PRODUCT INFORMATION & SAFETY GUIDE

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

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INTRODUCTION

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INTRODUCTION

The *X-Porte Product Information & Safety Guide* provides information on preparing and using the X-Porte ultrasound system. It also provides references for calculations, system specifications, and safety and acoustic output information.

The guide is intended for a user familiar with ultrasound. It does not provide training in sonography, ultrasound, or clinical practices. Before using the ultrasound system, you must receive such training.

See the applicable FUJIFILM SonoSite accessory user guide for information on using accessories and peripherals. See the manufacturer's instructions for specific information about peripherals.

Conventions

This guide follows these conventions:

- **WARNING** introduces precautions necessary to prevent injury or loss of life.
- **Caution** introduces precautions necessary to protect the products.
- Numbered steps in procedures must be performed in order.

Symbols and terms used on the system and transducer are explained in **CHAPTER 4** and the **GLOSSARY**.

Customer comments

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
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CHAPTER 1: SAFETY

This chapter contains general safety information that applies to the ultrasound system, transducers, accessories, and peripherals.

Ergonomic safety

These scanning guidelines are intended to assist you in the comfortable and effective use of your ultrasound system.

WARNING: To prevent musculoskeletal disorders, follow the guidelines in this section.

Use of an ultrasound system may be linked to musculoskeletal disorders (MSDs)[a,b,c].

Use of an ultrasound system is defined as the physical interaction between the operator, the ultrasound system, and the transducer.

When using an ultrasound system, as with many similar physical activities, you may experience occasional discomfort in your hands, fingers, arms, shoulders, eyes, back, or other parts of your body. However, if you experience symptoms such as constant or recurring discomfort, pain, throbbing, aching, tingling, numbness, burning sensation, or stiffness, do not ignore these warning signs. Promptly see a qualified health professional. Symptoms such as these can be linked with MSDs. MSDs can be painful and may result in potentially disabling injuries to the nerves, muscles, tendons, or other parts of the body. Examples of MSDs include carpal tunnel syndrome and tendonitis.

While researchers are not able to definitively answer many questions about MSDs, there is a general agreement that certain factors are associated with their occurrence including preexisting medical and physical conditions, overall health, equipment and body position while doing work, frequency of work, duration of work, and other physical activities that may facilitate the onset of MSDs[d]. This section provides guidelines that may help you work more comfortably and may reduce your risk of MSDs[e,f].

a. Magnavita, N., L. Bevilacqua, P. Mirk, A. Fileni, and N. Castellino. "Work-related Musculoskeletal Complaints in Sonologists." *Occupational Environmental Medicine*. 41:11 (1999), 981-988.
b. Craig, M. "Sonography: An Occupational Hazard?" *Journal of Diagnostic Medical Sonography.* 3 (1985), 121-125.
c. Smith, C.S., G.W. Wolf, G. Y. Xie, and M. D. Smith. "Musculoskeletal Pain in Cardiac Ultrasonographers: Results of a Random Survey." *Journal of American Society of Echocardiography*. (May1997), 357-362.
d. Wihlidal, L.M. and S. Kumar. "An Injury Profile of Practicing Diagnostic Medical Sonographers in Alberta." *International Journal of Industrial Ergonomics*. 19 (1997), 205-216.
e. Habes, D.J. and S. Baron. "Health Hazard Report 99-0093-2749." *University of Medicine and Dentistry of New Jersey*. (1999).
f. Vanderpool, H.E., E.A. Friis, B.S. Smith, and K.L. Harms. "Prevalence of Carpal Tunnel Syndrome and Other Work-related Musculoskeletal Problems in Cardiac Sonographers." *Journal of Medicine.* 35:6 (1993), 605-610.

Position the system

Minimize eye and neck strain

- If possible, position the system within reach.
- Adjust the angle of the clinical monitor or touch panel to minimize glare.
- Adjust the height so that the clinical monitor is at or slightly below eye level.

Position yourself

Support your back during an exam

- Use a chair that supports your lower back, that adjusts to your work surface height, that promotes a natural body posture, and that allows quick height adjustments.
- Always sit or stand upright. Avoid bending or stooping.

Minimize reaching and twisting

- Use a bed that is height adjustable.
- Position the patient as close to you as possible.
- Face forward. Avoid twisting your head or body.
- Move your entire body front to back, and position your scanning arm next to or slightly in front of you.
- Stand for difficult exams to minimize reaching.
- Position the monitor directly in front of you.

Promote comfortable shoulder and arm postures

- Keep your elbow close to your side.
- Relax your shoulders in a level position.
- Support your arm using a support cushion or pillow, or rest it on the bed.

Promote comfortable hand, wrist, and finger postures

- Hold the transducer lightly in your fingers.
- Minimize the pressure applied on the patient.
- Keep your wrist in a straight position.

Take breaks, exercise, and vary activities

- Minimizing scanning time and taking breaks can effectively allow your body to recover from physical activity and help you avoid MSDs. Some ultrasound tasks may require longer or more frequent breaks. However, simply changing tasks can help some muscle groups relax while others remain or become active.
- Work efficiently by using the software and hardware features correctly.

- Keep moving. Avoid sustaining the same posture by varying your head, neck, body, arm, and leg positions.
- Do targeted exercises. Targeted exercises can strengthen muscle groups, which may help you avoid MSDs. Contact a qualified health professional to determine stretches and exercises that are right for you.

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. *Note: AC-powered peripherals that may be used with the system are Class I and are individually protectively earthed. Ground bond testing may be conducted on each AC-powered peripheral.*
Internally powered equipment	Ultrasound system not connected to the AC supply
Type BF applied parts	Ultrasound transducers
Type CF applied parts	ECG module/ECG leads
IPX-7	Ultrasound transducers
IPX-8	Footswitch
Non AP/APG	Ultrasound system power supply, docking system, and peripherals. Equipment is not suitable for use in the presence of flammable anaesthetics.

Electrical safety

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

This system complies with the applicable medical equipment requirements published in the Canadian Standards Association (CSA), European Norm Harmonized Standards, and Underwriters Laboratories (UL) safety standards. See **CHAPTER 3, "SPECIFICATIONS AND STANDARDS."**

For maximum safety observe the following warnings and cautions.

WARNING:	To avoid the risk of injury, do not operate the system in the presence of flammable gasses or anesthetics. Explosion can result.
WARNING:	To avoid the risk of electrical shock or injury, do not open the system enclosures. All internal adjustments and replacements, 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 only be achieved when equipment is connected to a receptacle marked "Hospital Only" or "Hospital Grade" or the equivalent. The grounding wire must not be removed or defeated.
- This equipment must be connected only to a 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 or ECG leads, touch the patient.
- Do not touch the power supply and the patient at the same time.
- Do not touch any of the following:
  - The signal input/output connectors on the back of the ultrasound system.
  - The system transducer connector when the transducer or Triple Transducer Connect (TTC) is disconnected.
  - Any unused TTC transducer connector when the TTC is connected.
- 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 engine off when cleaning.
- Do not use any transducer that has been immersed beyond the specified cleaning or disinfection level. See **CHAPTER 5, "TROUBLESHOOTING AND MAINTENANCE."**
- Use only accessories and peripherals recommended by FUJIFILM SonoSite, including the power supply. Connection of accessories and peripherals not recommended by FUJIFILM SonoSite could result in electrical shock. Contact FUJIFILM SonoSite or your local representative for a list of accessories and peripherals available from or recommend by FUJIFILM SonoSite.

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

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

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

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

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.

Caution: Do not use the system if an error message appears on the image display: 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 holes on the front and back of the system.

Isolating the X-Porte ultrasound system from power

The X-Porte ultrasound system does not become completely isolated from power by pressing the Power button. The only way to completely remove power is to press the Power button, disconnect the AC input power cord from the stand base, and set all three battery switches to the off position.

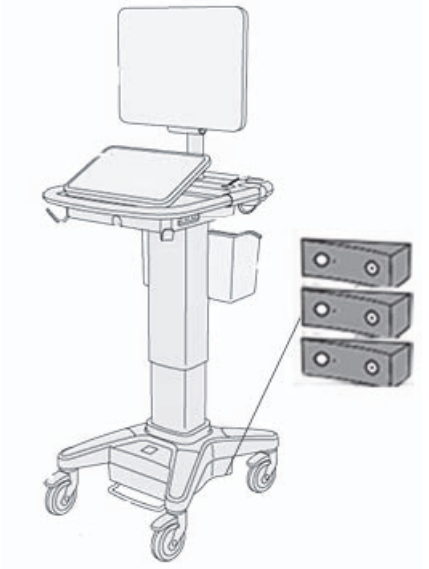
To isolate the system from power

1. Press the Power button.
2. Listen for the audio tone.

Caution: Unplugging the AC power cord before you hear the tone may result in loss of data. If you don't hear a tone, then your system may be set up to mute all sounds. To reinstate sounds, see the topic titled "Audio settings" in the X-Porte Help.

3. Disconnect the AC input power cord from the stand base.

4 Set all three battery switches to the off position.



Equipment safety

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

WARNING:	When transporting your system, to avoid possible injury from the system tipping, always collapse 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 *Cleaning and Disinfecting X-Porte Products*.
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:	Do not spill liquid on the system.
Caution:	Position the system to allow access to the mains power-cord connector.
Caution:	At high elevations (greater than 1948 meters / 6391 feet above sea level), always operate the ultrasound engine in the stand.

Clinical safety

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

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

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

WARNING: Some transducer sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals. 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 attentuation 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 high-level 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 device damage or patient injury, do not use the P21xp needle guide bracket on patients with pacemakers or medical electronic implants. The needle guide bracket for the P21xp transducers contains a magnet that is used to ensure the bracket is correctly oriented on the transducer. The magnetic field in direct proximity to the pacemaker or medical electronic implant may have an adverse effect.

Hazardous materials

WARNING: Products and accessories may contain hazardous materials. When disposing of products and accessories, be environmentally responsible 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 60601-1-2:2007. 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 FUJIFILM SonoSite. See **"Compatible accessories and peripherals"** on page 17.

Caution: Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency (RF) electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources, could result in performance disruption of the ultrasound system. Evidence of disruption may include image degradation or distortion, erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site to determine the source of disruption, and take the following actions to eliminate the source(s).

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

Caution: 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.

