



USER GUIDE

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Caution

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CHAPTER 1

Introduction

This *SonoSite Edge II Ultrasound System User Guide* provides information on preparing and using the SonoSite Edge II ultrasound system and on cleaning and disinfecting the system and transducers. It also provides system specifications, and safety and acoustic output information.

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

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

Changes in this version

Features	Description
Patents	Removed specific patents and added reference to patents website
Sector control	Sector removed from Color Controls in Imaging
Centerline	Clarified centerline availability in Imaging
Labeling symbols updated	Updated the Labeling symbols to comply with new definitions and regulations.
Incorporated user guide errata	P23353-01

Document conventions

The user guide follows these conventions:

- ▶ A **WARNING** describes precautions necessary to prevent injury or loss of life.
- ▶ A **Caution** describes precautions necessary to protect the products.
- ▶ A **Note** provides supplemental information.

- ▶ Numbered and lettered steps must be performed in a specific order.
- ▶ Bulleted lists present information in list format but do not imply a sequence.
- ▶ Single-step procedures begin with ❖.

Symbols and terms used on the system and transducer are explained in “**Labeling symbols**” on page 9-25 and the “**Glossary**” on page A-1.

Getting help

In addition to this user guide, the following resources are available:

- ▶ Instructional videos available on-line.
- ▶ FUJIFILM SonoSite Technical Support:

United States or Canada	+1 877-657-8118
Other regions	+1 425-951-1330, or call your local representative
Europe and Middle East	Main: +31 20 751 2020 English support: +44 14 6234 1151 French support: +33 1 8288 0702 German support: +49 69 8088 4030 Italian support: +39 02 9475 3655 Spanish support: +34 91 123 8451
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Web	www.sonosite.com

CHAPTER 2

Getting Started

About the system

The SonoSite Edge II ultrasound system is a portable, software-controlled device using all-digital architecture.

The system has multiple configurations and feature sets used to acquire and display high-resolution, real-time ultrasound images. Features available on your system depend on system configuration, transducer, and exam type.

License key

A license key is required to activate the software. Refer to **“Software licensing”** on page 7-3. On occasion, a software upgrade may be required. FUJIFILM SonoSite provides a USB device containing the software. One USB device can upgrade multiple systems.

Intended uses

The SonoSite Edge II Ultrasound System is a general purpose ultrasound system intended for use by qualified physicians and healthcare professionals for evaluation by ultrasound imaging or fluid flow analysis of the human body.

The system is used with a transducer attached and is powered either by battery or by AC electrical power. The clinician is positioned beside the patient and places the transducer onto (or into, for invasive procedures) the patient’s body where needed to obtain the desired ultrasound image.

The system transmits ultrasound energy into the patient’s body to obtain ultrasound images as described below. Abdominal imaging applications

You can assess the liver, kidneys, pancreas, spleen, gallbladder, bile ducts, transplanted organs, abdominal vessels, and surrounding anatomical structures for the presence or absence of pathology transabdominally.

Cardiac imaging applications

You can assess the heart size and function, cardiac valves, great vessels, visualize blood flow through cardiac valves, and assess for the presence or absence of pathology. In addition, you can identify the presence and location of fluid around the heart and lungs used to assist in pericardiocentesis and thoracentesis procedures. You can detect normal lung motion for the presence or absence of pathology.

You can use the licensed FUJIFILM SonoSite ECG function to display the patient's heart rate and to provide a cardiac cycle reference when viewing an ultrasound image.

WARNING

Do not use the FUJIFILM SonoSite ECG to diagnose cardiac arrhythmias or to provide long-term cardiac monitoring.

Gynecology and infertility imaging applications

You can assess the uterus, ovaries, adnexa, and surrounding anatomical structures for the presence or absence of pathology transabdominally or transvaginally.

Interventional imaging applications

You can use the system for ultrasound guidance in biopsy and drainage procedures, vascular line placement, peripheral nerve blocks, ova harvesting, amniocentesis and other obstetrical procedures.

Obstetrical imaging applications

You can assess the fetal anatomy, viability, estimated fetal weight, gestational age, amniotic fluid, and surrounding anatomical structures for the presence or absence of pathology transabdominally or transvaginally. CPD and Color imaging are intended for high-risk pregnant women. High-risk pregnancy indications include, but are not limited to, multiple pregnancy, fetal hydrops, placental abnormalities, as well as maternal hypertension, diabetes, and lupus.

WARNINGS

- ▶ During the first trimester, you should limit the duration of ultrasound imaging based on MI/TI. See **Chapter 10, “Acoustic Output,”** for more information.
- ▶ To prevent injury or misdiagnosis, do not use this system for fetal growth screening if the advanced OB calculations and reports package is not available.
- ▶ To prevent injury or misdiagnosis, do not use this system for Percutaneous Umbilical Blood Sampling (PUBS) or *in vitro* Fertilization (IVF) The system has not been validated to be proven effective for these two uses.
- ▶ CPD or Color images can be used as an adjunctive method, not as a screening tool, for the detection of structural anomalies of the fetal heart and as an adjunctive method, not as a screening tool, for the diagnosis of Intrauterine Growth Restriction (IUGR).

Pediatric and neonatal imaging applications

You can assess the pediatric and neonatal abdominal, pelvic and cardiac anatomy, pediatric hips, neonatal head, and surrounding anatomical structures for the presence or absence of pathology.

Prostate imaging applications

You can assess the prostate and surrounding anatomical structures for the presence or absence of pathology.

Superficial imaging applications

You can assess the breast, thyroid, testicles, lymph nodes, hernias, musculoskeletal structures, soft tissue structures, spine, ophthalmic structures and surrounding anatomical structures for the presence or absence of pathology. You can use the system for ultrasound guidance in biopsy and drainage procedures, vascular line placement, peripheral nerve blocks.

WARNING

To avoid injury to the patient, use only an Orbital (Orb) or Ophthalmic (Oph) exam type when performing imaging through the eye. The FDA has established lower acoustic energy limits for ophthalmic use. The system will not exceed these limits only if the Orb or Oph exam type is selected.

Transcranial imaging applications

You can assess the anatomical structures and vascular anatomy of the brain for presence or absence of pathology. You can use imaging temporally, trans-occipitally, or trans-orbitally.

Arterial and venous imaging applications

You can assess the carotid arteries, deep veins and arteries in the arms and legs, superficial veins in the arms and legs, great vessels in the abdomen, and various small vessels feeding organs for the presence or absence of pathology.

Note

For the intended transducer and imaging modes for each exam type, see [“Imaging modes and exams available by transducer”](#) on page 4-16.

Contraindications

The SonoSite Edge II ultrasound system has no known contraindications.

Hardware features

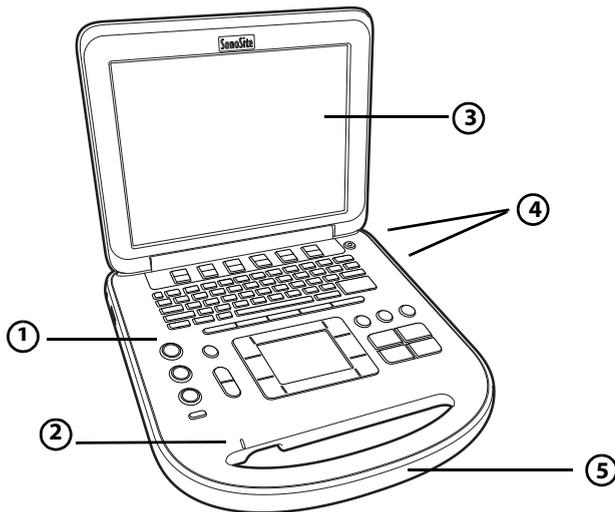


Figure 2-1 Front of the SonoSite Edge II Ultrasound System

- | | | | |
|---|--------------------|---|-----------|
| 1 | Control panel | 4 | USB ports |
| 2 | AC power indicator | 5 | Handle |
| 3 | Display | | |

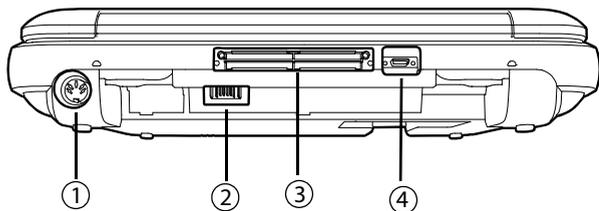


Figure 2-2 Back of the SonoSite Edge II Ultrasound System

- | | | | |
|---|----------|---|---------------|
| 1 | DC input | 3 | I/O connector |
| 2 | Battery | 4 | ECG connector |

Basic operating steps

- 1 Attach a transducer.
- 2 Turn the system on. For power switch location, see “[System controls](#)” on page 2-11.
- 3 Press the **PATIENT** key, and complete the patient information form.
- 4 Press an imaging mode key:
 - ▶ **2D**
 - ▶ **M MODE**
 - ▶ **C COLOR**
 - ▶ **D DOPPLER**

Preparing the system

Installing or removing the battery

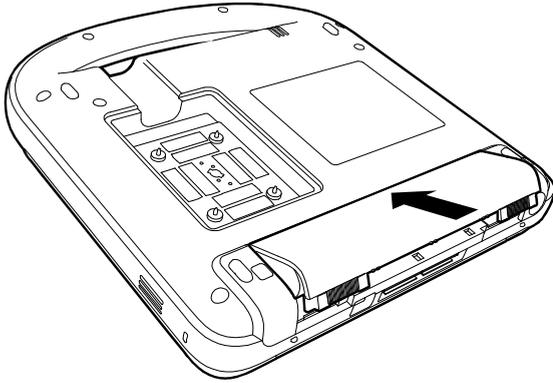
WARNINGS

- ▶ To avoid injury to the operator and to prevent damage to the ultrasound system, inspect the battery for leaks prior to installing.
- ▶ To avoid data loss and to conduct a safe system shutdown, always keep a battery in the system. See “[Battery safety](#)” on page 9-9.

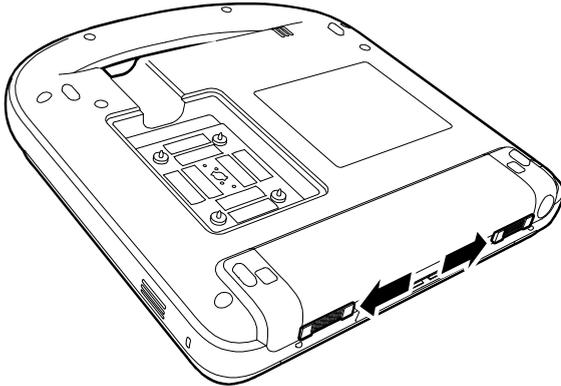
To install the battery

- 1 Disconnect the power supply from the ultrasound system.
- 2 Remove the system from the mini-dock (if present) and turn it upside down.

- 3 Place the battery into the battery compartment, at a slight angle.



- 4 Slide the battery forward until it locks into place.
- 5 Slide the two locking levers outward to secure the battery.



To remove the battery

- 1 Disconnect the power supply from the ultrasound system.
- 2 Remove the system from the mini-dock (if present) and turn it upside down.
- 3 Pull up the two locking levers.
- 4 Slide the battery back.
- 5 Lift the battery from the compartment.

Using AC power and charging the battery

When using AC power, position the system to allow easy access to disconnect it.

The battery charges when the system is connected to the AC power supply. A fully discharged battery recharges in less than five hours. The system can run on AC power and charge the battery if AC power is connected to the system directly, to a mini-dock, or to a docking system.

The system can run on battery power for up to two hours, depending on the imaging mode and the display brightness. When running on battery power, the system may not restart if the battery is low.

To continue, connect the system to AC power.

WARNINGS

- ▶ Verify that the hospital supply voltage corresponds to the power supply voltage range. See **“Specifications”** on page 9-32.
- ▶ Plug the system only into a grounded hospital-grade outlet.
- ▶ Use only power cords provided by FUJIFILM SonoSite with the system.

To operate the system using AC power

- 1** Connect the DC power cable from the power supply to the connector on the system. Refer to **Figure 2-2** on page 2-5.
- 2** Push the cable in firmly to ensure a secure connection.
- 3** Connect the AC power cord to the power supply and to a hospital-grade electrical outlet.

To separate the system (and any connected equipment) from a supply mains

Cautions

- ▶ The equipment is not provided with an AC mains power switch. To disconnect the equipment from mains, use the appliance coupler or mains plug on the power supply cord.
- ▶ Install the ultrasound system in a place where you can easily connect or disconnect the AC power cord.
- ▶ Disconnecting only the DC power cable from the system does not separate the system from the supply mains.

- ❖ Disconnect the AC power cord from the power supply or (alternatively, if using a stand) from the AC adapter on the stand base.

Turning the system on or off

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.

To turn the system on or off

- ❖ Press the power switch. See **“System controls”** on page 2-11.

To wake up the system

To conserve battery life while the system is on, the system goes into sleep mode if the lid is closed or if the system is untouched for a preset time.

- ❖ Press a key, touch the touchpad, or open the lid.

To adjust the time for sleep delay

- ❖ Refer to **“Audio, Battery setup”** on page 3-8.

Connecting transducers

WARNING

To avoid injury to the patient, do not place the connector on the patient. Operate the ultrasound system in a docking system or on a flat hard surface to allow air flow past the connector.

Caution

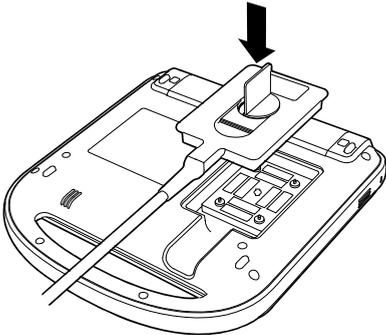
To avoid damaging the transducer connector, do not allow foreign material in the connector.

Note

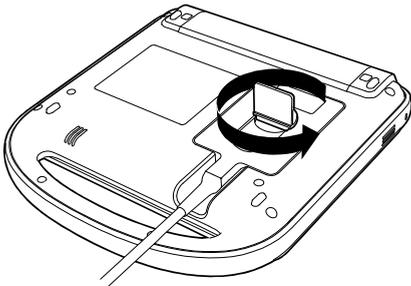
The system automatically checks for and notifies you of errors when connecting a transducer.

To connect a transducer

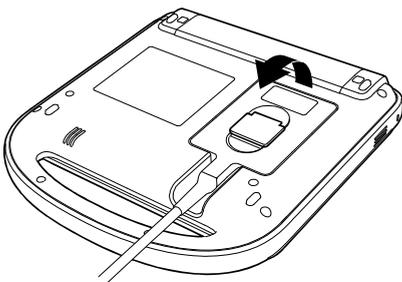
- 1 Remove the system from the mini-dock (if present), and turn it upside down.



- 2 Pull the transducer latch up, and rotate it clockwise. Align the transducer connector with the connector on the bottom of the system.



- 3 Insert the transducer connector into the system connector.
- 4 Turn the latch counterclockwise.
- 5 Press the latch down, securing the transducer connector to the system.



To remove a transducer

- 1 Pull the transducer latch up.
- 2 Rotate it clockwise.
- 3 Pull the transducer connector away from the system.

Inserting and removing USB storage devices

You can use a USB storage device to import and export various logs and setup configurations, and to archive images and clips.

Note

- ▶ The system does not support password-protected or encrypted USB storage devices. Make sure that the USB storage device you use does not have password protection or encryption enabled.
- ▶ USB storage devices must be in FAT-32 format.

Images and clips are saved to internal storage and are organized in a sortable patient list. You can archive the images and clips from the ultrasound system to a PC using a USB storage device or Ethernet connection. Although the images and clips cannot be viewed from a USB storage device on the ultrasound system, you can remove the device and view them on your PC.

There are two USB ports on the system, and one on the mini-dock. For additional USB ports, you can connect a USB hub into any USB port.

Caution

To avoid damaging the USB storage device and losing patient data from it, observe the following:

- ▶ Do not remove the USB storage device or turn off the ultrasound system while the system is exporting.
- ▶ Do not bump or otherwise apply pressure to the USB storage device while it is in a USB port on the ultrasound system. The connector could break.

Caution

If the USB icon does not appear in the system status area on-screen, the USB storage device may be defective or software-encrypted. Turn the system off and replace the device.

To insert a USB storage device

- ❖ Insert the USB storage device into any USB port on the system or mini-dock. See [Figure 2-1](#) on page 2-4. The USB storage device is ready when the USB icon appears.

To view information about the device

- ❖ Refer to **“USB Devices setup”** on page 3-16.

To remove a USB storage device

Removing the USB storage device while the system is exporting to it may cause the exported files to be corrupted or incomplete.

- 1 Wait five seconds after the USB animation stops.
- 2 Remove the USB storage device from the port.

