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SONOSITE

Sonosite PX
Ultrasound System

Service Manual

Legal Notices

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

Patents: US 9,895,133; US 9,848,851; US 9,671,491; US 9,420,998; US 9,151,832; US 8,876,719; US 8,861,822; US 8,568,319; US 8,500,647; US 8,398,408; US 8,213,467; US 8,088,071; US 8,066,642; US D625,015; US D625,014; US 7,740,586; US 7,591,786; US 6,962,566; US 6,569,101; US 6,471,651; US 6,364,839; CA 2,372,152; CA 2,371,711; CN ZL201180028132.X; CN ZL2010800609363; EP 2498683 validated in DE and FR; EP 1589878 validated in DE, FR, and GB; EP 1180971 validated in DE and GB; EP 1180970 validated in DE, FR, and GB; JP 6258367; JP 6227724; JP 5973349; JP 5972258.

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Chapter 1: **Introduction**

Before servicing the Sonosite PX 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.

Audience

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

Contact Information

Questions and comments are encouraged. Fujifilm Sonosite is interested in your feedback regarding the system and user documentation. Please call Fujifilm Sonosite at 888-482-9449 in the U.S. Outside the U.S., call the nearest Fujifilm Sonosite representative.

For technical support, please contact Fujifilm Sonosite as follows:

Fujifilm Sonosite Technical Support

Phone (U.S. or Canada):	877-657-8118
Phone (Outside U.S. and Canada):	425-951-1330 Or call your local representative.
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Terms and symbols

The service manual follows these conventions:

- A **WARNING** describes precautions necessary to prevent injury or loss of life.
- A **Caution** describes precautions necessary to protect the products.
- Numbered steps in procedures must be performed in order.
- Items in bulleted lists do not require performance in 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
	Refer to instruction manual for use
	Consult instructions for use
	Medical Device
	Device complies with relevant Australian and New Zealand regulations for electronic devices
	Batch code, date code, or lot code type of control number
	Biological risk
	Device complies with relevant Brazilian regulations for electro-medical devices
	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

Table 1: Labeling Symbols (Continued)

Symbol	Definition
	Canadian Standards Association component certification mark
REF	Catalog number
	BS EN 50419:2016 Marking of Electrical and Electronic Equipment in accordance with Directive 2012/19/EU for electrical and electronic equipment (WEEE) and 2006/66/EC for Batteries (WEEE)
	Corrugated recycle
	Dangerous voltage
	Date of manufacture
	Manufacturer
	Direct Current (DC)
	Do not get wet.
	Do not stack over n high, where n represents the number on the label
	Electrostatic sensitive devices
	Device complies with relevant FCC regulations for electronic devices
	Fragile
GEL	Gel
STERILE R	Sterilized using irradiation
STERILE EO	Sterilized using ethylene oxide

Table 1: Labeling Symbols (Continued)

Symbol	Definition
	Caution Hot
	Device emits a static (DC) magnetic field
	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 in water
IP22	Protection against solid foreign objects
	Handle transducer with care
	Follow manufacturer’s instructions for disinfecting time
	Disinfect transducer
	Type BF patient applied part (B = body, F = floating applied part)
	Defibrillator proof type CF patient applied part
	Potential equalization terminal
	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.)

Table 1: Labeling Symbols (Continued)

Symbol	Definition
	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
	European community authorized representative
	Maximum weight load. Indicates total weight of the equipment, including the safe working load
WARNING: Connect Only Accessories and Peripherals Recommended by Sonosite	WARNING: Connect Only Accessories and Peripherals Recommended by Fujifilm Sonosite

Chapter 2: Specifications

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

Specifications

Dimensions

System:

- **Length:** 15.45 in. (39.25 cm)
- **Width:** 13.32 in. (33.84 cm)
- **Height:** 14.60 in. (37.09 cm)
- **Weight:** 17.92 lbs (8.13 kg) with the L15-4 transducer and batteries installed.

Stand

- **Depth:** 22 in. (55.9 cm)
- **Width:** 20.25 in. (51.4 cm)
- **Height:** 45 in. (114.3 cm) maximum, 33 in. (83.8 cm) minimum
- **Height range:** 9.84 in. (25 cm)
- **Weight:** 40.0 lbs. (18.1 kg)
- **Storage bin capacity:** 11 lbs. (5 kg)
- **Total stand weight with system and peripherals:** 101 lbs. (46 kg) maximum

Touch Panel

- Projected Capacitive (PCAP) Display Type
- **Diagonal:** 11.6 in. (29.46 cm)
- Multi-touch Gestures for System Controls

Display

- **Diagonal:** 15.6 in. (39.62 cm)
- **Length:** 13.55 in. (34.42 cm)
- **Height:** 7.62 in. (19.36 cm)
- **Resolution:** 1920 x 1080

Electrical specifications

- **Stand Input:** 100-240VAC, 50 - 60 Hz 6.0 - 2.5 A
- **Stand Output:** 100 - 240 VAC, 50 - 60 Hz, 2.5 - 1.0 A (for printer only)
- **Power Supply Input:** 100-240VAC 3.4A - 1.3A, 50-60Hz

- **Power Supply Output:** 26.7 VDC, 8.24A, 220W max; Class I, continuous use
- **Batteries:** 2 Lithium-ion batteries (21.6VDC, 64.8Wh each)
- **Battery Use Time:** Up to 1.0 hour
- **Battery Charge Time:** 2.5 hours
- **Battery Life**: 3-5 years

Environmental limits

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

Operating

System and Transducer

0–40°C (32–104°F), 15–95% R.H.

700 to 1060hPa (0.7 to 1.05 ATM)

Stand

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

-35-65°C (-31-149°F), 15-95% R.H.

500 to 1060hPa (0.5 to 1.05 ATM)

Battery

Operating

0-40°C (32–104°F), 15–95% R.H.

700 to 1060hPa (0.7 to 1.05 ATM)

Shipping and Storage

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

15-95% R.H.

500hPa to 1060hPa (0.5 to 1.05 ATM)

Battery specifications

The Sonosite PX system uses two lithium-ion batteries that are charged and controlled by the system.

Run time is up to one hour depending on imaging mode and display brightness. This chapter contains electrical and clinical safety information required by regulatory agencies.

Accessories and peripherals

The Sonosite PX ultrasound system is designed to support a variety of accessories and peripherals including:

WARNING: 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 and system malfunction. Contact Fujifilm Sonosite or your local representative for a list of accessories and peripherals available from or recommended by Fujifilm Sonosite.

Description	Part Number	Maximum Cable Length
C5-1 transducer	P08010	5.5 ft/1.7 m
IC10-3 transducer	P07678	5.7 ft/1.7 m
L12-3 transducer	P21070	5.5 ft/1.7 m
L15-4 transducer	P21636	7.5 ft/2.3 m
L19-5 transducer	P21015	7.5 ft/2.3 m
P5-1 transducer armored	P21556	6.0 ft/1.8 m
Batteries (2)	P27852	—
Ethernet cable	NA	49.2 ft./15 m
Black & white printer	P20006	—
Stand	P25002	—
Stand Head	P25001	—
Stand AC power cord	P00848	10 ft./3.1 m
USB (64 GB)	P25039	—
Power Supply (Desktop)	P25969	—
Stand Power Supply	P23596	—
Wipe holder	P26838	—
Gel holder	P26839	—
Lockable drawer	P26835	—
Storage container	P27399	—
Needle guide kit and bracket		—
Bar code scanner	P14166	4.8 ft/1.5 m

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 (transducers) 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.

For maximum safety observe the following warnings and cautions..

WARNING:	To avoid discomfort or minor risk of patient injury, keep hot surfaces away from the patient.
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, including battery replacement, must be made by a qualified technician.

WARNING:	To avoid the risk of electrical shock:
	• 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.
	• This equipment must be connected only to supply mains with protective earth.
	• Do not let any part of the system (including the bar code scanner, power supply, or power supply connector), except for the transducer, touch the patient.
	• Do not touch any of the following:
	  • The signal input/output connectors on the system and the stand.
	  • The system battery contacts (inside the battery compartment)
	  • ***The system transducer connector on the bottom of the system when the system is used off the stand and the transducer is disconnected***
	  • ***Any unused transducer connector when the system is installed on the stand.***

	• Do not connect the system's power supply to an 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. • Turn the system off and 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 the “Cleaning and Disinfecting” chapter in the Sonosite PX user guide. • 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 orstand to mains power must only be used with the power supply, and cannot be used to connect other devices to mains power.
WARNING:	To avoid the risk of electrical shock, burn, or fire, use only AC power supplies specified by Fujifilm Sonosite.
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:	Because the only method of completely removing AC power from the stand is to disconnect the AC input power cord from the stand base, ensure that you place the stand in a location in which you can easily remove the AC input power cord if necessary.
WARNING:	Failures in the electrical safety design of connected devices may result in a voltage on the ultrasound system. To minimize the risk of electrical shock to the patient and/or operator: • Use medical-grade devices. • After connections are made, test the electrical safety utilizing biomedical department electrical safety procedures.
WARNING:	Under certain conditions, the area where the system docks to the stand may become hot to the touch. Use caution when handling.

Caution:	Do not use the system if an error message appears on the display monitor: note the error code; call Fujifilm Sonosite or your local representative; turn off the system by pressing and holding the power key until the system powers down.
Caution:	To avoid increasing the system and transducer connector temperature, do not block the airflow to the ventilation openings on the front and back of the system.
Caution:	If the system overheats, it will shut down automatically.
Caution:	If the system’s handle becomes too hot to touch, allow the system to cool for a few minutes before relocation or use gloves for protection.

Note: A potential equalization terminal compliant with IEC 60601-1-1, subclause 8.6.7 is provided at the base of the system to be used in situations where potential equalization bonding is required at the site of installation.

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	The ultrasound system is classified as internally powered equipment when powered from internal battery packs (not connected to AC power).
Type BF applied parts	Ultrasound transducers
Ingress Protection IPX0	Ultrasound system (on the stand)
Ingress protection IP22	Ultrasound system (off the stand)
IPX-7 (watertight equipment)	Ultrasound transducers
Non AP/APG	Ultrasound system including power supply, stand elements, and connected peripherals is not suitable for use in the presence of flammable anaesthetic mixture with air or oxygen or nitrous oxide.
Mode of operation	Continuous

Equipment safety

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

WARNING:	When transporting your system, to avoid possible injury from the system tipping, always lower the clinical monitor and push forward on the bar on the platform instead of pushing downward on the bar or pushing the clinical monitor.
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 the “Cleaning and Disinfecting” chapter in the Sonosite PX user guide.
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.
Caution:	Position the system to allow access to the mains power-cord connector.

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 is fixed and cannot be switched or reversed. Ensure that the batteries are in the correct orientation.
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. Replace the battery.
WARNING:	Do not ship a damaged battery without instructions from Fujifilm Sonosite Technical Support. (See “Introduction” on page 1.)
WARNING:	If the battery leaks or emits an odor, remove it from all possible flammable sources.

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.
- Periodically check to make sure that the battery charges fully. If the battery fails to charge fully, replace it.
- Use only Fujifilm Sonosite batteries.
- Do not use or charge the battery with non-Sonosite equipment. Only charge the battery with the system.

Clinical safety

WARNING: To avoid injury, inspect all fasteners and connections.

WARNING: Fujifilm Sonosite does not recommend the use of high-frequency electromedical devices in proximity to its systems. Fujifilm Sonosite equipment has not been validated for use with high-frequency electrosurgical devices or procedures. Use of high-frequency electrosurgical devices in proximity to its systems may lead to abnormal system behavior or shutdown of the system. 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: The maximum temperature of the transducer scan head may be greater than 41 °C (105.8 °F), but is less than 43 °C (109.4 °F) when in contact with the patient. Special precautions should be considered when using the transducer on children or on other patients who are sensitive to higher temperatures.

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. Fujifilm Sonosite recommends identifying your latex- and talc-sensitive patients and being prepared to treat allergic reactions promptly.

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: Use market-cleared, sterile transducer sheaths and sterile coupling gel for transrectal, transvaginal, or guided-needle procedures. Do not apply the transducer sheath and coupling gel until you are ready to perform the procedure. After use, remove and discard the single-use sheath, and clean and disinfect the transducer using a Fujifilm Sonosite recommended disinfectant.

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

- Follow Universal Precautions when inserting and maintaining a medical device for interventional procedures.
- Appropriate training in interventional 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, and guidewire misplacement.

WARNING: To avoid applying unsafe voltage levels to the patient while a device is connected to the digital video out port, do not touch the ultrasound system and the patient simultaneously. Check the electrical safety of your system with a trained biomedical engineer.

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 60601-1-2:2014 (Edition 4). The ultrasound system is suitable for use in the professional healthcare facility environment except for near active high frequency surgical equipment or in a RF shielded room where magnetic resonance imaging is performed because both produce high electromagnetic disturbances which could result in performance disruption of the ultrasound system. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

WARNING: 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 could result in malfunctioning of your 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 Sonosite. See the Fujifilm Sonosite accessories user guide.

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.
- Connect the ultrasound equipment and the interfering equipment (or equipment being interfered with) to different power outlet circuits.
- 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.
- Do not stack other equipment on the ultrasound system or use other equipment in close proximity and adjacent to the ultrasound system. If stacking or using other equipment in close proximity is unavoidable, then you must observe the system to verify normal operation.

Caution: The EMC performance of the ultrasound system may be degraded if the product is used in harsh environments where the system is exposed to high humidity, elevated temperatures, high vibration, or high shock for extended durations. If the system shows symptoms of degraded EMC performance, see the precautions (above). If, after taking the listed precautions, the degraded EMC performance persists, the system may need to be serviced to maintain optimum EMC performance.

Wireless transmission

The Sonosite PX ultrasound system contains an internal IEEE 802.11 transmitter that uses the Industrial, Scientific, and Medical (ISM) frequency bands from 2.412 to 2.484 GHz and/or 5.15 to 5.825 GHz. The transmitter supports the 802.11 a/b/g/n/ac wireless communication protocol (five different methods of

transmission)*:*

- IEEE 802.11a (5.150 to 5.850GHz) with Orthogonal Frequency Division Multiplexing (OFDM) at 13 dBm +/- 2 dBm @ 54 Mbps
- IEEE 802.11ac (5.150 to 5.850GHz) with Orthogonal Frequency Division Multiplexing (OFDM) at 17 dBm +/- 2 dBm @ MCS 0
- IEEE 802.11b with Direct Sequence Spread Spectrum (DSSS) at 15 dBm +/- 2 dBm @ 11 Mbps
- IEEE 802.11g with Orthogonal Frequency Division Multiplexing (OFDM) at 14 dBm +/- 2 dBm @54 Mbps
- IEEE 802.11n with Orthogonal Frequency Division Multiplexing (OFDM) at 18 dBm +/- 2 dBm @MCS 0

Note: This device is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC, the FCC, and Industry Canada.

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 PX ultrasound system

WARNING:Portable RF communications equipment (including peripherals, such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Sonosite PX ultrasound system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The Sonosite PX 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 PX ultrasound system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sonosite PX 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.

Manufacturer's declaration

The tables in this section document the intended use environment and EMC compliance levels of the

system. For maximum performance, ensure that the system is used in the environments described in these tables.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions per IEC 60601-1-2:2014

The Sonosite PX ultrasound system is intended for use in the electromagnetic environment specified below.

Emissions Test	Compliance	Electromagnetic Environment
RF emissions ClSPR 11	Group 1	The Sonosite PX 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 ClSPR 11	Class B	The Sonosite PX 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 per IEC 60601-1-1-2:2014

The Sonosite PX ultrasound system is intended for use in the electromagnetic environment specified below.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	±8.0KV contact ±2.0KV, ±4.0KV, ±8.0KV, ±15.0KV air	±8.0KV contact ±2.0KV, ±4.0KV, ±8.0KV, ±15.0KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
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.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity per IEC 60601-1-1-2:2014

The Sonosite PX ultrasound system is intended for use in the electromagnetic environment specified below.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T) for 0.5 cycle 0% U_T) for 1cycle *70*% U_T (30% dip in U_T) for 500msec <5% U_T (>95% dip in U_T) for 5s	0% U_T) for 0.5 cycle 0% U_T) for 1cycle *70*% U_T (30% dip in U_T) for 500msec <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 Fujifilm Sonosite ultrasound system requires continued operation during power mains interruptions, it is recommended that the Sonosite PX 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	If image distortion occurs, it may be necessary to position the Fujfilm Sonosite ultrasound system further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the Intended installation location to assure that it is sufficiently low.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6Vrms in ISM bands	3 Vrms 6 Vrms in ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the Sonosite PX 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 per IEC 60601-1-1-2:2014

The Sonosite PX ultrasound system is intended for use in the electromagnetic environment specified below.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 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:  (IEC 60417 No. 417-IEC-5140: "Source of non-ionizing radiation")
Proximity fields from wireless communicatio ns equipment IEC 61000-4-3	Per 60601-1-2:2014 Table 9	Per 60601-1-2:2014 Table 9	

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.

Essential performance requirements

Per 60601-2-37, the following have been determined to be essential performance for the Sonosite PX ultrasound system. The Sonosite PX ultrasound system must be 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 intracorporeal use.

Results of EMC immunity testing show that the Sonosite PX ultrasound system meets the essential performance requirements in 60601-2-37. If the operator detects unacceptable degradation of basic safety or essential performance, they should stop using the equipment and take suitable precautions as detailed on **page 12**.

FCC Caution: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a professional healthcare facility environment. This equipment generates, uses and can radiate harmful radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other medical or electronic equipment, take suitable precautions as detailed on page 12.

Standards

Electrical safety standards

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

CAN/CSA C22.2 No. 60601-1:2014 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (Edition 3.1)

IEC 60601-2-37:2008 (+A1:2019) Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasound medical diagnostic and monitoring equipment (Adopted IEC 60601-2-37:2007, Edition 2.1)

CSA C22.2 60601-1-6:2011 (+A1:2013) Medical Electrical Equipment Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability (Adopted IEC 60601-1-6:2013, Edition 3.1)

IEC 60601-1:2012 Medical electrical equipment, Part 1: General requirements for basic safety and essential performance (Edition 3.1)

IEC 60601-2-37:2015 Medical Electrical Equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (Edition 2.1)

IEC 60601-1-6:2013 Medical Electrical Equipment Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability (Edition 3.1)

EMC standards classification

IEC 60601-1-2:2014, 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, docking system, accessories, and peripherals when configured together: Group 1, Class A.

DICOM standard

Digital Imaging and Communications in Medicine (DICOM), Version 3.1, 2007 (NEMA).
The system conforms to the DICOM standard as specified in the Sonosite PX DICOM Conformance Statement, available at **www.sonosite.com**. This statement provides information about the purpose, characteristics, configuration, and specifications of the network connections supported by the system.

Security and privacy standards

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.

