gynesonics®

Sonata®
SYSTEM

Instructions for Use

with Technical Appendix

SONATA2-110/-220 *with*
Radiofrequency Handpiece RFA-002, RFA Handpiece Cable ACCY-008, and Software SW-002

Sonata Transcervical Fibroid Ablation System 2.2

CE
2797

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Notice

Sonata® System Instructions for Use

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About this Instructions for Use

This Instructions for Use (IFU) covers the Sonata System, Intrauterine Ultrasound (IUUS) Probe, and all accessories and materials needed for the procedure. This IFU is provided by Gynesonics as a component in the Sonata System and should be kept on the System Cart for reference at all times. Contact Gynesonics for additional copies of this IFU and any additional questions or support required for training and service, including installation, and maintenance. For detailed technical information or maintenance and service information, refer to the Technical Manual in Appendix B.

Instructions for Use originally issued in English.

Table of Contents

Symbols Glossary

The following tables show the safety symbols that are used on the Sonata System and throughout this IFU.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1 #5.1.1	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.12	Symbols for use in the labeling of medical devices.
			ISO 7000 - 3082	Graphical symbols for use on equipment.
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1 #5.1.3	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.6	Symbols for use in the labeling of medical devices.
			ISO 7000-2497	Graphical symbols for use on equipment.
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1 #5.1.6	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.10	Symbols for use in the labeling of medical devices.
			ISO 7000-2493	Graphical symbols for use on equipment.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1 #5.1.7	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.5	Symbols for use in the labeling of medical devices.
			ISO 7000-2498	Graphical symbols for use on equipment.
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 #5.1.5	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.4	Symbols for use in the labeling of medical devices.
			ISO 7000-2492	Graphical symbols for use on equipment.

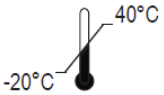
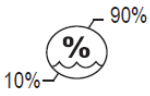
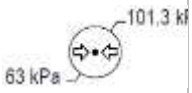
SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Use by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 #5.1.4	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.3	Symbols for use in the labeling of medical devices.
			ISO 7000-2607	Graphical symbols for use on equipment.
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	ISO 15223-1 #5.1.2	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.13	Symbols for use in the labeling of medical devices.
	Follow instructions for use	Refer to instruction manual/booklet.	IEC 60601-1 Table D.2, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			ISO 7010-M002	Graphical symbols – Safety colors and safety signs – Registered safety signs.
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1 #5.2.4	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.8.3	Symbols for use in the labeling of medical devices.
			ISO 7000-2502	Graphical symbols for use on equipment.
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1 #5.2.3	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.8.2	Symbols for use in the labeling of medical devices.
			ISO 7000-2501	Graphical symbols for use on equipment.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	ISO 15223-1 5.2.7	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.23	Symbols for use in the labeling of medical devices.
			ISO 7000-2609	Graphical symbols for use on equipment.
	DO NOT re-use	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.	ISO 15223-1 #5.4.2	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.2	Symbols for use in the labeling of medical devices.
			ISO 7000-1051	Graphical symbols for use on equipment.
	DO NOT resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1 #5.2.6	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #5.22	Symbols for use in the labeling of medical devices.
			ISO 7000-2608	Graphical symbols for use on equipment.
	DO NOT use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1 #5.2.8	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			EN 980 #6.3	Symbols for use in the labeling of medical devices.
			ISO 7000-2606	Graphical symbols for use on equipment.
	Fuse	To identify fuse boxes or their location. Accompanied by the type and full rating of the fuse.	IEC TR 60878#5016	Graphical symbols for electrical equipment in medical practice.
			IEC 60417 #5016	Graphical symbols for use on equipment.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Type BF applied part	To identify a Type BF applied part complying with IEC 60601-1. Type BF refers to classification of the nature of patient contact and degree of patient protection from risk of electrical shock.	IEC 60601-1 Table D.1. Symbol 20	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			IEC 60417 #5333	Graphical Symbols for Use on Equipment.
	High Frequency (HF) isolated patient circuit	Indicates connection to a high frequency (HF) isolated patient circuit.	IEC 60601-2-2 #201.7.2.10	Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.
	Linear or curved array probe	To identify the control or the indicator to activate a linear array or curved array probe for the electronic generation of a sound field and to identify the corresponding connector.	TR 60878 #5710	Graphical Symbols for electrical equipment in medical practice.
	Non-ionizing electro-magnetic radiation	To indicate generally elevated, potentially hazardous, levels of nonionizing radiation, or to indicate equipment or systems, e.g., in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or ablation.	IEC 60878 #5140	Graphical Symbols for electrical equipment in medical practice.
			IEC 60417 #5140	Graphical Symbols for Use on Equipment.
	Dangerous voltage	To indicate hazards arising from dangerous voltages.	IEC 60601-1 Table D.1 symbol 24	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			IEC 60417 #5036	Graphical Symbols for Use on Equipment.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Equipo-tentiality	To identify the terminals which, when connected together, bring the various parts of equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g., for local bonding.	IEC 60601-1 Table D.1 symbol 8	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			IEC 60417 #5021	Graphical Symbols for Use on Equipment.
IPX7	Degree of Ingress Protection Provided by Enclosure	Protected against the effects of temporary immersion in water.	IEC 60601-1 Table D.3, Symbol 2	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			IEC 60529 section 6	Degrees of Protection Provided by Enclosures.
IPX6	Degree of Ingress Protection Provided by Enclosure	Protected against powerful water jets	IEC 60601-1 Table D.3, Symbol 2	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			IEC 60529 section 6	Degrees of Protection Provided by Enclosures.
	"ON" (power)	To indicate connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved.	IEC 60601-1 Table D.1 symbol 12	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			IEC 60878 #5007	Graphical Symbols for electrical equipment in medical practice.
	"OFF" (power)	To indicate disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved.	IEC 60601-1 Table D.1 symbol 13	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			IEC 60878 #5008	Graphical Symbols for electrical equipment in medical practice.
	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.	IEC 60601-1 Table D.1 symbol 29	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			IEC TR 60878 #5009	Graphical Symbols for electrical equipment in medical practice.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	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.	IEC 60601-1 Table D.1 symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			ISO 7000-0434A	Graphical symbols for use on equipment
	General warning sign	To signify a general warning.	IEC 60601-1 Table D.2 symbol 2	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			ISO 7010 W001	Graphical symbols – Safety colours and safety signs – Registered safety signs.
	Alarm warning sign	Displayed on the ultrasound display screen to signify a potential or actual hazardous situation exists for physician awareness or response is required.	IEC 60601-1-8:2007+A11:2017 Annex C No. 1 Reference 60417-5307	General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006)
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	ISO 15223-1 #5.3.1	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-0621	Graphical symbols for use on equipment.
	DO NOT stack	To indicate that the item shall not be vertically stacked, either because of the nature of the transport packaging or because of the nature of the items themselves.	ISO 7000-2402	Graphical symbols for use on equipment.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1 #5.3.4	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-2626	Graphical symbols for use on equipment.
			EN 980 #5.21	Symbols for use in the labeling of medical devices.
	This side up	To indicate correct upright position of the transport package.	ISO 7000-0623	Graphical symbols for use on equipment.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1 #5.3.7	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-0632	Graphical symbols for use on equipment.
			EN 980 #5.17.3	Symbols for use in the labeling of medical devices.
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 15223-1 #5.3.8	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-2620	Graphical symbols for use on equipment.
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	ISO 15223-1 #5.3.9	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.
			ISO 7000-2621	Graphical symbols for use on equipment.
	Prescription Only	Requires a prescription in the United States.	21 CFR 801.15(c)(1)(i) F	Labeling-Medical devices; prominence of required label statements.
			21 CFR 801.109	Labeling-Prescription devices.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	Alternating current	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.	IEC 60601-1 Table D.1. Symbol 1	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
			ISO 7000-5032	Graphical symbols for use on equipment.
	Mass; weight	For the Sonata System, this indicates the total weight of the fully loaded System Cart including safe working load.	ISO 7000-1321B	Graphical symbols for use on equipment.
	Autoclave symbol	Sterilizable in a steam sterilizer (autoclave) at temperature specified	ISO 7000-2868	Graphical symbols for use on equipment.

Symbols Not from Standards

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	REFERENCE	TITLE
CE 2797	CE marking	Signifies European technical conformity.	Directive 93/42/EEC Annex XII	Medical Device Directive
TÜVRheinland c us	TUV Mark	Indicates that the product was tested and met the certification requirements for electrical, and/or mechanical products.	N/A	N/A
	Recycle: electronic equipment	DO NOT dispose of electronic equipment in normal trash.	Directive 2012/19/EU Annex IX	Marking of Electrical and Electronic Equipment in accordance with Article 15 (2) of Directive 2012/19/EU
STERILE H_2O_2	Sterilized using Hydrogen Peroxide	Indicates a medical device that has been sterilized using Hydrogen Peroxide	N/A	N/A
STERILE PLASMA	Sterilized using plasma	Indicates a medical device that has been sterilized using plasma	N/A	N/A
MD	Medical Device	Indicates that the device is a Medical Device	MedTech Europe Guidance May 2019	Use of Symbols to Indicate Compliance with the MDR
STERILE VH2O2	Sterilized using vaporized hydrogen peroxide	Indicates a medical device that has been sterilized using vaporized hydrogen peroxide	MedTech Europe Guidance May 2019	Use of Symbols to Indicate Compliance with the MDR

Glossary of Terms, Acronyms, and Definitions

TERM	DEFINITION
Ablation (RF Ablation)	The application of radiofrequency (RF) energy to tissue.
Ablation Zone	A graphical element of the SMART Guide (red inner ellipse) that is a two-dimensional representation of the average region of tissue ablation for the selected ablation size.
Administrator	The person responsible for managing user profiles and image files within the Sonata System (GGS) software.
AIUM	American Institute of Ultrasound in Medicine
Articulation Lever	The self-locking control arm used to pivot the Articulating Tip on the IUUS Probe.
Articulating Tip	The three-position articulating Imaging Surface of the IUUS Probe, controlled by the Articulation Lever.
Button	A software command with words inside a rectangular shape that provides options for the user. Also used to describe the hardware buttons for RF ON/OFF, SMART Tablet Power ON, and Confirm Button.
Cleaning	Physical removal of soil and contaminants to the extent necessary for further processing.
Confirm Button	During the targeting steps, the Confirm Button (located on the top side of the RFA Handpiece) is used by the Operator to verify when a step in the sequence has been completed.
DE	Abbreviation for Dispersive Electrode.
Disinfection	The destruction of pathogens and other microorganisms by physical or chemical means.
Dispersive Electrodes	Two (2) adhesive pads, each applied to an anterior thigh of the patient, to return energy from the patient back to the RF Generator, completing an electrical connection.
EMC	Electromagnetic Compatibility
EMI	Electromagnetic Interference
Enzymatic Detergent	A solution for medical device cleaning designed for removal of biological soil such as blood, tissue, and biofilms.
FIGO	The International Federation of Gynecology and Obstetrics (Fédération Internationale de Gynécologie et d'Obstétrique) that has established a fibroid subclassification system.
Graphical Guidance Software (GGS)	User interface software installed on the SMART Tablet to allow the operation of the Treatment Device.
Gynesonics	Sonata System manufacturer
Icon	A software graphic on the Ultrasound Display Screen that provides access to additional functionality, such as the Preferences icon.
Imaging Surface	The transducer surface at the tip of the Intrauterine Ultrasound Probe.
Intrauterine Ultrasound (IUUS) Probe	A reusable imaging device that connects to the single-use RFA Handpiece to create the Sonata Treatment Device. The IUUS Probe images the uterus from within the endometrial cavity.
Introducer	A sharpened cannula deployed from the shaft of the RFA Handpiece. The Introducer enables penetration into dense fibroid tissue as an initial stage of deploying the Needle Electrodes.

TERM	DEFINITION
Introducer Guide	A graphical element of the SMART Guide, represented by a blue dashed line, that identifies the projected path of the Introducer when advanced.
Introducer Plan Line	A graphical element of the SMART Guide, represented by a yellow or red line, used to guide the Operator when advancing the Introducer Tip.
Introducer Slider(s)	A sliding control on the RFA Handpiece that allows the Operator to advance or retract the Introducer.
Introducer Tip	The sharp point of the Introducer.
Introducer Tip Alignment Guide	A graphical element of the SMART Guide, represented by a yellow diamond with arrows, that is aligned to the Introducer Tip.
Introducer Tip Marker	A graphical element of the SMART Guide represented by Red Diamond after the Introducer Tip Alignment Guide is aligned to the Introducer Tip and the Confirm Button is pressed.
Introducer Tracker	A graphical element of the SMART Guide, represented by an arrowhead, that moves with the Introducer tip during advancement.
Needle Electrode(s)	Seven (7) nickel-titanium (nitinol) needles that deploy radially from the Introducer Tip to distribute RF energy within a volume of tissue.
Needle Electrode Plan Lines	Graphical elements of the SMART Guide, represented by three yellow or red lines used to guide the Operator when deploying the Needle Electrodes.
Needle Electrode Slider(s)	A sliding control on the RFA Handpiece that allows the Operator to deploy or retract the Needle Electrodes.
Needle Electrode Tip Trackers	Graphical elements of the SMART Guide, represented by three arrowheads, that move with the Needle Electrodes.
Operator	The clinician or supporting staff operating the Sonata System.
Peripheral Zone Marker	A graphical element of the SMART Guide, graphically represented by pin stripes, that shows regions of the Thermal Safety Border that extend beyond the ultrasound view.
Point-of-Use	The location and time where the device is used.
Radiofrequency Energy (RF)	A general designation for energy delivered in the frequency range of 3 kHz to 300 GHz. The Sonata System operates at 460 kHz.
Radiofrequency Ablation (RFA)	The process of destroying a volume of tissue using radiofrequency energy to sufficiently elevate temperatures for a period of time, which results in thermal fixation and coagulative necrosis.
RF	Radiofrequency
RFA Handpiece	A single-use component of the Treatment Device with deployable electrodes used to deliver thermal energy to fibroids. The RFA Handpiece attaches to the IUUS Probe.
RFA Handpiece Cable	A reusable cable that connects the RFA Handpiece to the RF Generator.
Radiofrequency (RF) Generator	Controls the delivery of energy to the RFA Handpiece.
Reprocessing	The entire procedure of cleaning, disinfecting (if required), and sterilizing the IUUS Probe when being used for the first time or after a procedure in preparation for the next use.
SMART	Setting Margins of Ablation in Real Time
SMART Control	A 4-directional control on the handle of the RFA Handpiece that allows the Operator to plan ablation depth and size.

TERM	DEFINITION
SMART Guide	Graphical overlay on the ultrasound image that displays required information for targeting and deployment of the Treatment Device components used to deliver radiofrequency ablation.
SMART Tablet	Unit on top of the System Cart that provides ultrasound imaging, ablation planning, and communications with the RF Generator.
Strain Relief	The flexible tapered elastomer portions at the ends of the cable
Sterilization	A process that renders product free from viable microorganisms.
Thermal Safety Border	A graphical element of the SMART Guide (green outer ellipse) that indicates the distance from the Needle Electrodes at which tissue is safe from the potential of thermal damage.
Thermocouple	An electrical instrument used to measure temperature.
Treatment	The sonography-guided transcervical fibroid ablation procedure
(Sonata) Treatment Device	The assembly of the RFA Handpiece and the IUUS Probe creates the Treatment Device.
Ultrasound Scan Plane	The plane in which the ultrasound image is collected. It is defined by the ultrasound Imaging Surface orientation.
Ultrasound Display Screen	The screen of the SMART Tablet that displays the SMART Guide, GGS software and ultrasound images.
User	Person with permission to log into the Sonata System user interface and manage their own image files through the GGS software
WEEE	Waste Electronic and Electrical Equipment (WEEE) Regulations for proper disposal within European Union.

Chapter 1 General Information

1.1 Device Description

The Sonata® Transcervical Fibroid Ablation System 2.2 provides radiofrequency (RF) ablation of uterine fibroids (myomata; leiomyomata uteri) using a transcervical approach without incisions or material uterine distension.

The Sonata System is comprised of durable medical equipment, software, and various single-use and reusable instruments. A Radiofrequency Ablation (RFA) Handpiece attaches to an Intrauterine Ultrasound (IUUS) Probe to provide sonography-guided RF ablation. The Sonata Graphical Guidance Software (GGS) integrates ablation planning, targeting, and ablation of fibroids. The SMART Guide displays a real-time graphic overlay on the live ultrasound image for targeting and deployment of radiofrequency ablation. The system enables a clinician to deliver radiofrequency energy to fibroid tissue resulting in thermal fixation and coagulative necrosis of the tissue.

1.2 Intended Use

The Sonata® Transcervical Fibroid Ablation System 2.2 is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.

1.3 Contraindications

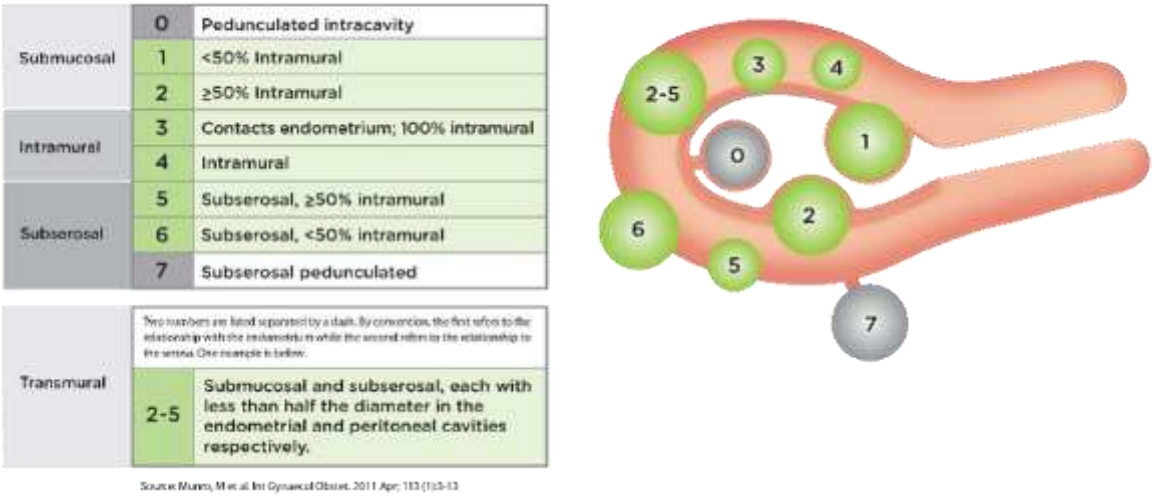
The Sonata System is contraindicated in the following conditions:

- Current pregnancy;
- Active pelvic infection;
- Known or suspected gynecologic malignancy or premalignant disorders such as atypical endometrial hyperplasia;
- Presence of one or more intratubal implants for sterilization; and
- Presence of an intrauterine device (IUD), unless removed prior to the introduction of the Sonata Treatment Device.

1.4 Patient Selection

The Sonata System is designed to completely or partially ablate FIGO (International Federation of Obstetricians and Gynecologists) types 1, 2, 3, 4, 5, 6, and 2-5 fibroids, see Figure 1-1.

Extramural (e.g., cervical, broad ligament) and pedunculated fibroids (types 0, 7) are not intended for treatment with the Sonata System. However, presence of these fibroids is not a contraindication for use.



Submucosal	0	Pedunculated intracavity
	1	<50% Intramural
	2	≥50% Intramural
Intramural	3	Contacts endometrium; 100% intramural
	4	Intramural
Subserosal	5	Subserosal, ≥50% intramural
	6	Subserosal, <50% intramural
	7	Subserosal pedunculated
Transmural	2-5	Submucosal and subserosal, each with less than half the diameter in the endometrial and peritoneal cavities respectively.

Figure 1-1. The Sonata System is designed to ablate a wide range of fibroids.

- Safety and effectiveness with regard to fertility and fecundity after the use of the Sonata System have not been established.
- Effectiveness in women with clinically significant adenomyosis has not been established.
- Not intended for use in women with an unusually short endometrial cavity (< 4.5 cm fundus-to-external os)
- Not intended for use in women with any abnormality of the endometrial cavity that, in the judgment of the physician, prevents sufficient access to the endometrial cavity.
- The RFA Handpiece Needle Electrodes contain nickel and should be used with caution in patients with a known nickel allergy.
- Transcervical radiofrequency ablation with the Sonata System should not be performed in patients with known hardware in one or both lower extremities (e.g., hip implants). The safety of abdominopelvic radiofrequency ablation in such situations has not been established.
- Transcervical radiofrequency ablation with the Sonata System should not be performed in the presence of metal jewelry that cannot be removed (including from abdominal and genital piercings).
- Sonata System not intended for use on patients whose thighs cannot accommodate the Dispersive Electrodes without overlap.
- As with any surgical procedure, the Sonata System should be used with caution in patients with a known coagulopathy, with appropriate medical measure available to correct a bleeding disorder if deemed necessary by the physician.

1.5 Patient Counseling, Potential Postoperative Events, and Risks

As with any procedure, the clinician should discuss the potential risks and expected outcomes related to the Sonata procedure with patients. The Sonata System is intended for the transcervical ablation of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding. Full benefits may not be realized for several months, as the ablated fibroids shrink over time.

- **Anticipated postoperative events** include: abdominopelvic pain/cramping; back pain; constipation; dizziness/fatigue; headache; fever; malaise; nausea/vomiting; sloughing and, less commonly, intact expulsion of ablated fibroid tissue *per vaginam* (particularly after ablation of submucous fibroids), and vaginal spotting/bleeding/dysmenorrhea.
- **Potential risks associated with fibroid ablation using the Sonata System** include: allergic reactions (including rash) to device materials; bowel or bladder perforation; cervical/vaginal laceration or tear; dysmenorrhea; electrical shock; hematometrium; hemorrhage; infections: major and minor local and systemic infections, including intrauterine infection; retention of device fragment; skin burn from the dispersion of RF energy; thrombotic events; unintended injury to the uterus, cervix or vaginal vault, adjacent organs or tissue; unknown risk to future pregnancies; and complications including death.

Additionally, the clinician should include in their discussion the risks associated with the anesthesia regimen selected for performing the Sonata procedure.

In the event of a serious incident related to use of the Sonata System, notify Gynesonics. If located within the European Union, also notify the competent authority of the EU Member State in which the user and/or patient is established.

1.6 Initial Installation and Setup

A Gynesonics Representative will perform all system unpackaging, assembly, and functional checks. Please contact Gynesonics to schedule this service.

CAUTION	
⚠	INSTALLATION AND SERVICE PERSONNEL System assembly, installation, configuration, and service is to be performed by Gynesonics personnel only. Improper servicing may lead to system damage or compromised performance.

1.6.1 Biomedical Electrical Testing (Medical Physics)

The Operator is responsible for testing to requirements (such as electrical safety) that are specific to the treatment facility policies and guidelines. Contact Gynesonics or see Technical Manual, Appendix B for technical support.

Potential equalization provisions may be required per treatment facility or regional governing body requirements. Biomedical Engineering should be consulted. The RF Generator is provided with a terminal conforming to IEC 60601-1 edition 3.1 for the connection of a potential equalization conductor.

Select environmentally controlled storage per recommended conditions, including security against theft. (Refer to Technical Manual for storage and transport conditions.)

1.7 Room Requirements

The Sonata System is intended for use in locations in which minimally invasive procedures are performed. The Sonata System is suitable for use within the patient environment as defined by IEC 60601-1.

- **Anesthesia**: Access to appropriate patient anesthesia (e.g., general, regional, conscious sedation) as determined by the treating physician in consultation with an anesthesiologist.
- **Patient Positioning**: The patient must be positioned in a dorsal lithotomy position, in appropriate stirrups (e.g., Allen stirrups) to minimize the risk of lower extremity nerve compression.
- **Power**: AC 100-240V, 50/60 Hz, 15A max, grounded. Backup is recommended.
- **Temperature**: 10°C to 35°C for all equipment and components.
- **Lighting**: Adjustable lighting will help for visualization, bright lighting for access, and dim lighting for better visualization of the ultrasound screen during the procedure
- **Cleanliness**: Should be maintained per treating facility standards for similar transcervical procedures, including cleaning between cases, air quality, and infection control processes.
- **Sterile Field**: Required for assembly of the Sonata Treatment Device.
- **Emergency Care**: Availability of emergency medical treatment such as IV access, airway management, medication, means to provide CPR, and access to transportation to an emergency care facility.
- **External Monitors**: The SMART Tablet may be connected to an external monitor through a video cable and adapter. The output format is micro HDMI. An adapter from Micro HDMI to HDMI is provided.

CAUTIONS	
⚠	EXTERNAL MONITORS Any external monitor that is connected to the system must support a resolution of 1920 x 1080 pixels or greater. Use of an external monitor at lower resolution may result in reduced ultrasound image quality.
⚠	DO NOT STACK EQUIPMENT DO NOT stack heavy items on top of the top shelf or in the storage bin. Any additional equipment or weight stacked on the System Cart will reduce the stability and increase the risk of it falling over.

1.8 Manufacturer and Service

MANUFACTURER	AUTHORIZED EUROPEAN REPRESENTATIVE
Gynesonics, Inc. 600 Chesapeake Drive Redwood City, CA 94063 USA Telephone: +1 650-216-3860 Fax: +1 650-299-1566 EU: customersupport@gynesonics.com US: UScustomerservice@gynesonics.com www.gynesonics.com	Obelis s.a Bd. Général Wahis 53 1030 Brussels, BELGIUM Telephone: +(32) 2.732.59.54 Fax: +(32) 2.732.60.03 mail@obelis.net EC REP

1.9 Intended Operators and Support Personnel

1.9.1 Operator

Operators should be a licensed and board eligible/board certified clinician, such as an obstetrician/gynecologist, proficient with hysteroscopic and/or laparoscopic surgery, electrosurgery, and sonography. Only clinicians who have completed a Gynesonics-approved training program and understand the contents of this IFU should treat patients using the Sonata System.

1.9.2 Support Personnel

Support personnel should be trained in the operation of electrosurgical instruments and management of sterile surgical environments. Only support personnel who have read and understood the Sonata Instructions for Use and received instruction and relevant training from a Gynesonics Representative should support the treatment of patients using the Sonata System.

1.9.3 Reprocessing Personnel

Personnel involved in reprocessing of the reusable IUUS Probe and RFA Handpiece Cable should be knowledgeable in general principles and risks associated with the reprocessing of reusable medical devices and be competent in common practices and safety procedures used in reprocessing. Reprocessing personnel are expected to have adequate understanding and skills with regards to hazards associated with contaminated medical devices and reprocessing chemical exposure.

CAUTION	
⚠	SALE AND USE Federal law restricts this device to sale by or on the order of a physician.

1.10 General Warnings

The following warnings identify known operations, procedures, or practices that should be heeded immediately or risk injury or death to patient or Operator.

WARNINGS		
1		READ IFU BEFORE USE Read this IFU in its entirety before 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 system be read, understood, and followed in order to enhance safety and effectiveness. This includes following the indications and contraindications for use.
2		FOR USE ONLY BY QUALIFIED CLINICIAN To reduce the possibility of patient or Operator injury, products covered in this IFU are intended for use only by qualified healthcare professionals trained in the safe use of electrosurgery and in the Sonata System. Contact Gynesonics for information regarding approved training programs.
3		DVT PROPHYLAXIS MAY BE APPROPRIATE Any surgical procedure may involve a risk of deep vein thrombosis or pulmonary embolism. Please consult institutional/national guidelines.
4		RISK OF UTERINE PERFORATION The Sonata System requires device insertion via a transcervical approach. As with similar procedures, risks include uterine perforation, cervical laceration, and other injuries; the probabilities of such risks may be reduced, but not eliminated, through attention to uterine size and position, as well as to any undue resistance during cervical and uterine instrumentation. A false passage within the cervical stroma or frank uterine perforation can occur during any procedure in which the uterus is instrumented, especially in cases of severe uterine anteversion, retroversion, or lateral displacement of the uterus.
5		DO NOT TREAT EXTRAUTERINE FIBROIDS DO NOT treat extrauterine (broad ligament, cervical) fibroids with the Sonata System due to the potential for causing extrauterine tissue or organ injury.
6		DO NOT EXPOSE TO FLAMMABLE AGENTS DO NOT operate the Sonata System during exposure to flammable agents, endogenous gases, and oxygen. Non-flammable agents should be used for cleaning and disinfection wherever possible. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of RF energy. 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 mopped up before the Sonata System is used. Some materials (e.g., cotton, wool, and gauze), when saturated with oxygen, may be ignited by sparks produced during use of radiofrequency electrosurgical equipment. Failure to follow these recommended mitigations compromise fire and electrical safety for patients and Operators.

WARNINGS		
7		PACEMAKERS AND ACTIVE IMPLANTS Pacemakers and other active implants in patients or in Operators within proximity of medical electrical equipment may present a possible hazard to proper function. If interference with the action of the pacemaker or active implant occurs, or if the pacemaker or active implant has been damaged, DO NOT continue using the Sonata System. In case of doubt, approved qualified advice should be obtained. Failure to monitor for signs of interference or physiological anomalies during the procedure may cause complication and risk patient injury.
8		PATIENT MONITORING EQUIPMENT Radiofrequency electrosurgery equipment, such as the Sonata System, is considered high frequency and may adversely affect the performance of patient monitoring equipment. Place physiological monitoring electrodes as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended. If critical patient monitoring appears compromised, stop the ablation procedure.
9		ELECTROMAGNETIC INTERFERENCE (EMI) Use of the Sonata System may cause electromagnetic or other interference. It may be necessary to take mitigating measures, such as avoiding simultaneous use, reorienting/relocating the RF Generator, rerouting cables to avoid overlap, connecting the equipment on a separate outlet, or reorienting or relocating the interfering device. Refer to the Technical Manual, Appendix B for further specifications on Electromagnetic Compatibility (EMC) and recommended separation distances.

WARNINGS		
10		ELECTROMAGNETIC SUSCEPTIBILITY This equipment has been tested and found to comply with the EMC limits for the Medical Device (EN/IEC 60601-1-2, CISPR 11 Group 1, Class A). 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 stand-by mode. If the unit responds to an EMI event by shutting down, then it will be necessary to manually restart the Sonata System. The equipment generates, uses, and can radiate RF energy, and if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. Per the EN/IEC 60601-2-2 standard, compliance to radiated emissions is only tested in the Ready Mode; however, during ablation, known interference will be generated that degrades nearby AM radio receivers and other equipment sensitive to harmonics of the RF Generator. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Sonata System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. There is no guarantee that interference will not occur in a particular installation. If this equipment does cause interference with other devices, the Operator is encouraged to try to correct the interference by: • Reorienting or relocating the interfering device. Connect the equipment into an outlet on a circuit different from that to which the other device(s) is/are connected. • Consulting the Gynesonics Representative for help.
11		DO NOT MODIFY SYSTEM DO NOT make any modifications to Gynesonics instruments or hardware as any changes may compromise safety and performance. 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.
12		AVOID PATIENT CONTACT TO GROUND To reduce the likelihood of accidental burns, DO NOT allow the patient to contact electrically-grounded metal parts that have an appreciable capacitance to earth (for example, operating table supports).
13		DO NOT BUNDLE CABLES Ensure that Sonata System cables (including the IUUS Probe cable, RFA Handpiece cable, and DE cables) are routed off the sterile field and are not bundled tightly to minimize the potential for high-frequency coupling and potential skin burns.

WARNINGS		
14		DO NOT REMOVE COVERS DO NOT attempt to remove protective covers on any components of the Sonata System. None of the parts within the protective covers of any component are Operator serviceable. As outlined in Technical Manual Chapter 1, Operator serviceable parts may be accessed without removal of the protective covers. The protective covers prevent access to potential electrical and mechanical hazards. Touching any components behind access covers may create a pathway for current leakage, presenting an electrical shock hazard to the Operator or to the patient. If the system function is in question, call a Gynesonics Representative for service.
15		USE PROPER STERILITY CONTROL MEASURES Plan sterility control methods for appropriate Operator/patient/component contact per setup and ablation instructions. Observe instructions in this IFU for proper use of materials that require maintenance of sterile contact. Operation of the soft keyboard or mouse, for example, would require a non-sterile Operator assistant or sterile cover.
16		USE PROPER INFECTION CONTROL MEASURES System Operators must take measures to prevent the transfer of infection between persons in contact with non-sterile equipment such as the soft keyboard, mouse, cables, or System Cart. Improper sterile technique increases the risk of infection to patients and Operators.
17		CHECK CORD AND CABLE CONDITION Periodically check power cords and cables for damage, including damage to metal blades, cut or frayed rubber jackets, or crushed connectors. Replace cords if their blades are bent. DO NOT re-straighten and DO NOT attempt to repair abnormal cables. If damage has occurred to the insulation, replace the cord or cable immediately, as electric shock and/or equipment damage may result. To prevent damage to plugs (on the hospital grade cords, for example), properly connect/disconnect wall plugs by grasping the plug body, not the cord. In applications involving frequent connections and disconnections, inspect wall plugs, the flexible cable, and connectors frequently for potential damage. If safety of a cord is in doubt, cord replacement is strongly recommended to maintain safety against electric shock.
18		USE GROUNDED CONNECTIONS Use only grounded electrical connections. Connecting the Sonata System to a power source that is not equipped with a protective earth contact creates a shock hazard for the Operator or may compromise the reliability of the system and other equipment attached to the same circuit. Interrupting the protective conductor inside or outside the device, or interrupting the protective earth terminal, can create a shock hazard for the Operator. To achieve the enhanced grounding reliability of the hospital-grade plug provided, use an outlet marked “hospital only” or “hospital grade,” if available.

WARNINGS		
19		USE ONLY UNDER SONATA INTRAUTERINE ULTRASOUND GUIDANCE RF ablation with the Sonata System is intended for use with intrauterine ultrasound guidance only. DO NOT attempt to perform ablation using the RF Generator without the intrauterine ultrasound guidance of the Sonata System, which provides the Operator with guidance regarding ablation position and size relative to patient anatomy. Improper positioning and planning of ablations can lead to unintended thermal injury to the patient.
20		DO NOT REUSE DEVICES MARKED SINGLE USE Any devices marked “for single patient use only” should be used only once. For example, the RFA Handpiece and Dispersive Electrodes are for single-patient use only. DO NOT reuse or re-sterilize these components. Lack of sterility and/or mechanical weakening of the components will pose infection and device failure risks if they are re-used. Note that the Dispersive Electrodes are marked for single use only but are NOT sterile.
21		NOT FOR SIMULTANEOUS USE DO NOT use other electrosurgery equipment (such as an electrocautery device) during a Sonata System ablation cycle, as a disturbance in the power output of the RF Generator may result. Note that the simultaneous use of another electrosurgical system or medical electronic system connected to the patient during the ablation may compromise the electrical safety of the system as designed. Combining other medical electrical systems, including by simultaneous use, connection to the patient, connection to the system, or in direct contact with the current path, may lead to poor performance, incomplete ablation, damage to the system, or unpredictable electric current dispersion.
22		LIMIT ULTRASOUND USE Ultrasound procedures should be used for valid reasons and for the shortest period of time. For systems distributed in the United States of America, refer to the Medical Ultrasound Safety Education Program brochure produced by the AIUM.
23		AVOID CONTACT WITH CONDUCTIVE OBJECTS DO NOT apply RF with active introducer or Needle Electrodes in close proximity or electrically conductive contact with any other conductive object such as metallic implants or the conductive leads of other medical electrical equipment. Doing so could cause other leads to misdirect RF energy resulting in unintended ablations causing patient injury or dissipate energy causing partial ablation.
24		PATIENT MOVEMENT High frequency electrosurgical procedures could cause neuromuscular stimulation and may result in unanticipated patient movement. Patient movement during ablation should be minimized to prevent device movement during ablation, which could result in patient injury. If excessive movement is observed, stop RF ablation.
25		NICKEL ALLERGIES The RFA Handpiece electrodes contain nickel and should be used with caution in patients with a known nickel allergy.

WARNINGS		
26		USE THE INNER BOUNDARY OF SEROSAL MARGINS The uterine serosa may appear to have a “thick” border on the ultrasound image. In order to avoid injury to organs adjacent to the serosa, the Thermal Safety Border must never extend beyond the inner portion of the serosa.
27		IMPLANTS Transcervical radiofrequency ablation with the Sonata System should not be performed in patients with known hardware in one or both lower extremities (e.g., hip implants). The safety of abdominopelvic radiofrequency ablation in such situations has not been established.
28		PIERCINGS Transcervical radiofrequency ablation with the Sonata System should not be performed in the presence of metal jewelry that cannot be removed (including abdominal and genital piercings).
29		STACKED EQUIPMENT Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
30		INTRA CORPORAL ULTRASOUND USE ONLY Use ultrasound transducers as described in this IFU. Do not activate the transducer outside the patient’s body as the transducer assembly, when so activated, would not comply with electromagnetic compliance requirements and may cause harmful interference with other equipment in the environment. If interference is detected, do not proceed until interference is resolved by proper use. Transducers, when used for prolonged periods of time, may produce heat. The transducers do not have protective means against thermal burns, so safe operation requires that the transducers are applied only where as directed in this IFU.

1.11 Cautions

The following cautions identify known operations, procedures, or practices which should be addressed promptly or risk undesired outcomes or material damage.

CAUTIONS		
1		ELECTROMAGNETIC COMPATIBILITY The Sonata System has special precautions regarding Electromagnetic Compatibility (EMC) and must be installed and set up as configured by Gynesonics. The Sonata System has been EMC-tested as configured on the System Cart by a Gynesonics Representative. DO NOT attempt to disassemble the Sonata System as it is installed in the System Cart to use in another configuration. Placement of other electromagnetic radiating equipment near the system hardware may affect the conformity of the system to tested standards. No additional equipment, besides those listed as part of the system, are certified for stacking on or placement adjacent to the components.
2		OPEN CONNECTORS DO NOT immerse electrical connectors on any device cables, especially during cleaning. Damage may result to the instruments. Refer to the Reprocessing Instructions for IUUS Probe for immersion limitations.
3		COMPONENT OPENINGS DO NOT obstruct any openings on Sonata System components, such as cooling vents for the SMART Tablet and for the RF Generator. Doing so may result in compromised product life or cause overheating of equipment.
4		CONNECT ONLY SPECIFIED COMPONENTS Only connect items that have been specified as part of the Sonata System, or that have been specified in this IFU, as being compatible. Unspecified configurations may not comply with the requirements of IEC 60601-1 including local deviations. Anyone connecting unspecified equipment is responsible to confirm compliance of the new configuration.
5		POWER CORDS AND EXTENSION CORDS Use only approved line cords provided by Gynesonics. DO NOT use additional multiple portable socket-outlet strips or extension cords.
6		FOOTSWITCH CARE Protect the Pneumatic Footswitch. Use care to keep the connection from the RF Generator to the Footswitch clear of obstructions. Footswitch damage could lead to a delayed RF energy termination in the case where the Operator needs to terminate ablation.

CAUTIONS		
7	⚠	SYSTEM INPUTS AND OUTPUTS The Sonata System has input/output (I/O) ports that are only intended for particular functions with regards to external I/O. Procedure images or videos may be accessed by connecting a standard USB drive to the SMART Tablet when the system is not being used for targeting or treatment. A video output cable may be attached to the Tablet monitor port for a supplemental signal to an external monitor. Beyond these two (2) ports, no other ports should be used externally for other functions. Attempting to attach any other form of external I/O may result in a system malfunction or damage.
8	⚠	MOVABLE COMPONENTS The Sonata System controls, connectors, shelves, mechanisms, etc., include movable components. Actuation may present glove snag, finger pinches, puncture risk to gloves, or other physical risk to Operator. When operating controls, be aware to avoid excess glove material. Should a snag occur, inspect the glove for any punctures and replace the device and gloves as needed, taking preventative measures against Operator biohazard soil.
9	⚠	EXTERNAL MONITOR STANDARDS An IEC 60601-1 compliant video monitor is the only device that should be connected to the video adapter. Connecting non-conforming devices could adversely affect compliance with electrical safety standards, result in increased emissions or decreased immunity, and/or affect product performance.
10	⚠	DO NOT USE AS A TABLET COMPUTER The SMART Tablet resembles a tablet computer but DO NOT attempt to use it as one. Actions to use it as a tablet computer may damage the system and expose it to risks such as attacks by viruses. These actions include; installing or updating software, connecting the system to a network or printer, or attempting to access the native operating system.
11	⚠	BATTERY DO NOT attempt to remove or use the battery inside the SMART Tablet.
12	⚠	FLUID INGRESS The SMART Tablet is not protected from fluid spills. The RF Generator is not protected against excess fluid ingress. Always disconnect cables before cleaning. DO NOT spray cleaners directly into vents, sockets, or other openings. Fluid ingress may cause device malfunction.
13	⚠	OTHER IMAGING MODALITIES DO NOT use the Sonata System simultaneously with MRI, CT, fluoroscopy, or other radiating imaging modalities. DO NOT use the system simultaneously with an external ultrasound system as the intrauterine imaging may become compromised. None of the Sonata System equipment, including devices and durable equipment, are safe for use within or near an MRI system. Use in proximity with an MRI system may cause equipment damage or Operator/patient injury.

CAUTIONS		
14	⚠	DEFIBRILLATORS DO NOT use the Sonata System simultaneously with a defibrillator. The system and components are not designed to be isolated from high voltage and could cause damage to the system or injury to Operators.
15	⚠	PREVENTING CABLE DAMAGE DO NOT lift the SMART Tablet or pull the System Cart using any of the cables. Doing so could damage the system or cause a heavy part to fall on Operator or patient.
16	⚠	GROUND WIRES DO NOT remove or try to circumvent any grounding wires.
17	⚠	OTHER HIGH FREQUENCY SURGICAL EQUIPMENT The Sonata System is not approved for use with other high frequency surgical equipment. DO NOT use the Sonata System during another high frequency electrosurgical procedure or risk failure of electrical isolation resulting in injury or death.
18	⚠	CLEANING PROCEDURES Always follow proper cleaning procedures. Failure to adhere to cleaning, disinfection, and sterilization procedures outlined in this IFU could result in transmission of disease and cause infection, endangering Operators and patients.
19	⚠	SALE AND USE Federal law restricts this device to sale by or on the order of a physician.

Chapter 2 Sonata System Overview

2.1 Sonata System Components

The Sonata System consists of durable equipment, software, and various single-use and reusable components.

The Sonata System components, see Figure 2-1, include:

- Sonata System durable equipment – Sonata2-110 or Sonata2-220;
  - SMART Tablet – USCON-2200;
  - Radiofrequency (RF) Generator – RFG2-110 or RFG2-220;
  - System Cart – ACCY-002;
- Sonata System Software SW-002, including Graphical Guidance Software (GGS)
- Intrauterine Ultrasound (IUUS) Probe – IUSP-002;
- RFA Handpiece Cable (Reusable) – ACCY-008
- Radiofrequency Ablation (RFA) Handpiece (Single Use) – RFA-002
- Dispersive Electrodes - quantity two (2) (Single Use) – DE-001

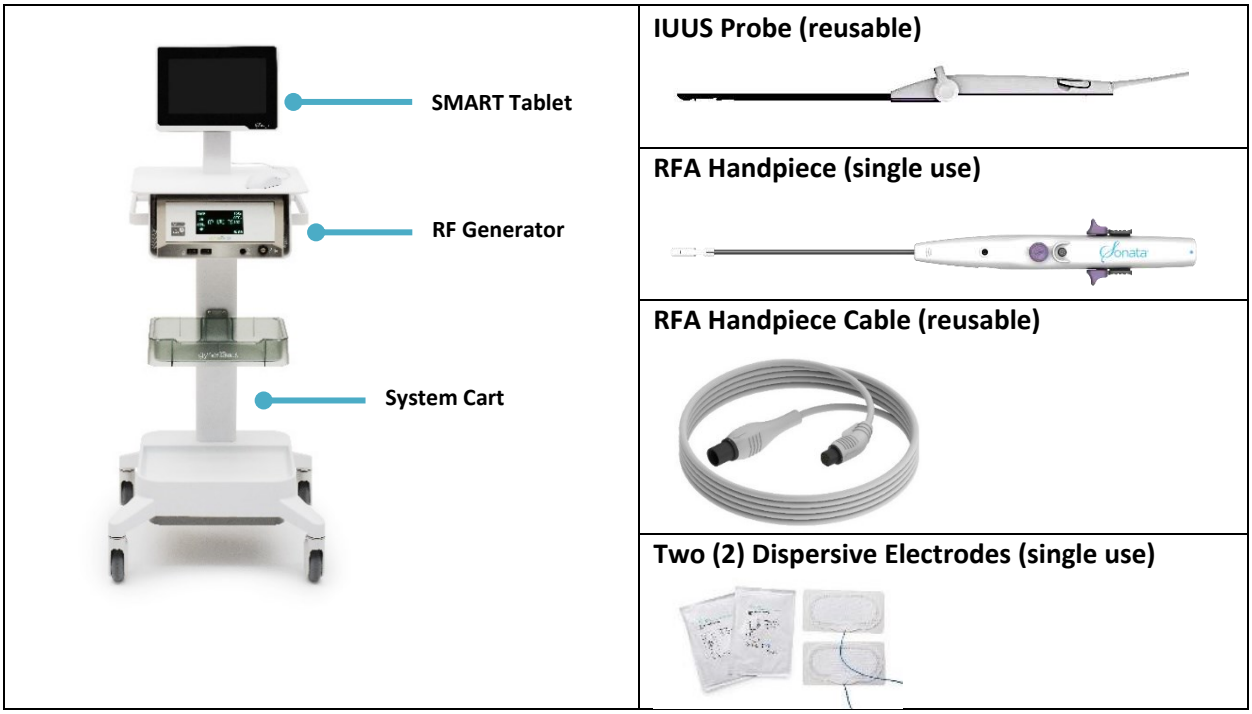


Figure 2-1. Sonata System Components.

