supplied Accessory Cables with the System.

4.2.7 Do not use this System in the presence of flammable anesthetics, other flammable gases, near flammable fluids (e.g. skin preparation agents and tinctures), flammable objects, or with oxidizing agents. Observe appropriate fire precautions at all times.

4.2.8 Allow flammable agents used for cleaning, disinfecting, or as solvents to evaporate completely before use of the equipment or application of RF energy.

4.2.9 Do not use this device in oxygen-enriched atmospheres or in the presence of nitrous oxide (N_2O).

4.2.10 Prior to delivery of RF energy, apply a generous amount of Thermage Coupling Fluid to the targeted treatment area. Do no use other fluids such as irrigation solutions (e.g. saline, Ringer's lactate, sterile water).

4.2.11 The activation tone and lights on the Thermage CPT System are important safety features. Do not obstruct the visual indicators or disable the audible tone.

4.2.12 During treatment, precautions must be taken so the patient cannot come into contact with earthed metal parts or parts with appreciable capacitance to earth (e.g. operating table supports, etc.). The use of antistatic sheeting is recommended for this purpose.

4.2.13 The System operator should avoid direct contact with the patient while the RF energy is being applied. Use of insulating gloves is recommended to prevent inadvertent electrical shock.

4.2.14 Use only Solta-supplied components and accessories.

4.2.15 Do not wrap instrument cables around metal objects as doing so may induce hazardous currents.

4.2.16 Skin to skin contact (e.g. between a patient's arms and body) should be avoided. The insertion of dry gauze between adjacent body parts is advised.

4.2.17 Place all monitoring electrodes, such as for an electrocardiogram (ECG, EKG), as far as possible from the treatment area when the System and physiological monitoring equipment are used simultaneously on the patient. The use of monitoring systems incorporating high frequency current-limiting devices is recommended.

4.2.18 Interference produced by the System may adversely influence the operation of other electronic equipment.

4.2.19 Verify that the reusable cables and Handpieces have been cleaned prior to each use.

4.2.20 After use, Thermage Treatment Tips, Skin Marking Paper, and Return Pads should be treated as biohazardous waste and disposed of in accordance with applicable laws and regulations.

4.2.21 Keep Treatment Tips evenly in contact with treatment area skin throughout the treatment application. The Thermage CPT System senses contact with the skin and deactivates the RF energy if contact is lost. When vibration is on, the System senses contact with skin in the same way as when vibration is off.

RF Generator

4.2.22 The AC mains power cord of the RF Generator must be connected to a properly grounded receptacle. Extension cords and / or adapter plugs must not be used.

4.2.23 Unauthorized or improper service, repair or modifications performed by unauthorized personnel may pose a hazard and will invalidate any warranty agreement.

Skin Marking Grid Paper

4.2.24 Use in a well-ventilated area.

4.2.25 For use only with specified Thermage Treatment Tip.

4.2.26 Avoid eye contact with alcohol. If irritation occurs, flush eye(s) with water for 5 minutes.

4.2.27 Flammable agents used for cleaning or disinfecting or as solvents should be allowed to evaporate before application of RF Energy.

4.2.28 For use only with Thermage Systems.

4.2.29 Single-patient-use only. Do not reuse skin marking grids once they have been applied to skin.

4.2.30 Do not use if the paper is damaged.

Return Pad

4.2.31 The Return Pad is the RF Generator's Neutral Electrode. Therefore, it is an integral part of the Thermage RF energy delivery System. The proper use and placement of the Return Pad are key elements in the safe and effective utilization of this device. The following precautions are necessary to prevent burns at the Return Pad (Neutral Electrode) site.

4.2.32 The Return Pad is single-patient use only. Reusing the Return Pad may result in poor contact quality, patient burns, and / or poor system performance.

4.2.33 The Return Pad was designed to be used with Thermage Systems only. Use only a Solta-supplied Return Pad.

4.2.34 Do not use a Return Pad on patients with known sensitivity to acrylates.

4.2.35 Do not cut or modify the Return Pad or its connector in any way.

4.2.36 Periodically inspect the Return Pad Cable for any signs of damage or wear that may have exposed wiring or produced other defects and each that the Return Pad connects are intact.

4.2.37 To properly place a Return Pad before the treatment:

- 4.2.37.1 Select a well vascularized area that is free of hair and tattoos, has minimal curvature, and is appropriately distanced from the treatment area. Avoid placement over scars, breached or inflamed skin, fatty tissue, bony prominences, metal prosthesis, and where fluids pool. Do not place the Return Pad on the shoulder, neck, or head region.
- 4.2.37.2 To ensure better adherence, cleanse the area with a 70% alcohol solution and allow it to completely dry.

4.2.37.3 Inspect the cable and connector for any signs of damage or wear that may have exposed wiring or other defects.

4.2.37.4 Inspect the Return Pad package. Do not use if the package is opened, damaged, or expired.

4.2.37.5 Peel off the blue plastic backing. Place the Return Pad with its entire area adhering to the patient's skin with the tab pointing away from the treatment area. Avoid touching the patient contacting region of the Return Pad. The entire area of the Return Pad must be in full contact with the patient's body. Failure to achieve good skin contact by the entire adhesive surface may result in a burn or poor system performance.

4.2.37.6 To prevent patient burns at the Return Pad application site due to improper adhesion, verify that the Return Pad cable is not pulling on the Return Pad with more force than the cable's own weight.

4.2.37.7 Insert the Return Pad tab into the connector. Close the clamp until a click is heard. Tug lightly to verify the connection is secure. When placed correctly, the blue tab at the neck of the Return Pad should be only partially visible.

4.2.37.8 When positioning the patient for treatment, check and verify that no object is placed under the connector in a manner such that the Return Pad tab is lifted from the skin.

4.2.38 During the treatment:

4.2.38.1 Attention should be given to the Return Pad for signs of heating. The patient should feel no sensation of heat at the Return Pad site during tuning or treatment. If the patient reports feeling heat or electrical stimulus at the site, immediately discontinue RF delivery and check the Return Pad's placement and all cable connections. Do not continue treatments until this condition is corrected. (Refer to Section 4.2 – Precautions).

4.2.38.2 The Return Pad must be kept dry. Avoid contaminating the Return Pad connector with Coupling Fluid or other types of creams or lotions. A patient's excessive sweating may warrant replacing the Return Pad during the treatment.

4.2.38.3 Prior to increasing treatment level settings, check that the Return Pad has full contact with the patient's skin. Check cables and connectors, and inspect active accessories as well.

4.2.38.4 If the patient is repositioned during treatment, always verify the Return Pad maintains contact to the skin in its entirety and the cable connections are not compromised before resuming treatment.

4.2.38.5 Do not relocate the Return Pad after initial application. Use a new pad if relocation is needed.

4.2.38.6 Periodically check that the Return Pad Cable for any signs of damage or wear that may have exposed wiring or produced other defects and check that the Return Pad cable connections are intact.

4.2.38.7 Poor Return Pad contact may lead to low RF delivery and / or a system error condition.

4.2.39 At the end of the treatment:

4.2.39.1 Disconnect the tab from the connector. Gently remove the Return Pad and discard it. Do not reuse it, as the Return Pad is designed for single patient use. Reuse of return pads may lead to reduced efficacy or increased sensation of heating. See section 4.2.37.1.

4.2.39.2 Inspect the Return Pad site on the patient to ascertain whether any skin compromises occurred during the treatment.

Coupling Fluid

4.2.40 Use coupling fluid with only Thermage Systems.

4.2.41 Single-patient-use only. Do not reuse. Reuse of coupling fluid may result in poor system performance.

4.2.42 Do not use if the bottle is opened or damage.

Cryogen and Cryogen Canister

4.2.43 Avoid breathing high concentrations of cryogen vapor. Deliberate inhalation of the vapor will cause asphyxiation. Death can occur without warning.

4.2.44 **FIRST AID:** If overcome by vapors, move to fresh air. For skin or eye contact, thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical attention.

4.2.45 Direct contact with liquid cryogen may cause tissue to freeze. Avoid contact with eyes and skin when handling cryogen. Wear protective goggles and gloves when handling open Cryogen Canisters.

4.2.46 Do not store the canister near heat or open flame.

4.2.47 Do not puncture, incinerate, or expose the canister to temperatures above 49°C (120°F).

4.2.48 Prolonged exposure to sunlight or other sources of heat may cause the canister's content to vent or burst.

4.2.49 Do not leave Cryogen Canisters in vehicles in which temperatures may rise above 49°C (120°F).

4.2.50 Keep canisters out of the reach of children.

4.2.51 Remove all cryogen from the System prior to transportation. A 'flushing' sound may be heard during coolant release. Parts of the System may be very cold—use caution and avoid contact with these parts. See Section 11.2.

Warning Non-Sterile Treatment Tip Cleaning - User

4.2.52 Non-Sterile Treatment Tips are provided clean by the manufacturer; however, it is the responsibility of the user to clean the tip before treatment use. The tip should be wiped with 70% alcohol (preps) and inspected for debris and other contamination.

4.2.53 Treatment Tips are for single patient use only. Do not reuse. Multiple patient use creates a risk of cross contamination of microorganisms from one patient to another.

Warning: Maintenance is not to be performed while system is in use with the patient.

Follow local governing ordinances and recycling plans regarding the recycling or disposal of this equipment and its accessories.

5. Possible Adverse Patient Reactions and Management Options

5.1 Surface Irregularities

Surface Irregularities are variously described as (localized) "small dents in the surface of the skin", "rippling", "ridging", "waffle patterns", or "fat loss" (covering a larger surface area). Frequently, surface irregularities are not evident immediately post-treatment, but show up later (1 or more months post-treatment). In most cases Solta recommends that surface irregularities be monitored for a period of six months post onset. Tissue fillers may be considered as a treatment option if the condition does not resolve on its own.

5.2 Altered Sensation

Altered sensation has been described as "numbness", "tingling" or "temporary paralysis". Altered sensation typically resolves in a short period of time, but infrequently may persist up to several weeks. This adverse event is rare and, as is the case with an invasive face-lift procedure, resolves over time without intervention.

5.3 Burns, Blisters, Scabbing, and Scarring

The procedure may produce heating in the upper layers of the skin, causing burns and subsequent blister and scab formation. There is a small chance of scar formation. Application of topical steroidal or antibiotic preparations may be of benefit. In the rare instance of a burn that results in a scar, the scar will probably be very small and respond readily to removal with a laser device.

5.4 Lumps / Nodules

Reports of sub-cutaneous "Lumps" or "Nodules" occurring primarily in the neck area may occur. It typically self-resolves within 1 or 2 weeks without adverse sequelae.

5.5 Pigment Changes (Focal)

Cases of hyperpigmentation usually resolve over the course of time (within several months).

5.6 Bruising

Bruising may occur in rare cases and typically dissipates within several days. Bruising may be more typically associated with the use of some injected anesthetic agents (e.g. nerve blocks).

5.7 Erythema / Blanching

Erythema / blanching may occur in mild form and typically resolve within a few hours. However, on rare occasions, erythema has been reported to last longer (up to several weeks). Blanching usually resolves within twenty-four (24) hours.

5.8 Swelling (Edema)

Swelling may occur and typically resolves within 5 days, but can persist up to several weeks. Application of cold compresses or gels immediately following the treatment may help to reduce the occurrence of this event.

5.9 Mild / Moderate Pain During Treatment (Common and Expected)

Typically, the discomfort is temporary during the procedure and localized within the treatment area. Rarely, patients have reported transient aching in the treatment area lasting up to several months.

5.10 Urticaria (Itching)

There have been occasional reports of a mild to moderate, transient itching sensation in the treatment area. Application of over-the-counter topical preparations may be helpful in relieving the symptoms.

5.11 Herpes Simplex Virus

Herpes simplex eruption may result in rare cases in a treated area that has previously been infected with the virus. Reactivation of HSV is generally thought to occur most commonly in the perioral and genital skin areas after various stimuli.

6. Thermage CPT System

Inspect the System for any signs of physical damage to the front panel, chassis or cover, and Handpieces (refer to Figure 6.1 - Thermage CPT System). Inspect the Handpieces and return pad cables for possible damage to their insulation. The user is advised to perform thorough, periodic inspections of the System and its accessories.

If any physical damage is found, **DO NOT USE THE SYSTEM**. Contact Solta Medical, Inc., Customer Service at (877) 782-2286 to request a replacement.

Recommended ESD Training and Precautionary Procedures

Prior to assembly, install or interconnection of the Thermage CPT System, it is recommended that any staff (i.e., biomedical engineers and health care staff) that could touch connectors identified with the ESD warning symbol undergo ESD training. At minimum, ESD training should include an introduction to the physics of electrostatic charge, the voltage levels that can occur in normal practice and the damage that can be done to electronic components if they are touched by an operator who is electrostatically charged. Further, an explanation should be given of methods to prevent build-up of electrostatic charge, and how and why to discharge one's body to earth or to the frame of the equipment or system, or bond oneself by means of a wrist strap to the equipment or system or to earth prior to making a connection. Finally, staff must be made aware that accessible pins of connectors identified with the ESD warning symbol should not be touched with the fingers or with a handheld tool unless proper precautionary procedures have been followed.

6.1 Preparing the System for Use

Provide at least 10 inches (25 cm) space around the back, sides and top of the System for convective cooling. Under continuous use for extended periods of time, it is normal for the top and rear panels to become warm.

6.2 System AC Mains Power Cord

The System is shipped with an approved, hospital-grade AC mains power cord. Do not use extension cords or three-to-two-prong adapters. The AC mains power cord assembly should be periodically checked for damaged insulation or connectors.

6.3 System Cleaning

Clean the System only when it is unplugged from the mains power source. A 70% isopropyl alcohol solution or damp cloth may be used to clean the System cover, front panel, and AC mains power cable. Allow isopropyl alcohol solution to evaporate before using the System. Do not allow fluids to enter the chassis. Do not spray or pour liquids directly on the unit.

Figure 6.1 Thermage CPT System

6.4 System Controls, Displays, and Indicators

Figure 6.2 shows the Thermage CPT System front panel controls and indicators. Table 6.1 provides a description of the System buttons and their functions.

Figure 6.2 Thermage CPT System Front Panel

Table 6.1 System Buttons

	**Treatment Level Knob** Increases or decreases the value displayed in the on-screen Treatment Level window by rotating the knob clockwise or counter clockwise, respectively. The Treatment Level increases or decreases in increments of 0.5 from 0.5 to 9.5.
	**[ADJUST] Button** The function of this button depends on the system mode. To adjust the Treatment Level and set the level, press [ADJUST], set the Treatment Level desired, then press [CONTINUE] to confirm the level. Pressing and holding the [ADJUST] button at System startup, or when READY or READY TO TUNE, places the System into SYSTEM TOOLS mode.

	**[CONTINUE] Button** The function of this button is dependent upon the System mode. On-screen instructions will prompt the operator to press the [CONTINUE] button, if required.

Figure 6.3 shows the System's front panel. Tables 6.2 and 6.3 show the System's front panel display indicators and system indicators, respectively.