HIPAA:1996, 45 CFR Parts 160 and 164; Subparts A, C, and E, Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules

NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations

Security and privacy

- The port for DICOM communication (specified by the user in the system settings; typically port 104, 2762,or 11112) is used for outgoing communication to the network.
- Anti-virus software is not installed on this device.
- This device has a single configurable listening port for the purposes of DICOM Echo and Storage Commitment.
- The security and privacy-related configurable controls in Sonosite PX are:
  - User roles and responsibilities
  - Automatic user log off
  - User authorization and authentication
  - Data backup and recovery
  - Data encryption (at rest and in transit)
- System and department administrators should follow the suggested technical and physical safeguards listed below, as well as the detailed HIPAA guidelines to ensure HIPAA compliance:
  - **Room Access Control:** Local procedures must be put in place to limit physical access to medical equipment, to prevent accidental, casual, or deliberate contact by unauthorized individuals.
  - **System Access Controls:** Access the system only through unique user accounts. Login credentials must not be disclosed.

- **Audit Controls:** Each user action associated with patient data will be tracked through ePHI audit logs, which are accessible to and should be routinely audited by the administrator.
- **De-identification:** Use a de-identification option before exporting patient data to removable media used for system troubleshooting or repair.
- **Removable media handling:** Removable media that contains images or other medical information must be stored in a secure area that is not accessible by unauthorized individuals.
- **Transmission Security:** Clinical data transmitted over the network may not be encrypted. Add only trusted devices to the network. (We highly recommend the use of encrypted DICOM. If secure DICOM is not supported, then network security controls shall be implemented to protect integrity and confidentiality of data).
- **Data Integrity:** Cryptographic methods should be used at all times to ensure the integrity of personal data. When possible, perform integrity checks to identify unauthorized changes in personal data. In case there is suspicion of improperly altered or destroyed clinical data, notify Fujfilm Sonosite service.
- **Data Encryption:** Data at rest should be encrypted at the disk level as well as the database level with a valid FIPS 140-2 compliant encryption method. Encryption keys should be kept secured and maintained only by system administrators.
- **System Hardening:** The application and database hosting server(s) should be hardened according to the NIST 800-123 server security controls. Software Updates: Only Fujfilm Sonosite authorized updates and/or patches should be applied to the medical device.

Managing users on the system

Only administrators can manage user accounts, including importing user accounts from another system, creating or editing a user account, or deleting user accounts from the system.

To manage users by synchronizing with a directory server and using server-based user accounts, see "Configuring a connection to a directory server" below.

Required fields are indicated by an asterisk (*).To add a new user on the system

1 Using your administrative login information, log into the administrative settings page.
2 Tap User Management.
3 On the user management page, tap Add User. Fill in the user information fields.
4 If you want to require that the user change their password, select Require password change on next login, and then enter a temporary password for the new user to gain initial access.

Note: To ensure security, choose a password that contains uppercase characters (A-Z), lowercase characters (a-z), special characters, and numbers (0-9).

Note: Passwords are case-sensitive.

5 If you want the user account to expire on a given date (such as accounts for students, interns, or other temporary personnel), select Enable account expiration, and then enter the number of days (such as 90) until the account will expire into the Set account expiration in days field.
6 When you have finished configuring the new user account, tap Save to Database.

Configuring a connection to a directory server

In order to use server-based user accounts, you should configure the system in secure mode.

To configure the connection to a directory server

1 Using your administrative login information, log into the administrative settings page.
2 Tap **LDAP/AD**.
3 Select **Use LDAP/AD authentication**.

Note: Enabling a connection to a corporate directory server disables local account creation. You can continue to use pre-existing local user accounts, but you cannot add new local accounts while this setting is enabled.

4 In the **Remote server** field, type the IP address of the remote server.
5 In the **Port** field, type the port number of the directory.
6 (Optional) If you want to encrypt the communication between the ultrasound system and the directory server, tap the checkbox next to **Secured**.
7 In the **Search root** field, type the path to the root directory.
8 In the **User DN** field, type the user domain name.
9 In the **Manager name** field, type the username of an account that has LDAP access.
10 In the **Manager password** field, type the password for the account that has LDAP access.
11 When you've finished configuring your connection, tap **Test Connection**.

Note: If the connection fails, make sure that you have entered the correct information and that there are no issues with the network or server.

12 Tap **Save**.

Chapter 4: System Overview

About the System

The Sonosite PX high-resolution ultrasound system is a portable, full featured, general purpose, 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, M Mode, Pulsed Wave (PW) Doppler, Continuous Wave (CW) Doppler, 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. The system has a PW and CW Doppler audio output feature, cine review, image zoom, labeling, biopsy, measurements and calculations, image storage and review, printing, and recording capabilities.

The system includes optional Digital Imaging and Communications (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 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.

Theory of Operation

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

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

The following block diagram shows the relationship of the functional groups.

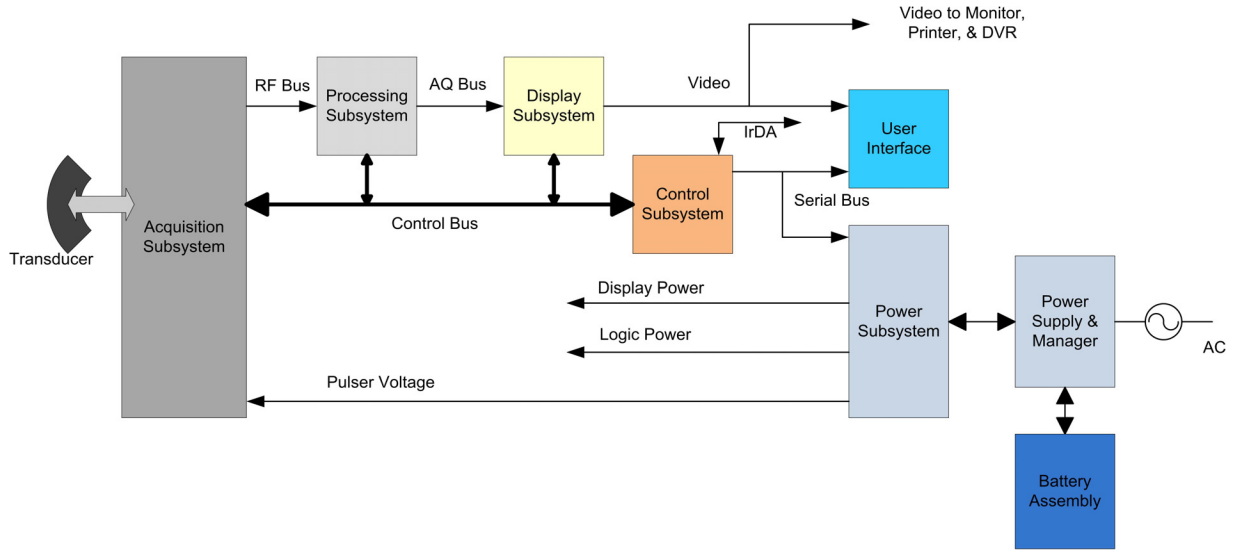


Figure 4.1 Ultrasound System Functional Group

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, 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 batteries (quantity of two lithium-ion) 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.

M Mode

M Mode is also known as “T-M mode” or “time-motion” mode. It is used primarily for cardiac measurements such as valve timing and septal wall thickness when accurate timing information is required.

Ultrasound echoes of different intensities are mapped to different gray scale values in a scrolling display. M Mode displays time motion information of the ultrasound data derived from a stationary beam. Depth is arranged along the vertical axis with time along the horizontal axis. M Mode can be used alone but is normally used in conjunction with a 2D image for spatial reference. The 2D image has a graphical line (M-line) superimposed on the 2D image indicating where the M Mode beam is located.

Color Doppler (Color)

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

The 2D cross-section 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. 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 Velocity Color Doppler (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 battery.

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. The 2D cross-section may be presented as a rectangle, parallelogram, trapezoid, sector, or a full circle, depending on the particular transducer used.

The 2D cross-section is presented as a full color display, with various colors being used to represent the power in blood flow echoes. 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 battery.

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.

Continuous Wave (CW) Doppler

CW provides a real-time representation of blood flow and is displayed as a velocity-versus-time sweeping output. Velocity (or frequency) is presented as the vertical axis with time along the horizontal axis. The magnitude of the detected signal is represented as different gray scale values.

CW Doppler mode provides the clinician with the ability to obtain blood flow velocities focused about a user specified focal region. A continuous transmit waveform of ultrasound energy with a known frequency is transmitted and focused by the system; on the receive side, the transducer receive echoes are continuously amplified, focused about the focal region and converted to a base band quadrature signal. The signal is analyzed by a quadrature phase detector that establishes two receive channels to allow detection of flow direction. These two channels are then analyzed by a fast complex Fourier transform (FFT) circuit to establish the spectrum of frequencies present in the echoes. The data are displayed as spectrum frequencies with respect to time.

CW can be used alone but is normally used in conjunction with a 2D image for spatial reference. The 2D image has a graphical line (D-line) superimposed on the 2D image indicating where the M-mode beam is located.

Pulsed Wave (PW) Doppler

PW provides a real-time representation of blood flow and is displayed as a velocity-versus-time sweeping output. Velocity (or frequency) is presented as the vertical axis with time along the horizontal axis. The magnitude of the detected signal is represented as different gray scale values. The ultrasound data is derived from a single area, the sample volume, on a stationary beam.

PW Doppler mode provides the clinician with the ability to obtain blood flow velocities about a spatial sample volume. A burst of ultrasound with a known spectrum is transmitted by the system; on the receive side, the transducer receive echoes are amplified and range gated at the appropriate depth. The signal is analyzed by a quadrature phase detector that establishes two receive channels to allow detection of flow direction. These two channels are then analyzed by a fast complex Fourier transform (FFT) circuit to establish the spectrum of frequencies present in the echoes. The data are displayed as spectrum frequencies with respect to time.

PW can be used alone but is normally used in conjunction with a 2D image for spatial reference. The 2D image has a graphical line (D-line) superimposed on the 2D image indicating where the M-mode beam is located. The sample volume position (depth) and size are also indicated on the D-Line.

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.

Tissue Specific Imaging

In this feature, parameters for signal and image processing are optimized to maximize the image quality or to obtain the best compromise of resolution and penetration for different specific clinical applications. These parameters include: the order of received filters, the bandwidth, the dynamic range, the compression curve, the gain setting, and parameters for compounding frequency band, etc. For example, different system parameter setups are used for abdominal or peritoneal scanning. This feature is for ease of use for the operator by automatically setting up system control parameters rather than manually adjusting settings for best performance.

Biopsy Guidance

The system can display a pair of biopsy guidelines that represent the anticipated path of the biopsy needle. The image of an anatomical target, biopsy guidelines, a scan plane marker, and a biopsy needle are displayed to assist in guiding the biopsy needle to the target. The system also provides needle guidance for vascular access procedures. For additional information see the biopsy user guides.

Measurement and Calculation Capabilities

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

Continuous Wave Doppler Audio Output	The system provides for audio output of the CW velocity information. This can be presented as stereo information, with flow moving towards the transducer on one channel and flow away on the other, or as a mono output with the single audio output representing the summation of the flow directions.
Pulsed Wave Doppler Audio Output	The system provides for audio output of the PW velocity information. This can be presented as stereo information, with flow moving towards the transducer on one channel and flow away on the other, or as a mono output with the single audio output representing the summation of the flow directions.

Front End Overview

The Front End is designed to support various imaging modalities such as 2D, M-Mode, Spectral Doppler 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 of 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 shown below in Figure 4.2 on page 33

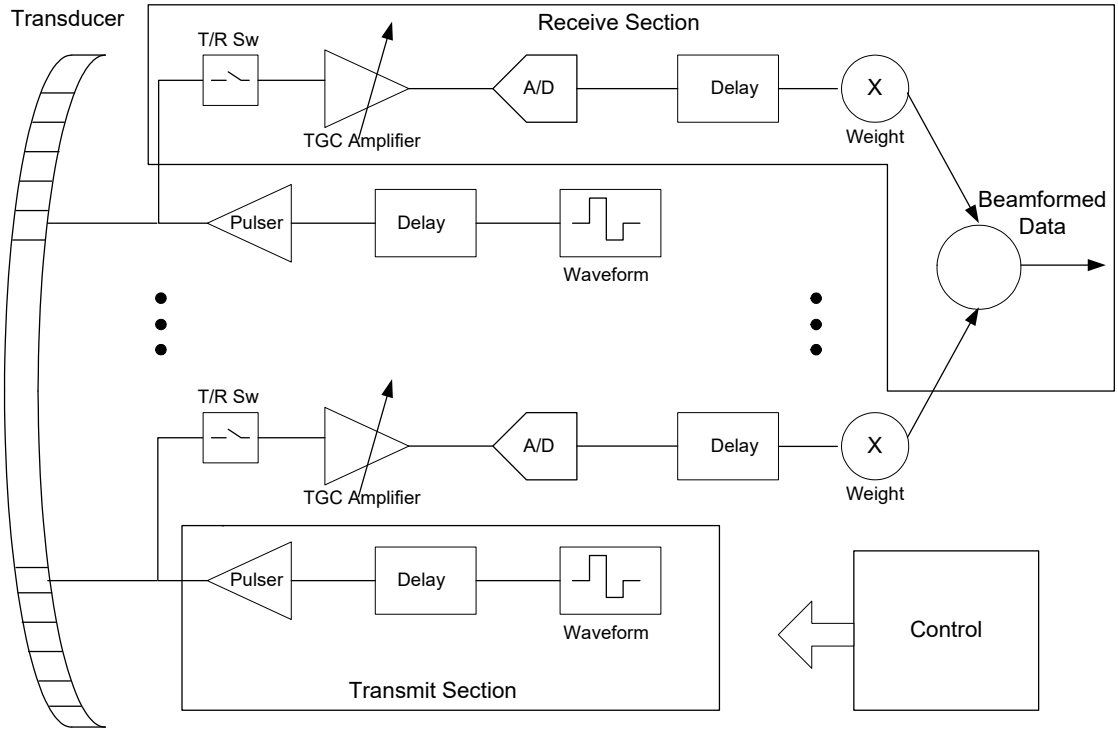


Figure 4.2 Generic Front End Block Diagram

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/Dconverter 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.

Sonosite PX Overview

The Sonosite PX ultrasound system is made up from several assemblies. The block diagram below shows the high-level architecture of the system, with the portable system highlighted in blue. Please refer to Figure 4.3 on page 34. Optional components are shown with dashed lines. The AC/DC Power Supply may be connected in one of two places: directly to the Portable System when not docked in the Stand Head, or through the Stand Head via an AC/DC Power Supply located in the stand base.

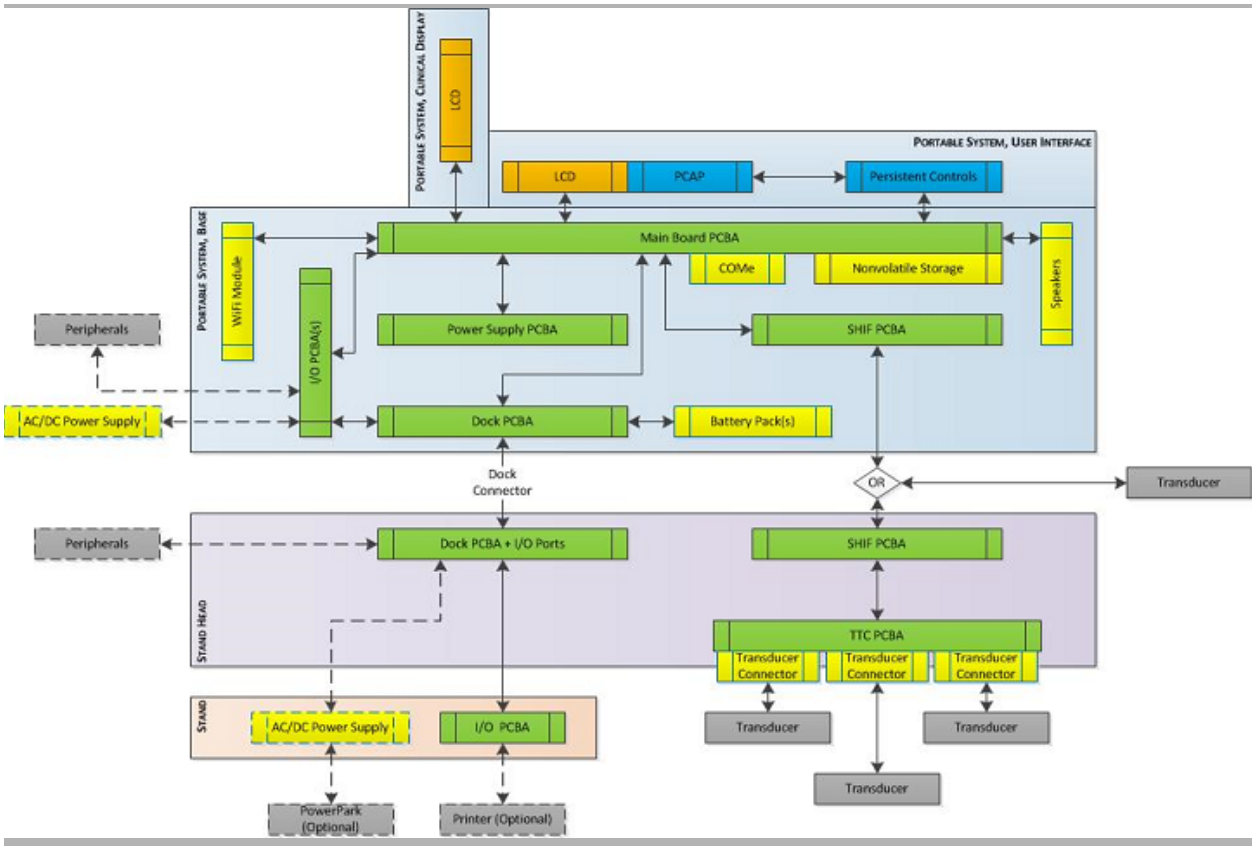


Figure 4.3 Sonosite PX System Block Diagram

In contrast with many prior Sonosite systems, all portable System I/O ports have been located on ancillary boards that are, with the exception of the dock and battery connectors, essentially specific to the respective connector. These boards include the Power In PCBA, USB Aux PCBA, Power Button with ECG PCBA, and SHIF PCBA. While this increases the number of internal interconnects, this architecture was chosen specifically to prevent damage to the much more expensive Main PCBA. A frequent reason for service returns in legacy systems is I/O port damage; in the Sonosite PX, these returns will be repairable by replacing a smaller, less expensive secondary board instead of the Main PCBA.

Additionally, this architecture allowed the selection of bulkhead mounted connectors. The intent is that this will decrease the likelihood of connector/board damage when compared to a PCB mounted connector as the solder joint will not be subjected to loads when the mating connector is plugged in. Locating the bulkhead mounted connectors on multiple PCBAs also eliminates the concern of tolerance stack between connectors.

The Sonosite PX Portable System, is the main functional module of the Sonosite PX System, and contains the necessary hardware to produce an ultrasound image, which is shown on the Clinical Display. The Clinical Display is hinged to allow repositioning for easy viewing. The User Interface is composed of both a software-configurable touch screen and a set of persistent (permanent) physical controls. An integrated connector allows a transducer or Triple Transducer Connector (TTC) to connect to the System. A movable handle allows easy transport; it is also configurable to allow use of the Portable System flat on a tabletop or propped up at an angle. I/Os include USBs and WiFi. The Portable System also contains a docking connector and features that allow integration with the Stand Head.

