USER'S GUIDE

℞ONLY

CAUTION: Federal Law (U.S.) restricts this device to sale by or on the order of a physician.

CONTENTS

1. Introduction

Hologic Inc. is dedicated to providing service and support to its customers. If there are any questions concerning the use of the Acessa System, please contact Customer Service at:

Hologic Incorporated
250 Campus Drive
Marlborough, MA 01752 USA
Telephone: 800.442.9892

2. Indications For Use

The Acessa procedure is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance.

The Acessa procedure includes optional three-dimensional (3D) electromagnetic guidance, or 3D Guidance. This allows visualization of the Acessa Handpiece relative to the Ultrasound Transducer, and for predicting the Handpiece travel path on a user-provided display which simultaneously shows the ultrasound B-scan image.

3. Device Description and Components

The Acessa procedure provides radiofrequency (RF) ablation, Ultrasound Image and 3D Guidance within a single console and includes additional accessories.

The Acessa procedure is designed to deliver monopolar radiofrequency (RF) energy to tissue through a disposable Handpiece. The System is capable of delivering up to 200W of power. The Console is specifically designed to be used only with Hologic manufactured devices. The Acessa procedure displays temperature or power depending on the mode being used to assist the physician with monitoring and controlling the ablation throughout the procedure.

The Acessa procedure must be used under laparoscopic ultrasound guidance. The basic function of ultrasound is to acquire ultrasound echo data and to display the image in ultrasound B-Mode. Ultrasound wave pulses released from a transducer are reflected at the internal body system. Reflected waves are transmitted from the transducer, and ultrasound images are produced on the monitor. The system is designed for imaging with the Acessa Ultrasound Transducer (5-12 MHz).

The Acessa Guidance System feature is an advanced electromagnetic 3D spatial tracking system designed to display the position and orientation of sensors within a defined volume. The sensors are embedded in the tip of the Acessa Handpiece and the Acessa Ultrasound Transducer, so that the system can determine the position and orientation relative to each other within the patient's abdominal cavity and display a visual image on a monitor.

The Acessa procedure consists of the following components:

The Console contains the following hardware and electronic components:

- RF Ablation system
- Ultrasound Image system
- 3D Guidance system

The following accessories connect to the Console:

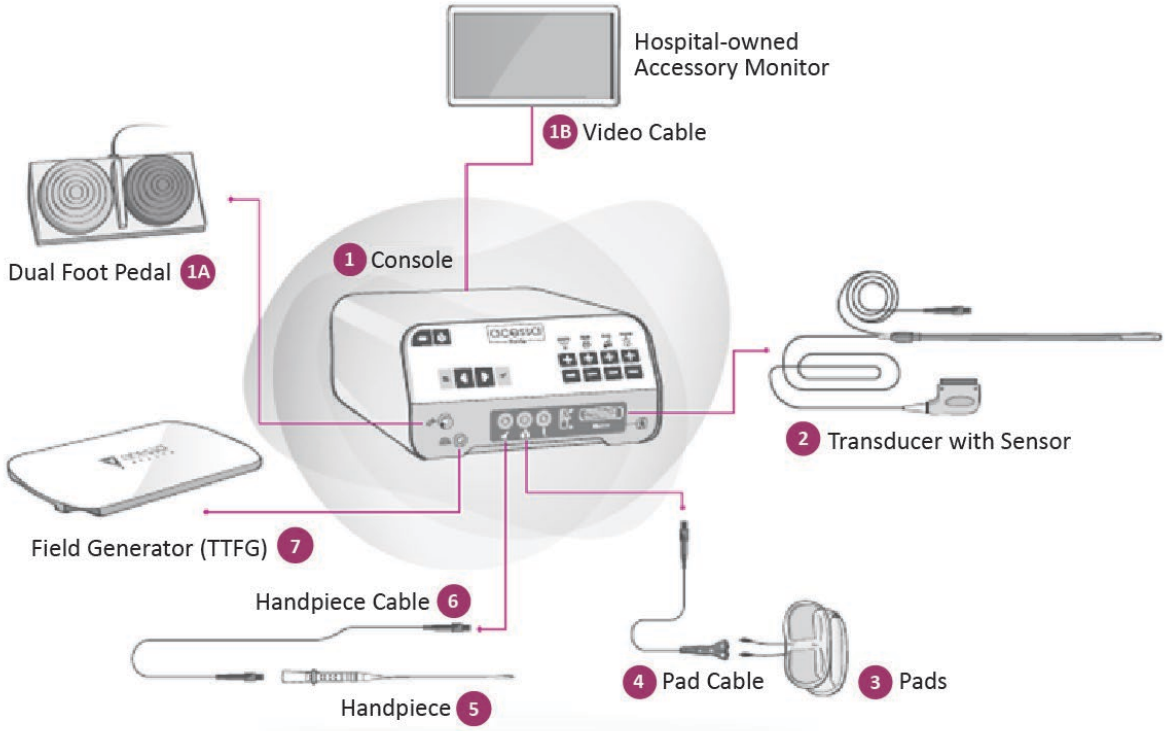
- Foot Pedal (one pedal for ablation, one for coagulation)
- Video Cable (HDMI connector for Acessa console, DVI connector for customer display)
- Power Cord
- Acessa Leg Pads (For IFU see PL-01-0015) and Acessa Leg Pads Cable (For IFU see PL-01-0012)
- Acessa Handpiece with 3D Guidance Sensor (For IFU see PL-01-0038) and Acessa Handpiece Cable (For IFU see PL-01-0041)
- Acessa Ultrasound Transducer with 3D Sensor (For IFU see PL-01-0044)
- Acessa Table Top Field Generator (TTFG) and Table Pads (Not Shown)
- Monitor (Hospital-owned, not provided by Hologic Inc. Monitor must have at least a 1920 x 1080 resolution and 27" or larger diagonal screen diameter preferred.

The Handpiece and Leg Pads are single use, the remaining components are multi-use.

The Acessa Procedure System

The Acessa Procedure system consists of the following components:

Figure 3-1 Acessa System Components



1. **Acessa ProVu System Console (Model Number 7100)**

1A. **Dual Foot Pedal (Part Number MS-06-0171):** Prenumatic foot pedals with tubing used to turn RF energy on and off. The foot pedal with the tubing is provided with the Console.

1B. **Video Cable (Part Number MS-25-0107):** An HDMI to DVI cable that connects the Console to the hospital-owned accessory video monitor.

1C. **Power Cord (Part Number MS-20-0060):** (not shown) A medical grade power cord that provides AC power to the Console. The Power Cord is provided with the Console.

2. **Acessa ProVu Transducer with Sensor (Model Number 7700):** A rigid probe, ultrasound transducer with sensor that connects to the Acessa ProVu Console.

3. **Acessa Pads (Model Number 3000):** A disposable set of 2 units, providing the return path for the RF energy applied by the Handpiece. Use only the Pads provided by Acessa Health Inc.

4. **Acessa Pad Cable (Model Number 4300):** Connects the Pads to the Console by a 2.9m extension cable.

5. **Acessa ProVu Handpiece (Model Number 7300):** The disposable, guidance Handpiece delivers the RF energy used in the Acessa procedure.

6. **Acessa ProVu Handpiece Cable (Model Number 7400):** Connects the Acessa ProVu Handpiece to the Console. This 2.4m cable is provided separate from Handpiece.

7. **Acessa Table Top Field Generator (TTFG) (Model Number 5200):** The Table Top Field Generator (TTFG) generates a magnetic field that is picked up by the magnetic guidance sensors in the Handpiece and the Ultrasound Transducer with Sensor. A 2.4m cable is provided with the TTFG that connects to the Console.

4. Contraindications

4.1 Patients who are not candidates for laparoscopic surgery (e.g. patients with known or suspected intra-abdominal adhesions that would interfere with safe use of the Handpiece).

4.2 Uterus adherent to pelvic tissue or viscera.

4.3 Non-uterine pelvic mass.

4.4 Acessa ProVu System's procedure's guidance system is not intended for diagnostic use.

4.5 The Acessa ProVu System's procedure's guidance system may not be used to guide the tip of the Handpiece once the tip has penetrated the uterine serosa. Ultrasound visualization must be used during fibroid penetration and treatment.

5. Warnings

5.1. General Warnings

5.1.1. The safety of the electrosurgery will be greatly enhanced by a thorough knowledge of the medical literature on the subject. Study of specific information on the hazards and complications of the procedure in question is especially recommended.

5.1.2. Read all instructions for use of the Acessa ProVu System procedure prior to its use. Safe and effective electrosurgery is dependent not only on equipment design but also on factors under control of the operator. It is important that the instructions supplied with this equipment be read, understood, and followed in order to enhance safety and effectiveness.

5.1.3. The safety and effectiveness of the Acessa ProVu System's procedure's electromagnetic tracking system to guide the tip of the Handpiece has not been evaluated in clinical trials. Therefore, the electromagnetic tracking system should only be used until the device has penetrated the uterine serosa.

5.1.4. The Acessa ProVu System procedure should only be used by physicians and qualified medical personnel trained in the safe use of electrosurgery and in the proper use of the Acessa ProVu System procedure. After utilizing the Acessa ProVu System procedure to determine the desired entry location into the uterus, the physician must verify the final placement of the Handpiece shaft and needles within the target tissue using ultrasound.

5.1.5. DO NOT USE with hybrid trocar systems, i.e. a combination of metal and plastic, when using monopolar active components. This may result in alternate site burns due to capacitive coupling. Use only all-metal or all-plastic trocar systems.

5.1.6. When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

5.1.7. Due to concerns about the carcinogenic and infectious potential of electrosurgical byproducts (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in laparoscopic procedures.

5.1.8. DO NOT activate the Handpiece when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment.

5.1.9. The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.

5.1.10. Re-use of the Handpiece may result in patient post-operative infection. These accessories are for single use only.

5.1.11. When positioning the Handpiece, confirm proper placement prior to initiating treatment (RF energy activation). Neuromuscular stimulation could cause injury due to unwanted muscle contractions.

5.1.12. Electric shock hazard. Acessa ProVu System Console must only be used with an IEC/EN/UL/CSA 60950 or 60601-1 certified monitor.

5.1.13. Electric shock hazard. Do not remove the cover of the Console. Refer all service to Hologic Inc. There are no user-serviceable parts inside the Console.

5.1.14. Electric shock hazard. Do not saturate the Console with liquids. Do not allow liquids to run inside the unit. Do not immerse the unit in water. Shut off the Console and disconnect power before cleaning. Do not sterilize the unit.

5.1.15. Electric shock hazard. Console must only be connected to a supply mains with protective earth.

5.1.16. When applying the Pads as described in this document or the Pad IFU (PL-01-0015), if it is found that the Pads will overlap, the Acessa ProVu System procedure cannot be used for that patient. SEVERE SKIN BURNS MAY RESULT.

5.1.17. FOR SINGLE USE ONLY! Re-use of the Pads may result in patient burn and/or infection.

5.1.18. FOR SINGLE USE ONLY! Re-use of the Handpiece may result in patient post-operative infection.

5.1.19. Treatment of children is limited due to the physical size and placement of Pads with respect to RF ablation site.

5.1.20. Treatment with the Acessa ProVu System procedure is not recommended for nursing mothers or pregnant women.
5.1.21. Electrosurgery is not recommended for patients with metal implants near the ablation site or along the RF return path to Pads.
5.1.22. Safety of using heat or cryo during or following the Acessa procedure has not been studied.
5.1.23. If the patient has a pacemaker, consult the patient's cardiologist prior to this procedure. Using the Acessa ProVu System procedure in the presence of an internal or external pacemaker may require special considerations.
5.1.24. In the case of a pacemaker, a possible hazard exists because interference with the action of the pacemaker may occur, and the pacemaker may become damaged. Questions should be directed to the attending Cardiologist, or to the pacemaker manufacturer.
5.1.25. Do not use the Acessa ProVu System procedure during cardiac defibrillation.
5.1.26. The Transducer should not be used to manipulate the bowel during the procedure due to the risk of bowel injury.
5.1.27. ONLY Hologic Inc. accessories may be attached to and used with the Acessa ProVu System procedure. The Acessa ProVu System procedure is not compatible with any other RF devices or electro-magnetic guidance devices.
5.1.28. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
5.1.29. For surgical procedures where the RF current could flow through parts of the body having a relatively small cross sectional area, the use of bipolar techniques may be desirable in order to avoid unwanted tissue damage.
5.1.30. The device should not be used on patients with bleeding disorder or an anticoagulant therapy.
5.1.31. No modification of this equipment is allowed.
5.1.32. The connector of the TTFG must be positioned on the side of the patient opposite the physician.
5.1.33. The Acessa ProVu System procedure is sensitive to strong radiated and conducted electromagnetic interference. In the event of such interference, the Console will cease displaying guidance information and will display an alert message. The user should discontinue use of the Acessa ProVu System procedure until the source of the interference can be determined and removed.

5.2. Environmental and EMI Warnings

5.2.1. In the case of a pacemaker, a possible hazard exists because interference with the action of the pacemaker may occur, and the pacemaker may become damaged. Questions should be directed to the attending Cardiologist, or to the pacemaker manufacturer.
5.2.2. Any additional monitoring electrodes should be placed as far as possible from the Handpiece and should incorporate high-frequency current limiting devices. Needle monitoring electrodes are not recommended.
5.2.3. Do not use flammable anesthetics, gases, or liquids while the system is in use. The risk of igniting flammable gases or other materials is inherent in electrosurgery and cannot be eliminated by device design. Precautions must be taken to avoid contact of flammable materials and substances with electrosurgical electrodes, whether they are in the form of an anesthetic or skin preparation agent, or produced by natural processes within body cavities, or originate in surgical drapes, tracheal tubes or other materials.
5.2.4. ASPIRATE fluid from the area before activating the instrument. Conductive fluids (e.g. blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.
5.2.5. There is a risk of pooling of flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be removed before RF surgical equipment is used.
5.2.6. The presence of endogenous gases may create an ignition hazard. Ensure that the operating room is well ventilated.
5.2.7. Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in normal use of the RF surgical equipment.
5.2.8. This equipment has been tested and found to comply with the EMC limits for the Medical Device (CISPR 11 Class A and IEC 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation, however, in some cases of input power fluctuations or transients (electrical fast transient, conducted immunity, and voltage dips/interrupts), compliance is achieved by safe shutdown into standby mode. If the unit responds to an EMI event by shutting down, then it will be necessary to manually reboot the system by use of the Standby pushbutton on the front of the Console. The equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. Per the IEC 60601-2-2 standard, compliance to radiated emissions is only tested in the Ready Mode; however, during ablation or coagulation

known interference will be generated which degrades nearby AM radio receivers and other equipment sensitive to harmonics of the 460 kHz RF Generator operating frequency. There is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

5.2.9. The use of Pads, Handpiece, Cables, and accessories other than specified, with the exception of those devices sold by Hologic Inc. for the system as replacement parts for components may result in increased emissions or decreased immunity of the Acessa ProVu System procedure.

5.2.10. Electric shock hazard. Do not saturate Console with liquids. Do not allow liquids to run inside the unit. Do not immerse the Console in water. Shut off the Console and disconnect power before cleaning. Do not sterilize the Console or Pads.

5.3. Warnings During Electrosurgical Device Use

5.3.1. Pad temperatures normally remain within a few °C of their starting temperature but occasionally can rise further for long ablations or higher than normal tissue impedance. The user is advised to have an external cooling system setup nearby in standby for this contingency. Do not use dry ice.

5.3.2. Cables connected to the device should not contact the patient or other electrical leads.

5.3.3. Skin-to-skin contact, such as between the torso and the arms or between the legs of the patient should be avoided by insulating these contacts with sheets or dry gauze.

5.3.4. Keep the Handpiece active electrode arrays clean. Build-up of eschar may reduce the instrument's effectiveness. Do not activate the instrument while cleaning. Injury to operating room personnel may result.

5.3.5. Do not touch the Handpiece tip and Pads at the same time especially when operating the Console, as capacitive coupling may lead to burns.

5.3.6. When using the device in situations where vision may be limited, burns may result if the device is activated outside the field of view.

5.3.7. Failure of high frequency surgical equipment could result in an unintended increase of output power.

5.3.8. Ablation RF Output is active without continuous activation of the Foot Pedal. Care needs to be taken to avoid over-exposure of RF energy which may result in tissue damage or adjacent tissue damage.

5.3.9. When not in use, electrosurgical leads (active or return) should be positioned so that they cannot come into contact with the patient, other leads or any metal objects.

5.4. Warnings Specific to the Acessa ProVu System Procedure

5.4.1. Apparent low power output or failure of the electrosurgical equipment to function correctly at normal settings may indicate faulty application of the Pads or failure of an electrical lead.

5.4.2. For monopolar surgery, effective contact between the patient and the Pads must be verified whenever the patient is repositioned.

5.4.3. The proper use and placement of the Pads are key elements in the safe and effective use of monopolar electrosurgery, particularly in the prevention of burns. Follow directions and recommended practices for the preparation, placement, surveillance, removal and use of the Pads. Use with the system in accordance with your facility's standard operating procedure, Hologic's instructions, and AAMI standards.

5.5. Warnings Concerning Acessa ProVu System Procedure Guidance Accuracy

5.5.1. Do not use the Acessa ProVu System procedure guidance system without the Table Top Field Generator (TTFG) and Pad Set (MS-26-0022). The generator should be below the patient's pelvis.

5.5.2. Do not drop the Field Generator or subject it to impact. Physical damage to the Field Generator may alter its calibration and contribute to inaccurate guidance.

5.5.3. Do not place the Acessa ProVu System console closer than 1m from the Field Generator. To do so may affect the tracking accuracy.

5.5.4. Only plastic or compatible metals may be in the magnetic field. The Acessa ProVu System procedure guidance system works by generating magnetic fields from its TTFG. Take care when using the system to not place ferromagnetic objects upon the Field Generator or within the tracking volume, or accuracy may be affected. Those metals specifically known to **cause tracking disruptions** are: mild steels such as DIN 1.4034 or DIN 1.4021, Aluminum alloys and 400 series stainless steel. The following metal alloys **do not affect the Acessa ProVu System procedure**: titanium (TiA16V4); and 300 series stainless steel.

5.5.5. Do not coil the TTFG cable or place it inside the tracking volume or wrap it around the TTFG, as it may create magnetic interference.
5.5.6. Do not place the Handpiece cable within 30 mm of the TTFG cable.
5.5.7. Do not wrap the Handpiece cable around the Transducer cable or Console cables.