The following cables and accessories are provided with the Sonata System:

- AIUM Handbook: "Medical Ultrasound Safety;"[1]
- Intrauterine Ultrasound Probe Instructions for Use – REF-003;
- Sonata Intrauterine Ultrasound Probe IUSP-002 Reprocessing Guide – REF-004;
- Radiofrequency Handpiece Cable Instructions for Use – REF-008;
- Sonata Radiofrequency Handpiece Cable ACCY-008 Reprocessing Guide – REF-012
- Pneumatic Footswitch – ACCY-011;
- Optical Mouse – ACCY-012;
- USB 2.0 Cable, 0.9 m;
- Cable, 8-pin, MINI-DIN, Male to Male, 0.5 m;
- Potential Equalization (PE) Lead, 1 m; and
- Micro HDMI to HDMI adaptor.

Other available accessories include:

- IUUS Probe Sterile Shipper Kit – SHPR-001;
- IUUS Probe Return Kit – RTN-001;
- RFA Handpiece Return Kit – RTN-002;
- Potential Equalization Kit – PE-002;
- Power Cord, Hospital Grade (Continental Europe) – CORD-002;
- Power Cord, Hospital Grade (Australia) – CORD-003;
- Power Cord, Hospital Grade (UK/Ireland) – CORD-004;
- Power Cord, Hospital Grade (Denmark) – CORD-005;
- Power Cord, Hospital Grade (Switzerland) – CORD-006;
- Sonata IUUS Probe Reprocessing Tray – OM-1000-GS; and
- Sonata IUUS Probe Leak Tester – ACCY-016.

Other ultrasound transducers compatible with the Sonata System:

- Terason® Model 8EC4A
  The Terason 8EC4A transducer may be used with the Sonata System for routine transvaginal diagnostic imaging as an adjunctive imaging modality if desired in order to obtain a higher level view of the uterus in coronal and sagittal planes, for example to confirm the number and location of fibroids. The Terason 8EC4A transducer may not be used for treatment guidance; the Sonata Intrauterine Ultrasound Probe must be connected to the Sonata SMART Tablet in order for the GGS software to proceed to the targeting and treatment workflow.

[1] American Institute of Ultrasound Medicine ISBN 1-932962-30-1

Use of the Terason 8EC4A transducer with the SMART Tablet for diagnostic imaging is identical to use of the Sonata IUUS Probe. Instructions provided in the sections listed below are equally applicable when using either the IUUS Probe or the Terason model 8EC4-A transducer:

- Connection to SMART Tablet §2.2.2
- Measurements §6.3
- Annotation §6.4
- Ultrasound Controls §6.5.1
- Ultrasound Parameters §6.5.2
- Show Scale §6.7
- Image Management §6.8

2.2 SMART Tablet

The SMART Tablet is an ultrasound system used for displaying ultrasound imaging, see Figure 2-2. The main features of the SMART Tablet include:

- 11.6" Backlit High-Resolution LCD Touchscreen,
- Communication with RF Generator and the RFA Handpiece,
- SMART Guide controlled through the RFA Handpiece and
- USB port available for copying procedure data.

Figure 2-2. SMART Tablet.

CAUTION	
⚠	SMART TABLET CANNOT BE USED AS COMPUTER The SMART Tablet resembles a tablet computer, but DO NOT attempt to use it as one. Actions to use it as a tablet computer may damage the system and expose it to risks such as attacks by viruses. These actions include installing or updating software, connecting the system to a network, or attempting to access the native operating system.

2.2.1 Power ON/OFF SMART Tablet

To Power ON the SMART Tablet:

Press the power button on the left-hand side of the top of the SMART Tablet, see Figure 2-3.

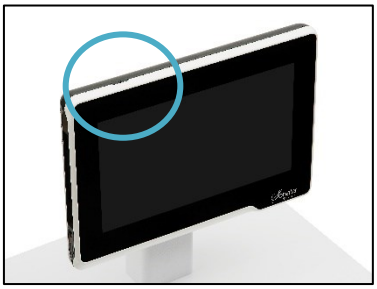


Figure 2-3. Power ON with button.

To Power OFF the SMART Tablet:

On the ultrasound display screen, select the power icon in the upper right-hand corner, see Figure 2-4.

DO NOT power off the SMART Tablet by pressing power button on the Tablet.

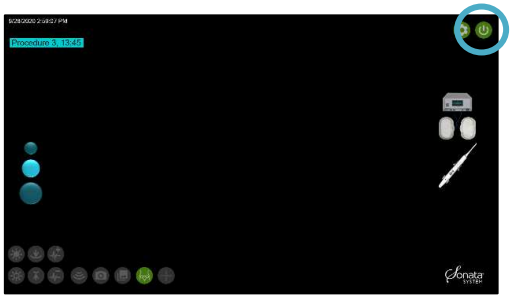


Figure 2-4. Power OFF with software.

CAUTION	
⚠	DO NOT HOLD POWER BUTTON ON SMART TABLET TO SHUTDOWN Pressing and holding the power button on the top left-hand side of the SMART Tablet to power off will force a "hardware" shutdown which may disrupt normal processes such as video capture. Use hardware shutdown only if SMART Tablet is unresponsive.

2.2.2 SMART Tablet Connections

The SMART Tablet has multiple ports to connect to the RF Generator, Mouse, Power, and IUUS Probe, see Figure 2-5.

- Two (2) cables, connected on the either side of the SMART Tablet and the back of the RF Generator, provide the necessary communications.
  - For proper operation, the RF Generator cable must be connected to the top USB port on the left side of the SMART Tablet.
- The Mouse is connected to the lower USB port on the left side of the SMART Tablet.
- The Power Cord is connected to the round receptacle on the lower left corner of the SMART Tablet.
- The IUUS Probe is connected to the receptacle on the right side of the SMART Tablet.

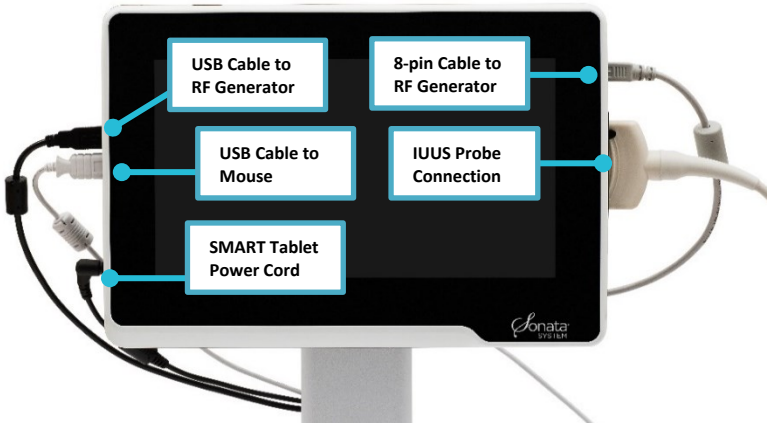


Figure 2-5. Connection ports on the SMART Tablet.

2.2.3 Mouse and Touchscreen Control

Mouse Control

- The mouse operates as a standard two-button mouse.
- Left-click functions as an enter button.
- Right-click will display a drop-down menu for additional commands.
- The mouse is NOT STERILE. It must be cleaned after each procedure. See Section 5.7.

Touchscreen Control

- Tap icon with one figure to use the control. For example, tap the Freeze icon with one finger to freeze the image.

CAUTION	
⚠	MAINTAIN STERILE PRACTICE The mouse and touchscreen are NOT STERILE. Use these controls prior to putting on sterile gloves, have support staff operate NON-Sterile components, or use the SMART Control on the RFA Handpiece when the IUUS Probe is at 0°.

2.2.4 Setting System Date, Time, and Language

Select the Preferences icon. 

Set System Date and Time and Language Region preferences, see Figure 2-6.

Figure 2-6. Set System Date and Time and Language Region.

2.3 Graphical Guidance Software (GGS)

The user interface software installed on the SMART Tablet can be operated either by mouse or use of the Tablet's touchscreen, see Figure 2-7. Refer to Section 2.3.1 to learn about the SMART Guide controls and a more detailed description of each on-screen element.

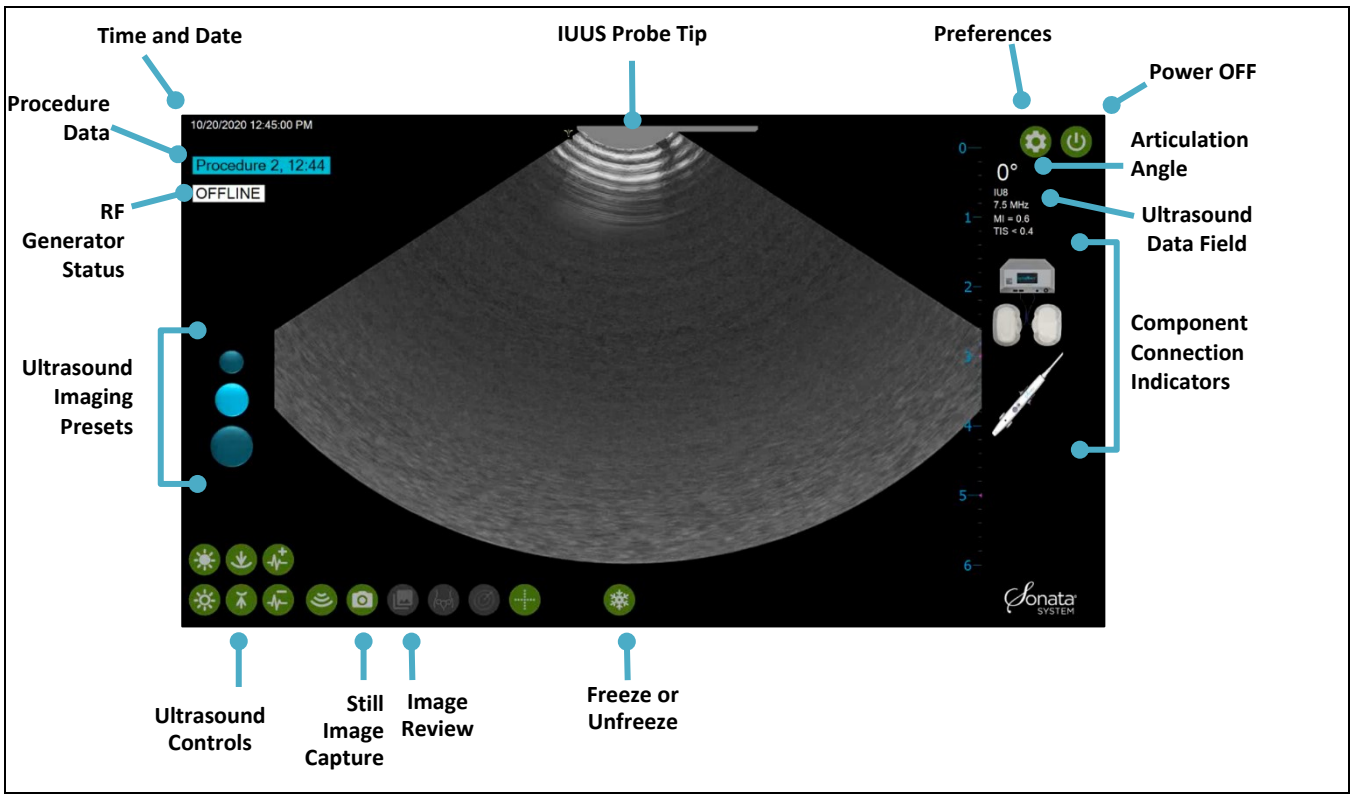


Figure 2-7. User interface of the Graphical Guidance Software (GGS).

2.3.1 SMART Guide "Setting Margins of Ablation in Real Time"

The SMART Guide is the graphical overlay on the ultrasound image to facilitate the targeting of fibroids and the placement of the Introducer and Needle Electrodes for ablation.

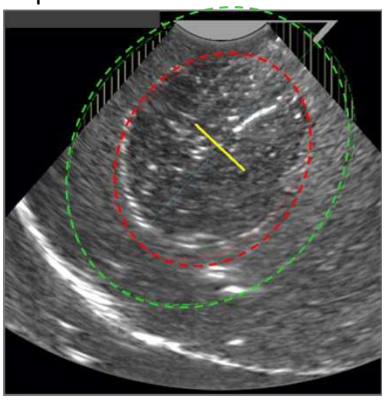
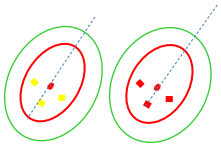


Figure 2-8. Illustration of the Treatment Device with the Ablation Zone and Thermal Safety Border displayed.

The SMART Guide is comprised of the following graphical elements.

SMART Graphic	SMART Graphic Name	SMART Graphic Description
	IUUS Probe Tip	Illustration at the top of the screen represents Articulating Tip angle (0°, 45° or 60°)
	Ablation Zone	Ablation Zone is indicated by the red inner ellipse
	Thermal Safety Border	Thermal Safety Border is indicated by the green outer ellipse
	Introducer Tracker	Yellow arrowhead representing the Introducer Tip as it is advanced into tissue.
	Introducer Plan Line	Represents the intended depth for the Introducer Tip advancement based upon the SMART Guide settings. The yellow line turns red when the Introducer Tip reaches the Introducer Plan Line depth
	Introducer Tip Alignment Guide	Graphic to be aligned to the Introducer Tip visualized on the ultrasound image
	Introducer Tip Marker	Graphic displayed after confirming the alignment of the Introducer Alignment Guide to the Introducer Tip
	Needle Electrode Tip Trackers	Yellow arrowheads representing the Needle Electrode Tips as they are advanced into tissue.
	Needle Electrode Plan Lines	Three (3) lines that represent where the Needle Electrode Tips will be positioned when deployed to planned location. The yellow lines turn red when the Needle Electrodes have reached planned location.
	Peripheral Zone	Pin stripes displayed when area peripheral to the live ultrasound image is overlapped by the Thermal Safety Border

The depth of the Introducer Plan Line (yellow/red line) is controlled by the moving the SMART Control forward or backward.

- The size of the Ablation Zone (red inner ellipse) and location of the Needle Electrode Plan Lines is controlled by the moving the SMART Control side to side.
- The size of the Thermal Safety Border (green outer ellipse) adjusts automatically in relationship to the Ablation Zone.

2.4 Radiofrequency (RF) Generator

The RF Generator, see Figure 2-9, provides RF energy through the RFA Handpiece, completes the circuit through the Dispersive Electrodes, dynamically regulates the RF ablation temperature, and communicates with the SMART Tablet.

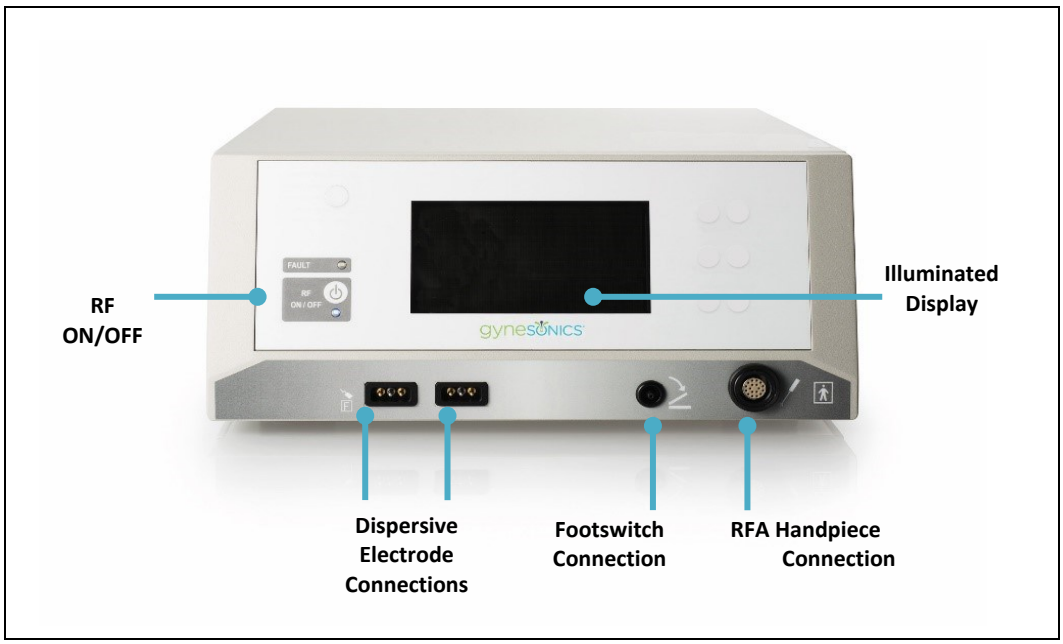


Figure 2-9. Controls and connections on front panel of RF Generator.

RF ablation parameters, including power, time, and target temperature, are set based upon the Operator-selected ablation size.

When initiated, the RF Generator will automatically start and stop the ablation cycle. If unusual ablation conditions are detected, the system software will warn the Operator and, if appropriate, automatically stop the RF ablation cycle.

2.4.1 Front Panel and Illuminated Display

The RF Generator illuminated display will show general RF ablation cycle information. This information does not need to be monitored. All information relevant to the procedure is displayed on the SMART Tablet.

2.4.2 Power Ramp and Modulation

RF ablation is initiated with a period of automated power “ramp-up” limited to the maximum of 150 watts. During this time, the temperature of the Needle Electrodes, measured at their tips, rises from body temperature to the target temperature of 221°F (105°C).

The ramp-up time is variable and is dependent on tissue composition and the size of the planned Ablation Zone. The ramp-up time takes between 1 to 4 minutes. If the ramp-up parameters are abnormal, the system will initiate a warning to the Operator and prompt Operator action.

2.4.3 Temperature Control of RF Ablation

The Sonata System automatically regulates power to maintain a target temperature of 221°F (105°C). This temperature is held for a predetermined time, based on the Operator-selected ablation size.

2.4.4 Operator-Adjustable Controls and Connections for the RF Generator

Operator-adjustable controls and connections for the RF Generator include (see Figure 2-10):

- Pneumatic Footswitch – activates/stops the RF ablation with a single step.
- RF Generator Power Cord – housed in the system cart, plugs in receptacle next to ON/OFF power switch, see Figure 2-10.
- RF ON/OFF Button – alternative control to Footswitch; activates/stops the RF ablation with a single push.
- Power Switch – toggle switch on the back of the unit that should be switched on when in use and switched off before unplugging.
- RF Generator Volume Control Knob (on back panel) – controls the audible tone that begins when the RF ablation cycle begins.
- Potential Equalization (PE) Conductor Terminal – provides connection between the RF Generator and the Cart.

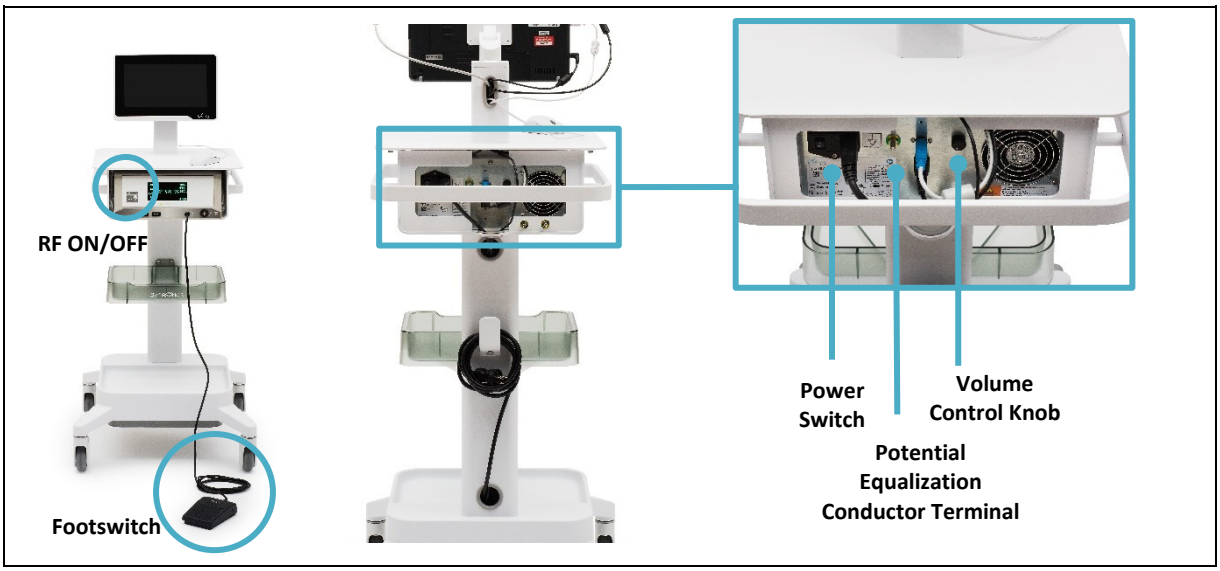


Figure 2-10. Connections and Controls on the RF Generator.

2.5 System Cart

The System Cart houses the durable components of the system, power components, and cords. Features include:

- Adjustable viewing angle of the SMART Tablet,
- Storage tray; and
- Lockable wheels, see Figure 2-11.

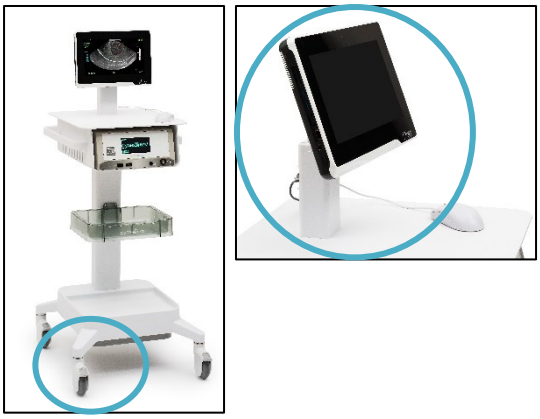


Figure 2-11. System Cart an adjustable mount for the SMART Tablet, and lockable wheels.

2.6 Dispersive Electrodes

The Dispersive Electrodes are single-use, non-sterile, flexible pads that provide the return path for RF energy that is passed from the RF Generator through the Sonata Treatment Device, see Figure 2-12.

Each Sonata Treatment needs:

- Two (2), non-sterile pouches of Dispersive Electrodes,
- One (1) Dispersive Electrode for each anterior thigh.

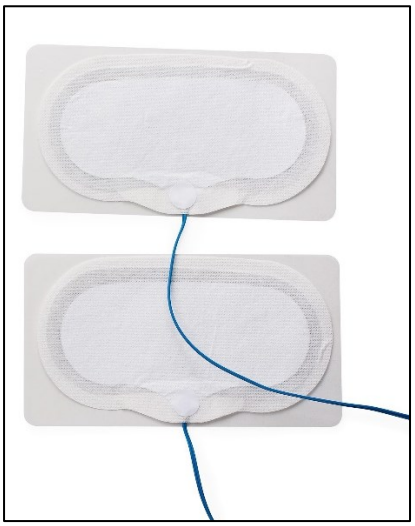


Figure 2-12. Dispersive Electrodes (DE).

2.7 Intrauterine Ultrasound (IUUS) Probe

The IUUS Probe, see Figure 2-13, is reusable and must be reprocessed (cleaned and sterilized) prior to use and between treatments. For IUUS Probe reprocessing (cleaning, disinfecting, and sterilization) instructions and options, see the IUUS Probe Instructions for Use.

The IUUS Probe includes the following parts (see Figure 2-13):

- Articulation Tip – Articulates to 45° and 60° with a 114° field of view,
- Articulation Lever – Press down to unlock and move forward to adjust angle,
- Release Latches,
- Handle,
- Shaft – 8.3 mm diameter, and
- A 3-meter Connector Cable.

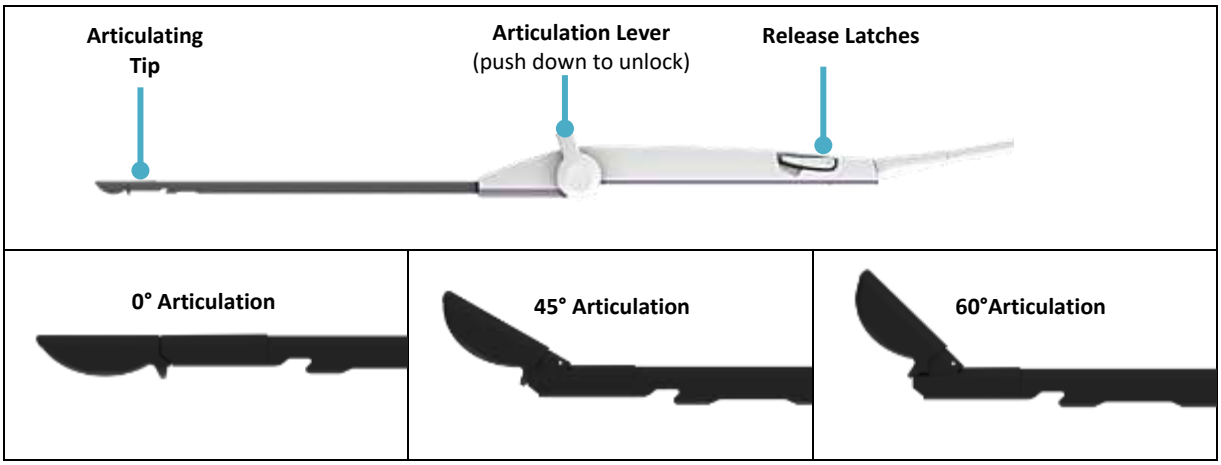


Figure 2-13. IUUS Probe (reusable) parts and examples of Articulating Tip angle at 0°, 45° and 60°.

CAUTIONS	
⚠	PROTECT IMAGING SURFACE The Imaging Surface of the IUUS Probe is fragile. Damage to the Imaging Surface can result in poor imaging or safety hazard.
⚠	CLEAN AND STERILIZE AFTER USE, DO NOT AUTOCLAVE The IUUS Probe should be cleaned and sterilized following each procedure. Steam sterilization (autoclave) of the IUUS Probe will result in device damage.
⚠	FOR INTRAUTERINE USE ONLY The IUUS Probe has an Articulating Tip with ultrasonic Imaging Surface. DO NOT attempt to use the IUUS Probe Tip in any application other than intrauterine. DO NOT apply force on the Tip while trying to articulate or the Tip may become permanently misaligned.

2.7.1 IUUS Probe Storage

Following cleaning and sterilization, store per treatment facility protocols for sterile products. See the Instructions for Use, IUUS Probe (REF-003) for reprocessing information and instructions.

2.8 Radiofrequency Ablation (RFA) Handpiece

The RFA Handpiece, see Figure 2-14, is single-use and provided sterile. It is not intended for use without the IUUS Probe. The RFA Handpiece includes the following parts:

- SMART Control (see Section 2.8.1 and Figure 2-16),
- Confirm Button (see section 2.8.2 and Figure 2-17),
- Introducer Sliders (see Section 2.8.2 and Figure 2-19,
- Needle Electrode Sliders (see Section 2.8.4 and Figure 2-21),
- Fluid Infusion Port (see Section 2.8.5 and Figure 2-22), and
- Attachable RFA Handpiece Cable (see Section 2.8.6).

The main features of the RFA Handpiece include:

- Controls for operating the SMART Guide,
- Housing for the Introducer and Needle Electrodes,
- Docking features to connect to the IUUS Probe, and
- A magnetic socket to connect the RFA Handpiece Cable to the RFA Handpiece.

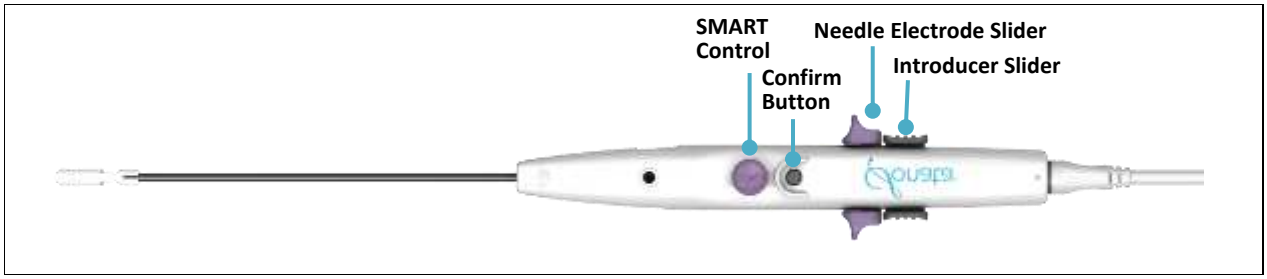


Figure 2-14. RFA Handpiece.

Figure 2-15. Introducer and Needle Electrodes.

WARNING	
⚠	NEEDLE ELECTRODES ARE SHARP The Introducer and Needle Electrodes are sharp. Handle device with care.

2.8.1 SMART Control

The SMART Control, see Figure 2-16, allows the Operator to adjust the ablation depth and size using the SMART Guide when targeting a fibroid. The Operator moves the SMART Control forward and back to adjust the depth of the SMART Guide. Moving the SMART Control to one side or the other adjusts the size of the SMART Guide, for detailed instructions see 4.4.3. The planned ablation depth and size are displayed on the screen as the Operator adjusts the SMART Control. The SMART Control also functions as a Mouse when the IUUS Probe angle is 0°. The on-screen cursor can be positioned by moving the SMART Control.

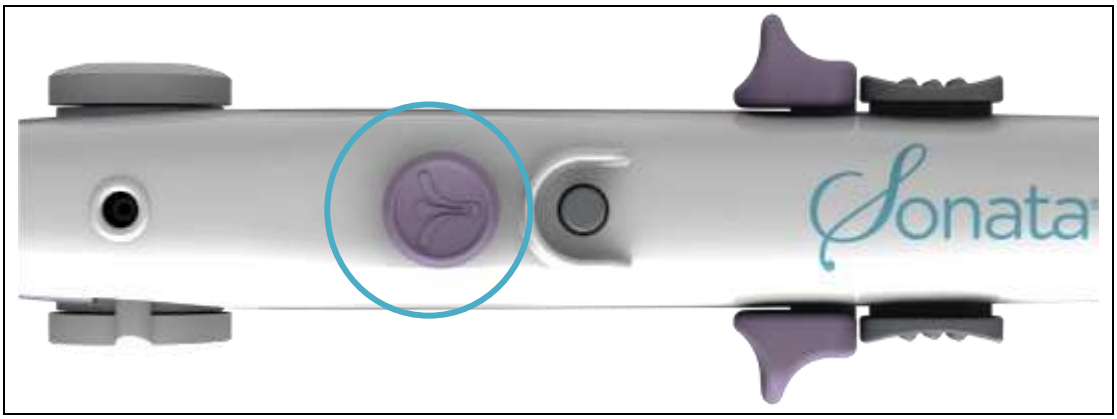


Figure 2-16. SMART Control.

2.8.2 Confirm Button

The Confirm Button has several functions depending on the state of the Treatment device.

SEQUENCE OF TREATMENT	FUNCTION OF CONFIRM BUTTON DURING THAT SEQUENCE
Articulation of tip is 0°, everything retracted	Single click on the Confirm Button along with the SMART Control works as a mouse click to select options on screen. Double click on Confirm Button will take an image that saves to procedure file.
After Deployment of Introducer	Single Click after alignment of SMART Guide with the SMART Control sets the location on screen. Double click on Confirm Button will take an image that saves to procedure file.
After Safety Rotations	Confirms the completion of the safety rotation check and indicates to system readiness to move to next step. Double click on Confirm Button will take an image that saves to procedure file.

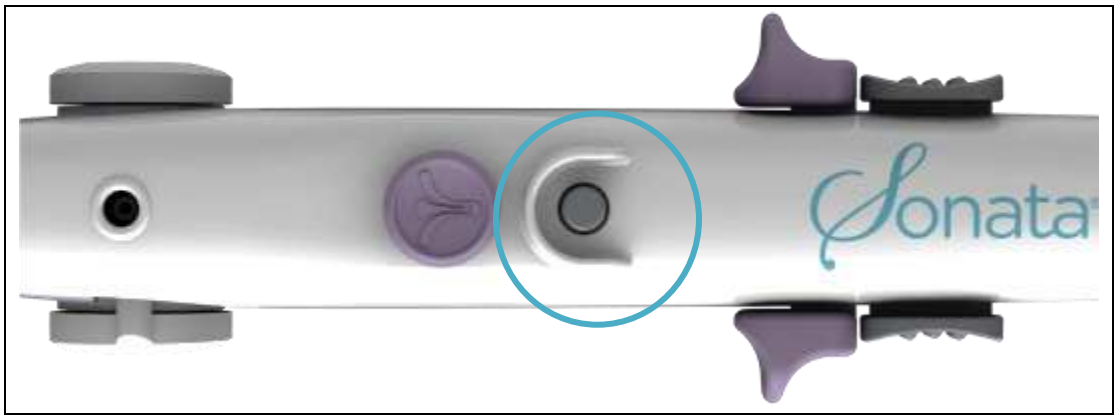


Figure 2-17. Confirm Button.

2.8.3 Introducer Sliders

The Introducer Sliders advance the Introducer into the fibroid tissue prior to deploying the Needle Electrodes, see Figure 2-18 and Figure 2-19. Both Introducer Sliders must be depressed and pushed at the same time to advance the Introducer.

Figure 2-18. Introducer deployment.

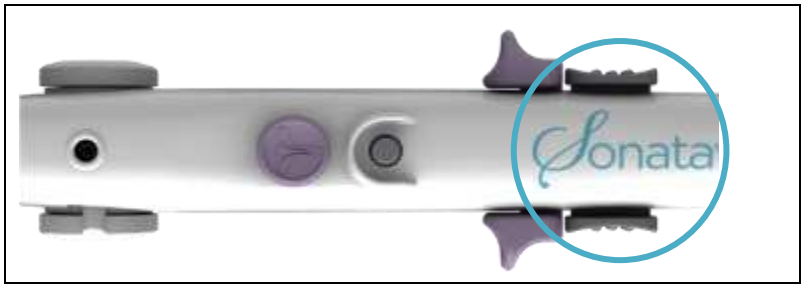


Figure 2-19. Introducer Slider.

2.8.4 Needle Electrode Sliders

The Needle Electrode Sliders control the deployment of the Needle Electrodes radially from the Introducer Tip into a conical-shaped array consisting of seven (7) nitinol electrodes, see Figure 2-20 and Figure 2-21. Both Needle Electrode Sliders must be advanced at the same time to deploy the Needle Electrodes.

Figure 2-20. Needle Electrode deployment.

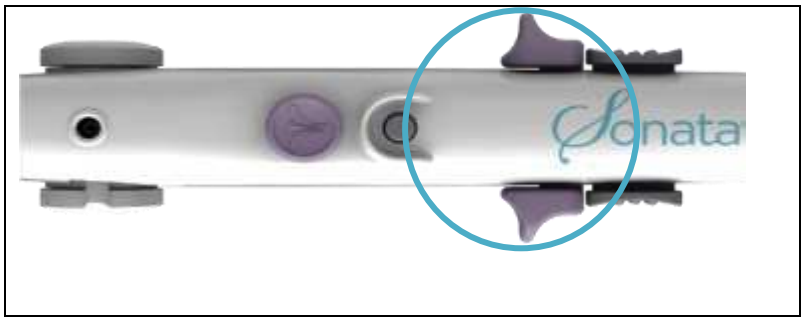


Figure 2-21. Needle Electrode Sliders.

2.8.5 Fluid Infusion Port

The RFA Handpiece has a port for infusing hypotonic fluid into the endometrial cavity, see Figure 2-22.

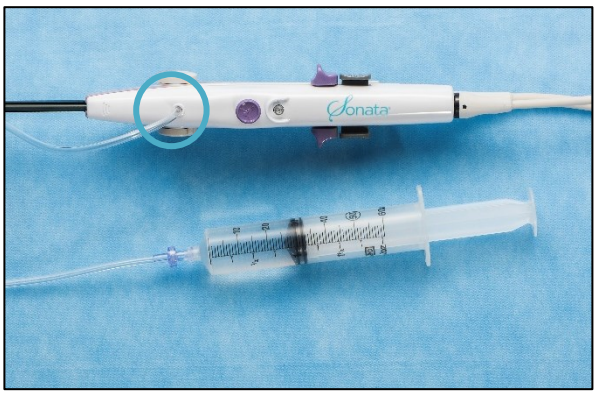


Figure 2-22. Fluid infusion port on the RFA Handpiece.

2.8.6 RFA Handpiece Cable

The RFA Handpiece Cable is a 3 m detachable cable that connects the RFA Handpiece to the RF Generator. The RFA Handpiece Cable is reusable and must be reprocessed (cleaned and sterilized) prior to use and between treatments. For RFA Handpiece Cable reprocessing instructions and options, see the RFA Handpiece Cable Instructions for Use (REF-008).

Figure 2-23.ACCY-008 RFA Handpiece Cable, Reusable

2.9 Pneumatic Footswitch

The Pneumatic Footswitch activates/stops the delivery of RF energy. The Footswitch may be safely operated in the presence of liquid.

2.10 System Power Cord

The power cord provided is a medical grade line cord that delivers AC power to the entire Sonata System. This cord is region specific and is 2.5 m to 3 m long.

DO NOT connect any additional power strip or extension cord to the system.

2.11 Safety Information

Read all General Warnings, see Section 1.10, and Cautions, see Section 1.11, and note that additional Warnings and Cautions are placed on product labels and located in pertinent sections of this IFU. Refer to the Symbols Glossary, in the front of this IFU, for an explanation of symbols.

2.11.1 Compliance to Safety and Performance Standards

This system has been tested to the following standards:

- EN/IEC 60601-1, Medical Electrical Equipment: General Requirements for Safety and Essential Performance.
- EN/IEC 60601-1-2, Medical Electrical Equipment: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – requirements and tests.
- EN/IEC 60601-1-6, Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN/IEC 60601-1-8, Medical electrical equipment Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
- EN/IEC 60601-2-2, Medical Electrical Equipment: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.
- EN/IEC 60601-2-37, Medical Electrical Equipment: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

2.11.2 Ablation Monitoring

Predictable and repeatable ablation sizes are achieved as a result of active temperature monitoring and automatic power regulation by the Sonata System.

Based on the Operator-selected ablation size, the Sonata System will deliver RF energy monitored with built-in safety measures to automatically stop RF delivery in the event of abnormal parameters in time, impedance, and temperature.

The Thermal Safety Border (green outer ellipse) provides a graphical indication of the distance from the Needle Electrodes at which tissue is safe from the potential of thermal damage. Maintaining this region within the uterine serosal margin assures that thermal effects will not extend to the serosa or adjacent structures in the peritoneal cavity.

The Peripheral Zone Marker, graphically represented by pin stripes, shows regions of the Thermal Safety Border (green outer ellipse) that extend beyond the ultrasound view. The Operator must ensure these regions of the Thermal Safety Border (green outer ellipse) are positioned safely within the serosa.

2.11.3 Electrical Isolation

The IUUS Probe and the RFA Handpiece are electrically floating relative to each other so that there is no return path between the IUUS Probe and the RFA Handpiece. This configuration ensures that the patient is protected against electrical currents.

2.11.4 Ultrasound-Related Safety

The SMART Tablet complies with the international standard IEC 60601-2-37 for real-time display of Thermal and Mechanical Acoustic Output Indices. When operating in any mode with the Freeze function disabled, the window displays the acoustic output indices relevant to the currently active probe. The acoustic power indices are constant at each imaging frequency/depth setting; there are no Operator-accessible adjustments. The Mechanical Index (MI) and Thermal Index Soft Tissue (TIS) are displayed to allow you to monitor the amount of ultrasound energy that is transferred to the patient.

With respect to use of the Sonata System, practice of the ALARA principle (exposure of the patient to ultrasound energy at a level that is as low as reasonably achievable) includes performing ultrasound procedures only for valid reasons, and for the shortest period of time practicable.

Note: For systems distributed in the United States of America, refer to the Medical Ultrasound Safety ultrasound education program brochure produced by the AIUM.

2.11.5 Latex Allergies

None of the patient or user contacting components of the Sonata System are manufactured with natural rubber latex.

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Chapter 3 Preparation for Treatment

This chapter outlines how to prepare the Sonata System and patient for treatment.

3.1 Position the System Cart and Lock Wheels

The System Cart is designed and tested to operate safely in a hospital setting.

To move, unlock all wheels:

- Unlock all wheels before transport, see Figure 3-1.

During use, lock two (2) or more wheels:

- Lock two (2) or more wheels for use during a procedure. Push the gray lock down to lock the wheel, see Figure 3-2.

The weight of the System Cart with its safe working load is 45 Kg (99 lbs.).

DO NOT add additional equipment to the System Cart.

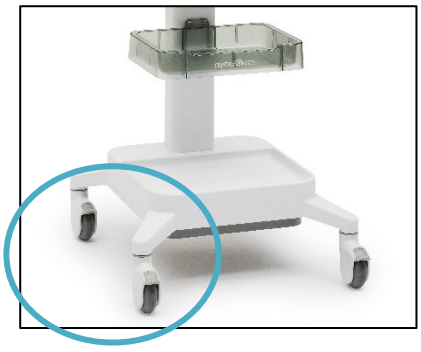

Figure 3-1. Unlocked wheels.

Figure 3-2. Lock wheels before a procedure.

CAUTIONS	
⚠	UNLOCK WHEELS BEFORE TRANSPORT The System Cart has locking wheels that must be unlocked before attempting to move the System Cart. Attempting to move the System Cart while the wheels are locked will reduce the stability of the System Cart and may cause it to fall over.
⚠	BEWARE OF ROLLING OVER OBSTACLES When moving the System Cart, the Operator must exercise caution when rolling over objects on the ground, including door thresholds, cables and wires, or other physical obstructions that may cause excessive shock to the system components or tip-over risk.

CAUTIONS	
⚠	DO NOT MODIFY CART DO NOT modify the System Cart. Components are intended for use as initially installed. Components should not be removed from the System Cart and operated in a different configuration, such as stacking on other medical equipment. The System Cart should not be used to mount any additional equipment or attachments. Doing so will jeopardize the stability of the System Cart. The weight of the System Cart with its safe working load is 45 Kg (99 lbs.). DO NOT add additional equipment to the System Cart.

3.2 Set Up the Sonata System

CAUTIONS	
⚠	CORD HANDLING SAFETY Stretching cords and cables above the ground can present procedural hazards. Hanging cords or cables under tension can cause sterile objects to be dropped, power to become disconnected mid-procedure, or create a risk of tripping. Plan each procedure around management of these connections and position equipment to minimize the required distances.
⚠	EXTERNAL MONITOR ELECTROMAGNETIC COMPATIBILITY Compliance with Electromagnetic Compatibility Standards has not been established when an external monitor is connected to the system.
⚠	AMBIENT OPERATING TEMPERATURE Operate the RF Generator in ambient temperatures between 50°F to 95°F (10°C to 35°C). If the RF Generator's internal components are outside of this range, a fault may occur upon system activation. For example, if the System Cart has been stored in a cold storage room, allow time for the system to reach normal ambient temperature before use.

3.2.1 Position and Power ON the Sonata System

Position the System Cart near the patient's legs on the Operator's preferred side (left or right). The System Cart must be close to the patient, so the DE cables reach from the patient's legs to the RF Generator.

- Verify the Power Cable is connected to the SMART Tablet, see Figure 3-3.

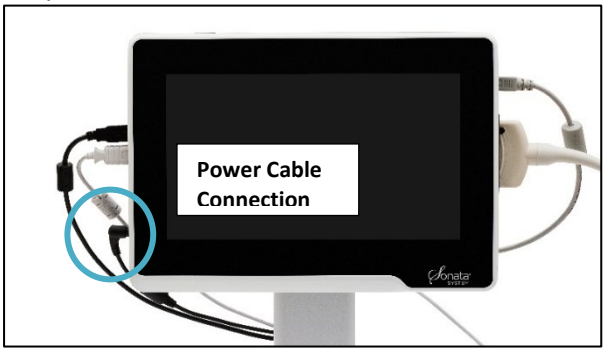

Figure 3-3. Power Cable connection to the SMART Tablet.

Connect the System Cart power cord into an isolated electrical outlet.

Connect any external monitors if they are going to be used. The output format is Micro HDMI and an adapter to HDMI is provided.

Turn on the RF Generator using the power switch on the back, see Figure 3-4.

- The RF Generator will make an audible tone and illuminate the front panel.
- Adjust the volume if needed using the Volume Control Knob, see Figure 3-4.

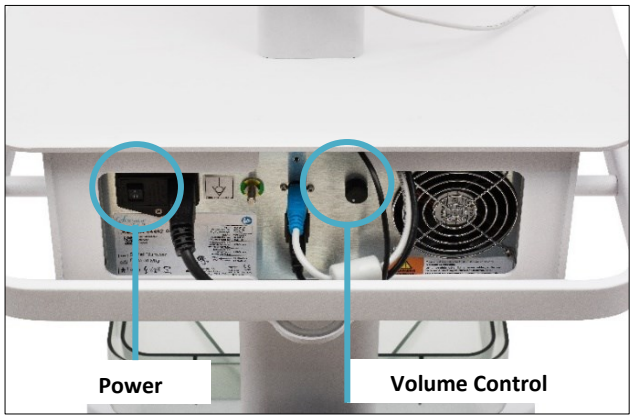

Figure 3-4. Back panel of RF Generator showing the Power Switch and Volume Control Knob.

Firmly connect the pneumatic tube of the Footswitch to the RF Generator, see Figure 3-5.

Figure 3-5. Attach the Footswitch to the front of the RF Generator.

Press the power button on the upper-left side of the SMART Tablet to power on the SMART Tablet, see Figure 3-6.

Wait for the Login screen to appear.

