User Manual
COOLTONE™ System

Manufactured for:
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CS-UM-EMS-01-EN2-C

CoolTone is a trademark.

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Customer Service

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

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

Supplies

Contents of the CoolTone™ System

1 CoolTone™ System including:

- 1 Control Unit
- 2 Applicators
- 1 Securement system (including 2 applicator covers and 2 straps)

- 1 CoolTone™ System User Manual
- 2 Mains cable – user select plug type based upon outlet type

Foreword

The CoolTone™ System is an electrically powered device intended for medical purposes that repeatedly contracts muscle tissue by passing electrical currents through applicators not in contact with the affected body area. The CoolTone System is intended to provide entirely non-invasive electromagnetic stimulation for:

• Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen,

• Strengthening, toning and firming of buttocks and thighs.

Indications for Use

The CoolTone is indicated for:

- Improvement of abdominal tone
- Strengthening of the abdominal muscles
- Development of firmer abdomen
- Strengthening, Toning and Firming of buttocks and thighs

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

Contraindications

- Active applicator should never be placed over implanted electrical devices like cardiac pacemakers, cochlear implants, intrathecal pumps, hearing aids etc.
- The CoolTone should be used with caution in persons with Graves' disease, active bleeding disorders or seizure disorders.
- Women who are close to menstruation may find that it comes sooner, or cramping is increased / intensified with CoolTone treatments. Therefore, it is recommended to not undergo treatment during this time of the month.

Other Contraindications:

- Fever
- Application over menstruating uterus
- Application over areas of the skin that lack normal sensation
- Metal or electronic implants in the treatment area

- Implanted defibrillators
- Implanted neurostimulators
- Drug pumps
- Malignant tumor
- Hemorrhagic conditions
- Epilepsy
- Recent surgical procedure
- Pulmonary insufficiency
- Pregnancy

Safety Cautions and 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. Any unauthorized modification or repair will void the warranty.

During treatment, do not place any ferromagnetic or metallic materials (such as metal buttons, clasps, piercings, zippers, coins, keys, metallic fibers in the fabrics, etc.), data carriers (creditcards, USB flash drives etc.) or electronic devices (mobile phones, tablets, watches, PCs etc.) and other medical device applicators or accessories in the direct vicinity (less than 30 cm / 1 foot) of the applicator(s). Do not place the device near other devices that produce strong electromagnetic field (diathermy, X-Ray, cell phones, radiofrequency) in order to prevent mutual functionality influence. If this happens, move the device further away from the source of interference or contact an authorized service personnel.

Ensure that persons with pacemakers are not present in vicinity of the device in operation less than 1.2 meters, or approx. 4 feet.

Application of CoolTone must be in the abdomen, buttocks and thighs areas. Application in the heart, head area or area of growth plate is not permitted.

To avoid the risk of electric shock, the mains plug of the device must be disconnected from the mains before maintenance and cleaning work.

The device is intended to be used exclusively by medical professionals only.

Any treatment instructions regarding treatment location, duration and intensity require medical knowledge and should be given by authorised physicians, therapists and health paraprofessionals. It is imperative that these instructions are followed.

Please refer to the Material Safety Data Sheet of Isovoltine II, in case of leaking oil or contact your service engineer.

In case of leaking oil, please wear gloves providing adequate chemical resistance, specifically to aromatic hydrocarbons, while cleaning.

Ventilate the room in case of leaking oil.
Disposal of the gloves and the oil-soaked cloth according to local regulations. Do not dispose of in domestic waste.

The use in wet areas is not permitted and may lead to considerable damage to the device. This non-compliance can endanger both the patient and the user.

Packaging materials must be disposed of properly. It is important to ensure that these are not accessible to children.

The CoolTone is intended as a standalone device. No other electrical device should be operated on the patient while being treated with the CoolTone.

The device may not be connected to other devices.

Maximum surface temperature of the applicator is 43^{o}C.

Thermal energy may be accumulated in the applicators at the end of the treatment. Allow device to cool down before next treatment or turning off the device.

Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.

Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.

Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.

Caution should be used for patients with suspected or diagnosed heart problems.

For adults use only.

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

Common adverse events may include but may not be limited to:

- Muscular pain
- Temporary muscle spasm
- Temporary joint or tendon pain
- Local erythema or skin redness

Application Information

Before using the CoolTone on a patient, the user should become acquainted with the operating instructions and individual treatment methods as well as the indications / contraindications, warnings and application information. Additional sources of information about types of treatment should be consulted.

Before use, ensure that the device is powered via a properly earthed plug with a grounded mains outlet. The device must only be operated with the supplied power cord.

During use, the device is to be located in a position allowing direct access to the central mains supply so that it can be disconnected for the mains at any time.

The CoolTone is not suitable for use in areas with an oxygen rich, explosive, flammable or combustive environment.

Inspect the device before use. If there is any damage, it must not be used.

Only accessories provided by the manufacturer must be used.

The maximum treatment time is 30 minutes per treatment cycle. Allow a cool down period after each treatment.

Maximum surface temperature of the applicator is 43°C. If the maximum temperature is reached allow the system to cool down. Place the applicators as defined in the chapter about applicator placement.

During treatment the applicator will warm up, this is normal, If the patient experiences any discomfort due to excessive heat from the applicator (>43°C) then discontinue treatment.

CHAPTER 1

System Overview

This chapter describes the control unit, the applicator, and the user interface.