System controls

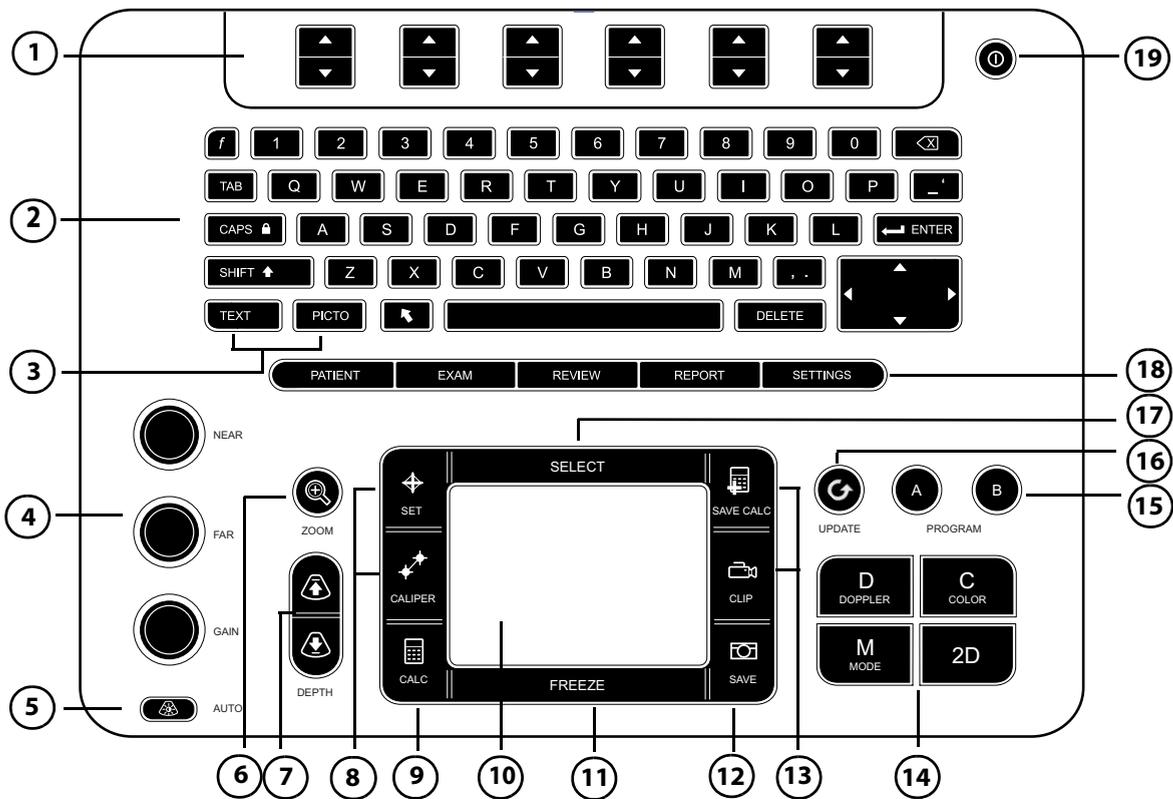


Figure 2-3 Control panel

Table 2-1: Keyboard map

1	Control keys	Adjust on-screen controls.
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Table 2-1: Keyboard map (continued)

2	Alphanumeric keys	Enter text and numbers.
3	Annotation keys	See “Annotation and text” on page 2-16.
4	Gain	
	NEAR	Adjusts the gain applied to the near field of the image.
	FAR	In live imaging, adjusts the gain applied to the far field of the image. On a frozen PW Doppler image, adjusts the angle.
	GAIN	In live imaging, adjusts the overall gain applied to the entire image. On a frozen image, moves the cine buffer.
5	AUTO	Adjusts gain automatically.
6	ZOOM	Magnifies the image 100%.
7	DEPTH UP, DEPTH DOWN	Decreases and increases imaging depth.
8	SET	Sets a trace measurement.
	CALIPER	Displays calipers on-screen for measuring.
9	CALC	Turns the calculations menu on and off.
10	Touchpad	Selects, adjusts, and moves items on-screen.
11	FREEZE	Stops live imaging and displays a frozen image.
12	SAVE	Saves an image to internal storage. If configured, also saves calculations to the report. Refer to “Presets setup” on page 3-14.
13	SAVE CALC CLIP	Saves calculations and their measurements to the patient report. Saves a clip to internal storage.
14	Imaging Modes	
	M MODE	Turns M Mode on, toggles between M-line and M Mode trace.
	DOPPLER	Turns Doppler on, toggles between D-line and Doppler trace.
	COLOR	Turns CPD/Color on and off.
	2D	Turns 2D on.

Table 2-1: Keyboard map (continued)

15	A & B shortcut keys	Keys that you can program to perform common tasks.
16	UPDATE	Toggles between dual and duplex screens and imaging modes in M Mode and Doppler (for example, between D-line and Doppler spectral trace).
17	SELECT	Used with the touchpad to select items on-screen. Also switches between Color and Doppler controls, calipers for measurement, pictograph-marker position and angle, frozen images in duplex and dual screens, and arrow position and orientation.
18	SETTINGS	Accesses the setup pages.
	PATIENT	Accesses patient information.
	EXAM	Opens exam menu.
	REVIEW	Accesses the patient list, saved images, and archiving functions.
	REPORT	Accesses the patient report and EMED worksheets.
19	Power switch	Turns system on and off.

Screen layout

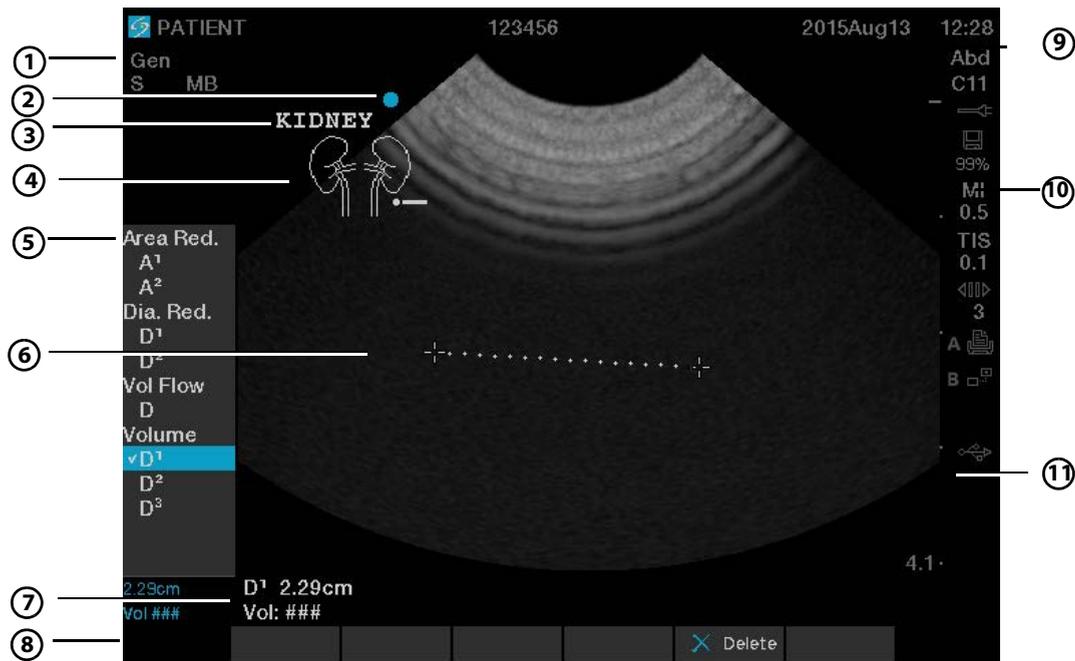


Figure 2-4 Sample screen

Table 2-2: Screen map

1	Mode Data Area	Current imaging mode information (for example, Gen, Res, THI, and PW).
2	Orientation Marker	Indication for image orientation.
3	Text	Text entered using keyboard.
4	Pictograph	Pictograph to indicate anatomy and transducer position. You can select anatomy and screen location.
5	Calculations Menu	Contains available measurements.
6	Image	Ultrasound image.
7	Measurement and Calculations Data Area	Current data on measurements and calculations.
8	On-screen Controls	Controls available in the current context.

Table 2-2: Screen map (continued)

9	Patient Header	Header details such as current patient name, ID number, user, and date/time. Specified on the display information setup page.
10	System Status	Information on system status (for example, exam type, transducer, AC connected, battery charging, and USB).
11	Depth Marker	Marks in .5 cm, 1 cm, and 5 cm increments depending on depth.

General interaction

Touchpad and cursor

Caution

Make sure to keep the touchpad dry while in use. Moisture on the touchpad can cause the cursor to respond erratically.

Use the touchpad to adjust and move objects on-screen. The touchpad controls caliper position, CPD, or Color box position and size, the cursor, and more. The arrow keys control much of the same functionality as the touchpad.

The cursor appears in the setup pages, the patient information form, and patient report. You control the cursor through the touchpad. For example, in the patient information form, place the cursor over the last name field and press the **SELECT** key to activate that field. Additionally, you can use the cursor to select check boxes and items in lists.

On-screen controls

The on-screen controls let you make adjustments and select settings. The controls available depend on context. Each control is controlled by the pair of keys below it. Depending on the control, the keys function in one of four ways:

Cycle

Moves through a list of settings continuously. The upper key cycles upward. The lower key cycles downward.

Up-Down

Moves through a list of settings, stopping at the top or bottom. The upper key moves upward. The lower key moves downward. By default, a beep sounds when you reach either end of the range. Refer to [“Audio, Battery setup”](#) on page 3-8.

On-Off

Turns a feature on or off. You can press either key. In forms, you can instead select the control by using the touchpad and the **SELECT** key.

Action

Performs an action. You can press either key. Or you can instead select the control by using the touchpad and the **SELECT** key.

Annotation and text

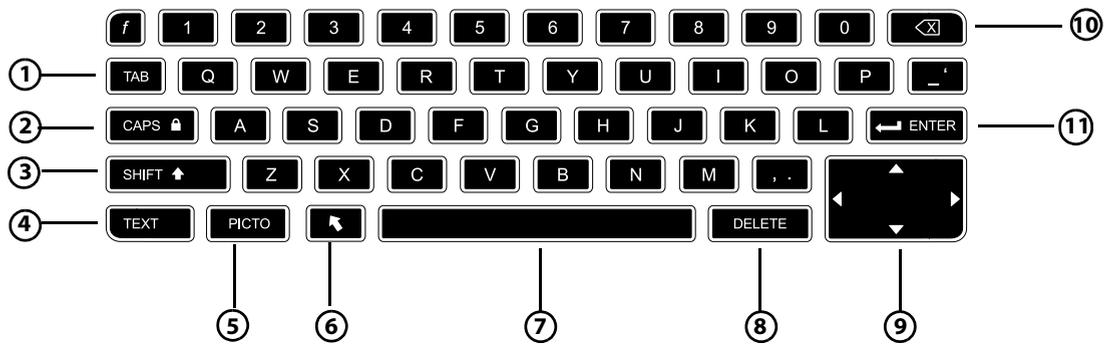


Figure 2-5 Alphanumeric keyboard

Table 2-3: Alphanumeric keyboard map

1	TAB	Moves cursor among fields in the forms, and tabs between text position in dual screens.
2	CAPS lock	Sets the keyboard to capital letters.
3	SHIFT	Allows entry of capitalized characters and international characters.
4	TEXT	Turns the keyboard on and off for text entry.
5	PICTO	Turns pictographs on and off.
6	arrow	Displays an arrow graphic that can be moved and rotated within the image area.
7	spacebar	Turns the keyboard on for text entry. In text entry, adds a space.
8	DELETE	Removes all text from the screen during text entry and when not measuring.

Table 2-3: Alphanumeric keyboard map (continued)

9	Arrow Keys	Move highlighted selection in calculations menu, move cursor one space when entering text, move caliper position, move cine buffer forward and backward, and move among pages in image review and reports.
10	backspace	Removes the character left of the cursor in text-entry mode.
11	ENTER	Moves cursor among fields in forms and saves calculations to report.

Symbols

You can enter symbols and special characters in select fields and forms. The symbols and special characters available depend on context.

Patient information form:

- ▶ Last, First, Middle
- ▶ Patient ID
- ▶ Accession
- ▶ Indications
- ▶ Procedure ID
- ▶ User
- ▶ Reading Dr.
- ▶ Referring Dr.
- ▶ and
- ▶ Institution fields

DICOM or SiteLink configuration page:

Alias and AE Title fields

A & B Key, Footswitch setup page:

Text field

Text mode (imaging):

Annotation field

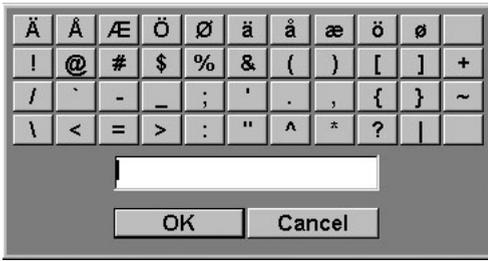


Figure 2-6 Symbols Dialog Box

To enter symbols or special characters

- 1 Select the field, and then select **Symbols**.
- 2 Select the desired symbol or character. You can also press the keys on the keyboard.
- 3 Select **OK**.

Preparing the transducers

WARNINGS

- ▶ Some transducer sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals. Refer to 21 CFR 801.437, User labeling for devices that contain natural rubber.
- ▶ Some gels and disinfectants can cause an allergic reaction in some individuals.

Cautions

- ▶ To avoid damage to the transducer, use only gels recommended by FUJIFILM SonoSite. Using gels other than the one recommended by FUJIFILM SonoSite can damage the transducer and void the warranty. If you have questions about gel compatibility, contact FUJIFILM SonoSite or your local representative.
- ▶ FUJIFILM SonoSite recommends that you clean transducers after each use. Refer to [Chapter 8, "Cleaning and Disinfecting."](#)

Note

Acoustic coupling gel must be used during exams. Although most gels provide suitable acoustic coupling, some gels are incompatible with some transducer materials. FUJIFILM SonoSite recommends Aquasonic[®] gel and provides a sample with the system.

To use the transducer

- ❖ For general use, apply a liberal amount of gel between the transducer and the body.

WARNING

To prevent contamination, the use of sterile transducer sheaths and sterile coupling gel is recommended for clinical applications of an invasive nature. Do not apply the transducer sheath and gel until you are ready to perform the procedure.

To apply a transducer sheath

- ❖ For invasive use, apply a transducer sheath.

FUJIFILM SonoSite recommends the use of market-cleared, transducer sheaths for intracavitary applications. To lessen the risk of contamination, apply the sheath only when you are ready to perform the procedure.

- 1 Place gel inside the sheath.
- 2 Insert the transducer into the sheath.
- 3 Pull the sheath over the transducer and cable until the sheath is fully extended.
- 4 Secure the sheath using the bands supplied with the sheath.
- 5 Check for and eliminate bubbles between the face of the transducer and the sheath. Bubbles between the face of the transducer and the sheath may affect the ultrasound image.
- 6 Inspect the sheath to ensure that there are no holes or tears.

CHAPTER 3

System Setup

The setup pages let you customize the system and set preferences.

Displaying the setup pages

To display a setup page

- 1 Press the **Settings** key.
- 2 Select the setup page under **Setup Pages**.
- 3 To return to imaging from a setup page, select **Done** on-screen.

Restoring default settings

To restore default settings for a setup page

- ❖ On the setup page, select **Reset** on-screen.

To restore all default settings

- 1 Turn the system off.
- 2 Connect the system to AC power. See [“To operate the system using AC power”](#) on page 2-7.
- 3 Simultaneously press **1** and the **power** key. The system beeps several times.

A & B Key, Footswitch setup

On the A & B Key, Footswitch setup page, you can program the shortcut keys and footswitch to perform common tasks.

- ❖ Select from the following lists:

- ▶ **A Key, B Key.** By default, the **A** shortcut key is set to **Print** and the **B** shortcut key is set to **none**. The shortcut keys are below the alphanumeric keypad.
- ▶ **Footswitch (L), Footswitch (R).** Set the left and right footswitches to: **Save Clip, Freeze, Save Image, or Print**. See [“To connect the footswitch”](#) on page 3-2.

To connect the footswitch

The FUJIFILM SonoSite footswitch allows hands-free operation with a customizable two-pedal footswitch. The footswitch is an optional feature.

WARNING To avoid contamination, do not use the footswitch in a sterile environment. The footswitch is not sterilized.

- 1 Connect the footswitch USB cable to the USB port on the system or mini-dock.
- 2 On the A & B Key, Footswitch setup page, select a function for the left and right footswitches.

Administration setup

On the **Administration** setup page, you can configure the system to require users to log in and enter passwords. Required login helps protect patient data. You can also add and delete users, change passwords, disable USB export, import and export user accounts, and view the event log.

Security settings

Caution Health care providers who maintain or transmit health information are required by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the European Union Data Protection Directive (95/46/EC) to implement appropriate procedures: to ensure the integrity and confidentiality of information; to protect against any reasonably anticipated threats or hazards to the security or integrity of the information or unauthorized uses or disclosures of the information.

Security settings on the system allow 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.

To log in as Administrator

- 1 On the **Administration** setup page, type **Administrator** in the **Name** box.

Note The entries for **Name** and **Password** are case-sensitive.

2 Type the administrator password in the **Password** box.

If you don't have the administrator password, contact FUJIFILM SonoSite. Refer to ["Getting help"](#) on page 1-2.

WARNING

Restoring an administrative password will result in the deletion of data. Back up all data prior to resetting the administrative password.

3 Select **Login**.

To log out as Administrator

❖ Turn off or restart the system.

To require user login

You can set the system to display the **User Login** screen at startup.

1 Log in as Administrator.

2 In the **User Login** list, select **On**.

- ▶ **On** requires a user name and password at startup.
- ▶ **Off** allows access to the system without a user name and password.

To change the administrator password or let users change passwords

1 Log in as Administrator.

2 Under **User List**, select **Administrator**.

3 To change the administrator password:

- a Under **User Information**, in the **Password** box, type the new password.
- b In the **Confirm** box, type the new password again. For more information about passwords, see ["Choosing a secure password"](#) on page 3-6.

4 To let users change their passwords, select the **Password changes** check box.

5 Select **Save**.

To enable encryption

1 Log in as Administrator.

2 Enter the encryption key in the text box.

To disable USB export

1 Log in as Administrator.

- 2 Select **Disable USB Export**.

User setup

To add a new user

- 1 Log in as Administrator.
- 2 Select **New**.
- 3 Under **User Information**, fill in the **Name**, **Password**, and **Confirm** boxes. For more information about passwords, see [“Choosing a secure password”](#) on page 3-6.
 - **(Optional)** In the **User** box, type the user’s initials to display them in the patient header and the User box in the patient information form.
 - **(Optional)** Select the **Administration Access** check box to allow access to all administration privileges.
- 4 Select **Save**.

To modify user information

- 1 Log in as Administrator.
- 2 Under **User List**, select the user.
- 3 Under **User Information**, make changes as desired.
- 4 Select **Save**. Any change to the user name replaces the previous name.

To delete a user

- 1 Log in as Administrator.
- 2 Under **User List**, select the user.
- 3 Select **Delete**.
- 4 Select **Yes**.

To change a user password

- 1 Log in as Administrator.
- 2 Under **User List**, select the user.
- 3 Type the new password in the **Password** box and **Confirm** box.
- 4 Select **Save**.

Exporting or importing user accounts

The export and import commands let you configure multiple systems and back up user account information.

To export user accounts

- 1 Insert a USB storage device. For more information, see [“Inserting and removing USB storage devices”](#) on page 2-10.
- 2 Log in as Administrator.
- 3 Select **Export** on-screen. A list of USB devices appears.
- 4 Select the USB storage device, and then select **Export**.
All user names and passwords are copied to the USB storage device. Passwords are encrypted.