Main PCBA

The Main PCBA is comprised of an analog section and a digital section. The analog section contains the Front End transmit and receive circuitry and the digital section contains the processor and is responsible for interfacing with the other modules in the system.

Analog Section

The analog domain is the primary data imaging path to the analog section. It contains the high voltage transmitters with integrated T/R switches, Analog Front-End (AFE) chips, TGC DAC, CW components, and analog power conditioning. The Scanhead Interface (SHIF) connector resides on a separate PCB with a high density connector connecting the Main PCBA to the SHIF board.

All 128 element signals from the SHIF connector are connected to sixteen transmitters containing eight three level transmit channels each. The transmitters also contain eight T/R switches which will have their low voltage side connect directly to an AFE input channel for a total of 128 receive channels.

Digital Section

The digital section contains the main CPU (on a computer module) and two programmable devices (an FPGA and a DSP) to create rasterized video from the element level data which is displayed on the clinical display. Along with the signal path digital processing, the digital section provides clock distribution and power conditioning.

The digital section also provides user I/O such as video outputs, audio outputs, USB ports, Ethernet ports, and ECG ports.

The Main PCBA accommodates a COM Express (ComE) module as the main processor. The ComE supports the following interfaces:

USB Allocation: four USB 3.0 ports (supports USB 2.0) and four USB 2.0 ports are provide by the ComE. 2 USB 3.0 ports are provided on the back of the system. The remainder are for the Stand Head USB ports and USB ports for the WiFi module and User Interface.

Ethernet Port: The COMe module will provide a 10/100/1000 GbE connection. The Phoenix Main PCBA passes those transmit/receive signals, as well as LED indicator signals, on to the dock connector. Consequently, wired Ethernet will only be available when the engine is in the stand.

SATA Allocation: The ComE provides two SATA interfaces. One for the boot drive and the other for the patient data drive.

Video Outputs: These outputs support the clinical display, User Interface and auxiliary HDMI Video outputs.

Audio Output: The audio stream is output via an HD Audio interface. The main board has an audio codec that receives the digital audio data and outputs stereo analog audio. This analog audio is then amplified by a linear Audio Amplifier and output on two connectors to drive stereo speakers.
A USB headphone will be used in the Sonosite PX system. When headphones are plugged in the operating system should disable the speaker output and enable the headphone output.

Real Time Clock Battery: The Real Time Clock on the COMe draws approximately 6 uA from a 3V nominal battery. Sonosite PX uses a rechargeable Lithium battery to avoid ever having to replace the battery. The disadvantage, however, is that the length of time the system can maintain the correct time is shorter than it would be with a primary cell (non-rechargeable). In order to limit the size of the battery, a 7 mA-hour battery was chosen which gives approximately 48 days of maintaining the correct time if the system is not powered up. Beyond that time, the user may have to re-enter the correct time and date.

Power State Indicator LED and Battery Status Indicator LED: The system has two user accessible indicator LEDs; power state LED and battery status LED. Power status LED is a dual color LED onthe ECG board which indicates the system's current power status: orange for idle state, green when the system is active. The battery status indicator LED shows the battery charge status and this signal drives two LEDs; one in ECG board and one in back of clinical display. The Main Board receives control signals from the power supply board and generates the necessary LED drive signals.

Power Supply PCBA

The Power Supply PCBA receives commands from the Main PCBA. Based upon the commands, the Power Supply processor will control, adjust and monitor the power supply rails required for the system. low -voltage power supplies are fed to the Main PCBAs analog and digital sections. The high-voltage power supplies are for the Main PCBA analog section to drive the transmit/receive circuits as well as a connected transducer or TTC through the SHIF connector.

Dock Interface PCBA

The Dock Interface PCBA has connections to the Main Board, Power In Board (Desktop AC/DC Power Supply input), two system battery packs, and the system stand.It contains circuitry for power-path and battery charger control. These functions are controlled by the processor on the Power Supply PCBA. For power-path control, the Power Supply PCBA processor can receive information on which input rail is valid (external wall power, internal battery pack, or external battery pack). In addition, it can control the system power, either turning it completely on or completely off with input from the power button. This circuitry will also control power off and power on of the system during software upgrades. The Power Supply PCBA processor also enables and disables the battery charger, which selects which battery is being charged.

I/O PCBA Assemblies

As mentioned previously, I/O functions are handled by PCBA's specific to their functions.

Power In PCBA: This PCBA is comprisedof an input connector which serves as 27V power supply input, and an output connector with EMI filtering circuitry which provides a filtered output of 27V to the Main PCBA. A green LED on the board indicates the presence of input power. The input connector utilizes a plastic cap that prevents arcing during a connection event with the external power supply.

Power Button with ECG PCBA: This PCBA contains the system on/off button as well as an ECG connector reserved for future use. It connects to the Main PCBA via a flex connector.

USB Aux PCBA: This PCBA functions as the interconnection between the Main PCBA and the USB connectors on the enclosure via a Flexible Printed Circuit (FPC).

Clinical Display

The Clinical Display receives power and video signals from the Main PCBA to display the clinical image. The LCD is a full HD 15.6” display with a 16:9 aspect ratio (1920x1080, 60Hz, LED backlight). The LCD has optically bonded cover glass, enclosure, display cable, and magnets to hold the display in the closed position. Due to the design, there are no field serviceable items and the assembly must be replaced as a whole unit.

User Interface

User Interface, Touch: The touch portion of the UI presents customizable controls to the user. It includes an LCD with optically bonded cover glass, a PCAP layer, and a PCAP controller board.

LCD: The LCD will be a full HD 11.6” display with a 16:9 aspect ratio (1920 x 1080, 60 Hz, LED backlight). This display also has eDP and backlight interfaces which will be generated on the Main PCBA;

PCAP: A PCAP layer is incorporated between the LCD and cover glass to allow user input.

Persistent Controls: The customizable touch UI is augmented with a series of persistent controls for high-use functions (e.g. power, freeze, gain), with the goal of providing users with controls they can find and activate without visualizing the control surface. These controls consist of discrete buttons, a touchpad, and a touch-activated rotational control.

Power Supply and Control

The Sonosite PX ultrasound system utilizes one of two types of power supply arrangements depending on the mode used, which can be Desktop or Stand. The Desktop system uses a separate external power supply (EPS) unit. In the event of a power issue in the stand, this would be a good troubleshooting tool. The stand base contains the EPS used by the system while mounted in the stand. Both power supplies are 220W and provide +27VDC to operate the system and charge the batteries.

DICOM

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

Please refer to the Sonosite PX User Guide (P21894) for DICOM setup

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, the patient data needs to be wiped from the system whenever possible (certain conditions may prevent this, such as a system that fails to power on). If unable to power on, the Patient Data Drive can be removed as shown in *Figure 6.2 on page 48**.*

There are two methods available to wipe patient data. Full Factory Reset or ePHI Reset. The ePHI Reset deletes all patient data and re-encrypts the drive. The Full Factory Reset performs a full reset of all user, patient, preference data, re-encrypts the drives and starts the Out of Box Experience wizard. **Both options are available to Administrators and users.** A third method is to install a properly configured USB drive into the system.

Warning: This will erase all patient data saved on the system and re-encrypt the patient drive. Patient images should be exported or archived before proceeding.

Administrator

1 Using your administrative login information, log into the administrative settings page.
2 Tap **Admin Settings**.
3 Tap **Delete all patient data** for the ePHI reset or the **Factory Reset** button for Full Factory Reset**.**
4 Make sure the system is connected to AC power, and tap **Yes** to continue. The process will take approximately 35 minutes.

Note: If you are not connected to AC power and the batteries die, you will need to restart the process.

5 When the wipe is complete, tap **OK** to restart the system.

User

1 Simultaneously press the **AUTO**, **DEPTH DOWN**, AND **M** buttons for the ePHI Reset or **AUTO, DEPTH DOWN,** AND **2D** buttons for the Full Factory Reset.
2 Make sure the system is connected to AC power, and tap **Yes** to continue. The process will take approximately 35 minutes.

Note: If you are not connected to AC power and the batteries die, you will need to restart the process.

3 When the wipe is complete, tap **OK** to restart the system.

USB

If the user inserts a properly configured flash drive and then powers on the device, the system will start the Full Factory Reset procedure. This mechanism is provided in order to allow the user to attempt recovering the system in the event that the application has failed and is no longer able to start the reset via the combination of keys.

Flash drive procedure

1 create a text file named “factoryreset.info” (do not include quotations) on the root of the drive.
2 Insert the flash drive at boot or after the application is running: in either case, the reset will start.

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
Assert Codes	Figure 5.1; Table 5.2
DICOM	Table 5.3
Clinical Monitor Display	Table 5.4
Battery Charging	Table 5.5
Battery	Table 5.6
User Interface	Table 5.7
No Power	Table 5.8

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 entities voids the Fujifilm Sonosite warranty.

Test Equipment

Test equipment is not required for this troubleshooting section.

Assert(Failure) Codes

The Sonosite PX system is capable of displaying an “assert screen-call for help” instructing the user to contact Sonosite Technical Support for hardware and software issues related to failures. PCB failures typically result in “assert codes” that are output to both the clinical display monitor and the user interface

display. If an assert screen appears, note the assert code information and contact Fujifilm Sonosite Technical Support to clarify the fault or failure. Refer to Figure 5.1 for how this assert screen will be displayed and the information Technical Support will be asking for from this screen.

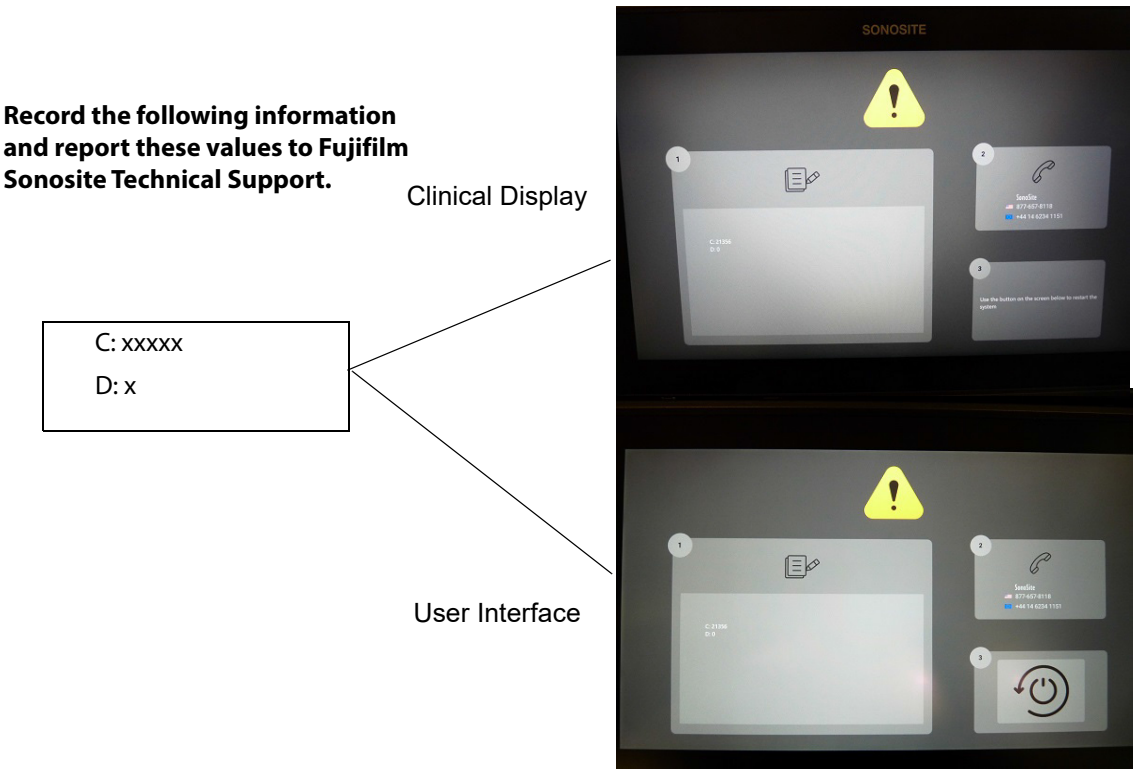


Figure 5.1 Assert Screen-Call For Help

Verifying a System Assert Code

System asserts are caused by hardware and/or software faults. Hardware asserts typically require a PCB or hardware replacement. Software asserts can often 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 on the **User Interface** to power the system down.
3. Press the **Power** button to power on the system.
   - If the system powers on normally, it has likely 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 a PCB or hardware 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. I.e., disconnect AC power and remove the two internal batteries. Refer to Figure 6.1 on page 47

Table 5.2: Assert Codes

Code	Code Description Information	Probable Cause	Solution
21356	Bitlocker encryption issue	Patient Data Drive missing or defective	If location of data drive is known, re-install. If not, system will require servicing to install new data drive
21196		Main PCBA	Replace Main PCBA
278		ComE failure	Replace ComE

Note: Assert Code Table will be updated in future Sonosite PX Service Manual revisions

DICOM

Table 5.3: DICOM Troubleshooting

Error Message	Tiller Error Code	Possible 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 device's IP address, Sonosite PX 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 PX. b) Check Archiver AE Title c) 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 Transfer Syntax setting, e.g., US Image, SC Image or US-Ret Image.

Table 5.3: DICOM Troubleshooting (Continued)

Error Message	Tiller Error Code	Possible Cause	Troubleshooting
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 PX, rejects association	Verify that Sonosite PX AE Title or IP address is correctly configured on the Printer/Archiver. Note: Some devices require that the Imaging modality (Sonosite PX) be recognized in order to accept images. This requires configuration on the device.
Internal failure detected	TDNETWORK_READ_FAILURE	Invalid DICOM Attribute	Check Sonosite PX Printer DICOM settings for correctness (e.g., film size, format)

Clinical Display

Table 5.4: Clinical Display Troubleshooting

Problem	Cause	Troubleshooting
No Display	Faulty display or Main PCBA	Feed video to an external monitor from the HDMI port on the Stand Head • 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 Display Assembly is likely at fault. • Check the Clinical Display cable connection to the Main PCBA.
Display Image Quality Issue	Faulty display or system fault	Feed video to an external monitor from the HDMI port on the Stand Head • 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 Display Assembly is likely at fault.

Battery

Table 5.5: Battery Charging

Normal Operation Conditions	Top Blue LED on back of Display	User Interface Blue LED
Connected to AC, no batteries	ON	same
Connected to AC, system off, batteries charging	see below	see below
Connected to AC, batteries fully charged	ON	same
Connected to AC, batteries up to 25%	one long flash followed by one short flash	same
Connected to AC, batteries up to 50%	one long flash followed by 2 short flashes	same
Connected to AC, batteries up to 75%	one long flash followed by 3 short flashes	same
No AC, operation on battery power	OFF	same

Table 5.6: Battery Troubleshooting

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

User Interface

Table 5.7: User Interface Troubleshooting

Symptom	Possible Causes
User Interface is black or not functional	Check the connections between the User Interface and Main PCBA. If the connections are good, the issue could be the User Interface or the ComE.
Persistent Controls not functional	Check the connections to the Main PCBA. Check connections between the Touch Controller Board and the Persistent Controls. If one or more buttons fail to operate, or if the touchpad does not function, replace the Persistent Controls.

No Power

Table 5.8: No Power Troubleshooting

Problem	Troubleshooting
No Power	• Check for the green AC led on the base of the Stand. If it is on, AC is present and the External Power Supply is providing power. • Check for the green led on the Stand Head where the DC power enters. If it is lit, power is present. • If issue still exists and a Desktop Power Supply is present, remove the system from the Stand Head and connect the Desk Top Power supply to the Power in connector on the left side of the system. If the issue persists, the cause is likely in the system. If the system powers on, the issue is likely in the Stand Head.

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. Two ranges of torque screwdrivers will be required as torque requirements range from 2-inch pounds to 24-inch pounds. Generally the torque screwdrivers ranges are 1.0-10.0 inch pounds (0.23-1.1 Newton meter) and 10.0-25.0 inch pounds (1.1-2.8 Newton meter)

Note: When repairs are performed, the system should be fully tested in accordance with Chapter 8.

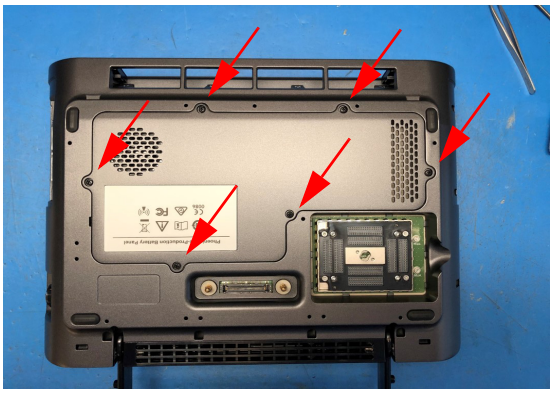
Required Tools

- Torx bits: T6, T8, T10,T20 and T30
- Torque screwdriver, 1.0-10.0 inch pounds (0.23-1.1 Newton meter)
- Torque screwdriver, 10.0-25.0 inch pounds (1.1-2.8 Newton meter)
- Small flat head screwdriver
- #2 Phillips screwdriver
- Anti-Static mat
- Wrist grounding strap

Remove Batteries

Remove the batteries and disconnect DC power before servicing the Sonosite PX. Any action taken in this chapter assumes this as the first step.

1 Place the system on its top so the serial number label is facing up.
2 Remove the six Phillips screws from the battery cover per Figure 6.1 on page 47.
3 Remove the battery cover.
4 Disconnect battery connectors.
5 Remove batteries.



Remove 6 Phillips screws and remove Battery Cover

Disconnect Batteries and remove from enclosure

Figure 6.1 Battery Removal

Patient Data Drive Removal

The Patient Data Drive is responsible for storing all patient images and data. If this drive is missing, the system will fail to operate. If the system is ever in a non-operational condition with patient data left on the drive, many customers are required by local law, regulation or company policy to prevent patient data from being removed from the facility. This will require the removal of the Patient Data Drive. If the system is operational, it may be possible to wipe the data on the drive.

If the Main PCBA is replaced or a repair performed, the new board/repaired system will include a new Patient Data Drive. Patient Data Drives are encrypted and cannot be swapped between systems. Therefore, if a Patient Data Drive is retained, it will no longer be usable after a system repair is performed.

Patient Data Drive Removal

1 Remove the Left Enclosure Pocket cover from the left front side of the system as shown in Figure 6.2 on page 48.
2 Use a T10 bit to remove two screws from the Encrypted Memory Enclosure cover and remove.
3 Remove the Patient Data Drive with tweezers or small needle nose pliers.

Install Patient Data Drive Cover

1 Place the Encrypted Memory Enclosure over the opening as shown in Figure 6.2 on page 48.
2 Use a T10 bit to secure and tighten to 5.5 inch pounds.
3 Snap the Left Enclosure Pocket cover in place.