5.6. Warnings Specific to Uterine Fibroid Ablation

5.6.1. Insufficient data exist on which to evaluate the safety and effectiveness of Acessa procedure in women who plan future pregnancy. Therefore, the Acessa procedure is not recommended for women who are planning future pregnancy.
5.6.2. To reduce the risk of injury to organs outside of the uterus, electrode tips must be deployed no closer than 1 cm from the fibroid margin in all planes.
5.6.3. Always verify that the electrode arrays are fully retracted before positioning, advancing, or withdrawing the Handpiece.
5.6.4. The Handpiece tip should be allowed to cool for at least 60 seconds after the ablation has stopped, prior to removing it from the target tissue.
5.6.5. To reduce the risk of hematoma, identify the inferior epigastric arteries prior to percutaneous insertion of the Handpiece.
5.6.6. The safety and effectiveness of the Acessa procedure has not been evaluated in women with uterine size >14 weeks.
5.6.7. Uterine tissue may contain unsuspected cancer, particularly in patients who are peri- or post-menopausal. Insufficient data exist on which to evaluate the safety and effectiveness of Acessa procedure for treatment of cancerous uterine tissue. Thoroughly discuss the benefits and risks of all treatments with patients.
5.6.8. Do not substitute transabdominal or transvaginal ultrasound for laparoscopic ultrasound when performing the Acessa procedure.

6. Precautions

6.1. General Precautions

6.1.1. Do not use the Acessa ProVu System procedure if any of the hardware components, cables, or connectors are damaged. Such damage may affect system functionality.
6.1.2. If the system becomes unresponsive during a procedure, reboot the system. If the problem persists, call Hologic Inc. customer service, refer to §1 for applicable contact information.
6.1.3. Reusable accessory cables should be periodically inspected for damage to insulation and tested for function and safety in accordance with the cable's instructions for use.
6.1.4. The Hospital-owned accessory video monitor (an IEC/EN/UL/CSA 60950 or 60601-1 certified monitor) must have at least a 1920 x 1080 resolution and a DVI input. A 27" or larger diagonal screen is preferred.
6.1.5. Position the Console to allow adequate ventilation during operation.
6.1.6. Arrange cables to minimize trip hazard and avoid damage.
6.1.7. Position the Console to allow easy access to the On/Standby power switch on front of Console.
6.1.8. Dispose of used Handpieces, Pads, and Cables in accordance with local, state, and national bio-waste laws and regulations.
6.1.9. Always turn the Console power OFF before connecting or disconnecting the power cord and TTFG cable. Not doing so may result in sparks being generated.
6.1.10. The Console should not be used adjacent to or stacked with other equipment. The system should be observed to verify normal operation in the configuration in which it will be used.
6.1.11. Portable and mobile radio frequency (RF) communications equipment can affect the Acessa ProVu System procedure functionality.
6.1.12. Do not expose the Handpiece or Ultrasound Transducer to a high magnetic field such as a Magnetic Resonance Imaging (MRI) scanner, as they may become magnetized and affect system functionality.
6.1.13. Mains power quality should be that of a typical commercial or hospital environment. If the user of the Acessa ProVu System procedure requires continued operation during power mains interruptions, it is recommended that the Console be powered from an uninterruptible power supply.
6.1.14. Do not use abrasives, caustics, or mineral spirits. Use of these agents to clean the Console or any of its accessories may cause damage and voids the warranty. All electrical connection ports must be air-dried before use.
6.1.15. The output power selected should be as low as possible for the intended purpose.

6.2. Environmental and EMI Precautions

6.2.1. Non-flammable agents should be used for cleaning and disinfection wherever possible. (See Cleaning and Disinfecting instructions and precautions for the validated cleaning agent. (§17.3)

6.2.2. Interference produced by operation of high-frequency surgical equipment may adversely affect the operation of other electronic medical equipment such as monitors and imaging systems. This can be minimized or resolved by rearranging monitoring device cables so they do not overlap the Acessa ProVu System procedure's cables.

6.3. Precautions During Electrosurgical Device Use

6.3.1. Due to the non-homogenous conduction that occurs near organ surfaces or vasculature, shapes of ablations performed in these areas may be altered. Careful planning is needed for targets in these locations

6.3.2. Any application or procedure that alters tissue perfusion and affects temperature elevation should be monitored carefully.

6.4. Precautions Specific to the Acessa ProVu System Procedure

6.4.1. A USB flash memory device is the only device that should be inserted into the back panel USB port (USB port, Item T as shown in §8.4). This port is for Hologic personnel only.

6.5. Precautions Concerning Acessa ProVu System Procedure Guidance Accuracy

6.5.1. The System's guidance capability has ±10 mm accuracy.

6.6. Precautions Specific to Uterine Fibroid Ablation

6.6.1. Avoid excessive pressure (e.g. lateral pressure) on the Handpiece which could bend or damage the shaft and/or electrode array.

6.6.2. To avoid damage to the electrode arrays, maintain stability of the uterus position and do not rotate the Handpiece when electrodes are deployed in tissue.

7. Sterilization and Safety Checks

Prior to performing a procedure, the following checks should be performed.

1. Inspect the Handpiece and Leg Pads and packaging for damage.

2. Inspect the Handpiece and Leg Pads for any obvious damage.

3. Inspect the medical grade power cord for insulation damage or frayed wire connections.

4. Clean and sterilize the Ultrasound Transducer in accordance with the recommended process in the Instructions for Use accompanying the Acessa Ultrasound Transducer. Ensure that the cable interconnections are clean and dry prior to use.

5. Clean and sterilize the Handpiece Cable in accordance with the recommended process in the Instructions for Use accompanying the Handpiece cable. Ensure that the cable interconnections are clean and dry prior to use.

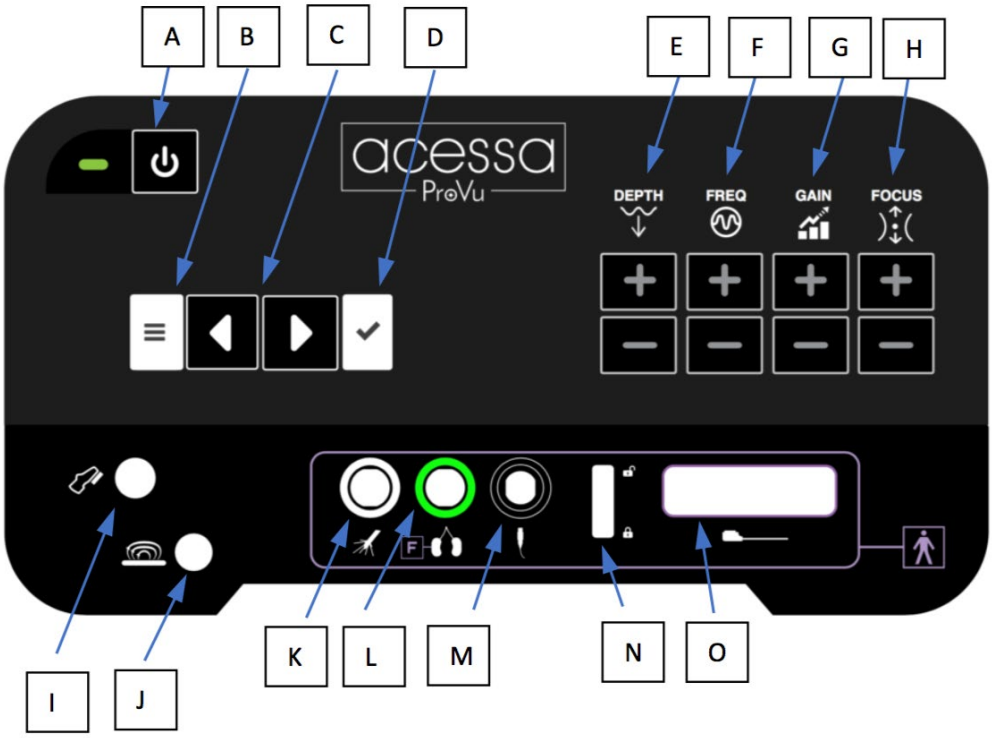
6. Clean and disinfect the Leg Pads Cable in accordance with the recommended process in the Instructions for Use accompanying the cable. Ensure that the Pad cable interconnections are clean and dry prior to use.

7. The Console, Foot Pedal, and Table Top Field Generator (TTFG) should be cleaned and disinfected per Section 17 Care and Maintenance.

8. Switches, Buttons, Connections, and Display

Front panel controls are shown below.

Figure 8-1 Front Panel



Buttons, Connections and Display

A. ON/OFF Button, LED (power status) Indicator
- When OFF (Console disabled, no display), the LED will be orange.
- Push ON/OFF button to turn Console ON (LED will turn green). The Console is in "ready" mode when on. If emergency RF shutoff is required during ablation, the user can turn off RF power by momentarily pressing the front panel ON/OFF button.

B. MENU Button

Brings up the menu to access the user-adjustable settings. Press to alternately show/hide the menu on the display. NOTE: Because the displayed menu will hide certain messages, it is recommended that the menu NOT be displayed during active use.

C. MENU SCROLL Buttons

Allows the user to scroll through the menu items. The user-adjustable items are:
- Full-screen Ultrasound Image or split-screen mode Ultrasound Image/3D Guidance Image
- Estimated ablation volume image on/off
- Coagulation relative power level
- OR setup establishes position of surgeon, patient, and displays
- Sound volume allows audible sound level adjustment

The menu will be visible when the user presses the menu button on the front console, and otherwise hidden.

D. Check Button

Used to accept the current menu item.

E. Ultrasound Depth Adjustment

Pressing the + (up) or – (down) buttons will adjust the Depth or magnification of the ultrasound image. The supported ultrasound depths are: 3cm, 4cm, 5cm, 6cm, 7cm, 8cm, 9cm, 10cm, 11cm and 12cm.

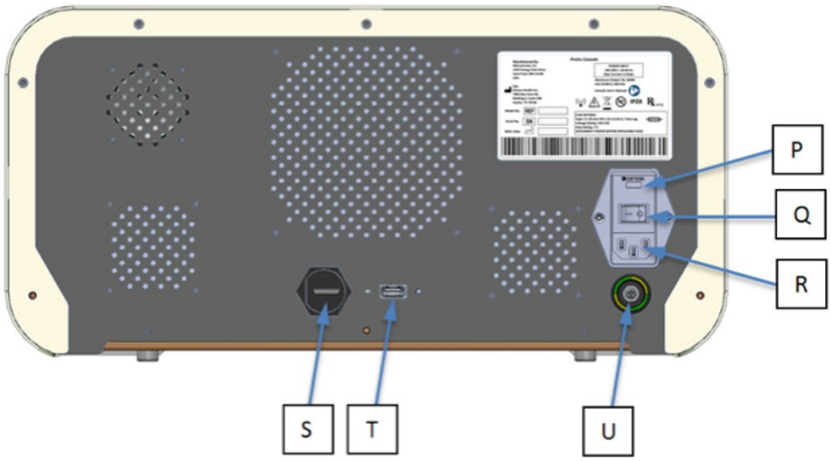
F. Ultrasound Frequency Adjustment

Pressing the + (up) or – (down) buttons will adjust the Frequency of the ultrasound. The supported frequencies are: 5MHz, 6MHz, 9MHz, and 12MHz.

G. Ultrasound Gain Adjustment
   Pressing the + (up) or – (down) buttons will adjust the Gain of the ultrasound.
H. Ultrasound Focus Adjustment
   Pressing the + (up) or – (down) buttons will move the Focus of the ultrasound. The supported focal depths are: 0.2cm, 0.4cm, 0.7cm, 1cm, 1.4cm, 1.8cm, 2.3cm, 3cm, 4cm, 5cm, 6cm, and 8cm.
I. Dual Foot Pedal Connector
   Accepts the connector from the Foot Pedal tubing.
J. Field Generator (TTFG) Connector
   Accepts the connector from the Table Top Field Generator Cable.
K. Handpiece Connector
   Accepts the connector from the Handpiece Cable.
L. Return Pad Connector
   Accepts the connector from the Pad Cable.
M. Ultrasound Transducer 3D Sensor Connector
   Accepts the 3D Guidance Sensor cable from the Ultrasound Transducer.
N. Ultrasound Transducer Image Connector Lock
   Locks the Ultrasound Transducer connector in place.
O. Ultrasound Transducer Image Connector
   Accepts the connector from the Ultrasound Transducer.

Rear panel components are shown below.

Figure 8-2 Rear Panel



Rear Panel Switches and Connections

P. Fuse Door
   The power Inlet takes two 5.0 Amp 250 volt fuses.
Q. Main Power Switch
   AC mains power switch. Positions are ON (I) and OFF (0).
R. Power Cord Inlet
   Port for connecting the Console to AC mains power via the medical-grade Power Cord.
S. HDMI Video Connector
   Port for connecting an external 1920 x 1080p monitor.
T. USB Port
   This port is for Hologic personnel only.
U. Equipotential Terminal (EP terminal)
   Safety ground equalization terminal. This terminal is available for providing a direct connection between safety ground of other nearby electrical equipment, if needed. Consult facility biomed engineering department for applicability.

9. Setting up the Acessa Procedure

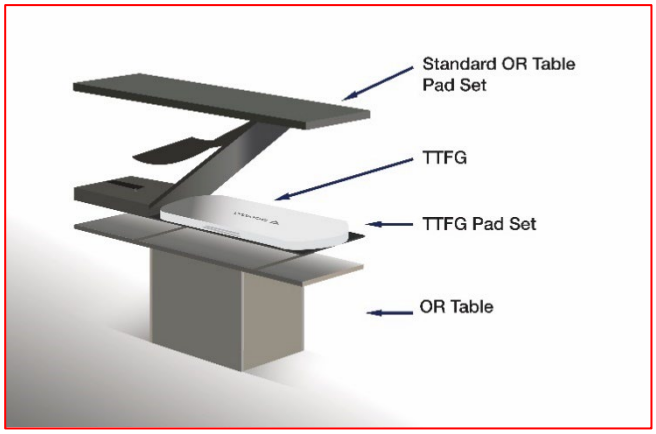
Connecting System Components

Verify that components have been checked and sterilized as described in Section 7.
Note: As used below, "Ports" refer to **Figure 8-1** and **Figure 8-2** as identified above.

Before Patient Arrives

1. Before the Patient arrives, set up appropriate Field Generator.
2. Acessa Table Top Field Generator (TTFG) setup: Remove the standard OR table pad from the OR table first.
3. Place the TTFG Table Pad (MS-26-0022) on the OR table.
4. Place the TTFG inside of the Table Pad.
5. Position the TTFG and Table Pad configuration, end with the TTFG closest to the end of the Table Pads, aligned with the break in the bed.
6. Place and align the remaining Table Pad to cover the remainder of the exposed OR table.
7. Next place the standard OR table pad back on top of the Table Pad by aligning the adjoining Velcro strip of the OR pad with the Table Pad.

Figure 9-1 Table Setup



8. Plug the TTFG Cable into the TTFG Cable port.
9. Connect the supplied medical grade Power Cord into the Console at **Port R** on the rear panel, and then to the wall outlet.
10. Connect the Video Cable to **Port S** on the rear panel and the other end to a 1920 x 1080p hospital-owned monitor. A screen size of 27 inches *minimum* is recommended.

    Note: Console will not fully boot if 1920x1080 display resolution is not being used. A message will appear that informs the user a 1920x1080 must be connected.

Setup Notes

1. Skin-to-skin contact, such as between the torso and the arms and between the legs of the patient should be avoided by insulating these contacts with sheets or dry gauze.

2. Any monitoring electrodes should be placed as far as possible from the Handpiece and should incorporate high-frequency current limiting devices. Cables connected to the Console should not contact the patient or other electrical leads.

3. Low power output or failure of the Console to achieve target temperature within approximately 2 minutes may indicate faulty application or connection of a Pad.

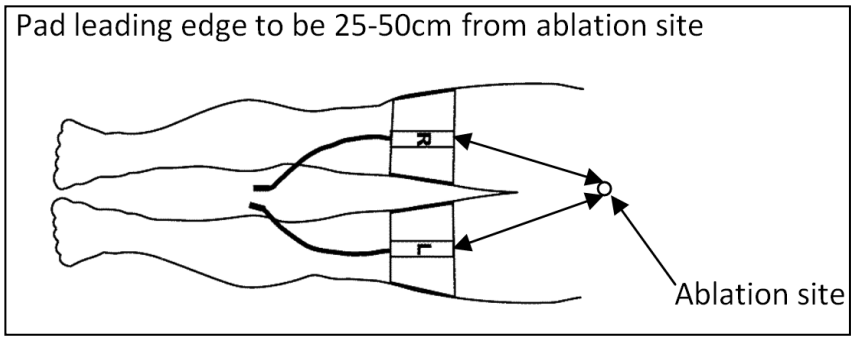
4. The accessories can be connected before or after the system has been powered ON (Power Cord must be connected prior to system power ON).

Patient Preparation

1. Remove a set of Leg Pads from its pouch. Leave the Mylar covers intact over the gel and connect the pigtail cables to the wye of the Leg Pads cable. Ensure that the pad marked "R" is connected to the wye marked "R" and similarly "L" to "L" for the other pad. Affix the Leg Pads to the patient per the Pad IFU (PL-01-0015). Consult Leg Pads Instruction for Use for prep of patient and proper Leg Pads placement.

2. Apply the Leg Pads per the figure below. The Leg Pads must be used with the Acessa procedure. The entire surface area of the Leg Pads must be reliably attached to the patient's body.

Figure 9-2 Return Pad Setup



3. The leading edge of the Leg Pads should be between 25cm and 50cm from the ablation site.

   Note: If desired fibroid treatment temperatures are not achieved when RF energy is delivered, check that the Leg Pads have been placed according to the Instructions for Use PL-01-0015. Proper Leg Pads placement is essential to a successful Acessa procedure.

   WARNING: Skin burns can occur if the Pads are not placed as instructed.

4. Prepare the patient using the standard technique for electrosurgery. The patient's entire body, including extremities, must be insulated against contacts with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.). The operating table should be grounded, and sufficient layers of electrically insulated sheets should be placed underneath the patient. The use of antistatic sheeting is recommended for this purpose. A waterproof cover should be placed over the insulating sheets, with absorbent sheets placed between the patient and the waterproof cover to absorb any moisture.

5. Connect the Pad Cable to the Console at **Port L**.

6. Connect the Handpiece to the Handpiece Cable, pass the other end of the cable from the sterile field and connect it to **Port K** on the front of the Console. The Console and Handpiece use the same connector which makes the cable bidirectional.

7. Connect the Dual Foot Pedal to the Console at **Port I**. (Note: The Dual Foot Pedal may be elevated off the floor via foot stool to limit accidental activation/deactivation.)