To import user accounts

- 1 Insert the USB storage device that contains the accounts. For more information, see [“Inserting and removing USB storage devices”](#) on page 2-10.
- 2 Log in as Administrator.
- 3 Select **Import** on-screen.
- 4 Select the USB storage device, and then select **Import**.
- 5 Select **Restart** in the dialog box that appears. The system restarts.
All user names and passwords on the system are replaced with the imported data.

Exporting and clearing the Event log

The Event log collects errors and events and can be exported to a USB storage device and read on a PC.

To display the Event log

- 1 Log in as Administrator.
- 2 Select **Log** on-screen. The Event log appears.

To return to the previous screen, select **Back**.

To export the Event log

The Event log and the DICOM network log have the same file name (log.txt). Exporting either one to a USB storage device overwrites any existing log.txt file.

- 1 Insert a USB storage device.

- 2 Select **Log** and then select **Export** on-screen. A list of USB devices appears.
- 3 Select the USB storage device, and select **Export**.

Note

The Event log is a text file that you can open in a text-editing application (for example, Microsoft Word or Notepad).

To clear the Event log

- 1 Display the Event log.
- 2 Select **Clear** on-screen.
- 3 Select **Yes**.

Logging in as user

If user login is required, the User Login screen appears when you turn on the system. For more information, see [“To require user login”](#) on page 3-3.

To log in as user

- 1 Turn on the system.
- 2 In the **User Login** screen, type your name and password, and select **OK**.

To log in as guest

Guests can scan but can't access system setup and patient information.

- 1 Turn on the system.
- 2 In the **User Login** screen, select **Guest**.

To change your password

- 1 Turn on the system.
- 2 In the **User Login** screen, select **Password**.
- 3 Type your old and new passwords, confirm the new password, and then select **OK**.

Choosing a secure password

To ensure security, choose a password that contains uppercase characters (A-Z), lowercase characters (a-z), and numbers (0-9). Passwords are case-sensitive.

Annotations setup

On the **Annotations** setup page, you can customize predefined labels and set the preference for managing text when unfreezing images.

For instructions to annotate images, refer to [“Annotating images”](#) on page 4-22.

To predefine a label group

You can specify which labels are available for an exam type when annotating an image. Refer to [“To place text on an image”](#) on page 4-22.

- 1 On the **Annotations** setup page, in the **Exam** list, select the exam type that includes the labels you want to specify.
- 2 For **Group**, select **A**, **B**, or **C** for the label group you want associated with that exam. The preset labels appear for the selected group.
- 3 Do any of the following:
 - ▶ Add a custom label to the group: Type the label in the **Text** box, and select **Add**.
 - ▶ Rename a label: Select the label, type the new name in the **Text** box, and select **Rename**.
 - ▶ Move a label within the group: Select the label, and then select the on-screen up or down arrow.
 - ▶ Delete a label from a group: Select the label, and select **Delete**.

You can use symbols in labels. See [“Symbols”](#) on page 2-17.

To specify text retention when unfreezing

You can specify which text to keep when you unfreeze an image or change the imaging layout.

In the **Unfreeze** list on the **Annotations** setup page, select **Keep All Text**, **Keep Home Text**, or **Clear All Text**.

Note

The default setting is **Keep All Text**. For information on setting the home position, see [“To reset the home position”](#) on page 4-22.

To export predefined label groups

- 1 Insert a USB storage device.
- 2 On the **Annotations** setup page, select **Export**. A list of USB devices appears.
- 3 Select the USB storage device, and then select **Export**.

A copy of all predefined label groups for all exams saves to the USB storage device.

To import predefined label groups

- 1 Insert the USB storage device that contains the label groups.
- 2 On the **Annotations** setup page, select **Import**.
- 3 Select the USB storage device, and then select **Import**.
- 4 Select **Done** in the dialog box that appears.

All predefined label groups for all exams are replaced with those from the USB storage device.

Audio, Battery setup

On the **Audio, Battery** setup page, you can select options from the following lists:

Key click

Controls whether the controls make a clicking sound when pressed.

- ❖ Choose either **On** or **Off**.

Beep alert

Controls whether the system beeps when saving, warning, starting, or shutting down.

- ❖ Choose either **On** or **Off**.

Sleep delay

Specifies the period of inactivity before the system goes into sleep mode. Set to either five minutes, ten minutes, or Off. Turning off the sleep delay prevents the system from going into sleep mode.

- ❖ Choose either **Off**, **5**, or **10**.

Power delay

Specifies the period of inactivity before the system automatically turns off. Set to either 15 minutes, 30 minutes, or Off. Turning off the power delay prevents the system from turning itself off.

- ❖ Choose either **Off**, **15**, or **30**.

Cardiac Calculations setup

On the Cardiac Calculations setup page, you can specify measurement names that appear in the Tissue Doppler Imaging (TDI) calculations menu and on the report page. See “[Cardiac calculations](#)” on page 5–15.

To specify cardiac measurement names

❖ Under **TDI Walls** on the Cardiac Calculations setup page, select a name for each wall.

Connectivity setup

On the **Connectivity** setup page, you specify options for using non-USB devices and for alerts when internal storage is full. You may also import wireless certificates. Settings (including **Transfer Mode** and **Location**) for the SiteLink Image Manager and DICOM are also included.

To specify SiteLink settings

❖ See the *SiteLink Image Manager User Guide*.

To specify DICOM settings

❖ See *Sending and Receiving DICOM Data on SonoSite Systems*.

To configure the system for a printer

- 1 Set up the printer hardware. Refer to instructions included with the printer or docking system.
- 2 In the **Printer** list on the Connectivity setup page, select the printer.

To enable wireless connection

❖ See *Setting Up a Network Connection*.

To receive storage alerts

❖ On the Connectivity setup page, select **Internal Storage Capacity Alert**.

The system displays a message if internal storage is near capacity when you end an exam. The system then deletes archived patient exams if specified in DICOM setup.

Date and Time setup

On the Date and Time setup page, you can set up the date and time and enable synchronization with a clock on a server (Time Server).

WARNING

To obtain accurate obstetrics calculations, an accurate date and time are critical. Verify that the date and time are accurate before each use of the system. The system does not automatically adjust for daylight saving time changes.

To set the date and time

- 1 On the **Date and Time** setup page, do the following:
 - a In the **Date** box, type the current date.
 - b In the **Time** box, type the current time in 24 hour format (hours and minutes).

To enable the time server

- 1 On the Date and Time setup page, select the box under **Time Server**.
- 2 Enter the server IP address.
- 3 Select the appropriate time zone.

Display Information setup

On the **Display Information** setup page, you can specify which details appear on-screen during imaging. For example, you can help protect patient privacy by not displaying the patient name and ID on the screen. You can select check boxes in the following sections:

Patient Header

Information from the patient information form. Refer to [“Patient information form”](#) on page 4-23.

Mode Data

Imaging information.

System Status

Power, battery, connectivity, and similar information.

Network Status setup

The **Network Status** setup page displays information on system IP address, Location, Ethernet MAC address, and the wireless connection if any.

If your Network Status screen displays a failed wireless device message, your network password may be expired. Make sure that you have an updated network password before connecting your wireless device.

OB Calculations setup

WARNING

To prevent injury or misdiagnosis, do not use this system for fetal growth screening if the advanced OB calculations and reports package is not available.

On the **OB Calculations** setup page, you can select authors for OB gestational calculation tables. Refer to “**OB calculations**” on page 5-30.

To specify gestational age and growth analysis

- 1 On the OB Calculations setup page, select the desired OB authors (or select **None**) in the measurement lists under **Gestational Age** and **Growth Analysis**.

Selecting an author places the associated measurement on the calculations menu.

- 2 (Optional) Select **More** to display the list of user-defined custom measurements and to associate a custom table for the custom measurement.

Note

This option is available only when a user-defined custom table has been created for the custom measurement.

To export OB calculation tables

- 1 Insert a USB storage device.
- 2 On the OB Calculations setup page, select **Export**. A list of USB devices appears.
- 3 Select the USB storage device, and select **Export**. All user-defined tables and measurements are copied to the USB storage device.

To import OB calculation tables

Tables that you import are added to those already on the system.

- 1 Insert the USB storage device that contains the tables.
- 2 On the OB Calculations setup page, select **Import** on-screen.
- 3 Select the USB storage device, and then select **Import**.

4 Select **OK** in the dialog box that appears. The system restarts.

OB Custom Measurements setup

On the OB Custom Measurements setup page, you can define measurements that appear in the OB calculations menu and OB report. OB Custom Measurements is an optional feature. See “[OB calculations](#)” on page 5-30.

WARNING

When you create, remove, or import a custom obstetric measurement, the system clears all saved measurements and calculations for the current patient.

To set up OB custom measurements

You can save up to five custom measurements that appear in the OB calculations menu and OB report.

- 1 On the OB Custom Measurements setup page, select **New**.
- 2 In the **Name** box, type a unique name.
- 3 In the **Type** list, select the desired measurement type.
- 4 Select **Save**.

To delete an OB custom measurement

WARNING

If you delete an OB custom measurement during an exam, the exam ends. You must make changes before you begin the clinical exam.

- 1 On the OB Custom Measurements setup page, highlight the measurement in the **Custom Measurements** list.
- 2 Select **Delete Last**.
- 3 Select **Yes**. The exam ends, and any tables and report data associated with the measurement are removed from the system.

OB Custom Tables setup

On the OB Custom Tables setup pages, you can customize growth tables that appear in the calculations menu and patient report.

Gestational Age Table Measurements

The system provides gestational age measurements by selected authors for the following:

- ▶ GS
- ▶ BPD
- ▶ HC
- ▶ APTD
- ▶ FTA
- ▶ EFW
- ▶ HL
- ▶ CRL
- ▶ OFD
- ▶ TTD
- ▶ AC
- ▶ FL
- ▶ Tibia
- ▶ Five additional custom measurement labels

Growth Analysis Table Measurements

The system provides growth graphs or curves for the following:

- ▶ BPD
- ▶ AC
- ▶ EFW
- ▶ HC
- ▶ FL
- ▶ HC/AC

WARNING

Prior to use, verify that custom table data entries are correct. The system does not confirm the accuracy of the custom table data entered by the user.

To view OB tables

- 1 On the OB Calculations or OB Custom Measurements setup page, select **Tables** on-screen.
- 2 Select the desired table and measurement/author.

To create a new OB custom table

You can create two custom tables for each OB measurement.

- 1 On the OB Calculations or OB Custom Measurements setup page, select **Tables** on-screen.
- 2 Select the desired table (**Gestational Age** or **Growth Analysis**).
- 3 In the **Measurement** list, select the measurement for the custom table.
- 4 Select **New** on-screen.

- 5 In the **Author** box, type a unique name.
- 6 Enter the data.
- 7 Select **Save** on-screen.

To display the measurement for the custom table in the calculations menu, see [“To specify gestational age and growth analysis”](#) on page 3-11.

To edit or delete an OB custom table

- 1 On the OB Calculations or OB Custom Measurements setup page, select **Tables** on-screen.
- 2 Select the OB custom table.
- 3 Select one of the following on-screen:
 - ▶ **Edit**. Enter data, and then select **Save** on-screen.
 - ▶ **Delete** to remove the custom table. Select **Yes**.

Presets setup

The **Presets** setup page enables you to choose some general preferences. Use the following information to help you choose the presets that are right for you:

Doppler scale

- ❖ Select **cm/s** or **kHz**.

Duplex

Specifies the screen layout when displaying M Mode trace and Doppler spectral trace:

- ▶ **1/3 2D, 2/3 Trace**
Divides the screen so that the top 1/3 shows the 2D image, while the bottom 2/3 displays the trace.
- ▶ **1/2 2D, 1/2 Trace**
The 2D image and the trace each occupy 1/2 of the screen.
- ▶ **Full 2D, Full Trace**
You can switch between the two full-screen views.

Live Trace

- ❖ Select **Peak** or **Mean**.

Thermal Index

❖ Choose between **TIS**, **TIB**, or **TIC**.

By default, this setting is based on exam type: OB is **TIB**, TCD is **TIC**, and all others are **TIS**.

Save Key

Determines the behavior of the **Save** key:

▶ **Image Only**

Saves the image to internal storage.

▶ **Image/Calcs**

Saves the image to internal storage and saves the current calculation to the patient report.

Dynamic Range

❖ Choose between **-3**, **-2**, **-1**, **0**, **+1**, **+2**, or **+3**.

Note

Negative numbers show higher contrast images, and positive numbers show lower contrast images.

Units

Choose the units you want to use for patient height and weight in cardiac exams: **in/ft/lbs** or **cm/m/kg**.

Auto save Pat. Form

When turned on, automatically saves the patient information form as an image in the patient's file.

System Information setup

The **System Information** setup page displays system hardware and software versions, patents, and license information.

To enter a license key, see ["To enter a license key"](#) on page 7-3.

To display patents

❖ On the **System Information** setup page, select **Patents**.

USB Devices setup

On the **USB Devices** setup page, you can view information about connected USB devices, including space availability. You can also specify a file format for images in patient exams that you export to a USB storage device. See [“To export patient exams to a USB storage device”](#) on page 4-31.

Notes

- ▶ USB storage devices must be in FAT-32 format.
- ▶ The system does not support software-encrypted USB memory sticks.

To help secure sensitive patient information, the USB export feature can be disabled by the administrator. For more information about disabling USB export, see [“To disable USB export”](#) on page 3-3.

To specify a file format for exported images

- 1 On the USB Devices setup page, select **Export**.
- 2 Under **USB Export**, select an export type:
 - ▶ **SiteLink** organizes files in a SiteLink-style folder structure. Clips export in H.264 video saved as MP4 files. To view them, FUJIFILM SonoSite recommends QuickTime 7.0 or later.
 - ▶ **DICOM** creates files readable by a DICOM reader.
- 3 Select an image format for your export type. For JPEG image format, also select a JPEG compression. Refer to [“Limitations of JPEG format”](#) on page 3-17.

Notes

- ▶ A high compression has a smaller file size but less detail.
- ▶ For **SiteLink** export type, the image format affects only still images.
- ▶ For **DICOM** export type, the image format affects both still images and clips.

- 4 For **SiteLink** export type, select a sort order under **Sort By**.

To return to the previous screen, select **Devices**.

To enable automatic exam export

- 1 On the USB Devices setup page, select **Export**.
- 2 Under **USB Export** select the AutoExport box.

To include private tags

- 1 If you use DICOM export type and a FUJIFILM SonoSite software product, include private tags on the images.

2 On the USB Devices setup page, select **Include private tags**.

Note

Because the tags may be incompatible with some earlier archivers, keep this check box unselected unless you use FUJIFILM SonoSite software products. For more information, refer to the ultrasound system's DICOM conformance statement.

Limitations of JPEG format

When transferring or exporting images in JPEG format, the system uses *lossy compression*. Lossy compression may create images that have less absolute detail than BMP format and that don't render identically to the original images.

JPEG settings:

Setting	Quality Level
Low	100%; Difference in compressed and uncompressed images is near 0
Medium	90%; Generally, loss of detail occurs only in high frequency content (edges)
High	75%; General loss of detail

In some circumstances, lossy-compressed images may be inappropriate for clinical use. For more information on using lossy-compressed images, consult the industry literature, including the following references:

"Physics in Medicine and Biology, Quality Assessment of DSA, Ultrasound and CT Digital Images Compressed with the JPEG Protocol," D Okkalides et al. 1994 Phys Med Biol 39 1407-1421 doi: 10.1088/0031-9155/39/9/008 www.iop.org/EJ/abstract/0031-9155/39/9/008

"Canadian Association of Radiologists, CAR Standards for Irreversible Compression in Digital Diagnostic Imaging within Radiology," Approved: June 2008. www.car.ca/Files/%5CLossy_Compression.pdf

CHAPTER 4

Imaging

Imaging modes

The SonoSite Edge II system has a high-performance display and advanced image-optimization technology that simplifies user controls. Available imaging modes depend on the transducer and exam type. Refer to **“Imaging modes and exams available by transducer”** on page 4-16.

2D imaging

2D is the system's default imaging mode. The system displays echoes in two dimensions by assigning a brightness level based on the echo signal amplitude. To achieve the best image quality, properly adjust the gain and depth settings, viewing angle, and exam type. For more information about presets, see **“Presets setup”** on page 3-14.

To display the 2D image

- 1 Do one of the following:
 - ▶ Turn on the system.
 - ▶ From another imaging mode, press the **2D** key.
- 2 Adjust the controls. For more information, see **“2D controls”** on page 4-2.