Control Unit

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

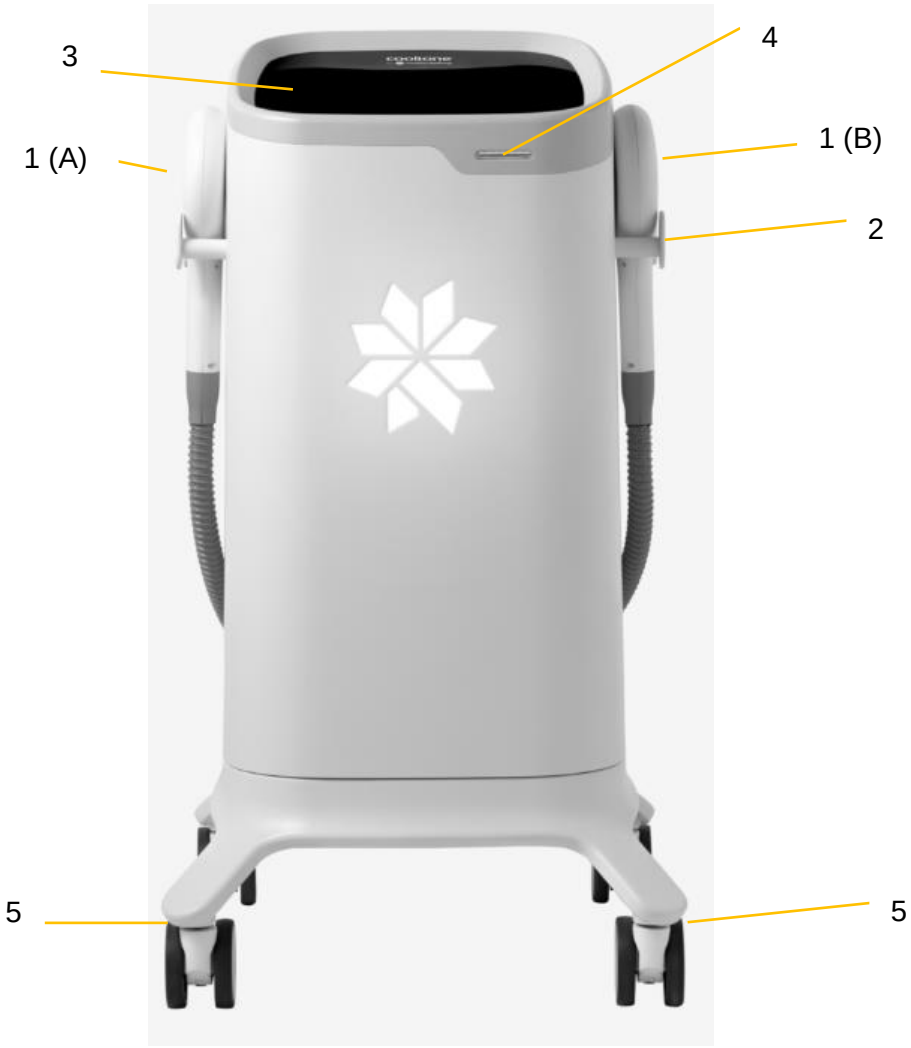


Figure 1: Front of the Control Unit

1 Applicators A and B
2 Applicator holder
3 Touch Screen Display
4 Card Slot
5 Castors

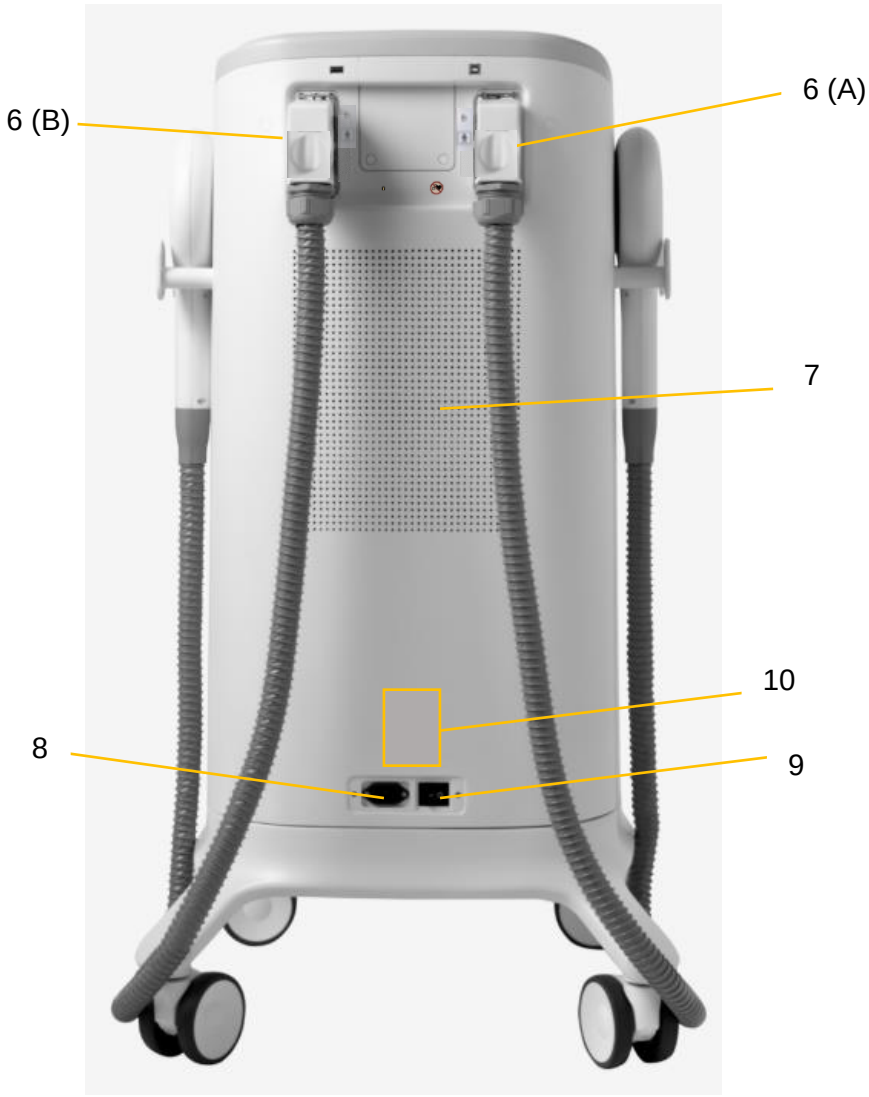


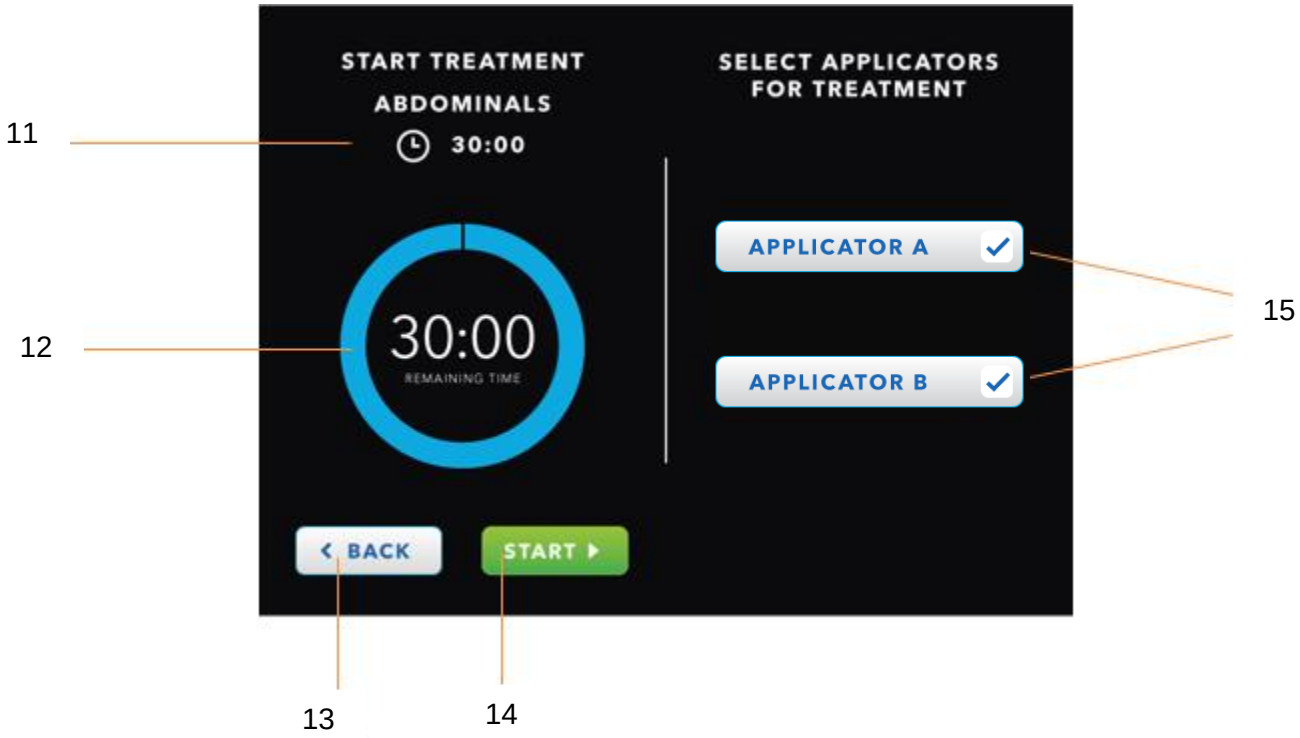
Figure 2: Rear of the Control Unit

6 Connectors for applicators A and B
7 Ventilation grid
8 Mains connector
9 Main switch
10 Serial no / Identification plate

Figure 3: Applicators

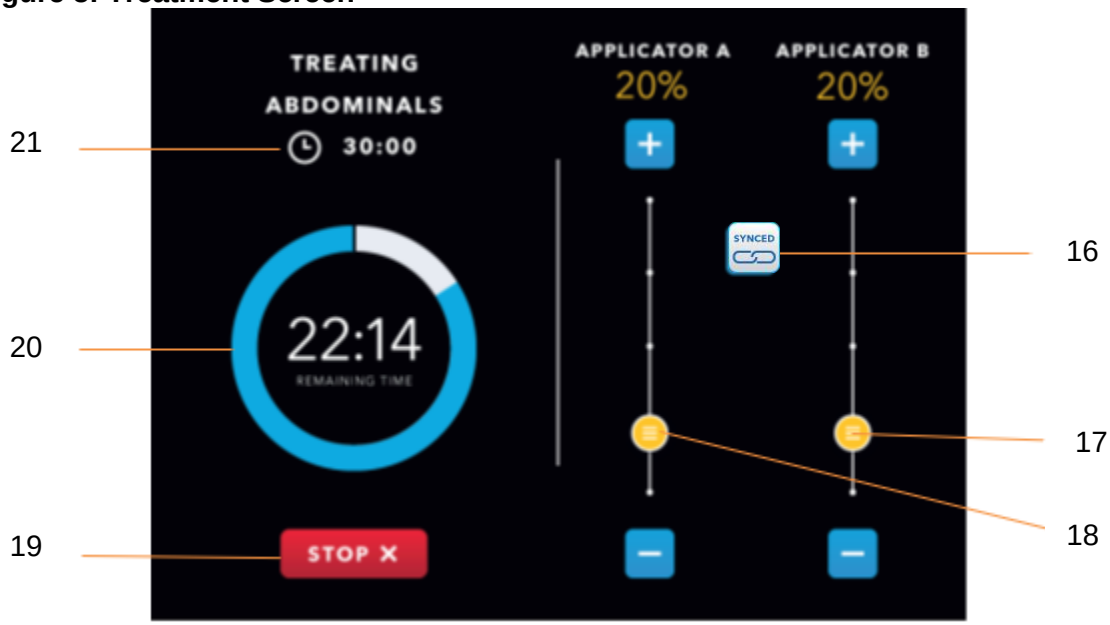
Touch Screens and Displays

Figure 4: Start Treatment



11 Total operating time
12 Remaining treatment time
13 Back to Previous Screen
14 Start Treatment
15 Applicator selection (A and/or B)

Figure 5: Treatment Screen



16 Sync button (option to sync applicator intensity)
17 Intensity of Applicator B
18 Intensity of Applicator A
19 Stop Treatment
20 Remaining treatment time
21 Total treatment time

Device Set Up

After the transport and before switching on the device, make sure that the castors are in the 'locked' position.

