ULTHERA® SYSTEM

INSTRUCTIONS FOR USE

Featuring DeepSEE Technology for Ultherapy PRIME

Control unit shown with optional cart and work surface pad.

Ultherapy PRIME

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Ultherapy
PRIME

Published in the USA

CAUTION: UNITED STATES FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

THE ULTHERA® SYSTEM IS INTENDED FOR USE ONLY BY PROPERLY TRAINED PHYSICIANS AND PROPERLY TRAINED PERSONS UNDER THE SUPERVISION OF SUCH A TRAINED PHYSICIAN (HENCEFORTH "THE USER").

PRIOR TO OPERATING THE SYSTEM, THE USER MUST THOROUGHLY READ AND UNDERSTAND THIS MANUAL. IMPROPER USE OF THE SYSTEM MAY CAUSE PERSONAL INJURY AND/OR DAMAGE TO THE SYSTEM THAT MAY INVALIDATE THE WARRANTY AGREEMENT.

Table of Contents

1 Introduction to Manual

1.1 Purpose

This Instructions for Use manual provides a description of the system components, its controls and displays, instructions for its operation, and other equipment information important to the user.

Warning: Do NOT operate the Ulthera® System before reading this manual thoroughly. Clinical training with additional materials are available by the Company or your local distributor. For more information on training available please contact your local representative.

1.2 Conventions

NOTE: Notes designate information of special interest.

CAUTION: Cautions alert the user to precautionary steps necessary to properly operate the system. Failure to observe these cautions may void the warranty.

Warning: Warnings alert the user to information that is of the highest importance and vital to the safety of the patient and user.

All procedures are broken down by numbered steps. Steps must be completed in the sequence they are presented.

Bulleted lists indicate general information about a particular function or procedure. They do not imply a sequential procedure.

Control names are spelled as they are on the system, and they appear in **Bold** text.

2 Medical Safety

2.1 Indications for Use

The Ulthera® System is indicated for use as a non-invasive dermatological aesthetic treatment to:

- Lift the eyebrow
- Lift lax submental (beneath the chin) and neck tissue; which can also affect the appearance of lax tissue in the submental and neck regions
- Improve lines and wrinkles of the décolleté
- Improve the appearance of skin laxity on the abdomen, anterior arms, and posterior arms

The Ulthera® System, in conjunction with the Ulthera® DeepSEE® transducer, allows for ultrasonic visualization of depths up to 8 mm below the surface of the skin. The indicated use of the imaging is to visualize the dermal and subdermal layers of tissue to:

- Ensure proper coupling of the transducer to the skin
- Confirm appropriate depth of treatment such as to avoid bone

2.1.1 Intended Use & Intended Population

The Ulthera® System is intended to apply focused ultrasound energy to the body to achieve temporary changes in the physical appearance of the skin.

Treatment with the Ulthera® System is intended for adult patients of all races/ethnicities, regardless of gender or Fitzpatrick Skin Type, seeking treatment for any indication listed in Section 2.1 and excluding those patients for whom treatment with the Ulthera® System is contraindicated in Section 2.2.

2.2 Contraindications

The Ulthera® System is contraindicated for use in patients with:

- Open wounds or lesions in the treatment area
- Severe or cystic acne in the treatment area
- Active implants (e.g., pacemakers or defibrillators), or metallic implants in the treatment area

2.3 Precautions

When not in use by trained personnel, the Ulthera® System Access Key should be removed from the system to help prevent unauthorized use. Keep the Ulthera® System Access Key in a designated place accessible only to authorized and trained personnel.

The Ulthera® System has not been evaluated for use over various materials. Therefore, treatment is not recommended directly over those areas with any of the following:

- Mechanical implants
- Dermal fillers
- Breast implants

Treatment energy is not recommended for use directly on an existing keloid.

The Ulthera® System has not been evaluated for use in patients on an anticoagulant treatment plan.

It is recommended that the following areas should be avoided during treatment:

- Thyroid gland, thyroid cartilage and trachea
- Major vessels and nerves
- Breast tissue
- Implants
- Eyes, eyelids, and within the orbital rim

The Ulthera® System has not been evaluated for use in the following patient populations:

- Pregnant or breast-feeding women
- Children
- Those with the following disease states:

- A hemorrhagic disorder or hemostatic dysfunction
- An active systemic or local skin disease that may alter wound healing
- Herpes Simplex
- Autoimmune Disease
- Diabetes
- Epilepsy
- Bell's Palsy

2.4 Patient Safety

Warning: Ulthera® should not be used on a patient's eyes or in a location or technique where ultrasound energy can reach the eye, such as on or over the eyelids or within the orbital rim.

Warning: Use this system only if you are trained and qualified to do so.

Warning: If any problems occur during system operation, take immediate action(s): lift the transducer off the patient's skin, press the **See** pushbutton on the handle to discontinue the treatment in progress, and/or press the red emergency **Stop** button to completely halt system operation**.**

Warning: Keep the system components 6 inches (15 cm) away from magnetically susceptible medical devices such as cochlear implants, neurostimulators, stents and shunts.

2.5 Potential Side Effects

2.5.1 Face and Neck

Side effects reported in the clinical evaluation of the Ulthera® System for the brow, submental (under the chin) area and neck treatment(s) were mild and transient in nature. These were limited to:

- Erythema (redness): The treated area may exhibit erythema immediately following treatment. This typically resolves within a few hours of treatment.
- Edema (swelling): The treated area may exhibit mild edema following treatment. This typically resolves within 3 to 72 hours of treatment.
- Welting: The treated area may exhibit a localized area of linear visible edema following treatment. This typically resolves within a week.
- Pain: Momentary discomfort may be experienced during the procedure while energy is being deposited. Post procedure discomfort typically resolves within 2 hours and 2 days. Tenderness to the touch is also possible and typically resolves within 2 days to 2 weeks of treatment.
- Bruising: Mild bruising, which is caused by damage to soft tissue blood vessels, may occur occasionally and typically resolves within 2 days to 2 weeks of treatment.
- Nerve Effects:
  - Transient local muscle weakness may result after treatment due to inflammation of a motor nerve. This typically resolves in 2 to 6 weeks of treatment.
  - Transient numbness may result after treatment due to inflammation of a sensory nerve. This typically resolves in 2 to 6 weeks of treatment.
  - Transient pain, paresthesia and/or tingling may be experienced. This typically resolves in 2 to 6 weeks of treatment.

No permanent injuries to facial nerves were reported during clinical trials.

- Burns/Scarring: The possibility for burns, which may or may not result in permanent scar formation, may occur if incorrect treatment technique is used (e.g., tilting transducer, incorrect line spacing, gel pockets, etc. see Sections 7.3.4 & 7.3.5). Some scars may respond to medical treatment and resolve fully.

2.5.2 Décolleté

Side effects reported in the clinical evaluation of the Ulthera® System for the décolleté treatment were mild and transient in nature. These were limited to:

- Erythema (redness): The treated area may exhibit erythema immediately following treatment. This typically resolves within a few hours of treatment.
- Edema (swelling): The treated area may exhibit mild edema following treatment. This typically resolves within 3 to 48 hours of treatment.
- Pain: Momentary discomfort may be experienced during the procedure while energy is being deposited. Post procedure discomfort typically resolves within 2 hours and 2 days. Tenderness to the touch is also possible and typically resolves within 2 days to 2 weeks of treatment.
- Welting: The treated area may exhibit a localized area of linear visible edema following treatment. This typically resolves within 1 day to 3 weeks of treatment.
- Raised area of edema: The treated area may exhibit a localized area of linear visible edema following treatment. This typically resolves within 1 day to 3 weeks of treatment.
- Bruising: Mild bruising, which is caused by damage to soft tissue blood vessels, may occur occasionally and typically resolves within 3 days and 3 weeks of treatment.
- Transient Sensory Nerve Effects (as a result of inflammation of the nerve):
  - Paresthesia and/or numbness may be experienced and typically resolves within 4 days to 5 weeks of treatment.
  - Tingling may result after treatment and typically resolves within 3 to 5 days of treatment.
  - Itching may result after treatment and typically resolves within 1 to 3 weeks of treatment.

No permanent nerve injuries were reported during clinical trials.

- Burns/Scarring: The possibility for burns, which may or may not result in permanent scar formation, may occur if incorrect treatment technique is used (e.g., tilting transducer, incorrect line spacing, gel pockets, etc. see Sections 7.3.4 & 7.3.5). Some scars may respond to medical treatment and resolve fully.

2.5.3 Abdomen, Anterior Arms, and Posterior Arms

Side effects reported in the clinical literature review of the Ulthera® System for treatment of the abdomen, anterior arms, and posterior arms were mild and transient in nature and showed to resolve within a few hours to 2 weeks after treatment. These were limited to:

- Bruising
- Edema
- Erythema
- Pain
- Tenderness
- Welting

2.6 Complaints and Adverse Events

No serious related adverse events were observed during the clinical study evaluation of the Ulthera® System.

Ulthera, Inc. follows MDR (Medical Device Reporting) rules for handling complaints and adverse events. Should an adverse event be suspected or reported, contact Ulthera, Inc. at the number on the back page of this document; for those outside the U.S., contact your local Ulthera representative.

2.7 Post-Market Safety Surveillance

The following adverse events have been identified during routine clinical use following FDA clearance (post market) of the Ulthera® System, specifically, and generally in the clinical literature for devices using micro-focused ultrasound. Because they are reported voluntarily from a population of uncertain size it is not always possible to reliably estimate their frequency or establish a causal relationship to the Ulthera® System. These events have been chosen for inclusion due to a combination of their seriousness, frequency of reporting, or potential causal connection to a micro-focused ultrasound system:

- Skin/Soft Tissue:
- Edema
- Erythema
- Bruising
- Pain or burning/tingling sensation
- Burns or blisters
- Nodules
- Fat/volume loss
- Skin sagging/drooping, asymmetry
- Urticaria, rash, pruritus
- Pigmentary change
- Scarring

Neurological:

- Numbness
- Paresthesia
- Palsy, paresis (muscle weakness)
- Speech difficulty
- Headache/migraine
- Vision changes

Reported severity and duration of these effects has varied, and nerve effects lasting for months have been described. For the specific adverse events that occurred in the clinical evaluation of the Ulthera® System, please see Section 2.5.

3 System Overview

3.1 System Description

The Ulthera® System integrates the capabilities of ultrasound imaging with those of ultrasound therapy.

The imaging feature allows the user to visualize the skin and sub-dermal regions of interest before treatment. It also allows the user to assure proper skin contact in order to deliver the energy at desired depths.

The therapy feature directs acoustic waves to the treatment area. This acoustic energy heats tissue as a result of frictional losses during energy absorption, producing discrete points of coagulation.

3.2 System Components and Features

The Ulthera® System consists of three primary components: the control unit with integrated touchscreen, the handpiece with cable, and interchangeable transducers (see Figure 3.1).

Figure 3.1: Main components of the Ulthera® System: control unit (top), handpiece (bottom right), and image/treat transducer (bottom left) that inserts into the handpiece receptacle.

3.2.1 Control Unit

The control unit (UC-1 Control Unit (PRIME)) is the tabletop information center for the Ulthera® System. It houses the touchscreen monitor and Graphical User Interface (GUI) that allows the user to interact with the device. This screen sets and displays the operating conditions, including equipment activation status, treatment parameters, system messages and prompts, and ultrasound images. Figure 3.2 illustrates the physical features of the control unit, such as the various connector ports and power controls.

Figure 3.2: Control Unit front view (left) and rear view (right). See Table 3.1 for a description of the controls and connector ports of the control unit.

Table 3.1: Control Unit Connector Ports and Controls (See Figure 3.2)

ITEM		DESCRIPTION
1	Handpiece Connector Receptacle	Socket for plugging in handpiece cable
2	USB Ports (two)	For Ulthera® System Access Key
3	Emergency Stop	Halts system operation if pressed
4	On/Off Button	• Momentarily press to turn system ON • Momentarily press to turn system OFF • Press and hold to force system shutdown
5	Rear Panel Banana Jack	Banana jack is used during product servicing only and is not to be used during normal system operation.
6	Main Power Switch	Supplies power to system. Leave ON (symbol "|" pressed in)
7	Power Cord Receptacle	Socket for attachment of power cord pigtail

Below the monitor, on the front panel of the control unit is a handpiece connector receptacle that interfaces with the handpiece cable. On the front right of the panel is an On/Off button and an emergency Stop button. When turned OFF via the On/Off button the system goes into a very low power standby mode unless the Main Power Switch is also turned to the OFF position by pressing the 'O' symbol. The front of the control unit also has two Universal Serial Bus (USB) ports: both ports may be used for the Ulthera® System Access Key.

Warning: When not in use by trained personnel, the Ulthera® System Access Key should be removed from the system to help prevent unauthorized use. Keep the Ulthera® System Access Key in a designated place accessible only to authorized and trained personnel.

The rear of the control unit has an AC power receptacle and the main power switch. The main power switch should be left in the powered position (with the "|" pressed inward). In such a configuration, the control unit may be turned ON via the front panel On/Off button and can be turned OFF via either the front panel On/Off button or the graphical user interface.

3.2.2 Handpiece

The handpiece is a handle with an integrated receptacle for insertion of a transducer on one end and an electrical cable for attachment to the control system on the other end. The handpiece has two types of buttons: one to image (SEE) and the other to deliver therapy (TREAT). Figure 3.3 provides two

views of the handpiece, including one showing it connected to an Image/Treat transducer. Table 3.2 is a description of the various components and features illustrated in Figure 3.3.

