FUJIFILM
Value from Innovation

SonoSite SII

SERVICE MANUAL

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Caution: Federal (United States) law restricts this device to sale by or on the order of a physician.

The FUJIFILM SonoSite ultrasound system(s) referenced in this document may be covered by one or more of the following U.S. patents: US 8,861,822; US 8,858,436; US 8,834,372; US 8,805,047; US 8,439,840; US 8,398,408; US 8,355,554; US 8,216,146; US 8,213,467; US 8,147,408; US 8,137,278; US 8,088,071; US 8,066,642; US 8,052,606; US 7,819,807; US 7,804,970; US 7,740,586; US 7,686,766; US 7,604,596; US 7,591,786; US 7,588,541; US 7,534,211; US 7,449,640; US 7,169,108; US 6,962,566; US 6,648,826; US 6,575,908; US 6,569,101; US 6,471,651; US 6,416,475; US 6,383,139; US 6,364,839; US 6,203,498; US 6,135,961; US 5,893,363; US 5,817,024; US 5,782,769; US 5,722,412; AU: 730822; AU: 727381; CA: 2,372,152; CA: 2,371,711; CN 103237499B; CN 101231457B; CN 98108973.9; CN 98106133.8; CN 97113678.5; DE 69831698.3; DE 69830539.6; DE 69730563.5; DE 602004027882.3; DE 602004023816.3; DE 60034670.6; DE 60029777.2; EP 1589878; EP 1552792; EP 1180971; EP 0875203; EP 0815793; EP 1180970; EP 0881492; ES 2229318; ES 159878; ES 1552792; ES 0881492; FR 158978; FR 1552792; FR 1180970; FR 0881492; FR 0875203; FR 0815793; GB 158978; GB 1552792; GB 1180971; GB 1180970; GB 0881492; GB 0875203;GB 0815793; IT 1589878; IT 1552792; IT 0881492; IT 0815793; JP 5782428; JP 4696150; KR 532359; KR 528102; NO 326814; NO 326202 and pending.

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Chapter 1: Introduction

Before servicing the SonoSite SII ultrasound system, please read this manual.

The ultrasound system has multiple configurations and feature sets. All are described in this service manual but not every option may apply to your system. System features depend on your system configuration, transducer, and exam type.

Refer to the *SII Ultrasound System User Guide* for additional information regarding safety, system controls, operation, capabilities, and specifications.

Audience

The intended audience of this manual is properly trained field and in-house service personnel.

Contact Information

Questions and comments are encouraged. FUJIFILM SonoSite is interested in your feedback regarding the service manual. If you encounter difficulty with the system, use the information in this manual to help correct the problem. If the problem is not covered here, contact FUJIFILM SonoSite Technical Support as follows:

Technical Support (USA, Canada)	1-877-657-8118
Technical Support fax:	1-425-951-6700
Technical Support e-mail:	service@sonosite.com
FUJIFILM SonoSite website:	**www.sonosite.com**
International Technical Support:	Contact your local representative or call (USA) +425-951-1330
European Service Center	United Kingdom Tel: 0044 01462341151 e-mail: uk-service@sonosite.com France Tel: 0033 01/82880702 e-mail: ERAF-service@sonosite.com Germany Tel: 0049 069/80884030 e-mail: ERAF-service@sonosite.com Spain Tel: 0034 911238451 e-mail: ERAF-service@sonosite.com Italy Tel 0039 02 94753655 e-mail: ERAF-service@sonosite.com
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Conventions

These conventions are used in this service manual:

- A **WARNING** describes precautions necessary to prevent injury or loss of life.
- A **Caution** describes precautions necessary to protect the products.
- Numbered steps must be performed in a specific order.
- Bulleted lists present information in list format but do not imply a sequence.

Labeling symbols

The following symbols are used on the products, packaging, and containers.

Table 1: Labeling Symbols

Symbol	Definition
	Alternating Current (AC)
	Class 1 device indicating manufacturer's declaration of conformance with Annex VII of 93/42/EEC
	Class 1 device requiring verification by the Notified Body of sterilization or measurement features, or to a Class IIa, IIb, or III device requiring verification or auditing by the Notified Body to applicable Annex(es) of 93/42/EEC
	Attention, see the user guide
	Follow instructions for use.
	Device complies with relevant Australian regulations for electronic devices.
	Batch code, date code, or lot code type of control number
	Biological risk
	Authorized representative in the European Community
	Canadian Standards Association. The "C" and "US" indicators next to this mark signify that the product has been evaluated to the applicable CSA and ANSI/UL Standards, for use in Canada and the US, respectively.
	Catalog number

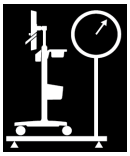
Table 1: Labeling Symbols (Continued)

Symbol	Definition
	Collect separately from other household waste (see European Commission Directive 93/86/EEC). Refer to local regulations for disposal.
	Corrugated recycle
	Dangerous voltage
	Date of manufacture
	Manufacturer
	Direct Current (DC)
	Do not get wet.
	Do not stack over 2 high.
	Do not stack over 5 high.
	Do not stack over 10 high.
	Electrostatic sensitive devices
	Device complies with relevant FCC regulations for electronic devices.
	Fragile
GEL	Gel
STERILE R	Sterilized using irradiation

Table 1: Labeling Symbols (Continued)

Symbol	Definition
STERILE EO	Sterilized using ethylene oxide
	Hot
	Indoor use only.
	Non-ionizing radiation
	Paper recycle
SN	Serial number type of control number
	Temperature limitation
	Atmospheric pressure limitation
	Humidity limitation
IPX7	Submersible. Protected against the effects of temporary immersion.
IPX8	Water-Tight Equipment. Protected against the effects of extended immersion.
	Handle transducer with care.
	To avoid tipping, do not move the system using the handle on the front of the SonoSite SII ultrasound system.
	When moving the system, push the stand using the tray assembly.
	Type BF patient applied part (B = body, F = floating applied part)
	Defibrillator proof type CF patient applied part
	A mandatory action that the user shall read the accompanying documentation for more information.

Table 1: Labeling Symbols (Continued)

Symbol	Definition
	Pollution Control Logo. (Applies to all parts/products listed in the China RoHS disclosure table. May not appear on the exterior of some parts/products because of space limitations.)
	China Compulsory Certificate mark (“CCC Mark”). A compulsory safety mark for compliance to Chinese national standards for many products sold in the People’s Republic of China.
	Maximum weight load
WARNING: Connect Only Accessories and Peripherals Recommended by FUJIFILM SonoSite	WARNING: Connect Only Accessories and Peripherals Recommended by FUJIFILM SonoSite

Chapter 2: Specifications

System Specifications

This chapter contains information regarding system specifications and accessory compatibility. The information applies to the ultrasound system, transducers, accessories, and peripherals.

System Dimensions

Height: 17.6 in. (44.7 cm)

Max height with stand: 59.5 in. (151 cm)

Min height with stand: 49 in. (124.5 cm)

Width: 11.3 in. (28.7 cm)

Depth: 4.8 in. (12.2 cm)

Weight:12.5 lbs. (5.7 kg)

Weight with stand 57.5 lbs. (26.1 kg)

Display Dimensions

Length: 9.7 in. (24.6 cm)

Height: 7.3 in. (18.5 cm)

Diagonal: 12.1 in. (30.7 cm)

Environmental limits

Note: The temperature, pressure, and humidity limits apply only to the ultrasound system and transducers.

Operating (system, battery, and transducer)

10–40°C (50–104°F), 15–95% R.H.

700 to 1060hPa (0.7 to 1.05 ATM)

Shipping and storage (system and transducer)

-20–60°C (-4–140°F), 15–95% R.H.

500 to 1060hPa (0.5 to 1.05 ATM)

Shipping and storage (battery)

-20–60°C (-4–140°F), 15–95% R.H. (For storage longer than 30 days, store at or below room temperature.)

500 to 1060hPa (0.5 to 1.05 ATM)

Electrical specifications

Power Supply Input:	100-240 VAC, 50/60 Hz, 2.0 A Max @ 100 VAC.
Power Supply Output 1:	15 VDC, 5.0A Max (system)
Power Supply Output 2:	12 VDC, 2.3A Max (battery)

Combined output not exceeding 75W.

Battery specifications

The battery is comprised of six lithium-ion cells plus electronics, a temperature sensor, and battery contacts. Run time is up to two hours, depending on imaging mode and display brightness.

Imaging Modes

2D (256 gray shades)

Color power Doppler (CPD) (256 colors)

Color Doppler (Color) (256 colors)

M Mode

Tissue Harmonic Imaging (THI)

Image and Clip Storage

The number of images and clips you can save varies with imaging mode and file format.

Compatible accessories and peripherals

FUJIFILM SonoSite has tested the SonoSite SII ultrasound system with the following accessories and peripherals and has demonstrated compliance to the requirements of IEC60601-1-2:2007.

You may use these FUJIFILM SonoSite accessories and third-party peripherals with the SonoSite SII ultrasound system.

WARNING:	Use of the accessories with medical systems other than the SonoSite SII ultrasound system may result in increased emissions or decreased immunity of the medical system.
WARNING:	Use of accessories other than those specified may result in increased emissions or decreased immunity of the ultrasound system.

Accessories and peripherals compatible with SonoSite SII ultrasound system

Description	Part Number	Maximum Cable Length
C11x transducer	P07678	6.0 ft/1.8 m
rC60xi transducer	P21070	5.5 ft/1.7 m
rC60xi transducer armored	P21636	5.5 ft/1.7 m
rP19x transducer	P21015	6.0 ft/1.8 m
rP19x transducer armored	P21556	6.0 ft/1.8 m
HFL38xi transducer	P20311	5.5 ft/1.7 m
HFL50x transducer	P07693	5.5 ft/1.7 m
HSL25x	P20679	8.0 ft/2.4 m
ICTx transducer	P07690	5.5 ft/1.7 m
L25x transducer	P07691	7.5 ft/2.3 m
L38xi transducer	P12742	5.5 ft/1.7 m
L38xi transducer armored	P19626	5.5 ft/1.7 m

Accessories and peripherals compatible with SonoSite SII ultrasound system (Continued)

L52x transducer (Vet)	V00033	7.9 ft/2.4 m
P10x transducer	P07696	6.0 ft/ 1.8m
P11x transducer	P16665	6.5 ft/2.0 m
Bar code scanner	P14166	4.8 ft/1.5 m
PowerPack	P13122	—
Battery for PowerPack	P13123	—
Black & white printer	P20006	—
Black & white printer power cable	—	3.3 ft/1 m
Black & white printer USB cable	—	10.8 ft/3.3 m
SII Stand	P21432	—
Storage bin kit, SII stand	P22048	—
Power cord (system)	P00848 (USA)	10 ft/3 m
Power Supply/Battery Charger	P09823	6.8 ft/ 2 m
PowerPark	P12822	—
USB wireless adapter	P17725	—
SII Battery Pack	P20664	—

Chapter 3: Safety

This chapter contains electrical and clinical safety information required by regulatory agencies. The information applies to the ultrasound system, transducers, accessories, and peripherals.

Electrical safety

This system meets EN60601-1, Class I/internally-powered equipment requirements and Type BF and Type CF isolated patient-applied parts safety requirements.

This system complies with the applicable medical equipment requirements published in the Canadian Standards Association (CSA), European Norm Harmonized Standards, and Underwriters Laboratories (UL) safety standards. See “Standards” on page 21.

For maximum safety observe the following warnings and cautions.

WARNING: To avoid the risk of injury, do not operate the system in the presence of flammable gasses or anesthetics. Explosion can result.

WARNING: To avoid the risk of electrical shock or injury, do not open the system enclosures. All internal adjustments and replacements, except battery replacement, must be made by a qualified technician.

WARNING: To avoid the risk of electrical shock:

- This equipment must be connected only to a supply mains with protective earth.
- Use only properly grounded equipment. Shock hazards exist if the power supply is not properly grounded. Grounding reliability can be achieved only when equipment is connected to a receptacle marked “Hospital Only” or “Hospital Grade” or equivalent. The grounding wire must not be removed or defeated.
- When using the system in an environment where the integrity of the protective earth conductor arrangement is in doubt, operate the system on battery power only and disconnect the power supply.
- Do not let the bar code scanner touch the patient.
- Do not touch any of the following:
  - The power supply and the patient at the same time
  - The ungrounded signal input/output connectors on the back of the ultrasound system
  - The system battery contacts (inside the battery compartment)
  - The system transducer connector when the transducer is disconnected

- Do not connect the system power supply or docking system to a multiple portable socket outlet (MPSO) or extension cord.
- Before using the transducer, inspect the transducer face, housing, and cable. Do not use the transducer if the transducer or cable is damaged.
- Always disconnect the power supply from the system before cleaning the system.
- Do not use any transducer that has been immersed beyond the specified cleaning or disinfection level. See Chapter 7, “Maintenance”
- Use only accessories and peripherals recommended by FUJIFILM SonoSite, including the power supply. Connection of accessories and peripherals not recommended by FUJIFILM SonoSite could result in electrical shock. Contact FUJIFILM SonoSite or your local representative for a list of accessories and peripherals available from or recommended by FUJIFILM SonoSite.

WARNING: To avoid the risk of electrical shock and fire hazard:

- Inspect the power supply, AC power cords, cables, and plugs on a regular basis. Ensure that they are not damaged.
- The power cord set that connects the power supply of the ultrasound system or the stand to mains power must only be used with the power supply or docking system, and cannot be used to connect other devices to mains power.

WARNING: To prevent injury to the operator/bystander, the transducer must be removed from patient contact before the application of a high-voltage defibrillation pulse.

WARNING: To avoid possible electrical shock or electromagnetic interference, verify proper operation and compliance with relevant safety standards for all equipment before clinical use. Connecting additional equipment to the ultrasound system constitutes configuring a medical system. FUJIFILM SonoSite recommends verifying that the system, all combinations of equipment, and accessories connected to the ultrasound system comply with JACHO installation requirements and/or safety standards such as AAMI-ES1, NFPA 99 OR IEC Standard 60601-1-1 and electromagnetic compatibility standard IEC 60601-1-2 (Electromagnetic compatibility), and are certified according to IEC Standard 60950 (Information Technology Equipment (ITE)).

Caution: Do not use the system if an error message appears on the LCD display. Note the error code and call FUJIFILM SonoSite Technical Support for further assistance.

Caution: To avoid increasing the system and transducer connector temperature, do not block the airflow to the ventilation holes on the side of the system.

Electrical safety classification

Class I equipment	The ultrasound system is classified as Class I equipment when powered from the external power supply or mounted on the stand because the external power supply is a Class 1 protectively earthed power supply. The stand has no protective earth. Ground bond testing is not applicable to the ultrasound system or the stand. *Note:AC powered peripherals that may be used with the system are Class I and are individually protectively earthed. Ground bond testing may be conducted on each AC powered peripheral.*
Internally powered equipment	Ultrasound system not connected to the power supply (battery only)
Type BF applied parts	Ultrasound transducers
Type CF applied parts	ECG module/ECG leads
IPX-7 (watertight equipment)	Ultrasound transducers
Non AP/APG	Ultrasound system power supply, docking system, and peripherals. Equipment is not suitable for use in the presence of flammable anaesthetics.

Equipment safety

To protect your ultrasound system, transducers, and accessories, follow these precautions.

Caution:	Excessive bending or twisting of cables can cause a failure or intermittent operation.
Caution:	Improper cleaning or disinfecting of any part of the system can cause permanent damage. For cleaning and disinfecting instructions, see Chapter 7, “Maintenance”
Caution:	Do not submerge the transducer connector in solution. The cable is not liquid-tight beyond the transducer connector/cable interface.
Caution:	Do not use solvents such as thinner or benzene, or abrasive cleaners on any part of the system.
Caution:	Remove the battery from the system if the system is not likely to be used for a month or more.
Caution:	Do not spill liquid on the system.

Battery safety

To prevent the battery from bursting, igniting, or emitting fumes and causing personal injury or equipment damage, observe the following precautions.

WARNING:	The battery has a safety device. Do not disassemble or alter the battery.
WARNING:	Charge the batteries only when the ambient temperature is between 0° and 40°C (32° and 104°F).
WARNING:	Do not short-circuit the battery by directly connecting the positive and negative terminals with metal objects.
WARNING:	Do not touch battery contacts.
WARNING:	Do not heat the battery or discard it in a fire.
WARNING:	Do not expose the battery to temperatures over 60°C (140°F). Keep it away from fire and other heat sources.
WARNING:	Do not charge the battery near a heat source, such as a fire or heater.
WARNING:	Do not leave the battery in direct sunlight.
WARNING:	Do not pierce the battery with a sharp object, hit it, or step on it.
WARNING:	Do not use a damaged battery.
WARNING:	Do not solder a battery.
WARNING:	The polarity of the battery terminals isfixed and cannot be switched or reversed. Do not force the battery into the system.
WARNING:	Do not connect the battery to an electrical power outlet.
WARNING:	Do not continue recharging the battery if it does not recharge after two successive six hour charging cycles.
WARNING:	Do not ship a damaged battery without instructions from FUJIFILM SonoSite Technical Support. (See “Contact Information” on page 1.)
WARNING:	If the battery leaks or emits an odor, remove it from all possible flammable sources.
WARNING:	Periodically check to make sure that the battery charges fully. If the battery fails to charge fully, replace it.

Caution:	To avoid the battery becoming damaged and causing equipment damage, observe the following precautions: • Do not immerse the battery in water or allow it to get wet. • Do not put the battery into a microwave oven or pressurized container. • If the battery emits an odor or heat, is deformed or discolored, or in any way appears abnormal during use, recharging or storage, immediately remove it and stop using it. If you have any questions about the battery, consult FUJIFILM SonoSite or your local representative. • Store the battery between -20°C (-4°F) and 60°C (140°F). • Use only FUJIFILM SonoSite batteries. • Do not use or charge the battery with non-FUJIFILM SonoSite equipment. Only charge the battery with the system.

Clinical safety

WARNING: Non-medical (commercial) grade peripheral monitors have not been verified or validated by FUJIFILM SonoSite as being suitable for diagnosis.

WARNING: To avoid the risk of a burn hazard, do not use the transducer with high frequency surgical equipment. Such a hazard may occur in the event of a defect in the high frequency surgical neutral electrode connection.

WARNING: Do not use the system if it exhibits erratic or inconsistent behavior. Discontinuities in the scanning sequence are indicative of a hardware failure that must be corrected before use.

WARNING: Some transducer sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals. Refer to 21 CFR 801.437, User labeling for devices that contain natural rubber.

WARNING: Perform ultrasound procedures prudently. Use the ALARA (as low as reasonably achievable) principle and follow the prudent use information concerning MI and TI.

WARNING: FUJIFILM SonoSite does not currently recommend a specific brand of acoustic standoff. If an acoustic standoff is used, it must have a minimum attenuation of .3dB/cm/MHz.

WARNING: Some FUJIFILM SonoSite transducers are approved for intraoperative applications if a market-cleared sheath is used.

WARNING: To avoid injury and reduce risk of infection to the patient, observe the following:

- Follow Universal Precautions when inserting and maintaining a medical device for interventional and intraoperative procedures.
- Appropriate training in interventional and intraoperative procedures as dictated by current relevant medical practices as well as in proper operation of the ultrasound system and transducer is required. During vascular access, the potential exists for serious complications including without limitation the following: pneumothorax, arterial puncture, guidewire misplacement, and risks normally associated with local or general anesthesia, surgery, and post-operative recovery.