Wireless transmission

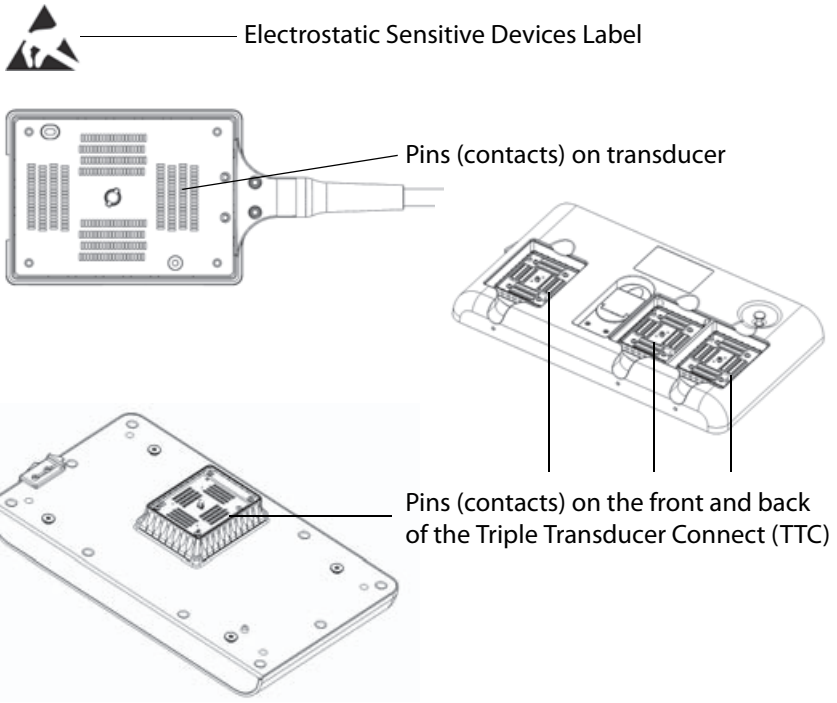
The X-Porte ultrasound system contains an IEEE 802.11 transmitter that utilizes the ISM frequency bands from 2.412 to 2.484GHz or 4.915 to 5.824 GHz. It implements four different methods of transmission:

- IEEE 802.11a (4.915 to 5.824 GHz) with Orthogonal Frequency Division Multiplexing (OFDM) at 11 dBm $\pm$ 1.5 dBm @ 54 Mbps
- IEEE 802.11b (2.412 to 2.484GHz) with Direct Sequence Spread Spectrum (DSSS) at 16 dBm $\pm$ 1.5 dBm @ 11 Mbps
- IEEE 802.11g (2.412 to 2.484GHz) with Orthogonal Frequency Division Multiplexing (ODFM) at 13 dBm $\pm$ 1.5 dBm @ 54 Mbps
- IEEE 802.11n (2.412 to 2.484GHz or 4.915 to 5.824 GHz) Orthogonal Frequency Division Multiplexing (ODFM) at 10 dBm $\pm$ 1.5 dBm (802.11an) or at 12 dBm $\pm$ 1.5 dBm (802.11gn)

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.

WARNING: Unless following ESD precautionary procedures, do not connect to or touch (with body or hand-held tools) pins (contacts) of connectors that have the ESD Sensitive Devices label:



If the symbol is on a border surrounding multiple connectors, the symbol pertains to all connectors within the border.

ESD precautionary procedures include the following:

- All staff involved must receive training about ESD, including the following at a minimum: an explanation of the ESD warning symbol, ESD precautionary procedures, an introduction to the physics of electrostatic charge, the voltage levels that can occur in normal practice, and the damage that can occur to electronic components if equipment is touched by an individual who is electrostatically charged (IEC 60601-1-2, section 5.2.1.2 d).
- Prevent the buildup of electrostatic charge. For example, use humidification, conductive floor coverings, nonsynthetic clothing, ionizers, and minimizing insulating materials.
- Discharge your body to earth.
- Use a wrist strap to bond yourself to the ultrasound system or to earth.

Separation distance

Recommended separation distances between portable and mobile RF communications equipment and the X-Porte ultrasound system

The X-Porte 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 X-Porte ultrasound system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the X-Porte ultrasound system as recommended below, according to the maximum output power of the communications equipment.

Table 1: Separation distance

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.

Compatible accessories and peripherals

FUJIFILM SonoSite has tested the X-Porte ultrasound system with the following accessories and peripherals and has demonstrated compliance to the requirements of IEC 60601-1-2:2007.

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

WARNING: Use of the accessories with medical systems other than the X-Porte ultrasound system may result in increased emissions or decreased immunity of the medical system.

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

Table 2: Accessories and peripherals compatible with X-Porte ultrasound system

Description	Maximum Cable Length
L25xp transducer	7.25 ft / 2.2 m
L38xp transducer	5.5 ft / 1.7 m
P21xp transducer	5.75 ft / 1.75 m
ICTxp transducer	5.5 ft / 1.7 m
HFL50xp transducer	5.5 ft / 1.7 m
C60xp transducer	5.5 ft / 1.7 m
Bar code scanner	4.8 ft/ 1.5 m
Batteries (set of 3)	-
Clinical monitor	-
Dock	-
DVR USB flash memory (64 GB)	-
ECG lead wires	24 in / 0.6 m (USA/Japan) 24 in / 0.6 m (EU)
ECG module	5.8 ft / 1.8 m (USA) 5.8 ft / 1.8 m (Japan) 5.8 ft / 1.8 m (EU)
Ethernet cable	10 ft / 3 m
Footswitch	10 ft / 3 m
Kensington security cable	6 ft / 1.8 m
Power Park Docking Station	-

Table 2: Accessories and peripherals compatible with X-Porte ultrasound system (Continued)

Printer (black and white)	-
SPMU (Stand Power Management Unit)	-
Stand	-
Stand power cord	10 ft / 3.1 m
Touch panel	-
Triple Transducer Connect	-
Ultrasound engine	-
USB flash memory (16 GB)	-
USB flash memory (32 GB)	-
USB flash memory (64 GB)	-
Isolation transformer (desktop configuration only)	-
Power cord, isolation transformer (desktop configuration only)	6 ft / 1.8 m
Monitor pedestal mount (desktop configuration only)	
Power supply, monitor (desktop configuration only)	6 ft / 1.8
Power supply (engine, desktop configuration only)	4 ft / 1.2 m
Power cords (engine and monitor, desktop configuration only)	3.3 ft / 1 m
Mouse (desktop configuration only)	6 ft / 1.8 m
Digital video cable (desktop configuration only)	22.5 in / 0.57 m

Manufacturer's declaration

Table 3 and **Table 4** 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 this table.

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

Table 3: Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The X-Porte ultrasound system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The X-Porte 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	

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

Table 4: Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	± 2.0KV, ± 4.0KV, ± 6.0KV contact ± 2.0KV, ± 4.0KV, ± 8.0KV air	± 2.0KV, ± 4.0KV, ± 6.0KV contact ± 2.0KV, ± 4.0KV, ± 8.0KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient burst IEC 61000-4-4	± 2KV on the mains ± 1KV on signal lines	± 2KV on the mains ± 1KV on signal lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1KV line(s) to line(s) ± 2KV line(s) to earth	± 1KV line(s) to line(s) ± 2KV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles *70*% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles *70*% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FUJIFILM SonoSite ultrasound system requires continued operation during power mains interruptions, it is recommended that the FUJIFILM SonoSite ultrasound system be powered from an uninterruptible power supply or a battery.

Table 4: Manufacturer's Declaration - Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
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 FUJIFILM 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	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the FUJIFILM SonoSite ultrasound system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 Vim 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).

Table 4: Manufacturer's Declaration - Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
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")

Note: U_T is the AC mains voltage prior to application of the test level.

At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

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

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

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

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

Immunity testing requirements

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

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

CHAPTER 2: ACOUSTIC OUTPUT

This chapter contains information about the ALARA (as low as reasonably achievable) principle, the output display standard, and acoustic power and intensity tables. The information applies to the ultrasound system, transducer, accessories, and peripherals.

ALARA principle

ALARA is the guiding principle for the use of diagnostic ultrasound. Sonographers and other qualified ultrasound users, using good judgment and insight, determine the exposure that is "as low as reasonably achievable." There are no set rules to determine the correct exposure for every situation. The qualified ultrasound user determines the most appropriate way to keep exposure low and bioeffects to a minimum, while obtaining a diagnostic examination.

A thorough knowledge of the imaging modes, transducer capability, system setup and scanning technique is necessary. The imaging mode determines the nature of the ultrasound beam. A stationary beam results in a more concentrated exposure than a scanned beam, which spreads that exposure over that area. The transducer capability depends upon the frequency, penetration, resolution, and field of view. The default system presets are reset at the start of each new patient. It is the scanning technique of the qualified ultrasound user along with patient variability that determines the system settings throughout the exam.

The variables which affect the way the qualified ultrasound user implements the ALARA principle include patient body size, location of the bone relative to the focal point, attenuation in the body, and ultrasound exposure time. Exposure time is an especially useful variable, because the qualified ultrasound user can control it. The ability to limit the exposure over time supports the ALARA principle.

Applying the ALARA principle

The system imaging mode selected by the qualified ultrasound user is determined by the diagnostic information required. 2D imaging provides anatomical information; CPD imaging provides information about the energy or amplitude strength of the Doppler signal over time at a given anatomical location and is used for detecting the presence of blood flow; Color imaging provides information about the energy or amplitude strength of the Doppler signal over time at a given anatomical location and is used for detecting the presence, velocity, and direction of blood flow; Tissue Harmonic Imaging uses higher received frequencies to reduce clutter, artifact, and improve resolution on the 2D image. Understanding the nature of the imaging mode used allows the qualified ultrasound user to apply the ALARA principle.

Prudent use of ultrasound means limiting ultrasound to situations in which it is medically useful and limiting patient exposure to the lowest ultrasound output for the shortest time necessary to achieve acceptable diagnostic results. Although there are no direct user controls for acoustic output, users can indirectly control output by varying depth. Decisions that support prudent use are based on the type of patient, exam type, patient history, ease or difficulty of obtaining diagnostically useful information, and potential localized heating of the patient due to transducer surface temperature.

The system has been designed to ensure that temperature at the face of the transducer will not exceed the limits established in Section 42 of EN 60601-2-37: Particular requirement for the safety of ultrasound medical diagnostic and monitoring equipment. See **"Transducer surface temperature rise"** on page 30. In the event of a device malfunction, there are redundant controls that limit transducer power. This is accomplished by an electrical design that limits both power supply current and voltage to the transducer.

