User Manual

CoolSculpting® Elite System

ZELTIQ Aesthetics, Inc.
4410 Rosewood Drive
Pleasanton, CA 94588 USA
www.coolsculpting.com

ZELTIQ Customer Service
Worldwide: (+1) 925-474-8160
USA: (+1) 888-935-8471
(1-888-ZELTIQ1)

Intellectual Property

Table of Contents

Customer Service

To report issues with the performance or use of your System, contact ZELTIQ Customer Service:

- Worldwide: (+1) 925-474-8160
- U.S.A.: 1-888-935-8471 (1-888-ZELTIQ1)
- Email: CoolSculpting.support@allergan.com

Routine Issues

For questions regarding device performance or to report issues that do not interfere with current patient treatments:

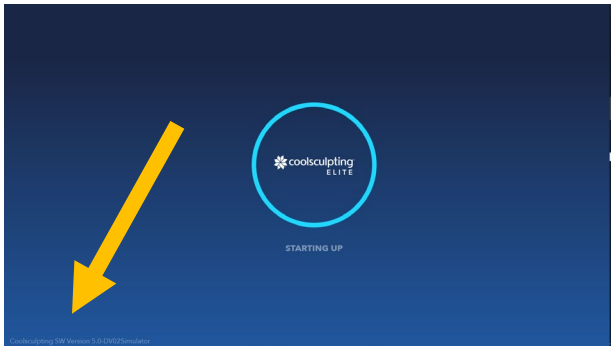
- Call during regular business hours: Monday through Friday, 6 AM to 6 PM Pacific Time
- Calls are answered in the order received.

Urgent Issues

To report safety concerns or issues that interfere with current patient treatments:

- Call at any time.
- If you call outside of regular business hours, leave a voicemail. A technician will be paged and will return your call promptly.

Note: The software version within your system is located within the lower left-hand corner of the screen.



***Example**: Location of Software version information*

Foreword

The *CoolSculpting® Elite* System is a skin cooling or heating device. The system comprises of a control unit, applicators, and supplies such as cards, gelpads, pretreatment skin wipes, liners, foam borders, and comfort straps. The applicators, gelpads, pretreatment skin wipes, liners, foam borders, and comfort straps are patient-applied parts.

During a treatment, the operator applies a gelpad and applicator to the patient's skin. For a treatment where two applicators are used simultaneously (Dual *CoolSculpting® Elite* treatment), a second applicator is applied with another gelpad. The applicator(s) draw tissue into the applicator cup(s) and hold the tissue against the cooling surfaces of the applicator(s). The operator then starts the treatment.

The Surface S150 applicator is a surface applicator and not have a cup. During the cooling cycle, sensors in the cooling surfaces of the applicator(s) monitor the skin surface and provide feedback that controls the rate of heat flux. The gelpad(s) protect the skin by providing thermal coupling at the interface between the cooling surfaces of the applicator(s) and the skin. The Dual and Solo cards provide treatments and profiles for use with the system.

Note: Dual *CoolSculpting® Elite* treatment is to use Applicator A and Applicator B at the same time during treatment.

Indications for Use

The *CoolSculpting® Elite* System is a skin cooling or heating device. It can be used in cooling or heating mode, or in an optional massage mode. Table 1 lists the indications for use for each mode.

Table 1: *CoolSculpting® Elite* Intended Use

Mode	Indications
Cooling	• Indicated for cold-assisted lipolysis (breakdown of fat) of the upper arm, bra fat, back fat, banana roll, thigh, abdomen and flank, or "love handles" in individuals with a Body Mass Index (BMI) of 30 or less. • Intended for cold-assisted lipolysis of the submental and submandibular areas in individuals with a BMI up to 46.2. • Intended to affect the appearance of visible fat bulges in the upper arm, bra fat, back fat, banana roll, submental and submandibular areas, thigh, abdomen, and flank. • When used for cold-assisted lipolysis of the submental area, the device can also affect the appearance of lax tissue in the submental area. • Can be used to minimize pain and thermal injury during laser and dermatological treatments. • Can be used as a local anesthetic for procedures that induce minor local discomfort.

Mode	Indications
Heating or cooling	• Can be used to minimize pain post-trauma and post-surgery. • Can be used to provide temporary relief of minor aches, pains, and muscle spasms. • The ZELTIQ Pretreatment Skin Wipe and Gel/Gelpad facilitate thermal contact of the device with a patient's skin by mitigating minor variances in device-to-skin contact.
Massage (optional function)	• Can be used to provide temporary relief of minor muscle aches, pain, and spasm. • Can be used to provide temporary improvement in local circulation. • Can be used to provide temporary reduction in the appearance of cellulite.

℞ ONLY In the United States of America, federal law restricts this device to sale by or on the order of a physician.

Contraindications

Localized skin cooling is contraindicated in patients who have:

- Cryoglobulinemia
- Cold agglutinin disease
- Paroxysmal cold hemoglobinuria

Warnings

Unauthorized modification or repair of the control unit, its components, or supplies may result in unsafe conditions and/or impaired performance. No modification of this equipment is allowed without express authorization from ZELTIQ. Any unauthorized modification or repair will void the warranty.

The use of the *CoolSculpting® Elite* System has not been studied in children, those who are pregnant or lactating, or patients with:

- Known sensitivity to cold such as cold urticaria, Raynaud's disease, or Chilblains (pernio)
- Known sensitivity or allergy to fructose, glycerin, isopropyl alcohol, or propylene glycol
- Impaired peripheral circulation in the area to be treated
- Neuropathic disorders such as post-herpetic neuralgia or diabetic neuropathy
- Impaired skin sensation
- Open or infected wounds
- Bleeding disorders or concomitant use of blood thinners
- Recent surgery or scar tissue in the area to be treated
- Hernia in or adjacent to the treatment site
- Skin conditions such as eczema, dermatitis, or rashes in the area to be treated

The effect of performing a *CoolSculpting® Elite* treatment with a vacuum applicator on a patient who has a hernia in or adjacent to the treatment site has not been studied. The applicator uses vacuum pressure to draw tissue into the applicator cup during the treatment. The vacuum pressure may therefore apply pressure on a pre-existing hernia or pre-existing structurally weak area such as a surgical scar, causing further complications. Physicians should examine that patient for evidence of pre-existing abdominal or femoral hernia prior to use of the device.

The system operates at temperatures below 0°C, which can freeze tissue; clinical events that are common to freezing tissue should be considered.

The use of this device on areas with superficially located nerve branches, arteries, or veins has not been demonstrated to be safe and effective. Such use may result in injury to the patient.

The effect of performing treatments directly over active implanted devices, such as pacemakers and defibrillators, is not known.

Patients with chronic pain, sensitivity to cold, or an anxiety disorder may be more prone to pain or discomfort during the treatment.

Do not use the *CoolSculpting® Elite* on areas with a subcutaneous fat layer thickness of less than 1cm.

Do not use the *CoolSculpting® Elite* on areas of decreased sensation or perfusion.

Do not use the *CoolSculpting® Elite* on areas with minimal underlying muscle mass or on areas with superficially located nerve branches, arteries, or veins.

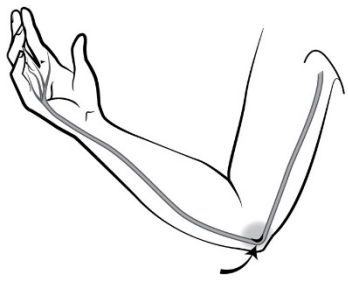
Do not use the *CoolSculpting® Elite* on the face, head, genitalia, inguinal creases, axillae, popliteal fossae, antecubital fossae, hands, or feet.

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

The use of other electronic medical devices on a patient who is undergoing a treatment might interfere with the correct functioning of the system, possibly resulting in injury to the patient. Do not use other electronic medical devices on a patient who is undergoing a treatment.

WARNING: Before using the system, read and understand the additional warnings that are specific to a treatment site within Table 2 on the following page.

Table 2: Warnings for Specific Treatment Sites

Treatment Site	Warning	
Submental and submandibular areas	Cold exposure to the hypoglossal nerve may cause tongue deviation following treatment of the submental and submandibular areas.	 Hypoglossal nerve
	Cold exposure to the marginal mandibular nerve may cause lower lip weakness following treatment of the submental and submandibular areas.	 Marginal mandibular nerve
	Cold exposure to the submandibular gland may cause xerostomia, or decrease in saliva production, following treatment of the submental and submandibular areas.	 Submandibular gland
Upper arm	Avoid compression of the ulnar nerve during treatment of the upper arm.	 Ulnar nerve

Precautions

The system is intended for use by a trained physician or by a physician-designated medical professional.

If the operator observes a potential safety issue or operational abnormality during use, the operator should stop the treatment immediately and contact ZELTIQ Customer Service (see page 5).

The use of other equipment and supplies with the system has not been tested and may cause unexpected results.

Adverse Events

Table 3 lists common adverse events that can occur in the treatment area during and after a treatment. These effects are temporary and generally resolve within days or weeks.

Table 3: Common Adverse Events

When Occurs	Common Side Effects
During a treatment	• Sensations of pulling, tugging, and mild pinching at treatment site • Intense cold, tingling, stinging, aching, cramping **Note:** These sensations subside as the area becomes numb.
Immediately after a treatment	• Redness and firmness • Transient blanching and/or mild bruising around the edges of the treatment area • Tingling and stinging
One to two weeks after a treatment	• Redness, bruising, and swelling • Tenderness, cramping, and aching • Itching, skin sensitivity, tingling, and numbness **Note:** Numbness can persist up to several weeks after treatment. • Sensation of fullness in the back of the throat after submental area treatment

Table 4: Rare Adverse Events

Rare Event	Description
Paradoxical hyperplasia	Visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment. Surgical intervention may be required.
Late-onset pain	Late-onset pain may begin several days after a treatment and usually resolves within several weeks.
Severe pain	Patients may experience pain of varying severity, which more commonly can be described as mild to moderate, and in rare instances, can be severe.
Freeze burn	First and second-degree freeze burn may occur during treatment. It typically resolves without sequelae with proper care.
Vasovagal symptoms	Dizziness, lightheadedness, nausea, flushing, sweating, or fainting might occur during or immediately after the treatment.
Subcutaneous induration	Generalized hardness and/or discrete nodules within the treatment area can develop after the treatment and might present with pain and/or discomfort.
Hyperpigmentation	Hyperpigmentation can occur after treatment and usually resolves spontaneously.
Hernia	Treatment might cause new hernia formation or exacerbate a pre-existing hernia, which can require surgical repair.
Treatment area demarcation	An aesthetic outcome of treatment in which the patient experiences excessive fat removal in the treatment area, resulting in a visible disruption to the continuous contour of fat, or unwanted indentation in the treated area.
Cold panniculitis	Cold panniculitis results from injury to adipose tissue exposed to cold and may result in a mild to severe inflammatory response. In mild cases, the symptoms are self-resolving and may include redness, swelling, skin nodules, warmth, tenderness, and possible low-grade fever. These cases typically resolve without long-term sequelae. In more severe cases, an intense inflammatory response may result in more extensive tissue damage, including fat necrosis, which may require medical or surgical intervention.

Freeze Detect System

The system operates at temperatures below 0°C, which can freeze tissue. Therefore, the system monitors tissue during cooling and employs multiple safety features including the Freeze Detect® system, to minimize the risk of damage to tissue. Despite these measures, on rare occasions, the Freeze Detect system can detect a possible freeze condition.

The Freeze Detect system is comprised of several features, including thermal sensors and proprietary algorithmic software. Freeze Detect is an integral part of the *CoolSculpting® Elite* System and is automatically employed when a treatment is initiated.

When the Freeze Detect system detects a possible freeze condition, it stops the treatment and displays a Z409 message. If you receive this message, remove the applicator and gelpad, assess the tissue, and discontinue the treatment. Failure to follow instructions could result in injury to the patient, including first or second-degree burns. Second-degree burns or complications of second-degree burns may result in hypopigmentation.

User Documentation

Before using the system, read and understand the user documentation. Table 5 lists the types of user documentation provided with the *CoolSculpting® Elite* System.

Note: All images in ZELTIQ user documentation are sample images. Your hardware and information on the system screen may differ from those depicted in the documentation.

Note: ZELTIQ reserves the right to modify the content of the user documentation at any time. Retain the most current user documentation and always review it prior to using any component of the system.

Table 5: Type of User Documentation

Item	Description
User Manual	Provides detailed information on the components of the system, lists contraindications and side effects, and describes how to perform treatments, troubleshooting, cleaning, and maintenance.

CHAPTER 1

System Overview

This chapter describes the control unit, the applicators, and supplies such as Card, Gelpad, Gel Trap, Pretreatment Skin Wipe (Skin Wipe), and Comfort Strap.

Control Unit

The control unit (Figure 1) is a portable device that is used to start, stop, and monitor treatments.

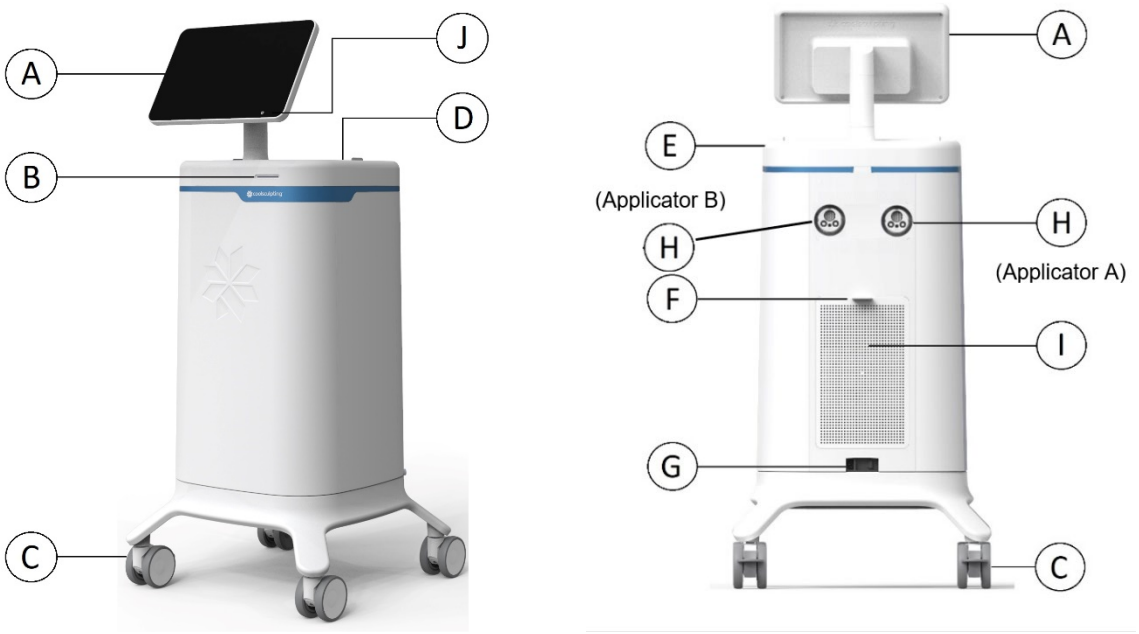


Figure 1: Control Unit

A: Touchscreen display
B: Card slot
C: Casters and locks
D: Bucket
E: Top cap lip
F: Access panel
G: Power receptacle and power switch
H: Connector Ports for umbilical cords for Applicators A and B
I: Vents
J: Soft power button

Touchscreen Display

The touchscreen displays system controls, information about the status of the system, information about the treatment, and messages for the operator. You can rotate or tilt the display to accommodate better access.