Note: *Make sure that the CoolTone is placed on a stable and flat surface*

1. **Connect mains cable**

Connect the mains cable to the socket as shown below on the device (8, Figure 2) and connect it to the mains.

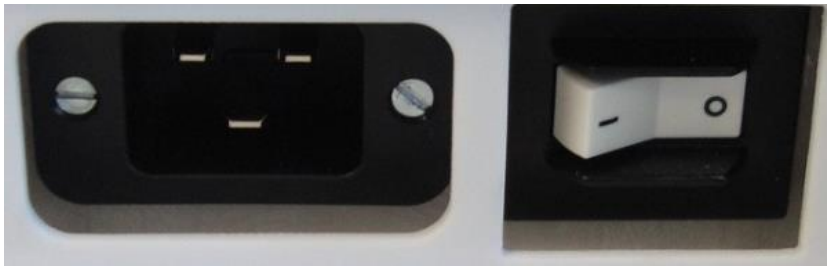


Figure 6: Mains connector and Main Switch

The device may only be connected to earthed sockets.

Be aware that connecting the power cable with the power switch turned on may cause malfunction.

2. **Switching the device on**

Switch on the device with the power switch (9, Figure 2).

If the applicator is used while in a tilted position, the cooling oil will not reach all sections of the applicator and will damage the applicator due to overheating. For this reason, it is recommended to place the applicator in a horizontal position as much as possible.

3. **Switching the device off**

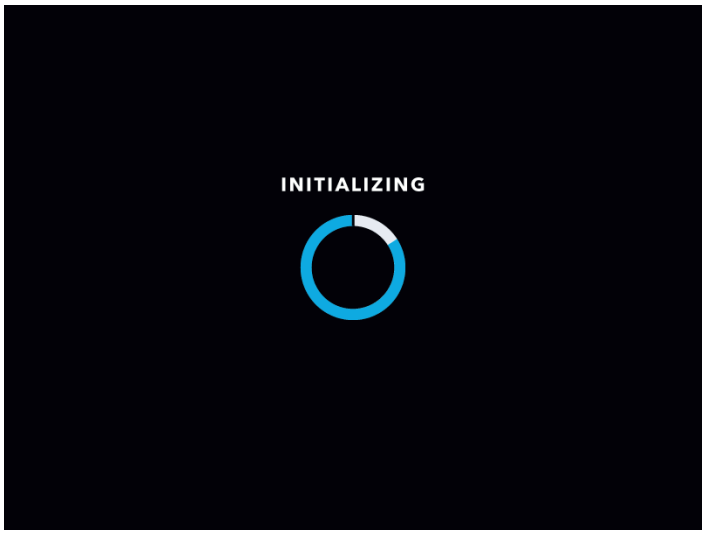
Do not switch off system when it is cooling down post treatment. When cooling down completes, the device is switched off using the power switch (9, Figure 2).

In order to completely disconnect the device (all-phase) from the mains, remove the mains cable.

Settings

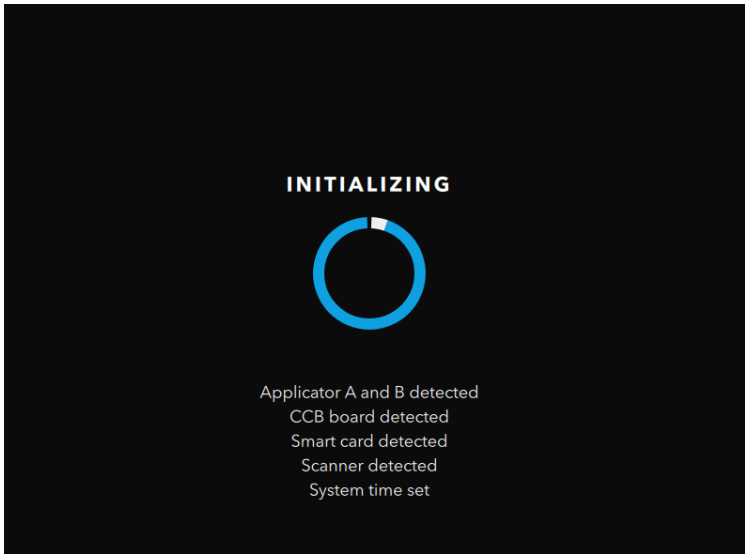
1. Startup screen

Once the device is switched on, a self-test is carried out and the start-up screen opens.



2. Initialization screen

After the start-up, the device continues the self-test while the initializing screen is shown.



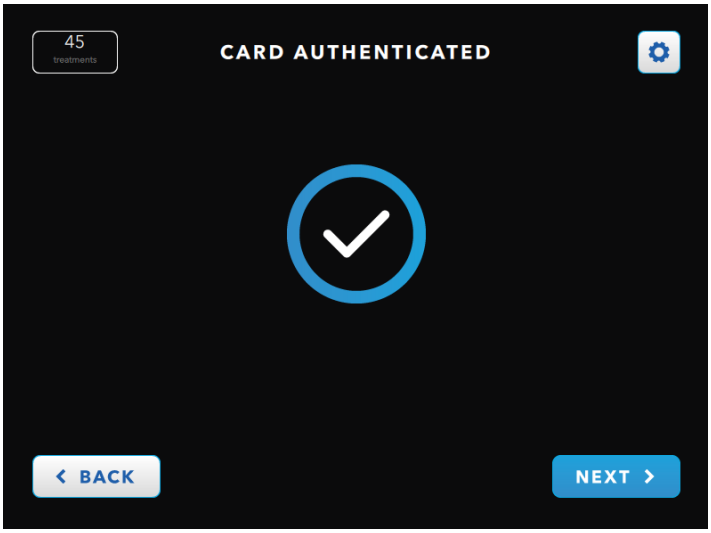
3. Home screen

After performing the self-test, the device automatically displays the home screen.

Pressing “New Treatment button” starts a new treatment.

Insert treatment card in slot.

Leave treatment card in the slot. The confirmation image should appear.



4. Select Patient Details

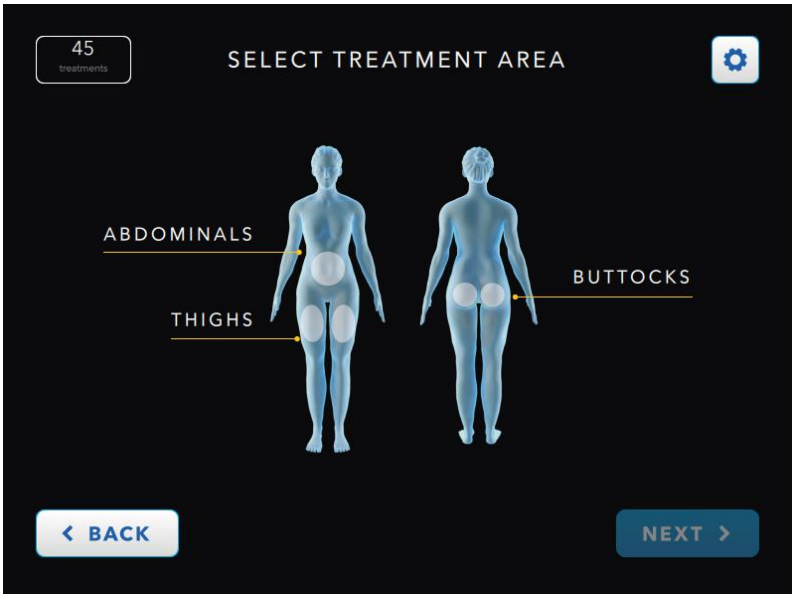
A. Select the patient gender by pressing the button “Male” or “Female.”