2D controls

Table 4-1: 2D on-screen controls

Control	Description
Optimize 	<p>Settings are as follows:</p> <ul style="list-style-type: none"> ▶ Res provides the best possible resolution. ▶ Gen provides a balance between resolution and penetration. ▶ Pen provides the best possible penetration. <p>Some of the parameters optimized to provide the best image include focal zones, aperture size, frequency (center and bandwidth), and waveform. They cannot be adjusted by the user.</p>
Dynamic Range 	<p>Adjusts the grayscale range: -3, -2, -1, 0, +1, +2, +3. Remember, the positive range increases the number of grays displayed, and the negative range decreases the number of grays displayed.</p>
Dual 	<p>Displays side-by-side 2D images. Select Dual, and then press the UPDATE key to display the second screen and to toggle between the screens. With both images frozen, press the UPDATE key to toggle between the images. To return to full-screen 2D imaging, select Dual or press the 2D key.</p>
LVO On, LVO Off 	<p>LVO On turns on Left Ventricular Opacification. LVO Off turns off this control. Use LVO for cardiac exams in 2D imaging mode. LVO lowers the mechanical index (MI) of the system. This control depends on transducer and exam type.</p>
Orientation 	<p>Select from four image orientations: U/R (Up/Right), U/L (Up/Left), D/L (Down/Left), D/R (Down/Right).</p>
Brightness 	<p>Adjusts the display brightness. Settings range from 1 to 10. The display brightness affects battery life. To conserve battery life, adjust brightness to a lower setting.</p>

Table 4-1: 2D on-screen controls (continued)

Control	Description
<p>Guide</p> 	<p>Turns guidelines on and off. Guidelines are for needle guidance, are an optional feature, and depend on transducer type.</p> <p>For transducers with a single-angle or multi-angle bracket, the touchpad moves the depth cursor.</p> <p>If the transducer uses a multi-angle bracket, select Guide and then select the angle: A, B, or C. To exit angle selection, select Back. To clear the guides, do either of the following:</p> <ul style="list-style-type: none"> ▶ Select the angle again (A, B, or C). ▶ Exit angle selection and press Guide. <p>See the needle guide’s user documentation.</p> <p>Guide is not available when the ECG cable is connected.</p>
<p>Sector</p> 	<p>Specifies the sector width.</p> <p>Available only for the cardiac exam.</p>
<p>SonoMB (MB)</p> 	<p>MB On and MB Off turn SonoMB multi-beam imaging technology on and off. When SonoMB is on, <i>MB</i> appears in the upper left-hand screen.</p> <p>SonoMB depends on transducer and exam type.</p>
<p>SNP</p>	<p>Turns on Steep Needle Profiling technology. See “Visualizing needles” on page 4-11.</p> <p>SNP depends on transducer and exam type.</p>
<p>ECG</p>	<p>Displays the ECG signal. Refer to “ECG” on page 4-32.</p> <p>This feature is optional and requires a FUJIFILM SonoSite ECG cable.</p>
<p>Clips</p>	<p>Displays the clip controls. Refer to “To save a clip” on page 4-27.</p>
<p>THI</p> 	<p>Turns Tissue Harmonic Imaging on and off.</p> <p>When on, <i>THI</i> appears in the upper left-hand screen. This feature depends on transducer and exam type.</p>
<p>Centerline</p>	<p>Turns the centerline graphic on or off. See “Centerline” on page 4-14.</p>
<p>Page x/x</p>	<p>Indicates which page of controls is displayed. Select to display the next page.</p>

M Mode imaging

Motion mode (M Mode) is an extension of 2D. It provides a trace of the 2D image displayed over time. A single beam of ultrasound is transmitted, and reflected signals are displayed as dots of varying intensities, which create lines across the screen.

To display the M-line

- 1 Press the **M** key.

Note

If the M-line does not appear, make sure that the image isn't frozen.

- 2 Use the touchpad to position the M-line where desired.
- 3 Adjust controls as desired.

Many optimization and depth controls available in 2D imaging are also available in M Mode imaging. See ["2D controls"](#) on page 4-2.

To display the M Mode sweep

- 1 Display the M-line.
- 2 Adjust the depth if necessary to show the structure you want to scan. For more information, see ["To adjust depth"](#) on page 4-9.
- 3 Press the **M** key. The time scale above the trace has small marks at 200ms intervals and large marks at one-second intervals.
- 4 Do any of the following as needed:
 - ▶ Select the sweep speed  (**Slow**, **Med**, or **Fast**).
 - ▶ Press the **UPDATE** key to toggle between the M-line and M Mode sweep.
 - ▶ If using a duplex layout, press the **M** key to toggle between the full-screen M-line and the duplex layout.

To set a duplex layout, see ["Presets setup"](#) on page 3-14.

CPD and Color imaging

Color power Doppler (CPD) is used to visualize the presence of detectable blood flow. Color is used to visualize the presence, velocity, and direction of blood flow in a wide range of flow states.

To display the CPD or Color image

- 1 Press the **C** key.

A ROI box appears in the center of the 2D image. The current selection (**Color** or **CPD**) appears in the upper left-hand screen.

Note

In Color imaging, the Color indicator bar on the upper left-hand screen displays velocity in cm/s.

- 2 To change to CPD, select **CPD**.
- 3 Using the touchpad, you can change the position or size of the ROI box as needed. Press the **SELECT** key to toggle between position and size.

Note

While you position or resize the ROI box, a color outline shows the change. The ROI box indicator on the left-hand screen shows which touchpad function is active.

- 4 Adjust controls as desired. Refer to [“CPD and Color controls.”](#)

CPD and Color controls

Table 4-2: CPD and Color on-screen controls

Control	Description
Color, CPD 	Toggle between CPD and Color. The current selection appears in the upper left-hand screen.
Color Suppress 	Shows or hides color information. You can select Show or Hide while in live or frozen imaging. The setting shown on-screen is the current selection.
Flow Sensitivity 	The current setting appears on-screen. <ul style="list-style-type: none">▶ Low optimizes the system for low flow states.▶ Med optimizes the system for medium flow states.▶ High optimizes the system for high flow states.
PRF Scale 	Select the desired pulse repetition frequency (PRF) setting by pressing the control keys. There is a wide range of PRF settings for each Flow Sensitivity setting (Low, Med, and High). Available on select transducers.

Table 4-2: CPD and Color on-screen controls

Control	Description
Wall Filter 	Settings include Low , Med , and High .
Steering 	Select the steering angle setting of the color ROI box (-15 , 0 , or +15). If adding PW Doppler, see "PW Doppler controls" on page 4-7. Available on select transducers.
Variance 	Turns variance on and off. Available only for the cardiac exam.
Invert 	Switches the displayed direction of flow. Available in Color imaging.
Page x/x	Indicates which page of controls is displayed. Select to display the next page.

PW and CW Doppler imaging

Pulsed wave (PW) Doppler and continuous wave (CW) Doppler imaging modes are optional features. The default Doppler imaging mode is PW Doppler. In cardiac exams, you can select the CW Doppler on-screen control.

PW Doppler is a Doppler recording of blood flow velocities in a range specific area along the length of the beam. CW Doppler is a Doppler recording of blood flow velocities along the length of the beam.

You can use PW/CW Doppler and CPD/Color simultaneously. If CPD/Color imaging is on, the color ROI box is tied to the D-line. The **SELECT** key cycles among color ROI box position; color ROI box size; the D-line and gate location; and (in PW Doppler) angle correction. The active selection is highlighted. Also, the indicator on the left-hand screen shows which touchpad function is active.

To display the D-line

- 1 Press the **D** key.

Note

If the D-line does not appear, make sure that the image isn't frozen.

- 2 Do any of the following as needed:

- ▶ Adjust controls as described in **"PW Doppler controls"** on page 4-7.

- ▶ Using the touchpad, position the D-line and gate where desired. Horizontal movements position the D-line. Vertical movements position the gate.

PW Doppler

- ▶ To correct the angle manually, do one of the following:
 - ▶ Press the **SELECT** key and then use the touchpad. The **SELECT** key toggles between the D-line and angle correction.
 - ▶ Freeze the image, and then use the **FAR** gain knob to adjust the angle in 2° increments from -74° to +74°.

To display the spectral trace

- 1 Display the D-line.
- 2 Press the **D** key. The time scale above the trace has small marks at 200 ms intervals and large marks at one-second intervals.
- 3 Do any of the following as needed:
 - ▶ Adjust controls, as described in **“Spectral trace controls”** on page 4-8.
 - ▶ Press the **UPDATE** key to toggle between the D-line and spectral trace.
 - ▶ If using a duplex layout, press the **D** key to toggle between the full-screen D-line and the duplex layout.
To set a duplex layout, see **“Presets setup”** on page 3-14.

PW Doppler controls

Table 4-3: PW Doppler on-screen controls

Control	Description
PW, CW 	CW applies to Cardiac exam only. Toggle between PW Doppler and CW Doppler. The current selection appears in the upper left-hand screen.
Angle Correction 	Corrects the angle to 0° , +60° , or -60° . You may also adjust the angle using the touchpad.
Gate Size 	Settings depend on transducer and exam type. In TCD or Orb exams, use the touchpad to specify the Doppler gate depth (the depth of the center of the gate in the Doppler image). The Doppler gate depth indicator is on the lower right-hand screen.
TDI On, TDI Off	Select TDI On to turn on Tissue Doppler Imaging. When on, <i>TDI</i> appears in the upper left-hand screen. The default is TDI off . Available only in cardiac exams.

Table 4-3: PW Doppler on-screen controls (continued)

Control	Description
Steering 	<p>Select the desired steering angle setting. Settings available depend on the transducer. The PW Doppler angle correction automatically changes to the optimum setting.</p> <ul style="list-style-type: none"> ▶ -15 and -20 have an angle correction of -60°. ▶ 0 has an angle correction of 0°. ▶ +15 and +20 have an angle correction of $+60^\circ$. <p>You can manually correct the angle after selecting a steering angle setting. See “To display the D-line” on page 4-6.</p> <p>Available on select transducers.</p>
Page x/x	<p>Indicates which page of controls is displayed. Select to display the next page.</p>

Spectral trace controls

Table 4-4: Spectral trace on-screen controls

Control	Description
Scale 	<p>Select the desired scale [pulse repetition frequency (PRF)] setting.</p> <p>To change the Doppler scale to cm/s or kHz, see “Presets setup” on page 3-14.</p>
Line 	<p>Sets the baseline position.</p> <p>(On a frozen trace, the baseline can be adjusted if Live Trace is off.)</p>
Invert 	<p>Vertically flips the spectral trace.</p> <p>(On a frozen trace, Invert is available if Live Trace is off.)</p>
Volume 	<p>Increases or decreases Doppler speaker volume (0-10).</p>
Wall Filter 	<p>Settings include Low, Med, High.</p>

Table 4-4: Spectral trace on-screen controls (continued)

Control	Description
Sweep Speed 	Settings include Slow, Med, Fast .
Live Trace 	Displays a live trace of the peak or mean. See “Presets setup” on page 3-14 to specify peak or mean.
Page x/x	Indicates which page of controls is displayed. Select to display the next page.

Adjusting depth and gain

To adjust depth

You can adjust the depth in all imaging modes except M Mode. The vertical depth scale is marked in 0.5 cm, 1 cm, and 5 cm increments, depending on the depth.

❖ Press the following keys:

- ▶ **DEPTH UP** key to decrease the displayed depth.
- ▶ **DEPTH DOWN** key to increase the displayed depth.

As you adjust the depth, the maximum depth number changes in the lower right screen.

To adjust gain automatically

❖ Press the **AUTO** key. The gain adjusts each time you press this key.

To adjust gain manually

❖ Turn the gain knobs to the left to decrease gain. Turn the knobs to the right to increase gain:

- ▶ **NEAR** adjusts the gain applied to the near field of the 2D image.
- ▶ **FAR** adjusts the gain applied to the far field of the 2D image.
- ▶ **GAIN** adjusts the overall gain applied to the entire image. In CPD or Color imaging, the **GAIN** knob affects the color gain applied to the region of interest (ROI) box. In PW and CW Doppler imaging, the **GAIN** knob affects Doppler gain.

NEAR and **FAR** correspond to the time gain compensation (TGC) controls on other ultrasound systems.

Freezing, viewing frames, and zooming

To freeze or unfreeze an image

- ❖ Press the **Freeze** key.

On a frozen image, the cine icon and frame number appear in the system status area.

To move forward or backward in the cine buffer

- ❖ Freeze the image, and do one of the following:
 - ▶ Turn the **GAIN** knob left to move backward or right to move forward
 - ▶ Use the touchpad. Left moves backward, and right moves forward.
 - ▶ Press the **left arrow** and **right arrow** keys.

The frame number changes as you move forward or backward. The total number of frames in the buffer appears on-screen in the system status area.

To zoom in on an image

You can zoom in 2D or Color imaging. You can freeze or unfreeze the image or change the imaging mode at any time while zooming.

- 1 Press the **ZOOM** key. A ROI box appears.
- 2 Using the touchpad, position the ROI box as desired.
- 3 Press the **ZOOM** key again. The image in the ROI box is magnified by 100%.
- 4 **(Optional)** If the image is frozen, use the touchpad to pan the image up, down, left, and right. (You cannot pan in Dual.)
- 5 To exit zoom, press the **ZOOM** key again.

Visualizing needles

WARNING

To avoid incorrect needle placement when Steep Needle Profiling (SNP) is on:

- ▶ Use only FUJIFILM SonoSite or CIVCO approved needle guides, brackets, supplies, components, and accessories. Other brands may not properly fit FUJIFILM SonoSite transducers.
- ▶ Use only needle guides compatible with the transducers listed in [Table 4-5](#) on page 4-11.
- ▶ Using movement and fluid injection, verify the needle-tip location and trajectory. Steep Needle Profiling technology enhances linear structures within a selected angle range on the ultrasound plane. Linear structures outside the selected angle range or the ultrasound plane—such as a bent needle—may be less apparent.
- ▶ Note that linear structures are enhanced only in an outlined portion of the image. The area outside the outline remains unchanged.
- ▶ Note that the beam divergence of a curved array transducer may prevent a segment of the needle shaft from showing in the image. The needle tip may not show.

About Steep Needle Profiling technology

The SNP control turns on Steep Needle Profiling technology, which enhances linear structures within a selected angle range and can facilitate needle guidance during catheter placement and nerve-block procedures. A three- or four-sided outline indicates the enhancement area as shown in [Figure 4-1](#) on page 4-13.

For curved array transducers, Steep Needle Profiling technology can help identify the direction of the needle, although only segments of the needle shaft may show in the image. See [Figure 4-2](#) on page 4-13. Use movement and fluid injection to help verify the needle-tip location.

The SNP control is available in 2D full-screen imaging only and on the following:

Table 4-5: Transducers and exam types available with Steep Needle Profiling

Transducer	Arterial	Breast	Musculoskeletal	Nerve	Small Parts	Spine	Venous
C35x			✓	✓		✓	
rC60xi standardarmored			✓	✓			

Table 4-5: Transducers and exam types available with Steep Needle Profiling

Transducer	Arterial	Breast	Musculoskeletal	Nerve	Small Parts	Spine	Venous
HFL38xi standard/armored	✓	✓	✓	✓	✓		✓
HFL50x		✓	✓	✓	✓		
HSL25x	✓		✓	✓			✓
L25x standard/armored	✓		✓	✓			✓
L38xi standard/armored				✓			

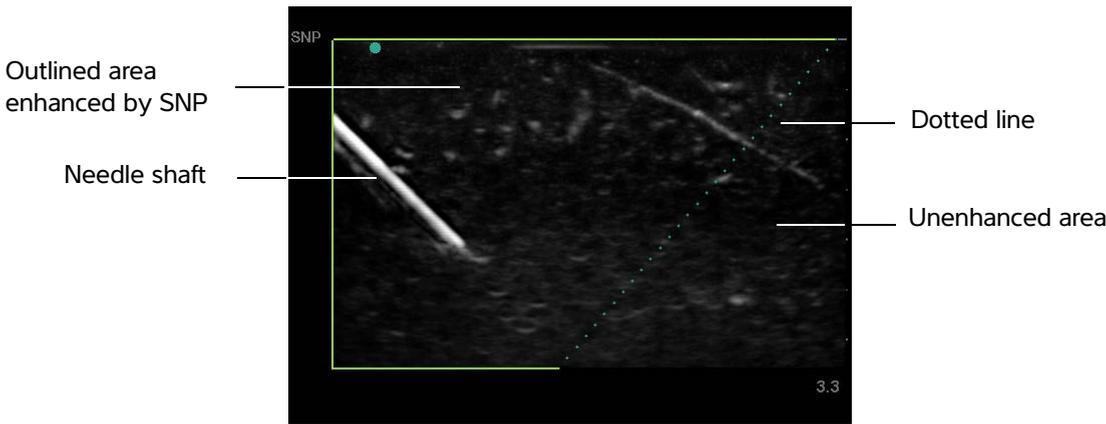


Figure 4-1 Image with SNP on (linear transducer)

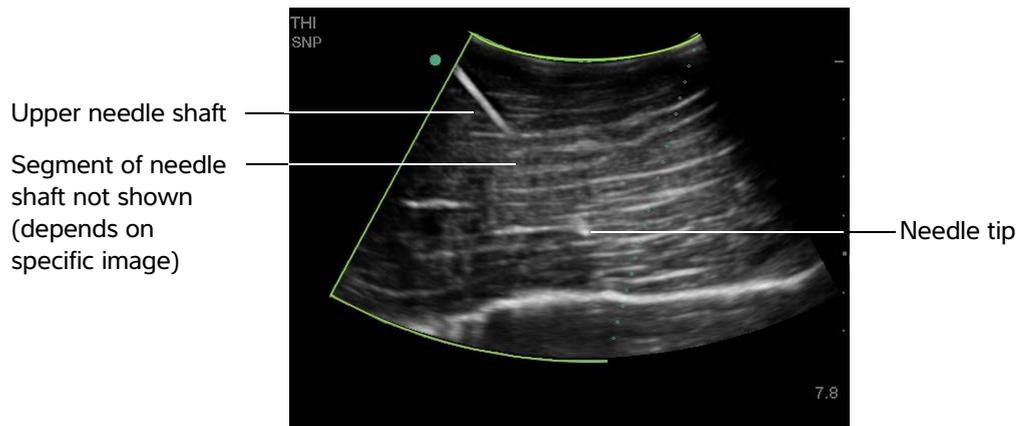


Figure 4-2 With a curved array transducer, only segments of the needle shaft may show

Needle size and angle

Use a 17-gauge to 25-gauge needle (recommended). Enhancement results can depend on the type and brand of needle used. For more information, consult the medical literature on needle visibility in ultrasound-guided procedures.

You can angle the needle up to 50° from the transducer surface as shown in [Figure 4-3](#) on page 4-13. Beyond 50°, the needle may be less enhanced.

WARNING To avoid patient injury when using a multi-angle bracket, make sure that the same angle is selected (A, B, or C) on both the bracket and the ultrasound system.

Note Steep Needle Profiling technology is intended for in-plane procedures only. Steep Needle Profiling technology has little or no benefit to out-of-plane procedures.

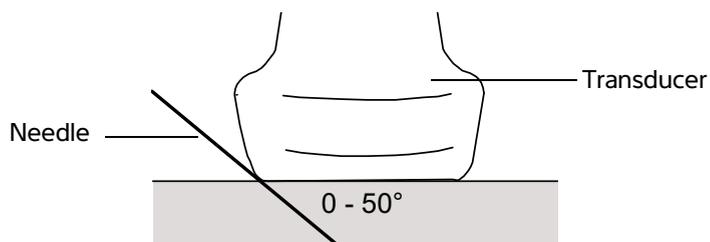


Figure 4-3 For best results, angle the needle only up to 50° from the transducer surface.