8. Connect the Field Generator cable to the Console at **Port J**.

9. Pass the Ultrasound Transducer Image connector from the sterile field and connect to the Console at **Port O**. Use the toggle lock at **Port N** on the Console front panel to lock the Ultrasound Transducer connector in.

10. Pass the Ultrasound Transducer 3D Sensor connector from the sterile field, and connect it to the Acessa Console's front panel via **Port M**.

10. Use of the Acessa System

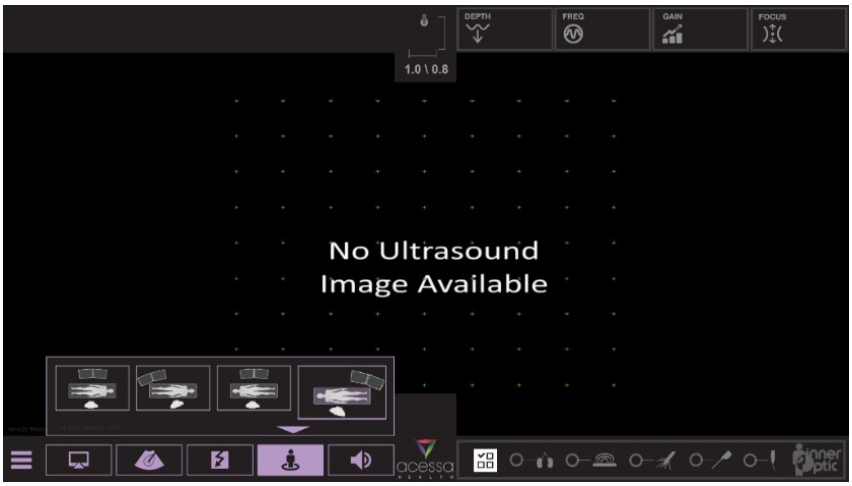
Getting Ready – Power On

1. Toggle the power switch on the rear panel, **Switch Q** in **Figure 8-2**, to the ON (I) position. This provides AC mains power to the console and illuminates the orange LED light on the front panel.

2. Press the front panel ON / OFF button to turn console fully on. The LED will turn green.

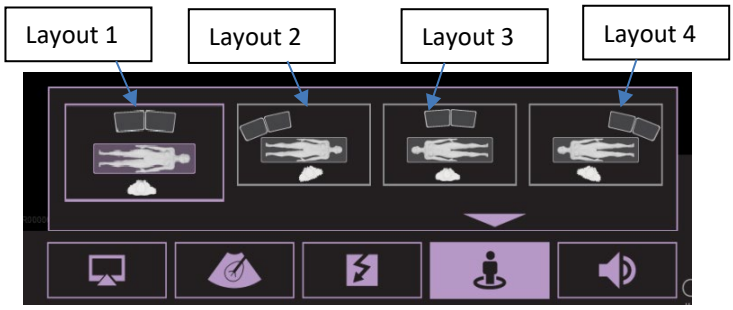
3. As the console starts up, it will go through a Power On Self Test (POST). This tests the system to ensure that everything is functioning correctly. When this test passes, three beeps will be heard that means the system is ready to use. With no accessories connected the display will appear as shown below.

Figure 10-1 Initial Display with No Accessories Connected



Initially, an Operating Room layout can be selected. Four options are available depending on positioning of patient, surgeon, and OR displays.

Figure 10-2 OR Layout Buttons



The four options are:

1. Layout 1: Monitors are at the patient's right, surgeon is on the patient's left. The left side shows 3D Guidance, and the right side shows the Ultrasound Image.

2. Layout 2: Monitors are at the patient's feet, surgeon is on the patient's left. The right side shows 3DGuidance, and the left side shows the Ultrasound Image.

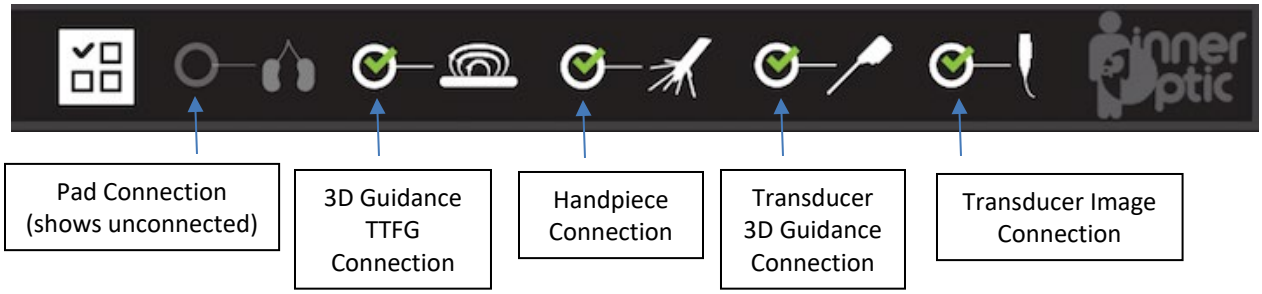
3. Layout 3: Monitors are at the patient's left, surgeon is on the patient's right. The right side shows 3DGuidance, and the left side shows the Ultrasound Image.

4. Layout 4: Monitors are at the patient's feet, surgeon is on the patient's right. The left side shows 3DGuidance, and the right side shows the Ultrasound Image.

Accessory Connections

If not already done, accessories can be connected. As each accessory is connected, an indication will appear with a green check. The Accessory Connection Dialogue Box is displayed in the lower right corner of the screen.

Figure 10-3 Accessory Connections



As the accessories are connected, the screen will display proper connection by changing the gray icon to a white icon with a green check inside the white icon.
When all the accessories are connected, the Accessory Connection dialogue box will disappear, and the user interface will become full screen. This means that all accessories are connected and working properly. The system is now ready to use.

User Interface

The User Interface is described below.

Figure 10-4 User Interface – Dual Screen

Menu Selections

Press the Menu button to turn ON and OFF the Menu Selections. **When Menu Selections are turned OFF, non-critical messages can be viewed.**

Note: So non-critical messages can be seen when they occur, it is recommended that Menu Selections be turned OFF while performing the Acessa procedure.

- The menu is accessed by pressing the Menu button.
- The Scroll buttons moves left or right to the next menu item.
- The Accept/Acknowledge button accepts a selection. Additionally, if a message or alert appears that requires acknowledgement, this button must be pressed.

Figure 10-5 Menu Navigation Buttons

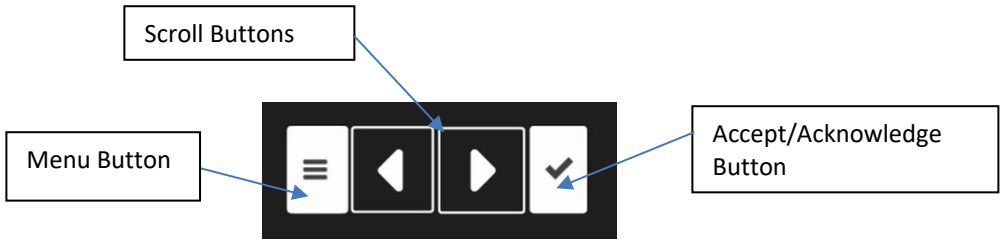
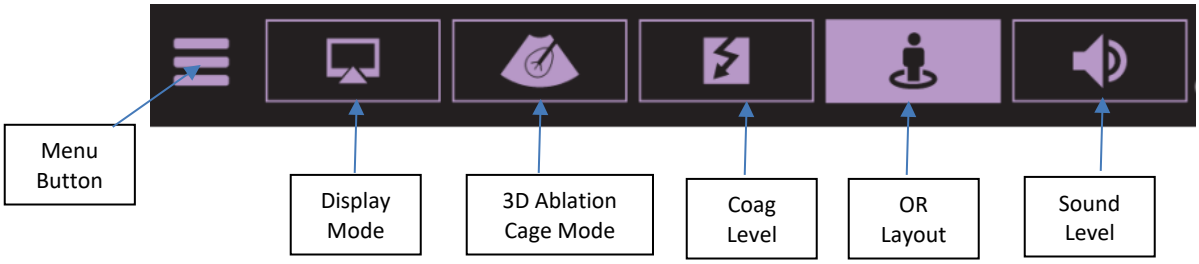


Figure 10-6 shows the Menu layout.

Figure 10-6 Menu Selections



1. Display Mode – Switch between Ultrasound Image plus 3D Guidance Image (dual screen) or full Ultrasound Image only. When in dual screen mode the screen layout is most efficient if the Ultrasound Image side is closest to the laparoscope monitor.

2. 3D Ablation Cage Mode – This mode turns the optional 3D Ablation Cage ON or OFF. This tool is used to approximate the expected fibroid volume to be ablated.

3. Coag Level – This allows the user to select the relative Coag power level. The range is 1 – 20, with 12 or the last used setting as the default, refer to **Figure 18-4** for setting information.

4. OR Layout – This allows the user to select one of the four (4) Operating Room layout options. Orientation of the displayed Ultrasound Image and 3D Guidance Image.

5. Sound Level - This allows the user to select the sound output power level. The range is 1 – 15. The sound level cannot be changed for alert notification sounds.

6. Pressing the Menu button once on the front panel will activate the menu items and pressing a second time will minimize the menu.

Ultrasound Settings

Ultrasound settings is via the front panel of the Console.

1. Depth – The Depth (magnification) options are: 3cm, 4cm, 5cm, 6cm, 7cm, 8cm, 9cm, 10cm, 11cm, and 12cm.

2. Frequency – The Frequency (penetration/resolution) options are: 5MHz, 6MHz, 9MHz, and 12MHz.

3. Gain – The Gain (brightness) options are: 0 – 100%, in 1% increments.

4. MI – Ultrasound Mechanical Index will be constantly displayed: ranges from 0.1 – 1.9

5. Focus – The Focus (near zone/far zone) options are: 0.2cm, 0.4cm, 0.7cm, 1cm, 1.4cm, 1.8cm, 2.3cm, 3cm, 4cm, 5cm, 6cm and 8cm.

Figure 10-7 Ultrasound Settings

Expected Ablation Size

Both a numerical pair of values and a pictorial representation of the expected ablation are displayed, based on the user Handpiece deployment.

- The numerical value pair, (length x width) in centimeters, correlates with the tables in **Figure 12-2** and **Figure 12-3** in Section 12 Ex-Vivo Studies. This is always displayed, regardless of display mode.
- The pictorial representation appears as an orange image around the tip of the Handpiece. The orange ring is only shown in the 3D Guidance view and can be enabled/disabled in the Menu Selections. Refer to **Figure 10-4**.

Needle Deployment

Displays the length of needle extension (deployment) of the electrode arrays in centimeters.

Target Ablation Time

Target ablation time is set based on the Handpiece deployment settings chosen.

Pad Temperatures

1. Each pad has three thermocouples. Only the temperature of the warmest thermocouple is displayed on the screen. The left temp is for the left pad, and the right temp is for the right pad.
2. The Graphical User Interface (GUI) displays a numeric indicator in yellow if either pad temperature reading is equal to or greater than 41°C and less than 45°C.
3. The Graphical User Interface (GUI) displays a numeric indicator in red and RF delivery for ablation cannot be started or, if currently active, will be stopped if either pad temperature reading is equal to or greater than 45°C. The Leg Pads must be cooled before ablation can be restarted.
   Coagulation mode remains enabled regardless of the pad temperatures.

Mechanical Index

This is a standard ultrasonic imaging parameter. The displayed value represents potential cavitation bioeffects of ultrasound energy on tissue. The potential for the cavitation bioeffects varies with frequency, focal depth and power and the higher MI values, the higher the likelihood of cavitation bioeffects occurring. An MI value is displayed for each ultrasound setting.

Enabling RF Energy – Ablation and Coagulation

Overview

RF energy is used for both ablation and coag functions. The upper left corner of the display is used to report the status of RF delivery once either Foot Pedal is pressed.

Figure 10-8 Foot Pedals

When the YELLOW Foot Pedal is pressed once and released the console enters the Ready-Ablate state. Pressing a second time, then releasing, will enable RF.

- If needle deployment is 0cm (not extended), RF power will ramp to 15W then remain at that level.
- If needle deployment is extended, RF power will ramp the power level up until the temperature measured by the needles reaches 95°C.
- RF power will then be reduced so that 95°C is maintained in the ablation volume.

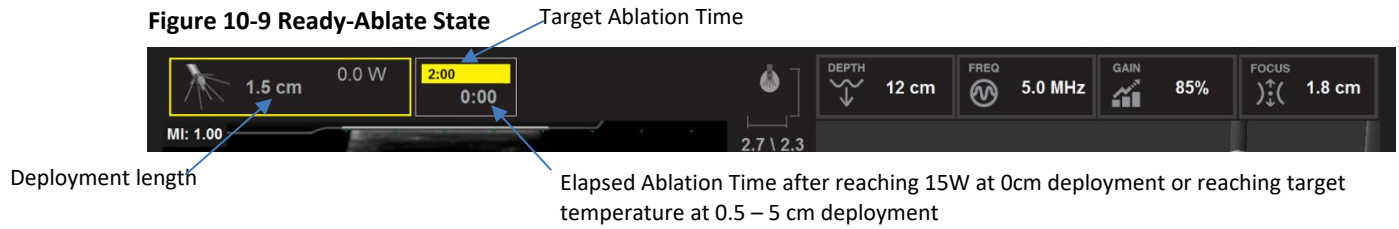
Ablation continues until the YELLOW pedal is pressed a third time, when the RF will then stop. Refer to **Figure 12-2** and **Figure 12-3** for suggested ablation times based on needle deployment. **It is the responsibility of the user to stop ablation at the appropriate time, based on the Ultrasound Image and the treatment volume, i.e. needle deployment length.**

When the BLUE Foot Pedal is pressed once and released the console enters the Ready-Coag state. Pressing and holding the BLUE pedal will continue to deliver coag RF energy as long as the pedal is pressed. When in the Coag State, the orange ablation cage, and the yellow ablation area cross section will disappear from the viewing monitor.

These RF energy delivery modes are described in further detail below.

Ready-Ablate State. After the first YELLOW pedal press, Ready-Ablate State is entered. See **Figure 10-9**. The upper left-hand frame has a yellow outline. The yellow highlight indicates the Ready-Ablate state visually to the user. Target ablation time is also displayed. The user will use the left Foot Pedal (YELLOW) to activate ablation when ready.

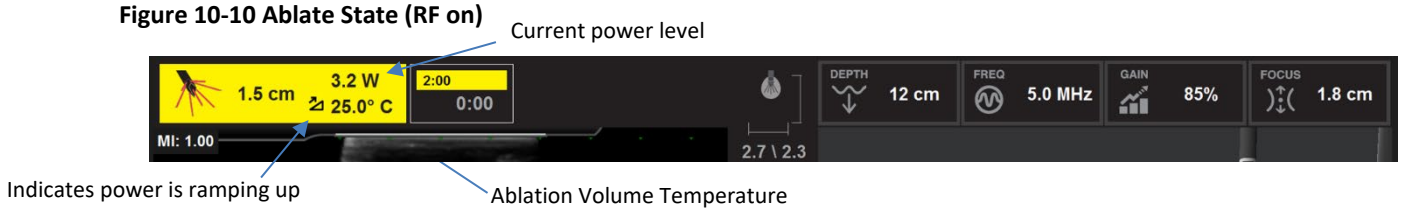
Figure 10-9 Ready-Ablate State



Ablate State. The user depresses the left Foot Pedal (YELLOW) a second time to activate RF and enter the Ablate State. In Ablate State (**Figure 10-10** below), the upper left-hand frame has a yellow background, and the array is colored maroon to indicate RF delivery.. If the user does not depress the Foot Pedal a second time within 5 seconds, the system goes back to a neutral state. The RF system adjusts power to provide a smooth upward ramp until target temperature has been reached. Ramp icon is displayed beside the ablation temperature. Under normal conditions the ablation should be continued until the time at target 95°C corresponds to the empirically determined recommended time and deployment for the desired ablation size. Refer to **Figure 12-2** and **Figure 12-3** for recommended times for all ablation sizes.

Note: At this point the user must manually turn off the RF energy by again depressing the Foot Pedal. The target time is intended as a guide only, and ablation does not stop when the target time is reached. When the Foot Pedal is pressed again to stop ablation, an audible tone sounds.

Figure 10-10 Ablate State (RF on)



Ready-Coag State. In Ready-Coag State a different left-hand frame is outlined in blue. The coag setting allows for 1-20 relative power level. Default coag power is set to the last setting chosen. Immediately following a completed ablation, the user is ready to cauterize the Handpiece track. First, the user retracts the device electrode arrays, then depresses the right Foot Pedal (BLUE) to activate the Ready Coag state.

Note: When in the Ready Coag and Coag States, the orange ablation cage, and the yellow ablation area cross section will disappear from the viewing monitor.

Figure 10-11 Ready-Coag State

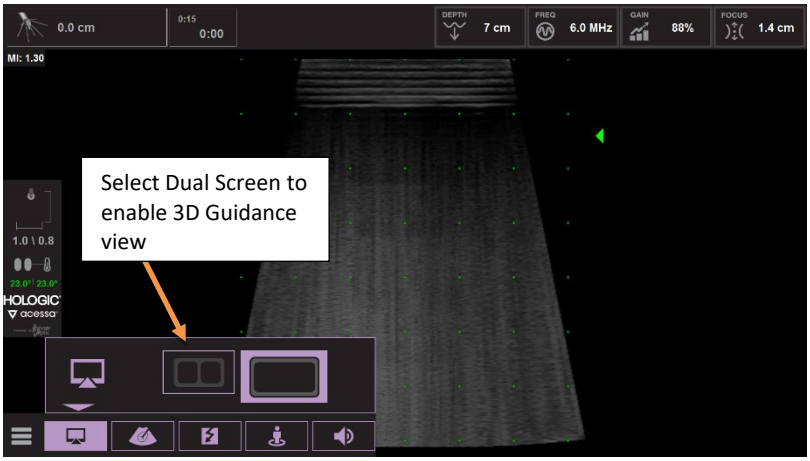
Coag State. In Coag State, the upper frame has a blue background to indicate RF delivery and the timer panel will show the elapsed time for coagulation. While in the Coag Ready state the user depresses and holds the right Foot Pedal (BLUE) to begin coag RF delivery. If the user stops pressing the right Foot Pedal (BLUE), RF delivery stops and the Console returns to the Ready-Coag State. If the user has not reactivated the Coag State after ten (10) seconds in the Ready-Coag State, the system returns to a neutral state. The system provides a coag power output proportional to the level setting. The user slowly withdraws the Handpiece while visually monitoring the coag laparoscopically, adjusting level setting as necessary to achieve optimal results. Turn off RF power when coagulation is completed by releasing the Foot Pedal.

