Thermage FLX™ System
Model Number: TG-3A
User Manual

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Patents

US patents and pending patent applications apply to this product. For details, visit http://www.thermage.com/patents

Rx Only



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

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1 INTRODUCTION

Read the information in the User Manual in its entirety before using the Thermage FLX™ System, accessories, components, and performing the Thermage® procedure.

Please contact Solta Medical Customer Service or your local authorized distributor of Solta Medical products if you have any questions.

1.1 ABOUT THIS MANUAL

This manual is a reference for the Thermage FLX System. It is intended to be used by healthcare professionals with appropriate training.

This manual includes a general overview of the System along with detailed instructions for using the System. This manual also supplies other information of importance to the user and is intended as a User Manual only.

1.2 CONVENTIONS USED IN THIS MANUAL

The following list shows conventions that are used throughout this manual.

 **Warning**	**Warnings consist of alert information necessary to prevent death, serious injury, or adverse effects to the patient or user.**
Notice	Notices consist of alert information necessary for the user to take action for proper use of the System, or to protect the System from malfunction or damage.

THE THERMAGE FLX SYSTEM



1.3 INTENDED PURPOSE

The Thermage FLX System ('System') is a monopolar, capacitively coupled RF system designed for use in non-invasive dermatological procedures.

1.4 INTENDED PATIENT POPULATION

The Thermage FLX System is intended for adult patients aged 35-60 years old, regardless of ethnicity or gender, who do not meet contraindications.

1.5 INTENDED USER

This equipment/system is intended for use by healthcare professionals with appropriate training.

1.6 INTENDED USE, INDICATIONS AND CONTRAINDICATIONS

This device is not intended to treat or alleviate a disease or injury and is not intended to modify anatomy.

INTENDED USE/INDICATIONS

Region	Indication for Use
USA	The radiofrequency energy delivery components of the Thermage FLX System 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 FLX System 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).

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Region	Indication for Use
CE Compliant	The radiofrequency (RF) energy delivery components of the Thermage FLX System and Accessories are indicated for use in: • 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 FLX System and Accessories are indicated for use in: • Non-invasive treatment of periorbital wrinkles and rhytids • Non-invasive treatment of wrinkles and rhytids
Singapore	The radiofrequency (RF) energy delivery components of the Thermage FLX System and Accessories are indicated for use in: • Dermatologic and general surgical procedures for electrocoagulation and hemostasis. The simultaneous application of radiofrequency energy and skin vibration by the Thermage FLX System are indicated for use in: • Dermatologic and general surgical procedures for electrocoagulation and hemostasis. • Relief of minor muscle aches and pains. • Relief of muscle spasms.

Region	Indication for Use
Brazil	The radiofrequency (RF) energy delivery components of the Thermage FLX System and Accessories are indicated for use in: • Dermatologic and general surgical procedures for electrocoagulation and hemostasis; • Assisting in non-invasive treatment of periorbital wrinkles and rhytids including upper and lower eyelids; • Assisting in non-invasive treatment of wrinkles and rhytids. The simultaneous application of radiofrequency energy and skin vibration by the Thermage FLX System are indicated for use in: • Dermatologic and general surgical procedures for electrocoagulation and hemostasis; • Assisting in non-invasive treatment of periorbital wrinkles and rhytids; • Assisting in 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).

CONTRAINDICATIONS

For all regions, the Thermage System is contraindicated for use in patients with 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.

1.7 IMPORTANT PATIENT SAFETY INFORMATION



For treatment over the eye (upper and lower eyelid, or within the periorbital rim), ensure the use of plastic ocular shields.

Do not use metal eye shields.

Before using the Thermage FLX System, read the safety considerations outlined in this manual.

The Thermage FLX System must be used by health care professionals who have adequate training in the use of the device.

Earlier generations of the Thermage System (e.g. ThermaCool, NXT, CPT) have 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”.

The side effects associated with treating “off-label” have not been evaluated in clinical studies. “Off-label” treatment may result in a different safety profile.

Professional discretion by the health care professional is necessary when treating body areas in proximity to major nerve bundles otherwise it may result nerve damage.

Be aware that there are potential risks resulting from neuromuscular stimulation when using the System.

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.

Most frequently reported side effects during a Thermage FLX treatment are mild to moderate pain. 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.

The most frequently reported side effects after a Thermage treatment are:

- **Burns** - The procedure produces heating in the upper layers of the skin, and may cause 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.
- **Surface Irregularities** - 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.
- **Altered sensations** - 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.
- **Lumps or Nodules** - Sub-cutaneous nodules occurring primarily in the neck area may occur. It typically self-resolves within 1 or 2 weeks without adverse sequelae.
- **Hyperpigmentation** - Usually resolve over the course of time (within several months).
- **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).

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- **Erythema** - 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.
- **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.
- **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.
- **Herpes simplex** - 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.

1.8 PATIENT TYPES NOT STUDIED

For all regions, the Thermage System is contraindicated for use in patients with 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.

Solta Medical has not studied the following patient types:

- Thermage FLX System with pregnant and/or breast feeding women, children, people with diabetes, auto-immune disease (e.g. Lupus), herpes simplex, or epilepsy has not been studied.
- Thermage FLX System with patients with permanent make-up and/or tattoos has not been studied.
- Thermage FLX System over dermal fillers has not been studied.

1.9 EQUIPMENT SAFETY

The safe and effective use of Thermage system is highly dependent upon factors under the control of the user.

It is important that all warnings, notices, and the supplied user manual be read, understood and followed before proceeding with treatment.

For maximum safety, observe the following warnings and notices.



To avoid risk of electrical shock or injury:

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.

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

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

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.

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

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

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 FLX 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 FLX System, including cables specified by Solta. Otherwise, degradation of the performance of this equipment could result.** **Be aware that failure of the System could result in an unintended increase in output power.** **This equipment must only be connected to a supply mains with protective earth (i.e. grounded outlet). Extension cords and/or adapter plugs must not be used.** **Do not modify or attempt to service the equipment (e.g. System and accessories).** **Use only Solta-supplied components and accessories:** **- System console, power cord, handpiece, and treatment tips** **- Return pad, cryogen, coupling fluid, and skin marking paper** **All Solta-supplied components and accessories should be inspected regularly for any signs of damage prior to use.**

The Thermage FLX System is intended to be used in a Professional healthcare facility environment (e.g.; doctor's offices, clinics, surgery room, intensive care, and patient rooms). 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 FLX System not deliver an excessive amount 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.

NOTE: The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

1.10 COMPLAINTS

Any serious incident related to the Thermage FLX System should be reported to Solta and the appropriate competent authority where the incident occurred.

Solta Medical Customer Service should be contacted if the Thermage FLX System is involved in a complaint or adverse event.

2 THERMAGE FLX SYSTEM OVERVIEW

The Thermage FLX System ('System') is a monopolar, capacitively coupled radiofrequency System designed for use in non-invasive dermatological procedures.

The System consists of the following components: Console, including touchscreen, a Handpiece, Treatment Tip(s), AC power cord and an optional footswitch.

The System is used with the following Solta-supplied accessories: cryogen canister, return pad, coupling fluid and skin marking paper.

Only Solta-supplied components and accessories should be used with the System to avoid unsafe use or product malfunction.

Listing of all major System components and accessories, along with their respective model numbers are as follows:

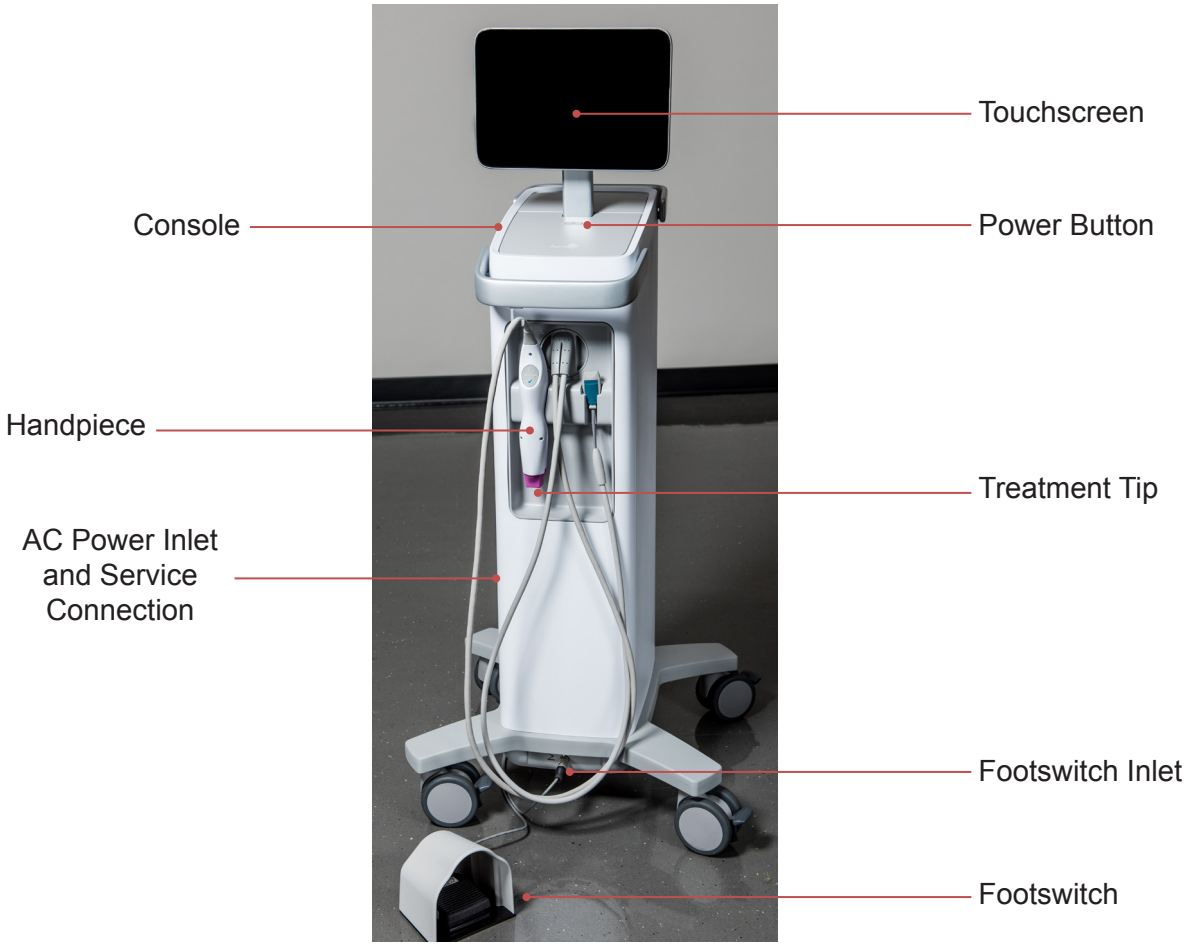
Thermage FLX System Components and Accessories

Description	Model #
Console, including Touchscreen	TG-3A
Handpiece	TH-6 series
Treatment Tip(s) (Non-sterile)	TT series
Footswitch (optional)	TW series
Cryogen canister	TC-2 series
Return pad	TR-4 series
Coupling fluid	TF series
Skin marking paper	SM series

The System continuously monitors output power, output energy, treatment duration, and measured impedance.

The System also controls the coolant delivery through the Handpiece. The Handpiece delivers RF energy while cooling tissue by thermal conduction.

Figure 1 Thermage FLX System Components and Accessories



Component Name	Function
Console	Houses all electro-mechanical components for system operation including generation of RF energy
Touchscreen	Interactive controls for system operation
Power Button	Turns system on and off. The power button illuminates when the system is connected to electrical outlet
Handpiece	Primary option to activate treatment; location for treatment tip
Treatment Tip	Electrode containing the primary treatment parameters; determines treatment site size
AC Power Inlet and Service Connection	To connect system power cord and service cable port. NOTE: Service port is for trained service technicians only.
Footswitch Inlet	To connect footswitch to the system
Footswitch	Secondary option to activate treatment

3 SYSTEM CONTROLS

The System controls include the power button, Touchscreen, Handpiece, and footswitch.

Power Button

Press ⏻ button to power the system on and off.

The ⏻ is illuminated when the system is connected to an electrical outlet.

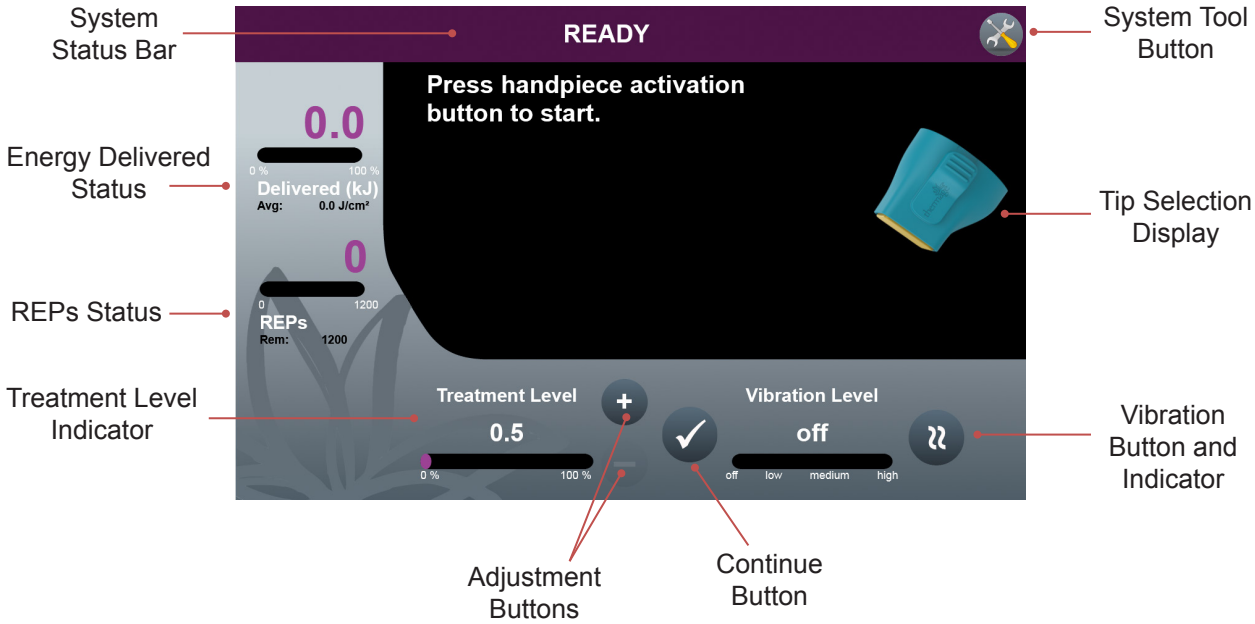
By pressing ⏻ the system will be powered on, the screen activates, and the system conducts a startup process verifying system functions. The system may take up to 5 minutes to complete the startup process.