SNP subcontrols

When Steep Needle Profiling technology is on, additional controls are available:

- ▶ **L/R Flip** flips the affected area (the outline) horizontally on the image. For reorienting the entire image, use the orientation control. See “**2D controls**” on page 4-2.
- ▶ **Shallow, Medium, or Steep** sets the outline’s sloped edge, which is indicated by a dotted line. The current selection is highlighted.
 - ▶ **Linear transducer:** Use whichever setting best provides a perpendicular intersection with the dotted line. Within the enhancement area, the more perpendicular that a linear structure is to the dotted line, the more it is enhanced. Similarly, the less perpendicular (and more parallel) that a linear structure is to the dotted line, the less it is enhanced.
 - ▶ **Curved array transducer:** For a linear structure angled 30° or less from the transducer surface, use **Shallow** for best enhancement. For a linear structure angled 30-40°, use **Medium**. For a linear structure angled 40° or greater, use **Steep**.
- ▶ **Off** turns off SNP. Temporarily turning off SNP can help you identify artifacts and other structures not of interest.
- ▶ **Back** returns to the previous screen. If Steep Needle Profiling technology is on, SNP is highlighted and SNP appears in the mode data area. Pressing SNP again redisplay the SNP controls.

Note

If Steep Needle Profiling technology is on, the MB control is unavailable.

Additional recommendations

Avoid setting the gain too high when using Steep Needle Profiling technology, as unnecessarily high gain can cause artifacts in the image. Also, respiratory and cardiac movement in the image may cause bright pulsating artifacts.

If you use Steep Needle Profiling technology frequently, consider using a shortcut key to turn on the SNP control. For instructions to program a shortcut key, see “**A & B Key, Footswitch setup**” on page 3-1.

Centerline

Centerline is only available with certain transducers. The centerline graphic aligns with the center mark of the transducer and serves as a reference mark for the center of the displayed image.

When using the Centerline feature as a reference during a freehand procedure, be aware that the centerline represents only the center of the ultrasound image and is not an accurate predictor of the path the needle will take.

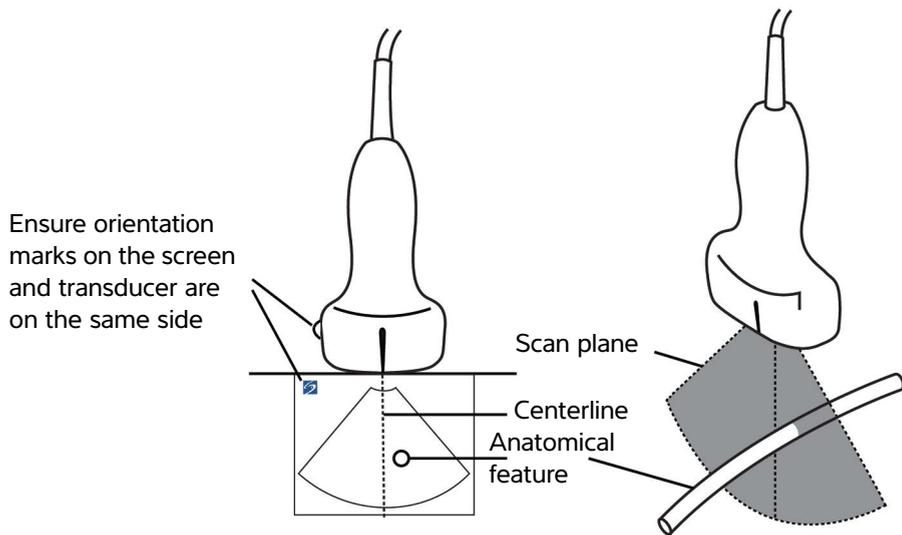


Figure 4-4 Relationship of the centerline graphic to the transducer and the ultrasound image.

Small tilts or rotations of the transducer can affect the relationship between any external reference points and the anatomy that appears on the ultrasound image.

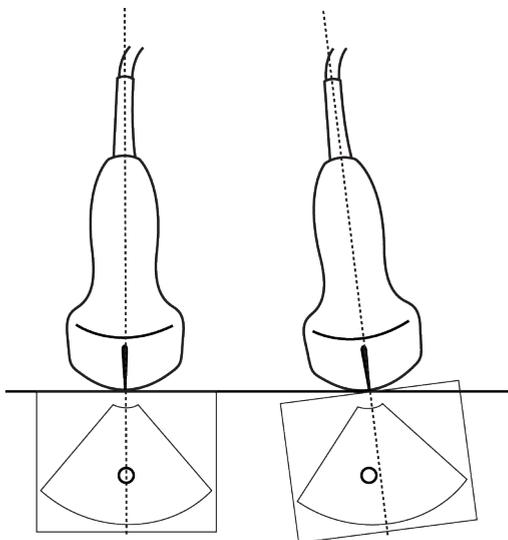


Figure 4-5 Relationship of the ultrasound image to the transducer angle or tilt.

Imaging modes and exams available by transducer

WARNING

- ▶ To prevent misdiagnosis or harm to the patient, understand your system’s capabilities prior to use. The diagnostic capability differs for each transducer, exam type, and imaging mode. Transducers are developed to specific criteria depending on their physical application. These criteria include biocompatibility requirements. Understand the system’s capabilities prior to use.
- ▶ To avoid injury to the patient, use only an Ophthalmic (Oph) or Orbital (Orb) exam when performing imaging through the eye. The FDA has established lower acoustic energy limits for ophthalmic use. The system will not exceed these limits only if the Orb or Oph exam type is selected.

The transducer you use determines which exam types are available. In addition, the exam type you select determines which imaging modes are available. Depending on the configuration of your system, not all transducers and exam types may be available,

To change the exam type

- ❖ Do one of the following:
 - ▶ Press the **Exam** key, and select from the menu.
 - ▶ On the patient information form, select from the **Type** list in the **Exam** window. Refer to **“Patient information form”** on page 4-23.

Table 4-6: Imaging modes and exams available by transducer

Transducer	Exam type ^a	Imaging mode				
		2D ^b M Mode	CPD ^c	Color ^c	PW Doppler ^d	CW Doppler
C8x ^e	Pro	✓	✓	✓	✓	

^aExam type abbreviations are as follows: Abd = Abdomen, Art = Arterial, Bre = Breast, Crd = Cardiac, Gyn = Gynecology, Msk = Musculoskeletal, Neo = Neonatal, Nrv = Nerve, OB = Obstetrical, Oph = Ophthalmic, Orb = Orbital, Pro = Prostate, SmP = Small Parts, Spn = Spine, Sup = Superficial, TCD = Transcranial Doppler, Ven = Venous.

^bThe optimization settings for 2D are Res, Gen, and Pen.

^cThe optimization settings for CPD and Color are low, medium, and high (flow sensitivity) with a range of PRF settings for Color depending on the setting selected.

^dFor the cardiac exam type, PW TDI is also available. See **“PW Doppler controls”** on page 4-7.

^eNeedle guide-capable. For more information, refer to *Using CIVCO Products with FUJIFILM SonoSite Systems*.

^fFor more information refer to the *TEEXi Transducer User Guide*, included with the TEEXi transducer.

Table 4-6: Imaging modes and exams available by transducer (continued)

Transducer	Exam type ^a	Imaging mode				
		2D ^b M Mode	CPD ^c	Color ^c	PW Doppler ^d	CW Doppler
C11x	Abd	✓	✓	✓	✓	
	Art	✓	✓	✓	✓	
	Neo	✓	✓	✓	✓	
	Nrv	✓	✓	✓	✓	
	Ven	✓	✓	✓	✓	
C35x ^e	Abd	✓	✓	✓	✓	
	Msk	✓	✓	✓	✓	
	Nrv	✓	✓	✓	✓	
	OB	✓	✓	✓	✓	
	Spn	✓	✓	✓	✓	

^aExam type abbreviations are as follows: Abd = Abdomen, Art = Arterial, Bre = Breast, Crd = Cardiac, Gyn = Gynecology, Msk = Musculoskeletal, Neo = Neonatal, Nrv = Nerve, OB = Obstetrical, Oph = Ophthalmic, Orb = Orbital, Pro = Prostate, SmP = Small Parts, Spn = Spine, Sup = Superficial, TCD = Transcranial Doppler, Ven = Venous.

^bThe optimization settings for 2D are Res, Gen, and Pen.

^cThe optimization settings for CPD and Color are low, medium, and high (flow sensitivity) with a range of PRF settings for Color depending on the setting selected.

^dFor the cardiac exam type, PW TDI is also available. See **"PW Doppler controls"** on page 4-7.

^eNeedle guide-capable. For more information, refer to *Using CIVCO Products with FUJIFILM SonoSite Systems*.

^fFor more information refer to the *TEExi Transducer User Guide*, included with the TEExi transducer.

Table 4-6: Imaging modes and exams available by transducer (continued)

Transducer	Exam type ^a	Imaging mode				
		2D ^b M Mode	CPD ^c	Color ^c	PW Doppler ^d	CW Doppler
rC60xi standard/ armored ^e	Abd	✓	✓	✓	✓	
	Gyn	✓	✓	✓	✓	
	Nrv	✓	✓	✓	✓	
	Msk	✓	✓	✓	✓	
	OB	✓	✓	✓	✓	
HFL38xi standard/ armored ^e	Art	✓	✓	✓	✓	
	Bre	✓	✓	✓	✓	
	Lung	✓	✓	✓	✓	
	Msk	✓	✓	✓	✓	
	Nrv	✓	✓	✓	✓	
	Oph	✓	✓	✓	✓	
	SmP	✓	✓	✓	✓	
	Ven	✓	✓	✓	✓	

^aExam type abbreviations are as follows: Abd = Abdomen, Art = Arterial, Bre = Breast, Crd = Cardiac, Gyn = Gynecology, Msk = Musculoskeletal, Neo = Neonatal, Nrv = Nerve, OB = Obstetrical, Oph = Ophthalmic, Orb = Orbital, Pro = Prostate, SmP = Small Parts, Spn = Spine, Sup = Superficial, TCD = Transcranial Doppler, Ven = Venous.

^bThe optimization settings for 2D are Res, Gen, and Pen.

^cThe optimization settings for CPD and Color are low, medium, and high (flow sensitivity) with a range of PRF settings for Color depending on the setting selected.

^dFor the cardiac exam type, PW TDI is also available. See **"PW Doppler controls"** on page 4-7.

^eNeedle guide-capable. For more information, refer to *Using CIVCO Products with FUJIFILM SonoSite Systems*.

^fFor more information refer to the *TEExi Transducer User Guide*, included with the TEExi transducer.

Table 4-6: Imaging modes and exams available by transducer (continued)

Transducer	Exam type ^a	Imaging mode				
		2D ^b M Mode	CPD ^c	Color ^c	PW Doppler ^d	CW Doppler
HFL50x ^e	Bre	✓	✓	✓	✓	
	Msk	✓	✓	✓	✓	
	Nrv	✓	✓	✓	✓	
	SmP	✓	✓	✓	✓	
HSL25x	Art	✓	✓	✓	✓	
	Lung	✓	✓	✓	✓	
	Msk	✓	✓	✓	✓	
	Nrv	✓	✓	✓	✓	
	Oph	✓	✓	✓	✓	
	Sup	✓	✓	✓	✓	
	Ven	✓	✓	✓	✓	
ICTx ^e	Gyn	✓	✓	✓	✓	
	OB	✓	✓	✓	✓	

^aExam type abbreviations are as follows: Abd = Abdomen, Art = Arterial, Bre = Breast, Crd = Cardiac, Gyn = Gynecology, Msk = Musculoskeletal, Neo = Neonatal, Nrv = Nerve, OB = Obstetrical, Oph = Ophthalmic, Orb = Orbital, Pro = Prostate, SmP = Small Parts, Spn = Spine, Sup = Superficial, TCD = Transcranial Doppler, Ven = Venous.

^bThe optimization settings for 2D are Res, Gen, and Pen.

^cThe optimization settings for CPD and Color are low, medium, and high (flow sensitivity) with a range of PRF settings for Color depending on the setting selected.

^dFor the cardiac exam type, PW TDI is also available. See **"PW Doppler controls"** on page 4-7.

^eNeedle guide-capable. For more information, refer to *Using CIVCO Products with FUJIFILM SonoSite Systems*.

^fFor more information refer to the *TEExi Transducer User Guide*, included with the TEExi transducer.

Table 4-6: Imaging modes and exams available by transducer (continued)

Transducer	Exam type ^a	Imaging mode				
		2D ^b M Mode	CPD ^c	Color ^c	PW Doppler ^d	CW Doppler
L25x standard/ armored ^e	Art	✓	✓	✓	✓	
	Lung	✓	✓	✓	✓	
	Msk	✓	✓	✓	✓	
	Nrv	✓	✓	✓	✓	
	Oph	✓	✓	✓	✓	
	Sup	✓	✓	✓	✓	
	Ven	✓	✓	✓	✓	
L38xi standard/ armored ^e	Art	✓	✓	✓	✓	
	Lung	✓	✓	✓	✓	
	Nrv	✓	✓	✓	✓	
	SmP	✓	✓	✓	✓	
	Ven	✓	✓	✓	✓	

^aExam type abbreviations are as follows: Abd = Abdomen, Art = Arterial, Bre = Breast, Crd = Cardiac, Gyn = Gynecology, Msk = Musculoskeletal, Neo = Neonatal, Nrv = Nerve, OB = Obstetrical, Oph = Ophthalmic, Orb = Orbital, Pro = Prostate, SmP = Small Parts, Spn = Spine, Sup = Superficial, TCD = Transcranial Doppler, Ven = Venous.

^bThe optimization settings for 2D are Res, Gen, and Pen.

^cThe optimization settings for CPD and Color are low, medium, and high (flow sensitivity) with a range of PRF settings for Color depending on the setting selected.

^dFor the cardiac exam type, PW TDI is also available. See **"PW Doppler controls"** on page 4-7.

^eNeedle guide-capable. For more information, refer to *Using CIVCO Products with FUJIFILM SonoSite Systems*.

^fFor more information refer to the *TEExi Transducer User Guide*, included with the TEExi transducer.

Table 4-6: Imaging modes and exams available by transducer (continued)

Transducer	Exam type ^a	Imaging mode				
		2D ^b M Mode	CPD ^c	Color ^c	PW Doppler ^d	CW Doppler
P10x ^e	Abd	✓	✓	✓	✓	
	Crd	✓		✓	✓	✓
	Neo	✓	✓	✓	✓	
rP19x standard/ armored ^e	Abd	✓	✓	✓	✓	
	Crd	✓		✓	✓	✓
	Lung	✓	✓	✓	✓	
	OB	✓	✓	✓	✓	
	Orb	✓	✓	✓	✓	
	TCD	✓	✓	✓	✓	
TEExi ^f	Crd	✓		✓	✓	✓

^aExam type abbreviations are as follows: Abd = Abdomen, Art = Arterial, Bre = Breast, Crd = Cardiac, Gyn = Gynecology, Msk = Musculoskeletal, Neo = Neonatal, Nrv = Nerve, OB = Obstetrical, Oph = Ophthalmic, Orb = Orbital, Pro = Prostate, SmP = Small Parts, Spn = Spine, Sup = Superficial, TCD = Transcranial Doppler, Ven = Venous.

^bThe optimization settings for 2D are Res, Gen, and Pen.

^cThe optimization settings for CPD and Color are low, medium, and high (flow sensitivity) with a range of PRF settings for Color depending on the setting selected.

^dFor the cardiac exam type, PW TDI is also available. See **"PW Doppler controls"** on page 4-7.

^eNeedle guide-capable. For more information, refer to *Using CIVCO Products with FUJIFILM SonoSite Systems*.

^fFor more information refer to the *TEExi Transducer User Guide*, included with the TEExi transducer.

Annotating images

You can annotate live images as well as frozen images. (You cannot annotate a saved image.) You can place text (including predefined labels), an arrow, or a pictograph. To set preferences for annotations, refer to [“Annotations setup”](#) on page 3-7.

To place text on an image

You can place text manually or add a predefined label.

- 1 Press the **TEXT** key. A highlighted cursor appears.
- 2 Move the cursor where desired:
 - ▶ Use the touchpad or arrow keys.
 - ▶ Select **Home** to move the cursor to the home position.
The default home position depends on the imaging screen layout. You can reset the home position as described in [“To reset the home position”](#) on page 4-22.
- 3 Using the keyboard, type text.
 - ▶ The arrow keys move the cursor left, right, up, and down.
 - ▶ The **DELETE** key deletes all text.
 - ▶ **X Word** removes a word.
 - ▶ **Symbols** lets you enter special characters. See [“Symbols”](#) on page 2-17.
- 4 (Optional) To add a predefined label, select **Label**, and then select the desired label group: , , or . Select the group again for the desired label.
The first number shows which label in the group is selected. The second number is the number of labels available. See [“Annotations setup”](#) on page 3-7.

To turn off text entry, press the **TEXT** key.

To reset the home position

- 1 Press the **TEXT** key.
- 2 Using the touchpad or arrow keys, position the cursor where desired.
- 3 Select **Home/Set**.

To place an arrow on an image

You can add an arrow graphic to point out a specific part of the image.

- 1 Press the **arrow** key .

- 2 If you need to adjust the arrow's orientation, press the **SELECT** key and then use the touchpad. When the orientation is correct, press the **SELECT** key again.
- 3 Using the touchpad, position the arrow where desired.
- 4 Press the **arrow** key to set the arrow. The arrow turns white.
- 5 To remove the arrow, press the arrow key and then select **Hide**.

To place a pictograph on an image

The pictograph set available depends on transducer and exam type.

- 1 Press the **PICTO** key.
- 2 Select  **x/x** to display the desired pictograph, and then press the **SELECT** key.
The first number shows which pictograph in the set is selected. The second number is the number of pictographs available.
- 3 Using the touchpad, position the pictograph marker.
- 4 (**Optional**) If the image is frozen, use the touchpad or arrow keys to pan the image up, down, left, and right. You cannot pan in Dual.
- 5 To rotate the pictograph marker, press the **SELECT** key and then use the touchpad.
- 6 Choose a screen location for the pictograph:
 - ▶ **U/L** (Up/Left)
 - ▶ **D/L** (Down/Left)
 - ▶ **D/R** (Down/Right)
 - ▶ **U/R** (Up/Right)In a duplex layout, the pictograph is restricted to upper left. In Dual, all four positions are available.
- 7 To remove the pictograph, select **Hide**.

Patient information form

The patient information form lets you enter patient identification, exam, and clinical information for the patient exam. This information automatically appears in the patient report.

