gynesonics®

Sonata® SYSTEM

Sonata System Service Manual

For
Sonata System 2.1 and Sonata System 2.2
SONATA2-110 with software SW-002

Manual Catalog #: REF-011US.
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Notice

Sonata® System 2.1 and Sonata System 2.2 Service Manual

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About this Instruction Manual

This Manual covers the routine inspections and checks that may be performed of the Sonata System. Refer to the Sonata System 2.1 or Sonata System 2.2 *Instructions for Use with Technical Appendix* for detailed information regarding the Sonata System. Contact Gynesonics for additional copies of this manual, any additional questions or support required for training and service, including installation, and maintenance.

Manual originally issued in English.

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Symbols Glossary

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

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.
	Catalogue number	Indicates the manufacturer's catalogue 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.
	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 colours and safety signs – Registered safety signs.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	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.
	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.
	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.

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	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.
	Equipotentiality	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. The handle and device shaft and tip are IPX 7 rated.	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.
	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.
	"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.
			ISO 7000-2621	Graphical symbols for use on equipment.
	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
	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.
	Medical Device	Indicates that the device is a Medical Device	MedTech Europe Guidance May 2019	Use of Symbols to Indicate Compliance with the MDR

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	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.

Glossary of Terms, Acronyms, and Definitions

TERM	DEFINITION
AP	APPLIED PART: part of ME EQUIPMENT that in NORMAL USE necessarily comes into physical contact with the PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function. [IEC 60601-1 #3.8]
DUT	Device Under Test which may be either the ESU or the SMART Tablet
ESU (RFG)	Electrosurgical Unit: Sonata Radiofrequency Generator.
I_A	Leakage current from the applied part. For the ESU (RFG) this consists of leakage from both Handpiece signals and the Neutral electrode connections. For the SMART Tablet this consists of leakage from the Sonata Intrauterine Ultrasound Probe.
I_P	Patient leakage is the current which flows to ground (PE) from the applied parts via the patient.
IN or IT	Isolated neutral (terre) describes a wiring system where the neutral line connection N is not directly referenced to earth. Electrical Safety tester displays IT at top of display when IT configuration is detected.
L	Line connection which is typically measures 230 ± 20 VAC to PE in an earth referenced neutral wiring system. (TN)
LN	Line connection to DUT with normal polarity-L to L and N to N. Leakage currents are measured with both normal and reversed polarity.
MAP	Mains on APPLIED PART: A method of assessing patient leakage current under the single fault condition where MAINS VOLTAGE is present on the APPLIED PART.
MAINS PLUG	Part, integral with or intended to be attached to a POWER SUPPLY CORD of electrical equipment, to be inserted into a mains socket-outlet. [IEC 60601-1 #3.50]
MSO	MULTIPLE SOCKET OUTLET: One or more socket-outlets intended to be connected to, or integral with, flexible cables, cords or ME EQUIPMENT providing SUPPLY MAINS or equivalent voltage. [IEC 60601-1 #3.67]
N	Neutral line connection which typically measures 0 V ± 15 VAC in an earth referenced neutral wiring system. (TN)
NE (DE)	Neutral electrode (DE dispersive electrode) provides return path for HF energy from patient to ESU (RFG)
NL	Line connection to DUT with reversed polarity. DUT N lead measures 230 ± 20 VAC to PE.
PE	PROTECTIVE EARTH. The PROTECTIVE EARTH CONDUCTOR is a conductor to be connected between the PROTECTIVE EARTH TERMINAL and an external protective earthing system. [IEC 60601-1 #3.93]
PET	PROTECTIVE EARTH TERMINAL: The PROTECTIVE EARTH TERMINAL is a terminal connected to conductive parts of CLASS I equipment for safety purposes. This terminal is intended to be connected to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR. [SOURCE: IEC 60601-1:2005, 3.95]
TN	Terre neutral describes an earth referenced wiring system where the Neutral connection is connected to earth.
R_{INS}	The insulation resistance includes two resistance measurements. Resistance is measured between shorted mains L and N connections and the PE at the test socket. Resistance is separately measured between the shorted mains L and N connections to the applied part connections.
R_{PE}	Resistance between protective earth lead and the protective earth terminal in the ESU (RFG)

GENERAL WARNINGS AND CAUTIONS	
	REFER TO SONATA SYSTEM INSTRUCTIONS FOR USE FOR COMPLETE WARNINGS AND CAUTIONS
	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.
	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
	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.
	SALE AND USE Federal law restricts this device to sale by or on the order of a physician.
	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
	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
	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
	BATTERY DO NOT attempt to remove or use the battery inside the SMART Tablet.