WARNING: To avoid device damage or patient injury, do not use the P10x or rP19x needle guide bracket on patients with pacemakers or medical electronic implants. The needle guide bracket for the P10x and rP19x transducers contains a magnet that is used to ensure the bracket is correctly oriented on the transducer. The magnetic field in direct proximity to the pacemaker or medical electronic implant may have an adverse effect.

Hazardous materials

WARNING: Products and accessories may contain hazardous materials. Ensure that products and accessories are disposed of in an environmentally responsible manner and meet federal and local regulations for disposing hazardous materials.

Electromagnetic compatibility

The ultrasound system has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2:2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

WARNING: The Sonosite SII ultrasound system should not be used adjacent to or stacked with other equipment. If such use occurs, verify that the SonoSite SII ultrasound system operates normally in that configuration.

Caution: Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. Portable and mobile RF communications equipment can affect the ultrasound system. Electromagnetic interference (EMI) from other equipment or interference sources could result in performance disruption of the ultrasound system. Evidence of disruption may include image degradation or distortion, erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site to determine the source of disruption, and take the following actions to eliminate the source(s).

- Turn equipment in the vicinity off and on to isolate disruptive equipment.
- Relocate or re-orient interfering equipment.
- Increase distance between interfering equipment and your ultrasound system.
- Manage use of frequencies close to ultrasound system frequencies.
- Remove devices that are highly susceptible to EMI.
- Lower power from internal sources within facility control (such as paging systems).
- Label devices susceptible to EMI.
- Educate clinical staff to recognize potential EMI-related problems.
- Eliminate or reduce EMI with technical solutions (such as shielding).
- Restrict use of personal communicators (cell phones, computers) in areas with devices susceptible to EMI.
- Share relevant EMI information with others, particularly when evaluating new equipment purchases which may generate EMI.
- Purchase medical devices that comply with IEC 60601-1-2 EMC Standards.

Caution: To avoid the risk of increased electromagnetic emissions or decreased immunity, use only accessories and peripherals recommended by FUJIFILM SonoSite. Connection of accessories and peripherals not recommended by FUJIFILM SonoSite to the ultrasound system may result in malfunction of the ultrasound system or other medical electrical devices in the area. Contact FUJIFILM SonoSite or your local representative for a list of accessories and peripherals available from or recommended by FUJIFILM SonoSite. See the FUJIFILM SonoSite accessories user guide.

Electrostatic discharge

Caution: Electrostatic discharge (ESD), or static shock, is a naturally occurring phenomenon. ESD is common in conditions of low humidity, which can be caused by heating or air conditioning. ESD is a discharge of the electrical energy from a charged body to a lesser or non-charged body. The degree of discharge can be significant enough to cause damage to a transducer or an ultrasound system. The following precautions can help reduce ESD: anti-static spray on carpets, anti-static spray on linoleum, and anti-static mats.

Separation distance

Recommended separation distances between portable and mobile RF communications equipment and the SonoSite SII ultrasound system

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

Rated maximum output power of transmitter *Watts*	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz **d=1.2** $\sqrt{P}$	**80 MHz to 800 MHz** **d=1.2** $\sqrt{P}$	**800 MHz to 2.5 GHz** **d=2.3** $\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: 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.

Guidance and manufacturer's declaration

WARNING: Other equipment, even equipment that complies with CISPR emission requirements, can interfere with the SonoSite SII ultrasound system.

The SonoSite SII wireless adapter contains an IEEE 802.11 transmitter that utilizes the ISM frequency band from 2.412 to 2.4835 GHz and implements two methods of transmission:

- IEEE 802.11b with Complementary Code Keying (CCK), Differential Quaternary Phase Shift Keying (DQPSK), and Differential Binary Phase Shift Keying (DBPSK) at 16 dB
- IEEE 802.11g with Orthogonal Frequency Division Multiplexing (OFDM) at 13 dBm

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The SonoSite SII ultrasound system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The SonoSite SII ultrasound system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network which supplies buildings used for domestic purposes.±
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	±6.0KV contact ±8.0KV air	±6.0KV contact ±8.0KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (Continued)

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Electrical fast Transient burst IEC 61000-4-4	±2KV for power supply lines ±1KV for input/output lines	±2KV for power supply lines ±1KV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1KV line(s) to line(s) ±2KV line(s) to earth	±1KV line(s) to line(s) ±2KV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles *70*% U_T (30% dip in U_T) for 25 cycles >5% U_T (>95% dip in U_T) for 5s	>5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles *70*% U_T (30% dip in U_T) for 25 cycles >5% U_T (>95% dip in U_T) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SonoSite SII ultrasound system requires continued operation during power mains interruptions, it is recommended that the SonoSite SII ultrasound system be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the SonoSite SII ultrasound system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.2\sqrt{P}$

Guidance and Manufacturer's Declaration - Electromagnetic Immunity (Continued)

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Radiated RF IEC 61000-4-3	3 Vim 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3 (continued)			Field strengths from fixed RF transmitters, as determined by an electromagnetic Site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note:U_T is the AC mains voltage prior to application of the test level.
At 80 MHz and 800 MHz, 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.

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

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

FCC Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Immunity testing requirements

The SonoSite SII ultrasound system complies with the essential performance requirements specified in IEC 60601-1-2 and IEC 60601-2-37. Results of immunity testing show that the SonoSite SII ultrasound system meets these requirements and is free from the following:

- Noise on a waveform or artifacts or distortion in an image or error of a displayed numerical value that cannot be attributed to a physiological effect and that may alter the diagnosis
- Display of incorrect numerical values associated with the diagnosis to be performed
- Display of incorrect safety related indications
- Production of unintended or excessive ultrasound output
- Production of unintended or excessive transducer assembly surface temperature
- Production of unintended or uncontrolled motion of transducer assemblies intended for intra-corporeal use

Standards

Electromechanical Safety Standards

ANSI/AAMI ES60601-1:2005/(R) 2012, and A1:2012, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance (Consolidated Edition 3.1)

CAN/CSA C22.2 No. 60601-1:2014 (Edition 3.1), Medical electrical equipment-Part 1: General Requirements for Basic Safety and Essential Performance.

IEC 60601-1:2012 (Edition 3.1), Medical electrical equipment-Part 1: General Requirements for Basic Safety and Essential Performance.

IEC 60601-2-37:2007, Medical Electrical Equipment-Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

IEC 60601-1-6:2010, Medical Electrical Equipment part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability.

JIS T0601-1:2013 (3rd Edition), Japanese Industrial Standard, General Requirements for Safety of Medical Electrical Equipment.

EMC Standards Classification

IEC 60601-1-2:2007, Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance - Collateral Standard. Electromagnetic Compatibility. Requirements and Tests.

CISPR 11:2009, Industrial, Scientific, and Medical (ISM) Radio-Frequency Equipment Electromagnetic Disturbance Characteristics-Limits and Methods of Measurement.

The Classification for the ultrasound system, stand, accessories, and peripherals when configured together is: Group 1, Class A.

Acoustic standards

NEMA UD 2-2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.

NEMA UD 3-2004, Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine.

Biocompatibility standards

AAMI/ANSI/ISO 10993-1, Biological evaluation of medical devices—Part 1: Evaluation and testing (2009).

AAMI/ANSI/ISO 10993-5, Biological evaluation of medical devices—Part 5: Tests for In Vitro cytotoxicity (2009).

AAMI/ANSI/ISO 10993-10, Biological evaluation of medical devices—Part 10: Tests for irritation and delayed-type hypersensitivity (2014).

AAMI/ANSI/ISO 10993-11, Biological evaluation of medical devices—Part 11: Tests for systemic toxicity (2006).

AAMI/ANSI/ISO 10993-12, Biological evaluation of medical devices—Part 12: Sample preparation and reference materials (2012).

Airborne Equipment Standards

RTCA/DO-160E, Radio Technical Commission for Aeronautics, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21.0 Emission of Radio Frequency Energy, Category B.118.

DICOM Standard

NEMA PS 3.15, Digital Imaging and Communications in Medicine (DICOM)—Part 15: Security and System Management Profiles.

HIPAA Standard

The system includes security settings that help you to meet the applicable security requirements listed in the HIPAA standard. Users are ultimately responsible for ensuring the security and protection of all electronic protected health information collected, stored, reviewed, and transmitted on the system.

Health Insurance Portability and Accountability Act, Pub.L. No. 104-191.

45 CFR 160, General Administrative Requirements.

45 CFR 164, Security and Privacy.

Chapter 4: System Overview

About the System

The SonoSite SII high-resolution ultrasound system is a portable, software controlled, diagnostic ultrasound system using all digital architecture. The system is used to acquire and display high-resolution, real-time ultrasound data in 2D, Color Power Doppler (CPD), and Color Doppler (Color) or in a combination of these modes.

The system provides measurement capabilities for anatomical structures and fetal biometry that provide information used for clinical diagnostic purposes. System features include cine review, image zoom, labeling, biopsy, measurements and calculations, and image storage, review, printing, recording capabilities.

The system includes optional Digital Imaging and Communications in Medicine (DICOM) capabilities as well as general computer communication capabilities to provide the acceptance, transfer, display, storage, and digital processing of ultrasound images and loops. Security support is also provided to facilitate HIPAA compliance.

The system/transducer is capable of exceeding a TI or an MI of 1.0 in certain operating modes or mode combinations. The system displays the current output level in terms of one of two bioeffects indices (“Mechanical Index [MI]” and “Thermal Index [TI]”) in accordance with the AIUM/NEMA Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.

The SonoSite SII utilizes AES-256 encryption with the internal SD card for the purpose of encrypting Protected Health Information (PHI). The system specific encryption key is programmed at the factory and cannot be changed. Since this key is always specific between the system and SD card, the SD card cannot be replaced in the field and the system must be returned to the factory for repair of an SD card failure. Main PCBA Service Assemblies will ship with an SD card installed and this card must be used when the assembly is installed in a system to perform a repair

Theory of Operation

The Sonosite SII ultrasound system has seven (7) major functional groups:

- Transducer
- Acquisition Subsystem
- Processing Subsystem
- Display Subsystem
- Control Subsystem
- User Interface Subsystem
- Power Subsystem

Relationship of the functional groups is shown in Figure 4.1 below.

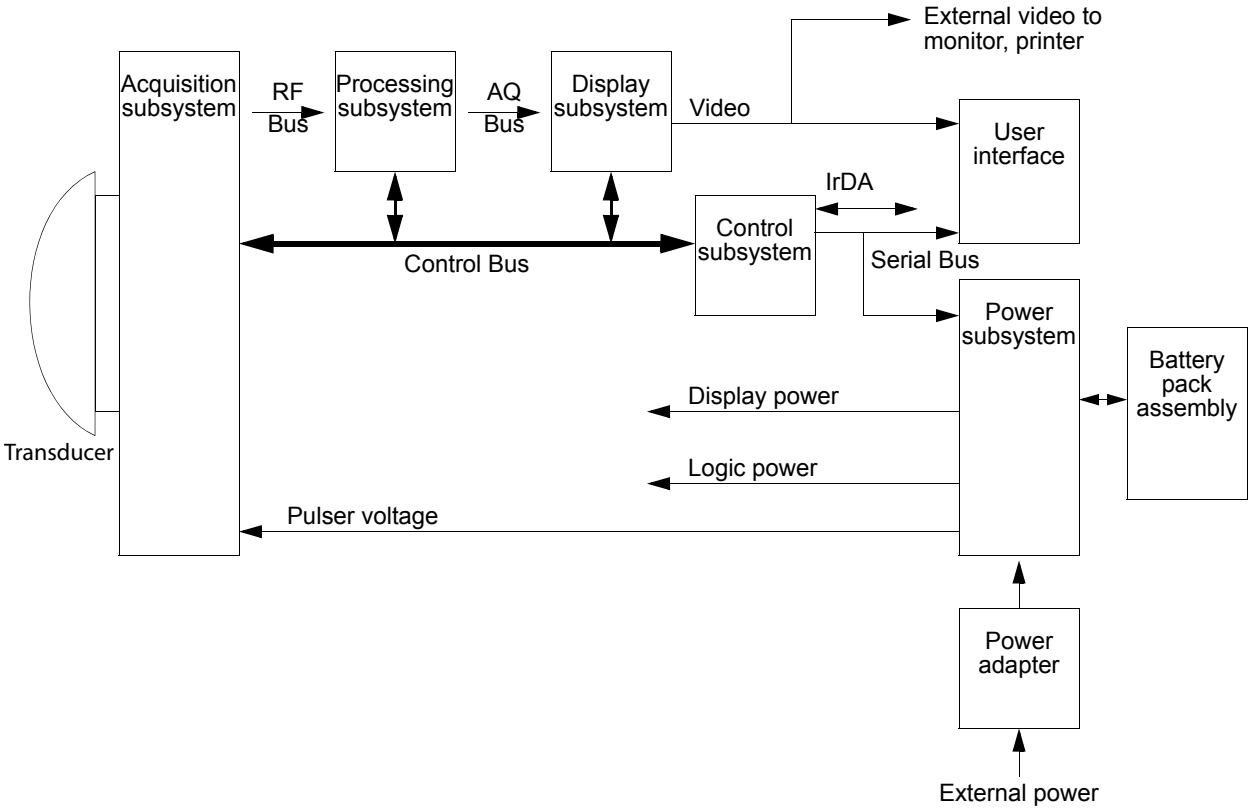


Figure 4.1 SonoSite SII High-Resolution Ultrasound System Block Diagram

The **Transducer** elements convert the pulser voltage to acoustic energy during the transmit portion of the ultrasound acquisition cycle. The elements convert the acoustic echo to voltage in the receive portion of the acquisition. The voltage developed on the transducer elements is sensed by the acquisition subsystem. The system transducers have 64 to 256 elements.

The **Acquisition Subsystem** consists of the beamformer and interface to the transducer. The beamformer controls the timing of the transmit pulses to focus the acoustic beam. The beamformer amplifies the low-level received echos and controls the receive focusing. The system beamformer transmits on up to 128 elements and receives on 64 elements.

The **Processing Subsystem** includes capabilities for interfacing with the beamformer and performing high speed processing. The processing subsystem demodulates, filters, detects, and compresses the signal supplied by the beamformer into display information.

The **Display Subsystem** converts the detected ultrasound data into picture elements (pixels). The software user interface graphics are combined with the ultrasound information and converted to a video stream. The external video port supports NTSC and PAL format.

The **Control Subsystem** consists of the central processing unit, program and video memory, permanent image storage and retrieval memory, external communication interface ports, and connection to the user interface keys. The control software includes the acoustic power and intensity software subsystem, power group monitors, and a beamformer monitor. This software guarantees a level of patient safety by ensuring the system is operating within acoustic power and intensity limits.

The **User Interface Subsystem** represents the software interface and form factor. The software interface is the interaction between the user and the screen layout components. The form factor is the type of physical buttons, location, and grouping of the buttons and the device size, shape, and weight. Dedicated controls are for high usage activities and grouped according to the user workflow.

The **Power Subsystem** provides the system power and protects the hardware from destructive and/or unsafe conditions by detecting failures in the system through hardware and software monitors. Detection of a fault results in disabling of the pulser supply, and signaling of an error to the Control Group. The power subsystem includes the battery pack and battery charging electronics.

Description of Operating Modes

2D Mode

2D mode is a two dimensional image of the amplitude of the echo signal. It is used for location and measurement of anatomical structures and for spatial orientation during operation of other modes. In 2D, a two-dimensional cross-section of a 3-dimensional soft tissue structure such as the heart is displayed in real time. Ultrasound echoes of different intensities are mapped to different gray scale or color values in the display. The outline of the 2D cross-section may be a rectangle, parallelogram, trapezoid, sector, or a full circle, depending on the particular transducer used. 2D mode can be used in combination with any other modes.

Color Doppler (Color)

In color Doppler, a real-time, two-dimensional cross-section of blood flow is displayed in a Region of Interest (ROI) box. The 2D cross-section may be presented as a rectangle, parallelogram, trapezoid or sector, depending on the particular transducer used.

The ROI is presented as a full color display, with various colors being used to represent the velocity, both positive and negative, of the blood flow echoes. This is used to evaluate the speed and direction of blood flow. Often, to provide spatial orientation, the full color blood flow cross-section is overlaid on top of the gray scale cross-section of soft tissue structure (2D echo). For each pixel in the overlay, the decision of whether to display VCD, gray scale (echo) information or a blended combination is based on the relative strength of echoes from the soft-tissue structures and from the red blood cells.

A high pass filter (wall filter) is used to remove the signals from stationary or slowly moving structures. Tissue motion is discriminated from blood flow by assuming that blood is moving faster than the surrounding tissue, although additional parameters may also be used to enhance the discrimination. The remaining signal after wall filtering may be averaged over time (persistence) to present a steady state image of blood flow distribution. Variance information may also be displayed to provide information when large variance is observed in the velocity information.

Color Power Doppler (CPD)

In CPD, a real-time two-dimensional cross-section of blood flow is displayed in a Region of Interest (ROI) box. The 2D cross-section may be presented as a rectangle, parallelogram, trapezoid, sector, depending on the particular transducer used.

The ROI is presented as a full color display, with various colors being used to represent the power (amplitude) of blood flow echoes. This is used primarily to detect the presence or absence of flow; it does not indicate velocity. Often, to provide spatial orientation, the full color blood flow cross-section is overlaid on top of the gray scale cross-section of soft tissue structure (2D echo). For each pixel in the overlay, the decision of whether to display CPD, gray scale (echo) information or a blended combination is based on the relative strength of echoes from the soft-tissue structures and from the red blood cells.

A high pass filter (wall filter) is used to remove the signals from stationary or slowly moving structures. Tissue motion is discriminated from blood flow by assuming that blood is moving faster than the surrounding tissue, although additional parameters may also be used to enhance the discrimination. The power in the remaining signal after wall filtering may be averaged over time (persistence) to present a steady state image of blood flow distribution.

Additional System Feature Performances

Broadband Imaging

This ultrasound acquisition system uses high resolution broadband technology in the transmit pulsers, transducer, and receivers. The receive path can capture and process signals over a wide spectrum, from below 2.0 MHz to beyond 10 MHz. For each application, the transmit pulse is designed to produce an appropriate bandwidth. For example, in 2D grayscale imaging, a wide band pulse is used to support good axial resolution. For Doppler modes, a narrower band pulse is used, which improves the spectral resolution of the detected Doppler signal.

In addition to transmit pulse control, programmable digital signal processing is used in the receive path to further refine the bandwidth used to produce the final image. Digital filters are applied to the digitized received signal to limit and shape the spectral bandwidth used to generate the displayed output.

Needle Guidance

The system is capable of displaying guidelines that represent the anticipated path of a biopsy, nerve block, or vascular access needle. The image of an anatomical target, needle guidelines, a scan plane marker, and a needle are displayed on the monitor to assist in guiding the needle to the target. Additional information regarding this feature can be found in the needle user guides provided.

Steep Needle Profiling

Steep Needle Profiling technology (formerly SonoMBe™ imaging), enhances linear structures within a selected angle range and can facilitate needle guidance during catheter placement and nerve-block procedures. For details, please see the SonoSite SII User Guide.

Measurement and Calculation Capabilities

The system offers a variety of measurements and calculations, specific to exam type and transducer. A list of them, and author references, are in the system user guide. Measurement accuracy is also discussed.