Note

When you create a new patient information form, all images and other data you save during the exam are linked to that patient. See ["Patient reports and worksheets"](#) on page 5-38.

To create a new patient information form

Creating a new patient information form removes any unsaved patient information, including calculations and report page.

- 1 Press the **PATIENT** key.

The current patient information form appears.

- 2 Select  **New/End**.

A new patient information form appears.

- 3 Fill in the form fields. For more information, see [“Patient information form fields”](#) on page 4-25.

- 4 Select **Done**. See also [“To append images and clips to a patient exam”](#) on page 4-29.

To enable bar code lookup of patient data

WARNING

To avoid damage to the eye, do not look directly into the beam on the bar code scanner.

You can query the worklist for patient data by scanning a Patient ID bar code with the bar code scanner. The patient data are then automatically entered into the patient information form.

- ❖ Select **Bar Code Auto Lookup** on the Connectivity setup page. For more information about the bar code scanner, refer to the *Bar Code Scanner User Guide*.

WARNING

After using the bar code scanner to retrieve patient records, verify that the patient information is correct. If the patient information retrieved using the bar code scanner is incorrect, enter the information manually.

To edit a patient information form

You can edit patient information if the exam has not been archived or exported; if a clip, image or calculation has not been saved; and if the information is not from a worklist.

See [“To edit patient information from the patient list”](#) on page 4-29.

- 1 Press the **PATIENT** key.

- 2 Make changes as desired.

- 3 Select one of the following:

- ▶ **Done**

Saves your changes and returns to imaging.

- ▶ **Cancel**

Discards your changes and returns to imaging.

To end the exam

- 1 Make sure that you have saved any images and other data you want to keep. See [“Saving images and clips”](#) on page 4-26.
- 2 Press the **PATIENT** key.
- 3 Select  **New/End**. A new patient information form appears.

Patient information form fields

The patient information form fields available depend on exam type. In some fields you can select **Symbols** to enter symbols and special characters. See [“Symbols”](#) on page 2-17.

Patient

▶ **Last, First, Middle**

Patient name

▶ **ID**

Patient identification number

▶ **Accession**

Enter number, if applicable

▶ **Date of birth**

▶ **Gender**

▶ **Indications**

Enter desired text

▶ **User**

User initials

▶ **Procedure (button)**

Available if the DICOM worklist feature is licensed and configured. See the DICOM user guide.

- ❖ Select **Back** to save entries and return to the previous screen.

Exam

▶ **Type**

Exam types available depend on transducer. Refer to [“Imaging modes and exams available by transducer”](#) on page 4-16.

▶ **LMP or Estab. DD** (OB or Gyn exam)

- ▶ In an OB exam, select **LMP** or **Estab. DD** and then enter either the date of the last menstrual period or the established due date.
- ▶ In a Gyn exam, enter the date of the last menstrual period. The LMP date must precede the current system date.

▶ **Twins** (OB exam).

Select the Twins check box to display Twin A and Twin B measurements on the calculations menu and for access to Twin A and Twin B screens for previous exam data.

▶ **Previous Exams (button)** (OB exam).

Displays fields for five previous exams. The date for a previous exam must precede the current system date. For twins, select Twin A/B to toggle between Twin A and Twin B screens.

Note

If the **Twin A/B** control does not appear, select **Back**, and make sure that the **Twins** check box is selected.

Select **Back** to save changes and return to the previous screen.

▶ **BP** (Cardiac, Arterial, Orbital, or Transcranial exams)

Blood Pressure

▶ **HR** (Cardiac, Arterial, Orbital, or Transcranial exams)

Heart Rate. Enter the beats per minute. Using the system to measure heart rate overwrites this entry.

▶ **Height** (Cardiac exam)

The patient height in feet and inches or meters and centimeters. To change the units, see "**Presets setup**" on page 3-14.

▶ **Weight** (Cardiac exam)

The patient weight in pounds or kilos. To change the units, see "**Presets setup**" on page 3-14.

▶ **BSA** (Cardiac exam)

Body Surface Area. Automatically calculated after you enter height and weight.

▶ **Reading Dr.**

The name of the physician reading or reporting on the study.

▶ **Referring Dr.**

The name of the physician who ordered the study.

▶ **Institution**

The name of the hospital, clinic, or medical facility where the exam is performed.

▶ **Department ID**

The name of the department where the exam is performed.

Images and clips

Saving images and clips

When you save an image or clip, it saves to internal storage. The system beeps afterward if **Beep Alert** is on, and the percentage icon flashes. For more information on audio configuration, see "**Audio, Battery setup**" on page 3-8.

To ensure that patient data is not lost, make sure you enter patient information before you take an image or clip. See “[Patient information form](#)” on page 4-23.

The percentage icon shows the percentage of space available in internal storage. For information on receiving alerts when storage is near capacity, see “[To receive storage alerts](#)” on page 3-9.

To access saved images and clips

- ❖ Open the patient list. For more information, see “[Reviewing patient exams](#)” on page 4-28.

To save an image

- ❖ Press the **SAVE** key. The image saves to internal storage.

By default, the **SAVE** key saves only the image. As a shortcut during calculations, the **SAVE** key can save both the image to internal storage and the calculation to the patient report. See “[Presets setup](#)” on page 3-14.

To save a clip

1 Set Clips controls as described in “[To set Clips controls](#)” on page 4-27.

2 Press the **CLIP** key.

One of the following occurs:

- ▶ If **Prev/Off** is selected, the clip saves directly to internal storage.

If **Prev/On** is selected, the clip plays back in preview mode. You can select any of the following on-screen:

- ▶ A playback speed  (1x, 1/2x, 1/4x)
- ▶ **Pause** to interrupt playback
- ▶ **Left: x** or **Right: x** to remove frames from the left or right sides of the clip (where x is the beginning or ending frame number)
- ▶ **Save** to save the clip to internal storage
- ▶ **Delete** to delete the clip.

3 To stop saving a clip, press the **CLIP** key again. Data already acquired is saved.

To set Clips controls

Setting Clips controls ensures that clips are captured to your specifications.

1 In 2D imaging mode, select **Clips** on-screen.

2 Set controls as desired.

Clips controls

Table 4-7: Clip on-screen controls

Control	Description
Time, ECG 	Time and ECG share the same location on-screen. <ul style="list-style-type: none">▶ With Time, capturing is based on number of seconds. Select the time duration.▶ With ECG, capturing is based on the number of heart beats. Select the number of beats.
Preview On, Preview Off 	PrevOn and PrevOff turn the preview feature on and off. <ul style="list-style-type: none">▶ With Prev/On, the captured clip automatically plays on-screen. The clip can be trimmed, saved, or deleted.▶ With Prev/Off, the clip saves to internal storage, and the trim and delete controls are not available.
Prospective, Retrospective 	Pro and Retro determine how clips are captured: <ul style="list-style-type: none">▶ With Pro, a clip is captured prospectively, after you press the CLIP key.▶ With Retro, a clip is captured retrospectively, from pre-saved data before you press the CLIP key.

Reviewing patient exams

Caution

If the internal storage icon does not appear in the system status area, internal storage may be defective. Contact FUJIFILM SonoSite Technical Support. See [“Getting help”](#) on page 1-2.

The patient list organizes saved images and clips in patient exams. You can delete, view, print, or archive exams. You can also copy them to a USB storage device.

To display the patient list

- 1 Press the **REVIEW** key.
- 2 If there is an active exam, select **List** on-screen.

To sort the patient list

After the system starts, the patient list is arranged by date and time, with the most recent patient exam first. You can re-sort the patient list as needed.

- ❖ Select the column heading that you want to sort by. Select it again if sorting in reverse order.

To select patient exams in the patient list

- ❖ Do one of the following:
 - ▶ Using the touchpad, select the check box for one or more patient exams.
 - ▶ Use **Select All** to select all patient exams.

To deselect patient exams

- ❖ Do one of the following:
 - ▶ Clear checked boxes.
 - ▶ Select **Clear All**.

To edit patient information from the patient list

You can edit the patient name and ID from the patient list instead of from the patient information form if the exam is closed but has not been exported or archived.

- 1 In the patient list, select the patient exam.
- 2 Select **Edit**.
- 3 Fill in the form fields, and then select **OK**.

To append images and clips to a patient exam

Although you cannot add images and clips to a patient exam that is ended, exported, or archived, you can automatically start a new patient exam that has the same patient information. Depending on your archiver, the two exams appear as one study when exported or archived.

- 1 In the patient list, select the patient exam.
- 2 Select **Append**. A new patient information form appears. The form has the same information as the patient exam you selected.

To review images and clips

Note | You can review only one patient exam's images and clips at a time.

- 1 In the patient list, select the patient exam whose images and clips you want to review. The patient row is highlighted.
- 2 Select **Review** on-screen.
- 3 Select  **x/x** to cycle to the image or clip you want to review.
- 4 To view a clip, select **Play**. The clip plays automatically after loading. The load time depends on clip length.
While reviewing a clip, you can do any of the following:

- ▶ Select **Pause** to freeze the clip. Select **Play** again to resume.
- ▶ Select a playback speed  | **1x, 1/2x, 1/4x**.

5 Select  **x/x** to cycle to the next image or clip you want to view.

6 To return to the patient list, select **List**.

7 To return to imaging, select **Done**.

Printing, exporting, and deleting images and clips

Caution

To avoid damaging the USB storage device and losing patient data from it, observe the following:

- ▶ Do not remove the USB storage device or turn off the ultrasound system while the system is exporting.
- ▶ Do not bump or otherwise apply pressure to the USB storage device while it is in a USB port on the ultrasound system. The connector could break.

To print an image

- 1 Verify that a printer is selected. For more information, see [“To configure the system for a printer”](#) on page 3-9.
- 2 Do one of the following:
 - ▶ In the patient list, review the patient’s images. Select **Print** when the image appears.
 - ▶ With the image displayed, press the **A** shortcut key. By default, the **A** shortcut key prints. To reprogram the **A** and **B** shortcut keys, see [“Presets setup”](#) on page 3-14.

To print multiple images

- 1 Verify that a printer is selected. For more information, see [“To configure the system for a printer”](#) on page 3-9.
- 2 Do one of the following:
 - ▶ To print all images for multiple patient exams, select one or more patient exams in the patient list, and then select **Print**.
 - ▶ To print all images for one patient exam, highlight the patient exam in the patient list, and then select **Print**.

Each image appears briefly on-screen while printing.

To export patient exams to a USB storage device

Note

USB export can be disabled by the Administrator. See [“To disable USB export”](#) on page 3-3.

A USB storage device is for temporary storage of images and clips. Patient exams should be archived regularly.

Exporting large amounts of data can take as long as a few hours depending on compression, file type, file size, and number of files. To avoid this issue, export data frequently—for example, after each patient exam or at the end of each day.

Note

You can export patient exams only if they have ended. Refer to [“To end the exam”](#) on page 4-25.

- 1 Insert the USB storage device. See [“Inserting and removing USB storage devices”](#) on page 2-10.
- 2 In the patient list, select the patient exams you want to export.
- 3 Select **Exp. USB** on-screen. A list of USB devices appears.
- 4 Choose the USB storage device you want to use.

If you want to hide patient information, clear the **Include patient information on images and clips** check box.

Note

Only available USB devices are selectable.

- 5 Select **Export**. The files are finished exporting approximately five seconds after the USB animation stops.

Note

Removing the USB storage device or turning off the system while exporting may cause exported files to be corrupted or incomplete.

- 6 To stop in-progress exporting, select **Cancel Export**.

To export patient exams automatically

To export patient exams automatically to a USB memory stick:

- 1 Make sure that automatic export is enabled. See [“To enable automatic exam export”](#) on page 3-16.
- 2 Insert a USB memory stick into a USB port on the side of the system.
- 3 End the exam.

To delete images and clips

- 1 Select one or more patient exams in the patient list.

2 Select **X Delete** to delete the selected exams. A confirmation screen appears.

To manually archive images and clips

You can send patient exams to a DICOM printer or archiver, or to a PC using SiteLink Image Manager. DICOM and SiteLink Image Manager are optional features. For more information about archiving, refer to the DICOM and SiteLink Image Manager documentation.

1 Select one or more patient exams in the patient list.

2 Select **Archive**.

To display information about a patient exam

1 In the patient list, select the patient exam.

2 Select **Info**.

ECG

ECG is an option and requires a FUJIFILM SonoSite ECG cable.

ECG is available only on the cardiac exam type.

WARNINGS

- ▶ Do not use the FUJIFILM SonoSite ECG to diagnose cardiac arrhythmias or to provide long-term cardiac monitoring.
- ▶ To avoid electrical interference with aircraft systems, do not use the ECG cable on aircraft. Such interference may have safety consequences.

Caution

- ▶ Use only accessories recommended by FUJIFILM SonoSite with the system. Connecting an accessory not recommended by FUJIFILM SonoSite can damage the system.

To use the ECG

1 Connect the ECG cable to the ECG connector on the ultrasound system, mini-dock, or docking system. The ECG signal turns on automatically if the system is in live imaging mode.

Note

The ECG signal may take up to one minute to restabilize after defibrillator use on the patient.

2 Select **ECG** on-screen. **ECG** may be on another page. It appears only if the ECG cable is connected.

3 Adjust controls as desired.

ECG controls

Table 4-8: ECG on-screen controls

Control	Description
Show/Hide 	Turns on and off ECG signal.
Gain 	Increases or decreases ECG gain. Settings are 0-20 .
Position	Sets the position of the ECG signal.
Sweep Speed 	Settings are Slow, Med, and Fast .
Delay	Displays Line and Save for clip acquisition delay. For instructions to capture clips, see “To save a clip” on page 4-27.
Line 	The position of the delay line on the ECG signal. The delay line indicates where the clip acquisition is triggered.
Save	Saves the current position of the delay line on the ECG signal. (You can change the position of the delay line temporarily. Starting a new patient information form or cycling system power reverts the delay line to the most recently saved position.) Select Delay to display these controls.

CHAPTER 5

Measurements and Calculations

You can measure for quick reference, or you can measure within a calculation. You can perform general calculations as well as calculations specific to an exam type.

Measurements are performed on frozen images. For references used, see [Chapter 6, “Measurement references.”](#)

Measurements

Available measurement options depend on your configuration, transducer, and exam type.

You can perform basic measurements in any imaging mode and can save the image with the measurements displayed. Except for the M Mode HR measurement and Doppler HR Measurement, the results do not automatically save to a calculation and the patient report. To save measurements as part of a calculation, you can first begin a calculation and then measure. For more information, see [“To save a measurement to a calculation and patient report”](#) on page 5-2.

Working with calipers

Most measurements are performed using calipers, often in pairs, that you position by using the touchpad. In distance and area measurements, results are based on the calipers’ positions relative to each other, and appear at the bottom of the screen. The results update automatically as you reposition the calipers. In trace measurements, the results appear after you complete the trace.

Outside a calculation, you can add calipers by pressing the **CALIPER** key. You can have multiple sets of calipers and can switch from one set to another, repositioning them as needed. (The calipers available depend on the number and type of measurements already performed.) Each set shows the measurement result. A measurement is complete when you finish moving its calipers.

Note

For a reliable measurement, accurate placement of calipers is essential.

To switch the active calipers

Some measurements use two calipers. Only one caliper can be repositioned at a time. Use this procedure to toggle between the two calipers. The active caliper is highlighted.

- ❖ Do one of the following:
 - ▶ To switch the active caliper within a set, press the **SELECT** key.
 - ▶ To switch the active set when measuring outside a calculation, select **Switch** on-screen.

To delete or edit a measurement

- ❖ With the measurement active (highlighted), do one of the following:
 - ▶ Select **Delete** on-screen.
 - ▶ Use the touchpad to reposition one or more of the calipers.

To place calipers more precisely

- ❖ Do any of the following:
 - ▶ Adjust the display for maximum sharpness.
 - ▶ Use leading edges (closest to the transducer) or borders for starting and stopping points.
 - ▶ Maintain a consistent transducer orientation for each type of measurement.
 - ▶ Make sure that the area of interest fills as much of the screen as possible.
 - ▶ (2D) Minimize the depth, or zoom.

Saving measurements

After performing a measurement, you can save the image with the measurements displayed. See [“To save an image”](#) on page 4-27. Some measurements can be saved to a calculation and the patient report.

If you prefer to select a measurement name before performing a measurement, start a calculation. See [“General Calculations”](#) on page 5-7.

To save a measurement to a calculation and patient report

- 1 With the measurement active (highlighted), select **CALCS**.
- 2 From the calculations menu, select a measurement name. See [“To select from the calculations menu”](#) on page 5-8.

Note

Only measurement names available for the imaging mode and exam type are selectable.

- 3 Save the calculation. See [“To save a calculation”](#) on page 5-8.

2D measurements

The basic measurements that you can perform in 2D imaging are as follows:

- ▶ Distance in cm
- ▶ Area in cm²
- ▶ Circumference in cm

You can also measure area or circumference by tracing manually.

You can perform a combination of distance, area, and circumference measurements at one time. The total number possible depends on their order and type.

To measure distance

You can perform up to eight distance measurements on a 2D image.

- 1 On a frozen 2D image, press the **CALIPER** key. A pair of calipers appears, connected by a dotted line.
- 2 Using the touchpad, position the first caliper.
- 3 Press the **SELECT** key.
The second caliper becomes active.
- 4 Using the touchpad, position the other caliper.
The distance measurement appears at the bottom of the screen. You can reposition each caliper as often as necessary to achieve an accurate measurement.

To measure area and circumference

Area and circumference measurements use an ellipse with calipers.

- 1 On a frozen 2D image, press the **CALIPER** key.
- 2 Select **Ellipse** on-screen.

Note

If you exceed the allowed number of measurements, Ellipse is not available.

- 3 Use the touchpad to adjust the size and position of the ellipse. The **SELECT** key toggles between position and size.
The circumference and area measurements appear at the bottom of the screen. You can reposition each caliper as often as necessary to achieve an accurate measurement.

To perform manual trace measurements

- 1 On a frozen 2D image, press the **CALIPER** key.

2 Select **Manual** on-screen.

Note

If you exceed the allowed number of measurements, Manual is not available.

3 Using the touchpad, position the caliper where you want to begin.

4 Press the **SELECT** key.

5 Using the touchpad, complete the trace, and press the **SET** key.

To make a correction, select **Undo** on-screen, backtrack with the touchpad, or press the **backspace** key.