GENERAL WARNINGS AND CAUTIONS	
⚠	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.
⚠	UNPLUG MAIN POWER TO CHECK CONNECTIONS For optimum safety, unplug the main system power cord before attempting to check power cord connections to system.
⚠	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. Patient ablation data records and images 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.

Chapter 1 Introduction

1.1 Manufacturer

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Redwood City, CA 94063 USA
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Fax: +1 650-299-1566
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1.2 Device Intended Use

The Sonata® Transcervical Fibroid Ablation System 2.1 and 2.2 are intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.

1.3 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. Additional room requirements are defined in the Sonata System Instructions for Use.

- **Power**: AC 100-240V, 50/60 Hz, 15A max, grounded. Backup is recommended.
- **Temperature**: 10°C to 35°C for all equipment and components.
- **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.

1.4 System Overview

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. Once connected, the assembly of the RFA Handpiece and the IUUS Probe is referred to as the Treatment Device. 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.

Electrical Overview:

Electrical input ratings (V~, Hz, VA):	100-240 VAC, 50-60 Hz, < 15 A
Electrical classification:	Class I
Mode of operation:	Suitable for continuous operation
Applied Part (patient lead):	Type BF

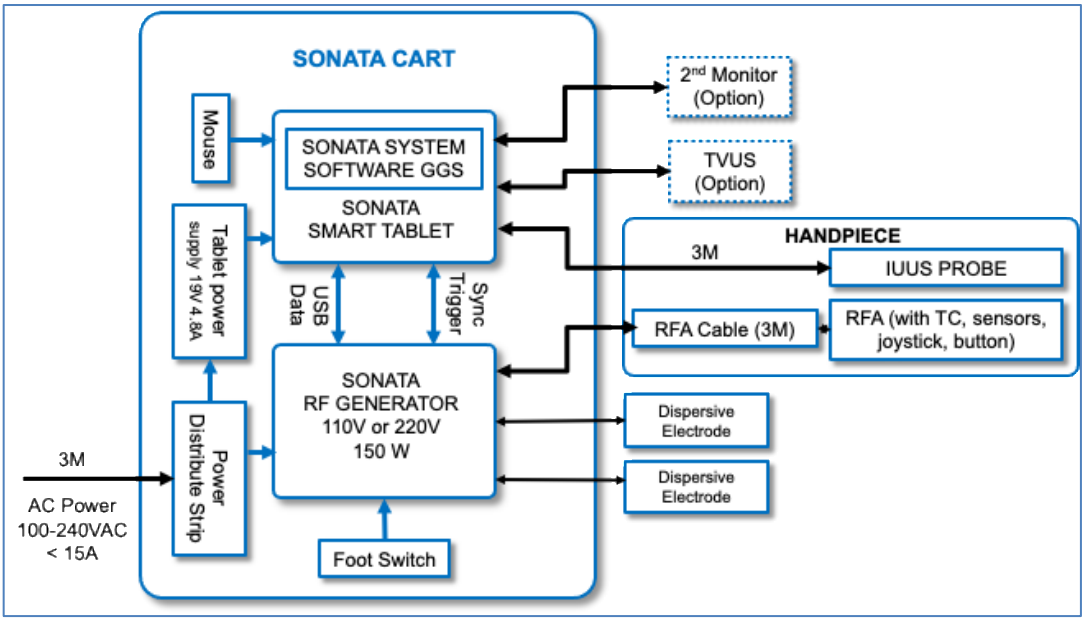


Figure 1-1. System Block Diagram

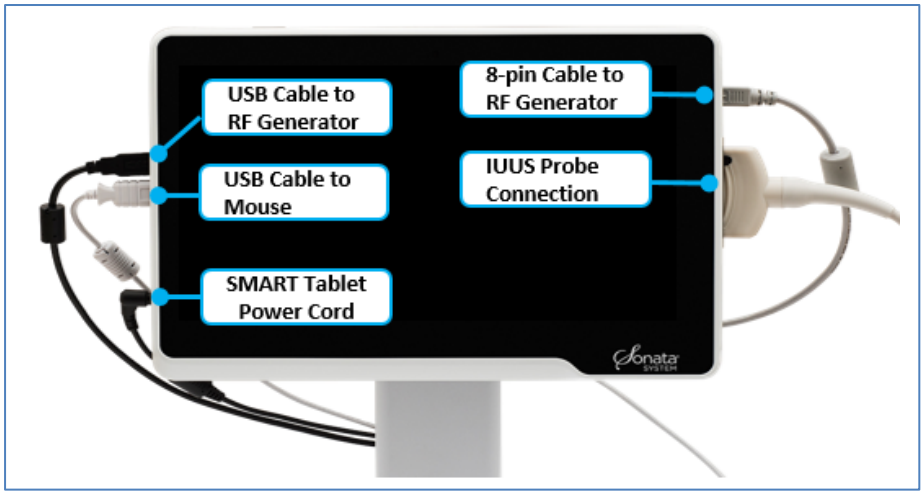


Figure 1-2. Connection ports on the SMART Tablet.

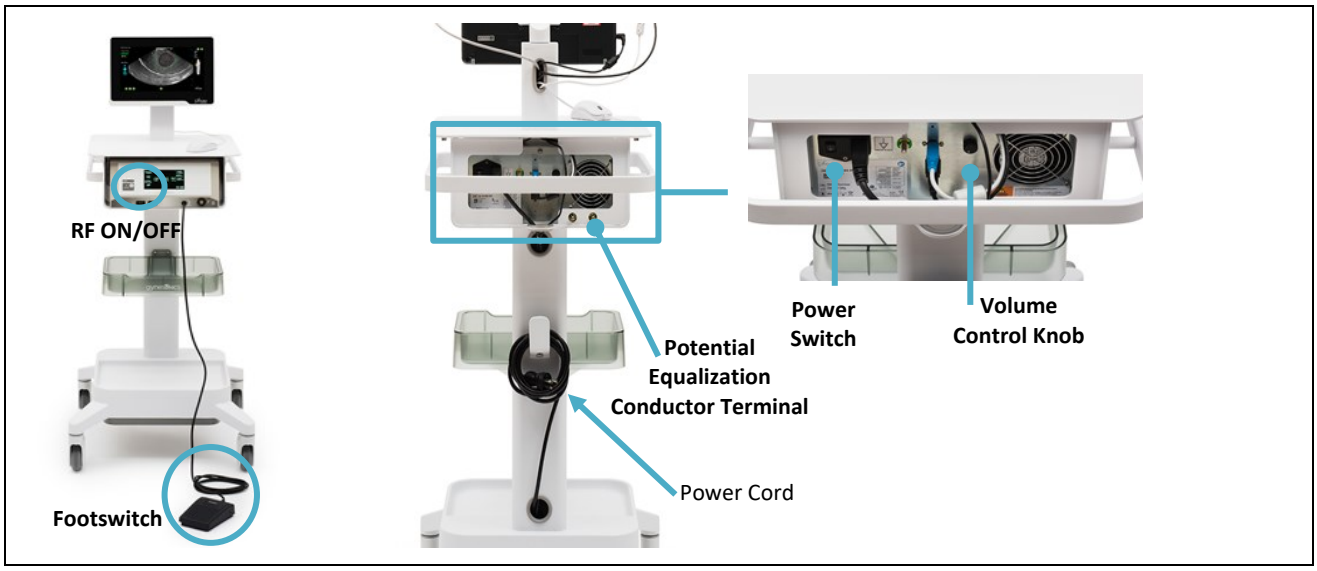


Figure 1-3. Connections and Controls on the RF Generator.

CAUTIONS	
⚠	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

1.5 Standards

The Sonata 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.