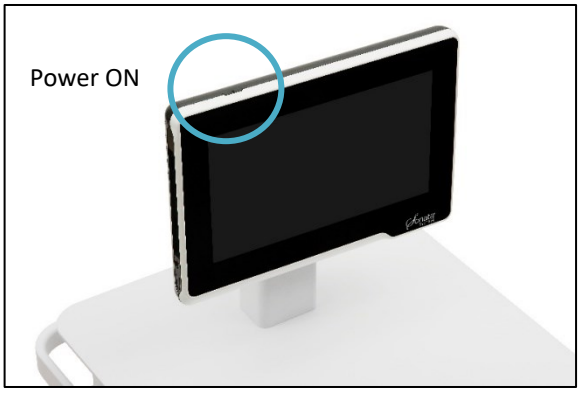

Figure 3-6. Power ON by pressing the power button on upper-left corner of SMART Tablet.

3.2.2 Login and User Profiles

At time of installation, the Gynesonics Representative will establish an Administrator User Name and Password. Record this information securely; it will be used when logging into the system for the first time.

There are two (2) categories of user profiles:

- **Administrator:**
  - Can create other users or administrators for the system.
  - Can copy or delete all image files.
- **User:**
  - Must log in under his/her user name established by an administrator.
  - May only view, copy, or delete their procedure image files.

To login to the Sonata System, on the Login screen (see Figure 3-7):

- Enter the user name into the User Name field.

Enter the password into the Password field.

Click on the “Login” button (by mouse or by finger on screen).

Figure 3-7. Login screen.

3.3 Unpackage Required Supplies

The following equipment is needed for the procedure:

- Sterile RFA Handpiece (single-use)
- Sterile RFA Handpiece Cable (reusable)
- Sterile IUUS Probe (reusable)
- Two (2) Dispersive Electrodes (DEs)

Inspect the expiration date on the front of the RFA Handpiece and DE packaging.

DO NOT use if beyond the expiration date.

3.3.1 Inspect and Remove the RFA Handpiece from Packaging (Sterile)

Inspect the expiration date on the RFA Handpiece package.

DO NOT use if beyond the expiration date.

Look for any breaks in the seal between the Tyvek film cover and the clear plastic tray. If there are breaks, discard and replace the RFA Handpiece.

Remove the RFA Handpiece ensuring sterility is maintained:

- The non-sterile assistant should hold the bottom of the tray (or if alone, place the tray on a Tabletop).
- The non-sterile assistant peels back and removes the Tyvek film layer, see Figure 3-8.
- Using sterile technique, grasp the center of the RFA Handpiece to remove the RFA Handpiece, see Figure 3-8Inspect the RFA Handpiece for evidence of damage. If there is damage, replace the RFA Handpiece.

Figure 3-8. Peel back Tyvek layer back to fully expose tip and shaft. Operator grasps and removes the RFA Handpiece.

3.3.2 Inspect and Remove RFA Handpiece Cable from Packaging (Sterile)

Make sure that the reusable RFA Handpiece Cable has been reprocessed (cleaned and sterilized) prior to use.

DO NOT use if the RFA Handpiece Cable has not been reprocessed (Refer to the Reusable RFA Handpiece Cable Instructions for Use, REF-008, for proper sterilization).

DO NOT use if there is damage to the sterile packaging of the RFA Handpiece Cable. If there is damage to the sterile packaging, the affected RFA Handpiece Cable requires repeat cleaning, disinfection, and sterilization. Obtain a replacement sterile RFA Handpiece Cable for use.

Remove the RFA Handpiece Cable from its sterile packaging.

Inspect the RFA Handpiece Cable for any defect, such as cracks or cuts.

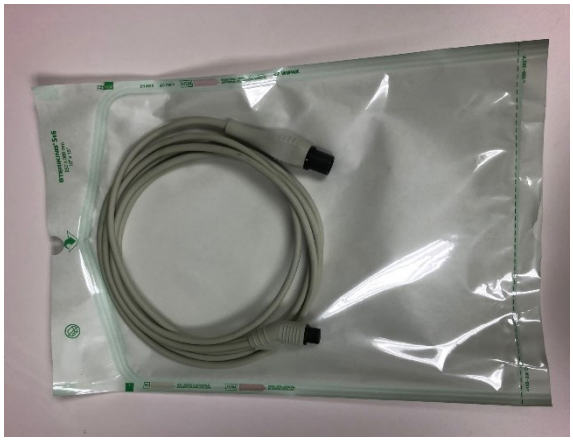

Figure 3-9. Representative of a Reusable RFA Cable in a sterile pouch

3.3.3 Connect the RFA Handpiece to the RFA Handpiece Cable

Connect the end of the RFA Handpiece Cable by aligning the arrow on the RFA Handpiece Cable to the arrow on the RFA Handpiece, see Figure 3-10.

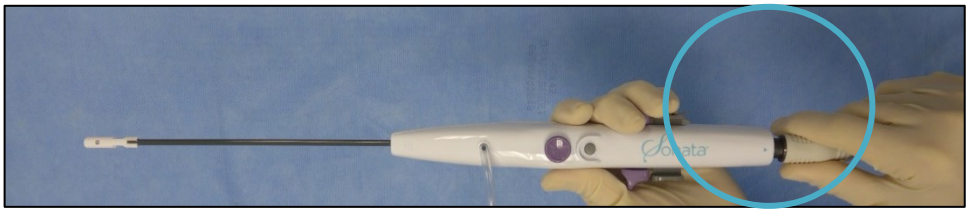

Figure 3-10. Connect the RFA Handpiece Cable to the RFA Handpiece.

Ensure the connection is secure.

3.3.4 Inspect and Remove the Dispersive Electrodes from Packaging (Non-Sterile)

Inspect the expiration date on each Dispersive Electrode package.

DO NOT use if beyond the expiration date.

Inspect the Dispersive Electrode packages for damage such as punctures or peeling of seal. If expired or the packaging is damaged, replace the Dispersive Electrodes.

Remove the Dispersive Electrodes from the packages.

Figure 3-11. Representative of single-use Dispersive Electrode Pouch and Dispersive Electrodes (non-sterile).

CAUTION	
⚠	DISPERSIVE ELECTRODES NOT STERILE Dispersive Electrodes are not sterile. DO NOT place on a sterile field.

3.4 Additional Required Procedure Supplies

Additional supplies required for procedures with the Sonata include:

- Standard D&C set that includes cervical dilators (dilatation to 27 Fr [9 mm]),
- Two (2) sterile 60 cc syringes,
- 250 cc of hypotonic fluid; non-electrolytic fluids must be used (e.g., sterile water, glycine [Irrigation USP 1.5%], sorbitol, or mannitol). DO NOT use electrolyte-containing fluids (eg, no lactated Ringers solution, normal saline, etc), and
- Allen stirrups (or equivalent).

3.5 Position Patient

Position the patient in the dorsal lithotomy position.

Place legs in appropriate stirrups (e.g., Allen stirrups) to minimize the risk of lower extremity nerve compression.

WARNING	
⚠	DVT PROPHYLAXIS DVT prophylaxis may be appropriate. Any surgical procedure may involve a risk of deep vein thrombosis or pulmonary embolism. Please consult institutional/national guidelines.

3.6 Apply Dispersive Electrodes and Connect both Dispersive Electrode Cables to RF Generator

The Dispersive Electrodes are self-adhesive. Make sure both anterior thighs are clean and dry before applying Dispersive Electrodes.

- Remove the clear plastic liner from the adhesive side of each Dispersive Electrodes and inspect to make sure the adhesive fully covers the electrode surface and does not appear dry.

DO NOT use electrode gel.

Apply both Dispersive Electrodes, one (1) on each anterior thigh.

Position Dispersive Electrodes with the cable toward the patient's knee, see Figure 3-12.

Figure 3-12. Apply both Dispersive Electrodes, one (1) on each anterior thigh.

DO NOT place Dispersive Electrodes over scars, bony prominences, metal prostheses, or EKG electrodes.

DO NOT treat the patient if the patient's thighs are smaller than 28 cm in circumference such that the Dispersive Electrodes wrap entirely around and overlap on themselves.

DO NOT attempt to reuse the Dispersive Electrodes. Doing so could degrade the conductive properties of the adhesive gel.

Make sure both Dispersive Electrode pads have good skin contact throughout the entire adhesive surface with the patient's skin.

- Poor connection may lead to uneven heat distribution and possible patient injury.

The Dispersive Electrode adhesive may inadvertently stick to itself. If this happens, peel it back open and inspect the adhesive gel. Replace the Dispersive Electrode if it has lost its shape or adhesive backing.

Verify that metal snaps from hospital gowns and other metal objects near the patient are not in contact with the patient's skin near the Dispersive Electrodes, as burns may occur.

Connect both Dispersive Electrode cables into the front of the RF Generator, see Figure 3-13.

Figure 3-13. Connect both Dispersive Electrode cables to the front of the RF Generator.

WARNINGS		
1	⚠	USE SONATA DISPERSIVE ELECTRODES ONLY Use only the Dispersive Electrodes provided in the Sonata Procedure Kit for the procedure. DO NOT substitute Dispersive Electrodes intended for alternate medical devices (Bovie, LEEP, etc.).
2	⚠	DISPERSIVE ELECTRODE ADHESION Both Dispersive Electrodes must be in full contact with patient's skin during treatment. Partial contact may result in a burn or poor electrical performance. Placement of Dispersive Electrodes over parts of the body that are not smooth, or over materials such as surgical drapes, will lead to incomplete contact or partial adhesion. Partial Dispersive Electrode contact may lead to compromised energy dispersion resulting in possible skin burns or incomplete ablations. The system has only limited ability to detect partially attached Dispersive Electrodes.

WARNINGS		
3		USE BOTH DISPERSIVE ELECTRODES Use BOTH Dispersive Electrodes, applying one (1) on each anterior thigh at the same height on both legs, as directed. The system will not allow activation of RF energy if patient contact with both electrodes is not detected. However, the system will NOT detect placement in an improper location of either or both Dispersive Electrodes on the patient's body. DO NOT attempt to place both Dispersive Electrodes on the same leg. Doing so will risk patient skin injury. Place them bilaterally, one (1) on each anterior thigh.
4		MODIFYING DISPERSIVE ELECTRODES DO NOT cut or modify the Dispersive Electrodes in any manner. Using an incomplete Dispersive Electrodes on the patient would result in higher energy concentrations and possible skin burns.
5		CONTACT OF OTHER MATERIALS TO DISPERSIVE ELECTRODES Dispersive Electrodes should be placed such that they are not in contact with each other or with pooled conductive liquid such as blood or saline. Such contact could result in unintended energy dispersion and potential burns.
6		REPLACING DISPERSIVE ELECTRODES DO NOT reuse or relocate a Dispersive Electrode after initial application. Should it become necessary to move a Dispersive Electrode during the procedure, replace with a NEW Dispersive Electrode. Reapplication of a Dispersive Electrode could result in poor adhesion to the skin, resulting in thermal skin injury.
7		PATIENT MOVEMENT AFTER DISPERSIVE ELECTRODES APPLIED If a patient is repositioned during the procedure, re-inspect the Dispersive Electrodes for proper placement/adhesion to site, as they may have become dislodged or were peeled off during movement, causing poor or partial skin contact.
8		DO NOT TREAT IF DISPERSIVE ELECTRODE OVERLAPS DUE TO SMALL PATIENT LEG SIZE If a patient's thighs are smaller than 28 cm in circumference such that the Dispersive Electrodes wrap entirely around and overlap on themselves, the patient should not be treated with the Sonata System. This would concentrate energy over a smaller surface than intended and could lead to thermal skin injury.
9		RISK OF SKIN BURNS There is a risk of skin burns associated with the use of any electrosurgical device. The Dispersive Electrodes and instructions for use on proper placement are designed to minimize, but not eliminate, such risk. The risk of burns at the site of one or both Dispersive Electrodes may be greater in those cases where RF ablation times are longer and more power is used.

WARNINGS		
10		USE OF OTHER DISPERSIVE ELECTRODES DO NOT simultaneously use other Dispersive Electrodes (“grounding pads”) from another system or place them in contact with, or in close proximity to, Dispersive Electrodes. DO NOT have other return circuits, including other electrically conductive tools or devices, or their cables, in contact with any part of the Dispersive Electrodes. DO NOT have any other electrodes from other electrosurgical systems on the patient or simultaneously connected to their respective systems.
11		LOW OUTPUT FAILURES AND POOR CABLE CONNECTIONS Apparent low output or failure of the RF electrosurgical equipment to function correctly at normal operating settings may indicate an improper application of one or both Dispersive Electrodes or poor contact with the RF Generator resulting from Dispersive Electrode damage or a poor cable connection.
12		PROXIMITY WITH OTHER CONDUCTIVE MATERIALS There should be no other Dispersive Electrodes or conductive object (e.g., metal) between the pelvis and the Dispersive Electrodes during the procedure. Metal objects could concentrate energy, causing thermal skin injury.

3.7 Prepare the Sonata System

3.7.1 Assemble Sonata Treatment Device (IUUS Probe and RFA Handpiece)

Make sure that the reusable IUUS Probe has been reprocessed (cleaned and sterilized) prior to use.

DO NOT use if the IUUS Probe has not been reprocessed (Refer to the IUUS Probe Instructions for Use, REF-003 for proper sterilization).

DO NOT use if there is damage to the sterile packaging of the IUUS Probe. If there is damage to the sterile packaging, the affected IUUS Probe requires repeat cleaning, disinfection, and sterilization. Obtain a replacement sterile IUUS Probe for use.

Remove the IUUS Probe from its sterile packaging.

Inspect the IUUS Probe:

- Check the Imaging Surface of the IUUS Probe to make sure it is free of cracking, peeling, or any damage, see Figure 3-14.

Make sure the Hinge Cover and Hinge Mechanism are free from defects or damage, see Figure 3-14.

Replace the IUUS Probe if there is any damage.

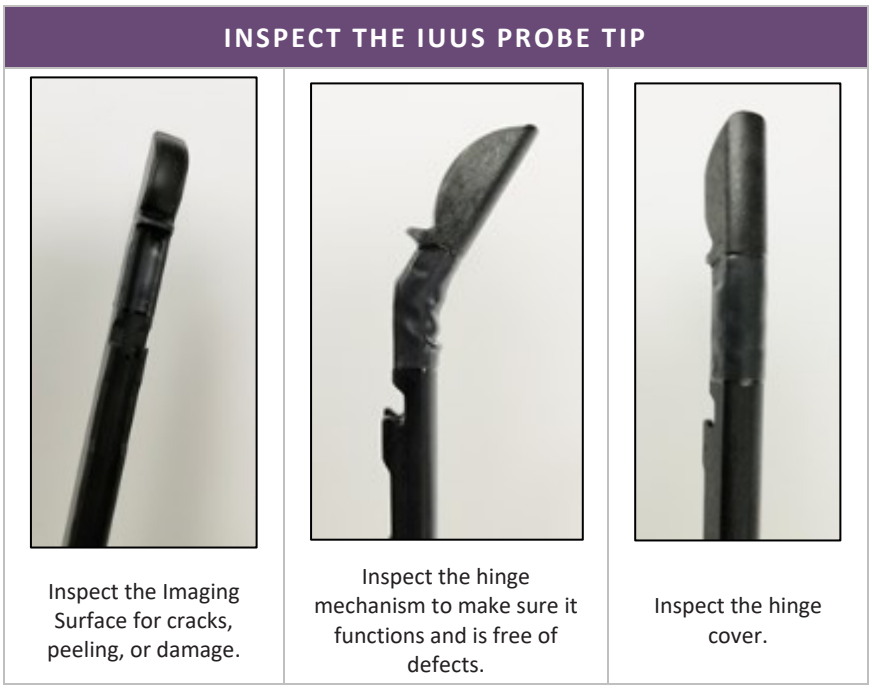

Figure 3-14. Inspect the IUUS Probe Tip before using.

Connect the IUUS Probe and RFA Handpiece tips by hooking the RFA Handpiece posts to the slots of the IUUS Probe shaft, see Figure 3-15.

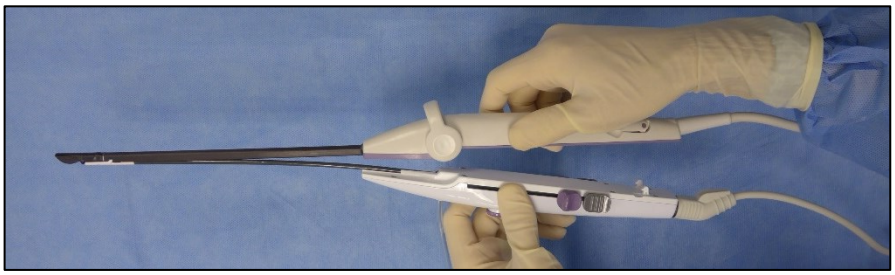

Figure 3-15. Connect IUUS Probe Tip and RFA Handpiece Tip.

Snap the handles together at the base of the Sonata Treatment Device, so that the tips stay connected, see Figure 3-16.

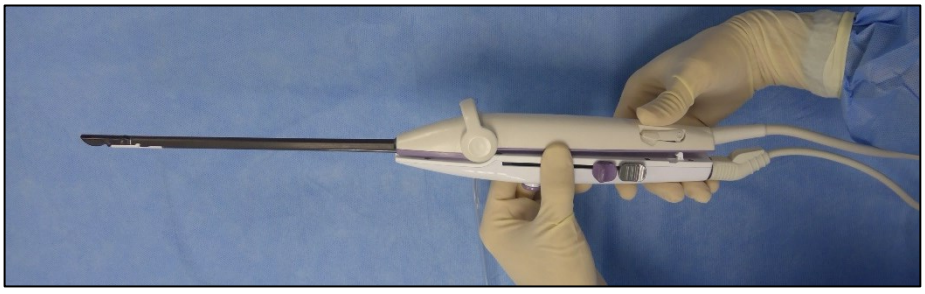

Figure 3-16. Snap the handles together while keeping the IUUS Probe Tip and the RFA Handpiece Tip connected.

Fill a Luer lock syringe (60 cc recommended) with hypotonic fluid. Remove all air and bubbles. Introducing bubbles may cause image degradation.

Connect the syringe filled with hypotonic solution to the RFA Handpiece infusion port, see Figure 3-17.

Flush the Sonata Treatment Device until fluid exits the RFA Handpiece Tip.

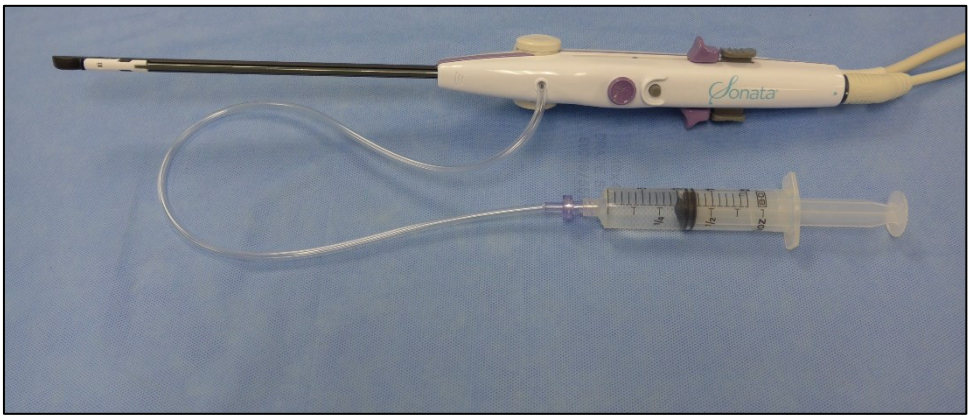

Figure 3-17. Connect luer lock syringe filled with hypotonic fluid and flush the Sonata Treatment Device until fluid exits the tip.

CAUTIONS	
⚠	HYPOTONIC SOLUTIONS ONLY Use only hypotonic fluids (non-electrolytic) for acoustic coupling to reduce the risk of unintended RF energy dispersion. Such energy dispersion may result in damage to unintended tissue or a reduced ablation volume within the target tissue. Recommended fluids include sterile water, 1.5% glycine, mannitol, or sorbitol, all of which do not contain appreciable electrolytes. Normal saline, hypertonic saline, lactated Ringer's solution, D5.45N saline, and other electrolyte-containing fluids are contraindicated for use with the Sonata System. Minimize fluid infusion to an amount necessary for visualization.
⚠	TIGHTENING LUER FITTINGS Be careful not to over tighten the connection between the syringe and infusion line. Tighten only to a light fit with fingers (no tools). Over tightening could cause leakage.
⚠	USE OF FLUID SOURCES DO NOT attach another fluid instillation source such as a pressure bag or fluid pump. The fluid port and Sonata Treatment Device are NOT intended for distension of the uterine cavity. Use of alternative instillation sources may result in excessive pressure on the Sonata Treatment Device and carries the risk of fluid overload.

3.7.2 Connect and Lock IUUS Probe Connector to SMART Tablet

Connect the IUUS Probe Connector to the SMART Tablet. With the post facing up, insert the Connector into the receptacle on the right-side of the SMART Tablet, see Figure 3-18.

Lock the Connector in place by sliding the latch, see Figure 3-18.

Figure 3-18. Connect IUUS Probe to SMART Tablet and slide latch to lock.

3.7.3 Connect RFA Handpiece to RF Generator

Connect the RFA Handpiece Cable to the front of the RF Generator (bottom-right side) with the orientation marker (black dot) facing up, see Figure 3-19.

Figure 3-19. Connect RFA Handpiece Cable to front of RF Generator.

3.7.4 Check Component Connection Indicators

The SMART Tablet display shows three (3) graphical indicators on the right-hand side of the display, see Figure 3-20. The indicators communicate whether the following components have been properly connected:

- RF Generator,
- Dispersive Electrodes, and
- RFA Handpiece.
- Check the Component Connection Indicators on the right-hand side of the screen to make sure all components are connected.

If a component is not connected or detected, its graphic will blink until the component is connected.

If a component is connected, detected, and functioning, the graphic will be solid (not blink).

When all three (3) components are connected and detected, the indicators will disappear.

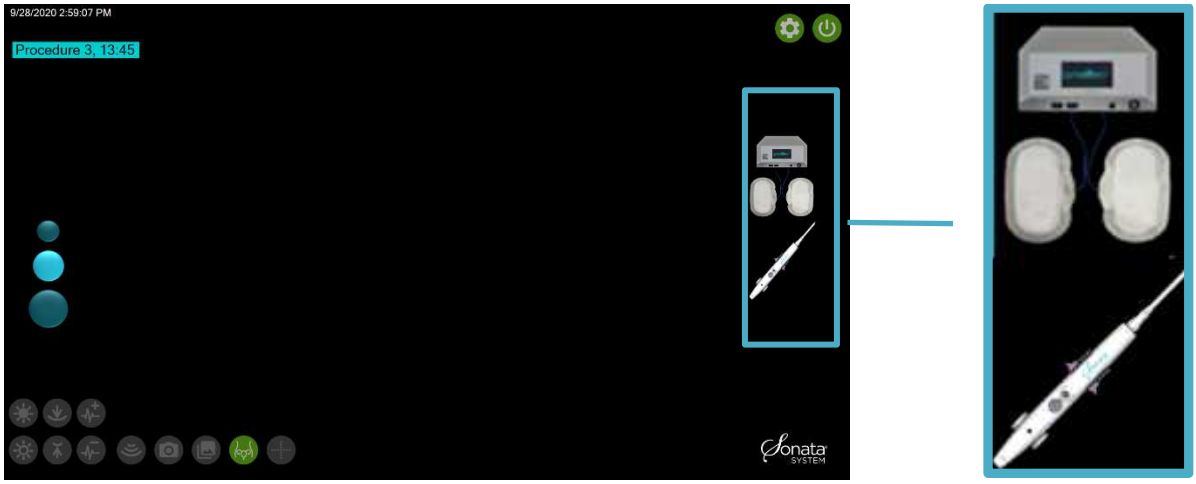

Figure 3-20. Component Connection Indicators (RF Generator, Dispersive Electrodes and RFA Handpiece).

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Chapter 4 Sonata Transcervical Fibroid Ablation (TFA) Procedure

4.1 Inspect the Sonata Treatment Device

Use the device controls in order of the procedure to deploy and inspect the Sonata Treatment Device prior to insertion into the patient, see Figure 4-1.

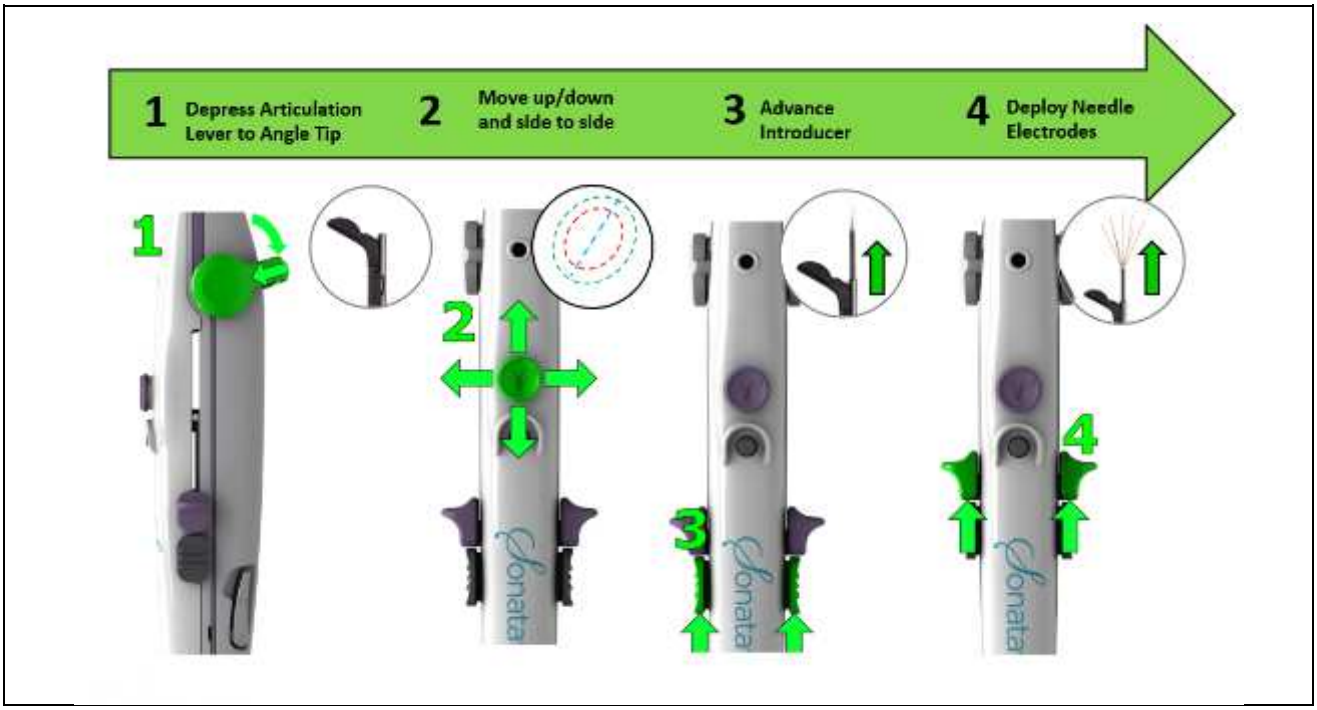


Figure 4-1. Deploy the Sonata Treatment Device controls for inspection.

Confirm that the tips of the RFA Handpiece and IUUS Probe are connected on both sides.

Use each control as outlined above in order to make sure each control works as intended.

- Control 1 - Use the Articulation Lever to angle the Articulating Tip to 45° and 60°.
- Control 2 - Move the SMART Control in all 4 directions to verify function.
- Control 3 - Advance the Introducer to verify smooth movement.
- Control 4 - Deploy the Needle Electrodes to make sure all seven (7) electrodes are deployed and appear straight.
- Confirm Button – double click to take an image

Reverse all actions to reset the Sonata Treatment Device, see Figure 4-2.

- Retract the Needle Electrodes (Control 4).
- Retract the Introducer (Control 3).

- Needle Electrodes and Introducer must be completely retracted before articulating the IUUS Probe Tip to 0°.
- Reset IUUS Probe Tip to 0° (Control 1).

  Note: Resetting the SMART Control (Control 2) is not necessary.

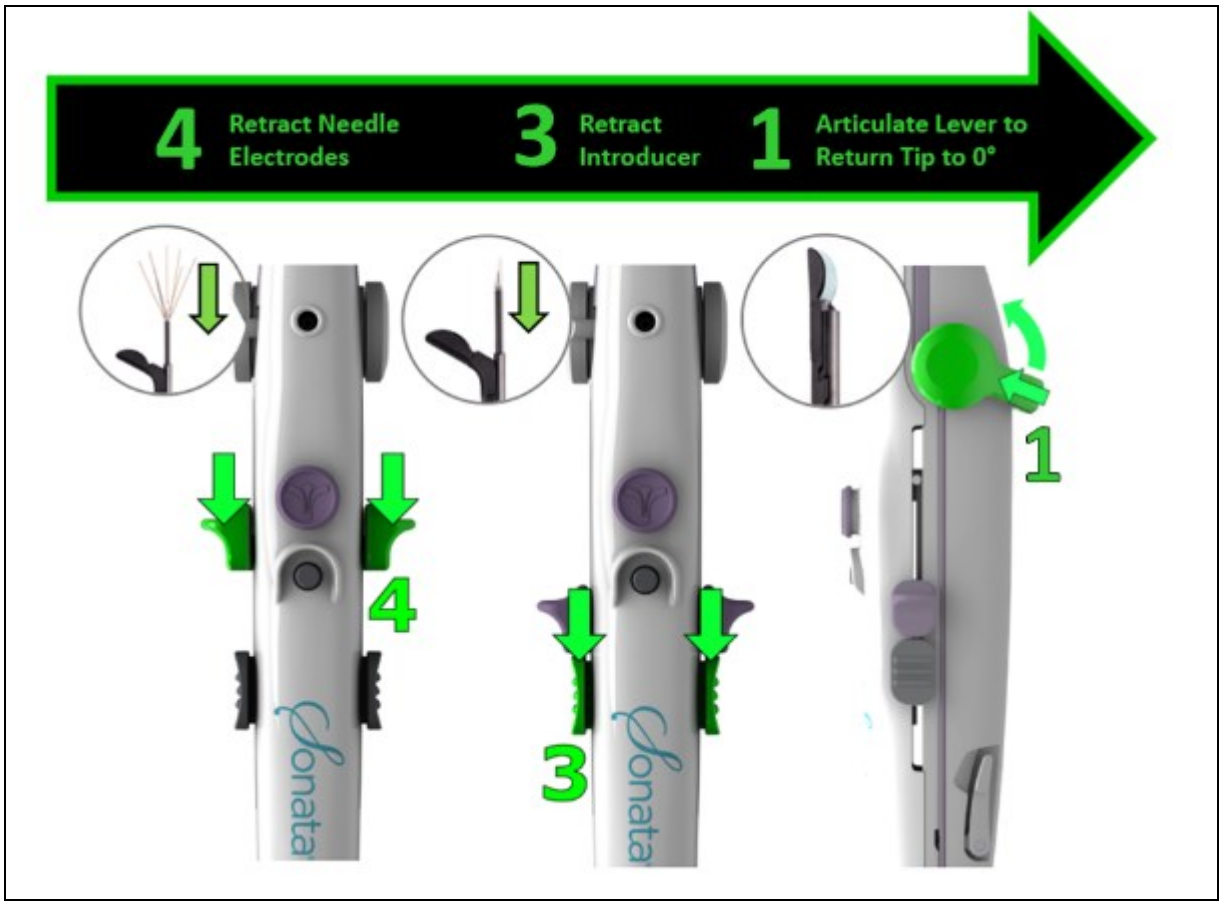


Figure 4-2. Retract the Sonata Treatment Device controls after inspection.

WARNING	
⚠	HANDLE WITH CARE. NEEDLE ELECTRODES AND INTRODUCER ARE SHARP The Needle Electrodes and Introducer are sharp. Handle device with care.

CAUTIONS	
⚠	DEPLOYING DEVICE OUTSIDE PATIENT Deploying outside the patient requires less force. Be aware to reduce stress on mechanisms to avoid device damage during checks.
⚠	RETRACT NEEDLE ELECTRODES AND INTRODUCER BEFORE INSERTING Needle Electrodes and Introducer must be completely retracted and Articulating Tip at 0° before insertion.

4.2 Insert Sonata Treatment Device

Determine the position and size of the uterus using sonography or bimanual examination.

Insert a fenestrated speculum or other retractor(s) to aid with insertion.

- Place a tenaculum to provide stability.
- Dilate the cervix manually or medicinally to 9 mm (27 Fr).
- With the IUUS Probe Tip at 0°, carefully insert the Sonata Treatment Device.
- Infuse a small amount hypotonic fluid through the fluid infusion port.
- Select the Ultrasound Imaging Preset appropriate for visualizing the serosal margin, see Figure 4-3.
    - The default setting is for an average sized fibroid (the middle blue circle on the left side of the screen). To change to a preset, Click on a circle (small, medium, or large).
    - The presets are programmed to adjust the image depth, ultrasound frequency, and other imaging parameters.

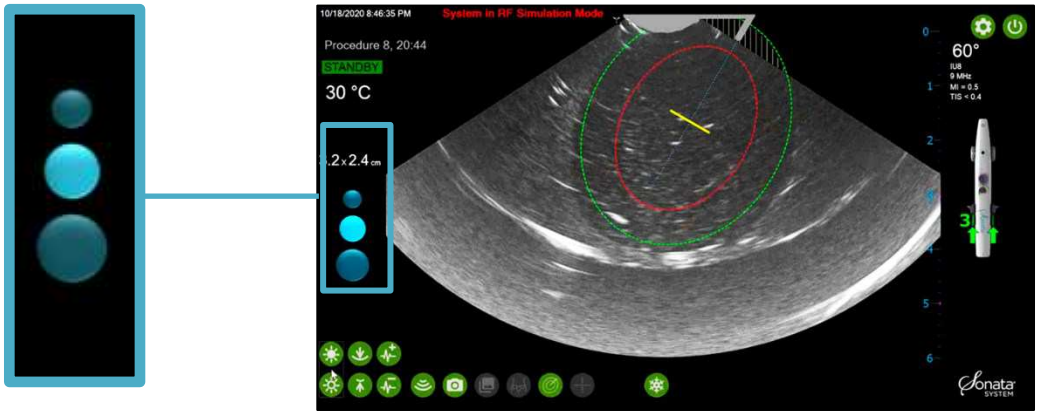


Figure 4-3. Ultrasound Imaging Presets.

CAUTION	
⚠	CARE WHEN USING TENACULUM If using a tenaculum, be careful to avoid crimping or damaging the Sonata Treatment Device shaft or the IUUS Probe hinge cover. Damage may compromise electrical isolation and sterility.
⚠	APPLY LIGHT FORCES DURING INFUSION During infusion of fluid into endometrial cavity, use light force to infuse just enough fluid for contact to avoid causing irritation to the patient or fluid backflow into the device.

4.3 Identify Pertinent Anatomy

Perform a survey of the uterus to locate fibroids.
Note the orientation of the ultrasound scan plane, see Figure 4-4, relative to the Imaging Surface.

To target a specific fibroid, rotate the device until the ultrasound scan plane passes through the center of the fibroid, see Figure 4-5.

- Small, controlled motions help to locate fibroids and keep them in view.

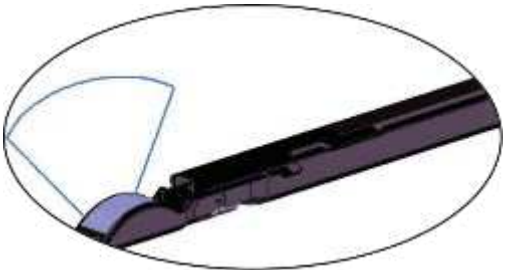


Figure 4-4. Ultrasound scan plane.

Identify the uterine serosa.

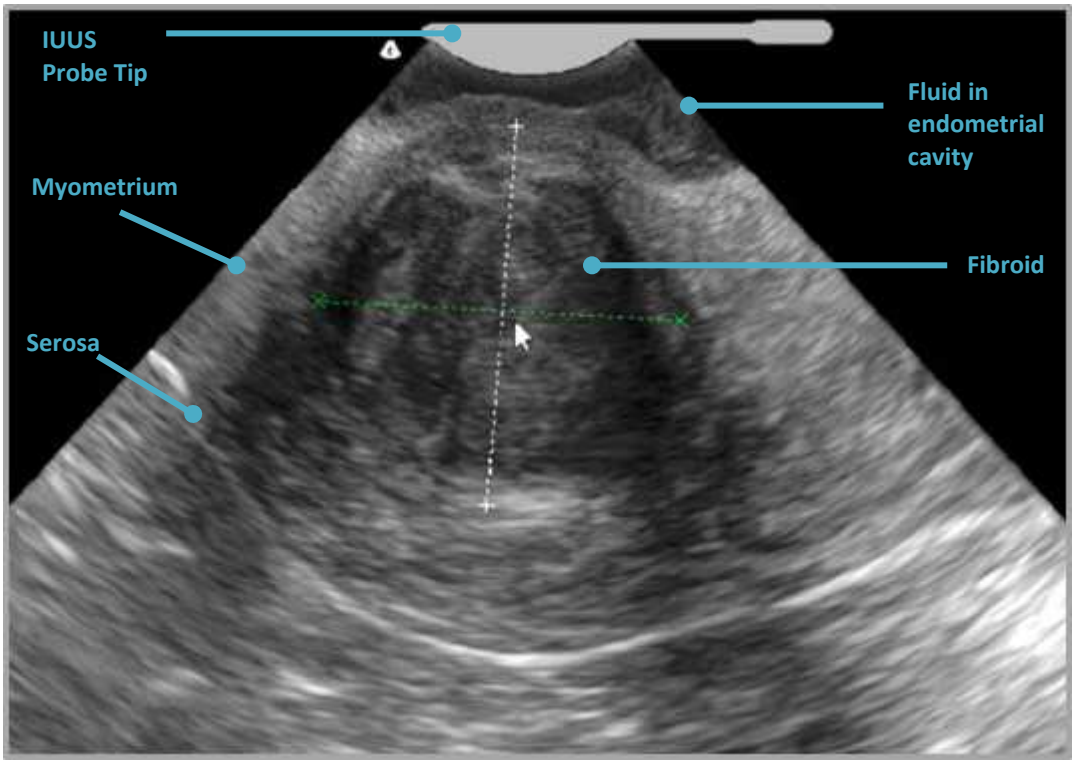


Figure 4-5. Survey the uterus to target a fibroid.

WARNING	
⚠	DO NOT PROCEED IF UTERINE SEROSA IS NOT IDENTIFIED WITH CERTAINTY DO NOT proceed if the uterine serosa cannot be clearly identified by any combination of the ultrasound settings. Inability to visualize the uterine serosal margin may indicate positioning of the device within a false passage, a substantially enlarged uterus, uncertain position, or unfavorable anatomy for imaging.

4.4 Target a Fibroid

The SMART Guide and five (5) controls on the Treatment Device work together to target a fibroid.

The SMART Guide, see Figure 4-6, is a graphical overlay on the ultrasound image that is comprised of the following graphical elements:

- IUUS Probe Tip (illustration at the top)
- Introducer Guide (blue dashed line),
- Ablation Zone (red inner ellipse),
- Thermal Safety Border (green outer ellipse),
- Introducer Tip Tracker (yellow arrowhead),
- Introducer Plan Line (yellow line turns red when the Introducer Tip reaches the Introducer Plan Line depth),
- Introducer Tip Alignment Guide (yellow diamond with arrows),
- Needle Electrode Tip Trackers (three yellow arrowheads)
- The Needle Electrode Plan Lines (three (3) yellow lines that represent the Needle Electrode planned depth. The Needle Electrode Plan Lines turn red when the Needle Electrodes are deployed to planned depth).

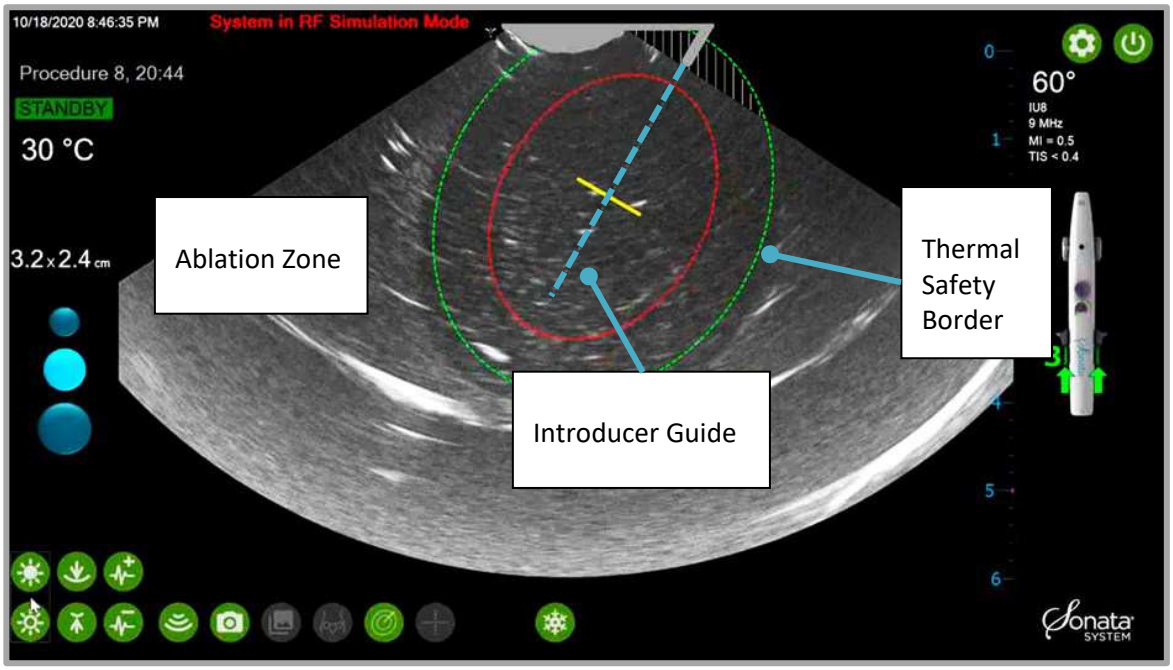


Figure 4-6. Ablation Zone (red inner ellipse), Thermal Safety Border (green outer ellipse), and Introducer Guide (blue dashed line).

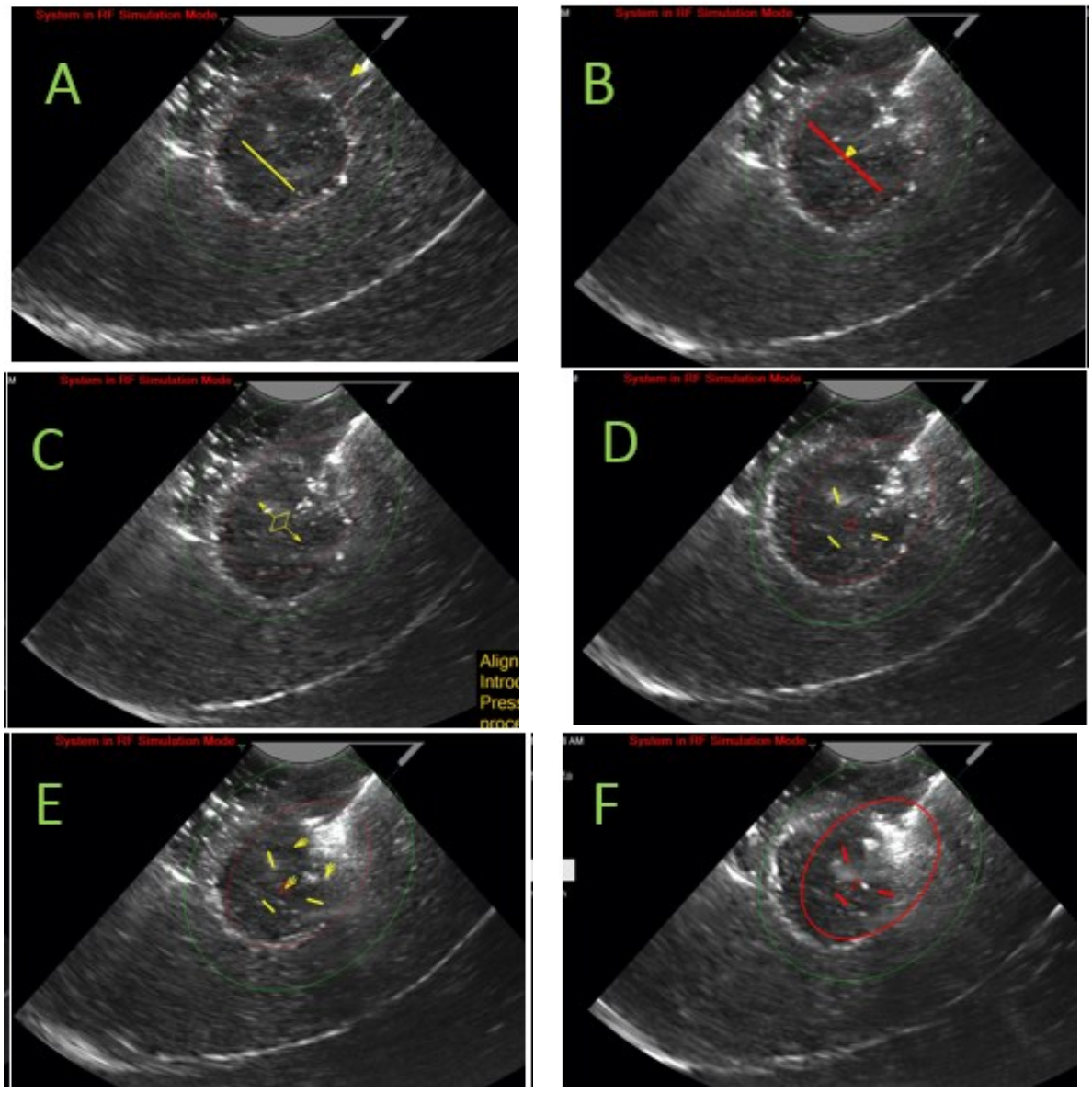


Figure 4-7. SMART Guide graphic during stages of targeting. A. Introducer Tracker advancing to Introducer Plan Line. B. Introducer Tracker reaching depth of Introducer Plan Line. C. Align SMART Guide to Introducer Tip. D. Advance Needle Electrodes to Needle Plan Lines. E. Needle Electrode Trackers advancing to Needle Plan Lines. F. Needle Electrodes advanced to Needle Electrode Plan Lines.