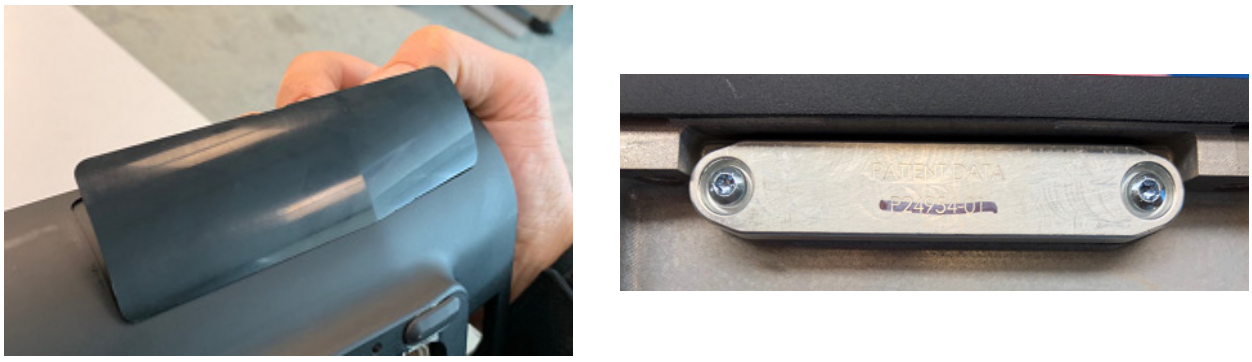


Figure 6.2 Data Drive Removal

User Interface Replacement

Required Parts

- P24503-XX Service Assembly, User Interface, Sonosite PX
- P29064-01N Service Assembly, User Interface, Sonosite PX, International

Remove User Interface

1 Place the system on its top so the serial number label is facing up.
2 Use a T10 bit to remove the 14 screws indicated. Refer to Figure 6.3 on page 49
3 Turn the system over and keep the front of the system facing towards you and raise the display until upright. Refer to Figure 6.4 on page 49

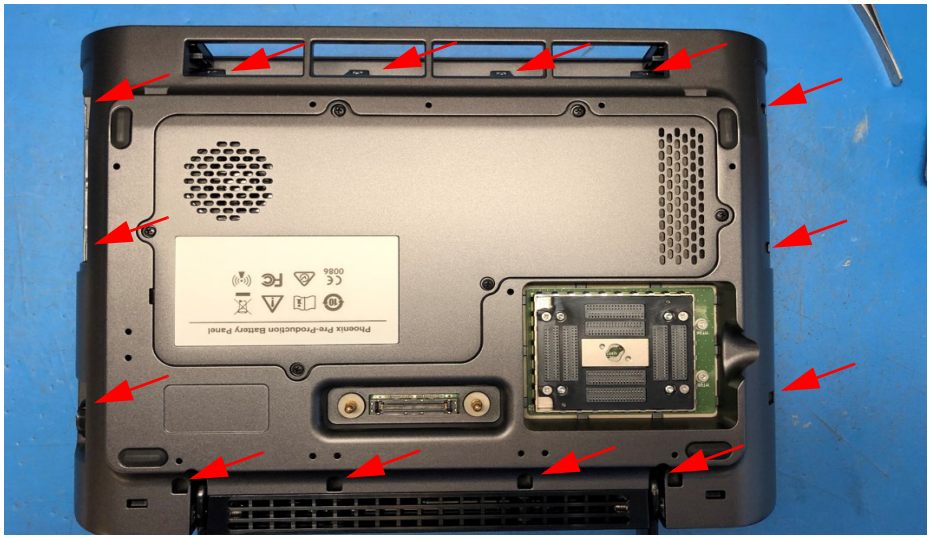


Figure 6.3 System Bottom View

Figure 6.4 System Top View

4 Remove the Front Panel Enclosure by lifting slightly on the front edge of the user interface. The Front Panel Enclosure will come out easily. Refer to Figure 6.5 on page 50

Figure 6.5 Front Panel Enclosure

5 Lift the User Interface from the system as shown in Figure 6.6 on page 50

Caution:Do not lift the User Interface from the front. Two tabs on the back of the UI sit in recesses in the Bottom Enclosure and this may break the tabs on the UI. Begin by lifting straight up until the tabs clear the enclosure.

6 Once the tabs are clear, the rear of the UI may be placed on the Bottom Enclosure and the front lifted up to access the interconnection cables.

7 Remove the UI to Main PCBA Cable and Persistent Control to Main Flex Cable from the Main PCBA.

8 Remove the UI from the system.

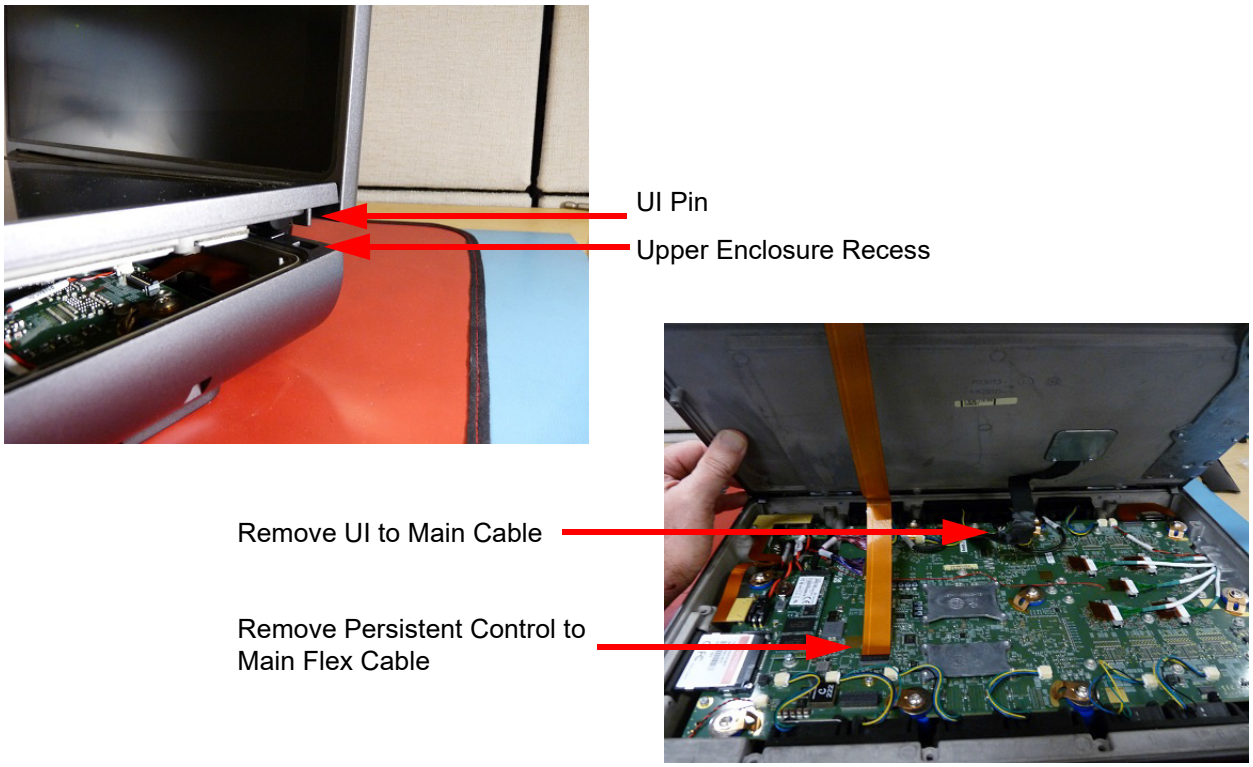


Figure 6.6 User Interface Removal

Install User Interface

1 Place the User Interface on the upper Enclosure as shown in Figure 6.6 on page 50.
2 Connect the UI to Main Cable and Persistent Control to Main Flex Cable.
3 Put the Front Panel Enclosure in place per Figure 6.5 on page 50.
4 Set the User Interface in place with the tabs seated in the recesses on the Upper Enclosure.
5 Turn the system over and install 14 screws with the T10 bit per Figure 6.3 on page 49.
6 Install the batteries per Figure on page 48.

Clinical Display Replacement

Required Parts

- P24504-XX Service Assembly, Clinical Display, Sonosite PX

Remove Clinical Display

1 Remove the User Interface as shown above.
2 Place the system upright with the back facing toward you. Remove the WiFi Dongle by pressing on the right side to release. Refer to Figure 6.7 on page 51.
3 Disconnect the USB cable from the WiFi Dongle.
4 Place a piece of tape over the on/off button. This will keep it from falling out when the Rear Enclosure is removed.

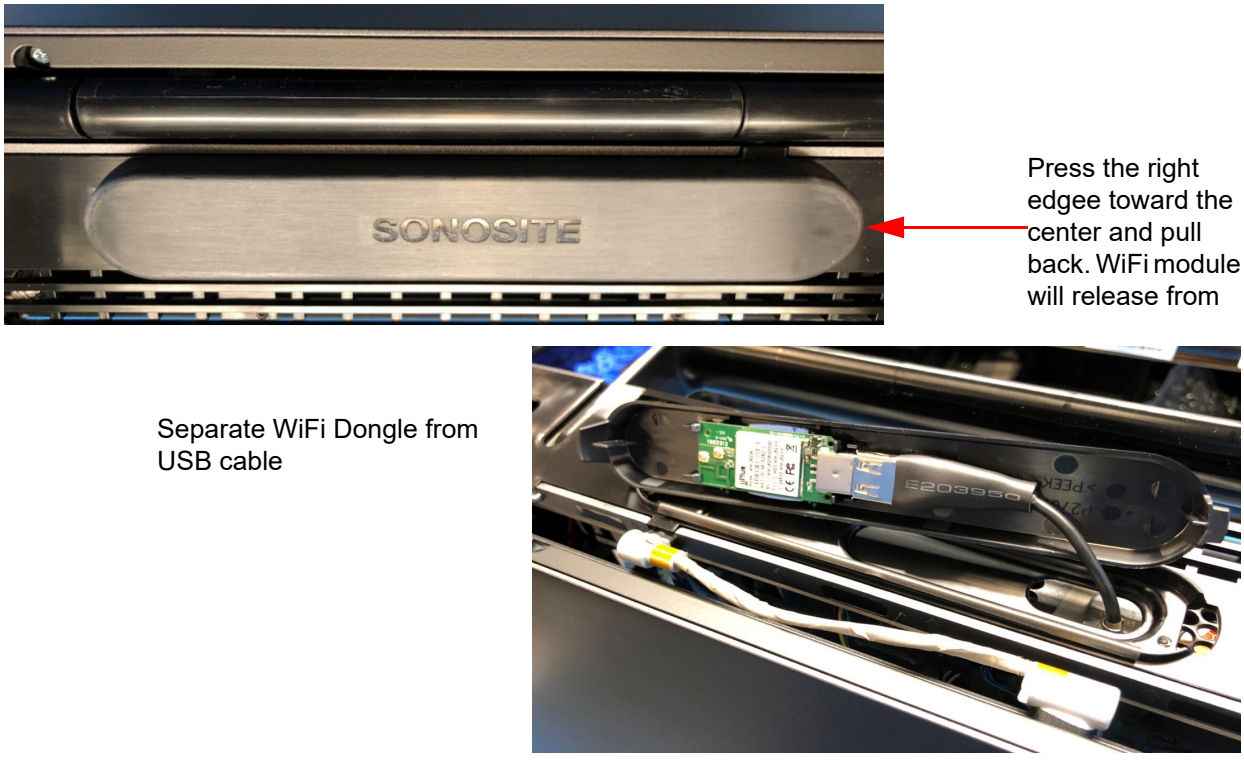


Figure 6.7 WiFi Dongle

5 Remove Rear Enclosure by gently prying with a small screwdriver or equivalent at the two locations indicated in Figure 6.8 on page 52. Apply pressure to move the Rear Enclosure in a downward direction. This will free it from being retained by the Display hinges.

6 Once the two locations are free. Grab the Rear Enclosure with both hands and pull it free. It will still be held by one tab on each end, but they will release with a small amount of force.

7 Feed the wireless USB cable through the Rear Enclosure to complete the removal.

8 Use a T6 bit to Remove the 2 screws securing the Display Cable EMI Shield per Figure 6.9 on page 53.

9 Disconnect the Clinical Display Cable from the Main PCBA per Figure 6.10 on page 53.

10 Move the Clinical Display to the lowered or closed position.

11 Use a T20 bit to remove the 2 screws in each hinge per Figure 6.10 on page 53.

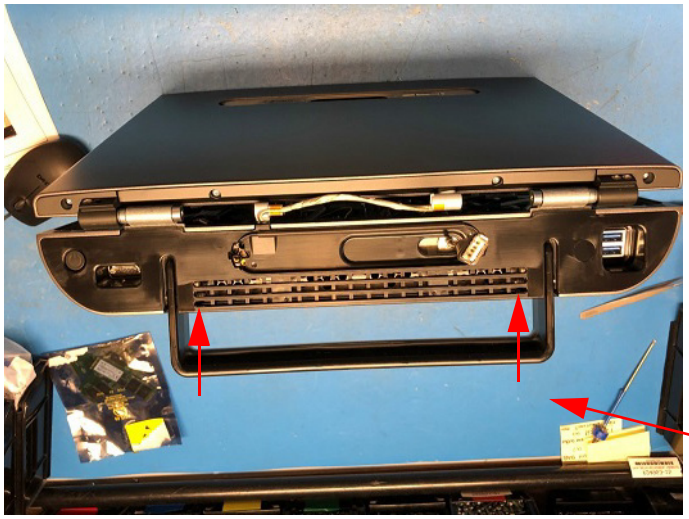
12 Carefully lift the Clinical Display and feed the Clinical Display Cable through the Bottom Enclosure to complete the removal.

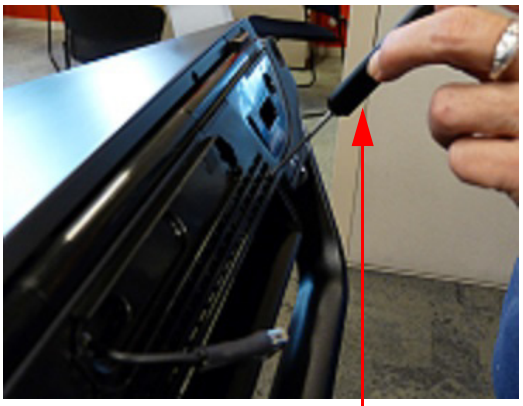
Caution:The following steps remove the Hinge Tubes. The display cable is housed inside so extra care is required to protect the cable.

13 The Hinge Tubes can be removed for transfer to a new display if needed per Figure 6.11 on page 54

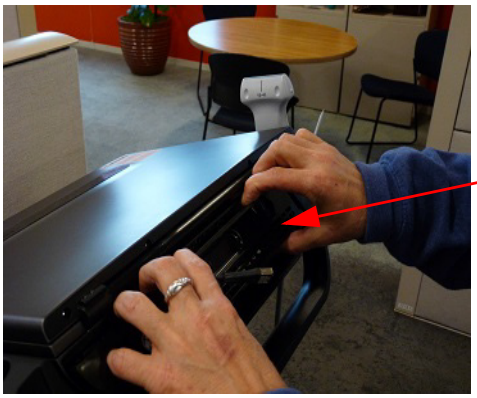
14 Remove the center Hinge Tube first.

15 Remove the right and left Hinge Tubes.





Apply upward force on tool in both locations to dislodge Rear Enclosure from system



Pull Rear Enclosure from system. The remaining locking tabs on the ends are also on the bottom edge of the Enclosure