Card Slot

The card slot accepts treatment cards. You must insert an appropriate Solo or Dual treatment card with active credits to begin a treatment.

Casters and Locks

The control unit has four casters that swivel. Each caster has a lock. Always engage all four caster locks when the unit is stationary. Disengage the caster locks to move the unit.

► **To engage the caster locks:** Press down on the locking lever with the toe of your shoe.

► **To release the caster locks:** Pull up on the locking lever with the toe of your shoe.

► **To move the control unit:**

1. Power off the control unit.
2. Unplug the power cord from the wall outlet and place it in the bucket of the control unit.
3. Release the lock on each caster.
4. Push or pull the lip of the top cap to move the control unit to the new location.
   Note: Do not push or pull on the touchscreen display or the display post to move the unit.
5. When you have placed the control unit in its new location, engage the lock on each of the four casters.

While moving the system within the office, place the applicator in the bucket provided on top of the control unit. In addition, grasp the top cap lip of the system to guide the unit from one location to another.

Bucket

The bucket is a storage area for applicators and/or consumables. You can remove the bucket from the control unit for cleaning.

Figure 2: Image of the top the system that shows the bucket

Top Cap Lip

When the applicator is resting on top of the control unit, the top cap lip helps keep the applicator in place.

Access Panel

The access panel covers vents, a USB port, and the chiller tank cap (Figure 3):

- **Vents:** Vents provide airflow that reduces heat build-up inside the control unit. Ensure that all vents are free from obstructions when the control unit is in operation
- **USB port:** The USB port (rectangular) is intended for use with approved software and hardware provided by ZELTIQ.

Chiller tank cap: The cap is for covering the coolant tank. A service technician is required to add coolant to the system. Please contact customer service.

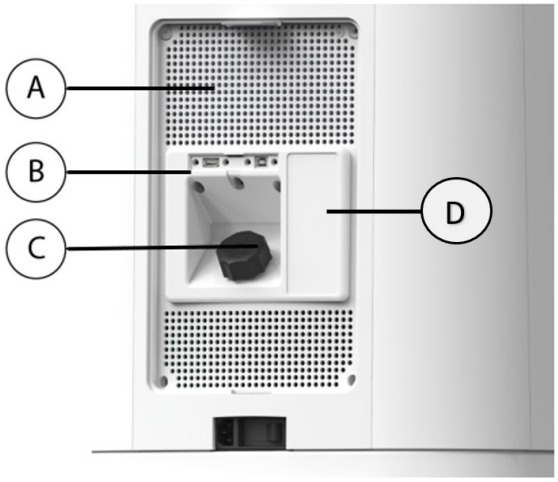


Figure 3: Rear of control unit with access panel removed

A: Vents
B: USB port (rectangular)
C: Chiller tank cap;
D: Product code and Serial Number

► **To remove the access panel:** Gently pull the tab at the top of the door toward you to disengage the magnetic seal; then lift off the entire panel.

► **To replace the access panel:** Align the access panel with the recess and hold it close to the control unit until the magnets snap it into place.

Power Receptacle and Power Switch

Do not use the Control Unit if the Power Switch, Power Cord and/or Power Receptacle become damaged.

If the Power Switch, Power Cord and/or Power Receptacle appears to be damaged, contact Customer Service as listed in the User Manual.

Power Cord Clamp

The power cord clamp attaches the power cord to the rear of the control unit, and it acts as a strain relief to protect the Power Receptacle if the cord is pulled. Install the power cord clamp before using the system. If the power cord is dislodged during a treatment, the treatment will be ended abruptly.

► **To install the power cord clamp:**

1. On the back of the control unit, insert the thumbscrew into the hole in the base.
2. Using your fingers, turn the thumbscrew until it is snug. See illustration below.

Example: *Power cord clamp installed in base*

► **To power on the control unit:**

1. Insert one end of the power cord into the power receptacle.
2. Insert the other end of the power cord into a grounded wall outlet.

   To minimize the risk of electric shock, connect this equipment to a grounded electrical outlet.

3. Press the power switch on the back of the control unit to the “On” position (Figure 4).

The control unit powers on and illuminates the soft power button (Figure 5).

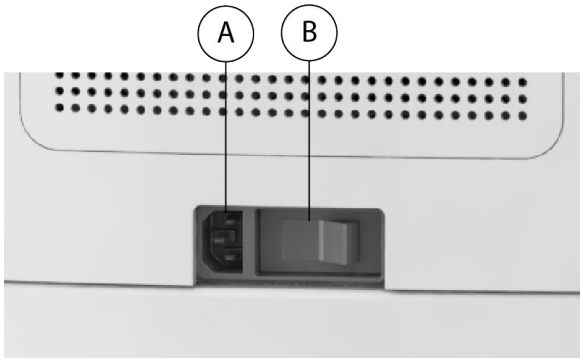


Figure 4: Close-up of power receptacle and power switch

A; Power receptacle
B: Power switch (current position is “Off”, which is the “0”. The “On” has a “1”)

► **To power off the control unit:**

1. Press the power switch on the back of the control unit to the Off position.
2. Unplug the power cord from the wall outlet.
3. Unplug the power cord from the power receptacle on the rear of the control unit.

Soft Power Button

The display includes a soft power button at the lower right corner, which is used to power on the system, after turning the power switch on the rear of the system to the “On” position. The soft power button may also be used to power off the system.

When the system is in standby or sleep mode, the power button is illuminated and will pulse. This indicates that the system is asleep. Pressing the button will awaken the system.

► **To power on the control unit:**

1. While the power switch is On, and the system is off, press the soft power button on the display.

► **To power off the control unit:**

1. While the power switch is On, and the system is on, press the soft power button on the display
2. A pop-up message will be displayed asking “Are you sure you want to power off the device?”
3. Select “Yes”

Figure 5: Soft Power Button

Applicator Connectors

The control unit has two connector ports where two umbilical cords attach to perform a simultaneous treatment. Simultaneous treatment is an option, but not necessary.

Vents

Vents provide airflow that reduces heat build-up inside the control unit. Ensure that all vents are free from obstructions when the control unit is in operation.

Applicators

The applicator delivers controlled cooling and heating to the treatment site.

The applicator consists of the applicator connector, the applicator umbilical, and the applicator head. The applicator is used with supplies provided by ZELTIQ.

The handpiece of the applicators can be disconnected from the umbilical, except for the C80 and S150, which are used with standalone umbilical.

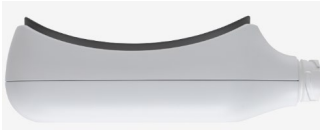
Always use gelpads with the applicator as instructed in this document.

The applicators are designed to treat most body areas. There are 7 applicators supplied with the system (Table 6). Clinicians should consider all physical aspects of the area to be treated and use the applicator that will fit best for each patient.

ZELTIQ defines a specific combination of treatment temperature and duration for each profile. Typically, a colder treatment temperature is paired with a shorter treatment duration.

Table 6: Applicators supplied with *CoolSculpting® Elite* System.

Applicator	Total Cooling Area (cm^2)	Recommended Treatment Sites	Profile Temp. Range	Profile Duration Range	Pre-Treatment Skin Care	Post-Treatment Care Option
CoolSculpting Curve 80 (C80™) 	35	Small areas with pinchable fat, such as the submental and submandibular areas	Down to -15°C	Up to 60 minutes	Skin wipe	Manual massage
CoolSculpting Curve 120 (C120™) 	84	Areas with pinchable fat, such as the flanks, abdomen, banana roll, back fat, and bra fat	Down to -15°C	Up to 60 minutes	Skin wipe	Manual massage
CoolSculpting Curve 150 (C150™) 	133	Areas with pinchable fat, such as the flanks and abdomen	Down to -15°C	Up to 60 minutes	Skin wipe	Manual massage

CoolSculpting Curve 240 (C240™) 	225	Large areas with pinchable fat, such as the flanks and abdomen	Down to -15°C	Up to 60 minutes	Skin wipe	Manual massage
CoolSculpting Flat 125 (F125™) 	83	Vertical bulges of pinchable fat, such as the inner thigh and upper arm*	Down to -15°C	Up to 60 minutes	Skin wipe	Manual massage
CoolSculpting Flat 165 (F165™) 	96	Vertical bulges of pinchable fat, such as the inner thigh and upper arm*	Down to -15°C	Up to 60 minutes	Skin wipe	Manual massage
CoolSculpting Surface 150 (S150™) 	134	Areas with non-pinchable fat, such as the lateral thigh and upper abdomen	Down to -15°C	Up to 120 minutes	Skin wipes	Manual massage

*The cleared treatment profile for the upper arm is -11ºC for 35 minutes.

User Interface

A treatment involves a mix of physical setup at the control unit, interactions with the patient, and interactions with the system software via the touchscreen. The system guides you through these transitions with a series of prompts, cues, and feedback as you progress through the treatment procedure.

Screen Elements

When interacting with the touchscreen, tap a button or other element to select it.

Treatment Status

During a treatment, the screen displays status information to help you monitor progress (

Figure 6).

As soon as a treatment begins, the status changes to “Treating” and the system begins counting down from the total scheduled time. The remaining time is displayed in large numbers within a “clock” graphic. A blue indicator bar recedes clockwise from the 12:00 position as the treatment progresses.

The treatment temperature, total scheduled treatment time, and the vacuum status are displayed above the remaining time.

Figure 6: Example of status information displayed prior to starting a treatment

A: Treatment time remaining
B: System status
C: Visual indicator of remaining time
D: Treatment temperature
E: Duration of treatment
F: Vacuum status (on or off)
G: Applicators A and B

Audible Tones

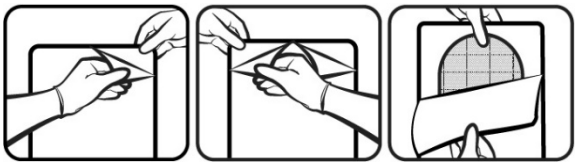
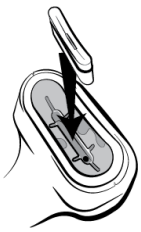
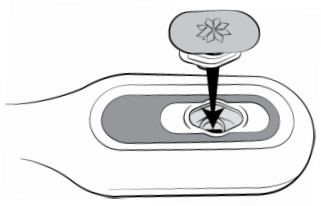
The system provides audible feedback. The control unit beeps:

- When the operator presses a button on the screen
- When a treatment begins
- When the system detects an error
- When a treatment ends
- When a remote notification is sent

Supplies

To order supplies for your *CoolSculpting® Elite* System, visit CoolSculpting.support@allergan.com or contact Customer Service (see page 5).

Table 7: Supplies

Item	Description
Card	Provides treatments and profiles for use with the system: • Profiles define the number of timed segments of cooling and heating. • For the Solo card, each cycle provides a single treatment for one applicator. • For the Dual card, each cycle provides a single treatment for both applicators The card is considered an active device that is inserted in the System when starting treatment. The card uses software to provide users with the treatment parameters (temperature and time) with which to conduct treatments.
Filter	The purpose of this filter is to extend the service life of your control unit. Refer to the Maintenance section for filter replacement instructions.
Gelpad	Provides thermal contact between the applicator and the patient's skin; mitigates minor variances in device-to-skin contact. **Note:** Single-use item; use a new gelpad for each treatment. Reuse of a gelpad may result in tissue injury. Use a new gelpad each time you place the applicator on an application site. Ensure gelpad is appropriate size for the applicator.  If a gelpad package shows signs of damage, such as leakage, do not use the gelpad. Store gelpads flat and at room temperature.
Gel Trap	 Fits into the slot of the applicator; prevents the ingress of gel into the vacuum system. Single-use item; use a new gel trap for each treatment.  Refer to Chapter 2 Treatment in the User Manual.
Pretreatment Skin Wipe	Use the Pretreatment Skin Wipe (skin wipe) to prepare the treatment site before applying a gelpad by cleaning for 60 seconds.  Single-use item; use a new pretreatment skin wipe for each treatment.

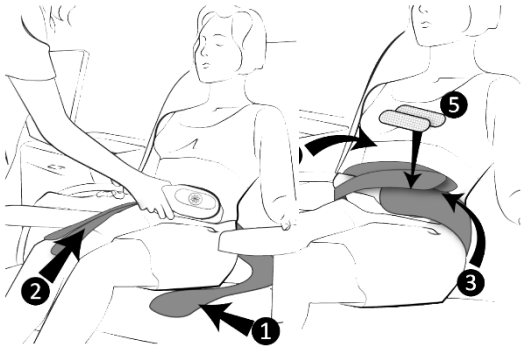
Item	Description

Comfort Strap

Minimizes movement of the applicator during treatment.

1. Place bonnet on applicator.
   a. Insert applicator in bonnet.
   b. Secure bonnet over applicator.
   c. Zip the backside of the bonnet.

2. Position Comfort Strap.
3. Apply the applicator over the desired treatment area.
4. Wrap the Comfort Strap around the applicator.
5. Secure the Comfort Strap and attach hook tab.



Foam borders

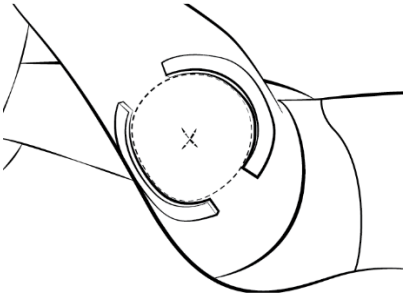
Foam borders minimize movement of the surface applicator during treatment.
The foam borders are for the S150 Applicator only.

⚠ Some individuals may be sensitive to crosslinked ethyl vinyl acetate (EVA) foam or 3M Double Coated Medical Tape. If a rash develops, discontinue use and contact a physician.

Note: Use a new set of borders for each treatment site. Do not reuse borders.

To apply foam borders for S150 Applicator:

1. ⚠ Clean the treatment site with an alcohol wipe.
2. Remove the backing from one pair of foam borders.
3. Apply one pair of foam borders around the treatment site.
4. Repeat above two steps for the other pair of borders.
5. Wipe the treatment site with a pretreatment skin wipe.
6. Repeat above for the other foam borders for Dual treatment using the S150 Applicator.
7. Apply a gelpad to the treatment site.



Liner

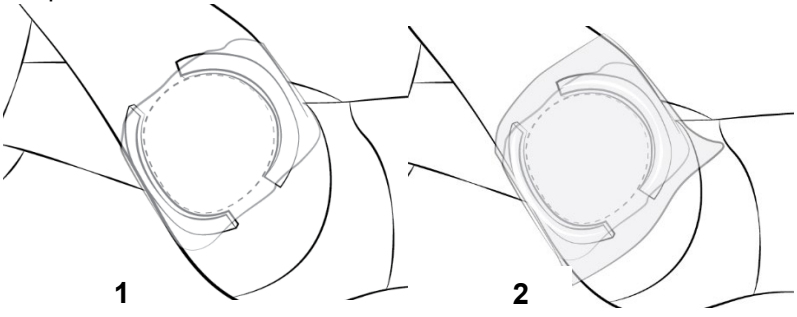
The liner is disposable and provides an interface between the gelpad and applicator.
The liner is for S150 applicator only.

⚠ Used liners are considered medical waste. Dispose of used liners according to your site's medical waste protocol.