The Sonata System components are not anticipated to degrade in performance under normal use within the expected use life of 5 years. As such, periodic maintenance inspections are not mandatory. For provider facilities with Quality Assurance Programs that may require routine inspections the following standards and guidance are recommended for service tests:

- NFPA® 99 *Health Care Facilities Code*
- NFPA 99 *Health Care Facilities Code Handbook*
- IEC 62353 *Recurrent test and test after repair of medical electrical equipment*
- ANSI/AAMI ES 60601-1; EN 60601-1

1.6 Reference Documents

The Sonata System 2.1 and 2.2 Instructions for Use with Technical Appendix describe:

- Intended use, patient selection, and risks;
- Room requirements, system setup, and accessories;
- Sonata System description and procedure, including user control Interface and messages
- Troubleshooting
- Clinical trial results
- Technical information

Additional copies of the Sonata System Instructions for Use with Technical Appendix may be obtained from Gynesonics.

Table 1 Sonata System 2.1 and 2.2 Instructions for Use (IFU) with Technical Appendix

Sonata System Durable Equipment	Sonata System Software	IFU Order #
SONATA2-110	SW-002	Sonata System 2.1: REF-005 Sonata System 2.2: REF-009

1.7 Personnel Qualification and Service Documentation

The procedures in this manual are intended to be performed by personnel who are trained in the maintenance of electrical equipment, such as typically found in hospital biomedical engineering departments. Personnel should review and understand this manual thoroughly prior to performing procedures described herein. Supplemental training is available from Gynesonics upon request. For all other service, contact Gynesonics or an authorized distributor.

All service information and data should be recorded on the FRM 06311-004 Sonata System Service Form: Basic Safety and Function Checks. An updated safety check label should be added to the system cart with date and service signature.

CAUTION	
⚠	Procedures in this manual are intended to be performed by personnel who are trained in the maintenance of electrical equipment. Electrical testing may present shock risk to the testing personnel and if performed improperly may lead to reduced safety or loss of function.

1.8 Tools Recommended for Service

Various measurement instruments for Medical Electronic (ME) Equipment devices may be used to perform these tests. The instruments should conform to one or more of the requirements in the standards outlined in Section 1.5.

Examples of appropriate instruments include:

- DALE 601 Electrical Safety Analyzer
- Fluke ESA620/615/614/612 Electrical Safety Analyzer

The following connective tools are necessary for the testing and can be obtained from Gynesonics.

- ACCY-014 Patient Lead Grounding Cable
  Used for measurement of Patient Lead leakage current

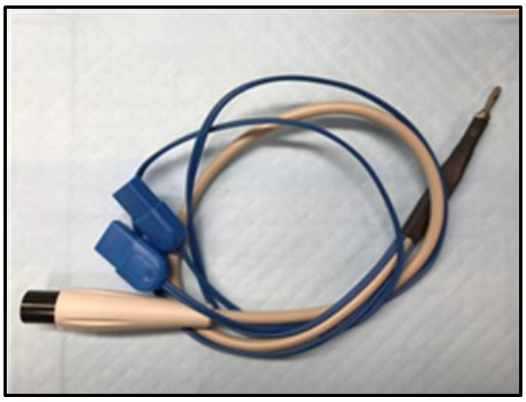


Figure 1-4. ACCY-014 Patient Lead Grounding Cable

Chapter 2 Electrical Safety Tests

The electrical safety tests in this section are based on and conform to IEC 62353 and NFPA 99[1]. They are intended for electrical safety evaluation of cord-connected, electrically operated, patient care equipment. If additional information is needed, refer to IEC 62353 and NFPA 99 or the corresponding Handbook.

The tests summarized in Table 2 should be performed at regular intervals. The suggested interval is annual or consistent with user site policy.

All tests listed in Table 2 can be done with a Safety Analyzer listed in 1.8 or equivalent.

To connect to the Safety Analyzer, use ACCY-014 Patient Lead Grounding Cable.

To connect to the chassis for leakage tests, connect to the Potential Equalization post on the chassis.