Figure 6.3 Front Panel Display

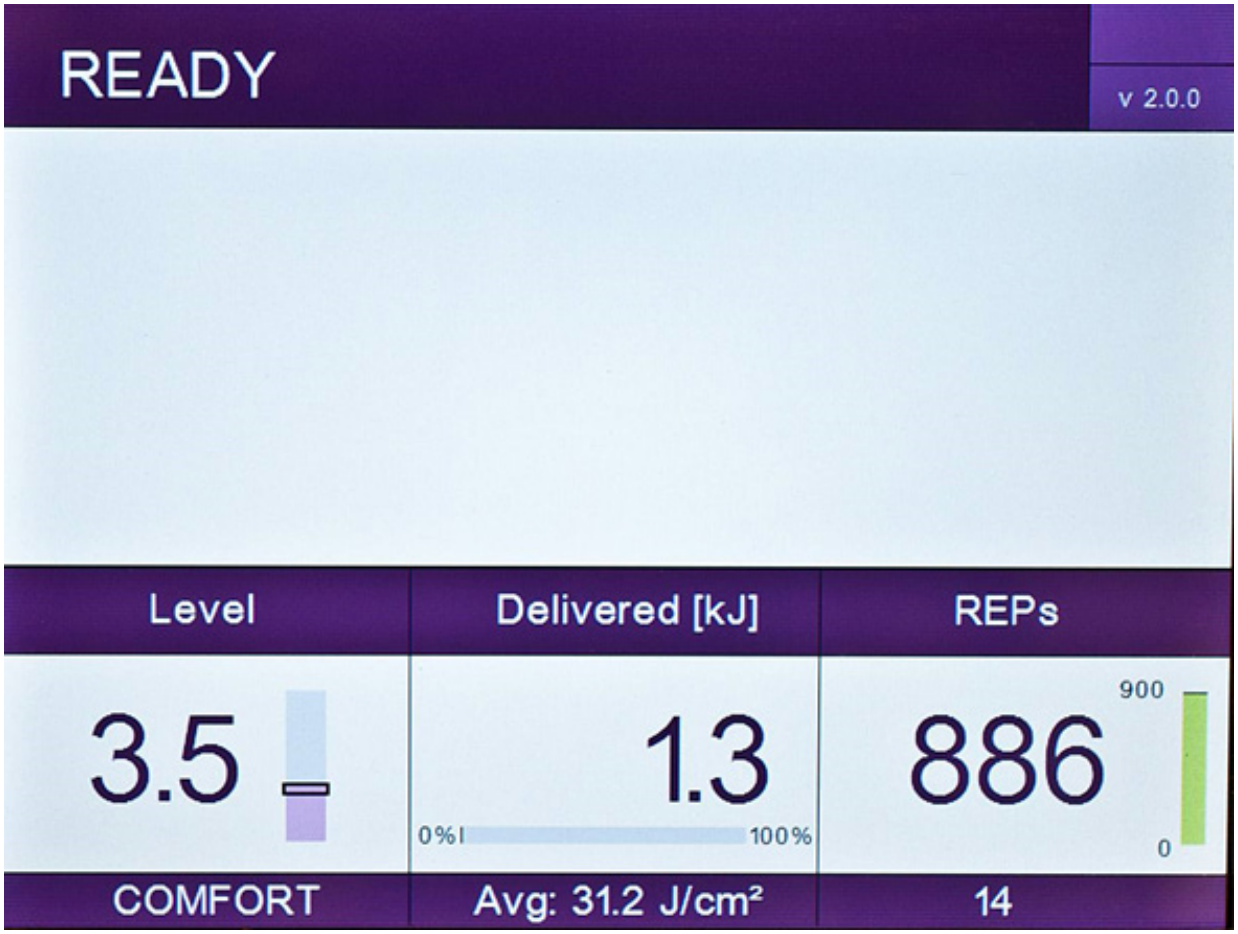
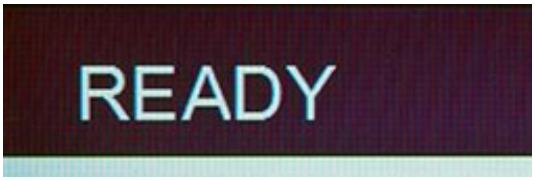


Table 6.2 Front Panel Display Indicators

	**System Status Display** Indicates the current status of the System and provides step-by-step instruction on how to proceed with the treatment. Text in the upper left corner of the screen indicates the status (e.g. READY, ACTION REQUIRED, etc.). Events / Alerts will appear in black text in the middle of the screen. Text will change to grey when the event has cleared and READY will re-appear in the upper left corner of the screen.
	**Level Display** **Displays the selected Treatment Level.** For each Treatment Tip type, there are pre-selected combinations of Power, Energy, Current, Time and Cooling parameters that correspond to each Level. Higher numbers correspond to increased Power and Energy. Refer to the Treatment Level Settings section. The colored bar next to the energy level is a visual aid only and does not correlate to actual tissue temperature.
	**Energy Delivered Display** During and after the treatment cycle, displays the total energy delivered in kJ and per square centimeter. **Avg:** This figure represents the average energy density (in Joules per cm²) delivered per pulse over the course of the treatment.
	**Comfort** The word "Comfort" will appear when the vibratory element of the Handpiece is enabled.

 	**Tip Summary Display** Displays a summary of the treatment level parameters for the tip that is currently in use. The parameters are presented in both text and graphics. Summary screens can be accessed both during and after treatment by pressing the CONTINUE button. Press CONTINUE once to access TIP SUMMARY 1 and twice to access TIP SUMMARY 2.

Table 6.3 Front Panel System Indicators

Graphic	Description
	**POWER LED** This green indicator illuminates when the System is powered ON.
	**Fault LED** This red indicator illuminates when the System is in the FAULT (error condition) state.

6.5 Thermage Handpiece Assemblies

The Thermage CPT Body Handpiece (TH-3) and Face Handpiece with Vibration (TH-4) are used to deliver RF energy for selective coagulation of tissue while conductively cooling the epidermis.

Both Handpieces are provided with the System and both should be readily available during treatment.

Each Handpiece Assembly consists of two components: the Handpiece and the selected Thermage Treatment Tip. A Thermage Treatment Tip must be attached to the Handpiece before using the System. The 0.25 cm² and 3.0 cm² Treatment Tips attach to the Face Handpiece with Vibration and the 16.0 cm² Treatment Tip attaches to the Body Handpiece.

Note: The Handpiece Assembly contains delicate components. Do not drop the Handpiece Assembly. Do not use a damaged Handpiece Assembly. The user should not cover air holes when using the Handpiece.

Note: Each handpiece type has a lifespan of 100,000 pulses. The System will issue an alert to the user that the handpiece is nearing the 100,000 pulse limit (see E220 in Section 11.1.2) at every system startup when the affected handpiece is attached. The first alert will occur at 95,000 pulses. Once the limit has been reached, the system will display "Handpiece expired" when the Handpiece is attached to the system and will need to be replaced with another handpiece.

The Body Handpiece and Face Handpiece with Vibration are individually packaged and labeled. Both are reusable and non-sterile. The Handpieces must be cleaned prior to each use. Do not sterilize the Handpieces. Store the Handpieces in a cool, dry place.

When using the Face Handpiece with Vibration, the user selects one of three Vibration Intensity settings: low, medium, and high. Higher intensity results in increased vibration of contacted tissue. Vibration should be adjusted based on patient comfort and preference.

Warning – Potential Overheating: If the Handpiece becomes excessively hot, discontinue its use and call Solta Medical Customer Service or your local authorized Solta Medical Representative before any further use of the Handpiece. Under normal operating conditions, a Handpiece will become warm, but a continuous increase in temperature is abnormal and could cause injury.

Figure 6.4 Thermage CPT Face Handpiece

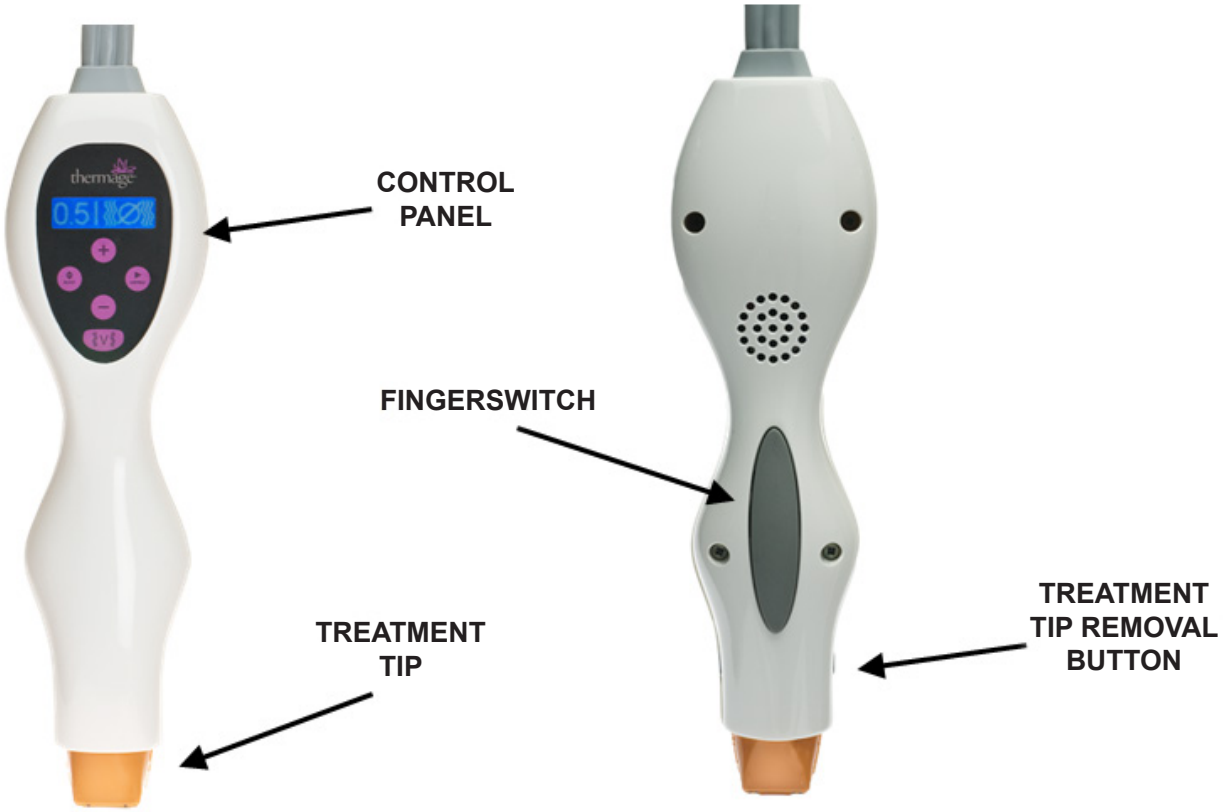
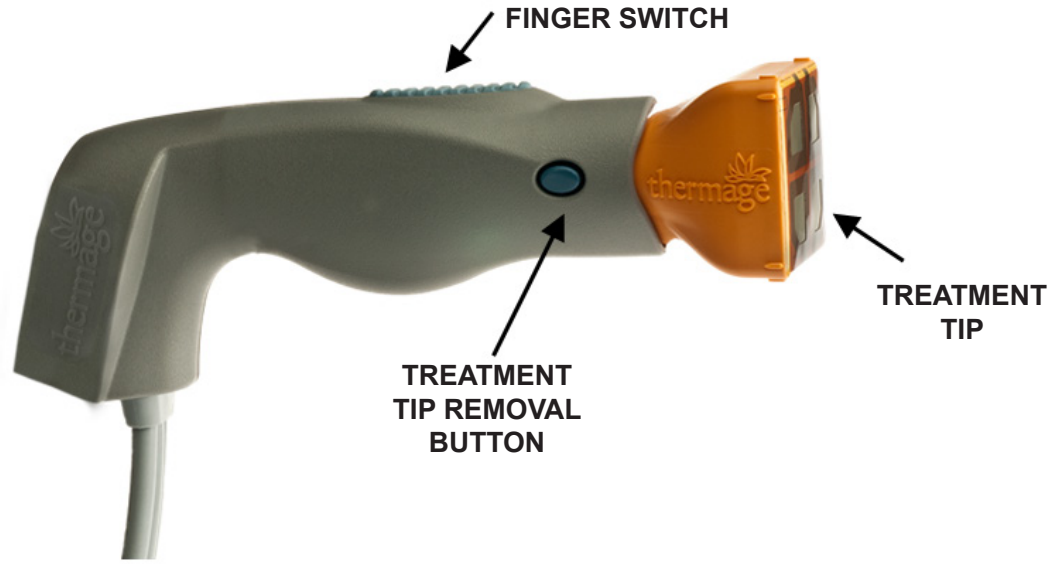


Figure 6.5 Thermage CPT Body Handpiece



6.6 Handpiece Cleaning Instructions

Only clean Handpieces when they are not connected to the System. A 70% isopropyl alcohol solution or damp cloth may be used to clean the Handpieces. Allow the isopropyl alcohol solution to evaporate before using the Handpieces.

Do not spray or pour liquids directly onto the Handpieces. Do not allow fluids to enter the Handpiece casing.

Note: The Handpieces cannot be sterilized. Be sure that the reusable cable and reusable Handpieces have been cleaned prior to use. All listed cleaning methods are recommended by Solta Medical for compatibility with product materials, not for biologic effectiveness.

6.7 Thermage CPT Treatment Tips

Inspect the treatment tips for any signs of physical damage prior to treatment. If any physical damage is found, **DO NOT USE THE DAMAGED TIP** and replace it before initiating any treatment. Contact Solta Medical, Inc., Customer Service at (877) 782-2286 to request a replacement.

Thermage Treatment Tips are provided in Non-Sterile configuration.

The Non-Sterile Treatment Tips are supplied in a clean packaging. Prior to commencing treatment, wipe the Treatment Tip surface with 70% alcohol (preps).

The Non-Sterile Treatment Tips are designed for single patient use only. Do not reuse or reprocess. Reuse or reprocessing may compromise the structural integrity of the device and / or lead to device failure. Reuse or reprocessing may also create the potential risk of cross contamination of biological agents from one patient to another.

The 0.25 cm², 3.0 cm², and 16.0 cm² Treatment Tips are designed for efficient treatment of small and large areas.

<u>0.25 cm² and the 3.0 cm² Treatment Tips: Attach to the **Face** Handpiece:</u>

- The 0.25 cm² Treatment Tip may be used for precise treatments of small areas, such as when performing "Eyes by Thermage" treatments. The 0.25 cm² Treatment Tip may <u>not</u> be used with vibration.
- The 3.0 cm² Treatment Tips may be used to treat a wide range of surface areas and may be used with vibration.

<u>16.0 cm² Treatment Tip: Attach to the **Body** Handpiece:</u>

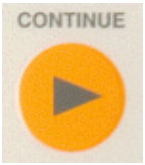
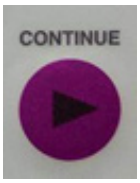
- The 16.0 cm² Treatment Tip attaches to the Body Handpiece for efficient treatment of larger areas.

6.8 Handpiece Assembly Controls

See Figure 6.6 and Table 6.4 for the locations and descriptions of the Handpiece control buttons. The same Handpiece Control Buttons are found on the Face Handpiece with Vibration and the Body Handpiece with the exception of the vibration button, which is found only on the Face Handpiece.

Figure 6.6 Handpiece Control Buttons

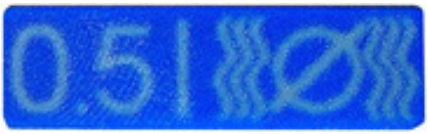
Table 6.4 Handpiece Control Buttons

Body	Face	
		**Finger Switch** Depressing and holding the Finger Switch allows the operator to initiate the ACTIVE mode, without use of a Footswitch. Releasing the Finger Switch terminates the ACTIVE mode and will interrupt RF delivery.
		**Treatment Level Increase Button** Increases the value displayed in the on-screen Treatment Level window when the System is in ADJUST LEVEL mode. **Treatment Level Decrease Button** Decreases the value displayed in the on-screen Treatment Level window when the System is in ADJUST LEVEL mode.
		**[ADJUST] Button** The function of this button depends on the System mode. To adjust the Treatment Level and set the level: press [ADJUST], set the Treatment Level desired, and then press [CONTINUE] again to confirm the Treatment Level. Pressing and holding the [ADJUST] button at System startup or when READY or READY TO TUNE loads the SYSTEM TOOLS Screen.
		**[CONTINUE] Button** The function of this button depends on the current System mode. Text on the screen will indicate the current state or operator action required. In most cases, pressing the CONTINUE button twice will load the TIP SUMMARY page.
Not Available on This Handpiece		**Vibration** When using the Face Handpiece, the operator must ADJUST VIBRATION by pressing the Vibration Button on the Handpiece. The Vibration button allows the operator to set the desired Vibration Intensity Level (LOW, MEDIUM, or HIGH). The default state is OFF. By pressing the Vibration button once, Vibration will be set to the LOW setting. Pressing the Vibration button a second time will set Vibration to the MEDIUM setting. Pressing the button a third time will set Vibration to the HIGH setting. Pressing the Vibration button a fourth time will turn the vibration off. After setting the Vibration Intensity Level, the operator must then press [CONTINUE] on either the front panel or on the Handpiece before commencing patient treatment.

6.9 Indicators for the Face Handpiece

Figure 6.7 shows the Face Handpiece with Vibration's indicators.

Figure 6.7 Face Handpiece: Indicators, Treatment Level I Vibration Setting



7. Thermage Accessories

7.1 Footswitch (optional)

Use of the Thermage Footswitch (TW-1) allows the operator to initiate or terminate the ACTIVE mode without pressing the Handpiece Finger Switch. Pressing the Footswitch changes the System mode from READY to ACTIVE in preparation for RF delivery. A release of the Footswitch will cause the System to exit the ACTIVE mode and return to the READY mode. Release of the Footswitch will also interrupt RF delivery.

Initiation or termination of the ACTIVE mode can also be performed with the Handpiece Finger Switch. Actions performed by the Handpiece Finger Switch and the Footswitch are interchangeable.

A mild detergent and damp cloth may be used to clean the Footswitch and guard.

The Footswitch cannot be sterilized.

7.2 Return Pad

Use only Thermage Return Pad (TR-2) with the Thermage Return Pad Cable (TP-2 as accompanied with your system).

The Return Pad is a disposable, 20 sq. inch (130 cm²) dispersive electrode that completes the circuit for the RF Energy. The system monitors the contact quality of the Return Pad and halts treatment if a condition is present that may lead to a hazardous condition. The Return Pad is intended for single patient use only. It does not need to be cleaned prior to use. The Return Pad is a non-sterile device.

7.3 Cryogen Canister

Use only a Solta-supplied Thermage Cryogen Canister (TC-1-4 / TC-2-4). The Thermage Cryogen Canister is disposable, does not require cleaning, and is non-sterile.

Each radiofrequency energy pulse (REP) reduces the volume of cryogen in the canister. The number of REPs delivered varies widely (100-2000) based on the size and cooling profile of the Treatment Tip in use. Thus, a Cryogen Canister's contents will be depleted more rapidly for a 3.00 cm² or 16.00 cm² tip than for a 0.25 cm² tip. The reduction in cryogen volume is also more rapid for higher level settings than for lower settings.

8. Thermage CPT System Setup Instructions

8.1 Installing System Accessories

8.1.1 Patient Data Card Installation

The System is shipped with a Patient Data card in the SD card slot. A second Patient Data card is attached to the inside of the System's front panel. The Patient Data card allows Solta personnel to analyze treatment data. Prior to powering ON the System, ensure that this card is installed in the SD card slot. If a card is not already present, insert the card into the slot as shown in Figure 8.1. Be sure to install the card in the direction shown in Figure 8.1 - with the electrical contacts facing toward the right.

Note: Use only Solta-supplied SD cards with the System.