Figure 6.8 Rear Enclosure Removal

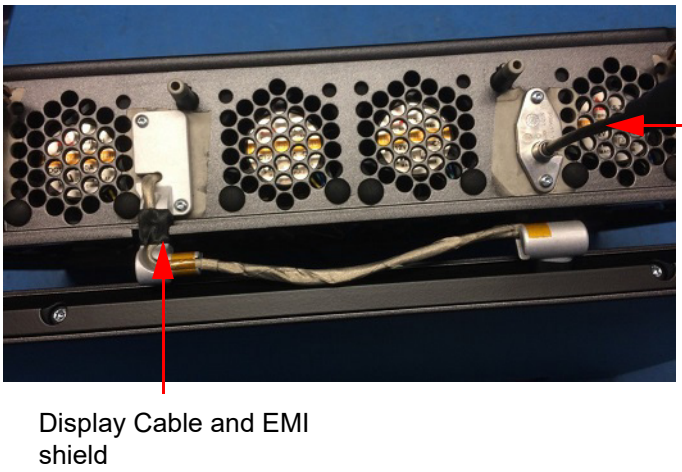


Figure 6.9 Rear EMI Shields

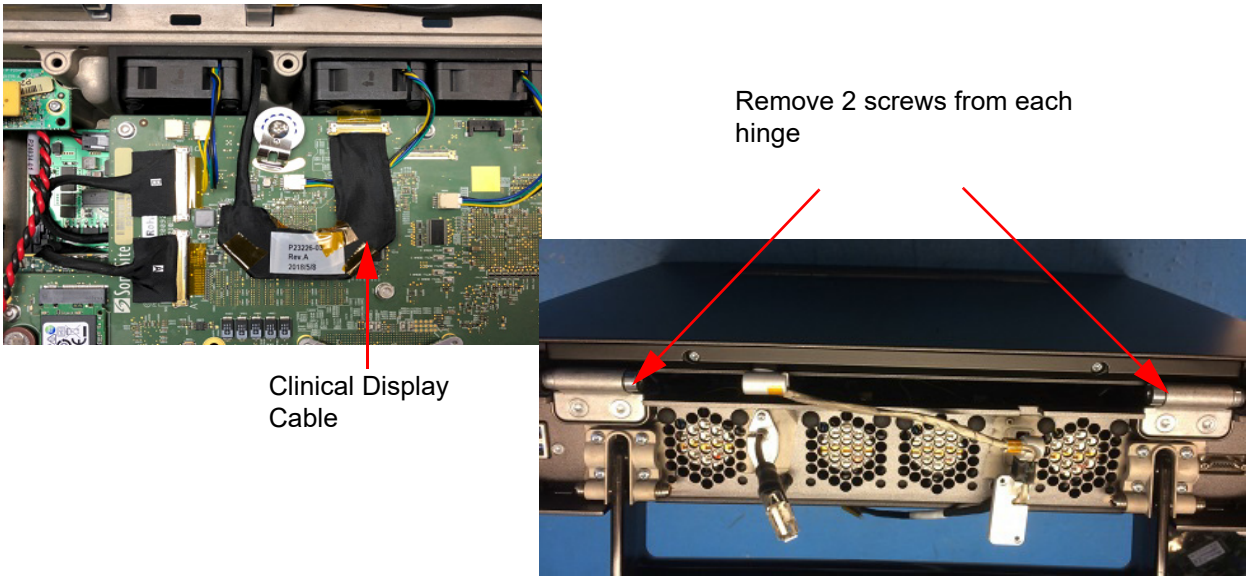


Figure 6.10 Clinical Display Removal

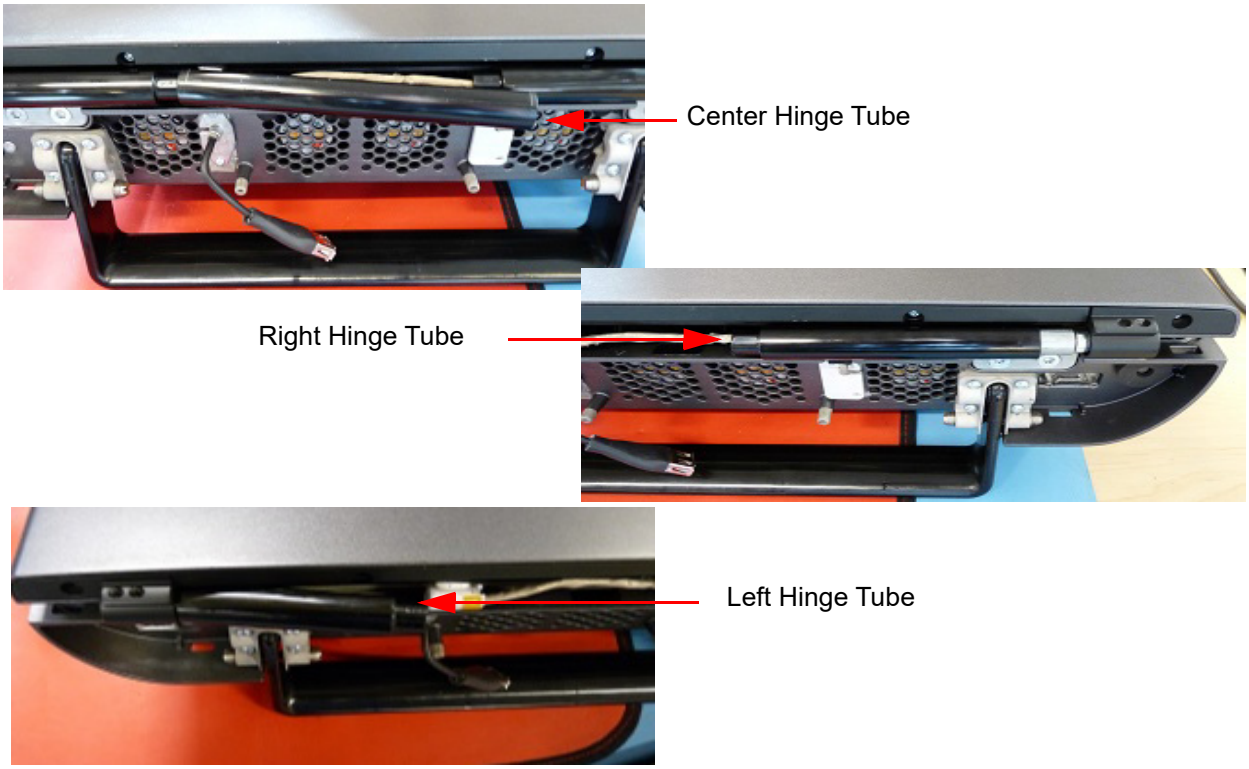


Figure 6.11 Display Hinge Tubes

Install Clinical Display

1 Install the left and right Hinge Tubes on new Clinical Display per Figure 6.11 on page 54.
2 Install the center Hinge Tube.
3 Carefully feed the Clinical Display cable through the Bottom Enclosure shown in Figure 6.9 on page 53.
4 Place the Clinical Display on top of Bottom Enclosure and line the hinges up with the screw holes per Figure 6.10 on page 53.
5 Install two screws in each hinge with a T20 bit and tighten to 5.5 inch pounds.
6 Connect the Clinical Display Cable to the Main PCBA, J3002 per Figure 6.10 on page 53.
7 Put Display Cable EMI Shield in place and secure the two screws with a T6 bit. Tighten to 2.0 inch pounds.
8 Feed the Wireless Dongle USB Cable through the Rear Enclosure and snap Rear Enclosure in place per Figure 6.8 on page 52.
9 Remove tape holding On/Off Button in place.
10 Connect the Wireless Dongle to the USB cable.
11 Install the Wireless Dongle onto the Rear Enclosure per Figure 6.7 on page 51.
12 Install the User Interface.
13 Install the Batteries.

Main System Disassembly for Repair and/or Replacement

Required Tools

- Torx bits, T6, T8, T10, T20 and T30
- Torque screwdriver, 1.0-10.0 inch pounds (0.23-1.1 Newton meter)
- Torque screwdriver, 10.0-25.0 inch pounds (1.1-2.8 Newton meter)
- Tool, Power in, Sonosite PX (only required for Power in Aux PCBA)
- Small regular screwdriver
- #2 Phillips screwdriver
- Anti-Static mat
- Wrist grounding strap

System Disassembly

1 Remove the User Interface
2 Remove the Clinical Display
3 The Base Assembly replaceable parts are now exposed per Figure 6.12 on page 56.

Speaker Replacement

Required Parts

- P26357 Speaker
- P26388 Speaker Gasket

Note: A small amount of RTV664 will be needed to secure the speaker to the speaker housing

Remove Speaker

1 Disconnect the speaker wire from the Main PCBA shown in Figure 6.12 on page 56.
2 Use the small regular screwdriver to dislodge the speaker from the speaker housing per Figure 6.13 on page 56.
3 Remove speaker and feed speaker wire connector through the hole in the Base Enclosure.

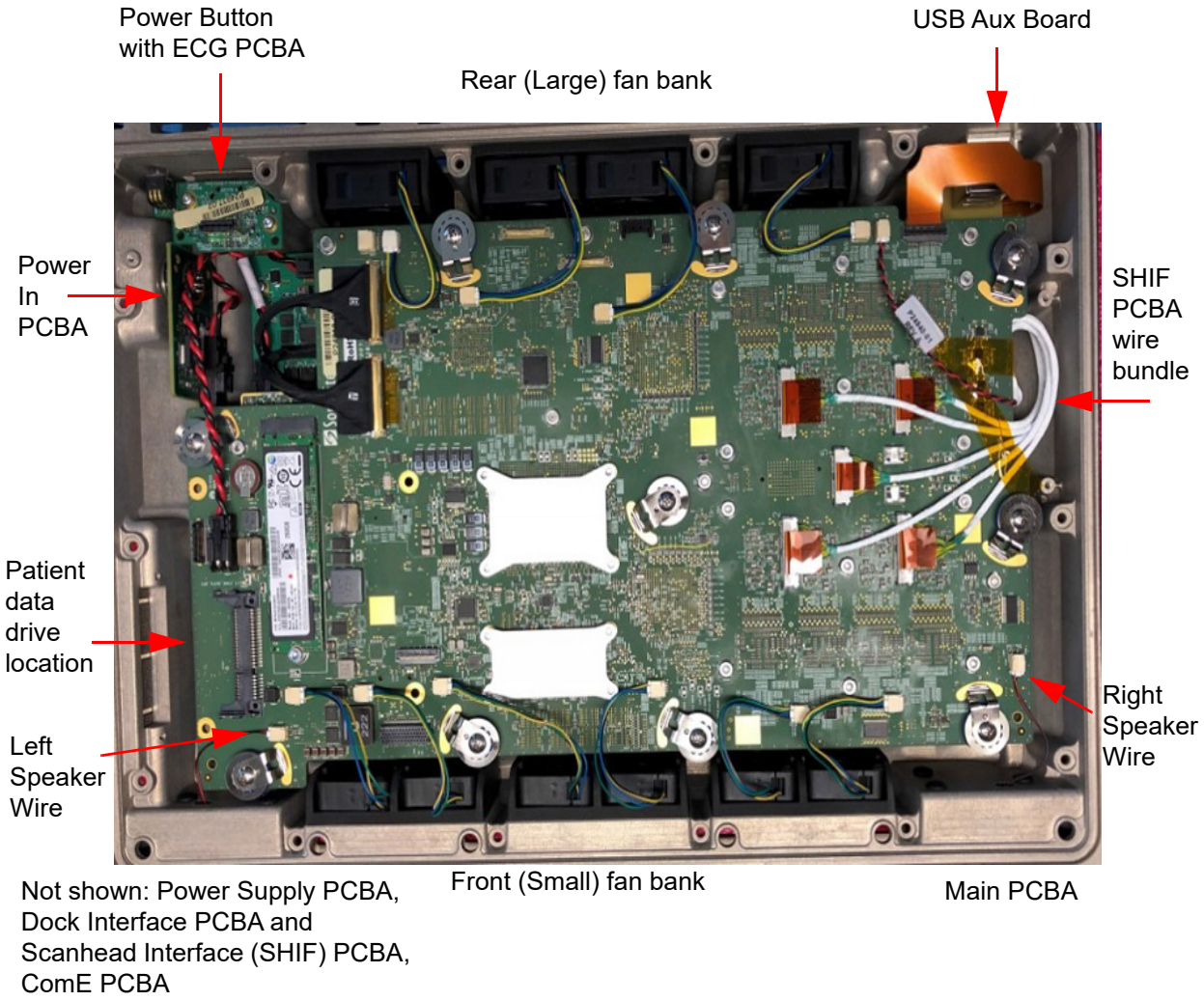
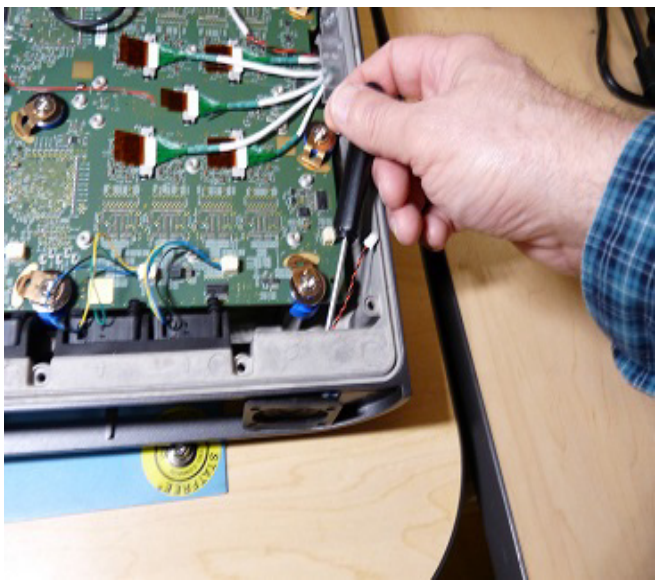


Figure 6.12 System Components



Insert screwdriver through speaker wire hole in Bottom Enclosure and press against speaker to dislodge

Figure 6.13 Speaker Removal

Install Speaker

1 Apply a small amount of RTV664 onto Speaker Housing per Figure 6.14 on page 57
2 Feed Speaker Wire through Bottom Enclosure and plug into Main PCBA
3 Seat Speaker in Speaker Housing, pressing into the RTV applied in step 1
4 Remove adhesive backing from Speaker Gasket and apply per Figure 6.14 on page 57

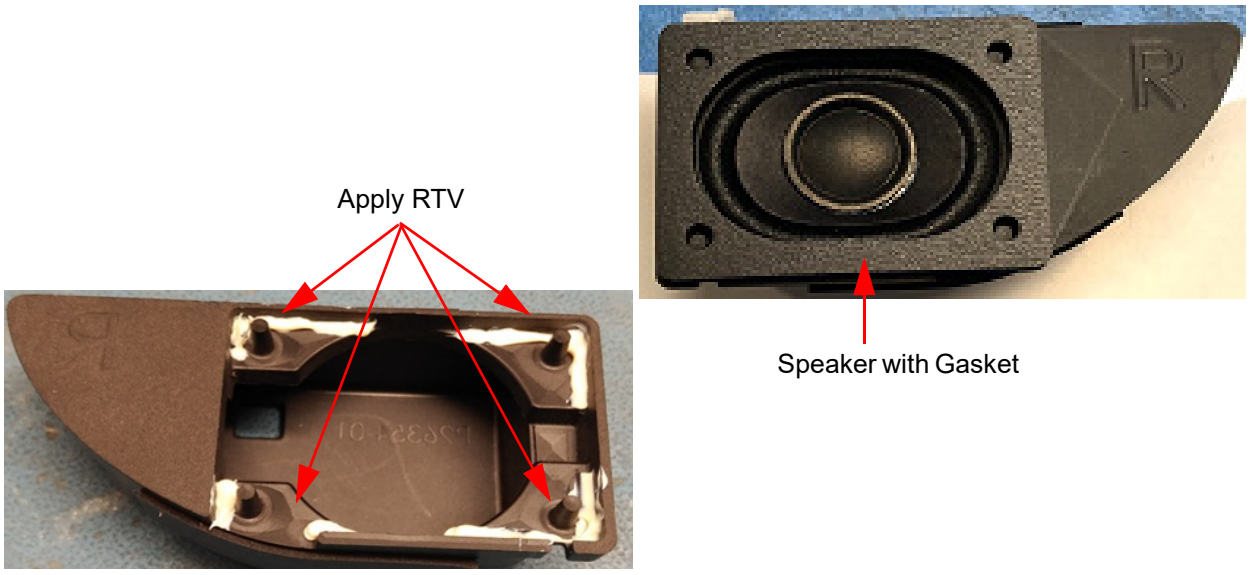


Figure 6.14 Speaker Installation

USB Aux Board Replacement

Required Part

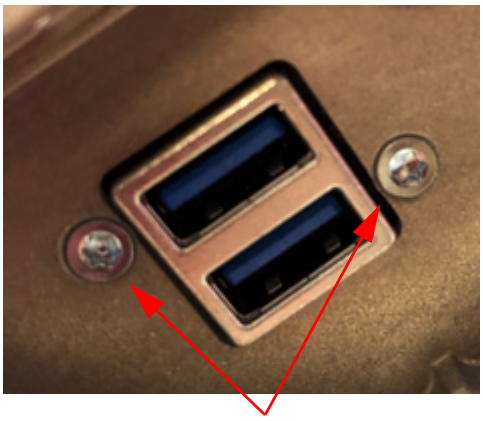
- P24915-XX Service Assembly, USB AUX Board PCBA, Sonosite PX

Remove USB Aux Board

1 Disconnect USB Aux Board from Main PCBA per Figure 6.15 on page 58
2 Use a T10 bit to remove the two screws securing the USB Aux Board.
3 Remove the USB Aux Board from the system.

Install USB AUX Board

1 Place USB Aux Board in the system
2 Use a T10 bit to install two screws per Figure 6.15 on page 58 and tighten to 5.5 inch pounds.
3 Connect USB Aux Board to Main PCBA J3017.



Remove screws

Disconnect from Main PCBA

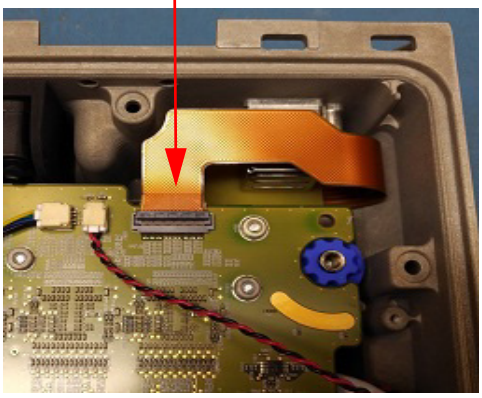


Figure 6.15 USB AUX Board

Power Button with ECG PCBA Replacement

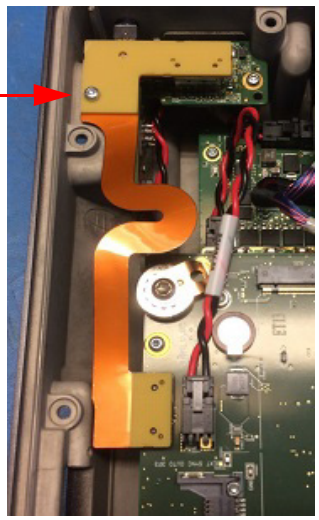
Required Part

- P27479-XX Service Assembly, Power Button with ECG PCBA, Sonosite PX

Remove Power Button with ECG PCBA

1 Remove screw from the ECG Flex Interconnect Cable using a T8 bit per Figure 6.16 on page 58
2 Disconnect the ECG Flex Interconnect Cable from the Main PCBA and Power Button with ECG PCBA and remove.
3 Remove two screws from the Power Button with ECG PCBA and remove.

Screw (T8)



Screws (T8)

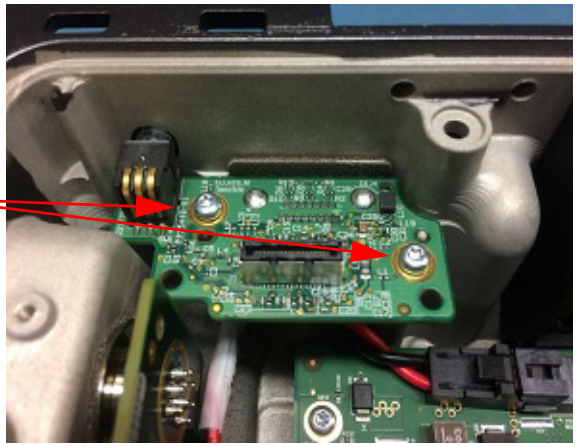


Figure 6.16 Power Button with ECG PCBA

Install Power Button with ECG PCBA

1 Place Power Button with ECG PCBA in the system per Figure 6.16 on page 58.
2 Install two screws and tighten with a T8 bit to 5.5 inch pounds.
3 Install the ECG Flex Interconnect Cable on the Main PCBA and Power Button with ECG PCBA.
4 Install screw and tighten with a T8 bit to 5.5 inch pounds.

Power In Aux Board PCBA Replacement

Required Part

- P24915-XX Service Assembly, Power In Aux Board PCBA, Sonosite PX

Remove Power In Aux Board PCBA

1 Remove the ECG Flex Interconnect Cable from the system as shown in previous section per Figure 6.16 on page 58. This will ensure the easiest access to the item being removed.
2 Use the Power In Tool to remove the plastic cap on the Power In connector per Figure 6.17 on page 59
3 Use the Power In Tool to remove the Power In nut from the Power In connector.
4 Lift the Power in Aux Board PCBA slightly and remove the Docking to Power In Cable.
5 The Power In Aux Board PCBA is now free to remove.

Power in Cap

Power in Nut

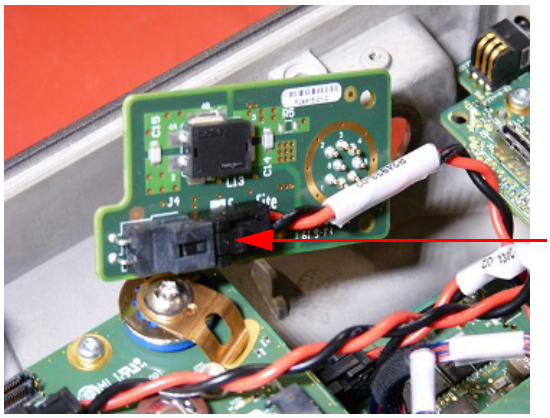


Figure 6.17 Power in Aux Board PCBA

Install Power in Aux Board PCBA

1 Connect the Docking to Power in Cable to the board being installed per Figure 6.17 on page 59
2 Put the Power in Aux Board PCBA in place and secure with the Power in Nut. Tighten to 10.0 inch pounds using the Power in Tool.
3 Install the Power in Cap and tighten to 10.0 inch pounds using the Power in Tool.
4 Install the ECG Flex Interconnect Cable on the Main PCBA and Power Button with ECG PCBA.
5 Install screw and tighten with a T8 bit to 5.5 inch pounds.

Main PCBA Replacement

Required Part

- P26956-XX Service Assembly, Main PCBA, Sonosite PX

Remove Main PCBA

Note: This procedure will also remove the ComE PCBA and Power Supply PCBA. Their removal will be a part of this process.