Front End Overview

The Front End is designed to support various imaging modalities such as 2D and Color Doppler. From the Front End's perspective, all modes can be grouped into a few basic types: Single mode, simultaneous modes and triggered modes. All these modes are built from similar, basic transmit and receive sequences controlled within the Front End. A generic top level block diagram of a typical Front End is in the figure below.

The transmit section consists of a waveform generator, delay block, and high power high voltage driver to excite the transducer element. Multiple elements are driven with delays determined by the time of flight in the medium from the elements to the point in space where the beam is to be focused. The longer the time of flight is to the focal point the smaller the delay is for a given transmit element to allow all to arrive at the focal point at the same time. The number of elements driven is determined by element sensitivity off axis and depth of field considerations. The waveform is selected to drive the transducer at a certain center frequency, bandwidth, and power and is optimized for the given mode.

The receive section consists of a transmit/receive switch to protect the receiver from the transmit voltage, a variable gain receiver to amplify and condition the return echoes, an A/D to digitize the data, a delay block to focus the return signals and a weight block to scale the return echoes for each channel. All the signals are then summed together to generate the beam-formed receive data. The analog gain varies with depth to compensate for signal attenuation through the medium. The delays and weights are independent for each channel. The delay and weight for the receive channel can typically be changed dynamically to keep the receive beam in continuous focus. The delay is simply set by the time of flight in the medium from the point of interest to the element, which starts at skin-line and proceeds to the deepest depth of interest.

The control section drives the data to the various data path elements on a line by line basis, controls the timing of the transmit and receive sections and controls the tagged information and timing of the data to the rest of the system.

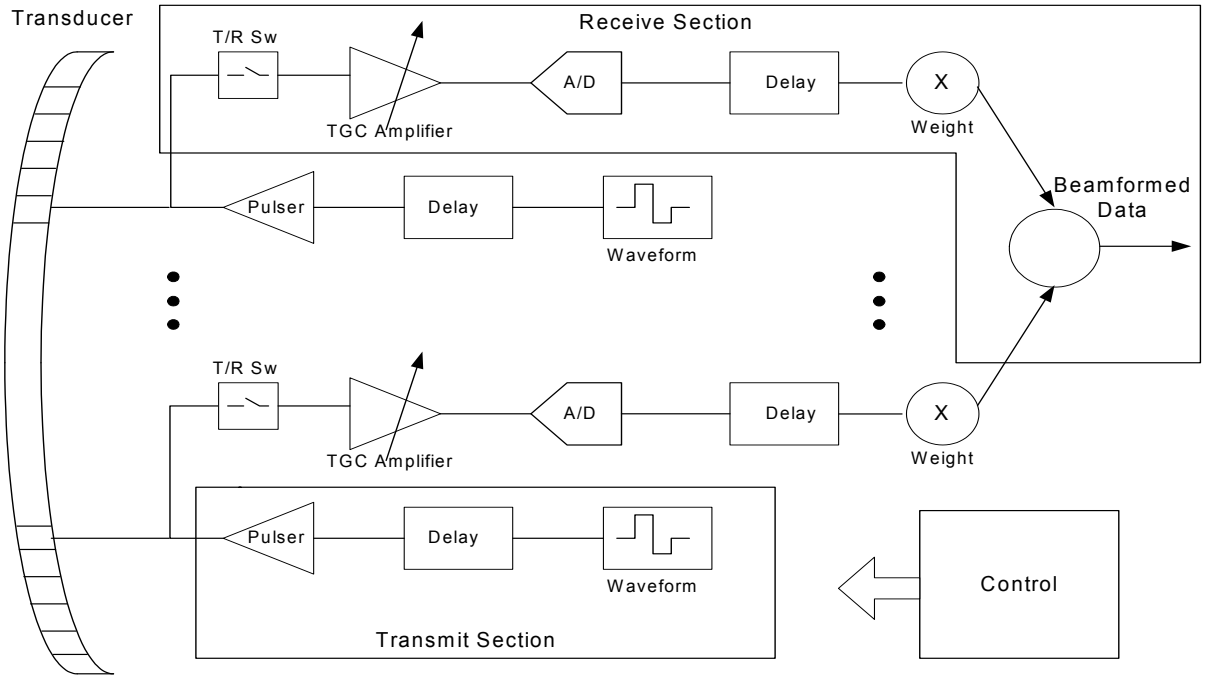


Figure 4.2 SII Front End block diagram

Back End Overview

The Back End subsystem is responsible for the conversion of raw acquisition data into a raster image ready for display. The Back End subsystem also contains the video data path that supports generation of video comprising of the ultrasound image as well as graphics annotation. Video generation of both standard composite interlaced video and progressive scan video is supported. Most functionality is within the ASIC but the memory resources for acquisition memory, and display memory are found in external memory components. The conversion from PC type video to TV type video is also performed externally.

Control is received initially from the CPU to setup each functional block and afterward the hardware is completely data driven. This control takes the form of programming setup registers inside the blocks and setting up scan conversion tables. Each block provides temporary storage as required to buffer data and keep their respective processing pipeline full and operating. Also note that the block diagrams show only the data path, but each block is responsible for generating any necessary memory addresses for their respective input data stream.

The SonoSite SII Back End subsystem is shown in the figure below.

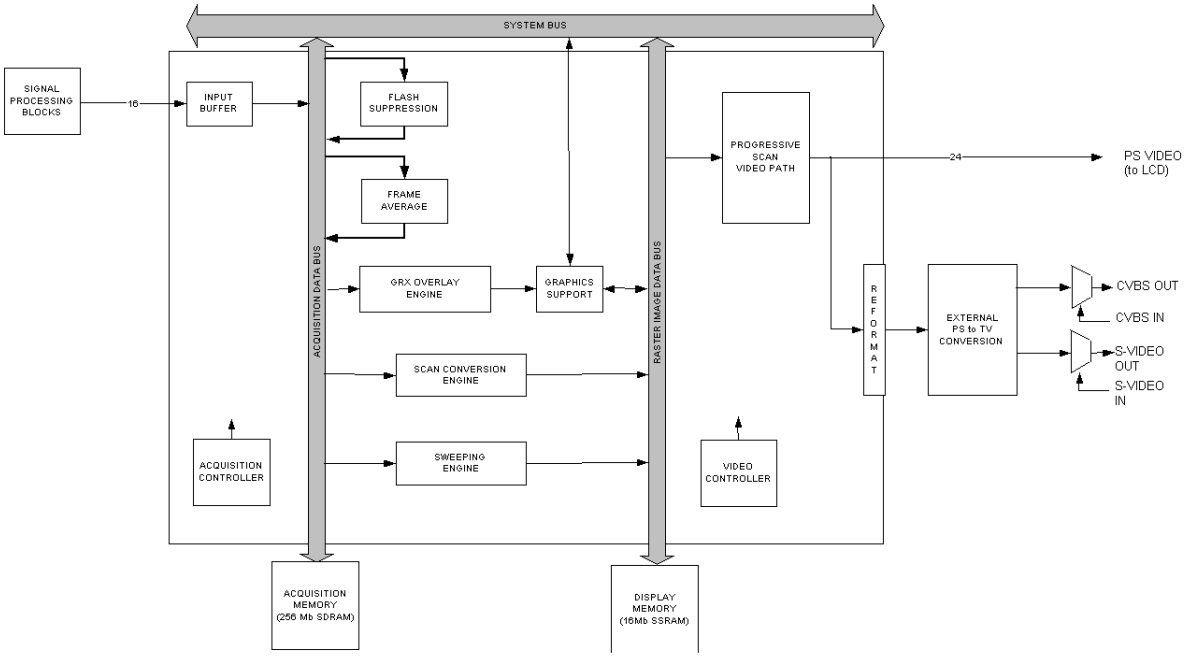


Figure 4.3 Back End Subsystem Block Diagram

The Back End Subsystem performs processing encompassing three main data domains, acquisition data, raster data, and video data. Support for acquisition data includes the input buffer, flash suppression, frame average, and external ACQ memory. Cine buffer management is performed by the acquisition controller. Conversion from acquisition data to raster data is performed by the graphics overlay, scan conversion engine, sweeping engine, and 3D engine. Raster data is stored in an external DISPLAY memory. Also supporting raster operations is the graphics support block that provides acceleration hardware for pixel operations from the CPU and graphics overlay engine. Video data is processed as progressive scan and supplied externally on a digital bus. In addition, interlaced video is supplied in both composite and S-video formats. The progressive video path includes buffers, priority logic, and LUTs. External video in signals are input and multiplexed onto the external video out path to allow for external sources to display information on connected displays or printers.

Control Subsystem

The SonoSite SII Control Subsystem is shown in the figure below.

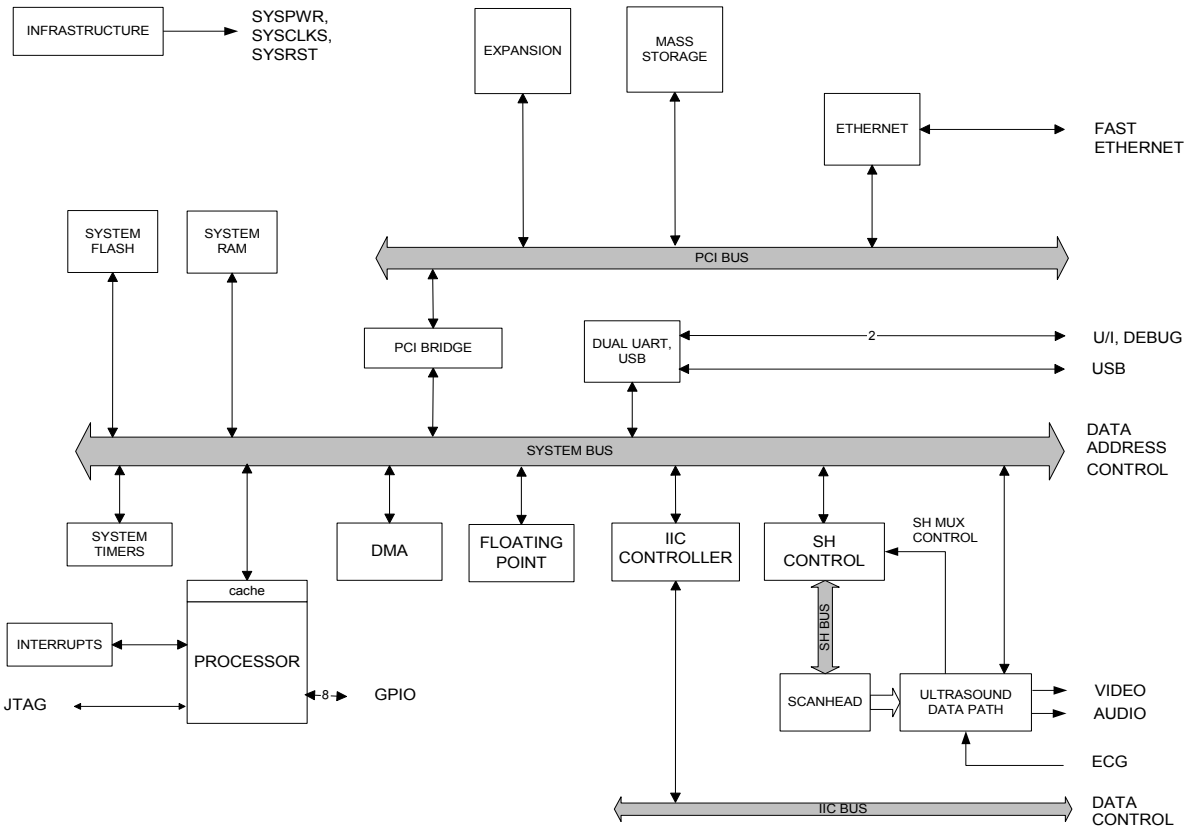


Figure 4.4 Control Subsystem Block Diagram

The core control subsystem contains the processor, the system bus, the system memory resources of FLASH and RAM, the interrupt logic, system timers, a DMA engine, and a floating point unit. Support for the ultrasound subsystem consists of a scanhead interface, scanhead mux control.

Communication interfaces consists of an Ethernet interface, USB port, two general purpose serial bus interfaces, and the IIC bus. The SonoSite SII control architecture is an open architecture. It supports functionality extension through the incorporation of the PCI bridge to the PCI bus. Functionality may be added by adding to the PCI Bus.

Power Supply and Control

The SonoSite SII Power Supply and Control System consists of an easily replaced rechargeable battery pack; an On/Off Key; a standby power regulator; digital, analog, display and transducer power supplies; a power monitor and a power control system. Operating current is drawn from the battery or an external AC/DC Adapter which also contains circuitry for charging the battery. A fan and provision for a temperature sensor are also included.

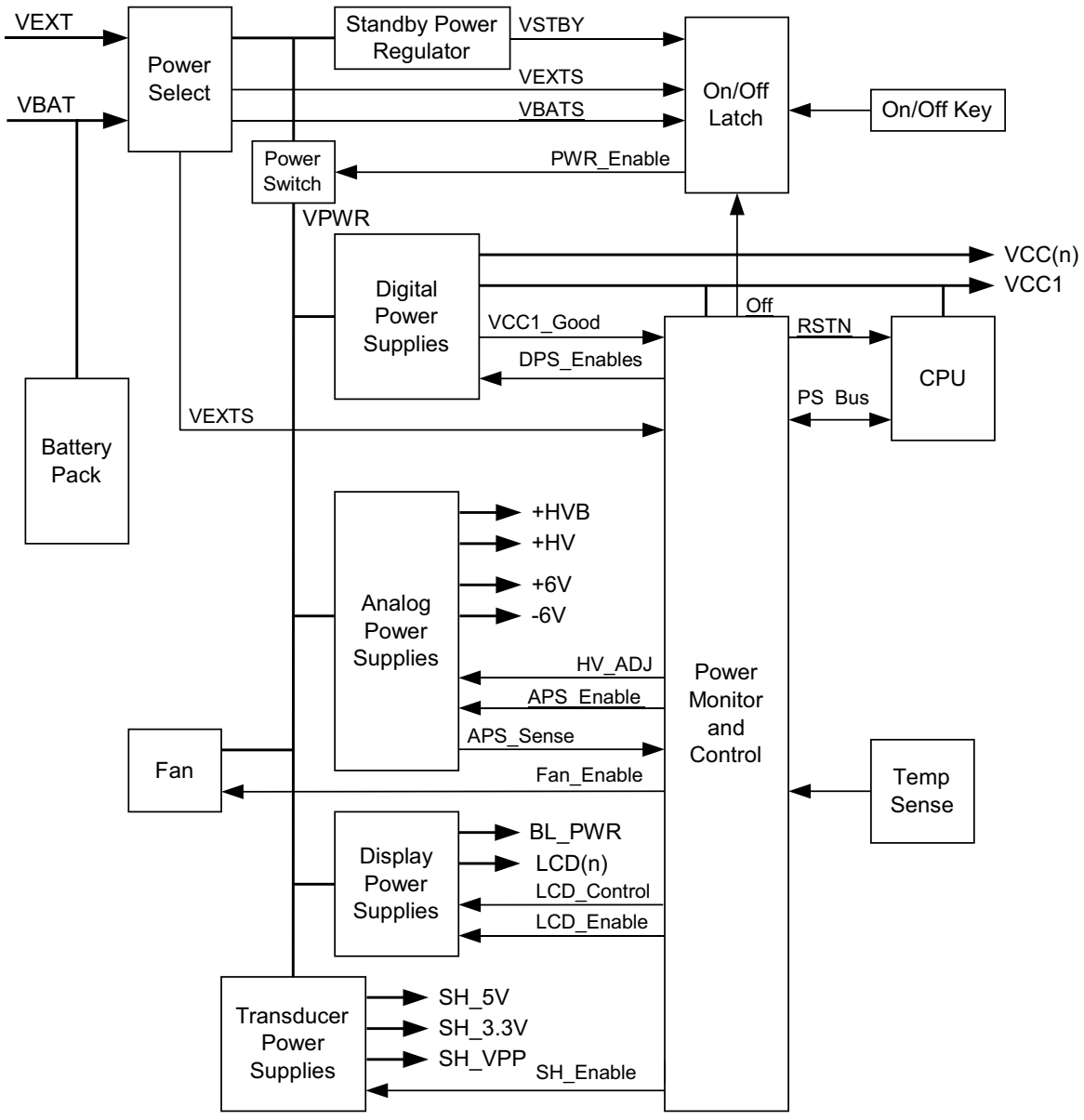


Figure 4.5 Power Supply and Control Subsystem Block Diagram

Battery Pack (VBAT)

A rechargeable lithium-ion battery pack will be used to operate the unit in battery mode. The pack will include a capacity monitoring circuit and any required pack protection circuitry. A one-wire, bidirectional, serial interface (BDATA) will be used to read and write the pack data.

Battery Charger

The charge circuitry is in the external AC/DC Adapter as shown in the following block diagram.

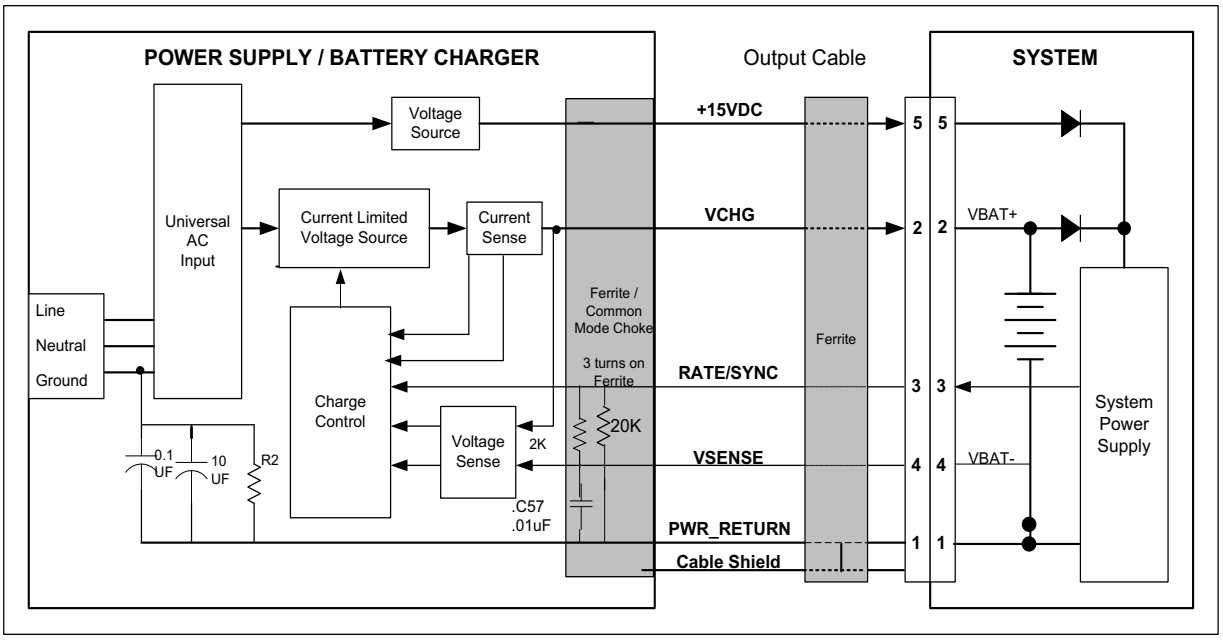


Figure 4.6 Battery Charging Subsystem Block Diagram

DICOM

The system features Digital Imaging and Communications in Medicine (DICOM) capability to provide the acceptance, transfer, display, storage, and digital processing of single ultrasound images as well as loops of ultrasound images.