The SMART Guide is directed by controls on the Treatment Device. The software will guide the Operator through the order of the procedure using illustrations of the device, see Figure 4-8.

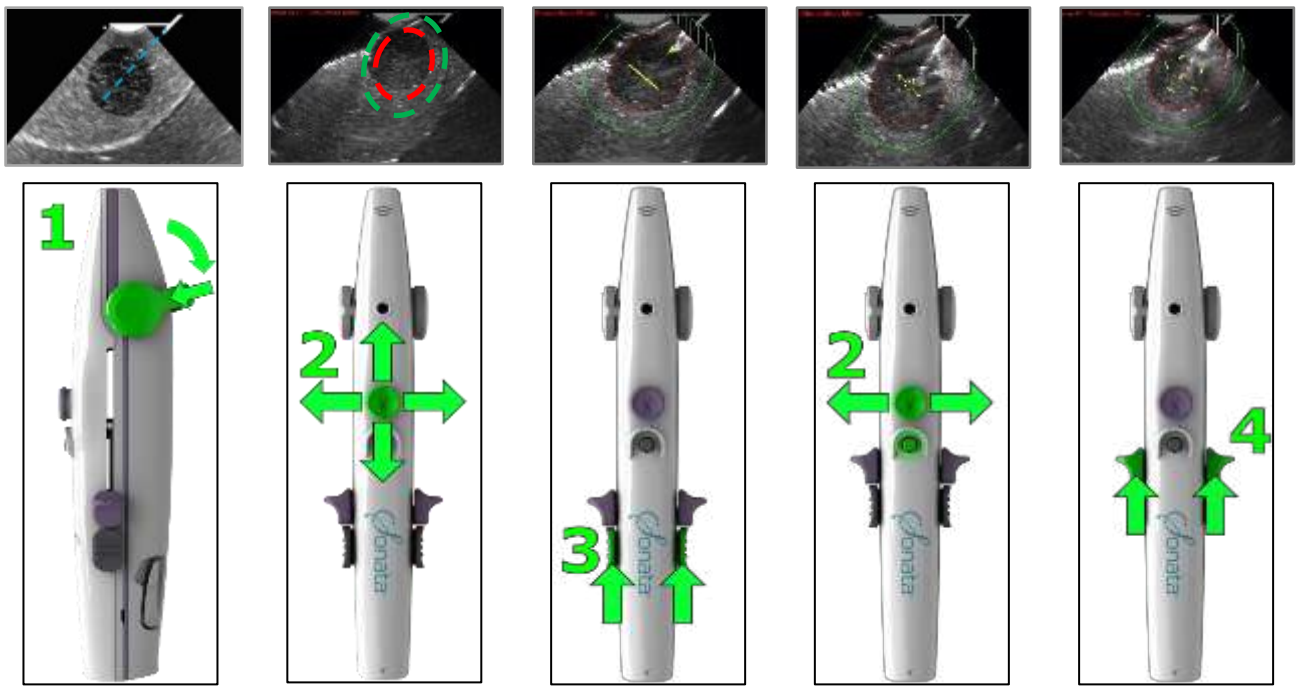


Figure 4-8. Sonata Treatment Device controls and their corresponding SMART Guide graphical overlay.

4.4.1 Peripheral Zone Marker

The Peripheral Zone Marker is the area depicted by pin stripes as shown in Figure 4-9. The Peripheral Zone Marker graphically represents the regions of the Thermal Safety Border that extend beyond the ultrasound view. The Operator must verify that the Thermal Safety Border never extends beyond the inner portion of the serosa.

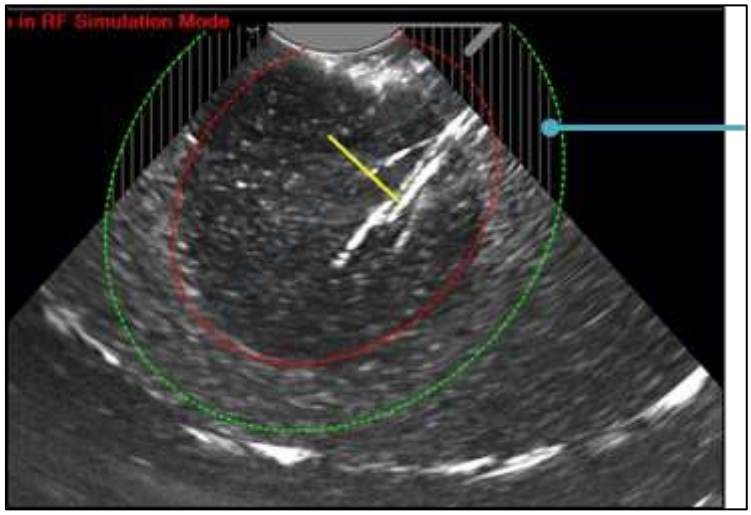


Figure 4-9. Peripheral Zone Marker.

4.4.2 Articulate to Center the Introducer Guide

Once a fibroid is identified, depress the Articulation Lever and pull back toward the Operator to angle the Articulating Tip.

The Introducer Guide Line, the blue dashed line, will be displayed.

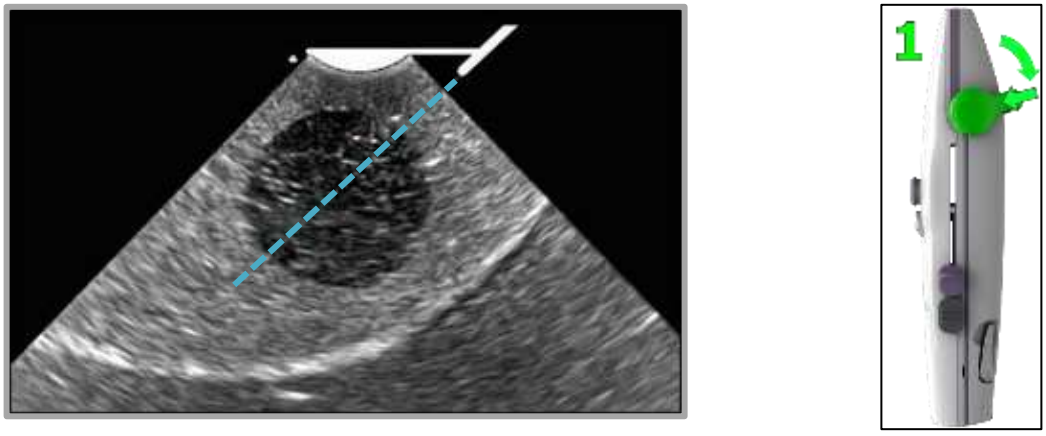


Figure 4-10. Introducer Guide displays upon adjustment of Articulating Tip.

Release the lever at the mechanical stops of 45° or 60° to set the articulation angle and center the Introducer Guide (blue dashed line) in the widest part of the fibroid, see Figure 4-11.

Point the device toward the fibroid.

Maintain IUUS Probe Tip contact with tissue for optimal image quality.

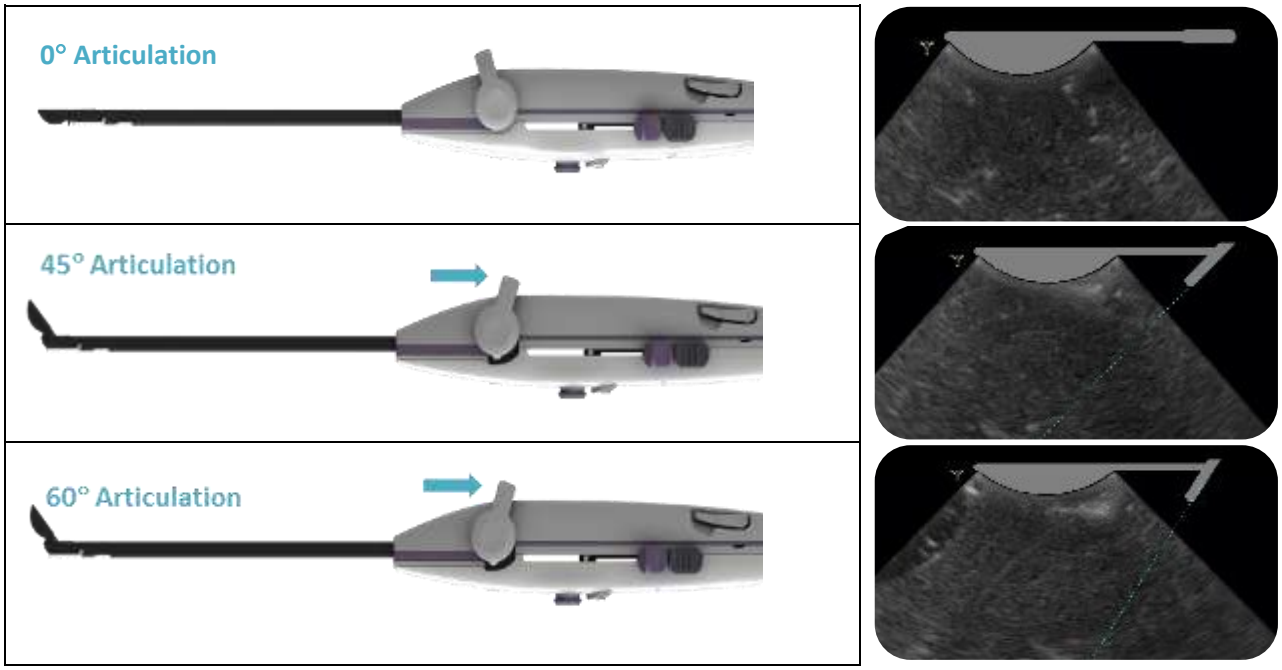


Figure 4-11. Articulation Lever and Articulating Tip at 0°, 45°, and 60° with corresponding illustration on ultrasound image.

4.4.3 Set Ablation Depth and Size

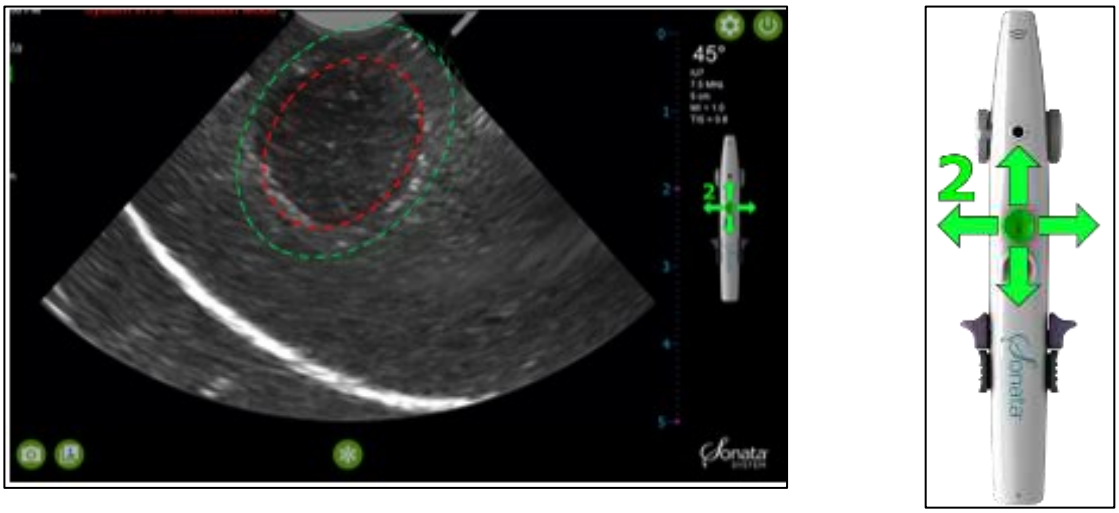


Figure 4-12. Use SMART Control to adjust the ablation depth and size.

To display the Ablation Zone (red inner ellipse) and Thermal Safety Border (green outer ellipse), push the SMART Control forward, see Figure 4-12.

Using the SMART Control, adjust the size and depth of the Ablation Zone (red inner ellipse) over the fibroid while maintaining the Thermal Safety Border (green outer ellipse) inside the serosal margin.

To adjust the ablation depth, move the SMART Control forward or backward.

To adjust the ablation size, move the SMART Control side to side until the Ablation Zone (red inner ellipse) is at the desired size while keeping the Thermal Safety Border (green outer ellipse) within the inner portion of the serosa. The direction of the side to side movement to adjust the size will depend on the orientation of the Treatment Device. For example, if the SMART Control is facing up, moving the SMART Control to the right will enlarge the size of the Ablation Zone (red inner ellipse). If the SMART Control is facing down, moving the SMART Control to the right will decrease the size of the Ablation Zone (red inner ellipse).

- The minimum size is 20 x 13 mm.
- The maximum size is 49 x 42 mm.

The size of the Thermal Safety Border (green outer ellipse) adjusts automatically in relationship to the Ablation Zone (red inner ellipse).

The relative distance of the Needle Electrode Tip Markers from the Needle Electrode Origin is also determined by the size of the Ablation Zone. The larger the Ablation Zone (red inner ellipse), the greater the distance between the Needle Electrode Tip Markers and the Needle Electrode Origin.

Confirm the location of the serosal margin. The serosal margin must be definitively visualized to proceed.

- Always keep the Thermal Safety Border (green outer ellipse) on the inside of the serosal border to maintain the safety margin. Because of ultrasound physics, the uterine serosal margin may appear to have a “thick” border on the ultrasound image. To avoid injury to organs adjacent to the serosa, the Thermal Safety Border must never extend beyond the inner portion of the serosal margin, as depicted in-Figure 4-13.

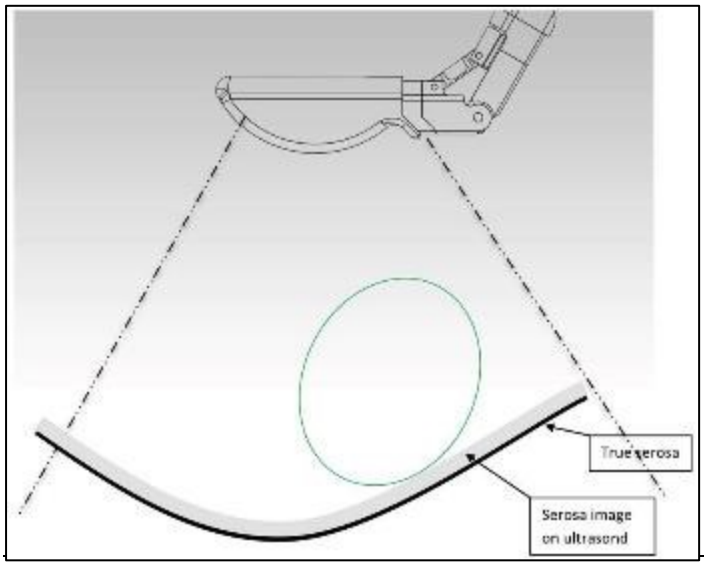


Figure 4-13 Ultrasound image of serosa may be thickened towards the transducer due to finite slice thickness.

If the Peripheral Zone Marker (pin stripes) are visualized, verify the Thermal Safety Border (green outer ellipse) is within the serosa.

If uncertain of serosal margin (due to ultrasound artifact, for example), use gentle and minimal forward/backwards device motion, identification of extrauterine tissue/organs, and uterine manipulation to aid in the identification of the uterine serosal margin. Never proceed with ablation unless the uterine serosa is clearly identified.

If the Thermal Safety Border (green outer ellipse) crosses the serosal margin, reposition or adjust the size of the SMART Guide, see Figure 4-15.

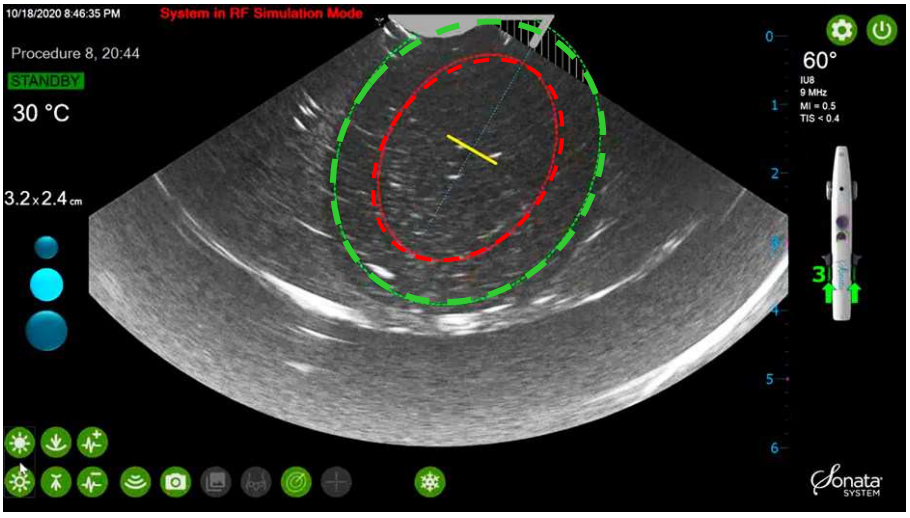


Figure 4-14. Be aware the Thermal Safety Border (green outer ellipse) is out of the ultrasound image. Peripheral Zone Markers (pin stripes) represent area outside of the ultrasound image.

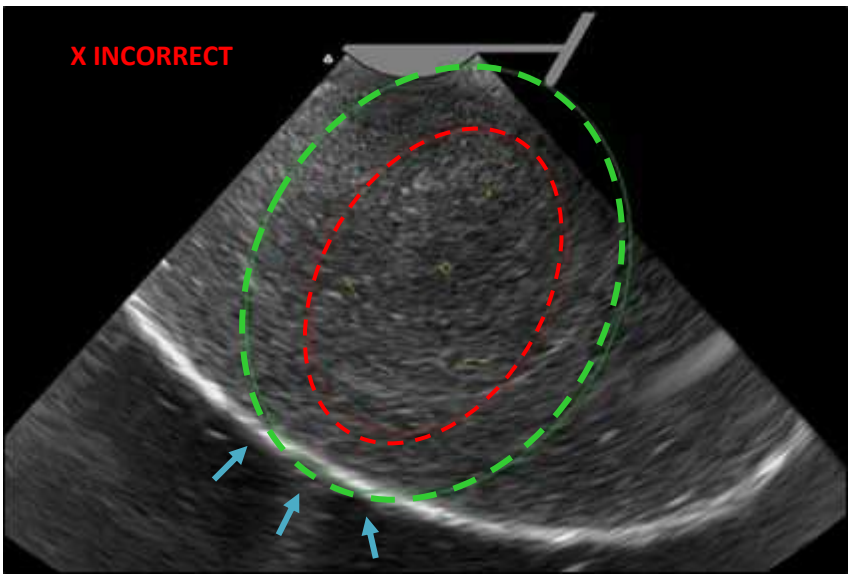


Figure 4-15. Example of Thermal Safety Border outside of the serosa. Reposition SMART Guide inside the serosal margin.

WARNINGS	
⚠	MAINTAIN THERMAL SAFETY BORDER INSIDE SEROSAL MARGIN Always maintain the Thermal Safety Border (green outer ellipse) within the uterine serosal margin.
⚠	USE THE INNER BOUNDARY OF SEROSAL MARGINS The uterine serosal margin may appear to have a “thick” border on the ultrasound image. To avoid injury to organs adjacent to the serosa, the Thermal Safety Border must never extend beyond the inner portion of the serosal margin.

4.5 Position Introducer Tip to the Introducer Plan Line

4.5.1 Advance Introducer Tip to Introducer Plan Line

While observing the live ultrasound image, depress the Introducer Sliders and advance the Introducer in a controlled fashion to the yellow Introducer Plan Line into the fibroid, see Figure 4-16. Always hold the Treatment Device by the handle, not by the Cables.

- **Important:** Advance carefully to prevent the Introducer Tip from advancing beyond the Introducer Plan Line. DO NOT push in an uncontrolled fashion or beyond the yellow Introducer Plan line. If the Introducer is advanced rapidly the sharp trocar tip may extend past the intended depth (Introducer Tip Plan Line) and result in of uterine perforation.
- Stabilize the Sonata Treatment Device through countertraction (e.g., using the previously-applied tenaculum) when deploying Introducer into tissue to limit motion from the tissue.
- As the Introducer Sliders are pushed forward, the Introducer Tip Marker (yellow arrowhead) will move and point toward the yellow Introducer Plan Line.

- The Introducer Tracker (yellow arrowhead) indicates the approximate depth of the Introducer Tip and tracks the penetration into tissue.

When the Introducer Tip reaches the depth of the Introducer Plan Line, release the Introducer Sliders.

- The Introducer Plan Line will change from yellow to red and an audible tone will sound, see Figure 4-16.
- **Important:** DO NOT continue to push the Introducer Sliders beyond the depth of Introducer Plan Line. If the tip is beyond the plan line, retract back to the line (See Section 4.5.2 for further instructions). If it is desired to place the ablation deeper into tissue, retract the Introducer fully and retarget.

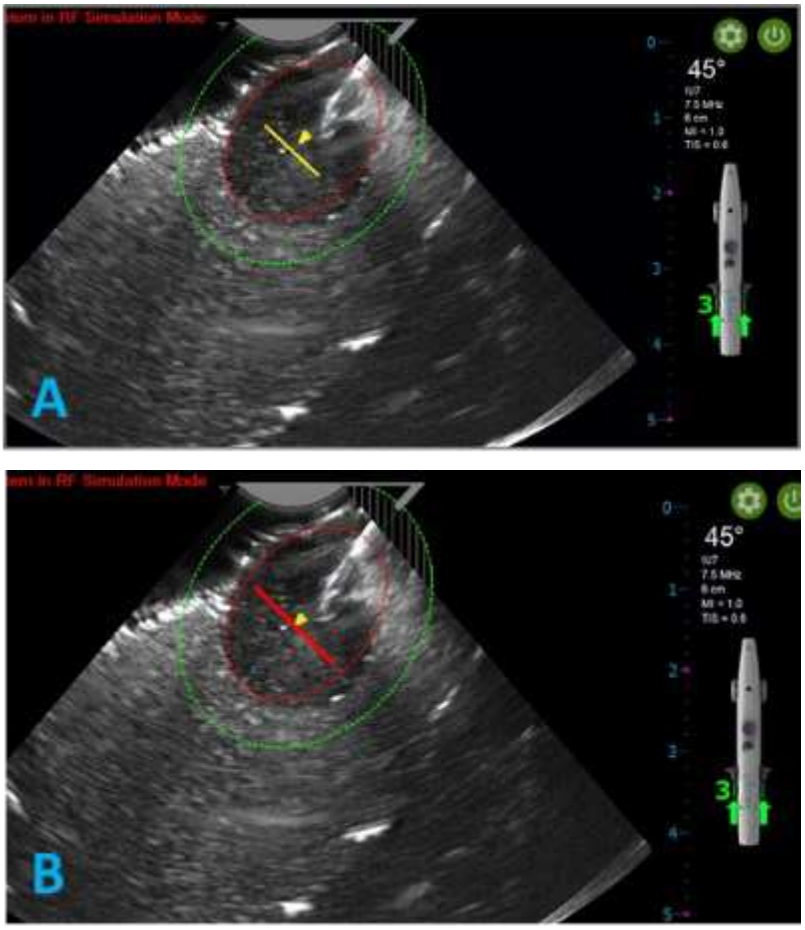


Figure 4-16.A. Advance Introducer Tip to Introducer Plan Line. B. Introducer Tip at Introducer Plan line. Plan line is red.

When the Introducer Tip reaches the intended depth, the Introducer Tracker and Plan Line are replaced with the yellow Introducer Tip Alignment Marker (yellow diamond with arrows), see Figure 4-17 .

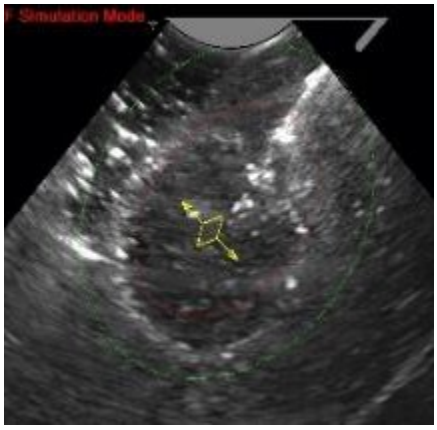


Figure 4-17. Introducer Tip Alignment Guide (yellow diamond with arrows).

4.5.2 How to Retract Introducer Tip to Introducer Plan Line

If the Introducer Tip Tracker is advanced beyond the Introducer Plan Line:

- The yellow Introducer Tracker arrowhead will change direction,
- An auditory warning will be sounded, and
- The message “STOP Retract Introducer to Plan Line” will be displayed.

Important: DO NOT advance the Introducer Tip any further past the Introducer Plan Line.

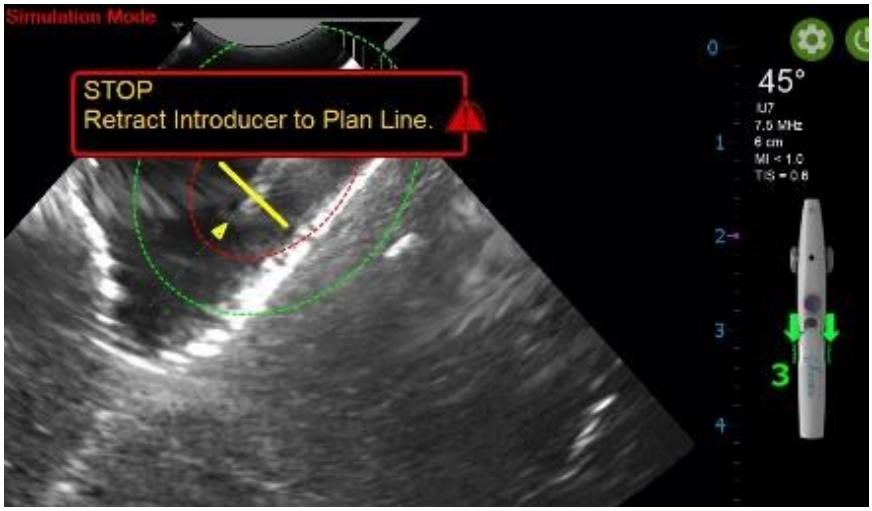


Figure 4-18. Introducer advanced beyond Introducer Plan Line. Advancement must be stopped, and Introducer retracted.

To retract the Introducer Tip and return to the Introducer Plan Line, see Figure 4-18 :

- STOP advancing the Introducer Tip immediately if the Introducer Tip penetrates beyond the Introducer Plan Line.

To retract the Introducer Tip depress the Introducer Sliders and slide Introducer Sliders towards the Treatment Device cables until the Introducer Tip Tracker meets the Introducer Plan Line.

The Introducer Plan Line will turn red when the appropriate depth is met with the Introducer Tip.

4.6 Align SMART Guide to Introducer Tip and Confirm

Move the SMART Control side to side to align the Introducer Tip Alignment Guide (yellow diamond) with the Introducer Tip, or by placing the cursor on the visible tip of the introducer and left clicking. see Figure 4-19.

- If needed, move the SMART Control forward and back to adjust the depth of the Introducer Tip Marker to align with the Introducer Tip.
- Press the Confirm Button when the Introducer Tip Alignment Guide (yellow diamond) is aligned with Introducer Tip.
- Alternately, a non-sterile assistant may use the mouse to position the alignment point to the visible introducer tip and left click.
- The Introducer Tip Alignment Guide will change to the Introducer Tip Marker (red diamond) when the Confirm Button is pressed, see Figure 4-20.
- If after confirming alignment, the Operator desires a re-alignment, retract the Introducer fully and re-deploy to plan line.

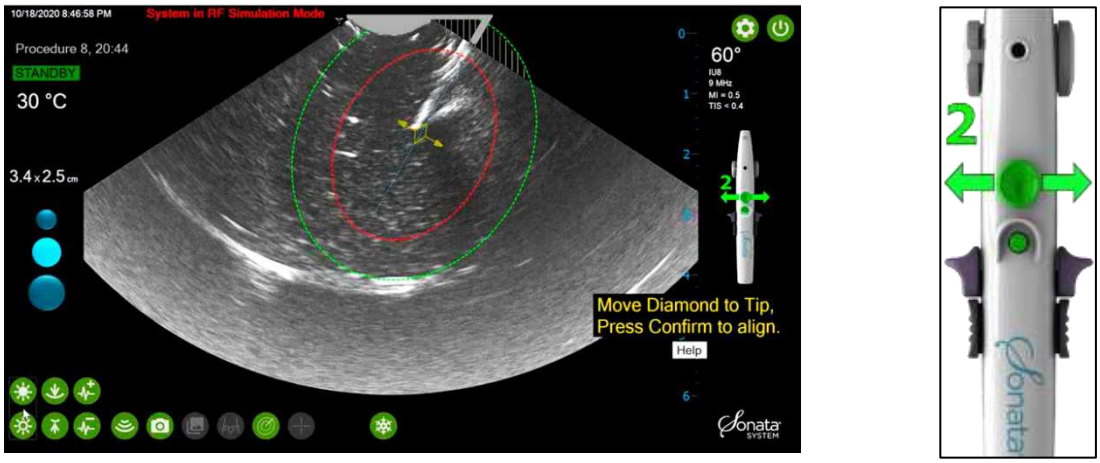


Figure 4-19. Press SMART Control side to side to Align SMART GUIDE to Introducer Tip Alignment Guide (yellow diamond).

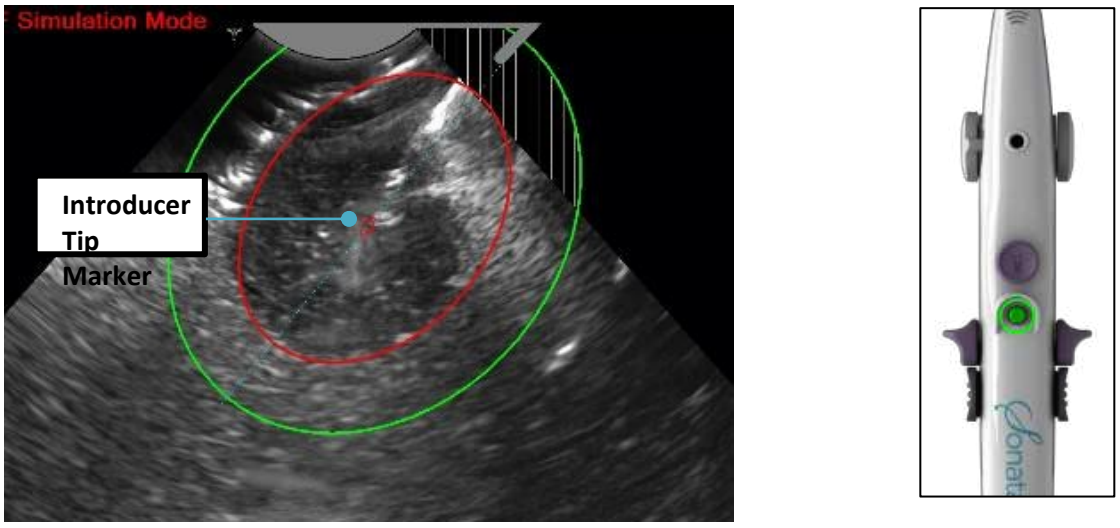


Figure 4-20. Press Confirm Button after aligning SMART Guide to Introducer Tip. The graphic changes to the Introducer Tip Marker (red diamond).

WARNINGS	
⚠	VISUALIZE THE INTRODUCER Deploy the Introducer carefully under observation of the ultrasound image. If the Introducer Tip is not visualized within a few millimeters of deployment, stop and retract the device for inspection outside the patient. An inability to visualize the Introducer may signify that the RFA Handpiece Tip and IUUS Probe Tip have become disengaged, or that there is a problem with the ultrasound image. Proceeding without visualization may result in uterine perforation or unintended RF ablation of abdominopelvic viscera.
⚠	ALIGN THE INTRODUCER TIP MARKER (YELLOW DIAMOND) TO INTRODUCER Ensure the Introducer Tip Marker is aligned to the actual Introducer Tip in the ultrasound image. Misalignment will result in inaccuracy of the location of the RF ablation, potentially increasing the risk of patient injury.
⚠	DO NOT EXCEED THE INTRODUCER PLAN LINE The Introducer should be advanced into the fibroid toward the Introducer Plan Line in a controlled manner. If the Introducer is advanced rapidly the sharp trochar tip may extend past the intended depth (Introducer Tip Plan Line) and create a risk of perforation of the serosa.

4.7 Perform First Safety Rotation

Once the Introducer has been advanced to the Introducer Plan Line, perform the first safety rotation to make sure the Thermal Safety Border (green outer ellipse) does not cross the serosal margin.

- Rotate the Sonata Treatment Device in both directions to verify that the Thermal Safety Border (green outer ellipse) does not cross the serosal margin in all adjacent visual planes, see Figure 4-21.
- Rotate far enough for visualization without forcing the Introducer out of the fibroid (45° in both directions will fully scan the entire view plane).

If the Thermal Safety Border (green outer ellipse) crosses the serosal margin in any view angle, choose one of the following options:

- Reduce ablation size by moving the SMART control sideways for a smaller ablation,
- Pull back on the Introducer Slider to bring the SMART Guide away from the serosa,
- Pull back on the entire Treatment Device to pull everything away from the serosa, or
- Retract the Introducer fully and reposition the SMART Guide, see Figure 4-22.

If adjustments to the SMART Guide position are made, perform safety rotation before continuing.

Once you have confirmed the Thermal Safety Border has not crossed the serosal margin, press the gray Confirm Button on the handpiece to proceed.

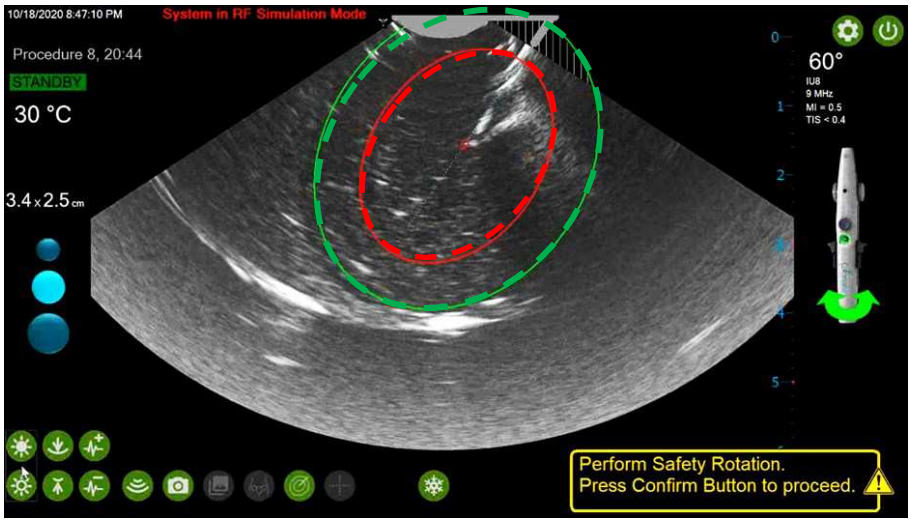


Figure 4-21. Example of SMART Guide aligned and Thermal Safety Border (green outer ellipse) within serosal margin.

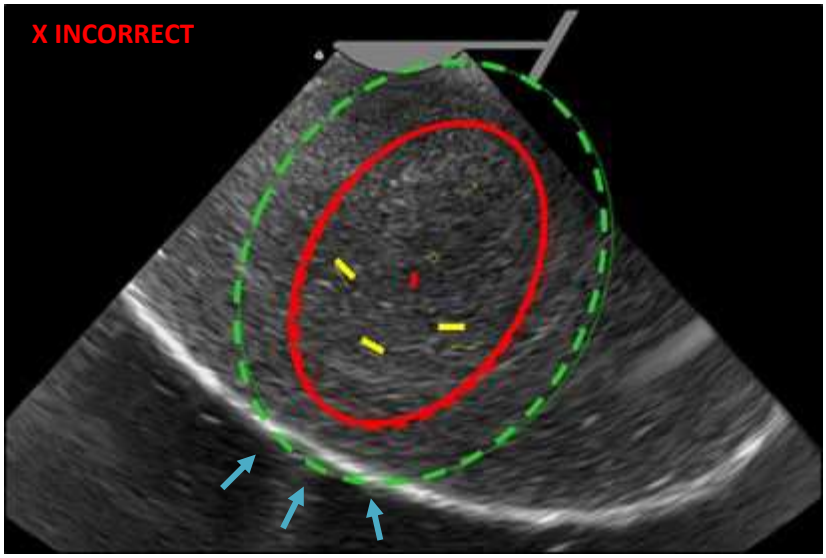


Figure 4-22. Example of Thermal Safety Border crossing serosa. Reposition and repeat safety rotations.

WARNINGS	
⚠	PERFORM FIRST SAFETY ROTATION The Thermal Safety Border (green outer ellipse) must remain contained within the uterine serosal margin during RF ablation. The first Safety Rotation helps ensure position prior to Needle Electrode deployment.
⚠	DO NOT EXCEED THE NEEDLE ELECTRODE PLAN LINES The Needle Electrodes should be deployed into the fibroid toward the Needle Electrode Plan Lines in a controlled manner. If the Needle Electrodes are advanced rapidly the sharp tips may extend past the intended depth (Needle Electrode Tip Plan Lines) and create a risk of perforation of the serosa.

4.8 Position Needle Electrodes to Needle Electrode Plan Lines

4.8.1 Advance Needle Electrodes to Needle Electrode Plan Lines

Confirm the Thermal Safety Border does not cross the serosal margin, see Section 4.7, before deploying the Needle Electrodes.

Stabilize the Sonata Treatment Device when deploying the Needle Electrodes into tissue to limit motion from the tissue. Tension on the tenaculum can provide counter-traction when deploying Needle Electrodes.

- The Needle Electrode Trackers, three yellow arrows, indicate the approximate depth of the Needle Electrode Tips and tracks the penetration into tissue.
- While observing the live image, push the Needle Electrode Sliders forward slowly to deploy the Needle Electrodes to the Needle Electrode Plan Lines, see Figure 4-23.
- Deploy slowly to prevent the Needle Electrodes from penetrating beyond the Needle Electrode Plan Lines.
- DO NOT deploy the Needle Electrodes beyond the Needle Electrode Plan Lines.

Release the Needle Electrode Sliders when the Needle Electrodes reach the depth of the Needle Electrode Plan Lines.

- The Plan Lines will change from yellow to red and an audible tone will sound.
- DO NOT continue to push the Needle Electrode Sliders beyond the Needle Electrode Plan Lines depth. If plan lines are exceeded, retract to line (see Section 4.8.2). If a larger ablation is desired, retract Needle Electrodes and Introducer fully and retarget.

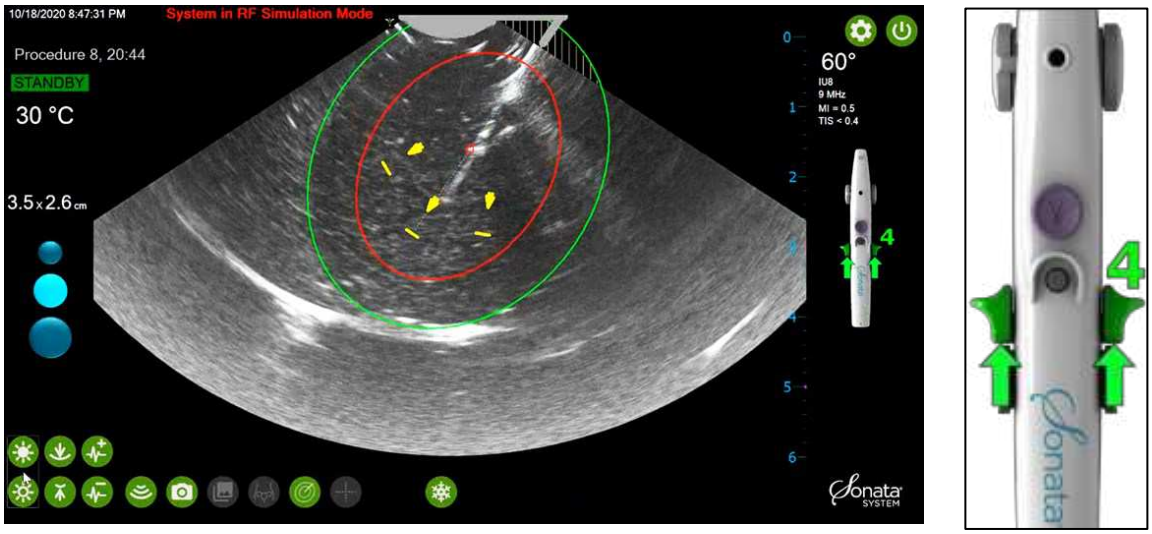


Figure 4-23. Deploy Needle Electrodes by advancing Needle Electrode Slides forward.

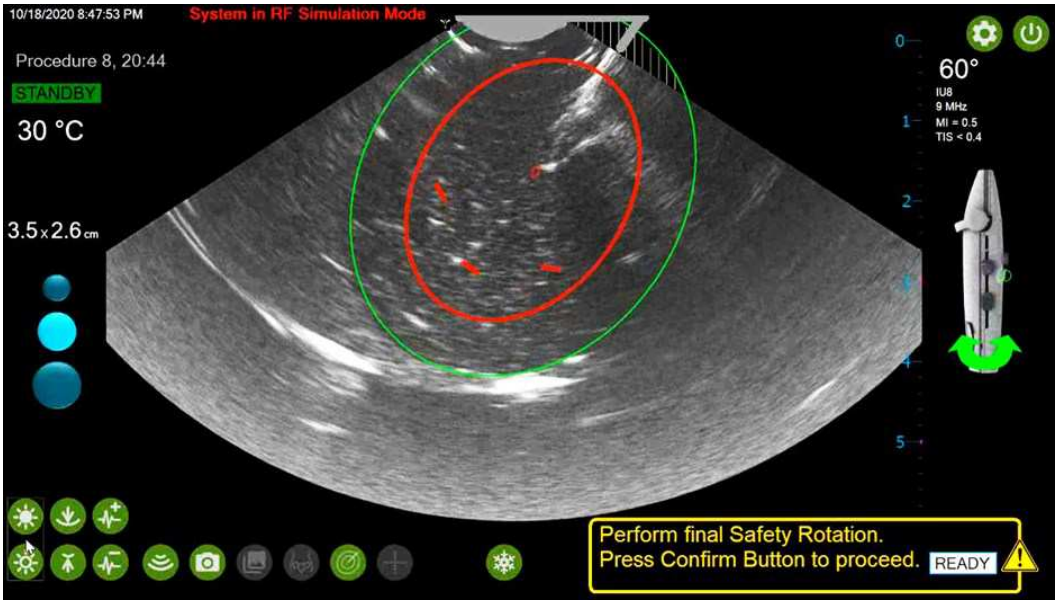


Figure 4-24. Needle Electrode Tip Markers turn red when Needle Electrodes are deployed to planned depth.

4.8.2 How to Retract Needle Electrodes to Needle Electrode Plan Lines

If the Needle Electrode Trackers are advanced beyond the Needle Electrode Plan Lines, see Figure 4-25:

- The three yellow Needle Electrode Trackers arrows will change direction,
- An auditory warning will be sounded, and
- The message “STOP Retract Needle Electrodes to Plan Lines” will be displayed.

Important: DO NOT deploy the Needle Electrode Trackers beyond the Needle Electrode Plan Lines.

To retract the Needle Electrodes and return to the Needle Electrode Plan Lines, see Figure 4-25.

- STOP advancing the Needle Electrodes immediately if the Needle Electrode Tips penetrate beyond the Needle Electrode Plan Lines.

Retract the Needle Electrode Trackers using the Needle Electrode Sliders and slide toward the Treatment Device cables. Slide Needle Electrodes until the Needle Electrode Trackers meet the Needle Electrode Plan Lines.

- The Needle Electrode Plan Lines will turn red when the appropriate depth is met with the Needle Electrode Tips.

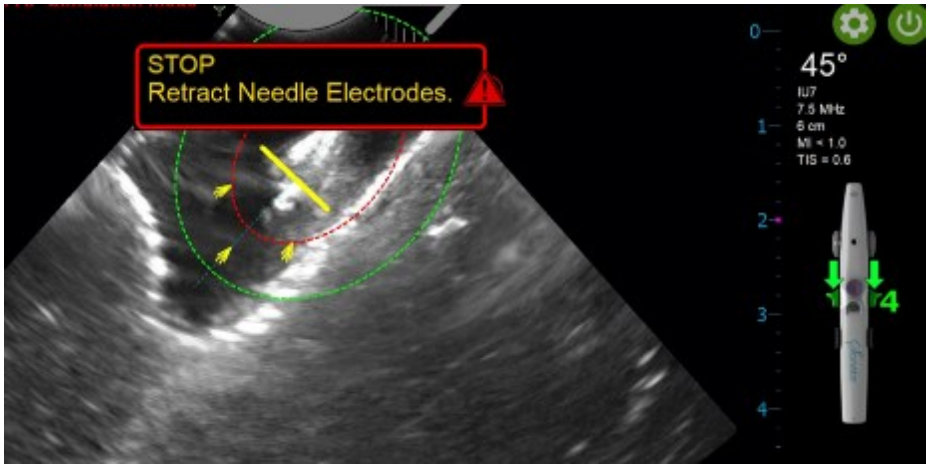


Figure 4-25. Example of Needle Electrode Tips advanced beyond the Needle Electrode Plan Lines. Retract Needle Electrode Tips to yellow Needle Electrode Plan Lines.