Figure 10-12 Coag State (RF on)

The Acessa Procedure 3D Guidance System

- The 3D Guidance System feature allow the physician to see the Ultrasound Transducer and the Handpiece shaft images in real time as they are being positioned within the abdominal cavity. It places the image from the ultrasound machine onto a virtual ultrasound transducer plane and displays a "Target Zone" with purple lines where the Handpiece shaft will intersect the plane. **Fig 10-13** shows how the 3D Guidance screen is enabled through the Menu by selecting the Dual Screen mode.

Figure 10-13 Set View Mode to Dual Screen



- The 3D Guidance System feature is intended to be used as an adjunct to the standard ultrasound image to assist the positioning of the Handpiece during the Acessa Procedure. The 3D Guidance System feature aids in showing where the tip of the Handpiece would intersect the ultrasound plane. Once the tip of the Handpiece penetrates the uterine serosa, ultrasound visualization must be used to complete the process of positioning the Handpiece in the fibroid for the Acessa procedure treatment.

- After using standard ultrasound imaging as described in the Acessa procedure to locate and map a fibroid for treatment, the 3D Guidance System can be used to help determine the optimum location to enter the uterus with the tip of the Handpiece.

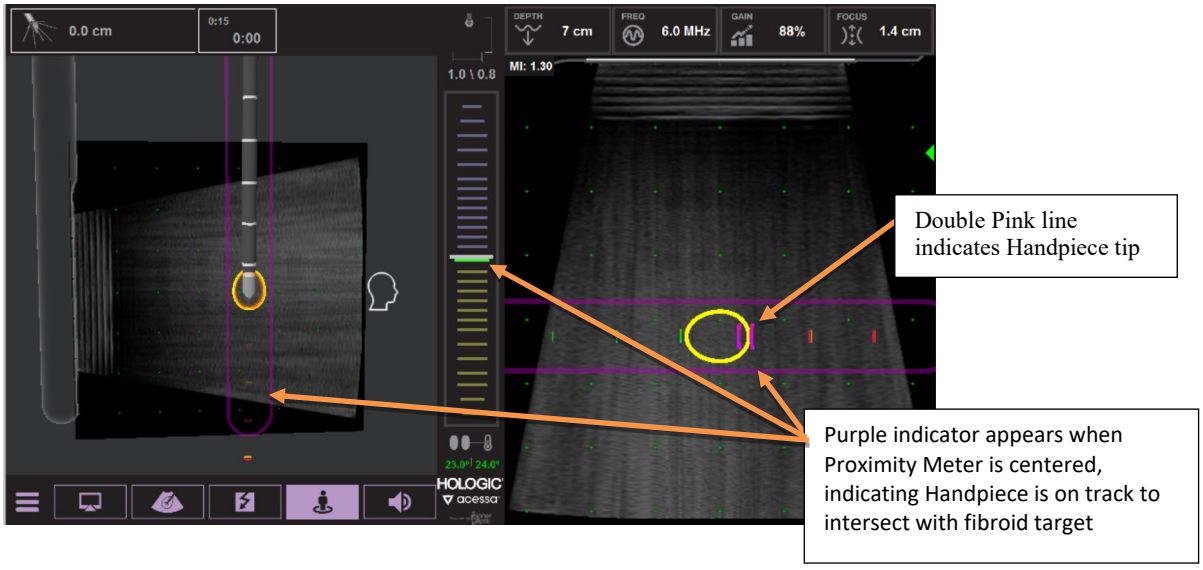
Proximity Meter: The meter in the center of the screen shows the location of the Handpiece tip relative to the ultrasound plane and is most useful when approaching the target with the Handpiece tip in the plane of the ultrasound. When the "indicator" on the Proximity Meter is centered, it shows that the Handpiece is "on plane" with the Ultrasound Transducer. When the tip is "on plane" with the ultrasound image, a green bar line in the center of the Proximity Meter will be highlighted.

Position lines: On the 3D view, if the trajectory is "in front of" the ultrasound plane (i.e. between user and plane) , YELLOW lines will appear. If the trajectory is "behind" the ultrasound plane, BLUE lines will appear. The spacing of these lines does not represent any specific distance or measurement.

Figure 10-14 3D Guidance Features – Proximity Meter and Position Lines

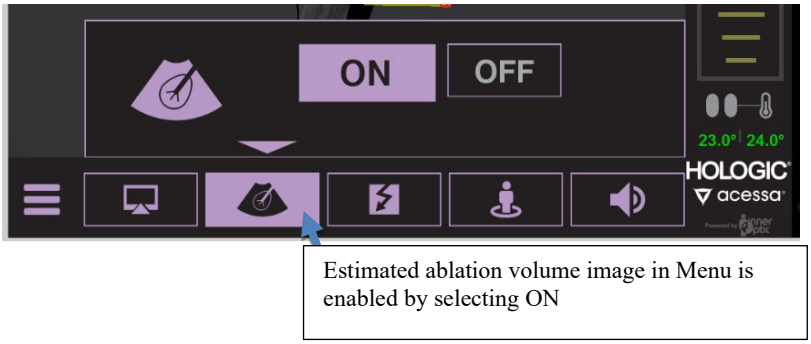
Handpiece-Ultrasound Target Zone The software provides a prediction of the Handpiece's path and its projected intersection point with the ultrasound scan (target zone), so the user can orient the Handpiece to the target fibroid before inserting it. It is drawn in both the 2D (Ultrasound Image) and 3D (3D Guidance) views as a PURPLE obround-shaped indicator, the "on path" indicator, and is superimposed over the ultrasound scan plane. The size of the PURPLE obround changes with the angle of the Handpiece to the ultrasound scan plane; when the Handpiece is perpendicular to the scan plane, the obround is a circle, and as the angle decreases toward parallel, the obround is drawn as two lines capped with semi-circles at the ends. The Handpiece trajectory hash marks are displayed in both the 2D and 3D views. When the hash marks are displayed as red and yellow the Handpiece trajectory is distal to the ultrasound scan plane and when green hash marks are displayed the Handpiece is within the ultrasound plane. The double PINK hash mark is representative of the Handpiece tip.

Figure 10-15 3D Guidance Features – Purple "on path" Indicator



Expected 3D Ablation Volume. The software can optionally display a visual indicator of the expected ablation volume at the end of the Handpiece. When the estimated ablation volume mode is turned on via the Menu, it helps the user to visualize the treatment area. These guides provide the user with a 3D visual reference for physical dimensions to further assist in electrode array placement. The dimensions and distance from the Handpiece's tip are drawn according to **Figure 12-1**.

Figure 10-16 Selecting Display of Ablation Volume



The ablation volume is shown in two ways, using both orange and yellow graphical images.

- ORANGE is shown in the 3D Guidance view. Orange always represents the cross-section looking through the middle (large axis) of the ablation volume. ORANGE represents the maximum cross section through the ablation volume (through the center of the ablation volume) and does not change with Ultrasound Transducer rotation.

- YELLOW is shown in both the 3D Guidance and Ultrasound Image views. Yellow represents the plane of the ultrasound image as it cuts through the ablation volume, thus it changes size as the Ultrasound Transducer window is rotated. YELLOW represents the 2D cross sectional area through the ablation volume as defined by the ultrasound scan line.

Figure 10-17 Ablation Zone

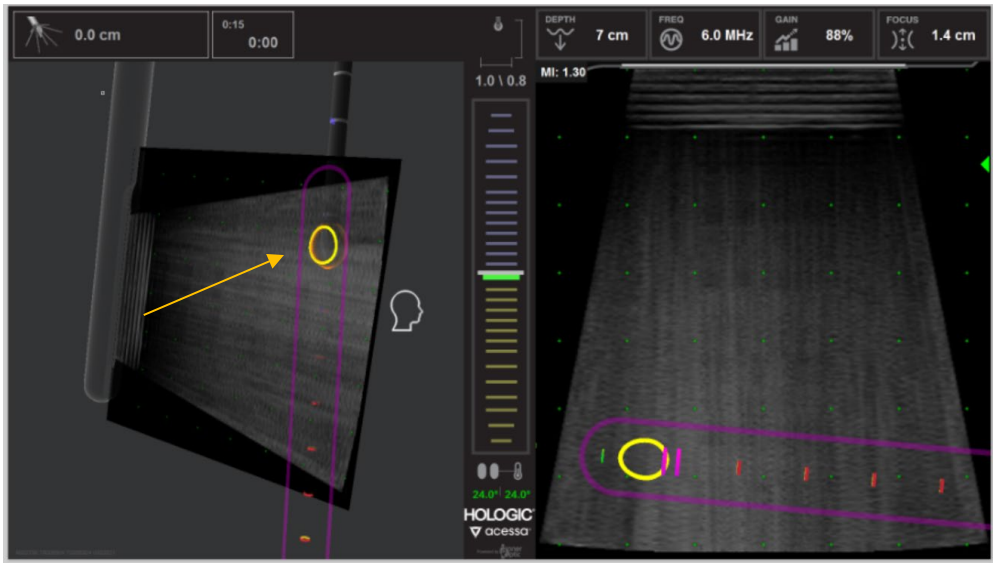
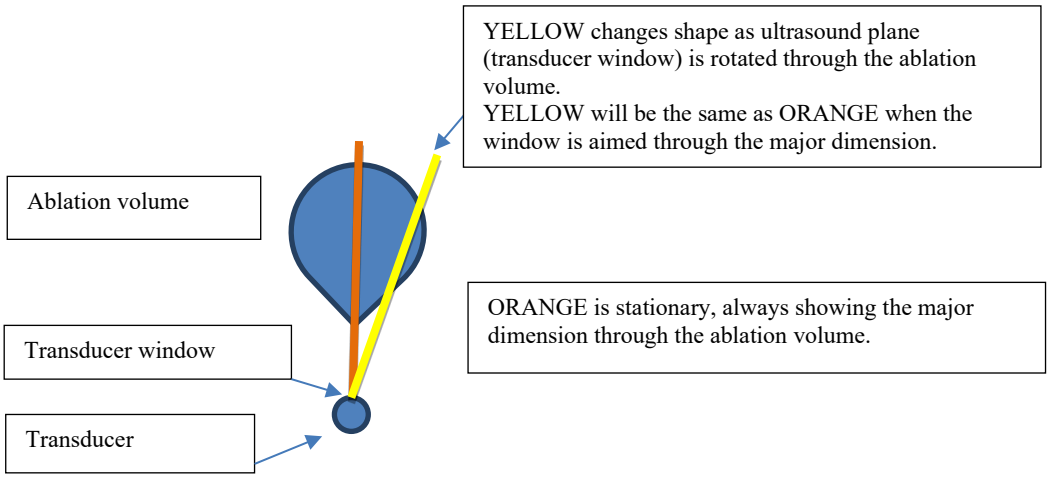


Figure 10-18 Ablation Zone



These guides provide the user with a visual reference for physical dimensions of the ablation volume, superimposed over the ultrasound image of the fibroid, to assist in electrode array placement. This will provide users a continuous view of the approximate cross-section of the ablation volume as the electrode array are deployed further to best assist user of desired ablation size.

Figure 10-19 Picture of deployment at 2.7 cm – Cage Display Turned Off

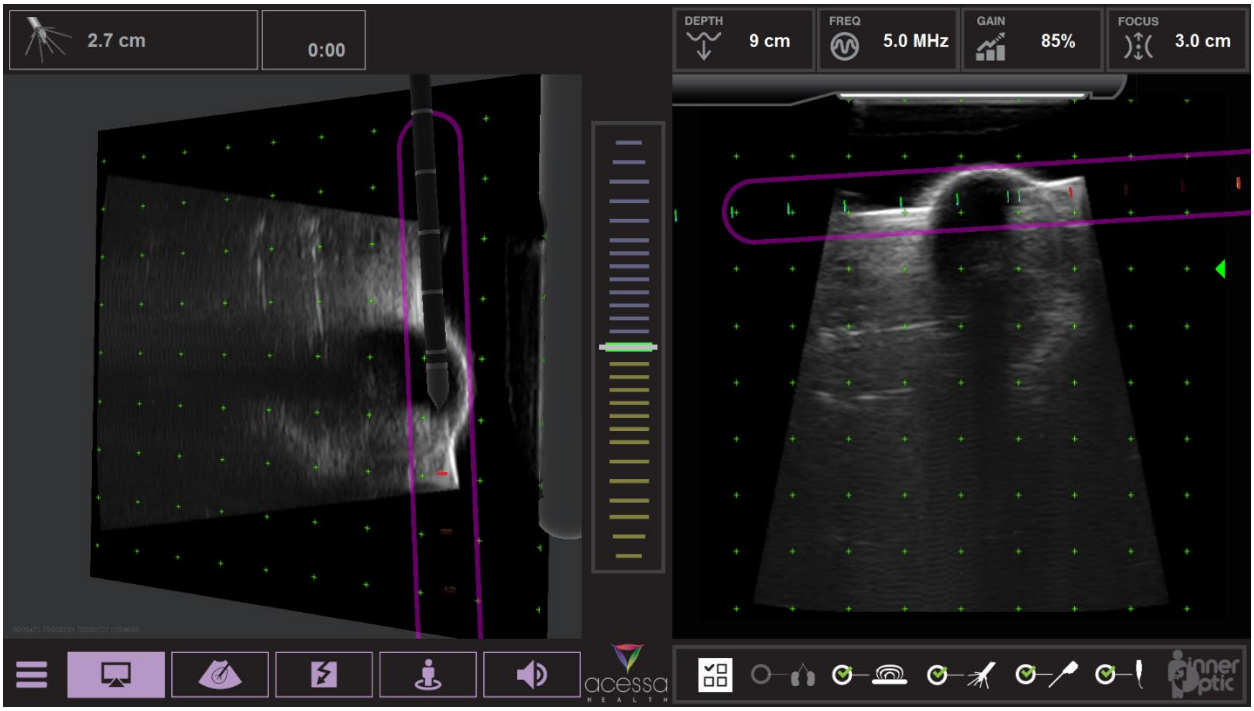
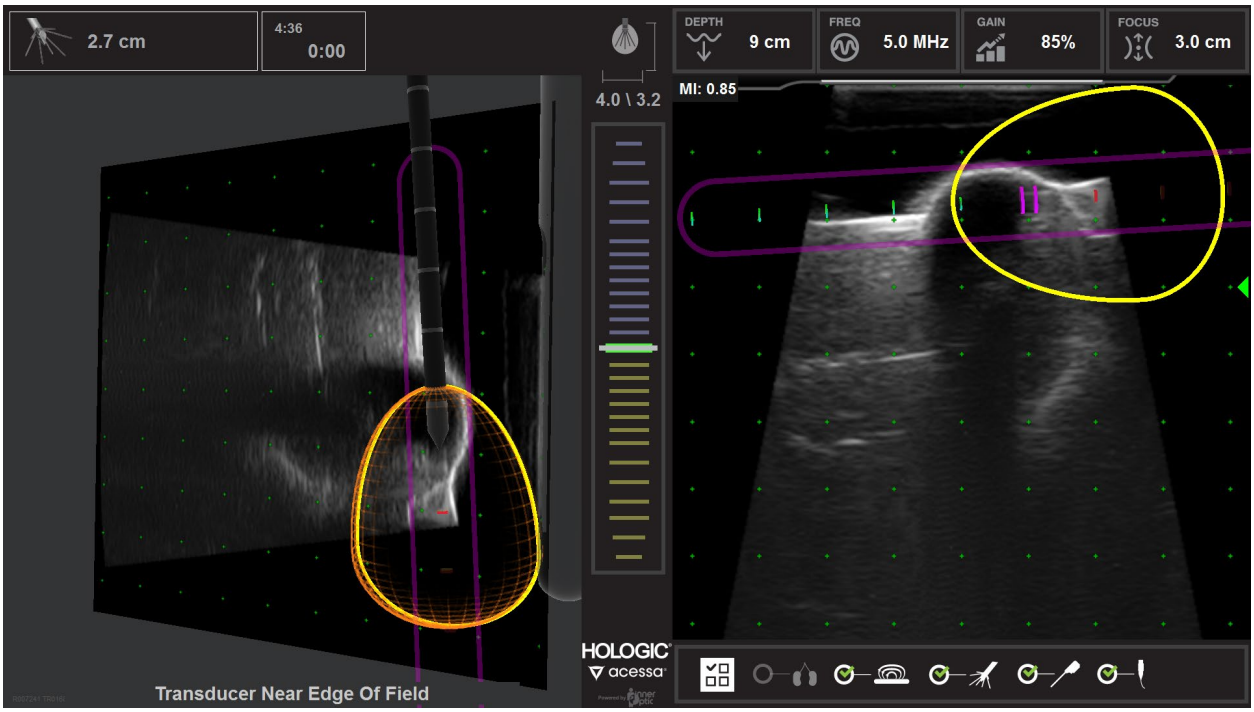


Figure 10-20 Picture of deployment at 2.7 cm – Cage Display Turned On



Procedure Planning

The physician should determine the scope and sequence of ablations prior to starting any RF energy. Using the ultrasound, examine the uterus and map the fibroids that are present. After all fibroids are documented, determine the sequence of ablations and path of Handpiece insertion.

Performing an Ablation

1. Locate the fibroid targeted for treatment on the ultrasound image.

2. Determine the location of the tip of the Handpiece where it should enter the fibroid on the ultrasound image. Place the tip of the Handpiece at a location on the patient's abdomen aligned with the targeted entry point on the fibroid.

3. At this point, the Guidance can be used to help confirm this location by adjusting the angle of the Handpiece so that the trajectory lines go through the targeted area on the ultrasound image and the purple target zone lines become visible on the image, indicating alignment with the target.

4. Advance the tip of the Handpiece through the abdomen and into the abdominal cavity.

5. Ensuring that the purple target zone remains located on the targeted entry point on the fibroid, advance the Handpiece until the tip is at the serosa of the uterus viewed on the laparoscopic monitor.

6. After the tip penetrates the serosa, view image on the ultrasound monitor. Corrections to the path of the tip must be made using ultrasound imaging. Inserting the tip into the fibroid and deploying the electrode array must be done under ultrasound visualization only.

7. Continue into the fibroid until the point of the tip is approximately 1 cm into the fibroid.

For fibroids less than 1.5 cm in diameter:

- If the fibroid is 1 cm or less, press the Foot Pedal (yellow) to ready the system for an ablation, then press it again to start RF.
- If the fibroid is 1.5 cm in diameter, deploy slightly (about .2 cm) until the expected ablation size on the screen shows a 1.5 cm ablation size. Then press the Foot Pedal (yellow) to ready the system for an ablation, then press it again to start RF.
- The ablation time will count up. When it reaches the correct time, a "Finished" tone will be heard.
- Once the tone is heard, press the Foot Pedal (yellow) to stop the RF energy.