Chapter 5: Troubleshooting

This chapter contains information to help you correct problems with system operation.

Note: If the system requires repair, certain steps must be taken to remove patient data from the system prior to return to FUJIFILM SonoSite. To accomplish this, a Power-0 Reset must be performed whenever possible (certain conditions may prevent this, such as a system that fails to power on).

Power-0 Reset formats the system SD memory.

Warning: This will erase all patient data saved on the system, but will not delete an already established partition for the transducer database. Patient images should be exported or archived before proceeding.

The procedure for performing the Power-0 Reset is as follows:
Start with the system powered off.
1) Press and hold the “M” key.
2) Press and release the system On/Off button while continuing to hold down the “M” key.
3)When the system emits a high-low sound, release the “M” key. This sound will occur after 5-10 seconds and indicates that the system is reset. The reset will be complete about 1 minute after the system has booted up, when the system emits a low-high sound.

Power-1 Reset causes the system settings to revert back to factory defaults. This includes the following:

Sets system date/time to January 1, 2003, 02:00.

Sets IP address to 169.254.254.254. DICOM or SiteLink network configurations already saved to the system will still present, but must be selected again in the Connectivity screen.

Resets the Audio, Battery settings.

The procedure for performing the Power-1 Reset is as follows:

Start with the system powered off.

1) Press and hold the “2D” key.

2) Press and release the system On/Off button while continuing to hold down the “2D” key.

3) Release the when the system emits a high-low then low-high sound. This sound will occur after 5-10 seconds and indicates that the system is reset.

System and Subsystem Diagnosis

This section covers basic diagnostic and troubleshooting procedures you may follow if the system does not operate properly. To diagnose system failures, consult the referenced diagnostic figures that follow or FUJIFILM SonoSite Technical Support.

Table 5.1: Troubleshooting Subassemblies and Diagnostic Figures

Subassemblies	Diagnostic Figures or Table
DICOM	Table 5.2
User Interface	Table 5.3
Battery	Table 5.4

System Repair

The system is repairable through subassembly replacement or through replacement of parts as recommended by FUJIFILM SonoSite. Component level repair of Printed Circuit Board Assemblies is performed only at the FUJIFILM SonoSite repair facility. Replacement of board level components by unauthorized service facilities voids the FUJIFILM SonoSite warranty and will prevent receipt of credit on a returned assembly.

Test Equipment

Test equipment is not required for this troubleshooting section. Troubleshooting test aids include an external monitor and a spare battery.

Failure (Assert) Codes

The system displays an “assert screen” for hardware and software issues related to Main PCBA failures. Main PCBA failures typically result in “assert codes” that are output to the display. If an assert screen appears, note the assert information and contact FUJIFILM SonoSite Technical Support to clarify the failure. Figure 5.1 shows an assert screen. The assert information required is the information listed on the “C:” line and the “D:” line.

Figure 5.1 Assert Screen

Verifying a System Assert Code

System asserts are caused by hardware and/or software faults. Hardware asserts typically require main PCBA replacement. Software asserts can be reset and the system may recover. A simple method to identify the cause of the assert is identified here:

Assert Cause

1. Record the assert code.
2. Press and release the **Power** button to power the system down.
3. Press the **Power** button again to power on the system.
   - If the system powers on normally, it has recovered from the fault (software assert) and you may use the system.
   - If the assert condition remains, corrective action must be taken; usually replacement of the main PCBA is required. Contact FUJIFILM SonoSite Technical Support for assistance and to obtain repair parts.

   If the **Power** button is not functional, all sources of power must be removed to allow the system to power down. That is, disconnect AC power and remove the battery.

DICOM

Table 5.2: DICOM Troubleshooting

Error Message	Tiller Error Code	Cause	Troubleshooting
Socket communication failed	TSOCKET_CONNECT_FAILURE	Invalid network configuration. Wrong port number. Application is not running. Printer is offline.	Using Ping, verify that the Printer/Archiver is connected. • If Ping fails, check the devices IP address, SonoSite SII IP address, Subnet mask, and Gateway IP address. • If Ping is OK, use Verify to check if device is available. If Verify fails: a) Check the Printer/Archiver's Port configuration on the SonoSite SII. b) Ensure that the Printer is online and the Archiver's application is running.
Archiver transaction failed	TDICARCH_OPEN_FAILURE	Wrong Capture Type selected	Verify that the Archiver supports the selected Capture Type setting, e.g., US Image, SC Image or US-Ret Image.
Printer transaction failed	TDICPRNT_OPEN_FAILURE	Wrong Image settings	Verify that the printer supports the selected Image settings. E.g,. Color (RGB) or Grayscale (Monochrome)
DICOM network communication failed	TDNETWORK_OPEN_FAILURE	Device does not recognize SonoSite SII, rejects association	Verify that SonoSite SII AE Title or IP address is correctly configured on the Printer/Archiver. *Note: Some devices require that the Imaging modality (SII) be recognized in order to accept images. This requires configuration on the device.*
Internal failure detected	TDNETWORK_READ_FAILURE	Invalid DICOM Attribute	Check SonoSite SII Printer DICOM settings for correctness (e.g., film size, format)

User Interface

Table 5.3: User Interface Troubleshooting

Problem	Cause	Troubleshooting
No Display	Faulty Display or Main PCBA	Feed video from back of system to external monitor • If the video is not present on the external display, the Main PCBA is likely at fault. • If the video is present on the external display, the User Interface Assembly is likely at fault.
Display Image Quality Issue	Faulty Display or system fault	Feed video from back of system to external monitor • If the issue is present on the external monitor, the issue is caused by a fault on the system. • If the issue is not present on the external monitor, the User Interface Assembly is likely at fault.
LED not working/key(s) not responding/touchpad issue	Faulty User Interface or Main PCBA	Perform checks in the following order: • Check internal cable connections • Replace UI • Replace Main PCBA
Gain function not working	Faulty Gain circuit	Perform checks in the following order • Check Gain cable connection • Replace TGC PCBA

Note: Any failure in the User Interface with the exception of parts listed inTable 1 on page 40,will require replacement of the User Interface as it contains no field serviceable parts.

Battery

Table 5.4: Battery Troubleshooting

Problem	Cause	Troubleshooting
Will not power on	Battery Issue	• Remove battery. Inspect battery and battery compartment contacts for damage/corrosion. Install battery and try again. • Remove battery and connect system to AC power only. If it works, try a different battery. • If issues still exist, attempt to charge the battery or replace it. • Check the lot code on the battery. If older than 3 years, battery may be past useful life period.

Chapter 6: Replacement Procedures

Caution:	Always use correct ESD procedures. ESD damage is cumulative and may not be noticeable at first. Initial ESD symptoms may be slightly degraded performance or image quality.
Caution:	All fasteners should be torqued to 5.5-inch pounds except where noted.

Required Tools

- #1 Phillips screwdriver
- #2 Phillips screwdriver
- 1/8 inch flat blade screwdriver
- X-Acto knife or equivalent
- Torque screwdriver, 2.0–15.0 inch pounds (0.23–1.7 newton-meter)
- Anti-static mat
- Wrist grounding strap
- Loctite 4541 adhesive gel or equivalent

User Interface Removal

Note: There is no need to specify language when replacing the User Interface as it supports all languages. Language support is determined by the software in the Main PCBA.

Required Parts

- P20475-XX Service Assembly, User Interface, SII
- V20475-XX Vet Service Assembly, User Interface, SII

User Interface Removal

Removal of the User Interface is required to access all other system components.

1 Remove the battery from the system.

2 Use X-Acto knife or equivalent to remove screw caps from the Top Cap Assembly and Bottom Cap as shown in Figure 6.1.

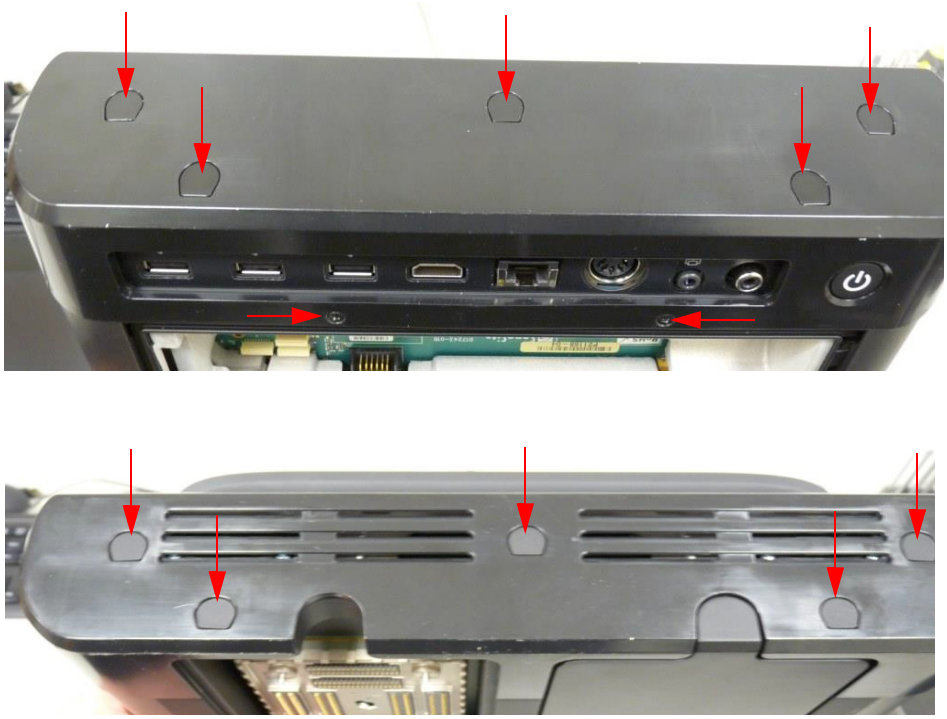


Figure 6.1 Screw Cap Removal

3 Remove five screws each from Top Cap Assembly and Bottom Cap. Remove additional two screws from back of Top Cap Assembly also shown in Figure 6.1

4 Remove Top Cap Assembly and Bottom Cap.

5 Remove Side Extrusions from both sides of system as shown in Figure 6.2. Extrusions slide towards the ends. Removal may be difficult if skin is dry. Latex gloves may help to attain grip.

Figure 6.2 Side Extrusion Removal

6 Remove four screws holding the handle in place as shown in Figure 6.3.

7 Slide handle towards bottom of system to remove.

Figure 6.3 Handle Removal

8 Remove eight screws securing the Base Assembly to the User Interface as shown in Figure 6.4

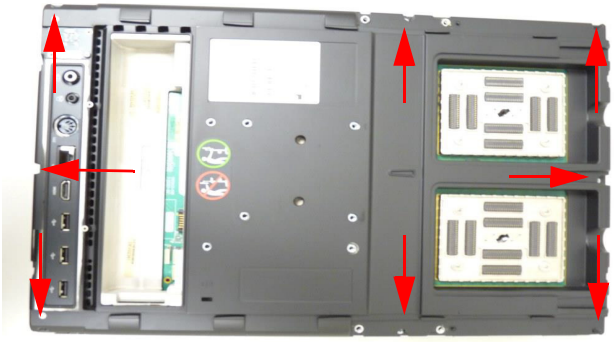


Figure 6.4 Base Assembly Screw Removal

9 Carefully turn the system over so the User Interface is facing up and rotate the system so the bottom (dual fan) is pointing toward you.

10 Partially lift the UI from the Base as shown in Figure 6.5. Be careful as opening too far may damage speaker wires.

11 Disconnect speaker wires from speaker wire extensions.

12 Lift User Interface far enough to disconnect the Video, Gain and Control Board cables.

13 The User Interface can now be removed from the Base Assembly.

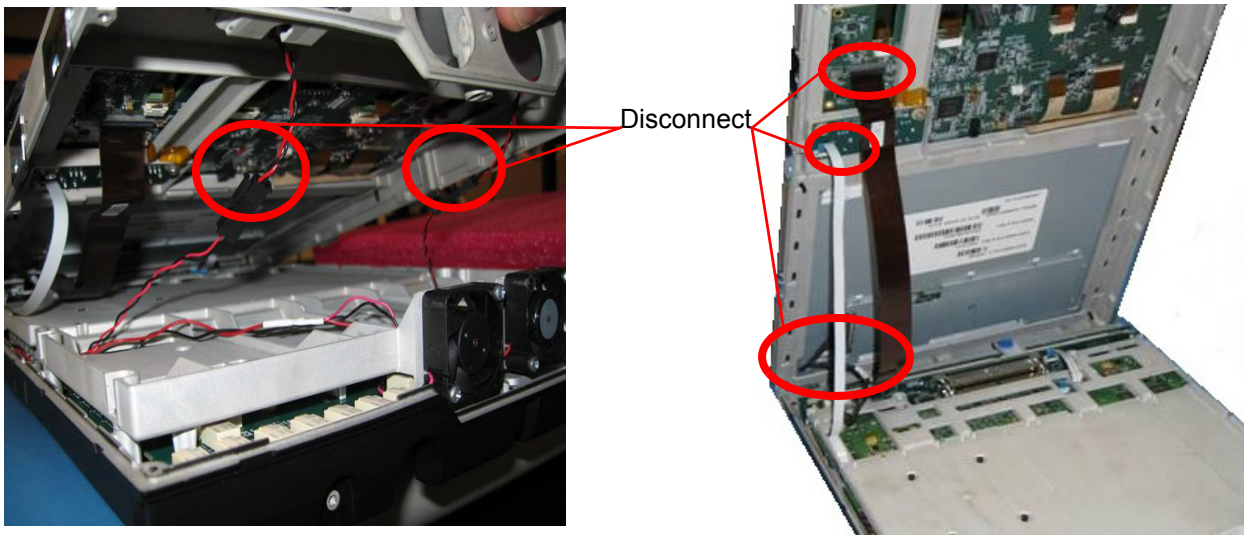


Figure 6.5 User Interface Removal

Note: If the User Interface is removed for replacement, several parts need to be removed and installed on the new User Interface.

Item Number	Part Number	Description
1	P20814	Speaker Cable Assembly (x2)
2	P21440	TGC PCBA
3	P20492	Light Pipe
4	P21082	Right Slide Lock Spring (x5)
5	P21083	Left Slide Lock Spring (x5)
6	P21081	Slide Lock Plate (x10)
7	P21662	Metal Knob (x2)

Table 1: UI replacement parts to transfer

User Interface Parts Transfer

1. Remove the two metal knobs from the front of the system. They should pull off with little effort.
2. Remove four screws in each speaker and gently pull speakers from midframe per Figure 6.6.

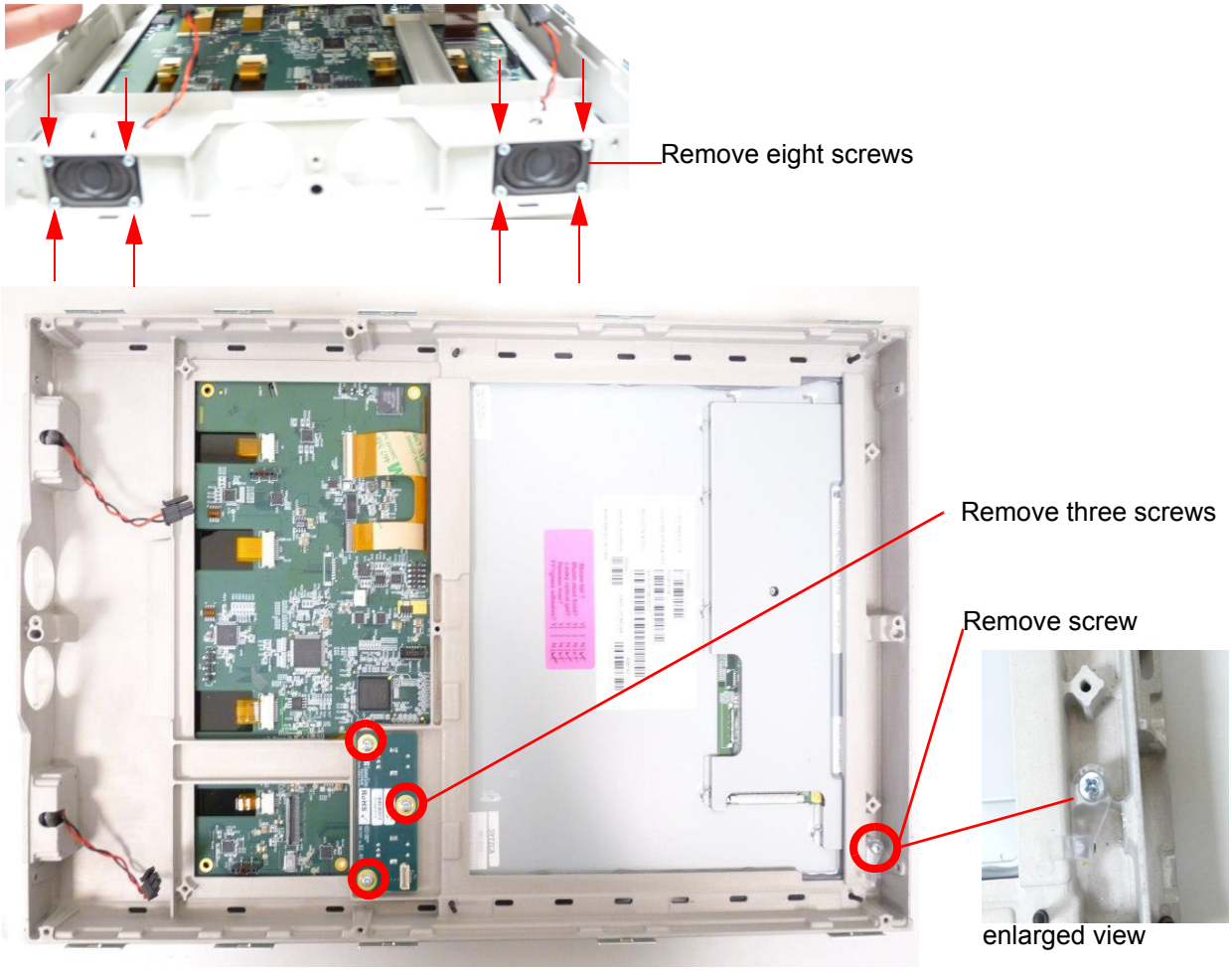


Figure 6.6 User Interface speaker, TGC and light pipe removal

3 Remove three screws from TGC and lift from midframe per Figure 6.6.

4 Remove screw from light pipe and remove from midframe.

5 With a 1/8 in screwdriver, remove ten Slide Lock Plates from sides of UI per Figure 6.7.

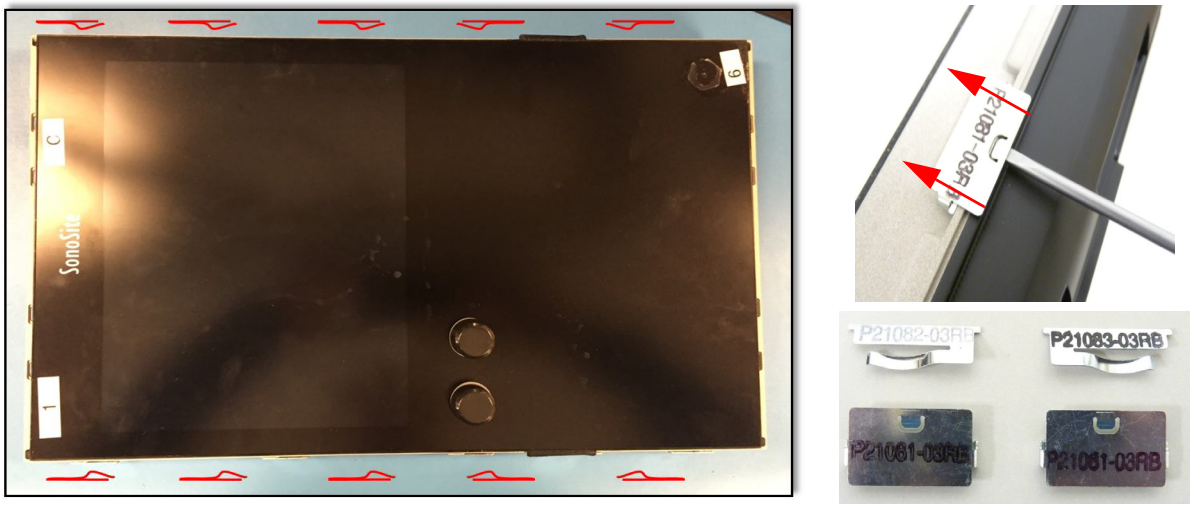


Figure 6.7 Slide Lock Spring and Plate removal

6 Screwdriver is used to lift locking tab, allowing removal by sliding plate in direction of arrows.

7 Figure 6.7 shows the proper orientation of the Slide Lock Springs. Make note of proper orientation before removal.

UI Parts Installation

1 Reverse steps above starting with step 7.

2 Place Slide Lock Springs on Slide Plates before installation

3 Tighten the light pipe screw to 5.5 in-lbs

4 Tighten the TGC screws to 5.5 in-lbs.

5 Tighten the speaker assembly screws to 2.0 in-lbs

Install User Interface

1 Place User Interface on Base Assembly as shown in Figure 6.5

2 Connect Video, Gain and Control Board cables from Base Assembly to User Interface.

3 Lower the User Interface until you can connect the Speaker cable extensions to the speaker cables.

4 Lower the User Interface until it rests on the Base Assembly.

5 Flip the system over so it appears as shown in Figure 6.4 and fasten with eight screws at 5.5 in-lbs.

6 Slide the handle over the bottom portion of the assembly as shown in Figure 6.3 and fasten at 15.0 in-lbs with four screws.