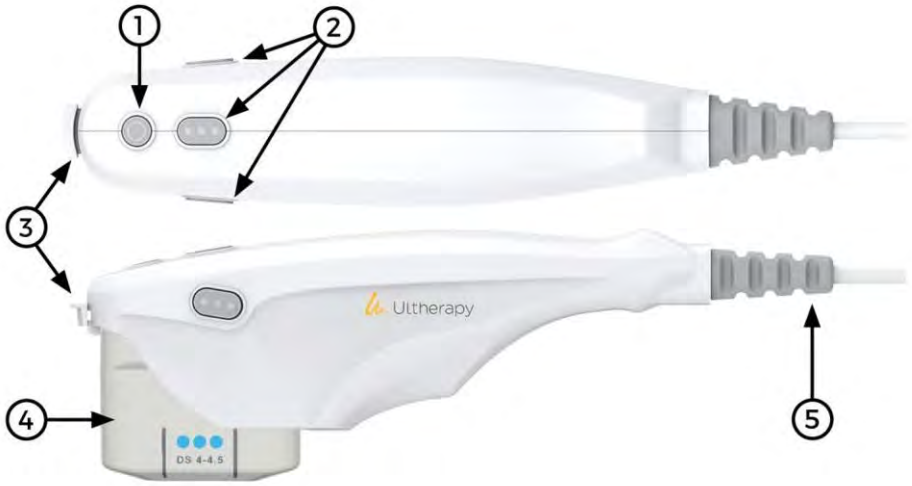


Figure 3.3: Handpiece with transducer inserted, (top and side views)

Table 3.2: Handpiece and Transducer Description

ITEM		**DESCRIPTION**
1	**SEE** Pushbutton	• Engages IMAGING state (if not already imaging) • Places system in READY state (times out in 40 seconds) • Stops TREATING if treatment is in progress
2	**TREAT** Pushbuttons	Engages TREATING state
3	Latch	Locks transducer into handpiece
4	Transducer	Image/Treat transducer
5	Strain Relief/Cable	Connects handpiece to Control Unit

3.2.3 Transducers

Figure 3.4 is an illustration of an image/treat transducer. The transducer can image and treat a region of tissue up to 25 mm long and can image a depth of up to 8 mm. Treatment occurs along a line less than or equal to the transducer's active length, which is indicated by guides on the sides of the transducer, as described in Table 3.3. An additional guide at the front tip of the transducer represents the center of the treatment line. In therapy mode, bursts of sound energy create a linear sequence of individual, discrete, thermal coagulation points (TCPs). A label atop the transducer provides the transducer type, expiration date, and other information.

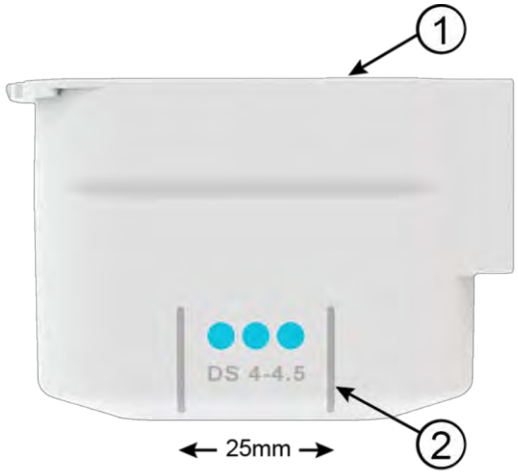


Figure 3.4: Image/Treat transducer separated from handpiece (see Table 3.3)

Table 3.3: Transducer Description

ITEM		DESCRIPTION
1	Labeling	Transducer type and other information
2	Treat guides	Markers denoting maximum treatment line length and center of treatment line (center of transducer)

The types of transducers reflect variations in frequencies and treatment depths as shown in Table 3.4.

Table 3.4: Transducer Types

TRANSDUCER TYPE	TREAT FREQUENCY	TREAT DEPTH	IMAGE DEPTH	SCAN LENGTH
DS 7 – 3.0	7 MHz	3.0 mm	0 – 8 mm	25 mm
DS 7 – 3.0N	7 MHz	3.0 mm	0 – 8 mm	14 mm
DS 4 – 4.5	4 MHz	4.5 mm	0 – 8 mm	25 mm
DS 7 – 4.5	7 MHz	4.5 mm	0 – 8 mm	25 mm
DS 10 – 1.5	10 MHz	1.5 mm	0 – 8 mm	25 mm
DS 10 – 1.5N	10 MHz	1.5 mm	0 – 8 mm	14 mm

3.2.4 Essential Components

Other essential components provided for the operation of the Ulthera® System are the AC power cord with line filter and plug that connects to the AC power outlet, a power cord pigtail that connects the AC power cord to the Ulthera® System and the proprietary Ulthera® System Access Key.

Ultrasound gel to facilitate transmission of the acoustic energy is also required, but is not provided as part of the system.

3.3 System Specifications

3.3.1 Physical Dimensions

Control Unit

Open height of control unit at 90 degrees	<16.69" (424 mm)
Width	19.4" (493.6 mm)
Depth	13.1" (338.5 mm)
Weight	≤ 27 lbs. (12.2 kg)

Handpiece and cable, with transducer

Height	3.9" (99 mm)
Width	2.1" (53 mm)
Depth	11.1" (282 mm)
Weight	1.5 lbs. (0.7 kg)
Cable Length	75" (1.9 m)

System (control unit, handpiece with cable – including transducer)

Weight	28.5 lbs. (12.9 kg)

3.3.2 Monitor

18.5" (469.9 mm) TFT LCD, 1920 x 1080 resolution, with integrated touchscreen.

3.3.3 I/O Connections

USB 2.0, two on the front panel

3.3.4 Transducers

DS 7 - 3.0	7 MHz Treatment frequency, 3.0 mm depth, (UT-1)
DS 7 - 3.0N	7 MHz Treatment frequency, 3.0 mm depth, narrow patient contact footprint, (UT-1N)
DS 4 - 4.5	4 MHz Treatment frequency, 4.5 mm depth, (UT-2)
DS 7 - 4.5	7 MHz Treatment frequency, 4.5 mm depth, (UT-3)
DS 10 - 1.5	10 MHz Treatment frequency, 1.5 mm depth, (UT-4)
DS 10 - 1.5N	10 MHz Treatment frequency, 1.5 mm depth, narrow patient contact footprint, (UT-4N)

3.3.5 Handpiece

Ulthera® DeepSEE® Handpiece (UH-2)

3.3.6 Access Key

Ulthera® System User Access Key (UK-1)

3.3.7 Treatment Controls

Energy, Length

See, Treat, Stop, and Cancel

3.3.8 Treatment Parameters

Treat Depths: Probe dependent, 1.5 mm to 4.5 mm

Treat Frequency: 4 MHz, 7 MHz, 10 MHz nominal

Treat Energy: Less than 3 J

Treat Time On: 0 to 150 ms, 1 ms resolution, (Energy < 3 J)

TCP Spacing: 1 to 5 mm, 1.5 mm standard, 0.1 mm resolution

Treat Line Length: 5 to 25 mm

Treatment Output Energy Accuracy: + 20%

3.3.9 Image Display

Modes: B-Mode

Ultrasound Frequency Range: 12-25 MHz
System Dynamic Range: 110 dB total
Instantaneous Displayed Dynamic Range: 53 dB
Scan Lines: 250, at 0.1 mm spacing
Displayed Field of View: 25 x 8 mm

3.3.10 Measurement Tools

Distance calipers, 0.1 mm precision, and measurement accuracy ± 5%.

3.3.11 Power

100 – 240 VAC, 50/60 Hz, 3 A maximum
Fuse: (2) 5 x 20 mm, 6.3 A fast acting, 250 V

3.3.12 Environmental

Operating Environment, System, Handpiece and Transducers

Dry location (non-condensing), indoor use only.
10 to 30°C (50 to 86°F), 30 to 85% R.H.
700 to 1060hPa (0.7 to 1.05 ATM)

Shipping and Storage, System without Transducers

Dry location (non-condensing)
-20 to 65°C (-4 to 149°F), 15 to 95% R.H.

Shipping and Storage, Transducers

15 to 30°C (59 to 86°F) Room Temperature, 15 to 95% R.H.
Protect from freezing
500 to 1060hPa (0.5 to 1.05 ATM)

4 System Safety

The following precautions and warnings must be reviewed and observed:

4.1 Electrical and Fire Safety

Warning: To avoid risk of electric shock, always inspect the Ulthera® transducer, handpiece and cable before use. Do not use a damaged cable or a transducer that has been damaged or is leaking fluid. Only use supplied AC power cord with line filter and plug and supplied power cord pigtail. If either is damaged, contact Ulthera, Inc.

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

The Ulthera® System is designed for efficiency and ease of use, requiring no calibration, or preventive maintenance by the user. It contains no user-serviceable components. Should service be necessary, please contact Ulthera, Inc. directly for professional assistance.

The Ulthera® System is intended for indoor, dry location use. Avoid liquid spills and splashes. Keep coupling gel away from the handpiece-transducer connections.

The Ulthera® System is supplied with a custom three-conductor AC power cord with a line filter and plug along with a power cord pigtail. Use of a non-supplied power cord/pigtail or any other unapproved cables/accessories may lead to an increase in electromagnetic emissions. Use a properly grounded outlet and always plug the power cord directly into the outlet. Never remove the ground conductor or compromise the ground conductor via any AC adapter plugs or extension cords.

Disconnect the power cord from the outlet by pulling on the plug not the cord.

AC powered USB printers or storage devices may pose a shock hazard. Do not touch the USB connectors and the patient at the same time.

Turn off the AC power switch and disconnect the AC power supply before cleaning the control unit.

Do not remove the covers on the control unit or handpiece; the control unit contains hazardous voltages. The Ulthera® System contains no user-serviceable components. If the system requires service, contact Ulthera, Inc.

No modification of this equipment is allowed.

The Ulthera® System should not be used near flammable gases or anesthetics. Fire or explosion can result. The Ulthera® System is not AP or APG rated.

Avoid restricting ventilation under and behind the Ulthera® control unit. Maintain an open space of at least 4 inches/10 cm around the control unit. If ventilation holes are obstructed, the system could overheat.

The Ulthera® transducers are rated as a Type B patient applied part. It may provide a connection between the patient and protective earth. This may present a hazard if the patient becomes connected to other equipment with excessive electrical current leakage.

Do not touch the handpiece electrical contacts and patient simultaneously.

To avoid a burn hazard, remove the transducer from the patient before performing HF electrosurgical procedures.

4.2 Equipment Use and Care

CAUTION: Failure to observe these precautions may void the warranty.

The Ulthera® handpiece connectors must be kept clean and dry. Do not use the transducer if the connectors have been immersed in liquid. See the instructions for cleaning the transducer.

Every effort has been made to make the transducers as rugged as possible; however, they may be permanently damaged if dropped onto a hard surface or if the membrane is punctured. Transducers damaged in this manner are not covered by the warranty.

The Ulthera® System has no user-serviceable components. Do not attempt to open the control unit enclosure or transducers. Contact Ulthera, Inc. if service is required.

When not in use by trained personnel, the Ulthera® System Access Key should be removed from the system to help prevent unauthorized use. Keep the Ulthera® System Access Key in a designated place accessible only to authorized and trained personnel.

4.3 Ergonomic Safety

Warning: Ultrasound scanning has been associated with repetitive motion injuries such as carpal tunnel syndrome. To reduce chances of such injury, maintain a balanced, comfortable posture while scanning, avoid gripping the handpiece too tightly, and keep hands and arms in a comfortable position while using.

4.4 Medical Ultrasound Safety

Warning: Use this system only if you are trained and qualified to do so.

The Ulthera® System has a fixed, non-adjustable output power level for imaging, well below the limits set by FDA guidelines. However, ultrasound exposure times should be limited to the shortest amount of time needed to complete the treatment. The ALARA principle (As Low As Reasonably Achievable) can be followed by minimizing the examination time.

If the system displays unusual/inconsistent behavior, discontinue use and contact Ulthera, Inc.

Under some conditions (for example, high ambient temperature and long scanning period), the transducer surface temperature may exceed 41°C. Scanning will be automatically disabled if the internal transducer temperature reaches 43°C.

4.4.1 The ALARA Principle and Usage

ALARA (As Low As Reasonably Achievable) is the recommended guidance for ultrasound scanning. Details are thoroughly described in "Medical Ultrasound Safety", published by the American Institute of Ultrasound in Medicine (AIUM). The Ulthera® System has a fixed, low acoustic output for imaging which helps keep exposure and bio-effects to a minimum. This simplicity of the Ulthera® System and clinical protocols enhances the user's ability to follow the ALARA principle.

The imaging mode determines the nature of the ultrasound beam. The Ulthera® system has B-mode scanning only, whereby the acoustic beam is scanned over a wide field-of-view. The Ulthera® System has a fixed transmit focal depth and power level, relieving the user of adjusting these parameters. Limiting imaging time therefore minimizes exposure time.

The Ulthera® imaging/therapy transducer selection depends upon the desired clinical protocol. The variables which affect the way the user implements the ALARA principle include: patient body size, location of the bone relative to the focal point, attenuation in the body, ultrasound exposure time, and potential localized heating of the patient due to transducer surface temperature.

System controls are divided into three categories relative to output: controls that directly affect output, controls that indirectly affect output, and receiver controls.

Direct Controls. Fixed settings limit acoustic output through default. The acoustic output parameters that are set at default levels are the mechanical index (MI), thermal index (TI), and the spatial peak temporal average intensity (I_{SPTA}). The system does not exceed an MI and TI of 1.0 or an I_{SPTA} of 720 mW/cm^2 for all modes of operation.

Indirect Controls. The controls that indirectly affect output are controls affecting freeze (Scan N) or scan (Scan Y). Tissue attenuation is directly related to transducer frequency.

Receiver Controls. The only receiver control is the display brightness control and it does not affect output. It should be used if necessary to improve image quality.

4.4.2 Acoustic Output Measurement

The acoustic output for the Ulthera® was measured and calculated in accordance with the IEC 60601-2-37 (imaging) and IEC 60601-2-62 (therapy).

Table 4.1: Acoustic Output Parameter Description

PARAMETER	**DESCRIPTION**
MI	Mechanical Index
TIS	Soft Tissue Thermal Index in an auto-scanning mode
$I_{pa,a}$@MI_{max}	Derated pulse average intensity at MI maximum
$I_{spta,a}$	Derated spatial peak temporal average
p_r, $p_{r.3}$	Peak, and derated peak rare factional pressure associated with the transmit pattern giving rise to the value reported under MI (megapascals)
PII, $PII_{.3}$	Pulse intensity integral, and derated PII
W_O	Ultrasonic power (milliwatts)
f_c	Center frequency (MHz). For MI, f_c is the center frequency associated with the transmit pattern giving rise to the global maximum reported value of MI

The system meets the imaging output display standard for MI and TI of IEC 60601-2-37 (see Table 4.2). The system and transducer combination do not exceed an MI or TI of 1.0 in any operating mode. Therefore, the MI or TI output display is not required and is not displayed on the system for these modes.