WARNINGS	
⚠	APPLYING FORWARD OR SIDE FORCES Forward or side forces during Needle Electrode deployment or retraction will increase the likelihood of Needle Electrode damage or even breakage.
⚠	MAINTAIN VISUALIZATION When deploying Introducer or Needle Electrodes into tissue, the Operator must have good visualization of the Introducer features and of the uterine serosal margin. If the image is lost during Needle Electrode deployment, before or during RF ablation, stop the treatment and resolve the imaging problem before restarting RF ablation.

CAUTION	
⚠	DEFORMED NEEDLE ELECTRODES If there is tactile or visual evidence of deformation of the Needle Electrodes upon deployment, the Operator should retract the device fully then deploy it in air to visually inspect the Needle Electrodes. If they are deformed, replace the RFA Handpiece before proceeding.

4.9 Perform Final Safety Rotation

Once the Needle Electrodes are deployed to the Needle Electrode Plan Lines, the screen will remind the Operator to perform the second, and final, safety rotation.

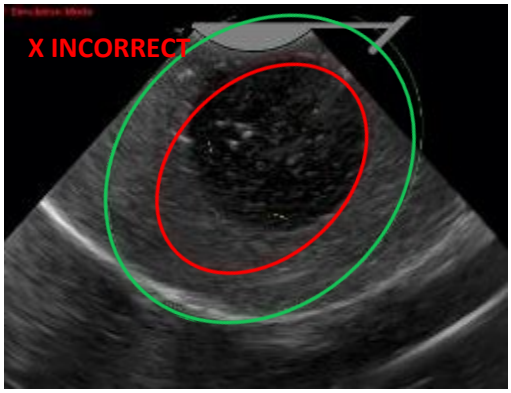
- Rotate the Sonata Treatment Device in both directions to verify that the Thermal Safety Border (green outer ellipse) is fully contained within the uterine serosal margin in all adjacent visual planes.
- Rotate far enough for visualization without forcing the Needle Electrodes out of the fibroid.

If the Thermal Safety Border (green outer ellipse) crosses the serosal margin, SMART Guide adjustments must be made to ensure proper placement before continuing. See Figure 4-26 for an example of correct and incorrect positions.

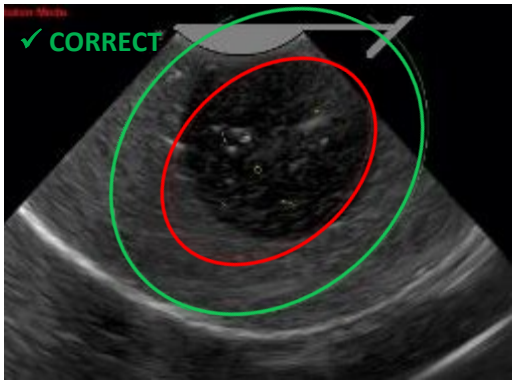
- Peripheral Zone Markers (pinstripes) will be displayed when the Thermal Safety Border (green outer ellipse) overlaps the area adjacent to the displayed ultrasound image. The Operator should be aware when the Thermal Safety Border (green outer ellipse) is in the Peripheral Zone and ensure it will not cross the serosa in this area, see Figure 4-27.
- If the Thermal Safety Border crosses the serosal margin slightly, a small reduction to the ablation size can be made in order to keep the Thermal Safety Border within the serosal margin by retracting the Needle Electrode Slider slightly to a smaller size. Repeat the Safety Rotation.

Upon completion of the final Safety Rotation and confirmation that the Thermal Safety Border (green outer ellipse) is within the serosa in all views, press the gray Confirm Button on the handpiece to proceed, see Figure 4-28.

Once confirmed, the RF Generator will be in READY Mode. Continue to Section 4.10 for how to activate the RF ablation. This must be activated by the Operator and does not happen automatically.



Example of incorrect position and unsafe to proceed.
Green outer ellipse extends past serosal margin.



Example of correct positon and safe to proceed.
Green outer ellipse inside serosal margin.

Figure 4-26. Thermal Safety Border (green outer ellipse) must be within serosal margins. Examples of incorrect (left) and correct (right) position.

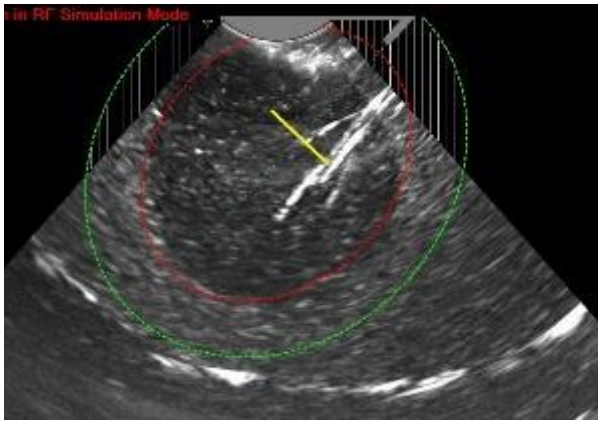


Figure 4-27. Peripheral Zone Marker (pin stripes) highlights areas outside the live ultrasound image that can be overlapped by the Thermal Safety Border (green outer ellipse) in some SMART Guide settings.

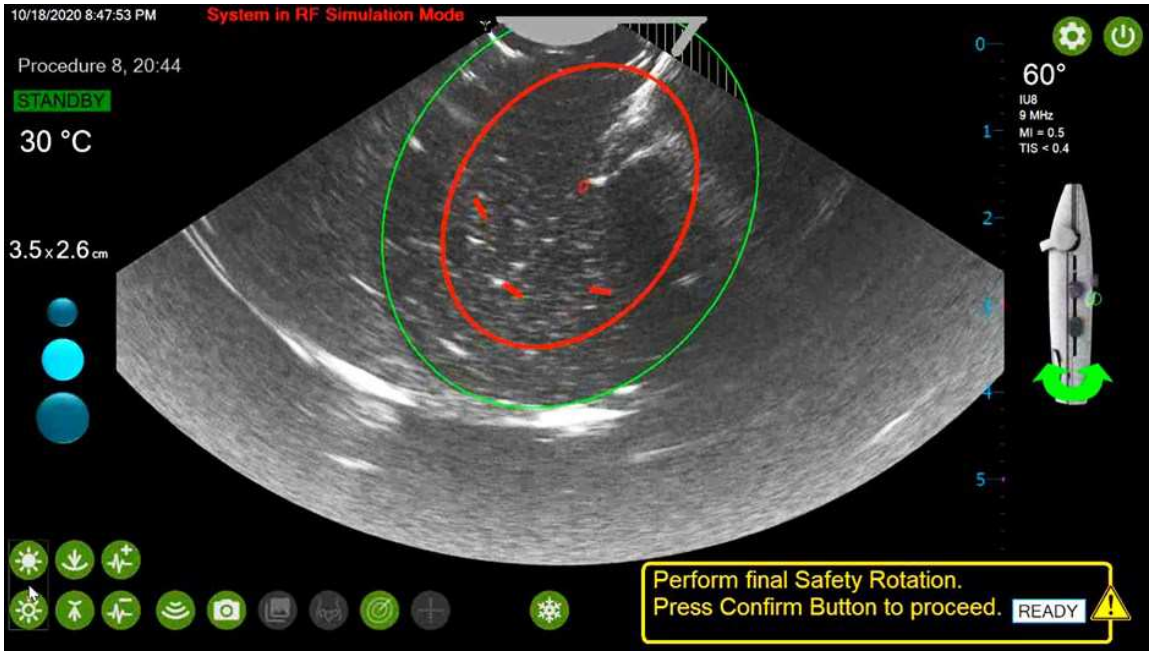


Figure 4-28. Perform Safety Rotation and press Confirm Button on Handpiece to set RF Generator to READY status.

WARNING	
⚠	PERFORM FINAL SAFETY ROTATION All tissue within the volume defined by the Thermal Safety Border (green outer ellipse) could be exposed to elevated temperatures. Verify before RF ablation, by a careful rotation of the Sonata Treatment Device in adjacent ultrasound scan planes, that the Thermal Safety Border is fully contained within the serosal margin. Failure to do so could expose critical structures not intended for RF ablation, including bowel, ureters, bladder, and uterine arteries. RF ablation of critical viscera could lead to patient injury or death.

4.10 Activate RF Ablation, Hold Device Steady, and Monitor RF Generator Status

4.10.1 Activate and Hold Steady

Once the system in in READY mode, the RF ablation does not begin until activated by stepping on the Footswitch or pressing the RF ON/OFF button on the front of the RF Generator, see Figure 4-29.

- To activate RF energy, momentarily step on the Footswitch one (1) time or press the RF ON/OFF button on the front of the RF Generator, see Figure 4-29. The RF Generator will then apply RF energy to the tissue through the Introducer and Needle Electrodes.
- DO NOT hold the Footswitch down or rest your foot on the Footswitch. This will result in the RF ablation being interrupted unintentionally.
- DO NOT move the Introducer or Needle Electrode sliders, nor the Articulation Lever during the RF Ablation process (SMART control is disabled).

During the RF ablation, hold the Sonata Treatment Device steady during the entire period of RF energy delivery so there is no movement relative to the tissue.

- If the patient moves or the Operator's hand position has changed, the Thermal Safety Border may be crossing over the serosal margin. Immediately stop the RF ablation, retract Needle Electrodes, retract Introducer, and retarget, see Figure 4-29.

If any irregularities arise, the system will warn the Operator and may prematurely terminate the RF ablation.

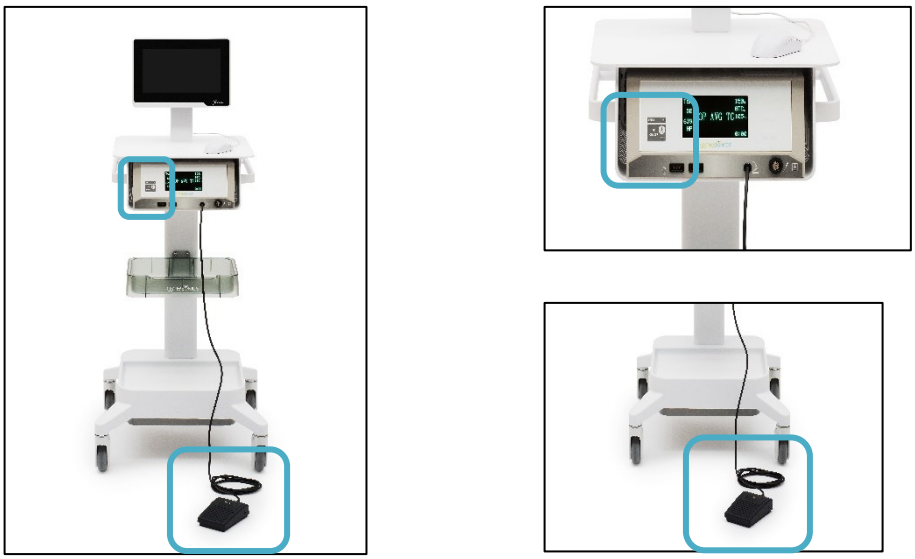


Figure 4-29. To manually stop RF energy, step on Footswitch or press RF Generator ON/OFF button.

4.10.2 RF Status

The status of the RF Generator is on the left side of the ultrasound display screen, see Figure 4-30. During the ablation (Active Status), the parameters being displayed include temperature, Ablation Time Remaining, and Ablation Size.

- RF ablation is initiated when the Footswitch is stepped on or the RF ON/OFF button on the front of the RF Generator is pressed. A beeping tone and a flashing blue light on the RF Generator indicate that the RF energy is being delivered. The RF Generator status on the screen will display ACTIVE and be blue, see Figure 4-30.
- The RF Generator automatically regulates the rate and amount of energy delivered.

When activated, the RF Generator takes 1 to 4 minutes to “ramp up” to treatment temperature. During this period, the temperature of the Needle Electrodes rises from body temperature to the target temperature of 221°F (105°C).

- When the temperature of the Needle Electrodes reaches the target temperature, the ablation time will begin counting down and the status bar will fill with green as the RF ablation proceeds.
- The RF Generator will maintain the RF ablation temperature for the time indicated. Depending on the size of the ablation, RF energy delivery times range from 1.5 to 7 minutes.

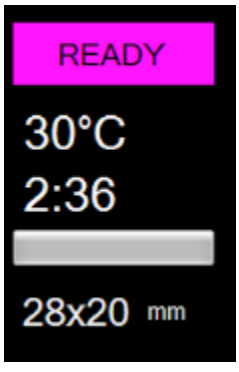
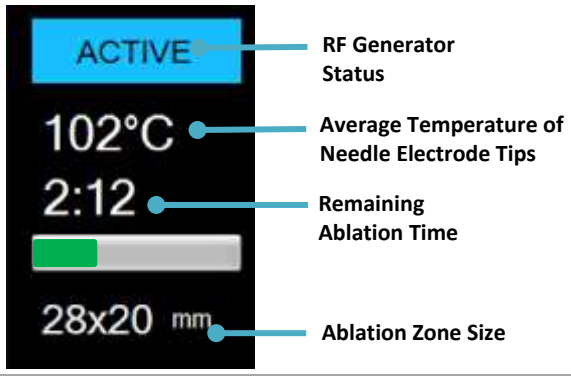
RF GENERATOR STATUS DISPLAYED ON THE UPPER-LEFT SIDE OF IMAGING SCREEN		
Prior to Needle Electrode Deployment:	**After Needle Electrode Deployment, Safety Check, and Click on Confirm Button:**	**After RF Ablation initiated:**
RF Generator is in STANDBY for the Operator to finalize the deployment of Needle Electrodes.	The system is READY to start RF ablation when the Operator steps on the Footswitch or presses RF ON/OFF button.	RF Ablation is ACTIVE and will complete in time indicated.
		

Figure 4-30 RF Generator status display.

4.10.3 RF Completion

The RF Generator will turn off automatically upon completion of the RF ablation.

- To stop the RF ablation at any point, step on the Footswitch or press the RF ON/OFF button on the RF Generator, see Figure 4-29.
- DO NOT attempt to remove the device when the RF ablation is active, see Section 4.10.2.
- DO NOT remove while Needle Electrodes or Introducer are deployed, see Section 4.10.2.
- DO NOT remove before returning the Articulating Tip to 0°, see Section 4.10.2.

WARNINGS	
	KEEP THE DEVICE STEADY DURING RF ABLATION Hold the Sonata Treatment Device steady during ablation. Movement during RF ablation could change the ablation position relative to the targeted tissue. If the Thermal Safety Border position within the serosal margin of the uterus has been altered because of possible movement or another factor, the Operator should stop the RF ablation.
	OUTGASSING DURING RF ABLATION During RF ablation, imaging may be obscured due to outgassing from heated tissue. Motion between device and tissue MUST NOT occur during RF ablation.
	HYPERECHOIC REGIONS OUTSIDE THE THERMAL SAFETY BORDER A hyperechoic region in the intrauterine ultrasound image may indicate an area in which RF ablation is occurring. If a hyperechoic region is observed outside of the Thermal Safety Border, stop RF ablation.

4.10.4 RF Early Termination and Restart Treatment

If an ablation must be terminated or stopped for any reason, the system will present the Operator with a choice to “restart” the ablation or to remove the device and move on to another fibroid or finish the procedure by retracting the Needle Electrodes and Introducer.

- Selecting Confirm to “restart” may be done ONLY if the user has NOT moved the device relative to the anatomy at all.
- A safety rotation should be done before restarting the ablation.
- A restart will initiate a new ablation with full ablation duration based on planned ablation size.

When restarting ablations in the same location, continue to use the SMART Guide in the same method as ablating untreated tissue. The dimensions of the Thermal Safety Border apply even if the ablation is in the same location.

4.10.5 RF Early Termination for Large Fibroids and Restarting Treatment

In some cases involving fibroids with diameter larger than 4 cm, tissue volume and characteristics may prevent the tissue from reaching target temperature within the 4 minute ramp time limit. If the system

determines that temperature is unlikely to reach target prior to time-out, a message will be displayed advising the user to retarget to a smaller ablation size. If this message appears, stop RF ablation and retract the needle electrodes to a smaller size. Repeat safety check and restart the treatment. The original ablation size may be attempted again after the smaller ablation is complete.

4.11 Perform Multiple Ablations, Perform Multiple Treatments, or Retract Sonata Treatment Device

A single ablation may not provide a complete treatment if multiple or large fibroids are present. Additional ablations may be performed in the same fibroid or in multiple fibroids during the same treatment session. Continue to use the SMART Guide in the same manner, always keeping the Thermal Safety Border within the inner portion of the serosal margin, see Section 4.4.

After completing an ablation, there are several options for the next step in the procedure. The options are:

- Perform an additional ablation on the already treated fibroid,
- Plan and perform an ablation on a different fibroid, or
- Finish the procedure by removing the Treatment Device from the patient.

The sequence of steps for retraction depends on which option is chosen.

4.11.1 Fully Retract Needle Electrodes

When an RF ablation has ended, three yellow arrows will be displayed on the ultrasound image to retract the Needle Electrodes. The Treatment Device illustration on the right side of the Ultrasound Display Screen will have green arrows indicating the direction the Needle Electrode Sliders should be moved to retract the Needle Electrodes.

- Retract the Needle Electrodes until the Needle Electrode Sliders are firmly set against the Introducer Sliders, see Figure 4-31.

DO NOT move the Sonata Treatment Device forward or sideways. Doing so could cause the Needle Electrodes to be bound against the Introducer Tip and bend or even break off.

TIP: When retracting the Needle Electrodes, be sure no forward or sideways force is applied to the Treatment Device. Apply slight traction on the Treatment Device p for smooth retraction.

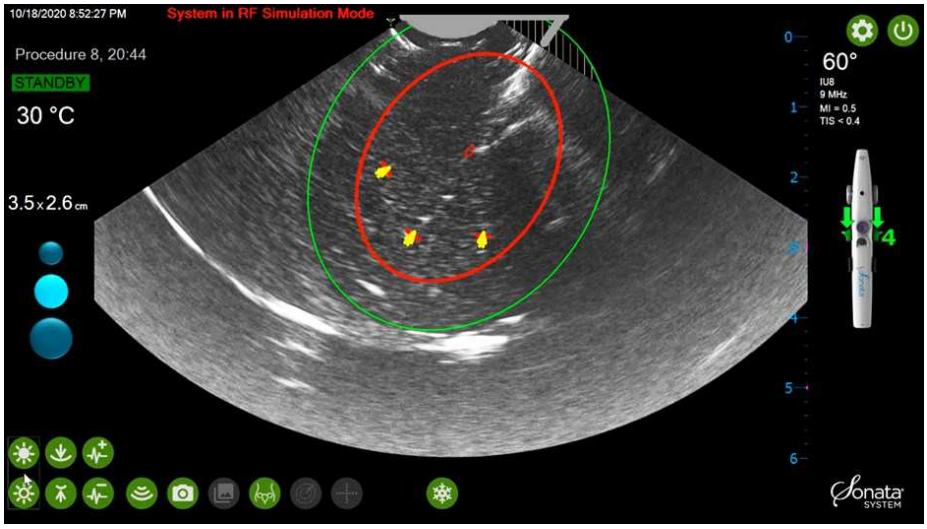


Figure 4-31. Yellow arrows will prompt the Operator retract Needle Electrodes by sliding the Needle Electrode Sliders back to the Introducer Sliders.

WARNING	
⚠	FORCES DURING RETRACTION When retracting the Needle Electrodes, DO NOT move the Sonata Treatment Device forward or sideways. Doing so could cause the Needle Electrodes to be bound against the Introducer Tip and bend or even break off. Hold device in place when retracting to make sure Needle Electrodes retract properly.

4.11.2 Fully Retract Introducer

After the Needle Electrodes are retracted the Introducer Tip Tracker will be displayed pointed towards the direction of retraction. The Treatment Device illustration on the right side of the Ultrasound Display Screen will have green arrows indicating the direction the Introducer Sliders should be moved to retract the Introducer, see Figure 4-32.

- Depress the Introducer Sliders.
- Retract the Introducer completely by sliding the Introducer Sliders towards the Treatment Device Cables.

The Introducer Tip Tracker will display the approximate position of the Introducer Tip as it is retracted.

Tip: If the Introducer Sliders will not depress, be sure to fully retract the Needle Electrode Sliders before retracting the Introducer.

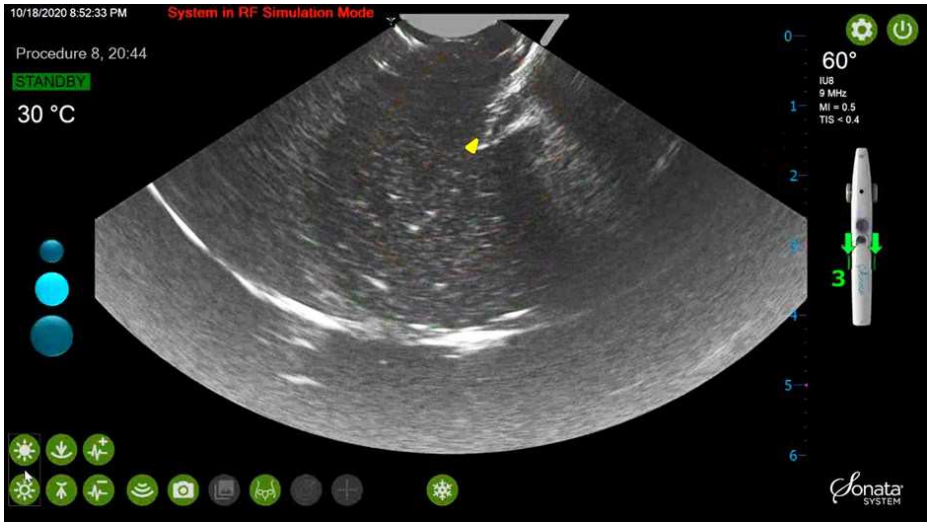


Figure 4-32. Depress Introducer Slider locks to retract Introducer.

4.11.3 Return IUUS Probe Tip to 0°

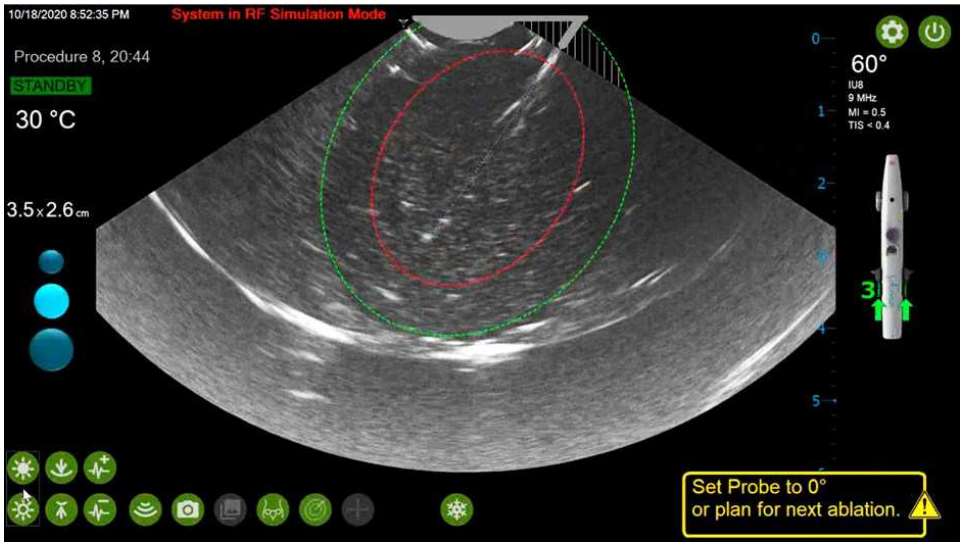


Figure 4-33. Depress Articulation Lever and push forward to return IUUS Probe Tip to 0°.

4.11.4 Additional Ablations on the Same Fibroid

To perform an additional ablation on the same fibroid, the Needle Electrodes and Introducer must be retracted, and the SMART Guide positioned, see Figure 4-34. If the purpose of the additional ablation is to cover more fibroid, move the device so that the targeting is of a part of the fibroid that appears on screen like the untreated fibroid (generally, darker than the treated tissue). Treated tissue will take on a lighter appearance on imaging due to presence of gasses from elevated temperature.

- Fully retract Needle Electrodes (control 4) all the way by sliding the Needle Electrode Sliders towards the Treatment Device Cables.

- Fully retract Introducer (control 3) all the way by sliding the Introducer Sliders towards the Treatment Device Cables.
- Begin planning for the next ablation by positioning the SMART Guide with the SMART Control.

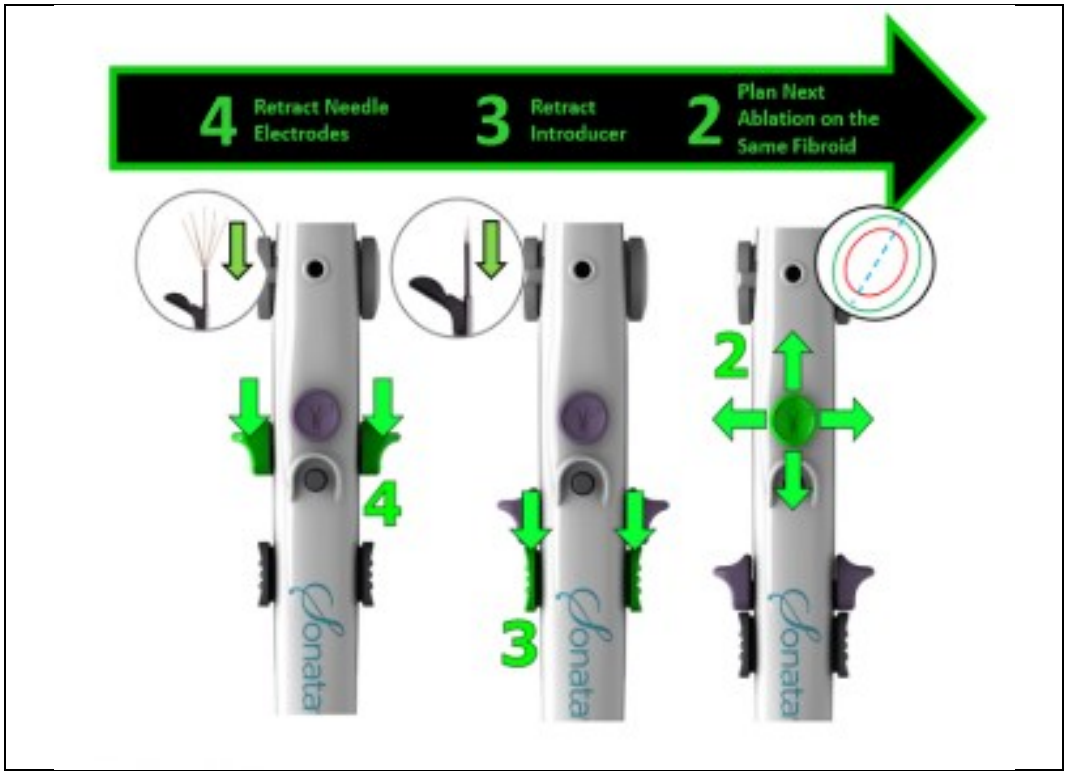


Figure 4-34. Retract Needle Electrodes and Introducer when performing an additional ablation on the same fibroid.

4.11.5 Retract to Remove the Treatment Device or Plan and Perform an Ablation on a Different Fibroid

To remove the Treatment Device or target an additional fibroid the Needle Electrodes and Introducer must be retracted and the IUUS Probe Tip returned to 0°, see Figure 4-35.

- Fully retract Needle Electrodes (control 4) all the way by sliding the Needle Electrode Sliders towards the Treatment Device Cables, see Section 4.11.1.
- Fully retract Introducer (control 3) completely by sliding the Introducer Sliders towards the Treatment Device Cables, see Section 4.11.2.
- Articulate IUUS Probe Tip back to 0° by using the Articulation Lever (control 1). Confirm on the screen that the angle is returned to 0°, see Section 4.11.3.
- Remove the Treatment Device from the patient or begin planning ablation for a different fibroid using the SMART Control (control 2).

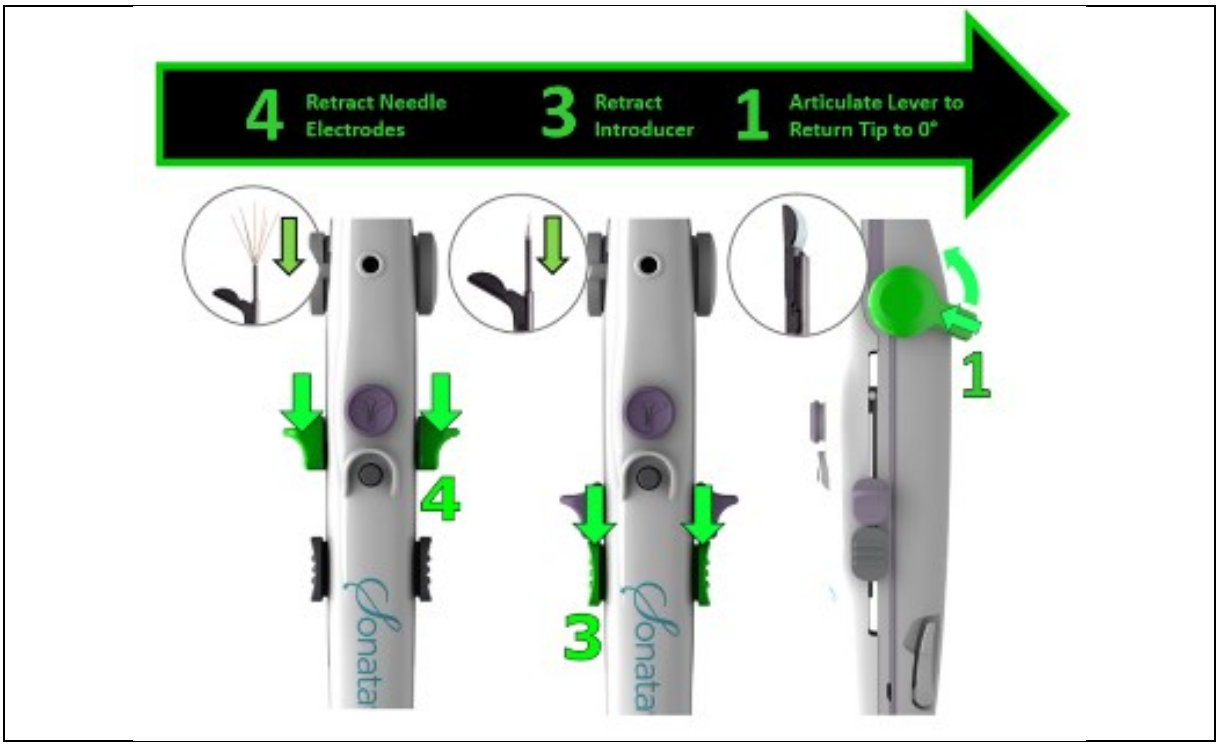


Figure 4-35. Fully Retract and return to 0° when removing Treatment Device from patient or beginning an ablation on an additional fibroid.

CAUTION	
⚠	RETRACT NEEDLE ELECTRODES AND INTRODUCER BEFORE REMOVAL DO NOT attempt to remove the device until Needle Electrodes and Introducer have been retracted and Articulating Tip has been set at 0°. The IUUS Tip must be at 0° before the Treatment Device is removed.

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Chapter 5 Post-Procedure Instructions

5.1 Disconnect and Remove Dispersive Electrodes

At the end of the procedure, once the Treatment Device has been removed from the patient:

- Disconnect the Dispersive Electrode cables from the front of the RF Generator, see Figure 5-1.

Figure 5-1. Disconnect Dispersive Electrodes Cables from RF Generator.

- Gently peel the Dispersive Electrodes from the patient, see Figure 5-2.

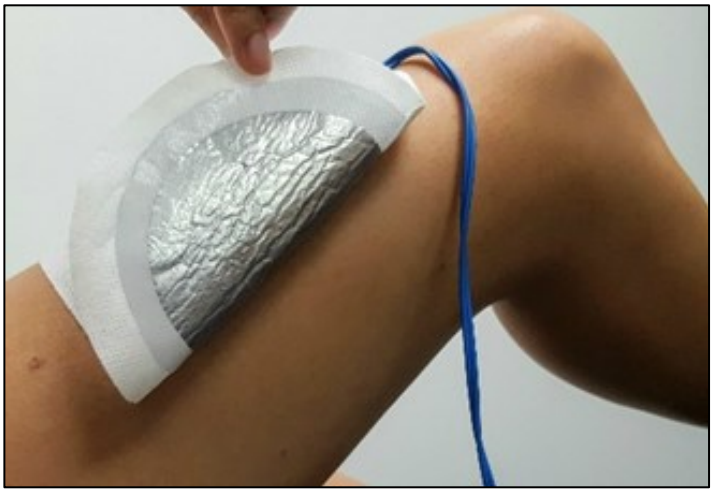


Figure 5-2. Remove Dispersive Electrodes from patient and inspect skin.

- Inspect the skin surface for evidence of thermal injury.
- Dispose of the Dispersive Electrodes.

DO NOT attempt to reuse Dispersive Electrodes.

CAUTION	
⚠	DISPERSIVE ELECTRODE ARE SINGLE-USE DO NOT attempt to reuse the Dispersive Electrodes. Doing so could degrade the conductive properties of the adhesive gel. Dispose of them in a biohazard container following the procedure.

5.2 Disconnect Sonata Treatment Device Components

Disconnect the RFA Handpiece from the front of the RF Generator (bottom-right side), see Figure 5-3.

Figure 5-3. Disconnect RFA Handpiece.

Unlock the latch and disconnect the IUUS Probe from the right side of the SMART Tablet, see Figure 5-4.

Figure 5-4. Disconnect IUUS Probe from SMART Tablet.

When the IUUS Probe is disconnected, the system will display a dialog and ask the Operator to “Keep” or “Discard” the recorded video. Refer to Section 6.8 for details on managing procedure data.

- Select “Keep” to save the video. The video will be saved to the current procedure data file.
- Select “Discard” to permanently delete the video.

Figure 5-5. Video “Keep” or “Discard” window will be displayed when IUUS Probe it disconnected.

5.3 Shut Down System

Power OFF the SMART Tablet with the power icon on the upper right-hand of the ultrasound display screen, see Figure 5-6.

- Power OFF the RF Generator with the switch on the back of the System Cart before unplugging.

Figure 5-6. Power OFF with software.

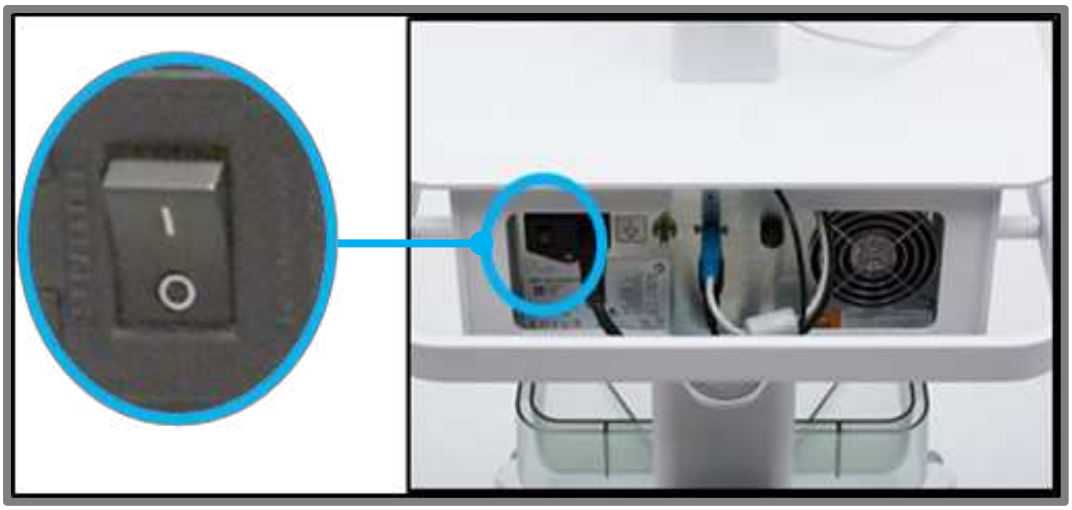


Figure 5-7. Power OFF RF Generator.

5.4 Disassemble Sonata Treatment Device – Separate RFA Handpiece from the IUUS Probe

Separate the RFA Handpiece from the IUUS Probe by holding the device with both hands and lifting up the release latches simultaneously, see Figure 5-8.

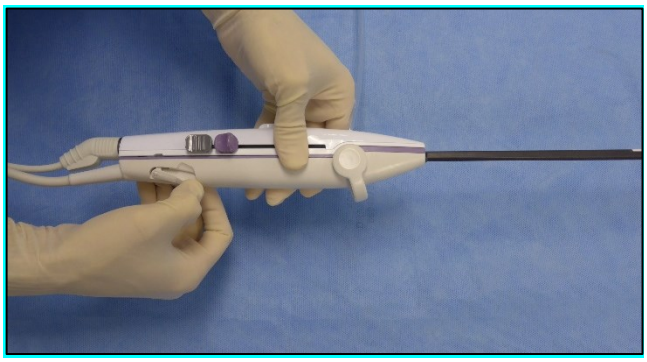


Figure 5-8. Lift Release Latches simultaneously to separate RFA Handpiece from IUUS Probe.

Slide the RFA Handpiece forward to dislodge the tips and separate, see Figure 5-9.

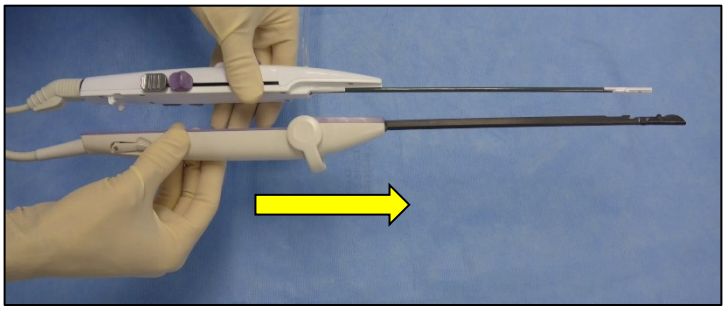


Figure 5-9. Slide RFA Handpiece forward to separate from IUUS Probe.

Disconnect the RFA Handpiece from the RFA Handpiece Cable. Dispose of the RFA Handpiece per proper disposal procedures for biomedical sharps. The Needle Electrodes should be fully retracted when disposing, as instructed in Section 4.11.1.

Perform point-of-use pre-cleaning of the IUUS Probe and RFA Handpiece Cable and prepare them for reprocessing, as instructed in Section 5.5.

WARNINGS	
	RETRACT SHARP SURFACES BEFORE DISPOSAL Upon disposal, be sure to fully retract the Needle Electrodes and Introducer as they present a sharp hazard for staff.
	DISPOSE OF RFA HANDPIECE AS BIOMEDICAL SHARP WASTE RFA Handpiece is single use and should be disposed of after use as a biomedical sharp.

5.5 IUUS Probe and RFA Handpiece Cable Point-of-Use Pre-Cleaning

5.5.1 IUUS Probe Pre-Cleaning Overview

A Point-of-Use pre-cleaning is conducted immediately after using the IUUS Probe. The IUUS Probe should also be prepared and transferred to reprocessing. Reprocessing should be performed within 24 hours unless the IUUS Probe is packaged in the IUUS Probe Return Kit.

For pre-cleaning of the IUUS Probe, follow the process outlined in the table below.

IUUS PROBE POINT OF USE PRE-CLEANING OVERVIEW	SEE SECTION
Pre-Clean IUUS Probe to Remove Visible Biological Material from IUUS Probe and Cable	Section 5.5.2
Prepare the IUUS Probe for Transfer to Reprocessing	Section 5.5.4

5.5.2 Materials Needed for Pre-Cleaning the IUUS Probe

- IUUS Probe (separated from RFA Handpiece and unplugged from console, see Section 5.4),
- Enzymatic detergent spray or water, and
- Towel or sponge.

WARNINGS	
⚠	WEAR PERSONAL PROTECTIVE EQUIPMENT Wear protective equipment including gloves and follow procedures for handling soiled equipment.
⚠	DO NOT WET OPEN CONNECTOR When wiping down or cleaning, DO NOT wet the open end of the electronic connector. This may lead to device damage.
⚠	PROECT THE IUUS PROBE ARTICULATING TIP When transporting, handling, and reprocessing, take measures to protect the Transducer Tip from damage.

5.5.3 Pre-Clean IUUS Probe to Remove Visible Soil from IUUS Probe

Set the IUUS Probe Articulating Tip to a 0° angle.

Use enzymatic spray or water and a sponge or towel to remove visible soil from the IUUS Probe including the cable.

- Follow manufacturer's instructions when using enzymatic detergent and solutions.
- Protect the connector opening from liquid contact.
- DO NOT use strong force on the Imaging Surface or Articulating Tip. Apply the minimum force needed to avoid damaging surfaces.

Dispose of cloth or sponge after use in a biohazard container.

Prepare the IUUS Probe for transfer to the reprocessing area, see Section 0.

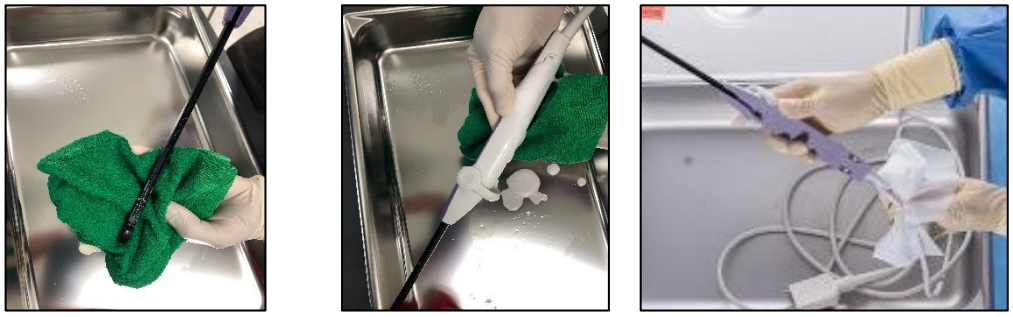
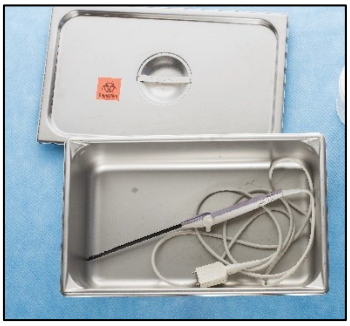


Figure 5-10. Use enzymatic spray or water and a sponge or towel to remove visible soil.

5.5.4 Prepare the IUUS Probe for Transfer to Reprocessing

Ensure the Probe Tip is set to 0°.

Place the IUUS Probe into a container that has a lid, is puncture proof, and is labeled as containing biohazard. Make sure the IUUS Probe Tip is protected during transport to the reprocessing area, see Figure 5-11.



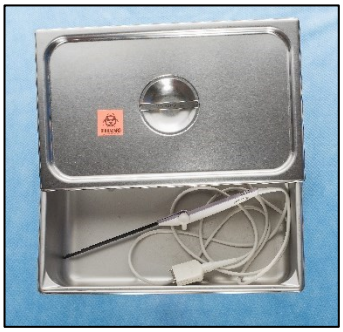


Figure 5-11. Utilize leak proof container with a lid to transport the IUUS Probe to Central Processing.

Transfer to the reprocessing area as soon as possible.

5.6 RFA Handpiece Cable Point-of-Use Pre-Cleaning

5.6.1 RFA Handpiece Cable Pre-Cleaning Overview

A Point-of-Use pre-cleaning is conducted immediately after using the RFA Handpiece Cable. The RFA Handpiece Cable should also be prepared and transferred to reprocessing. Reprocessing should be performed within 24 hours.

For pre-cleaning of the RFA Handpiece Cable, follow the process outlined below:

- Use gauze or surgical towel wetted with water. Use of a pre-moistened, low alcohol surface wipe appropriate for medical instruments is also acceptable.
- Follow manufacturer instructions for use.
- Wipe from one end of the connector to the other and visually inspect for remaining contaminants. If blood or tissue is on the connector openings, remove to prevent drying of contaminants on the connectors. Low pressure liquid directed at the connectors is acceptable.
- Place the Reusable RFA Handpiece Cable into a container that has a lid, is puncture proof, and is labeled as containing biohazard. Use of a damp cloth to prevent surface drying of remaining contaminants is acceptable.

Refer to the reprocessing instructions LS 06305 (REF-008) for reprocessing instructions.

5.7 Clean the System Equipment with Low Alcohol Disinfectant

Clean the following parts and exterior surfaces of the system with medical grade low alcohol disinfectant, particularly any surfaces that were contaminated, including:

- RF Generator,
- System Cart,
- Footswitch,

- Mouse, and
- Cables.

Clean the SMART Tablet.

- Blow dust off the screen with compressed air.

Slightly dampen a soft, clean cloth with isopropyl alcohol or 75% ethanol, and gently wipe the screen with the cloth.

Figure 5-12. Clean parts and external surfaces with a medical grade low alcohol disinfectant.

CAUTIONS	
⚠	DO NOT SPRAY LIQUIDS DIRECTLY INTO EQUIPMENT OPENINGS DO NOT spray cleaning solution or water into sockets or ports of any piece of equipment. Doing so will cause damage.
⚠	CLEAN AND DISINFECT FOOTSWITCH POST PROCEDURE The Footswitch will be placed close to the Operator's feet during setup. It will be in a location where fluid, including blood, may make contact. Carefully disinfect and clean the Footswitch and cable with low alcohol, medical grade disinfectant between uses to prevent contamination.

5.8 Store System

Wrap up the power cord and stow the Footswitch for System Cart transport and storage.

Unlock all wheels before transport, see Figure 3-1.