WARNING: Do not advance, reposition or rotate Handpiece when electrode arrays are deployed.

For fibroids greater than 1.5 cm in diameter:

- Deploy the electrode array until the distal point of the center needle is approximately 1 cm away from the distal edge of the fibroid.
- Read the amount of deployment on the Handpiece handle. Adjust the deployment until it is on a centimeter or half centimeter mark.
- Confirm that the deployment displayed on the screen matches the deployment on the Handpiece handle.
- Press the Foot Pedal (yellow) once to ready the system for ablation, then press again to start RF.
- The system will display the Ramp icon signifying that the temperature is rising to the target temperature of 95°C.
- When the temperature gets to 95°C, a tone will sound signifying that target temp has been reached. The the timer will begin to count up.
- When it reaches the correct time, a "Finished" tone will be heard.
- Once the tone is heard, press the Foot Pedal (yellow) to stop the RF energy.

To shut off RF energy, depress the left Foot Pedal (YELLOW).
The most important predictor of the completeness of the ablation is having reached the desired target temperature for the prescribed amount of time at set deployments of the electrodes of the Handpiece. For more information and guidance, see Sections 11 and 12.
Retract the Handpiece's electrode arrays and move to the next fibroid. Continue until all the fibroids have been treated.
Immediately following a completed ablation, the user is ready to cauterize the Handpiece tract.
When the Handpiece is removed, perform Coag as described in Section 10

Operation of System During Coagulation

1. Retract the Handpiece's electrode arrays completely by sliding the electrode array knob to its mechanical stop.

2. Depressing the right Foot Pedal (BLUE) activates the Ready Coag. The settings allow for 1-20 (power level), and default is always set to 12 or the last setting chosen.

WARNING: Always verify that the electrode arrays are retracted fully before withdrawing the Handpiece to avoid patient injury!

1. The Handpiece tip should be allowed to cool for 60 seconds after the ablation has stopped prior to removing it from the target tissue

2. When ready to Coag, turn the RF energy on by pressing and holding the right Foot Pedal (BLUE). The user judges proper coagulation by visual observation and experience.

3. Observe the Coag on the laparoscope and pull back the device slowly until the tip is visible.

4. Turn off RF power when track coagulation is completed by releasing the right Foot Pedal (BLUE).

Note: During Coag mode the user may experience char on the tip. A sterile disposable wipe moistened with 70/30 isopropyl alcohol may be used to clean the trocar tip. Dry the Trocar or allow it to evaporate before use. Before Handpiece insertion into peritoneal cavity, deploy electrode arrays and inspect.

After the Procedure

Disposable items should be disposed of according to normal hospital practices. Additionally, follow local governing ordinances and recycling plans regarding disposal or recycling of disposable items.

Clean the non-disposable Acessa components according to the directions in Section 7 or in their Instructions for Use.

Shutting Down the System

To shut down the system, press the ON/OFF button for approximately 4 seconds. Then turn the switch on the rear panel to Off (O).

11. Special Considerations: General Ablation Procedures

Highly Vascularized Tissue

If all connections are verified to be correct and desired temperatures continue to not be obtainable, the electrode array may have been deployed into a highly vascular area. Consider withdrawing the electrode arrays (if deployed) into the Handpiece and then rotating or repositioning the Handpiece.

One or More Electrode Arrays in a Duct or Vessel

If one or more Electrode temperatures reads much lower than the rest of the temperatures, the electrode array may be in or near a vessel or duct. To correct this condition, stop the delivery of RF energy by depressing the Foot Pedal. Fully retract the electrode array (if deployed), then rotate the Handpiece. Redeploy the electrode arrays and restart the ablation by depressing the Foot Pedal again.

Ablation of Dense or Calcified Fibroid Tissue

Incremental advancement of the electrode arrays will aide in penetrating dense tissue. With needles deployed (Console set for temperature control to 95°C) and the Handpiece tip placed at the required depth for ablation, activate RF until target temperature is reached. Deploy the electrode arrays ½ cm and maintain this deployment until target temperature is reached. Continue with ½ cm to 1 cm deployment increments, reaching target temperature, until the last deployment is achieved (e.g., 5 cm deployment for 12 minutes creating a final ablation size of 5.6 cm by 4.4 cm).

Maintain target temperature for stated target time for the last deployment stage to allow for complete tissue destruction.

If a fibroid is densely concentrated with calcium to the degree that there is abnormal resistance to insertion and/or rotation of the Acessa Handpiece tip (with electrode arrays fully retracted):

- discontinue rotating the device
- withdraw the Handpiece by pulling back along the path of insertion (electrode arrays retracted, do not rotate)
- re-enter the fibroid from another direction (ideally where the sonographic appearance demonstrates fewer/smaller calcium deposits).

Once the tip of the Handpiece is positioned in a desired location, if deployment of the electrode arrays is impeded by calcium deposits:

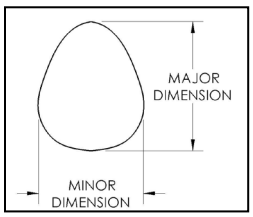
- Fully retract the electrode arrays and carefully rotate the device 3-5 degrees, then re-attempt deployment (repeat the retraction/slight rotation/deployment method if necessary until deployment is achieved).
- deployment cannot be achieved in spite of repeated efforts, fully retract the electrode arrays and attempt deployment with the Acessa Handpiece tip repositioned in another location within the fibroid.

12. Ex-Vivo Studies

Ex-Vivo Studies

Bench top studies were conducted using Bovine liver. The purpose of these studies was to characterize the ablation size when created with different deployments for varying amounts of time and at different power and temperature settings. Generally, for a given time, increasing the target power or temperature tends to produce larger ablation sizes. For a given target power or temperature, increasing the time tends to produce larger ablation sizes.

Figure 12-1 Representative Ablation Shape per Deployment



*Major dimension = length or axial length
*Minor dimension = width

Results from Ex-Vivo Bovine Liver Studies

The system uses a power control mode for ablating target zones less than 1.5 cm in diameter. The electrode array is not deployed when using power control mode and the ablation time is 1 minute or less. The following table shows the average ablation zone and the recommended times at 0.0 deployment using an ex-vivo bovine liver at 15 W power. Target ablation zone sizes and on-screen visualization are provided as a guide based on ex-vivo bovine liver modeling. Individual ablation zones may vary by fibroid composition. It is the ultimate responsibility of the user to determine adequate fibroid treatment.

Figure 12-2 Ablation Volume at 0cm Needle Deployment

TISSUE: Liver	CONTROL MODE: Power	POWER: 15 W

ABLATION SIZE (cm)		DEPLOYMENT (cm)	TIME	POWER
MAJOR DIAMETER	MINOR DIAMETER			
1.0 ± 0.11	0.8 ± 0.09	0.0	15 sec	15W
1.5 ± 0.06	1.2 ± 0.14	0.0	1 min	15W

Representative Ablation Sizes in Ex-vivo Bovine Liver with Settings in Temperature Control

The system uses a temperature control mode for ablating target zones greater than 1.5 cm in diameter, and with the electrode array deployed. The following table shows the average ablation zone and the recommended times and deployments, using an ex-vivo bovine liver with a target temperature of 95°C. Target ablation zone sizes and on-screen visualization are provided as a guide based on ex-vivo bovine liver modeling. Individual ablation zones may vary by fibroid composition. It is the ultimate responsibility of the user to determine adequate fibroid treatment.

Figure 12-3 Ablation Volume at Non-0cm Needle Deployment

TISSUE: Liver	CONTROL MODE: Temperature	TEMPERATURE: 95°C

ABLATION SIZE (cm)		DEPLOYMENT (cm)	TIME	TARGET TEMPERATURE
MAJOR DIAMETER	MINOR DIAMETER			
1.9 ± 0.06	1.7 ± 0.12	0.5	1 min	95°C
1.9	1.7	0.6	54 sec	95°C
2.0	1.8	0.7	48 sec	95°C
2.0	1.8	0.8	42 sec	95°C
2.1	1.9	0.9	36 sec	95°C
2.1 ± 0.15	1.9 ± 0.15	1.0	30 sec	95°C
2.2	2.0	1.1	48 sec	95°C
2.3	2.1	1.2	1 min 06 sec	95°C
2.5	2.1	1.3	1 min 24 sec	95°C
2.6	2.2	1.4	1 min 42 sec	95°C
2.7 ± 0.05	2.3 ± 0.11	1.5	2 min	95°C
2.2	2.0	1.6	2 min 12 sec	95°C
2.3	2.1	1.7	2 min 24 sec	95°C
2.5	2.1	1.8	2 min 36 sec	95°C
2.6	2.2	1.9	2 min 48 sec	95°C
3.3 ± 0.11	2.7 ± 0.25	2.0	3 min	95°C
3.4	2.8	2.1	3 min 12 sec	95°C
3.5	2.8	2.2	3 min 24 sec	95°C
3.7	2.9	2.3	3 min 36 sec	95°C
3.8	2.9	2.4	3 min 48 sec	95°C
3.9 ± 0.11	3.0 ± 0.21	2.5	4 min	95°C
4.0	3.1	2.6	4 min 18 sec	95°C
4.0	3.2	2.7	4 min 36 sec	95°C
4.1	3.2	2.8	4 min 54 sec	95°C
4.1	3.3	2.9	5 min 12 sec	95°C
4.2 ± 0.32	3.4 ± 0.23	3.0	5 min 30 sec	95°C
4.3	3.5	3.1	5 min 48 sec	95°C
4.4	3.5	3.2	6 min 06 sec	95°C
4.6	3.6	3.3	6 min 24 sec	95°C
4.7	3.6	3.4	6 min 42 sec	95°C
4.8 ± 0.32	3.7 ± 0.64	3.5	7 min	95°C
4.9	3.8	3.6	7 min 06 sec	95°C
5.0	3.9	3.7	7 min 12 sec	95°C
5.0	4.1	3.8	7 min 18 sec	95°C

ABLATION SIZE (cm)		DEPLOYMENT (cm)	TIME	TARGET TEMPERATURE
MAJOR DIAMETER	MINOR DIAMETER			
5.1	4.2	3.9	7 min 24 sec	95°C
5.2 ± 0.04	4.3 ± 0.50	4.0	7 min 30 sec	95°C
5.3	4.3	4.1	7 min 36 sec	95°C
5.4	4.3	4.2	7 min 42 sec	95°C
5.4	4.4	4.3	7 min 48 sec	95°C
5.5	4.4	4.4	7 m in 54 sec	95°C
5.6 ± 0.38	4.4 ± 0.38	4.5	8 min	95°C
5.7	4.5	4.6	7 min 48 sec	95°C
5.8	4.6	4.7	9 min 36 sec	95°C
5.8	4.8	4.8	10 min 24 sec	95°C
5.9	4.9	4.9	11 min 12 sec	95°C
6.0 ± 0.35	5.0 ± 0.69	5.0	12 min	95°C

13. Clinical Studies – Fibroids

Prospective, non-randomized, longitudinal Phase II studies using the Acessa System were conducted at two separate centers to establish early safety and effectiveness data. A total of 69 premenopausal females (average age 42.1 ±5.5 years); the average reproductive status was gravida 2.8 ± 2.0 and para 2.1 ± 1.6. At the time of screening, 81% of the subjects reported having regular menstrual cycles, and 77% reported having heavy-to-very heavy bleeding volume. Nearly 85% of the subjects reported bleeding between periods. Fibroid symptoms of menorrhagia and dysmenorrhea were found in 98% and 38% of the subjects, respectively. A total of 285 fibroids were ablated (median = 3) with one patient having 20 fibroids treated.

Results: The mean uterine volume at baseline was 204.4 cm^3. At 6 months and 12 months post-treatment, the mean uterine volume was significantly reduced to 155.0 cm^3 (p= 0.012) and 151.4 cm3 (p = 0.009), respectively. The percent of subjects demonstrating reduced uterine volume in contrast to baseline was 82.2%, 80.0%, and 79.3% at the 3-, 6-, and 12-month visits, respectively. At baseline, 77% of subjects reported heavy to very heavy bleeding prior to the treatment. After 12 months post-treatment, 3.5% (p<0.0001) reported heavy to very heavy bleeding based on the patient reported survey. The UFS-QOL questionnaire was administered at baseline and at all follow-up visits. The mean percent improvement in Symptom Severity Scores from baseline to post-treatment was 59.6% at 3 months, 65.0% at 6 months, and 79.0%, at 12 months. The mean percent change in HRQL Scores from baseline to 3 months post-procedure was 41.6%, from baseline to 6 months post-procedure was 39.7%, and from baseline to 12 months post-procedure was 42.9%. Overall, sixty-five subjects (94.2%) reported improved Symptom Severity Scores and sixty-one subjects (88.4%) reported improved HRQL Scores. In terms of safety, there was only one (1.4%) serious adverse event (i.e., abdominal wall hematoma), which was determined to be related to the procedure. It was treated by laparotomy and vessel ligation.

The device pivotal (Phase III) study included the treatment of 137 women with symptomatic fibroids including menorrhagia. A total of 11 centers in the United States (9 centers) and Latin America (2 centers) and 13 investigators participated in the study:

Study Design

This prospective, multicenter, longitudinal, single-arm, paired-comparison, interventional study was designed to evaluate the efficacy and safety of radiofrequency ablation (RFA) treatment of symptomatic uterine fibroids with the Acessa System. All study subjects who underwent uterine fibroid ablation with the Acessa System were expected to continue to participate in the study for 36 months following the procedure. Primary endpoint analysis was conducted at one year post treatment.

Study Objectives

Primary Objectives

The primary objectives of the study were to confirm the safety and efficacy of the Acessa System for the treatment of symptomatic uterine fibroids.

Secondary Objectives

The secondary objectives of the study were to evaluate the change in uterine and fibroid volume, symptom severity, health related quality of life, general health status, and subject satisfaction at 12 months post treatment compared to baseline.

Inclusion and Exclusion Criteria

Subjects were included if they were 25 years of age or older, desired uterine preservation but did not desire current or future childbearing, had symptomatic uterine fibroids, had a uterine gestational size ≤ 14 weeks, ≤ 6 treatable fibroids, with no single fibroid exceeding 7 cm in any diameter as measured by transvaginal ultrasound and a total uterine fibroid volume that did not exceed 300 cc on ultrasound or contrast-enhanced MRI evaluation. In addition, the subject was required to have clinical menorrhagia, as indicated by menstrual blood loss of ≥ 160 mL to ≤ 500 mL along with a 3-month history of menorrhagia within the last 6 months. Subjects were required to have a normal coagulation profile, a normal Pap smear, and pass a preoperative health examination (American Society of Anesthesiologists [ASA] physical status I-III). Subjects were excluded from the study is they had contraindications for laparoscopic surgery and/or general anesthesia, had undergone pelvic radiation or had a gynecologic malignancy or premalignancy within the past 5 year, had a non-uterine pelvic mass, had prior pelvic surgery that was known to cause significant intra-abdominal adhesions or had a history of, or active, pelvic inflammatory disease, had undergone endometrial ablation, uterine artery embolization, uterine artery ligation, or any other uterine-preserving technique for reduction of menstrual bleeding, had taken any gonadotropin-releasing hormone (GnRH) agonist within 3 months prior to the screening, had an implanted intrauterine or fallopian tube device for contraception that could not be or would not have been removed 1 month prior to treatment, or if they required elective concomitant procedures. Peri-menopausal and menopausal women were excluded in the study due to the requirement for collection of used catamenial products. Pregnant or breastfeeding women, women with dysfunctional uterine bleeding or chronic pelvic pain, adenomyosis, or endometriosis were excluded. Women with cervical myomas, pedunculated subserosal fibroids or "type zero" (completely intracavitary) submucous fibroids were also excluded.

Study Demographics

A total of 137 women were enrolled and treated in the Acessa Health pivotal study. The study demographics are shown in the table below.

Figure 13-1 Pivotal Study Demographics

Variable	Statistic/Response	All Sites (N=137)
Age (years)	n	137
	Mean (SD)	42.4 (4.72)
	Median	43.0
	Min, Max	31, 55
Race	White or Caucasian	62 (45.3%)
	Black or African American	46 (33.6%)
	Asian	2 (1.5%)
	Other	27 (19.7%)
Ethnicity	Hispanic or Latino	62 (45.3%)
	Not Hispanic or Latino	75 (54.7%)

Fibroid Symptoms and Characteristics Reported at Baseline – All Subjects

As required by the protocol, all 137 of the subjects reported menorrhagia at baseline and that they had experienced 3 or more heavy periods in the last 6 months. Other than menorrhagia, dysmenorrhea (51.1%), backache (44.5%), increased abdominal girth (43.8%), and pelvic pressure (43.8%) were the most commonly reported fibroid-related symptoms at baseline.

Figure 13-2 Reported Fibroid Symptoms - Pivotal Study Baseline

Variable	Response	(N=137)
Fibroid Symptoms	Menorrhagia	137 (100.0%)
	Dysmenorrhea	70 (51.1%)
	Backache	61 (44.5%)
	Increased Abdominal Girth	60 (43.8%)
	Pelvic Pressure	60 (43.8%)
	Urinary Frequency/Retention	52 (38.0%)
	Sleep Disturbance	48 (35.0%)
	Dyspareunia	45 (32.8%)
	Uterine Pain	41 (29.9%)

Variable	Response	(N=137)
	Localized Pain	23 (16.8%)
	Other	13 (9.5%)

Treatment

All 137 enrolled subjects were treated using the following principles of volumetric thermal ablation:

1) The Handpiece tip was placed approximately 1 cm into the fibroid,
2) Deployment of the needles was not necessary unless the diameter of the fibroid was ≥ 2 cm,
3) In cases where deployment of the electrode array was performed, the array was deployed so that the electrode tips were at least 1 cm away from the fibroid margin in all three planes.

Laparoscopic ultrasound guided the placement of the Handpiece, deployment of the electrode array, and confirmation of the 1 cm margins before each ablation. The following chart was used to guide the ablation.