Table 4.2: Acoustic Output Tables

TRANSDUCER MODEL	**$I_{spta,a}$ [mW/CM²]**	**TI TYPE**	**TI VALUE**	**MI**	**$I_{pa,a}$ @MI_{MAX} [W/CM²]**
DS 7 - 3.0	0.0618	TIS	0.000738	0.22	19
DS 7 - 3.0N	0.0618	TIS	0.000738	0.22	19
DS 4 - 4.5	0.0483	TIS	0.000494	0.19	17
DS 7 - 4.5	0.0483	TIS	0.000494	0.19	17
DS 10 - 1.5	0.0674	TIS	0.000869	0.19	19
DS 10 - 1.5N	0.0674	TIS	0.000869	0.19	19

Measurement uncertainty for power, pressure, intensity, and other quantities that are used to derive the values in the acoustic output table were derived in accordance with IEC 60601-2-37 and were

below limits which would affect global output levels. The measurement uncertainty values were determined by making repeat measurements.

Table 4.3: Acoustic Measurement Precision and Uncertainty

PARAMETER	UNCERTAINTY (95% CONFIDENCE)
p_r	9.6%
$p_{r.3}$	9.6%
W_O	19.2%
f_c	2%
PII	19.1%
$PII_{.3}$	19.1%

Ultrasound energy is delivered to discrete locations, not able to be modified by the user. Outside of the treatment area, the average acoustic intensity does not produce a tissue effect. Although the treatment area is small and volume of TCP created is less than 1 mm^3 for all transducers, care should be taken not to treat successive lines without first moving the transducer to the next treatment area. Having discrete energy settings and treatment locations that are fixed minimize the risk of unintended tissue heating. Parameters associated with therapy ultrasound field distribution by transducer per IEC 60601-2-62 are presented in Table 4.4 and Figure 4.1.

Table 4.4: Therapy Ultrasound Field Distribution by Transducer

TRANSDUCER	I_{SPTA}* [x 10^8 W/M^2]	BEAM WIDTH (AT FOCUS)	ORTHOGONAL BEAM WIDTH (AT FOCUS)
DS 4 - 4.5	2.57	0.39 mm	0.39 mm
DS 7 - 3.0	2.59	0.27 mm	0.29 mm
DS 7 - 3.0N	2.59	0.27 mm	0.29 mm
DS 7 - 4.5	4.32	0.27 mm	0.29 mm
DS 10 - 1.5	0.62	0.24 mm	0.25 mm
DS 10 - 1.5N	0.62	0.24 mm	0.25 mm

*Linearly calculated per IEC 60601-2-62 and without attenuation of soft tissue assumption.

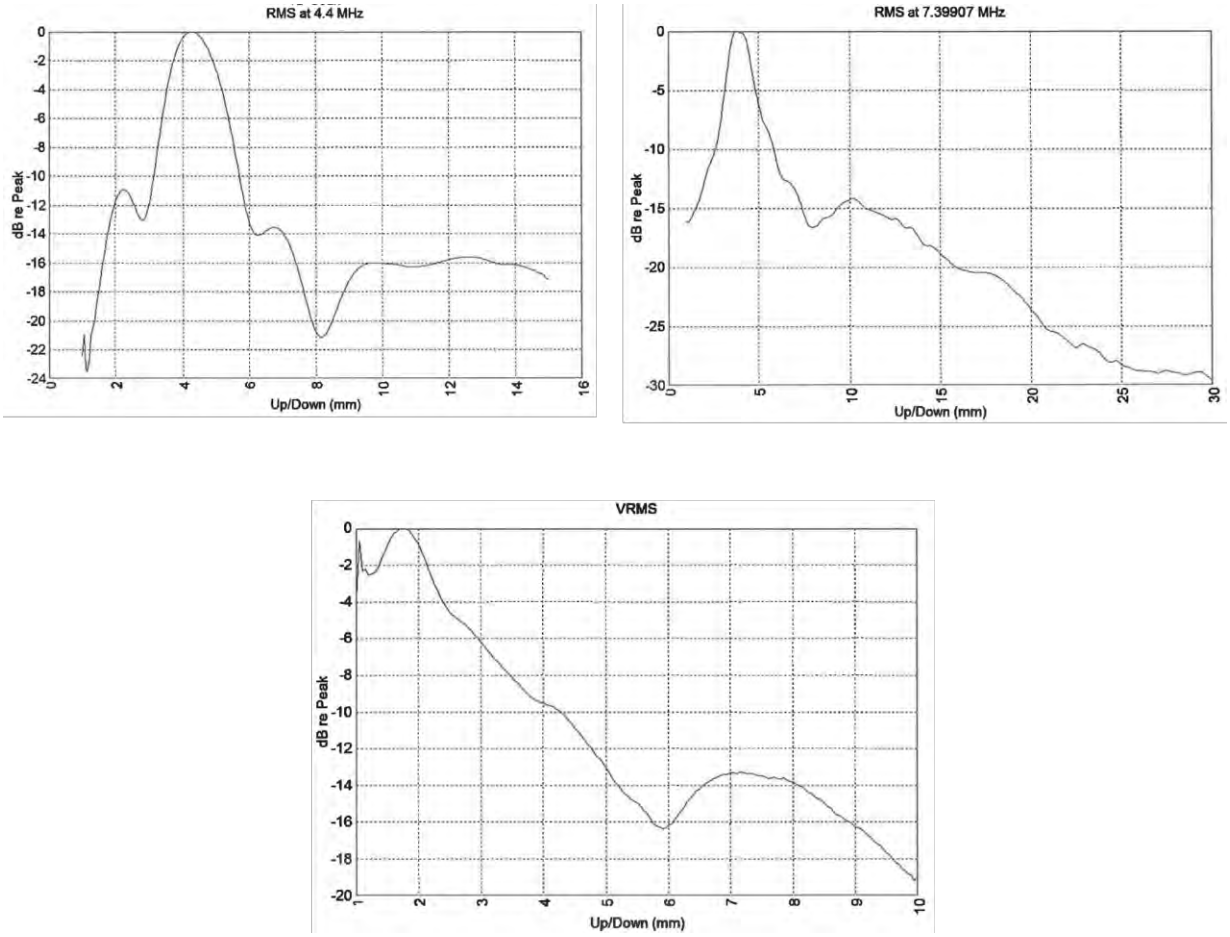


Figure 4.1: 1-D Z Scan Plots (Data gathered from 1005101RPT)

Cavitation is not expected due to insufficient total entry power. The peak negative pressure does not generate cavitation or sufficient heating to produce a tissue effect outside of the designated treatment area.

Table 4.5: Ultrasound Entry Power

4 MHz	
Total Entry Power (W) at Clinical Settings	27
Z_E (mm)	0
R_{Ipta}	1
Entry Effective Intensity at Clinical Settings (I_{eff}) x10^6 W/m^2	1.1
Peak Rarefactional Acoustic Pressure at Clinical Settings (Pa x 10^6)	27.5
7 MHz	
Total Entry Power (W) at Clinical Settings	22
Z_E (mm)	0
R_{Ipta}	1
Entry Effective Intensity at Clinical Settings (I_{eff}) x10^6 W/m^2	1.4
Peak Rarefactional Acoustic Pressure at Clinical Settings (Pa x 10^6)	36
10 MHz	
Total Entry Power (W) at Clinical Settings	4
Z_E (mm)	0
R_{Ipta}	1
Entry Effective Intensity at Clinical Settings (I_{eff}) x10^6 W/m^2	3.8
Peak Rarefactional Acoustic Pressure at Clinical Settings (Pa x 10^6)	14

4.5 Electromagnetic Compatibility and Immunity

The Ulthera® System's RF emissions are very low and are not likely to cause interference in nearby electronic equipment.

The Ulthera® System is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

Mains (AC) power quality should be that of a typical commercial or hospital environment.

Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% to avoid excessive static electricity.

The Ulthera® System has essential performance requirements developed in accordance with current electrical safety and electromagnetic compatibility (EMC) standards and guidances. They are as follows:

- Free from the display of incorrect numerical values associated with either therapy or imaging. (Incorrect in the sense that the displayed value differs from what is produced or intended.) Measurements must be accurate. The output energy tolerance is ±20%.
- Free from the production of unwanted, unintended, or excessive ultrasound output in either therapy or imaging modes.
- Free from the display of incorrect safety indications.
- Free from the production of excessive transducer surface temperature.
- Free from the production of unwanted tissue damage outside of the target region.

- Free from noise or distortion in the image which might appear to be a physiological effect, and which might alter treatment.

Warning: The Ulthera® System should not be situated adjacent to, or stacked with, other electronic equipment. If the system must be installed in close proximity to other equipment, both the Ulthera® System and the nearby equipment should be observed to verify normal operation in that configuration.

CAUTION: EMI (Electro-Magnetic Interference) from other electronic systems may cause degradation of the ultrasound image. The Ulthera® System has been designed to meet the standards of IEC60601-1-2 for electromagnetic compatibility; however some computer equipment unintentionally emits strong interfering RF signals. The imaging element of the Ulthera® System operates in the frequency range of 12-25 MHz. Any electronic equipment in close proximity to the system which operates in this range may cause interference in imaging. Portable RF communication devices may also affect The Ulthera® System. If image quality is degraded by EMI, the system may need to be relocated or reconfigured.

Warning: Use of accessories other than those specified, may result in increased emissions, or decreased immunity of this system. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Ulthera® System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

4.5.1 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Ulthera® System is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.

Table 4.6: Electromagnetic Emissions

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions (CISPR 11)	Group 1	The Ulthera® 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	The Ulthera® System is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions (IEC 61000-3-2)	Class A	
Voltage fluctuations/flicker (IEC 61000-3-3)	Complies	

Warning: The Ulthera® System should not be used adjacent to, or stacked with other electronic equipment. If the system must be installed in close proximity to other equipment, both the Ulthera® System and the nearby equipment should be observed to verify normal operation in that configuration.

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

4.5.2 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Table 4.7: Electromagnetic Immunity

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT– GUIDANCE
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8, 15 kV air	±8 kV contact ±2, 4, 8, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. Note: Electrostatic discharge (ESD) from other electronic systems or the environment may cause degradation of the Ulthera® system performance. The Ulthera® System has been designed to meet the standard of IEC 60601-4-2, *Medical electrical equipment-Guidance and interpretation. Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems*. However, due to software and firmware limitations, there is potential for ESD to cause the Ulthera® system to require the user to re-log in, re-insert the Access Key or handpiece, or present with error codes that require a reboot of the system to resolve. If these occur, follow the on-screen prompts to resolve the issue. If a reboot of the system is required, turn off the system using the power button on the front, and follow the instructions in Section 7.3 to restart the system. If errors persist, please contact Ulthera Support.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV and 1 kV differential mode ±0.5 kV, 1kV and 2 kV common mode	±0.5 kV and 1 kV differential mode ±0.5 kV, 1kV and 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% of U_N for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% of U_N for 1 cycle at phase angle of 0° 70% of U_N for 25/30 cycles at phase angle of 0° 0% of U_N for 250/300 cycles	0% of U_N for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% of U_N for 1 cycle at phase angle of 0° 70% of U_N for 25/30 cycles at phase angle of 0° 0% of U_N for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Ulthera® System requires continued operation during power mains interruptions, it is recommended that the Ulthera® System be powered from an uninterruptible power supply.
Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m at 60Hz	30 A/m at 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE 1: U_N is the AC mains voltage prior to application of the test level.

NOTE 2: System interruption may result in a safe restart classified as a nuisance.

Table 4.8: Electromagnetic Immunity Continued

IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Portable and mobile RF communications equipment should be used no closer to any part of the Ulthera® System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 V in ISM bands	3 Vrms 150 kHz to 80 MHz 6 V in ISM bands	Recommended separation distance: $d = 0.35 \sqrt{P}$ (80 MHz to 800 MHz) $d = 0.70 \sqrt{P}$ (800 MHz to 2.7 GHz) where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment containing a transmitter. (See NOTE 1 and NOTE 2)
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	
Proximity magnetic fields IEC 61000-4-39	134.2 kHz @ 65 A/m 13.56 MHz @ 7.5 A/m Note 3	134.2 kHz @ 65 A/m 13.56 MHz @ 7.5 A/m Note 3	

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.

NOTE 3: Table 9 IEC 60601-1-2; see Table 4.9.

Table 4.9: IEC 60601-1-2 Test Specifications for Enclosure Port Immunity to RF Wireless Communication Equipment

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation	Immunity Test Level (V/m)
385	380 to 390	TETRA 400	Pulse Modulation [b] 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse Modulation [b] 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation [b] 18 Hz	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation [b] 217 Hz	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation [b] 217 Hz	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	Pulse Modulation [b] 217 Hz	9
5 500				
5 785				
If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.				
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50% duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.				

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

4.5.3 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Ulthera® System

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

Table 4.10: Recommended Separation Distances

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER IN W	**SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER, METERS**		
	150 kHz to 80 MHz $d=1.17\sqrt{P}$	80 MHz to 800 MHz $d=1.17\sqrt{P}$	800 MHz to 2.5 GHz $d=2.33\sqrt{P}$
0.01	0.12 m	0.12 m	0.23 m
0.1	0.37 m	0.37 m	0.74 m
1	1.2 m	1.2 m	2.3 m
10	3.7 m	3.7 m	7.4 m
100	12 m	12 m	23 m

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.

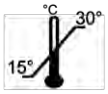
4.6 Disposal

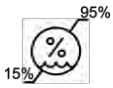
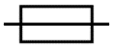
Depleted transducers should be disposed of in accordance with federal, state, and local regulations.

4.7 Safety Symbols

A variety of symbols appear on the transducer, handpiece, or control unit in accordance with regulatory guidance.