The circumference and area measurements appear at the bottom of the screen.

M Mode measurements

The basic measurements that you can perform in M Mode imaging are as follows:

- ▶ Distance in cm/Time in seconds
- ▶ Heart Rate (HR) in beats per minute (bpm)

The time scale above the trace has small marks at 200 ms intervals and large marks at one-second intervals.

To measure distance in M Mode

You can perform up to four distance measurements on an image.

1 On a frozen M Mode trace, press the **CALIPER** key.

A single caliper appears.

2 Using the touchpad, position the caliper.

3 Press the **SELECT** key.

4 Using the touchpad or the touchscreen, position the second caliper.

5 See [“To save a measurement to a calculation and patient report”](#) on page 5-2.

To measure Heart Rate in M Mode

For more information about how heart rate (HR) is used in calculations, see [“Cardiac calculations”](#) on page 5-15.

1 On a frozen M Mode trace, press the **CALIPER** key.

2 Select **HR** on-screen.

A vertical caliper appears.

3 Using the touchpad, position the vertical caliper at the peak of the heartbeat.

4 Press the **SELECT** key.

A second vertical caliper appears.

5 Using the touchpad, position the second vertical caliper at the peak of the next heartbeat.

6 See [“To save a measurement to a calculation and patient report”](#) on page 5-2.

Note

Saving the heart rate measurement to the patient report overwrites any heart rate entered on the patient information form.

See also [“To measure Fetal Heart Rate”](#) on page 5-34.

Doppler measurements

The basic measurements that you can perform in Doppler imaging are:

- ▶ Velocity (cm/s)
- ▶ Pressure Gradient
- ▶ Elapsed Time
- ▶ +/- Ratio
- ▶ Resistive Index (RI)
- ▶ Acceleration

You can also trace manually or automatically. For Doppler measurements, the Doppler scale must be set to cm/s. See [“Presets setup”](#) on page 3-14.

To measure Velocity (cm/s) and Pressure Gradient

- 1 On a frozen Doppler spectral trace, press the **CALIPER** key.
A single caliper appears.
- 2 Using the touchpad, position the caliper to a peak velocity waveform.

To measure Velocities, Elapsed Time, Ratio, and Resistive Index (RI) or Acceleration

- ▶ **RI** appears only if the velocity associated with the first caliper is greater than the velocity associated with the second caliper.
 - ▶ **ACC** appears only when the velocity associated with the second caliper is greater than the velocity associated with the first caliper.
- 1 On a frozen Doppler spectral trace, press the **CALIPER** key.
A single caliper appears.
 - 2 Using the touchpad, position the caliper to a peak velocity waveform.
 - 3 Press the **SELECT** key.
A second vertical caliper appears.
 - 4 Using the touchpad, position the second vertical caliper at the end diastole on the waveform.

Elapsed time between the times indicated by the two calipers is calculated. Measured velocities are given as results, and a generic ratio between the velocities indicated by the two calipers is calculated.

To measure time duration

- 1 On a frozen Doppler spectral trace, press the **CALIPER** key.
- 2 Select **Time** on-screen.
A vertical caliper appears.
- 3 Using the touchpad, position the caliper where desired.
- 4 Press the **SELECT** key.
A second caliper appears.
- 5 Using the touchpad, position the second caliper where desired, and press the **SELECT** key.

To perform manual trace measurements in Doppler

- 1 On a frozen Doppler spectral trace, press the **CALIPER** key.
- 2 Select **Trace** then **Manual** on-screen.
A single caliper appears.
- 3 Using the touchpad, position the caliper at the beginning of the desired waveform, and press the **SELECT** key.

Note

If calipers are not positioned correctly, the result is inaccurate.

- 4 Using the touchpad, trace the waveform.
 - a To make a correction, select **Undo** on-screen, backtrack with the touchpad, or press the **backspace** key.
 - b Press the **SET** key. The measurement results appear.

To trace automatically in Doppler

After tracing automatically, confirm that the system-generated boundary is correct. If you are not satisfied with the trace, obtain a high-quality Doppler spectral trace image, or trace manually. See [“To perform manual trace measurements in Doppler”](#) on page 5-6.

- 1 On a frozen Doppler spectral trace, press the **CALIPER** key.
- 2 Select **Trace** then **Auto** on-screen.
A vertical caliper appears.
- 3 Using the touchpad, position the caliper at the beginning of the waveform.
If calipers are not positioned correctly, the calculation result is inaccurate.
- 4 Press the **SELECT** key.
A second vertical caliper appears.
- 5 Using the touchpad, position the second caliper at the end of the waveform.
- 6 Press the **SET** key.
The measurement results appear.

Automatic trace results

Depending on the exam type, the results from automatic tracing include the following:

- ▶ Velocity Time Integral (VTI)
- ▶ Peak Velocity (Vmax)
- ▶ Mean Pressure Gradient (PGmean)
- ▶ Mean Velocity on Peak Trace (Vmean)
- ▶ Pressure Gradient (PGmax)
- ▶ End Diastolic Velocity (EDV)
- ▶ Acceleration Time (AT)
- ▶ Gate Depth
- ▶ Cardiac Output (CO)
- ▶ Peak Systolic Velocity (PSV)
- ▶ Time Average Mean (TAM)
- ▶ +/- or Systolic/Diastolic (S/D)
- ▶ Pulsatility Index (PI)
- ▶ Resistive Index (RI)
- ▶ Time Average Peak (TAP)
- ▶ MDV (Minimum Diastolic Velocity)

General Calculations

Within calculations, you can save measurement results to the patient report. You can display and delete measurements from a calculation. Some measurements can be deleted directly from the patient report pages. See [“Patient reports and worksheets”](#) on page 5-38.

WARNING | To avoid misdiagnosis or harming the patient outcome, do not use single calculations as sole diagnostic criteria. Use calculations in conjunction with other clinical information.

Note | Calculation packages depend on exam type.

Calculations menu

The calculations menu contains measurements available for the imaging mode and exam type. After you perform and save a measurement, the result saves to the patient report. A check mark appears next to the measurement name in the calculations menu. If you highlight the checked measurement name, the results appear below the menu. If you repeat the measurement, the results below the menu reflect either the last measurement or the average, depending on the measurement.

Note | Menu items followed by ellipses (. . .) have subentries.

To select from the calculations menu

- 1 On a frozen image, press the **CALCS** key. The calculations menu appears.
- 2 Using the touchpad or arrow keys, highlight the desired measurement name. Press the **SELECT** key.
 - a To display additional measurement names, highlight **Next**, **Prev**, or a measurement name that has ellipses (. . .). Then press the **SELECT** key. Only measurement names available for the imaging mode are selectable.
- 3 To return to the main menu, highlight **Main** and press the **SELECT** key.
- 4 To close the calculations menu, press the **CALCS** key once (if the menu is active) or twice (if the menu is inactive).

Performing and saving measurements in calculations

Calculations usually involve more than one measurement. Instead of pressing the **CALIPER** key, as you would for a single measurement, pressing the **CALCS** key opens the calculations menu, from which you can choose a calculation and perform all of the associated measurements.

When performing a measurement within a calculation, select a measurement from the calculations menu, position the calipers that appear, save the measurement, and then move on to the next measurement. The type of calipers that appear depends on the measurement. After you are done making all of the measurements in the calculation, you can save the calculation to the exam.

To save a calculation

- ❖ Do one of the following:
 - ▶ Save the calculation only: Press the **SAVE CALC** key, or select **Save** on-screen.
The calculation saves to the patient report. To save the image with the measurements displayed, see [“To save an image”](#) on page 4-27.
 - ▶ Save both the image and calculation: Press the **SAVE** key if the **SAVE** key functionality is set to **Image/Calcs**. See [“Presets setup”](#) on page 3-14.
The calculation saves to the patient report, and the image saves to internal storage with the measurements displayed.

Displaying, repeating, and deleting saved measurements

To display a saved measurement

- ❖ Do one of the following:
 - ▶ Highlight the measurement name in the calculations menu. The result appears below the menu.
 - ▶ Open the patient report. Refer to [“Patient reports and worksheets”](#) on page 5-38.

To repeat a saved measurement

- 1 Highlight the measurement name in the calculations menu.
- 2 Press the **SELECT** key or the **CALIPER** key.

- 3 Perform the measurement again. The new results appear on-screen in the measurement and calculations data area. See **“Screen layout”** on page 2-14. You can compare them to the saved results below the menu.
- 4 To save the new measurement, press the **SAVE CALC** key. The new measurement saves to the patient report and overwrites the previously saved measurement.

To delete a saved measurement

- 1 Select the measurement name in the calculations menu.
- 2 Select **Delete** on-screen. The measurement last saved is deleted from the patient report. If it is the only measurement, the check mark is deleted from the calculations menu.

Note

Some measurements can be deleted directly from the report pages. See **“Patient reports and worksheets”** on page 5-38.

EMED calculations

The results from EMED calculations automatically appear in the EMED worksheets. All EMED calculations are available for each exam type.

To perform an EMED calculation:

- 1 Press the **CALCS** key.
- 2 Select **EMED** on-screen. The calculations menu becomes the EMED calculations menu.
- 3 Select the calculation name.
- 4 Perform a distance measurement.
- 5 Save the measurement.

To return to the calculations menu, select **CALCS** on-screen.

Percent reduction calculations

WARNINGS

- ▶ To avoid incorrect calculations, verify that the patient information, date, and time settings are accurate.
- ▶ To avoid misdiagnosis or harming the patient outcome, start a new patient form before starting a new patient exam and performing calculations. Starting a new patient form clears the previous patient’s data. The previous patient’s data will be combined with the current patient if the form is not first cleared. Refer to **“To create a new patient information form”** on page 4-24.

Percent reduction calculations are available in the following exam types: Abdomen, Arterial, Musculoskeletal, and Small Parts.

For a list of exam types on each transducer, see [“Imaging modes and exams available by transducer”](#) on page 4-16.

To calculate percent area reduction

The percent area reduction calculation involves two manual trace measurements.

- 1** On a frozen 2D image, press the **CALCS** key.
- 2** Do the following for **A¹** and then for **A²**:
 - a** From the calculations menu, select the measurement name under **Area Red**.
 - b** Using the touchpad, move the caliper to the trace starting point, and press the **SELECT** key.
 - c** Using the touchpad, trace the desired area.
To make a correction, select **Undo** on-screen or press the **backspace** key.
 - d** Complete the trace, and press the **SET** key.
 - e** Save the calculation as described in [“To save a calculation”](#) on page 5-8.

The percent area reduction result appears on-screen in the measurement and calculation data area and in the patient report.

To calculate percent diameter reduction

- 1** On a frozen 2D image, press the **CALCS** key.
- 2** Do the following for **D¹** and then for **D²**:
 - a** From the calculations menu, select the measurement name under **Dia Red**.
 - b** Use the touchpad to position the calipers.
 - c** Save the calculation as described in [“To save a calculation”](#) on page 5-8.

The percent diameter reduction result appears in the measurement and calculation data area and in the patient report.

Volume calculation

WARNINGS

- ▶ To avoid incorrect calculations, verify that the patient information, date, and time settings are accurate.
- ▶ To avoid misdiagnosis or harming the patient outcome, start a new patient form before starting a new patient exam and performing calculations. Starting a new patient form clears the previous patient's data. The previous patient's data will be combined with the current patient if the form is not first cleared. Refer to ["To create a new patient information form"](#) on page 4-24.

The volume calculation involves three 2D distance measurements: D^1 , D^2 , and D^3 . After all measurements are saved, the result appears on-screen and in the patient report.

The volume calculation is available in the following exam types: Abdomen, Arterial, Breast, Gynecological, Musculoskeletal, Nerve, Small Parts, Superficial and Venous.

For a list of exam types on each transducer, see ["Imaging modes and exams available by transducer"](#) on page 4-16.

To calculate volume

Do the following for each image you need to measure:

- 1 On a frozen 2D image, press the **CALCS** key.
- 2 Do the following for each measurement you need to take:
 - a From the calculations menu, select the measurement name under **Volume**.
If **Volume** is not available in a Gyn exam, select **Gyn** and then select **Volume**.
 - b Position the calipers.
 - c Save the measurement as described in ["To save a calculation"](#) on page 5-8.

Volume flow calculation

The volume flow calculation is available in the following exam types: Abdomen, Arterial.

For a list of exam types on each transducer, see ["Imaging modes and exams available by transducer"](#) on page 4-16.

Both a 2D and a Doppler measurement are required for the volume flow calculation:

Table 5-1: Required measurements

Calculation list	Measurement name (Imaging Mode)	Calculation result
Volume Flow	D (2D)*, TAM or TAP (Doppler)	Vol Flow (Volume Flow ml/min)
*Required if measuring the diameter instead of using the gate size		

For the 2D measurement, you can do either of the following:

- ▶ Measure the diameter of the vessel. This approach is more precise. The measurement overrides the gate size.
- ▶ Use the gate size. If you do not measure the diameter of the vessel, the system automatically uses the gate size and "(gate)" appears in the calculation results.

The Doppler sample volume should completely insonate the vessel. You can measure either the time average mean (TAM) or time average peak (TAP). To specify the live trace setting, see "[Presets setup](#)" on page 3-14.

The system is limited to the following sample volume sizes:

- ▶ C11x transducer: 1, 2, 3 Gate Size (mm)
- ▶ rC60xi and P10x transducer: 2, 3, 5, 7, 10, 12 Gate Size (mm)
- ▶ HFL38xi and L25x: 1, 3, 5, 6, 7, 8, 10, 12 Gate Size (mm)
- ▶ L38xi transducer: 1, 3, 5, 6, 7, 8, 10, 12 Gate Size (mm)

Considerations

Consider the following factors when performing volume flow measurements:

- ▶ You should follow current medical practice for volume flow calculation applications.
- ▶ The accuracy of the volume flow calculation largely depends on the user's measurement technique.
- ▶ The factors identified in the literature that affect the accuracy are as follows:
 - ▶ Using the diameter method for 2D area
 - ▶ Precision in placing the caliper
 - ▶ Difficulty ensuring uniform insonation of the vessel

For more information about the considerations and degree of accuracy for volume flow measurements and calculations, see the following reference:

- ▶ Allan, Paul L. et al. *Clinical Doppler Ultrasound*, 4th Ed., Harcourt Publishers Limited, (2000) p.36-38.

To calculate volume flow

- 1 If measuring the diameter instead of using the gate size, perform the 2D measurement:
 - a On a frozen full-screen 2D image or duplex image, press the **CALCS** key.
 - b From the calculations menu, select **D** (distance) under **Vol Flow**.
 - c Position the calipers.
 - d Save the calculation as described in **"To save a calculation"** on page 5-8.
- 2 Perform the Doppler measurement:
 - a On a frozen Doppler spectral trace, press the **CALCS** key.
 - b From the calculations menu, select **TAM** or **TAP** under **Vol Flow**.
A vertical caliper appears.
 - c Using the touchpad, position the vertical caliper at the beginning of the waveform.

Note

If calipers are not positioned correctly, the calculation result is inaccurate.

- d Press the **SELECT** key to display a second vertical caliper.
- e Using the touchpad, position the second vertical caliper at the end of the waveform.
- f Press the **SET** key to complete the trace and to display the results.
- g Save the calculation as described in **"To save a calculation"** on page 5-8.

Exam-based calculations

Arterial calculations

WARNINGS

- ▶ To avoid incorrect calculations, verify that the patient information, date, and time settings are accurate.
- ▶ To avoid misdiagnosis or harming the patient outcome, start a new patient form before starting a new patient exam and performing calculations. Starting a new patient form clears the previous patient's data. The previous patient's data will be combined with the current patient if the form is not first cleared. See **"To create a new patient information form"** on page 4-24.

The Arterial calculations that you can perform are listed in **Table 5-2** on page 5-14.

In the Arterial exam, you can calculate ICA/CCA ratio, volume, volume flow, and percent reduction. See **"Volume calculation"** on page 5-11, **"Volume flow calculation"** on page 5-11, and **"Percent reduction calculations"** on page 5-9.

Table 5-2: Arterial calculations

Calculation list	Measurement name	Results
CCA	<ul style="list-style-type: none">▶ Prox (Proximal)▶ Mid (Middle)▶ Dist (Distal)▶ Bulb	s (systolic), d (diastolic)
ICA	<ul style="list-style-type: none">▶ Prox (Proximal)▶ Mid (Middle)▶ Dist (Distal)	s (systolic), d (diastolic)
ECA	<ul style="list-style-type: none">▶ Prox (Proximal)▶ Mid (Middle)▶ Dist (Distal)▶ VArty	s (systolic), d (diastolic)

WARNINGS

- ▶ Trace only a single heartbeat. The VTI calculation is not valid if measured with more than one heartbeat.
- ▶ Diagnostic conclusions about blood flow based on VTI alone can lead to improper treatment. Accurate blood flow volume calculations require both the vessel area and velocity of blood flow. In addition, accurate blood flow velocity is dependent on a correct Doppler angle of incidence.

To perform an Arterial calculation

After you perform arterial measurements, values in the ICA/CCA ratios are selectable on the arterial page of the patient report.

- 1 On a frozen Doppler spectral trace, press the **CALCS** key.
- 2 Do the following for each measurement you want to take:
 - a Under **Left** or **Right**, select the measurement name.
 - b Using the touchpad, position the caliper at the peak systolic waveform.
 - c Press the **SELECT** key.
A second caliper appears.
 - d Using the touchpad, position the second caliper at the end diastole point on the waveform.
 - e Save the calculation as described in **"To save a calculation"** on page 5-8.

Cardiac calculations

WARNINGS

- ▶ To avoid incorrect calculations, verify that the patient information, date, and time settings are accurate.
- ▶ To avoid misdiagnosis or harming the patient outcome, start a new patient information form before starting a new patient exam and performing calculations. Starting a new patient information form clears the previous patient's data. The previous patient's data will be combined with the current patient if the form is not first cleared. Refer to ["To create a new patient information form"](#) on page 4-24.