Figure 8.1 SD Card Installation

8.1.2 Power On the System

Plug the System into a grounded receptacle (extension cords and / or adapter plugs must not be used). Power the System ON using the ON / OFF switch, which is located on the System's side panel. See Figure 8.2.

Figure 8.2 Power Switch

The System will initialize soon after the power is turned ON. After initialization, the Power On Self Tests (POST) will run. During the POST, all indicators (LEDs) will be illuminated. When the POST is complete, a five (5) second tone will sound indicating that the System is ready for use.

If the screen or indicators fail to light or if no tone is heard, **DO NOT USE THE SYSTEM** and contact Solta Medical, Inc. for service. If the System goes directly into the FAULT mode upon start-up, **DO NOT USE THE SYSTEM** and contact Solta Medical, Inc., Customer Service at (877) 782-2286.

8.1.3 Installing the Cryogen Canister

8.1.3.1 Unscrew the cryogen cap on the cover of the System.

8.1.3.2 Invert and then insert the new canister into the System Canister Port.

8.1.3.3 Install the new canister by rotating it clockwise until hand-tight: approximately 3.5 turns. There may be a small release of coolant while installing the canister. **CAUTION:** Do not over-tighten canister.

8.1.3.4 Screw the cap on over the Canister Port.

Figure 8.3 Installing the Cryogen Canister

8.1.4 Handpiece Connection

Power ON the System and allow it to complete the POST prior to connecting the Handpiece cable to the System. Select the desired Handpiece (either Face or Body).

Figure 8.4 System Front Panel

Insert the Handpiece cable into the Handpiece connection on the System front panel as shown in Figure 8.5. (Push in until the connector clicks.)

Figure 8.5 Return Pad Cable (left) and Handpiece (right) connected

8.1.5 Return Pad Cable Connection

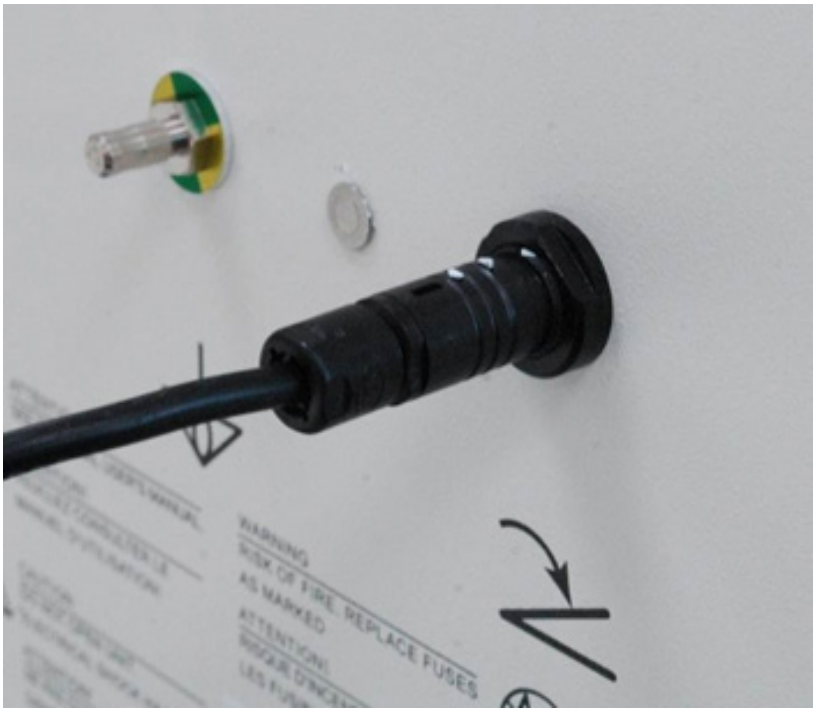
Insert the Return Pad Cable into the Return Pad connection located on the System front panel. Tighten the thumbscrews to secure the connector. See Figure 8.5.

Note: Position the System so the cables are not in contact with the System operator, the patient, or other cables.

8.1.6 Footswitch Connection

Connect the Footswitch to the Footswitch connector on the back of the System as shown in Figure 8.6 (if Footswitch use is desired).

Figure 8.6 Footswitch Connection



8.1.7 Equipotential Grounding Post

The grounding post located on the System back panel is for use only by Solta-trained service personnel and should not be used during in normal operation.

8.1.8 Service Port

The port located on the System front panel and inferior to the SD card slot is for use only by Solta-trained service personnel. Inserting anything into this port can cause damage to the CPT System and may lead to injury.

8.2 System Configuration

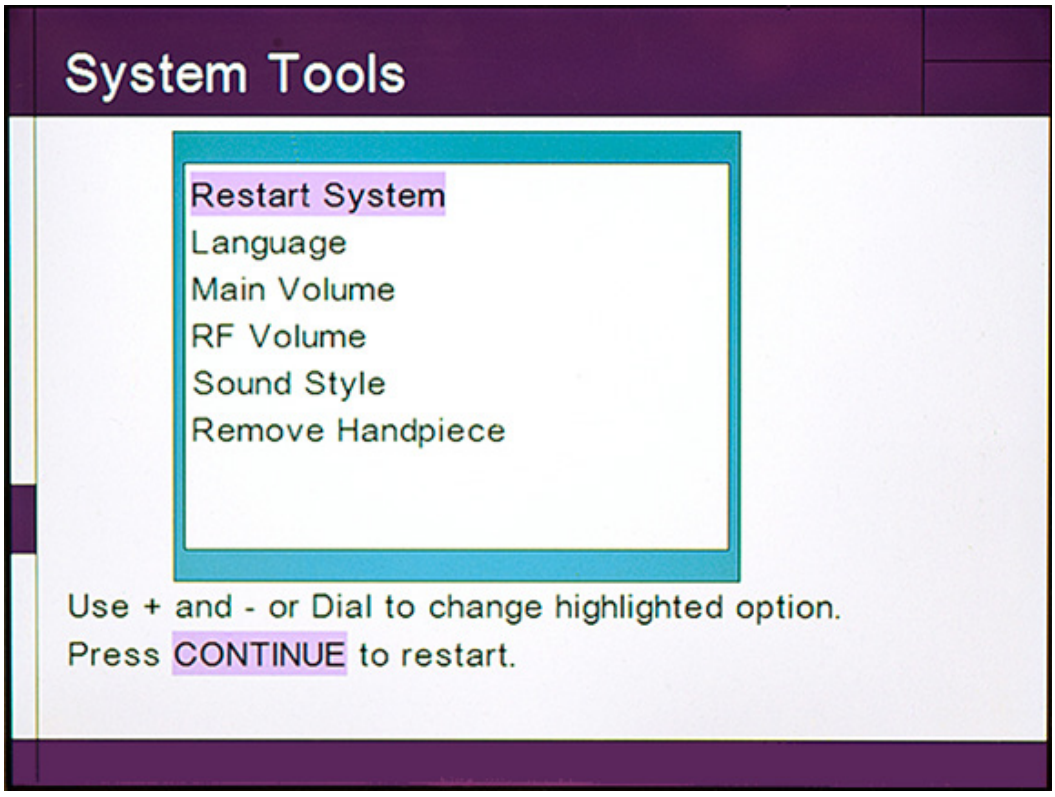
8.2.1 System Tools Screen

To access the SYSTEM TOOLS screen, press and hold the [ADJUST] button on the front panel or Handpiece for at least 3 seconds. (If the SYSTEM TOOLS screen does not appear remove the Treatment Tip from the Handpiece, and press the [ADJUST] button again for at least 3 seconds.)

As shown in Figure 8.7, the System Tools menu presents the following options:

- Restart System
- Language
- Main Volume
- RF Volume
- Sound Style
- Remove Handpiece

Figure 8.7 Generator SYSTEM TOOLS Screen



Note: If the System Tools menu is accessed during treatment, the System must be restarted.

Turn the Treatment Level Setting Knob (or use the Handpiece [arrow up] or [arrow down] to highlight a menu option and press [CONTINUE] to select and save that option. Once option(s) is adjusted, select Restart System and press [CONTINUE] to reboot the System. (Refer to Table 8.1 - How to Adjust System Tools Screen - Menu Options.) Once the System has been rebooted, it is necessary to tune again prior to commencing treatment.

Table 8.1 How to Adjust System Tools Screen - Menu Options

Menu Item	Description
Restart System	Select to save desired options and reboot the System.
Language	Select the language you would like the screen to display: English, Español, Français, Deutsch, Italiano, Português, etc.
Main Volume	Select the volume for audible tones for System Events, Chime, etc. Allows the operator to adjust the volume from 10-100% of preset volume.
RF Volume	Select the volume for RF energy delivery tone. Allows the operator to adjust the tone from 50-100% of preset tone. (Per Regulatory requirements the RF tone volume cannot be reduced below 50%.)
Sound Style	Select the style of audible tone: Comforting or Classic.
Remove Handpiece	Select to release cryogen pressure at the Handpiece connection. When complete, provides operator with instructions for disconnecting the Handpiece from the System.

9. Principles of Operation

The System is rated for 400 Watts of power. The System continuously monitors output power, output energy, treatment duration, and measured impedance. The System also controls the coolant delivery through the Handpiece Assembly. The Handpiece Assembly delivers RF energy while cooling tissue by thermal conduction.

9.1 System Modes

The System operates in the following modes: SYSTEM TOOLS, ACTION REQUIRED, PLEASE WAIT, READY TO TUNE, TUNING, ADJUST LEVEL, ADJUST VIBRATION, READY, and ACTIVE. RF energy is delivered only during portions of the TUNING and ACTIVE modes.

9.1.1 Action Required Mode

The System automatically enters ACTION REQUIRED mode after the POST mode is completed. If the Handpiece, Treatment Tip, or Return Pad Cable is not connected, the System will prompt the operator to complete the process.

Once all three components are installed and verified, the System prompts the operator to verify that the Return Pad is attached to the patient and the Return Pad Cable is connected to the Return Pad.

The System reenters the ACTION REQUIRED mode whenever an action is required of the operator in order to proceed to READY or READY to TUNE mode.

9.1.2 Ready to Tune Mode

After the operator presses [CONTINUE] to clear the Return Pad prompt, the System enters READY TO TUNE mode.

The operator is prompted with messages in the status display to tune the System before adjusting the Treatment Level setting.

9.1.3 Adjust Level Mode

Upon entering ADJUST LEVEL, the operator must use the Treatment Level knob on the front panel or the [arrow up] or [arrow down] button on the Handpiece to set the desired Treatment Level. The operator must then press [CONTINUE] on either the front panel of the System or on the Handpiece to confirm the Treatment Level.

9.1.4 Please Wait Mode

The System enters PLEASE WAIT mode when it checks the Handpiece and / or Treatment Tip connection or when the coolant pressure is either too low or too high.

After the System has verified the Handpiece and / or Treatment Tip connection, or corrected the coolant pressure, it will provide an audible chime and automatically transition to the next mode.

9.1.5 ADJUST VIBRATION Mode (applies to the Face Handpiece only)

When using the Face Handpiece, the operator must ADJUST VIBRATION by pressing the Vibration Button on the Handpiece. The Vibration button allows the operator to set the desired Vibration Intensity Level (LOW, MEDIUM, or HIGH). The default state is 'OFF'.

By pressing the Vibration button once, Vibration will be set to the LOW setting. The operator must press the Vibration button two times to set Vibration to the MEDIUM setting and three times to set Vibration to the HIGH setting. To turn Vibration off at any time, the operator must again press the Vibration button. After setting the Vibration Intensity Level, the operator must then press [CONTINUE] on either the front panel of the System or on the Handpiece before commencing patient treatment.

9.1.6 READY Mode

Upon entering READY, the System's Handpiece Assembly cooling function is initiated. This allows delivery of coolant to the Handpiece Assembly if the Treatment Tip temperature sensors indicate that the Treatment Tip is not within the acceptable temperature range.

The System is ready to enter the ACTIVE mode. The System remains in READY mode until either the Finger Switch on the Handpiece Assembly or the Footswitch is pressed to cause the System to enter the ACTIVE mode.

9.1.7 Active Mode

The System will enter the ACTIVE mode from the READY mode when the Finger Switch on the Handpiece Assembly or the Footswitch is pressed and the Handpiece Treatment Tip is at the correct temperature.

The System is ready to deliver RF energy for treatment once tissue contact is sensed.

Note: If the Finger Switch on the Handpiece Assembly or the Footswitch is released, the unit returns to READY mode.

The Handpiece tissue contact force sensor ultimately initiates the application of RF energy. However, the tissue contact force sensor remains inactive until other controls are activated and the System is ready. RF application can be manually terminated during a delivery by releasing the Finger Switch or Footswitch. Once treatment has begun it is strongly recommended to stop energy delivery by releasing the Finger Switch (or Footswitch) while maintaining tip contact with the patient. This will stop energy delivery and go into Post-Cooling.

The System transitions from the ACTIVE mode "Armed..." Phase to:

- "Treating..." Phase, if tissue contact is initiated within 3 seconds
- READY mode, if the cycle timer "times out" or the Finger Switch / Footswitch is released, or
- ADJUST LEVEL mode, if [ADJUST] is pressed in the READY mode.

There are two phases in the ACTIVE mode: "Armed..." and "Treating....". When the System enters the ACTIVE mode it begins in the "Armed..." Phase.

ACTIVE MODE: "Armed..." Phase

The System in the "Armed..." Phase is ready to deliver RF energy for treatment once tissue contact is sensed. A timer is started and the operator will have three (3) seconds to initiate tissue contact before the timer "TIMES OUT" and returns the System to READY mode. The Handpiece contains a force sensor that determines when the proper activation force of tissue contact has been achieved. The tissue contact force must be sufficient to ensure complete contact of the Treatment Tip on the skin, but not so great that the skin is over compressed.

ACTIVE MODE: "Treating...." Phase

When correct tissue contact is sensed, the System enters the "Treating..." Phase. The "Treating..." Phase consists of three (3) steps: Pre-Cooling, delivering RF, and Post-Cooling.

The System transitions from the "Armed..." Phase to the "Treating..." Phase when tissue contact is sensed. A change in the audible tone accompanies this transition.

There are three steps of treatment in the "Treating…" Phase of the ACTIVE mode:

- Pre-Cooling
- Delivering RF
- Post-Cooling

During the Pre-Cooling step, coolant is applied to the Treatment Tip for a pre-programmed duration, delivery rate, and frequency with temperature feedback control. Once the Pre-Cooling step has terminated, the System enters the Delivering RF step.

In the Delivering RF step, the System delivers the operator-selected Treatment Level at pre-programmed values of RF current, power, and delivery time, while controlling cooling rates. The System continuously measures and monitors relevant parameters such as RF energy delivery, power, current, and impedance.

The REPs remaining display will decrease by one when the appropriate amount of RF energy has been delivered.

After completion of the Delivering RF step, the System initiates the Post-Cooling step in which it supplies coolant for a pre-programmed duration, delivery rate, and frequency with temperature feedback control. The audible tone ends upon termination of the Post-Cooling step.

Termination of the tone indicates a treatment is complete. The Handpiece Assembly should be lifted off of the patient and the Finger Switch (or Footswitch) released.

Note: Do not lift the Handpiece Assembly off of the patient until the long tone terminates to ensure cooling is completed.

Once the Finger Switch (or Footswitch) has been released and the Handpiece lifted from the patient, the System re-enters the READY mode. This completes the treatment cycle.

The early release of the Finger Switch (or Footswitch) or the detection of an abnormal System event will terminate the Delivering RF step prematurely and begin the Post-Cooling step. Interruption of the treating phase will be indicated by two short beep tones.

9.2 Delivery of RF Energy

Once the System is activated, tissue contact must be sensed within three (3) seconds to commence RF Energy delivery or the ACTIVE mode ends. Press the Treatment Tip lightly and evenly against the skin to ensure full contact of the Treatment Tip surface with the treatment zone. The audible tone changes and the treatment cycle begins as soon as the System determines that the operator is applying the appropriate amount of force to the tissue.

The treatment cycle starts with a Pre-Cooling step. RF application occurs immediately after the Pre-Cooling step. The System displays measured values for impedance and percent of TARGET LEVEL ENERGY achieved. The Post-Cooling step follows RF delivery. The audible tone ceases and upon termination of the Post-Cooling step.

To end the treatment cycle before time has elapsed, release the Finger Switch (or Footswitch) to Dis-Arm the System. Two short tones will indicate an incomplete delivery. Do not lift the Handpiece Assembly prior to cessation of the Active tone to ensure complete cooling.

9.3 Shutdown Conditions

The following Conditions will cause the System to terminate RF output during the RF Delivery step:

- The Handpiece Assembly Finger Switch (or Footswitch) is released ('Dis-arming' the unit).
- Tip is lifted from contact with the tissue.
- Return Pad contact quality failure.
- ERROR or FAULT is encountered.

9.4 Abnormal System Events

Abnormal System conditions are divided into three categories: ALERT, ERROR, and FAULT. In all cases, the cause of the abnormal System condition is assigned an event number which is shown in the upper right corner of the display along with a message number for the text message which accompanies it.

IT IS IMPORTANT TO REPORT THE EVENT NUMBER WHEN CONTACTING CUSTOMER SERVICE. The event number is often the single most important piece of information that can be used for troubleshooting a problem.

9.4.1 ALERTS

An Alert tone indicates a minor problem that will resolve without operator action or a very common problem that requires routine user intervention (for instance, installing a Treatment Tip). If the Alert event occurs during an RF treatment, the RF delivery will be terminated, then a Post-Cooling step will be completed prior to generating an "Alert tone" and displaying the event code and event message.