7 Install the side extrusions on both sides of system as shown in Figure 6.2. The two long extrusions are identical but the short extrusions are not, and only fit on their specific sides.

8 Install the Top Cap Assembly and Bottom Cap using 10 screws at 5.5 in-lbs.

9 Install the two small screws in the Top Cap Assembly and tighten to 3.0 in-lbs. as shown in Figure 6.1

10 Install ten screw caps over screws in Top and Bottom Caps. Use a conservative amount of Loctite to fasten the screw caps in place.

11 Install the battery.

Base Assembly Disassembly for Repair and/or Replacement

All of the components shown in Figure 6.8, including the frame they are mounted on, are called the *Base Assembly.* The Base Assembly cannot be ordered but is referenced throughout these instructions. Removal of the User Interface as described in "User Interface Removal" on page 37 is required to replace most of the the following components.with the exception of the Power Button PCA described below.

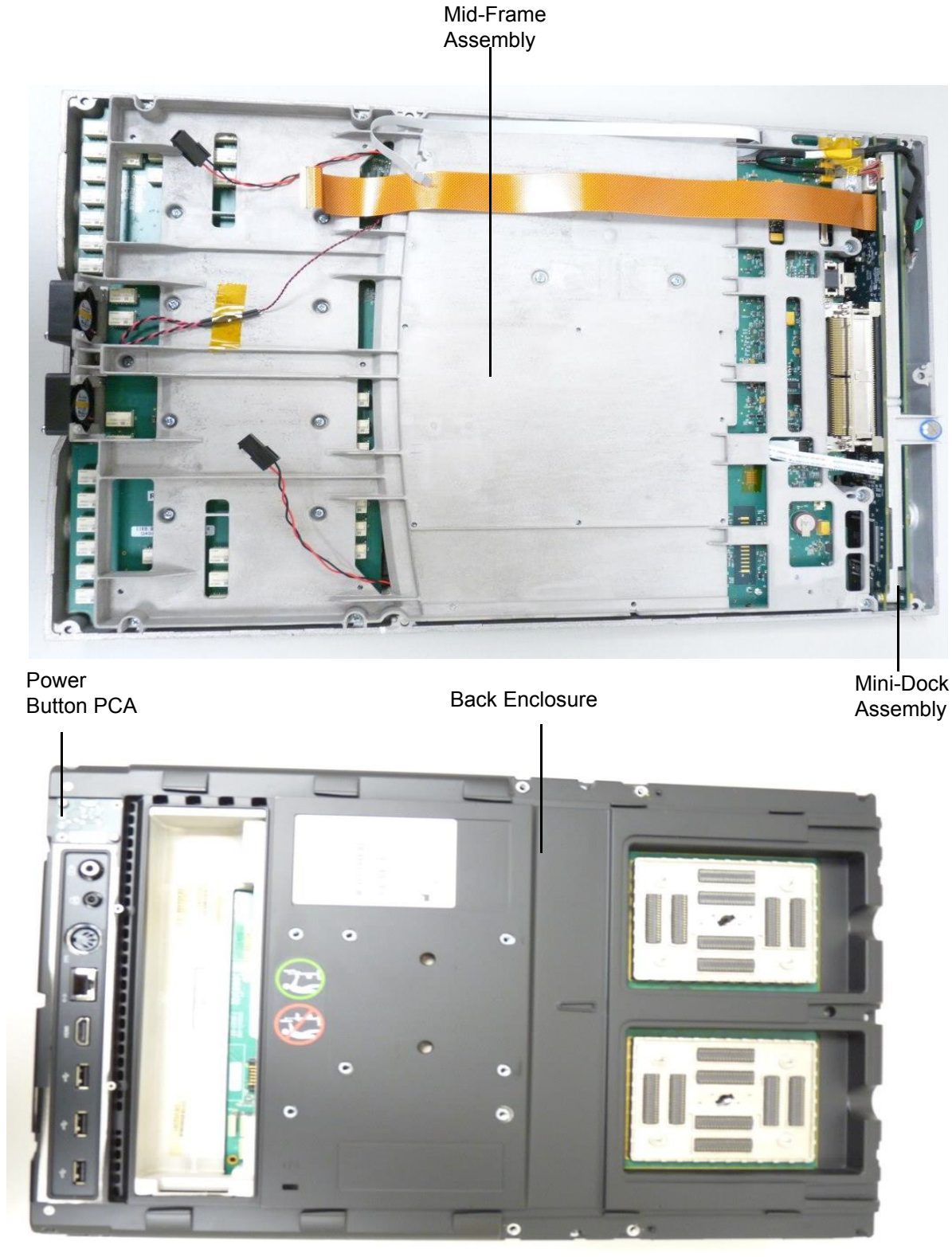


Figure 6.8 Base Assembly top and bottom

Caution: Always use correct ESD procedures. ESD damage is cumulative and may not be noticeable at first. Initial ESD symptoms may be slightly degraded performance or image quality.

Required Tools

- #1 Phillips screwdriver
- 1/4 inch flat blade screwdriver
- Torque screwdriver, 2.0–15.0 inch pounds (0.23–1.7 newton-meter)
- Anti-static mat
- Wrist grounding strap

Power Button PCA Replacement

Required Parts

- P21439, Power Button PCA

Power Button PCA Removal

Note: The User Interface does not need to be removed to replace the Power Button PCA. Only the Top Cap assembly should be removed to replace this item.

1 Remove Top Cap Assembly referenced in "User Interface Removal" on page 37, steps 1 - 4.

2 Remove two screws from Power PCA shown in Figure 6.9

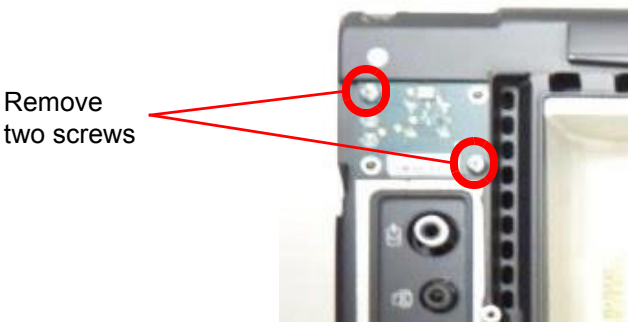


Figure 6.9 Power Button PCA

3 Remove PCA far enough to disconnect Power Cable. If cable is not damaged, it can be reused.

Power Button PCA Replacement

1 Connect Power PCA cable to Power Button PCA and place as shown in Figure 6.9

2 Install two screws and torque to 3.0 in-lbs.

3 Install Top Cap Assembly by performing steps 8-11 in reverse order in "Install User Interface" on page 42 on page 14.

Back Enclosure Replacement

Note: Contact SonoSite Technical Support if it is necessary to replace the Back Enclosure. Ordering the Back Enclosure requires special handling due to the serial number label..

Back Enclosure Removal

1 Remove nine screws plus three securing the Mini-Dock as shown in Figure 6.10.

2 For systems that have the STC option, also remove the four screws securing the STC cover indicated by the black squares in Figure 6.10. This step can be ignored if the system has a DTC.

3 Lift the Mid-Frame Assembly from the Back Enclosure.

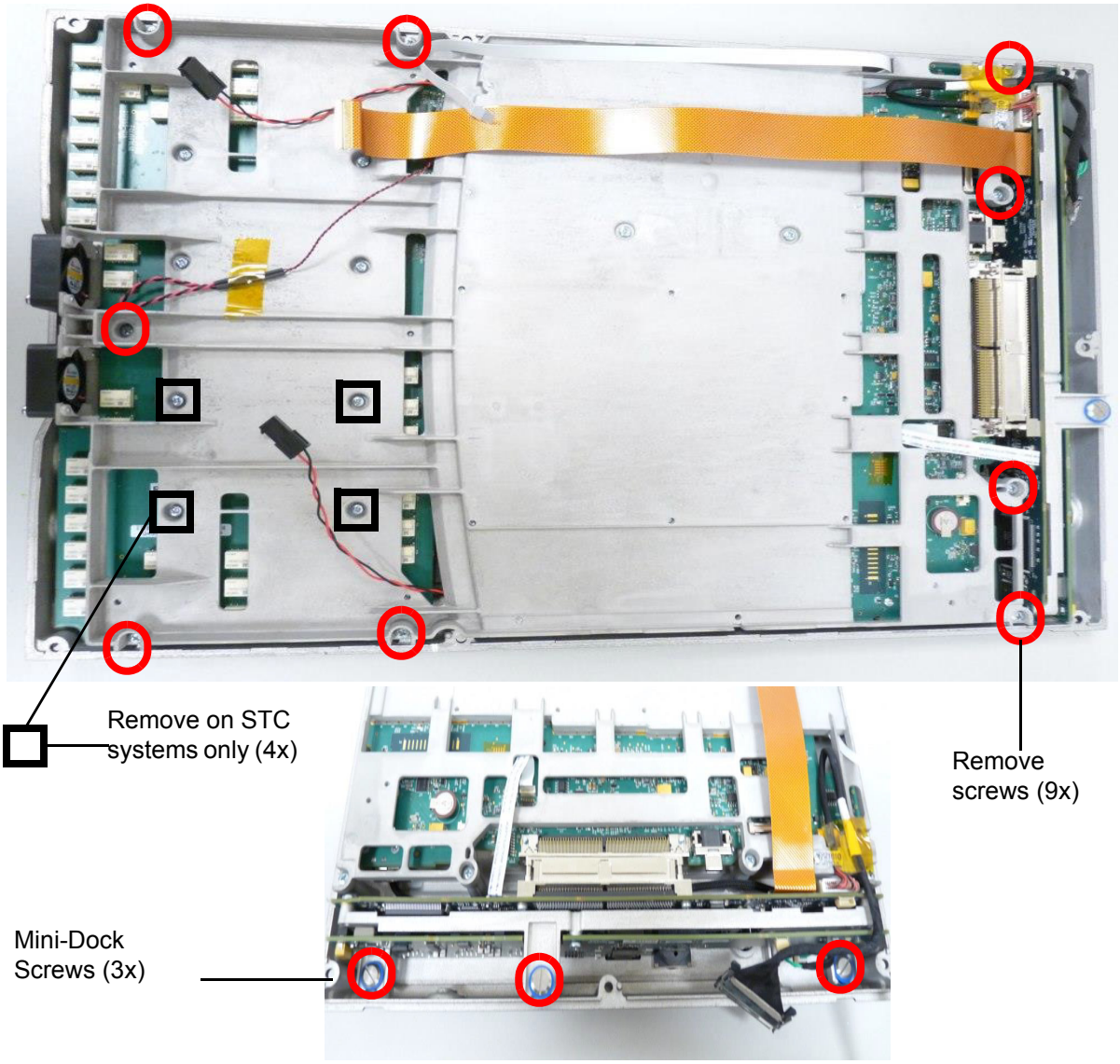


Figure 6.10 Back Enclosure Removal

Back Enclosure Replacement

1 Install the Back Enclosure by reversing steps 1-4 “Back Enclosure Replacement” on page 45.

2 For systems with STC, the STC cover needs to be placed in the blank port from the rear of the Back Enclosure.

3 Torque the four STC cover screws to 5.5 in-lbs.

4 Torque the nine screws securing the Mid-Frame Assembly plus three screws securing the Internal Mini-Dock to 5.5 in-lbs.

5 Perform “Install User Interface” on page 42.

Internal Mini-Dock Replacement

Required Parts

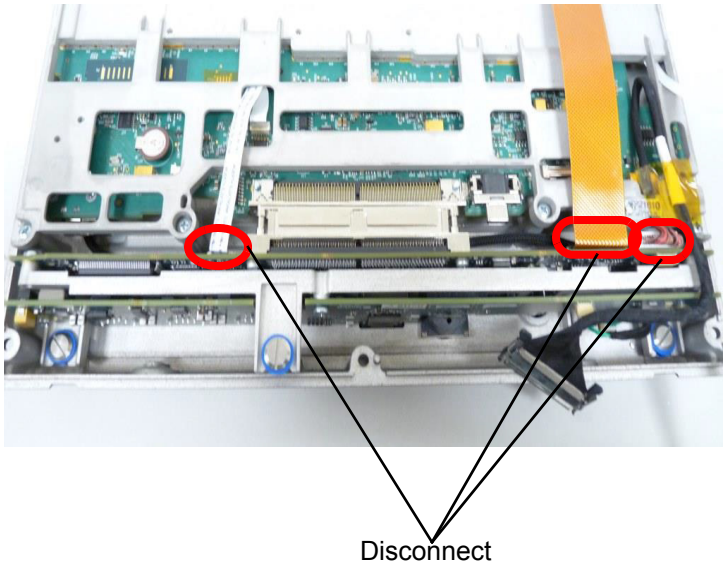
- P22444-XX Service Assembly, Internal Mini-Dock
- V22444-XX Vet Service Assembly, Internal Mini-Dock

Internal Mini-Dock Removal

1 Disconnect small flex cable, large flex cable and video cable from Internal Mini-Dock per Figure 6.11.

2 Pull Internal Mini-Dock slightly away from Main PCBA.

3 Remove backlight cable from Internal Mini-Dock.



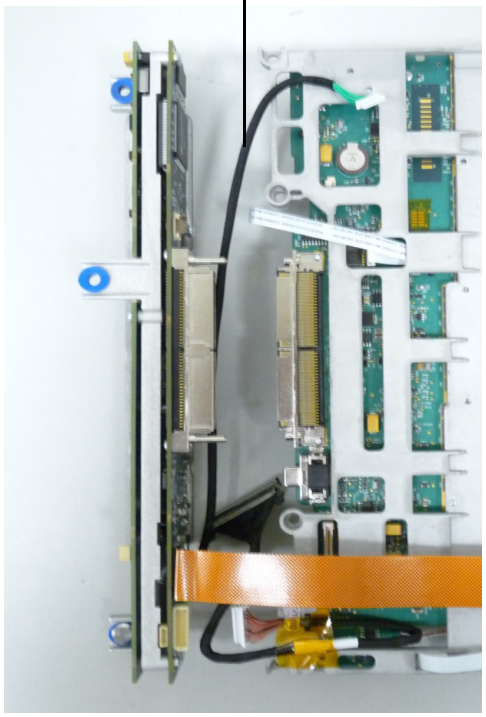


Figure 6.11 Internal Mini-Dock Removal

Internal Mini-Dock Replacement

1 Perform steps for “Internal Mini-Dock Removal” on page 46 in reverse order.

2 Ensure one end of backlight cable is connected to the Internal Mini-Dock and the other to the Main PCBA.

3 Install Internal Mini-Dock on Main PCBA and connect 3 cables in Figure 6.11

DTC/STC Replacement

Note: For simplification, only the procedure for DTC removal will be shown. The STC procedure is much the same.

Required Parts

- P21441-XX Service Assembly, Dual Transducer Connect (DTC)
- V21441-XX Vet Service Assembly, Dual Transducer Connect (DTC)
- P20662-XX Service Assembly, Single Transducer Connect (STC)

Note: The replacement DTC/STC PCBA does not include the Transducer Nest Frame Assembly. These parts must be transferred from the original DTC/STC PCBA. If new parts are required, please order the following components to complete the Transducer Nest Frame Assembly.

- Nest Frame Assembly Components
  - P07750 Nest Frame Assembly
  - P00364 Connector, Interposer (8x)
  - P03833 Shield, Perimeter, Short (2x)
  - P03834 Shield, Perimeter, Long (2x)
  - P00924 Screw, Shoulder, Thrust Plate (4x)
  - P00353 Wear Plate
  - P00646 Spring, Thrust Plate, .047 wire (4x)
  - P08200 Socket Head Cap Screw, M2.5-.45x10mm (4x)

DTC Removal

1 Orient Mid-Frame Assembly per Figure 6.12and remove eight screws securing the nest frame assemblies

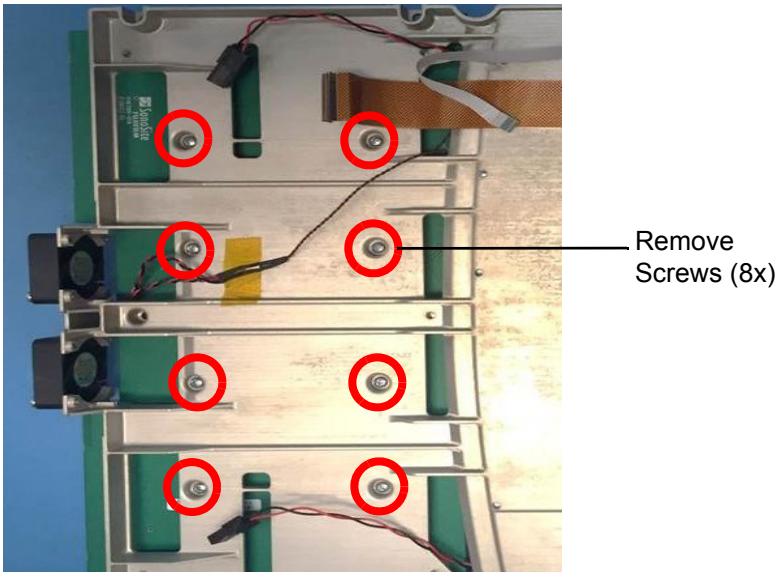


Figure 6.12 DTC Nest Frame removal

2 Lift Mid-Frame Assembly and move nest frame assemblies out of the way. Be careful when moving nest frame assemblies as turning them over will cause the interposers to fall out.