B. Select “Yes” or “No” to confirm if patient is new to practice.

C. Press “Next” to proceed to Treatment Area screen

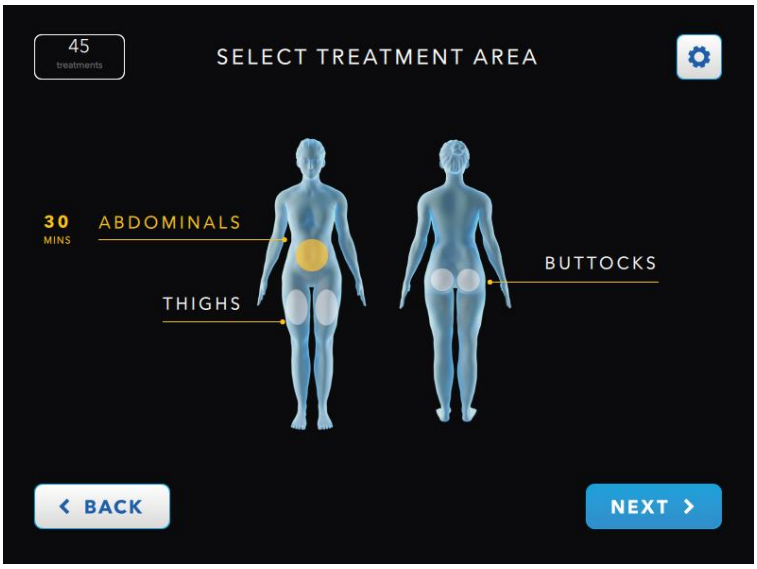
5. Select the Treatment Area

The user can select one of the treatment areas: “Buttocks,” “Abdominals” or “Thighs” by pressing on the treatment area as indicated by the white circular regions.



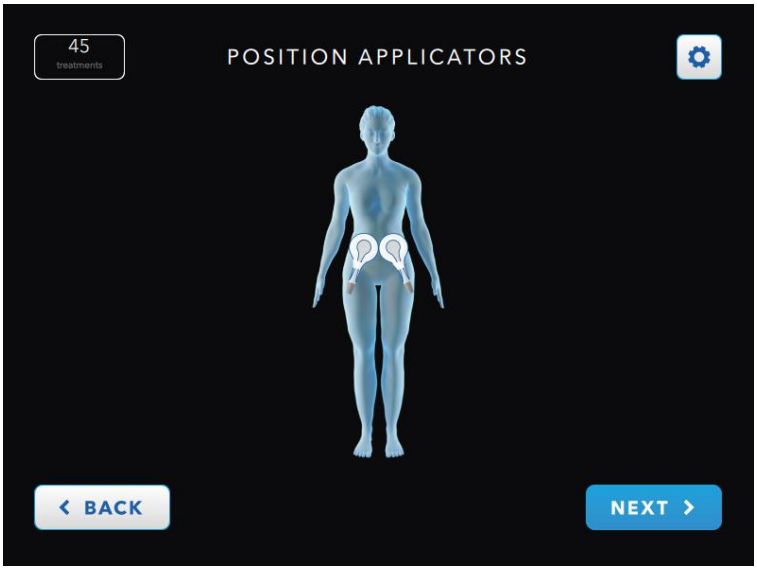
A. Press “Next” to proceed to the Position Applicator screen

B. Select one of the treatment areas by pressing on the area of treatment. The selected treatment area is highlighted in yellow.



6. Position Applicator

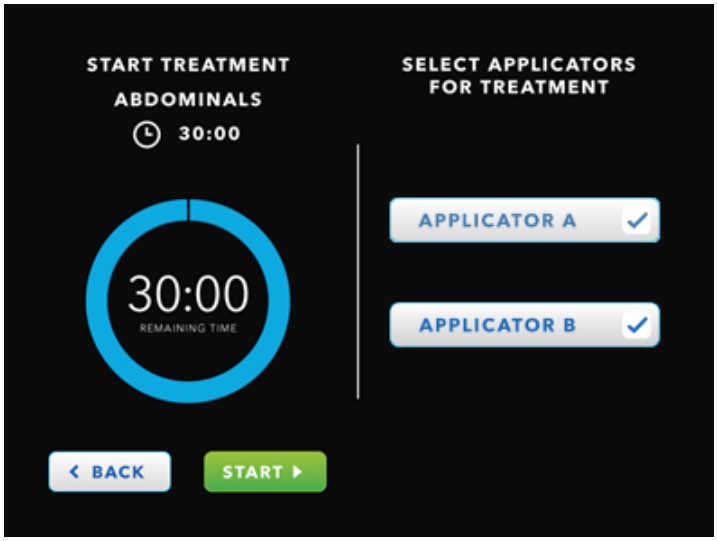
Once the applicators are placed on the selected treatment area, the user can press the button “Next” to get to the treatment screen.



Press “Next” to proceed to the “Start Treatment” screen.

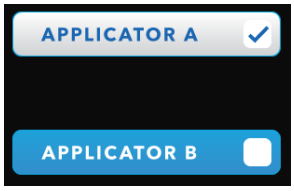
7. Start Treatment

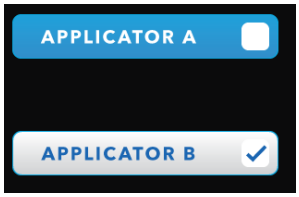
Select the applicator(s) applied for treatment and start the treatment.



To select Applicator “A” or “B” or both “A” and “B”:

Ensure that the Applicator box is checked. Default is unchecked blue box.

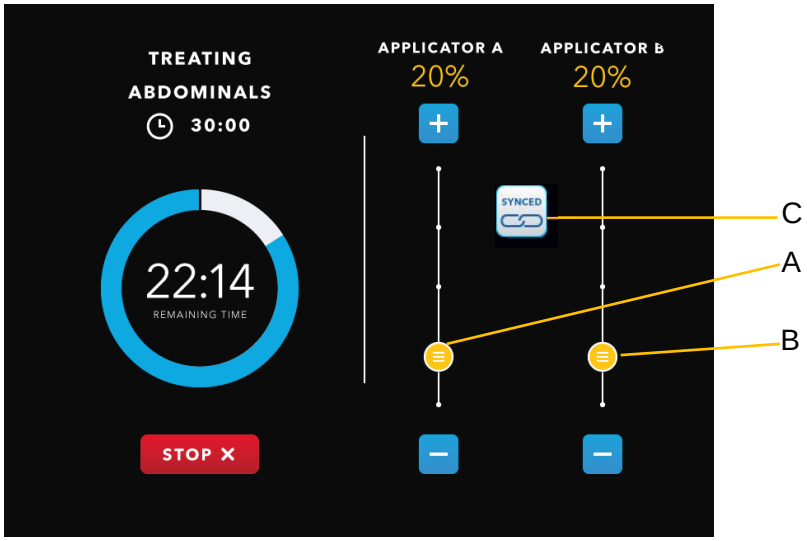




Press “Start” button to start the treatment

8. Running Treatment

Adjust treatment intensity as needed throughout treatment. Refer to Chapter 2 Treatment for detailed description of conducting a treatment.



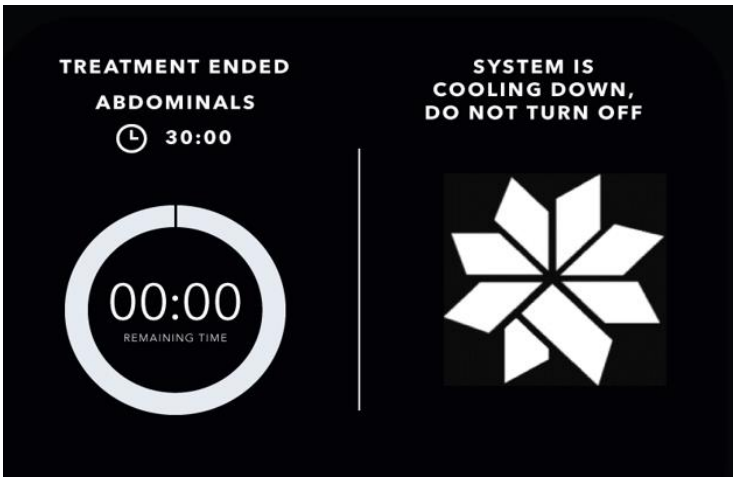
(A) Selection of the Intensity of Applicator A

(B) Selection of the Intensity of Applicator B

(C) Option to sync the intensity of both applicators. (Synced box is blue when synced. Default Sync button is white).

Press red “Stop” button to stop the treatment.