SYMBOL	**DEFINITION**
	Type B Applied Part (Reference Number 5840)**
	CE marking indicating manufacturer's declaration of compliance with appropriate EU product directives
	UL Certification Mark Medical – Ultrasound Equipment as to Electrical Shock, Fire and Mechanical Hazards Only In Accordance with standards listed in Section 11 Not including the Ulthera® System Cart
	UL Rebuilt Certification Mark Medical – Ultrasound Equipment as to Electrical Shock, Fire and Mechanical Hazards Only In Accordance with standards listed in Section 11 Not including the Ulthera® System Cart

SYMBOL	DEFINITION
	Consult instructions for use (Reference Number 5.4.3)*
	Date of Manufacture (Reference Number 5.1.3)*
	Serial Number (Reference Number 5.1.7)*
	Emergency Stop (Reference Number 5638)**
	Power Standby Switch (Reference Number 5009)**
	Indoor Use Only (Reference Number 5957)**
	Keep electrical waste separate from municipal waste (Reference Number 6414)***
	Recycle Packaging (Reference Number 1135)***
IPX1	Mated handpiece and transducer protected from the effects of vertically dripping water (Reference IEC 60529 Table 3)
IPX0	No protection from water (Reference IEC 60529 Table 3)
IPX7	Protected against the effects of temporary immersion in water (Reference IEC 60529 Table 3)
	Catalogue Number (Reference Number 5.1.6)*
	Manufacturer (Reference Number 5.1.1)*
	Authorized representative in the European Community (Reference EU Blue Book Guide)
	Storage Temperature Limit (Reference Number 5.3.7)*

SYMBOL	DEFINITION
	Keep Dry (Reference Number 5.3.4)*
	Fragile, handle with care (Reference Number 5.3.1)*
	Relative Humidity Limitation (Reference Number 5.3.8)*
	Use-by date (Reference Number 5.1.4)*
	Batch code (Reference Number 5.1.5)*
	Alternating Current (Reference Number 5032)**
	Fuse (Reference Number 5016)**
	General Mandatory Action (Reference Number M001)***
	Refer to Instruction Manual/Booklet (Reference Number M002)***
	Importer in the European Community (Reference Number 5.1.8)*
℞ ONLY	Rx Symbol for Prescription Only Devices (Reference FDA 21 CFR 801.109)
	Medical Device (Reference Number 5.7.7)* Note: The Ulthera® System is not considered a medical device within the European Union

*Symbol from ISO 15223-1, Medical devices - Symbols to be used with information to be supplied by the manufacturer

**Symbol from IEC 60417, Graphical symbols for use on equipment, Database Snapshot

***Symbol from ISO 7000, Graphical symbols for use on equipment - Registered symbols

5 Setting Up for First-Time Use

5.1 Unpacking

The control unit and handpiece are shipped together in one container. Transducers are packaged and shipped separately from the control unit and handpiece, in ready-to-use, non-sterile pouches.

5.2 Physical Environment

5.2.1 System Base

The system may be placed on a cart or counter with the depth to accommodate the control unit, handpiece and power cord/pigtail provided. A cart is recommended to offer maximum mobility for the user when treating the patient and provide a more secure housing for the handpiece. System weight and dimensions are listed in Section 3.3 System Specifications.

Space should be provided around the back, sides, bottom and top of the system for cooling. In continuous use for extended periods of time, it is normal for the system to be warm.

Always position the Ulthera® System so that the power cord is easily accessible. This is essential for quick disconnection in case of an emergency. Be sure to avoid tight spaces where the power cord is pressed against walls or squeezed into tight spaces. There should always be a clear path to the power cord. Avoid placing objects or equipment in a way that blocks access to the power cord.

5.2.2 Electromagnetic Environment (See the detailed EMC Guidance in Section 4.5)

The system is not likely to cause interference in nearby electronic equipment; however, other electronic equipment should not be stacked or placed immediately adjacent to the system.

Flooring should be wood, concrete or ceramic tile. If covered with synthetic material, the relative humidity should be at least 30%.

Warning: The Ulthera® System should not be situated adjacent to, or stacked with, other electronic equipment. If the system must be installed in close proximity to other equipment, both the Ulthera® System and the nearby equipment should be observed to verify normal operation in that configuration.

CAUTION: EMI (Electro-Magnetic Interference) from other electronic systems may cause degradation of the ultrasound image. The Ulthera® System has been designed to meet the standards of IEC60601-1-2 for electromagnetic compatibility; however, some computer equipment unintentionally emits strong interfering RF signals. Portable RF communication devices may also affect the Ulthera® System. If image quality is degraded by EMI, the system may need to be relocated or reconfigured.

5.2.3 User Environment

Treatments with the Ulthera® System will be primarily conducted in the treatment room, a professional healthcare facility environment, or office. This room should be well-lit, indoor, climate-controlled, clean environment with minimum distractions. During treatment, the system is typically placed on either side of the patient treatment chair, with the patient fully reclined in a horizontal position, and the clinician seated or standing at the head of the patient.

5.3 Electrical Requirements

The Ulthera® System has an international power supply and may be used with 100-240 VAC, 50/60 Hz power systems. See Section 4.1 Electrical and Fire Safety for additional information.

5.4 Connecting Components

5.4.1 Connecting the Handpiece

The handpiece connector receptacle is located on the left side of the control unit's front panel as shown in Figure 5.1. To attach the handpiece connector, align it with the white dot facing up and push it into the receptacle. It will latch when seated properly.

Figure 5.1: Handpiece Connector Receptacle

To disconnect the handpiece, twist the coupling ring on the connector counterclockwise while pulling outwards.

5.4.2 Identifying and Connecting Transducers

Transducers are identified by the label on the top of the transducer, which includes the name of the transducer (Ulthera® DeepSEE®), treatment frequency and treatment depth (DS X-X), a unique serial number, a part number, and date of manufacture.

The Treatment Guidelines on the control unit interface will display the recommended transducer to utilize based on the anatomical area you have selected to treat.

Remove the transducer indicated from its protective pouch. To connect the transducer, slide the transducer into the handpiece as shown in Figure 5.2. When the transducer is fully seated, you will hear a tone indicating that it has been correctly inserted.

Figure 5.2: Connecting a Transducer

To disconnect the transducer, lift the latch at the tip of the handpiece and slide the transducer straight out of the handpiece.

CAUTION: Do not apply force/displacement to latching cantilever without a transducer installed in the handpiece.

When the transducer is inserted, the control unit automatically detects it and updates the graphical user interface.

5.4.3 Connecting Access Key

The Ulthera® System Access Key should be inserted into one of the available USB ports; otherwise, the message "No Key" will appear and the software will not allow user access.

6 Treatment Guidelines

6.1 Preset Guidelines and Energy Levels

The Ulthera® System is programmed with preset guidelines that have been established through clinical experience. Table 6.1 describes the preset guidelines available on your system.

Table 6.1: Guideline Names and Energy Levels

Guideline Name	Energy Level Range	Default Energy Level
Face & Neck (Amplify)	1–4	2
Chest	1-4	4
General Regions (Face & Neck)	1–4	2
Train: Face & Neck (Amplify)	0 only	0
Train: Chest	0 only	0

To facilitate training with your system, specific training guidelines have been pre-programmed into the guideline list as well. These are noted as "Train: …" These training guidelines should be used for training purposes only where no energy delivery is desired. Lines available for the transducer will not be decremented while in a training guideline.

To treat regions other than those depicted in the preset guidelines (e.g., the abdomen, anterior arms, and posterior arms), it is recommended that you utilize the **User Regions** function as described in Section 7.2.3. This function will allow you to define text-based regions to select and treat against.

Each transducer is programmed with set energy levels. Table 6.2 describes the energy levels available for each transducer.

Table 6.2: Transducer Energy Levels

TRANSDUCER	ENERGY LEVELS [J]				
	LEVEL 4	LEVEL 3	LEVEL 2	LEVEL 1	LEVEL 0
DS 4 - 4.5	1.20	1.00	0.90	0.75	0.00
DS 7 - 4.5	1.05	0.90	0.75	0.66	0.00
DS 7 - 3.0	0.45	0.35	0.30	0.25	0.00
DS 7 - 3.0N	0.45	0.35	0.30	0.25	0.00
DS 10 - 1.5	0.25	0.20	0.18	0.15	0.00
DS 10 - 1.5N	0.25	0.20	0.18	0.15	0.00

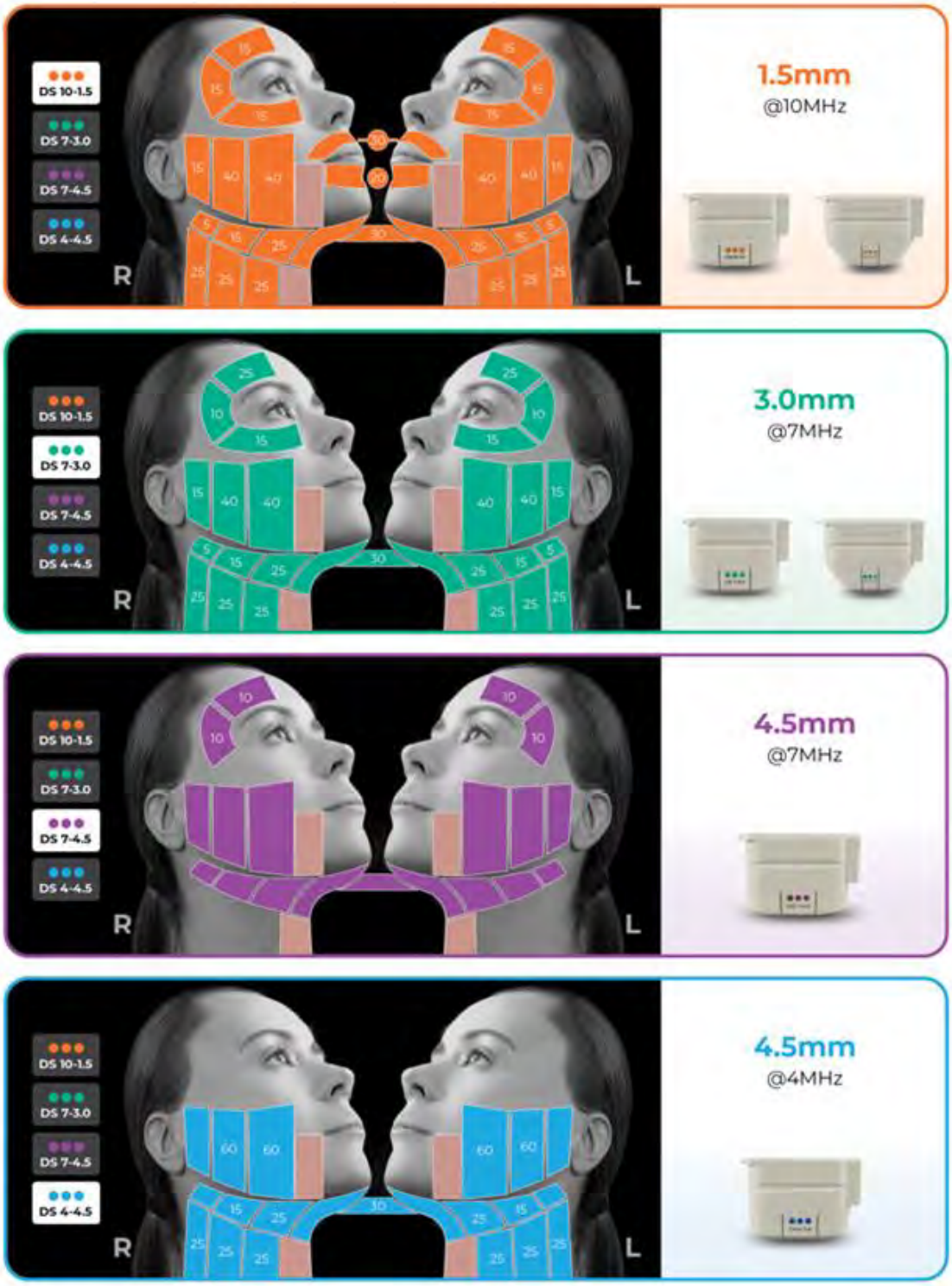
NOTE: Energy level defaults may vary depending on the guidelines selected prior to performing a treatment. The user has the ability to adjust these energy settings by using the Energy control described in Section 7.2.1. If adjusted, the system shall retain the setting across all regions for that particular transducer and for the duration of the treatment session.

NOTE: Removing and re-inserting a transducer within a treatment session shall put the transducer back to the energy setting used last, not to the default for the guideline.

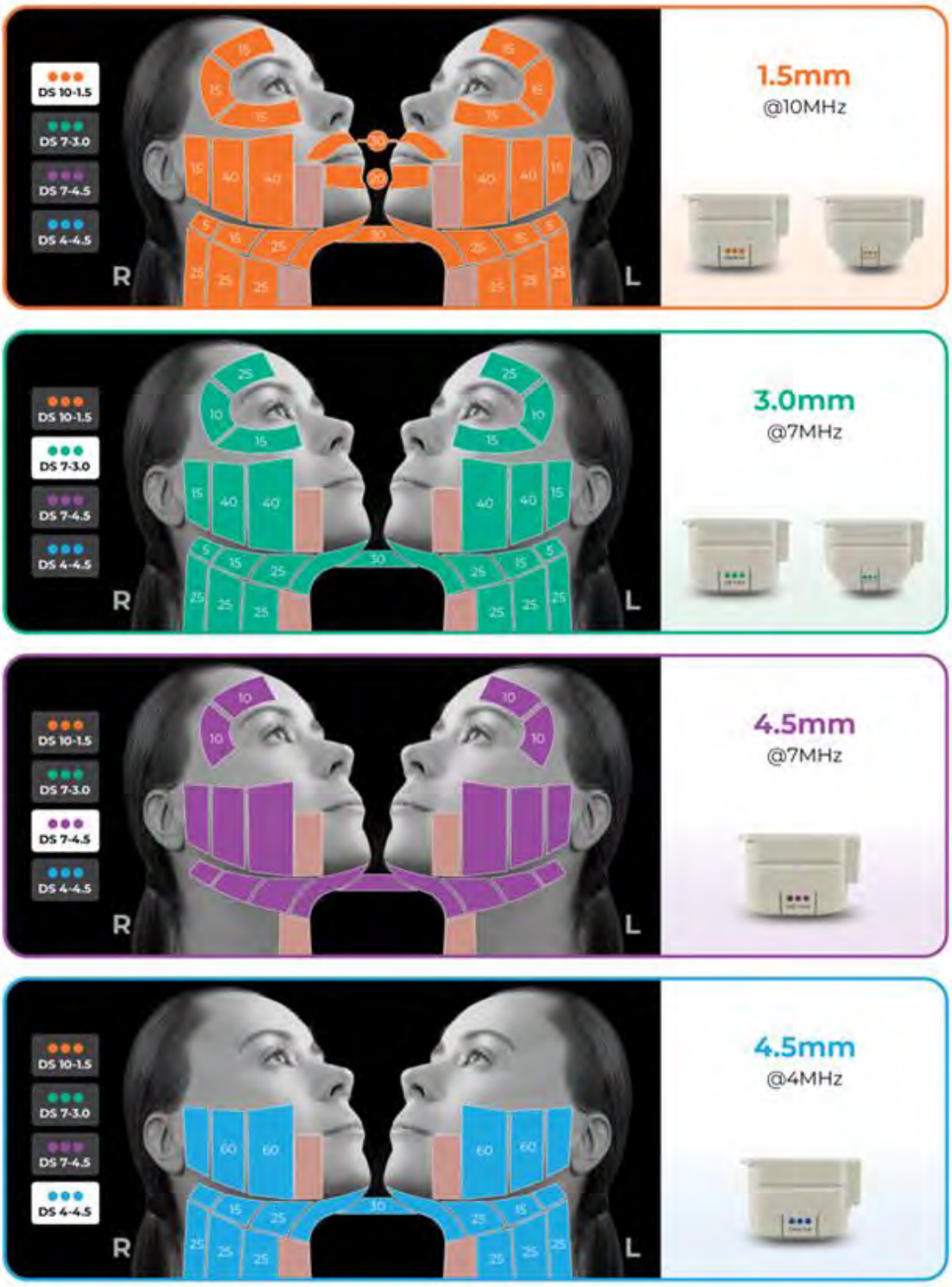
NOTE: Ending the treatment session and starting a new session with the same or different guideline will put all transducers back to the default energy settings as prescribed by the guideline.