The sonographer uses the system controls to adjust image quality and limit ultrasound output. The system controls are divided into three categories relative to output: controls that directly affect output, controls that indirectly affect output, and receiver controls.

Direct, indirect, and receiver controls

Direct controls The system does not have a direct user control for output. Rather, the system has been designed to automatically adjust output to ensure that acoustic and thermal limits are not exceeded for all imaging modes. Since there is no direct user control for output, the sonographer should rely on controlling exposure time and scanning technique to implement the ALARA principle.

The system does not exceed a spatial peak temporal average intensity (ISPTA) of 720 mW/cm^2 for all imaging modes. The mechanical index (MI) and thermal index (TI) may exceed values greater than 1.0 on some transducers in some imaging modes. For either the Ophthalmic or Orbital exam, the acoustic output is limited to the following values: ISPTA does not exceed 50 mW/cm2; TI does not exceed 1.0, and MI does not exceed 0.23. Ultrasound users can monitor the MI and TI values on the right side of the clinical monitor and implement the ALARA principle accordingly. For more information on MI and TI, see BS EN 60601-2-37:2001: Annex HH.

Indirect controls The controls that indirectly affect output are controls affecting imaging mode, freeze, and depth. The imaging mode determines the nature of the ultrasound beam. Freeze stops all ultrasound output but keeps the last image displayed on screen. Freeze can by used by the ultrasound user to limit exposure time while studying an image and maintaining probe position during a scan. Some controls, such as depth, show a rough correspondence with output, and may be used as a general means for indirectly reducing MI or TI. See **"Guidelines for reducing MI and TI"** on page 27.

Receiver controls The receiver controls are the gain controls. Receiver controls do not affect output. They should be used, if possible, to improve image quality before using controls that directly or indirectly affect output.

Acoustic artifacts

An acoustic artifact is information, present or absent in an image, that does not properly indicate the structure or flow being imaged. There are helpful artifacts that aid in diagnosis and those that hinder proper interpretation. Examples of artifacts include shadowing, through transmission, aliasing, reverberations, and comet tails

For more information on detecting and interpreting acoustic artifacts, see the following reference:

Kremkau, Frederick W. *Diagnostic Ultrasound: Principles and Instruments*. 7th ed., W.B. Saunders Company, (Oct. 17, 2005).

Guidelines for reducing MI and TI

The following are general guidelines for reducing MI or TI. If multiple parameters are given, the best results may be achieved by minimizing these parameters simultaneously. In some modes changing these parameters does not affect MI or TI. Changes to other parameters may also result in MI and TI reductions. Please note the MI and TI values on the right side of the screen.

Table 1: Guidelines for Reducing MI

Transducer	Depth
C60xp	↑
HFL50xp	↑
ICTxp	↑
L25xp	↑
L38xp	↑
P21xp	↑

↓ Decrease or lower setting of parameter to reduce MI.
↑ Increase or raise setting of parameter to reduce MI.

Table 2: Guidelines for Reducing TI (TIS, TIC, TIB)

Transducer	CPD Settings						PW Settings
	Box Width	Box Height	Box Depth	PRF	Depth	Optimize	
C60xp	↑		↑				↑ (Depth)
HFL50xp	↑		↑				↓ (Depth)
ICTxp			↑				↑ (Depth)
L25xp			↑				↓ (Depth)
L38xp			↑				↓ (Depth)
P21xp			↑				↓ (PRF)

↓ Decrease or lower setting of parameter to reduce TI.
↑ Increase or raise setting of parameter to reduce TI.

Output display

The system meets the AIUM (American Institute of Ultrasound in Medicine) output display standard for MI and TI (see **"Related guidance documents"** on page 29). **Table 3** indicates for each transducer and operating mode when either the TI or MI is greater than or equal to a value of 1.0, thus requiring display.

Table 3: TI or MI ≥ 1.0

Transducer Model	Index	2D/ M Mode	CPD/ Color	PW Doppler	CW Doppler
C60xp	MI	Yes	Yes	Yes	-
	TIC, TIB, or TIS	Yes	Yes	Yes	-
HFL50xp	MI	Yes	Yes	No	-
	TIC, TIB, or TIS	No	No	Yes	-
ICTxp	MI	Yes	No	Yes	-
	TIC, TIB, or TIS	No	No	Yes	-
L25xp	MI	Yes	Yes	No	-
	TIC, TIB, or TIS	No	No	Yes	-
L38xp	MI	Yes	Yes	Yes	-
	TIC, TIB, or TIS	Yes	No	Yes	-
P21xp	MI	Yes	Yes	Yes	No
	TIC, TIB, or TIS	Yes	Yes	Yes	Yes

Even if MI is less than 1.0, the system provides a continuous real-time display of MI in all imaging modes, in increments of 0.1.

The system meets the output display standard for TI and provides a continuous real-time display of TI in all imaging modes, in increments of 0.1.

The TI consists of three user-selectable indices, and only one of these is displayed at any one time. In order to display TI properly and meet the ALARA principle, the user selects an appropriate TI based on the specific exam being performed. FUJIFILM SonoSite provides a copy of *AIUM Medical Ultrasound Safety*, which contains guidance on determining which TI is appropriate (See **"Related guidance documents"** on page 29).

MI and TI output display accuracy

The accuracy result for the MI is stated statistically. With 95% confidence, 95% of the measured MI values will be within +18% to -25% of the displayed MI value, or +0.2 of the displayed value, whichever value is larger.

The accuracy result for the TI is stated statistically. With 95% confidence, 95% of the measured TI values will be within +21% to -40% of the displayed TI value, or +0.2 of the displayed value, whichever value is larger. The values equate to +1dB to -3dB.

A displayed value of 0.0 for MI or TI means that the calculated estimate for the index is less than 0.05.

Factors that contribute to display uncertainty

The net uncertainty of the displayed indices is derived by combining the quantified uncertainty from three sources: measurement uncertainty, system and transducer variability, and engineering assumptions and approximations made when calculating the display values.

Measurement errors of the acoustic parameters when taking the reference data are the major source of error that contributes to the display uncertainty. The measurement error is described in **"Acoustic measurement precision and uncertainty"** on page 54.

The displayed MI and TI values are based on calculations that use a set of acoustic output measurements that were made using a single reference ultrasound system with a single reference transducer that is representative of the population of transducers of that type. The reference system and transducer are chosen from a sample population of systems and transducers taken from early production units, and they are selected based on having an acoustic output that is representative of the nominal expected acoustic output for all transducer-system combinations that might occur. Of course every transducer-system combination has its own unique characteristic acoustic output, and will not match the nominal output on which the display estimates are based. This variability between systems and transducers introduces an error into displayed value. By doing acoustic output sampling testing during production, the amount of error introduced by the variability is bounded. The sampling testing ensures that the acoustic output of transducers and systems being manufactured stays within a specified range of the nominal acoustic output.

Another source of error arises from the assumptions and approximations that are made when deriving the estimates for the display indices. Chief among these assumptions is that the acoustic output, and thus the derived display indices, are linearly correlated with the transmit drive voltage of the transducer. Generally, this assumption is very good, but it is not exact, and thus some error in the display can be attributed to the assumption of voltage linearity.

Related guidance documents

Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, 1997.

Medical Ultrasound Safety, American Institute of Ultrasound in Medicine (AIUM), 1994. (A copy is included with each system.)

Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, NEMA UD2-2004.

Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine, 1993.

Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, NEMA UD3-2004.

Guidance on the interpretation of TI and MI to be used to inform the operator, Annex HH, BS EN 60601-2-37 reprinted at P05699.

Transducer surface temperature rise

Table 4 and **Table 5** list the measured surface temperature rise from ambient (23°C ± 3°C) of transducers used on the ultrasound system. The temperatures were measured in accordance with EN 60601-2-37 with controls and settings positioned to give maximum temperatures.

Table 4: Transducer Surface Temperature Rise, External Use (°C)

Test	C60xp	HFL50xp	L25xp	L38xp	P21xp
Still air	12.2°C	11.1°C	12.8°C	11.5°C	14.7°C
Simulated Use	8.2 (≤10°C)	9.0 (≤10°C)	8.6 (≤10°C)	8.8 (≤10°C)	9.5 (≤10°C)

Table 5: Transducer Surface Temperature Rise, Non-External Use (°C)

Test	ICTxp
Still air	8.9
Simulated Use	4.7 (<6°C)

Acoustic output measurement

Since the initial use of diagnostic ultrasound, the possible human biological effects (bioeffects) from ultrasound exposure have been studied by various scientific and medical institutions. In October 1987, AIUM ratified a report from its Bioeffects Committee (Bioeffects Considerations for the Safety of Diagnostic Ultrasound, J Ultrasound Med., Sept. 1988: Vol. 7, No. 9 Supplement). The report, sometimes referred to as *the Stowe Report*, reviewed available data on possible effects of ultrasound exposure. Another report, "Bioeffects and Safety of Diagnostic Ultrasound," dated January 28, 1993, provides more current information.

The acoustic output for this ultrasound system has been measured and calculated in accordance with "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (NEMA UD2-2004), and "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment" (NEMA UDe3-2004).

In Situ, derated, and water value intensities

All intensity parameters are measured in water. Since water does not absorb acoustic energy, these water measurements represent a worst case value. Biological tissue does absorb acoustic energy. The true value of the intensity at any point depends on the amount, type of tissue, and the frequency of the ultrasound passing through the tissue. The intensity value in the tissue, *In Situ*, has been estimated by using the following formula:

In Situ= Water $e^{-(0.23alf)}$]

where:

In Situ = *In Situ* intensity value

Water = Water intensity value

e = 2.7183

a = attenuation factor (dB/cm MHz)

Attenuation factor (a) for various tissue types are given below:

brain = 0.53

heart = 0.66

kidney = 0.79

liver = 0.43

muscle = 0.55

l = skinline to measurement depth in cm

f = center frequency of the transducer/system/mode combination in MHz

Since the ultrasonic path during the exam is likely to pass through varying lengths and types of tissue, it is difficult to estimate the true *In Situ* intensity. An attenuation factor of 0.3 is used for general reporting purposes; therefore, the *In Situ* value commonly reported uses the formula:

In Situ (derated) = Water $e^{-(0.069lf)}$]

Since this value is not the true *In Situ* intensity, the term "derated" is used to qualify it.