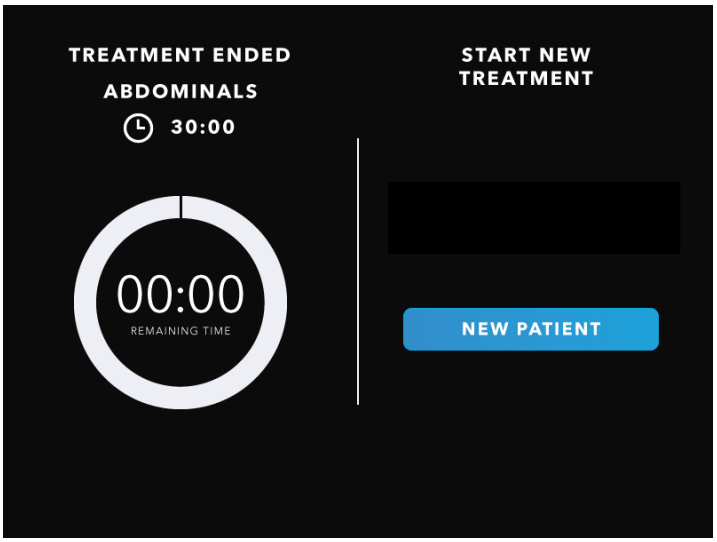
9. Completed or Interrupted treatment



Once the treatment is completed, the user can start a new treatment for the same patient or for a new patient after cooldown is completed

Do not turn system off when it is cooling down.

If the treatment is interrupted before completion, the user should start a new treatment to complete the prescribed treatment.



Press “New Patient” to start a new treatment for a new patient

CHAPTER 2

Treatment

Device Description

The CoolTone consists of a control unit and 2 applicators.

The CoolTone control unit monitors the temperature of the applicator. In addition, the device will check with regular intervals the connection between applicator and control unit. Please refer to Chapter 3 in case any error message should pop-up.

The rated power for this equipment is 220-240 V max. 3kVA.

Repair, expansion, and installation of equipment shall not be performed by anyone other than the specialized personnel authorized by the manufacturer. Arbitrary disassembling/assembling of equipment by the user is absolutely prohibited.

As a strong magnetic field is generated around the magnetic field generating section, equipment operation technicians, assistants, and patients must not wear or hold any items which can be affected by the magnetic field.

Use of this device in the presence of strong electromagnetic fields (e.g., tomographs, X-ray or diathermia devices) may impair the operation of the device.

Note *When CoolTone is operated, do not use any items such as wristwatches, mobile phones, radio sets, transmitters or wireless toys as they may be damaged by magnetic fields. So please be careful and keep them separate at a minimum distance of 30 cm (approx. 1 foot).*

Note *To avoid electromagnetic disturbance during use, the CoolTone shall be installed at a minimum distance of 30 cm (approx. 1 foot) from any generator, X-ray equipment, broadcasting device, mobile electric wire, and other electromagnetic radiation emitting devices.*

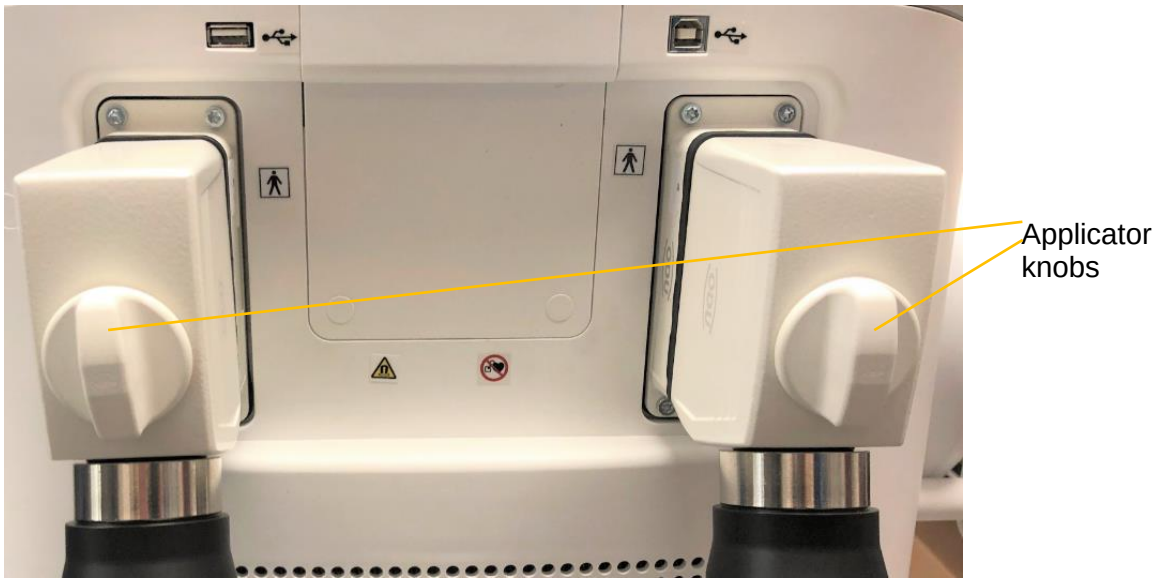
Note *During the operation of the CoolTone, the patient shall not consume drinks, water, etc. which can influence the equipment.*

Applicator Placement

Applicator connection

Before connecting or disconnecting the applicators, check that the device is turned off.

To disconnect the applicators, turn the knob to the left. To connect the applicators, hold the applicator end to the connecting pins and slowly turn the knob to the right side. If the knob is engaged properly, a click will be heard.



Placing the Applicator

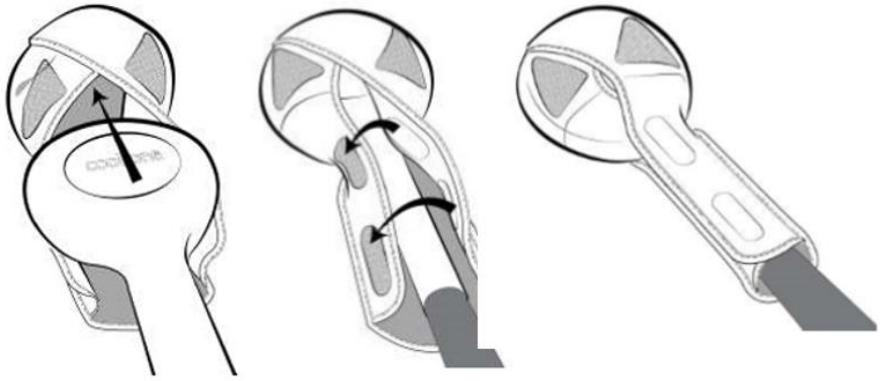
Before placing the applicators for treatment, confirm that the applicators are connected to the device properly.

Securement System

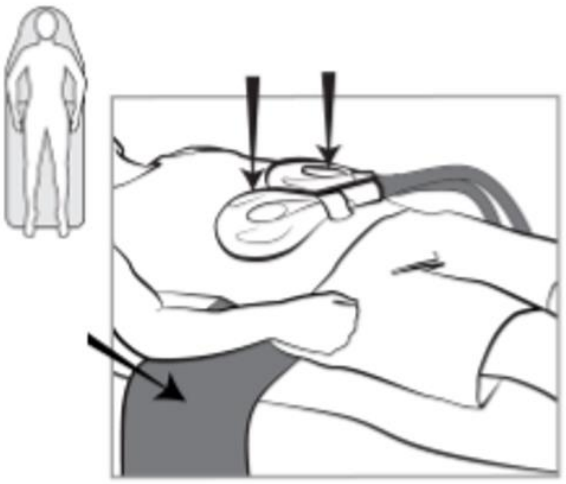
The CoolTone securement system is composed of two applicator covers, a strap, and a connection piece. The cover provides a comfortable, cushioned barrier between the applicator and patient, and connects to the strap via the connection piece. The system is designed to maintain applicator position throughout the treatment.

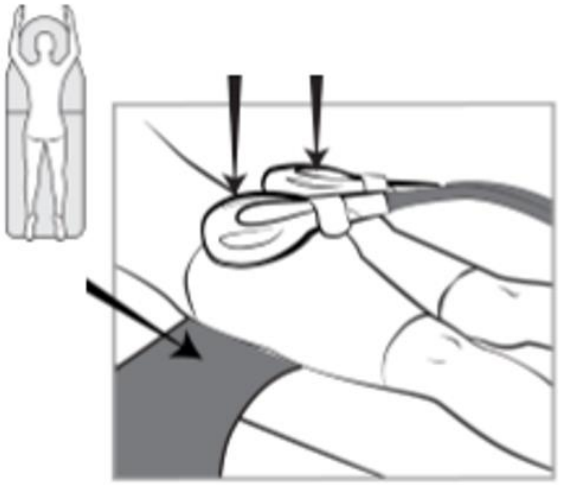
Ensure that the CoolTone logo on the applicator is visible through the white securement cover. If the CoolTone logo is not visible, adjust securement cover. The blue side of the cover should be in contact with treatment area. This proper placement ensures that the magnetic field is facing the patient during treatment.