After the "Alert tone" sounds, the System will transition to PLEASE WAIT, READY, or ACTION REQUIRED mode depending on the type of Alert.

If the condition that caused the Alert still exists, for example, if the tip temperature is still too cold, the System will stay in PLEASE WAIT mode until the condition resolves or a higher priority event occurs.

If the condition that caused the Alert has already resolved, the System will automatically return to the READY mode allowing the operator to immediately continue. Although the System is in READY mode, the event message text and event number will continue to be displayed in gray text. This is done to de-emphasize the message since it reflects a condition that has already cleared, while allowing the operator to determine why the alert tone was generated.

If the condition requires routine user intervention, the System will stay in the ACTION REQUIRED mode until the user clears the condition (e.g. by removing or installing a Treatment Tip).

It will be necessary with many Alert events to release the Finger Switch (or Footswitch) and / or terminate tissue contact before the System will return to READY mode.

9.4.2 ERROR

An Error indicates a recoverable problem that requires operator intervention. If the Error occurs during an RF treatment, the RF delivery will be stopped, then a Post-Cooling step will be completed prior to generating an "Error tone" and displaying the event code and event message.

After the Error tone, the System will transition into ACTION REQUIRED mode and will display text with instructions for the operator indicating what action may be required to resolve the issue.

After the condition is resolved, press the [CONTINUE] button to clear the Error.

9.4.3 FAULT

A Fault is an unrecoverable problem that requires System Reset. If the Fault event occurs during an RF treatment, the RF delivery will be stopped, then a Post-Cooling step will be completed prior to generating a "Fault tone" and displaying the event code and event message.

The System will neither operate nor will it respond to any switches while the System is in FAULT. The System must be powered OFF and back ON to exit FAULT. A System Reset will then initiate a POST.

10. Clinical Instructions

10.1 Pre-treatment Preparation

10.1.1 Patient Selection and Preparation

To ensure that the patient is suitable for treatment with the Thermage CPT System, refer to the contraindications in Section 3 of this manual. Adverse events can be mitigated by careful attention to the following information.

Counsel the patient regarding expectations and desired outcomes. For instance, for facial treatments, it should be explained that the Thermage results are not intended to replace the results typically seen following a surgical face-lift. Set patient expectations for improvement in the treated area. Patients with an expectation of improvement of the treated area and improvements in collagen structure are the most satisfied. The desired Thermage CPT treatment outcome is a younger, healthier and more vibrant look. Photographs taken of the patient before the procedure will provide a visual baseline to review results. Gradual improvements can best be evidenced in follow-up photographs.

It is important to be candid with a patient in your discussion of the treatment and potential patient discomfort. Let patients know that they will feel heat, but that they should experience only moderate discomfort. Treatment Level Settings can be adjusted to reduce discomfort without compromising the treatment outcome. In addition, consult with the patient about more aggressive pain management, if needed. For treatments performed using Vibration, explain that in combination with the radiofrequency energy, Vibration further contributes to temporary improvement in blood flow, circulation, comfort and, where applicable, improvement in the appearance of cellulite.

Make sure that the patient understands that even though the risks associated with a Thermage procedure are very low relative to more invasive procedures, some risks do exist. See Section 5 of this manual for a more complete discussion of adverse events.

Instruct the patient to reserve at least two hours on the day of treatment and, if possible, to refrain from application of any makeup to the face or eyes for that day. Instruct the patient to arrive at least one hour prior to the planned treatment time.

Upon arrival, remove loose or dangling jewelry including necklaces, bracelets, watches, etc. and specifically all earrings. Remove or wash off all makeup, moisturizers, oils, deodorant, etc. from the treatment site using a gentle cleanser. For facial treatments, secure the patient's hair away from the treatment area using a headband or other similar device.

10.1.2 Anesthesia

Thermage procedures have been performed using several different types of anesthesia including topical and oral preparations as a means of pain management. Based on customer feedback and internal studies, Solta recommends that patient feedback regarding their perception of heat or discomfort during the procedure is essential input to guide the operator in determining safe and effective Treatment Levels.

IMPORTANT
IT IS VERY IMPORTANT TO THOROUGHLY REMOVE ALL OF THE TOPICAL ANESTHETIC MATERIALS AND / OR OTHER PREPARATIONS (COSMETICS, LOTIONS, ETC.) FROM THE SURFACE OF THE SKIN AT THE TREATMENT SITE. DURING THE PROCEDURE THERE MUST BE NO MATERIAL, OTHER THAN THE THERMAGE COUPLING FLUID, BETWEEN THE SURFACE OF THE TREATMENT TIP AND THE PATIENT'S SKIN AT THE TREATMENT SITE.

Note: Avoid injected or tumescent anesthesia or nerve blocks.

Solta strongly discourages the use of local injections and tumescent anesthetic techniques to manage patient comfort during the Thermage procedure. Injecting lidocaine or similar anesthesia or other substances into the treatment area will change the natural electrical resistance and alter the tissue heating profile in an unpredictable way.

Caution: Use of these types of pain management techniques increase the risk of tissue injuries; including surface irregularities.

10.1.3 Power On the System

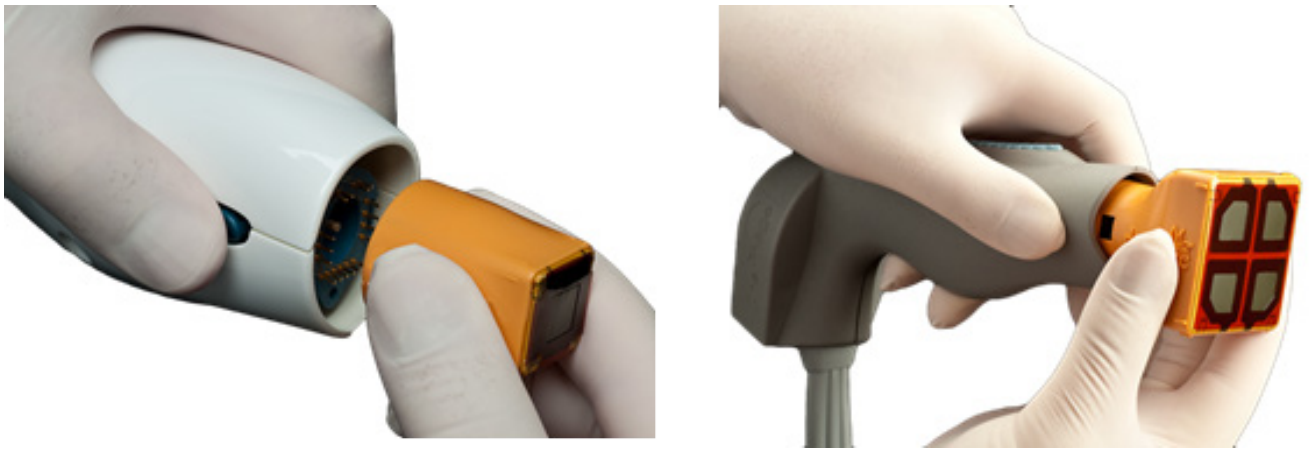
Power ON the System using the ON / OFF switch, which is located on the System side panel.

10.1.4 Attaching the Treatment Tip to the Handpiece

The geometry of the Treatment Tip only allows for insertion in one orientation. Holding it from the sides, press the Treatment Tip into the Handpiece until the tabs click into position. Avoid contacting the brown membrane surface of the Treatment Tip during installation and handling. Ensure the Treatment Tip is fully seated in the Handpiece prior to use.

Note: The Treatment Tip is for single-patient-use only. Do not reuse Treatment Tips.

Figure 10.1 Attaching the Treatment Tip



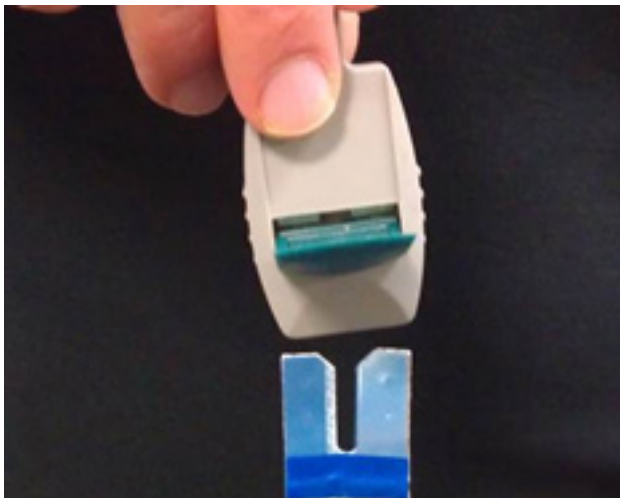
Caution: The Treatment Tip is fragile. Any damage to the surface of the tip may cause burns during the treatment.

10.1.5 Application of Return Pad to the Patient

Place the Return Pad on a well-vascularized area, for example, the lower back or side (just above the hip) that is free of hair and completely dry. Orient the Return Pad so that the connection tab faces in a lateral direction or away from the patient's midline. DO NOT place the Return Pad near shoulder, neck, head regions, legs or arms. Ensure the entire area of the Return Pad is in contact with the patient's skin by pressing, smooth to opposite end and applying finger pressure on the adhesive border and massage entire pad area. Use a new Return Pad if the location must be changed.

Insert the Return Pad Cable into the notched end of the Return Pad, as shown in Figure 10.2. Attach the other end of the Return Pad Cable to the RF Generator.

Figure 10.2 Return Pad / Return Pad Cable Connection



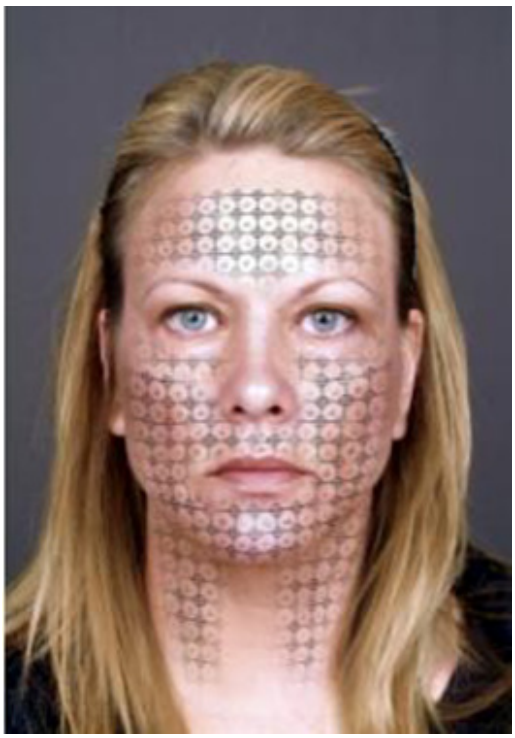
10.1.6 Skin Marking

NOTE: Use only 70% Isopropyl Alcohol to clean the skin. Do not use other fluids such as irrigation solution (e.g. saline).

Following the thorough removal of materials from the surface of the skin, mark the treatment site using Thermage Skin Marking Paper. Remove one or more sheets of Skin Marking Paper from the pouch. The grid cell size should match the size of the Treatment Tip (0.25 cm^2, 3.00 cm^2, 16.00 cm^2). Cut the selected sheet to the desired size and shape. While skin is still moist with alcohol apply marking paper, ink side down, directly onto the treatment area. Dab paper with alcohol until ink shows thru paper. Peel the backing paper slowly off of the skin's surface. Allow the skin to dry prior to next step. Discard used skin marking grip backing as biohazardous waste.

See Figure 10.3 for the recommended grid pattern for treatment of the facial region. For further information regarding the recommended grid pattern for other areas of treatment, refer to the appropriate Procedure Guidelines.

Figure 10.3 Grid Pattern in the Facial Region



10.1.7 Tuning the System

Generously apply an even coat of the Coupling Fluid to the middle of the targeted treatment area. Press [CONTINUE] button and begin tuning the System in the middle of a targeted treatment area. Tuning may require two or three cycles. When [CONTINUE] button lights yellow, treatment application may commence. When [CONTINUE] button is unlit, the System is idle and Treatment Level Settings may be changed.

10.1.7.1 Set Procedure Parameters

After tuning is successfully completed, the System automatically transitions to ADJUST LEVEL mode. The Treatment Level is adjusted by turning the Treatment Level knob (or pressing the [up arrow] or [down arrow] buttons on the Handpiece).

Note: The Treatment Level can only be adjusted while in the ADJUST LEVEL mode.

Turning the Treatment Level knob clockwise (or pressing the [up arrow] button on the Handpiece) will increase the Treatment Level in increments of 0.5. Turning the Treatment Level knob counter-clockwise (or pressing the [down arrow] button on the Handpiece) will decrease the Treatment Level by increments of 0.5. Continuously turning the dial will rapidly change the Treatment Level. The target energy in Joules per square centimeter will change as each new Treatment Level is displayed.

When the desired Treatment Level is displayed, press the [CONTINUE] button to confirm the Treatment Level.

Selection of the proper Treatment Level depends upon both the intensity of the effect desired and the Treatment Tip's electrode configuration.

10.1.8 Prepare the System

After adjusting the Treatment Level, press the [CONTINUE] button to enter the System READY mode. For the Standard Handpiece, the operator must then ADJUST VIBRATION by pressing the Vibration Button on the Handpiece and again press the [CONTINUE] button to enter the System READY mode. The operator must then allow the Handpiece Assembly to cool to its preset temperature.

Note: The System will prompt you to wait until the temperature is within acceptable limits.

10.2 Patient Treatment

10.2.1 Position the Handpiece Assembly as Desired

Choose the treatment site. Hold the Handpiece Assembly slightly above the treatment site in a vertical position, perpendicular to the surface being treated.

Note: Vertical positioning of the Handpiece is preferable, with the surface of the Treatment Tip parallel to the ground. Avoid positioning the Handpiece such that contact with the patient is made.

10.2.1.1 Examine the Treatment Tip

Prior to commencing treatment, inspect the Treatment Tip for signs of damage or wear. Ensure that the Treatment Tip surface is free from any scratches or other damage. Wipe the Treatment Tip surface with alcohol wipe if using a Non-Sterile Tip. Routinely inspect the Treatment Tip surface for damage or wear during treatment or if the tip makes contact with any surface other than the patient's skin during treatment. It is recommended that the condition of the patient's skin and the Treatment Tip membrane be carefully monitored throughout the treatment process.

If the Treatment Tip produces any uncharacteristic tissue outcomes (e.g. burns) and / or shows visual signs of membrane breakdown during treatment, discontinue use of the tip and call Solta Product Support at (877) 782-2286 for product assistance and investigation. Customers outside of the U.S. should contact their local Solta representative for product assistance and investigation.

10.2.2 Enable the System

With the Handpiece Assembly still slightly above the treatment site, activate the System using the Finger Switch (or Footswitch). As soon as the System is activated, an audible "Armed" tone (lasting up to 3 seconds) will be emitted.

Note: The Finger Switch (or Footswitch) must be pressed before the Treatment Tip comes into contact with tissue.

10.2.3 Treatment Level Settings

During treatment, Treatment Level settings will require frequent adjustment in response to variations in skin thickness, treatment area anatomy, and patient feedback. The treating physician is responsible for selecting appropriate and safe Treatment Levels at all times. The output power selected should be as low as possible for the intended purpose.

Start at the lowest Treatment Level setting for the Treatment Tip type and deliver RF energy to the treatment site. If the desired effect is achieved, continue delivering at the selected Treatment Level until the entire site has been treated. If the Treatment Level is not satisfactory, increase the Treatment Level by 0.5 and deliver RF energy at this setting. Repeat this process until the desired level of treatment is achieved.

Note: Ensure that the Treatment Tip is fully seated in the Handpiece prior to selecting a higher Treatment Level. Check connectors before selecting a higher treatment level.

After each delivery of RF energy, evaluate the treated location to ensure the desired level of treatment is being achieved. If the selected Treatment Level results in excessive treatment, the Treatment Level should be decreased until a satisfactory result is achieved.

10.2.3.1 Treatment Level Selection

Calibrate the Treatment Level setting according to the patient's feedback.

10.2.3.1.1 Begin with a tolerant area of the desired treatment location.

10.2.3.1.2 Select Treatment Level to desired starting fluence range. Press [ADJUST]. Press [CONTINUE].

10.2.3.1.3 Select an initial setting that is on the low end of the recommended range and treat one square.

10.2.3.1.4 Continue to treat, adjusting the Treatment Level setting up or down within the recommended range of Treatment Level settings, until the patient reports heat feedback of 2.0-2.5 on a scale of 0 to 4 as described on the Treatment Reference card. Avoid treatment at levels higher than recommended for the area treated, regardless of heat sensation feedback. Exceeding these maximum limits increases risk of tissue overheating and associated side effects.

10.2.4 Vibration Setting

When using the Face Handpiece, Vibration Level (NONE, LOW, MEDIUM, or HIGH) should be selected based upon subject's perception of the tactile sensation. In order to achieve maximal improvement in blood flow, circulation during facial treatments, and improvement in cellulitic skin, Vibration should be as high as tolerable while remaining pleasant. Vibration Level may be adjusted over the course of overall treatment based on the subject's feedback.

Caution: Operator comfort is also an important consideration in setting Vibration Level. **Repetitive use of any hand-held vibrating instrument could cause fatigue, irritation or injury to susceptible users.**

10.2.5 Treatment Delivery

Shake the Coupling Fluid well before use. Apply a generous amount of the Coupling Fluid to a small section of the targeted treatment area and re-apply throughout treatment.