3 Turn Mid-Frame Assembly over and orient per Figure 6.13

4 Remove five screws per Figure 6.13

5 Lift latch lever and rotate 90 degrees clockwise to disengage.

6 Remove DTC from Main PCBA.

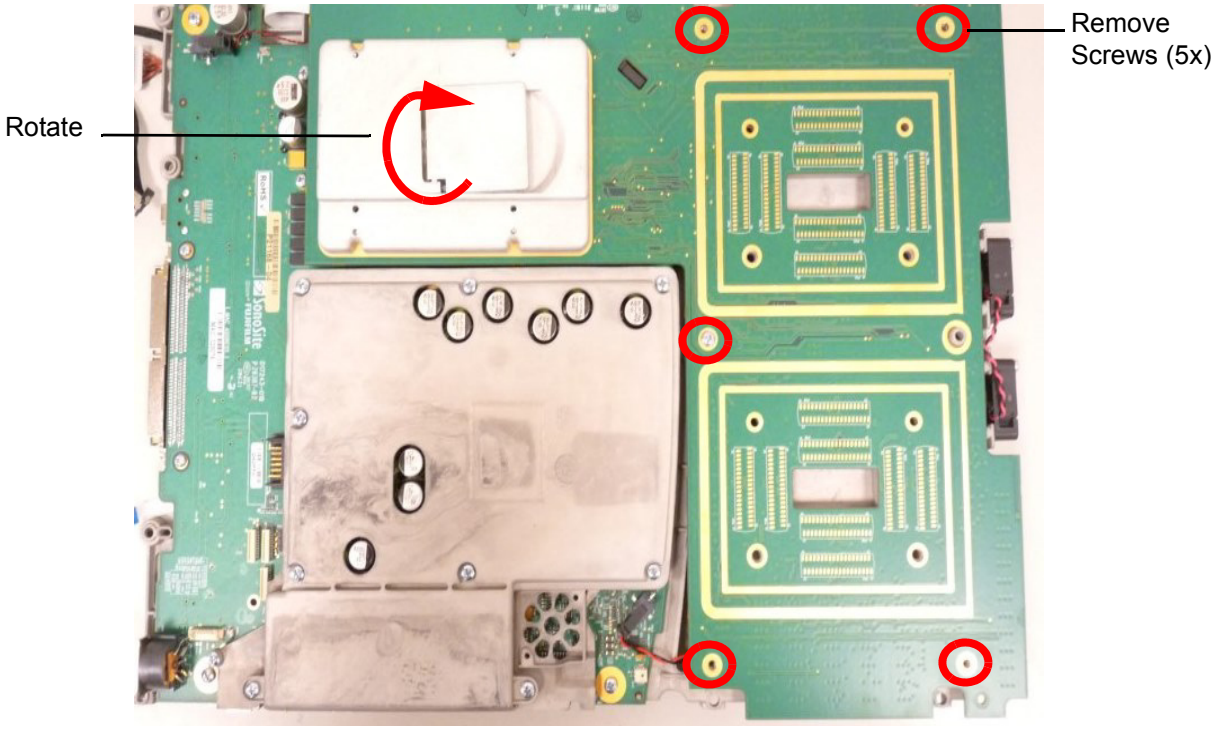


Figure 6.13 DTC Removal

DTC Replacement

1 Lift DTC latch lever and rotate 90 degrees clockwise to ensure it is in the disengaged position.

2 Install DTC onto Main PCBA as shown in Figure 6.12.

3 Rotate DTC latch lever 90 degrees counter-clockwise and close the latch.

4 install five screws and Torque to 5.5 in-lbs.

5 Turn Mid-Frame Assembly over and orient per Figure 6.12.

Caution:The Nest Frame is keyed onto the DTC via two smaller and two larger hole sizes. Installing incorrectly (180 degrees out) will result in the SII system being unable to recognize any connected transducers. Refer toFigure 6.14

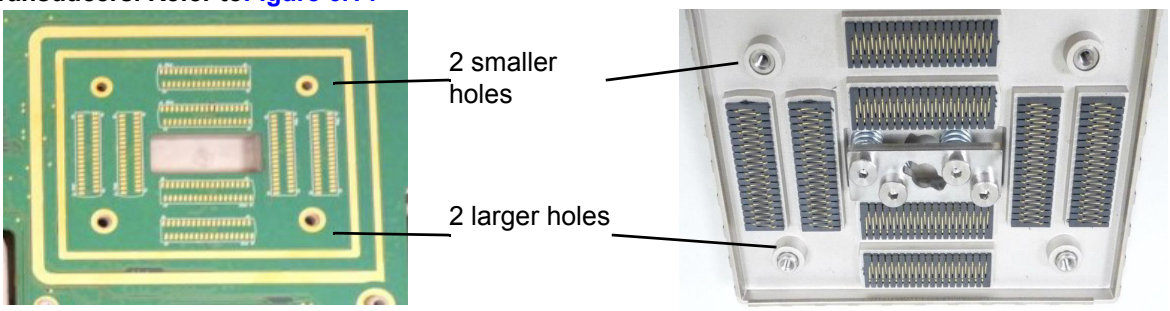


Figure 6.14 nest frame keying

6 Hold Nest Frame in the palm of your hand and put into place on the underside of the Mid-Frame Assembly using care to key it properly per Figure 6.14.

7 Install four screws as shown in Figure 6.12 and torque to 5.5 in-lbs.

8 Repeat steps 6 and 7 for other nest frame assembly.

Dual Fan Cable Assembly Replacement

Required Parts

- P21844 Dual Fan Cable Assembly

Dual Fan Cable Assembly Removal

1 Disconnect Dual Fan Cable Assembly from Main PCBA as shown in Figure 6.15

2 Remove four screws securing fans to Mid-Frame and remove assembly.

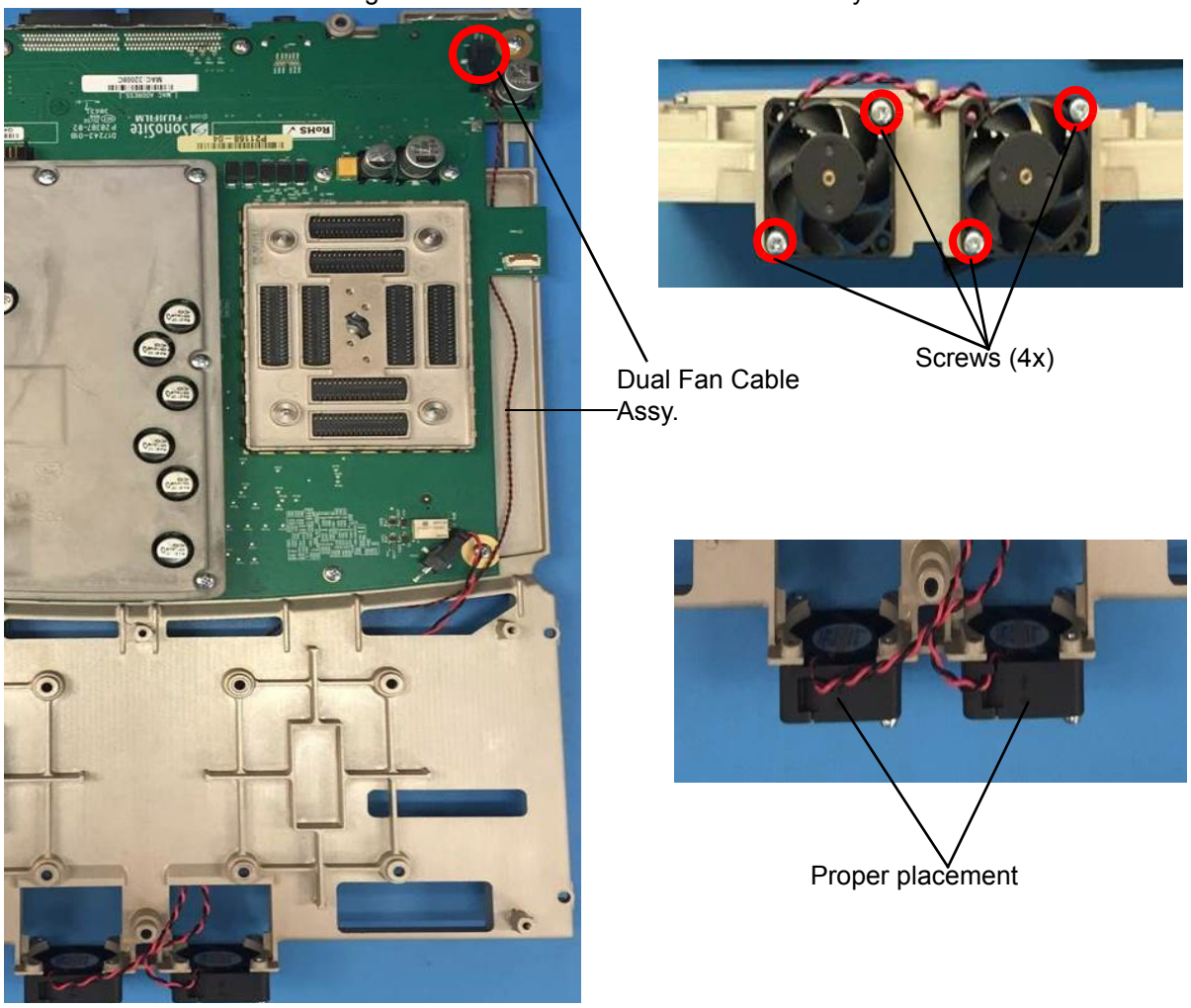


Figure 6.15 Dual Fan Removal

Dual Fan Cable Assembly Replacement

1 Install Dual Fans on Mid-Frame as shown in Figure 6.15. Ensure the orientation of each fan is so the arrows on the side of the fan point inwards towards the Mid-Frame and the fans are rotated as shown in the bottom picture. Torque screws to 5.5 in-lbs.

2 Route Dual Fan Cable Assembly Cable as shown and connect to Main PCBA.

Power Supply PCBA Removal

Required Parts

- P19909-XX Service Assembly, Power Supply PCBA
- V19909-XX Vet Service Assembly, Power Supply PCBA

Power Supply PCBA Removal

1 Remove Seven long screws and two short screws securing the digital shield lid. Please note the location of the 2 short screws as seen in Figure 6.16 . Also note the location marked with the black box. The screw hole should be empty and covered with kapton tape. Do not place a screw in this location. Remove lid and set aside.

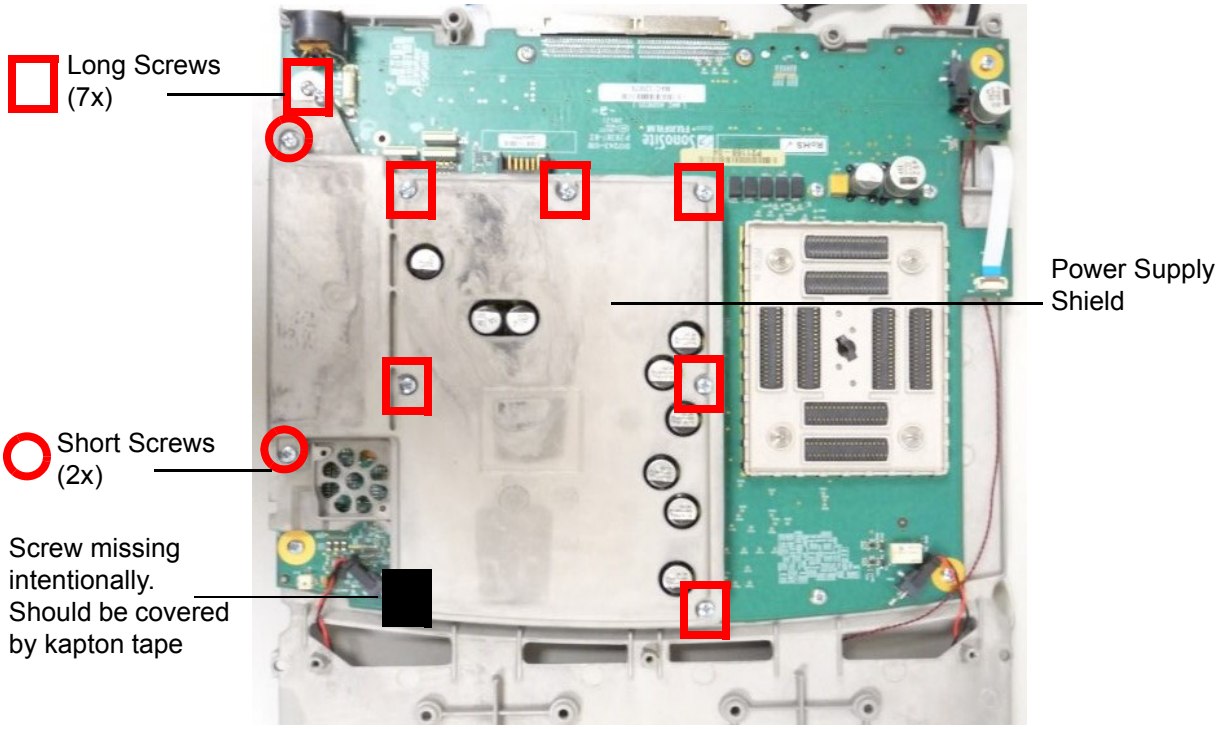


Figure 6.16 Power Supply Shield

2 Gently lift the Power Supply PCBA and Power Supply Shield away from the Main PCBA as shown in Figure 6.17 (The Power Supply PCBA connector is in the upper left corner. Removing the Power Supply PCBA without also removing the shield is difficult).

3 Once disconnected from the Main PCBA, separate the Power Supply PCBA from the Power Supply shield.

Power Supply PCBA Replacement

1 Place the Power Supply PCBA in the Power Supply shield and install on Main PCBA.

2 Install the Power Supply Digital Shield Lid.

3 Install the seven long screws and two short screws. Torque to 5.5 in-lbs.

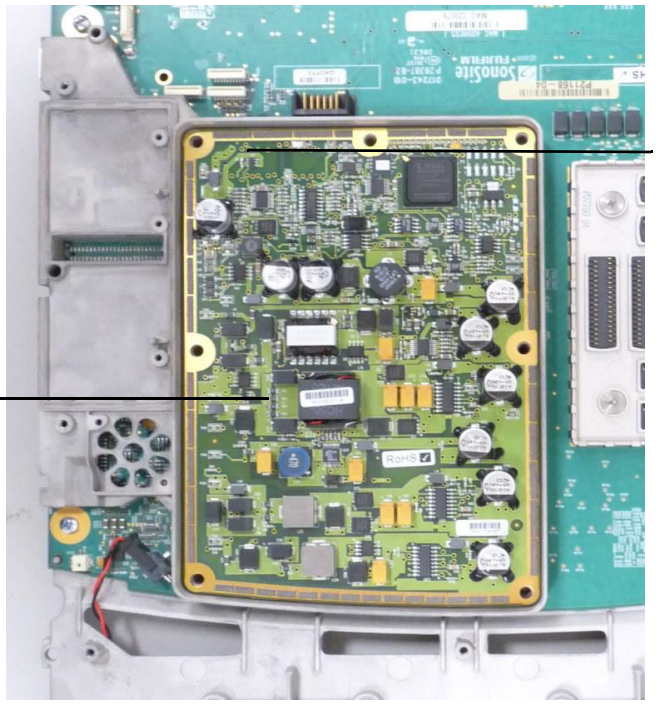


Figure 6.17 Power Supply PCBA

SD Card Replacement

Note: The SD card is not field replaceable as the encryption can only be set at the factory. Each Main PCBA is matched to their SD card and for this reason cards are also not interchangeable between systems.

Main PCBA Replacement

Required Parts

- P21168-XX Service Assembly, Main PCBA, SII
- V21168-XX Vet Service Assembly, Main PCBA SII
- P07885 Thermal Pad, 1.00 x 1.00 x 0.100” (4 Required)
- P07886 Thermal Pad, .035 x .035 x 0.100: (14 Required)

Main PCBA Removal

1. Remove the Power Supply PCBA as described in the previous steps.
2. Flip Mid-Frame Assembly over and remove four screws securing the Nest Frame Assembly per Figure 6.19.
3. Lift Mid-Frame and set Nest Frame Assembly aside.
4. Flip Mid-Frame over so the Main PCBA is facing up.
5. Disconnect the power cable to the Dual Fan Assembly as shown in Figure 6.18.
6. Disconnect the speaker wires from the Main PCBA
7. Disconnect the TGC cable if still present.

8 Remove eight screws as shown in Figure 6.18.

9 Lift Main PCBA from Mid-Frame

Main PCBA Replacement

1 Place Main PCBA on Mid-Frame and install seven screws as shown in Figure 6.18. Do not tighten the screws.

2 Tip Mid-Frame onto the side and Install Nest Frame Assembly with four screws as shown in Figure 6.19. Torque to 5.5 in-lbs.