⚠ Use a new liner on each treatment site. Do not reuse liners.

To apply a liner for S150 Applicator:

1. Center the liner above the gelpad.
2. Press the liner onto the gelpad.
3. Working from the center outward, gently smooth the liner to eliminate any wrinkles or bubbles.



CHAPTER 2

Treatment

A treatment is composed of timed segments of cooling and heating. Each treatment is based on a profile, which is contained on the card.

Profiles, Treatments, and Cards

The profile defines the temperature and duration of a treatment. Table 8 lists the elements that comprise a treatment profile.

A cycle is an individual instance of a treatment; that is, the application of one profile to one patient.

Each card contains a set number of treatments and a list of profiles. When all the treatments have been used, the card is expired.

Note: When a Dual card is used for two applicator placements per treatment, 1 unit of treatment is deducted. When a Solo card is used for one applicator placement per treatment, 1 unit of treatment is deducted.

Table 8: Elements of a Treatment Profile

Element	Units	Description
Temperature	°C	The treatment temperature
Time	minutes	The duration of the treatment

Treatment Procedure

1. Set up the control unit

a. Position the control unit next to the bed or chair that will be used for the treatment.

Note: Ensure that the vents have enough clearance for adequate ventilation and that the operator can access the power switch easily.

The Control Unit contains coolant and should not be operated/transported on its back as the coolant may escape.

b. Insert one end of the power cord into the power receptacle on the back of the control unit.

c. Plug the other end of the power cord into a grounded outlet.

To minimize the risk of electric shock, connect this equipment to a grounded electrical outlet.

d. Engage the lock on each of the four casters.

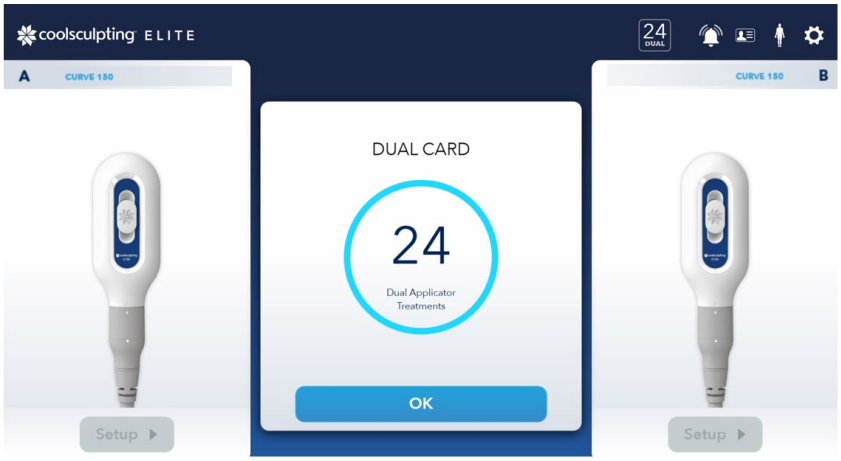
2. Set up the system

Materials required:

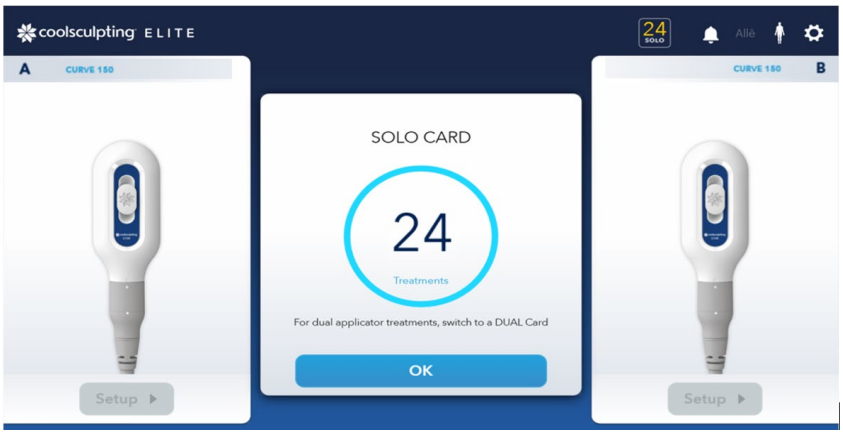
- Treatment Card
- Applicator(s)

a. Power on the control unit and wait for the touchscreen to display the “Insert Card” prompt.

b. Insert card into the slot on the control unit and wait a moment while the card authenticates. Screen should display “Reading Card.”



Example: *DUAL CARD Screen*



Example: *Solo CARD screen*

Note: The system displays the number of treatments remaining on the card in the top right area of the screen. Depending on the type card inserted, the “DUAL CARD” appears if using the Dual card or “SOLO CARD” if using the Solo card.

Note: If dual applicator treatment is desired, switch to a Dual card. Also, if Solo applicator treatment is desired, switch to a Solo card.

Note: If the system displays an error associated with the card (for example, an expired or incompatible card), find the message code in Table 11 and follow the recommended actions.

c. When the system detects that the card is authenticated, tap **OK**. The next prompt is "Attach Applicator A or B."

Note: The *CoolSculpting® Elite* System consists of Applicator Connector Ports (A and B), which operate independent of each other. There is an option of attaching either Applicator A or B or both applicators.

For C120, C150, C240, F125, and F165 applicators: Remove the cap and connect the applicator to the umbilical. The cap covers the connector of the applicator that connects to the umbilical.

For C80 and S150 applicators: The C80 and S150 applicators do not detach from the umbilical.

Plug the umbilical(s) into the connector port(s) on the control unit and rotate the collar clockwise until the indicator marking(s) line up with the lock symbol.

d. After confirming the Clinician Attestation statement, the Patient Information screen appears. The prompt changes to "Enter Patient Properties." Select Gender, Patient new to practice or otherwise, and number of previous CoolSculpting treatments used on the patient. When this information is entered, tap **Next** and the prompt changes to "Select Treatment Area."

Note: The user has the option of using Applicator A, B, or both. For Dual *CoolSculpting® Elite* treatment, it is recommended to set up one applicator at a time (either Applicator A or B) until ready to start treatment, before setting up the second applicator. The workflow in this section focuses on setting up Applicator A (instructs to tap "Next").

Note: Dual indicates two applicator placements per treatment, equivalent to two cycles. Solo indicates single applicator placement per treatment, equivalent to one cycle.

3. Allē Loyalty Program

a. On the Allē Loyalty Program screen, place Allē Code under the monitor where the red light is shown.

Note: The Allē Loyalty number or Patient information can be changed up to the starting treatment step. If the Allē Loyalty number or Gender of the Patient have been changed, the Clinician Attestation statement will need to be confirmed again.

b. Hold the Allē Code under the red light until a number appears in the entry field above; then tap **Next**. Screen should display "Applicator Authenticating" followed by "Applicator Ready" and "Select Treatment Area" screens.

Note: If no Allē Loyalty number appears in the entry field, then tap **Next** to enter the Allē Loyalty number After typing in the Allē number, tap **Next**.

Note: If no Allē Loyalty number is available, tap **No Allē.**

4. Select Treatment Area

a. On the Select Treatment Area screen, select the appropriate treatment area by tapping the location on the body.

The desired treatment area highlights bright yellow and remains highlighted.

Note: For cleared indications for use, contraindications, and warnings, see “Foreword.” For warnings related to specific treatment sites, see Table 2.

Example: *Treatment area selected for Applicator A*

a. After you select the treatment area, tap Next.

Note: When performing Dual *CoolSculpting® Elite* treatment, using both Applicators A and B, ensure that there is at least 2-minute window at the end of the treatment to allow for the optional massage. This applies if duration of treatment for Applicators A and B are the same, and both Applicators A and B are used.

b. On the Treatment Profile screen, select a profile from the list; then tap **Next**.

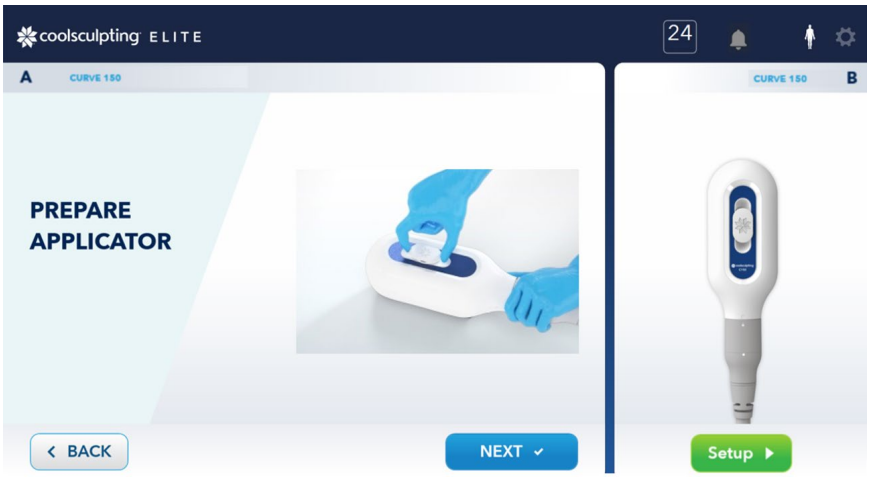
Note: The profile list displays applicator temperature and treatment duration.

5. Prepare the applicator

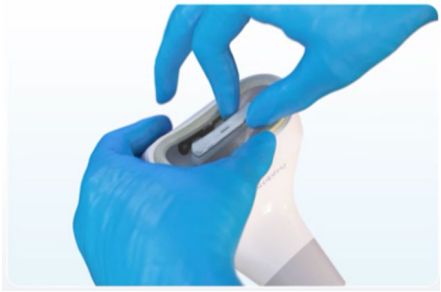
Materials required:

- Gel trap

a. After you tap **Next**, the prompt leads to a new screen for Applicator A to instruct the insertion of the gel trap on the back side of the applicator (for C120, C150, C240, F125, and F165). For C80 applicator, the gel trap is in the metal plate in the front of the applicator. The S150 applicator does not have a gel trap.



***Example**: Insert Gel trap on the back side of Applicator A*



***Example**: Insert Gel trap in metal plate in front of Applicator A (C80)*

b. Return to the touchscreen and tap **Next.**

The next screen instructs to apply gelpad.

6. Prepare the patient

Materials required:

- Gelpad
- Alcohol wipe
- Pre-treatment skin wipe

Use gelpads as instructed in this document. Failure to follow instructions may result in tissue injury.

The gelpad is designed for a single use only. Reuse of gelpad may result in tissue injury.

If the gelpad package shows signs of damage, such as leakage, do not use the gelpad.

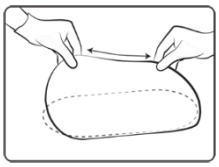
Inspect the treatment site to ensure that the skin is intact. Treat over intact skin only.

Remove jewelry that is in or directly adjacent to the treatment site.

⚠ Clean the treatment site with an alcohol wipe.

⚠ Clean the treatment site with a pretreatment skin wipe for 60 seconds.

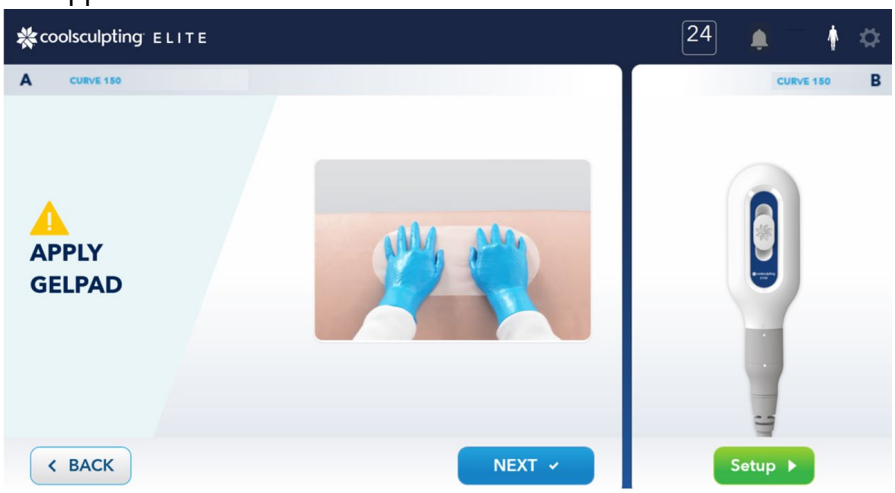
a. Open a gelpad pack and remove the gelpad.



Note: Gently grasp two corners on a long side of the gelpad and lift it off the package horizontally.

Example: grasp two corners on long side of the gelpad

b. Drape the gelpad over the center of the treatment site. Ensure that the gelpad is correct size for the applicator.



***Example**: Apply gelpad on area of treatment for Applicator A*

c. Inspect the visible side of the gelpad to ensure that it appears intact.

Use of a damaged gelpad may result in tissue injury. If a gelpad shows signs of damage, such as tearing, thin spots, or dryness, do not use it.

d. After applying the gelpad, return to the touchscreen and tap **Next**.
The screen showing placement of the applicator over the gelpad appears.

7. Turn on vacuum using single applicator (i.e. Vacuum or Surface Applicator)

Note: This step focuses on starting a single applicator (i.e. Applicator A).

a. For vacuum applicators, turn on the vacuum by tapping the **ON** button in the upper right corner, which is next to the vacuum image.

***Example**: Vacuum ON*
Blue highlight indicates on.

i. When you tap **ON**, the prompt changes to vacuum image with the following text “Waiting for tissue draw.”

The vacuum applicator draws tissue into the applicator cup and holds the tissue against the cooling surfaces of the applicator.

ii. Place the applicator over the center of the treatment site.

iii. Inspect the gelpad and applicator to ensure that the gelpad extends beyond the borders of the applicator.

***Example**: Position Applicator over gelpad*

If the gelpad slips and the cooling surfaces of the applicator come into contact with the patient's skin, tissue injury may result.

b. The Surface applicator (S150) does not use vacuum pressure or draw in tissue since it does not have a cup.

i. Plug the umbilical(s) into the connector port(s) on the control unit and rotate the collar clockwise until the indicator marking(s) line up with the lock symbol. The S150 applicator does not have a gel trap.

ii. Return to the touchscreen and tap Next. The next screen instructs to apply gelpad.

iii. On the Treatment Profile screen, select a profile from the list; then tap Next.
Note: The profile list displays applicator temperature and treatment duration.

Clean the treatment site with alcohol wipe.

Clean the treatment site with a pretreatment skin wipe for 60 seconds.

iv. Apply foam borders around the treatment site.

v. Apply a gelpad to the treatment site.

vi. Apply a liner over the gelpad.

vii. Place the applicator between the foam borders on the treatment site.
Ensure that the gelpad and liner extend beyond the outside edges of the foam borders.

viii. Wrap the Comfort strap around the patient to secure the applicator in place.