The table below provides guidance as to the typical minimum application quantities of Coupling Fluid during a procedure. The exact amount of fluid used during a procedure depends on a number of factors including total REPs applied, total number of passes, length of procedure, time between passes, time since last application, etc.

Number of REPs (3.00 cm² Treatment Tip)	Minimum Volume
100-300	10 ml
300-600	20 ml
600-900	30 ml
900-1200	40 ml

Align the Treatment Tip with one cell at the outermost margin in the grid pattern. Deliver treatment to the targeted tissue. After delivery, lift the Treatment Tip away from the treated cell and move systematically through the remaining cells in the grid. Press the [ADJUST] button to change Treatment Level Setting up or down.

Note: In the event that it is necessary to change the Cryogen Canister during a treatment session, remove the existing used canister for disposal by rotating it counter-clockwise until it is free. There may be a small release of cryogen while removing the canister. Dispose of the empty canister in accordance with applicable regulations for contaminated disposables. If an empty canister is replaced soon after the initial "EMPTY" message is received, no waiting will be required prior to resuming treatment. EMPTY is displayed when the canister is empty, but coolant is still in the internal reservoir.

Typically when the EMPTY message is first displayed, the System internal coolant reservoir still contains enough coolant for another 100 to 300 REPs with a 3.00 cm² treatment tip. If the canister is not changed before the coolant in the internal reservoir is also emptied, it can require up to 5 minutes after replacing the canister for the System to resume treatments.

10.2.6 Treatment Guidelines

To assure the safe and effective use of the CPT System, Solta recommends moderate Treatment Level settings. These settings should be used in conjunction with multiple passes over the selected areas where improvements and / or contour changes are desired.

The treatment settings act as a guideline only. The treating physician should always adjust Treatment Levels based on the individual's skin thickness, underlying tissue, clinical signs, and the patient's perception of heat.

Sensitive Areas

Always reduce Treatment Level settings for possible sensitive areas such as bony prominences and major nerve locations.

Treating over sensitive areas typically requires a reduction of one (1) full setting.

Skin Thickness

Thicker tissue (e.g. frontalis muscle) may require a slight increase in the Treatment Level setting.

Thinner tissue (e.g. temple area) typically requires the use of lower Treatment Level settings.

Multiple Passes

Always use the Thermage Skin Marking Paper. Tip placement for the initial pass should be within each square. Subsequent passes should alternate tip placement at the point of intersection of 4 squares with 3.00 cm² skin marking paper and the offset overlap with 16.00 cm² skin marking paper, and then within the square again.

If the patient is reporting heat sensation of more than 2.0 to 2.5 on a 0 to 4 scale, reduce the Treatment Level settings.

If, between passes, the Thermage Coupling Fluid has dried out leaving a gummy or gel-like residue, the skin's surface should be cleaned prior to the application of fresh Coupling Fluid. As a general rule, when in doubt, additional fluid should be applied, as an excess amount will not be problematic.

Thermage CPT System Variability

Due to the nature of radiofrequency energy, device-to-device variability can be significant. Do not assume transferability of settings from device-to-device.

Treating Eyelids using the 0.25 cm² Treatment Tip

IMPORTANT
A PLASTIC GLOBE PROTECTOR MUST BE IN PLACE PRIOR TO ANY EYELID TREATMENTS USING THERMAGE RADIO FREQUENCY TECHNOLOGY. ALL TREATMENTS DESCRIBED BELOW WERE COMPLETED USING AN OCULOPLASTIC® PLASTIC GLOBE PROTECTOR FOLLOWING THE MANUFACTURER'S INSTRUCTIONS FOR USE.

A prospective clinical study was conducted by 4 investigators treating 72 Subjects allowing for evaluation of 144 eyes. The vast majority of the Subjects were treated on their upper and lower lids including the "crow's feet" area. The minimum number of delivered radiofrequency energy pulses (REPS) delivered using the 0.25 cm² Treatment Tip to the upper and lower eyelids combined was 445. The maximum was 1190 and the average was 723.

Summary Measures for REP Groupings

Low REPs		Mid REPs		High REPs	
Min	131.00	Min	576.00	Min	850.00
Max	564.00	Max	833.00	Max	1190.00
Median	501.00	Median	669.00	Median	900.00
Ave	453.17	Ave	682.69	Ave	920.17
SD	110.15	SD	78.65	SD	152.85
Count	18.00	Count	36.00	Count	18.00

Outcome variables included investigator assessment of upper and lower eyelid tightening as well as hooding of the upper eyelid. Subject self reports included satisfaction levels for the upper lid and separately for the lower lid. At the 6 month follow-up interval, 86% of patients showed improvement in hooding, 88% and 83% showed improved tightening in the upper and lower lids respectively. 70% of Subjects were satisfied with their upper lid outcome and 69% with their lower lid outcome. No adverse events were reported.

10.2.7 Treatment Completion

The grid can be easily removed with isopropyl alcohol followed by a mild soap / warm water solution until the marking grid is no longer present. Remove the Treatment Tip from the Handpiece and discard. Wipe the Handpiece with a soft cloth and isopropyl alcohol. Allow time for the isopropyl alcohol to evaporate completely before using the Handpiece. Remove the Return Pad slowly and with great care to avoid skin trauma.

Dispose of the coupling fluid, following local governing ordinances and recycling plans.

Preparing the System for Shipment

10.3 Remove the Handpiece

Note: If the SYSTEM TOOLS option is not used, a puff of cryogen will escape as the Handpiece is removed. This puff of coolant strips lubricant from the o-ring at the cryogen fitting and may affect long-term reliability of the o-ring seal.

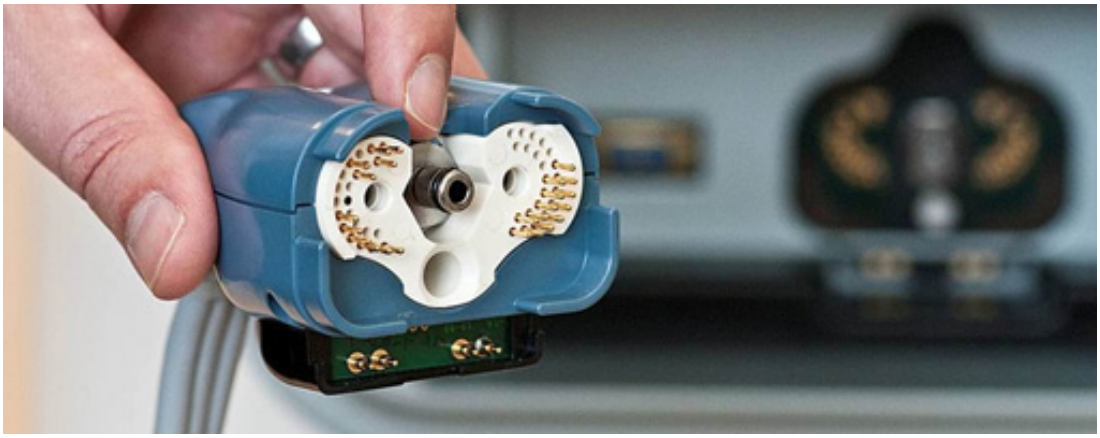
To release the Handpiece, press the release latch located at the top center of the Handpiece connector.

10.3.1 Power down the System.

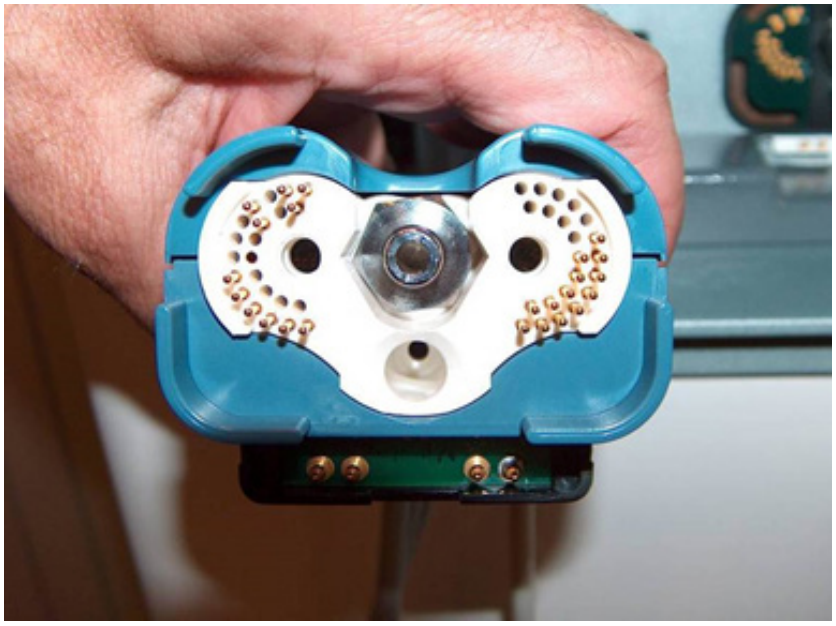
10.3.2 Press the release latch located at the top center of the Handpiece connector.

Figure 10.4 Handpiece Connector Releases

Face Handpiece Connector Release



Body Handpiece Connector Release



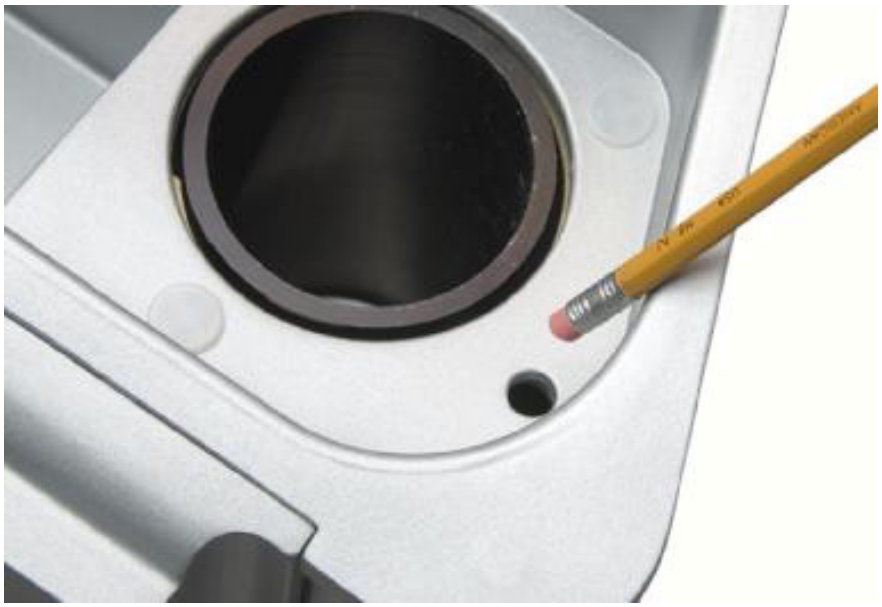
10.4 Drain Cryogen from the System

10.4.1 Remove the Cryogen Canister

10.4.2 Remove the cover over the vent valve.

10.4.3 Use a pen or other blunt tool to depress the vent valve. Press down on the valve until the hissing sound stops. Liquid cryogen may drip out the bottom of the Thermage CPT System.

Figure 10.5 Vent Valve Release



10.4.4 Wait 30 seconds then press the vent valve again.

10.5 Pack the System

10.5.1 With the reusable shipping crate lying flat, unlock the four (4) lid latches as shown in Figure 10.6.

Figure 10.6 Unlock Reusable Shipping Crate

10.5.2 Use two (2) people to remove the lid (see Figure 10.7) and lift the crate into an upright position.

Figure 10.7 Remove Shipping Crate Lid

10.5.3 Roll the System into the crate by gripping the handle on the rear of the instrument. (See Figure 10.8).

Figure 10.8 Roll System Into Shipping Crate

10.5.4 Use two people to lay the crate flat and replace the lid. Make sure that the ends of the arrows match up (see Figure 10.9). Lock the lid.

Figure 10.9 Close and Lock Shipping Crate

11. Troubleshooting

11.1 System Problems

11.1.1 No RF Output

- Broken instrument cable
- Cable(s) not connected
- Fault in Footswitch or Handpiece
- System ARMED Phase cycle timer "timed out" prior to ACTIVE mode initiation
- System in ERROR mode
- System internal failure
- System not in ACTIVE mode
- System not plugged in
- System not turned on
- Handpiece not connected
- Handpiece or Treatment Tip Failure
- Damaged RF Generator
- Return Pad not connected / poor connection

11.1.2 System Event Codes

System event codes are displayed in the upper right corner of the screen when the System detects a condition that interrupts the normal progression of treatment.

Table 11.1 System Messages

Message Identification	Description
E001-E013, E015-E031, E033, E035, E037-E040, E048, E066-E068, E070, E074, E075, E078, E080, E083-E086, E090, E092, E095-E097, E152, E181, E219, E224, E231, E242, E243, E244, E247, E249-E251, E253, E255, E259, E260-E262, E265-E269, E275, E276, E280, E286, E288-E292, E294-E301, E303, E304, E306, E311, E312, E314, E315, E328	Turn main power switch off and back on. If event repeats, call for service.
E061	Incompatible Return Pad Cable. Replace with Thermage TP-2 Return Pad Cable.
E062	Incompatible Return Pad Cable. Replace with Thermage TP-2 Return Pad Cable.
E076	Treatment Tip not in full contact with skin. Ensure tip is not tilted or lifted during REP. Press [CONTINUE].
E077, E099	COOLANT RESERVOIR OVERPRESSURE. Turn main power switch off. Wait 2 minutes then turn back on. If event repeats, call for service.
E081, E082, E155, E240-E242	Call service and report event number. Turn main power switch off and back on.
E087	Unable to tune after 5 attempts. Turn main power switch off and back on. If event repeats, call for service.
E088, E189, E195	Problem detected. Press [CONTINUE] to resume operation.
E088, E189, E195	Problem detected. Press [CONTINUE] to resume operation.
E089	COOLANT CANISTER TOO HOT. Turn main power switch off. Wait 2 minutes then turn back on. If event repeats, call for service.

Message Identification	Description
E091	COOLANT RESERVOIR TOO HOT. Turn main power switch off. Wait 2 minutes then turn back on. If event repeats, call for service.
E094	COOLANT CANISTER OVERPRESSURE. Turn main power switch off. Wait 2 minutes then turn back on. If event repeats, call for service.
E098	System restart required after 24 hours of operation. Turn main power switch off and back on.
E100-E102, E104-E111, E113, E116-E120, E122, E123, E125, E129, E130, E145, E146, E316, E317	Check all patient connections including Return Pad and Return Pad Cable. Press [CONTINUE].
E112	Check all patient connections including Return Pad and Return Pad Cable. Press [CONTINUE], then repeat tuning.
E128, E164	Excessive force.
E131-E133	Insufficient force. Maintain full contact until tone ends.
E134-E137	Activation switch released too soon.
E138	TIP TEMPERATURE LIMIT EXCEEDED. Apply more Coupling Fluid. Ensure full tip-to-skin contact. Do not treat same area. Press [CONTINUE].
E139, E310	Tip is too warm.
E140, E141, E153	Coolant system not ready.
E142	Check connection between RF Generator and Return Pad Cable.
E143	Handpiece not connected. Disconnect and reconnect the Handpiece. If event repeats, call for service.
E144	Make sure the Treatment Tip is securely connected to the Handpiece.
E147	Excessive force. Repeat tuning.
E148	Insufficient force. Maintain constant force until tone ends. Repeat tuning.
E149	Activation switch released too soon. Repeat tuning.

Message Identification	Description
E150, E151-E169, E170, E178, E218, E232, E233, E277-E279, E285, E287, E293	Disconnect and reattach Treatment Tip. If event repeats, call for service.
E159	Tip is too cold.
E154, E156	Coolant Reservoir is empty. Replace Coolant Canister now.
E157	Please allow 5 minutes for reservoir to re-fill.
E158, E161, E180	Time limit exceeded. You have 3 seconds after pressing the activation switch to contact the skin. Release activation switch.
E160, E162, E194	Treatment Tip not in full contact with skin.
E163	Release activation switch and lift tip from skin.
E166, E179, E182, E183, E186-E188, E230, E237, E238, E319, E322, E324	Tip is not compatible with the System. Call for service.
E167, E196, E197, E228, E313, E318	Disconnect and reconnect the Handpiece. If event repeats, call for service.
E171-E174	Tip is not fully connected. Disconnect and reattach Treatment Tip to the Handpiece.
E175, E234	0 REPs remaining. Replace Treatment Tip.
E176, E177	Treatment Tip time limit reached. Replace Treatment Tip.
E198	Must update Handpiece firmware. Leave the Handpiece plugged in. Press [CONTINUE] to reboot.
E199	Handpiece firmware update failed. Disconnect and reconnect the Handpiece. Turn main power switch off and back on. If event repeats, call for service.
E201-E204, E206, E208, E215	Replace Patient Data Card or press [CONTINUE]. If event repeats, call for service.
E207	Cannot use the attached Treatment Tip. Replace Treatment Tip.
E211	Press activation switch BEFORE making contact with skin. If event repeats, call for service.