The maximum derated and the maximum water values do not always occur at the same operating conditions; therefore, the reported maximum water and derated values may not be related by the *In Situ* (derated) formula. For example: a multi-zone array transducer that has maximum water value intensities in its deepest zone, but also has the smallest derating factor in that zone. The same transducer may have its largest derated intensity in one of its shallowest focal zones.

Tissue models and equipment survey

Tissue models are necessary to estimate attenuation and acoustic exposure levels *In Situ* from measurements of acoustic output made in water. Currently, available models may be limited in their accuracy because of varying tissue paths during diagnostic ultrasound exposures and uncertainties in the acoustic properties of soft tissues. No single tissue model is adequate for predicting exposures in all situations from measurements made in water, and continued improvement and verification of these models is necessary for making exposure assessments for specific exam types.

A homogeneous tissue model with attenuation coefficient of 0.3 dB/cm MHz throughout the beam path is commonly used when estimating exposure levels. The model is conservative in that it overestimates the *In Situ* acoustic exposure when the path between the transducer and site of interest is composed entirely of soft tissue. When the path contains significant amounts of fluid, as in many first and second-trimester pregnancies scanned transabdominally, this model may underestimate the *In Situ* acoustic exposure. The amount of underestimation depends upon each specific situation.

Fixed-path tissue models, in which soft tissue thickness is held constant, sometimes are used to estimate *In Situ* acoustic exposures when the beam path is longer than 3 cm and consists largely of fluid. When this model is used to estimate maximum exposure to the fetus during transabdominal scans, a value of 1 dB/cm MHz may be used during all trimesters.

Existing tissue models that are based on linear propagation may underestimate acoustic exposures when significant saturation due to non-linear distortion of beams in water is present during the output measurement.

The maximum acoustic output levels of diagnostic ultrasound devices extend over a broad range of values:

- A survey of 1990-equipment models yielded MI values between 0.1 and 1.0 at their highest output settings. Maximum MI values of approximately 2.0 are known to occur for currently available equipment. Maximum MI values are similar for real-time 2D and M Mode imaging.
- Computed estimates of upper limits to temperature elevations during transabdominal scans were obtained in a survey of 1988 and 1990 pulsed Doppler equipment. The vast majority of models yielded upper limits less than 1° and 4°C (1.8° and 7.2°F) for exposures of first-trimester fetal tissue and second-trimester fetal bone, respectively. The largest values obtained were approximately 1.5°C (2.7°F) for first-trimester fetal tissue and 7°C (12.6°F) for second-trimester fetal bone. Estimated maximum temperature elevations given here are for a "fixed path" tissue model and are for devices having I_{SPTA} values greater than 500 mW/cm^2. The temperature elevations for fetal bone and tissue were computed based on calculation procedures given in Sections 4.3.2.1-4.3.2.6 in "Bioeffects and Safety of Diagnostic Ultrasound" (AIUM, 1993).

Acoustic output tables

Table 6 through **Table 27** indicate the acoustic output for the system and transducer combinations with a TI or MI equal to or greater than one. These tables are organized by transducer model and imaging mode. For a definition of terms used in the tables, see **"Terminology in acoustic output tables"** on page 79.

Table 6: Transducer Model: C60xp, Operating Mode: 2D

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.3	(a)	-	-	-	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.15					
	W_0	(mW)		#	-		-	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					-	
	$z@PII_{.3max}$	(cm)	4.4					
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	2.73	#	-	-	-	#
	Dim of A_{aprt}	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.517					
	PRF	(Hz)	6027					
	$p_r@PII_{max}$	(MPa)	3.26					
	$d_{eq}@PII_{max}$	(cm)					-	
	Focal Length	FL_x (cm)		#	-	-		#
		FL_y (cm)		#	-	-		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	322					
Operating Control Conditions	Control 1: Exam Type		Nrv					
	Control 2: Optimization		Diff					
	Control 3: Depth		9.9cm					
	Control 4: MB/THI		On/Off					

(a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 7: Transducer Model: C60xp, Operating Mode: M Mode

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	-	(a)	-	1.7	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.48					
	W_0	(mW)		-	#		55.0	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					4.90	
	z@$PII_{.3max}$	(cm)	4.2					
	$d_{eq}(z_{sp})$	(cm)					0.34	
	f_c	(MHz)	2.73	-	#	-	2.16	#
	Dim of A_{aprt}	X (cm)		-	#	-	1.87	#
		Y (cm)		-	#	-	1.30	#
Other Information	PD	(µsec)	0.534					
	PRF	(Hz)	800					
	p_r@PII_{max}	(MPa)	3.70					
	d_{eq}@PII_{max}	(cm)					0.33	
	Focal Length	FL_x (cm)		-	#	-		#
		FL_y (cm)		-	#	-		#
	$I_{PA.3}$@MI_{max}	(W/cm^2)	392					
Operating Control Conditions	Control 1: Exam Type		Abd				Abd	
	Control 2: Optimization		Diff				Avg	
	Control 3: Depth		7.7 cm				11 cm	
	Control 4: THI		Off				On	

(a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 8: Transducer Model: C60xp, Operating Mode: Color/CPD Mode

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.2	1.0	-	-	-	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	1.99					
	W_0	(mW)		81.3	-		-	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					-	
	z@$PII_{.3max}$	(cm)	4.4					
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	2.63	2.63	-	-	-	#
	Dim of A_{aprt}	X (cm)		0.81	-	-	-	#
		Y (cm)		1.3	-	-	-	#
Other Information	PD	(µsec)	1.415					
	PRF	(Hz)	2645					
	p_r@PII_{max}	(MPa)	2.96					
	d_{eq}@PII_{max}	(cm)					-	
	Focal Length	FL_x (cm)		2.71	-	-		#
		FL_y (cm)		6.5	-	-		#
	$I_{PA.3}$@MI_{max}	(W/cm^2)	346					
Operating Control Conditions	Control 1: Exam Type		ABD	OB				
	Control 2: Mode		Color	Color				
	Control 3: 2D Optimization/THI/Depth		Avg/On/11 cm	Avg/Off/6.0 cm				
	Control 4: Color Optimization/PRF		High/3049Hz	Low/414Hz				
	Control 5: Color Box Position/Size		Def/Wide & Tall	Def/Narrow				

(a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

—Data are not applicable for this transducer/mode.

Table 9: Transducer Model: C60xp, Operating Mode: PW Doppler

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.55	-	-	1.1	3.2	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.44					
	W_0	(mW)		-	-		66.9	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				84.1		
	z_1	(cm)				3.9		
	z_{bp}	(cm)				3.8		
	z_{sp}	(cm)					0.40	
	$z@PII_{.3max}$	(cm)	1.9					
	$d_{eq}(z_{sp})$	(cm)					0.45	
	f_c	(MHz)	2.64	-	-	2.67	2.67	#
	Dim of A_{aprt}	X (cm)		-	-	3.98	0.31	#
		Y (cm)		-	-	1.30	1.30	#
Other Information	PD	(µsec)	1.233					
	PRF	(Hz)	1302					
	$p_r@PII_{max}$	(MPa)	2.89					
	$d_{eq}@PII_{max}$	(cm)					0.45	
	Focal Length	FL_x (cm)		-	-	15.90		#
		FL_y (cm)		-	-	6.50		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	239					
Operating Control Conditions	Control 1: Exam Type		OB			OB	OB	
	Control 2: Sample Volume Size		1 mm			12 mm	12 mm	
	Control 3: Sample Volume Position		Zone 2			Zone 10	Zone 0	
	Control 4: PRF		1302 Hz			1302 Hz	2604 Hz	

(a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

\# No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 10: Transducer Model: ICTxp, Operating Mode: M Mode

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.1	-	(a)	-	(a)	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.46					
	W_0	(mW)		-	#		#	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	1.4					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	4.64	-	#	-	#	#
	Dim of A_{aprt}	X (cm)		-	#	-	#	#
		Y (cm)		-	#	-	#	#
Other Information	PD	(µsec)	0.322					
	PRF	(Hz)	1600					
	$p_r@PII_{max}$	(MPa)	3.07					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal Length	FL_x (cm)		-	#	-		#
		FL_y (cm)		-	#	-		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	347					
Operating Control Conditions	Control 1: Exam Type		Gyn					
	Control 2: Optimization		Diff					
	Control 3: Depth		4.1 cm					
	Control 4: THI		Off					

a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 11: Transducer Model: ICTxp, Operating Mode: PW Doppler

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.0	-	(a)	-	1.4	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.01					
	W_0	(mW)		-	#		19.8	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					1.66	
	$z@PII_{.3max}$	(cm)	1.4					
	$d_{eq}(z_{sp})$	(cm)					0.20	
	f_c	(MHz)	4.38	-	#	-	4.36	#
	Dim of A_{aprt}	X (cm)		-	#	-	0.72	#
		Y (cm)		-	#	-	0.50	#
Other Information	PD	(µsec)	1.144					
	PRF	(Hz)	1302					
	$p_r@PII_{max}$	(MPa)	2.49					
	$d_{eq}@PII_{max}$	(cm)					0.19	
	Focal Length	FL_x (cm)		-	#	-		#
		FL_y (cm)		-	#	-		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	263					
Operating Control Conditions	Control 1: Exam Type		OB				OB	
	Control 2: Sample Volume Size		1 mm				12 mm	
	Control 3: Sample Volume Position		Zone 2				Zone 3	
	Control 4: PRF		1302 Hz				1562 Hz	

(a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 12: Transducer Model: L25xp, Operating Mode: M Mode

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.0	-	(a)	-	(a)	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.67					
	W_0	(mW)		-	#		#	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					#	
	z@$PII_{.3max}$	(cm)	0.9					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	6.85	-	#	-	#	#
	Dim of A_{aprt}	X (cm)		-	#	-	#	#
		Y (cm)		-	#	-	#	#
Other Information	PD	(µsec)	0.207					
	PRF	(Hz)	800					
	p_r@PII_{max}	(MPa)	3.30					
	d_{eq}@PII_{max}	(cm)					#	
	Focal Length	FL_x (cm)		-	#	-		#
		FL_y (cm)		-	#	-		#
	$I_{PA.3}$@MI_{max}	(W/cm^2)	267					
Operating Control Conditions	Control 1: Exam Type		Ven					
	Control 2: Optimization		Diff					
	Control 3: Depth		3.5 cm					

(a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 13: Transducer Model: L25xp, Operating Mode: Color/CPD