For the following steps, reference Figure 6.19 on page 61

1 Disconnect Left and Right Speaker connections.
2 Disconnect 10 Fan connections.
3 Remove the ECG Flex Interconnect Cable.
4 Disconnect the USB Aux Cable.
5 Disconnect the WiFi Dongle USB cable if present.
6 Disconnect the AB cable.
7 Disconnect the 5 SHIF Assembly Cables.
8 Remove the Docking to Main Board Cable.
9 Remove the SHIF to Main Board Power Cable.
10 Use a T20 bit to remove the 10 screws securing Main PCBA to Bottom Enclosure.

Note: Each screw also secures 3 items to the Main PCBA. Take care to retain all items.

- P24968, Spring Clip (9 each) The left front assembly will not contain this part
- P24967, Flat Washer (10 each)
- P25716, Upper Grommet (10 each)

See Figure 6.18 on page 60 for visual of these items.

Spring Clip Flat Washer Upper Grommet

Figure 6.18 Screw Stack

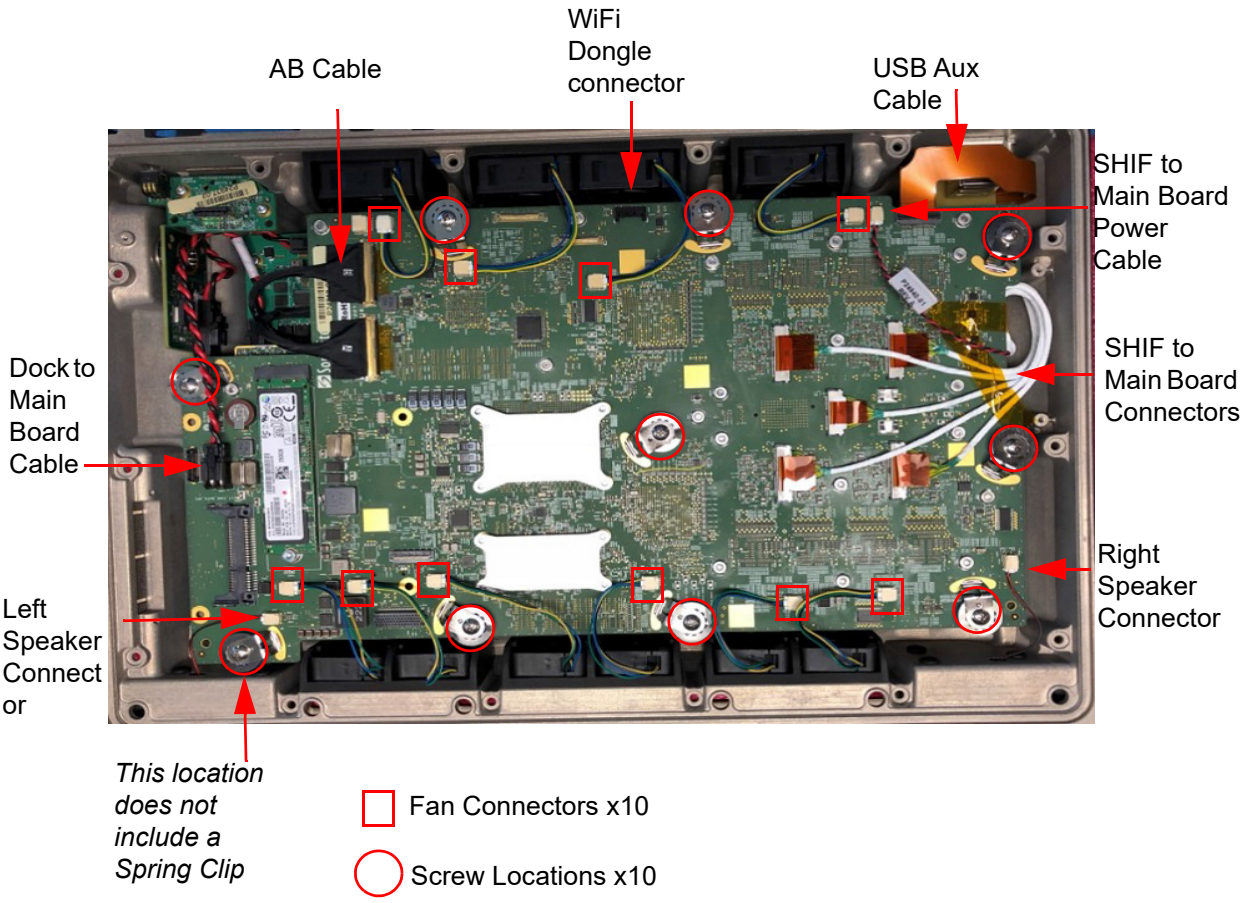


Figure 6.19 Main PCBA Removal

11 The Main PCBA is now free for removal. The ComE PCBA and Power Supply PCBA are also connected to the Main PCBA and these will all come out as one assembly.

Note: If the Main PCBA is the only item being replaced, the Power Supply PCBA and ComE must be removed and transferred to the new PCBA per the steps below. If the ComE or Power Supply PCBA need to be replaced, then follow the steps for the specific item only.

Power Supply PCBA Replacement

Required Part

- P24174-XX Service Assembly, Power Supply PCBA

Remove Power Supply PCBA

1 Use a T10 bit to Remove the 7 screws securing the Power Supply PCBA to the Main PCBA per Figure 6.20 on page 62

2 Gently lift the Power Supply PCBA using a slight “rocking motion” to release the connections

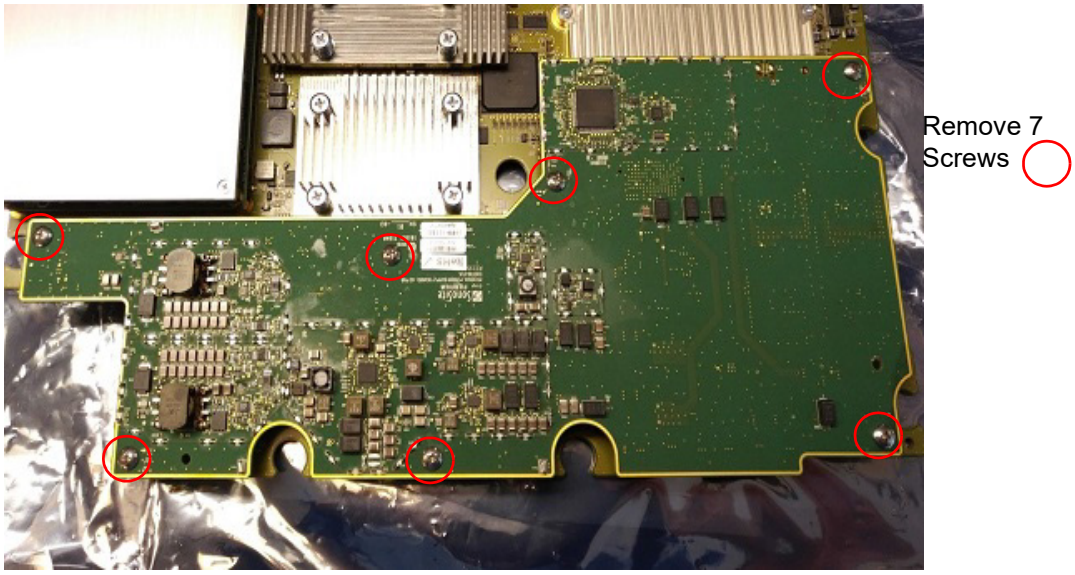


Figure 6.20 Power Supply PCBA

Install Power Supply PCBA

1 Place Power Supply PCBA onto Main PCBA. Make sure connectors are aligned and press into place per Figure 6.21 on page 62.

2 Use a T10 bit to install 7 screws and tighten to 5.5. inch pounds.

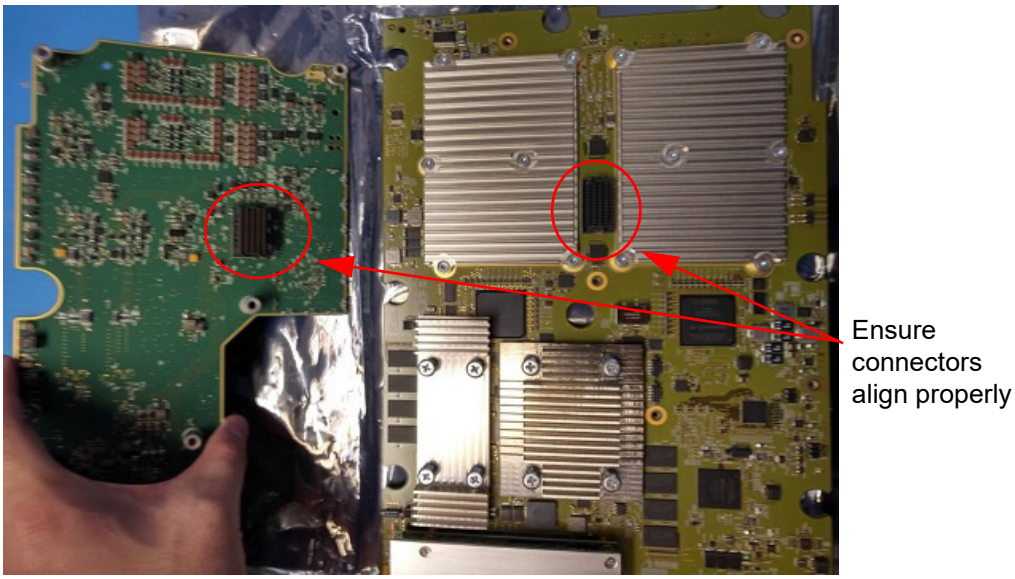


Figure 6.21 Power Supply PCBA Install

ComE PCBA Replacement

Required Part

- P27411-XX Service Assembly, ComE PCBA

Remove ComE PCBA

1 Use a T8 bit to remove the 4 screws securing the ComE PCBA to the Main PCBA
2 Gently lift the ComE PCBA using a slight “rocking motion” to release the connections

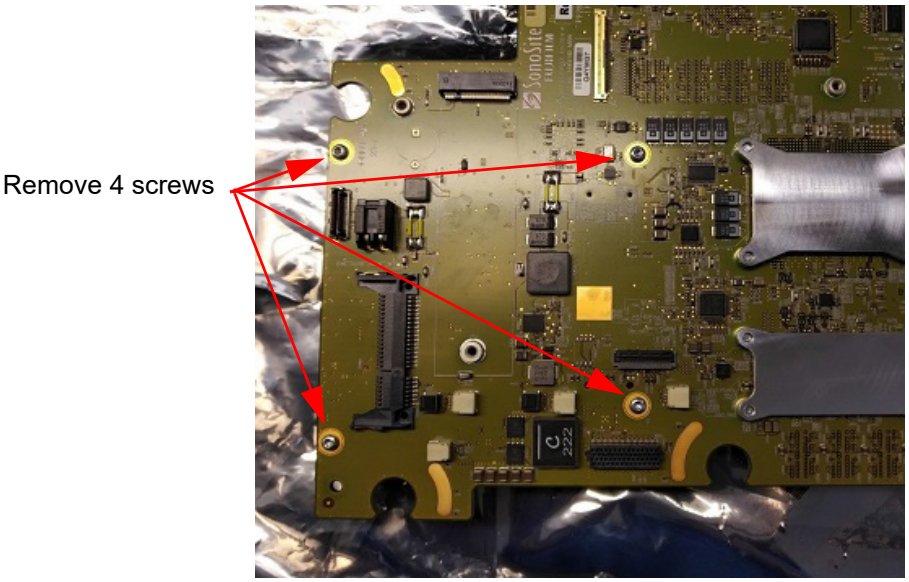


Figure 6.22 ComE PCBA removal

Install ComE PCBA

1 Place ComE PCBA onto Main PCBA. Make sure connectors are aligned and press into place per Figure 6.23 on page 63.
2 Use a T8 bit to install 4 screws and tighten to 5.5 inch pounds.

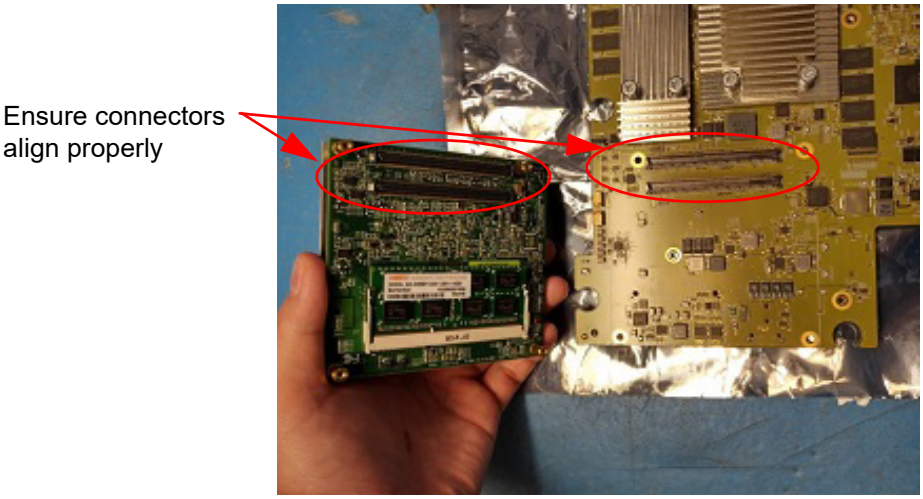


Figure 6.23 Install ComE PCBA

Install Main PCBA

1 Install the Main PCBA into the Bottom Enclosure. Align the cut-outs over the grommets on the mounting stand-offs and lower into place. It will be necessary to move wires and cabling to keep them out of the way as the board assembly is put into place. Reference Figure 6.24 on page 64.

2 Use a T20 bit to Install 10 screws along with the spring clip, flat washer and upper grommet and tighten t o 5.5 inch pounds. The indent in the spring clip must sit inside one of the holes of the flat washer and the spring clip must make contact with the ground plane on the Main PCBA. Per Figure 6.24 on page 64, the left front screw does not include the spring clip.

3 Install the SHIF to Main Board Power Cable. Reference Figure 6.19 on page 61 for this and following connections.

4 Install the Docking to Main Board Cable.

5 Install the 5 SHIF Assembly Cables. The numbers on the cables will match to the Numbers on the Main PCBA.

6 Connect the AB cable ensuring each cable matches the lettering on the Main PCBA.

Caution:If the connections for the AB cable are reversed, the Main PCBA will be damaged and require replacement.

7 Install the USB Aux Cable.

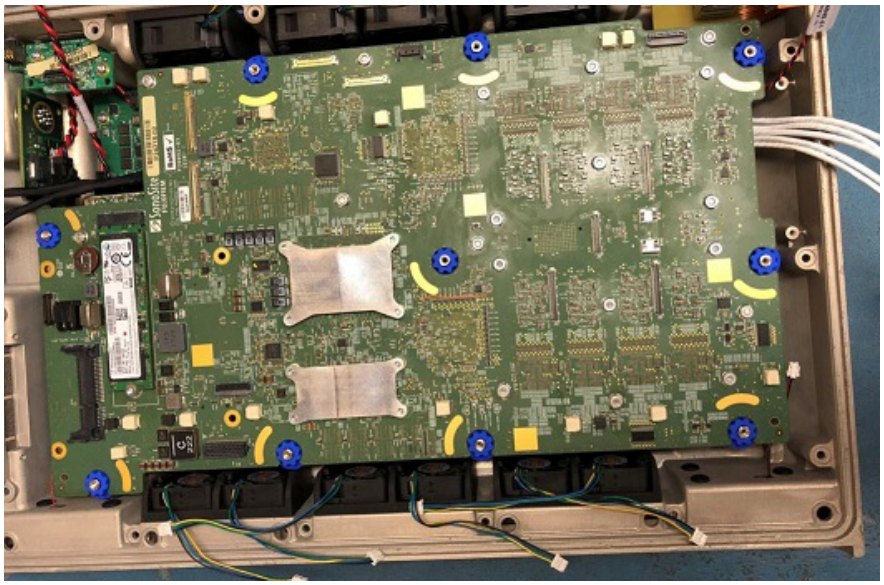
8 Install the ECG Flex Interconnect Cable.

9 Install the 10 Fan connections.

10 Install the Left and Right Speaker connections.

11 Install the Clinical Display.

12 Install the User Interface.



Screw stack assembly and proper installation

Figure 6.24 Main PCBA Install

Dock PCBA Replacement

Required Part

- P26765-XX Service Assembly, System Dock PCBA

Remove Dock PCBA

1 Remove the Main PCBA per “Main PCBA Replacement” on page 60.
2 Use a T30 bit to remove the 2 Dock Alignment pins per Figure 6.25 on page 65
3 Use a T8 bit to remove the 7 screws.
4 The Dock PCBA is free to remove.

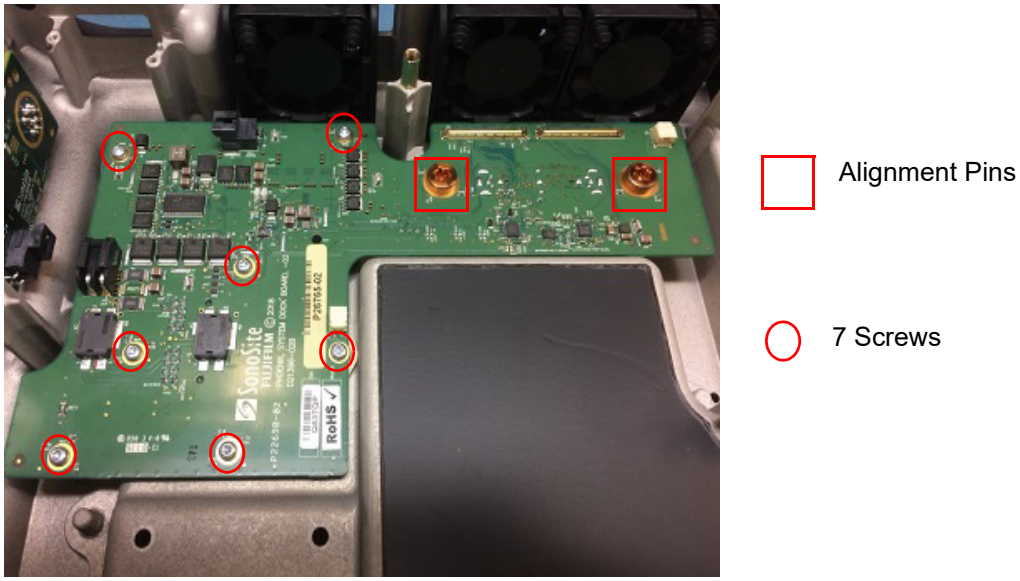


Figure 6.25 Dock PCBA

Install Dock PCBA

1 Put the Dock PCBA in place
2 Hand thread 2 Alignment Pins until screw head makes contact and is flush with Dock PCBA. If necessary, wiggle the screws or board until they are flush.

Caution:Do not force Alignment Pins in place. Failure to align them correctly will lead to a damaged board.

3 Use a T8 bit to install the 7 screws and tighten to 5.5 inch pounds.
4 Use a T30 bit to tighten the Alignment Pins to 20 inch pounds.
5 Install the Main PCBA.
6 Install the Clinical Display.
7 Install the User Interface.