Message Identification	Description
E213	Remove and reinstall Patient Data Card. Turn main power switch off and back on. If event repeats, call for service.
E220, E223, E284	Handpiece expired. Use spare Handpiece. Call for service.
E221, E222	Handpiece incompatible. Use spare Handpiece. Call for service.
E225	Treatment Tip is not compatible with Handpiece. Please attach a compatible combination of Treatment Tip and Handpiece.
E226	Handpiece is not compatible with attached 16.0 cm Treatment Tip. Please attach the correct Handpiece and reattach Treatment Tip.
E227	Handpiece is not compatible with attached Treatment Tip. Please attach the correct Handpiece and reattach Treatment Tip.
E229	Coolant Canister is empty. (Now using coolant from reservoir.) Replace the Coolant Canister soon. Press [CONTINUE].
E236	Treatment Tip has exceeded shelf life limit. Replace Treatment Tip.
E239	Coolant Canister is missing. Install Coolant Canister.
E273	Return Pad not in full contact with skin. Ensure that Return Pad is fully adhered to patient. Press CONTINUE when done.
E274	Incompatible Return Pad detected. Replace with Thermage TR-2 Return Pad. Press CONTINUE when done.
E283	Incompatible Return Pad Cable. Replace with Thermage TP-2 Return Pad Cable.
E309	Handpiece nearing expiration. Please call customer service. Press [CONTINUE].
E323	One-half of tip REP count remaining. Press [CONTINUE].

12. Technical Specifications

12.1 AC Input Rating

- 100-240 V, 50 Hz, 10 A
- 100-220 V, 60 Hz, 10 A

12.2 RF Output

- RF energy: 6.78 MHz ± 0.1%.
- Maximum Power: 400 W
- Maximum current: 2.0 ARMS + 10%
- Duty Cycle: 50%, intermittent use

12.3 Electrical Safety

- Class 1, Type BF Applied Parts – Handpiece, Tips, and Return Pad
- Ordinary Equipment RF System
- Certified to:
  - IEC 60601-1:2012, Edition 3.1
  - EN 60601-1-2:2015, Edition 4.0
  - IEC 60601-1-2:2014, Edition 4.0
  - EN 60601-2-2:2009, Edition 4.0
  - CAN / CSA-C22.2 No. 60601-2-2:2009 Edition 5.0
  - CSA / 22.2 No. 60601-1:2014, Edition 3.0

12.4 Electromagnetic Compatibility

The Thermage CPT System is intended to be used in a Professional healthcare facility environment (e.g.; single office or outpatient clinical facility). It does not include areas where there are sources of intense electromagnetic disturbances, such as a RF shielded room of magnetic resonance imaging, or in operating rooms near active HF surgical equipment.

It is essential the Thermage CPT System deliver the correct output of energy to the patient per the selected treatment setting. Placing the system in areas where intense electromagnetic disturbances could be present may result in excessive energy delivered to the patient, or unexpected changes in treatment levels that could lead to possible burns to the patient.

	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 use of accessories, transducers and cables other than those specified could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Thermage CPT system and result in improper operation.
	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 Thermage CPT system, including cables specified by Solta. Otherwise, degradation of the performance of this equipment could result.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

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

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11 EN 55011	Class A Group 1	The Thermage CPT System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11 EN 55011	Class A Group 1	The Thermage CPT System is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment / system is intended for use by healthcare professionals only. This equipment / system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Thermage CPT System or shielding the location.
Harmonics IEC / EN 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC / EN 61000-3-3	Complies	

NOTE 1: The Emission characteristics of this equipment make is suitable for the use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential / domestic 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.

NOTE 2: There were no test level or compliance deviations to IEC 60601-1-2, 4th edition.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

The Thermage CPT System is intended for use in the electromagnetic environment specified below. The customer or the user of the Thermage CPT 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 / EN 61000-4-2	± 8 kV contact ± 2, 4, 8, 15 kV air	± 8 kV contact ± 2, 4, 8, 15 kV air	An ESD warning label adjacent to the rear USB connector and precautionary user manual documentation are required. 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 / EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines, 100 KHz	± 2 kV for power supply lines ± 1 kV for input / output lines, 100 KHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge Line to Line (AC Power) IEC / EN 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
Voltage dips IEC / EN 61000-4-11	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25 / 30 cycles Single phase: at 0°	0% UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT; 1 cycle and 70% UT; 25 / 30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Thermage CPT System requires continued operation during power mains interruptions, it is recommended that the Thermage CPT System be powered from an uninterruptible power supply or a battery.
Voltage Interruptions IEC 61000-4-11	0% UT; 250 / 300 cycle	0% UT; 250 / 300 cycle	
Power frequency (50/60 Hz) magnetic field IEC / EN 61000-4-8	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.
NOTE 1: UT is the a.c. mains voltage prior to application of the test level. NOTE 2: There were no test level or compliance deviation to IEC 60601-1-2, 4th edition.			

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The Thermage CPT System is intended for use in the electromagnetic environment specified below. The customer or the user of the Thermage CPT 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 / EN 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 V	Portable and mobile 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 Thermage CPT system, including cables specified by Solta. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC / EN 61000-4-3	3 V / m 80 MHz to 2.7 GHz 80% @ 1 KHz	3 V / m	
NOTE: There were no test level or compliance deviations to IEC 60601-1-2, 4th edition.			

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The Thermage CPT System is intended for use in the electromagnetic environment specified below. The customer or the user of the Thermage CPT System should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Proximity field from RF wireless communications equipment IEC 61000-4-3	See table 9 in IEC 60601-1-2, 4th Edition	See table 9 in IEC 60601-1-2, 4th Edition	
NOTE: There were no test level or compliance deviations to IEC 60601-1-2, 4th edition.			

TABLE 9: IEC 60601-1-2, 4TH ED. - TEST SPECIFICATIONS FOR ENCLOSURE PORT IMMUNITY TO RF WIRELESS COMMUNICATION EQUIPMENT.

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V / m)
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c] ± 5 KHz deviation 1 KHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800 / 900 TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b / g / n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a / n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the Thermage CPT System may be reduced to 1 m. The test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50% duty cycle square wave signal.

[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

12.5 Power Output Restrictions

The maximum output power is 400 W. The System will operate over the limited impedance range of 75Ω to 400Ω. Output power may be limited by the current / impedance limits.

12.6 Fuses

- 100-240 VAC T 10 A L, 250 V 5 x 20 mm

12.7 Settings

- Treatment Level: up to 19 Levels per Treatment Tip
- Vibration Level: 3 levels: Low, Medium, High

12.8 Measurement Accuracy[1]

- Power: ± 20% of reading
- Output Current ± 20% of reading

[1]For impedances in the range 75Ω to 400Ω

12.9 Enclosure Material

- System: Aluminum

12.10 Mechanical Specifications—System

- Size: 49.5 cm (W) x 43 cm (L) x 125.7 cm (H)
  19.5" (W) x 17" (L) x 49.5" (H)
- Weight: 38 kg (84 lb) maximum
- Moisture protection rating: IPX0

12.11 Footswitch Specifications

- Moisture protection rating: IPX8

12.12 Environmental Conditions

Transportation	Temperature	-40°C to 49°C (-40°F to 120°F)	
Storage, Coupling Fluid	Temperature Humidity	-40°C to 49°C (-40°F to 120°F) 20% to 95% RH	Non-Condensing
Storage, Coolant Canister	Temperature Humidity	18°C to 49°C (64.4°F to 120°F) 20% to 95% RH	Non-Condensing
Storage, Skin Marking Paper	Temperature Humidity	-14°C to 25°C (6.8°F to 77°F) 20% to 95% RH	Non-Condensing
Storage, all other components	Temperature Humidity	-40°C to 49°C (-40°F to 120°F) 20% to 95% RH	Non-Condensing
Operating	Temperature Humidity	15°C to 25°C (59°F to 77°F) 30% to 75% RH	Non-Condensing

Note: Allow the System to equilibrate to room temperature for a minimum of 4 hours if the System has been stored or transported at temperatures outside of the operating temperature range.

12.13 Sterilization

Components and accessories cannot be sterilized.

12.14 Maintenance

No routine maintenance is required. Inspections are recommended after each completed treatment.

12.15 Disposal

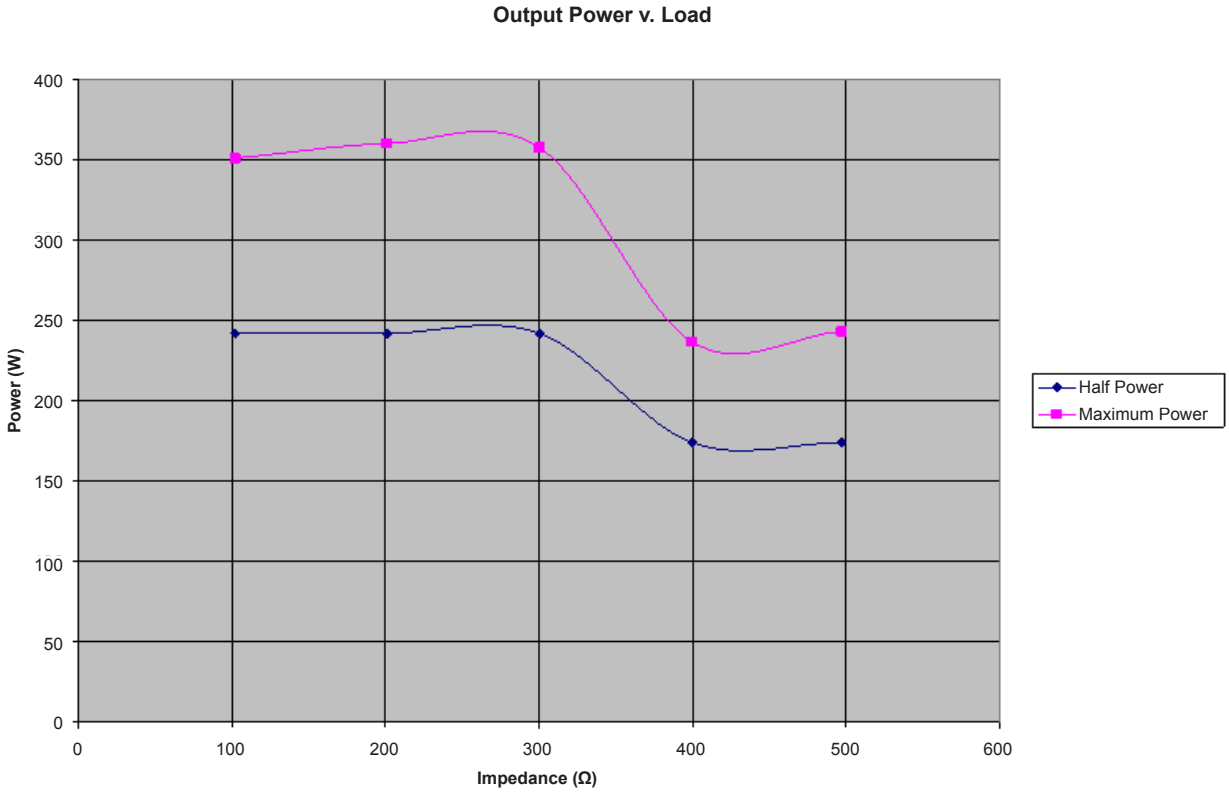
Follow all local ordinances and recycling regulations regarding disposal or recycling of this system or of its components.

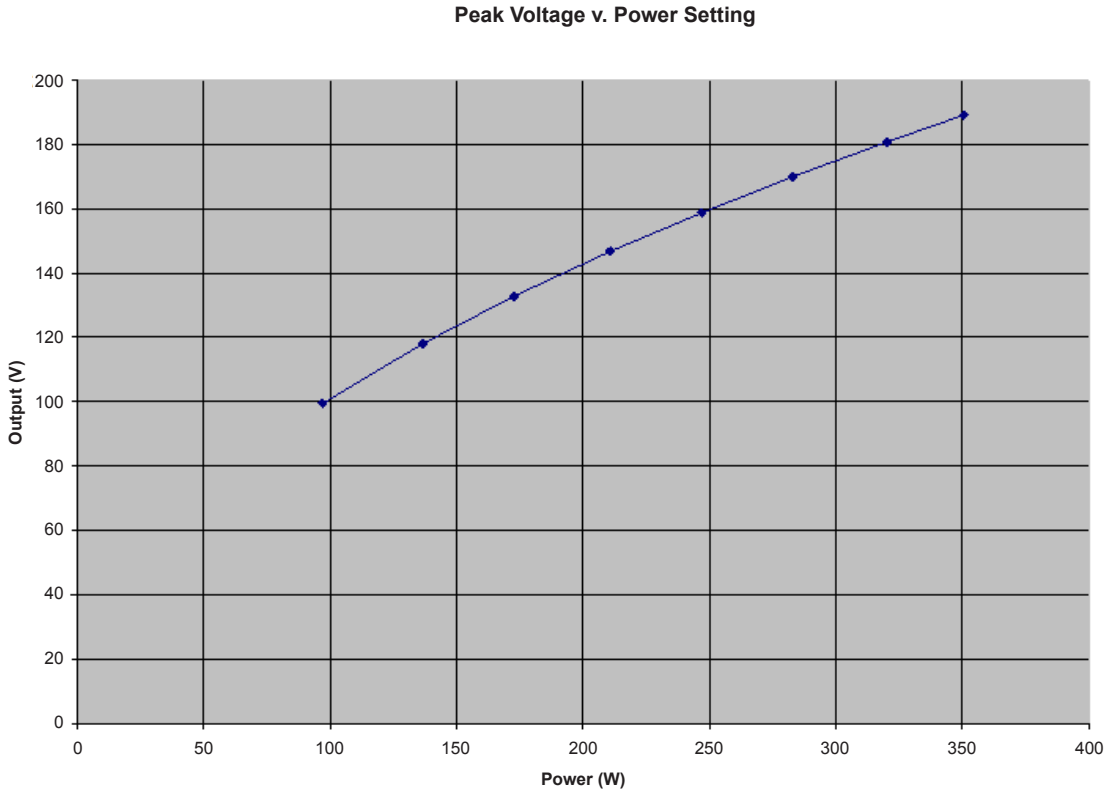
It is recommended to commission the disposal of the system to a designated waste disposal contractor. When disposing of packaging materials, sort them by material and follow local ordinances and recycling regulations.

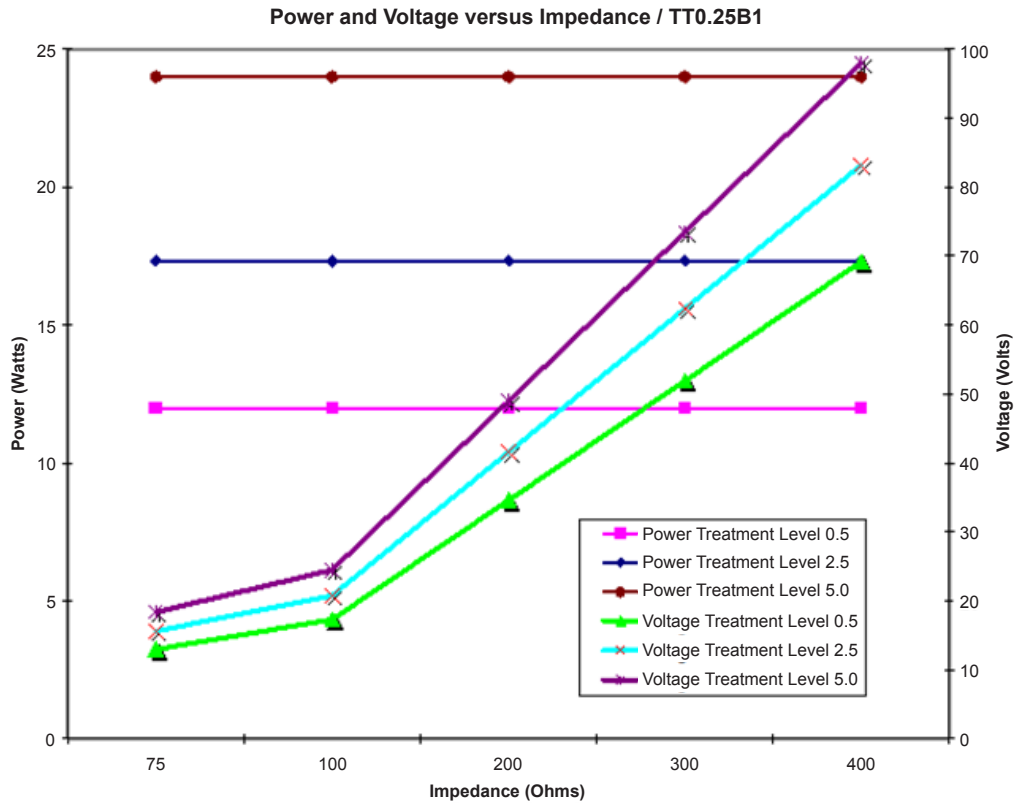
12.16 Technical Specifications

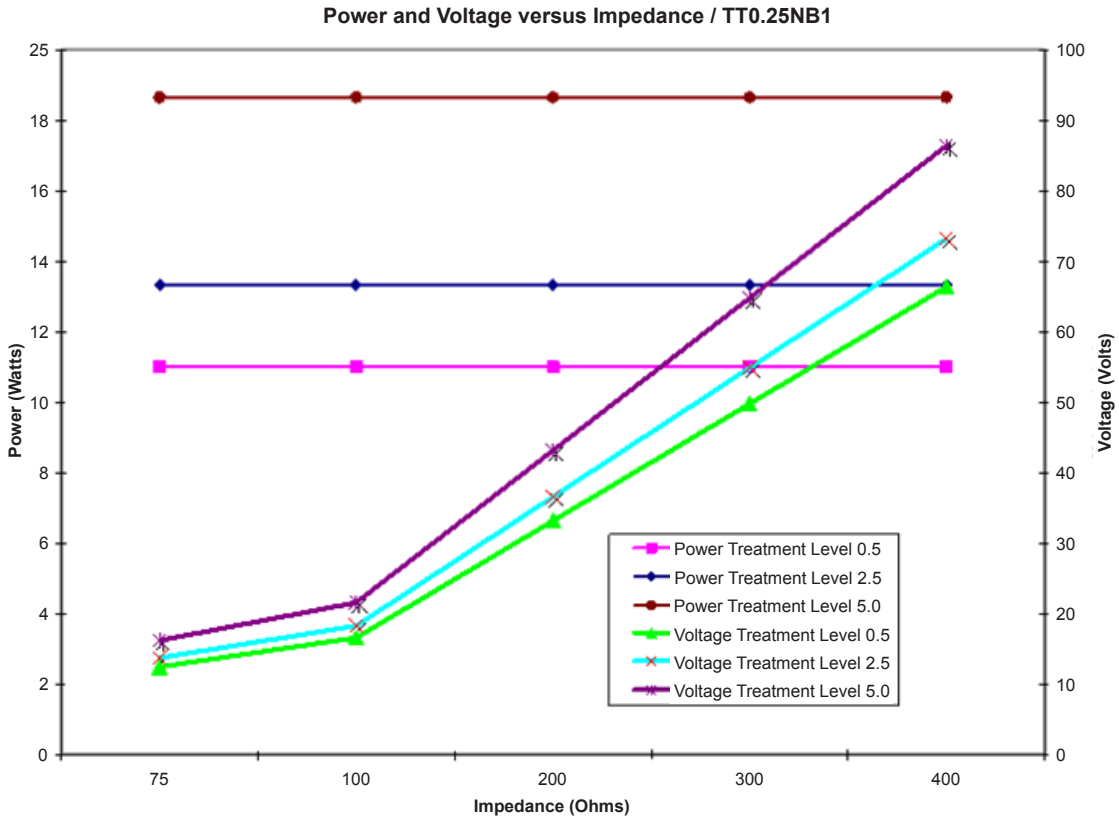
From	To	Cable Length
Power Input	Power Supply	10 ft / 3 m
Foot Switch	Foot Switch	10 ft / 3 m
Patient Return	Return Pad	6 ft / 1.8 m
Hand Piece Communication	Hand Piece	6 ft / 1.8 m