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.1	(a)	-	-	-	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.64					
	W_0	(mW)		#	-		-	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					-	
	$z@PII_{.3max}$	(cm)	0.8					
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	6.11	#	-	-	-	#
	Dim of A_{aprt}	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.630					
	PRF	(Hz)	1599					
	$p_r@PII_{max}$	(MPa)	3.13					
	$d_{eq}@PII_{max}$	(cm)					-	
	Focal Length	FL_x (cm)		#	-	-		#
		FL_y (cm)		#	-	-		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	362					
Operating Control Conditions	Control 1: Exam Type		Msk					
	Control 2: Mode		CPD					
	Control 3: 2D Optimization/Depth		Avg/2.4 cm					
	Control 4: Color Optimization/PRF		Low/312 Hz					
	Control 5: Color Box Position/Size		Def/Narrow					

(a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 14: Transducer Model: L25xp, Operating Mode: PW Doppler

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			(a)	-	-	-	1.1	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	#					
	W_0	(mW)		-	-		14.8	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					1.40	
	z@$PII_{.3max}$	(cm)	#					
	$d_{eq}(z_{sp})$	(cm)					0.17	
	f_c	(MHz)	#	-	-	-	6.00	#
	Dim of A_{aprt}	X (cm)		-	-	-	0.60	#
		Y (cm)		-	-	-	0.30	#
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	p_r@PII_{max}	(MPa)	#					
	d_{eq}@PII_{max}	(cm)					0.16	
	Focal Length	FL_x (cm)		-	-	-		#
		FL_y (cm)		-	-	-		#
	$I_{PA.3}$@MI_{max}	(W/cm^2)	#					
Operating Control Conditions	Control 1: Exam Type						Ven	
	Control 2: Sample Volume Size						7 mm	
	Control 3: Sample Volume Position						Zone 6	
	Control 4: PRF						1562	

(a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 15: Transducer Model: L38xp, Operating Mode: 2D

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	(a)	-	-	-	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	3.32					
	W_0	(mW)		#	-		-	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					-	
	z@$PII_{.3max}$	(cm)	1.1					
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	4.83	#	-	-	-	#
	Dim of A_{aprt}	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.426					
	PRF	(Hz)	790					
	p_r@PII_{max}	(MPa)	4.02					
	d_{eq}@PII_{max}	(cm)					-	
	Focal Length	FL_x (cm)		#	-	-		#
		FL_y (cm)		#	-	-		#
	$I_{PA.3}$@MI_{max}	(W/cm^2)	622					
Operating Control Conditions	Control 1: Exam Type		Ven					
	Control 2: Optimization		Avg					
	Control 3: Depth		3.5 cm					
	Control 4:MB		On/Off					
	Control 5: Needle Profiling		On					

a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 16: Transducer Model: L38xp, Operating Mode: M Mode

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	-	1.5	-	2.0	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	3.37					
	W_0	(mW)		-	66.8		66.8	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					1.0	
	z@$PII_{.3max}$	(cm)	1.2					
	$d_{eq}(z_{sp})$	(cm)					0.62	
	f_c	(MHz)	5.22	-	4.40	-	4.40	#
	Dim of A_{aprt}	X (cm)		-	2.40	-	2.40	#
		Y (cm)		-	0.40	-	0.40	#
Other Information	PD	(µsec)	0.277					
	PRF	(Hz)	800					
	p_r@PII_{max}	(MPa)	4.18					
	d_{eq}@PII_{max}	(cm)					0.62	
	Focal Length	FL_x (cm)		-	7.02	-		#
		FL_y (cm)		-	1.50	-		#
	$I_{PA.3}$@MI_{max}	(W/cm^2)	538					
Operating Control Conditions	Control 1: Exam Type		Ven		Ven		Ven	
	Control 2: Optimization		Diff		Diff		Diff	
	Control 3: Depth		4.0 cm		9.0 cm		9.0 cm	

a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 17: Transducer Model: L38xp, Operating Mode: Color/CPD

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	(a)	-	-	-	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	3.20					
	W_0	(mW)		#	-		-	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					-	
	$z@PII_{.3max}$	(cm)	1.1					
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	4.63	#	-	-	-	#
	Dim of A_{aprt}	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.578					
	PRF	(Hz)	5064					
	$p_r@PII_{max}$	(MPa)	3.78					
	$d_{eq}@PII_{max}$	(cm)					-	
	Focal Length	FL_x (cm)		#	-	-		#
		FL_y (cm)		#	-	-		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	678					
Operating Control Conditions	Control 1: Exam Type		Ven					
	Control 2: Mode		Color					
	Control 3: 2D Optimization/Depth		Avg/3.5 cm					
	Control 4: Color Optimization/PRF		High/6250 Hz					
	Control 5: Color Box Position/Size		Def/Wide-Tall					

a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 18: Transducer Model: L38xp, Operating Mode: PW Doppler

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.0	-	2.0	-	2.9	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.21					
	W_0	(mW)		-	80.5		80.5	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					1.00	
	z@$PII_{.3max}$	(cm)	0.3					
	$d_{eq}(z_{sp})$	(cm)					0.43	
	f_c	(MHz)	5.28	-	5.33	-	5.33	#
	Dim of A_{aprt}	X (cm)		-	1.80	-	1.80	#
		Y (cm)		-	0.40	-	0.40	#
Other Information	PD	(µsec)	1.201					
	PRF	(Hz)	1562					
	p_r@PII_{max}	(MPa)	2.33					
	d_{eq}@PII_{max}	(cm)					0.40	
	Focal Length	FL_x (cm)		-	7.02	-		#
		FL_y (cm)		-	1.5	-		#
	$I_{PA.3}$@MI_{max}	(W/cm^2)	210					
Operating Control Conditions	Control 1: Exam Type		Nrv		Nrv		Nrv	
	Control 2: Sample Volume Size		1 mm		3 mm		3 mm	
	Control 3: Sample Volume Position		Zone 0		Zone 11		Zone 11	
	Control 4: PRF		1562 Hz		1562 Hz		1562 Hz	

a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 19: Transducer Model: HFL50xp, Operating Mode: 2D

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.1	(a)	-	-	-	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.61					
	W_0	(mW)		#	-		-	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					-	
	z@$PII_{.3max}$	(cm)	1.3					
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	5.30	#	-	-	-	#
	Dim of A_{aprt}	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.493					
	PRF	(Hz)	1084					
	p_r@PII_{max}	(MPa)	3.31					
	d_{eq}@PII_{max}	(cm)					-	
	Focal Length	FL_x (cm)		#	-	-		#
		FL_y (cm)		#	-	-		#
	$I_{PA.3}$@MI_{max}	(W/cm^2)	427					
Operating Control Conditions	Control 1: Exam Type		SmP					
	Control 2: Optimization		Avg					
	Control 3: Depth		4.8 cm					
	Control 4: MB		On/Off					
	Control 5: Needle Profiling		On					

a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 20: Transducer Model: HFL50xp, Operating Mode: M Mode

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.2	-	(a)	-	(a)	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	3.40					
	W_0	(mW)		-	#		#	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					#	
	z@$PII_{.3max}$	(cm)	1.1					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	7.82	-	#	-	#	#
	Dim of A_{aprt}	X (cm)		-	#	-	#	#
		Y (cm)		-	#	-	#	#
Other Information	PD	(µsec)	0.230					
	PRF	(Hz)	800					
	p_r@PII_{max}	(MPa)	4.51					
	d_{eq}@PII_{max}	(cm)					#	
	Focal Length	FL_x (cm)		-	#	-		#
		FL_y (cm)		-	#	-		#
	$I_{PA.3}$@MI_{max}	(W/cm^2)	401					
Operating Control Conditions	Control 1: Exam Type		Bre					
	Control 2: Optimization		Diff					
	Control 3: Depth		1.9 cm					

a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 21: Transducer Model: HFL50xp, Operating Mode: Color/CPD

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.1	(a)	-	-	-	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.62					
	W_0	(mW)		#	-		-	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					-	
	z@$PII_{.3max}$	(cm)	1.2					
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	5.93	#	-	-	-	#
	Dim of A_{aprt}	X (cm)		#	-	-	-	#
		Y (cm)		#	-	-	-	#
Other Information	PD	(µsec)	0.629					
	PRF	(Hz)	6649					
	p_r@PII_{max}	(MPa)	3.35					
	d_{eq}@PII_{max}	(cm)					-	
	Focal Length	FL_x (cm)		#	-	-		#
		FL_y (cm)		#	-	-		#
	$I_{PA.3}$@MI_{max}	(W/cm^2)	398					
Operating Control Conditions	Control 1: Exam Type		SmP					
	Control 2: Mode		CVD					
	Control 3: 2D Optimization/Depth		Avg/4.0 cm					
	Control 4: Color Optimization/PRF		High/7812 Hz					
	Control 5: Color Box Position/Size		Def/Wide and Tall					

a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 22: Transducer Model: HFL50xp, Operating Mode: PW Doppler

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			(a)	-	1.0	(a)	1.5	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	#					
	W_0	(mW)		-	33.7		23.0	#
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					1.68	
	$z@PII_{.3max}$	(cm)	#					
	$d_{eq}(z_{sp})$	(cm)					0.19	
	f_c	(MHz)	#	-	6.00	#	5.99	#
	Dim of A_{aprt}	X (cm)		-	1.20	#	0.72	#
		Y (cm)		-	0.40	#	0.40	#
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.18	
	Focal Length	FL_x (cm)		-	4.68	#		#
		FL_y (cm)		-	2.50	#		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Control 1: Exam Type				SmP		SmP	
	Control 2: Sample Volume Size				6 mm		1 mm	
	Control 3: Sample Volume Position				Zone 11		Zone 7	
	Control 4: PRF				1562 Hz		1953 Hz	

a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 23: Transducer Model: P21xp, Operating Mode: 2D

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	(a)	-	-	-	2.0
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.02					
	W_0	(mW)		#	-		-	146.2
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					-	
	z@$PII_{.3max}$	(cm)	4.1					
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	1.85	#	-	-	-	2.09
	Dim of A_{aprt}	X (cm)		#	-	-	-	2.10
		Y (cm)		#	-	-	-	1.30
Other Information	PD	(µsec)	1.134					
	PRF	(Hz)	2933					
	p_r@PII_{max}	(MPa)	2.63					
	d_{eq}@PII_{max}	(cm)					-	
	Focal Length	FL_x (cm)		#	-	-		18.94
		FL_y (cm)		#	-	-		9.00
	$I_{PA.3}$@MI_{max}	(W/cm^2)	240					
Operating Control Conditions	Control 1: Exam Type		Crd					Crd
	Control 2: Optimization		Avg					Diff
	Control 3: Depth		9.0 cm					35 cm
	Control 4: MB/THI		Off/On					Off/On
	Control 5: Sector Size		Full					Narrow

a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 24: Transducer Model: P21xp, Operating Mode: M Mode