SHIF PCBA Replacement

Required Part

- P25394-XX Service Assembly, SHIF PCBA

Remove SHIF PCBA

1 Remove the Main PCBA per “Main PCBA Replacement” on page 60.

2 Pull up on the Ferrite and remove it from the SHIF connectors by feeding them through one by one per Figure 6.26 on page 66.
3 Use a T8 bit to remove the two screws securing the SHIF Cable Retainer.
4 Turn the system over with the bottom facing up.
5 Use a T10 bit to remove the 4 screws securing the Interposer Assembly.
6 Remove the Interposer Assembly.
7 The SHIF PCBA and cables are now free to remove from the system.

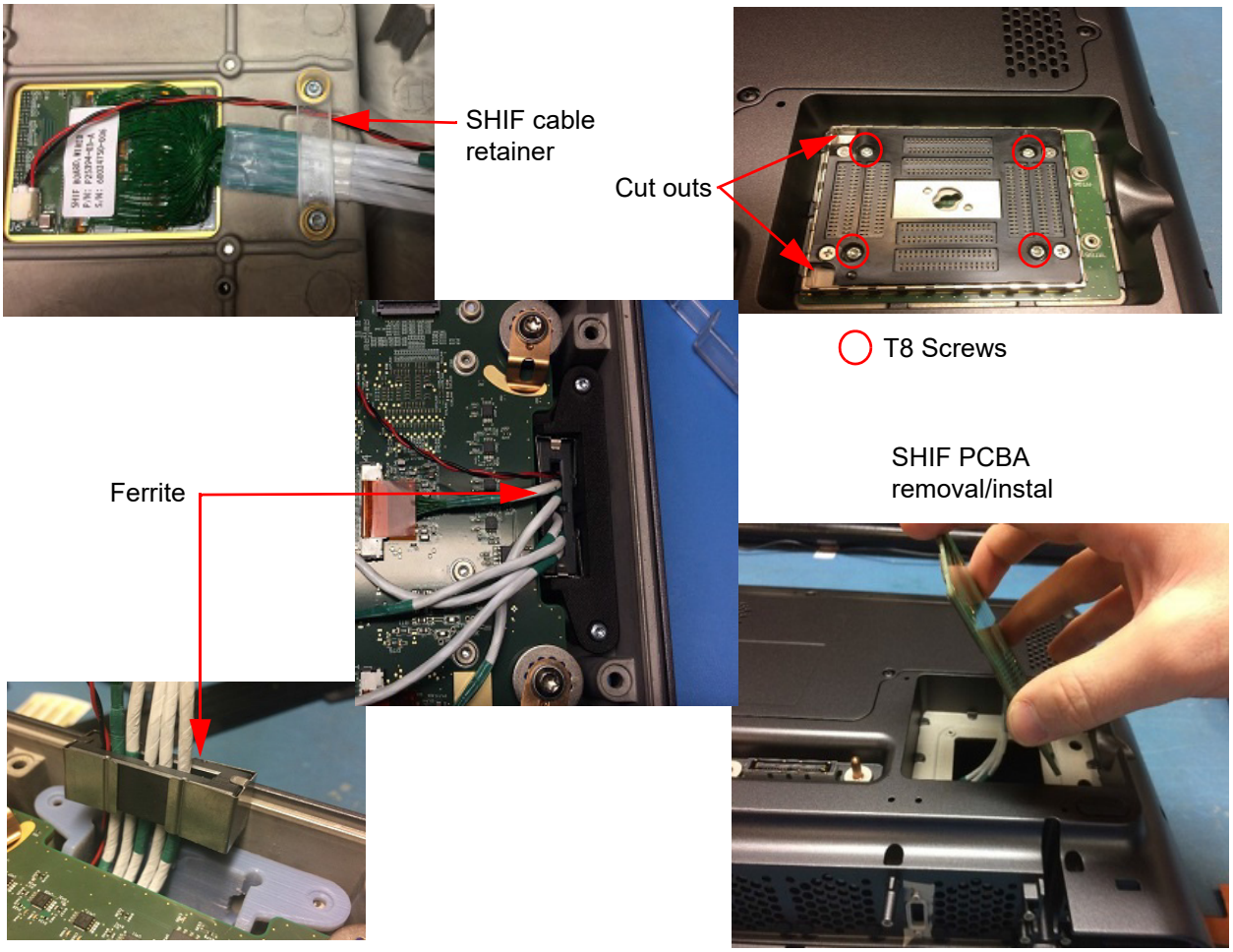


Figure 6.26 SHIF PCBA

Install SHIF PCBA

1 Position the system with the bottom facing up as shown
2 Feed SHIF PCBA cables through the Bottom Enclosure as shown and seat the SHIF PCBA in place.
3 Install the Interposer Assembly with the cut outs facing as shown and align guide pins into holes
4 Use a T8 bit to install 4 screws and tighten to 5.5 inch pounds.
5 Turn the system over with the top facing up.
6 Use a T8 bit to install 2 screws in the SHIF Cable Retainer and tighten to 5.5 inch pounds.
7 Feed the SHIF cables through the Ferrite and install as shown.
8 Install the Main PCBA.
9 Install the Clinical Display.
10 Install the User Interface.

Nest Frame Replacement

Required Part

- P21601 Interposer Assembly

Remove Interposer Assembly

1 Place the system top down with the bottom facing up
2 Use a T8 bit to remove the 4 screws securing the Interposer Assembly per Figure 6.26 on page 66.
3 Remove the Interposer Assembly.

Install Interposer Assembly

1 Install the Interposer Assembly with the cut outs facing as shown and align guide pins into holes per Figure 6.26 on page 66.
2 Use a T8 bit to install 4 screws and tighten to 5.5 inch pounds.

Fan Replacement

Note: Parts listed below are for reference and merely reflect the possibilities of items that may need replacement. Only order parts needed to perform the repair.

Required Parts

P24944 Fan, Axial, 40MM x 15MM, 1 each (large fan)

P24945 Fan, 30MM x 10MM, 1 each (small fan)

P25921 Fan Mount Rivet, 1 each (2 per fan)

Other Parts - As Required

P24959 Fan Gasket for 2 P24945 Fans (3 sets)

P24958 Fan Gasket for 4 P24944 Fans (inner group)

P25688 Fan Gasket for 1 P24944 Fan (outer group)

P27225 Fan Baffle Plate, 1 each (only required for 1 small fan mounted on the left front of the system)

Remove Fan

1 Cut the button on the outside end of the Fan Mount Rivet and pull the rivet through from the inside of the system. Reference Figure 6.27 on page 68.
2 Remove the fan.

Note: If the Fan Gasket a particular fan sits in also needs to be replaced, all fans mounted in that gasket will also need to be removed. The required number of Fan Mount Rivets will need to be ordered to accommodate this.

Install Fan

1 Install the fan in the required location. Reference Figure 6.27 on page 68.
2 Ensure the airflow direction on the fan matches the airflow direction arrow on the Bottom Enclosure.
3 Route a Fan Mount Rivet through each of the top fan holes as shown and pull tight.
4 Trim the Fan Mount Rivets as shown, leaving 3 segments protruding from the fan.

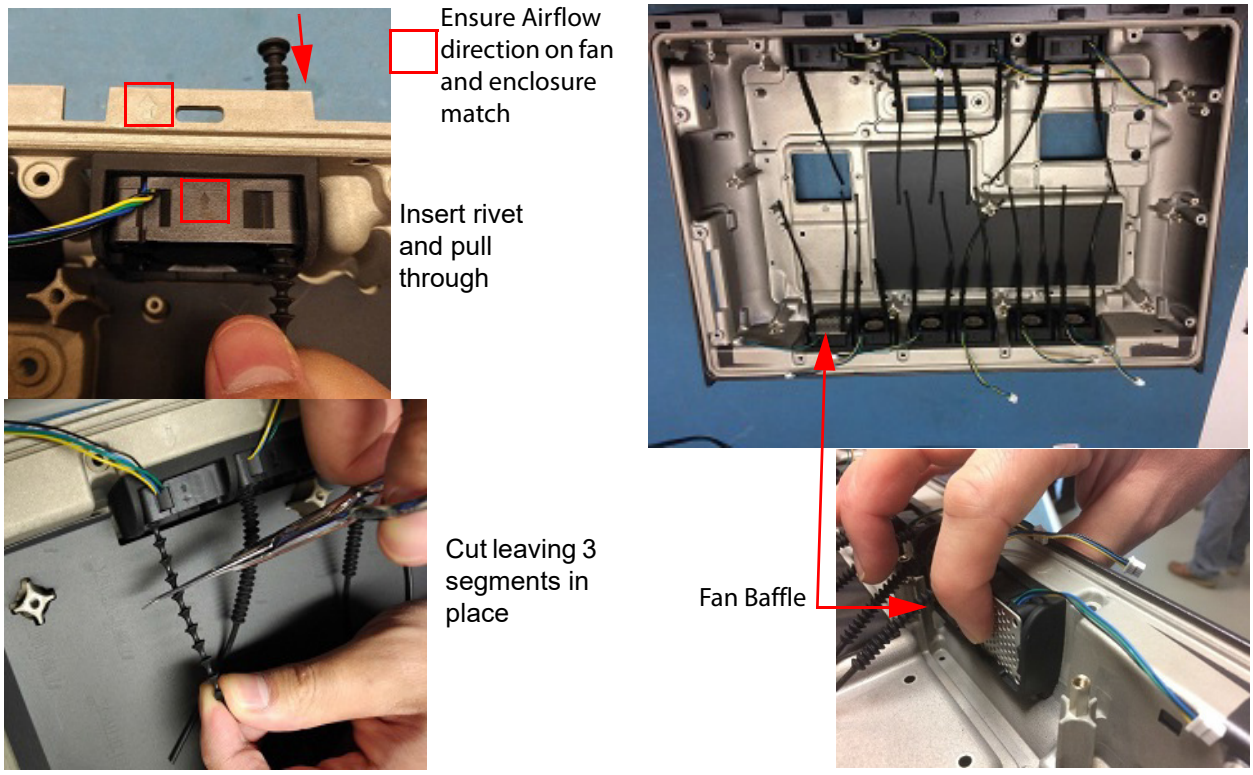


Figure 6.27 Fan Assembly

Stand Head Replacement

Remove Stand Head

1. Remove the Sonosite PX from the Stand Head.
2. Remove the stand power supply connection from the back of the Stand Head per Figure 6.28 on page 69
3. Use a #1 Phillips screwdriver to remove two screws from the column cover and remove. It will still be connected to the power cable.
4. Disconnect the USB cable in the column from the port inside the base of the Stand Head.
5. Use a 4mm hex bit to loosen the two screws securing the Stand Head.
6. Lift on the Stand Head to remove from the column.

Install Stand Head

1. Install the Stand Head by following the prior removal steps 1-5 in reverse order.

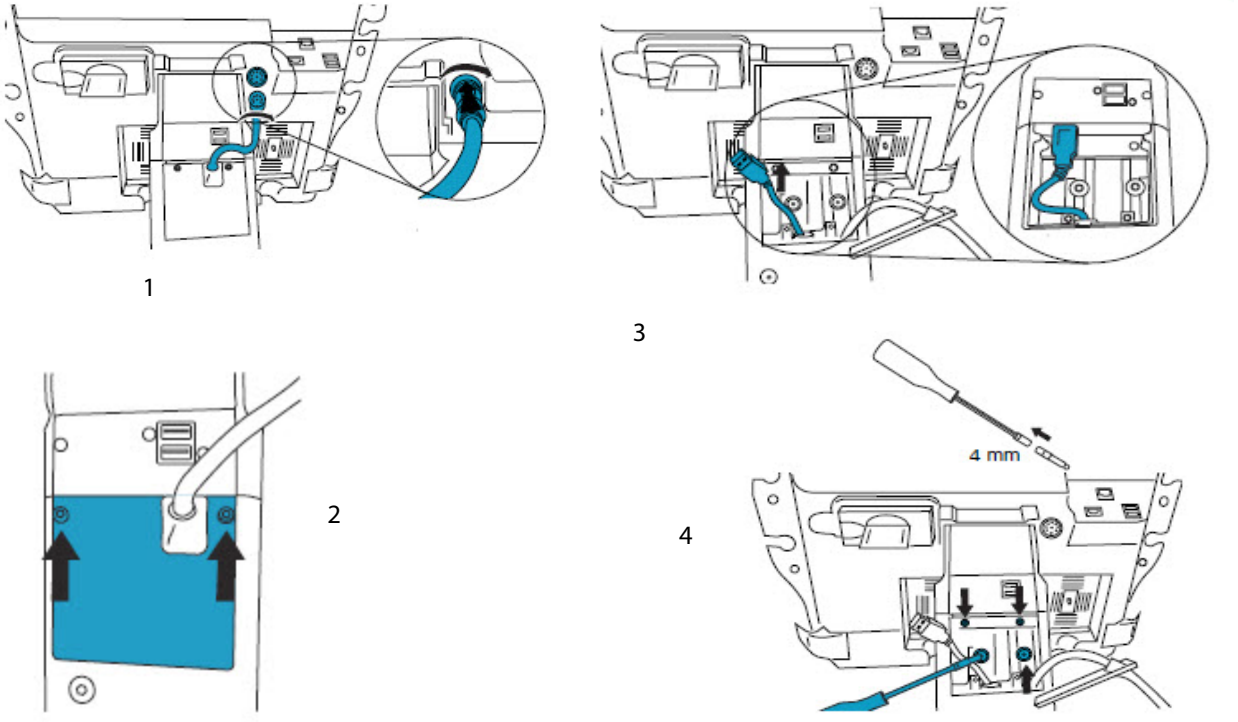


Figure 6.28 Stand Head Replacement

Optional Equipment - Stand System

Sony UP-X898MD Printer

The Sony UP-X898MD thermal printer is a monochrome black and white printer which uses the USB 2.0 port to integrate with the Sonosite PX Stand. This is an optional device. The following instructions are for any replacement needs if the Sony UP-X898MD has to be replaced.

Required Part

- P20006 Sony UP-X898MD B&W Printer

Required Tools

- #1 Phillips screwdriver
- 5mm hex bit with driver

Remove Printer

1 Remove the rear cover on the printer, exposing the USB and power cables per Figure 6.29 on page 70
2 Disconnect the USB and power cables from the rear of the printer
3 Use a 5mm hex bit to loosen the two screws under the printer.
4 Lift the printer and mounting box from the stand.
5 Use a Phillips #1 bit to remove the 4 screws securing the printer to the mounting box.
6 Remove the Printer from the mounting box.

Install Printer

1 Install the Printer by following the prior removal steps 1-5 in reverse order.

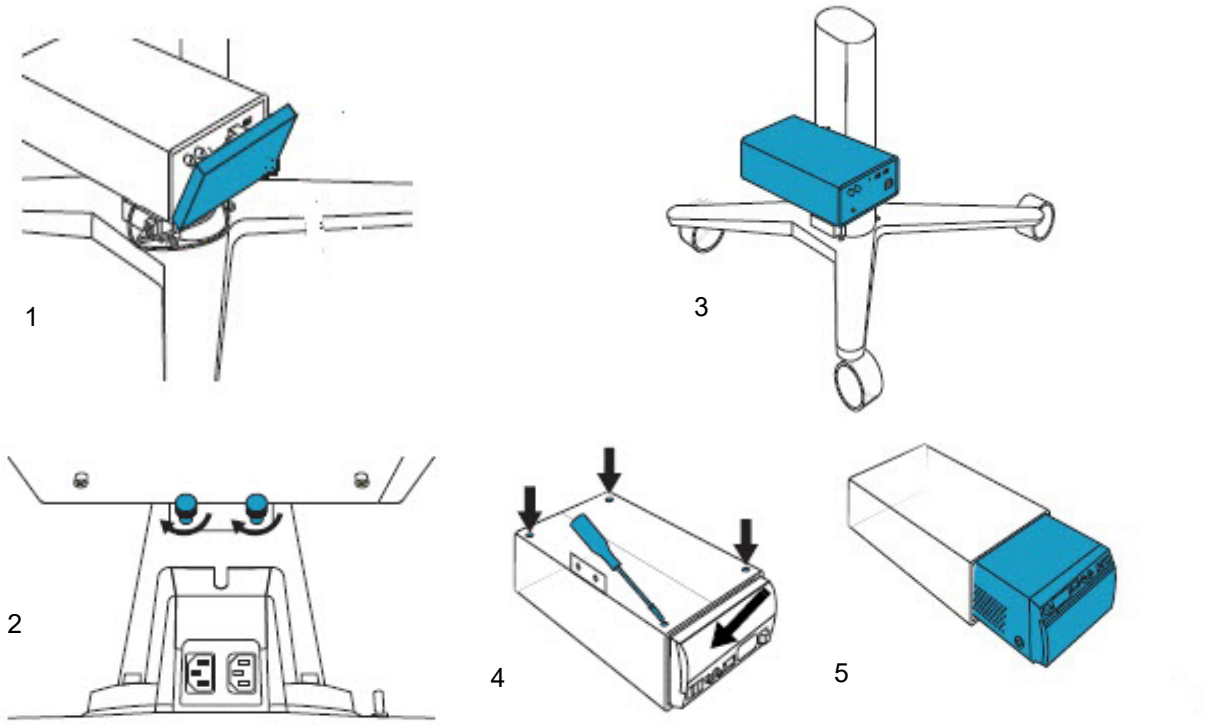


Figure 6.29 Printer Replacement

Chapter 7: Maintenance

This chapter directs you to information about 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 transducers after every use. (See the *"Cleaning and Disinfecting chapter"* in the Sonosite PX user guide P21894). 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.)

Cleaning and Disinfecting

Please refer to Warnings, Cautions, and Step by Step procedures outlined in the *"Cleaning and Disinfecting chapter"* in the Sonosite PX user guide (P21894). For a current list of compatible cleaners and disinfectants, visit the cleaners and disinfectants tool on www.sonosite.com

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 recommend 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
- C5-1 transducer
- P5-1 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 C5-1 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 probe and run it across the transducer face. Your finger touching the transducer face should appear at the orientation mark on the display image format.
	4	Verify that all of the User Interface and persistent control features are functional. Verify that all controls operate smoothly over their full range 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	Verify the airflow from the fan vents on the rear of the system flow outward.

2D Performance Tests

2D Performance / Image Quality

Test 2D Performance and Image Quality	1	Use a C5-1 transducer in 2D mode.
	2	Adjust the position of the C5-1 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	Press the **Freeze** button and then save the image. Press the **Freeze** button 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	Press the **Freeze** button.
	3	Press the **Caliper** button. The caliper appears on the image display. (See the *Sonosite PX Ultrasound System User Guide*, if necessary, for caliper operation.)
	4	Use the touchpad to position one of the calipers.
	5	Press the **Select** button to fix the caliper and enable the other caliper.
	6	Use the touchpad to move the other caliper. The results update as you move the caliper, and the measurement is complete when you finish moving the calipers. (Press the **Select** button to alternate the active caliper, and adjust the measurement with the touchpad.)
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 77.	
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	Press 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	Press 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	Press the **Freeze** button to return to live imaging.

Additional Performance Tests

Color Doppler (Color)

Test Color	1	Connect any transducer.
	2	Press 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 Touch Control Panel 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	Press the **Freeze** button and then save the image. Press the **Freeze** button to return to live imaging.