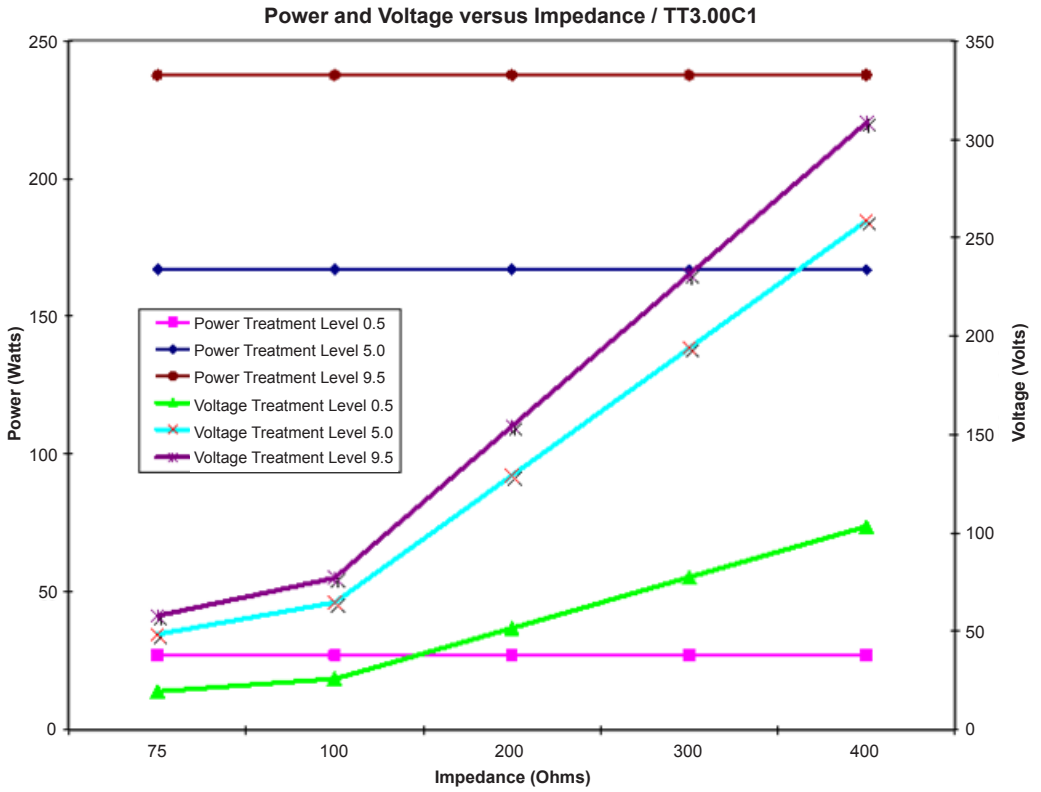
13. Power Output Curves

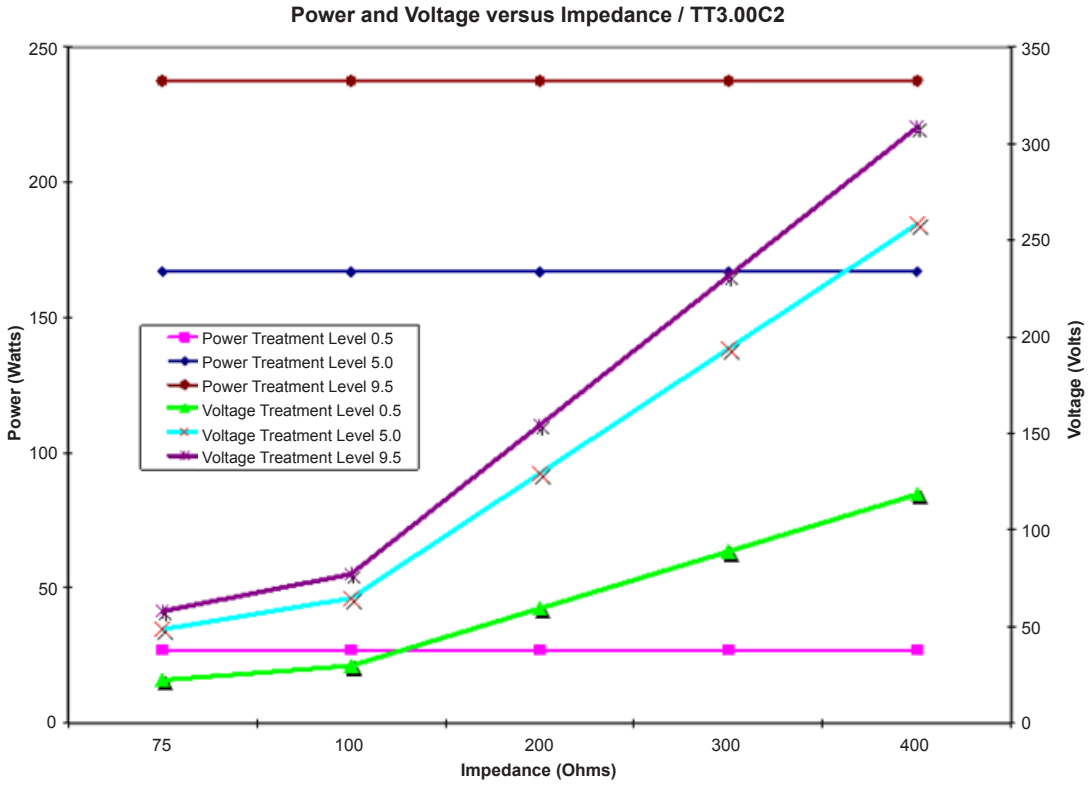




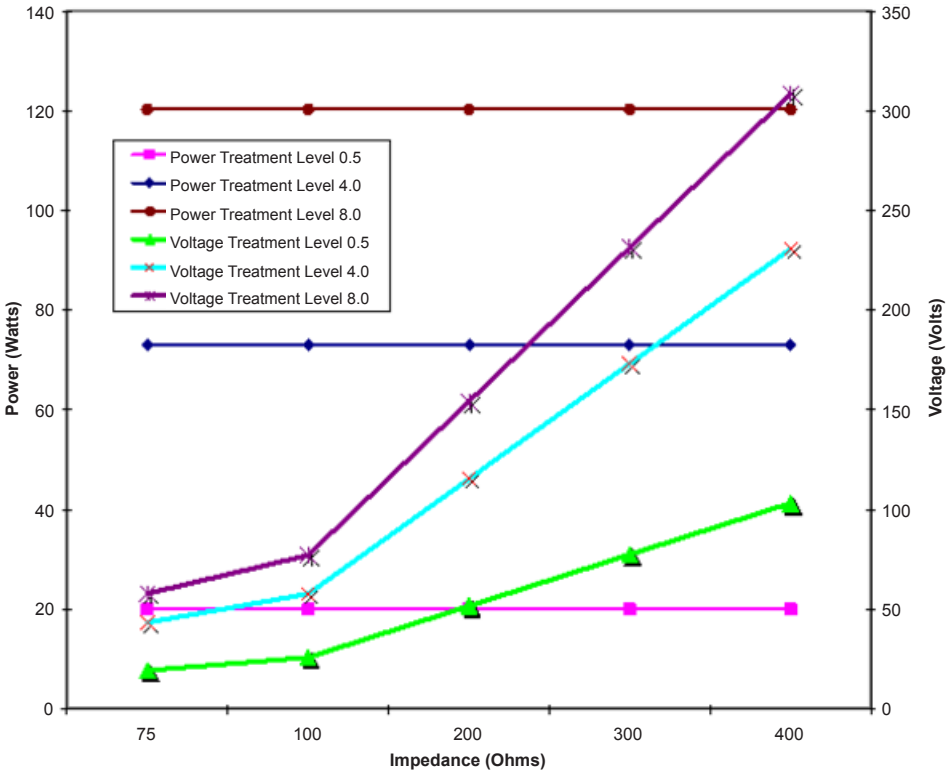




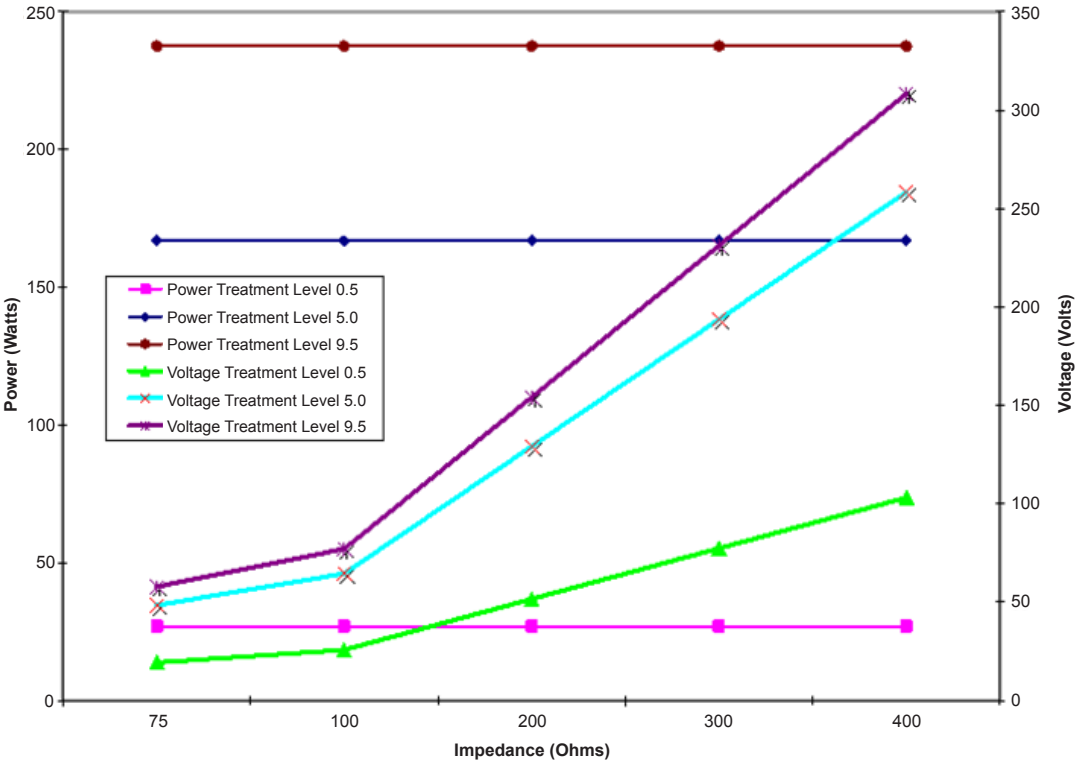




Power and Voltage versus Impedance / TT3.00C3



Power and Voltage versus Impedance / TT3.00E1



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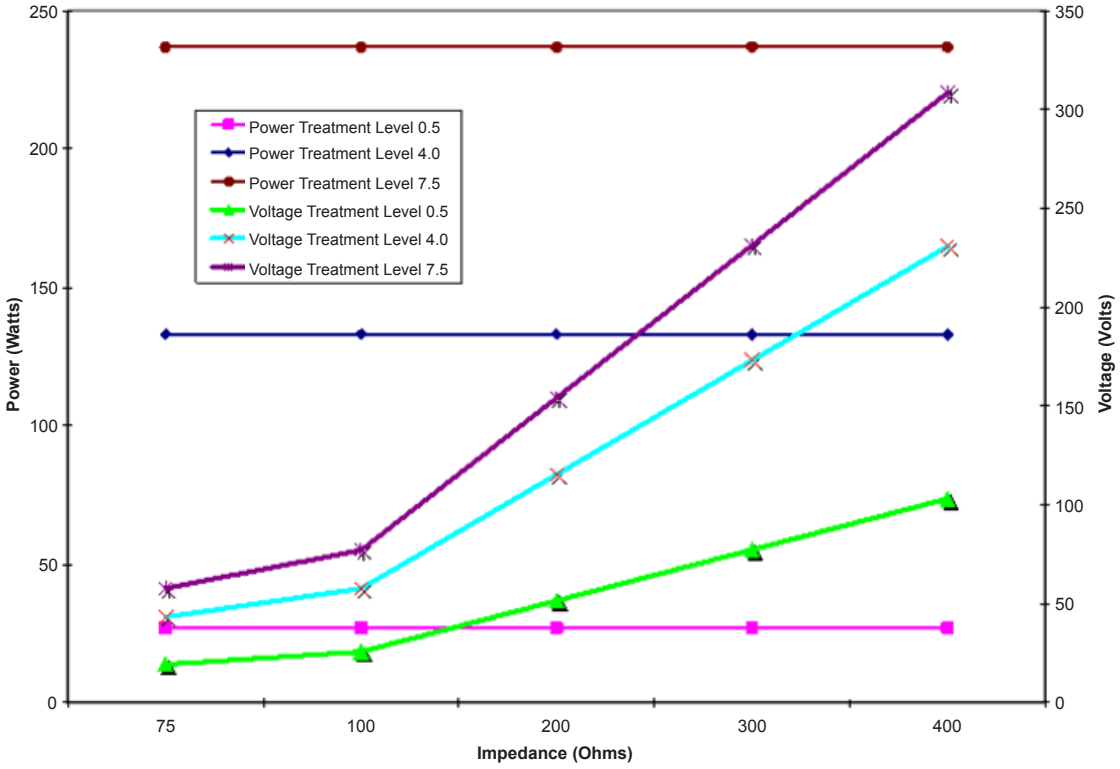
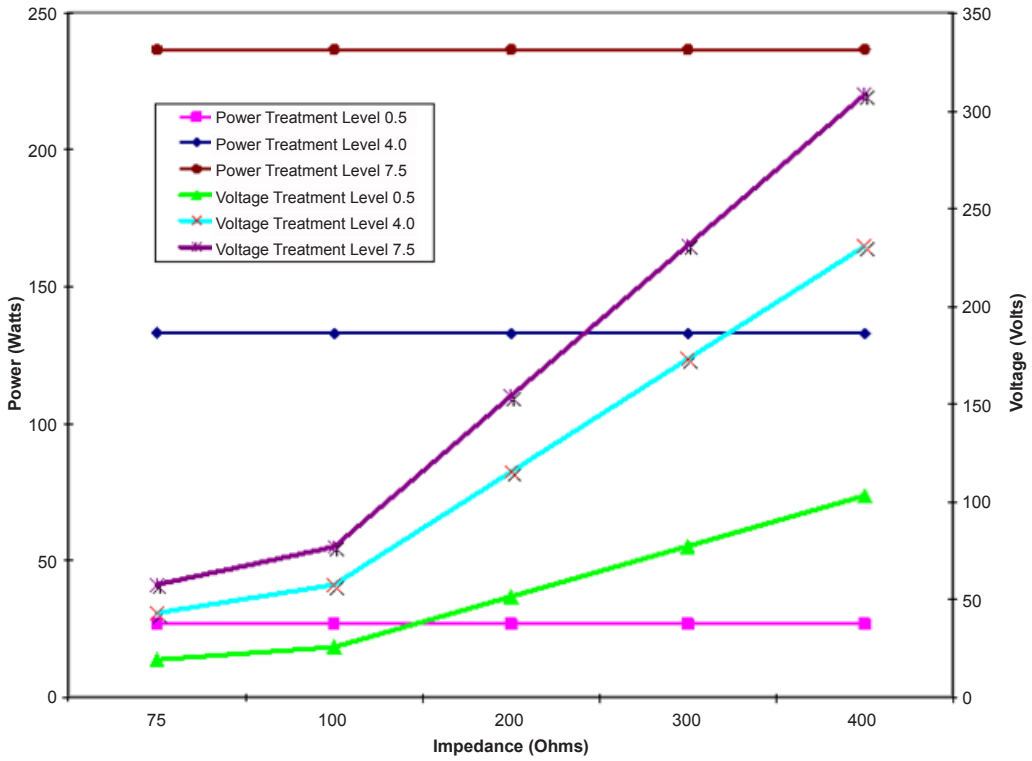
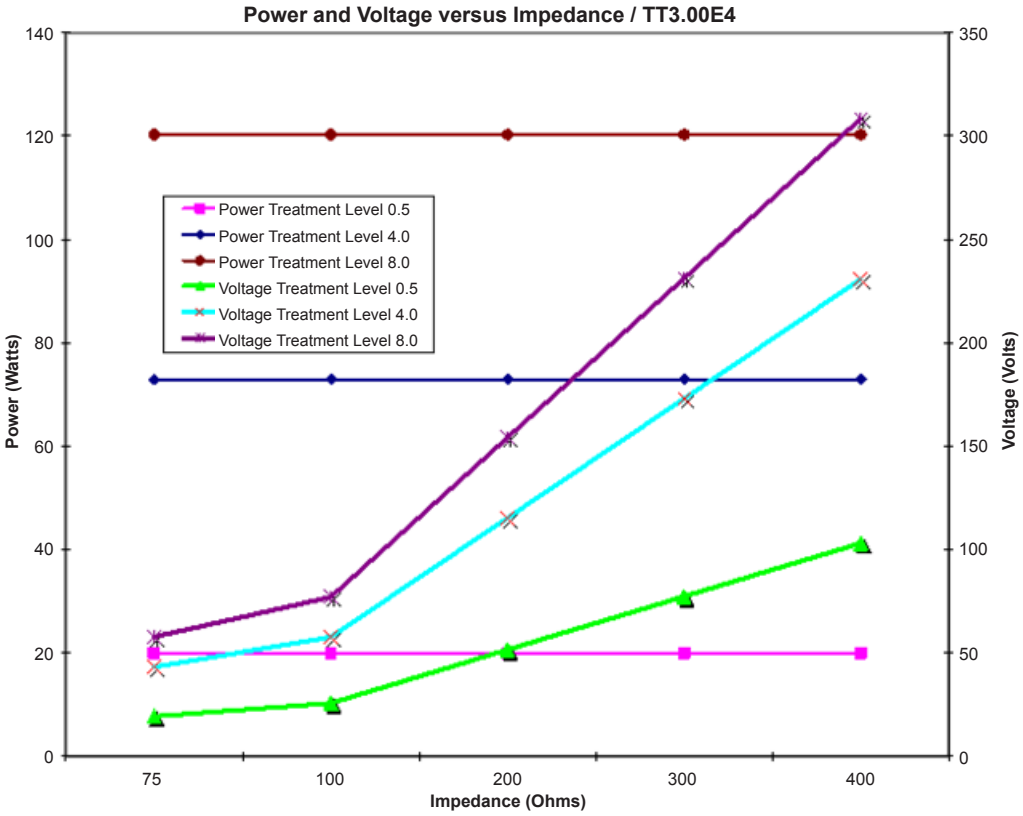
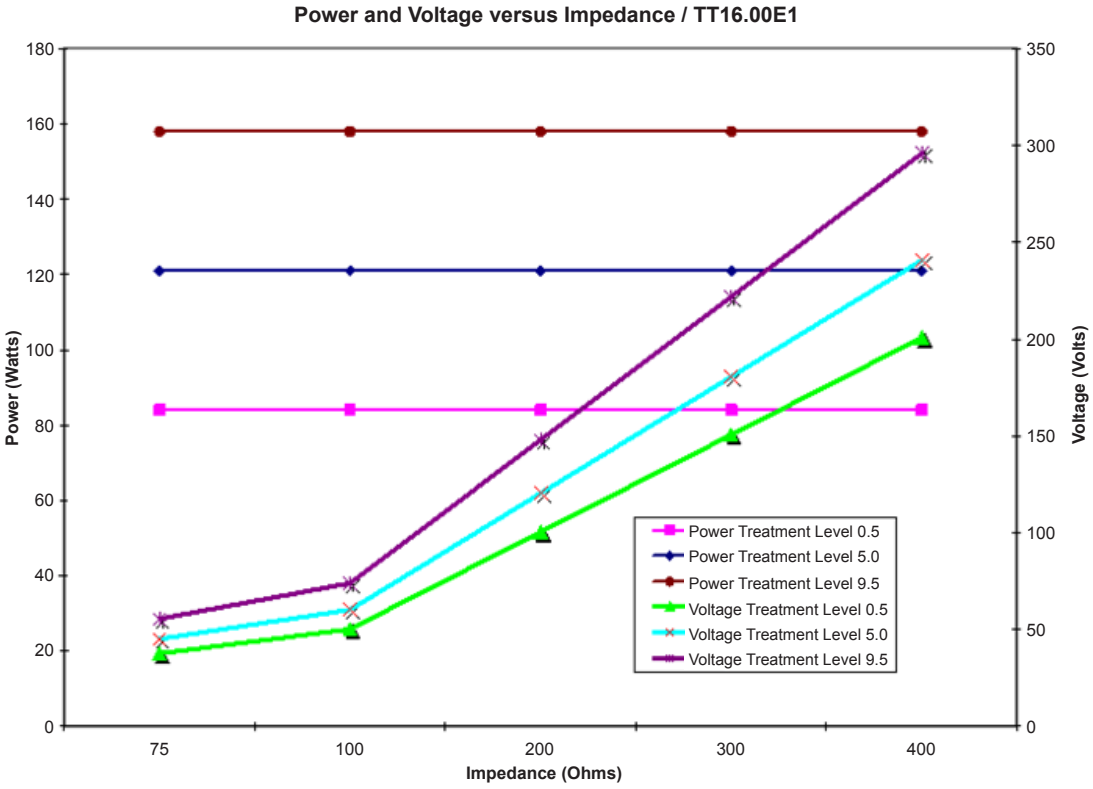
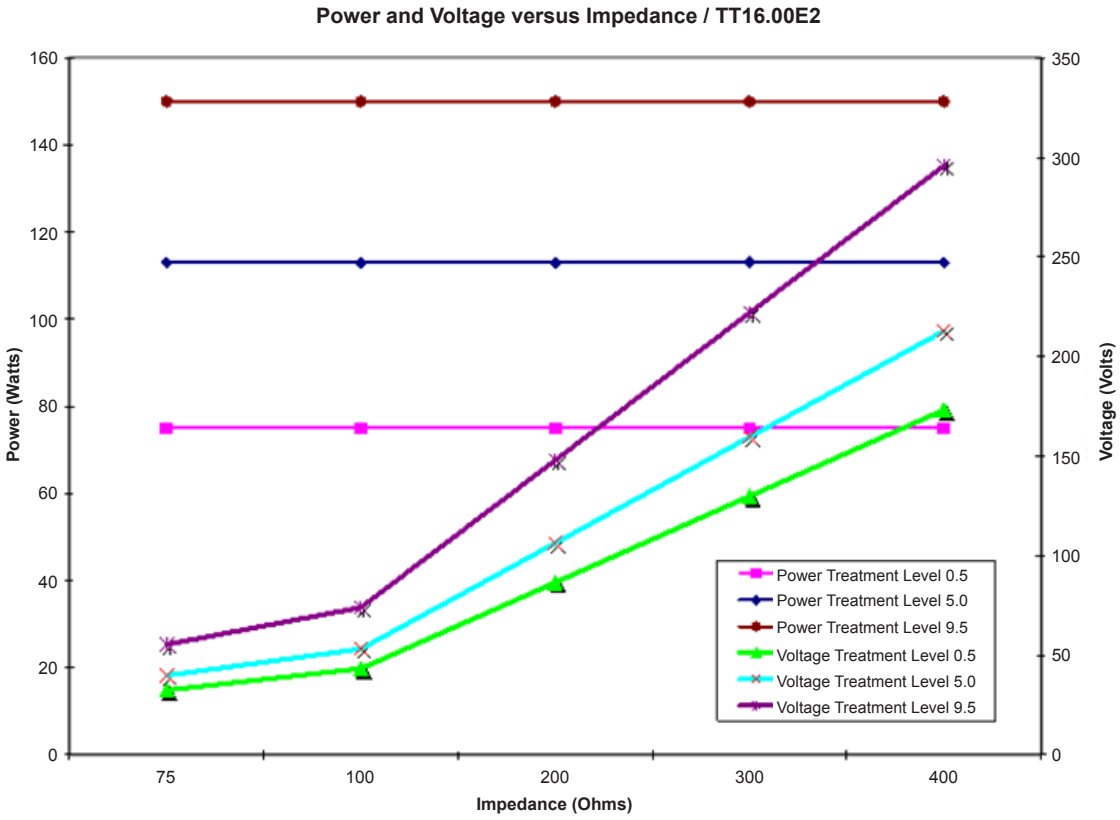


Power and Voltage versus Impedance / TT3.00E3



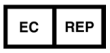






14. Labeling Symbols

Table 14.1 Labeling Symbols

BS EN ISO 15223-1: 2016 Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied. Part 1: General requirements			
Symbol	**Symbol Ref. No.**	**Symbol Title**	**Additional Information**
	5.1.1	Manufacturer	The date of manufacture, as well as the name and address of the manufacturer, can be combined in one symbol. Additional reference ISO 7000-3082.
	5.1.2	Authorized representative in the European Community	
	5.1.3	Date of manufacture	This symbol can be filled or unfilled. If filled, the date of manufacture as well as the name and address of the manufacturer can be combined in one symbol. Additional reference ISO 7000-2497.
	5.1.4	Use-by date	Synonym for "use-by date" is "use by". Also called "expiration date". Additional reference ISO 7000-2507.
	5.1.5	Batch code	Synonyms for "batch code" are "lot number" and "batch number". Additional reference ISO 7000-2492.
	5.1.6	Catalogue number	Synonyms for "catalogue number" are "reference number" and "reorder number". Additional reference ISO 7000-2493.
	5.1.7	Serial number	Additional reference ISO 7000-2498.
	5.2.7	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process. Additional reference ISO 7000-2609.
	5.2.8	Do not use if package is damaged	This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised". Additional reference ISO 7000-2506.
	5.3.1	Fragile, handle with care	Additional reference ISO 7000-0621.
	5.3.2	Keep away from sunlight	This symbol may also mean "Keep away from heat". Additional reference ISO 7000-0624.
	5.3.4	Keep dry	Additional reference ISO 7000-0626.
	5.3.7	Temperature limit	Additional reference ISO 7000-0632.
	5.3.8	Humidity limitation	Additional reference ISO 7000-2620.

BS EN ISO 15223-1: 2016 Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied. Part 1: General requirements			
Symbol	**Symbol Ref. No.**	**Symbol Title**	**Additional Information**
	5.3.9	Atmospheric pressure limitation	Additional reference ISO 7000-2621.
	5.4.2	Do not re-use	Synonyms for "Do not re-use" are "single use" and "use only once". Additional reference ISO 7000-1051.
	5.4.3	Consult instructions for use	Synonym for "Consult instructions for use" is "Consult operating instructions". Additional reference ISO 7000-1641.
	5.4.4	Caution	This symbol is essentially a cautionary symbol and should be used to highlight the fact that there are specific warnings or precautions associated with the medical device, which are not otherwise found on the label. Additional reference ISO 7000-0434A.

IEC TR 60878 Ed. 3.0 b:2015 Graphical symbols for electrical equipment in medical practice			
Symbol	**Symbol Ref. No.**	**Symbol Title**	**Additional Information**
	5007	"ON" (power)	To indicate connection to the mains, at least for mains switches, or their positions, and all those cases where safety is involved. Additional reference IEC 60417-5007 (2002-10).
	5008	"OFF" (power)	To indicate disconnection from the mains, at least for main switches, or their positions, and all those cases where safety is involved. Additional reference IEC 60417-5008 (2002-10).
	5016	Fuse	To identify fuse (fuse boxes) or their location. Additional reference IEC 60417-5016 (2002-10).
	5019	Protective earth; protective ground	To identify any terminal; this is intended for connection to an external conductor for protection against electric shock in case of fault, or the terminal of a protective earth (ground) electrode. Additional reference IEC 60417-5019 (2006-08).
	5021	Equipotentiality	To identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding. Additional reference IEC 60417-5021 (2002-10).
	5114	Foot switch	To identify a foot switch or the connection for a foot switch. Additional reference IEC 60417-5114 (2002-10).

IEC TR 60878 Ed. 3.0 b:2015 Graphical symbols for electrical equipment in medical practice			
Symbol	**Symbol Ref. No.**	**Symbol Title**	**Additional Information**
	5140	Non-ionizing electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems, e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment. Additional reference IEC 60417-5140 (2003-04).