Touchscreen

All system controls are accessed through the interactive touchscreen allowing the user to quickly navigate the menus, prepare for treatment, and make adjustments during a treatment.

The layout of the touchscreen consists of the system status display bar, system tools button, energy delivered and REPs status, tip selection display, vibration control button, treatment level controls and continue button.

Controls on the Touchscreen



Functions of the System Controls and Indicators

Screen Function	Description
System Status Bar	The status bar at the top of each screen indicates the current System mode. The message on this bar is dependent upon the System mode; follow the instructions on the screen, if required.
System Tools Button	Press the System Tools button at any time to display the System Tools menu.
Energy Delivered Status	The number represents the total energy delivered (kJ) over the course of the treatment. % bar: represents the energy delivery progress during each REP. Avg: represents the average energy density (J/cm^2) delivered per radiofrequency energy pulse (REP) over the course of the treatment.
REPs Status	REPs bar: presents the number of REPs completed with the attached Treatment Tip. 'REP' stands for Radiofrequency Energy Pulse, which means a single pulse transmission of the RF energy through a given electrode (Tip). Rem: represents the number of REPs remaining on the attached Treatment Tip.
Treatment Level Indicator	The number displays the selected treatment level. For each Treatment Tip size, 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. The percentage bar is a visual aid only and does not correlate to actual tissue temperature. Increase or decrease the treatment level with the Increment and Decrement buttons. Each press of the or increases or decreases the treatment level by 0.5. Press and hold on the buttons to continuously change the value.
Adjustment Buttons	In general, the and buttons are used to increase or decrease the selected function respectively, depending on the System mode, such as treatment level or volume control.
Continue Button	In general, the continue button is used to confirm a setting change or acknowledge a System message. The function of this button is dependent upon the System mode; follow the instructions on the screen.
Vibration Button and Indicator	The vibration button changes the vibration level when used with selected Treatment Tips. Tapping the vibration level button cycles the intensity between off (default), low, medium and high. The vibration level is identified to the left of the button. Vibration Indicator displays current vibration level selected.
Tip Selection display	The tip selection display indicates the Treatment Tip type currently attached to the Handpiece.

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Footswitch

The footswitch (also referred to as foot pedal) is an alternative method for activating treatment rather than using the handpiece for activation control. When connected to the system, the treatment activation control will default to the footswitch.

Disconnect the footswitch from system when handpiece activation control is desired.

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4 HANDPIECE CONTROLS

The Handpiece is the primary option to activate treatment in the delivery of RF energy for selective coagulation of tissue while conductively cooling the epidermis. A treatment tip must be securely attached to the handpiece before use.

The Handpiece is provided with the System.

The Handpiece treatment controls allow the user to select treatment level and vibration level (off, low, medium, and high).



Shown with a treatment tip attached

Functions of the Control Buttons on the Handpiece

Controls	Description
Handpiece Activation Button	Press and hold the activation button to initiate the Active mode. Release the activation button to terminate the Active mode and interrupt RF delivery. Note: Treatment control activation will default to the footswitch when footswitch is connected to system.
Handpiece Control Buttons 	**Treatment Control Buttons** Increase or decrease the treatment level with the Increment and Decrement buttons. Each press of the or increases or decreases the treatment level by 0.5. Press and hold a button to continuously change the value. **Vibration Button ( ):** The vibration button changes the vibration level when used with selected Treatment Tips. Press the vibration level button to cycle the vibration between off (default), low, medium and high. **Continue Button (√)** In general, the continue button is used to confirm a setting change or acknowledge a System message. The function of this button is dependent upon the System mode; follow the instructions on the screen.

5 TREATMENT TIPS

	**Solta-supplied Treatment Tips are for single patient use. Do not reuse or attempt to reprocess. Multiple patient use creates a risk of cross contamination of microorganisms from patient to another.**

The Treatment Tips are single use accessories, available in various treatment site REP counts, and are designed for efficient treatment of small and large treatment areas.

Treatment Tip sizes are available for treatment over the eye, treatment of the face, and treatment of off-face body areas such as abdomen, arms, thighs, buttocks, and knees.

The System allows vibration mode to be active with all Treatment Tip sizes except for Treatment Tips dedicated for treating over the eye.

The treatment tip type will be displayed on the touchscreen when attached to the handpiece.

The treatment tip types provided on the Thermage FLX system consist of the following:

5.1 EYE TIP 0.25cm^2 – FOR TREATMENT OVER EYE

	**Ensure the use of plastic ocular eyeshields when treating over the eye (upper and lower eyelid), or within the periorbital rim.** **Do not use metal eye shields.** **Solta Medical recommends Oculoplastic® plastic globe protector to use. Refer to manufacturer's instructions for proper placement and use of eye shields.**
	**Do not use vibration when treating the face around the eye areas while plastic ocular shields are in use.** **Vibration may cause displacement of the ocular shields resulting in increased risk of corneal abrasions or ocular damage.**

The eye tip (0.25cm^2) is the smallest of the treatment tips provided and is used for treating over the eye (upper and lower eyelid), or within the periorbital rim.

Vibration is not available when using any version of the eye tip.

5.2 TOTAL TIPS – 3.0cm^2 OR 4.0cm^2 – FOR TREATMENT OF FACE AND OFF-FACE BODY AREAS

Total Tips come in different sizes (3.0cm^2 and 4.0cm^2) and are distinguishable by different colors. These tips are used for treatment of the face (excluding over the eye) as well as for smaller treatment areas of the abdomen, neck, arms, thighs, buttocks, and knees.

Vibration is available for all versions of the Total Tips.

5.3 BODY TIP 16.0cm^2 – FOR OFF-FACE BODY TREATMENT

The Body Tip (16.0cm^2) is the largest of the treatment tips provided and is used for treatment of larger treatment areas of the abdomen, arms, thighs, buttock, and knees.

Vibration is available for all versions of the Body Tip.

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6 ACCESSORIES

RETURN PAD

	**Use only Solta-supplied Return Pad.**
	**Solta-supplied Return Pad is for single patient use only. Reusing the Return Pad may result in poor contact quality, patient burns, and/or poor system performance.**
	**Do not use a Return Pad on patients with known sensitivity to acrylates.**

The Return Pad is a disposable, 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 improper function.

The Return Pad is provided non-sterile and does not need to be cleaned prior to use.

CRYOGEN CANISTER

	**Use only Solta-supplied Cryogen Canisters.**
	**Avoid breathing high concentrations of cryogen vapor. Deliberate inhalation of the vapor will cause asphyxiation. Death can occur without warning.** **First Aid - If overcome by vapors, move to fresh air. For skin and eye contact, thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical attention.**
	**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 Cryogen Canisters.**
	**Do not store canister near heat or open flame.**

	**Do not puncture, incinerate, or expose the canister to temperatures above 49°C (120°F).**
	**Prolonged exposure to sunlight or other sources of heat may cause the canisters content to vent or burst.**
	**Keep canisters out of the reach of children.**

The Cryogen Canister is a disposable accessory and does not require cleaning.

When performing a treatment, the cryogen is released to the non-patient side of the treatment tip electrode, cooling the surface to assist in patient comfort and minimize the likelihood of overheating the skin surface at a given treatment site.

Each treatment REP reduces the volume of cryogen in the canister. The number of REPs each cryogen canister can deliver varies widely (i.e. 100-2,000) based on the size and cooling profile of the Treatment Tip, treatment setting in use and the individual cooling characteristics of the cryogen used.

For example, a cryogen canister contents will be depleted more rapidly when using larger body tips compared to the smaller tips used to treat over the eye.

The reduction in cryogen volume is also more rapid for higher treatment settings than for lower treatment settings.

COUPLING FLUID

	**Use only Solta-supplied Coupling Fluid.**
	**Solta-supplied Coupling Fluid is for single patient use only. Do not reuse.**

The Coupling Fluid is used to help make an effective coupling connection between the Treatment Tip and the patient’s skin.

SKIN MARKING PAPER

	**Use only Solta-supplied Skin Marking Paper.**
	**Solta-supplied Skin Marking Paper is for single patient use only. Do not reuse once they have been applied to skin.**
	**Do not use if paper is damaged.**
	**Use in a well-ventilated area.**
	**Avoid eye contact with alcohol. If irritation occurs, flush eye(s) with water for 5 minutes.**
	**Flammable agents use for cleaning or disinfecting or as solvents should be allowed to evaporate before application of RF Energy.**

The Skin Marking Paper is a temporary ink transfer applied to the treatment area of the patient to imprint a marking grid for assisting the user in treatment tip placement alignment and tracking when performing treatment.

Specific skin marking paper is provided for each treatment tip size.

The treatment tip size information is contained on the skin marking paper.

FOOTSWITCH (OPTIONAL)

Use of the footswitch (also referred to as foot pedal) allows for alternative method of treatment activation.

When connected, the footswitch becomes the default method of treatment activation and the handpiece activation switch is disabled. Disconnect the footswitch to enable treatment activation from the handpiece.

7 SYSTEM STATUS MODES

The System provides the user with sequential process of status modes in order to proceed with performing a treatment.

After initial system power up, the full complement of status modes consists of (1) ACTION REQUIRED (2) ADJUST LEVEL (3) READY (4) ARMED (5) ACTIVE and (6) REP COMPLETE.

The current state of the system at power-up will determine which status mode will be displayed after initial power-up is completed. For instance, if all components are connected to the system prior to power-up, no further action is required so, the system will skip the ACTION REQUIRED mode, progressing to the next mode, ADJUST LEVEL.

RF energy is delivered only during the ACTIVE mode.

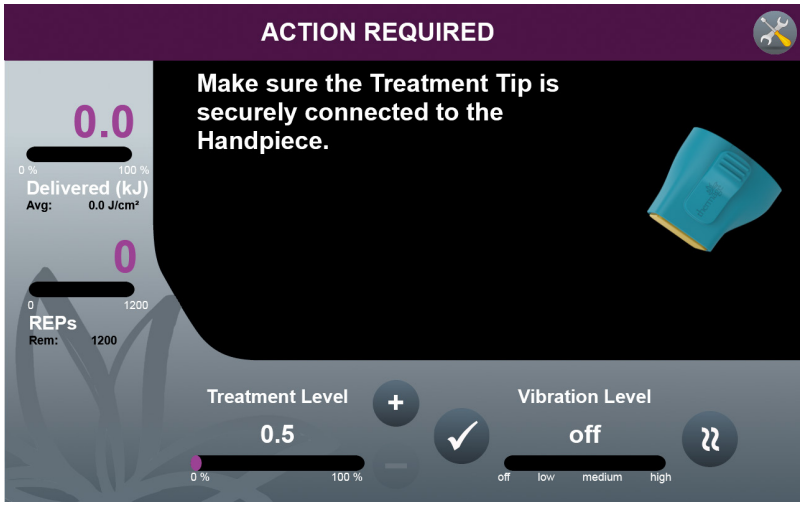
Each status mode is displayed at the top of the touchscreen display, to indicate the current mode state of the system.

7.1 ACTION REQUIRED

The System automatically enters ACTION REQUIRED mode after system power up initialization is completed.

If the Cryogen Canister, Handpiece, Treatment Tip, or Return Pad is not connected to the System, the System will prompt the user to take action to complete the process.

Once all four are installed, the System will proceed to the next mode.



Example shown: Action required for connection of Treatment Tip.

For the Eye Tip Only – An additional ACTION REQUIRED message will be displayed to notify the user that plastic ocular shields are required when using the Eye Tip.



Example shown: Reminder to use ocular shields for eyelid treatment.

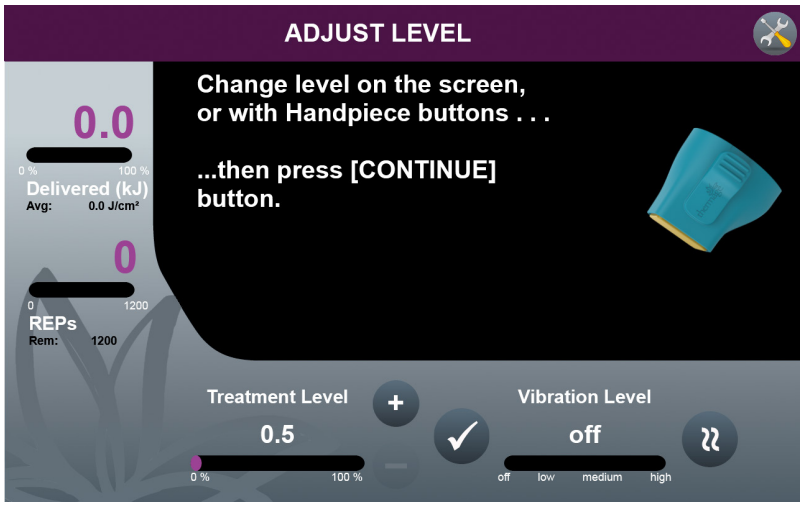
7.2 ADJUST LEVEL

After completing the ACTION REQUIRED, the system will automatically progress to the next system mode, ADJUST LEVEL.