Table 2 Routine Electrical Safety Tests

Testing Item	Instructions and Test Conditions	Standards Clause	Acceptance Criteria
Visual Inspection of Physical Integrity	§2.1	IEC 62353: Clause 5.2 NFPA 99:2018 10.3.1	Any condition that appears to affect proper operation or present an otherwise unsafe condition should be repaired or replaced.
			Safety related markings and labels should be legible and complete
			Sonata System documentation is available and reflects the current configuration of the system
Ground Resistance (PE to Ground)	§2.2	IEC 62353: Clause 5.3.2.2b NFPA 99:2018 10.3.2	≤ 0.30 Ω (IEC 62353) ≤ 0.50 Ω (NFPA 99)
Insulation Resistance (Mains to PE)	§2.2	IEC 62353: Clause 5.3.3	≥ 2 M Ω
Earth Leakage Current (LN)	§2.3	IEC 60101-1 subclause 8.7.3	≤ 500 µA
Earth Leakage Current (NL)	§2.3	IEC 60101-1 subclause 8.7.3	≤ 500 µA
Touch (Chassis) Current,	§2.3	IEC 62353: Clause 5.3.4.1 NFPA 99:201810.3.3, 10.3.5	≤ 500 µA
Patient Lead Leakage, Ground switch CLOSED	§2.4	NFPA 99:2018 10.3.6	≤ 100 µA
Patient Lead Leakage,	§2.4	IEC 62353: Clause 5.3.4.3	≤ 500 µA

[1] IEC 62353, ED 2.0:2014; NFPS® 99 Health Care Facilities Code Eleventh Edition 2018, §10.3

Ground switch OPEN		NFPA 99:2018 10.3.6	
Functional Test	§2.5	EN 62353 #5.4	The minimum and maximum of all 4 temperature channel read by the RF Generator are within 4°C.

CAUTION	
⚠	Electric Shock Hazard. When the meter's ground switch is OPEN, don't touch the unit!

2.1 Visual Inspections

Visual inspections form a critical part of the general safety inspections during the functional life of the product. Confirm the physical integrity of the power cord assembly and other Sonata System components as listed in Table 3.

Table 3 Visual Inspection

SPECIFICATION	INSPECTION
System Safety Marking and Labeling	Labels are intact and legible
Physical integrity	Check for any obstructions on Cart wheels, wheel locks, and handles.
Housing and Enclosure	No external damages or cracks on housing and enclosure of the RF Generator and Tablet.
Cabling, including power cords, USB and Sync cables	Look for defects such as cuts and wear.
User documentation or IFU	The documentation is accessible and up to date

Replace cords if the attachment plug 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.

Any condition that appears to affect proper operation or present an otherwise unsafe condition should be repaired or replaced. For replacement of cords, connectors, or accompanying documentation, contact the Gynesonics Representative.

2.2 Insulation Resistance

Measure resistance between the chassis and the ground pin of the attachment plug as shown in Figure 1-1 through 2-3. During test, the cord shall be flexed at its connection to the attachment plug or connector, and at its connection to the strain relief on the chassis. Note that vigorous flexing is not needed.

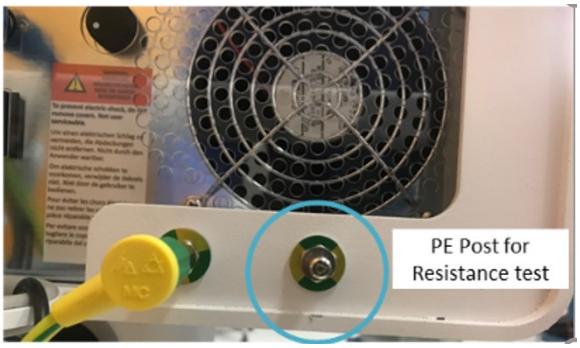


Figure 1-1. Connections for the Ground Resistance Test

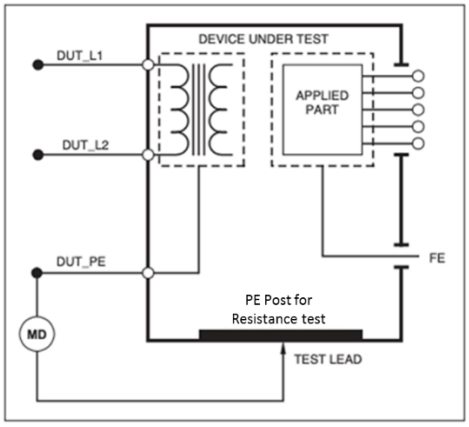


Figure 2-2. The measurement of the Ground Resistance (Ref IEC 62353 Figure 1)