1. Insert the applicator into the cover and secure with Velcro tab.

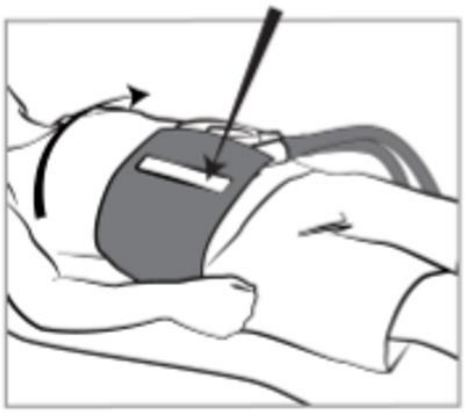


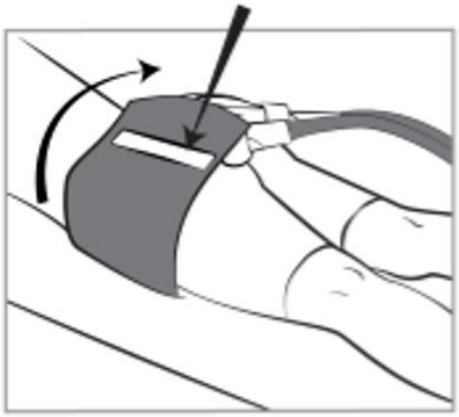
2. Place the strap under the patient. Apply the applicator(s) over the desired treatment area(s).



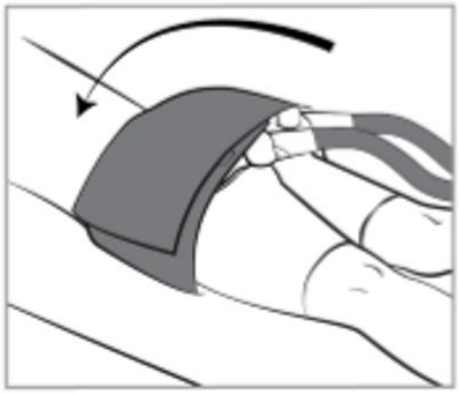


3. Place one end of the strap over the applicator(s). Place the connection piece on the strap.



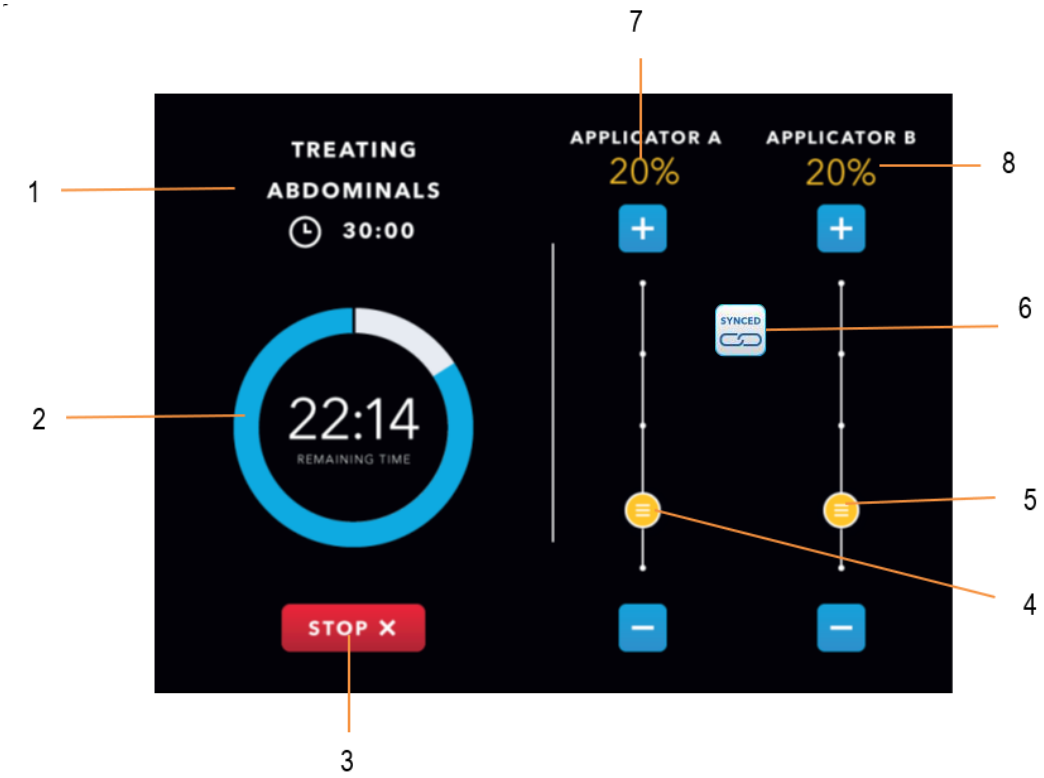


4. Secure the other end of the strap over the connection piece.



At the end of a treatment, detach the strap from the connection piece, unwrap the strap, and remove the applicator(s) from treatment area(s).

General treatment screen



(1) Program information

This screen shows the selected treatment program (buttocks, abdominals or thighs).

(2) Remaining treatment time

Graphically displays the course of treatment.

(3) Start/ Stop

By pressing the button “Start,” the treatment starts and the button changes into “Stop.” Pressing the button again stops the treatment.

(4) Intensity of Applicator A

To adjust the intensity of applicator A only, check that the button “Synced” is not activated. If the button is not activated, it shows “Sync” instead of “Synced”. Otherwise press the “Synced” button to deactivate it and change back to “Sync.” Move the yellow button up and down to change the intensity of the applicator A in increments of 1 percent. You can also touch the plus (+) button or the minus (-) button to increase or decrease the intensity.

(5) Intensity of Applicator B

To adjust the intensity of applicator B only, check that the button “Synced” is not activated. If the button

is not activated, it shows “Sync” instead of “Synced”. Otherwise press the “Synced” button to deactivate it and change back to “Sync.” Move the yellow button up and down to change the intensity of the applicator B in increments of 1 percent. You can also touch the plus (+) button or the minus (-) button to increase or decrease the intensity.

(6) Sync/Synced button

By pressing this button, the intensity of the applicators can be synced together or can be operated independently. If the button shows “Sync” the applicators can be adjusted individually. If the button shows” Synced” the adjustment of the intensity of the applicators can be done for both applicators at the same time. To do this, move one of the yellow buttons or one of the plus/minus buttons to decrease or increase the intensity for both applicators at the same time.

(7) Intensity value of applicator A

The actual value of applicator A intensity is displayed.

(8) Intensity value of applicator B

The actual value of applicator B intensity is displayed.

CHAPTER 3

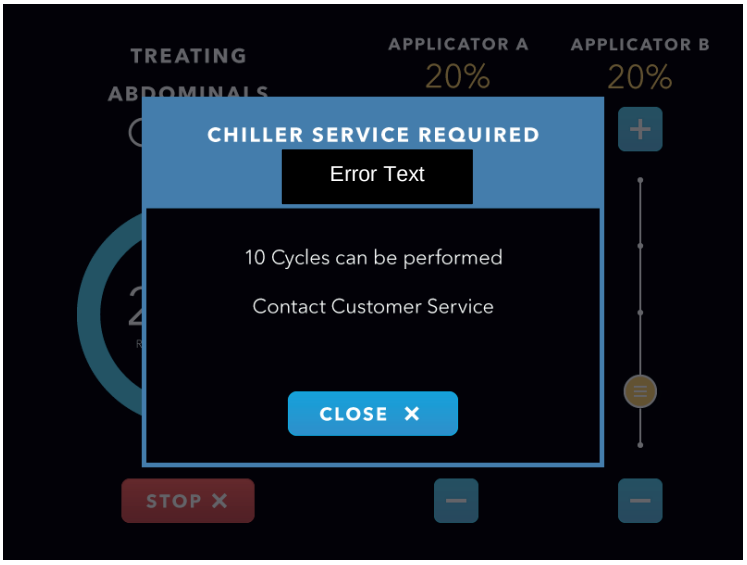
Error Messages / Troubleshooting

If the equipment does not operate normally during use, please check the items listed in Table 1 before requesting service. If none of the following problems apply, or if the following remedies do not help, turn off the power to the equipment and contact Zeltiq Customer Service.