Prior to the first REP activated, the System will always progress to the ADJUST LEVEL mode. The treatment level is defaulted to the lowest treatment level setting, requiring the user to adjust treatment level to the desired setting.

User may select the desired Treatment Level by tapping on the Touchscreen  or  buttons or use the Buttons on the Handpiece.

The user must then press the Continue button to confirm the Treatment Level.



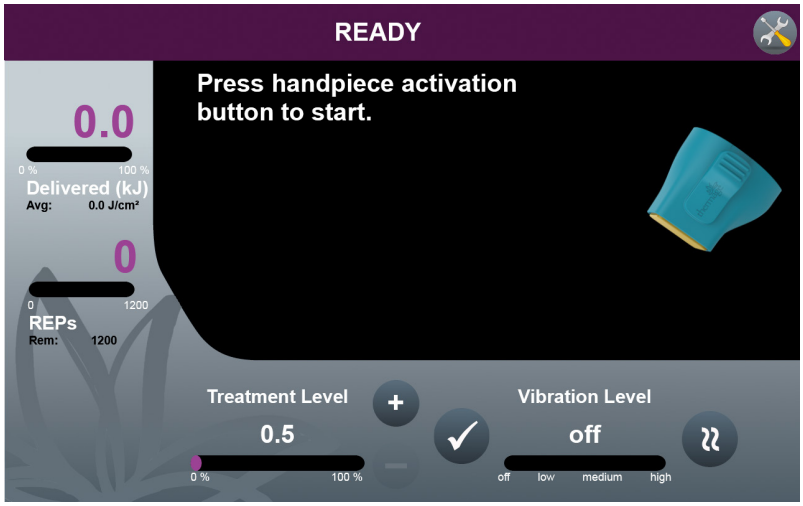
Example shown: Change treatment level and press to continue.

Follow the instructions on the Touchscreen to progress to next mode.

7.3 READY

Upon entering READY, the System Handpiece Assembly cooling function is initiated. This allows delivery of coolant to the Handpiece.

The System remains in READY mode until the Activation Button on the Handpiece or the Footswitch is pressed.



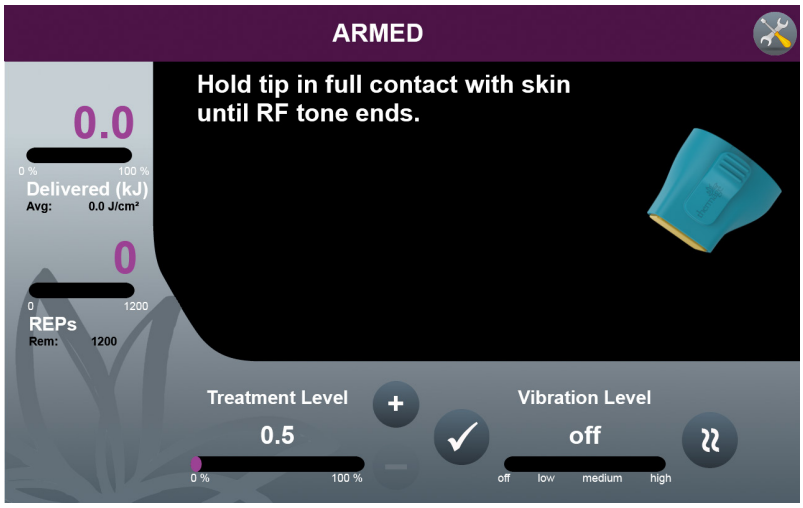
Example shown: If ready, press handpiece activation to start.

7.4 ARMED

After activation is pressed, the System will automatically enter ARMED mode. In the ARMED mode, the System is ready to deliver the RF energy treatment (REP).

The user aligns the handpiece and treatment tip to the intended treatment site and once the System senses that the treatment tip has made proper contact to the patient, the System will automatically deliver the intended REP to the treatment site.

Delivery of REP will not occur until the System senses contact to the patient treatment site. Proper contact and a predetermined range of applied force to the treatment site is required in order for the System to correctly sense and deliver the REP.



Example shown: Armed for treatment.

7.5 ACTIVE

If proper tissue contact is initiated within 3 seconds of pressing the Activation Button, the System transitions from the ARMED mode to ACTIVE mode. An audible tone indicates RF delivery during the ACTIVE mode.

The ACTIVE Mode consists of three (3) phases to deliver a REP.

1. Pre-Cooling: the System supplies cryogen coolant to the Treatment Tip.
2. RF Delivery: the System delivers the user-selected Treatment Level REP.

   (Note: The REPs remaining display will decrease by one when REP delivered.)
3. Post-Cooling: the System supplies cryogen coolant to the Treatment Tip.

Should a REP be interrupted and ends prematurely, it is strongly recommended to release the Activation Button (or Footswitch) and maintain Tip-tissue contact with the patient. This will stop energy delivery and go into Post-Cooling.

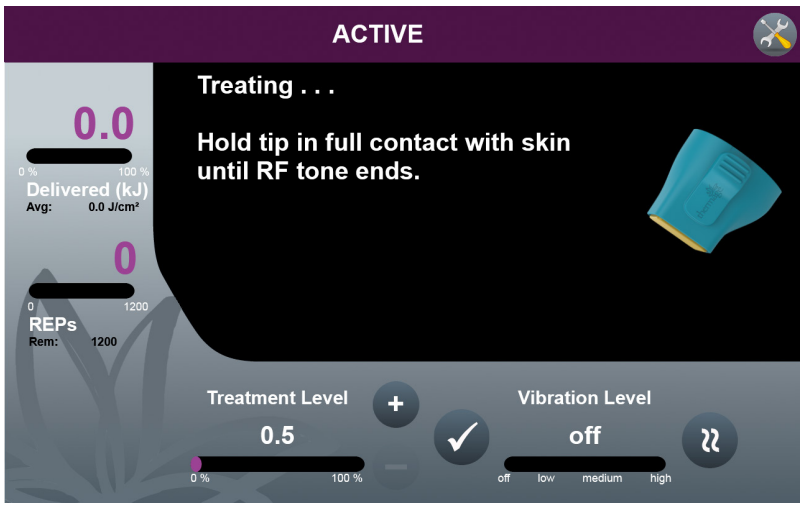
Interruption of the “Treating” phase will be indicated on the touchcreen. Follow the instructions on the Touchscreen to continue.

During a REP treatment, the following conditions will interrupt and end the REP prematurely:

- The Handpiece Activation Button (or Footswitch) is released, “disarming” the system from delivering a REP.
- Tip-tissue contact is insufficient or too hard (improper skin contact).
- Return Pad contact quality monitoring system detects a failure.
- Abnormal System Event is encountered.

If the Activation Button or the Footswitch is released at any time, the System returns to READY mode.

If the System does not detect proper tissue contact within 3 seconds of pressing the Activation Button, the System will display the TIME LIMIT EXCEEDED error message. Push the Activation Button to return to the READY mode.



Example shown: Treatment REP is being delivered.

If the Treatment Control Buttons on the Handpiece or the Touchscreen is pressed, the System reverts to ADJUST LEVEL mode.

7.6 REP COMPLETE

Upon completion of the ACTIVE mode, the System transitions to REP COMPLETE mode. Termination of the audible tone and the REP COMPLETE screen indicate a treatment REP has completed.

The Handpiece/tip should be lifted off of the patient and the Activation Button (or Footswitch) released.



Example shown: REP complete. Release activation and lift from skin.

Once the Activation Button (or Footswitch) has been released and the Handpiece/tip lifted from the patient, the System re-enters the READY mode.

8 GETTING STARTED

8.1 INSTALLATION

The System is designed to be installed prior to use. Installations are completed by Solta Medical Global Sales representative and/or Clinical Education personnel. Contact Solta Medical Customer Service, a local representative, or an authorized distributor for installation of the System.

8.2 TRAINING

The System must only be operated by trained and accredited users. Training is to be performed by Solta Medical authorized personnel only.

8.3 SETTING UP THE SYSTEM

INSPECT SYSTEM FOR DAMAGE

	**All Solta-supplied components and accessories should be inspected regularly for any signs of damage prior to use.**

Inspect all System components for any signs of damage including the System console, touchscreen, and handpiece and handpiece cabling.

Inspect all Solta-supplied accessories for any signs of damage, including treatment tips, return pad, cryogen canister, coupling fluid, skin marking templates, as well as all packaging that these accessories are contained in.

If any physical damage is found, **DO NOT USE THE SYSTEM**. Contact Solta Medical Product Support or your local authorized distributor of Solta Medical products for service.

POSITIONING THE SYSTEM

1. Position or move the System by grasping the handle bars on either the front or back of the System.
2. Provide at least 10 inches (25cm) space around the back, sides and top of the console for cooling.

   Under continuous use for extended periods of time, it is normal for the top and rear panels of the console to become warm.
3. Position the System such that the AC power cord is accessible and can be disconnected from the console.
4. Make sure the wheel locks are engaged before using the System.

CONNECTING THE AC POWER CORD

	**To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth (ie. grounded outlet).**

The System is shipped with a hospital-grade AC power cord. Do not use extension cords or three-to-two-prong adapters.

The AC power cord should be periodically checked for damage, including kinks or twists, to insulation or connectors. Use only the Solta-supplied AC power cord.

To connect the AC Power Cord:

1. Insert the AC power cord into the AC Inlet located in the back of the System.
2. Connect the other end of the AC Power Cord to a grounded, hospital-grade electrical outlet. The power button on the front of the console turns blue when power is connected.

CONNECTING THE FOOTSWITCH (OPTIONAL)

1. Insert the footswitch cord into the footswitch inlet located in the front of the System.
2. Place the footswitch next to the patient bed and where the user can reach it comfortably during treatment.

When connected, the footswitch becomes the default method of treatment activation and the handpiece activation switch is disabled. Disconnect the footswitch to enable treatment activation from the handpiece.

CRYOGEN CANISTER INSTALLATION

	**Use only Solta-supplied Cryogen Canisters.**
	**Avoid breathing high concentrations of cryogen vapor. Deliberate inhalation of the vapor will cause asphyxiation. Death can occur without warning.**
	**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.**

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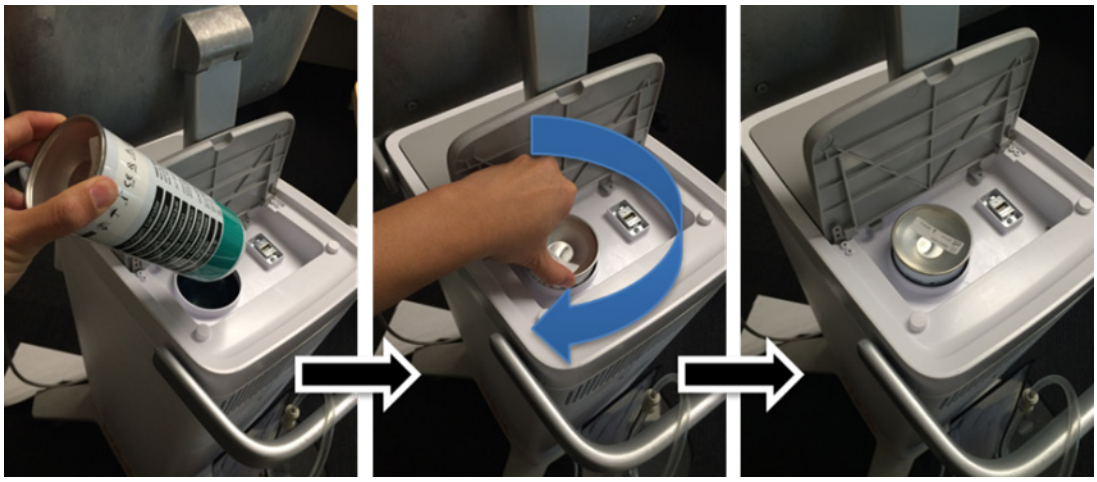
⚠	**Do not store the Cryogen Canisters near heat or open flame.**
⚠	**Keep canisters out of the reach of children.**

To install and replace the Solta-supplied Cryogen Canister:

1. Locate the cryogen canister compartment on top of console, behind the touchscreen.
2. Lift the lid to the cryogen canister compartment.
3. Invert the cryogen canister such that the connector end is pointing downward.
4. Insert the cryogen canister into the canister port of the System.
5. Rotate the cryogen canister clockwise until resistance is met. Three complete rotations are typically required. Do not over tighten.
6. Close the lid to the cryogen canister compartment.
7. To remove or replace, rotate the cryogen canister counter-clockwise. Lift canister out of the port.

   When the EMPTY message is displayed on the touchscreen, it is necessary to replace the used Cryogen Canister.

   Dispose of empty Cryogen Canisters in accordance with applicable regulations for contaminated disposables.



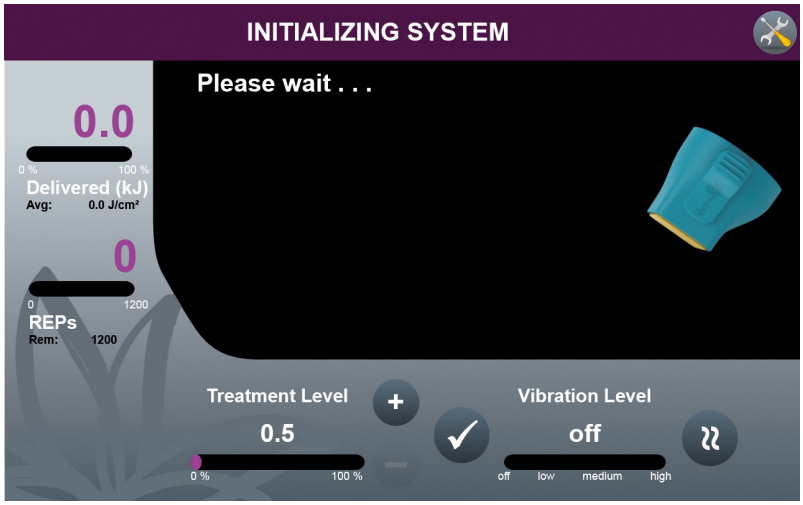
Example shown – Cryogen canister being installed.