3 Tighten screws previously installed on Main PCBA to 5.5 in-lbs.

4 Install TGC cable.

5 Install speaker wires.

6 Install power cable to the Dual Fan Assembly.

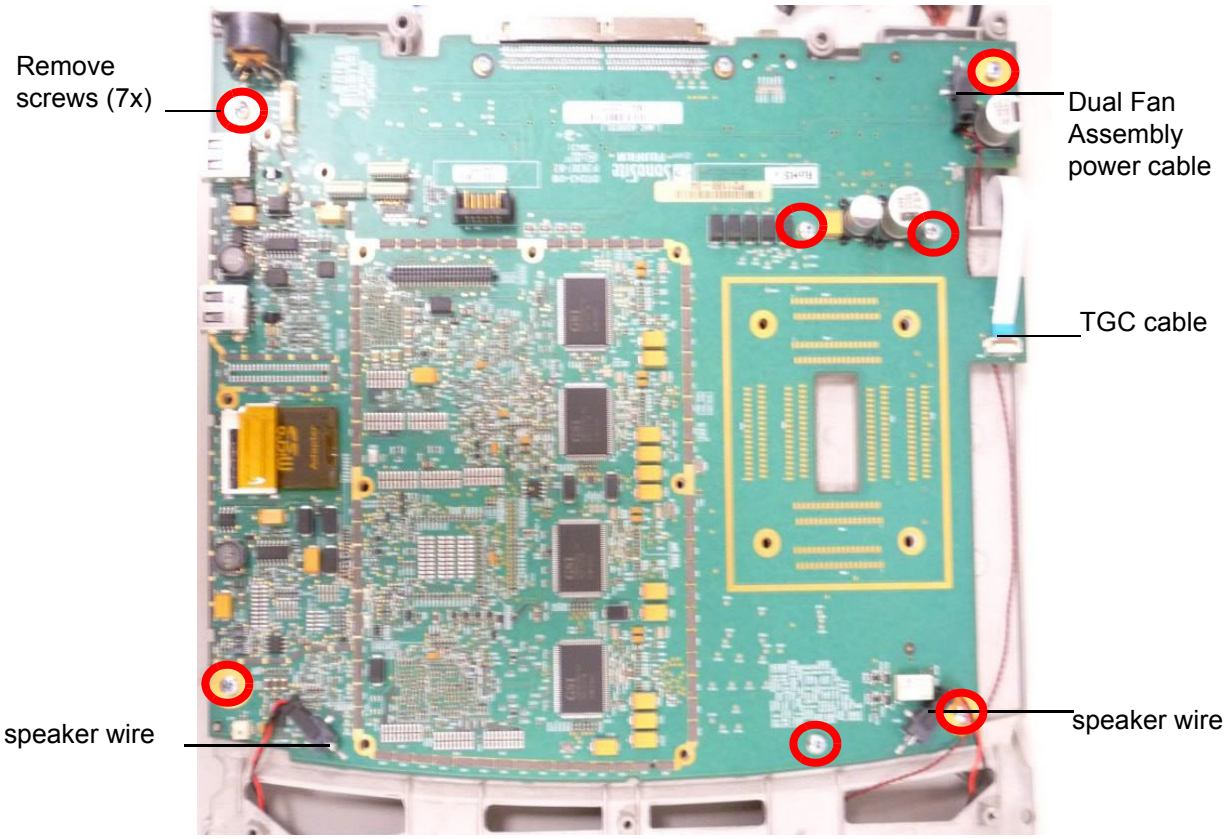


Figure 6.18 Main PCBA

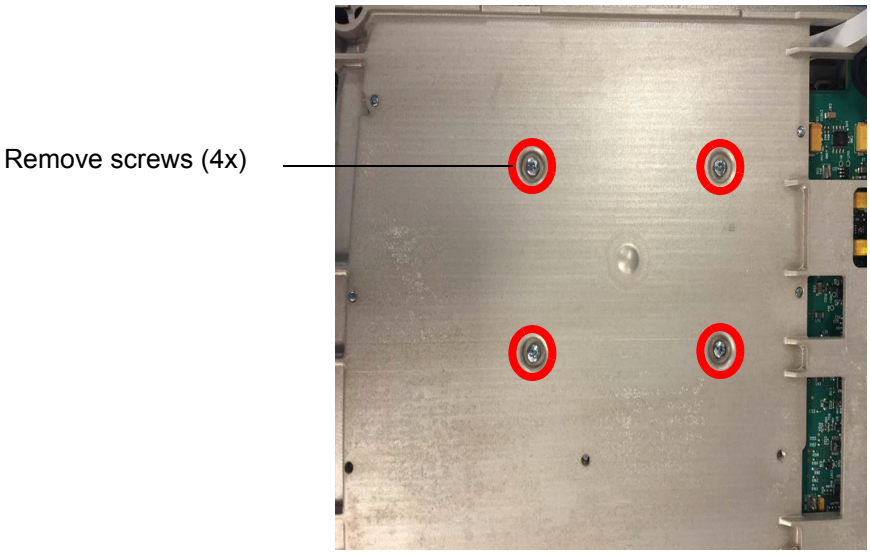


Figure 6.19 Nest Frame Removal

Mid-Frame Replacement

Required Parts

- P20501 Mid-Frame, SII
- P07885 Thermal Pad, 1.00 x 1.00 x 0.100” (4 Required)
- P07886 Thermal Pad, .035 x .035 x 0.100: (14 Required)

Mid-Frame Replacement

1. Follow all the above procedures to remove all PCB assemblies and hardware fastened to the original Mid-Frame.
2. Install new thermal pads on the new Mid-Frame, do so per Figure 6.20
3. Reverse the procedures used in step 1 to install all PCB assemblies and hardware to the new Mid-Frame.

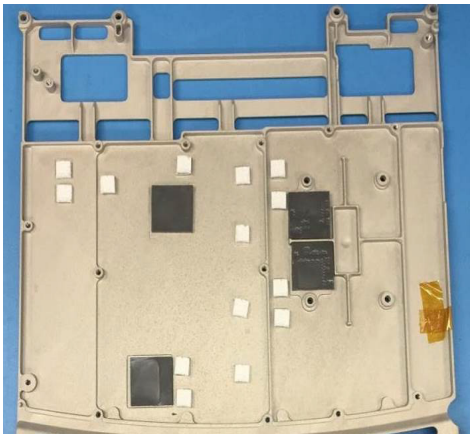


Figure 6.20 Thermal Pad placement

Chapter 7: Maintenance

This chapter contains information to help you properly care for the system, transducers, and accessories.

Periodic Maintenance

No periodic or preventive maintenance is required for the system, transducers, or accessories other than cleaning and disinfecting the transducer after every use. For cleaning and disinfecting, please reference the SonoSite SII User Guide. For a complete list of approved cleaners and disinfectants, please visit www.sonosite.com.

There are no internal adjustments or alignments required and there are no internal components that require periodic testing, calibration, adjustment, or alignment. Performance tests are described in Chapter 8, “Performance Testing” of this manual. Performing maintenance procedures not described in this manual may void the product warranty.

Local regulations may require electrical safety testing.

Contact FUJIFILM SonoSite Technical Support for any maintenance questions. (See “Contact Information” on page 1.)

Chapter 8: Performance Testing

Overview

WARNING: **Critical Test Function** — A failure of the system functions tested in this section could affect safety or effectiveness of the system adversely. While performing the steps in this section, verify that the images on the system display and on the external monitor are acceptable.

To obtain 2D images, FUJIFILM SonoSite recommends using the Gammex 403GS Soft Tissue Phantom or the Gammex 413A Multipurpose Phantom. A .7db/cm phantom is recommended but not required.

Some features and capabilities are optional and therefore may be unavailable to test.

Recommend Test Equipment

- FUJIFILM SonoSite ultrasound system under test
- rC60xi/5-2 MHz transducer
- rP19x/5-1 MHz transducer
- Gammex 403 GS Multipurpose Phantom, 413A Soft Tissue Phantom, or equivalent.
- Acoustic gel

Setting Up Performance Tests

Set up Performance Tests	1	Attach the rC60xi/5-2 MHz transducer to the system.
	2	Select Gen for optimization and OB for exam type.
	3	Couple the transducer to the phantom, adjusting gain settings and transducer for a proper phantom image (e.g., pins are high-level echoes positioned in straight lines; cysts are sonolucent, edges are sharp, and graphite particles of the phantom are mid-grays).

Basic Operational Tests

Basic System Operation Tests	1	Verify that the correct transducer name appears in the upper right corner of the system display.
	2	Verify proper date and time.
	3	Verify that the scan plane orientation mark in the image located near the skinline corresponds to element #1 on the transducer. To test, put your finger on the transducer lens at the edge closest to the orientation bump on the transducer enclosure. Run your finger across the transducer lens. Your finger touching the transducer lens should appear at the orientation mark on the display image when your finger is near the orientation bump on the transducer.
	4	Verify that all of the touchscreen keyboard keys are functional. Verify that all touch controls operate and that the system responds properly.
	5	Verify that as the Gain controls are increased and decreased, there is a corresponding increase and decrease in echo intensity.
	6	Capture a Cineloop buffer. Exercise the Cineloop controls and verify proper operation.
	7	Set the sleep and power delay settings and ensure they work properly.
	8	Verify the airflow from the vent on the bottom of the system is drawing air in.

2D Performance Tests

2D Performance / Image Quality

Test 2D Performance and Image Quality	1	Use an rC60xi/5-2 MHz transducer in 2D mode.
	2	Adjust the position of the rC60x/5-2 MHz transducer on the phantom.
	3	With the array pointing down and the orientation mark to the operator's left, element #1 corresponds with the left side of the array.
	4	Use the 2D system controls to obtain a clear image that shows both the horizontal and vertical rows of pins.
	5	Verify that the ultrasound image appears uniform in both the axial and lateral direction, with no dropouts or intensity variations.
	6	Verify that the cystic structure at the focal zone is clearly differentiated from the surrounding tissue and is echo-free, while solid tissue with numerous echo sources, appears solid.
	7	Tap the **Freeze** button and then save the image. Tap the **Freeze** button again to return to live imaging.

Axial Measurement Accuracy

Note: Measurements must be performed while the image is frozen.

Set Up Axial Measurement Accuracy	1	Acquire the image.
	2	tap the **Freeze** button.
	3	tap **Calipers**. The calipers appear on the image display. (See the *SonoSite SII Ultrasound System User Guide*, if necessary, for caliper operation.)
	4	Use the touchpad or touchscreen to position the active caliper.
	5	Select the other caliper in either of the following two methods. • If using the touchpad, move the on-screen cursor to the other caliper and tap the touchpad • If using the touchscreen, tap on the other caliper
	6	Use the touchpad or touchscreen to move the other caliper. The results update as you move the caliper, and the measurement is complete when you finish moving the calipers. Alternate between calipers by selecting on touchscreen or using the touchpad to move the on-screen cursor.
Test Axial Measurement Accuracy	1	Measure the distance, center to center, of any two pins that are 5-12 cm apart vertically.
	2	Verify that the distance measured is within the tolerance listed in Table 8.1.

Lateral Measurement Accuracy

Set Up Lateral Measurement Accuracy		Perform “Set Up Axial Measurement Accuracy” on page 59.
Test Lateral Measurement Accuracy	1	Measure the distance, center to center, of any two pins that are 4-10 cm apart horizontally.
	2	Verify that the distance measured is within the tolerance listed in Table 8.1.
	3	tap the **Freeze** button to return the system to live 2D mode.

Table 8.1: System Measurement Accuracy

Measurements	Tolerance
Axial Distance	+/- 2%
Lateral Distance	+/- 2%

Penetration

The penetration measurement is an integral part of the quality assurance program. Penetration is defined as the deepest depth at which an ultrasound system can provide adequate image quality of small anatomical structures.

Penetration measurements should be performed and the results retained for comparison to future measurements. Penetration measurements should remain fairly consistent over time assuming use of the same system settings and scanhead. Degradation of the penetration measurement in excess of 1cm may indicate a transducer or system electronics issue.

Loss of measured penetration may also be caused by degradation (dessication) of the ultrasound phantom. Ultrasound phantoms used for penetration measurements must also be part of a quality assurance program to maintain their integrity. Follow all of the phantom manufacturer recommendations for use, storage, and maintenance of the phantom.

Test Penetration

1. Use the same scanhead and system settings as previous measurements if possible.
2. Adjust the system controls to obtain a clear image that shows the limits of echo penetration.
3. tap the **Freeze** button and then save the image.
4. Measure from the center of the skinline to the deepest vertical position—where the scatter echoes start to break up and tissue definition is lost.
5. Record and retain the results for future reference. Scanhead type and system settings (exam type, depth, resolution mode, etc.) should also be recorded to ensure proper comparison with future tests.
6. tap the **Freeze** button again to return to live imaging.

Additional Performance Tests

Color Doppler (Color)

Test Color

1. Connect any transducer.
2. tap the **Color** button. “Color” should be annotated in the top left corner of the display.
3. A Region of Interest (ROI) box is displayed on top of the grayscale image. Use the touchpad to move the Color ROI. Verify that the ROI moves to the new position on the display.
4. Adjust the **Depth** control for minimum depth in the image.
5. Adjust the **Gain** control so that color speckles just appear inside the ROI box.
6. Gently tap the face of the transducer and observe that the ROI box fills with color information.
7. tap the **Freeze** button and then save the image. tap the **Freeze** button again to return to live imaging.

Color Power Doppler (CPD)

Test CPD	1	Connect any transducer.
	2	tap the **Color** button. A Region of Interest (ROI) box is displayed on top of the grayscale image.
	3	tap the **Color** button to switch to CPD. “CPD” should be annotated in the top left corner of the display.
	4	Adjust the **Depth** control for minimum depth in the image.
	5	Adjust the **Gain** control so that color speckles just appear inside the ROI box.
	6	Gently tap the face of the transducer and observe that the ROI box fills with color information.

M Mode Imaging

Test M Mode Imaging	1	Attach an rC60xi transducer and acquire an image.
	2	tap the **M Mode** button for the M Mode sample line.
	3	Position the M Mode sample line over the image using the touchpad.
	4	tap the **M Mode** button again to turn on M Mode.
	5	Select the desired sweep speed from the on-screen menu (slow, med, or fast). The on-screen menu will show the selected sweep speed.
	6	tap the **Freeze** button to freeze the image. Save the image. tap the **Freeze** button again to return to live imaging.
	7	tap the **2D** button to return to 2D imaging.

Tissue Harmonic Imaging

Test THI Imaging	1	Attach the rC60xi transducer and acquire an image.
	2	Set the depth to maximum and note the depth at which echo information is lost.
	3	Tap the **THI** button on the screen controls so it displays THI in the mode area. Tissue Harmonic Imaging in now active.
	4	Observe a decrease in dot size and a significant loss in penetration due to the higher frequency. Image resolution increases.
	5	tap the **Freeze** button and then save the image. tap the **Freeze** button again to return to live imaging.
	6	tap the **THI** button again to turn off Tissue Harmonic Imaging.

Image Quality Verification Test/Livescan

- Products with replaced subassemblies, or products that have been otherwise disassembled, must undergo an Image Quality Verification Test/Livescan.
- The Image Quality Verification Test/Livescan should be performed after successfully completing all applicable performance tests listed prior in this chapter.
- The test is completed before returning the system to service.
- A certified sonographer must perform the test.
- The Livescan test performed is at the discretion of the Sonographer and will represent their acceptance of a successful service event.
- Review all saved images and verify that the images are displayed properly.

Printer

The printer test is an optional test that requires a video printer to be connected to the system under test. Skip this test if a printer is not available.

Test Printer Operation	1	Connect a video output and print control cable from the rear of the system to the printer.
	2	Verify proper printer type is configured in the system Settings page.
	3	tap the print button and verify that the printer begins to print an image. After the image begins to emerge from the printer, tap the print button again. The printer should ignore the second print command.
	4	Verify the proper content of the printed image.

Battery Charging

Test Battery Charging Operation	1	Remove the AC power cord and insert a battery into the system.
	2	Press the **Power** button to turn the system on. Allow the battery to discharge. The battery indicator icon on the display, below the Transducer Type indicator, will extinguish from right to left as the battery discharges. *Note: The Power and Sleep delays in the Setup page should be selected to "Off" to properly perform this test. The battery may take 1–2 hours to discharge.*
	3	Reattach the AC power cord to the power connector and power the system on.
	4	Note that the battery indicator indicates that the battery is charging. The sections of the battery indicator will light sequentially from left to right as the battery charges.

Video Output

The video output test is an optional test that requires an external video monitor to be connected to the system under test. Skip this test if an external monitor are not available.

Test Video Output	1	Connect the video output on the back of the system to an external video monitor.
	2	Turn on the system power and verify that the video on the external monitor matches the video on the system display. If the video does not appear similar, or there is no display on the external monitor, see Chapter 5, "Troubleshooting" for troubleshooting procedures.

Appendix A: Replacement Parts List

The following tables contain all the field-replaceable parts for the S II ultrasound system. Quantities are one unless otherwise noted.

Base Assembly Components

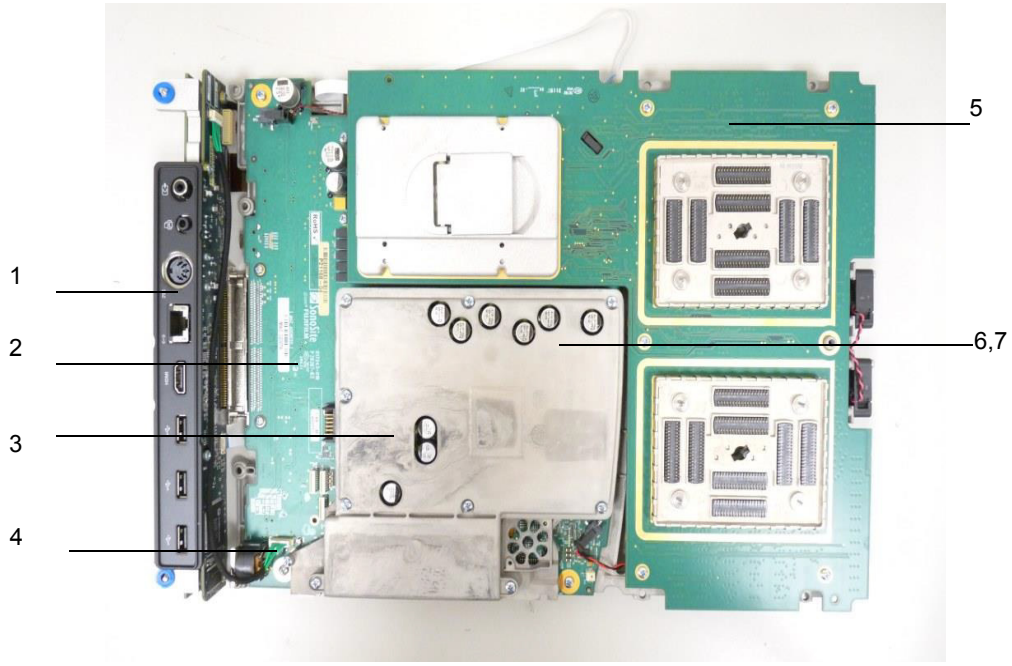


Table 1: Base Assembly Components

Item Number	Part Number	Description
1	P22444-XX	Service Assembly, Internal Mini-Dock, SII
	V22444-XX	Vet Service Assembly, Internal Mini-Dock, SII
2	P21168-XX	Service Assembly, Main PCBA, SII
	V21168-XX	Vet Service Assembly, Main PCBA SII
		Note: This part does not include the transducer nest frame assembly. The nest frame from the old Main PCBA should be reused unless determined to be defective. Those parts must be ordered separately if needed to complete the replacement of the Main PCBA.
3	P19909-XX	Service Assembly, Power Supply PCBA
	V19909-XX	Vet Service Assembly, Power Supply PCBA
4	P21157	Cable Assembly, Display Backlight
5	P21441-XX	Service Assembly, Dual Transducer Connect (DTC)
	V21441-XX	Vet Service Assembly, Dual Transducer Connect (DTC)
		Note: The note above concerning nest frame assemblies applies to DTC.
6	P09541	Digital Shield
7	P09542	Digital Shield Lid