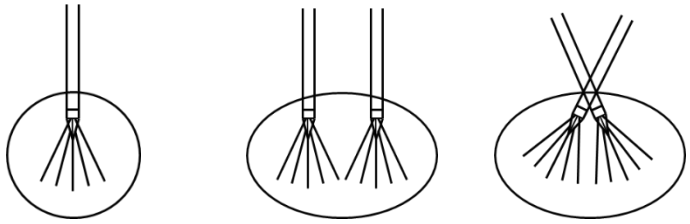
Figure 13-3 Pivotal Study Treatment Parameters

Deployment	0	0	0.5	1	1.5	2	2.5	3.5	4.5	5
Setting	15 Watt	15 Watt	100°C	100°C	100°C	100°C	100°C	100°C	100°C	100°C
Target Time	15 sec[1]	1 min[2]	1 min	30 sec	2 min	3 min	4 min	7 min	8 min	12 min

[1] For 1 cm fibroids
[2] For 1.5 cm fibroids

For larger fibroids or fibroids that were more irregular or oval, overlapping ablations were used. In such cases, the smallest diameter of the fibroid determined the degree of Handpiece insertion and the length of deployment of the electrode electrode array. Often, the same serosal puncture was used to treat overlapping ablations in one fibroid or to treat other fibroids in close proximity.

Figure 13-4 Needle Placement used in Pivotal Study



Appropriate tip placement for spherical, irregular, or oval fibroids

Once an ablation was initiated, the serosa overlying the fibroid was directly observed with the laparoscope. Once all fibroids were treated appropriately, the array was retracted and the track was coagulated using "coag mode."

Figure 13-5 Types and Number of Fibroids Treated in the Pivotal Study

Variable			N = 135[2]
Number of fibroids treated per patient			**1 to 29**
Mean number of fibroids treated per patient			5
Median number of fibroids treated per patient			4
Number of total fibroids treated within the study			**674**
Types of fibroids[1]	*Intramural*		347
	Subserosal		193
	Submucosal		164
	Transmural		39
	Missing Type		18

Variable			N = 135[2]
Location of fibroids[1]	*Fundal*		148
	Mid Uterus		41
	Lower Uterine		118
	Anterior		235
	Posterior		236
	Left		144
	Right		153
	Broad Ligament		2
	Missing Location		2

[1]A fibroid may be in more than one location or be of more than one type.
[2]Full analysis set excludes two subjects who did not meet the bleeding criteria

Results of the Pivotal Study

Of the 137 subjects enrolled and treated under this protocol, 124 (90.5%) were considered "evaluable" in terms of their 1) ability to provide a menstrual blood loss assessment, 2) lack of concomitant disease that affects the menstrual cycle, 3) baseline menstrual blood loss was within protocol inclusion limits. The table below shows the subject disposition at 12 months post treatment.

Figure 13-6 Subject Disposition at 12 Months Post Treatment

	n (%)
Total Treated	***137 (100%)***
Evaluable for Menstrual Blood Loss Using Alkaline Hematin*	124 (90.5%)
Withdrew prior to 12 months*	2
Lost to follow up*	1
Pregnant	3
Menstrual blood loss baseline outside protocol inclusion limits	2
Hashimoto's Disease	1
Menopause/amenorrhea	4

*The primary full analysis set (PFAS, N=127) for bleeding relief is composed of subjects who withdrew, were lost to follow up, or are evaluable.

Subject Disposition at 24 and 36 Months Post Treatment

	n (%)
Total Evaluable at 12 months	***124 (100%)***
Withdrew or lost to follow up between 12 and 24 months	3
Withdrew or lost to follow up between 24 and 36 months	2
Pregnant	1
12-24 month reintervention	6
24-36 month reintervention	4
Elective endometrial ablation	1

*3 additional subjects underwent a reintervention after the 36 month visit was completed.

Safety

Summary of Treatment-Emergent Adverse Events by Relationship to the Device, Laparoscopic Procedure, and/or Classified as Serious.

Urinary tract infection, which was reported in 7 of the 137 subjects (5.1%) was the most commonly reported adverse event during the three year follow up followed by bacterial vaginitis (6/137, 4.4%), influenza (4/137, 2.9%), pharyngitis (4/137, 2.9%), lower abdominal pain (4/137, 2.9%) and dizziness (4/137, 2.9%).

Adverse Events Classified as Possibly, Probably, or Definitely related to the Device – Pelvic Abscess, serosal colon injury, lower abdominal pain superficial uterine serosal burn and post-procedural hemorrhage were each reported as single adverse events for a total device-related adverse event rate of 3.6%.

Adverse Events Classified as Possibly, Probably, or Definitely related to the Procedure - Lower abdominal pain, dysuria and dysmenorrhea were each reported in 3 of the 137 subjects (2.2%). Procedural pain, procedural vomiting, dizziness

and hypoesthesia were each reported in 2 of the 137 subjects (1.5%)Cystitis, pelvic abscess, wound infection, oral hypoesthesia, vomiting, pain, post-operative anemia, uterine serosal burn, serosal colon injury, post procedural hemorrhage, post-procedure shivering, incisional rash, contusion, incisional site hemorrhage, wound hematoma, spontaneous abortion, hematuria, premenstrual syndrome, atelectasis, seroma, and endometritis were each reported as single adverse events (0.7%)..

Adverse Events Classified as Serious -Seventeen of the adverse events occurring in fifteen subjects were considered serious; atelectasis (1 subject, 0.7%), chest pain (2 subjects, 1.5%), viral infection with otitis externa (1 subject, 0.7%), pyelonephritis (1 subject, 0.7%), uterine hemorrhage resulting in anemia and requiring blood transfusion (1 subject, 0.7%), Achilles tendon rupture and intervertebral disc repair (1 subject, 0.7%), laceration in serosa of colon (1 subject, 0.7%), spontaneous abortion (1 subject, 0.7%) pelvic abscess (1 subject, 0.7%), hemiparesis (1 subject, 0.7%), dyspnea (1 subject, 0.7%), motor vehicle accident, (1 subject, 0.7%), anemia, resulting in blood transfusion following Cesarean delivery, (1 subject, 0.7%), shortness of breath and pulmonary embolism, (1 subject, 0.7%) postoperative anemia following a reintervention (hysterectomy), and cerebrovascular accident (1 subject, 0.7%). Of these serious adverse events, only the pelvic abscess and the serosal colon injury were considered to be both device and procedure related. Additionally, the atelectasis was considered definitely related to the procedure and the spontaneous abortion and anemia were possibly related to the procedure.

Efficacy

Menstrual Blood Flow as Assessed by Alkaline Hematin (AH): In the evaluable subjects (n=124), the mean reduction in menstrual blood flow at 12 months post treatment was 103.6 ml. One hundred four of the 124 (83.9%) evaluable subjects experienced a reduction in bleeding at 12 months post treatment. Nineteen of the 124 subjects (15.3%) experienced an increase in bleeding at 12 months post baseline. When including the subjects lost to follow up as treatment failures, 40.2% (95% CI 31.6% - 48.7%) met the protocol criterion for bleeding relief (defined as ≥50% reduction in menstrual bleeding at 12 months post-treatment) though this did not meet the pre-specified study hypothesis that the lower bound of the 95% CI would be ≥45%.

Surgical Reintervention Rate

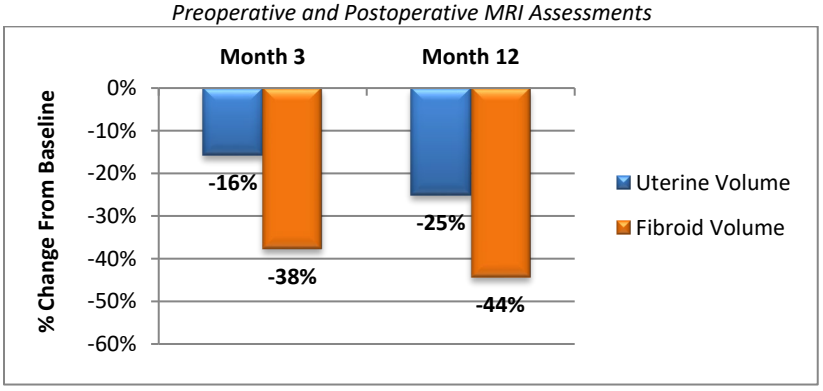
There was 1 subject (1/127, 0.8%) in the primary full analysis set (PFAS) who had a surgical reintervention (UAE) for bleeding after she withdrew from the study but prior to 12 months of follow up. The study did not include a prospectively developed hypothesis test for the 24 or 36-month surgical reintervention rate. The 24-month status has been documented on all of the 124 subjects in the PFAS who entered their second year of follow up. Three subjects were lost to follow up in the second year (3/124, 2.4%) and six of the remaining subjects (6/121, 5.0%) reported a surgical reintervention for fibroid-related bleeding between 12 and 24 months (4 hysterectomies and 2 hysteroscopic myomectomies). One subject reported an endometrial ablation at 16 months for heavy bleeding with no evidence of fibroids and one additional subject became pregnant. One hundred thirteen subjects in the PFAS entered their third year of follow up. Four subjects underwent a hysterectomy (4/113, 3.5%) and two were lost to follow up prior to the 36 month visit. An additional three subjects (3/107, 2.8%) had hysterectomies after undergoing their 36 month visit. In total, 14 subjects have undergone surgical reintervention for fibroid-related bleeding for a cumulative reintervention rate of 11.0%*

*based on Kaplan-Meier statistical procedure

Uterine and Fibroid Volume

RFA treatment resulted in a reduction from baseline in total uterine and fibroid volume, as assessed by pretreatment and post treatment contrast-enhanced MRI, at 3 and 12 months post treatment. At 12 months post treatment, the mean reduction in uterine volume (n=128) was 25.1% and the mean reduction in fibroid volume (n=119) was 44.3%.

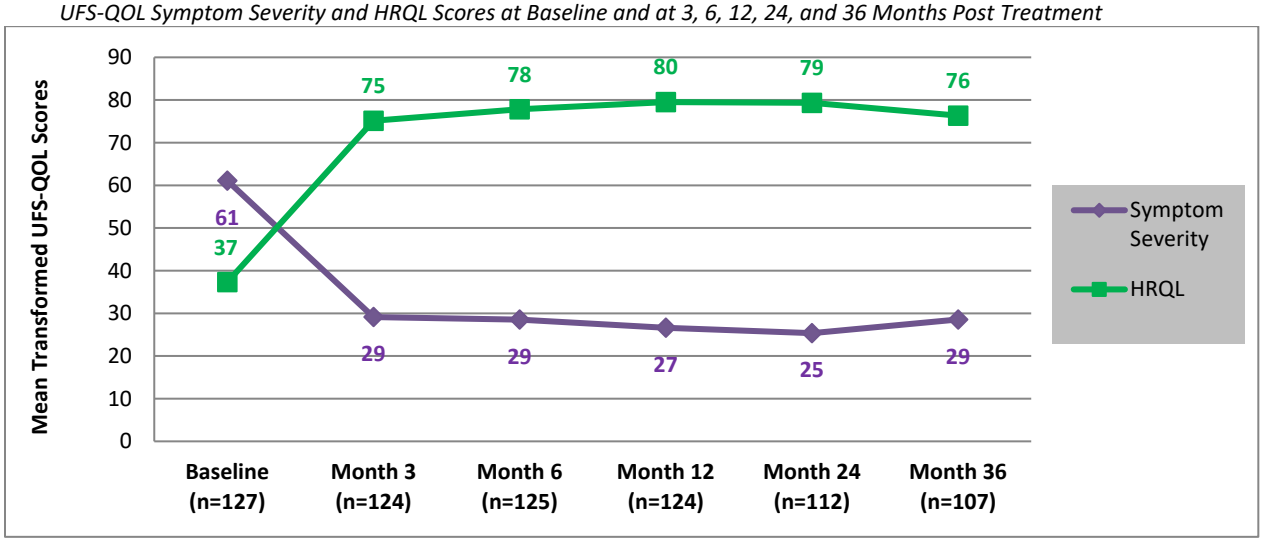
Percent Change From Baseline in Total Uterine and Fibroid Volume at 3 and 12 Months Post treatment Based on Preoperative and Postoperative MRI Assessments



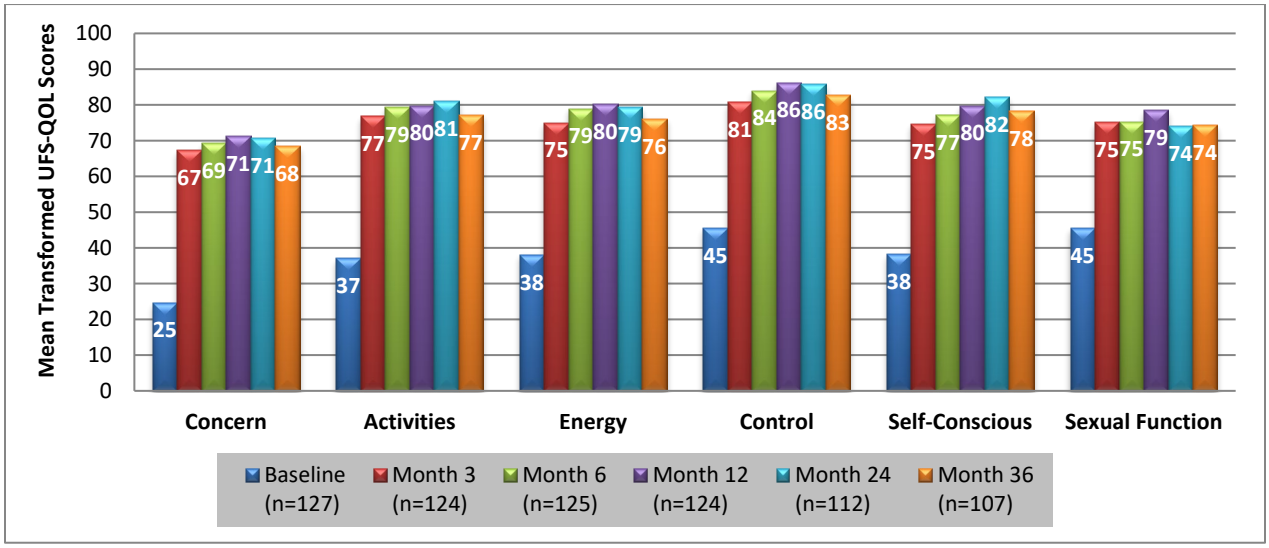
UFS-QOL Scores

Mean Health-Related Quality of Life (HRQL) scores and Symptom Severity Scores (SSS) improved significantly from baseline to 3 months, then remained similar at all intervals between 3 and 36 months post treatment.

UFS-QOL Symptom Severity and HRQL Scores at Baseline and at 3, 6, 12, 24, and 36 Months Post Treatment



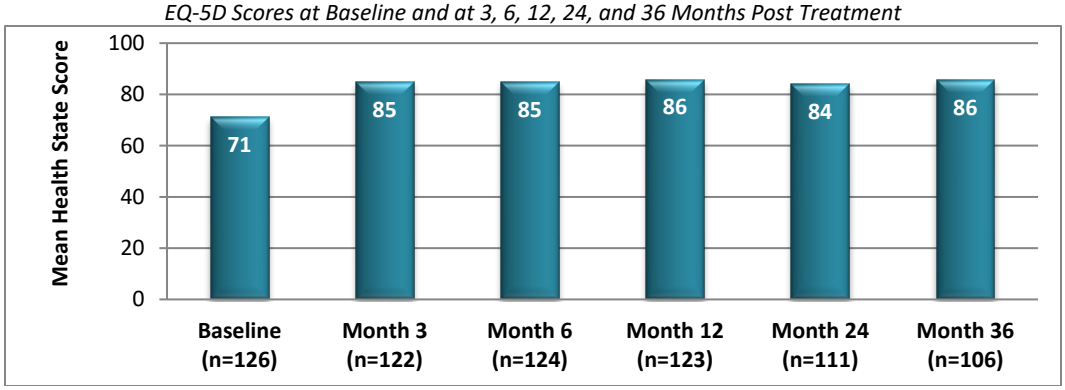
UFS-QOL Concern, Activities, Energy/Mood, Control, Self-Consciousness, and Sexual Function Scores at 3, 6, 12, 24, and 36 Months Post Treatment



EQ-5D Health State Score

The EQ-5D score ranges from 0 to 100. An increase in the score post treatment indicates less disease burden.

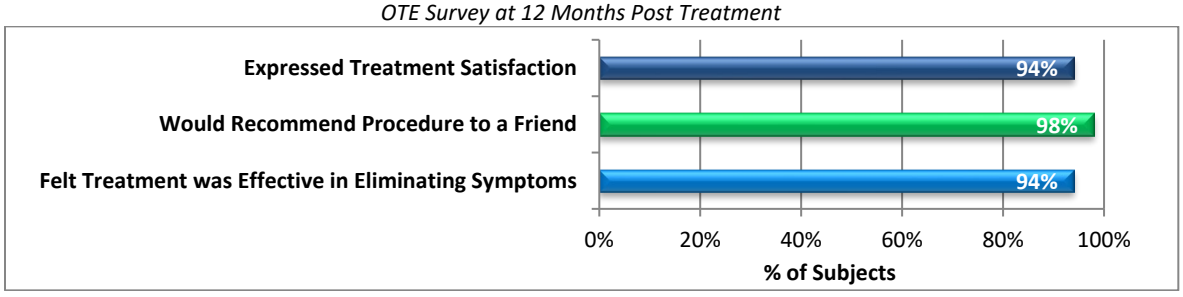
EQ-5D Scores at Baseline and at 3, 6, 12, 24, and 36 Months Post Treatment



Overall Treatment Effect (OTE) Survey

The results of the OTE surveys showed that 94% of the subjects responded that they were very satisfied, moderately satisfied, or somewhat satisfied with the treatment. At 12-months post treatment, 98% of the subjects reported that they would probably or definitely recommend the procedure to their friends with the same health problem. When asked about effectiveness of the treatment, at least 94% of the subjects responded that the treatment had been somewhat, moderately, and very effective in eliminating their symptoms.

OTE Survey at 12 Months Post Treatment



Data regarding return to work and return to normal activities

A total of 88 subjects reported that they were working. Subjects returned to work in a median of 5 days and all subjects reported that they returned to normal in a median of 9 days. Ninety-six percent of the subjects in the Acessa Health study were treated on an outpatient basis.

Data regarding pregnancy

Subjects recruited in the pivotal trial were to have completed their childbearing and were counseled to practice contraception. Despite this requirement, three subjects became pregnant within one year following the RF treatment and one subject became pregnant in the second year of follow up. One pregnancy resulted in a spontaneous abortion in the first trimester, one progressed normally resulting in a vaginal delivery, and two subjects had a C-section at 37 weeks due to hypertension (n=1) or gestational diabetes with hypertension (n=1). The latter C-section resulted in anemia which required several post-operative blood transfusions. Patients should be counseled that there are limited data regarding pregnancy following RF ablation of fibroids.

Data regarding calcified fibroids

Seven subjects (5.1%) had one or more calcified fibroids that were treated during the RF ablation procedure. Calcified fibroids did not appear to impact the physician's ability to insert the tip of the Handpiece but the data are minimal regarding calcified fibroids at this time.