POWERING ON THE SYSTEM

To power on the System, press the power button located on the top of the console.

After powering on, the System will perform a self-test to confirm functionality. The touchscreen will display INITIALIZING SYTEM.

An audible tone will indicate if the System self-test and initialization are successful.



If any of the following occur, **DO NOT USE THE SYSTEM**:

- Touchscreen does not light up
- No tone is heard
- System defaults to a Fault screen

Contact Solta Medical Product Support or your local authorized distributor of Solta Medical products for service.

CONNECTING THE HANDPIECE

To connect the Handpiece:

1. Locate and align the top of the Handpiece connector end with the Unlock ( ) position on the console connector port.
2. Insert the Handpiece connector into the console connector port.
3. Rotate the connector clockwise within the port until the connector clicks into the Lock ( ) position.
4. Place the Handpiece and Return Pad cabling into their associated holders located in the front of the console. A magnetic feature is provided on the handpiece holder for the handpiece to easily stow in place.



Example shown: Close up view of the console handpiece connection steps.



To disconnect the Handpiece:

1. Grasp the Handpiece and the Return Pad cable connector.
2. Rotate the connector counter clockwise within the port until the connector is aligned with the Unlock ( ) position on the console port.
3. Remove the Handpiece connector straight out of the console port.

ADJUSTING VOLUME

There are two audible tone functions on the System. One tone is for the Main System audible tones (e.g. System errors) and the other is for the RF treatment delivery tones.

Volume of the tones can be adjusted.

To adjust the Main Volume or RF Volume

1. Press the System Tools button ( ) located at the top right hand corner of the Touchscreen.
2. Select the tone function to adjust from the menu list - **Main Volume or RF Volume**.
3. Press button to increase volume or the button to decrease volume until desired volume is reached.
4. Press the OK button.

The System is designed such that the tones cannot be completely turned off.

USB PORT

The USB Port located in the Cryogen Canister compartment is meant to be used by Solta Medical personnel only for performing future updates to the System and for the user to upload system data to be sent electronically to Solta Medical for device evaluation.

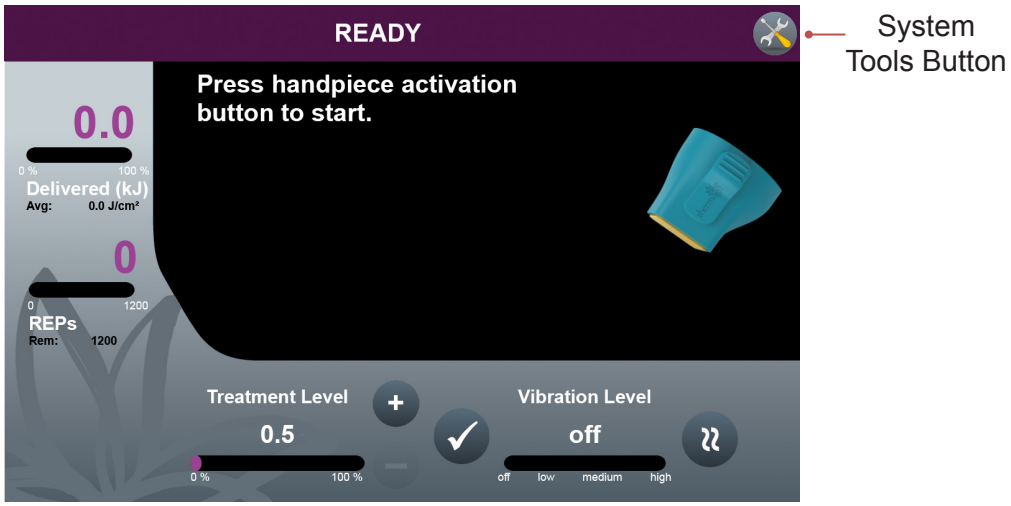


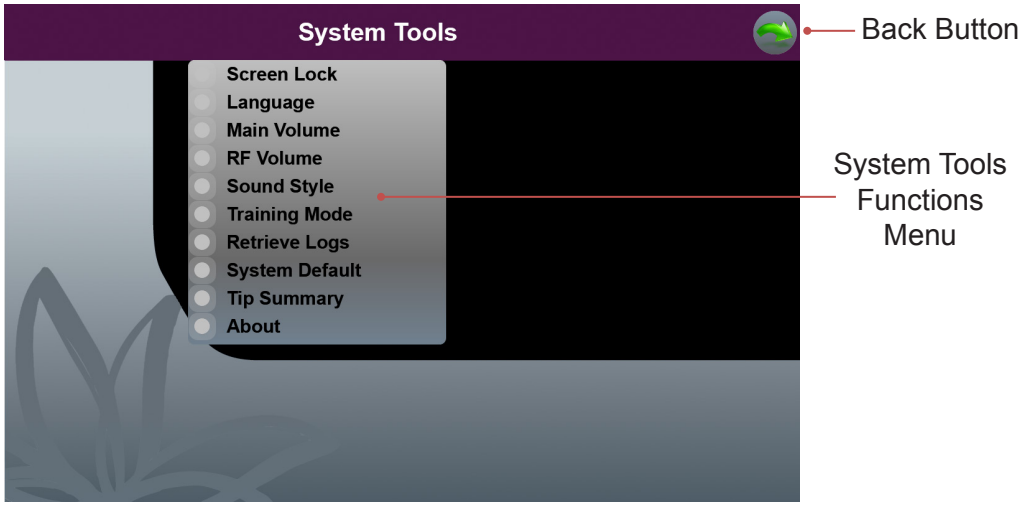
8.4 CONFIGURING THE SYSTEM

System settings and functions, not including treatment settings, can be adjusted using the System Tools menu.

To access the System Tools menu:

1. Press the System Tools button ( ) at the top right hand corner of the Touchscreen. The System Tools menu will appear.
2. Press to select the desired function, and follow the prompts on the Touchscreen to complete the intended action.





To exit the System Tools menu:

1. Tap on the Back button ( ) to exit the System Tools menu and follow the prompts on the screen.

System Tools Menu Functions

The System Tools menu consists of different System settings that allow the user to customize the System, to enter training mode, tip information, software version of the system, and allow Solta Medical personnel to retrieve system data logs.

After selecting a menu item from the list, follow the instructions on the screen.

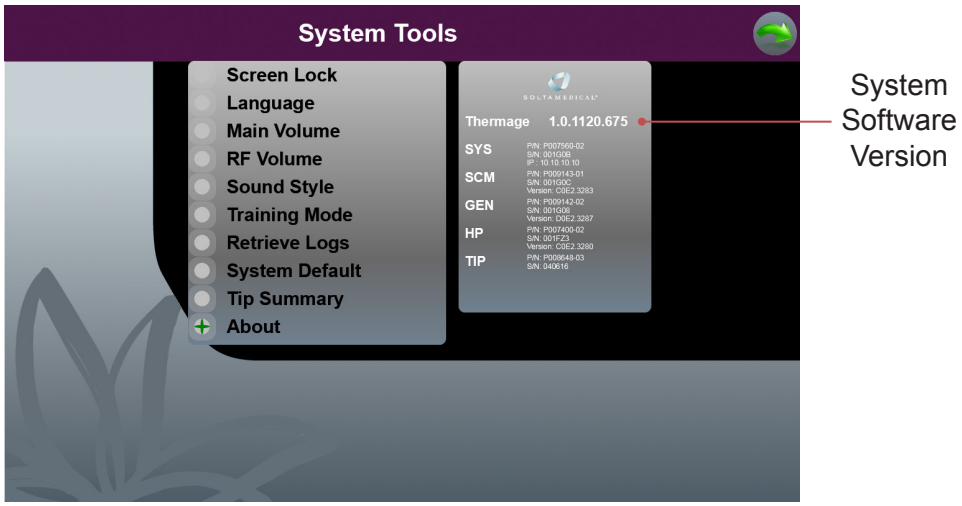
The System Tools menu items consist of the following selections:

- **Screen Lock** – This function locks the System touchscreen temporarily.
- **Language** – This function changes the language translation that is displayed. Requires reboot to save language selection.
- **Sound Style** – This function changes the style of audible tones used by the System.
- **Training Mode** – This function allows for System demonstrations or training by the user. In training mode, no RF energy or cryogen is delivered and the treatment progress bar does not function.

  Before proceeding in training mode, verify that the Training Mode is displayed at the bottom left corner of the touchscreen.

  To exit Training Mode, power off the System and then power back on. Verify that Training Mode is no longer displayed on the touchscreen.
- **Retrieve Logs** – This function is used to by Solta Medical personnel to retrieve and download information from the System and for the user to upload system data to be sent electronically to Solta Medical for device evaluation.
- **System Default** – This function adjusts the System to default settings for language, sound style, main volume and RF volume.
- **Tip Summary** – This function displays tip summary data of the current treatment tip attached to handpiece.
- **About** – This function displays System information such as the serial numbers of the System and attached components, as well as, displays the current software level of the System.

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Example shown – Software version displayed

POWER OFF/RESTART THE SYSTEM

1. Press the power button located on top of the console.
2. Follow the instructions on the Touchscreen.
3. Press the power button again to restart the System.

9 TREATING A PATIENT

9.1 PRE-TREATMENT PREPARATION

	**Use only Solta-supplied components and accessories including System console, handpiece, treatment tips, Return pad, cryogen, coupling fluid, and skin marking paper.**
	**All Solta-supplied components and accessories should be inspected regularly for any signs of damage prior to use.**
	**Remove all substances (topical anesthetic, cosmetics, lotions, oils, deodorant, etc.) from the surface of the skin at the treatment site.** **During the treatment process, there must be no material between the surface of the treatment tip and the patient's skin except for the Thermage Coupling Fluid.**
	**Remove all jewelry including necklaces, bracelets, watches and all earrings/piercings from patient.**
	**Thoroughly remove beard stubble prior to treatment.**
	**During treatment precautions must be taken so that 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 anti-static sheeting is recommended for this purpose.**
	**Do not use local injections or tumescent anesthetic or nerve block techniques to manage patient comfort during the Thermage procedure.** **Use of these types of pain management techniques increases the risk of tissue injuries.**

Step 1 - Removal of all Jewelry, Topical Applications including moisturizers, oils, deodorant, etc., and all hair from the Treatment area. For facial treatments, secure the patient's hair away from the treatment area using a headband or equivalent.

Step 2 - Instruct patient of the importance of providing feedback on their perception of heat and discomfort during the treatment procedure.

Patient feedback regarding their perception of heat or discomfort during the procedure is an essential input to guide the user in determining safe and effective Treatment Levels.

Step 3 - Apply the Skin Marking Paper to Patient

	**Use only Solta-supplied Skin Marking Paper.**
	**Solta-supplied Skin Marking Paper is for single patient use only. Do not reuse once they have been applied to skin.**
	**Do not use if paper is damaged.**
	**Use in a well-ventilated area.**
	**Avoid eye contact with alcohol. If irritation occurs, flush eye(s) with water for 5 minutes.**
	**Flammable agents used for cleaning or disinfecting or as solvents should be allowed to evaporate before application of RF Energy.**

The Skin Marking Paper is used to delineate a target treatment area to ensure total treatment of the surface area and to aid in the prevention of overlapping treatments. The paper and ink are specifically designed to work with the System and each treatment tip type.

Inspect skin marking paper or its packaging. Do not use if the package is opened or damaged.

To apply the Skin Marking Paper:

1. Select Skin Marking Paper with a grid cell size that matches the size of the Treatment Tip for a given treatment area.
2. Cut Skin Marking Paper to desired size and shape.
3. Use 70% Isopropyl Alcohol to clean the skin.
4. While skin is still moist with alcohol, apply the Skin Marking Paper with the ink side down, directly onto the treatment area.
5. Dab the Skin Marking Paper with 70% Isopropyl Alcohol until ink shows through the Skin Marking Paper.

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6. Peel Skin Marking Paper slowly off the skin and dispose of the used paper in accordance with applicable laws and regulations.
7. Allow skin to dry prior to Thermage treatment.

Step 4 - Attaching Return Pad to Patient

	**Use only Solta-supplied Return Pad.**
	**Solta-supplied Return Pad is for single patient use only. Reusing the Return Pad may result in poor contact quality, patient burns, and/or poor system performance.** **Do not cut or modify the Return Pad or its connector.**
	**Do not use a Return Pad on patients with known sensitivity to acrylates.**
	**Ensure proper Return Pad placement and contact to patient prior to treatment.**
	**Do not place Return Pad on the shoulder, neck, head region, legs or arms.**
	**Attention should be given to the Return Pad for signs of heating. The patient should feel no sensation of heat at the Return Pad during treatment. If patient reports feeling heat or electrical stimulus at the Return Pad site, stop treatment and verify placement and cable connections.** **Do not continue treatment until condition is corrected.**

Check the expiration date and inspect it and its packaging for any physical damage. Do not use the Return Pad if the package is opened, damaged, or expired.

Inspect the cable and connector to ensure no exposed wiring or other defects.

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 bodily fluids (e.g. sweating) may warrant replacing the Return Pad during the treatment.

The use and proper placement of the Return Pad is a key element in the safe and effective use of this device, particularly in the prevention of burns. The entire Return Pad must be in full contact with the patient's body.

To attach the Return Pad:

1. Select a location for Return Pad that is a well-vascularized area and has minimal curvature, for example, the lower back area, or side (just above the hip) that is free of hair, free of tattoos, and completely dry. DO NOT PLACE near shoulder, neck, head regions, legs or arms.
2. To ensure proper adherence to skin, clean the treatment area using 70% Isopropyl Alcohol and allow it to completely dry. Avoid skin and finger contact with the adhesive surface prior to application.
3. Peel off the backing and place the Return Pad with its entire area adhering to the patients skin with the tab pointing away from the treatment area and the patient's midline.
4. Verify that the Return Pad cable is not pulling on the Return Pad with more force than the cable's own weight.