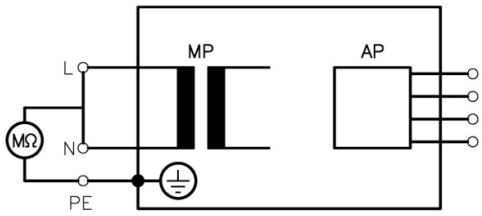


Figure 2-3. The measurement of the insulation resistance (Ref IEC 62353 Figure 3)

2.3 Earth Leakage and Touch Current

Earth Leakage Current is defined in IEC 60101-1 subclause 8.7.3. Measure Earth Leakage Current as shown in Figure 2-4.

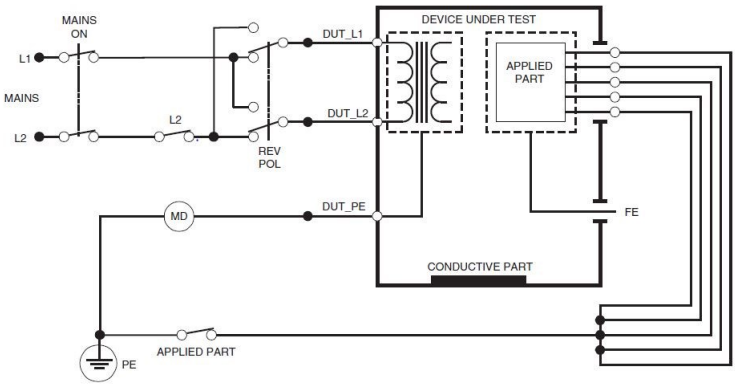


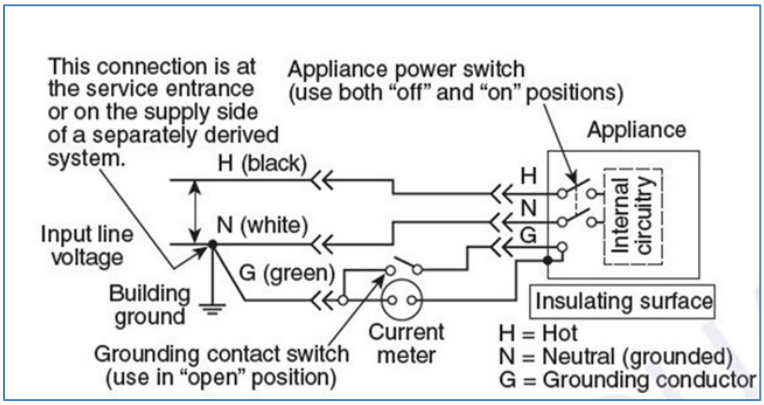
Figure 2-4 The measurement of earth leakage current (Open the "APPIED PART" switch)

Ensure that Resistance has been tested per §2.2 and Earth Leakages are also tested and meet acceptance criteria prior to testing touch current. Personnel safety may be compromised if the grounding conductor is not intact and the leakage (or touch) current is high.

Measure touch current as described below. Conditions of test include:

- Normal polarity
- Ground wire disconnected (SFC)

The cart is the only conductive surface accessible to the operator or patient when in normal use position. Therefore, the touch leakage current is measured between the PE post located on the rear of the cart and Grounding contact as shown in Figure 2-5.