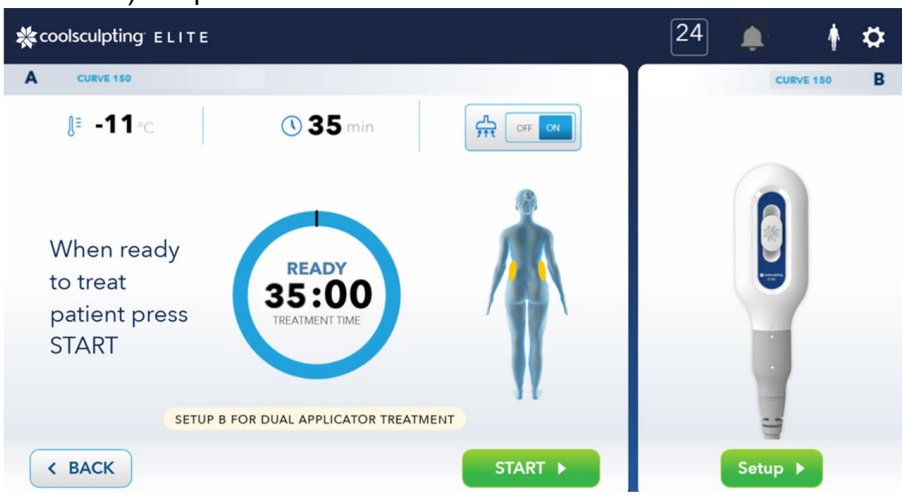
Note: Refer to the Supplies section for directions for use for information on securing the applicator in place.

8. Start Treatment

Note: If simultaneous treatment is desired, proceed “To perform a simultaneous treatment” step below.

a. The next screen prompts to start treatment. After confirming that the gelpad and applicator are positioned correctly, treatment can be started.

b. When ready to start treatment for Applicator A, press **Start**. If using Dual treatment card, proceed to “To perform a Dual treatment (i.e. to use Applicator B simultaneously during treatment)” step below.



***Example**: Start treatment screen for Applicator A*

Note: With a Dual card, if starting treatment for Applicator A without setting up treatment for Applicator B, the next prompt asks for confirmation by tapping **Proceed** or to go back to set up by tapping **Continue Setup**.

Note: When using the Dual card, there is one start button to start both applicators, after both applicators are set up.

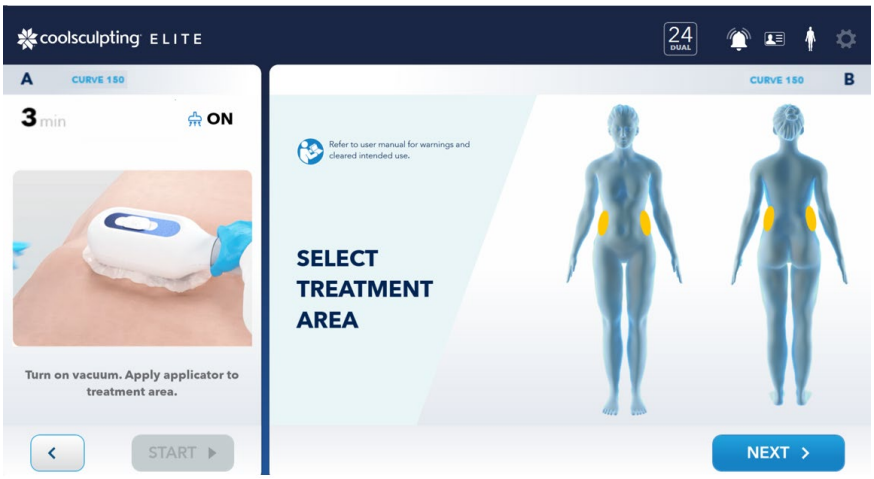
Note: If both applicators have the same treatment time, then choose either side A or side B first. There is a delay timer for start of treatment on the second side for Dual treatment. This allows time for removal of the first applicator and gelpad for the optional manual 2-minute massage on the first side before the second side.

Note: Treatment can be started for both Applicators A and B at the same. Otherwise, only one Applicator can be used, depending on the need.

► **To perform a Dual treatment (i.e. to use Applicator B simultaneously during treatment):**

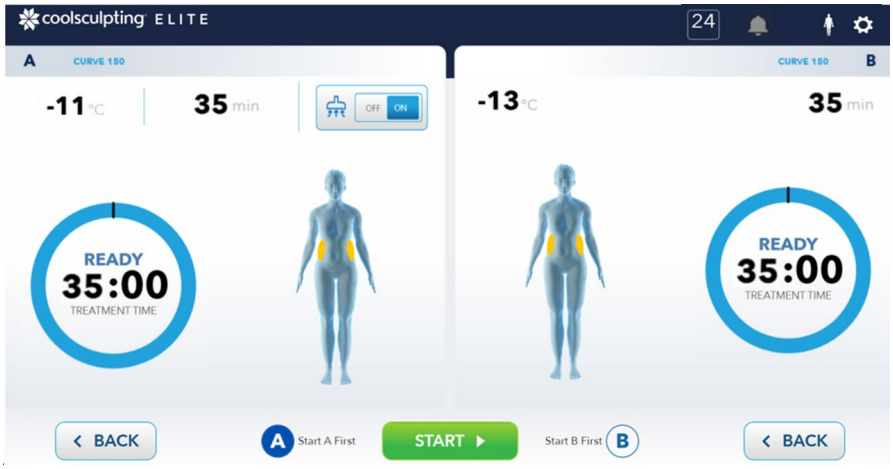
a. At the touchscreen, tap treatment area on the body.

The highlighted treatment area displays. Tap **Next.**



***Example**: Treatment for Applicator B*

b. Go to “Prepare the applicator” and repeat the procedure for Applicator B.



***Example**: Starting Dual treatment for Applicators A and B*

c. If the treatment times for both the applicators is same, tap **A** for starting Applicator A first or **B** for starting Applicator B first. There is a 5-minute window between end of treatment for Applicators A and B to allow 2-minute massage of the treatment areas. There is delay timer for start of treatment on the second side for Dual treatment.

   If the treatment times are different by 5 or more minutes, both the applicators are started at the same time. The massage will be performed on the treatment area that finishes first.

d. When ready to start treatment, tap **START**

9. End the treatment

Materials required:

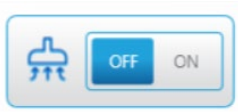
- Towel or other absorbent material
- Wet or damp towel/gauze or water-based wipes

- Optional: Gauze soaked in isopropyl alcohol or equivalent wipes

    a. Place a towel or other absorbent material into the bucket on top of the control unit.

    b. Grasp the applicator to hold it in position; then tap the **OFF** button on the touchscreen to toggle the vacuum from ON to OFF. The S150 applicator does not use the vacuum feature and can be removed by detaching the Comfort strap.

    ***Example**: Vacuum OFF*
    Blue highlight indicates off.



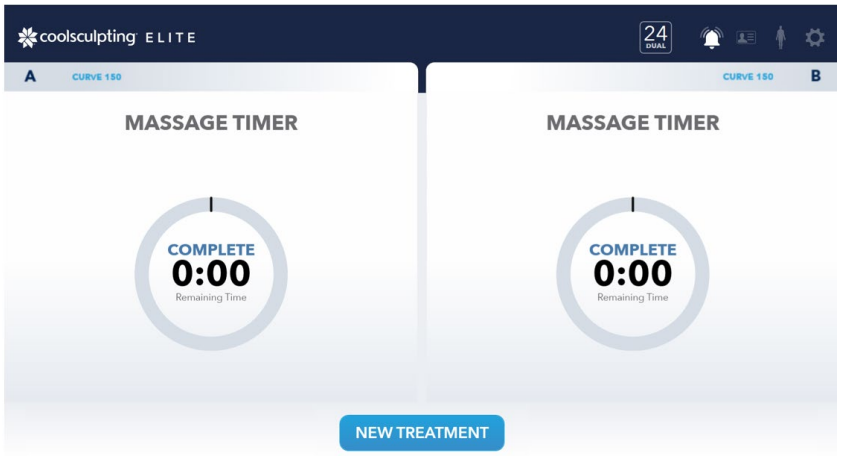
When the vacuum is turned off, the applicator may disengage from the patient. The applicator could fall and be damaged or cause injury. Grasp the head of the applicator firmly before turning off the vacuum or releasing the Comfort straps.

    c. After you turn off the vacuum, the prompt changes to “Massage” or “New Treatment.”

    d. Remove the applicator from the patient and place the applicator head in the bucket on top of the control unit with the cooling surfaces facing downward.

    e. Allow gel to drain into the bucket, or onto a towel or other absorbent material.

    f. Massage the treatment area for two minutes: For Dual treatment, the prompt shows 5-minute delay timer for massage timer for the second side. You can leave the massage screen when both treatments are completed.



***Example**: Massage timer for Applicators A and B for Dual treatment*

    g. Use towels, gauze or water-based wipes to remove any excess gel from the treatment area.

10. Clean the applicator

Materials required:

- Cotton towel
- Water-based wipe or wet gauze
- Gauze soaked in isopropyl alcohol or equivalent wipes

The electronic sensors on the cooling surfaces of the applicator are delicate and may be damaged by excessive pressure or unapproved cleaners. Use care when cleaning and storing the applicator. For more information, see “Cleaning and Maintenance”.

a. Wipe the applicator cup, the rim of the cup, the applicator housings, and the applicator cable with a water-based wipe or wet gauze to remove excess gel.

b. Remove Gel Trap:

For C80 applicator: Insert the tip of the gel trap removal tool into the gel trap; then slide the tip of the removal tool forward and extract the gel trap.

Note: The S150 applicator does not have a gel trap.

For C120, C150, C240, F125, and F165 applicators: Remove gel trap on the back side. Disconnect the applicator from the umbilical, then attach the cap.

Note: Be sure to put on the cap on the applicator handpiece before cleaning the applicator.

c. Use a cotton towel to remove any residual gel from the slot in the applicator cup.

d. Clean the applicator cup, the rim of the cup, the applicator housings, and the applicator cable with gauze soaked in isopropyl alcohol or with a wipe such as CaviWipes1™ or PDI Sani Cloth Plus wipes, according to the manufacturer’s instructions.

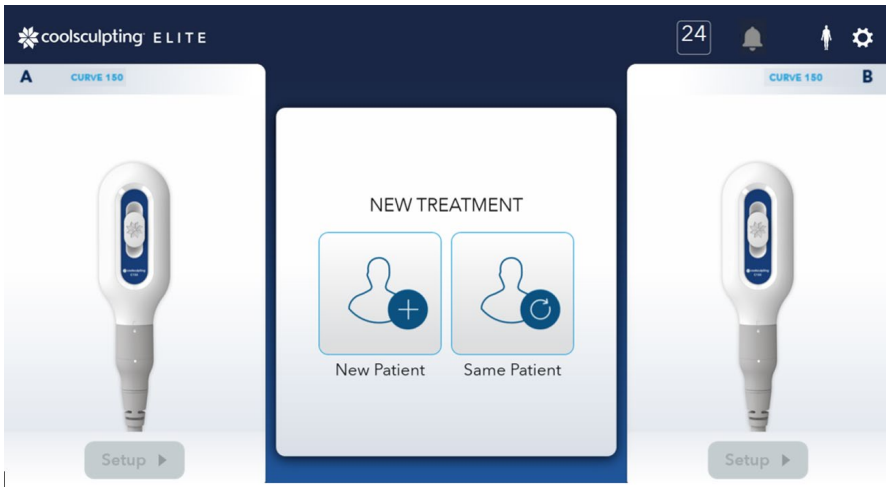
e. Inspect the applicator. Repeat the cleaning steps as needed to eliminate any residual gel.

f. Discard the used gelpad and gel trap according to your site’s medical waste protocols. For S150 applicators, discard the liner and foam borders according to your site’s medical waste protocols.

After a Treatment

When you turn off the vacuum after a treatment (there is no vacuum feature for the S150 applicator), the screen prompt changes to “Massage” or “New Treatment”, the two buttons become active: New Patient and Same Patient.

Note: The New Patient prompt is available when Applicator B is not running. Only one patient can be treated with either one or both applicators.



Example: *Start another treatment*

► **To perform another treatment on the same patient:**

a. At the touchscreen, tap **Same Patient**.

   The Select Treatment Area screen displays.

b. Go to “Setup the system” and repeat the procedure from that point.

► **To perform a treatment on a different patient:**

a. At the touchscreen, tap **New Patient**. The Patient Properties page displays.

b. Go to “Setup the system” step 1 and repeat the procedure from that point.

If you have finished performing treatments and want to power down the system, use the soft power off button. If moving the system, follow the instructions provided under “Power Receptacle and Power Switch”.

If you want to move the unit to a different location, follow the instructions provided under “Casters and Locks”.

Canceling a Treatment

You can cancel a treatment that is already in progress.

► **To cancel a treatment:**

a. During a treatment cycle, tap the **Stop** button.

   A confirmation dialog appears.

b. On the confirmation dialog, tap **Stop.**

   The confirmation dialog closes, and the system stops cooling. The treatment clock stops at its current time and displays “CANCELED.” The prompt displays the message “Operator canceled treatment.”

c. Tap **Next**.

d. Tap the **OFF** button on the touchscreen to toggle the vacuum from ON to OFF (the S150 applicator does not have the vacuum feature). The screen prompt changes to “Massage” or “New Treatment.”

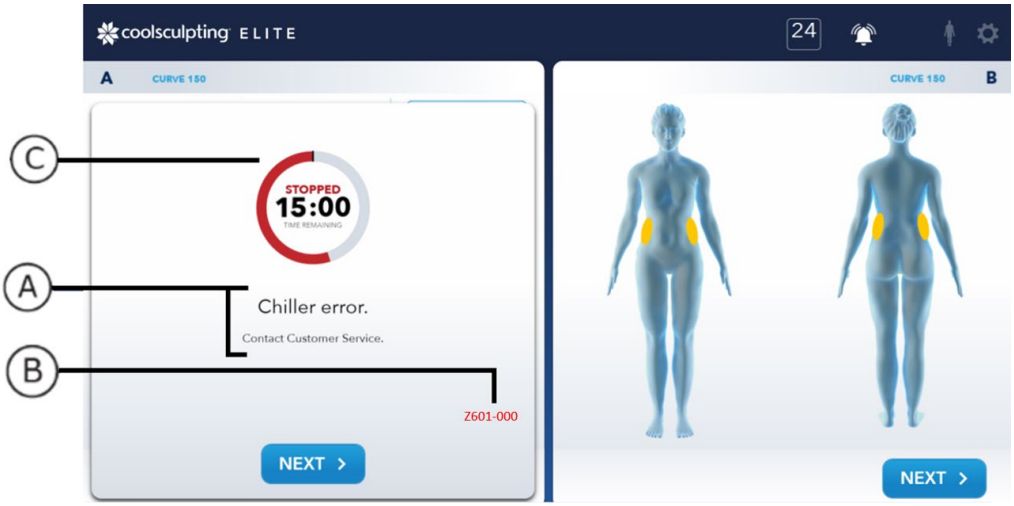
   If there are no active treatments running, two buttons become active: New Patient and Same Patient. Only one patient can be treated with either one or both applicators.

e. Go to task 9 of the treatment procedure (“End the treatment”) and follow the instructions from there until the end of the treatment procedure.

Treatment Stopped by System

If the system detects a condition that requires operator intervention, the system stops the treatment.

The treatment clock stops at its current time and displays “STOPPED.” An error message identifies the problem and provides guidance, including an error code.



***Example: S**creen when treatment is stopped by the system for Dual treatment*

A: Error text
B: Error code
C: STOPPED notice

► **To respond to a stopped treatment:**

a. Follow any instructions displayed on the screen.