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	-	(a)	-	1.9	1.4
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.02					
	W_0	(mW)		-	#		61.1	107.0
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					5.00	
	$z@PII_{.3max}$	(cm)	4.1					
	$d_{eq}(z_{sp})$	(cm)					0.36	
	f_c	(MHz)	1.85	-	#	-	1.99	2.14
	Dim of A_{aprt}	X (cm)		-	#	-	2.10	2.10
		Y (cm)		#	-	-	1.30	1.30
Other Information	PD	(µsec)	1.134					
	PRF	(Hz)	800					
	$p_r@PII_{max}$	(MPa)	2.63					
	$d_{eq}@PII_{max}$	(cm)					0.35	
	Focal Length	FL_x (cm)		-	#	-		22.01
		FL_y (cm)		-	#	-		9.00
	$I_{PA.3}@MI_{max}$	(W/cm^2)	240					
Operating Control Conditions	Control 1: Exam Type		Crd				Abd	Abd
	Control 2: Optimization		Avg				Avg	Diff
	Control 3: Depth		9.0 cm				11 cm	35 cm
	Control 4: THI		On				On	Off

a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 25: Transducer Model: P21xp, Operating Mode: Color/CPD

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	2.4	-	-		2.8
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.02					
	W_0	(mW)		141.3	-		-	150.9
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					-	
	$z@PII_{.3max}$	(cm)	4.1					
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	1.85	2.03	-	-	-	2.03
	Dim of A_{aprt}	X (cm)		0.33	-	-	-	0.33
		Y (cm)		1.30	-	-	-	1.30
Other Information	PD	(µsec)	1.134					
	PRF	(Hz)	800					
	$p_r@PII_{max}$	(MPa)	2.63					
	$d_{eq}@PII_{max}$	(cm)					-	
	Focal Length	FL_x (cm)		1.30	-	-		1.30
		FL_y (cm)		9.0	-	-		9.0
	$I_{PA.3}@MI_{max}$	(W/cm^2)	240					
Operating Control Conditions	Control 1: Exam Type		Crd	Abd				Abd
	Control 2: Mode		Color	Color				Color
	Control 3: 2D Optimization/ THI/Depth		Avg/On/9.0 cm	Avg/Off/5.0 cm				Avg/Off/5.0 cm
	Control 4: Color Optimization/PRF		Low/880 Hz	High/2500 Hz				High/2500 Hz
	Control 5: Color Box Position/Size		Top/Short-Wide	Top/Def				Top/Def

a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 26: Transducer Model: P21xp, Operating Mode: PW Doppler

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	-	-	1.3	3.7	2.8
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.15					
	W_0	(mW)		-	-		204.3	82.3
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				126.9		
	z_1	(cm)				3.1		
	z_{bp}	(cm)				2.8		
	z_{sp}	(cm)					3.90	
	$z@PII_{.3max}$	(cm)	1.4					
	$d_{eq}(z_{sp})$	(cm)					0.71	
	f_c	(MHz)	2.07	-	-	2.09	2.09	2.08
	Dim of A_{aprt}	X (cm)		-	-	2.10	2.10	0.33
		Y (cm)		-	-	1.30	1.30	1.30
Other Information	PD	(µsec)	1.195					
	PRF	(Hz)	1562					
	$p_r@PII_{max}$	(MPa)	2.37					
	$d_{eq}@PII_{max}$	(cm)					0.49	
	Focal Length	FL_x (cm)		-	-	14.01		1.30
		FL_y (cm)		-	-	9.0		9.0
	$I_{PA.3}@MI_{max}$	(W/cm^2)	184					
Operating Control Conditions	Control 1: Exam Type		Abd			Crd	Abd	Abd
	Control 2: Sample Volume Size		0 mm			14 mm	14 mm	7 mm
	Control 3: Sample Volume Position		Zone 1			Zone 8	Zone 8	Zone 0
	Control 4: PRF		1562 Hz			1562 Hz	1562 Hz	1953 Hz
	Control 5: TDI		-			Off	-	-

a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Table 27: Transducer Model: P21xp, Operating Mode: CW Doppler

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			(a)	-	1.1	-	4.0	2.6
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	#					
	W_0	(mW)		-	113.2		110.9	113.2
	min of $W_{.3}(z_1)$,$I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					1.25	
	$z@PII_{.3max}$	(cm)	#					
	$d_{eq}(z_{sp})$	(cm)					0.52	
	f_c	(MHz)	#	-	2.0	-	2.00	2.00
	Dim of A_{aprt}	X (cm)		-	0.72	-	0.85	0.72
		Y (cm)		-	1.30	-	1.30	1.30
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.47	
	Focal Length	FL_x (cm)		-	1.30	-		1.30
		FL_y (cm)		-	9.0	-		9.0
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Control 1: Exam Type				Crd		Crd	Crd
	Control 2: Sample Volume				Zone 0		Zone 1	Zone 0

a) This index is not required for this operating mode; value is <1.

(b) This transducer is not intended for transcranial or neonatal cephalic uses.

No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)

— Data are not applicable for this transducer/mode.

Acoustic measurement precision and uncertainty

All table entries have been obtained at the same operating conditions that give rise to the maximum index value in the first column of the table. Measurement precision and uncertainty for power, pressure, intensity, and other quantities that are used to derive the values in the acoustic output table

are shown in the table below. In accordance with Section 6.4 of the Output Display Standard, the following measurement precision and uncertainty values are determined by making repeat measurements and stating the standard deviation as a percentage.

Table 28: Acoustic Measurement Precision and Uncertainty

Quantity	Precision (% of standard deviation)	Uncertainty (95% confidence)
Pr	1.9%	±11.2%
$Pr_{.3}$	1.9%	±12.2%
Wo	3.4%	±10%
fc	0.1%	±4.7%
PII	3.2%	+12.5 to -16.8%
$PII_{.3}$	3.2%	+13.47 to -17.5%

CHAPTER 3: SPECIFICATIONS AND STANDARDS

For information on accessories and peripherals, see **"Compatible accessories and peripherals"** on page 17.

Dimensions

Stand

Length	26.4 in. (67.1 cm)
Width	21.2 in. (53.8 cm)
Height (max)	64 in. (162.6 cm)
Height (min)	42.2 in. (107.2 cm)

Clinical monitor

Length (exterior dimension)	18.8 in. (47.8 cm)
Height (exterior dimension)	14.2 in. (36 cm)
Diagonal (viewable area)	17 in. (43 cm) minimum

Touch panel

Length (exterior dimension)	16.1 in. (40.8 cm)
Height (exterior dimension)	10.2 in. (25.8 cm)
Diagonal (viewable area)	12.1 in. (30.7 cm)

Imaging modes

- 2D (256 gray shades)
- Color Power Doppler (CPD) (256 colors)
- Color Doppler (Color) (256 colors)
- M Mode

- Pulsed wave (PW) Doppler
- Continuous wave (CW) Doppler

Additionally, the system includes advanced imaging technologies:

- Tissue Doppler Imaging (TDI)
- Tissue Harmonic Imaging (THI)

Image and video clip storage capacity

The number of images and video clips you can save depends on imaging mode and file format.

Environmental limits

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

Operating

System and transducer

10–40°C (50–104°F), 15–95% R.H.

800 to 1060hPa (0.79 to 1.05 ATM)

Shipping and storage

System and transducer

-35–60°C (-31–140°F), 15–95% R.H.

500 to 1060hPa (0.5 to 1.05 ATM)

Electrical

Power Supply Input: 100-240V ~ 50/60 Hz 6.0A maximum

Electromechanical safety standards

Table 1: Electromechanical safety standards

Standard	Description
IEC 60601-1:1988	Medical Electrical Equipment–Part 1. General Requirements for Safety (2nd Edition including Amendment 1 and 2).

Table 1: Electromechanical safety standards

Standard	Description
IEC 60601-2-37:2001 + Amendment A1:2004	Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment; as applied to IEC 60601-1:1988, Medical Electrical Equipment–Part 1. General Requirements for Safety (2nd Edition including Amendment 1 and 2); including all national differences necessary to meet IECEE CB Scheme certification.
IEC 60601-1-1:2000	Medical Electrical Equipment–Part 1-1. General Requirements for Safety–Section 1-1. Collateral Standard. Safety Requirements for Medical Electrical Systems.
IEC 60601-1-4:2000	Medical Electrical Equipment–Part 1-4. General Requirements for Safety–Section 1-4. Collateral Standard. Programmable Electrical Medical Systems.
EC 60601-1:2005/A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
IEC 60601-2-37:2007	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment; as applied to IEC 60601-1:2005/A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (3rd Edition including Amendment 1); including all national differences necessary to meet IECEE CB Scheme certification.
IEC 61157:2007	Standard Means for the Reporting of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment.

EMC standards classification

Table 2: EMC standards classification

Standard	Description
IEC 60601-1-2:2007	Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance-Collateral Standard. Electromagnetic Compatibility. Requirements and Tests.
CISPR 11:2004	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 is: Group 1, Class A.

DICOM standard

NEMA PS 3.15: 2000, Digital Imaging and Communications in Medicine (DICOM)-Part 15: Security Profiles.

The system conforms to the DICOM standard as specified in the X-Porte 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.

HIPAA standard

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

The Health Insurance and Portability and Accountability Act, Pub.L. No. 104-191 (1996).

45 CFR 160, General Administrative Requirements.

45 CFR 164, Security and Privacy.

Measurement accuracy

The measurements from the system are of a physical property such as distance for evaluation by the clinician. The accuracy values require that you can place the calipers over one pixel. The values do not include acoustic anomalies of the body.

The 2D linear distance measurement results are displayed in centimeters with one place past the decimal point, if the measurement is ten or greater; two places past the decimal point, if the measurement is less than ten.

The linear distance measurement components have the accuracy and range shown in the following tables.