The preset guidelines as they appear on the system for each transducer type are listed below. The recommended line count for each region is depicted by the numerical value displayed. Regions shown without a numerical value are regions that are available for the treating clinician to select and treat at their discretion, but a specific line count is not directed. Regions shown in the peach color are "do not treat" areas.

6.1.1 Face & Neck (Amplify)



6.1.2 General Regions (Face & Neck)



6.1.3 Décolleté

6.1.3.1 Clinical Trial Results

To support the expanded indication, the Ulthera® System was evaluated in a prospective safety and efficacy study investigating the clinical response following treatment with the Ulthera® System to achieve improvement of lines and wrinkles of the décolleté. The clinical study's protocol was

approved under IDE G120004 for enrolling up to 130 female subjects between the ages of 35-60 at up to 4 sites with a 90 and 180 day follow up. The Fabi-Bolton Scale, a published validated scale, was prospectively defined to evaluate wrinkle improvement. However, successful validation of the Fabi-Bolton Scale during the clinical trial could not be accomplished due to kappa scores for both intra-rater and inter-rater reproducibility being low. Therefore, the primary endpoint was changed from the Fabi-Bolton Scale to a post-hoc retrospective masked assessment of pre and post treatment photographs. There were no pre-specified success criteria of the masked assessment established at the beginning of the clinical trial. In addition to masked assessment, there was also an unmasked assessment called the Clinician Global Aesthetic Improvement Scores (CGAIS). Finally, patient satisfaction questionnaires were also measured to assess improvement.

Table 6.3: Patient Accountability

N	125
Subject Drop out	17
Subject Per Protocol	108
Subject Eliminated based on Poor Quality Photographs	54
Evaluable Subjects	54

Upon analysis of the all the photographs used in the clinical study, 54 of 108 day 180 photos were identified as having inconsistencies in photo quality (changes in lighting, color, focus, patient positioning, cropping, etc.). Therefore, a sub-set analysis was conducted using the primary endpoint of masked assessment on the remaining 54-day 180 evaluable photo sets that were deemed the most consistent in photo quality.

Table 6.4 provides results from the masked assessment of the evaluable subject photos.

Table 6.4: Masked Assessment Results of Evaluable Subject Photos

N	54
Improvement	36 (~67%)
Incorrect	13 (24%)
No Change	5 (9%)

In the sub-set of evaluable photos, there were 36 of 54 (~67%) subjects that showed improvement by masked assessment of pre and post treatment photographs at the primary endpoint of 180 days.

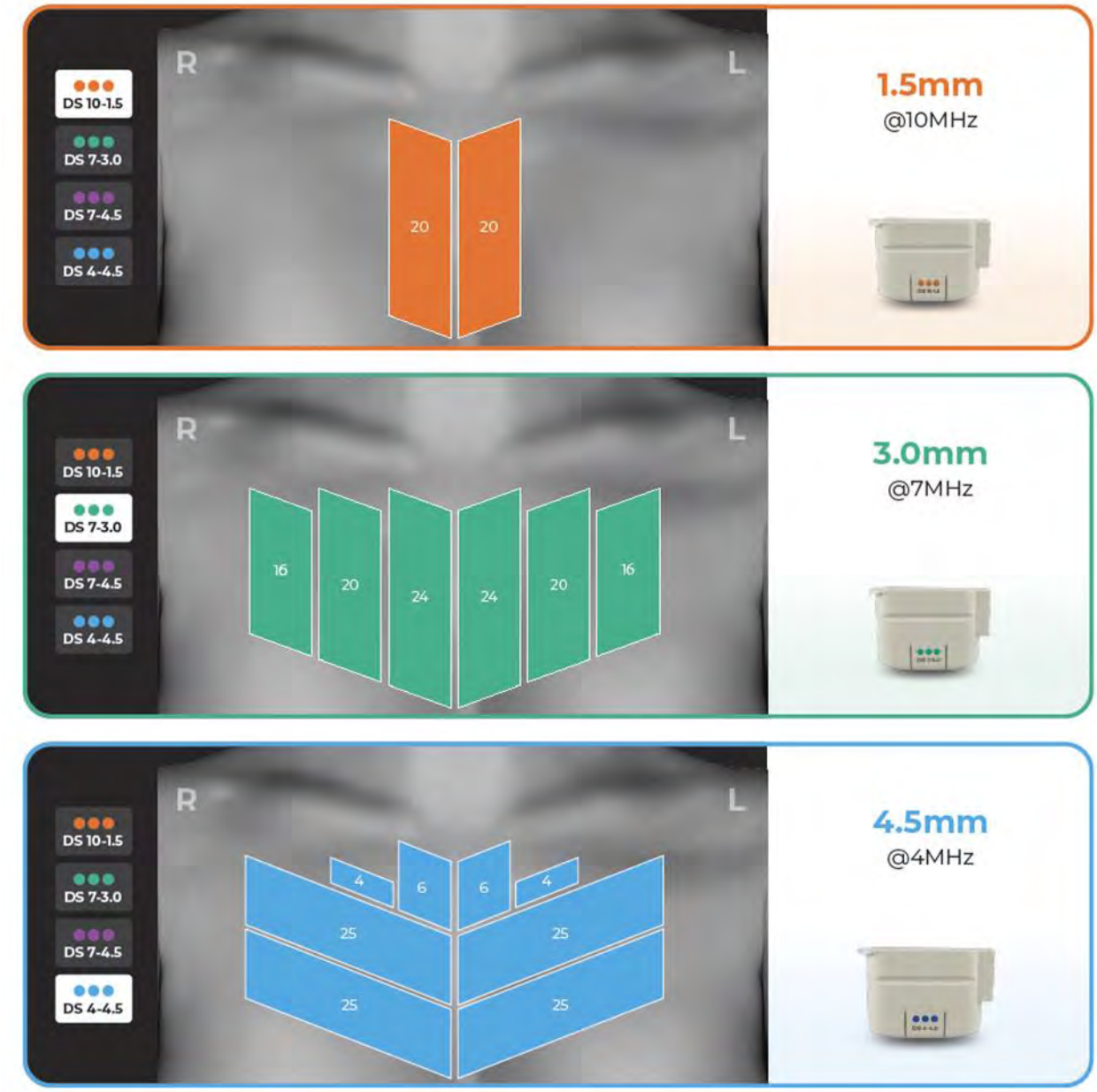
Table 6.5 provides CGAIS and Patient Assessments stratified by results of the primary endpoint of masked assessment for the subject sub-set with the most consistent photo quality.

Table 6.5: CGAIS and Patient Assessments Stratified by Masked Assessment Results for Sub-Set of Evaluation Photos at day 180.

Masked Assessment	CGAIS			Patient Satisfaction			Patient Reported Improvement	
	Improved (improved, much improved, very much improved)	**No Change**	**Worse**	**Satisfied** (satisfied & very satisfied)	**Neither Satisfied nor Dissatisfied**	**Dissatisfied** (dissatisfied & very dissatisfied)	**Yes**	**No**
Improvement n=36	27 (75%)	9 (25%)	0 (0%)	23 (64%)	9 (25%)	4 (11%)	32 (89%)	4 (11%)
Incorrect n=13	5 (38%)	7 (54%)	1 (8%)	8 (61%)	4 (31%)	1 (8%)	10 (77%)	3 (23%)
No Change n=5	3 (60%)	2 (40%)	0 (0%)	4 (80%)	0 (0%)	1 (20%)	4 (80%)	1 (20%)
TOTAL n=54	**35 (65%)**	**18 (33%)**	**1 (2%)**	**35 (65%)**	**13 (24%)**	**6 (11%)**	**46 (85%)**	**8 (15%)**

The results of the sub-set analysis demonstrate improvement of lines and wrinkles based on masked assessment of pre and post treatment photographs in 36 of 54 evaluable subjects with the most consistent photo quality after one Ultherapy® treatment 180 days post-treatment.

Please note that treatment efficacy was achieved at the pre-set energy levels of Level 4 for the 7 - 3.0 and 4 - 4.5 transducers and energy Level 3 for the 10 – 1.5 transducer. Changes in energy may impact efficacy.



The following transducers are not included in this treatment protocol:

UT-4N: Ulthera® DeepSEE® Narrow Transducer DS 10-1.5N

UT-1N: Ulthera® DeepSEE® Narrow Transducer DS 7-3.0N

UT-3: Ulthera® DeepSEE® Transducer DS 7-4.5

6.2 Abdomen, Anterior Arms, and Posterior Arms

To support the Ulthera® System's use on the abdomen, anterior arms, and posterior arms, a comprehensive literature search was performed (data on file: REG0957). The total number of clinical studies and number of subjects evaluated is found in Table 6.6.

Table 6.6: Number of clinical studies and number of subjects to support the use of the Ulthera® System in the abdomen, anterior arms, and posterior arms.

Device	Region of the Body	Total Number of Subjects Evaluated*	Total Number of Clinical Studies	Range of Follow-up**
Ulthera® System	Abdomen	54	3	One to six months
	Anterior Arms	70	3	One to six months
	Posterior Arms	43	2	One to six months

*Describes the aggregate number of patients evaluated per region of the body. Individual studies were not statistically powered.

**Describes the range of timepoints in which the safety and effectiveness endpoints were assessed per region of the body.

These clinical studies demonstrated clinically significant skin improvement ranging from one month to six months post-treatment via a variety of endpoints, including blinded clinician photographic assessment, physician and subject Global Aesthetic Improvement Scores (GAIS), patient satisfaction surveys, and other validated clinical endpoints. From a safety perspective, there were no unexpected or severe adverse events (AEs), and all observed AEs resolved without long-term sequalae.

Using these clinical studies, the treatment areas and guidelines outlined in Figure 6.1 and Table 6.7 were developed for treating the abdomen, anterior arms, and posterior arms with the Ulthera® System.

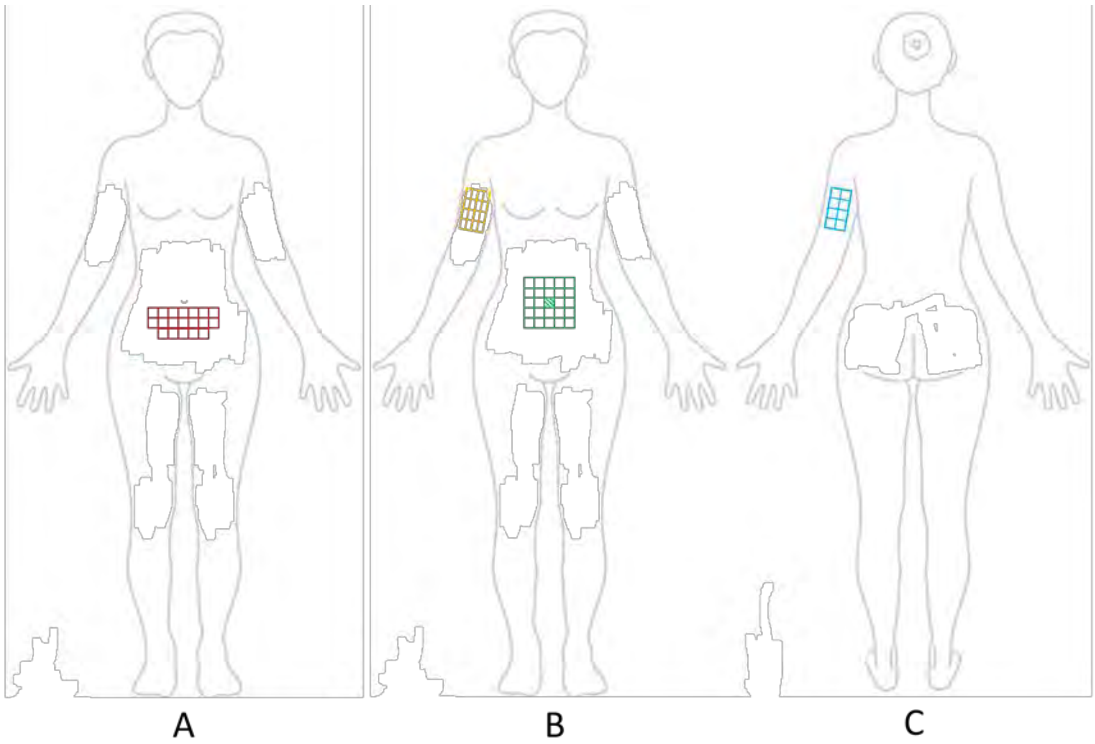


Figure 6.1: Treatment areas for the A) lower abdomen; B) anterior arm and peri umbilicus; C) posterior arm. See Table 6.7 for corresponding treatment guidelines.

Treatment of the abdomen, anterior arms, and posterior arms should only be performed on the regions indicated in Figure 6.1 above.

Treatment of the upper arm can be done anteriorly or posteriorly. For both areas, treatment should be restricted to the middle third region between the elbow and shoulder avoiding the medial and lateral portions of the arm containing major vessels and nerves. See Figure 6.1.

The safety and effectiveness for treatment in the upper arms have not been established for patients with a BMI less than 17.8 kg/m^2. Care should be taken in treatment of patients with low BMI, as these patients may have below normal adipose tissue relative to skin, which may increase the risk of injury to neurovascular structures of the arm.