Therapeutic medications at 24 and 36 months post-treatment

One subject (1/124, 0.8%) reported taking Depo-Provera for vaginal bleeding at Month 24. Three subjects (3/124, 2.4%)

reported taking progesterone or GnRH agonist for vaginal bleeding prior to surgical reintervention within 12-24 months post treatment. Between the 24 and 36 months visits, one subject (1/112, 0.9%) reported taking oral contraceptives, one subject (1/112, 0.9%) reported taking Depo-Provera prior to her reintervention, and one subject (1/112, 0.9%) reported taking oral progesterone.

14. Postmarket Surveillance Study – TRUST (Treatment Results of Uterine Sparing Technologies)

Summary of the Post-Approval Study Methods

Study Objective

The study objectives were to compare the rates of acute and near-term serious complications in the Acessa subjects to the acute and near-term treatment-related serious adverse event rates of the pivotal (pre-market) study.

Study Design

A multi-center, prospective, randomized, controlled, clinical trial, conducted at 11 sites in the U.S. and 3 sites in Canada.

Study Population

Premenopausal female patients ≥ 18 years old who had symptomatic fibroids, who desired uterine conservations, and who were indicated for a surgical intervention for their symptoms were enrolled in the study.

Data Source

Data were collected prospectively on each subject using dedicated case report forms that were source verified at all study visits.

Key Study Endpoints

Primary Endpoint

The primary endpoint was the overall rates of acute (within 48 hours post procedure) and near-term (between 2 and 30 days post procedure) serious complications in all GFA (Acessa) subjects compared to the acute and near-term treatment-related serious adverse event rates in the pivotal study.

Secondary Endpoint

The secondary endpoint was the incidence of serious complications per investigator-surgeon during training and post training.

Total Number of Enrolled Study Sites

14 sites in the United States and Canada enrolled participants in the study.

Total Number of Enrolled Subjects and Follow-up Rate

A total of 110 participants were enrolled. Five (5) subjects withdrew or were withdrawn prior to treatment. 105 subjects were treated per protocol between April 25, 2014 and October 2, 2017.

Figure 14.1 shows that of the 105 treated subjects, 100 completed both the 48-hour and 30-day follow up visits.

Figure 14.1 Number and percentage of subjects reaching each designated study phase

Number of Subjects Treated	Number and Percentage of Subjects With 48-hour Data (Median=2 days)	Number and Percentage of Subjects With 1 Week Data (Median=7 Days)	Number and Percentage of Subjects With 30-day Data (Median=37.5 days)	Number and Percentage of Subjects Who Have Completed the 522 Requirements (48 hr and 30 Days)	Number and percentage of subjects lost to follow up before 30 days
105/105 (100%)	101/105[1] (96.2%)	100/105 (95.2%)	104/105[2] (99.0%)	100/105 (95.2%)	1/105[2] (0.95%)

[1]Two subjects missed the 48-hour visit but reported no serious complications at the 1-week visit and two additional subjects missed
both the 48-hour visit and the 1-week visit but were followed by investigator on at the 30-day visit.
[2]One (1) subject was lost to follow up after the 48-hour visit but reported no serious complications at that time. Note that percentage is based on total number of subjects treated.

Study visits and length of follow up

After passing screening, subjects' baseline and procedure data were recorded. Subjects were followed at 48 hours (window 24-72 hours), 1 week (window 5-12 days), and 1 month (window 4-8 weeks) post treatment to assess for acute and near-term serious complications.

Summary of the Post-Approval Study Results

Final safety findings (key endpoints)

There were no significant differences between the acute serious events arising from the procedures performed by the investigators in the pivotal study compared to those of the investigators in the postmarket surveillance study.

Figure 14.2 provides a summary of serious complications reported (primary endpoint) and incidence of complications related to the investigator-surgeon (secondary endpoint) in the postmarket surveillance study. There were no acute serious complications. There was only one (1) serious complication (fever of unknown origin requiring hospitalization) which was categorized a "near-term" as it occurred more than 48 hours after the procedure.

Figure 14.2 Overall Summary of Serious Complications[1] Related to Subject Safety; Timing of Serious Complications, and Incidence by Investigator-Surgeons Trained (Postmarket Surveillance Study)

Category	Number (%)
Subjects Reporting at Least One Serious Complication (Subsets Below)	1/105 (0.95%)
• Subjects Reporting at Least One Serious Anesthesia-Related Complication	0/105 (0.0%)
• Subjects Reporting at Least One Serious Abdominal Entry Related Complication	0/105 (0.0%)
• Subjects Reporting at Least One Serious Uterine Related [2] Complication	1/105 (0.95%)
Rate of Acute Serious Complications (occurring within 48 hours of Treatment)	0/101 (0.0%)[3]
Rate of Near-Term Serious Complications (occurring between 2 and 30 days post treatment)	1/104 (0.96%)[3]
Incidence of serious complications per investigator-surgeon during training and post training.	1/29, 3.4%

[1]Serious complications are serious adverse events that are treatment related, i.e., related to anesthesia, abdominal entry, or uterine entry, manipulation, or treatment during the procedure.
[2]Uterine related - Related to uterine entry, manipulation, or treatment
[3]Percentages are based on the number of subjects who participated in that follow-up visit.

For the acute serious complication rate, the null hypothesis was that the acute serious complication rate for the Acessa procedure is no different than the observed acute treatment-related SAE rate of 1.46% in the pivotal study. The alternative hypothesis is that the acute serious complication rate is different. Setting a two-sided alpha level to 0.05 and the sample size to 100, the power to detect a difference in the acute serious complication rate is at least 0.80 if the true acute serious complication rate is at least 6.7%

For the near-term serious complication rate, the null hypothesis is that the near-term serious complication rate is no different than the observed near-term treatment-related SAE rate of 0.73% in the pivotal study. The alternative hypothesis is that the near-term serious complication rate is different. **Figure 14.3** provides a comparison of the pivotal study (premarket) and postmarket surveillance serious complications. In the pivotal study, there were two (2) acute serious complications (2/137, 1.46%) compared to

no acute serious complications in the postmarket surveillance study (0/101, 0.0%). Both studies reported one (1) serious complication in the near-term follow up phase for a rate of less than 1% in each study. Therefore, both null hypotheses are accepted.

Figure 14-3 Serious Events Compared: Premarket vs. Postmarket Data (Primary Endpoint)

Serious Events/Complications Related to Device or Procedure - ACUTE/48 hours (Window 24-72 hours)	**Pivotal Study (Premarket) Total N in Safety Group = 137**			**Postmarket Surveillance Total N in Safety Group = 105**		
	N	**Event**	**Rate**	**N**	**Event**	**Rate**
Related to Anesthesia?	1	Atelectasis	0.73%	0	N/A	0%
Related to Abdominal Entry during procedure?	0	N/A	0%	0	N/A	0%
Related to Uterine Entry/Manipulation/Treatment	1	Colon laceration	0.73%	0	N/A	0%
Serious Events/Complications Related to Device or Procedure - NEAR TERM/30 days (Window 4-8 weeks)	**N**	**Event**	**Rate**	**N**	**Event**	**Rate**
Related to Anesthesia?	0	N/A	0%	0	N/A	0%
Related to Abdominal Entry during procedure?	0	N/A	0%	0	N/A	0%
Related to Uterine Entry/Manipulation/Treatment	1	Pelvic Abscess	0.73%	1	Fever of Unknown Origin	0.96%

Study Strengths and Weaknesses

The target number of subjects was 100; however, the Sponsor allowed for a 5% over-recruitment to account for withdrawals, missed visits, and loss to follow up before 30 days. Each enrolling site contributed at least one (1) subject but no site contributed in excess of 22 subjects (21% of the total). Over 60% of the subject data come from the United States (U.S.). A weakness of this study is the small number of ethnic minority subjects, particularly Hispanic/Latin American women. **Table 14.4** provides the demographic data regarding the 105 treated subjects. The results of the postmarket surveillance study were consistent with results of the pivotal study, demonstrating the studies are reliable benchmarks for safety.

Figure 14-4: Demographics of subject population

Variable		(N=105)
Age (Yrs)	Mean (SD) Median Min Max	470.5 (6.88) 40.0 21 54
Height (cm)	Mean (SD) Median Min Max	164.18 (8.007) 164.20 147.3 185.0
Weight (kg)	Mean (SD) Median Min Max	77.81 (19.432) 73.00 48.6 137.0
Ethnicity	Caucasian Chinese Korean Black Latin American Japanese Filipino	43 (41.0%) 2 (1.9%) 1 (1.0%) 39 (37.1%) 4 (3.8%) 0 (0.0%) 3 (2.9%)

	Aboriginal	2 (1.9%)
	South Asian	2 (1.9%)
	SE Asian	0 (0.0%)
	West Asian	0 (0.0%)

15. Potential Risks of Acessa Procedure

Known risks associated with radiofrequency ablation of fibroids include: skin burn, mild intra-operative bleeding, transient urinary retention or urinary tract infection, adhesion formation, post-procedural discomfort (cramping, pelvic pain), and transient amenorrhea:

- The risk of skin burn from the dispersion of radiofrequency energy is minimal and is a common risk for electrosurgical procedures.
- Bleeding may be observed due to injury to blood vessels in the area that the sharp electrosurgical device is inserted and deployed. Hemorrhage may occur from thermal injury to large blood vessels in the area ablated.
- Urinary retention or urinary tract infection are common complications following bladder catheterization.
- The formation of adhesions (scar tissue formation) following laparoscopic surgery is an inherent risk to the procedure.
- Cramping or pelvic pain may be experienced after the procedure and may require non-steroidal anti-inflammatory drugs (NSAID) or other analgesic medication for relief.
- There is a possibility that transient amenorrhea may result from this or any surgical procedure due to the effects of surgery and anesthesia on hypothalamic function.

Additional potential risks include: infection, injury to adjacent structures, vaginal bleeding and temporary anemia, blood loss requiring transfusion or hysterectomy, pneumothorax, wound dehiscence, deep vein thrombosis and pulmonary embolus, treatment failure, and complications related to laparoscopy and/or general anesthesia, including death.

After radiofrequency ablation of fibroids, instrumentation of the uterine cavity should be performed with caution and only when absolutely necessary.

16. Patient Counseling

Symptomatic uterine fibroids can severely impact quality of life. Some medical therapies are available including surgical options. Women seeking uterine-sparing surgical intervention for fibroids should have an understanding of the potential benefits, risks and adverse events associated with the Acessa System and other available options.
There are surgical and anesthesia related risks that are common to all surgical procedures for fibroids, including injury to adjacent structures, amenorrhea, blood loss requiring transfusion, or hysterectomy. Although minimal, whenever radiofrequency energy is used in an operating room, there is a risk of skin burn from the dispersion of energy.

Use of the Acessa System offers a minimally invasive, low-risk technique to ablate fibroids while sparing the uterus. The system and the procedure provides benefits such as a reduction or elimination of uterine fibroid related symptoms, which includes menorrhagia, dysmennorrhea, dyspareunia, urinary frequency, and pressure pain, and return to normal activities.

See Section 13 for a full list of potential complications, adverse events, and benefits of the procedure.

17. Care and Maintenance

Software Upgrades and Installation

There is no installation required. Any software upgrades must be exclusively performed by Hologic.

Maintenance

The Console is designed for indoor use in a dry operating room/procedure room environment. The Console requires no maintenance or calibration by the user. The user should not remove the cover. Removal of unit cover voids the warranty. All issues or maintenance required must be referred to Customer Service at GSS Hologic Inc. Refer to §1 for applicable contact information.

Cleaning and Disinfecting the Console

The Console Foot Pedal, and Field Generators should be given reasonable care and be kept clean and sanitary. To clean the Console, Foot Pedal, and Field Generators wipe down the devices with a 70% isopropyl alcohol wipe. Clean surfaces until all visible soil is removed. Wipe critical areas such as the buttons and any other areas that may become soiled. After removing all visible, gross soil use a Super SaniCloth® 0.5%/55% (working solution) to wipe all surfaces. Make sure the surfaces remain visibly wet at room temperature for the minimum time specified by Super SaniCloth instructions. Remove any excess disinfectant solution using a soft lint-free cloth.

WARNING: Electric shock hazard. Do not saturate the Acessa System with liquids. Do not allow liquids to run inside the unit. Do not immerse the Console in water. Shut off the Console, and disconnect power before cleaning/disinfecting. Do not sterilize the Console.

CAUTION: Do not use abrasives, caustics, or mineral spirits. Use of these agents to clean the Console, or any of its accessories may cause damage and voids the warranty. All electrical connections must be air-dried before use.

Calibration Verification

There are no user calibration adjustments on the Console. The Console requires no calibration prior to use. Follow any procedures or tests (if any) required by the individual hospital policy. Once the Console is turned on, the software runs through a self-test verifying the functionality of the Console. If the Console fails the self-test, contact Customer Service at Hologic, Inc.

18. Specifications

System Specifications

Figure 18-1 Acessa System Performance Specifications

Type of Specification	Specification
Operating Modes	Constant Power, Constant Temperature, or Coag.
Max Output Power	200 W into 50 – 80 Ω. Max allowable power is reduced outside this resistance range. Note that typical body impedance is in the range of 50Ω to 80Ω.
Power Accuracy	Power accuracy over range of 20W to 200W is ±20%.
Temperature Measurement Accuracy	±4°C from 15°C - 125°C ±5°C below 15°C and above 125°C
Operating Frequency	460 kHz, ±5%
Operating Power	120 VAC ± 10%, 60 Hz ± 1 Hz, Max. 6A 240 VAC ± 10%, 50 Hz ± 1 Hz, Max. 3A Auto-Switching Power Supply
Ablate Temperature	The system sets the Ablate Target Temperature to 95 °C.
Power Range - Temperature Control Mode	The system software shall limit the Ablate Power Target to the range 1 to 200 (W).
Power Control Mode	The system shall limit the Ablate Power Target to 15 W.
Coag Level	Coag Level Target is limited to the range of 1 to 20 with Level 12 as default.
Max Output Voltage	240 Vpeak into 100 Ω ablation, 350Vpeak into 300 Ω coagulation Note that coag output voltage can go as high as 550Vpeak for high impedance loads and momentary overshoot due to energy storage in passive filter components.
Accessories Rated Voltage	The Acessa accessories are rated for the maximum peak output voltage as indicated. Only Acessa accessories are to be used with the Acessa procedure.
Fuses	Two 7.0 Amp 250 volt fuses (in the Power Entry Module on rear panel)
Dimensions	16.5" x 18.9" x 8.0" (width x depth x height) (41.9 cm x 48.0 cm x 20.3 cm)
Weight	30 lbs. (13.6 kg)
Controls	Power on/off, RF on/off, System Settings
Displays	ON/OFF Status Target Temperature in °C

Type of Specification	Specification
	Connected accessories Target timer in min:sec, Average temperature of all Handpiece thermocouples in °C Coag power level Hottest Pad thermocouples in °C, Expected ablation size (X & Y) Deployment in cm Ultrasound settings (Depth, Frequency, Gain, Focus)
Connections	Foot Pedal Port, Handpiece Port, Pad Port, Ultrasound Transducer Image Port, Transducer 3D Sensor Port, Field Generator Port, USB Port, Video Port (HDMI), Power Entry Module (with internal fuses)
Protection	Class I, – Type BF Applied Part - Rated for ordinary, Continuous Operation. Ingress of water classification: IP20 This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, Oxygen, or Nitrous Oxide. Applied Parts: Handpiece, Handpiece Cable, Leg Pads, Leg Pads Cable, Ultrasound Transducer, Ultrasound Transducer Cable
Transport and Storage	Temperatures: - 10°C to +50°C Humidity: 10 to 90% non-condensing Atmospheric Pressure: 80.1 kPA minimum
Operation	Temperatures: 10°C to 25°C Humidity: 30% to 75% non-condensing
Environment	Operating room, EMC Industrial, Class A

Electromagnetic Compliance (EMC) Declaration

The Acessa System is intended for use in the electromagnetic environment specified below. The customer or the end user of the system should assure that it is used in such an environment.

Figure 18-2 EMC Emissions Compliance

Guidance and manufacturer's declaration – Electromagnetic Emissions		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low
RF emissions CISPR 11	Class A	The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

If the system is operated within the electromagnetic environment listed in the Guidance and manufacturer's declaration – Electromagnetic Emissions table, the system will remain safe and provide the following functions:

- measure, monitor and control the RF energy output during ablation and coagulation
- monitor the temperature of the thermocouples in the needles of the Handpiece
- monitor the temperature of the thermocouples in the Leg Pads that provide a return path for the RF energy

Figure 18-3 EMC Immunity Compliance

Guidance and manufacturer's declaration – Electromagnetic Immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD)	± 8 kV contact ± 15 kV air	± 8 kV contact ±2kV, ±4kV, ±8kV, and	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic

Guidance and manufacturer's declaration – Electromagnetic Immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
IEC 61000-4-2		±15 kV air	material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5kV, ±1 kV for line to line ± 0.5kV, ±1 kV, ±2kV for line to ground	±0.5kV, ±1kV line-to-line ±0.5kV, ±1kV, ±2kV line to ground	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	100% drop, 0.5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 period 30% dip, 25/30 periods	100% drop, 0.5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 period 30% dip, 25/30 periods	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3 Radiated RF Proximity Fields	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM bands 150kHz to 80MHz 3 V/m 80 MHz to 2.7 GHz Per 60601-1-2 section 8.10 Table 9.	3 Vrms 6 Vrms 3 V/m Per 60601-1-2 section 8.10 Table 9.	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = [1.2]\sqrt{P}$ $d = [1.2]\sqrt{P}$ 80 MHz to 800 MHz $d = [2.3]\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
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 reflected from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land			

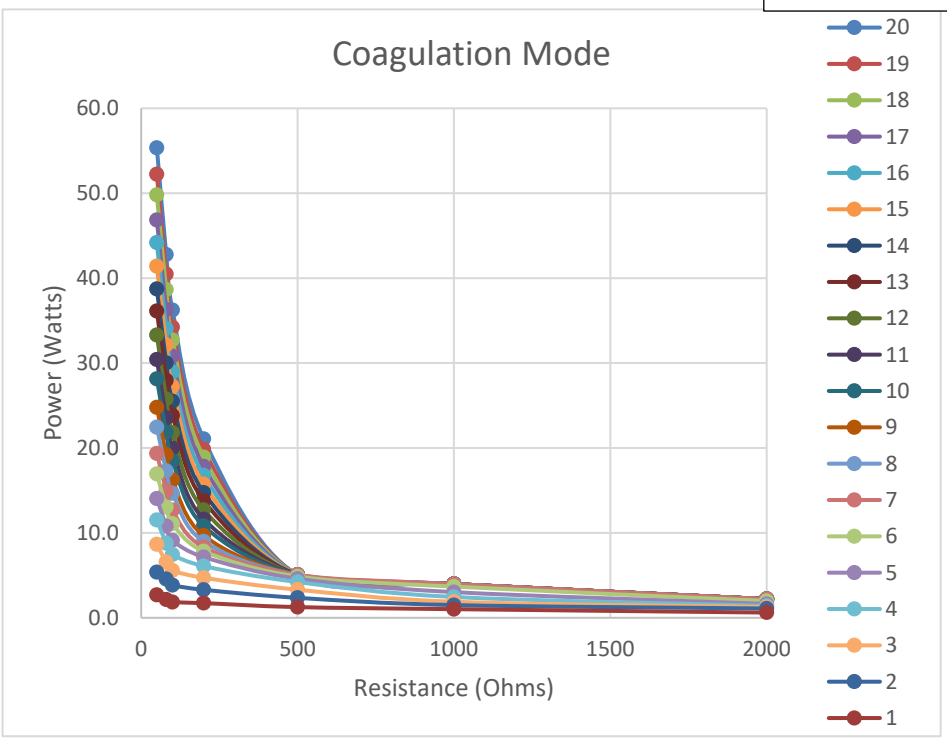
Guidance and manufacturer's declaration – Electromagnetic Immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the system. [b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than [V_1] V/m.			