Error messages:

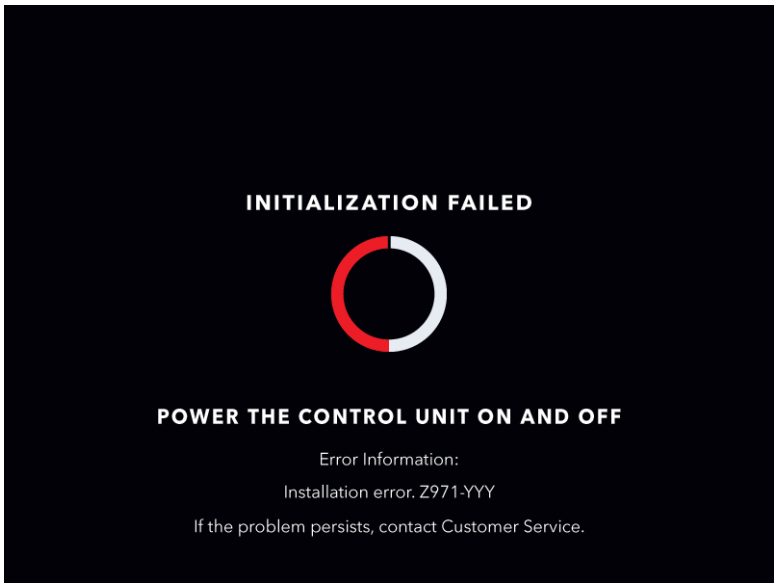
Service required

If a service must be performed, a message is displayed to inform the user to contact the service personnel.



Initialization failed

If the initialization fails, an error message occurs to inform the user to reboot the device. If the error occurs again, please contact the service personnel.



System errors

If an error in the system occurs, the information about the error and a corresponding error number as well as a short description how to proceed is shown in Pop Up screen:

Table 1: Error Messages and Action

Message number	Message text	Action
T100-YYY	Internal Temperature	Wait until the system is cooled down.
T200-YYY	Applicator Error	Power the control unit off, connect both applicators and power it on.
T201-YYY	Control Unit Error	Remove the USB stick if inserted and power the control unit off and on.
T230-YYY	No treatments remaining	Connect a new card.
T231-YYY	Card error	Disconnect and reconnect the card.
T500-YYY	Chiller Error	Power the control unit off and on. If the problem persists, contact Customer Service.
T501- YYY	Applicator Error	Power the control unit off and on. If the problem persists, contact Customer Service.
T502- YYY	Control Unit Error	Power the control unit off and on. If the problem persists, contact Customer Service.
T530-YYY	Control Unit Error	Power the control unit off and on. If the problem persists, contact Customer Service.
T531-YYY	Control Unit Error	Contact customer service.
T532-YYY	Software Installation Error	Power the control unit off and on and retry the installation. If the problem persists, contact Customer Service.
T533-YYY	Software Installation Error	Software installation cannot be performed as installation is an older version than the system. Remove the USB stick if inserted and power the control unit off and on.
T534-YYY	Software Installation Error	Power the control unit off and on and retry the installation. If the problem persists, contact Customer Service.

Self Trouble-Shooting

If the system encounters a problem, it displays a message to help you diagnose and resolve the issue.

When 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).

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

Table 2: Self trouble-shooting

Symptom	Action
Equipment does not turn on.	Check if the power connector of the equipment is properly connected. Check if the power switch of equipment is turned on.
Magnetic field is not generated from equipment	Confirm if the LCD displays an ERROR message. Check if the output strength is set by checking the intensity values after pressing the Start button.
Over Temperature message is displayed.	If applicator is in an upright position, it is easy for the applicator to overheat. Maintain a horizontal position as much as possible. If the room temperature is too high, disorder can be caused in the cooling. Maintain the room temperature at less than 28℃ as much as possible.
The main power switch spontaneously turns off.	Stop the operation by cutting off the power to the device and contact the service center.
The LCD screen of operation panel does not illuminate when power is turned off and then turned on again.	
Stimulation is not generated by applicator, even after intensity is increased.	
The temperature icon on the screen blinks and the equipment is not operating.	
In any case of oil leakage.	

CHAPTER 4

Cleaning and Maintenance

Device

The device always must be turned off before any cleaning and disinfecting activity.

Make sure that during cleaning and disinfection no liquids penetrate the device. Do not use sprays.

If liquid penetrates the device during cleaning or disinfecting, please put the unit out of service, protect it from being used again and contact your Zeltiq Customer Service.

Make sure that the labels of the device (such as warnings, labels of control devices, identification plate) are not damaged when cleaning and disinfecting.

Cleaning

Housing / Applicator

In the event of visible contamination, the housing, the applicator and all cables can be cleaned using commercially available soft alcohol-free plastic cleaners. Wipe the surface until the dirt is removed using a soft cloth soaked according to the specifications of the manufacturer of the cleaning agent but not dripping wet.

Securement System

Securement system

Components of the securement system:

- **100% Polyester**

Instructions for care:

It is recommended to wash the securement system after each patient and at the end of the day.

Mechanical cleaning of the securement system

Pre-Cleaning:

Turn over the applicator sleeves to be sure that they do not stick to other clothes. Close the Velcro of the applicator sleeves and the strap.

Cleaning:

1. Do not bleach
2. Tumble dry gentle low heat. Use very mild treatment.
3. Do not iron
4. Do not dry clean
5. Machine wash cold gentle cycle.

Reusability:

Over time, the material can become damaged depending on use and treatment.

Once the securement system is punctured, worn, has optical damages, has non-removable contaminations or the Velcro is not functional anymore, please do not reuse it.

Disinfection

We recommend that disinfection be carried out before every treatment and at the end of every day as well as in the event of evidence of possible contamination. Consult with your health professional when doing so. Always perform cleaning prior to disinfection.

Monitor housing and applicators can be disinfected using disinfectant wipes. Use a commercially available alcohol-free disinfectant for metal and plastic, with bactericidal, viricidal and fungicidal properties. Observe the application instructions of the manufacturer. Wipe all surfaces using a cloth soaked according to the specifications of the manufacturer of the disinfectant, but not dripping, or with cloth pre-impregnated with disinfectant (wipes).

If applicable, also observe requirements for drying or post-cleaning.

Caution

If flammable solutions are used for cleaning and disinfection, sufficient time must be allowed for the solutions to evaporate before using the device. Otherwise, it may lead to flammability.

Notice

Only use the device in a clean environment

Routine inspection of equipment

1. The covering for the power line of equipment, applicator connecting line, etc. shall not be peeled off and internal lines shall not be exposed and shall not be damaged by impact from outside.
2. There shall be no trace of oil leakage from applicator.
3. Assure there is no foreign material on the outside of the equipment.
4. The button for equipment operation, etc. must not shake.
5. The various parts attached to the device must not shake.
6. If any of the above occurs, contact Zeltiq Customer Service for assistance.

Safety inspection

1. In order to ensure safe use, be sure to check the equipment including internal components and output voltage by the person who has been given authorization from the company once per year.
2. Please clean the applicator before storing.
3. After storing the device for a long period of time, be sure to check the device before using it.
4. Please note the following regarding storage conditions:
    - Keep out of water
    - Keep the control monitor in an upright position
    - Keep away from direct sunlight
    - Do not store near heaters
    - Avoid locations subject to excessive shock or vibration, exposure to chemicals or explosive gases.

The CoolTone is manufactured according to the safety regulations of IEC 60601-1, Rev 3.1.

The manufacturer can only be considered responsible for the safety and reliability if:

1. the device is operated using a proper power outlet that is properly grounded and the electrical installation complies with the National safety requirements,
2. the equipment is operated in accordance with the instructions for use,
3. extensions, readjustments or modifications are carried out only by Zeltiq Customer Service.
4. the device is operated only by properly skilled personnel,
5. the device is not operated in hazardous areas and / or a combustive atmosphere,

6. the device is immediately disconnected from the mains in the event of the penetration of liquids.

The device does not contain any parts that can be repaired or serviced by the operator.

Modifications of this device are not permitted.

Service and replacement of components may only be performed by certified service technicians from Zeltiq Customer Service or the manufacturer.

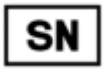
APPENDIX A

System Symbols

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

Table 3: System Symbols

Symbols	Reference No.	Title	Description
	ANSI Z535.6	Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials	**CAUTION:** Indicates a use or misuse of the device that is associated with a risk of minor, temporary injury or damage to the equipment.
	ANSI Z535.6	Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials	**WARNING:** Indicates a use of misuse of the device that is associated with a risk of serious and/or permanent injury and death.
	IEC 60417-5333	Type BF applied part	In the instructions for use, this symbol marks the applied parts.
	ISO7010-M002	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read
	ISO 7000-1641	Operating instructions	This symbol indicates to consider the operating instructions when operating the device.
	ISO7010-P007:	No access for people with active implanted cardiac devices	To prohibit people with active implanted cardiac devices from entering a designated area.
	ISO7010-W006	Warning, magnetic field	This symbol warns that a magnetic field is emanated by the device.