Significant (massive) weight loss may result in a thin adipose layer and the stretching of anatomical structure. This may lead to anomalous positioning of neurovascular structures in the upper arm which may increase risk of injury. Care should be taken in treatment of such patients. The safety and effectiveness for treating the upper arms have not been established in patients that have experienced significant (massive) weight loss.

Table 6.7: Treatment Guidelines for Abdomen, Anterior Arms, and Posterior Arms

Site(s)	Number of 2.5 x 2.5 cm squares*	Transducers	Recommended lines / 2.5 x 2.5 cm square (range)**	Energy Level Range	Recommended Energy Level***
Abdomen					
Lower Abdomen	19	DS 4-4.5	20 (4 – 20)	1 – 4	2
		DS 7-3.0	20 (4 – 20)		
		DS 10-1.5	20 (0 – 20)		
Peri umbilicus	24	DS 4-4.5 DS 7-3.0 DS 10-1.5	30	1 – 4	4
Arms					
Anterior Arm	16	DS 4-4.5	30 (13 – 30)	1 – 4	4
		DS 7-3.0	30 (0 – 30)		
Posterior Arm	8	DS 4-4.5	13 (13 – 25)	1 – 4	4
		DS 7-3.0	12 (0 – 20)		

*This column indicates the recommended number of treatment squares; however, the number of squares may vary based on individual patient anatomy.

**This column indicates the recommended number of lines per 2.5 x 2.5 cm square, as well as the range of treatment lines that demonstrated safety and effectiveness in the referenced clinical studies. Zero (0) treatment lines indicates this transducer was not used in one or more clinical studies.

***Energy level may be adjusted based on patient comfort.

7 System Operation

7.1 Ulthera® System Access Key

A secure USB Access Key is provided to give the user access to Ultherapy PRIME® treatment on the system. Ultherapy PRIME® treatment cannot be delivered until the Access Key is inserted into one of the USB ports on the control unit.

It is the responsibility of the user to:

1. Remove the Access Key when the system is not in use to prevent unauthorized treatment or access to patient data
2. Keep the Access Key in a safe and secured location that is only accessible to authorized personnel

Storage and transfer of patient treatment data, support logs, and images should only be done using the Access Key. The Access Key is also used to store and apply manufacturer approved software update files to the device. The user must contact Ulthera, Inc. to request any software updates for their registered control unit.

Do not connect the Ulthera® System to any other computer, cyber-device, or network. Only insert Ulthera, Inc. authorized USB devices into the control unit.

The user should contact Ulthera, Inc. with any cybersecurity concerns.

Figure 7.1: Ulthera® System Access Key

Warning: Do NOT format the Ulthera® System Access Key. Doing so could deactivate the key and prevent access to your Ulthera® System.

7.2 User Interface

The main screen on the Ulthera® System monitor has three tabs located in the upper right corner of the screen: **DeepSEE®**, **Patient Info**, and **Setup**. The **DeepSEE®** tab displays the controls for imaging and treating soft tissue. The **Patient Info** tab displays information and tools for beginning a treatment and setting up a patient record. The **Setup** tab allows you to recall patient treatment information and change system settings.

7.2.1 The DeepSEE® Screen

Figure 7.2 shows an example of the user interface when the DeepSEE® tab is active. Each element is described in Table 7.1.

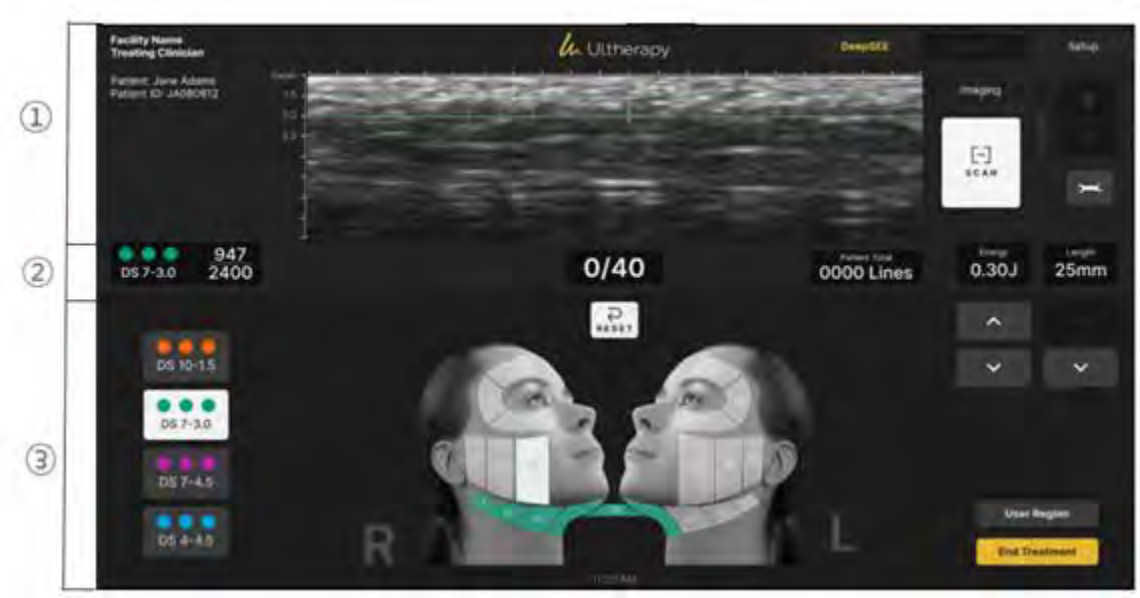


Figure 7.2: DeepSEE® Screen

1 Imaging Controls

2 Home Bar

3 Treatment Controls

Table 7.1: Elements on DeepSEE® Screen

ITEM		FUNCTION	
IMAGING CONTROLS	Ultrasound Image	Shows an ultrasound image of the tissues being imaged. The horizontal green line indicates the depth at which treatment will be delivered.	
	Scan Button	The circular icon to the right of the depth indicator starts or stops scanning (imaging).	
	Brightness Controls	Large Sun icon	Increases ultrasound image brightness during scanning.
		Small Sun icon	Decreases ultrasound image brightness during scanning.
	Tools	Displays the Tools menu (see Figure 7.3).	
HOME BAR	Patient Name and ID	Displays the name and ID information.	
	Total Line Count	Number of lines that have been delivered during this treatment session.	

ITEM		FUNCTION
	Current Line Count	The number of lines delivered. This line count value may be reset by tapping the **Reset** button immediately below the line count value.
	Recommended Line Count	The number of lines recommended for the region selected.
	Transducer Information	• Transducer type. • Number of treatment lines remaining/total treatment line capacity of transducer.
	Energy	The energy per TCP being delivered. May be adjusted with the buttons below.
	Length	The length of the treatment line being delivered. May be adjusted with the buttons below.
TREATMENT CONTROLS	Transducer Types	For planning purposes, toggling these buttons displays the associated treatment region information on the graphic or user regions window being displayed. The current transducer inserted is the default button selected.
	Graphic The graphic indicates the status of treatment regions.	An available region is displayed semi-highlighted and contains the recommended line count for that region. The number in the center represents the recommended line count for that region.
		A selected region is displayed in white and is outlined with the color of the transducer being used. The line count in the center represents the running line count for that region.
		A treated region is shown as a solid color of the transducer that was used in that region with the total lines delivered for the region being represented.
		A disabled region is transparent with a light gray border. Disabled regions cannot be selected.
	User Regions	Displays a list of regions as defined by the user.
	End Treatment	Tap **End Treatment** followed by **Confirm End** to end the treatment session.

7.2.2 Tools Menu

The **Tools** icon in the upper right corner of the screen displays the Tools menu shown in Figure 7.3 and described in Table 7.2.

Figure 7.3: Tools Menu

Table 7.2: Tools

ITEM		**FUNCTION**	
1	Volume Buttons	Decreases or increases the volume of the system.	
2	Image Buttons	Treat Line	The button with hash marks displays or removes the green treat line displayed on the ultrasound image.
		Save	The Save button saves the currently displayed image.
3	Marker Buttons	Measurement	Allows you to set markers for measuring distances within a scanned image.
		Text	The Text button displays a keyboard for recording notes on an image.

7.2.3 User Regions

The Ulthera® System allows you to create and edit treatment guidelines to more accurately reflect and record how treatments are performed. Treatment energies are not editable beyond the safety limits that have been previously determined.

Under **Treatment Settings** select **Edit User Regions** from the drop-down menu, as shown in Figure 7.4.

Figure 7.4: User Regions, Selection Screen

The User Regions section displays regions as created by the user, with functionality depicted in Table 7.3 below.

Table 7.3: User Regions Action Buttons

ITEM		FUNCTION
1	Add Guideline	Allows you to create a new guideline.
2	Edit Guideline	Allows you to edit an existing guideline.
3	Delete Guideline	Allows you to delete a guideline you created.

Figure 7.5 and Table 7.4 display the process and functionality of creating a User Region:

Figure 7.5: User Regions, Planning Screen

Table 7.4: User Regions Treatment Guideline Dialogue

ITEM		**DESCRIPTION**	
1	User Region Guideline Name Field	The name of the treatment guideline is entered in this field.	
2	Clinician Field	The name of the clinician treating is entered here.	
3	Edit Region Fields	Region Name	Field for entering or editing the name of the region.
		Transducer	Field for selecting the transducer for the region that is highlighted.
		Number of Lines	Field for entering or editing the number of lines that is going to be recommended for the region that is highlighted.
		Default Energy	Field for selecting the default energy that will be used for the region that is highlighted. When a transducer's energy level is changed in an existing *User Region Guideline*, all energy levels will be updated in that guideline for that transducer type.
4	List of Entered Regions	Lists the regions that have been entered into the user region treatment guideline. The highlighted region is populated into the *Edit Region Fields* to allow for editing. If using the *Edit Guideline* user region action button, changes will not be visible in the therapy screen until a system reboot is performed.	
5	Field Controls	Controls (keyboard or menu of options) used for entering information into fields. This section changes based on the field that is being edited.	

ITEM		DESCRIPTION
6	Save Button	Saves the current User Region Guideline and returns to the startup screen.
7	Add Region Button	Adds a new, unnamed region to the treatment guideline.
8	Delete Region Button	Deletes the highlighted region. NOTE: This action cannot be undone. In the event that a region is inadvertently deleted the region will need to be re-entered.
9	Close Button	Closes the User Region Guideline dialogue without saving any changes that have been made.

7.3 Operating Instructions

7.3.1 Activate the Control Unit

1. Connect the power cord pigtail to the rear of the control unit.
2. Connect the supplied AC power cord with line filter and plug to the power cord pigtail, then plug other end into a wall outlet.
3. Turn the main power switch to the ON position.
4. The power switch may be left in the ON position when the system is not in use.

NOTE: Do NOT use the power switch to shut down the system.

5. Insert the Ulthera® System Access Key into the USB port of the control unit.

NOTE: The Ulthera® System operates only with the authorized Access Key.

6. Press the green On/Off button on front of the control unit.
   The system will perform a brief self-test. After passing the self-test, a "NO KEY" message will be displayed if the Ulthera® System Access Key has not yet been inserted; otherwise, the starting screen will be displayed.

Warning: If the self-test screen displays any information messages, turn the system off by pressing the green On/Off button and follow the instructions in the "Troubleshooting" section.

7.3.2 Set Up a Treatment Record

1. The **Patient Info** screen shown in Figure 7.6 is the Patient Info Screen displayed when you turn on the system.

Figure 7.6: Patient Info Screen

2. Use the touchpad keyboard to enter the patient name, patient ID, and the name of the clinician who will perform the treatment.
3. Clinician names can be selected from the dropdown list by tapping the down arrow to the right of the field. Unwanted clinician names may be removed from this list by: 1) tapping the name; 2) tapping the Del key; and then 3) tapping the Enter key.
4. Select the desired treatment guideline from the list located above the touchpad keyboard.
5. Treatment guidelines display recommended treatment parameters for the treatment regions. These parameters are based on clinical trial results that determined safe settings for each treatment region.
6. Tap the Start Treatment button located in the upper right corner of the screen.

NOTE: When the Start Treatment button has been pressed, the patient name, patient ID, and treatment guideline may not be changed until the current treatment is ended.

7.3.3 Select a Transducer

The Ulthera® System has six types of transducers:

Table 7.5: Types of Transducers

TRANSDUCER	SPECIFICATIONS
DS 10 – 1.5	Low energy level and 1.5 mm focal depth.
DS 10 – 1.5N	Low energy level, 1.5 mm focal depth, and a narrower contact area than the DS 10 – 1.5.
DS 7 – 3.0	Low energy level and 3.0 mm focal depth.
DS 7 – 3.0N	Low energy level, 3.0 mm focal depth, and a narrower contact area than the DS 7 – 3.0.
DS 7 – 4.5	Intermediate energy level and 4.5 mm focal depth.
DS 4 – 4.5	High energy level and 4.5 mm focal depth.

1. Check the expiration date on the transducer package.
2. Open the sealed pouch.

3. Connect the transducer to the handpiece by sliding the transducer into the handpiece until the passive latch locks into place.

Figure 7.7: Connecting the Transducer

A tone will sound when the transducer has been correctly inserted. The Treatment Guideline area on the **DeepSEE®** screen will display the regions available for treatment with the inserted transducer.

CAUTION: If a warning or caution message is displayed, or a message that says “Transducer Not Connected,” disconnect and reconnect the transducer. If the problem persists, contact your Ulthera representative.

CAUTION: If the handpiece or transducer is dropped or broken, or any part of the system is damaged, disconnect the system from the power source outlet before touching any other part of the equipment. Thoroughly inspect the equipment for external damage before reconnecting. Do not use a damaged handpiece or transducer.

7.3.4 Scan the Region to be Treated

1. Tap the region to be treated from the available regions and it will highlight white, showing you the number of lines that have been delivered in the center of the region.
   The energy and treatment line length will be set to appropriate levels for the entire treatment session unless manually adjusted by the user.