Recommended separation distance between portable and mobile RF communications equipment and the system			
The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or its end user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.			
Related maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz d = $[3.5/V_1]\sqrt{P}$	**80 MHz to 800 MHz d = $[3.5/E_1]\sqrt{P}$**	**800 MHz to 2.5 GHz d = $[7/E_1]\sqrt{P}$**
0.01	**.17**	**.17**	**.23**
0.1	**.37**	**.37**	**.74**
1	**1.17**	**1.17**	**2.33**
10	**3.69**	**3.69**	**7.38**
100	**11.67**	**11.67**	**23.33**
For transmitter rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1. At 80 MHz and 800 MHz, the higher frequency range applies. Note 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflected from structures, objects and people.			

Technical Characteristics

Figure 18-4 Power vs Impedance Plot, Coagulation Mode

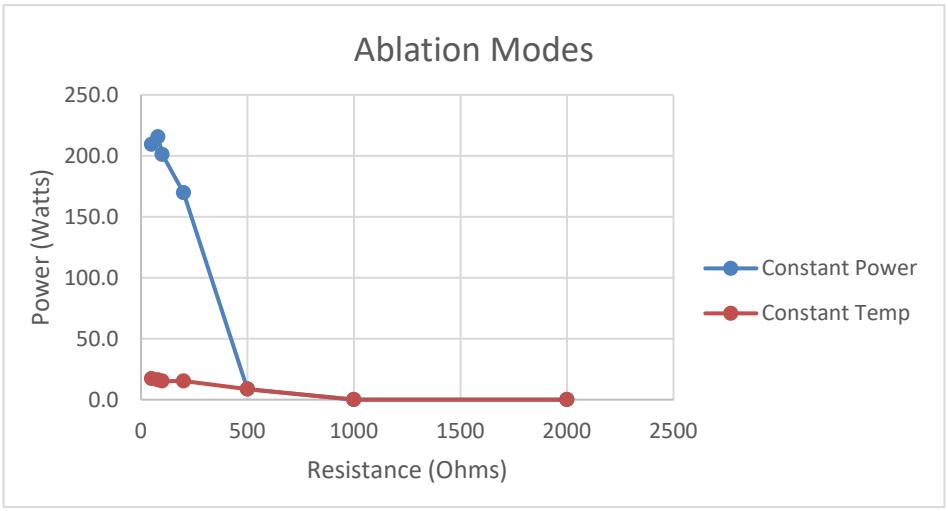
Coagulation Mode Output at Various Settings into Various Loads



Approximate peak coag power vs. load resistance at all user-settable levels ("coag level" per the user interface Menu, refer to **Figure 10-6**).

Note: The load for coag will increase as the affected tissue cauterizes and dries. As the voltage level increases, the effect of coag is more immediate. However, slower coagulation (lower levels) may be more effective.

Figure 18-5 Power vs Impedance Plot, Ablation Mode



Note: The unit is limited at low load impedances by maximum available current and is limited at high load impedances by maximum available voltage. 200 watts is only available over a load range of 50 Ω to 80 Ω. During ablation the system will not deliver RF energy to loads over 511Ω.

Compliance to Safety and Performance Standards

The Acessa procedure has been evaluated to, and is compliant with, the following medical device standards.

Figure 18-6 Medical Device Standards Compliance

Reference Number	Title
ISO 14971:2007	Medical devices – Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EU Directive 93/42/EEC	Medical Devices Directive (MDD)
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
IEC 60601-1 Ed. 3.1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Ed. 4.0	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-2 Ed 5.0:2017	Medical electrical equipment - Part 2-2: Particular requirements for basic safety and essential performance of electrosurgical equipment
IEC 60601-2-37	Medical electrical equipment – Part 2-37: Particular requirements for ultrasonic equipment
IEC 62304 Ed. 1.1	Medical Device Software – Software Life Cycle Processes
IEC 60529 Ed 2.2:2015	Degrees of Protection Provided by Enclosures (IP Code)
ISO 13485: Ed 3:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes

19. Trouble Shooting

Faults, Alerts, and Errors

The system detects and displays fault and error conditions.

Note on displaying messages

For non-critical messages, the Menu must be disabled to allow the message to be seen. Press the "Menu" button on the front panel to toggle the Menu ON and OFF.

1. A fault is a correctible condition that produces an Alert screen while an error is irreversible and requires system reboot to clear.
2. If a fault occurs with RF on, RF is automatically turned off with audible and visual alerts provided. The user will be required to press the Acknowledge (Check) Button to acknowledge the alert.
3. When a fault occurs with RF off, it is indicated by a visual alert only.
4. If the system components that provide Guidance fail, the display will revert to displaying the Ultrasound screen only.

Notes on rebooting Acessa console

1. Normally, the console is powered down by pressing the ON/OFF button on the front panel.
   - **a.** A message will appear with audible beeps, asking "Shutdown? Press Accept if yes, Menu to cancel"
   - **b.** Pressing the Acknowledge (Check) Button will cause the console to turn itself off.
   - **c.** Press front panel ON/OFF button to restart the Console.

2. If the normal power down procedure does not work, do the following to power down the console.
   - **a.** Press and hold the front panel ON/OFF pushbutton for about 7 seconds and then release it. Within 3 seconds the console should turn itself off.
   - **b.** The light should change from GREEN to ORANGE.
   - **c.** Turn off the rear panel AC mains power switch.
   - **d.** Wait for the ORANGE light to go out, about 30 seconds
   - **e.** Turn on the rear panel AC mains power switch.
   - **f.** The light should change turn to ORANGE.
   - **g.** Press front panel ON/OFF button to restart the Console.

Figure 19-1 Fault/Alert Code Table

ID	Condition	Visual Alert	Audible Alert	Solution
1	Tip of Ultrasound Ultrasound Transducer is near the edge of the 3D Guidance (TTFG) field.	"Transducer Near Edge Of Field"	No	Continue the procedure.
2	Tip of Handpiece shaft is near the edge of the 3D Guidance (TTFG) field.	"Handpiece Near Edge Of Field"	No	Continue the procedure.
3	Handpiece is out of the 3D Guidance (TTFG) tracking field.	"Handpiece Out Of Field"	No	Move the Handpiece into the field
4	Ultrasound Transducer is out of the 3D Guidance (TTFG) tracking field.	"Transducer Out Of Field"	No	Move the Ultrasound Transducer into the field
5	Metal has been detected in the 3D Guidance (TTFG) tracking field.	"Remove metal or interference"	No	Remove metal from the TTFG field.
6	The software is experiencing poor-quality 3D Guidance (TTFG) tracking	"Bad Tracking"	No	Monitor the tracking.

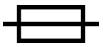
ID	Condition	Visual Alert	Audible Alert	Solution
7	Handpiece 3D Guidance Sensor signal is lost	"Handpiece Tracking Signal Lost"	No	1.Reconnect Handpiece connections 2. If connections are good, replace Cable. 3. If Cable was good, replace Handpiece.
8	Ultrasound Transducer is unplugged	"Connect Transducer Sensor"	No	1. Reconnect Ultrasound Transducer. 2. Replace Ultrasound Transducer.
9	Ultrasound Transducer 3D Sensor or cable is defective.	"Transducer Tracking Signal Lost"	No	1. Check Ultrasound Transducer or Sensor cable connection 2. Replace Ultrasound Transducer or continue without guidance.
10	The TTFG field generator signal is lost	"Field Generator Not Connected"	No	Check the Field Generator (TTFG) connections.
11	The user has plugged in a new tool and it takes time for the software to initialize it	""Wait While Tracker Is Configured""	No	Wait, can take up to one minute.
12	The system cannot read the Handpiece SROM ID or data	"Cannot read calibration data. Replace Handpiece"	No	Replace the Handpiece.
13	The system cannot read the Sleeve SROM ID or data	"Cannot read calibration data. Replace Transducer."	No	1. Change Sleeve 2. Continue case without guidance.
14	Handpiece disconnected	"Handpiece is Unplugged"	Yes	1. Press Acknowledge (Check) Button. 2. Check Handpiece or cable connection. 3. If connections are good, replace Cable. 4. If Cable was good, replace Handpiece.
15	Either one or both Leg Pads disconnected NOTE: Two Leg Pads are required for ABLATION, but only 1 pad is required for COAGULATION.	"Pad is unplugged"	Yes	1. Press Acknowledge (Check) Button. 2. Check Pad or cable connection. 3. If connections are good, replace Cable. 4. If Cable was good, replace Pad.
16	Fewer than 4 valid (functioning) Handpiece thermocouples.	"Handpiece: Not enough valid TCs"	Yes	1. Press Acknowledge (Check) Button. 2. Cool Handpiece tip. 3. If they are still invalid after cooling, replace Handpiece.
17	Fewer than **3** valid thermocouples on each of 2 Leg Pads	"Pads: Not enough valid TCs"	Yes	1. Press Acknowledge (Check) Button. 2. Check Pad Cable connection to the Pad and Console. 3. If Leg Pads are connected, replace the Leg Pads.
18	Either or both Leg Pads have a temperature ≥ 45 C	"Pad temperature over limit"	Yes	1. Press Acknowledge (Check) Button. 2. Wait for temperatures to cool or cool the pad to <40°C to continue the procedure.
19	Ablate high resistance	"RF output ended, ablate high resistance, possible desiccation"	Yes	1. Retract the Electrodes and rotate the Handpiece slightly, then deploy the Electrodes again. 2. Check that the Handpiece is placed into the tissue correctly and the Leg Pads are completely adhered to the skin. 3. Check proper connections at both ends of the extension cables. 4. Check for char on the Handpiece tip. A sterile disposable wipe moistened with 70/30 isopropyl alcohol may be used to clean the trocar tip. Dry the Trocar or allow it to evaporate before use.
20	RF target time limit exceeded	"RF output ended, maximum target time exceeded"	Yes	12 minute time limit has been reached. Re-start RF if desired.

ID	Condition	Visual Alert	Audible Alert	Solution
21	Pad contact resistance high during ablation	"RF output ended, high pad contact resistance"	Yes	A high pad contact resistance was detected. 1. Check the Leg Pads to ensure that they are in good contact with the patient. 2. Replace the Leg Pads if necessary.
22	Software error detected	"RFSys Error: <number>, <description>"	Possible	After rebooting, if problem persists contact Hologic Technical Support with error message.
23	Generator encounters an error condition.	An error number and error text will be displayed	Possible	After rebooting, if problem persists contact Hologic Technical Support with error message.
24	3D Guidance system not detected	"Guidance Failure: No Tracker Connected. Contact Technical Support"	No	After rebooting, if problem persists contact Hologic Technical Support with error message.
25	Ultrasound system not detected	"Guidance Failure: No U/S Scanner Connected"	No	After rebooting, if problem persists contact Hologic Technical Support with error message.
26	Software error detected	"AIM ™ Needle Guidance has stopped working"	No	After rebooting, if problem persists contact Hologic Technical Support with error message.
27	Console Overtemperature	"Console high internal temp"	Possible	Turn off console, allow 20 minutes to cool, then restart.
28	Console Overtemperature	"RF output ended, Console high internal temp. Coag okay."	Possible	Turn off console, allow 20 minutes to cool, then restart.
29	Target area could not achieve 95C	"Ablation failed to reach target temperature in specified time."	Yes	After rebooting, if problem persists contact Hologic Technical Support with error message.

20. Glossary of Symbols and Product Graphics

Figure 20-1 Symbols

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
	EN ISO 15223-1, 5.1.5 ISO 7000, 2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 7000 No. 659	Biological Hazard	Indicates that there are potential biological risks associated with the medical device.
	EN ISO 15223-1, 5.1.6 ISO 7000, 2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	IEC 60417. 6042 ISO 3864-1 ISO 7010-W012	Warning: Electricity	To identify equipment, for example, the welding power source, that has risk of electric shock

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
	EN ISO 15223-1, 5.4.4 ISO 7000, 0434A IEC 60601-1, Table D.1, 10	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	EN ISO 15223-1, 5.4.3 ISO 7000, 1641 IEC 60601-1, Table D.1, 11	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	EN ISO 15223-1, 5.1.3 ISO 7000, 2497	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO/DIS 15223-1, 5.7.11 ISO 7000, 6049	Country of manufacture	To identify the country of manufacture of products.
	EN ISO 15223-1, 5.2.6 ISO 7000, 2608	Do not resterilize	Indicates a medical device that is not to be resterilized.
	EN ISO 15223-1, 5.4.2 ISO 7000, 1051 IEC 60601-1, Table D.1, 28	Do not re-use	Indicates a medical device that is intended for one single use only.
	EN ISO 15223-1, 5.2.8 ISO 7000, 2606	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	IEC 60601-1, Table D.1, 8 IEC 60417, 5021	Equipotentiality	To identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.
	ISO 7010 ISO 3864-2, M002	Follow instructions for use	To signify that the instruction manual/booklet must be read.
	IEC 60143-1, 5016 IEC 60417-5016	Fuse	To identify fuse boxes or their location.
	IEC 60601-2-2, 201.2.10 ISO 60601-2-1:2009; IEC 1193/06, Figure 201.102: 2009	High Frequency (HF) isolated patient circuit	Indicates connection to a high frequency (HF) isolated patient circuit.
	ISO 15223-1 ISO 7000	Atmospheric Pressure Limitation	The atmospheric pressure limitation shall be indicated adjacent to the upper and lower horizontal lines.
	EN ISO 15223-1, 5.3.8 ISO 7000, 2620	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
	EN ISO 15223-1, 5.3.4 ISO 7000, 0626 ISO 780	Keep dry	Indicates a medical device that needs to be protected from moisture.
	EN ISO 15223-1, 5.1.1 ISO 7000, 3082	Manufacturer	Indicates the medical device manufacturer.
	EN ISO 15223-1, 5.2.7 ISO 7000, 2609	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 7000-3079	Open here	To identify the location where the package can be opened and to indicate the method of opening it.
	ISO 7000, 2794	Packaging unit	To indicate the number of pieces in the package.
℞ONLY	FDA 21 CFR 801.109	Prescription use only	Caution: Federal law restricts this device to sale by or on the order of a physician.
IP20	IEC 60529	Degree of Ingress Protection Provided by Enclosures	Indicates classification and rates the degree of protection provided by mechanical casings and electrical enclosures against intrusion, dust, accidental contact, and water
IPX7	IEC 60529	Protection against immersion	Indicates classification and rates the degree of protection protection against immersion up to 1 meter.
	IEC 60417, 5140	Non-ionizng electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
SN	EN ISO 15223-1, 5.1.7 ISO 7000, 2498	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	IEC 60417, 5009	Stand by	To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by-condition
STERILE EO	EN ISO 15223-1, 5.2.3 ISO 7000, 2501	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	IEC 60417, 5051	Television Monitor	To identify the terminal controls for a televison monitor.
	EN ISO 15223-1, 5.3.7 ISO 7000, 0632	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
	IEC 60601-1, Table D.1, 20 IEC 60417, 5333	Type BF applied part	To identify a Type BF applied part complying with IEC 60601-1
	N/A USB Implementors Forum, Inc.	USB Port	Identifies a USB (Universal serial bus) connection port.
	EN ISO 15223-1, 5.1.4 ISO 7000, 2607	Use-by date	Indicates the date after which the medical device is not to be used.

Figure 20-2 Product Graphics Glossary

Product Icon	Icon Name	Description
	Dual Foot Pedal Port	Port to connect Dual Foot Pedal Cable to Acessa Console
	Handpiece Port	Port to connect Acessa Handpiece cable to Acessa Console
	Pad Cable Port	Port to connect Acessa Pad cable to Acessa Console
	Ultrasound Transducer Image Port	Port to connect Acessa Ultrasound Transducer Image cable to Acessa Console
	Ultrasound Transducer 3D Sensor Port	Port to connect Acessa Ultrasound Transducer 3D Sensor cable to Acessa Console
	Field Generator Port	Port to connect either Acessa Table Top Field Generator or Acessa Planar Field Generator cable to Acessa Console

21. Warranty Statement

Except as otherwise expressly stated in an agreement between Hologic and its original customer ("Customer), Hologic equipment ("Equipment") is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment ("Warranty Period"). Replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or 90 days from shipment, whichever is longer. Consumable supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages. Licensed software is warranted to operate in accordance with published specifications. Services are warranted to be supplied in a workman-like manner. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products.

These warranties do not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer's refusal to allow Hologic recommended Software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or "as-is" basis.

22. Technical Support & Product Return Information

Contact Hologic Technical Support if the Acessa Provu System fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number and a biohazard kit if applicable. Return the Acessa Provu System according to the instructions provided by Technical Support.

If applicable, return used or opened product according to the instruction provided with the Hologic-supplied biohazard kit.

Disposal

The used disposable device must be treated as biohazardous waste and disposed of according to standard practices of the hospital or clinic where the treatment is performed.

Consult your local regulations for disposal and/or electronics recycling as applicable. Do not place into a municipal waste system unless authorized to do so by local authorities.

FOR MORE INFORMATION

For Technical Support or reorder information in the United States, please contact:

Hologic Inc.
250 Campus Drive
Marlborough, MA 01752 USA
Telephone: 800-442-9892
www.hologic.com

https://www.hologic.com/patent-information

NOTE: Any device-related incident or problem, which is believed to represent a safety issue, should be reported to Hologic Technical Support.