Chapter 6 Software Features

6.1 Graphical Guidance Software (GGS) Overview

The user interface software installed on the SMART Tablet can be operated by the mouse, by the SMART Tablet Touchscreen, or SMART Control and Confirm Button on the RFA Handpiece (when the IUUS tip is at an angle of 0°).

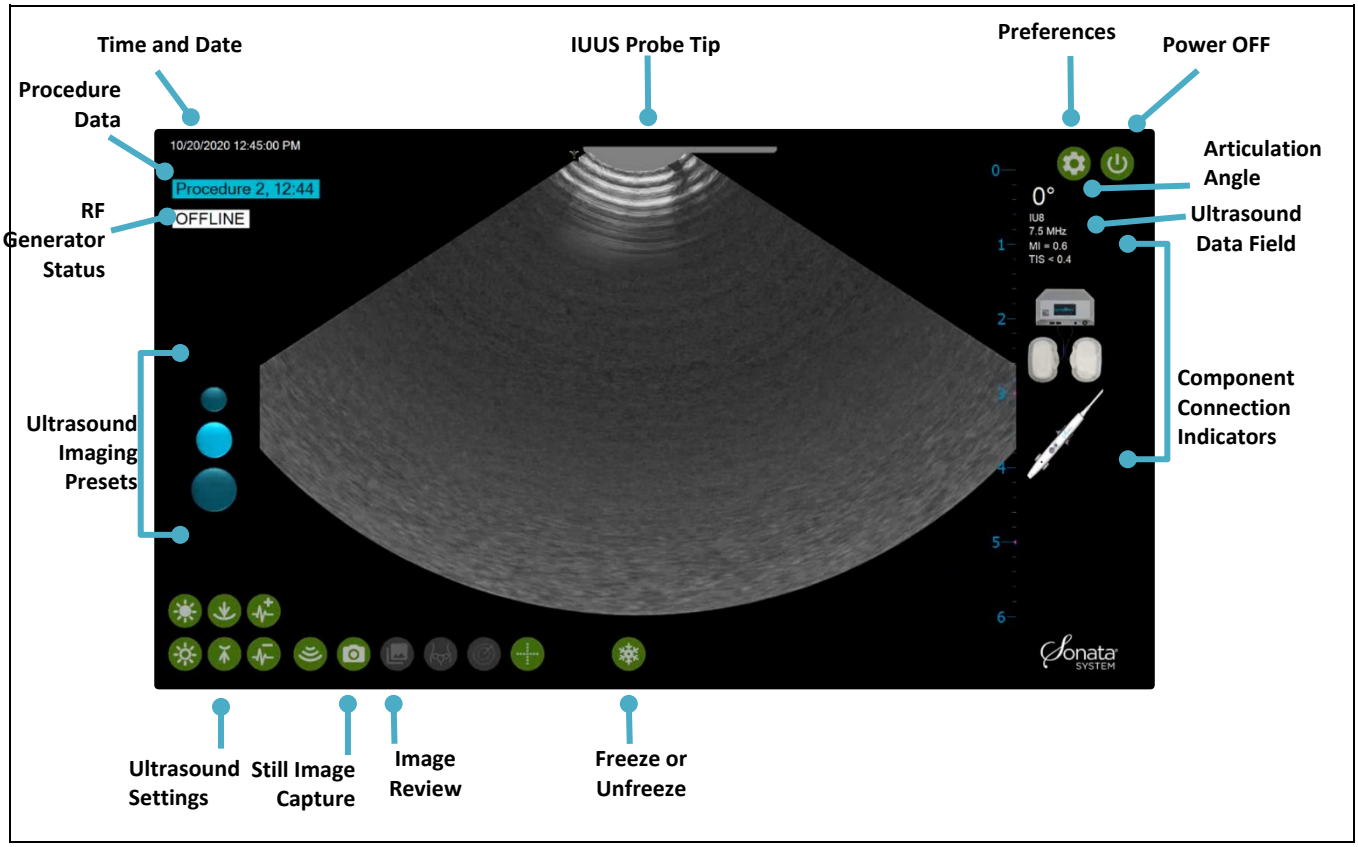
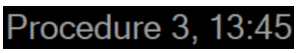


Figure 6-1. GGS user interface screen components.

ICON/IMAGE	LABEL	DESCRIPTION
	Procedure Data	This button shows the procedure number for that day (Procedure 3) and the beginning time of the procedure. Click or press with finger on this button to start a new procedure.
	RF Status	Indicates the status of RF Generator: Offline, Standby, Ready, or Active. See Section 4.10 for more information.
	Still Image Capture	Click to take an image of what is displayed on the screen.
	Image Review	Click to display thumbnail images that have been captured. As images are taken, the number of images will be communicated within the icon.
	Freeze/Unfreeze	Click to Freeze or Unfreeze image. Freeze enables measurement features.
	Preferences	Click to display the Preferences window to add or remove icons to the home page, manage users, and select language.
	Power OFF	Click to power off the SMART Tablet.
	Gain	Click to increase and decrease ultrasound gain settings.
	**D**epth	Click to increase and decrease depth in the ultrasound image.
	**F**requency	Click to increase and decrease frequency of the ultrasound beam.
	**A**blations Report	Click to display the ablations report which can be used to create an image-based map.
	Articulation Angle, Ultrasound Data Fields	Indicates the ultrasound parameters being utilized: • Articulation angle, • Probe model number, • Frequency, • Depth, • Mechanical Index and • Thermal Index.

ICON/IMAGE	LABEL	DESCRIPTION
	Component Connection Indicators	Indicates the connection status of RF Generator, Dispersive Electrodes, and RFA Handpiece. • Blinks when each component is not connected properly. • Disappears when all connections are complete.

6.2 Procedure Data

Procedure data information is captured as part of the procedure's digital file.

6.2.1 Start a New Procedure

To begin a new procedure without powering off the system:

- Click on the previous procedure number on the ultrasound display screen.
- Click the "New Procedure" button, see Figure 6-1.

6.2.2 Ablations Report

The Ablations Report collects the following information per procedure: number of ablations, depth and size, treatment time, and indication of completion. At the end of treatment, the user may specify location of ablation(s).

To access the Ablations Report, click on the Ablations Report button on the main screen: 

6.2.3 Manage Procedure Data

The "Manage Procedure Data" button shown in Figure 6-1 allows the Operator to copy or delete patient image files, verify hard drive space, and delete image files, see Section 6.8.

6.3 Measurements

6.3.1 Make a Measurement

Six (6) linear measurements are available on a frozen image.

- Click the Freeze icon  on the SMART Tablet to freeze the image.

Place cursor at the starting location for the measurement and double-click to set. Alternatively, after positioning the cursor at the starting location, right click to start the measurement.

- An active cursor is displayed. Position the active cursor to the end location of the desired measurement.

Click to set the cursor location.

- The measurement is displayed in the lower left corner of the ultrasound display screen.

Repeat to take up to six (6) measurements.

6.3.2 Edit a Measurement

Select the measurement to be adjusted by clicking on either marker of the measurement.

- Drag the marker to the desired location.
- The new measurement value is displayed.

6.3.3 Delete Measurement

Select the measurement to be deleted.

- Right-click and select “Delete selected measurement.”

To remove all measurements, unfreeze the image by clicking or tapping the Freeze icon .

6.4 Annotation

Text can be added and placed on the ultrasound image using the right-click menu, see Figure 6-2.

- Right-click on the mouse to display menu.
- Choose “Add new text.”
- Type text to be displayed.
- Select text and move to desired location.

To delete selected text or all text annotations:

- Select the text to be deleted.
- Right-click the mouse to display the menu.
- Choose “Delete selected text” or “Delete all text,” see Figure 6-2, depending on what you want to delete, and use the right-click menu.

Figure 6-2. Right-click menu displaying annotation options.

6.5 Preferences

The “Preferences” window allows for customization of the Sonata System. Additional controls can be chosen to be added to the bottom left side of the ultrasound display screen. When an item on the list is selected, it will be displayed and available for selection from the ultrasound display screen. Once selected, the control will be displayed until the Sonata System is rebooted.

- Click on the Preferences icon in the upper right-hand corner of the ultrasound display screen to display the Preferences menu, see Figure 6-3.

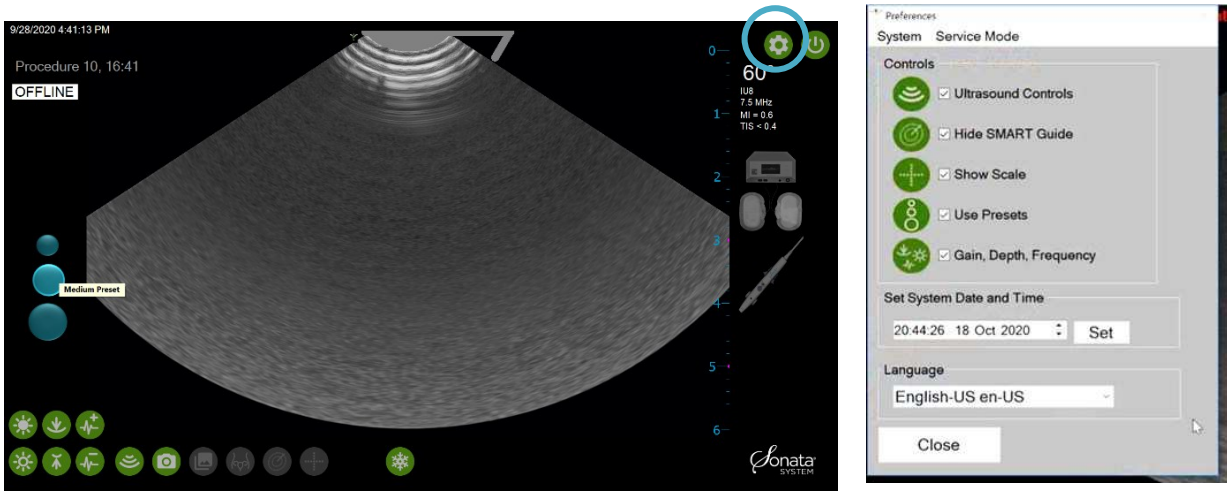


Figure 6-3. Customization is available through the Preferences window.

6.5.1 Ultrasound Controls

The Sonata System is delivered with factory default ultrasound parameters. To manipulate an individual ultrasound parameter, or modify a preset, select Ultrasound Controls. The “Ultrasound Control” icon will be available on the ultrasound imaging display. The “Ultrasound Controls” icon will remain on the ultrasound display screen until the Operator clicks or taps the check next to “Ultrasound Controls” on the Preferences window. In addition, the system allows the user to manipulate Gain, Depth, and Frequency, using the appropriate ultrasound controls on the main screen.

- Click on the Preferences icon to display the Preferences window.
- Select Ultrasound Controls, see Figure 6-4. The Ultrasound Controls icon will be displayed on the bottom left of the ultrasound display screen.
- Click the Ultrasound Controls icon to display the Ultrasound Parameters window, see Figure 6-4.

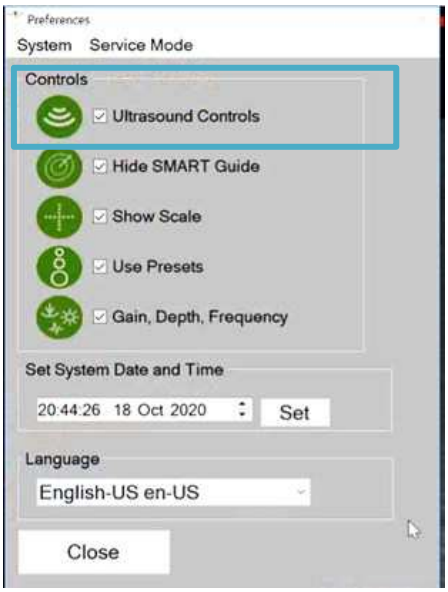


Figure 6-4. Preferences window with Ultrasound Controls selected.

6.5.2 Individual Ultrasound Parameters

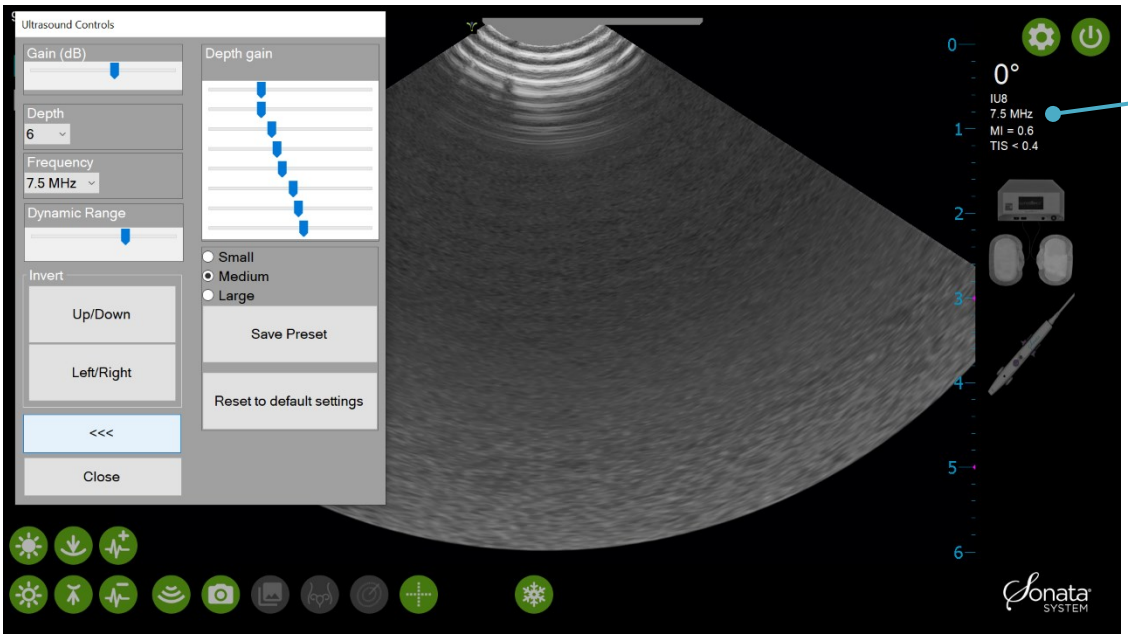


Figure 6-5. Ultrasound Controls window for individual ultrasound parameters for ultrasound image adjustments.

ITEM	DESCRIPTION
Depth	Changes the depth of image displayed. The depth must be set to include visualizing the serosa at all times when performing an RF ablation. • The scale on the right side of the display indicates centimeters. • To change, choose the drop-down menu and select the appropriate depth for anatomy to be visualized. • The depth is displayed in the Ultrasound data field in the upper right-hand corner, see Figure 6-5.
Frequency	Changes the ultrasound frequency being used to image. • Higher MHz produces higher resolution images but has less penetration. • Lower MHz provides increased penetration, but lower resolution images. • To change, choose the drop-down menu and select the appropriate frequency for anatomy to be visualized. • The frequency is displayed in the Ultrasound data field, see Figure 6-5.
Up/Down	Inverts image vertically. • Choose “Up/Down” to invert the image. • The change is reflected in all three (3) Ultrasound Presets and all ultrasound probes. The change is automatically saved and will be active until changed.
Left/Right	Inverts image horizontally. • Choose “Left/Right” to invert the image. • The change is reflected in all three (3) Ultrasound Presets and all ultrasound probes. The change is automatically saved and will be active until changed.
Gain	Adjusts overall brightness of the image. • To adjust, either drag the slider to the desired setting or Click on the desired setting.
Depth Gain	Adjusts gain in image based on the depth corresponding to the slider that is adjusted. • To adjust, either drag the slider to the desired setting or Click on the desired setting.
Small, Medium, Large Radio Buttons	Refers to the active ultrasound Preset represented by the circles on the ultrasound display screen. • Small, medium, and large radio buttons on the display correspond to the presets programed for each button. • To change, select the radio button for the desired preset (small, medium, or large).
Save Preset	Stores the changes made to the active Preset. Small, medium, and large correspond to the circles on the ultrasound display screen. Once saved, the Preset will be stored for use on subsequent patient procedures.
Reset to Default	Restores the ultrasound imaging parameters for the active Preset to the factory preset values.

6.6 Hide SMART Guide

When selected, the Hide SMART Guide icon removes the SMART Guide graphic including the Ablation Zone (red inner circle) and Thermal Safety Border (green outer ellipse) from the ultrasound display screen for five (5) seconds. This may be useful to the Operator in verifying the serosal margin.

- To enable the feature, Click on the Preferences icon.

Select “Hide SMART Guide” on the Preferences window, see Figure 6-6.

- Click the “Hide SMART Guide” icon from the ultrasound display screen, see Figure 6-7. The SMART Guide graphic will be removed from the image for five (5) seconds, see Figure 6-7.

During the 5 seconds, the “Hide SMART Guide” icon will be gray. The SMART Guide and icon will automatically be displayed again after five (5) seconds.

The “Hide SMART Guide” icon will remain on the ultrasound display screen until the Operator Clicks the check next to “Hide SMART Guide” on the Preferences window.

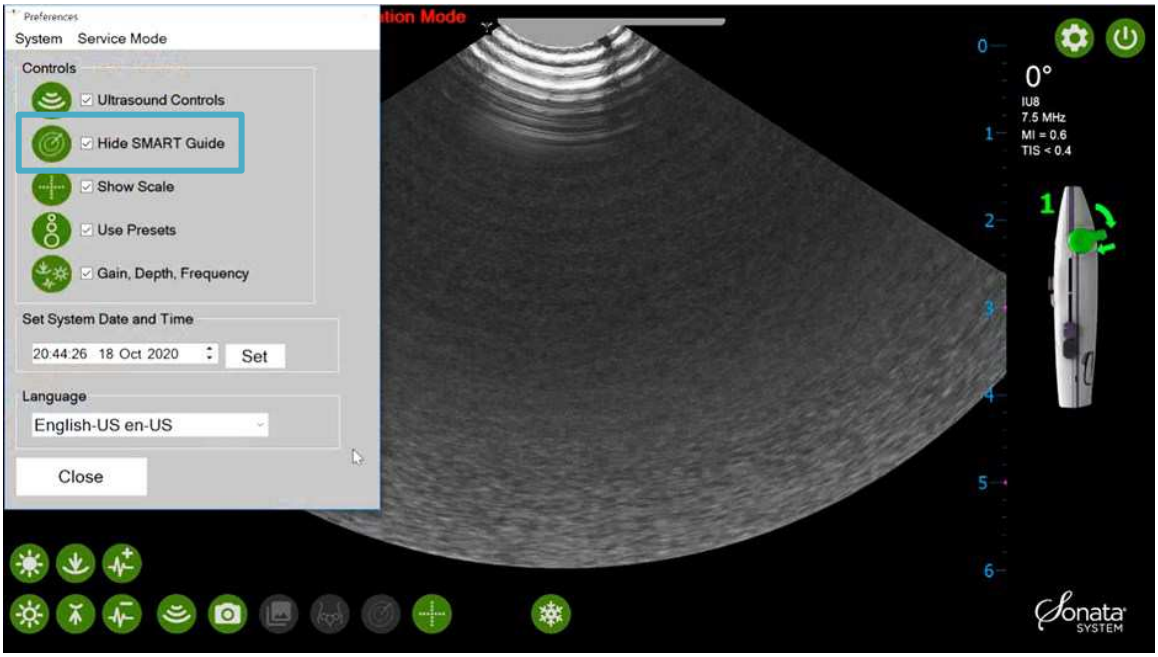


Figure 6-6. “Hide SMART Guide” icon. Click to “Hide SMART Guide.”

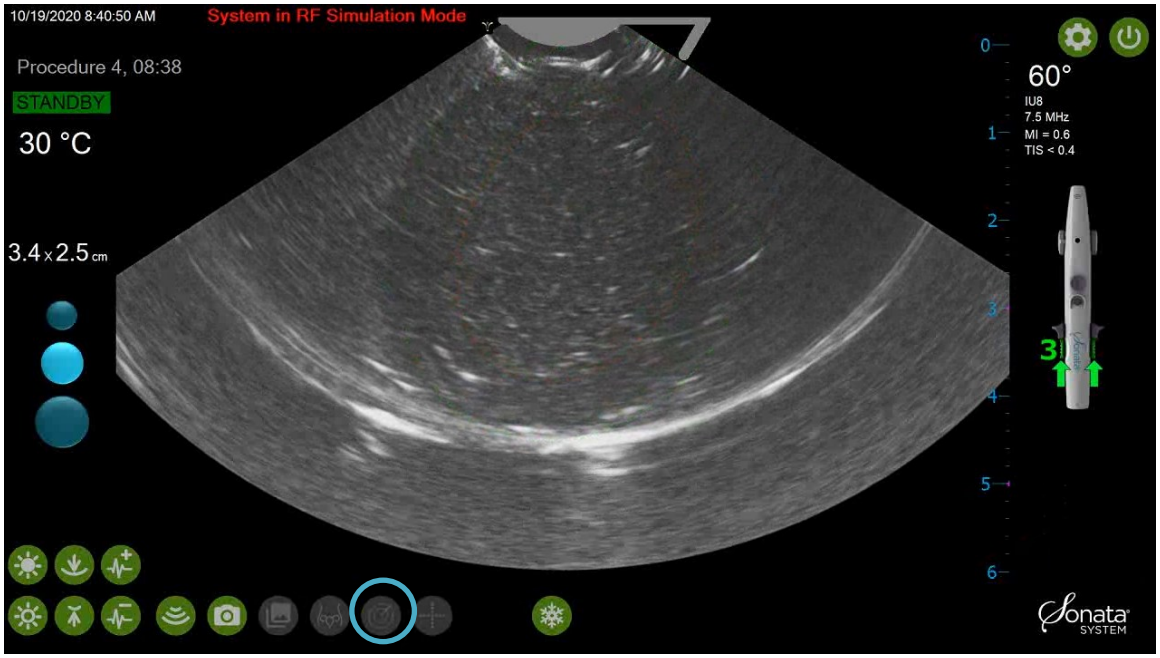


Figure 6-7. After "Hide SMART Guide" is chosen, the SMART Guide is removed for 5 seconds.

6.7 Show Scale

The show scale feature provides a graphic with centimeter markers to provide the Operator a quick method to estimate size.

- To enable the feature, Click on the Preferences icon.

Select "Show scale" checkbox, see Figure 6-8.

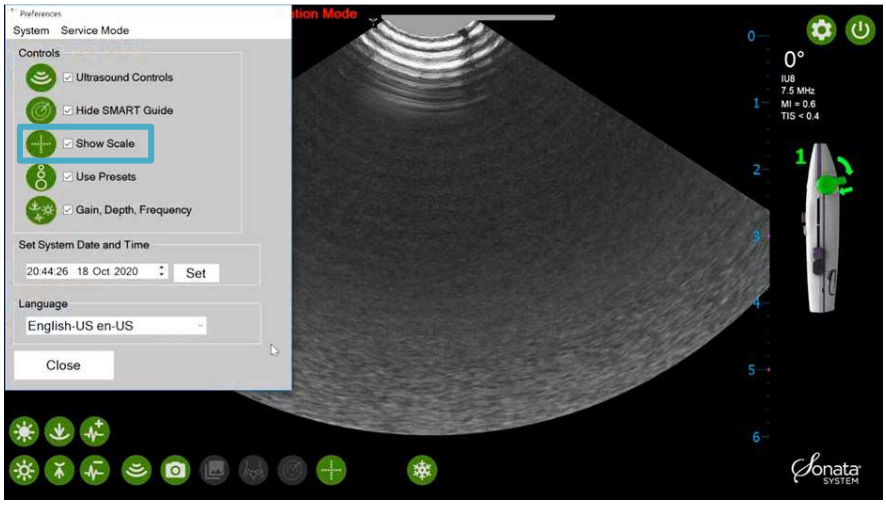


Figure 6-8. Show Scale icon. Select to show scale graphic.

Choose the “Show scale” icon to display the scale graphic, see Figure 6-9. This function is available on a live or frozen image using the IUUS Probe with the Articulating Tip at 0°.

The “Show scale” icon will remain on the ultrasound display screen until the Operator Clicks the checkbox next to “Show scale ” on the Preferences window.

Figure 6-10. Video “Keep” or “Discard” window.

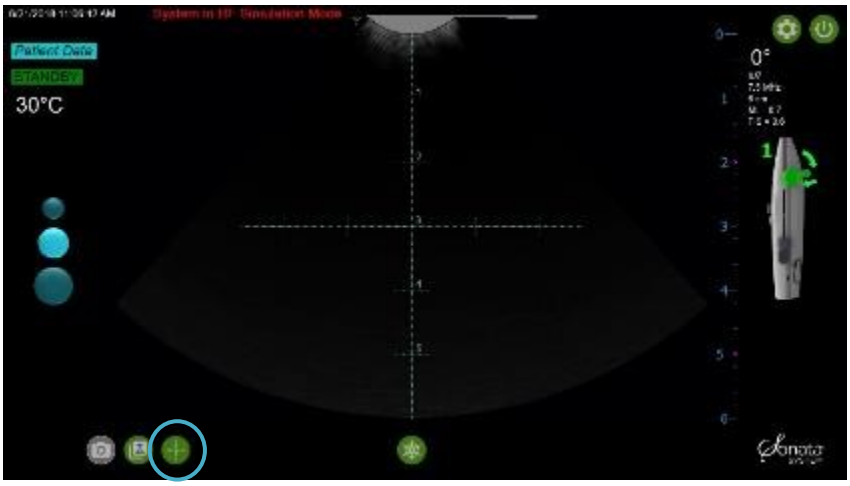


Figure 6-9. Scale shown.

6.8 Procedure Data and Image Management

A digital file is created, and a video recording is started each time the IUUS Probe is connected.

The Procedure Data (procedure number, date, and time) is captured on both the videos and the still images recorded during the procedure.

6.8.1 Video Recording Management

There is not a “Save” option to store a video recording. A prompt to “Keep” or “Discard” the video will be displayed, see Figure 6-10, when:

- The IUUS Probe is disconnected,
- “New Patient” or “Manage Procedure Data” is chosen,
- The current Operator logs out, or
- The system times out after one hour of inactivity, or
- The system is Powered OFF.

The Operator is given the option to “Keep” or “Discard” the video recording.

- To save the video recording to the digital file on the Sonata System hard drive, choose “Keep.”

To permanently delete the video recording, choose “Discard.”

6.8.2 Storing Still Images

A still image can be captured and stored while live scanning or from a frozen image.

There are several options to capture a still image:

- Click the Still Image Capture icon , see Figure 6-11.
- Double click the Confirm Button.

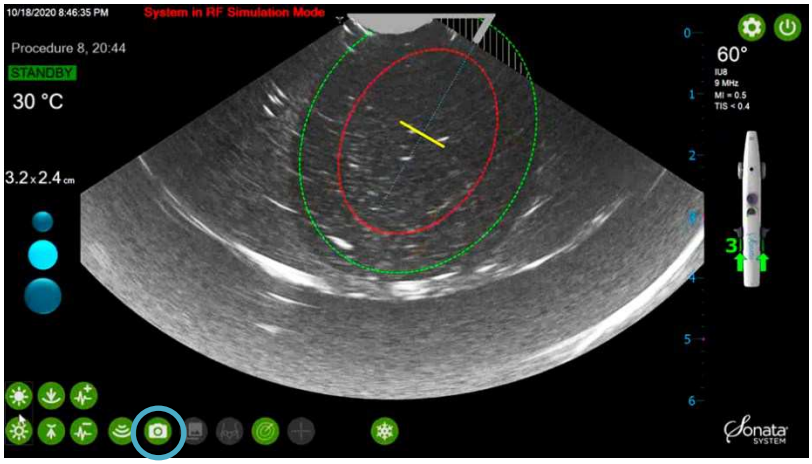


Figure 6-11. Capture Still Image.

- The Image Review icon will change from gray to green. The number of stored still images will be displayed within the Image Review icon at the bottom left, see Figure 6-12.

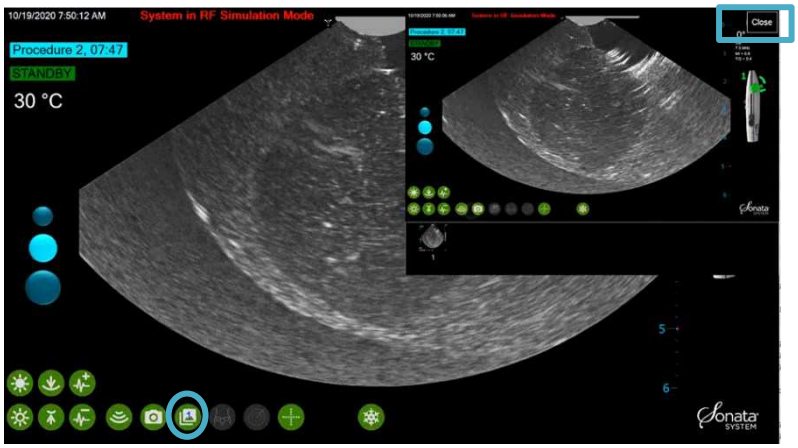


Figure 6-12. Image Review.

6.8.3 Reviewing Stored Still Images

Captured static images are stored in the Image Review library. To access the stored image(s):

- Click the Image Review icon.

An Image Review window will display in the upper right-hand corner of the ultrasound display screen. Select the image to be displayed from the thumbnail images, see Figure 6-12.

- Tap thumbnail image to enlarge the image.
- Tap Close the Image Review window when finished reviewing images, see Figure 6-12.

6.8.4 Copying Image Files to a USB Drive

To copy image files from the procedure digital file to a USB drive:

- As good practice verify the USB has sufficient storage and perform a virus scan prior to copying patient data files.
- Disconnect the SMART Tablet to RF Generator cable from the USB port, see Figure 6-13. This can be done when the system is not being actively used for treatment planning.
- Insert USB drive into the USB port, see Figure 6-13.

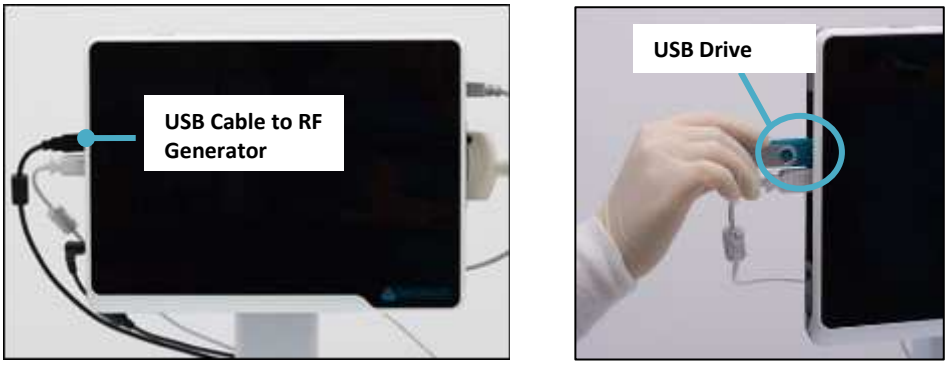


Figure 6-13. Remove USB cable from USB port and insert USB Drive in the USB port.

- At the top left, Click on the Procedure Data to display the Procedure Data Option window, see Figure 6-14.
- Click the “Manage Procedure Data” button, see Figure 6-15.

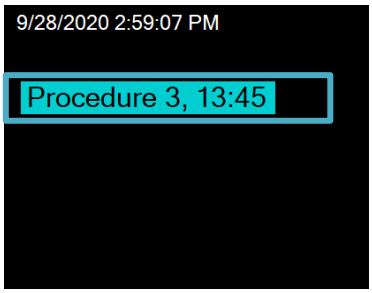


Figure 6-14. Patient Data.

Figure 6-15. Manage Patient Data.

The Procedure Explorer window will be displayed, see Figure 6-16. Select image files to be copied. Multiple files may be checked and will be exported.

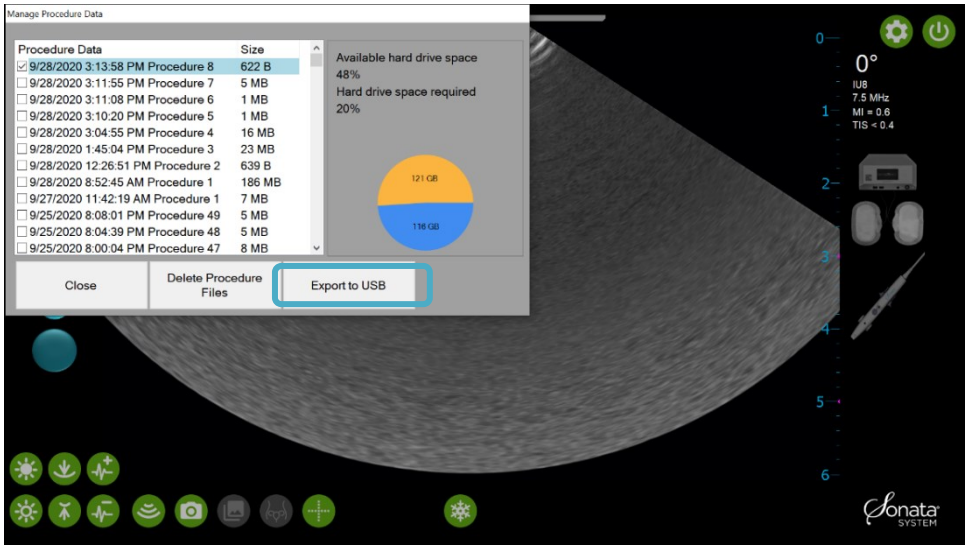


Figure 6-16. Patient Explorer window.

Click “Export to USB” button.

When you Click the “Export to USB” button, see Figure 6-17, a folder is automatically created on the USB drive named “Sonata System Files.” The image files will be copied and placed in this folder, see Figure 6-17.

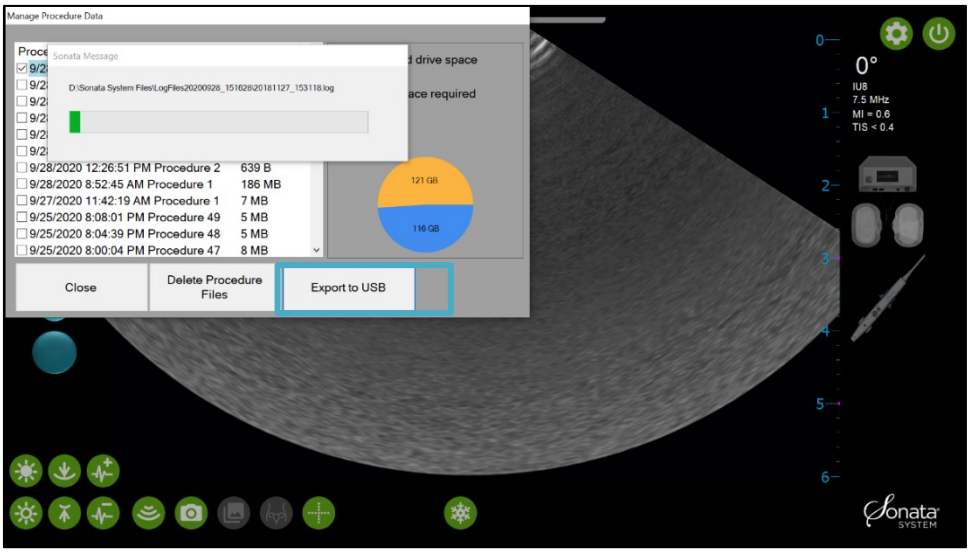


Figure 6-17. Click “Copy Selected Patients Files.”

A progress bar will be displayed as the image files are copied to the USB drive. When the copying is complete, remove USB drive.

A message will be displayed when the export (copying) of files is complete.

When finished exporting files, reconnect the RF Generator cable.

CAUTION	
⚠	MALWARE AND VIRUSES Before inserting USB drives to copy Procedure Data, be sure to use drives that are known to be free of malware, viruses, or other software that may automatically upload and damage the operating system or other software on the SMART Tablet. Before connecting to the Sonata System, it is recommended to pre-scan USB drives, and any computer the USB drive is connected to, using reliable virus scan software, or connect only new and dedicated USB drives.

6.8.5 Delete Image Files and Manage Hard Drive Space

To manage the hard drive space for storing images, it may be necessary to delete procedure digital files.

- Export (copy) files for permanent archiving, see Section 6.8.4, and
- Prior to deleting files from the hard drive, verify procedure files have been successfully copied.

6.8.6 Display Hard Drive Space

The amount of hard drive space available is shown with the Procedure Data files., see Figure 6-18.

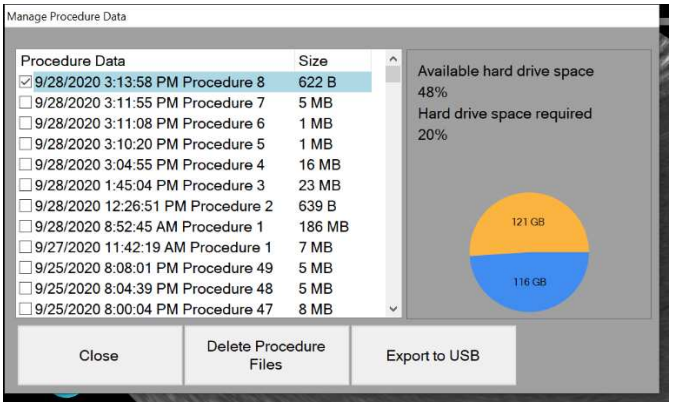
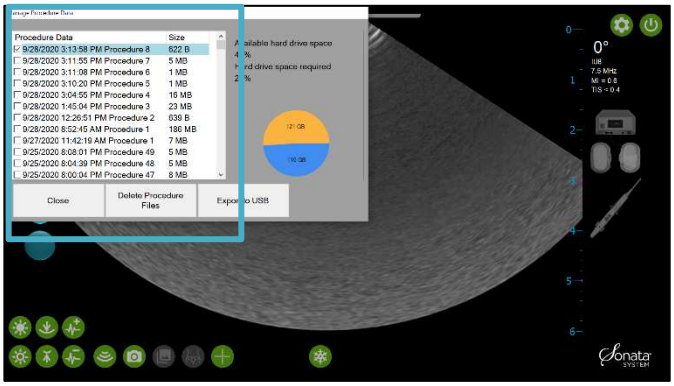


Figure 6-18. Hard drive space is shown along with the Procedure Data files.

6.8.7 Delete Image Files

To permanently delete image files:

- Open the Procedure Explorer window, see Section 6.8.
- Select the procedure file(s) to permanently delete the images.
- Select the file(s) to delete in the pane on the right side of the Procedure Explorer window, see Figure 6-19.
- Click the “Delete Procedure Files” button, see Figure 6-19.
- When prompted, confirm you wish to permanently delete the selected image and video file(s) by Clicking the “Delete” button.



Select Image and Video files to be deleted

Figure 6-19. Select files then click the "Delete Procedure Files" button to remove image files from system.

6.9 Transducer Element Check

When a probe is connected to the SMART Tablet, the user can pull up the Probe Elements screen via the Service Menu icon. The Probe Elements Screen shows the transducer element strength, as it relates to ultrasound imaging. The blue elements identify acceptable signal strength, while red elements identify signal strengths below the predefined threshold.

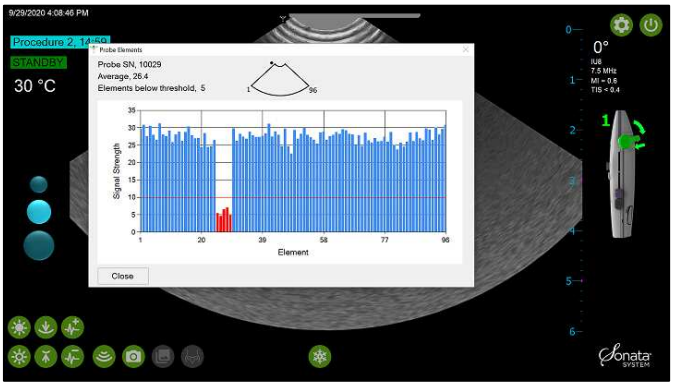


Figure 6-20. Transducer Element Check.

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Chapter 7 Troubleshooting

If the system fails to operate properly, this troubleshooting guide may help locate and resolve specific problems. Service or advice from a Gynesonics Representative is required if a problem cannot be resolved using this section.

In general, if a lack of power to or connections of components are encountered, check the following:

- **Electrical Power Source**
  If the system does not appear to be receiving power, be sure that the electrical outlet is live (request treatment facility biomedical engineering support if needed).
- **System Power**
  - Verify that the system is properly connected to an electrical outlet.
- **Component Power**
  - Power is supplied to the SMART Tablet via the power cable connector to the port on the lower left side. Verify that this cable is properly plugged into the SMART Tablet.
  - The RF Generator is connected by a power cord to the system. Check the connections at the back of the RF Generator if it will not power up or loses power.
- **System Device Connections**
  Verify that the RFA Handpiece, RFA Handpiece Cable, the IUUS Probe, and the Dispersive Electrodes are properly connected to their components. Check for loose connections between the two (2) communication cables from the SMART Tablet to the RF Generator.

7.1 Symptoms, Problems, and Potential Solutions

If you experience a problem that is not listed here, or if the suggestions provided do not resolve the problem, the device or system may be damaged. If the issue is not resolved, contact your local Gynesonics Representative.

SYSTEM SET UP AND OPERATION

	SYMPTOM	PROBLEM	POTENTIAL SOLUTIONS
1.1	SMART Tablet does not power up or shuts down unexpectedly.	• No power to SMART Tablet. • Internal software error.	• Terminate RF ablation if active. • Check power and restart tablet.
1.2	RF Generator does not power up or shuts down unexpectedly.	• No power to RF Generator. • RF Generator internal failure (overheated, fuse blown, etc.). • RF Generator is too hot or too cold from storage.	• Check RF Generator ON/OFF switch on back panel. • Check that the main power cord from the system is plugged into a live power receptacle. • Check that RF Generator vents are not obstructed. • Allow the RF Generator to adapt to a temperature range of 50°F to 95°F (10°C to 35°C).
1.3	RFA Handpiece Cable connector will not properly plug into the RF Generator receptacle or the RFA Handpiece.	• The connectors are not properly aligned to the receptacle. • The connector housing/pins or RF Generator receptacles are damaged.	• Line up the orientation marker on the cable connector housing to the receptacle. • Visually inspect the RFA Handpiece Cable connectors to RF Generator and RFA Handpiece receptacles for evidence of damage.
1.4	After completing an RF ablation, the system does not allow another treatment.	• The SMART Control must be moved or the Articulating Tip set to 0°	• Rotate or slide the SMART Control.
1.5	The mouse does not respond properly.	• The Console may not be connecting to the mouse.	• Disconnect and reconnect the mouse cable to the lower USB port.
1.6	The RF Generator does not produce audible beeps during treatment.	• The RF Generator is not active. • The volume is not set at a sufficiently loud level.	• Visually verify that the RF Generator status is active (blue light indicator). • Check the volume knob on back of RF Generator.

	SYMPTOM	PROBLEM	POTENTIAL SOLUTIONS
1.7	Component Connection Indicators blink	• A component is not connected • The RF Generator is not powered ON	• Check the Dispersive Electrode connections to the front of the RF Generator • Check the RFA Handpiece Cable connection to the RF Generator and to the RFA Handpiece • Check the cable connections from the SMART Tablet to the RF Generator • Check if the RF Generator is ON
1.8	The Procedure Menu is not displayed	• Unable to start a new procedure	• Click on the previous Procedure Number (procedure number, date, and time in the top left corner) • Choose “New Procedure” from the Procedure Data Menu • Ensure the IUUS Probe Tip is at 0°

TREATMENT DEVICE

	SYMPTOM	PROBLEM	POTENTIAL SOLUTIONS
2.1	The shaft of the Treatment Device does not readily pass through the cervix.	• The cervix has not been (adequately) dilated.	• Mechanically dilate the cervix to ease the passage of the shaft.
2.2	Hypotonic fluid cannot be injected via the RFA Handpiece.	• Poor connection between syringe and RFA Handpiece Luer fitting. • RFA Handpiece Luer fitting is broken.	• Reconnect syringe to RFA Handpiece Luer fitting. • Replace RFA Handpiece.

IMAGING

	SYMPTOM	PROBLEM	POTENTIAL SOLUTIONS
3.1	Poor ultrasound image quality – dark sections of image.	• Insufficient fluid in cavity. • Bubbles between the IUUS Probe Imaging Surface and the endometrium. • IUUS Probe Imaging Surface is not in contact with tissue.	• Inject hypotonic fluid as necessary. • Flush with additional hypotonic fluid to clear bubbles.
3.2	Poor ultrasound image quality – unclear images.	• Inadequate contact between the IUUS Probe Imaging Surface and tissue. • Insufficient hypotonic fluid in cavity.	• Carefully apply adequate force to the IUUS Probe Tip to ensure positive contact between the Imaging Surface and tissue. • Inject additional hypotonic fluid.

	SYMPTOM	PROBLEM	POTENTIAL SOLUTIONS
3.3	Poor ultrasound image quality - deployed Introducer not visible.	• The IUUS Probe is not properly connected to the RFA Handpiece.	• Retract the Introducer, align the IUUS Probe Tip to 0°, and remove the Treatment Device. • Verify that the IUUS Probe Tip is properly connected to the RFA Handpiece at the shaft and handle. If an issue is identified, replace the device that is causing the problem. If no issue is identified, continue to the next step. • On the sterile field, test the integrity of the alignment by submerging the tip of the Treatment Device in a container of sterile water, and deploy the Introducer to visually confirm alignment. • If properly aligned, continue the procedure. If not, replace the IUUS Probe.
3.4	Poor ultrasound image quality – sections of imaging lost.	• The IUUS Probe may be damaged.	• Check IUUS Probe for visible damage. • Check the connector and socket for obstructions or damage.
3.5	Ultrasound image becomes obscured during RF ablation.	• Outgassing from heated tissue (this is normal). • Loss of fluid from the cavity or contact between IUUS Probe and endometrial surface.	• Maintain Treatment Device position throughout the RF ablation. • If the Treatment Device moves during the RF ablation, interrupt the ablation and retarget. • Infuse additional fluid.
3.6	Ultrasound image display affected by electromagnetic interference (EMI).	• Noisy electrical equipment operating nearby or on the same power source as Sonata System.	• Try moving the System Cart and using a different wall outlet that is ideally isolated from other equipment.