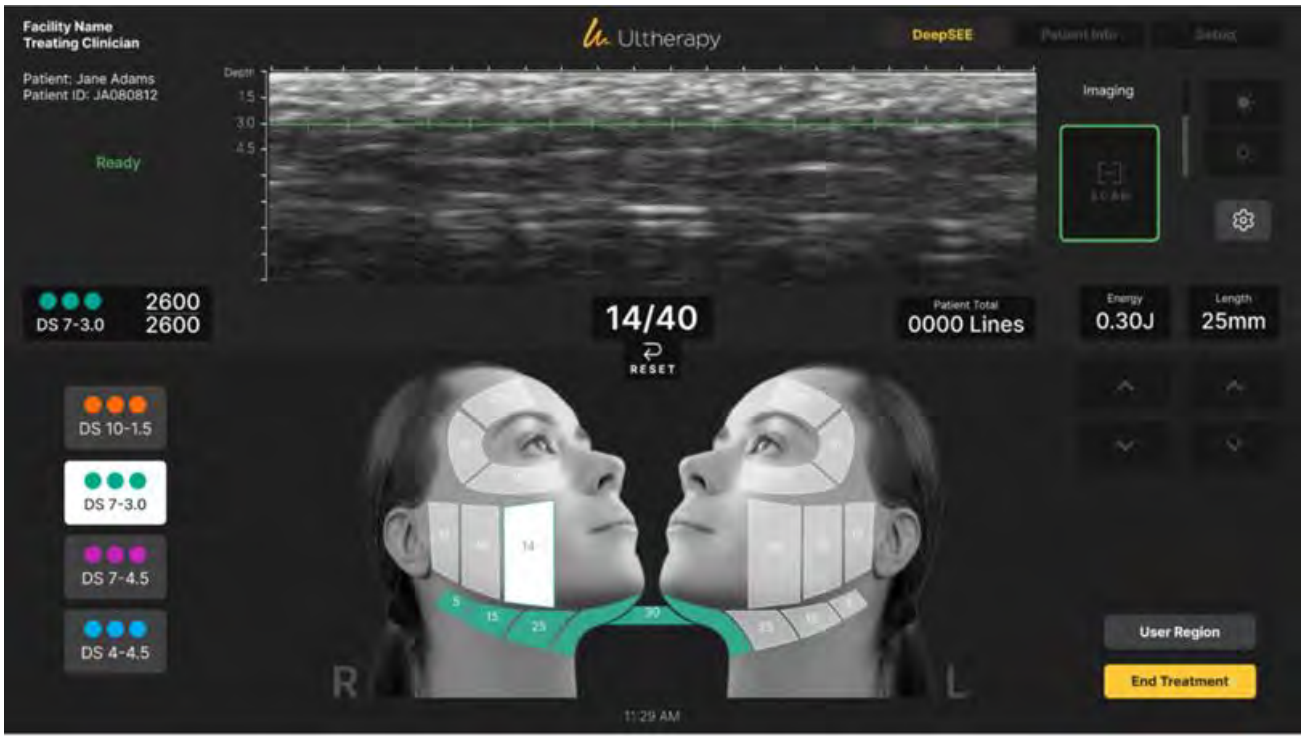


Figure 7.8: DeepSEE® Screen

2. Ensure that the region to be treated has been cleansed thoroughly.
3. Apply a thin layer of aqueous ultrasound gel to the area to be treated.

Warning: Too much or too little gel will obstruct skin contact and could cause adverse events such as those listed in Section 2.5. Do not use other lubricants or lotions because they may damage the transducer.

4. Place the transducer treatment window flush with the patient's skin and press the **See** button on the handpiece to begin imaging.
   An image of the patient's tissue appears. The green treat line on the image shows the depth at which treatment will be delivered. Green tick marks on the ruler show the lateral positions where the coagulative points will be placed along the horizontal plane. For example, with length set to 25 mm, and a spacing of 1.5 mm (center to center), a treatment line would have 17 TCPs.
5. Verify sufficient coupling between the transducer and the skin by ensuring that there are no dark, vertical artifact bars on the image.

Warning: Improper coupling could cause adverse events such as those listed in Section 2.5.

Figure 7.9 shows the difference between images when coupling is good versus poor.

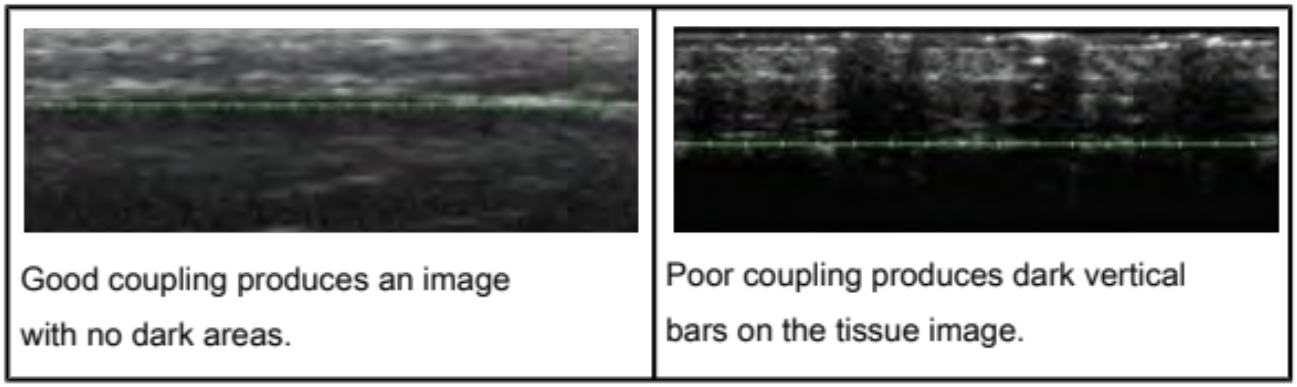


Figure 7.9: Images Affected by Coupling the Transducer to the Skin

Figure 7.10 shows the visualization of the dermal and subdermal layers and surface of the bone.

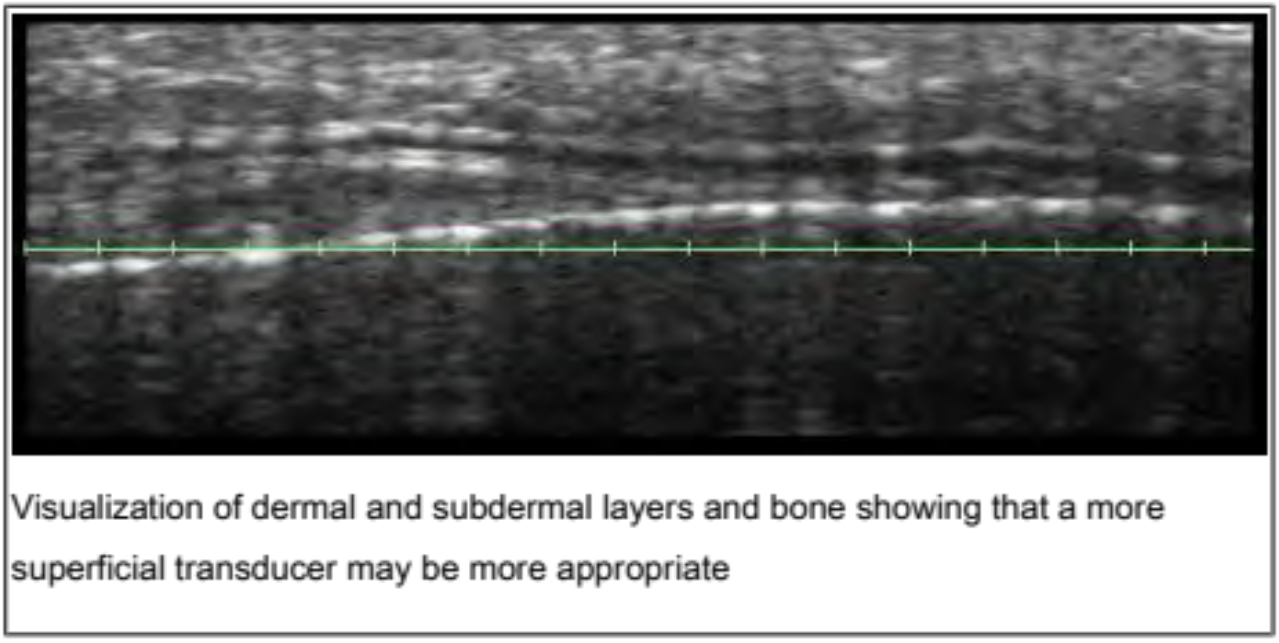


Figure 7.10: Image of Dermal Layers and Surface of the Bone

If the transducer is jostled, dropped, or shaken while scanning, it may pause to recalibrate its position before resuming normal scanning.

7.3.5 Deliver Treatment Lines

1. Press the **See** button on the handpiece when you have confirmed adequate coupling and transducer positioning to enter the Ready state.
   When the system enters or exits the Ready state, a tone will sound and buttons on the handpiece will be lit. The Ready state is terminated after 40 seconds if the **Treat** button is not pressed, but can be reactivated by pressing the **See** button again.
2. Press a **Treat** button on the handpiece to begin delivering treatment lines between the treat guides on the transducer.
   Keep your hand still and maintain a light constant pressure from the transducer on the patient's skin while delivering treatment lines.
   The **See** button will light up momentarily during the treatment; the **Treat** button will not be lit while energy is being delivered. A tone will sound quickly for each TCP created and the green ruler will change to yellow to indicate that treatment is occurring. You may adjust the volume of sounds by tapping the **Tools** button and adjusting it up or down.
3. To deliver the next treatment line within the same treatment region, move the transducer 2-3 mm to adjacent tissue and press the **Treat** button. It may be necessary, to use multiple transducer passes to ensure adequate line spacing within the recommended line count.
   If 40 seconds have elapsed since delivering the last treatment line, press the **See** button on the handpiece to ready the system and then press the **Treat** button again.

   Warning: Delivering lines without adequate spacing could overheat tissue causing adverse events such as those listed in Section 2.5.

4. After approximately every five treatment lines, visually check the image to determine if more gel needs to be applied.
   A small film of gel, adequate enough to achieve good coupling, should cover the window.
5. Continue delivering treatment lines until you complete the recommended number for the region.
6. To terminate therapy at any time, press the **See** button on the handpiece or lift the transducer off the patient's skin.

   NOTE: In case of emergency, press the red emergency Stop button on the front panel of the control unit.

7. To start treatment in another region, tap the desired region.
   The previously treated region will change to the color of the transducer that was used, and the selected region will become Active (white).
8. Previous treatment regions treated with a transducer other than the one currently inserted may be reviewed by tapping the appropriate transducer button on the left-hand side of the screen.
9. When all regions have been treated, tap the **End Treatment** button in the lower right corner of the **DeepSEE®** screen and then tap **Confirm End.**

   Warning: The End Treatment button must be tapped at the end of each patient's procedure to ensure that the current session's treatment record has been saved.

7.4 Adjunctive Functions

7.4.1 Measuring Distances

To measure distance on an ultrasound image:

1. Tap the **Tools** icon on the **DeepSEE®** screen.
2. Tap the **Marker** icon on the **Tools** menu.
   A starting point marker will appear near the center of the image.
3. Touch the marker and drag it to the starting point for the measurement.

4. Lift your finger off the screen when the marker is positioned at the starting point.
   The ending point marker will appear with a line between the two points.
5. Touch the ending point marker and drag it to the end point for the measurement.
   When you lift your finger from the ending point, the distance between the markers will be displayed.
6. To measure another distance, tap the **Marker** button on the **Tools** menu again and repeat steps 3-5.
   When imaging is restarted by pressing the **See** button on the handpiece or by tapping the **Scan** button on the **DeepSEE®** screen, the distance markers will disappear from the image.

7.4.2 Annotations

When the Ulthera® System is not actively imaging, you may add comments on the ultrasound image.

To make a note on ultrasound images:

1. Tap the **Tools** icon on the **DeepSEE®** screen.
2. Tap the Text icon on the Tools menu.
   A text box will appear near the center of the image and a keyboard will appear below the image.
3. If you want to reposition the text box, tap and drag it with your finger.
4. Use the keyboard to type your comments.
5. Tap Enter on the keyboard when you are finished entering comments and the text box is in the desired position.
6. To repeat this procedure and enter another comment, tap the Text icon again and repeat steps 3-5.
   A total of two annotations may be added to an image. After adding two annotations to an image, the Text button will then serve to remove the previous annotations.
   To save this image with annotations, press the **Tools** icon and then press **Save**.

7.4.3 Database Records

The Ulthera® System has a proprietary database for storing a limited number of images and treatment record information. Images are saved when the user taps the Save button on the DeepSEE® screen. Treatment records are automatically saved after ending a treatment session. The saved images and information can be browsed or exported to another storage device.

The database must be maintained by periodically exporting or deleting unused or old images and treatment records. The system is primarily designed for patient treatment and storing too much data reduces productivity and system performance.

The maximum number of images that can be stored is 100 and the maximum number of treatment records that can be stored is 200. If these numbers are exceeded, the user will be asked to delete records or images prior to continuing with treatments. If a procedure is in progress when the database reaches its limit, the additional records will be stored, but at the beginning of the next treatment, the user will be prompted to delete images and/or treatment records in the database.

Browsing the database:

1. Tap the **Setup** tab.
2. Tap the **Records** button to view stored treatment records or tap the **Images** button to view images.
3. When the data or images are displayed, you can browse through displayed items on the screen, save items to your Access Key, or delete items.

NOTE: It is advisable to save records before deleting them or prior to sending the system in for repair if necessary.