	ISO 7000-2794 (2011-06)	Packaging unit	To indicate the number of pieces in the package. Additional reference ISO 7000-2794 (2009-02). *Note – A number is inserted in the symbol to indicate the number of parts in the package.*
	5331	Not Type AP	Explosion Hazard. Do not use in the presence of flammable anesthetics.
	5334	Type BF applied part	To identify a type BF part complying with IEC 60601-1. Additional reference IEC 60417-5334 (2002-10). *Note 1 – B = Body.* *Note 2 – F = Floating applied part.*
	5569	Locking, general	To identify on a control that a function is locked or to show the locked status. Additional reference IEC 60417-5569 (2005-05).
	5570	Unlocking	To identify on a control that is a function is not locked or to show the unlocked status. Additional reference IEC 60417-5570 (2002-10).
	5655	Rotation around an axis	To identify the control or the indicator for rotating an object around an axis, typically for a footswitch or hand-piece control.
	ISO 7010-M002 (2011-06)	Refer to instruction manual / booklet	To signify that the instruction manual / booklet must be read.
	ISO 7010-W001 (2011-06)	General warning sign	To signify a general warning. *Note - This safety sign cannot be used on its own and requires a supplementary sign to give further information about the hazard.* *IEC TR 60878 note: On medical equipment, this safety sign shall only be used if there is no other safety sign for the corresponding hazard. If possible, the hazard or the appropriate precaution should be indicated.*
	ISO 7010-W005 (2011-06)	Warning: Non-ionizing radiation	To warn of non-ionizing radiation.
	ISO 7010-W012 (2011-06)	Warning: electricity	To warn of electricity.

IEC TR 60878 Ed. 3.0 b:2015 Graphical symbols for electrical equipment in medical practice			
Symbol	**Symbol Ref. No.**	**Symbol Title**	**Additional Information**
	ISO 7000-2402 (2011-06)	Stacking limit	To indicate that the items shall not be vertically stacked, either because of the nature of the transport packaging or because of the nature of the items themselves.
	ISO 7000-2403 (2011-06)	Stacking limit by number	To indicate that the items shall not be vertically stacked beyond the specified number, either because of the nature of the transport packaging or because of the nature of the items themselves.

BS EN 50419:2006 Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)		
Symbol	**Symbol Title**	**Additional Information**
	WEEE wheeled bin	This product contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or recycling instructions for this product. Residents outside the European Union must dispose or recycle this product in accordance with local laws or regulations that apply.

Other Marks and Symbols		
Symbol	**Symbol Description**	**Additional Information**
	Neutral Electrode, High Frequency Isolated Patient Circuit	IEC 60601-2-2 (2009)
	ESD Warning	MIL-STD-129 ESD Label Standard
	Compressed Gas	WHMIS 2015: Canada has aligned the Workplace Hazardous Materials Information System (WHMIS) with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).
	Hazard Class 9 Materials	D.O.T. "ID 8000 Consumer Commodity" symbol for Hazard Class 9.
	Limited Quantity per IATA Dangerous Goods Regulations	When shipped by ground, air, or vessel, small quantities of hazardous materials (or dangerous goods)—referred to as "limited quantities"—are granted relief from certain hazmat shipping requirements.

Other Marks and Symbols		
Symbol	**Symbol Description**	**Additional Information**
Rx Only	For U.S. Only: Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician or licensed health care professional.	USA Code of Federal Regulations 21 CFR Part 801§ 801.109(b)(1)
CE	European Conformity mark Notified Bodies: DEKRA (0344) TUV Rheinland (0197)	The product conforms to European Medical Directive 93/42/EEC and meets applicable health, safety and environmental requirements. If the mark is accompanied by a number, conformity is verified by the indicated notified body (CE marking excludes the CPT system console).
	TUV Rheinland classification mark	TUV Rheinland of North America classification mark that indicates compliance with both U.S. and Canadian National Standards.
thermage	Thermage Product Logo	Thermage Registered Trademark
PLASTIC	Plastic Ocular Shield required	Thermage Eyelid Treatment requires use of PLASTIC ocular shields. DO NOT use metal shields. Symbol appears on Eyelid Treatment Tips.
MADE IN USA	MADE IN USA	Country of origin symbol
	SD Card	SD memory card slot
	Return Pad Connector	Symbol designates the location of the return pad connector
	Hand Piece Connector	Symbol designates the location of the hand piece connector
1	Contents Listing Symbol	Lists the contents of the package