TARGETING

	SYMPTOM	PROBLEM	POTENTIAL SOLUTIONS
4.1	Introducer appears to be significantly misaligned from Introducer guide.	• Articulation lever is not in fully locked position. • Tip of IUUS Probe and RFA Handpiece may have become disconnected. • The IUUS Probe Articulating Tip may be damaged. • Too much mechanical force on IUUS Probe Tip.	• Confirm articulation lever is locked in one (1) of two (2) preset lock positions. • Remove the IUUS Probe and the RFA Handpiece and inspect the assembly. • Inspect the articulation action of the IUUS Probe Tip. • Immerse the Articulated Tip and deploy Introducer in sterile water to verify alignment. • Replace RFA Handpiece.
4.2	The system does not allow the Operator to realign the SMART Guide to the Introducer Tip visible in the screen.	• The Introducer has not been deployed close enough to the initial planned location of the SMART Guide.	• Check that the Introducer is deployed to the depth of the Introducer Plan Line. • Retract the Introducer and deploy again, observing if the Introducer Tracker (yellow arrow) is in close proximity with the Introducer Tip in the image. • Set IUUS Probe articulation angle to 0° and retry.

7.2 System Software Messages

The following Operator, error, and warning messages are system-detectable conditions that could appear on the SMART Tablet display as well as an explanation of corresponding Operator action.

The Sonata System Alarm Messaging will notify the Operator if the Sonata System detects a hazardous or potentially hazardous situation where an Operator response is required. These situations occur during therapeutic RF delivery and require the Operator to stop RF. The Operator stops RF by stepping on the Footswitch or pressing the RF On/Off button on the front panel of the RF Generator. RF must be stopped to clear the alarm. Any other required Operator action will be displayed on the Ultrasound Display Screen.

Alarm messages are displayed on the Ultrasound Display Screen. They are indicated by the alarm warning symbol shown in the Symbols Glossary. The alarm messages will always be visible to the Operator when the Sonata System is positioned for viewing the Ultrasound Display Screen during a procedure.

The full list of alarms and an explanation of each is given in Section 7.2.2. The alarms are considered High Priority and prompt Operator action is required to mitigate potential harm.

Alarms are logged in the System Log on the Sonata System hard drive. The System Log persists when the Sonata System powers down. The time of powering down is captured in the System Log. Each line of the System Log is output to the log file when complete. If the Sonata System were to lose power, the System Log would miss at most one line. The System Log is stored on the Sonata System hard drive. When the hard drive fills to 80% a message is displayed on the Ultrasound Display Screen instructing the Operator/User to remove

files to free up space. Therefore, it is highly unlikely that the System Log could not be stored on the Sonata System hard drive due to lack of disk space available.

7.2.1 Common System Software Messages

MESSAGE	HELP AND EXPLANATION
Move Diamond to Tip. Press Confirm to align.	Use the SMART Control to align the diamond shaped Introducer Tip Marker so that it is directly over the Introducer Tip in the image. Press on the Confirm button to complete the alignment of the SMART Guide to the Introducer.
Perform Safety Rotation. Press Confirm Button to proceed.	None.
Perform final Safety Rotation. Press Confirm Button to proceed.	Complete a Safety Rotation before RF ablation and press the Confirm button to put RF Generator into the READY state.
System ready. Step on footswitch to activate RF.	Step on the Footswitch to activate RF Ablation.
RF ablation in progress. Keep device steady.	DO NOT move the Treatment Device or its controls during the RF ablation.
Operator stopped RF ablation. {0:00} remaining. Press Confirm Button to restart.	Operator ended the RF ablation before completion. Click "Restart" and step on Footswitch when ready or retract and remove the Treatment Device if completed.
Set Probe to 0° or plan for next ablation.	Retract sliders and set Tip to 0° to remove device if all treatments are complete. If another ablation is desired, move the SMART Control or set tip to 0° to start targeting.

7.2.2 System Messages (Alarms) By Code

MESSAGE	HELP AND EXPLANATION
Stop RF ablation. Check connections. (068)	Communication interrupted between RF Generator and SMART Tablet. Confirm connections on both cables between the units.
Stop RF Ablation. System failure detected. (085)	The system has experienced a software failure. Stop RF Ablation and restart the SMART Tablet.
STOP. Retract Needle Electrodes fully. (088)	The Needle Electrodes have been deployed before proper Introducer placement or safety checks have been completed. Retract Needle Electrodes to continue.
STOP. Retract Needle Electrodes to Plan Lines. (089)	The Needle Electrodes have been deployed beyond the intended ablation size set with the SMART Control. Retract the Needle Electrodes to the Plan Lines or retract fully and resize with the SMART Guide.
STOP. Retract Introducer fully. (090)	The Introducer has been pushed out before targeting has been completed. Retract the Introducer to continue.
STOP. Retract Introducer to Plan Line. (091)	The Introducer has been deployed beyond the intended depth set with the SMART Control. Retract the introducer to the Plan Line or retract fully and retarget with the SMART Guide.

7.2.3 System Messages (Warnings) By Code

MESSAGE	HELP AND EXPLANATION
System error detected. Check connections. (004)	Communication between RF Generator and SMART Tablet has been interrupted. Confirm connections of both cables running between the units, then press “Retest.”
RF ablation interrupted. {0:00} remaining. Press Confirm Button to restart. (007)	Electrical connection was interrupted during RF ablation. Confirm Needle Electrodes are deployed into fibroid tissue, Dispersive Electrodes are fully adhered to the patient and connected at the RF Generator, and all cable connections between RF Generator and SMART Tablet are secured. Click "Restart" and step on Footswitch to restart RF ablation or retract and remove Treatment Device if completed.
RF ablation interrupted. {0:00} remaining. Press Confirm Button to restart. (008)	The tissue is requiring more time than normal to reach target temperature. Some Needle Electrodes may not be positioned in fibroid tissue or fibroid requires additional energy to reach target temperature. Click "Restart" to try again. Consider using a smaller ablation size or retracting and repositioning the device.
RF ablation interrupted. {0:00} remaining. Press Confirm Button to restart. (009)	RF ablation has been interrupted due to temperature readings. Click "Restart" to try again or retract and replace device.
RF ablation interrupted. {0:00} remaining. Press Confirm Button to restart. (010)	RF ablation has been interrupted due to temperature readings. Click "Restart" to try again or retract and replace device.
RF ablation interrupted. Device repositioning required. {0:00} remaining. Press Confirm Button to restart. (011)	RF ablation has been interrupted due to temperature readings. Some Needle Electrode Tips may not be positioned in fibroid tissue. If some Needle Electrode Tips are deployed in the endometrial cavity, fluid in the cavity may not heat like fibroid tissue. Retract the Needle Electrodes and Introducer. Retarget so that all Needle Electrode Tips are in fibroid tissue. Consider using a smaller ablation size.
System error detected. Restart SMART Tablet. (012)	Communication between RF Generator and SMART Tablet has been interrupted. Confirm connections of both cables running between the units and restart the SMART Tablet.
RF ablation interrupted. {0:00} remaining. Press Confirm Button to restart. (018)	Dispersive Electrode connection interrupted. Confirm the connections at the RF Generator and full adherence of the Dispersive Electrodes on the patient’s thighs. Click "Restart" and step on Footswitch when ready.
RF ablation interrupted. {0:00} remaining. Press Confirm Button to restart. (019)	Dispersive Electrode connection interrupted. Confirm the connections at the RF Generator and full adherence of Dispersive Electrodes on the patient’s thighs. Click "Restart" and step on Footswitch when ready.
IUUS Probe Articulating Tip angle has changed. Restore angle. (024)	The IUUS Articulating Tip angle has changed during RF ablation. Restore the Articulating Tip angle to previous setting. If the SMART Guide position relative to the serosal margin or the Introducer Tip position has changed, stop RF ablation, retract the Needle Electrodes and Introducer, and retarget.
RFA Handpiece failed. Replace RFA Handpiece. (026)	Remove the Treatment Device and replace the RFA Handpiece.
System error detected. Restart SMART Tablet. (030)	System error detected. Restart the SMART Tablet.

MESSAGE	HELP AND EXPLANATION
System not ready. (031)	Confirm full deployment of the Treatment Device to the SMART Guide target and complete safety checks prior to initiating RF ablation.
System not ready. Poor electrical connection. (046)	Confirm the Dispersive Electrode connectors are properly connected to the RF Generator, the Dispersive Electrodes are fully adhered to the patient's thighs, and the Needle Electrodes are deployed into tissue.
RFA Handpiece failed. Replace RFA Handpiece. (050)	Unable to detect the Introducer depth sensor. Retract the Treatment Device and replace the RFA Handpiece.
RFA Handpiece failed. Replace RFA Handpiece. (052)	Unable to detect the size sensor in RFA Handpiece. Retract the Treatment Device and replace the RFA Handpiece.
RF ablation interrupted. {0:00} remaining. Press Confirm Button to restart. (055)	Dispersive Electrode connection interrupted. Confirm the connections at the RF Generator and full adherence of the Dispersive Electrodes on the patient's thighs. Click "Restart" and step on Footswitch when ready.
Disk space low. Delete files. (057)	Access Manage Procedure Data and delete old procedure files to provide adequate storage space for new procedures. Videos will not be recorded until space is provided.
System error. Restart SMART Tablet. (058)	NONE
Diagnostic check. Please wait. (059)	The SMART Tablet has identified a system error. If not resolved in one minute, remove the Treatment Device and restart the SMART Tablet.
Incompatible Probe. (065)	Only use the Gynesonics-approved ultrasound probes.
No power connection. Check power cables on SMART Tablet and wall. (066)	Check power connection on the lower left side of the SMART Tablet. Then check the power cord from the cart to the wall and the wall outlet. If power cannot be restored, call Gynesonics for service.
Retract Needle Electrodes and Introducer before setting IUUS Articulating Tip to 0°. (067)	The Needle Electrodes and Introducer must be retracted before the IUUS Probe Articulating Tip can be set to 0°.
System error detected. Please wait... (074)	If error is not resolved within one minute, remove the Treatment Device and restart the SMART Tablet.
System failure detected. Restart SMART Tablet. (075)	NONE
RFA Handpiece failed. Replace RFA Handpiece. (078)	Remove the Treatment Device and replace the RFA Handpiece.
RFA Handpiece failed. Replace RFA Handpiece. (079)	Remove the Treatment Device and replace the RFA Handpiece.
RF ablation stopped. {0:00} remaining. Retract and retarget. (080)	The system has detected movement of the SMART Guide during RF ablation. If this movement was intentional, retract the Needle Electrodes, retarget, and redeploy before continuing treatment. Otherwise, the RFA Handpiece may be experiencing a malfunction and may require replacement.
System failure detected. (086)	The system has experienced a software failure. Stop RF Ablation and restart the SMART Tablet.
RFA Handpiece failed. Replace RFA Handpiece. (092)	Sensors in the RFA Handpiece are reading incorrectly. Retract the device and remove to replace the RFA Handpiece.

MESSAGE	HELP AND EXPLANATION
RFA Handpiece failed. Replace RFA Handpiece. (093)	Sensors in the RFA Handpiece are reading incorrectly. Retract the device and remove to replace the RFA Handpiece.
RFA Handpiece failed. Replace RFA Handpiece. (094)	Sensors in the RFA Handpiece are reading incorrectly. Retract the device and remove to replace the RFA Handpiece.
RFA Handpiece failed. Replace RFA Handpiece. (097)	Sensors in the RFA Handpiece are reading incorrectly. Retract the device and remove to replace the RFA Handpiece.
The quality of this probe has been degraded. Please replace the probe (098)	If 10% or more of transducer elements are below the predefined acceptable signal strength, the system displays the message to replace the ultrasound probe and the RF ablation treatment is not allowed to proceed.
RF Ablation Stopped. System error detected. (101)	SMART Tablet image display has been interrupted. Check system cables and restart treatment.
RF Ablation Stopped. Size changed. (123)	A change of Needle Electrode position has been detected. To change ablation size, Stop RF, retract the Needle Electrodes and Introducer, and retarget.
RF ablation stopped. IUUS Probe disconnected from SMART Tablet. (161)	Confirm the connection of the IUUS Probe to the SMART Tablet. If ultrasound image is not immediately restored, remove the Treatment Device and restart the SMART Tablet.
RF Ablation Stopped. SMART Guide depth changed. (164)	A change of Introducer depth has been detected. To change ablation depth, retract the Needle Electrodes and Introducer, and retarget.
RF Ablation Stopped. Replace RFA Handpiece. (172)	Failed sensor in the RFA Handpiece. Remove the Treatment Device and replace the RFA Handpiece.
RF Ablation Stopped. Replace RFA Handpiece. (173)	The RFA Handpiece has an electronic failure. Remove the Treatment Device and replace the RFA Handpiece.
RF Ablation Stopped. Handpiece disconnected. (175)	NONE

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Appendix A Clinical Trial Results

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Clinical Trial Results Table of Contents

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Results Chapter 1 SONATA Pivotal IDE Trial Summary

R1.1 SONATA Trial Overview and Design

The purpose of the SONATA Pivotal IDE Clinical Trial was to demonstrate that treatment of uterine fibroids with the Sonata System is safe and effective. SONATA was designed as a prospective, longitudinal, multicenter, single-arm, independent core lab-assessed cohort clinical trial. Subjects were evaluated at 10-day, 30-day, 3, 6, 12, 24, and 36-month visits for adverse events or for any need for surgical reintervention secondary to heavy menstrual bleeding (HMB). Subjects were also asked to complete a menstrual diary using the Janssen version of the Pictorial Blood Loss Assessment Chart (PBAC) calibrated for catamenial product used in this trial. Diaries were completed at baseline, 3, 6, and 12 months post-treatment with the Sonata System. Contrast-enhanced magnetic resonance imaging (MRI) at baseline and 12 months post-treatment were collected and sent to a core lab for independent review and measurements of the imaging data. In addition, subjects completed questions related to symptoms, quality of life, satisfaction, and activity levels through the 36 months of follow-up.

R1.2 Key Clinical Outcomes

R1.2.1 Co-Primary Endpoints

As shown in Table R-1, the co-primary efficacy endpoint of Reduction in Menstrual Blood Loss (MBL) at 12 months exceeded the success criteria of lower-confidence limit (LCL) ≥ 45%, with 64.8% of subjects having a reduction of at least 50% in the 12-Month Visit PBAC and a final 12-Month Visit PBAC score of less than 250 (LCL was 56.3%). There was a reduction in the 12-Month Visit PBAC score in 95.1% of subjects. The co-primary efficacy endpoint of Rate of No Surgical Re-intervention through 12 months exceeded the success criteria of LCL ≥ 75% with 99.3% of subjects being free from surgical re-intervention for HMB (LCL was 95.1%).

Table R-1: SONATA Pivotal IDE Clinical Trial Co-Primary Endpoints at 12 Months

Co-Primary Endpoints	Result	Success Criteria	Outcome
≥ 50% Reduction in PBAC and PBAC <250 at 12-Month Visit		Lower bound of 2- sided 95% CI ≥ 45%	Exceeds Endpoint Success Criteria
Total Number of Subjects in the Population[1]	142		
Success (%)	92 (64.8%)		
95% CI (LCL, UCL)	56.3%, 72.6%		
Rate of No Surgical Re-intervention through 12 Months		Lower bound of 2-sided 95% CI ≥ 75%	Exceeds Endpoint Success Criteria
Total Number of Subjects in the Population[2]	143		
Rate %	99.3%		
95% CI (LCL, UCL)	95.1%, 99.9%		

[1] Five (5) subjects were excluded due to interfering medical condition (4) and re-intervention (1) per protocol.
[2] Four (4) subjects were excluded due to interfering medical condition per protocol.

R1.2.2 Key results from secondary endpoint analyses include:

- 96% of subjects reported symptom improvement at 12 months; 88% at 24 and 36 months
- 97% of subjects were satisfied at 12 months; 94% at 24 and 36 months
- 97% of subjects were likely to recommend Sonata to friends at 12 months; 94% and 98% at 24 and 36 months, respectively
- 99% of subjects were free from surgical reintervention at 12 months, 95% at 24 months, and 92% at 36 months (Kaplan-Meier)
- 95% of subjects had a reduction in menstrual bleeding by 12 months
- 98% of subjects found the procedure tolerable
- 4.7% of subjects reported the procedure as minimally tolerable or intolerable
- At least 50% of subjects returned to normal activity the next day
- 74% of subjects had a short length of stay ≤ 3 hours
- Significant improvements achieved in overall work and activity at 12 months and maintained through 36 months

R1.3 Trial Endpoints

The safety of treatment was characterized by documenting all adverse events (AEs) that occurred on the day of the treatment through the 12-month follow-up phase. Effectiveness of the device was evaluated by reduction in menstrual blood loss and rate of surgical re-intervention for HMB at 12 months. Specifically, the co-primary efficacy endpoints are outlined in the following sections.

R1.3.1 Co-Primary Endpoints:

- Menstrual Blood Loss:
  - Subject Success: Subjects with a minimum of 50% reduction in 12-Month Visit PBAC and a final 12-Month Visit PBAC score of less than 250
  - Endpoint Success: The lower limit of the 2-sided 95% confidence interval (CI) of the percentage of subjects that are considered as success ≥ 45%
- Surgical Re-intervention:
  - Subject Success: Subjects without surgical re-intervention for HMB due to treatment failure at 12 months
  - Endpoint Success: Lower limit of the 2-sided 95% CI of the percentage of subjects that are considered as success ≥ 75%

R1.3.2 Secondary Endpoints:

- Safety - adverse device effects

- Reduction in dominant treated fibroid total and perfused volume as measured by contrast-enhanced magnetic resonance imaging (MRI) from baseline to 12 months
- Reduction in total uterine volume as measured by contrast-enhanced MRI from baseline to 12 months
- Change in Symptom Severity Score (SSS) and Health-Related Quality of Life (HR-QoL) subscales of the Uterine Fibroid Symptom and Quality-of-Life (UFS-QoL) Questionnaire from baseline to 12, 24, and 36 months
- Overall subject treatment outcome using the Overall Treatment Effect Scale at 12, 24, and 36 months
- Time to return to normal activity in days
- Subject satisfaction at 12, 24, and 36 months
- Change in general health outcome as measured with the EuroQoL EQ-5D questionnaire from baseline to 12, 24, and 36 months
- Subject pain and tolerance of procedure
- Mean institutional LOS
- Change in work productivity and activity impairment due to uterine fibroid symptoms as measured with the Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI:SHP) from baseline to 12, 24, and 36 months

R1.4 Key Inclusion and Exclusion Criteria

Subjects were included if they were premenopausal, between 25 and 50 years old, reported HMB associated with fibroids for ≥ 3 months, had at least one qualifying fibroid (types 1,2,3 and type 2-5), up to 10 clinically relevant fibroids (FIGO types 1, 2, 3, 4, 2-5) from 1-5 cm in diameter, a PBAC score from 150-500, regular menstrual cycles for at least 4 of the last 6 menstrual cycles, expressed a lack of desire for future pregnancy, and were willing to maintain consistent use or non-use of non-injectable hormonal contraception from 6 months pre-trial through 12-months.

Subjects were excluded if they were pregnant, needed emergency fibroid surgery, desired childbearing, had a tubal implant, were postmenopausal, had ≥1 type 0 fibroids > 1 cm in diameter, one endometrial polyp ≥ 1.5 cm or multiple polyps of any size, were status-post endometrial polypectomy within three months, had any treatable fibroid > 5.0 cm in diameter per transvaginal sonography or MRI, noted bulk symptoms associated with subserous fibroids, had one or more cervical fibroids, had an extrauterine pelvic mass of unknown diagnosis, had an intrauterine device *in-situ* without undergoing a required washout period, had a prior procedure for fibroids or HMB other than myomectomy, had myomectomy by any route within the prior 12 months and/or with < 6 months of symptom relief, had any abnormality that could obstruct device access, had a total uterine volume ≥ 1000 cc, had clinically-significant adenomyosis, confirmed or suspected clinically-relevant endometriosis, one or more clinically relevant calcified fibroids, prior pelvic radiotherapy, abdominopelvic malignancy within the previous five years, endometrial hyperplasia within 12 months, active pelvic infection, use of hormonally-relevant medication without washout , used an antifibrinolytic agent, used anticoagulant therapy (warfarin derivatives or heparin), had chronic pelvic pain or baseline pelvic or menstrual pain > 6 using the Numeric Rating Scale-11, had chronic uncontrolled moderate-severe hypertension, uterine hypoplasia.

R1.5 Results

A total of 147 subjects were enrolled and treated at 22 investigational centers located in the U.S. (21) and Mexico (1). Table R-2 and Table R-3 summarize subject demographics and fibroid characteristics at baseline.

R1.6 Baseline

Table R-2: Baseline Demographics

DEMOGRAPHIC VARIABLE	
Age (years), N	**147**
Mean ± SD	42.9 ± 4.28
Median	43.0
Min, Max	31, 50
Ethnicity, N	**147**
Hispanic or Latino	43 (29.3%)
Not Hispanic or Latino	104 (70.7%)
Race, N	**147**
American Indian or Alaska Native	3 (2.0%)
Asian	2 (1.4%)
Black or African American	49 (33.3%)
Native Hawaiian or Other Pacific Islander	1 (0.7%)
White	60 (40.8%)
Other	33 (22.4%)
Height (inches), N	**147**
Mean ± SD	64.4 ± 2.65
Median	64.0
Min, Max	59.8, 72.0
Weight (pounds), N	**147**
Mean ± SD	174.0 ± 40.23
Median	165.4
Min, Max	103.6, 308.2
BMI, N[1]	**147**
Mean ± SD	29.4 ± 6.22
Median	28.0
Min, Max	18.0, 49.8

[1] Calculated for those with both Height and Weight measurements.

Table R-3: Baseline Fibroid Characteristics

CHARACTERISTIC VARIABLE	
PBAC, N	**147**
Mean ± SD	300.6 ± 98.47
Median	284.5
Min, Max	150.2, 499.0
Total Fibroid Volume[1], N	**142**
Mean ± SD	71.1 ± 84.70
Median	42.5
Min, Max	0.8, 522.9
Total Uterine Volume[1], N	**147**
Mean ± SD	267.7 ± 148.40
Median	236.8
Min, Max	48.4, 868.1

[1] Volumes in cc.

R1.7 Procedure Summary

Table R-4 summarizes the procedure duration, institutional length of stay (LOS), and subjects' pain level and procedure tolerance. The mean procedure time was 46.9 ± 29.65 minutes with a median of 40.0 minutes. The mean LOS (start of procedure to discharge, including the procedure time) was 2.5 ± 1.24 hours, with a median of 2.3 hours.

Subjects reported an average procedure pain score of 0.2 ± 0.95 on a 10-point scale, across all anesthesia regimens. Overall pain during recovery was a mean of 2.6 ± 2.77, with a median of 2.0. With regard to the overall tolerability of treatment with the Sonata System, 64.6% of subjects noted that it was "very tolerable", 30.6% reported it as "moderately tolerable", 2.7% judged it as "minimally tolerable", and 2.0% found it "intolerable".

Table R-4: Procedure Summary

PROCEDURE PARAMETER	
Procedure Time (minutes), N	**147**
Mean ± SD	46.9 ± 29.65
Median	40.0
Min, Max	4.0, 162.0
LOS in hours, N	**147**
Mean ± SD	2.5 ± 1.24
Median	2.3
Min, Max	0.8, 7.7
LOS ≤ 3 hours	109 (74.1%)
Overall Pain During Procedure, N	**147**
Mean ± SD	0.2 ± 0.95
Median	0.0
Min, Max	0.0, 7.0
Overall Pain During Recovery, N	**147**
Mean ± SD	2.6 ± 2.77
Median	2.0
Min, Max	0.0, 10.0
Overall Tolerance of Procedure, N	**147**
Very Tolerable	95 (64.6%)
Moderately Tolerable	45 (30.6%)
Minimally Tolerable	4 (2.7%)
Intolerable	3 (2.0%)

Table R-5 summarizes characteristics of the treated fibroids. Four hundred and forty-two (442) fibroids with a mean diameter of 2.5 cm were ablated in 147 subjects with an average of 1.1 ablations per fibroid. Of the different fibroid diameters treated, 1-2 cm comprised the most frequently treated group (36.7%) followed by >2 -3 cm (26.5%). Nearly 81% (80.8%) of ablated fibroids ranged from 1-4 cm in diameter. The two most common fibroid FIGO types were that of type 3 (26.2%) and type 4 (22.6%). Submucous fibroids (FIGO type 1, type 2) made up 20.8% of treated fibroids while subserous fibroids (FIGO type 5, type 6) made up 9.7%, with the majority of those being type 5 fibroids. On average, subjects had 3.5 ± 2.15 fibroids, with a median of 3.0. There was an average of 3.0 ± 2.06 fibroids with mean diameter of 2.5 ± 1.22 cm treated in each subject. The minimum number of ablations per fibroid count was 0 as there were 12 fibroids that were ablated concurrently as a single cluster with an adjacent fibroid's ablation.

Table R-5: Characteristics of the Treated Fibroids

PROCEDURE PARAMETER	
Treated Fibroid Diameter, N	**442**
<1 cm	24 (5.4%)
1 – 2 cm	162 (36.7%)
>2 – 3 cm	117 (26.5%)
>3 – 4 cm	78 (17.6%)
>4 cm	61 (13.8%)
Treated Fibroid Type, N	**442**
Type 1	15 (3.4%)
Type 2	77 (17.4%)
Type 2-5	91 (20.6%)
Type 3	116 (26.2%)
Type 4	100 (22.6%)
Type 5	39 (8.8%)
Type 6	4 (0.9%)
Number of Fibroid/Subjects, N	**147**
Mean ± SD	3.5 ± 2.15
Median	3.0
Min, Max	1.0, 10.0
Number of Treated Fibroid/Subjects, N	**147**
Mean ± SD	3.0 ± 2.06
Median	2.0
Min, Max	1.0, 9.0
Treated Fibroid Diameter (cm), N	**442**
Mean ± SD	2.5 ± 1.22
Median	2.3
Min, Max	0.3, 6.5
Number of Ablations/Treated Fibroid, N	**442**
Mean ± SD	1.1 ± 0.45
Median	1.0
Min, Max	0.0, 4.0

R1.8 Co-primary Endpoints

Menstrual Blood Loss at 12 Months: There was a reduction in the 12-Month Visit PBAC score in 95.1% of subjects. When including all subjects with missing data in the analysis (Full Analysis Set), 64.8% (95% CI 56.3% - 72.6%) of subjects had a reduction of at least 50% in their 12-Month Visit PBAC and a final 12-Month Visit PBAC score of less than 250. This outcome met the pre-specified trial hypothesis that the LCL of the 95% Confidence Interval (CI) to be ≥45%.

Surgical Re-intervention at 12 Months: When including all subjects with missing data in the analysis using the Life-Table methods, 99.3% (95% CI 95.1% - 99.9%) of subjects were free from surgical re-intervention for HMB at 12 months. This outcome met the pre-specified trial hypothesis that the LCL of the 95% CI to be ≥75%.

With both co-primary efficacy endpoints declared as success, the trial met its primary objectives of bleeding reduction with minimal rate of surgical re-intervention at 12 months.

Surgical re-interventions for HMB during the 3 years of follow-up included 10 hysterectomies and 1 endometrial ablation and the corresponding rates (i.e., rates of No Surgical Re-intervention per Life-Table method) were 94.8% and 91.5 at 2-year and 3-year post-procedure. Additional analyses were conducted to determine the rate of surgical re-intervention through 3 years using other methodologies. The rates calculated using the binomial method were 0.7% at 1 year, 5.5% at 2 years, and 9.2% at 3 years post-procedure. The corresponding rates using the Kaplan-Meier estimates were 0.7%, 5.0%, and 8.2%, respectively.

R1.9 Safety

R1.9.1 Event Summary

A high-level summary of the events through 36 months of follow-up is provided in Table R-6. There were no procedure related events occurring after 12 months post-procedure.

Table R-6: Overall Summary of Adverse Events

Event Type	#AEs, #Subjects* (Incidence)
SAE	**2, 2 (1.4%)**
Procedure Related	2, 2 (1.4%)
Unrelated	0, 0 (0.0%)
AE	**151, 84 (57.1%)**
Procedure Related	107, 74 (50.3%)
Unrelated	44, 33 (22.4%)
Device Related SAE (SADE)	**0, 0 (0.0%)**
Device Related AE (ADE)	**0, 0 (0.0%)**
UADE	**0, 0 (0.0%)**
Total	**153, 85 (57.8%)**

*Some subjects experienced more than one event.
Note: Incidence is calculated as percentage of subjects with event.
SAE: Serious Adverse Event (Adverse event that led to a serious deterioration in the health of the subject)
AE: Adverse Event (Any untoward medical occurrence, unintended disease or injury or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons whether or not related to the investigational medical device)
ADE: Adverse Device Effect (Adverse Event related to the use of a medical device)
SADE: Serious Adverse Device Effect (Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event);
UADE: Unanticipated Adverse Device Effect (Serious adverse device effect which by its nature, incidence, severity or outcome was not identified in the risk analysis as presented in the Investigators Brochure).

R1.9.2 Procedure Related Events

All procedure related events occurred during the first 12 months of follow-up. There were 2 procedure related serious adverse events (SAEs) reported in 2 subjects (1.4%). One (1) involved a deep venous thrombus diagnosed 15 days post-procedure. The other event involved a subject who presented with a complaint of vaginal discharge, pelvic pain and self-reported low-grade fever at 28 days post-procedure that included an overnight hospital admission per local practice (thus elevating this event to an SAE).

Non-serious procedure related AEs were reported in 74 subjects (50.3%). As shown in Table R-7, these included fibroid sloughing (30.6%), cramping/pain (7.5%), vaginal discharge (6.1%), common genitourinary infections (4.8%), constitutional symptoms (3.4%), expelled fibroid (1.4%), flu-like symptoms (1.4%), and nausea/vomiting (0.7%).

Table R-7: Procedure Related AE Summary

Procedure Related AE	#AEs, #Subjects (Incidence)	AE Resolved #AE (%)	Median Start (Min, Max)	Median Duration[1] (Min, Max)
Constitutional Symptoms[2]	5, 5 (3.4%)	5 (100.0%)	6.0 (4, 15)	8.0 (1, 32)
Cramping/Pain[3]	12, 11 (7.5%)	11 (91.7%)	80.5 (15, 182)	11.0 (2, 161)
Fibroid Sloughing[4]	53, 45 (30.6%)	52 (98.1%)	15.0 (0, 297)	8.0 (1, 737)
Flu-like Symptoms[5]	2, 2 (1.4%)	2 (100.0%)	2.0 (1, 3)	2.5 (1, 4)
Infection[6]	8, 7 (4.8%)	8 (100.0%)	4.0 (0, 13)	18.5 (3, 96)
Miscellaneous[7] (gynecologic)	9, 9 (6.1%)	6 (66.7%)	130.0 (0, 390)	4.0 (1, 49)
Nausea/Vomiting[8]	1, 1 (0.7%)	1 (100.0%)	4.0 (4, 4)	1.0 (1, 1)
Other[9] (non-gynecologic)	8, 8 (5.4%)	8 (100.0%)	0.0 (0, 5)	4.5 (1, 14)
Vaginal Discharge[10]	9, 9 (6.1%)	8 (88.9%)	37.0 (12, 155)	30.0 (1, 316)
Total	**107, 74 (50.3%)**	**101 (94.4%)**	**13.0 (0, 390)**	**8.0 (1, 737)**

[1] Calculated for events with a specific reported end date. Unit in days.
[2] Individual symptoms such as chills, malaise, fatigue, decreased appetite, fever, and fever with chills up to 30 days post-treatment.
[3] Any uterine, pelvic, abdominal and menstrual cramping including pain in the pelvis, hip, vagina, abdomen, and lower back.
[4] Events describing passage of sloughed tissue *per vaginam* including symptoms such as odor, blood, cramping, and vaginal discharge.
[5] Constellation of symptoms such as fever/chills, cough, coryza, generalized aches and pains that, together, resemble symptoms of influenza.
[6] Genitourinary infections such as bacterial vaginosis, urinary tract infection, and yeast infection.
[7] Miscellaneous events of the pelvis, bladder, uterus, and vagina such as bloating, expelling of fibroid, perineal cyst, etc.
[8] Nausea and/or vomiting on or around the time of procedure.
[9] Other non-gynecologic events such as constipation, increased blood pressure, etc.
[10] Non-infection related discharge per *vaginam* other than tissue. Excludes blood.
Note: Incidence is calculated as percentage of subjects with event.

R1.9.3 Device Related Events

There was no occurrence (0.0%) of adverse device effect (ADE), serious adverse device effect (SADE), or unanticipated adverse device effect (UADE).

R1.10 Secondary Endpoints

R1.10.1 Uterine and Fibroid Volume

Treatment with the Sonata System resulted in a reduction in the uterine volume from baseline to 12 months, as assessed by contrast-enhanced MRI and measured by a central core lab. At 12 months post-procedure, the mean reduction in uterine volume was 12.9% (N=129), reflecting a change in uterine volume from 267.3 cc at baseline to 232.6 cc at 12 months. The mean reductions in dominant treated total and perfused fibroid volumes (defined as the fibroid with the greatest reduction in total volume per subject) from baseline to 12 months were 62.4% (N=129) and 63.9% (N=128) respectively.

R1.10.2 Symptom Severity Score and Health-Related Quality of Life

Mean SSS and HR-QoL improved significantly from baseline to 12 months. Subjects had a mean reduction of 32.1 points (N=135) from 54.9 at baseline to 22.6 in SSS at 12 months post-procedure. This improvement was maintained through the follow-up period (mean reduction of 30 and 31 points from baseline at the 24- and 36- months follow-ups, respectively). Similarly, subjects had a mean increase of 43.7 points (N=134) from 40.3 at baseline to 84.2 in HR-QoL at 12 months post-procedure. This improvement was maintained through the follow-up period (mean increase of 42 points from baseline at the 24- and 36- months follow-ups).

R1.10.3 European Quality of Life 5 Dimensions

The EQ-5D (EuroQOL) is a standardized questionnaire for measuring generic health status. Self-reported scores range from values of less than 0, representing health states worse than "death", to a maximum score of 1.0, representing "perfect health". Subjects in the SONATA Pivotal IDE Trial on average reported an improved health status at 12 months post-procedure. At baseline, subjects had a mean overall score of 0.72 (N=143), meaning that subjects on average rated their own health status as less than 75% of the ideal state. At 12 months, the mean EQ-5D score rose to 0.89 (N=133) at 12 months. This improvement was maintained through the follow-up period (mean EQ-5D of 0.89 at 24 months and 0.88 at 36 months post-procedure). A change of 0.1 in health status is generally considered a significant change by health economists.

R1.10.4 Return to Normal Functional Status

Mean duration of returning to normal daily activities was 2.2 days (N=139) with at least half of the subjects returning to normal activity 1 day post-procedure (median of 1.0 day). Subjects who were employed at the time of procedure reported returning to work at 3.6 days (N=111) post-ablation on average, with at least half of the subjects returning to work at 3.0 days following the procedure (median of 3.0 days).

R1.10.5 Overall Treatment Effect and Subject Satisfaction

At 12 months, 96.3% of reporting subjects noted improved fibroid symptoms, 3.0% reported no change in symptoms and 0.7% noted a worsening of symptoms. Similar results were demonstrated at 2 years and 3 years post-procedure. At 2 years, 87.7% of reporting subjects noted improved fibroid symptoms, 4.4% reported no change in symptoms and 7.9% noted a worsening of symptoms. At 3 years, 87.5% of reporting subjects noted improved fibroid symptoms, 8.7% reported no change in symptoms and 3.8% noted a worsening of symptoms.

The majority of subjects reported satisfaction with the treatment and were likely to recommend Sonata to a friend or family member. Specifically, 70.4% of subjects indicated that they were "very satisfied" with treatment, 17.8% were "moderately satisfied", 8.9% were "somewhat satisfied", 2.2% were "somewhat dissatisfied", and 0.7% were "moderately dissatisfied" at 12 months. Satisfaction with the treatment was maintained at the 2-year (74.6% of subjects were "very satisfied", 13.2% were "moderately satisfied", 6.1% were "somewhat satisfied", 0% were "somewhat dissatisfied", 4.4% were "moderately dissatisfied", and 1.8% "very dissatisfied") and 3-year (71.2% of subjects were "very satisfied", 14.4% were "moderately satisfied", 8.7% were "somewhat satisfied", 1.9% were "somewhat dissatisfied", 1.0% were "moderately dissatisfied", and 2.9% "very dissatisfied") follow-ups.

Similarly, 81.5% of reporting subjects would "definitely" recommend treatment with Sonata, 15.6% would probably recommend it, and 3.0% would probably not recommend it at 12 months. No subject indicated dissatisfaction with the treatment or that she would "definitely" not recommend the treatment at 12 months. These trends continued through 3 years post-procedure. At the 2-year follow-up, 79.8% would definitely recommend treatment with Sonata, 14.0% would probably recommend it, 5.3% would probably not recommend it, and 0.9% would definitely not recommend it. At the 3-year follow-up, 79.8% would definitely recommend treatment with Sonata, 18.3% would probably recommend it, 1.9% would probably not recommend it. No subject indicated that she would definitely not recommend the treatment at 3 years.

R1.10.6 Anesthesia Type and Recovery Medications

There was no required or recommended anesthesia regimen in the SONATA clinical trial. Rather, investigators could tailor anesthesia choices to individual subject requirements. Approximately half of the treated subjects (50.3%) received general anesthesia and 49.7% were treated under conscious sedation. Paracervical blockade was co-administered as an ancillary local anesthetic modality at the discretion of each physician and was used in 48.3% of subjects. Of the 30 subjects (20.4%) with "Other", total IV anesthesia either alone or in combination with other anesthesia types was administered in 21 (14.3%), and various sedation types in the remaining 9 (6.1%). Regional anesthesia (spinal, epidural) was not utilized in any treated subject. In the immediate post-treatment period, the majority of subjects receiving medication received a nonsteroidal anti-inflammatory drug (NSAID, 33.3%), while about half were prescribed opioid analgesics (26.5%). Antibiotics were administered to 0.7% of subjects, an antiemetic in 2.7%, an antispasmodic in 2.0% and a non-opioid, non-NSAID analgesic/antipyretic (such as Tylenol) in 2.7%.

R1.10.7 Work Productivity and Activity Impairment

Using the validated WPAI questionnaire, subjects reported at baseline that they missed an average of 2.9% ± 5.79% of work time and had an average of 50.0% ± 28.01% impairment while at work, 50.9% ± 28.17% overall work impairment, and 57.9% ± 27.55% impairment of overall activity. By 12 months these had decreased to 0.5% ± 2.04%, 10.8% ± 18.30%, 11.4% ± 18.80%,and 11.7% ± 17.98%, respectively. The improvements observed at 12 months post-procedure were maintained at 2 years (1.3% ± 5.93%, 13.9% ± 21.36%, 14.6% ± 22.39%, and 13.7% ± 21.65%, respectively) and 3 years (1.4% ± 6.39%, 12.7% ± 22.02%, 12.5% ± 21.96%, and 14.3% ± 25.33%, respectively) post-procedure.

R1.10.8 Pregnancy Outcomes

One pregnancy was reported in a 36-year-old multigravida who conceived 22 months after the Sonata treatment. The subject delivered a liveborn male infant at 38 2/7 weeks gestation by elective repeat cesarean section with Apgar scores of $9^{1}/10^{5}$ and a birth weight of 4005g. Visual inspection of the endometrial cavity appeared within normal limits and there was no evidence of uterine dehiscence or rupture or any other adverse event. One miscarriage was reported in a 40-year-old subject 29 months after the Sonata treatment.

R1.11 Summary and Conclusion

In summary, the data presented in this report demonstrates that the trial achieved its safety and effectiveness objectives. Specifically, safety was met as there was no occurrence of SADEs, ADEs, or UADEs in the trial per sponsor evaluation of AEs. A total of 2 procedure related SAEs occurred in 2 enrolled and treated subjects, both of which resolved with no sequela.

The co-primary efficacy endpoint of Reduction in MBL at 12 months exceeded the success criteria of LCL ≥ 45% with 64.8% of subjects having a reduction of at least 50% in the 12-Month Visit PBAC and a final 12-Month Visit PBAC score of less than 250 (LCL was 56.3%). There was a reduction in the 12-Month Visit PBAC score in 95.1% of subjects.

The co-primary efficacy endpoint of Rate of No Surgical Re-intervention through 12 months exceeded the success criteria of LCL ≥ 75% with 99.3% of subjects being free from surgical re-intervention at 12 months (LCL was 95.1%).

Additional analyses of secondary endpoints lead to the following observations:

- Mean reduction of 62.4% in dominant treated total fibroid volume, with a baseline mean of 22.0 cc to mean of 7.8 cc at 12 months. Mean reduction of 63.9% in dominant treated perfused fibroid volume with a baseline mean of 20.9 cc to mean of 6.8 cc at 12 months.
- Mean reduction of 12.9% in total uterine volume (baseline mean of 267.3 cc to mean of 232.6 cc at 12 months).
- Mean reduction of 32.1 points in Symptom Severity Score (SSS) from a baseline mean of 54.9 to mean of 22.6 at 12 months and mean increase of 43.7 points in Health-Related Quality of Life score (HR-QoL) from a baseline mean of 40.3 to mean of 84.2 at 12 months. Mean improvements in both measures were maintained at 24 and 36 months.
- 96.3% of subjects reported symptom improvement at 12 months; 88% at 24 and 36 months.
- 97.0% of subjects were either “very”, “moderately”, or “somewhat” satisfied with the treatment at 12 months; 94% at 24 and 36 months.
- 97.0% of subjects were either likely (“definitely” or “probably”) to recommend Sonata to friends at 12 months; 94% and 98% at 24 and 36 months, respectively.
- 99% of subjects were free from surgical re-intervention at 12 months, 95% at 24 months, and 92% at 36 months (Kaplan-Meier)
- Mean increase of 0.17 in health state from an average of 0.72 at baseline to 0.89 at 12 months as measure by the EuroQoL EQ-5D questionnaire. Mean improvement in EQ-5D was maintained at 24 and 36 months.
- 97.9% of subjects reported the procedure to be tolerable (either “very”, “moderately”, or “minimally” tolerable).
- 4.7% of subjects reported the procedure as minimally tolerable or intolerable.
- Nearly 80% of treated fibroids were FIGO types 2-5, 3, 4, 5, and 6, and considered not treatable with other transcervical technologies. Smaller intracavitary or indenting fibroids (FIGO type 1 and 2) are the only fibroids considered treatable with other transcervical technologies.
- Subjects returned to normal daily activities in an average of 2.2 days, with at least half of the subjects returning to normal activities within 1 day of the procedure (median of 1.0 day).
- Mean length of stay (LOS, from start of procedure to discharge) was 2.5 hours with a mean procedure duration of 46.9 minutes.

The treatment of symptomatic uterine fibroids with the Sonata System has been shown to be safe and effective, as the SONATA Pivotal IDE Trial met the pre-specified hypotheses of effectively reducing menstrual bleeding with a low surgical re-intervention rate at 12 months. Women experienced significant and durable improvement in fibroid-related symptoms with low surgical re-intervention rates over 3 years of follow-up. The trial provided assurance of safety and efficacy of the system when used as indicated and in accordance with the instructions for use.

Results Chapter 2 FAST-EU Clinical Trial

R2.1 FAST-EU Trial Outcomes Overview and Design

The Symptom Effectiveness Trial of VizAblate® Intrauterine Ultrasound-Guided RF Ablation (IUUSgRFA) in the Ablation of Uterine Fibroids (FAST-EU) was designed to establish the effectiveness and confirm the safety of transcervical intrauterine sonography-guided radiofrequency ablation (RFA) with the VizAblate System in the treatment of symptomatic uterine fibroids. This was a multicenter, prospective, longitudinal, single-arm trial involving academic and community hospitals in the United Kingdom, the Netherlands, and Mexico. The trial enrolled and treated 50 subjects with qualifying uterine fibroids (89) and heavy menstrual bleeding from 2011 to 2013. The primary trial endpoint was the percentage change in perfused fibroid volume, as assessed by contrast-enhanced magnetic resonance imaging (MRI) at 3 months by an independent core laboratory. Secondary endpoints, evaluated at 6 and 12 months, included safety, percentage reductions in the Menstrual Pictogram (MP) score, the Symptom Severity Score (SSS) subscale of the Uterine Fibroid Symptom-Quality of Life (UFS-QoL) questionnaire, rate of surgical re-intervention for abnormal uterine bleeding, and the mean number of days to return to normal activity. Additional assessments included the Health-Related Quality of Life (HR-QoL) subscale of the UFS-QoL, anesthesia regimen, subject satisfaction, and pain during the recovery period. Lastly, a subgroup of subjects underwent an additional MRI at 12 months.

R2.2 Key Clinical Outcomes

R2.2.1 Primary Endpoint

The primary endpoint of percentage change in perfused fibroid volume at 3 months was met. Perfused fibroid volumes were reduced from baseline by an average of 68.1% ± 28.6%, while total fibroid volumes were reduced from baseline by an average of 54.7% ± 37.4% (*p* values <.001 compared to baseline; Wilcoxon signed-rank test). At 12 months, perfused fibroid volumes were reduced from baseline by an average of 67.4% ± 31.9%, while total fibroid volumes were reduced from baseline by an average of 66.6% ± 32.1% (*p* values <.001 compared to baseline)[2].