Exporting data:

1. On the **Setup** screen, tap the **Images** button to view a list of treated patients like the one shown in Figure 7.11:

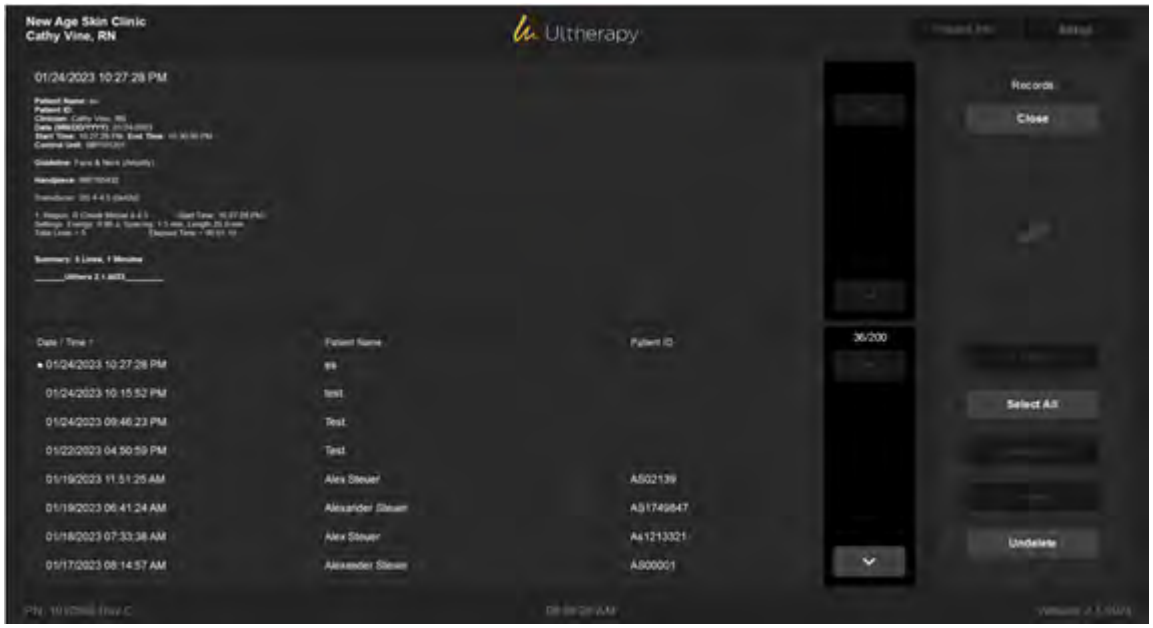


Figure 7.11: Patient Image Record List

2. Tap an individual **Patient** ID to access that individual image or tap the Select All button to access all stored images.

NOTE: You may select multiple images by tapping on them individually. Tapping a selected image again will deselect it. You may also tap **Deselect All** to deselect all images.

3. Tap the **Save** button.
4. If you want the data to remain on the system after exporting to the Access Key, tap the **Close** button to return to the Setup screen.
   Exporting treatment records may be done by following these same steps for **Records**.

NOTE: For quality and safety reasons, the Ulthera® System collects data regarding patient treatment and stores it on the device. If a device operator enters a patient name or static patient identifier into the user interface screen on the device, an identified patient record is created and stored. This is called the Exam Record and it can be viewed by anyone who powers on the device. Data that may be entered into the Exam Record include patient name, sex, clinician, facility name and details about the treatment delivered. To protect patient privacy, Ulthera recommends that you always delete the Exam Records from your device before sending it in for service.

To delete this data from your device prior to sending it in for service, follow the steps identified below:

Deleting data:

1. Save the records to be deleted from the database on an accessory device.
   (This step is not required, but it is highly recommended)
2. Tap the **Delete** button to remove an individual item or tap the **Select All** button and then the **Delete** button to remove all items from the database.

NOTE: If you delete one or more patients by mistake, tap the Undelete button to restore the items.

3. Tap the **Close** button to return to the **Setup** screen.

To recover deleted items from the database:

1. To recover one or more of the 50 previously deleted items, tap the **Undelete** button. (A maximum of 50 previously deleted items may be recovered.)
2. Select the images or records you would like to recover and tap **Undelete**.
   The selected items are restored to the current database.

Also, for quality and safety purposes, the device creates and stores a "Support Log" which contains all device parameters captured during single treatment sessions. The Support Log is stored on the device compact flash drive. Patient data contained in the Support Log is encrypted and can only be decrypted and read by specifically authorized safety personal from Ulthera, Inc. Ulthera, Inc. only decrypts and views identified patient data in the Support Log when investigating potential adverse events reported to Ulthera, Inc. regarding the use of the device.

7.5 Troubleshooting

7.5.1 Warning Screens

System warnings provide information and instructions for resolving issues that may occur. Follow the instructions provided, but please make note of any code letters presented in case Technical Support is needed. Figure 7.12 shows a sample warning screen.

Figure 7.12: Warning Screen

Warning: These dialogs indicate that a problem was detected. See System Messages section for more details.

7.5.2 Poor Image Quality

To improve image quality:

1. Check that the display brightness is set appropriately for the connected transducer.
2. Check the gel on the transducer.

If these steps do not resolve the problem, contact Ulthera, Inc. or your country representative for assistance.

7.5.3 Shutting Down the System

1. Stop any imaging and / or treatment in progress prior to shutting down the System.
2. From the Setup screen, tap the Shutdown button.
3. Remove the Ulthera® System Access Key to prevent unauthorized usage.
4. Leave the main power switch located on the rear panel of the control unit in the **ON** position; turn it off only when moving the system.

8 System Messages

The Ulthera® System is designed with internal checks to ensure that all aspects of the device are functioning appropriately. In the event that an information message presents itself during use, please follow the instructions on the screen or refer to the information listed below.

These messages are classified as INFORMATION SIGNALS per IEC 60601-1-8.

INFO CODE	MESSAGE DISPLAYED		DESCRIPTION
B		Code B Internal handpiece temperature is too high. If the problem persists please see the User's Manual for further information or contact Ulthera Support.	The internal handpiece temperature is above its limit. Allow the handpiece to cool down.
C		Code C Hardware halted Please restart the system. If the problem persists please see the User's Manual for further information or contact Ulthera Support.	Hardware was halted due to an event detected in the control unit.
E		Code E Communication halted Please restart the system. If the problem persists please see the User's Manual for further information or contact Ulthera Support.	Communication was halted due to an initialization event detected in the control unit.
G		Code G Hardware halted Please restart the system. If the problem persists please see the User's Manual for further information or contact Ulthera Support.	Hardware was halted due to an event detected in the control unit.
H		Code H Transducer motion not detected Please remove and reinsert the transducer. If the problem persists please see the User's Manual for further information or contact Ulthera Support.	Transducer motion was not detected. Ensure that the transducer is properly mounted in the handpiece. Please be sure to always hit Scan N before removing transducer. Remove and reinsert the transducer.
I		Code I Communication halted Please restart the system. If the problem persists please see the User's Manual for further information or contact Ulthera Support.	Communication halted due to an event detected in the control unit.

INFO CODE	MESSAGE DISPLAYED		DESCRIPTION
J		Code J Handpiece communication halted Please restart the system. If the problem persists please see the User's Manual for further information or contact Ulthera Support.	Communication halted due to an event detected in the control unit.
K		Code K Software halted Please restart the system. If the problem persists please see the User's Manual for further information or contact Ulthera Support.	Software was halted due to an event detected in the control unit.
L		Code L Transducer out of lines Please replace transducer and continue. See User's Manual for further information.	The Transducer's remaining line count is zero. Remove and replace the Transducer.
M		Code M Handpiece motion halted If the problem persists please see the User's Manual for further information or contact Ulthera Support.	Inspect handpiece. Ensure that the transducer is properly mounted and latched in the handpiece.
N		Code N USB flash memory connectivity Please check flash drive and continue. See User's Manual for further information.	A problem was detected with the attached USB flash memory drive. Make sure the drive is properly formatted and has enough free space. Do not remove the drive while the system is communicating with it.
P		Code P Hardware halted Please restart the system. If the problem persists please see the User's Manual for further information or contact Ulthera Support.	Hardware was halted due to an event detected in the control unit.
S		Code S The red STOP button has been pressed. Please restart the system. If the problem persists please see the User's Manual for further information or contact Ulthera Support.	The red **Stop** button was pressed.
T		Code T Internal transducer temperature is too high If the problem persists please see the User's Manual for further information or contact Ulthera Support.	The internal transducer temperature is above its limit. Allow the transducer to cool down or use another transducer.

INFO CODE	MESSAGE DISPLAYED		DESCRIPTION
U		Code U Control unit temperature too high If the problem persists please see the User's Manual for further information or contact Ulthera Support.	The internal control unit temperature is above its limit. Allow the control unit to cool down. Provide proper ventilation.
V		Code V Transducer energy delivery halted Tap Scan Y to resume scanning If the problem persists please see the User's Manual for further information or contact Ulthera Support.	Excessive reflected power has been detected. If the problem persists, please try another transducer and contact Ulthera Support. Use Transducer only as instructed. Tap Scan Y to resume scanning.
W		Code W Unauthorized transducer. Please replace the transducer and continue. Please contact your local representative for further assistance.	The transducer connected is not an authorized transducer. Contact your local representative for further assistance.
X		Code X Transducer cannot be read Please remove and reinsert the transducer. If the problem persists please see the User's Manual for further information or contact Ulthera Support.	The transducer cannot be read. Remove and reinsert the transducer. Check that the transducer contact area is clean.

9 Cleaning and Care

9.1 Cleaning the Transducer and Handpiece

NOTE: Transducers are packaged and shipped non-sterile and ready to use.

Because the transducer will come in contact with the skin of a patient, the standard practice is to clean and disinfect the transducer between patient uses. To clean the transducer, gently but thoroughly wipe the transducer with a standard 70% isopropyl alcohol prep pad for a minimum of one minute, paying careful attention to difficult to clean areas (e.g., seams, undercut, bondlines, etc.), and replacing the wipes as needed until no visible soiling remains. Do not clean the electrical board connection of the transducer.

To disinfect the transducer, gently but thoroughly wipe the transducer with a CaviWipes towelette for one minute, paying careful attention to the areas with direct patient contact. Allow the transducer to dry, then repeat the process twice with two additional CaviWipes towelettes. Do not wipe the electrical board connection of the transducer.

One may also use a standard 70% isopropyl alcohol prep pad to gently wipe the handpiece and cable. Neither the transducers nor the handpiece should be submerged in liquid. Place the transducer back into its original packaging between uses.

Warning: Use only this procedure for cleaning. Do not use acetone or other solvents as this can damage the transducer.

9.2 Cleaning the Control Unit & Cart

The control unit and cart may be cleaned by using lint free wipes and cotton-tipped swabs dampened with 70% isopropyl alcohol. The exterior surfaces should be thoroughly wiped and swabbed for approximately 1 minute (touchscreen and work surface pad) to 3 minutes (console and cart), paying careful attention to difficult to clean areas (e.g., screws, seams, recessed areas, undersurface of pad, handpiece holder, transducer drawer, etc.).

If wipes/swabs become visibly soiled, additional wipes should be used.

Replacement work surface pads are available through contacting Ulthera support.

9.3 General Care of the System

To ensure the best possible performance, treat the equipment carefully by adhering to the following guidelines:

1. Inspect the handpiece and connectors regularly for any problems.
2. Turn scanning off before changing transducers to ensure proper identification of transducers and to prolong the life of the system.
3. Do not drop the handpiece or transducers on the floor or other hard surfaces. This can cause permanent damage.
4. Do not twist or pull the handpiece cables. This could cause damage to internal wires and connections.
5. Use aqueous ultrasound gel only. Other lubricants or lotions, particularly mineral oil, could eventually damage transducers or cables.
6. Do not use acoustic standoff pads or any objects between the transducer and patient.
7. Apply ultrasound gel only to the area to be treated and wipe it from the transducer after completing a treatment. Avoid getting the gel on the handpiece or control unit.
8. Transducers should be cleaned between procedures. See cleaning procedure information immediately preceding this subsection.
9. Keep new transducers in sealed pouches until ready for use.

10. Take care to store transducers in a safe and secure location to prevent damage in between usage.
11. Do not hold the handpiece in a manner that could damage the cord or strain relief while removing or inserting transducers.

CAUTION: Always check the expiration date on the transducer before using. Expired transducers should not be used.

10 Reorder Information

Please contact Ulthera, Inc. or your country representative to order transducers or other items for your system.

DESCRIPTION	CATALOG/ REORDER NUMBER
Ulthera® Control Unit (PRIME)	UC-1
Ulthera® DeepSEE® Handpiece	UH-2
Ulthera® DeepSEE® Transducer DS 7-3.0	UT-1
Ulthera® DeepSEE® Transducer DS 7-3.0N	UT-1N
Ulthera® DeepSEE® Transducer DS 4-4.5	UT-2
Ulthera® DeepSEE® Transducer DS 7-4.5	UT-3
Ulthera® DeepSEE® Transducer DS 10-1.5	UT-4
Ulthera® DeepSEE® Transducer DS 10-1.5N	UT-4N
Ulthera® System Access Key	UK-1
Ulthera® System Cart	UR-1
(Optional) Ulthera® System Case	US-1
(Optional) Ulthera® work surface pad	UP-1

11 Safety Standards and Regulatory Classifications

FDA Product Classification 21 CFR § 878.4590. Class II Medical Device in the US
Type B applied part, non-AP/APG rated. CISPR 11 Group 1 Class A
Ingress protection: IPx0 (“Ordinary Equipment”) for Control Unit; IPx1 for mated transducer and handpiece.
Mode of operation: Continuous.
Patient contacting materials comply with ISO 10993-1
ISO 13485 Quality Assurance Standard
ISO 14971 Medical Device – Application of Risk Management to Medical Device
ISO 14155 Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practices
ISO 15223 Medical Devices – Symbols to be used with Medical Device labels, labeling and information to be supported
ISO 20417 Information Supplied by the manufacturer of medical device
ANSI/AAMI ES60601-1:2005/A2:2021 Medical Electrical Equipment, Part 1: General Requirements For Basic Safety And Essential Performance
BS EN 60601-1:2006+A2:2021 Medical Electrical Equipment, Part 1: General Requirements For Basic Safety And Essential Performance
CAN/CSA C22.2 NO. 60601-1:14 + A2:22 (R2022) (CONSOLIDATED) Medical Electrical Equipment, Part 1: General Requirements For Basic Safety And Essential Performance
IEC 60601-1:2005+A1:2012+A2:2020 Medical Electrical Equipment, Part 1: General Requirements For Basic Safety And Essential Performance
IEC 60601-1-2:2014/A1:2020: Electromagnetic disturbances - Requirements and tests. CISPR 11 class A Group 1
CAN/CSA C22.2 NO. 60601-1-6:11(R2021) CONSOLIDATED EDITION Collateral standard: Usability
IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 CSV Collateral standard: Usability
IEC 60601-2-37:2007/AMD1:2015 Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-62:2013 Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment
IEC 62304: 2006/A1: 2015 Medical Device Software – software life cycle processes
ANSI/AAMI/IEC 62366-1:2015 (R2021)+AMD1:2020 Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices + Amendment 1
CAN/CSA-IEC 62366-1:15 (R2020) + A1:21 (CONSOLIDATED) Medical devices - Part 1: Application of usability engineering to medical devices
IEC 62366-1:2015+AMD1:2020 CSV CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices

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Ulthera, Inc.
6501 Six Forks Rd
Raleigh, NC 27615
Phone: +1 919 582 8000 & +1 877 858 4372
Ultherapy.com

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