Color Power Doppler (CPD)

Test CPD	1	Connect any transducer.
	2	Press the **Color** button. A Region of Interest (ROI) box is displayed on top of the grayscale image.
	3	Press the **Color type** softkey to switch to CPD. “CPD” should be annotated in the lower right 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 a C5-1 transducer and acquire an image.
	2	Press the **M Mode** button for the M Mode sample line.
	3	Position the M Mode sample line over the image using the Touch Pad.
	4	Press the **M Mode** button 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	Press the **Freeze** key to freeze the image. Save the image. Slide the **Freeze Unlock** to return to live imaging.
	7	Press the **2D** key to return to 2D imaging.

Tissue Harmonic Imaging

Test THI Imaging	1	Attach the C5-1 transducer and acquire an image.
	2	Set the depth to maximum and note the depth at which echo information is lost.
	3	Press the **THI on** button on the User Interface **more controls** section so it displays THI on the display. 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	Press the **Freeze** button and then save the image. Press the **Freeze** button to return to live imaging.
	6	Press the **THI off** button to turn off Tissue Harmonic Imaging.

Pulsed Wave (PW) Doppler Imaging

Test PW Doppler Imaging	1	Attach the P5-1 transducer.
	2	Press the **Doppler** button for the Doppler sample gate.
	3	Press the **Doppler** button again for the Doppler spectral trace.
	4	Place a large drop of ultrasound gel on the transducer lens.
	5	Adjust the **Gain** control as necessary and then gently tap the top of the gel and observe a reflection on the spectral trace and the sound from the speakers.
	6	Press the **Freeze** button and then save the image. Press the **Freeze** button to return to live imaging.
	7	Press the **2D** key to return to 2D imaging.

Continuous Wave (CW) Doppler Imaging

Test CW Doppler Imaging	1	Attach the P5-1 transducer.
	2	Press the **Transducer icon** on the user interface.
	3	Select the **Cardiac** exam type.
	4	Press the **Done** softkey.
	5	Press the **Doppler** button for the Doppler sample gate.
	6	Press the **PW** softkey to switch to CW Mode.
	7	Press the **Doppler** key again for the Doppler spectral trace.
	8	Place a large drop of ultrasound gel on the transducer lens.
	9	Adjust the **Gain** control as necessary and then gently tap the top of the gel and observe a reflection on the spectral trace and the sound from the speakers.
	10	Press the **Freeze** buttonand then save the image. Press the **Freeze** button to return to live imaging.
	11	Press the **2D** key to return to 2D 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 the Sony UP-X898MD USB Black & White Printer (P20006) to be connected to the system under test. Skip this test if a printer is not available.

Test Printer Operation	1	Press the print button and verify that the printer begins to print an image.
	2	Verify the proper content of the printed image.

Appendix A: Replacement Parts

The following tables contain all the field-replaceable parts for the Sonosite PX ultrasound system. Quantities are one unless otherwise noted. Please refer to Figure A.1 on page 83 to identify the major components of the Sonosite PX.

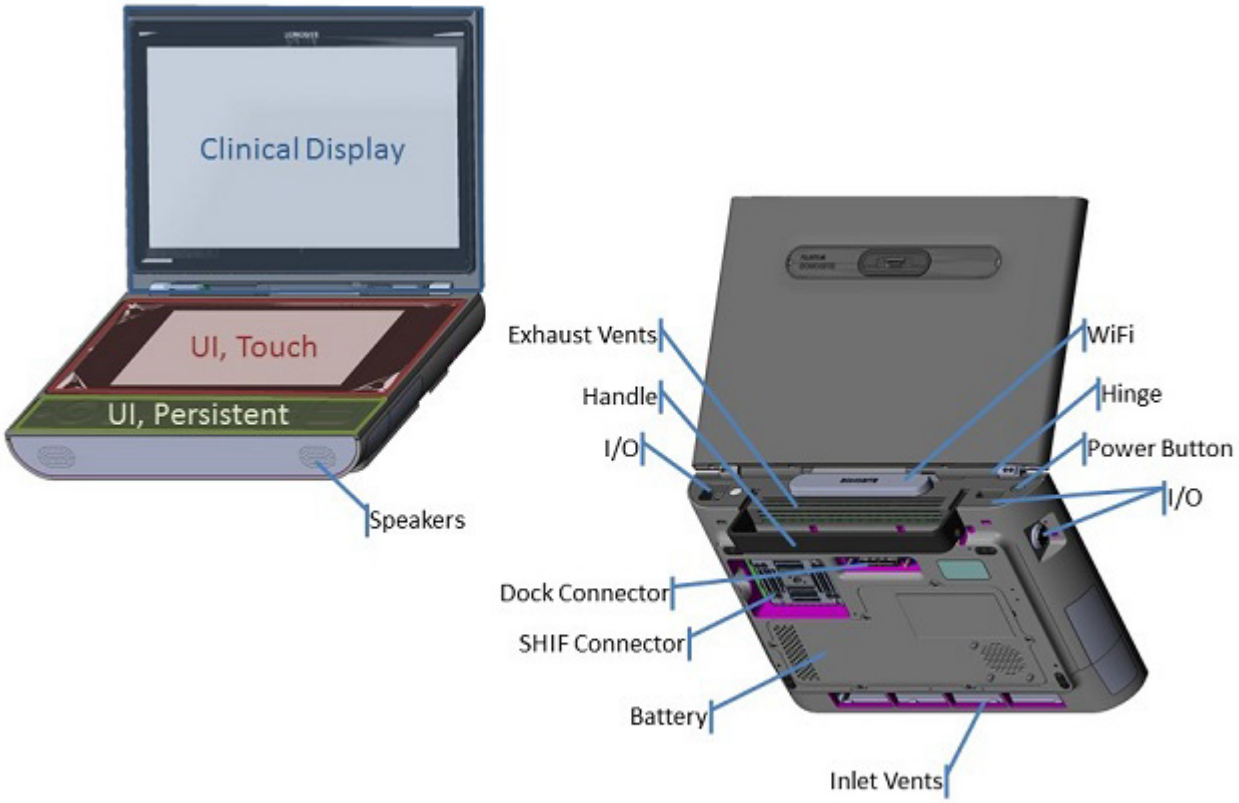


Figure A.1 Sonosite PX Major Components

Clinical Monitor

Figure A.2 Clinical Monitor Display

Table A.1: Clinical Monitor Display

Part Number	Description
P24504-XX	Service Assembly, Display, Sonosite PX

Table A.2: Clinical Monitor Display Associated Hardware

Part Number	Quantity	Description
P16667	4	SCREW,FLAT,6 LOBE,M4-0.7X10MM

User Interface

Figure A.3 User Interface

Table A.3: User Interface

Part Number	Description
P24503-XX	Service Assembly, User Interface, Sonosite PX
P29064-XX	Service Assembly, User Interface, Sonosite PX, International

Table A.4: User Interface Associated Hardware

Part Number	Quantity	Description
P24931	1	Main to Persistent Control Flex Cable

Persistent Controls

Figure A.4 Persistent Controls

Table A.5: Persistent Controls

Part Number	Description
P23160-XX	Service Assembly, Persistent Controls Assembly, Sonosite PX
P27041-XX	Service Assembly, Persistent Controls Assembly, Sonosite PX, International

Table A.6: Persistent Controls Associated Hardware

Part Number	Quantity	Description
P25992	12	SCREW,FLAT,6 LOBE,M3-0.5X6MM

Main PCBA

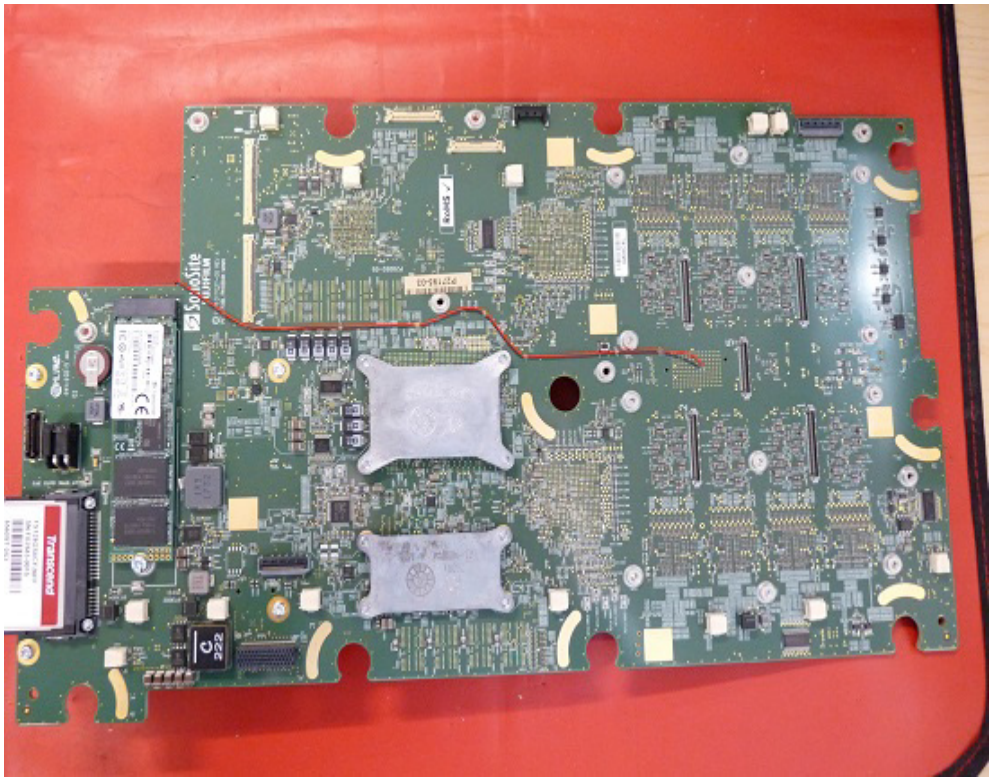


Figure A.5 Main PCBA

Table A.7: Main PCBA

Part Number	Description
P26956-XX	Service Assembly, Main PCBA, Sonosite PX

Table A.8: Main PCBA Associated Hardware

Part Number	Quantity	Description
P26599	4	Screw, 6 Lobe, M2.5-0.45x5MM
P24968	4	Spring Clip
P24967	4	Flat Washer
P25716	4	Grommet

Figure A.6 ComE

Table A.9: ComE

Part Number	Description
P27411-XX	Service Assembly, ComE, I5 With Heat Spreader, Sonosite PX

Table A.10: ComE Associated Hardware

Part Number	Quantity	Description
P24945	4	SCREW,PAN,6 LOBE,M2.5-0.45X5MM

Power Supply PCBA

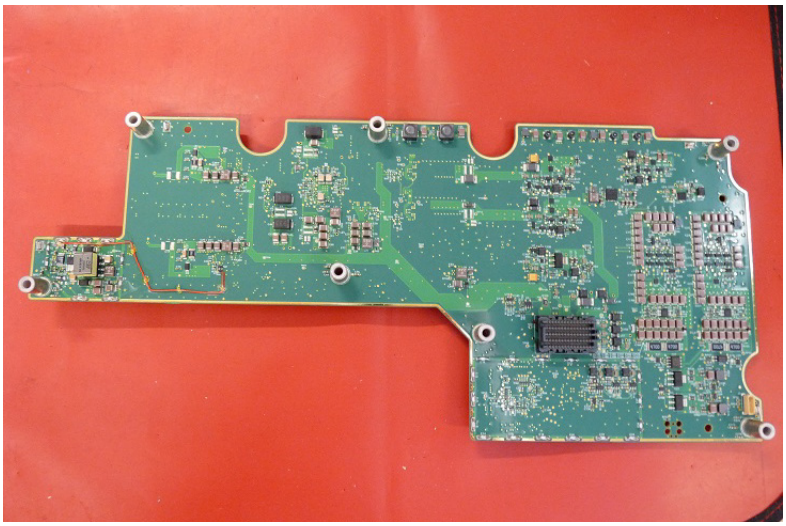


Figure A.7 Power Supply PCBA

Table A.11: Power Supply PCBA

Part Number	Description
P24174-XX	Service Assembly, Power Supply, Sonosite PX

Table A.12: Power Supply PCBA Associated Hardware

Part Number	Quantity	Description
P25951	4	SCREW,TRUSS,6 LOBE,M3-0.5X18MM

Power In Aux Board PCBA

Figure A.8 Power In Aux Board PCBA

Table A.13: Power In Aux Board PCBA

Part Number	Description
P24915-XX	Service Assembly, Power in Aux Board PCBA, Sonosite PX

Table A.14: Power In Aux PCBA Associated Hardware

Part Number	Quantity	Description
P27078	1	Power In plug gasket
P27116	1	Power In Cap
P25922	2	SCREW,FLAT,6 LOBE,M3-0.5X6MM

Power Button With ECG PCBA

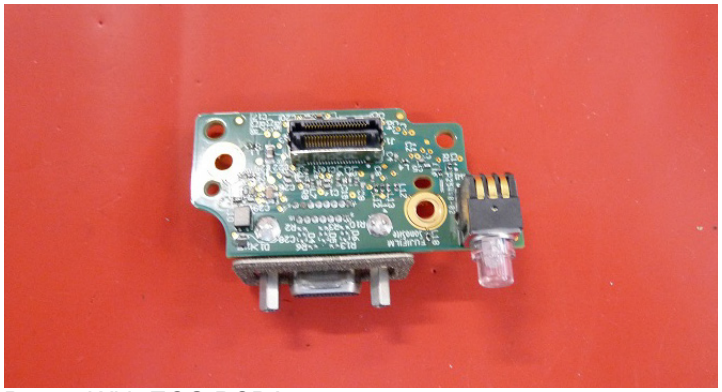


Figure A.9 Power Button With ECG PCBA

Table A.15: Power Button With ECG PCBA

Part Number	Description
P27479-XX	Service Assembly, Power Button With ECG PCBA, Sonosite PX

Table A.16: Power Button With ECG PCBA Associated Hardware

Part Number	Quantity	Description
P25945	2	SCREW,PAN,6 LOBE,M2.5-0.45X5MM
P25806	1	Flex Interconnect PCBA

USB Aux Board PCBA

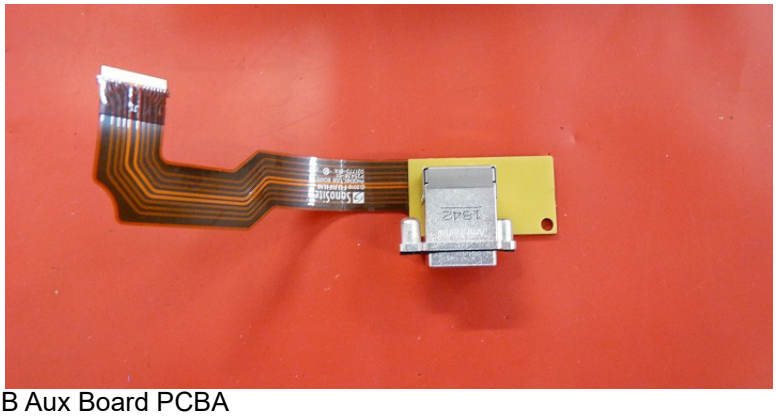


Figure A.10 USB Aux Board PCBA

Table A.17: USB Aux Board PCBA

Part Number	Description
P24939-XX	Service Assembly, USB Aux Board PCBA, Sonosite PX

Table A.18: USB Aux Board PCBA Associated Hardware

Part Number	Quantity	Description
P25992	2	SCREW,FLAT,6 LOBE,M3-0.5X6MM

SHIF PCBA

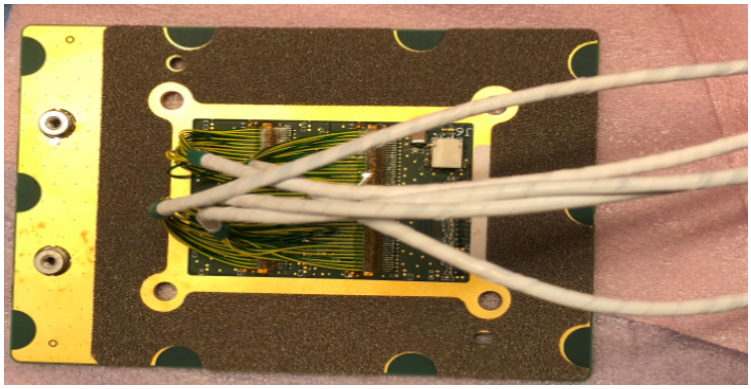


Figure A.11 SHIF PCBA

Table A.19: SHIF PCBA

Part Number	Description
P25394-XX	SHIF PCBA, Sonosite PX

System Dock PCBA

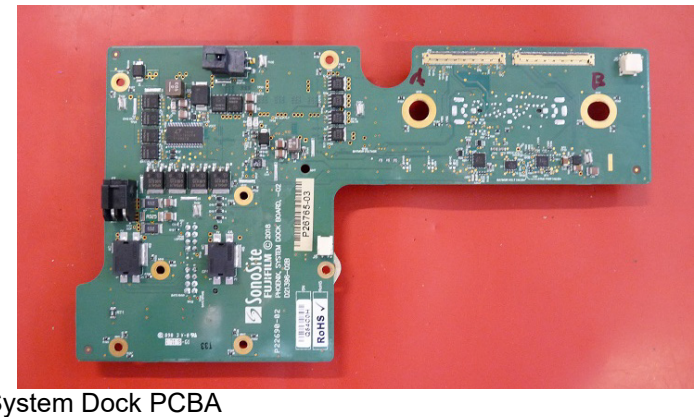


Figure A.12 System Dock PCBA

Table A.20: System Dock PCBA

Part Number	Description
P25394-XX	Service Assembly, System Dock PCBA, Sonosite PX

Table A.21: **System Dock PCBA Associated Hardware**

Part Number	Quantity	Description
P25945	7	SCREW,PAN,6 LOBE,M2.5-0.45X5MM

Optional Equipment

Sony UP-X898MD B&W Printer

Figure A.13 Sony UP-X898MD B&W Printer

Table A.22: Sony UP-X898MD B&W Printer & Hardware

Part Number	Description
P20006	Sony UP-X898MD B&W Hybrid Graphic Printer
P27276	Screw, Hex, M6-1.0X12MM, Steel (x4)
P27577	Cable, USB A to B
P27599	Cable, AC Power

Ordering Replacement Parts

To order parts, contact Fujifilm Sonosite Technical Support as indicated in “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 ffss-service@fujifilm.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

Choose a Service Type

Choose a Part Status

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 SonoSite.

For SonoSite Use C	
Service Request	
Order Number	
RMA Number	
Work Order	

Enter complete contact information

Service Provider

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

Enter product information for the system being repaired

Device Description

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

Put the system configuration here. You can find this on the System Information Page

Problem Found

Enter DETAILED problem description here.

Service Performed

Performed By:		Date:	

Parts Removed

Part Name	Part Number	Serial Number	Lot Number	Rev	Replace

Enter details for parts being removed from the system.

Enter details for parts being installed into the system.

Parts Installed

Part Name	Part Number	Serial Number	Lot Number	Rev	Replace

Tests Performed (attach test data)

Test:	Test:

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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