Additional Base Assembly Components

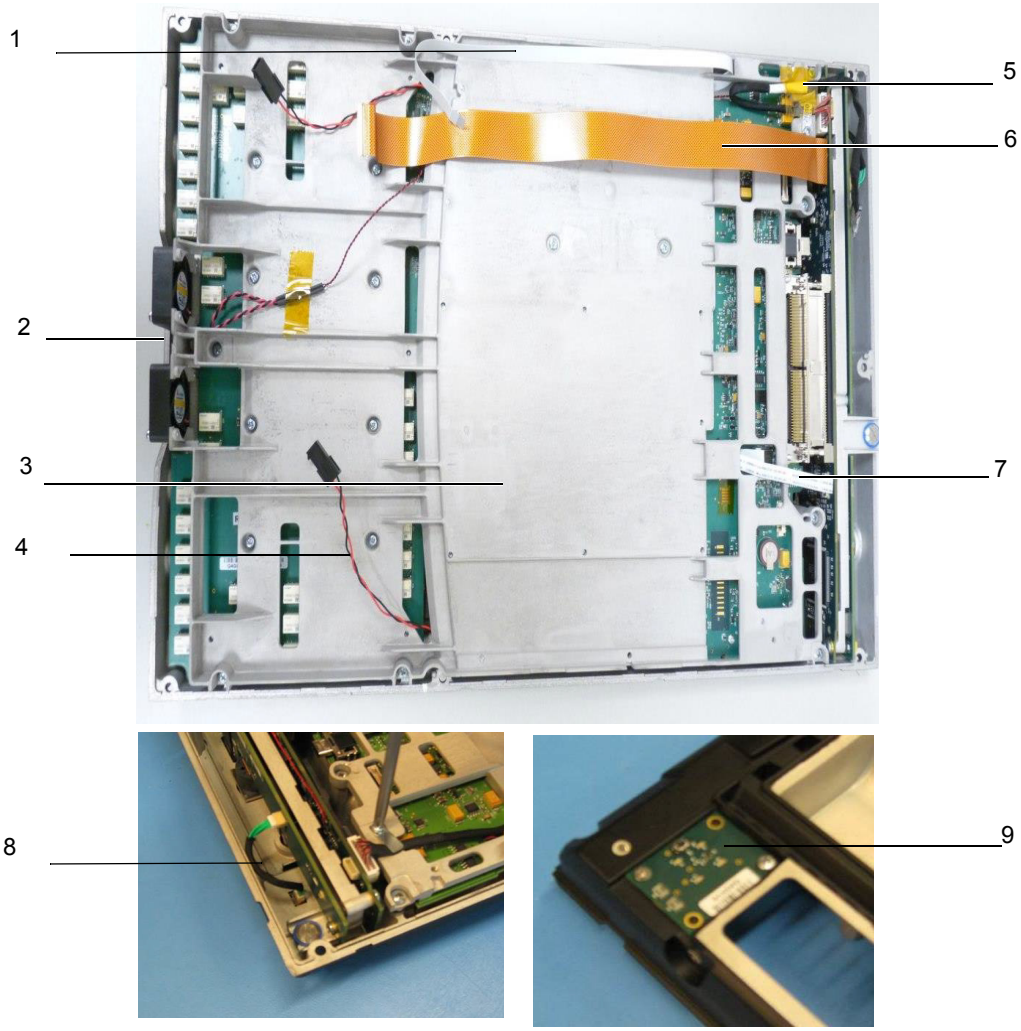


Table 2: Additional Base Assembly Components

Item Number	Part Number	Description
1	P20816	Cable, Main PCBA to Gain
2	P21844	Dual Fan Cable Assembly
3	P20501	Mid-Frame
4	P21193	Cable Assembly, Speaker Extension (2x)
5	P20818	Cable, LCD Video
6	P20819	Cable, Control Board to I/O
7	P20817	Cable Main PCBA to I/O
8	P20820	Cable Assembly, Power Button
9	P21439	Power Button PCA

User Interface Components

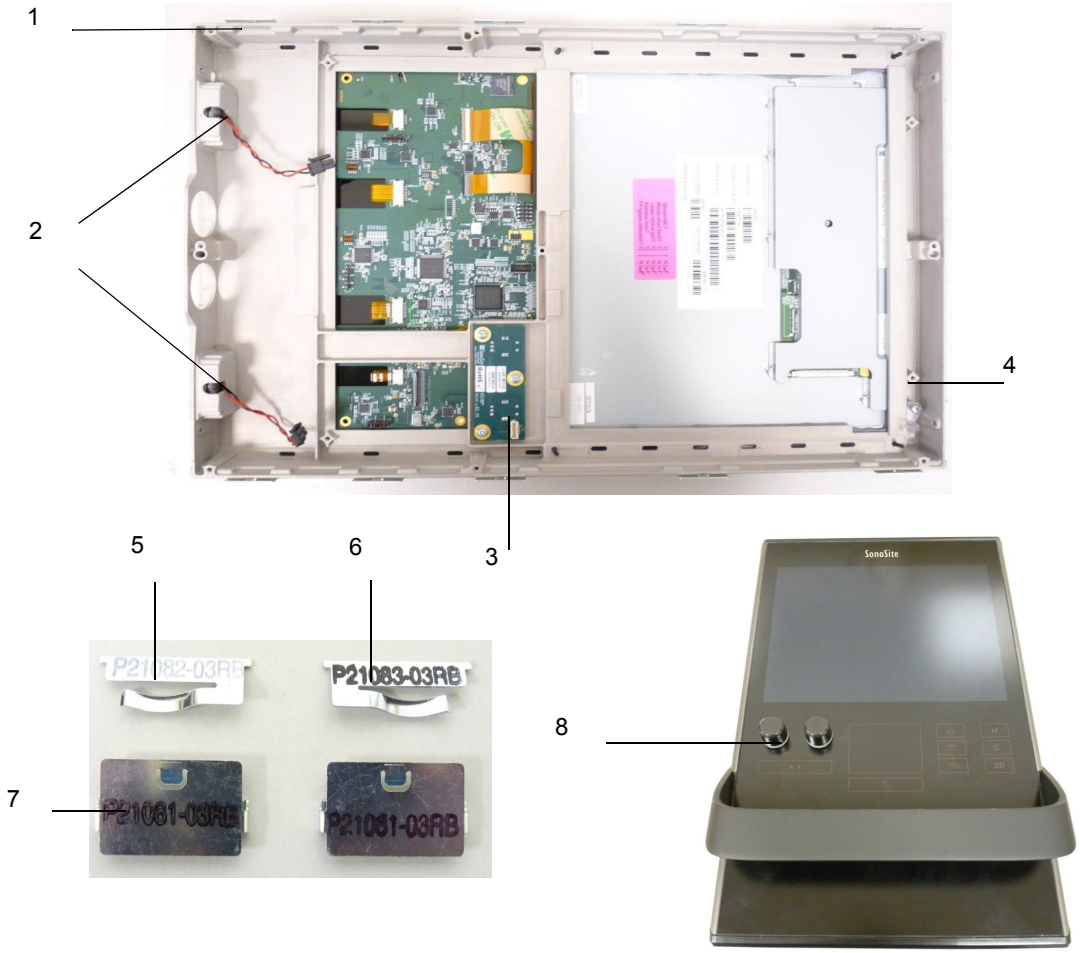


Table 3: User interface Components

Note: If the User Interface is replaced, items 2-8 below must be transferred from the old to the new.

Item Number	Part Number	Description
1	P20475-XX V20475-XX	Service Assembly, User Interface, SII (supports all languages) Vet Service Assembly, User Interface, SII (supports all languages)
2	P20814	Speaker Cable Assembly (x2)
3	P21440	TGC PCBA
4	P20492	Light Pipe
5	P21082	Right Slide Lock Spring (x5)
6	P21083	Left Slide Lock Spring (x5)
7	P21081	Slide Lock Plate (x10)
8	P21662	Metal Knob (x2)

Parts Unique to STC Systems

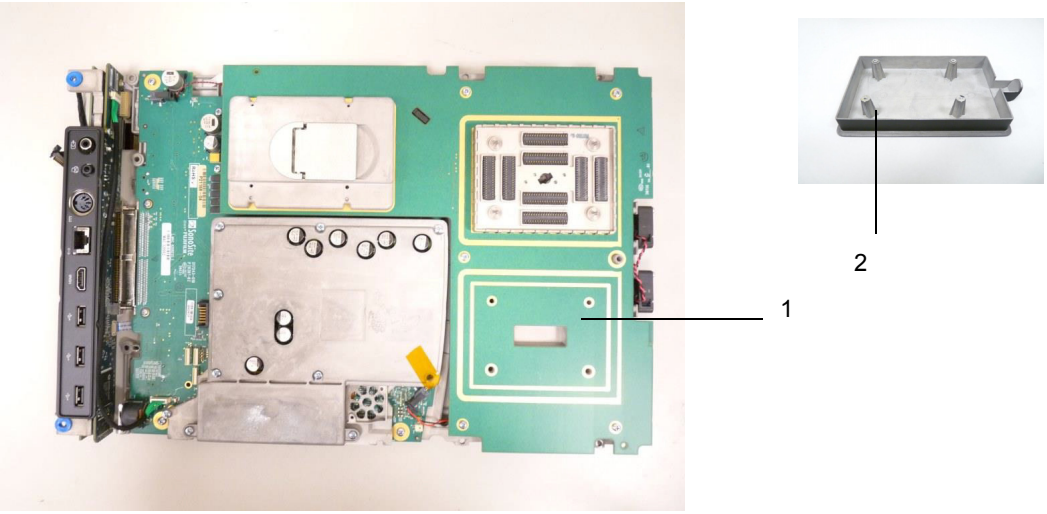


Table 4: Parts Unique to STC Systems

Item Number	Part Number	Description
1	P20662-XX	Service Assembly, Single Transducer connect (STC) *Note: Similar to DTC except only has parts and components for one port. The note above concerning nest frame assemblies applies to STC.*
2	P20472	STC Cover

Enclosure Parts

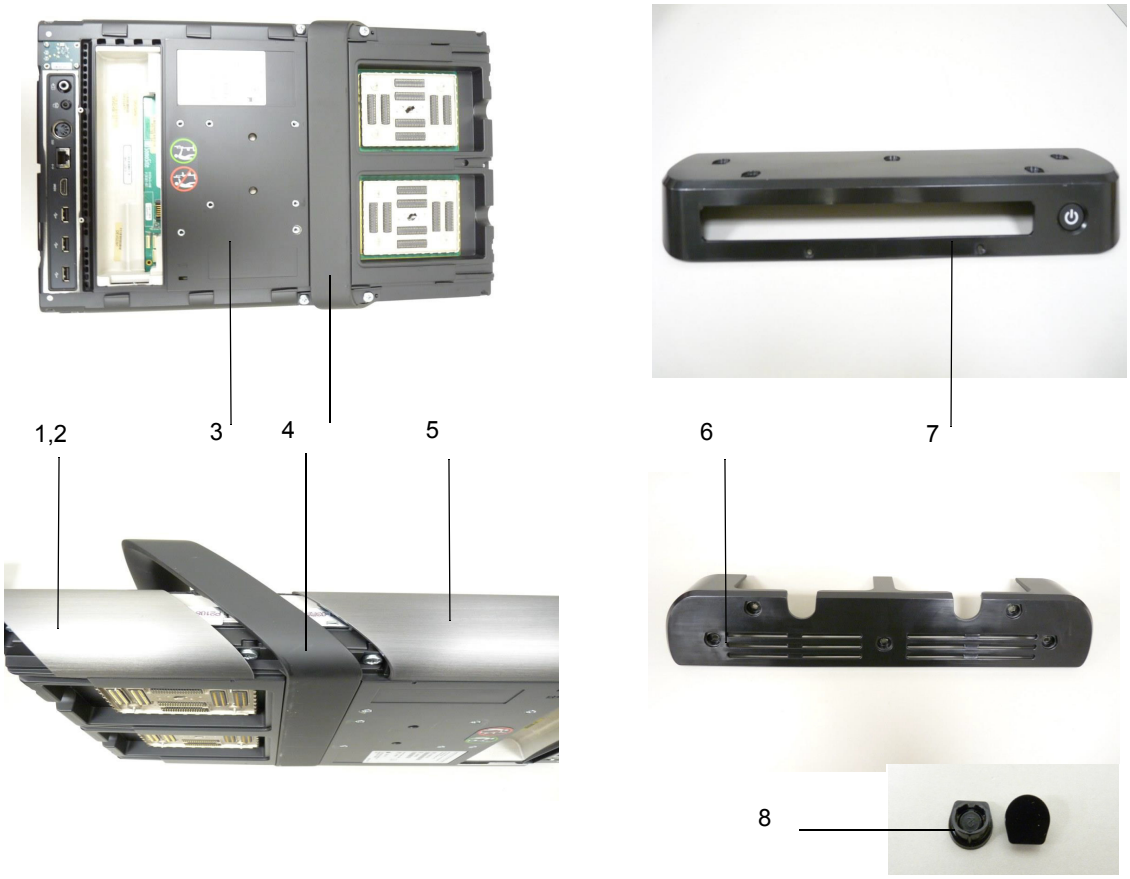


Table 5: Enclosure Parts

Item Number	Part Number	Description
1	P20470	Bottom Right Extrusion
2 (other side, not shown)	P20471	Bottom Left Extrusion
3	P20465	Back Enclosure
4	P20473	Handle
5	P20468	Top Extrusion (x2)
6	P20467	Bottom Cap
7	P21624	Top Cap Assembly (contains power button)
8	P21155	Screw Cover for Top/Bottom Cap (x10)

Transducer Nest Frame Assembly

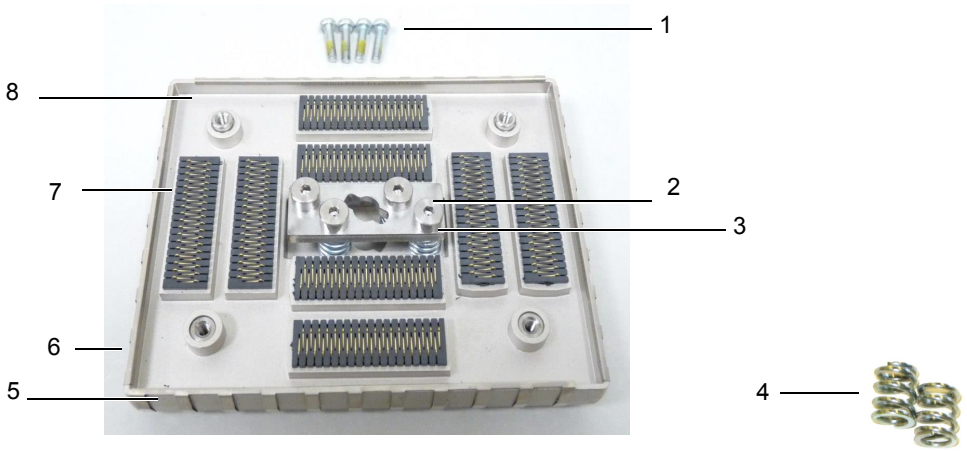


Table 6: Nest Frame Assembly

Item Number	Part Number	Description
1	P15551	Screw, PNHD, Phillips, M3-.5X8MM
2	P00353	Wear Plate
3	P00924	Screw, Shoulder, Thrust Plate (4x)
4	P00646	Spring, Thrust Plate, .047 wire (4x)
5	P03834	Shield, Perimeter, Long (2x)
6	P03833	Shield, Perimeter, Short (2x)
7	P00364	Connector, Interposer (8x)
8	P07750	Nest Frame Assembly

Ordering Replacement Parts

To order parts, contact SonoSite Technical Support. See “Contact Information” on page 1.

Appendix B: Service Event Reporting

The Service Event Report provides information about product failures to the manufacturer and to authorized service facilities, which provide approved warranty services for FUJIFILM SonoSite products. For all repairs completed, complete the form and email a copy of it to service@sonosite.com or mail to the following address:

Fujifilm SonoSite, Inc.
Technical Support
21919 30th Drive SE
Bothell, Washington 98021
USA

To contact FUJIFILM SonoSite Technical Support, see“Contact Information” on page 1.

Service Event Report Form

Service Event Report

Instructions on reverse

Service Type (check one)
☐ Out of Box Failure
☐ Warranty Service
☐ Out of Warranty Service

Parts Status (check one)	
☐	No parts necessary for this repair. Service Event Report for your information.
☐	I need parts for this repair (list the parts below and attach Purchase Order)
☐	I need parts to replenish my stock (list the parts used below and attach Purchase Order)
☐	Will not replenish stock. Please give me a RMA for the return of the faulty parts.
☐	No parts necessary. Please issue a RMA for repair at FUJIFILM SonoSite.

For FUJIFILM SonoSite Use Only	
Service Request	
Order Number	
RMA Number	
Work Order	

Service Provider

Name:		Provider Reference:	
Company:		Date Reported:	
Address:			
Phone Number:		Fax Number:	
E-mail address:			

Device Description

Ref Number:		Serial Number:	
Name:		Lot Number:	
ARM/SHDB Version:		Configuration:	

Problem Found

Service Performed

Performed By:		Date:	

Parts Removed

Part Name	Part Number	Serial Number	Lot Number	Rev	Replaced By

Parts Installed

Part Name	Part Number	Serial Number	Lot Number	Rev	Replaced By

Tests Performed (attach test data)

Test:	Test:
Performed By:	Performed By:
Result: Pass ☐ Fail ☐	Result: Pass ☐ Fail ☐

Attach additional sheets as required

Page ____ of ____

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Service Event Report Instructions

Instructions for completing the Service Event Report

Sections highlighted in yellow must be completed for SonoSite to accept the Service Event Report. If additional information is required for certain circumstances you will be advised.

Forward the completed form to:
Email: service@sonosite.com
Fax: +1-425-951-6700

Service Type

- **Out of Box Failure**: the item has arrived from SonoSite with failures.
- **Warranty Service**: the item has failed after arrival and is covered by either the included warranty or a valid extended warranty.
- **Out of Warranty Service**: the item has failed and it is no longer covered by a warranty.

Parts Status

- Check One.

Service Provider

- **Name**: the name of the technician performing the work.
- **Provider Reference**: a unique number used by the Provider to track Service Event Reports. Any format is acceptable.
- **Company**: the name of the Distributor or authorized repair facility.
- **Address**: the address replacement parts will be shipped to.
- **Date Reported**: the date the failure was reported to SonoSite.
- **Phone Number**: the phone number to contact the service technician.
- **Fax Number**: the fax number to contact the service technician.
- **Email Address**: the email address to contact the service technician.

Device Description:

- **Name**: the description of the failed product.
- **Ref Number**: the reference number from the part number label of the failed product.
- **Serial Number**: the serial number from the part number label of the failed product.
- **Lot Number**: if applicable, the Lot Number from the device identification label.
- **ARM/SHDB Version**: the software level of the failed device. Typically found on the system information screen.
- **Configuration**: for configurable devices, the optional features enabled.

Event Description

- A description of the problem in the words of the user. Typically what the user reports to the repair facility.

Diagnosis

- A description of what the repair technician found. Include a list of the suspect parts.

Service Performed

- A description of the work performed to repair the system. Typically only completed if it is repaired from stock repair parts.

Parts Removed

- **Part Name**: the name of the failed/suspect part to be replaced.
- **Part Number**: the part number of the failed/suspect part.
- **Serial Number**: the serial number from the failed/suspect part.
- **Lot Number**: the lot number if applicable.
- **Rev**: the revision of the failed/suspect part if available.
- **Replaced By**: the person replacing the part.

Parts Installed

- The same information as the Parts Removed except from the parts installed if work has already been performed. If you are waiting for parts to be ordered, leave this section blank.

Tests Performed

- The results of any testing performed, if testing has already been performed.

Returning Products to FUJIFILM SonoSite

You will be asked to provide the following information:

- Contact name and phone number
- Product name
- Serial number
- Description of the problem

Shipping Instructions

Please contact FUJIFILM SonoSite to get a return material authorization number (RMA). Contact FUJIFILM SonoSite before returning any product.

The shipping address for all returned products is:

FUJIFILM SonoSite, Inc.
Attn: Technical Support RMA _____
21919 30th Drive SE
Bothell, Washington 98021
USA

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