Symbols	Reference No.	Title	Description
	IEC 60417-5019	Protective earth (ground)	This symbol marks the parts of the device that are connected to PE (ground).
	ISO7000-2498	Serial number	This symbol indicates the manufacturer serial number of the device or accessories.
	ISO 7000-2493	Catalogue number	This symbol indicates the manufacturer article number of the device or accessories.
	ISO 7000-1497	Date of manufacture	This symbol indicates the date of manufacture of the device or accessories.
	21 CFR 801.109	Prescription Only	Caution: In the United States of America, federal law restricts this device to sale by or on the order of a physician.
	IEC 60417 Regulation: W005	Potential for Electromagnetic Interference	Near devices, bearing this symbol, interference is possible.
	WEEE- European Regulation: 2012	WEEE symbol	Disposal of electrical and electronic equipment as well as used batteries and accumulators. This product must not be disposed of with household waste.
	ISO 7000-0626	Keep packaging dry	This symbol instructs to keep the packaging of the device or accessories dry.
	ISO 7000-0621	Fragile; handle with care	This symbol indicates that the contents in the packaging of the device are fragile and the package should be handled with care.

Symbols	Reference No.	Title	Description
	ISO 7000-0632	Temperature limit	This symbol indicates the maximum and minimum temperature limits at which the device shall be stored and transported.
	ISO 7000-0623	This way up	This symbol indicates the correct upright position of the device package.
	ISO 7000-3124	Do not bleach	In the instruction for use this symbol indicates not to bleach the securement system.
	ISO 3758 Regulation: 3114	Tumble dry gentle low heat Very mild treatment	In the instruction for use this symbol indicates not to bleach the securement system.
	ISO 7000-3113	Do not iron	In the instruction for use this symbol indicates not to iron the securement system.
	ISO 7000-3114	Do not dry clean	In the instruction for use this symbol indicates not to dry clean the securement system.
	ISO 7000-3088	Machine wash cold gentle cycle	In the instruction for use this symbol indicates how to wash the securement system.

APPENDIX B

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 4: Magnetic field strength for both Applicators

Applicator	Magnetic Field Strength	Limits
A	0.5 – 1.35 T	± 20%
B	0.5 – 1.35 T	± 20%

Environmental Requirements

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

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 5: Environmental Requirements

Condition	Shipping/Storage Requirement	Operating Requirement
Temperature	14 - 140 F (-10°C to 60°C)	50 – 82.40 F (10°C to 28°C)
Humidity	10 ~ 90% RH	30 ~ 85% RH
Atmospheric pressure	700 - 1060 hPa	700 - 1060 hPa

Dimensions and Weight

Table 6: Dimensions and Weight

Item	Height	Depth	Width	Weight
Control unit	1100 mm	600 mm	600 mm	Approx 80 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 7: Electrical Specifications

REF	Voltage	Frequency	Current
Input power	220 – 240 VAC +/-10%	50/60 Hz	Maximum 3 kVA

Fuses

The main fuse of the system is a located in the main switch. No replacement of the fuse is necessary

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

Table 8: Fuse Specifications

Type	Rating	Quantity
hydraulic magnetic principle fuse	16A 250 VAC	1

***Notice**:*

Storage and transport only in original packaging.

Medical Safety Standards

The system complies with the following medical safety standards:

- IEC60601-1 AMD.1.ED.3.1.B2012
- IEC 60601-2-10:2016

Electromagnetic Compatibility

With regards to the EMC (electromagnetic compatibility) 4th Edition, medical electrical devices such - as the CoolTone are subject to special safety measures and must be installed and commissioned in accordance with the EMC instructions in the operating instructions or accompanying documents.

Portable and mobile HF communications equipment (e.g mobile telephones, cell phones) can impact medical electrical devices.

The CoolTone may only be operated using the original power cable indicated in the scope of delivery list. Operating the device with another power cable can lead to increased emissions or reduced interference resistance of the device.

The **CoolTone** must not be operated near active HF surgery devices or magnetic resonance tomography that can cause high levels of electromagnetic interference.

The device was tested for RF immunity only at selected frequencies. Nearby transients at other frequencies may result in degraded operation. The frequencies tested are listed in Table 4.

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

Use of accessories, applicators and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communication equipment (including peripherals such as antennas) should be used no closer than 30 cm (approx. 1 foot) to any part of the device **CoolTone** including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The **CoolTone** is developed according to the recognized standards of technology; the information on the intended use of the components is taken into account.

The electromagnetic compatibility of the **CoolTone** device has been tested on the original device with the applicators.

The **CoolTone device** contains no interchangeable components, cables or power cord that lead to deterioration of the EMC.

The **CoolTone device** does not contain any components which age over the course of the device life time and could lead to a deterioration of the electromagnetic compatibility. Thus, no maintenance is required during the life of the device to ensure basic safety. All tests according to standard IEC 60601-1-2 Ed. 4.0 were performed. No other standards and regulations for electromagnetic compatibility have been applied.

Table 9: Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The device **CoolTone** must emit electromagnetic energy in order to ensure its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class A	The device **CoolTone** is suitable for use in all establishments, including domestic establishments and those directly connected to the public supply network that also supplies buildings used for domestic purpose. CAUTION: The **CoolTone** is exclusively for professional health care facilities such as hospitals provided and tested. The **CoolTone** has an essential performance of 1.35T +/-20% which is not influenced by electromagnetic interference.
Harmonic emissions IEC 61000-3-2	Not performed because the device will not be connected to public grid.	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not performed because the device will not be connected to public grid.	

Table 10: 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	± 8 kV Contact Discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air Discharge	± 8 kV Contact Discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air Discharge	Floors should be made from wood, concrete or ceramic tiles. If floor is covered with synthetic material, the relative humidity must be at least 30 %
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	The supply voltage quality must correspond to that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 Line-to-Line	± 0,5 kV, ± 1 kV	± 0,5 kV, ± 1 kV	
Surge IEC 61000-4-5 Line-to-Earth	± 0,5 kV, ± 1 kV, ± 2 kV	± 0,5 kV, ± 1 kV, ± 2 kV	

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage dips in accordance with IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	The supply voltage quality must correspond to that of a typical commercial or hospital environment. If the user of the device CoolTone requires continued operation, even in the case of interruptions in the power supply, it is recommended that the device CoolTone be powered from an uninterrupted power supply or a battery.
	0 % U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°	0 % U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°	
Voltage interruptions accordance with IEC 61000-4-11	0% U_T; 250/300 cycle	0% U_T; 250/300 cycle	
Magnetic field of supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m 60 Hz	30 A/m 60 Hz	Magnetic fields at mains frequency should have the typical values found in a business or hospital environment. Note: U_T is the mains AC Voltage before application of the test level
Conducted **Disturbances induced by RF fields according IEC 610004-6**	3 V 0,15 MHz to 80 MHz 6 V in ISM Band between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz to 80 MHz 6 V in ISM Band between 0,15 MHz and 80 MHz 80% AM at 1 kHz	In the vicinity of devices, bearing the following symbol, interference is possible: 
Radiated RF EM fields according IEC 610004-3	3 V/m 80 MHz-2,7 GHz 80% AM to 1 kHz	3 V/m 80 MHz-2,7 GHz 80% AM to 1 kHz	

Table 11: Electromagnetic Immunity to HF radio communication equipment

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Energy (W)	Distance (m)	Immunity Test Level (V/m)
385	**380-390**	TETRA 400	Pulse Modulation 18 Hz	1,8	0,3	27
450	**430-470**	GMRS 460, FRS 460	FM 18Hz Derivation 1kHz Sine	2	0,3	28
710	**704-787**	LTE Band 13, 17	Pulse Modulation 217Hz	0,2	0,3	9
745						
780						
810	**800-960**	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 217Hz	2	0,3	28
870						
930						
1720	**1700-1990**	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0,3	28
1845						
1970						
2450	**2400-2570**	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0,3	28
5240	**5100-5800**	WLAN 802.11 a/n	Pulse Modulation 18Hz	0,2	0,3	9
5500						
5785						

Data Module Specifications

The device includes two data modules (Modem and Wi-Fi). Table 12 below lists the specifications for each model. Use each module only with the antenna provided by ZELTIQ.

Table 12: Data Module Specifications (Modem & 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 System with the data modem complies with the following medical safety standards:

- EN 60601-1-2: 2015 (provides the presumption of compliance to EN 60601-1:2006 + Amendment 1:2013

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 System with the data modem has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules (refer to Table 1 Data Modem 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 C

Disposal of Hazardous Materials

Various components of the system may contain materials whose disposal is subject to regulation. The upper module of 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.