Table 3: 2D Measurement Accuracy and Range

2D Measurement Accuracy and Range	System Tolerance[a]	Accuracy By	Test Method[b]	Range (cm)
Axial Distance	< ±2% plus 1% of full scale	Acquisition	Phantom	0-26 cm
Lateral Distance	< ±2% plus 1% of full scale	Acquisition	Phantom	0-35 cm
Diagonal Distance	< ±2% plus 1% of full scale	Acquisition	Phantom	0-44 cm
Area[c]	< ±4% plus (2% of full scale/smallest dimension) * 100 plus 0.5%	Acquisition	Phantom	0.01-720 cm^2
Circumference[d]	< ±3% plus (1.4% of full scale/ smallest dimension) * 100 plus 0.5%	Acquisition	Phantom	0.01-96 cm

a. Full scale for distance implies the maximum depth of the image.
b. An RMI 413a model phantom with 0.7 dB/cm MHz attenuation was used.
c. The area accuracy is defined using the following equation:
% tolerance = ((1 + lateral error) * (1 + axial error) – 1) * 100 + 0.5%.
d. The circumference accuracy is defined as the greater of the lateral or axial accuracy and by the following equation:
% tolerance = ($\sqrt{2}$ (maximum of 2 errors) * 100) + 0.5%.

Table 4: M Mode Measurement and Calculation Accuracy and Range

M Mode Measurement Accuracy and Range	System Tolerance	Accuracy By	Test Method	Range
Distance	< +/- 2% plus 1% of full scale[a]	Acquisition	Phantom[b]	0-26 cm

Table 4: M Mode Measurement and Calculation Accuracy and Range (Continued)

M Mode Measurement Accuracy and Range	System Tolerance	Accuracy By	Test Method	Range
Time	< +/- 2% plus 1% of full scale[c]	Acquisition	Phantom[d]	0.01-10 sec
Heart Rate	< +/- 2% plus (Full Scale[c] * Heart Rate/100) %	Acquisition	Phantom[d]	5-923 bpm

a. Full scale for distance implies the maximum depth of the image.
b. An RMI 413a model phantom with 0.7 dB/cm MHz attenuation was used.
c. Full scale for time implies the total time displayed on the scrolling graphic image.
d. FUJIFILM SonoSite special test equipment was used.

Table 5: PW Doppler Mode Measurement and Calculation Accuracy and Range

Doppler Mode Measurement Accuracy and Range	System Tolerance	Accuracy By	Test Method[a]	Range
Velocity cursor	< +/- 2% plus 1% of full scale[b]	Acquisition	Phantom	0.01 cm/sec-550 cm/sec
Frequency cursor	< +/- 2% plus 1% of full scale[b]	Acquisition	Phantom	0.01kHz-20.8 kHz
Time	< +/- 2% plus 1% of full scale[c]	Acquisition	Phantom	0.01-10 sec

a. FUJIFILM SonoSite special test equipment was used.
b. Full scale for frequency or velocity implies the total frequency or velocity magnitude, displayed on the scrolling graphic image.
c. Full scale for time implies the total time displayed on the scrolling graphic image.

Sources of measurement errors

In general, two types of errors can be introduced into the measurement:

Acquisition Error Includes errors introduced by the ultrasound system electronics relating to signal acquisition, signal conversion, and signal processing for display. Additionally, computational and display errors are introduced by the generation of the pixel scale factor, application of that factor to the caliper positions on the screen, and the measurement display.

Algorithmic Error The error introduced by measurements, which are input to higher order calculations. This error is associated with floating-point versus integer-type math, which is subject to errors introduced by rounding versus truncating results for display of a given level of significant digit in the calculation.

CHAPTER 4: LABELING SYMBOLS

Labeling Symbols

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

Symbol	Definition
	Alternating Current (AC)
CE	Class 1 device indicating manufacturer's declaration of conformance with Annex VII of 93/42/EEC
CE 0086	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
	Device complies with relevant Australian regulations for electronic devices.
LOT	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 certification mark. 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 U.S., respectively.
	Canadian Standards Association component certification mark.
REF	Catalog number

Symbol	Definition
	Collect separately from other household waste (see European Commission Directive 93/86/EEC). Refer to local regulations for disposal.
	Corrugated recycle
	Date of manufacture
	Manufacturer and, if co-located, date of manufacture
	Direct Current (DC)
	Do not get wet.
	Do not stack over # high, where # 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
	Hot

Symbol	Definition
	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.
IPX8	Water-Tight Equipment. Protected against the effects of extended immersion.
	Handle transducer with care.
	Follow manufacturer's instructions for disinfecting time.
	Disinfect transducer.
	Type BF patient applied part (B = body, F = floating applied part)
	Defibrillation-proof type CF applied part

Symbol	Definition
	Underwriter's Laboratories labeling
	Pollution Control Logo. (Applies to all parts/products listed in the China RoHS disclosure table. May not appear on the exterior of some parts/products because of space limitations.)
	China Compulsory Certificate mark ("CCC Mark"). A compulsory safety mark for compliance to Chinese national standards for many products sold in the People's Republic of China.
	Atmospheric pressure limitation
	Humidity limitation
	Follow instructions for use.
WARNING: Connect Only Accessories and Peripherals Recommended by FUJIFILM SonoSite	WARNING: Connect Only Accessories and Peripherals Recommended by FUJIFILM SonoSite
	Authorized representative in the European Community
	Equipotentiality
	Pushing Prohibited Do not push on monitor. System may tip due to pushing or leaning on the monitor.

CHAPTER 5: TROUBLESHOOTING AND MAINTENANCE

This chapter contains information to help correct problems with system operation, to enter a software license, and to take proper care of the system, transducer, and accessories.

Troubleshooting

If you encounter difficulty with the system, use the following list to help troubleshoot the problem. If the problem persists, contact FUJIFILM SonoSite Technical Support. (See **"FUJIFILM SonoSite Technical Support"** on page 5.)

System does not turn on. Check all power connections.

Unplug and plug back in the power supply AC and DC power cables (desktop system).

Check that all three battery switches are in the ON position and ensure that the batteries are charged (stand system).

Plug the system into AC power to reactivate battery operation if the battery switches have been in the OFF position (stand system).

System image quality is poor. Adjust the clinical monitor to improve viewing angle.

Adjust the brightness.

Adjust the gain.

No CPD image. Adjust the gain. CPD has a hide control. Ensure that this control is not activated.

No Color image. Adjust the gain or the PRF scale. Color has a hide control. Ensure that this control is not activated.

No measurement selections. Ensure the desired exam type has been selected and that the image is frozen. Tap **Calcs** in the Controls bar, or from **More Controls**.

Printing does not work. If you are printing to a DICOM printer, check with your system administrator to make sure that DICOM settings are accurate and that your system is connected to the network.

If you are printing to a local printer, do any of the following:

- Check the printer connections. The system will automatically detect the printer.
- Ensure that the local printer is turned on and set up properly. See the printer manufacturer's instructions, if necessary.

Only saved images and video clips and the current patient's worksheets can be printed.

DVR does not record. Make sure that the USB memory stick has enough available space.

System does not recognize the transducer. Disconnect and reconnect the transducer.

Maintenance icon  **appears on screen**. Restart the system. If the issue recurs, system maintenance may be required. Note the number that appears in parentheses on the C: line and contact FUJIFILM SonoSite or your FUJIFILM SonoSite representative.

System prompts you to ensure the USB device is valid. Use the USB memory stick included with the system.

Make sure that the USB memory stick does not have password protection enabled and is not defective.

System prompts you to ensure the USB device contains valid data. Make sure that the data are present on the USB memory stick.

Re-export the original data onto the USB memory stick.

Contact your system administrator.

USB device does not appear in the list. Check that the USB device has been properly inserted into an available USB slot. Use the USB memory stick that came with the system.

System displays the alert "Incompatible power supply. . ." Use the power supply that shipped with the system. See **"Compatible accessories and peripherals" on page 17**.

System displays the alert "…internal storage device is full." Free internal storage space by ending the current exam, archiving or exporting patient exams, and then deleting them from the system.

Cannot access Patient Form. Cannot access Patient List. Ensure that you are logged in as a user, not as a guest.

System does not export or transfer video clips (DICOM). In the **Archiver** settings of DICOM Config, make sure that **Exclude Video Clips** is not checked.

When you position the caliper on the touch panel, it appears higher than the point you actually touched. Reposition the caliper by aiming for the bottom half of the blue circle.

Software licensing

FUJIFILM SonoSite software is controlled by a license key. After you install new software, the system prompts you for a license key. You must obtain one key for each system and transducer package that uses the software.

The software will operate for a short time (the *grace period*) without a license key. During the grace period, all system functions are available. After the grace period, the system is not usable until you enter a valid license key. Grace period time is not used while the system is off or asleep. Grace period time remaining appears on the license update screen.

Caution:	After the grace period expires, all system functions except licensing are unavailable until you enter a valid license key.

To obtain a license key

1 Turn on the system.

2 Navigate to System Information to gather version information:

   a Tap **MORE** and then tap **System Settings**.

   b Tap **System Information** in the list on the left and scroll to display System Licensing and Scanhead Licensing.

3 Contact FUJIFILM SonoSite Technical Support. (See **"FUJIFILM SonoSite Technical Support"** on page 5. You will be asked for the following information from System Information:

   a Your name

   b System serial number

   c PCBA serial number

   d Transducer package version

After you obtain a license key, you must enter it into the system. You can enter it either at startup or in System Setup.

To enter the license key at startup

1 Turn on the system.

   The license update screen appears.

2 Enter the license key in the **Enter license number** box.

3 Tap **Done**.

   If the license update screen reappears, verify that you entered the license key correctly. If the license update screen still appears, contact FUJIFILM SonoSite Technical Support. (See **"FUJIFILM SonoSite Technical Support"** on page 5.)

To enter the license key in System Settings

1 Tap **MORE**, and then tap **System Settings**.

2 Tap **System Information** in the list on the left.

3 Enter the license key in the **Enter license key** boxes in the **System Licensing** or **Scanhead Licensing** section.

4 Tap **ENTER**.

Maintenance

WARNING: No modification of this equipment, except as described in this manual or the *X-Porte Service Manual*, is allowed.

WARNING: Do not service or perform maintenance procedures on the system while it is in use with a patient.

No periodic or preventive maintenance is required for the system, transducer, or accessories other than cleaning and disinfecting the transducer after every use. For information on cleaning and disinfecting your ultrasound system, see *Cleaning and Disinfecting X-Porte Products*. No internal components require periodic testing or calibration.

In addition to cleaning and disinfecting the transducer, FUJIFILM SonoSite recommends that you plug the system in when not in use to fully charge the batteries. When charging, all three battery switches must be in the ON position.