   Look up the error code in Chapter 4 System Messages and follow any recommended actions for the error.

b. Tap **Next**. The prompt displays the instruction: “Turn the vacuum OFF. Remove the applicator from the patient.” The S150 applicator does not have the vacuum feature.

c. Go to task 9 of the treatment procedure (“End the treatment”) and follow the instructions from there until the end of the treatment procedure.

CHAPTER 3

System Tools

System tools include performance logs, diagnostics, and system settings.

Controls for System Tools

The Tools button provides access to system tools. The Tools button is available in the upper right corner of the screen. Table 9 lists controls related to system tools.

► **To access system tools:**

1. From any treatment session screen, tap the **Tools** button.

   The Tools menu appears. From there, you can select Logs, Service, Settings, or About.

► **To exit system tools:**

1. When any Tools screen is active, tap the **Close** button.

   The Tools session closes and the system returns you to the treatment session.

Table 9: Controls for System Tools

Button	Name	Description
	Tools	Enters and exits the Tools session: • When a treatment session is active: Displays the Tools menu. • When any Tools screen is active: Exits the Tools session and returns you to the treatment session.
	Logs	Displays the Logs menu. From there, you can access the System Log and Card Log screens. The Systems Log allows uploading the log files.
	Service	Displays vacuum pressure and chiller temperature of the applicators, and modem test.
	Settings	Displays the Settings screen. From there, you can access the system's Notifications, Date, Time, Language, and Icon Control screens.
	About	Displays version information of the system.

System and Card Log Screens

The System Log and Card screens display information about system and card events (Table 10). Also the log screens lets you to upload system log files.

***Example**: System and Card Log buttons*

Table 10: System and Card Log Data

Item	Description
Year	The year that the event occurred in “yyyy” format (for example, 2018)
Date	The month and day that the event occurred in “mmm dd” format (for example, Jun 22)
Time	The time that the event occurred in HH:MM format, where HH = hours and MM = minutes (for example, 12:02 PM)
Code	The ZELTIQ error code and the Customer Service code in format *Z###-###*
Text	The text of the control unit message

► **To View the System or Card Log files and uploading System Logs:**

1. From the Tools menu, tap the **Logs** button. The Logs menu appears under the Tools menu.
2. From the Logs menu, tap the **System or Card** button. The Log screen appears.

   Note: The System and Card Log data is presented in table form. Within the table, you can click a column header to sort the data by that parameter. If the table contains more rows than can fit on one screen, a scroll bar allows you to view additional data rows.
3. If you would like to upload the System log files, within the System Log screen, tap on the **Upload log** tab and tap **Send**.

   The screen will display a progress wheel that shows status of the upload.

   Note: Two other ways to upload logs is to tap the **Last 24 Hours** button or tap the **Date** button and select a date. The Date button allows you to select the begin and end dates.
4. When you are finished with the Log, and the upload is completed, you can return to the Tools menu or exit the Tools session:
   - Tap the **Back** button to return to the Tools menu.
   - Tap the **Close** button to exit the Tools session and return to the treatment session.

Service Screens

The Service screens allow diagnostics of the vacuum system and the chiller system. Also the service screen allows access to the modem.

***Example**: Service buttons*

Vacuum

► **To view the Vacuum screen:**

Call Customer Service (page 5) for both chiller and vacuum issues due to available standards for testing. Do not adjust the chiller and vacuum without guidance from Customer Service.

1. From the Service menu, tap the **Vacuum** button. The Vacuum screen appears.
2. From the Tools menu, tap the **Service** button. The Service menu appears under the Tools menu.
3 When you are finished adjusting the vacuum, you can return to the Tools menu or exit the Tools session:
   a. Tap the **Back** button to return to the Tools menu.
   b. Tap the **Close** button to exit the Tools session and return to the treatment session.

Chiller

► **To view the Chiller screen:**

Call Customer Service (page 5) for both chiller and vacuum issues due to available standards for testing. Do not adjust the chiller and vacuum without guidance from Customer Service.

1. From the Tools menu, tap the **Service** button. The Service menu appears under the Tools menu.
2. From the Service menu, tap the **Chiller** button. The Chiller screen appears.

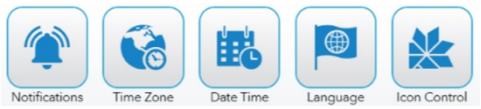
   Note: Either Applicator A or/and B must be attached to the system before accessing target temperatures. If testing both Applicators A and B, both applicators must be attached to the system.
3. When you are finished viewing the target temperature, you can return to the Tools menu or exit the Tools session:
   a. Tap the **Back** button to return to the Tools menu.
   b. Tap the **Close** button to exit the Tools session and return to the treatment session.

Modem

► **To view the Modem screen:**

1. From the Tools menu, tap the **Service** button. The Service menu appears under the Tools menu.
2. From the Service menu, tap the **Modem** button. The Modem screen appears.
3. If desired to test the modem, tap **Test**. Wait for modem initialization to complete. Information about the modem is displayed.
   a. Tap the **Back** button to return to the Tools menu.
   b. Tap the **Close** button to exit the Tools session and return to the treatment session.

Settings Menu



The Settings menu allows you to set the system's notifications, date, time, language, and icon control.

Notifications

The Notification screen allows the system to send text messages to the recipient notifying treatment status such as treatment nearing completion, treatment completed, or when a system error has occurred.

► **To set up:**

1. From the Tools menu, tap the **Settings** button. The Settings menu appears under the Tools menu.
2. From the Settings menu, tap the **Notifications** button. The System Notification screen appears.
3. For changing the System Name, type in new name and tap **Edit**.
4. Set up notification recipients in the Recipients field:
   a. To add a new recipient, tap **Add New** and type in name of recipient along with country code and phone number.
   b. To edit or delete recipient, click on the recipient name and tap **Edit** or **Delete**.
   c. To allow notification for the recipient, check the box to the right of the recipient names. This is the Notify checkbox for the recipient. Tap **Save** to save your changes.

   Note: Ensure that the checkmark is visible within the check box for active recipient. If the checkbox is not set, the recipient will not receive notification.

   Note: When turning notification off, uncheck the boxes next to the recipient names, then tap **Save** to save your changes.

   d. The pop-up closes. Tape Save again.
   e. Tap back to Exit.

   Note: The system can have multiple active notification recipients.

5. Return to the Tools menu or exit the Tools session:
   a. Tap the **Back** button to return to the Tools menu.
   b. Tap the **Close** button to exit the Tools session and return to the treatment session.

Time Zone

The Time Zone selects the system's time zone.

► **To set the time zone:**

1. From the Tools menu, tap the **Settings** button. The Settings menu appears under the Tools menu.
2. From the Settings menu, tap the **Time Zone** button. The Time Zone screen appears.
3. Tap the desired Regions in the Regions field.
4. Tap the desired zones in the Zones field.
5. Return to the Tools menu or exit the Tools session:
   a. Tap the **Back** button to return to the Tools menu.
   b. Tap the **Close** button to exit the Tools session and return to the treatment session.

Date and Time

The Date and Time screen allows you to set the system's date and time.

► **To set the date and time:**

1. From the Tools menu, tap the **Settings** button. The Settings menu appears under the Tools menu.
2. From the Settings menu, tap the **Date Time** button. The Date and Time screen appears.
3. Tap the desired date on the calendar.

   Note: The current date is highlighted. The left and right arrows change the displayed month.

4. Set the desired time in the Time field:
   a. To adjust minutes, tap the Up and Down arrows closest to the displayed time.
   b. To adjust the hour, tap the Down arrow in the highlighted box; then select the hour from the displayed menu.
5. Tap **Save** to save your changes.
6. Return to the Tools menu or exit the Tools session:
   a. Tap the **Back** button to return to the Tools menu.
   b. Tap the **Close** button to exit the Tools session and return to the treatment session.

Language

The Language screen allows you to set the system's language.

► **To set the language:**

1. From the Tools menu, tap the **Settings** button. The Settings menu appears under the Tools menu.
2. From the Settings menu, tap the **Language** button. The Language screen appears.
   a. Tap the desired language.
   b. Tap **Save** to save your changes.
3. Return to the Tools menu or exit the Tools session:
   a. Tap the **Back** button to return to the Tools menu.
   b. Tap the **Close** button to exit the Tools session and return to the treatment session.

Icon Control

The Icon Control screen allows you to turn the snowflake logo on or off.

► **To turn the snowflake logo on or off:**

1. From the Tools menu, tap the **Settings** button. The Settings menu appears under the Tools menu.
2. From the Settings menu, tap the **Icon Control** button. The Icon Control screen appears.
3. Tap the desired ON or OFF.

   Note: The On is selected as default.
4. Return to the Tools menu or exit the Tools session:
   a. Tap the **Back** button to return to the Tools menu.
   b. Tap the **Close** button to exit the Tools session and return to the treatment session.

About

The About screen allows you to view different components of the system and corresponding versions.

► **To view About the System screen:**

1. From the Tools menu, tap the **About** button. The About screen appears.
2. To exit the Tools session, tap the **Close** button to exit the Tools session and return to the treatment session.

CHAPTER 4

System Messages

If the system encounters a problem, it displays a message to help you diagnose and resolve the issue. The system provides four types of messages:

- **Recoverable exceptions:** See Table 11.
- **Error messages affecting only Applicator A or B:** See Table 12.
- **Error messages for the System:** See Table 13
- **Software launch messages**: See Table 14.
- **System Notification Text**: See Table 15

The system messages include a ZELTIQ code and a Customer Service code. These codes are written together using the format Z###-YYY, where:

- Z### is the ZELTIQ code (Z followed by a three-digit number)
- YYY is a three-digit Customer Service code that follows the ZELTIQ code

When a recoverable exception or an error message occurs, carry out the recommended action, if any. If the problem persists, record both codes and contact Customer Service (see page 5). The codes help Customer Service identify and resolve the issue.

For assistance with any message not listed here, contact Customer Service (see page 5).

Table 11: Recoverable Exceptions

ZELTIQ Code	Message text	Action
Z401	Applicator error. Z401-YYY Disconnect and reconnect the applicator.	Disconnect and reconnect the applicator.
Z402	The card expired. Z402-YYY Connect a new card.	Remove the card from the applicator and insert a new card.
Z404	The card and applicator are incompatible. Z404-YYY	Remove the card from the applicator. Insert a card that is appropriate for the applicator type.
Z405	Applicator software error. Z405-YYY Replace the applicator.	Use another applicator.
Z406	Card error. Z406-YYY Disconnect and reconnect the card.	Remove and reinsert the card.

ZELTIQ Code	Message text	Action
Z409	⚠ Thermal event detected. Z409-YYY Remove the applicator and gelpad. Refer to the User Manual.	Remove the applicator and gelpad. Do not retreat for at least 24 hours.
Z412	Treatment quality error. Z412-YYY Start a treatment. If the problem persists, contact Customer Service.	Restart the treatment or start a new treatment.
Z415	Potential loss of patient contact. Z415-YYY Reapply the applicator and start a treatment. If the problem persists, contact Customer Service.	Turn off the vacuum, remove the applicator cup from the patient, discard the used gelpad, and clean the treatment site. Then apply a new gelpad and reposition the applicator. Ensure that the applicator is secure. Restart an interrupted treatment or start a new treatment.
Z417	Card compatibility error. Z417-YYY Replace the card.	Insert a card that is compatible with the control unit.
Z426	Interference detected. Z426-YYY Start a treatment. If the problem persists, refer to the User Manual.	Identify and resolve possible causes: • Patient movement • Another medical device in close proximity If the problem persists, contact Customer Service.
Z430	Applicator compatibility error. Z430-YYY. Contact Customer Service.	Disconnect the current applicator and connect a compatible applicator.

Table 12: Error Messages: Affecting only Applicator A or B

ZELTIQ Code	Message text	Action
Z601	Chiller error. Z601-YYY This side is unavailable until the system has been powered off and on.	For all error messages: • If a system error occurs, treatment automatically stops. Contact Customer Service. • Power the control unit off and on. If the problem persists, contact Customer Service.
Z603	Control unit error. Z603-YYY This side is unavailable until the system has been powered off and on.	

Table 13: Error Messages: System

ZELTIQ Code	Message text	Action
Z801	Chiller error. Z801-YYY	For all error messages: • If a system error occurs, treatment automatically stops. Contact Customer Service. • Power the control unit off and on. • If the problem persists, contact Customer Service.
Z803	Control unit error. Z803-YYY	

Table 14: Software Launch Messages

ZELTIQ Code	Message text	Action
Z920	Z920-YYY Control Unit Error	Power the control unit off and on. If the problem persists, contact Customer Service.
Z980	Z980-YYY Software Installation Error	Power the control unit off and on and retry the software installation. If the problem persists, contact Customer Service.

Table 15: System Notification Text

The notification text is transmitted to the pager when the pager event occurs.

Notification Text	Notification Event
R01: System {side A or B (optional)} error detected.	System error
R02: Treatment {side A or B} complete.	Treatment completed successfully
R03: Treatment {side A or B} canceled.	Treatment canceled
R04: Error detected. Treatment {side A or B} stopped.	Treatment ended with an error
R05: Treatment {side A or B} ends in {0} minute(s).	Treatment almost complete
R06: Patient called.	Patient call

CHAPTER 5

Cleaning and Maintenance

Perform routine cleaning and maintenance according to your site's protocols.

Cleaning

The use of an unapproved cleaning solution or method on the control unit or applicator may result in damage. Always use approved products and follow the guidelines below.

Approved Products

The following products are approved for cleaning the control unit and applicators:

- Isopropyl alcohol
- Mild detergent and warm water
- PDI Sani Cloth Plus wipes or CaviWipes1™

Cleaning Guidelines

- Unplug the control unit before cleaning.
- Use cleaning wipes or spray the cleaning agent on a soft wipe, paper towel, or equivalent material.
- After cleaning the system components, dry them with a soft cloth to remove any cleaning residues.

Do not spill any fluid directly on any part of the control unit, or applicators.

Do not submerge the applicator or any other part of the system in any liquid.

Do not use excessive amounts of fluid.

Do not apply cleaning solution to the electrical connections.

Do not sterilize the control unit, applicator, or any other system components.

Cleaning the Touchscreen

For best performance, clean the touchscreen regularly.

Approved cleaning products include:

- Isopropyl alcohol
- Window cleaning fluid

► **To clean the touch screen:**

1. Dampen a soft lint-free cloth with isopropyl alcohol or window cleaning fluid.
2. Wipe the touch screen gently.

Cleaning the Bucket

Approved cleaning products include:

- Damp towel or water-based wipe
- Isopropyl alcohol
- Mild detergent and warm water
- PDI Sani Cloth Plus wipes

► **To clean the bucket:**

1. Dampen a towel with a cleaning solution or use a water-based or cleaning solution wipe, wipe away residual gel.
2. Or, pull out bucket to rinse with water. Dry the bucket with a cloth and return to its slot.

Maintenance

Filter Replacement

The purpose of this filter is to extend the service life of your control unit. It is recommended to replace the filter every 6 months.

To replace to the filter:

1. Access the filter door from the front of the console, located below the base.
2. Push the filter door to release the “push-push” latch.
3. Rotate the door down to access the filter attached.
4. Pull filter free from door.
5. Install new filter so that the plastic hooks on the door hold it in place.

Note: Ensure the filter is placed into the door with the flat side of the filter down, otherwise, the filter will not be secured into the door properly.