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

Step 5 - Dry Gauze between Patient's Extremities and Body

	**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.**

Insert dry gauze between the patient's extremities and body.

Step 6 - If Using Eye Tip, apply Plastic Ocular Shields before treatment

	**For Eyelid treatments, use only the Eye Tip 0.25cm^2 Treatment Tip.**
	**Ensure the use of plastic ocular eyeshields when treating over the eye (upper and lower eyelid), or within the periorbital rim.** **Do not use metal eye shields.** **Solta Medical recommends Oculoplastic® plastic globe protector to use. Refer to manufacturer's instructions for proper placement and use of eye shields.**
	**Do not use vibration when treating the face around the eye areas while plastic ocular shields are in use.** **Vibration may cause displacement of the ocular shields resulting in increased risk of corneal abrasions or ocular damage.**

For treatment over the eye (or within the periorbital rim), ensure that the plastic ocular shields are secure after skin marking grid paper has been applied.

The System does not allow vibration when the Eye Tip is used. The System will disable vibration function when an Eye Tip is attached to the Handpiece.

9.2 SYSTEM PREPARATION

Step 1 - Ensure the equipment, accessories and supplies to perform a treatment are prepared and available

- Equipment: System, Handpiece and Treatment Tip(s), Footswitch (Optional)
- Accessories: Return Pad, Cryogen Canisters (always have a replacement Cryogen Canister available), Coupling Fluid and Skin Marking Paper.
- Supplies: Gauze, 70% Isopropyl Alcohol, Gloves, Eye Shields if applicable

Step 2 - Power on the System

Power on the System by pressing the power button , located on top of the console.

After powering on, the System will run a self-test, followed by system initialization.

An audible tone will indicate if the System self-test and initialization are successful.

If any of the following occur, **DO NOT USE THE SYSTEM**:

- Touchscreen does not light up
- No tone is heard
- System defaults to a Fault screen

Contact Solta Medical Product Support or your local authorized distributor of Solta Medical products for service.

Step 3 - Attach the Treatment Tip to the Handpiece

	**Use only Solta-supplied Treatment Tips.**
	**Solta-supplied Treatment Tips are for single patient use. Do not reuse or attempt to reprocess. Multiple patient use creates a risk of cross contamination of microorganisms from patient to another.**

	**Inspect Treatment Tips prior to use. Do not use a tip that shows signs of damage. Damage to the surface of the tip may cause burns during the treatment.**
	**Treatment Tips are provided non-sterile and should be wiped using 70% Isopropyl Alcohol using a soft cloth.** **Inspect for debris and other contamination prior to use.**

To attach the Treatment Tip to the Handpiece:

1. Holding the Treatment Tip from the sides, align the Treatment Tip with the Handpiece. The geometry of the Treatment Tips only allows for insertion in one orientation.
2. Press the Treatment Tip into the Handpiece until resistance is achieved and the tip is secured. Upon successful attachment, the Touchscreen displays the Treatment Tip type, including number of REP's available for the Tip.

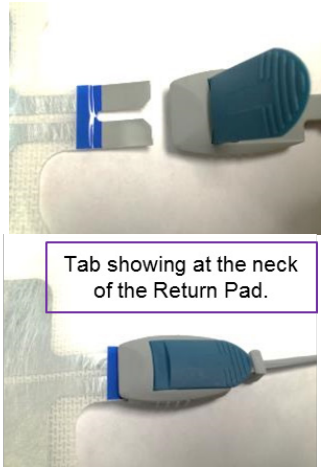
   Treatment tips are provided non-sterile by the manufacturer; however, it is the responsibility of the user to clean the Treatment Tip using 70% Isopropyl Alcohol prior to treatment.

   Inspect Treatment Tip for any physical damage to the electrode surface.



If a Treatment Tip for the Eye is attached to the Handpiece, the System will prompt the user by displaying a message on the touchscreen to the user to ensure that plastic ocular eye shields have been placed on eyes of patient.

Step 4 - Connecting Return Pad to the System



1. Lift clamp on Return Pad cable.
2. Insert the Return Pad tab into the connector on the Return Pad cable. When placed correctly, the tab at the neck of the Return Pad should be only partially visible.
3. Close the clamp on the cable.
4. Tug lightly on Return Pad tab to verify the connection is secure.
5. Ensure to keep the Return Pad and cabling free from coupling fluid and excessive sweating.
6. The System will prompt the user if the Return Pad connection is not valid.

Step 5 - System Ready for Treatment.

Assuming all required components are connected – Cryogen Canister, Handpiece, Treatment Tip, and Return Pad - the System is ready to proceed with treatment.

The System will be in READY mode.

The System remains in READY mode until the Activation Button on the Handpiece or the Footswitch is pressed.

9.3 TREATMENT SETUP

Initial Treatment Level and Vibration Setting

⚠	**Caution should be used when selecting Treatment Levels. The risks of adverse outcomes may be associated with higher treatment levels.**

Treatment level must be set before the treatment can begin. At initial power up, the system will be defaulted to the lowest treatment level setting and vibration setting will be off.

Based on historical references, it is recommended to start treatment at a treatment level as defined below:

Treatment Tip Type	Typical Starting Treatment Level
Eye Tip 0.25cm²	**2.0**
Total Tip 3.0cm²	**3.0**
Total Tip 4.0cm²	**3.0**
Body Tip 16.0cm²	**3.0**

The optimal treatment level for a given patient will be based on direct feedback from patient about his/her perception of heat and comfort level. Refer to Treatment Procedure section below for information on Heat Sensation Feedback Scale.

After each REP, evaluate the treated location to ensure the desired level of treatment is being achieved and adjust the Treatment Level setting according to the patient's feedback on perception of heat and comfort.

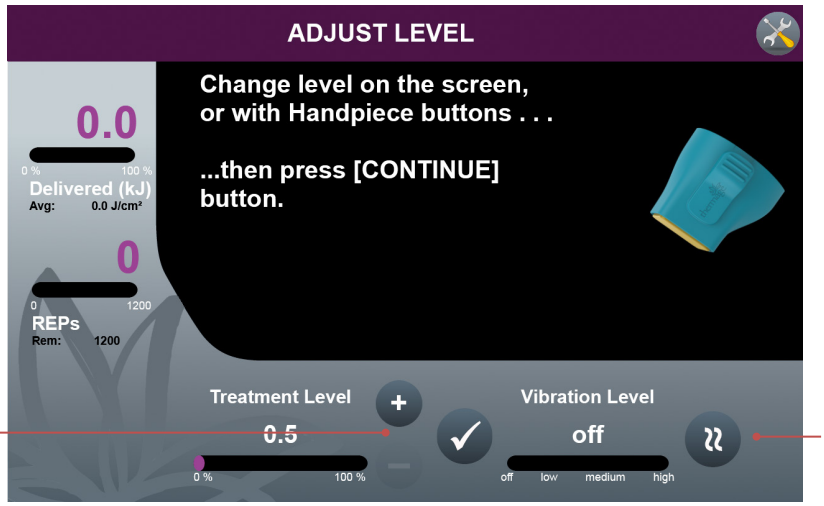
To adjust the treatment level:

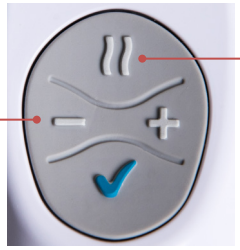
1. Pressing the  or  button on the Touchscreen or Handpiece until desired level is achieved.
2. Confirm the setting by pressing the  button.

To adjust the vibration:

Notice	Excessive repetitive use of any hand-held vibrating instrument could cause user fatigue, irritation, or injury to certain users. Use techniques such as repositioning of handgrip and/or alternating method of activation controls between handpiece and footswitch to minimize occurrence.

1. Press the  button on the Touchscreen or Handpiece to scroll through vibration levels.
2. Scroll through the off, low, medium, and high vibration settings until desired level is achieved. Vibration is not available for the Eye Tip.





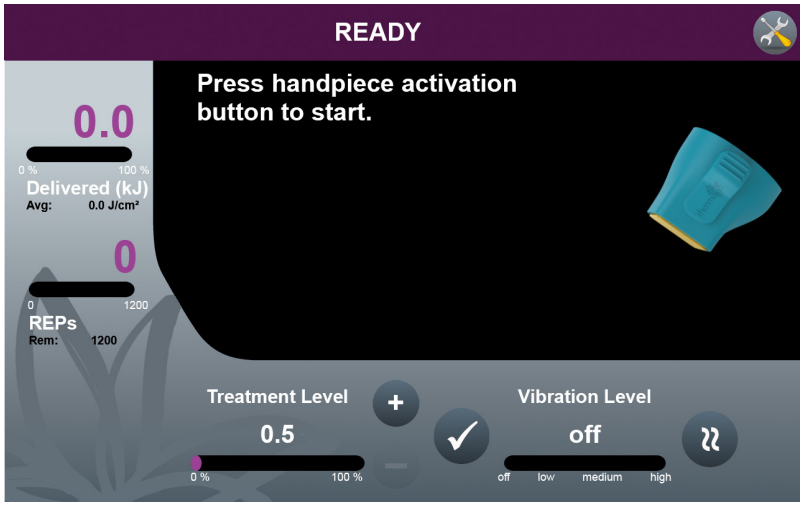
Example shown: Zoomed in view of Handpiece Controls.

9.4 TREATMENT PROCEDURE

⚠	**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.**

Prior to starting treatment procedure, it is recommended that the user wears gloves.

After the treatment parameters are set, the System then enters into the READY mode. READY mode is when the System is ready to begin the activation sequence.



Example shown: Press Handpiece activation to start.

EXAMINE THE TREATMENT TIP

⚠	**Inspect Treatment Tips prior to use. Do not use a tip that shows signs of damage on the patient contact surface of the tip.**
⚠	**Clean Treatment Tips surfaces using a soft cloth and 70% Isopropyl Alcohol.** **Inspect for debris and other contamination prior to use.**

Clean Treatment Tip using 70% Isopropyl Alcohol prior to use.

Routinely inspect the Treatment Tip surface for damage or wear during treatment or if the Treatment Tip makes contact with any surface other than the patient's skin during treatment.

Monitor the condition of the patient's skin and the Treatment Tip membrane carefully throughout the treatment process.

If the Treatment Tip produces any uncharacteristic tissue outcomes (e.g. burns) and/or shows visual signs of electrode membrane breakdown during treatment, discontinue use of the Treatment Tip and contact Solta Medical Product Support or your local authorized distributor of Solta Medical products for assistance and investigation.

APPLY COUPLING FLUID

	**Use only Solta-supplied Coupling Fluid.**
	**Solta-supplied Coupling Fluid is for single patient use only. Do not reuse.**

Check the expiration date and inspect the Coupling Fluid container and its packaging for any physical damage. Do not use the Coupling Fluid if the package is opened, damaged, or expired.

Inspect the coupling fluid expiration date on the bottle prior to use.

Shake the Coupling Fluid well before use.

Apply a generous amount of the Coupling Fluid to a small section of the targeted treatment site before beginning treatment. Re-apply throughout treatment. Do not use other fluids such as irrigation solutions (e.g. saline, Ringer's lactate, sterile water).

If the coupling fluid appears dried out or gummy/gel-like on the patient, clean the treatment site area and reapply coupling fluid.

As a general rule, when in doubt, additional coupling fluid should be applied.

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.

DELIVER TREATMENT

	**Caution should be used when selecting Treatment Levels. The risks of adverse outcomes may be associated with higher treatment levels.**

The System is designed to auto-tune to match skin impedance. When the System is in the ACTIVE mode and when tissue contact is sensed, the System will auto-tune at each REP, then therapeutic RF energy will be delivered for each treatment REP.

During RF energy delivery and for a short period of time after delivery of RF energy, the System will deliver a coolant to the patient's skin through the Handpiece.

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Step 1 - Position the Handpiece

1. Choose the treatment site.
2. Hold the Handpiece and Treatment Tip slightly above the treatment site in a vertical position, perpendicular to the surface being treated.

Step 2 - Arm the System

1. With the Handpiece and Treatment Tip still slightly above the treatment site, activate the System using an activation switch (Handpiece or footswitch).
2. As soon as the System is activated, the Touchscreen will progress to ARMED mode and an audible ARMED mode tone will be emitted.

Step 3 - Deliver a REP

1. Press and hold the Treatment Tip to the patient's skin.
2. Keep Treatment Tips evenly in contact with treatment area skin throughout the treatment application.

   If System senses a loss of contact with the skin, it deactivates the RF energy being delivered.
3. After delivery, lift the Treatment Tip away from the patient's skin.
4. If RF energy delivery is interrupted (e.g. System error), continue to hold the Treatment Tip to the patient's skin to ensure delivery of the coolant.

