1. Introduction to Manual

1.1. Purpose

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

Warning: Do NOT operate the Ulthera System before reading this manual thoroughly. In addition to this manual, additional clinical training may be available by 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.

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 eye brow
- lift lax submental (beneath the chin) and neck tissue

2.2. Contraindications

The Ulthera System is contraindicated for use in patients with:

- Open wounds or lesions on the face and/or neck
- Severe or cystic acne on the face and/or neck

2.3. Precautions

When not in use by trained personnel, the Ulthera System User Access Key should be removed from the system to help prevent unauthorized use. Keep the Ulthera System User 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 filters
- Implanted electrical devices in the face and/or neck
- Metal stents in the face and/or neck area

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

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 homeostatic 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.

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 handle to discontinue treatment in progress, and/or press the red emergency Stop button to completely half system operation.

2.5. Potential Side Effects

Side effects reported in the clinical evaluation of the Ulthera System 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 a few days of treatment.
- Pain: Momentary discomfort may be experienced during the procedure while energy is being deposited. Post procedure discomfort or tenderness to the touch is also possible.
- Bruising: Mild bruising, which is caused by damage to soft tissue blood vessels, may occur occasionally and typically resolves within a few days of treatment.

- Nerve Effects:
  - Transient local muscle weakness may result after treatment due to inflammation of motor nerve.
  - Transient numbness may result after treatment due to inflammation of a sensory nerve.
  - Transient pain, paresthesia and/or tingling may be experienced.

  No permanent injuries to facial nerves have been reported.
- Scarring: The possibility for scar formation (which may respond to medical care) may exist if incorrect treatment technique is used.

2.6. Complaints and Adverse Events

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

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

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 touch screen, the handpiece with cable, and inter changeable transducers (see Figure 3.1).

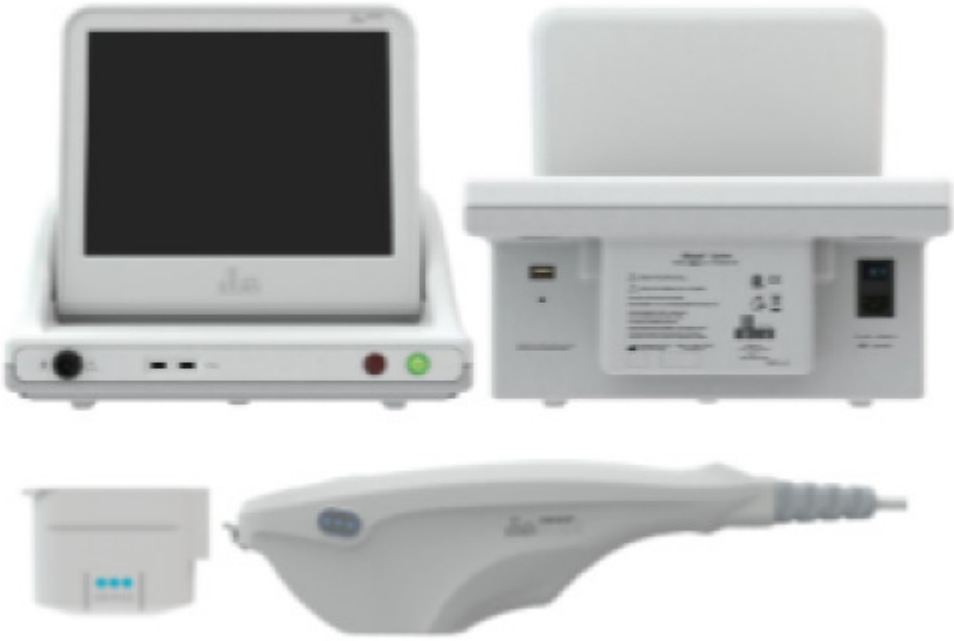

Figure 3.1 Main components of Ulthera System: Control Unit (top), Handpiece (bottom right), Image/transducer (bottom left) that inserts into the handpiece receptacle.

3.2.1. Control Unit

The control unit is the tabletop information center for the Ulthera System. It houses the touch screen monitor and Graphical User Interface (GUI) that allows the user to interact with the device. This screen sets and displays the operation 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.