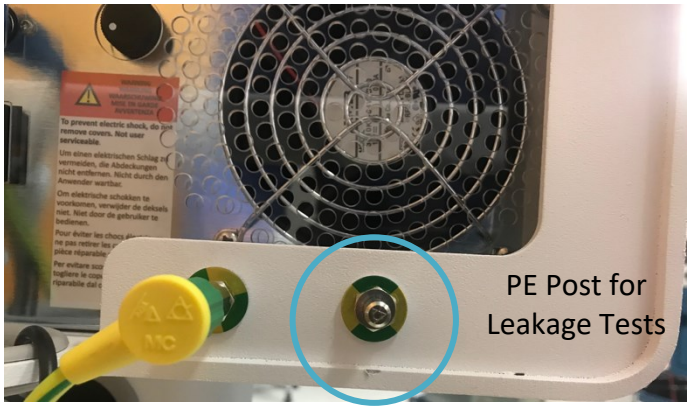
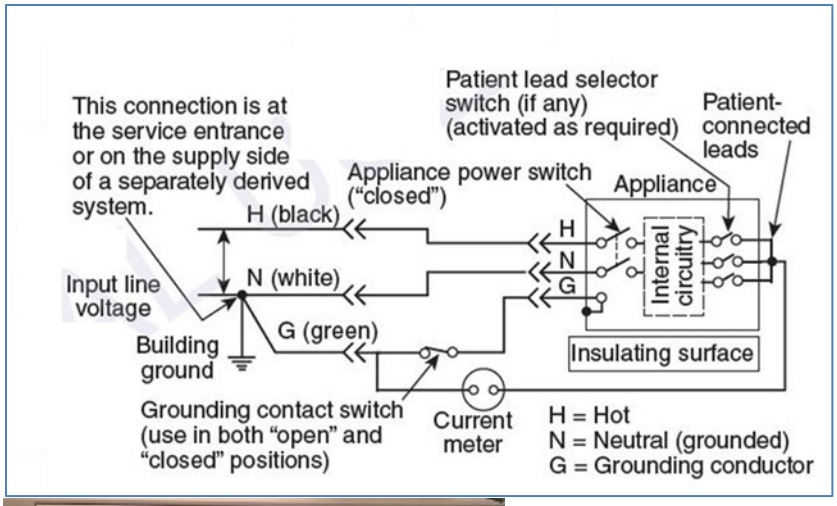


Figure 2-5. Touch Current Test Connections

2.4 Patient Lead Leakage

Measure patient lead leakage using Patient Lead Grounding Cable ACCY-014. Conditions of test include:

- Power plug connected normally
- System powered on
- Ground switch CLOSED (NC limit ≤ 100 µA), and separately with ground switch OPEN (SFC limit ≤ 500 µA)
- Leakage current measured between all patient leads (RFA Handpiece and Dispersive Electrodes) connected together and ground



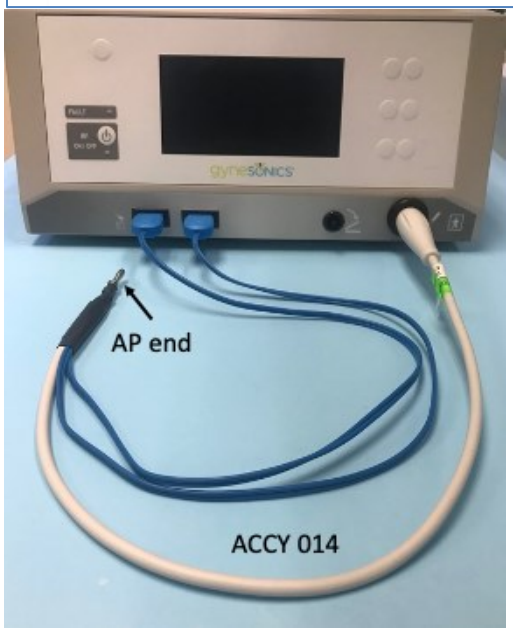


Figure 2-5. Patient Lead Leakage Test Connection

2.5 Temperature Sensing Accuracy Check

1. Sonata System is designed with built-in self-calibration and safety check functions. No manual calibration is needed during the regular service.
2. Sonata System RF energy delivery is controlled to reach and maintain tissue temperature of 105 ˚C as measured by thermocouples in the Radiofrequency Ablation (RFA) Handpiece.
3. Temperature variation (variation between signal to signal when measuring the same reference medium) is the primary test of temperature sensing accuracy. The test below evaluates the accuracy of the Sonata RF Generator to read all thermocouples of each handpiece which was calibrated at Gynesonics manufacture.