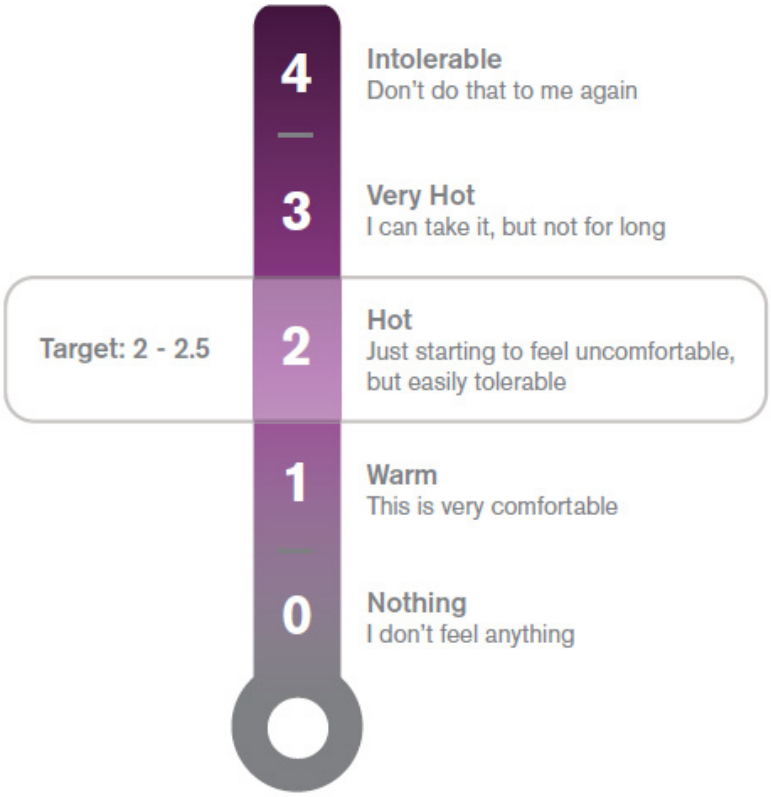
Step 4 - Finish REP and Evaluate Treatment Site

1. After delivery, lift the Treatment Tip away from the treated tissue and release the activation switch (Handpiece or footswitch).
2. Visually inspect the treatment site to ensure delivery of desired treatment effect.

   If the selected Treatment Level results in excessive treatment, the Treatment Level should be decreased until a satisfactory result is achieved.

   Seek feedback from patient about his/her perception of heat and comfort level. It is important to maintain a patient feedback level of 2.0-2.5 on the Heat Sensation Feedback Scale.

Heat Sensation Feedback Scale



3. If the desired effect is achieved, continue delivering at the selected treatment level until the entire site has been treated.

CHANGE TREATMENT LEVEL SETTING

⚠	**Caution should be used when selecting Treatment Levels. The risks of adverse outcomes may be associated with higher treatment levels.**
⚠	**Professional discretion by the health care professional is necessary when treating body areas in proximity to major nerve bundles or otherwise it may result in nerve damage.** **Treatment at superficial nerve locations may result in nerve damage.**

Throughout the treatment, treatment level settings will require frequent adjustment in response to variations in skin thickness, treatment area anatomy, and patient feedback.

The user is responsible for selecting appropriate and safe treatment levels at all times.

If the treatment level is not satisfactory, increase or decrease the treatment level by 0.5 and deliver RF energy at this setting. Repeat this process until the desired level of treatment is achieved.

The user should pay special attention to patient heat feedback and consider reducing the Treatment Level setting when treating over areas with superficial nerves.

To change the Treatment Level:

1. When in READY mode, select the desired treatment level by pressing on the  or  buttons on the Touchscreen or Handpiece.

   The output power selected should be as low as possible for the intended purpose and adjustments should increase in the lowest increment.
2. Confirm the setting by pressing the  button.

CHANGE VIBRATION LEVEL SETTINGS

Notice	Excessive repetitive use of any hand-held vibrating instrument could cause user fatigue, irritation, or injury to certain users. Use techniques such as repositioning of handgrip and/or alternating method of activation controls between handpiece and footswitch to minimize occurrence.

The vibration level may be adjusted over the course of the treatment based on the patient's feedback. Vibration should be as high as tolerable while remaining comfortable to patient.

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 comfortable to patient.

To change the vibration level:

1. Press the  button on the Touchscreen or Handpiece to scroll through vibration levels.
2. Scroll through the off, low, medium, and high vibration settings until desired level is achieved.

DURING TREATMENT

	**If patient reports feeling heat or electrical stimulus at the Return Pad site, stop treatment and verify placement and cable connections. Do not continue until condition is corrected.**

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.

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.

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

Prior to increasing treatment level settings, check that the Return Pad has full contact with the patient skin, and that the Return Pad cables connectors are secure.

Check and verify that during the treatment procedure no object obstructs the well vascularized pad site. During treatment, the Return Pad should be checked for signs of heating.

The patient should feel no sensation of heat at the point of placement of the Return Pad during treatment. If the patient reports feeling heat or electrical stimulus at the Return Pad site, discontinue RF delivery immediately and check the Return Pad placement and all cable connections. Do not continue treatments until condition is corrected.

Poor Return Pad contact may lead to lower RF energy delivery or a system error condition.

TREATMENT GUIDELINES

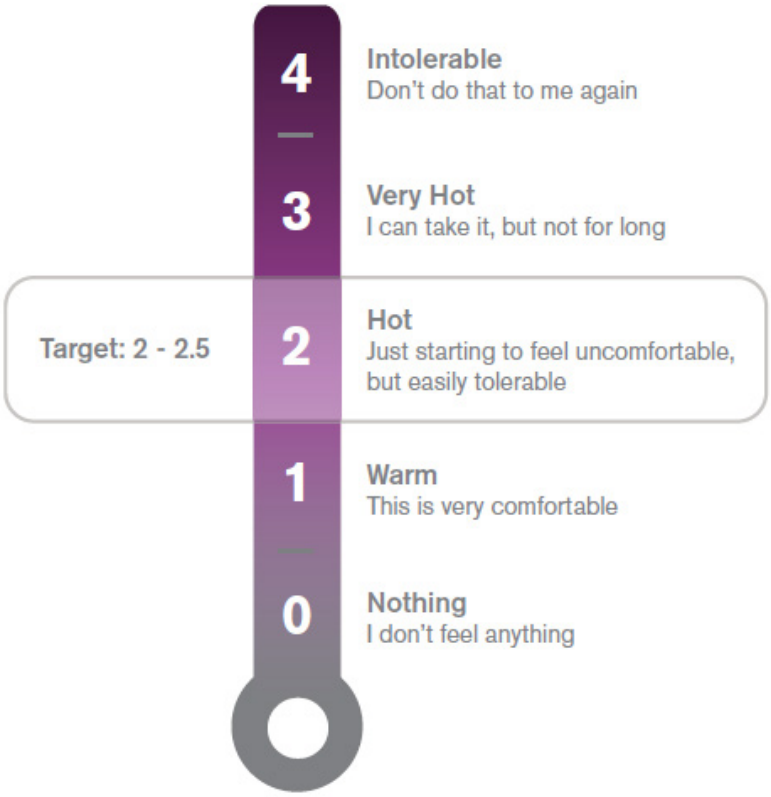
To assure the safe and effective use of the System, Solta recommends moderate treatment level settings. These settings should be used in conjunction with multiple passes over the selected areas where improvements and/or contour changes are desired.

Always adjust treatment levels based on the patient skin thickness, underlying tissue, clinical signs, and the patient's feedback on perception of heat and discomfort.

It is important to maintain a patient feedback level of 2 - 2.5 on the Heat Sensation Feedback Scale.

Usage of the Heat Sensation Feedback Scale, helps ensure that the patient understands the goal to stay between 2 - 2.5.

Heat Sensation Feedback Scale



- For 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.
- For 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.

If patient is reporting heat sensation of more than 2 - 2.5 on the referenced heat sensation scale above, reduce the treatment level settings and/or increase the vibration level to enhance the distraction technique.

TREATMENT COMPLETION

	**Solta-supplied Treatment Tips are for single patient use. Do not reuse or attempt to reprocess. Multiple patient use creates a risk of cross contamination of microorganisms from patient to another.**
	**Solta-supplied Skin Marking Paper is for single patient use only. Do not reuse once they have been applied to skin.**
	**Solta-supplied Return Pad is for single patient use only. Reusing the Return Pad may result in poor contact quality, patient burns, and/or poor system performance.**
	**Solta-supplied Coupling Fluid are for single patient use. Do not reuse.**

To remove grid from skin:

1. Remove Coupling Fluid.
2. Remove the ink grid using 70% Isopropyl Alcohol, followed by mild soap and warm water.

To remove and disconnect Return Pad:

1. Disconnect the Return Pad tab from the cable connector.
2. Gently remove the Return Pad from the skin to avoid skin trauma.
3. Inspect the Return Pad site on the patient to ascertain whether any skin compromises occurred during the treatment.
4. Discard Return Pad in accordance with applicable laws and regulations.

To review and record patient's treatment by accessing the Tip Summary:

The Tip Summary displays a summary of the treatment parameters for the Treatment Tip that is currently connected to the System.

1. Press the System Tools button
2. Press the Tip Summary menu item

To power off the System:

1. Press the power button, located on top of the console in front of the Touchscreen and follow the instructions.

To remove Treatment Tip from Handpiece:

1. Grasp along the sides of the Treatment Tip.
2. Pull the Treatment Tip away from the Handpiece.
3. Discard Treatment Tip in accordance with applicable laws and regulations.

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10 CLEANING

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

The Thermage FLX System, components and accessories are not intended for use in sterile environment and have not been designed to withstand the rigors of a sterilization process.

Do not sterilize any component or accessories.

TREATMENT TIP

Notice	Always be careful when handling the treatment tip prior to use as it is delicate and may be damaged if mishandled. Always inspect the treatment tip for damage prior to use. Do not use a treatment tip that appears damaged.

1. Clean treatment tips prior to use using soft cloth and 70% Isopropyl Alcohol.
2. Upon completion of treatment, dispose of treatment tip in accordance with applicable laws and regulations.

HANDPIECE

Notice	Always be careful when handling the handpiece as it contains delicate components and may be damaged if dropped. Do not use a damaged handpiece.

1. Disconnect the Handpiece from the system and clean Handpiece and associated cabling prior to and after use using soft cloth and 70% Isopropyl Alcohol.
2. Do not spray or pour liquids directly onto the handpiece and associated cabling when cleaning.
3. After cleaning, stow handpiece in handpiece holder of System.

CONSOLE

The console should be cleaned at the end of each treatment procedure.

1. Power down the System and unplug the System from AC Power outlet.
2. Use 70% Isopropyl Alcohol or damp cloth to wipe the console's cover, front panel, and AC power cable.

   Do not allow fluids to enter the chassis. Do not spray or pour liquids directly on the console.
3. Allow alcohol solution to evaporate before using the System.

TOUCHSCREEN

The touchscreen should be cleaned at the end of each treatment procedure.

1. Power down and unplug the System from AC power outlet.
2. Use 70% Isopropyl Alcohol or damp cloth to wipe the display screen.
   Do not spray or pour liquids directly on the display screen.
3. Allow alcohol solution to evaporate before using the System.

FOOTSWITCH

The footswitch should be cleaned at the end of the each treatment procedure.

1. Disconnect the footswitch from the System.
2. Clean footswitch using a mild detergent and damp cloth.
   Stow footswitch when not in use.

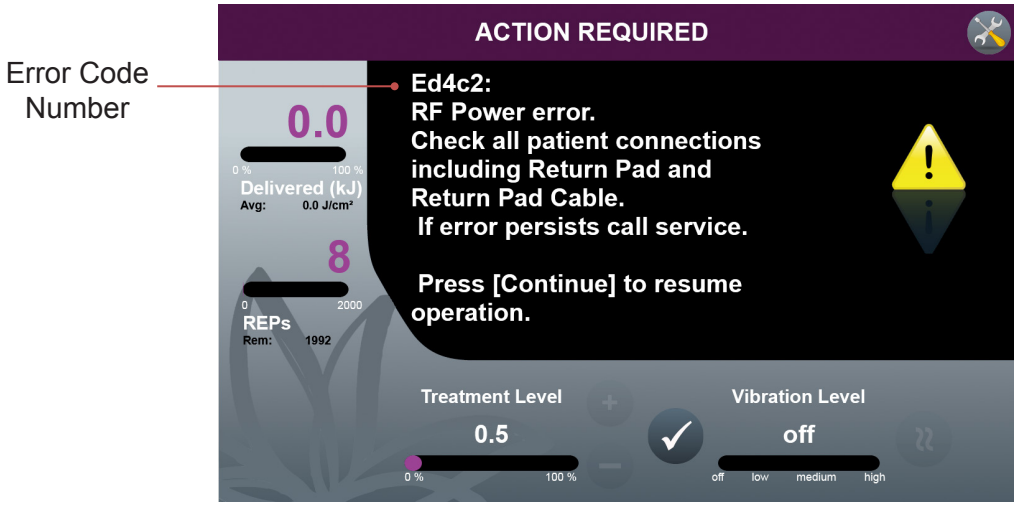
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11 TROUBLESHOOTING

Symptom	Solution
Activation Switch isn't working	1. Verify that Handpiece is connected to the System. 2. Ensure Footswitch is not connected to the System.
Touchscreen not accepting button press	1. Press directly in the center of the button. 2. Ensure touchscreen is not locked by entering System Tools Menu to verify.
Return Pad is hot	1. Check the Return Pad's placement and all cable connections. 2. Do not continue treatments until this condition is corrected.
Handpiece is excessively warm	1. Discontinue its use and call Solta Medical Product Support.

12 ERROR CODES

When the System detects a condition that interrupts treatment, a System error code is displayed. These System error codes provide an error code number and instructions for how to respond to the error.



In the event of a System error, follow the instructions on the Touchscreen to proceed.

If the System error persists, note the error code number, and contact Solta Medical Product Support or your local authorized distributor of Solta Medical products for assistance.

It is important to report the error code number when contacting Product Support.

The error code number is often the single most important piece of information that can be used for troubleshooting a problem.