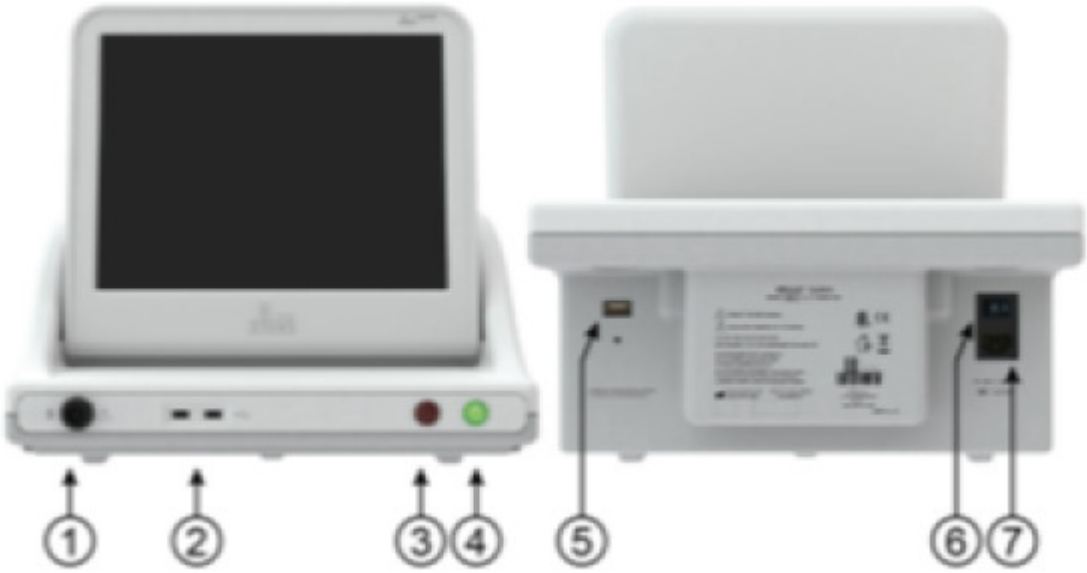

Figure 3.2 Control Unit front view (left) and rear view (right).
See table 3.1 for a description of the controls and connector parts of the control unit.

Table 3.1 Control Unit connector parts and controls (see figure 3.2)

ITEM		**DESCRIPTION**
1	Handpiece Connector Receptacle	Socket for plugging in handpiece cable
2	USB Parts (two)	For optional USB removable storage device
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 USB port	For Ulthera System User Access key
6	Main Power Switch	Supplies power to system. Leave ON (symbol “I” pressed in)
7	Power Card Receptacle	Socket for attachment of power card

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 on 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 parts may be used for the Ulthera System User Access Key or for an optional removable storage device [“thumb drive”].

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

The rear of the control unit has a USB port, and AC power receptacle and the main power switch. The main power switch should be left in the powered position (with the “I” 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 delivery therapy (TREAT). Figure 3.3 Handpiece with transducer inserted, top and side views. 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.

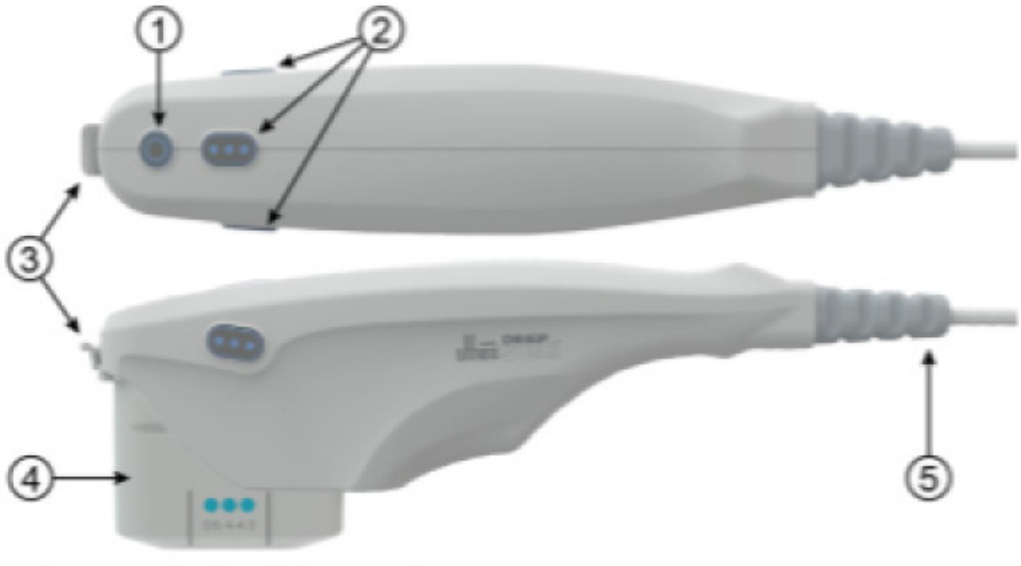

Figure 3.3 Handpiece with transducer inserted, top and side views.

Table 3.2 Handpiece and Transducer Description

ITEM		DESCRIPTION
1	SEE Pushbutton	● Engages IMAGEING state (if not already imaging) ● Places system in READY state (times out in 40 seconds) ● Stops TREATING if treatment 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 to 25 mm long and can image a depth of up to 8 millimeters. 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)

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 transducer that has been damaged or is leaking fluid.

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 comes with a three-conductor AC power cord and plug. Use a properly ground outlet and always plug the Ulthera System 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 card from the outlet by pulling on the plug not the card.

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/10cm around the control unit. If ventilation holes are obstructed, the system could overheat.

The Ulthera control unit is rated as a Type BF 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 regged as possible; however, the 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 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 User Access Key should be removed from the system to help prevent unauthorized use. Keep the Ulthera System User 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. (See explanation of ALARA in Technical Information Manual).

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℃. Scanning will be automatically disabled if the internal transducer temperature reaches 43℃.

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.

Ulthera 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.

Main (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.

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. Ulthera 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 Ulthera. 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.

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 BF Applied Part
	CE marking indicating manufacturer's declaration of compliance with appropriate EU product directives
	Canadian Standards Agency
	Consult instructions for use
	Date of Manufacture
SN	Serial Number
	Emergency Stop
	Power Standby Switch
	Indoor Use Only
	Keep electrical waste separate from municipal waste
	Recycle Packaging
IPx1	Mated handpiece and transducer protected from the effects of vertically dripping water
	Catalogue Number