R2.2.2 Key results from secondary endpoint analyses include:

- 100% procedural success rate.
- 92% of subjects were free from surgical re-intervention at 12 months.
- There were no adverse device effects or serious adverse device effects.
- 90% of subjects experienced a reduction in menstrual blood loss by 3 months post-ablation.
- 88% of subjects were satisfied at 12 months.
- 86% of fibroids in the 28 subjects imaged at 12 months demonstrated >30 % reduction in perfused fibroid volume at 12 months.

[2] Brölmann H, Bongers M, Garza-Leal J, Gupta J, Veersema S, Quartero R, et al. The FAST-EU trial: 12-month clinical outcomes of women after intrauterine sonography-guided transcervical radiofrequency ablation of uterine fibroids. *Gynecol Surg.* 2016;13(1):27-35.

- Mean MP score declined through 12 months, with median and mean reductions of 72% and 54% at 12 months, respectively.
- Mean reduction of 55.1% (mean of 35.3-point decrease from baseline) in SSS at 12 months.
- The majority of subjects experienced ≥ 10-point reduction in SSS: 82% of subjects at 3 months, 86% at 6 months, 78% at 12 months.
- Mean increase of 277% (mean of 46-point increase from baseline) in HR-QoL at 12 months.
- Mean return to normal activity of 4.4 ± 3.1 days (median 4.0 days, range 1–14 days), with some of the subjects being admitted overnight or longer per hospital policy.
- On average, subjects reported a mean recovery pain score of 3.0 ± 1.7 (median 3.0, range 0–9) on a 10-point visual analog scale.

R2.3 Summary and Conclusion

In summary, there were significant reductions in perfused and total fibroid volume, reduction in menstrual bleeding, and improvements in overall symptoms and quality of life. Symptom relief was sustained through 12 months. The data demonstrated the potential of intrauterine sonography-guided, transcervical RFA with the VizAblate System as a uterus-preserving technology for the treatment of uterine fibroids without incisions.

Appendix B Technical Manual

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Technical Manual Table of Contents

Technical Chapter 1 Maintenance and Service

T1.1 Operator-Serviceable Components

Operators or treatment facility should inspect and maintain the following items after each usage. (All other service should be performed only by Gynesonics authorized personnel.)

After each usage:

- Cleanliness of system (including wheels, keyboard, screen, cables) – Clean all components as needed or between uses;
- Line Cords (particularly main line cord for any breaks in insulation that may lead to fluid ingress and insulation damage at connector, replaceable cords shown in Table T-8); and
- Ultrasound Probe Cords and Connectors (particularly any breaks in insulation that may lead to fluid ingress).

WARNING	
	COMPONENTS ARE NOT OPERATOR SERVICEABLE Do not attempt to remove protective covers on any components of the Sonata System. Parts within the protective covers of any component are not serviceable by the operator.

CAUTION	
	RF GENERATOR IS NOT OPERATOR SERVICEABLE Do not attempt to service or replace the fuse in the RF Generator; this component is not serviceable by the operator.
	UNPLUG MAIN POWER TO CHECK CONNECTIONS For optimum safety, unplug the main system power cord before attempting to check power cord connections to system.

Table T-8. Replacement Accessories

REPLACEMENT ACCESSORIES
Pneumatic Footswitch – ACCY-011
Sealed Medical Mouse – ACCY-012

T1.2 Periodic System Maintenance/Calibration

Before every procedure, the operator should connect and check the system components per instructions in Chapter 3: Preparation for Treatment. Besides this functional and visual inspection, there may be periodic maintenance schedule or calibration required for the Sonata System by national, local, or facility guidelines. If any of the Sonata System components require calibration service, please contact Gynesonics.

T1.3 Service Personnel

Operator-serviceable components should be serviced by personnel who are trained in the maintenance of electrical equipment such as biomedical engineering. For all other service, contact Gynesonics or an authorized distributor.

T1.4 Service Life

- RF Generator: 5 years
- SMART Tablet: 5 years
- System Cart: 5 years
- IUUS Probe: use limit determined by operator inspection between use. Validated for up to 50 uses.[3]
- RFA Handpiece: Single use-by date on device label
- RFA Handpiece Cable: use limit determined by operator inspection between use. Validation for 50 procedures.
- Dispersive Electrode: Single use-by date on device label

Refer to individual component chapters of the Instructions for Use for functional and packaging inspection instructions prior to and between each use.

T1.5 Electrical Isolation

The IUUS Probe and the RFA Handpiece are electrically floating relative to each other so that there is no return path between the IUUS Probe and the RFA Handpiece. This configuration ensures that the patient is protected against electrical currents.

The Sonata System may be electrically decoupled from the supply main (wall outlet) by unplugging the system from the wall outlet. This should be done after the System has been shut down.

[3] 50 use validation for STERRAD® 100NX; other sterilization options validated for a minimum of 12 uses

Technical Chapter 2 Environmental Considerations of Used Materials

T2.1 Environmental Considerations

Used RFA Handpieces, Dispersive Electrodes, and other disposable, single-use items such as syringes or hypotonic fluid should be regarded as biohazard-contaminated material and should be properly disposed of as medical waste per treating facility procedures and local regulations.

System equipment, including Ultrasound Probes, are multi-use, medical grade electronics. Should they become obsolete, they should be handled per facility procedures. The equipment comprising the System may contain environmentally hazardous materials such as, but not limited to: heavy metals, general recyclable metals, and plastics. Contact Gynesonics for disposal advice or for recovery of equipment.

Disposal of System packaging materials may be made with recyclable materials. Observe plastics packaging recycling symbols and recycle all paper materials such as chipboard boxes and overshippers. Tyvek lids are not recyclable and should be disposed of as normal trash.

T2.2 European Union Environmental Considerations

WARNING	
	If the Waste Electronic and Electrical Equipment (WEEE) symbol, as shown to the left, is displayed on products, please follow the guidelines as outlined by WEEE Regulations for proper disposal within European Union

Equipment marked with the WEEE symbol shall not dispose of as unsorted municipal waste but should be collected separately for proper recycling.

Disposables and other items not marked with the WEEE symbol should be disposed of at the end of life by way of the facility's established procedure for contaminated or infected product.

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Technical Chapter 3 Technical Specifications

T3.1 Sonata System Specifications

T3.1.1 Input Power Specifications

Table T-9. Input Power Specifications

INPUT POWER	SPECIFICATION
Main Power Input	100 – 240 VAC, 50-60 Hz, < 15 A
Additional external, and replaceable internal power supplies (including batteries)	Lithium-Polymer Battery [SMART Tablet] (73 Whr) Note: the Sonata System will not initiate treatment if SMART Tablet is not connected to external power.

T3.1.2 Range of Settings and Defaults for Operator-Accessible Controls and Limits

Table T-10. Operator-Accessible Settings, Defaults, and Limits

OPERATOR-ACCESSIBLE SETTINGS	SPECIFICATION
IUUS Tip Angle	0°, 45°, 60°
Ablation Size	20 x 13 mm to 49 x 42 mm
Ultrasound Settings and Defaults	Basic controls: Three (3) presets Advanced controls: Depth, Frequency, Gain (overall and by depth), Dynamic Range, Invert (Up/Down), Invert (Left/Right)
RF Generator	RF On/Off, Volume
Screen resolution	1920 x 1080 pixels

T3.1.3 Displayed Values—Units, Range, Accuracy, Precision

Table T-11. Displayed Values

DISPLAYED VALUES	SPECIFICATION
SMART Tablet Measurements	Accurate to within 5% of measurement length +0.02 cm Note: The Ablation Zone and Thermal Safety Border are graphically relevant boundaries for ablation targeting and sizing.
Displayed Temperature	5 – 190 °C , 1 °C display resolution
Thermocouple Temperature Accuracy	25 °C within ± 2 °C 37 °C within ± 2 °C 105 °C within ± 3 °C
RF Ablation Time	1. to 7 minutes at temperature
RF Time Accuracy	± 1% of reading or ± 5 seconds, whichever is greater
Power Range	0 – 150 W
Impedance Range	10-999 Ohms
Impedance Accuracy	± 20% of reading or ± 5 Ohms, whichever is greater

T3.2 Sonata RF Generator Technical Details

Table T-12. RF Generator Control Features

RF GENERATOR CONTROL FEATURES	SPECIFICATION
Pre-set Quasi-Sinusoidal Waveform	460 kHz output frequency -- not operator-adjustable
ALGORITHM OPERATING IN CLOSED-LOOP TEMPERATURE CONTROL MODE	
Time and Temperature Treatment Parameters	Automatically determined by operator selected ablation size; determined during ablation planning.
Average Temperature of Thermocouples in Needle Electrodes	105 °C average ablation temperature across four Needle Electrode Tips, held for time duration dependent on operator selected ablation size.
Treatment Time	Dependent on size of desired ablation, from 1 to 7 minutes at temperature.
Operator-controlled Treatment Termination	Operator can terminate treatment anytime via Footswitch or RF ON/OFF button. Early termination of RF energy may result in incomplete treatments.
Automated Temperature and Impedance monitoring	System automatically stops RF energy if ablation parameters in temperature and impedance experience significant changes that may signify problems with the ablation.
RF Delivery Auto-Termination—Measured Impedance from Treatment Site to Dispersive Electrodes	If the measured RF impedance (from the treatment site to the Dispersive Electrodes) does not remain between 15 and 500 ohms, the RF Generator will automatically shut off.

RF GENERATOR CONTROL FEATURES	SPECIFICATION
RF Delivery Auto-Termination—Measured Output Power	If the measured output power is greater than set power by 2 W or more for more than 500 msec, the RF Generator will automatically shut off.
Real Time Routine—Measured Impedance Between Dispersive Electrodes	If the electrical impedance between the two patient Dispersive Electrodes does not remain within 20 ohms of the value measured at the start of RF therapeutic delivery, the RF Generator will automatically shut off.
Monitoring of Measured Impedance Between Dispersive Electrodes	Real time monitoring that, if the measured impedance is outside the range of 10 Ohms and 200 Ohms, the RF Generator will automatically shut off.
Real-Time Monitoring of RF Delivery	The return current balance between the two patient Dispersive Electrodes is monitored in real time and RF Generator will automatically shut off if the imbalance exceeds the preset limit.
Optimization of Ultrasound Image During RF Ablation	The RF Generator interfaces with the SMART Tablet to run in “Triggered Update Mode” during RF Ablation to minimize noise in the image. RF delivery is paused automatically in conjunction with a timed ultrasound image capture to prevent RF interference with imaging. This pause is very brief and does not affect the outcome of the RF Ablation. It will still provide a rate of imaging update to enable visualization of the serosa during the ablation.
Voltage and Current Accuracy	Verified to within 10% through test of a 100-Ohm reference resistor. Verification is performed during power-on self tests and after each hour of operation.
Thermocouple Temperature Accuracy	The controller reads the cold junction compensation signal and applies this to thermocouple (TC) readings to keep the TC readings accurate despite changes in ambient temperature.

Table T-13. RF Generator Specifications

RF GENERATOR SPECIFICATIONS	SPECIFICATION
Output Power	250 W maximum hardware limit, 150 W maximum software limit, optimized for 50 Ω; 280 V peak max, 15-500Ω, 460 kHz
Input Power	100 – 240 VAC, 50-60 Hz
Power Consumption	720 VA
Dimensions	32 cm W x 15 cm H x 42 cm (12.5” W x 5.7” H x 16.5” D)
Weight	10.5 kg (23 lb)
Electrical Safety Classification	Class I (grounded), suitable for continuous operation
Transport and Storage Environment	-20 °C to 45 °C 10% to 90% relative, non-condensing
Operating Environment	10 °C to 35 °C 30% to 75% relative, non-condensing
Dispersive Electrode	Dispersive electrode is isolated from earth at high frequencies

T3.2.1 Power Delivery Curve

The following figure shows a power delivery curve for the RF Generator, with a 150-watt power limit, and a power delivery curve with a 75-watt limit.

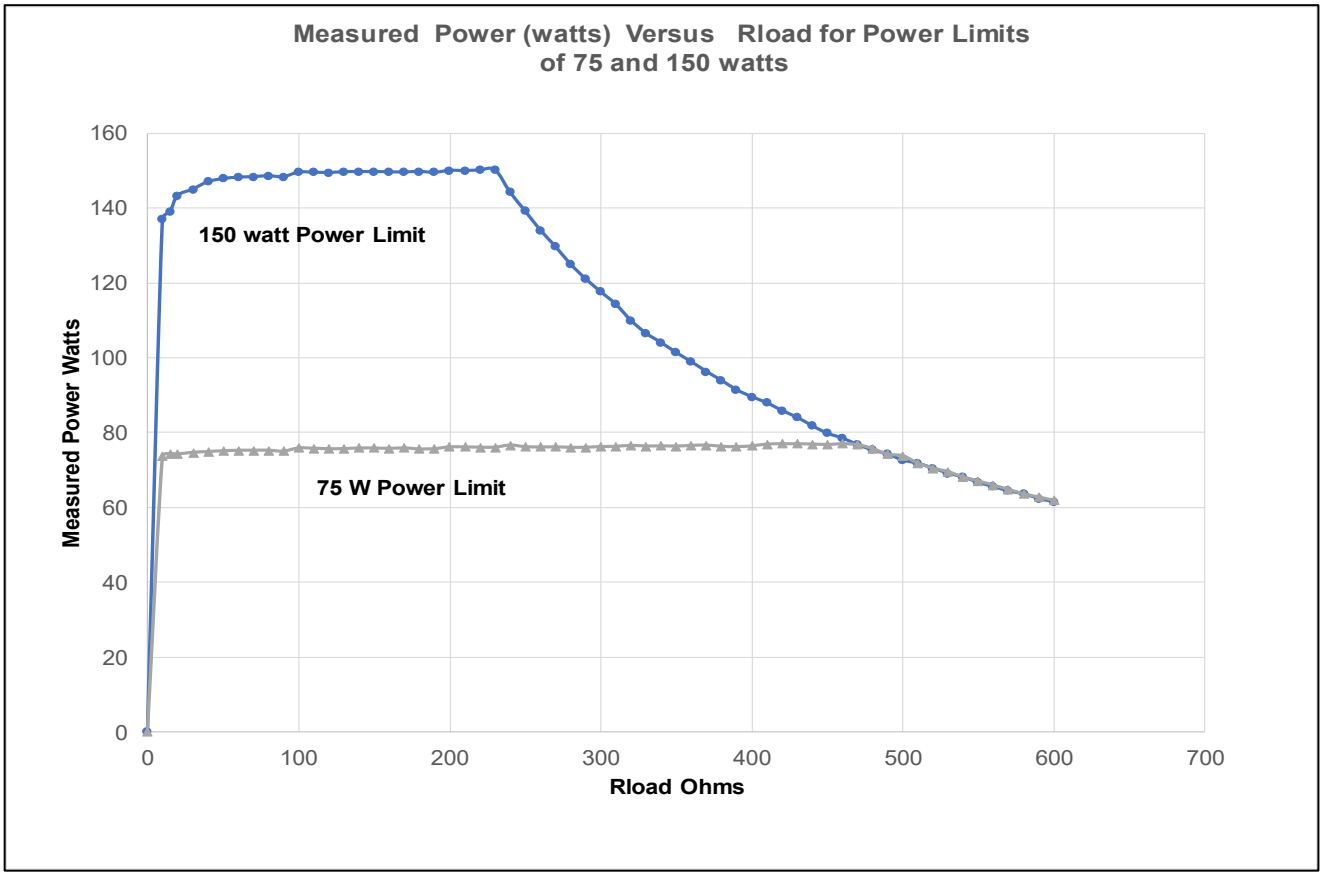

Figure 7-1 RF Generator - Power Delivery Curve

T3.3 SMART Tablet and Probes[4]

T3.3.1 Ultrasound Functions

The SMART Tablet consists of tablet computer unit and ultrasound engine (or "beamformer") along with a medical-grade power supply. The SMART Tablet is preloaded with the Graphical Guidance Software (GGS) that directs the operator through a series of treatment prompts.

[4] This section utilizes information directly from the technical manual of the SMART Tablet OEM manual (Part number 16-3033-00), produced by Teratech Corporation.

T3.3.2 Acoustic Output Reporting for Track 3

Gynesonics follows Track 3 of the Federal Drug Administration's (FDA) Information for Manufacturers Seeking Marketing Clearance of Diagnostic SMART Tablets and Probes. Track 3 does not require evaluation of acoustic output on an application-specific basis, but the global maximum derated ISPTA must not exceed 720 mW/cm^2 and the global maximum MI must not exceed 1.9.

T3.3.3 Probe Specifications

Table T-14. IUUS Probe Specifications

IUUS PROBE SPECIFICATIONS	SPECIFICATION
Usage Type	Reusable
Sterilization	STERRAD® 100NX (ASP), Ethylene Oxide (EO) , STERIS V-PRO® 1, STERIS V-PRO® 1 Plus, STERIS V-PRO® maX, STERIS V-PRO® maX 2, STERIS V-PRO® 60, STERIS V-PRO® s2, STERIS SYSTEM 1E®, and STERIS SYSTEM 1™ Express
Transducer Type	Curved linear
Number of Transducer Channels	96
Active (lateral) Aperture	14.25 mm
Elevation Aperture	4 mm
Transmit Frequency Range	6.0-9.0 MHz
Center Frequency	7.2 MHz
Bandwidth	>70% (at-6dB)
Field of View	114°
Penetration Depth	> 9 cm
Probe Dimensions	Length (Handle to tip): 21.3 cm Articulating Tip length: 2.34 cm Working Diameter: 8.3 mm (when assembled into Treatment Device)
Shaft Materials	Glass Fiber Reinforced Vinyl Ester
Transport and Storage Environment (non-sterile)	-20 °C to 40 °C 10% to 90% relative, non-condensing
Operating Environment	10 °C to 35 °C 30% to 75% relative, non-condensing
Fluid Immersion Rating	IPX7 (except the cable connector) Submergible section protected from the ingress of water during temporary immersion. The cable connector should never be immersed in fluid.

T3.3.4 Probe Acoustic Output

Table T-15. IUUS Probe Acoustic Output Reporting Table for Track 3

TRANSDUCER MODEL:	IUSP-002			OPERATING MODE:	B-MODE							
Index Label				MI	TIS			TIB			TIC	
					Scan	Non-scan		Scan	Non-Scan		Scan	Non-Scan
					At Surface	*At Surface*	*Below Surface*	*At Surface*	*At Surface*	*Below Surface*	*At Surface*	*At Surface*
Maximum index value				0.821	0.665			0.665			#	
Index Component value				0.821	0.665	-	-	0.665	-	-	#	#
	FDA – Track 3	**IEC**										
Associated acoustic parameter	$p_{r.3}$	$p_{r,a}$ at Z_{MI}	(MPa)	1.84								
	W_0	P	(mW)		36.5	-		3.65	-		#	#
	W_{o1}	P_{1x1}	(mW)		27.8	-		27.8	-			
	z_1	z_s	(cm)				-					
	z_{sp}	z_b	(cm)							-		
	$z@PII_{.3max}$	Z_{MI}	(cm)	1.36								
	$z@PII_{max}$	Z_{pii}	(cm)	1.56			-			-		
	f_c	f_{awf}	(MHz)	5.01	5.02	-		5.02	-		#	#
Other Information	**Mode Components**			B	B	-		B	-		-	-
	PRF	prr	(Hz)	3840								
	SRF	srr	(Hz)	15								
		n_{pps}		2								
	$I_{PA.3}$ @ MI_{max}	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	154								
	$I_{spta.3}$ @ $z_{pii.3}$ or $z_{sii.3}$	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	51.14								
	I_{spta} @ z_{pii} or z_{sii}	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	81.65								
	pr@PIImax	p_r at z_{pii}	(MPa)	2.33								
	deq@PIImax	d_{eq} at z_{pii}	(cm)							-		
Operating Control Conditions	Freq = 6 MHz, focus = 6.0 cm			X								
	Freq = 6 MHz, focus = 8.0 cm				X			X				

Note 1: Information need not be provided for any formulation of *TIS* not yielding the maximum value of *TIS* for that mode.

Note 2: Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).

(a) Intended use does not include cephalic so TIC is not computed

 # No data reported.

T3.4 Sonata SMART Tablet Specs

Table T-16. SMART Tablet Specs

CATEGORY	SPECIFICATION	SONATA SMART TABLET
Display		11.6” LED backlit wide-screen
Size	Width	321 mm
	Height	224 mm
	Depth	32 mm
Weight	Weight	2.21 kg
Tablet Battery	Input	Lithium-Polymer Battery (73 Whr) Connection to external power required for system operation
Operating Temperature		10-35^{O}C (50-95^{O}F)
Humidity		30-75% RH, non-condensing
Operating Altitude	Pressure	63 kPa to 101.3 kPa (472.5 to 759.8 mmHg)
Storage	Temperature	-24 to 45^{O}C (-13 to 113^{O}F)
	Humidity	10-90% RH, non-condensing

T3.5 Ultrasound Technical Features and Safety Information

T3.5.1 Exposure to Ultrasound

According to the American Institute of Ultrasound in Medicine (AIUM) Official Statement of the Clinical Safety of Diagnostic Ultrasound (March 1993): Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use: No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.

T3.5.2 Prudent Use Statement and Control of Acoustic Power Output

The following is a Prudent Use Statement regarding the use of ultrasound: Use diagnostic ultrasound only when there is a good medical reason. Also, the SMART Tablet does not provide explicit control of acoustic power output. Frequency and Depth Controls do affect acoustic outputs within the limits specified in the acoustic output tables. In general, to minimize the exposure to ultrasound energy, limit the duration of ultrasound exposure.

T3.5.3 Electrical Safety

The SMART Tablet conforms to the IEC/EN 60601-1 electrical safety standard. Each probe is insulated from the patient to minimize patient exposure in the presence of a system fault or a fault in other patient-connected equipment. The type of protection against electric shock is Class I. The degree of protection is Type BF, per safety standard IEC 60601-1.

To maintain compliance with electrical safety and emissions standards, the SMART Tablet must be used only with the supplied Medical Grade Power Adapters.

T3.5.4 Surface Heating of Invasive Probes

The average and peak radiated acoustic powers of all Gynesonics probes are limited to ensure that the surface heating of the probe array is less than 43ºC. The self-heating is a function of how many elements are being fired, how often they are being fired, the output (excitation) voltage and the transmit frequency. A software model has been developed to predict the surface heating under various operating conditions. To limit the temperature rise, the software first lowers the output voltage to limit, and then reduces the frame rate to keep the temperature rise below 6º C. Starting at body temperature (37º C) this means the maximum temperature will be 43º C when the probe is touching a patient. The peak acoustic power is constrained by the maximum voltage applied to the probe array elements.

T3.5.5 Electromagnetic Compatibility

The Sonata SMART Tablet complies with the IEC 60601-1-2:2014 standard.

The Sonata SMART Tablet is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. The customer or the operator of the Sonata SMART Tablet can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF

communications equipment (transmitters) and the Sonata SMART Tablet according to the maximum output power of the communications equipment. See “Electromagnetic Compatibility Tables,” in the Technical Manual for recommended separation distances.

T3.6 Acoustic Output Indices

The Sonata SMART Tablet complies with the international standard IEC 60601-2-37 for real-time display of Thermal and Mechanical Output Indices. When operating in any mode with the Freeze function disabled, the window displays the acoustic output indices relevant to the currently- active probe. The acoustic power indices are constant at each imaging frequency/depth setting; there are no operator-accessible adjustments. The Mechanical Index (MI) and Thermal Index (TIS) are displayed to allow you to monitor the amount of ultrasound energy that is transferred to the patient. With respect to use of the Sonata System, practice of the ALARA principle (exposure of the patient to ultrasound energy at a level that is as low as reasonably achievable) includes performing ultrasound procedures only for valid reasons, and for the shortest period of time practicable.

Warning: Ultrasound procedures should be used for valid reasons, and for the shortest period of time, necessary to produce clinically acceptable images.

Note: For systems distributed in the United States of America, refer to the Medical Ultrasound Safety ultrasound education program brochure produced by the AIUM.

T3.6.1 General Description of Indices

For a detailed explanation of the clinical significance and proper use of the real-time acoustic output indices displayed on the image display, consult relevant literature and educational materials available from industry and professional organizations concerned with medical ultrasound. To help understand how adjustment of the controls may affect the display of indices during an exam, read the following overview.

In general, indexes are described in terms of the following factors.

- Potential bioeffect of concern: Mechanical (cavitation or other non-thermal mechanical effects), or thermal (heating of tissue through absorption of the ultrasound energy) -for all indices, an index value less than 1.0 indicates relatively low risk for harm to the patient when the index is applied properly.
- Type of operating mode: Generally, mechanical effects are a greater concern during 2D-only operation, while thermal effects are a greater concern during any non-2D operation. The Sonata System images only in 2D (Bmode).
- Type of and location of tissue of concern: Bone or soft tissue, located either at the tissue surface nearest the probe, or at or near the beam focus.
- Measured acoustic parameters: Ultrasound power, time average intensity, or instantaneous peak pressure used in calculating the index value. All calculations assume an attenuation (or “derating”) rate of 0.3 dB/cm/MHz.

T3.6.2 MI: The Mechanical Index

MI has the following characteristics:

- Potential bioeffect: Any possible mechanical or non-thermal mechanisms although the likelihood of adverse consequences from these causes is not well understood, such risk may be highest in the presence of gas-saturated structures such as lung tissue.
- Mode type: Calculated for all modes of operation.
- Tissue type and location: Soft tissue at all locations in the scan field.
- Acoustic parameter: Maximum negative (rarefactional) ultrasound pressure at focus.

T3.6.3 TIS: The Soft Tissue Thermal Index

TIS has the following characteristics:

- Potential bioeffect: Thermal heating of soft tissue due to absorption of ultrasound. The TIS value is the ratio of the current transducer power to the reference level that would cause a 1ºC temperature rise in soft tissue.
- Tissue type and location: In scanned modes, soft tissue at the surface is of concern. In non-scanned modes, heating of soft tissue along the beam axis between the surface and focus is considered.
- Acoustic parameters: For scanned modes, the associated intensity at the surface is usually related to surface tissue heating. Total heating effects at the surface and focus are compiled separately, and the larger value is reported as TIS.

T3.6.4 Acoustic Index Display

MI and TIS index values appear in the column of text to the right of the scan image.

T3.6.5 Control of Acoustic Index Parameters

For any probe used in the intended clinical applications with the Sonata SMART Tablet at any available frequency/depth setting, operation is normally without significant risk due to mechanical effects or heating of tissues by ultrasound energy. The acoustic power indices are constant at each imaging frequency/depth setting; there are no operator-accessible adjustments. In keeping with the ALARA principal, imaging should only be performed for valid reasons, and for the shortest period of time practicable.

T3.7 Accuracy of Acoustic Output Display

The acoustic output display indices are calculated on the basis of measured values of acoustic parameters (acoustic power, intensity, pressure, etc.). The accuracy of the indices (discussed in the Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment) described below refers to accuracy of the measurement of the acoustic parameters and the effect of these errors on the estimated index values. (For a discussion of statistical considerations in acoustic measurement, refer to “Measurement Uncertainty in Ultrasonic Exposimetry, in Ultrasonic Exposimetry, M. C. Ziskin and P. A. Lewin, eds., CRC Press).

The remainder of this section lists the relative errors for the following items:

- Intensity measurements;
- Spatial-peak derated pulse-intensity integral, defined as ISPPA.3;
- Spatial-peak derated temporal average intensity for scanned modes;

- Peak derated rarefactional pressure;
- Mechanical Index;
- Soft-Tissue Thermal Index for scanned modes, total acoustic power at the scan/beam entrance to the body;
- Soft-Tissue Thermal Index for unscanned modes, when the beam-entrance dimension is less than 1 cm^2 in area; and
- Soft-Tissue Thermal Index for unscanned modes, when the beam-entrance dimension is Greater than 1 cm^2 in area.

The **relative error in intensity measurements due to uncertainty in the hydrophone calibration**, defined as E_k, is approximately:

$$\varepsilon_k = (\varepsilon_{Cal}^2 + \varepsilon_A^2 + \varepsilon_{V^2}^2)^{\frac{1}{2}} = 22\%$$ [5]

where the following are defined:

E_{Cal} Calibration error, as supplied by Sonic Consulting, Inc.; 21% at the frequency range of the probes tested.

E_A Relative error in the reproducibility of positioning the hydrophone at the point of the spatial peak of the pulse intensity integral, estimated as 5%.

E_{V^2} Relative error resulting from errors in reading peak squared voltage in the recorded waveform, estimated as 4%.

The **relative error in the spatial-peak derated pulse-intensity integral,** defined as $E_{SPPA.3}$, is approximately:

$$\varepsilon_{SPPA.3} = (\varepsilon_k^2 + \varepsilon_{TI}^2 + \varepsilon_{stab}^2 + \varepsilon_{.3}^2 + \varepsilon_{lin}^2 + \varepsilon_v^2 + \varepsilon_{PD}^2)^{1/2} = 23\%$$

where the following is defined:

E_{TI} Relative error due to hydrophone positioning and temporal integration of the waveform, estimated as 4%.

E_{stab} Relative error due to temporal instability of the hydrophone, estimated as 1%.

$E_{.3}$ Relative error in estimating derating factor, due to uncertainties in estimating frequency and reproducibility in determining derating location, estimated as 4%.

E_{lin} Relative error due to the effects of non-linearities in the pressure waveform upon the hydrophone and integral amplifier, estimated as 0% for this probe set.

E_{PD} Relative error in estimate of pulse duration, estimated as 5%.

[5] Calculations may require revision following full Ultrasound characterization, 12/18/13

The **relative error in the spatial-peak derated temporal average intensity for un-scanned modes,** defined as $E_{SPTA.3\text{-}unsc.}$, is approximately:

$$\varepsilon_{SPTA.3\text{-}unsc.} = (\varepsilon^2_{SPII.3} + \varepsilon^2_{prf})^{1/2} = 23\%$$

where the following is defined:

E_{prf} Relative error in prf estimation for operating condition giving actual peak ISPTA.3-unsc., estimated as 1%.

The **relative error in estimating spatial-peak derated temporal average intensity for scanned modes,** defined as $E_{SPTA.3\text{-}scan.}$, is approximately:

$$\varepsilon_{SPTA.3\text{-}scan.} = (\varepsilon^2_{SPII.3} + \varepsilon^2_{srf} + \varepsilon^2_{BOF})^{1/2} = 23\%$$

where the following are defined:

E_{srf} Relative error in estimating srf (scan repetition frequency) for operating condition giving actual peak $I_{SPTA.3\text{-}scan.}$, estimated as 1%.

E_{BOF} Relative error in estimating BOF (beam-overlap factor) for operating conditions giving actual peak $I_{SPTA.3\text{-}scan.}$, estimated as 5%.

The **relative error in the peak derated rarefactional pressure,** defined as $E_{pr.3}$, is approximately:

$$\varepsilon_{pr.3} = \left(\frac{1}{2}\right)\varepsilon_{SPPII.3} = 11\%$$

Note: In accordance with Subsection 6.4.3 (Measurement of Precision of Peak Rarefactional Pressure, p_r) the Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, a series of ten independent measurements on the specified standard test probe/driver combination yielded a relative standard deviation of p_r of less than 1% for the sample measurements.

The **relative error in the Mechanical Index**, defined as E_{MI}, is approximately:

$$\varepsilon_{MI} = \left(\varepsilon^2_{pr.3} + \left(\frac{\varepsilon_{fc}}{2}\right)^2 + \varepsilon^2_{DAMI} + \varepsilon^2_{TVMI} + \varepsilon^2_{SVMI}\right)^{1/2} = 31\%$$

where the following is defined:

E_{fc} Relative error in estimating center frequency, estimated as 8%.

E_{DAMI} Relative error in displaying the Mechanical Index, estimated as 20%.

E_{TVMI} Relative error in the Mechanical Index due to probe variability, estimated as 20%.

E_{SVMI} Relative error in the Mechanical Index due to ultrasound system variability, estimated as 2%.

Note: In accordance with Subsection 6.4.1 (Measurement of Precision of Center Frequency fc) of the Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, a series of ten independent measurements on the specified standard test probe/driver combination yielded a relative standard deviation of fc of less than 1% for the sample measurements.

The **relative error in the Soft-Tissue Thermal Index for scanned modes,** defined as $E_{TISscan}$, is approximately:

$$\varepsilon_{TISscan} = (\varepsilon^2_{W01} + \varepsilon^2_{fc} + \varepsilon^2_{DATISscan} + \varepsilon^2_{TVW0} + \varepsilon^2_{SVW0})^{1/2} = 35\%$$

where the following is defined:

E_{W01} Relative measurement error in estimating the peak acoustic power from 1cm width of the active scanned aperture, estimated as 10%.

$E_{DATISscan}$ Relative error in displaying the Soft-Tissue Thermal Index for scanned modes, estimated as 20%.

E_{TVW0} Relative error in peak acoustic power due to probe variability, estimated as 25%.

E_{SVW0} Relative error in peak acoustic power due to ultrasound system variability, estimated as 2%.

Note: In accordance with Subsection 6.4.2 (Measurement of Precision of Power, W) of the Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, a series of ten independent measurements on the specified standard test probe/driver combination yielded a relative standard deviation of W of less than 4% for the sample measurements.

The **relative error in total acoustic power at the scan/beam entrance to the body**, defined as E_{W0}, is approximately:

$$\varepsilon_{W0} = \varepsilon_{FB} = 10\%$$

The **relative error in the Soft-Tissue Thermal Index for unscanned modes, when the beam-entrance dimension is less than 1 cm^2 in area**, defined as $E_{TISunsc\text{-}A\leq1}$, is approximately:

$$\varepsilon_{TISunsc\text{-}A\leq1} = \left(\varepsilon^2_{W0} + \varepsilon^2_{fc} + \varepsilon^2_{DA\ TISunsc\text{-}\leq1} + \varepsilon^2_{TVW0} + \varepsilon^2_{SVW0}\right)^{1/2} = 35\%$$

where the following is defined:

$E_{DA\ TISunscan<1}$ Relative error in displaying the Soft-Tissue Thermal Index display for unscanned modes, when the beam-entrance dimension is less than 1 cm^2 in area, estimated as 20%.

The **relative error in the Soft-Tissue Thermal Index for unscanned modes, when the beam-entrance dimension is greater than 1 cm² in area**, defined as $E_{TISunsc\text{-}A>1}$, is approximately:

$$\varepsilon_{TISunsc\text{-}A>1} = \left(\varepsilon_{W0}^2 + \varepsilon_{fc}^2 + \varepsilon_{ITA.6}^2 + \varepsilon_{DA\ TISunsc\text{-}\leq 1}^2 + \varepsilon_{TVITA.6}^2 + \varepsilon_{SVITA.6}^2\right)^{1/2} = 47\%$$

where the following is defined:

$E_{ITA.6}$ Relative error in estimating the spatial peak intensity, when derated at 0.6 dB/ cm/MHz, estimated as 23%.

$E_{DA\ TISunsc>1}$ Relative error in displaying the Soft-Tissue Thermal Index display for unscanned modes, when the beam-entrance dimension is greater than 1 cm² in area, estimated as 20%.

$E_{TV\ ITA.6}$ Relative error in the spatial peak intensity, when derated at 0.6 dB/cm/MHz, due to probe variability, estimated as 34%.

$E_{SV\ ITA.6}$ Relative error in the spatial peak intensity, when derated at 0.6 dB/cm/MHz, due to ultrasound system variability, estimated as 2%.

The **relative error in the Bone Thermal Index for unscanned modes**, defined as $E_{TIBunsc.}$, is approximately:

$$\varepsilon_{TIBunsc.} = \left(\frac{1}{2}\right)\left(\varepsilon_{W0}^2 + \varepsilon_{ITA.6}^2 + \varepsilon_{DATIBunsc}^2 + \varepsilon_{TVW0}^2 + \varepsilon_{TVITA.6}^2 + \varepsilon_{SVW0}^2 + \varepsilon_{SVITA.6}^2\right)^{1/2} = 27\%$$

where the following is defined:

$E_{DATIBunsc}$ Relative error in displaying the Bone Thermal Index for unscanned modes, estimated as 20%.

The **relative error in estimating the Cranial Thermal Index**, defined as E_{TIC}, is approximately:

$$\varepsilon_{TIC} = \left(\varepsilon_{W0}^2 + \varepsilon_{Deq}^2 + \varepsilon_{DATIC}^2 + \varepsilon_{TVW0}^2 + \varepsilon_{SVW0}^2\right)^{1/2} = 34\%$$

where the following is defined:

E_{Deq} Relative error in estimating the equivalent diameter of the active aperture, estimated as 2%.

E_{DATIC} Relative error in displaying the Cranial Thermal Index, estimated as 20%.

The **estimated relative errors of the calculated indices** are as follows.

E_{MI}= 31%

$E_{TISscan}$= 35%

$E_{TISunsc\text{-}A<1}$= 35%

$E_{TISunsc-A>1}$ = 47%

$E_{TIBunsc}$ = 27%

E_{TIC} = 34%

T3.7.1 Relationship of Index to Display Accuracy

The discussion above concerns the relationship between the calculated index value.

(xCalc.), and the “true” value (xActual), which would be obtained under conditions without measurement uncertainty. Display precision is the relationship between the displayed index value (xDisplay) and (xCalc). The displayed values (shown in reverse video along with the corresponding labels) may take on the following values (where x indicates the calculated index value (xCalc.).

T3.7.2 Display Precision of MI Values

See the table Acoustic Index Parameters for a listing of the precision of the display for MI values. When the effects of calculation errors are combined with the effects of display precision, overall Display Accuracy can be defined as follows:

$$DisplayAccuracy = \frac{x_{Display} - x_{Actual}}{x_{Actual}}$$

T3.7.3 Measurement Accuracy

Accuracy Measures

The following general assumptions can be made about the accuracy of any ultrasound system:

- Velocity of sound uncertainty = 5%,
- Tissue shape is modeled as an ellipse or an ellipsoid,
- Caliper placement accuracy is one pixel (operator dependent),
- Measurement accuracy is based on the root-mean-square combination of all independent sources of error, and
- RMS errors are due to velocity of sound uncertainty, pixel error, and typical probe geometry.

Distance Accuracy

Distance accuracy measures are as follows:

Formula:

$$D = \sqrt{(x_1 + x_2)^2 + (y_1 + y_2)^2}$$

where (x_1,y_1) and (x_2,y_2) are the coordinates of the end points.

Range: 0-20 cm

Accuracy: For a 20 cm measurement, a 1 pixel error is 0.2 mm.

RMS errors:

- For D = 10mm, accuracy = 9%
- For D = 20mm, accuracy = 6%
- For D > 50mm, accuracy = 5%

T3.8 RFA Handpiece Technical Specifications

Table T-17. Handpiece Specifications

HANDPIECE SPECIFICATIONS	SPECIFICATION
Usage Type	Single-use, Disposable; sterile
Sterilization	Provided sterile by Ethylene Oxide (EO)
Shaft Materials	Composite Polymer
Introducer (operator accessible control)	2.4 mm diameter, Up to 3.2 cm deployment (Slide actuation)
Needle Electrodes (operator accessible control)	Seven Nitinol Electrodes maximum deployment 40 mm (Slide actuation)

HANDPIECE SPECIFICATIONS	SPECIFICATION
Electrode Thermocouples	4 T-type T/C's; Positioned within inner diameter at distal tip of 3 alternating circumferential Needle Electrodes and the center electrode for real-time continuous temperature monitoring.
Transport and Storage Environment	-20 °C to 40 °C 10% to 90% relative, non-condensing
Operating Environment	10 °C to 35 °C 30% to 75% relative, non-condensing
Rated Voltage	280 V

T3.9 Dispersive Electrode Technical Specifications

Table T-18. Dispersive Electrode Specifications

DISPERSIVE ELECTRODE SPECIFICATIONS	SPECIFICATION
Usage Type	Single-use, Disposable; non-sterile
Overall Dimensions	27.6 cm x 15.1 cm
Conductive Surface Area	Approximately 260 cm^2
Border Adhesive	Medical-grade Acrylic Adhesive
Hydrogel (Thickness)	0.040 inches +/- 0.005 inches (1.016 $\pm$ 0.127 mm)
Conductive Sheet (Thickness)	Aluminum, 0.002 inches +/- 0.0002 inches (.050 $\pm$ .005 mm)
Transport and Storage Environment	-20 °C to 40 °C 10% to 90% relative, non-condensing
Operating Environment	10 °C to 35 °C 30% to 75% relative, non-condensing

T3.10 Sonata Cables, Probes, and Accessories

Table T-19. RFA Handpiece Cable Specifications

RFA HANDPIECE CABLE SPECIFICATIONS	SPECIFICATION
Usage Type	Reusable
Sterilization	Moist Heat (steam)
Transport and Storage Environment	-20 °C minimum 10% to 90% relative, non-condensing
Operating Environment	10 °C to 35 °C 30% to 75% relative, non-condensing
Fluid Ingress Rating	IPX6; Protected against powerful water jets. The cable connectors should never be immersed in fluid.

The following is provided in accordance with IEC 60601-1-2:2014, section 5.2.2.1.

Table T-20. Sonata System Cable Dimensions

SONATA SYSTEM CABLE DIMENSIONS	MAXIMUM LENGTH
Sonata Intrauterine Ultrasound (IUUS) Probe Cable	3 m
RFA Handpiece Cable, attached to RFA Handpiece	3 m
USB Cable	.9 m
Cable, 8-pin, mini-DIN	.9 m
Jumper Cord, 10 Amp, 250V AC	1 m
Line cord, hospital grade, Australia & New Zealand, Denmark, Switzerland	2.5 m
Line cord, hospital grade, North American	3 m
Line cord, hospital grade, UK/Ireland, Continental Europe	3.5 m

T3.11 Power Strip

Table T-21. Power Strip

POWER STRIP	SPECIFICATIONS
Double Pole, Single Throw Circuit Breaker	10 Amp
Input Voltage Rating	125-240V AC

T3.12 SMART TABLET Power Adapter

Table T-22. SMART TABLET Power Adapter

SMART TABLET POWER SUPPLY	SPECIFICATIONS
Input Voltage Rating	90 - 264 VAC
Frequency	47-63 Hz
Input Current	1.5 A rms @ 115 VAC 0.6 A rms @ 230 VAC
Output Voltage Rating	19 VDC
Output Current Rating	4.74 A

T3.13 System “Applied Parts”

The following is provided in accordance with IEC 60601 3rd edition, §7.9.2.5.

Table T-23. Applied Parts List

APPLIED PARTS LIST	SPECIFICATIONS
IUUS Probe	See Table T-14
RFA Handpiece	See Table T-17
Dispersive Electrodes	See Table T-18

Technical Chapter 4 EMC Testing Results

The following information is provided in accordance with the fourth edition of IEC 60601-1-2:2014, section 5.2.2. The Sonata System is intended for use in the electromagnetic environment specified below. The customer or the operator of the System should assure that it is used in such an environment.

T4.1 Essential Performance and Device Function

Essential performance of the Sonata system is summarized below. No degradation of this performance was observed when tested against immunity requirements.

- Ultrasound image quality sufficient for targeting of region to be ablated and establishment of safe margin to uterine serosa;
- Correct display of safety-related indications (alarms);
- Proper control of IUUS probe acoustic output, as indicated by display of ultrasound indices;
- Proper control of IUUS probe self-heating;
- Proper display of SMART guide; and
- Controlled delivery of RF Energy.

Table T-24. Guidance and Manufacturer Declaration - Electromagnetic Emissions

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT GUIDANCE
Conducted Emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010	Group 1	The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated Emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010	Class A	NOTE The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonics IEC/EN 61000-3-2:2014	Class A	
Voltage Fluctuations/Flicker Emissions IEC/EN 61000-3-3:2013	Complies	

NOTES	
	U_T is the a.c. mains voltage before application of the test level.

Table T-25. Guidance and Manufacturer Declaration - Electromagnetic Immunity

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ± 2, 4, 8 & 15kV air discharge	± 8 kV contact discharge ± 2, 4, 8 & 15kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated Immunity IEC/EN 61000-4-3	80 MHz - 2.7 GHz 3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	80 MHz - 2.7 GHz 3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = (6/d)\sqrt{P}$ Where *P* is the maximum power in W, *d* is the minimum separation distance in m, and *E* is the IMMUNITY TEST LEVEL in V/m. If the ME EQUIPMENT or ME SYSTEM complies with higher IMMUNITY TEST LEVELS for this test, the 30 cm minimum separation distance in 5.2.1.1 f) may be replaced with minimum separation distances calculated from the higher IMMUNITY TEST LEVELS.
Proximity field from RF wireless communications equipment IEC 61000-4-3	See Section 6.17.3.1 Or Table 9 of standard	See Section 6.17.3.1 Or Table 9 of standard	
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	± 0.5 kV , ± 1 kV Line(s) to Lline(s) ± 0.5 kV , ± 1 kV ,± 2 kV Line(s) to Earth	± 0.5 kV , ± 1 kV Line(s) to Lline(s) ± 0.5 kV , ± 1 kV ,± 2 kV Line(s) to Earth	Mains power quality should be that of a typical commercial or hospital environment.
Conducted Immunity (AC Power) (I/O Lines) IEC/EN 61000-4-6	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM & amateur bands 1 kHz AC Mains	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM & amateur bands 1 kHz AC Mains	The ISM (industrial, scientific and medical) bands and the amateur radio bands between 0,15 MHz and 80 MHz. Interference may occur in the vicinity of equipment marked with the following symbol: 

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT
Voltage Dips, Short Interruptions and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	0% U_T .5 cycle 0% U_T 1 cycle 70% U_T 25 cycles 0% U_T5 Sec	0% U_T .5 cycle 0% U_T 1 cycle 70% U_T 25 cycles 0% U_T5 Sec	Mains power quality should be that of a typical commercial or hospital environment. If the operator of the Sonata System requires continued operation during power mains interruptions, it is recommended that the Sonata System be powered from an uninterruptible power supply or battery.
Power Frequency (50/60 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 commercial or hospital environment.

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

NOTES	
	At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Index of Terms

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