System Error Codes

Event Code Number	Description	Action
E2207	ERR_REGIMEN_FILE_CRC_ERROR	Cycle power, call service if error persists
E220B	ERR_DISPLAY_CRIT_CRC_ERROR	Cycle power, call service if error persists
E220C	ERR_SW_INSTALL_FAILED	Repeat operation, call service if error persists
E220D	ERR_ONE_WIRE_WRITE_FAILED	Replace treatment tip, call service if error persists
E220E	ERR_INVALID_TIP_SUMMARY_FILE	Cycle power, call service if error persists
E220F	ERR_READ_VERIFY_FAILED	Cycle power, call service if error persists
E2210	ERR_WRITE_VERIFY_FAILED	Cycle power, call service if error persists
E2211	ERR_INVALID_SW_VERSION	Cycle power, call service if error persists
E2212	ERR_CRIT_WRITE_CHECK_ERROR	Cycle power, call service if error persists
E2213	ERR_SYSTEM_INITIALIZATION_ERROR	Cycle power, call service if error persists
E2400	ERR_OS_PARAMETER_ERROR	Cycle power, call service if error persists
E2401	ERR_OS_TASK_CREATE_ERROR	Cycle power, call service if error persists
E2402	ERR_OS_TASK_PEND_ERROR	Cycle power, call service if error persists
E2403	ERR_OS_TASK_SUSPEND_ERROR	Cycle power, call service if error persists
E2404	ERR_OS_TASK_RESUME_ERROR	Cycle power, call service if error persists
E2405	ERR_OS_SHAREDMEMORY_CREATE_ERROR	Cycle power, call service if error persists
E2406	ERR_OS_SHAREDMEMORY_MAP_ERROR	Cycle power, call service if error persists
E2407	ERR_OS_QUEUE_CREATE_ERROR	Cycle power, call service if error persists
E2408	ERR_OS_QUEUE_GETINFO_ERROR	Cycle power, call service if error persists
E2409	ERR_OS_QUEUE_READMSG_ERROR	Cycle power, call service if error persists
E240A	ERR_OS_QUEUE_WRITEMSG_ERROR	Cycle power, call service if error persists
E240B	ERR_OS_SIGNALWAIT_ERROR	Cycle power, call service if error persists
E240C	ERR_OS_TIMERSTART_ERROR	Cycle power, call service if error persists
E240D	ERR_OS_WINSOCK_ERROR	Cycle power, call service if error persists
E240E	ERR_OS_FILEMAP_ERROR	Cycle power, call service if error persists
E2410	ERR_SC_LOGFILE_ERROR	Cycle power, call service if error persists
E2411	ERR_SC_SHAREDDATACREATE_ERROR	Cycle power, call service if error persists
E2412	ERR_SC_SHAREDDATAWRITE_ERROR	Cycle power, call service if error persists
E2413	ERR_SC_FPGADEF_ERROR	Cycle power, call service if error persists
E2610	ERR_SC_FPGA_WDOG_ERROR	Cycle power, call service if error persists
E3101	ERR_SCM_INIT_ERROR	Cycle power, call service if error persists
E3201	ERR_RTM_DEVICE_INFO_FAILURE	Cycle power, call service if error persists
E3301	ERR_SCM_MSG_SEND_ERROR	Cycle power, call service if error persists
E3302	ERR_SCM_MDATA_NOTIFICATION_ERROR	Cycle power, call service if error persists

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Event Code Number	Description	Action
E3303	ERR_SCM_DATABASE_NOTIFICATION_ ERROR	Cycle power, call service if error persists
E3304	ERR_SCM_GENERAL_NOTIFICATION_ERROR	Cycle power, call service if error persists
E3305	ERR_SCM_XADC_LIMIT_ERR	Cycle power, call service if error persists
E3401	ERR_SCM_RTC_STATE_ERROR	Cycle power, call service if error persists
E3402	ERR_SCM_AUDIO_DMA_ERR	Cycle power, call service if error persists
E3403	ERR_RTM_BOARD_TEMP_ERR	Cycle power, call service if error persists
E3601	ERR_RTM_FPGA_BIN_FILE_ERROR	Cycle power, call service if error persists
E3602	ERR_RTM_FIRMWARE_INSTALL_FAILED	Cycle power, call service if error persists
E3603	ERR_SCM_FPGA	Cycle power, call service if error persists
E4201	ERR_SDCARD_INTEGRITY_FAULT	Cycle power, call service if error persists
E4202	ERR_SDCARD_DEVICE_INFO_FAILURE	Cycle power, call service if error persists
E5202	ERR_GUI_DISPLAY_DEVICE_INFO_FAILURE	Cycle power, call service if error persists
EA201	ERR_SYS_CON_DEVICE_INFO_FAILURE	Cycle power, call service if error persists
EA202	ERR_HP0_CONN_DEVICE_INFO_FAILURE	Cycle power, call service if error persists
EB101	ERR_CRYO_INIT_ERROR	Remove and replace cryogen canister, call service if error persists
EB401	ERR_CRYO_PRESSURE_SENSOR_ERROR	Remove and replace cryogen canister, cycle power, call service if error persists
EB402	ERR_CRYO_SYSTEM_ERROR	Remove and replace cryogen canister, cycle power, call service if error persists
EB482	ERR_NOT_CONNECTED_CRYO_CAN	Remove and replace cryogen canister, call service if error persists
EB483	ERR_CRYO_CAN_OVER_PRESSURE	Remove and replace cryogen canister, call service if error persists
EB484	ERR_CRYO_CAN_UNDER_PRESSURE	Remove and replace cryogen canister, call service if error persists
EB485	ERR_CRYO_TANK_OVER_PRESSURE	Remove and replace cryogen canister, call service if error persists
EB486	ERR_CRYO_TANK_UNDER_PRESSURE	Remove and replace cryogen canister, call service if error persists
EB487	ERR_CRYO_WAIT_FOR_TANK_FILL	Remove and replace cryogen canister, call service if error persists
EC101	ERR_HP_INIT_ERROR	Cycle power, call service if error persists
EC201	ERR_HP_DEVICE_INFO_FAILURE	Cycle power, call service if error persists
EC204	ERR_HP_UNABLE_TO_READ_REGIMEN	Cycle power, call service if error persists
EC205	ERR_HP_REGIMEN_FILE_CRC_ERROR	Cycle power, call service if error persists
EC206	ERR_TREATMENT_TIP_OW_EPROM_CRC_ ERROR	Replace treatment tip and cycle power, call service if error persists

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Event Code Number	Description	Action
EC207	ERR_TREATMENT_TIP_SYSTEM_VERSION_MISMATCH	Replace treatment tip, call service if error persists
EC208	ERR_TREATMENT_TIP_REP_COUNT	Replace treatment tip and cycle power, call service if error persists
EC301	ERR_HP_COMM_FAILURE	Remove and replace handpiece and cycle power, call service if error persists
EC382	ERR_HP_THERMISTOR_READ_FAILURE	Replace treatment tip, call service if error persists
EC383	ERR_TREATMENT_TIP_READ_ERROR	Replace treatment tip. Call service if error persists
EC384	ERR_TREATMENT_TIP_EEPROM_READ_ERROR	Replace treatment tip. Call service if error persists
EC401	ERR_HP_HARDWARE_ERROR	Cycle power, call service if error persists
EC402	ERR_HP_VIBRATION_SYSTEM_FAILURE	Cycle power, call service if error persists
EC403	ERR_HP_MUX_RELAY_FAILURE	Remove and replace handpiece, cycle power, call service if error persists
EC484	ERR_NOT_CONNECTED_HP	Remove and replace handpiece, call service if error persists
EC485	ERR_TREATMENT_TIP_TOO_COLD	Repeat operation, call service if error persists
EC486	ERR_TREATMENT_TIP_TOO_HOT	Repeat operation, call service if error persists
EC601	ERR_HP_FPGA_BIN_FILE_ERROR	Cycle power, call service if error persists
EC682	ERR_HP_FIRMWARE_INSTALL_FAILED	Cycle power, call service if error persists
EC781	ERR_ACTIVATION_BUTTON_TIMED_OUT	Repeat operation, call service if error persists
EC782	ERR_POST_TREATMENT_FORCE_TIMED_OUT	Repeat operation, call service if error persists
EC783	ERR_HP_EXPIRED	Remove and replace handpiece, cycle power, call service if error persists
EC784	ERR_TREATMENT_TIP_NO_GOOD_CONTACT	Repeat operation, call service if error persists
EC785	ERR_TREATMENT_TIP_LIFTED_PREMATURELY	Repeat operation, call service if error persists
EC786	ERR_TREATMENT_TIP_REP_COUNT_LIMIT_REACHED	Replace treatment tip, call service if error persists
EC787	ERR_TREATMENT_TIP_EXPIRED	Replace treatment tip, call service if error persists
EC788	ERR_TREATMENT_TIP_INVALID	Replace treatment tip, call service if error persists
EC789	ERR_TREATMENT_TIP_INVALID_TIPTYPE	Replace treatment tip, call service if error persists

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Event Code Number	Description	Action
EC78A	ERR_TREATMENT_TIP_FORCE_HIGH	Repeat operation, call service if error persists
EC78B	ERR_TREATMENT_TIP_FORCE_LOW	Repeat operation, call service if error persists
EC78C	ERR_TREATMENT_TIP_TEMP_HIGH	Repeat operation, call service if error persists
EC78D	ERR_ACTIVATION_BUTTON_TIMED_OUT_ARM	Repeat operation, call service if error persists
EC78E	ERR_FORCE_BEFORE_ACTIVATION	Repeat operation, call service if error persists
ED101	ERR_GEN_INIT_ERROR	Cycle power, call service if error persists
ED204	ERR_GEN_RF_FACTORY_CAL_CHECKSUM	Cycle power, call service if error persists
ED205	ERR_GEN_RF_TUNING_CAL_CHECKSUM	Cycle power, call service if error persists
ED206	ERR_GEN_RF_DEVICE_INFO_FAILURE	Cycle power, call service if error persists
ED301	ERR_GEN_RF_SIO_LINK_ERR	Cycle power, call service if error persists
ED404	ERR_GEN_RF_BOARD_TEMP_ERR	Cycle power, call service if error persists
ED405	ERR_GEN_RF_XADC_LIMIT_ERR	Cycle power, call service if error persists
ED441	ERR_GEN_HARDWARE_ERROR	Cycle power, call service if error persists
ED4C2	ERR_GEN_TUNING_FAILURE	Check patient and return pad connections then repeat operation
ED4C6	ERR_GEN_RF_CURRENT_MON_ERR	Check patient and return pad connections then repeat operation
ED4C7	ERR_GEN_RF_TX_REAL_PWR_MON_ERR	Check patient and return pad connections then repeat operation
ED4C8	ERR_GEN_RF_TX_REFLECT_PWR_MON_ERR	Check patient and return pad connections then repeat operation
ED4C9	ERR_GEN_RF_HIGH_SIDE_PWR_MON_ERR	Check patient and return pad connections then repeat operation
ED4CA	ERR_GEN_RF_HV_ERR	Check patient and return pad connections then repeat operation
ED40B	ERR_GEN_RF_SELF_CAL_ERR	Cycle power, call service if error persists
ED4CD	ERR_GEN_RF_MAX_POWER_DELIVERED	Check patient and return pad connections then repeat operation
ED4CF	ERR_GEN_RF_UNDER_DELIVERY_ERROR	Check patient and return pad connections then repeat operation
ED601	ERR_GEN_FPGA_BIN_FILE_ERROR	Cycle power, call service if error persists
ED602	ERR_GEN_FIRMWARE_INSTALL_FAILED	Cycle power, call service if error persists
EF4C1	ERR NOT_CONNECTED_RETURN_PAD	Check patient and return pad connections then repeat operation

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13 MAINTENANCE, TRANSPORTATION AND WARRANTY

13.1 MAINTENANCE

ROUTINE MAINTENANCE

No routine or preventative maintenance is required. After each treatment, inspect the System for any physical damage. If any physical damage is found, DO NOT USE THE SYSTEM.

Unauthorized repairs or modifications by unqualified personnel may damage the unit and void the warranty.

Contact Solta Medical Product Support or your local authorized distributor of Solta Medical products for service.

DISPOSAL OF SYSTEM AND ACCESSORIES



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.

After use, the Treatment Tips, Skin Marking Paper and Return Pads should be disposed of in accordance with applicable laws and regulations.

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 applicable laws, ordinances and recycling regulations.

13.2 TRANSPORTATION

	**Remove Cryogen Canister from the System prior to transportation.**

When transporting or shipping the Thermage System, use only Solta-approved shipping container/packaging for console and handpiece components. Use of unapproved shipping material may result in product damage and risk voiding the warranty.

The Cryogen Canister must be removed from the System before transporting the System between buildings and/or shipping the System.

To remove the Cryogen Canister:

1. Locate the Cryogen Canister compartment behind the Touchscreen.
2. Lift the lid to the Cryogen Canister compartment.
3. Rotate the Cryogen Canister counter-clockwise until loose from console.
4. Lift the Cryogen Canister out of the port.
5. Store/dispose the Cryogen Canister according to local regulations.
6. Close the lid to the compartment.

There may be a small release of coolant while installing or removing the Canister.

13.3 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.

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14 CONTACT INFORMATION

PRODUCT COMPLAINT AND TECHNICAL SUPPORT CONTACT INFORMATION (INCLUDING PRODUCT RELATED COMPLAINTS):

Solta Medical Product Support

Telephone: +1-877-782-2286 or +1-510-259-5299 (option 2)

Or contact your local authorized distributor of Solta Medical products.

CUSTOMER SERVICE AND ORDERING CONTACT INFORMATION:

Solta Medical Customer Service

Telephone: +1-877-782-2286 or +1-510-259-5299 (option 1)

Or contact your local authorized distributor of Solta Medical products.

15 TECHNICAL INFORMATION

15.1 ELECTRICAL SPECIFICATIONS

	**This equipment must only be connected to a supply mains with protective earth (i.e. grounded outlet).** **Extension cords and/or adapter plugs must not be used.**

AC INPUT RATING

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

RF OUTPUT

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

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

ELECTRICAL SAFETY

- Class 1, Type “BF” Applied Part
- Ordinary Equipment IPX0
- Continuous Operation
- Certified to:
  - EN IEC 60601-1
  - EN IEC 60601-1-2
  - EN IEC 60601-2-2
  - CSA C22.2 NO 60601-1
- **Classification Medical – General medical equipment as to electrical shock, fire and mechanical hazards only in accordance with IEC 60601-1 2008 + 2014 (E487418)**
  - ANSI/AAMI ES 60601-1(2005) + AMD (2012)
  - CAN/CSA C22.2 No 60601-1 (2008) + (2014)

15.2 CYBERSECURITY SPECIFICATIONS

FDA UCM356190

FDA UCM077823

FDA UCM356423

Cyber Security Overview

The Thermage FLX product is a medical device that incorporates proprietary and off-the-shelf software. It contains no wireless communications devices and in its intended medical use environment it will not connect to any other devices, peripherals, or networks for data communications.