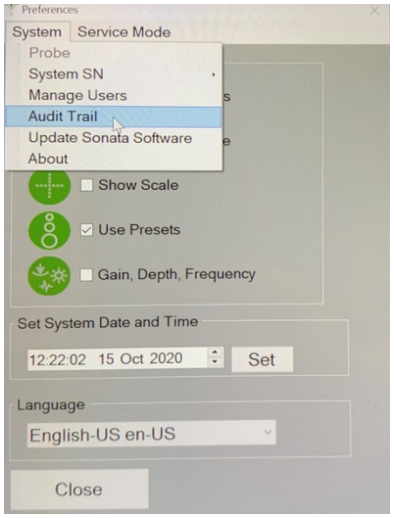


Figure 2-6. Open the Audit Trail File in the system configuration

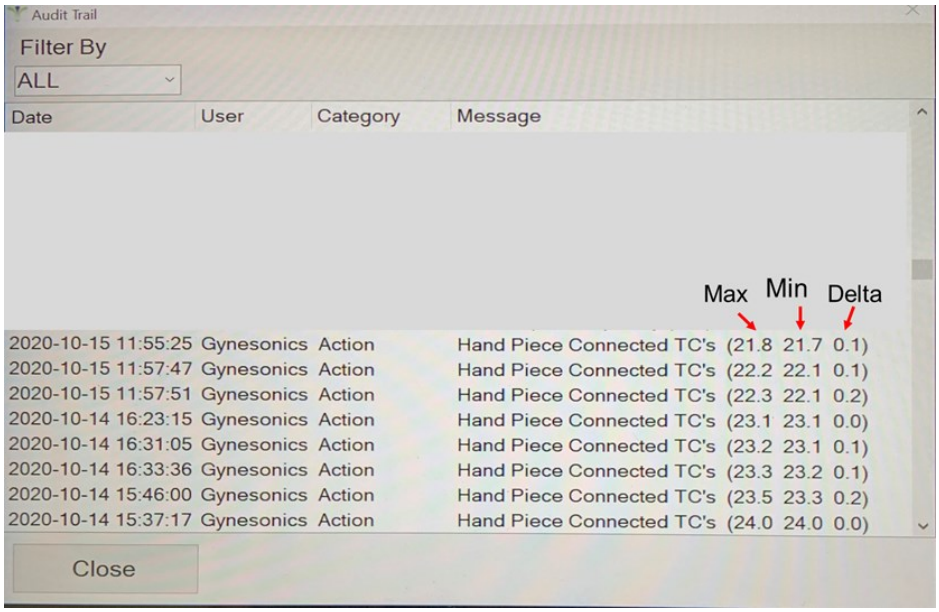


Figure 2-7. Check the thermocouple readings

Table 4. Recommended Temperature Sensing Test:

TITLE	NOMINAL TEST VALUE	PASS LIMIT	CHECK INSTRUCTION
Thermocouple Check	Site Room Ambient	The minimum and maximum of all 4 temperature channels read by the RF Generator are within 4°C.	Click the message column to sort data and scroll down to find “Hand Piece Connected TC’s” (Figure 2.7). If the maximum and minimum of the 4 temperature values are within a 4°C range, the test is passing.

If the difference of maximum and minimum values is larger 4°C, contact Gynesonics for replacement RF Generator unit.

Chapter 3 Troubleshooting

Sonata System provide comprehensive messages for the system and device errors. Please refer the error code list in Chapter 7 of the Sonata System Instructions for Use.

Anytime an abnormal condition is identified, contact Gynesonics Service.

Chapter 4 Field Replacement and Software Upgrade

WARNING	
	The Sonata System 2.2 is NOT designed to be field repairable. Do not attempt to service any defective components in field as doing so may compromise function, risk, or safety. Contact Gynesonics Service if any component needs to be replaced.

The Sonata System 2.1 or Sonata System 2.2 hardware upgrade should be performed by a Gynesonics service representative. After the upgrade, the system visual inspections and safety tests should be performed and documented per this procedure.

Manufacturer initiated periodic software updates may be required and can be performed by a Gynesonics service representative.

All service information and data should be recorded on the FRM 06311-004 Sonata System Service Form: Basic Safety and Function Checks. A safety check label should be added to the system cart with date and service signature.

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The Sonata System 2.2 is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding. To learn more, visit www.gynesonics.com/sonata-system.

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