Performing maintenance procedures not described in this document or the service manual may void the product warranty. Contact FUJIFILM SonoSite Technical Support for any maintenance questions. (See **"FUJIFILM SonoSite Technical Support"** on page 5.)

Disinfecting

Information for cleaning the ultrasound system, transducers, and accessories can be found in *Cleaning and Disinfecting X-Porte Products*.

System backups

To safeguard against loss of data, FUJIFILM SonoSite recommends that you routinely back up:

- Patient data
- System configuration settings

Patient data

Digital Imaging and Communications in Medicine (DICOM) provides a way to archive patient data by connecting your ultrasound system over a local area network (LAN) with various archivers for storage after every patient exam. FUJIFILM SonoSite recommends that you configure and use DICOM transfer to prevent patient data loss in the event of a system fault. For more information, see the topic titled "DICOM" in the X-Porte Help.

If you do not use DICOM networking, then FUJIFILM SonoSite recommends that you configure your system for automatic export of patient data to a USB memory stick after every exam. For more information, see the topic titled "USB settings" in the X-Porte Help.

System configuration settings

In addition to patient data, FUJIFILM SonoSite recommends that you back up ultrasound system configuration settings, called *presets,* after you have fully configured the system and any time you modify these settings. These backups preserve your customized settings in case of a fault in the system. For more information, see the topic titled "Presets settings" in the X-Porte Help.

Servicing

Your ultrasound engine may be repaired or replaced at the manufacturer's discretion. If servicing is necessary, then you must remove the ultrasound engine. Before the engine is removed and shipped to a repair facility, you must take precautions to protect patient data and to preserve your customized settings.

Caution:	To protect patient privacy, all patient procedure information must be exported to a USB memory stick or archived to a secure repository via DICOM transfer and then deleted from the Patient List.
Caution:	To preserve your configuration settings, export Presets and DICOM settings to a USB memory stick and store the stick in a secure location.

To prepare your system for service

1. End any in-progress procedures.
2. Export all patient procedure information to a USB stick or archive it to a DICOM device. For complete instructions, see the topic titled "Archiving and exporting" in the X-Porte Help.
3. To delete all patient data, tap **Patient** and then **Patient List**.
4. Tap **Select All** and then tap **Delete**.
5. Export the following items to a USB memory stick:
   - System preferences (that is, presets)
   - System log file
   - Assert log file

   Note: Exporting the Assert log file requires administrator access.
   - User log file
   - DICOM log file (DICOM users only)
   - DICOM settings (DICOM users only)

For information on importing and exporting, see the topics titled "Presets setups" and "Connectivity setups" in the X-Porte Help.

To remove the engine from the stand

Caution:	Disconnect any devices attached to the ultrasound engine (such as the Triple Transducer Connect, USB memory sticks, transducers, power cables, or ECG cables) before removing it from the stand.

1 Locate the two gray latch levers under the left and right sides of the stand head.

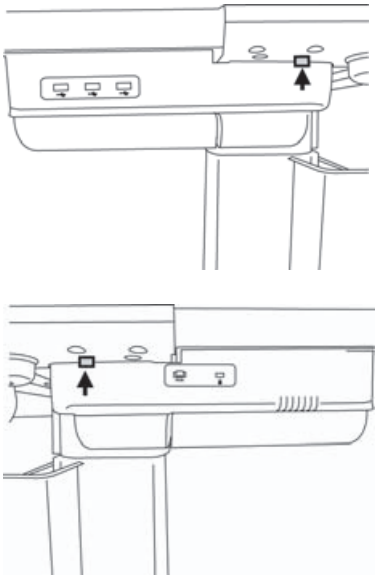
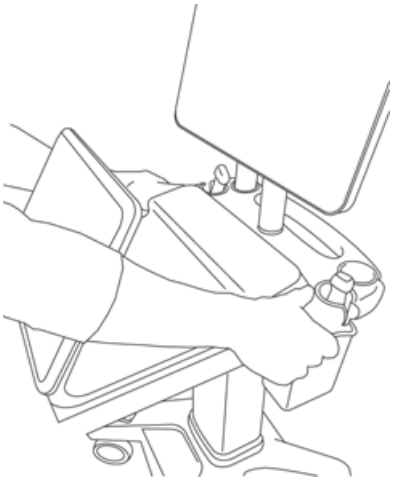


Figure 1 Two gray latch levers under the left and right sides of the stand

2 Simultaneously pull each latch outward, away from the engine and towards the stand's outer edges. The engine ejects from the stand.



3 Lift the engine from the back edge and lift forward and up away from the top of the stand.

To remove a transducer

1 Pull the transducer latch up, and rotate it clockwise.

2 Pull the transducer connector away from the system.

GLOSSARY

General terms

For ultrasound terms not included in this glossary, refer to *Recommended Ultrasound Terminology, Second Edition,* published in 1997 by AIUM.

AIUM	American Institute of Ultrasound in Medicine
as low as reasonably achievable (ALARA)	The guiding principle of ultrasound use, which states that you should keep patient exposure to ultrasound energy as low as reasonably achievable for diagnostic results.
curved array transducer	Identified by the letter C (curved or curvilinear) and a number (60). The number corresponds to the radius of curvature of the array expressed in millimeters. The transducer elements are electrically configured to control the characteristics and direction of the acoustic beam. For example, C60xp.
depth	Refers to the depth of the display. A constant speed of sound of 1538.5 meters/second is assumed in the calculation of echo position in the image.
in situ	In the natural or original position.
LCD	liquid crystal display
linear array transducer	Identified by the letter L (linear) and a number (38). The number corresponds to the radius of width of the array expressed in millimeters. The transducer elements are electrically configured to control the characteristics and direction of the acoustic beam. For example, L38xp.
mechanical index (MI)	An indication of the likelihood of mechanical bioeffects occurring: the higher the MI, the greater the likelihood of mechanical bioeffects. See **Chapter 2, "ACOUSTIC OUTPUT,"** for a more complete description of MI.
MI/TI	See *mechanical index (MI)* and *thermal index (TI)*.
phased array	A transducer designed primarily for cardiac scanning. Forms a sector image by electronically steering the beam direction and focus.
SonoMB technology	A subset of the 2D imaging mode in which the 2D image is enhanced by looking at a target from multiple angles and then merging or averaging the scanned data together to improve overall image quality and, in parallel, reducing noise and artifacts.

target depth	A depth on the display that corresponds to the skin/transducer interface.
thermal index (TI)	The ratio of total acoustic power to the acoustic power required to raise tissue temperature by 1°C under defined assumptions. See **Chapter 2, "ACOUSTIC OUTPUT,"** for a more complete description of TI.
TIB (bone thermal index)	A thermal index for applications in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.
TIC (cranial bone thermal index)	A thermal index for applications in which the ultrasound beam passes through bone near the beam entrance into the body.
TIS (soft tissue thermal index)	A thermal index related to soft tissues.
Tissue Doppler Imaging (TDI)	A pulsed wave Doppler technique used to detect myocardial motion.
Tissue Harmonic Imaging	Transmits at one frequency and receives at a higher harmonic frequency to reduce noise and clutter and improve resolution.
transducer	A device that transforms one form of energy into another form of energy. Ultrasound transducers contain piezoelectric elements, which when excited electrically, emit acoustic energy. When the acoustic energy is transmitted into the body, it travels until it encounters an interface, or change in tissue properties. At the interface, an echo is formed that returns to the transducer, where this acoustic energy is transformed into electrical energy, processed, and displayed as anatomical information.
variance	Displays a variation in Color Doppler flow imaging within a given sample. Variance is mapped to the color green and is used to detect turbulence.

Terminology in acoustic output tables

A_{aprt}	Area of the active aperture measured in cm^2.
$d_{eq}(z)$	Equivalent beam diameter as a function of axial distance z, and is equal to $\sqrt{(4/(\pi))((Wo)/(I_{TA}(z)))}$, where $I_{TA}(z)$ is the temporal-average intensity as a function of z in centimeters.
d_{eq}@PII_{max}	Equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum in centimeters.
Dim. of A_{aprt}	Active aperture dimensions for the azimuthal (x) and elevational (y) planes in centimeters.
fc	Center frequency in MHz.
FL	Focal length, or azimuthal (x) and elevational (y) lengths, if different measured in centimeters.
$I_{pa.3}$@MImax	Derated pulse average intensity at the maximum MI in units of W/cm^2.
$I_{SPTA.3}$	Derated spatial peak, temporal average intensity in units of milliwatts/cm^2.
$I_{SPTA.3}(z_1)$	Derated spatial-peak temporal-average intensity at axial distance z_1 (milliwatts per square centimeter).
MI	Mechanical index.
PD	Pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of MI.
$P_{r.3}$	Derated peak rarefactional pressure associated with the transmit pattern giving rise to the value reported under MI (Megapascals).
p_r@PII_{max}	Peak rarefactional pressure at the point where the free-field, spatial-peak pulse intensity integral is a maximum in Megapascals.
PRF	Pulse repetition frequency associated with the transmit pattern giving rise to the reported value of MI in Hertz.
TI type	Applicable thermal index for the transducer, imaging mode, and exam type.
TI value	Thermal index value for the transducer, imaging mode, and exam type.
TIB	(Bone thermal index) is a thermal index for applications in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone. TIB non-scan is the bone thermal index in the non-autoscanning mode.

TIC	(Cranial bone thermal index) is the thermal index for applications in which the ultrasound beam passes through bone near the beam entrance into the body.
TIS	(Soft tissue thermal index) is a thermal index related to soft tissues. TIS scan is the soft tissue thermal index in an auto-scanning mode. TIS non-scan is the soft tissue thermal index in the non-autoscanning mode.
$W_{.3}(z_1)$	Derated ultrasonic power at axial distance z_1 in units of milliwatts.
Wo	Ultrasonic power, except for TIS_{scan}, in which case it is the ultrasonic power passing through a one centimeter window in units of milliwatts.
z_1	Axial distance corresponding to the location of maximum min($W_{.3}(z)$, $I_{TA.3}(z)$ x 1 cm^2)], where $z \geq zbp$ in centimeters.
z_{bp}	*1.69* $\sqrt{(A_{aprt})}$ in centimeters.
z_{sp}	For MI, the axial distance at which $p_{r.3}$ is measured. For TIB, the axial distance at which TIB is a global maximum (for example, $z_{sp} = z_{b.3}$) in centimeters.

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