The Ethernet (Service) port communications are limited to a specific proprietary port address and protocol specifically for service level access.

There is a USB port which is configured to allow field upgrade of the embedded software and programmable devices. Data which is imported/exported is stored in a proprietary binary format and contains no patient data.

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<table>
<tr><td colspan="3">GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS</td></tr>
<tr><td colspan="3">The Thermage FLX System is intended for use in the electromagnetic environment specified below. The user of the Thermage FLX System should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions Test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Conducted RF emissions
CISPR 11
EN 55011</td><td>Class A, Group 1</td><td rowspan="4">The Thermage FLX System uses RF energy for its internal function and for delivering treatment to the patient. Nearby electronic equipment may be affected.

The Thermage FLX 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 FLX System or shielding the location.</td></tr>
<tr><td>Radiated RF emissions
CISPR 11
EN 55011</td><td>Class A, Group 1</td></tr>
<tr><td>Harmonics current emissions
IEC/EN 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage Fluctuations & Flicker
IEC/EN 61000-3-3</td><td>Complies</td></tr>
<tr><td colspan="3">Note 1: There were no test level or compliance deviations to IEC 60601-1-2, 4th edition.

Note 2: The emission characteristics of this equipment make it 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.</td></tr>
</table>

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The Thermage FLX System is intended for use in the electromagnetic environment specified below. The customer or the user of the Thermage FLX 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	± 8kV contact ± 2, 4, 8, 15kV air	± 8kV contact ± 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	± 2kV for power supply lines ± 1kV for input/ output lines, 100 kHz	± 2kV for power supply lines ± 1kV 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	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1kV line(s) to line(s) ± 2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips on power supply input lines 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 FLX System requires continued operation during power mains interruptions, it is recommended that the Thermage FLX System be powered from an uninterruptible power supply or a battery.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The Thermage FLX System is intended for use in the electromagnetic environment specified below. The customer or the user of the Thermage FLX System should assure that it is used in such an environment.			
IMMUNITY Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Voltage Interruptions on power supply input lines IEC/EN 61000-4-11	0% UT; 250/300 cycle	0% UT; 250/300 cycle	
Power frequency (50/60Hz) 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 deviations to IEC 60601-1-2, 4th edition.			

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The Thermage FLX System is intended for use in the electromagnetic environment specified below. The customer or the user of the Thermage FLX 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	3Vrms 150kHz to 80MHz	3V	**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Thermage FLX System, including cables specified by Solta. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC/EN 61000-4-3	3V/m 80MHz to 2.7GHz 80% @ 1kHz	3V/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 FLX System is intended for use in the electromagnetic environment specified below. The customer or the user of the Thermage FLX 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						

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
1,720	1,700-1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1,845						
1,970						
2,450	2,400-2,570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5,240	5,100-5,800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5,500						
5,785						

Note: if necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the Thermage FLX 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.

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CONNECTION TO THE ANALOG AND DIGITAL INTERFACES, SUCH AS ETHERNET PORT

Accessory equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC 60950 for information technology equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the medical electrical System requirements of IEC 60601-1. A user who connects additional equipment to the signal input part or signal output part configures a medical System, and is therefore responsible that the System complies with the requirements for a System in standard IEC 60601-1. If necessary, contact your local representative or an authorized distributor for more information.

POWER OUTPUT RESTRICTIONS

The maximum output power is 400W.

The System will operate over the limited impedance range of 75Ω to 400Ω.

Output power may be limited by the current/impedance limits.

SETTINGS LEVELS

- Treatment Level: up to 19 Levels per Treatment Tip
- Vibration Level: 3 levels: LOW, MEDIUM, HIGH

MEASUREMENT ACCURACY

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

For impedances in the range 75Ω to 400Ω.

15.3 ENCLOSURE MATERIAL

- System: Plastic

FOOTSWITCH SPECIFICATIONS

- Moisture protection rating: IPX8

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15.4 MECHANICAL SPECIFICATIONS – SYSTEM

- Size: 49.5cm (W) x 43cm (L) x 125.7cm (H)
  19.5” (W) x 17” (L) x 49.5” (H)
- Weight: Approximately 100lbs. (45kg)
- Moisture protection rating: IPX0
- Power Cord length: 3m (10ft)
- Footswitch Cord length: 3m (10ft)
- Return Pad Cable length: 2m (6.6ft)
- Handpiece Cable length: 2m (6.6ft)

To disconnect the Power Cord from the System or the AC mains, remove it from the AC Inlet connector at the rear of the system.

15.5 ENVIRONMENTAL CONDITIONS

OPERATIONAL CONDITIONS

Part	Temperature Range	Humidity	Condition
System	10°C to 30°C (50°F to 86°F)	Up to 90% RH	Non-Condensing

STORAGE AND TRANSPORTATION CONDITIONS

Part	Temperature Range	Humidity	Condition
System	-30°C to 60°C (-22°F to 140°F)	Up to 90% RH	Non-Condensing
Cryogen Canister	18°C to 49°C (64.4°F to 120°F)	20% to 95% RH	Non-Condensing
Coupling Fluid	-40°C to 49°C (-40°F to 120°F)	20% to 95% RH	Non-Condensing
Skin Marking Paper	-14°C to 25°C (6.8°F to 77°F)	20% to 95% RH	Non-Condensing
Return Pad components	-40°C to 49°C (-40°F to 120°F)	Up to 90% RH	Non-Condensing

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16 ENERGY OUTPUT TABLES

Energy Output Data – at Full and Half Output over the range of load resistance between 75 and 400 ohms

Treatment Tip Type	Half Output (Joules)	Full Output (Joules)
Total Tip 4.0cm^2	92	173
Total Tip 3.0cm^2	73	137
Eye Tip 0.25cm^2	10	15
Body Tip 16.0cm^2	452	600

*Note: Accuracy of energy output is ± 20%

Energy Output vs. Control Setting – Specified load resistance is between 75 and 400 ohm

Treatment Tip Type	Treatment Setting	Energy Range (Joules)
Total Tip 4.0cm^2	0.5 – 8.0	25 to 173
Total Tip 3.0cm^2	0.5 – 8.0	20 to 137
Eye Tip 0.25cm^2	0.5 – 5.0	6 to 15
Body Tip 16.0cm^2	0.5 – 9.5	300 to 600

*Note: Accuracy of energy output is ± 20%

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17 HISTORICAL EYELID CLINICAL DATA

IMPORTANT NOTE: Eyelid treatments described below were completed using plastic ocular eye shields.

A prospective clinical study was conducted on Thermage NXT 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 0.25cm² Treatment Tip to the upper and lower eyelids combined was 445. The maximum was 1,190 and the average was 723.

Summary Measures for REP Groupings

Low REPs		Mid REPs		High REPs	
Minimum	131.00	Minimum	576.00	Minimum	850.00
Maximum	564.00	Maximum	833.00	Maximum	1,190.00
Median	501.00	Median	669.00	Median	900.00
Average	453.17	Average	682.69	Average	920.17
Standard Deviation	110.15	Standard Deviation	78.65	Standard Deviation	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 patient’s 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.

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18 LABELING SYMBOLS

BS EN ISO 15223-1: 2021 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.
	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.
	5.1.4	Use-by date	Synonym for “use-by date” is “use by.” Also called “expiration date”
	5.1.5	Batch code	Synonyms for “batch code” are “lot number” and “batch number.”
	5.1.6	Catalogue number	Synonyms for “catalogue number” are “reference number” and “reorder number.”
	5.1.7	Serial number	
	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.”

BS EN ISO 15223-1: 2021 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**
	5.3.1	Fragile, handle with care	
	5.3.2	Keep away from sunlight	This symbol may also mean “Keep away from heat”
	5.3.4	Keep dry	
	5.3.7	Temperature limit	
	5.3.8	Humidity limitation	
	5.3.9	Atmospheric pressure limitation	
	5.4.2	Do not re-use	Synonyms for “Do not re-use” are “single use” and “use only once.”
	5.4.3	Consult instructions for use	Synonym for “Consult instructions for use” is “Consult operating instructions.”

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BS EN ISO 15223-1: 2021 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**
	5.7.7	Medical Device	Indicates the item is a medical device
	5.7.10	Unique Device Identifier	

IEC TR 60878 Ed. 3.0 b:2015 Graphical symbols for electrical equipment in medical practice			
Symbol	**Symbol Ref. No.**	**Symbol Title**	**Additional Information**
	5032	Alternating current	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals. Additional reference IEC 60417-5032 (2002-10).
	5019	Protective earth; protective ground	To identify any terminal 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).
	5114	Foot switch	To identify a foot switch or the connection for a foot switch. Additional reference IEC 60417-5114 (2002-10)
	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.*

IEC TR 60878 Ed. 3.0 b:2015 Graphical symbols for electrical equipment in medical practice			
Symbol	**Symbol Ref. No.**	**Symbol Title**	**Additional Information**
	5334	Type BF applied part	To identify a type BF part complying with IEC 60601-1. *Note 1 – B = Body.* *Note 2 – F = Floating applied part.*
	ISO 7010-W001	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-W012	Warning: electricity	To warn of electricity.
	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.
	ISO 7000-0623	This way up	To indicate correct upright position of the transport package

IS 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). Gases under pressure (Compressed gas, Liquefied gas, Refrigerated liquefied gas, and Dissolved gas)

Other Marks and Symbols		
Symbol	**Symbol Description**	**Additional Information**
	Hazard Class 9 Materials	D.O.T. “ID 8000 Consumer Commodity” symbol for Hazard Class 9.
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	USA Code of Federal Regulations 21 CFR Part 801 § 801.109(b)(1)
	European Conformity mark	This product conforms to the European Medical Devices Regulation (EU) 2017/745 and meets applicable health, safety and environmental requirements.
	C-UL US Classification mark	Underwriters Laboratories classification mark that indicates compliance with both Canadian and USA requirements. The ***Thermage FLX System and Thermage CPT System*** are UL Classified as to electrical safety, mechanical, and other specified hazards, in accordance with IEC 60601-1, second and third editions.
	Thermage Product Logo	Thermage Registered Trademark
	Thermage FLX Product Logo	Thermage Registered Trademark
	Plastic Ocular Shield required	Thermage Eyelid Treatment requires use of PLASTIC ocular shields. DO NOT use metal shields.

Other Marks and Symbols		
Symbol	**Symbol Description**	**Additional Information**
	On/Off (push/push)	Based on IEC 60417-5009 (2002-10) Stand-By Symbol
	System Fault	System Fault. Discontinue treatment and reboot System.
	MADE IN USA	Country of origin symbol

APPENDIX A: PATIENT NOTIFICATION (EU MDR)

Intended Patient Population

The Thermage FLX System is intended for adult patients aged 35-60 years old, regardless of ethnicity or gender, who do not meet contraindications.

Intended User

This equipment/system is intended for use by healthcare professionals with appropriate training.

Contraindications

The Thermage System is contraindicated for use in patients with 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.

Expected Performance

Non-invasive (no surgery or injections), with good safety profile.

The RF technology heats the deep, collagen-rich layers, causing the collagen to contract and cause a tightening effect; while the cryogen-based cooling process rendered by the tip allows the protection of superficial layers of the skin, thereby aiding patient comfort.

Residual Risks

Solta Medical Inc. has undertaken risk management activities in accordance with BS EN ISO 14971:2019 ‘Medical devices. Application of risk management to medical devices.’ All of the necessary steps have been taken to ensure the safe use of the target device and that all risks associated with the target device are minimized by applying the available SOTA techniques in the design and manufacture of the medical device.

The Safety Risk Assessment document lists all of the potential hazards and associated risks, as well as the risk control measures that have been implemented to reduce all known risks as far as possible. The residual risks are defined according to the following criteria: Severity Grade ≥ 5, Critical – risk of death to patient or operator; may cause severe damage to user environment.

The main residual risks identified for the target device include:

- Fibrillation
- Death
- Product/property damage
- Moderate allergic reaction
- Burn
- Toxic inhalation

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All residual risks were reduced as far as possible and were deemed to be within acceptable limits. All post-mitigated risk levels were found to be acceptable with 2 exceptions: PHX-HA-1147 associated with the use of the device where it is contraindicated (Use error: ‘health care professional is not aware of device contraindications’, or ‘device still used on persons with implantable electrical device’); and PHX-HA-8186 (Use error: misuse - ‘operator uses device for other than intended use, or off-label use’). The mitigation measure for these risks (PHX-HA-1147 and PHX HA-8186) is inclusion of contraindications in the labelling and user training, which leaves the residual risk as intolerable (Risk Priority Number [RPN] = 10 and RPN = 16). This is not a hazard that Solta Medical Inc. can mitigate by other means, since Solta Medical Inc. does not have control over a physician’s decision to use the device in contraindicated clinical situations or off-label. This hazard is deemed mitigated as far as possible. There have been no changes to the Thermage FLX System since the last CER (version G) which would influence the clinical safety or performance of the product.

Complaints

Product complaint and technical support contact information (INCLUDING PRODUCT RELATED COMPLAINTS):

Solta Medical Product Support Telephone:

+1-877-782-2286 or +1-510-259-5299 (option 2)

Or contact your local authorized distributor of Solta Medical products

Consultation

It is recommended to undergo a medical consultation, including a diagnostic examination, of the areas intended for the treatment.

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