6. Push door back into place to latch.

Steps 1 and 2

Step 3

Steps 4, 5, and 6

APPENDIX A

ZELTIQ Clinical Studies

Note: When the flank, abdomen, and thigh studies were performed, the degree of cooling or heating during a treatment was expressed as the Cooling Intensity Factor (CIF). The CIF was an index that represented the rate of heat flux into or out of tissue relative to 37°C. A positive CIF described the rate of heat flux out of tissue. A negative CIF referred to the rate of heat flux into tissue. The studies in this section used the CIF as a unit of measure. Current treatment parameters refer to the temperature at the surface of the applicator.

The ZELTIQ CoolSculpting System has undergone pre-clinical and clinical investigation (data on file at ZELTIQ). The clinical investigation and results pertaining to skin cooling for fat layer reduction in submental and submandibular areas, abdomen, flanks, thighs, and alternate treatment parameters are summarized in this section.

Table 16 summarizes the efficacy information for each study that has been conducted. Further details on each study can be found in the individual summaries below.

Table 16: Summary of Study Efficacy

Treatment Site	Photographic Review Results (% correct)	Ultrasound Results (mean reduction in mm)	Subject Satisfaction (% satisfied)
Flanks	88.6	N/A	82.1
Abdomen	85.3	1.9	62
Inner thigh	90.5	2.8	93.3
Outer thigh	83.9	2.5	86.5
Modified treatment parameters	85	3.92	88.37
Submental Area	91.4	2.0	83.3
Upper Arm	85.2 [72.9%, 93.4%]	3.2	63.3

Flank Study

Assessment Time Line

A clinical study that enrolled 60 healthy adult subjects, aged 23 to 65 years at two clinical centers was conducted from August 2007 through June 2008. Each individual received one or more applications of the ZELTIQ CoolSculpting System with a ZELTIQ vacuum applicator. Assessments of treatment efficacy and safety were performed as follows:

Table 17: Treatment Efficacy and Safety Assessments

Assessment	Prior to Day 0	Day 0 Treatment	1 week	2 months	6 months
Consent screening	🗐				
Baseline demographics		🗐			
Phone follow-up			🗐		
Photographs		🗐		🗐	🗐
Ultrasound		🗐		🗐	🗐
Clinical assessment		🗐	🗐	🗐	🗐

Four groups were treated with the treatment regimens shown in Table 18. A short period (two to five minutes) of simultaneous tissue cooling and massage was used during each treatment to facilitate lipolysis. For each subject, the larger of the two flank bulges was treated, leaving the contralateral side as an untreated control.

Table 18: Treatment Regimens

Treatment Group	Number of Subjects	Cooling Intensity Factor (CIF)	Temperature	Cooling Duration (minutes)	Energy Extraction Rate (mW/cm²)
Group 1	28	33	-4ºC	60 min	63.6
Group 2	11	37	-7ºC	30 min	68.3
Group 3	11	37	-7ºC	45 min	68.3
Group 4	10	42	-10°C	30 min	72.9

Clinical Efficacy Results: Blinded Photographic Evaluation

Efficacy was determined by photographic evaluation, ultrasound fat-thickness measurements, clinical assessments, and subject satisfaction. A blinded photographic evaluation was performed of 50 evaluable subjects in which three blinded reviewers were provided two series of photographs for each subject, one series taken at baseline, and the other taken post-treatment. Each reviewer was asked to identify the baseline photo series independently. In the blinded photographic review of all subjects the reviewers correctly identified the baseline photo series 88.6% of the time.

Table 19: Independent Photo Review Results

Treatment Group	Number of Subjects	All Data % Correct ± % SE	All Data p-values
All Groups	50	88.6 ± 4.1	< 0.001*
Group 1	20	90.7 ± 5.1	< 0.001*
Group 2	10	90.0 ± 9.5	< 0.005*
Group 3	11	90.9 ± 8.7	< 0.001*
Group 4	9	66.7 ± 15.7	< 0.4

Post-treatment ultrasound measurements of fat layer thickness were compared with baseline measurements, using the untreated control side to normalize for weight changes that may have occurred during the follow-up period. The fat layer reduction as measured with ultrasound averaged 18.7% from baseline, after being normalized by the untreated control side. Ultrasound measurements at two months and at six months indicate that on average, 75% of the total fat layer reduction for a subject was realized within two months of treatment. Overall, 82.1% of subjects enrolled in the study indicated they were satisfied with the treatment.

Clinical Safety Results

Reported side effects included pain during or post-treatment, minor or significant bruising of the treated area, temporary hypoesthesia, tingling, erythema, and edema. All side effects during this study resolved spontaneously, most resolved within hours or days of the treatment.

Resolution of Hypoesthesia

Partial numbness and, to a lesser extent tingling, over the skin of the application site were reported for all subjects immediately post-treatment and for 68% of subjects by one week post-treatment. Partial numbness or tingling is a temporary and anticipated effect of the treatment and was found to resolve without intervention within two to three weeks on average, although in 8.3% of the cases these effects endured for as long as two months.

Adverse Events

There were four relatively minor adverse events; each was anticipated and resolved without intervention. During treatment, two adverse events were reported involving pain and/or discomfort. Each of these resolved after treatment was discontinued. Following treatment, two adverse events were reported: severe bruising and minor cramping or muscle spasm in the treatment area. Both resolved without intervention within four weeks. None of the adverse events reported during this study was considered serious or unanticipated.

During the clinical investigation, serum lipids and liver enzymes were measured in a subset of 20 subjects at times from 1 week to 12 weeks post-treatment to determine whether the CoolSculpting treatment had an effect on clinical chemistry. The following analytes were measured: Cholesterol,

Triglycerides, HDL Cholesterol, LDL Cholesterol, VLDL Cholesterol, Cholesterol/HDL Ratio, Total Protein, Albumin, AST-SGOT, ALT-SGPT, Total Bilirubin, and Direct Bilirubin. No statistically significant changes were found for serum lipids or liver enzyme data from baseline over the duration of the study.

BMI Recommendations

For best results, patients should have a BMI of 30 or less and should maintain a healthy lifestyle following a treatment. The study evaluations for this clinical investigation included subjects with a Body Mass Index up to 38.7; however, patients who are significantly overweight are less likely to appreciate a significant improvement with a single treatment.

Skin Type

The clinical investigation subject population included Fitzpatrick skin types ranging from I to VI, with the majority of subjects being types II to IV. No change in skin pigmentation was observed following a treatment.

Based on the clinical data, ZELTIQ recommends that practitioners read this Preface carefully and pay special attention to warnings and cautions throughout the User Manual and Instructions for Use.

Abdominal Study

A separate clinical investigation with the CoolSculpting device on the fat layer of the abdomen resulted in a clinically measurable reduction of local subcutaneous fat of the abdomen, in the same manner that was previously demonstrated for the flank. Treatments were performed at -10°C (CIF 42) for 60 minutes. The primary endpoint results (Independent Photo Review) revealed that the percent correct identification of the pre-treatment images exceeded the pre-established 80% criterion and is statistically significant. Fat layer reduction in the treated area of the abdomen was further documented by ultrasound imaging which also revealed a statistically significant and clinically relevant reduction. Overall, 62% of subjects enrolled in the study indicated they were satisfied with the treatment.

Study data also revealed that the treatment is as safe when used in the abdomen as previously tested for the flank. Data collected during the study demonstrated that the post-treatment lipid profile and liver function tests showed no statistically significant difference from baseline. This was true for mean values for the entire population as well as for each individual subject. No serious adverse events were reported during the abdomen study. The results of this clinical study provide supportive evidence that treatment with the CoolSculpting device provides consistent and clinically significant reduction of the fat layer of the abdomen.

Summary of Thigh Studies

ZELTIQ conducted two clinical investigations to determine the safety and efficacy of cold-assisted lipolysis in the thigh region. In the inner thigh study, 90 treatments were completed with the flat cup vacuum applicator at -10°C (CIF 42); in the outer thigh study, 40 treatments were completed with the belt applicator at -10°C (CIF 23). Follow-up data is available for both studies up to 16 weeks post-

treatment. Three blinded evaluators assessed the photos for visible reduction of fat in the treatment areas at the 16-week follow-up visit. The evaluators were presented with the series of photographs and were asked to identify the pre-treatment photographs for each subject.

The overall correct identification rate by the three evaluators was 90.5% for the inner thigh study and 83.9% for the outer thigh study. At least two out of three evaluators correctly identified 90.5% of all photo pairs for the inner thigh study and 87.1% for the outer thigh study. The results demonstrate that the ZELTIQ CoolSculpting System affects the appearance of the thighs.

Change in subcutaneous fat layer thickness was also measured by ultrasound at 16 weeks: In the inner thigh study average fat thickness change was a 2.8 mm decrease. In the outer thigh study average fat thickness change was a 2.5 mm decrease. Overall for the inner thigh study, 93.3% of subjects enrolled in the study indicated they were satisfied with the treatment. Overall for the outer thigh study, 86.5% of subjects enrolled in the study indicated they were satisfied with the treatment.

Adverse events reported during the studies included numbness and mild contour irregularity. All adverse events but one resolved by the 16-week follow-up. A mild case of hyperpigmentation in the treatment area persisted beyond the 16-week follow-up. This is an adverse event that typically resolves spontaneously. The clinical investigations demonstrate that use of the ZELTIQ CoolSculpting System can safely and effectively induce cold-assisted lipolysis in the thigh in the same manner as in the abdomen and flanks.

Summary of Study with Modified Treatment Parameters

A study of a modified treatment parameter was designed to evaluate the safety and efficacy of the CoolSculpting System with a colder, shorter treatment. In this study, 63 treatments were completed with the CoolCurve+ applicator on 45 subjects. Each subject received one or two non-overlapping unilateral vacuum treatments of the flank at a treatment temperature of -15°C for 45 minutes; immediately after each treatment, the treated tissue was massaged manually for two minutes. Follow-up data is available for up to 16 weeks post-treatment.

Subject safety was assessed throughout the study, including immediately post-treatment, one-week post-treatment telephone follow-up, and at 8- and 16-week post-treatment clinic visits. The primary safety endpoint was the occurrence of device- or procedure-related adverse events. No serious adverse events were reported during the study or 16-week follow-up period. Adverse events reported during the study included mild numbness, post-treatment pain, hyperpigmentation, subcutaneous induration, and first-degree burn in the treatment area. All but three adverse events resolved by the 16-week follow-up. Three subjects reported mild numbness at the 16-week follow-up; all three reported resolution within the next 19 calendar days.

The primary efficacy endpoint was the change in fat layer thickness as measured with ultrasound. Fat layer reduction in the treated area of the flank was documented by ultrasound imaging pre-treatment and at 8 and 16 weeks post-treatment. Subsequent evaluation of the ultrasound images revealed a statistically significant and clinically relevant reduction.

Secondary efficacy endpoints included correct identification of pre- and post-treatment images by three blinded independent reviewers, and subject satisfaction assessment by subject questionnaire. Photos

taken at baseline and at the 16-week follow-up visits were reviewed by a blinded independent panel of three physicians board-certified in dermatology or plastic surgery. The overall correct identification rate by the three evaluators was 85%, which exceeded the pre-established 80% criterion and is statistically significant.

The secondary efficacy endpoint for subject satisfaction was performed by means of a questionnaire with questions about the comfort and subjective results of the treatment, and about the subject's attitudes toward CoolSculpting after treatment. With the exception of comfort, the majority of responses were positive to very positive. Overall, 88.37% of subjects enrolled in the study indicated they were satisfied with the treatment.

These clinical findings demonstrate that use of the CoolSculpting System can safely and effectively induce cold-assisted lipolysis with colder temperatures down to -15°C for shorter duration treatments with vacuum and surface applicators.

Submental Area Study

ZELTIQ conducted a clinical investigation to determine the safety and efficacy of the CoolSculpting System for affecting the appearance of visibly localized subcutaneous fat localized in the submental area.

In this study, 60 subjects were enrolled at three clinical sites. Sixty initial treatments were performed with the prototype CoolMini vacuum applicator; 59 subjects were re-treated at the 6-week follow-up visit. Treatments were performed at -10°C for 60 minutes. Follow-up data is available through 12 weeks post-treatment. Subject safety was assessed throughout the study.

The primary safety endpoint was the measurement of all device- or procedure-related adverse events. All adverse events reported during and after the treatment were included in the safety analysis. The primary safety endpoint was met. No device- or procedure-related serious adverse events (SAE) and no unanticipated adverse device effects (UADE) occurred during the study. Four device- or procedure-related adverse events were reported and have resolved. Clinical safety assessment showed anticipated side-effects, all of which resolved over the course of the study. The safety data recorded during this study supports the safety of the treatment parameters and device investigated.

The primary efficacy endpoint was correct identification of pre-treatment vs. 12-week post-final treatment images by 3 blinded independent reviewers. The overall correct identification rate by the 3 reviewers was 91% for the per-protocol population (n=58), which met the pre-established 80% criterion for success. The primary efficacy endpoint was met.

Reduction in subcutaneous fat layer thickness as measured by ultrasound at 12-weeks post-final treatment was a secondary efficacy endpoint for this study. Analysis of the per-protocol data (57 subjects) showed a statistically significant ($p<0.0001$) reduction of 0.20 cm. Therefore, the secondary efficacy endpoint for reduction of fat layer thickness was met.

The secondary efficacy endpoint for subject satisfaction was assessed by a questionnaire administered at 12 weeks post-final treatment. Overall, 83.3% of subjects enrolled in the study indicated they were satisfied with the treatment and 80% reported that they would recommend the treatment to a friend.

These clinical findings demonstrate that use of the CoolSculpting System can safely and effectively affect the appearance of visible fat bulges in the submental area with treatment at -10°C for 60 minutes.

Summary of Upper Arm Study

ZELTIQ conducted a clinical investigation to evaluate the safety and efficacy of cryolipolysis for non-invasive reduction of upper-arm fat.

In this study, 30 subjects were enrolled at two clinical sites. Sixty initial treatments were performed with a prototype of the CoolAdvantage applicator (CoolFit with aluminum Insert). Each subject was treated once on each upper arm, at -11°C for 35 minutes. Follow-up data is available through 12 weeks post-treatment. Subject safety was assessed throughout the study.

The primary safety endpoint was the incidence of unanticipated adverse device effects. Clinical safety assessment showed anticipated side-effects. There were 4 patients with prolonged numbness lasting greater than 12 weeks. No unanticipated adverse device effects, or serious device- or procedure-related adverse effects occurred. All device- and/or procedure-related adverse events resolved spontaneously. The primary safety endpoint was met.

The primary efficacy endpoint involved independent panel review of pre- and 12-week post-treatment photographs of the treatment area for discernible fat layer reduction. The per protocol population consisted of all the treated subjects followed for 12 weeks with weight change of no more than 5% of total body weight at the time the 12-week images were taken. For the per protocol population, the correct baseline photograph identification rate by the independent panel reviewers was 85.2% [72.9%, 93.4%].

Further evidence of treatment efficacy is found in the data from ultrasound measurements of fat reduction at the treated areas, with significant reduction in the fat layer (0.32 cm) from baseline to 12 weeks post-treatment.

The secondary efficacy endpoint for subject satisfaction was assessed by an IRB-approved questionnaire administered at 12 weeks post-treatment. 72.41% of the subjects found the procedure to be comfortable to very comfortable, and 63.3% of the subjects reported that they would recommend the procedure to a friend.

These clinical findings demonstrate that use of the CoolSculpting System can safely and effectively affect the appearance of visible fat bulges in the upper arm area with treatment at -11°C for 35 minutes.

Summary of Submental Area Study

A prior study (ZA14-002), approved by the Food and Drug Administration (FDA) under IDE G140083, reported the efficacy of cryolipolysis for non-invasive reduction of submental fat. Subsequently, a retrospective study was carried out in which standardized, masked, photographic images from the original ZELTIQ-sponsored clinical study were evaluated quantitatively to determine the efficacy of the CoolSculpting treatment in affecting the appearance of lax tissue in the submental area.

This retrospective study started with the ZA14-002 per-protocol population (n=58) for analysis, excluded one subject due to excessive hair in the submental region, and used the remaining fifty-seven (57) subjects for analysis. Lateral photographic views of the face taken at baseline and at the 12-week post-final treatment visit were included in the analysis. Each photograph was cropped and masked prior to evaluation. A board-certified plastic surgeon identified the following anatomical points on each photograph: the lateral canthus, the anterior-most point where the nostril meets the columella, and the point where the chin meets the neck (submental crease). AutoCAD software was used to apply lines to each photograph, and areas in the submental region were measured. A responder analysis was performed with the criteria being ≥ 20 mm^2 decrease in area as measured on both the right lateral and left lateral views of the region.

A second analysis was performed in which reviewers compared the results from the responder analysis against results from the independent physician review panel of photos, which had been conducted in the previous study. This second analysis indicated that 77.2% (44/57) of subjects exhibited a ≥ 20 mm^2 area reduction in the submental and neck tissue. Of those 44 subjects, 42 (95.5%) were correctly identified by the physician panel as having a visible response.

Summary of Clinical Study Publications

A review of clinical publications revealed 4,792 cryolipolysis treatments during clinical studies. From these studies, we compiled the numbers of treatments in several anatomical areas: 1,695 treatments in the abdomen, 1,987 treatments in the flanks, 501 treatments in the back, 323 treatments in the inner thigh, 150 treatments in the lateral thigh, 3 treatments in the anterior thigh, 119 treatments in the submental area, and 14 treatments in the banana roll region.

Efficacy was measured by several techniques including ultrasound and caliper measurements, circumferential measurements, 3D quantification of volume reduction, and blinded, independent review of clinical photographs. Based on the compilation of data from these studies, the overall mean ultrasound fat layer reduction ranged from 10.3 to 25.5% and 1.9 to 8.3 mm.

Compiled mean caliper fat layer reduction ranged from 14.7 to 23.0%. Single studies showed mean 0.9 cm circumferential reduction in the inner thigh, 2.4 cm circumferential reduction in the flanks, 6.8 cm circumferential reduction in the abdomen, and 39.6 cm^3 volumetric reduction in the flanks.

Based on the compilation of these various studies, the overall mean ultrasound fat layer thickness reduction was 20.6% and 3.9 mm. Compiled mean caliper fat layer reduction was 22.3%. The independent photo review was 89.7% correct, on average.

As shown by multiple clinical studies submitted for clearance to the agency, the summary of published data shows a similarly high safety and efficacy profile for the cryolipolysis procedure. Common procedural side effects include erythema, bruising, and numbness, which typically resolve within one month of treatment. Based on the literature review, 6 cases would be considered serious adverse events. These serious adverse events include three cases of paradoxical hyperplasia in the abdomen, one case of paradoxical hyperplasia in the abdomen, back, and flanks, one case of contour irregularity in the abdomen, and one case of contour irregularity in the flank. For 4,792 treatments in published studies, the incidence of serious adverse events is very low (0.13%). Given the fact that 76.8% of treatments were to the abdomen and flanks, this incidence rate shows no clear indication of treatment

site specificity. The clinical publications indicate that cryolipolysis is a safe and effective non-surgical procedure for subcutaneous fat reduction.

Summary of Clinical Study Publications for the Submental and Submandibular Areas

Six clinical publications reported safety and effectiveness of 228 cryolipolysis treatments in 102 patients to include 89 patients with a Body Mass Index (BMI) of up to 46.2 and 27 patients treated in the submental and submandibular areas.

Literature review of cryolipolysis indicates that clinicians are currently treating below the entire mandible, including both the submental and submandibular areas, in order to achieve best aesthetic outcome. See Table 20, which summarizes the applicator placement methods tabulated from the six publications. Two applicator placement approaches are identified: single cycle placed in the center submental area, as well as two cycles covering the bilateral submandibular area, with a 20 – 30% overlap in the center submental area. demonstrates a typical two-cycle placement method treating submental and submandibular areas.

Reported safety included common procedural side effects such as erythema, bruising, numbness, edema, blanching, tingling, increased sensitivity, itching, pigmentation changes, tenderness, and hoarseness, typically resolving within one month of treatment. It is believed that these side effects are not specifically quantified and reported in all publications because they are expected, self-resolving, and considered minor; thus, reports of erythema, bruising, pain, and transient numbness are likely under-reported. From the publications that reported a total of 228 treatment cycles, the most common side effects at 1-week post-treatment were numbness (105 reports), tingling (24), edema (9), and erythema (3 reports).

Several techniques measured effectiveness, techniques including ultrasound measurement, caliper measurement, Magnetic Resonance Imaging (MRI), three-dimensional (3D) quantification of volume reduction, patient satisfaction, and blinded, independent review of clinical photographs. The mean ultrasound measurement of fat layer reduction was 2.4 mm with a range from 2.0 to 2.8 mm. The mean caliper measurement of fat layer reduction was 3.17 mm (around 33%) with a range from 2.3 to 4.0 mm. The single study using MRI imaging showed mean reduction of 1.78 mm or 17% subcutaneous fat layer reduction. The 3D imaging showed a mean calculated reduction of 8.5 mL fat volume, and calculated reduction in submental laxity by 2.25 mm. Three-dimensional volumetric measurement showed a fat reduction of 4.82 cm^3. Blinded, independent photo review was conducted in several studies with correct identification of baseline photographs ranging from 60% to 91%, averaging 77%. Patient satisfaction ranged from 80% to 93%, averaging 85%.

There were no device or procedure-related serious adverse events related to treatment of the submental and submandibular areas in the six publications.

Table 20: Applicator Placement Methods

Reference	Treatment Area	Placement of the Applicator	Treatment Cycles (n)
Bernstein & Bloom, 2017	Submental and submandibular areas	Bilateral treatment cycles with 20% overlap in the center of the submental area.	52
		Single cycle placed in the center submental area.	2
Kilmer, Burns, & Zelickson, 2016	Submental area	Single cycle placed in the center submental area.	119
Leal Silva, Hernandez, Vazquez, Leal Delgado, & Blanco, 2017	Submental area	Single cycle placed in the center submental area.	30
Lee, Ibrahim, Arndt, & Dover, 2018	Submental and submandibular areas	Bilateral treatment cycles with 30% overlap in the center of the submental area. Applicator is placed 1 to 2 cm from inferior aspect of mandible, in sequence.	2
Li, DaSilva, Canfield, & McDaniel, 2018	Submental and submandibular areas	Single cycle placed in the center submental area.	1
		Bilateral treatment cycles with overlap in the center of the submental area.	2
Suh et al., 2018	Submental and submandibular areas	Bilateral treatment cycles with 30% overlap in the center of the submental area.	20

References

Published papers

1. Bernstein EF, Bloom JD. Safety and Efficacy of Bilateral Submental Cryolipolysis With Quantified 3-Dimensional Imaging of Fat Reduction and Skin Tightening. JAMA Facial Plast Surg. 2017; 19(5), 350-357.
2. Leal Silva H, Hernandez EC, Vazquez MG, Leal Delgado S, Blanco AP. Noninvasive submental fat reduction using colder cryolipolysis. J Cosmet Dermatol. 2017; 1-6.
3. Lee NY, Ibrahim O, Arndt KA, Dover JS. Marginal Mandibular Injury After Treatment With Cryolipolysis. Dermatol Surg. 2018; 1-3.
4. Li MK, DaSilva D, Canfield D, McDaniel DH. Use of 3-Dimensional Imaging in Submental Fat Reduction After Cryolipolysis. Dermatol Surg. 2018; 889-892.
5. Suh DH, Park JH, Jung HK, Lee SJ, Kim JH, Ryu JH. Cryolipolysis for submental fat reduction in Asians. Journal of Cosmetic and Laser Therapy. 2018; 24-27.

6. Kilmer SL, Burns AJ, Zelickson BD. Safety and efficacy of cryolipolysis for non-invasive reduction of submental fat. Lasers Surg Med. 2015 Nov 26.

7. Seaman SA, Tannan SC, Cao Y, Peirce SM, Gampper TJ. Paradoxical Adipose Hyperplasia and Cellular Effects after Cryolipolysis: A Case Report. Aesthet Surg J. 2016 Jan; 36(1):NP6-NP13.

8. Keaney TC, Gudas AT, Alster TS. Delayed Onset Pain Associated With Cryolipolysis Treatment: A Retrospective Study With Treatment Recommendations. Dermatol Surg. 2015 Nov; 41(11):1296-9.

9. Stefani WA. Adipose Hypertrophy Following Cryolipolysis. Aesthet Surg J. 2015 Sep; 35(7):NP218-20.

10. Mahmoud ELdesoky MT, Mohamed Abutaleb EE, Mohamed Mousa GS. Ultrasound cavitation versus cryolipolysis for non-invasive body contouring. Australas J Dermatol. 2015 Aug 24.

11. Wanitphakdeedecha R, Sathaworawong A, Manuskiatti W. The efficacy of cryolipolysis treatment on arms and inner thighs. Lasers Med Sci. 2015 Nov; 30(8):2165-9.

12. Garibyan L, Cornelissen L, Sipprell W, Pruessner J, Elmariah S, Luo T, Lerner EA, Jung Y, Evans C, Zurakowski D, Berde CB, Anderson RR. Transient Alterations of Cutaneous Sensory Nerve Function by Noninvasive Cryolipolysis. J Invest Dermatol. 2015 Nov; 135(11):2623-31.

13. Singh SM, Geddes ER, Boutrous SG, Galiano RD, Friedman PM. Paradoxical adipose hyperplasia secondary to cryolipolysis: An underreported entity? Lasers Surg Med. 2015 Aug; 47(6):476-8.

14. Zelickson BD, Burns AJ, Kilmer SL. Cryolipolysis for safe and effective inner thigh fat reduction. Lasers Surg Med. 2015 Feb; 47(2):120-7.

15. Stevens WG, Bachelor EP. Cryolipolysis conformable surface applicator for non-surgical fat reduction in lateral thighs. Aesthet Surg J. 2015 Jan; 35(1):66-71.

16. Carruthers J, Stevens WG, Carruthers A, Humphrey S. Cryolipolysis and skin tightening. Derm Surg. 2014 Dec; 40 Suppl 12:S184-9.

17. Bernstein EF, Bloom JD, Basilavecchio LD, Plugis JM. Non-invasive fat reduction of the flanks using a new cryolipolysis applicator and overlapping, two-cycle treatments. Lasers Surg Med. 2014 Dec; 46(10):731-5.

18. Boey GE, Wasilenchuk JL. Fat Reduction in the Inner Thigh Using a Prototype Cryolipolysis Applicator. Dermatol Surg. 2014; 40(9):1004-9.

19. Stevens WG. Does Cryolipolysis Lead to Skin Tightening? A First Report of Cryodermadstringo. Aesthet Surg J. 2014; 34(6): NP32-NP34.

20. Sasaki GH, Abelev N, Tevez-Ortiz A. Noninvasive Selective Cryolipolysis and Reperfusion Recovery for Localized Natural Fat Reduction and Contouring. Aesthet Surg J. 2014 Mar; 34(3):420-31.

21. Garibyan L, Sipprell WH 3rd, Jalian HR, Sakamoto FH, Avram M, Anderson RR. Three-Dimensional Volumetric Quantification of Fat Loss Following Cryolipolysis. Lasers Surg Med. 2014 Feb; 46(2):75-80.

22. Jalian HR, Avram MM, Garibyan L, Mihm MC, Anderson RR. Paradoxical Adipose Hyperplasia after Cryolipolysis. JAMA Dermatol. 2014 Mar; 150(3):317-9.

23. Boey GE, Wasilenchuk JL. Enhanced Clinical Outcome with Manual Massage Following Cryolipolysis Treatment: A 4-Month Study of Safety and Efficacy. Lasers Surg Med. 2014 Jan; 46(1):20-6.

24. Stevens WG, Pietrzak LK, Spring MA. Broad Overview of a Clinical and Commercial Experience with CoolSculpting. Aesthet Surg J. 2013 Aug 1; 33(6):835-46.

25. Dierickx CC, Mazer JM, Sand M, Koenig S, Arigon V. Safety, Tolerance, and Patient Satisfaction With Noninvasive Cryolipolysis. Dermatol Surg. 2013 Aug; 39(8):1209-16.

26. Bernstein EF. Longitudinal Evaluation of Cryolipolysis Efficacy: Two Case Studies. J Cosmet Dermatol. 2013 Jun; 12(2):149-52.

27. Kotlus BS, Mok C. Evaluation of Cryolipolysis for Subcutaneous Fat Reduction. Am J of Cosmet Surg. 2013; 30(2), 89-93.

28. Lee, J. Clinical Efficacy of Fat Reduction on the Thigh of Korean Women through Cryolipolysis. Obes Weight Loss Ther 2013, 3:6.

29. Shek SY, Chan NPY, Chan HL. Non-Invasive Cryolipolysis for Body Contouring in Chinese — a First Commercial Experience. Lasers Surg Med. 2012 Feb; 44(2):125-30.

30. Brightman L, Geronemus R. Can Second Treatment Enhance Clinical Results in Cryolipolysis? Cosmet Dermatol. 2011; 24(2):85-88.

31. Klein K, Zelickson B, Riopelle JG, Okamoto E, Bachelor EP, Harry RS, Preciado JA. Non-Invasive Cryolipolysis for Subcutaneous Fat Reduction Does Not Affect Serum Lipid Levels or Liver Function Tests. Lasers Surg Med. 2009 Dec; 41(10):785-90.

32. Coleman SR, Sachdeva K, Egbert BM, Preciado J, Allison J. Clinical Efficacy of Noninvasive Cryolipolysis and Its Effects on Peripheral Nerves. Aesthetic Plast Surg. 2009 Jul; 33(4):482-8.

Published abstracts

1. Loss L. Cryolipolysis Treatment of a Lipoma: A Case Study. Lasers Surg Med. 2014; 45(4):364.

2. Burns AJ, Saltz R, Stevens G, Kilmer S. Cryolipolysis Using the Treatment to Transformation Approach: One Year Follow Up. Lasers Surg Med. 2014; 46(S25):18.

3. Jalian HR, Tam J, Garibyan L, Anderson RR. Selective Cryolysis of Sebaceous Glands. Lasers Surg Med. 2014; 46(S25):2.

4. Macedo O, Corradini C, Matayoshi L. Cryolipolysis Treatment for Subcutaneous Fat Layer Reduction. Journal of the American Academy of Dermatology. 2012; 66(4):Suppl. 1: AB25.

5. Mayoral F, Kaminer M, Kilmer S, Weiss R, Zelickson B. Effect of Multiple Cryolipolysis Treatments on the Abdomen. Lasers Surg Med. 2012; 44(S24):15.

6. Dover J, Kaminer M, Teahan M, Barrett L. Patient Satisfaction at 2 and 6 Months after a Single Non-Invasive Cryolipolysis Treatment for Subcutaneous Fat Layer Reduction. Lasers Surg Med. 2011; 43(S23):968.

7. Kim H, Suh D, Park J, Rhue J, Lee S, Song K, Shin M, Ok C. Clinical Evaluation of a Non-Invasive Cryolipolysis for the Treatment of Subcutaneous Fat Removal in Korean Patients. Lasers Surg Med. 2011; 43(S23):973.

8. Burns JA, Allison J, Bachelor E, Dover J, Coleman S, Fitzpatrick R, Garden J, Geronemus R, Goldberg D, Kilmer S, Kramer S, Levinson M, Mayoral F, Okamoto E, Tanzi E, Riopelle J, Weiss R, Zelickson B. Analysis of Side Effects of Non-Invasive Cryolipolysis for Subcutaneous Fat Layer Reduction – Interim Report from Controlled Clinical Trials. Lasers Surg Med. 2010; 42(S22):21.

9. Dover J, Burns J, Coleman S, Fitzpatrick R, Garden J, Goldberg D, Geronemus R, Kilmer S, Mayoral F, Tanzi E, Weiss R, Zelickson B. A Prospective Clinical Study of Noninvasive Cryolipolysis for Subcutaneous Fat Layer Reduction – Interim Report of Available Subject Data. Lasers Surg Med. 2009; 41(S21):43.

10. Kaminer M, Weiss R, Newman J, Allison J. Visible Cosmetic Improvement with Cryolipolysis: Photographic Evidence. Presented at the Annual Meeting of the American Society for Dermatologic Surgery, 2009, Phoenix, AZ.

APPENDIX B

System Symbols

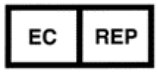
The following symbols are used on the components of the system and on its supplies and packaging.

Table 21: System Symbols

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ANSI Z535.6	Product Safety Information in Product Manuals, Instructions and Other Collateral Materials	Warning	Indicates a hazardous situation which, if not avoided, could result in death or serious injury.
	ANSI Z535.6	Product Safety Information in Product Manuals, Instructions and Other Collateral Materials	Caution	Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.
	ISO 15223-1, Clause 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Manufacturer	Indicates the medical device manufacturer.
	ISO 7000-3082	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Catalogue or model number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 7000- 2493	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.1.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 7000-2498	Graphical symbols for use on equipment.		
	93/42/EEC 2014/53/EU	Medical Device Directive 93/42/EEC Radio Equipment Directive 2014/53/EU	CE marking of conformity	Indicates manufacturer declaration that the product complies with the essential requirements of the relevant European safety and performance protection legislation.
	ISO 15223-1, Clause 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 7000-2492	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Use by date	Indicates the date after which the medical device is not to be used.
	ISO 7000-2607	Graphical symbols for use on equipment.		
	IEC 60601-1, Table D.2, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Follow instructions for use	Refer to instruction manual/booklet.
	ISO 15223-1, Clause 5.4.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	IEC 60601-1, Table D.1, Symbol 11	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 7000-1641	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.4.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
	IEC 60601-1, Table D.1, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.	Caution: Read all warnings and precautions in instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 7000-0434	Graphical symbols for use on equipment.		
	IEC 60601-1-2:2007, Clause 5.1.1	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests		
	IEC 60417-5140	Graphical symbols for use on equipment.	Non-ionizing electro-magnetic radiation	To indicate generally elevated, potentially hazardous, levels of nonionizing 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.
	IEC 60878-5140	Graphical symbols for electrical equipment in medical practice.		

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 15223-1, Clause 5.3.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Storage humidity range	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 7000-2620	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Storage temperature range	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 7000-0632	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.3.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 7000-0626	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.3.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	ISO 7000-0621	Graphical symbols for use on equipment.		
	IEC 60601-1, Table D.1, Symbol 20	Medical electrical equipment —	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.
	IEC 60417-5333	Part 1: General requirements for basic safety and essential performance.		
	ISO 15223-1, Clause 5.4.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 7000-1051	Graphical symbols for use on equipment.		
	ISO 7000-3079	Graphical symbols for use on equipment.	Open here	To identify the location where the package can be opened and to indicate the method of opening it.
	ISO 15223-1, Clause 5.2.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 7000-2606	Graphical symbols for use on equipment.		

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	EN 50419	Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	Recycle: Electronic Equipment	Do Not throw this unit into a municipal trash bin when this unit has reached the end of its lifetime. T ensure utmost protection of the global environment and minimize pollution, please recycle this unit.
	IEC 60417, Reference 5032	Graphical Symbols for Use on Equipment.	Alternating Current	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
	IEC 60417, Reference 5019	Graphical Symbols for Use on Equipment.	Protective Earth Ground	To identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of fault, or the terminal of a protective earth (ground) electrode. The location of this symbol shall be directly adjacent to the AC inlet or as close as is feasible.
	IEC 60601-1, Appendix D	Medical Device Marking and Labeling	Safe Working Load	Safe Working Load
	ISO 7000, Reference 0623	Graphical Symbols for use on equipment.	This Way Up	Indicates correct upright position of the transport package.
	ISO 7000; Reference 2402	Graphical Symbols for use on equipment – registered symbols.	Do Not Stack	To indicate that the items shall not be vertically stacked, either because of the nature of the transport packaging or because of the nature of the items themselves.
	ISO 7000, Reference 1135	Graphical Symbols for use on equipment – registered symbols.	Recycle	Indicates an item can be recycled.
	ISO 15223-1, Clause 5.1.2	Medical Devices-Symbols to be used with medical device labels, labeling and information to be supplied	Authorized Representative	Indicates the authorized representative in the European community.
	IEC 60417 Reg. No. 5021	Graphical symbols for use on equipment	Equipotential contact	To identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.
	IEC 60417 Reg. No. 5569	Graphical symbols for use on equipment	Locked position	To identify the location of a lock. To identify the control that effects a locking function. To indicate that the component or function is in its locked state.
	IEC 60417 Reg. No. 5570	Graphical symbols for use on equipment	Unlocked position	To identify the control that effects an unlocking function. To indicate that the component or function is in its unlocked state.

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	IEC 60417 Reg. No. 5007	Graphical symbols for use on equipment	On (Power)	To identify the control that starts a function or operation. To identify the control that enables a function or operation to be engaged or activated.
	IEC 60417 Reg. No. 5008	Graphical symbols for use on equipment	Off (Power)	To identify the control that stops a function or operation. To identify the control that disables a function or operation to be engaged or activated.
	IEC 60601-1	Identification of Testing entity for compliance with IEC 60601-1	cTUVus	The product has been assessed to and complies with US and Canadian national safety standards.
	21 CFR 801.15(c)(1)(i)F	Labeling-Medical devices; prominence of required label statements.	Prescription only	CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician
	21 CFR 801.109	Labeling-Prescription devices		
	ISO 3758 Reg. No. 3088	Textiles — Care labelling code using symbols	Machine wash, cold, very mild process	Machine wash, cold, Delicate/ Gentle
	ISO 3758 Reg. No. 3124	Textiles — Care labelling code using symbols	Do Not Bleach	Do Not Bleach
	Per ISO 3758 Reg. No. 3107	Textiles — Care labelling code using symbols	Tumble dry gentle, low heat, very mild process	Low Heat, Delicate/ Gentle
	Per ISO 3758 Reg. No. 3113	Textiles — Care labelling code using symbols	Do Not Iron	Do not iron
	ISO 3758 Reg. No. 3114	Textiles — Care labelling code using symbols	Do Not Dry Clean	Do not dry clean
	ISO 15223-1, Clause 5.7.10	Medical Devices-Symbols to be used with medical device labels, labeling and information to be supplied	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information
	ISO 15223-1, Clause 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Date of manufacture	Indicates the date when the medical device was manufactured. (the “xx” refers to the country code to identify the country of manufacture of products)
	ISO 7000-2497	Graphical symbols for use on equipment.		
	ISO 15223-1, Clause 5.7.7	Medical Devices-Symbols to be used with medical device labels, labeling and information to be supplied	Medical Device	Indicates the item is a medical device.

APPENDIX C

System Specifications

This product may contain remanufactured parts or parts that have had incidental use, all of which are equivalent in performance to new parts.

Essential Performance

Table 22: Performance Characteristics

Device State	When Target Is:	Required Device Performance Is:
Cooling	Below 5°C	No more than 1°C below the target temperature
Heating	Above 30°C	No more than 1°C above the target temperature
Steady state	2-10 InHg	Vacuum pressure controlled to within ± 0.5 inches of Hg

Environmental Requirements

The system and its components are designed to operate normally when stored, shipped, and operated under the conditions specified in Table 23: Environmental Requirements.

Use of the system in an oxygen-rich environment may cause fire. Do not use the system in an oxygen-rich environment.

The system may not operate as expected if it is stored or operated in conditions of excessive heat, humidity, or atmospheric pressure. Operate and store the system in a room that meets the stated requirements.

Table 23: Environmental Requirements

Condition	Shipping/Storage Requirement	Operating Requirement
Temperature	14°F to 140°F (-10°C to 60°C)	59°F to 82°F (15°C to 28°C)
Humidity	10% to 95% (non-condensing)	10% to 70% (non-condensing)
Atmospheric pressure	14.7 psi (101.33 kPa) to 10.1 psi (69.64 kPa).	14.7 psi (101.33 kPa) to 10.1 psi (69.64 kPa).

Dimensions and Weight

Table 24: Dimensions and Weight

Item	Height	Depth	Width	Weight
Control unit	53 in. 135 cm	24 in. 61 cm	24 in. 61 cm	150 lbs 68 kg

Electrical Specifications

Electrical Safety

Class I Equipment, Single-Phase AC, Continuous Operation

Contains Type BF Patient-applied Parts

Water Ingress Protection: Ordinary Equipment, IPX0

Table 25: Electrical Specifications

REF	Voltage	Frequency	Current
CS-S3-002-D-00	100 to 120 VAC	50 to 60 Hz	10A

Fuses

The fuses are located inside the unit and are not serviceable by the customer.

Table 26: Fuse Specifications

Type	Rating	Quantity
5x20 (glass body cartridge)	250VAC, 6.3A, Slo-Blo T	2

Medical Safety Standards

The system complies with the following medical safety standards:

- IEC 60601-1:2005/A1:2012

Electromagnetic Compatibility

The system has been tested and found to comply with Medical Standard Electromagnetic Compatibility (EMC) IEC 60601-1-2:2014. The system complies with the standards outlined below.

This system requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure EMC, the system must be installed and operated according to the information provided in this manual.

When the system is interconnected with other electrical devices, it may result in electromagnetic emissions that can interfere with the normal function of electronic medical equipment.

To properly control electromagnetic emissions and avoid potential harm to the patient or user, ensure all electrical devices are installed and interconnected.

Install the system in a room that complies with all applicable IEC, CEC, and NEC requirements for safety of electrical devices.

Portable and mobile RF communications equipment may affect the normal function of the system.

Use of the system adjacent to or stacked with other equipment may result in unexpected electromagnetic circumstances. Prior to such use, test the operation of the system in the proposed configuration and ensure it meets all requirements as defined in the tables below. Consult the tables below for guidance in placing the system.

Use ports on the system exactly as instructed in this manual. Any other use of these ports may cause unexpected results. See “System Overview”.

Do not use cables or accessories other than those provided by ZELTIQ. The use of other cables or accessories may result in increased electromagnetic emissions or decreased immunity to such emissions.

The system is intended for use in the electromagnetic environment specified in Table 27: Guidance and Manufacturer’s Declaration - Electromagnetic Emissions. The customer or user of the system should ensure that it is used in such an environment.

Table 27: Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The system uses RF energy only for its internal function; therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	(A) The 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 statement is heeded: ⚠ **CAUTION:** The system is intended for use by healthcare professionals only. The system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the system or shielding the location. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Class A	

Table 28: Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±2,4,6, 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 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for line to ground ±1kV for line to line	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	± 0.5, 1kV differential mode ±0.5, 1, 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_T: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T: 1 cycle and 70% U_T: 25/30 cycles Single phase: at 0° 0% U_T: 250/300 cycle	0% U_T: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T: 1 cycle and 70% U_T: 25/30 cycles Single phase: at 0° 0% U_T: 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
	* U_T is the AC mains voltage prior to application of the test level.		
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Portable and mobile RF communications equipment should be used no closer to any part of the system, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended Separation Distance:

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.17 \sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by the electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol: 

RF Wireless Communications Equipment IEC 61000-4-3	See Table 9 of EN 60601-1-2:2015.	See Table 9 of EN 60601-1-2:2015.	See table below for recommended separation distances.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

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

Table 29: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the System

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

Rated maximum output power (W) of transmitter	Separation distance (m) according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Data Module Specifications (Modem and Wi-Fi)

The device includes two data modules (Modem and Wi-Fi). Table 30 lists the specifications for each model. Use each module only with the antenna provided by ZELTIQ.

Table 30: Data Module Specifications (Modem and Wi-Fi)

Module Type	Manufacturer and Model	IC # and FCC ID #	Frequencies (MHz)	Network Type	Effective Radiated Power
Cell Modem: 4G LTE with HSPA+ fallback embedded cellular modem	Multitech MTSMC-LAT3-U.R2	IC 5131A-LE910NAV2 FCC ID RI7LE910NAV2	700 (B12/B13)/ 850 (B5)/ AWS 1700 (B4)/ 1900 (B2)	4G	Maximum 0.2W
			850 (B5)/ 1900 (B2)	HSPA+ (3G)	Maximum 0.25W
Wi-Fi: BLT	Redpine RS9113-NBZ-D3N	IC 8407A-RS9113DB FCC ID XF6-RS9113DB	802.11n: from 6.5 Mbps to 150 Mbps (MCS 0-7) 802.11a/g: from 6 Mbps to 54 Mbps 802.11b: from 1 Mbps to 11 Mbps Bluetooth: 1, 2, 3Mbps 802.15.4-2009: 250Kbps	Wi-Fi Bluetooth ZigBee	Wi-Fi: 18 dBm for 802.11b DSSS Power (+/-2 dBm) 18 dBm for 802.11g/n OFDM 12 dBm for 802.11a/n OFDM Bluetooth: 15 dBm ZigBee: 15 dBm

Electromagnetic Compatibility Compliance - Data Modem

The *CoolSculpting® Elite* System with the data modem complies with the following medical safety standards:

- IEC 60601-1-2:2014

The limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. There is no guarantee that interference will be prevented by following the manufacturer's instructions in a particular installation.

If this equipment causes interference with other devices, which may be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by carrying out one or more of the following measures:

- Reorient or relocate the device receiving the interference.
- Increase the separation between the equipment and the device receiving the interference.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

United States of America

The *CoolSculpting® Elite* System with the data modem and Bluetooth has been tested and found to comply with the limits for a Class A digital device, pursuant to parts 15 and 18 of the FCC Rules (refer to Table 30 Data Modules Specifications). These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

APPENDIX D

Disposal of Hazardous Materials

Do not dispose system in domestic waste stream. Various components of the system may contain materials whose disposal is subject to regulation. The system contains a lithium battery, which is not serviceable by the customer. Dispose of all components of the system in accordance with applicable regulations.

Contact your local environmental control agency for additional information on recycling or disposing of the system in your area.

11/2020