When performing cardiac calculations, the system uses the heart rate (HR) value present in the patient information form. The HR value can be obtained in four different ways:

- ▶ Manual entry in the patient information form
- ▶ Doppler measurement (for more information, see ["To measure Heart Rate in Doppler"](#) on page 5-22).
- ▶ M-Mode measurement (for more information, see ["To measure Heart Rate in M Mode"](#) on page 5-4).
- ▶ ECG measurement

The ECG heart rate measurement is only used if the other methods are not available. If the ECG measurement is used, and the HR value in the patient information form is empty, the new HR value is automatically inserted in the patient information form.

The following table shows the measurements required to complete different cardiac calculations. Not all calculations are listed. For definitions of acronyms, refer to “**Glossary**” on page A-1.

Table 5-3: Cardiac calculations and results

Calculation list	Measurement name (imaging mode)	Results
EF EF	<ul style="list-style-type: none"> ▶ LVDd (2D or M Mode) ▶ LVDs (2D or M Mode) 	EF LVDFS
LV Vol (EF)	<ul style="list-style-type: none"> ▶ A4Cd (2D) ▶ A4Cs (2D) ▶ A2Cd (2D) ▶ A2Cs (2D) 	A4C EF A2C EF LV Vol CO ^a SV CI ^a SI
IVC	<ul style="list-style-type: none"> ▶ Max D (2D or M Mode) ▶ Min D (2D or M Mode) 	Collapse ratio
LV LVd	<ul style="list-style-type: none"> ▶ RVW (2D) ▶ RVD (2D) ▶ IVS (2D) ▶ LVD (2D) ▶ LVPW (2D) 	EF LVDFS CO ^a SV LVESV LVEDV
LVs	<ul style="list-style-type: none"> ▶ RVW (2D) ▶ RVD (2D) ▶ IVS (2D) ▶ LVD (2D) ▶ LVPW (2D) 	IVSFT LVPWFT CI ^a SI LV Mass (M Mode only)
HR ^a	HR (M Mode or Doppler)	HR

^aHR needed for CO and CI. You can enter the HR measurement on the patient form, or obtain it by measuring in M Mode (page 4), Doppler (page 22), or ECG.

^bdP:dT performed at 100 cm/s and 300 cm/s.

^dSpecified on the cardiac patient report. See “**To modify the ICA/CCA ratio (Arterial)**” on page 5-39.

^eNeed to measure E (MV measurement) to get E/e’ ratio.

Table 5-3: Cardiac calculations and results

Calculation list	Measurement name (imaging mode)	Results
CO	<ul style="list-style-type: none"> ▶ LVOT D (2D) ▶ HR (Doppler) ▶ LVOT VTI (Doppler) 	CO ^a SV CI ^a SI VTI HR LVOT D
Ao/LA	▶ Ao (2D or M Mode)	Ao LA/Ao
	▶ AAo (2D)	AAo
	▶ LA (2D or M Mode)	LA LA/Ao
	▶ LVOT D (2D)	LVOT D LVOT area
	▶ ACS (M Mode)	ACS
	▶ LVET (M Mode)	LVET
MV	▶ EF: Slope (M Mode)	EF Slope
	▶ EPSS (M Mode)	EPSS

^aHR needed for CO and CI. You can enter the HR measurement on the patient form, or obtain it by measuring in M Mode (page 4), Doppler (page 22), or ECG.

^bdP:dT performed at 100 cm/s and 300 cm/s.

^dSpecified on the cardiac patient report. See **“To modify the ICA/CCA ratio (Arterial)”** on page 5-39.

^eNeed to measure E (MV measurement) to get E/e' ratio.

Table 5-3: Cardiac calculations and results

Calculation list	Measurement name (imaging mode)	Results
MV MR	▶ E (Doppler)	E E PG A A PG E:A
	▶ A (Doppler)	
	▶ PHT (Doppler)	PHT MVA Decel time
	▶ VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
	▶ IVRT (Doppler)	time
	▶ Adur (Doppler)	time
	▶ dP:dT ^b (CW Doppler)	dP:dT
Area	▶ MV (2D)	MV Area
	▶ AV (2D)	AV Area
Atria	▶ LA A4C (2D) ▶ LA A2C (2D)	LA Area LA Volume Biplane
	▶ RA (2D)	RA Area RA Volume
LV mass	▶ Epi (2D) ▶ Endo (2D) ▶ Apical (2D)	LV Mass Epi Area Endo Area D Apical

^aHR needed for CO and CI. You can enter the HR measurement on the patient form, or obtain it by measuring in M Mode (page 4), Doppler (page 22), or ECG.

^bdP:dT performed at 100 cm/s and 300 cm/s.

^dSpecified on the cardiac patient report. See **“To modify the ICA/CCA ratio (Arterial)”** on page 5-39.

^eNeed to measure E (MV measurement) to get E/e' ratio.

Table 5-3: Cardiac calculations and results

Calculation list	Measurement name (imaging mode)	Results
AV AV	▶ Vmax (Doppler)	Vmax PGmax
	▶ VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
LVOT	▶ Vmax (Doppler)	Vmax PGmax
	▶ VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
AI	▶ PHT (Doppler)	AI PHT AI slope
TV	▶ RA pressure ^d	RVSP
	▶ TR Vmax (Doppler)	Vmax PGmax
	▶ E (Doppler) ▶ A (Doppler)	E E PG A A PG E:A
	▶ PHT (Doppler)	PHT TVA Decel time

^aHR needed for CO and CI. You can enter the HR measurement on the patient form, or obtain it by measuring in M Mode (page 4), Doppler (page 22), or ECG.

^bdP:dT performed at 100 cm/s and 300 cm/s.

^dSpecified on the cardiac patient report. See **"To modify the ICA/CCA ratio (Arterial)"** on page 5-39.

^eNeed to measure E (MV measurement) to get E/e' ratio.

Table 5-3: Cardiac calculations and results

Calculation list	Measurement name (imaging mode)	Results
	▶ VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
PV	▶ Vmax (Doppler)	Vmax PGmax
	▶ PV VTI (Doppler) ▶ AT (Doppler)	VTI Vmax PGmax Vmean PGmean AT
P. Vein	▶ A (Doppler)	Vmax
	▶ Adur (Doppler)	time
	▶ S (Doppler) ▶ D (Doppler)	Vmax S/D ratio
PISA	▶ Radius (Color) ▶ MR VTI (Doppler) ▶ Ann D (2D) ▶ MV VTI (Doppler)	PISA Area ERO MV Rate Regurgitant Volume Regurgitant Fraction
Qp/Qs	▶ LVOT D (2D) ▶ RVOT D (2D) ▶ LVOT VTI (Doppler) ▶ RVOT VTI (Doppler)	D VTI Vmax PGmax Vmean PGmean SV Qp/Qs

^aHR needed for CO and CI. You can enter the HR measurement on the patient form, or obtain it by measuring in M Mode (page 4), Doppler (page 22), or ECG.

^bdP:dT performed at 100 cm/s and 300 cm/s.

^dSpecified on the cardiac patient report. See **“To modify the ICA/CCA ratio (Arterial)”** on page 5-39.

^eNeed to measure E (MV measurement) to get E/e' ratio.

Table 5-3: Cardiac calculations and results

Calculation list	Measurement name (imaging mode)	Results
TDI	<ul style="list-style-type: none"> ▶ Sep e' (Doppler) ▶ Sep a' (Doppler) ▶ Lat e' (Doppler) ▶ Lat a' (Doppler) ▶ Inf e' (Doppler) ▶ Inf a' (Doppler) ▶ Ant e' (Doppler) ▶ Ant a' (Doppler) 	E(MV)/e' ratio ^e
TAPSE	TAPSE (M Mode)	TAPSE cm

^aHR needed for CO and CI. You can enter the HR measurement on the patient form, or obtain it by measuring in M Mode (page 4), Doppler (page 22), or ECG.

^bdP:dT performed at 100 cm/s and 300 cm/s.

^dSpecified on the cardiac patient report. See **“To modify the ICA/CCA ratio (Arterial)”** on page 5-39.

^eNeed to measure E (MV measurement) to get E/e' ratio.

To calculate EF

- 1 On a frozen 2D image or M Mode trace, press the **CALCS** key.
- 2 Select **EF** from the **EF** calculations menu.
See **“To select from the calculations menu”** on page 5-8.
- 3 Do the following for both **LVDd** and **LVDs** measurements.
 - a Select the measurement from the **EF** calculations list.
 - b Use the touchpad to position the calipers.
For more information, see **“Working with calipers”** on page 5-1.
 - c Save the calculation as described in **“To save a calculation”** on page 5-8.

To calculate Atrial areas and volumes

- 1 On a frozen 2D image, press the **CALCS** key.
- 2 In the calculations menu, locate **Atria**, and then select the measurement name.
- 3 Position the caliper at the annulus, and press the **SELECT** key.
- 4 Using the touchpad, trace the atrial cavity.

To make a correction, select **Undo** on-screen or press the **backspace** key.

Note

If you start and stop the trace in the same annulus, you may not be able to adjust the vertical length.

5 Complete the trace at the other annulus, and press the **SET** key.

Note

Bi-plane volume is displayed when the length of the cavity as measured in the 2- and 4-chamber views differs by less than 5 mm.

6 Save the calculation as described in **“To save a calculation”** on page 5-8.

To calculate LV Volume (Simpson’s Rule)

- 1 On a frozen 2D image, press the **CALCS** key.
- 2 Select **LV Vol (EF)** from the **EF** calculations menu.
- 3 Do the following for each measurement:
 - a Select the measurement from the **LV Vol (EF)** calculations list.
 - b Position the caliper at the mitral annulus, and press the **SELECT** key to start the trace.
 - c Using the touchpad, trace the left ventricular (LV) cavity.
To make a correction, select **Undo** on-screen or press the **backspace** key.
 - d Complete the trace, and press the **SET** key.
 - e Save the calculation as described in **“To save a calculation”** on page 5-8.

To measure LVd and LVs

- 1 On a frozen 2D image or M Mode trace, press the **CALCS** key.
- 2 From the calculations menu, select the measurement name.
- 3 Position the active (highlighted) caliper at the starting point. Refer to **“Working with calipers”** on page 5-1.
- 4 Press the **SELECT** key, and position the second caliper.
- 5 Press the **SELECT** key. Another caliper appears, and the calculations menu highlights the next measurement name.
- 6 Position the caliper, and press the **SELECT** key. Repeat for each measurement name in the calculation group.

Note

Each time you press the **SELECT** key, another caliper appears, and the calculations menu highlights the next measurement name.

7 Save the calculation as described in **“To save a calculation”** on page 5-8.

To measure Heart Rate in Doppler

For more information about how heart rate (HR) is used in calculations, see **“Cardiac calculations”** on page 5-15

Saving the heart rate to the patient report overwrites any heart rate entered on the patient information form.

- 1 On a frozen Doppler spectral trace, press the **CALCS** key.

- 2 From the calculations menu, select **HR**.
A vertical caliper appears.
- 3 Using the touchpad, position the first vertical caliper at the peak of the heartbeat.
- 4 Press the **SELECT** key.
A second vertical caliper appears. The active caliper is highlighted.
- 5 Using the touchpad, position the second vertical caliper at the peak of the next heartbeat.
- 6 Save the calculation as described in **"To save a calculation"** on page 5-8.

To measure Ao, LA, AAO, or LVOT D

- 1 On a frozen 2D image or M Mode trace, press the **CALCS** key.
- 2 From the calculations menu, select the measurement name.
- 3 Position the calipers.
- 4 Save the calculation as described in **"To save a calculation"** on page 5-8.

To calculate MV or AV area

- 1 On a frozen 2D image, press the **CALCS** key.
- 2 In the **Area** menu, select **MV** or **AV**.
- 3 Position the caliper where you want to begin the trace, and press the **SELECT** key.
- 4 Using the touchpad, trace the desired area.
To make a correction, select **Undo** on-screen or press the **backspace** key.
- 5 Complete the trace, and press the **SET** key.
- 6 Save the calculation as described in **"To save a calculation"** on page 5-8.

To calculate LV mass

- 1 On a frozen 2D image, press the **CALCS** key.
- 2 In the calculations menu, locate **LV mass**.
- 3 Do the following for **EPI** and then for **Endo**:
 - a Select the measurement name from the calculations menu.
 - b Position the caliper where you want to begin the trace, and press the **SELECT** key.
 - c Using the touchpad, trace the desired area.
To make a correction, select **Undo** on-screen or press the **backspace** key.
 - d Complete the trace, and press the **SET** key.
 - e Save the calculation as described in **"To save a calculation"** on page 5-8.
- 4 Select **Apical** from the calculations menu.
- 5 Positioning the calipers, measure the ventricular length. See **"Working with calipers"** on page 5-1.
- 6 Save the calculation.

To measure Inferior Vena Cava (IVC) Collapse

- 1 On a frozen 2D image or M Mode trace, press the **CALCS** key.

- 2 From the calculations menu, select the measurement name.
- 3 Adjust the distance of the calipers using the touchpad.
- 4 Save the calculation as described in [“To save a calculation”](#) on page 5-8

To calculate Proximal Isovelocity Surface Area (PISA)

The PISA calculation requires a measurement in 2D, a measurement in Color, and two measurements in Doppler spectral trace. After all measurements are saved, the result appears in the patient report.

1 Measure from Ann D (2D):

- a On a frozen 2D image, press the **CALCS** key.
- b From the calculations menu, locate **PISA**, and then select **Ann D**.
- c Position the calipers.
- d Save the calculation as described in [“To save a calculation”](#) on page 5-8.

2 Measure from Radius (Color):

- a On a frozen Color image, press the **CALCS** key.
- b From the calculations menu, select **Radius**.
- c Position the calipers.
- d Save the calculation.

3 On a frozen Doppler spectral trace, press the CALCS key.

4 Do the following to measure from MR VTI and again to measure from MV VTI (Doppler):

- a From the calculations menu, select **PISA** and then select **MR VTI** or **MV VTI**.
- b Position the caliper at the start of the waveform, and press the **SELECT** key to start the trace.
- c Using the touchpad, trace the waveform.

To make a correction, select **Undo** on-screen, backtrack with the touchpad, or press the **backspace** key.

- d Press the **SET** key to complete the trace.
- e Save the calculation.

For information on the automatic trace tool, refer to [“To trace automatically in Doppler”](#) on page 5-6.

To calculate Tricuspid Annular Plane Systolic Excursion (TAPSE)

- 1 On a frozen M Mode trace, press the **CALCS** key.
- 2 From the calculations menu, select the measurement name.
- 3 Adjust the distance of the calipers using the touchpad.
- 4 Save the calculation as described in [“To save a calculation”](#) on page 5-8.

To measure peak velocity

For each cardiac measurement, the system saves up to five individual measurements and calculates their average. If you take more than five measurements, the most recent measurement replaces the oldest measurement. If you delete a saved measurement from the patient report, the next measurement taken replaces the deleted one in the patient report. The most recently saved measurement appears at the bottom of the calculations menu.

- 1 On a frozen Doppler spectral trace, press the **CALCS** key.
- 2 From the calculations menu, select **MV**, **TV**, **TDI**, or **P. Vein**.
- 3 Do the following for each measurement you want to take:
 - a Select the measurement name from the calculations menu.
 - b Position the calipers.
 - c Save the calculation as described in **"To save a calculation"** on page 5-8.

To calculate Velocity Time Integral (VTI)

This calculation computes other results in addition to VTI including Vmax, PGmax, Vmean, and PGmean.

- 1 On a frozen Doppler spectral trace, press the **CALCS** key.
- 2 From the calculations menu, select **VTI** under **MV**, **AV**, **TV**, **PV**, or **LVOT**.
- 3 Position the caliper at the start of the waveform, and press the **SELECT** key to start the trace.
- 4 Using the touchpad, trace the waveform.

To make a correction, select **Undo** on-screen, backtrack with the touchpad, or press the **backspace** key.
- 5 Press the **SET** key to complete the trace.
- 6 Save the calculation as described in **"To save a calculation"** on page 5-8.

To calculate Right Ventricular Systolic Pressure (RVSP)

- 1 On a frozen Doppler spectral trace, press the **CALCS** key.
- 2 From the calculations menu, select **TV** and then select **TRmax**.
- 3 Position the caliper. (Refer to "Working with calipers" on page 1.)
- 4 Save the calculation as described in **"To save a calculation"** on page 5-8.

Note: This calculation requires the RA pressure. If RA pressure has not been adjusted, the default value of 5 mmHg is used. To adjust the RA pressure, see **"To modify the ICA/CCA ratio (Arterial)"** on page 5-39.

To calculate Pressure Half Time (PHT) in MV, AI, or TV

- 1 On a frozen Doppler spectral trace, press the **CALCS** key.
- 2 From the calculations menu, select **MV**, **AV**, or **TV**, and then select **PHT**.

Position the first caliper at the peak, and press the **SELECT** key. A second caliper appears.
- 3 Position the second caliper:

- ▶ In MV, position the caliper along the EF slope.
- ▶ In AV, position the caliper at the end diastole.

4 Save the calculation as described in **“To save a calculation”** on page 5-8.

To calculate Isovolumic Relaxation Time (IVRT)

- 1 On a frozen Doppler spectral trace, press the **CALCS** key.
From the calculations menu, select **MV** and then select **IVRT**. A vertical caliper appears.
- 2 Using the touchpad, position the caliper at the aortic valve closure.
- 3 Press the **SELECT** key. A second vertical caliper appears.
- 4 Using the touchpad, position the second caliper at onset of mitral inflow.
- 5 Save the calculation as described in **“To save a calculation”** on page 5-8.

To calculate Delta Pressure: Delta Time (dP:dT)

To perform the dP:dT measurements, the CW Doppler scale must include velocities of 300 cm/s or greater on the negative side of the baseline (see **“Spectral trace controls”** on page 4-8).

- 1 On a frozen CW Doppler spectral trace, press the **CALCS** key.
- 2 From the calculations menu, select **MV**, and then select **dP:dT**.
A horizontal dotted line with an active caliper appears at 100 cm/s.
- 3 Position the first caliper along the waveform at 100 cm/s.
- 4 Press the **SELECT** key.
A second horizontal dotted line with an active caliper appears at 300 cm/s.
- 5 Position the second caliper along the waveform at 300 cm/s.
- 6 Save the calculation as described in **“To save a calculation”** on page 5-8.

To calculate Aortic Valve Area (AVA)

The AVA calculation requires a measurement in 2D and two measurements in Doppler. After the measurements are saved, the result appears in the patient report.

- 1 In 2D, measure from LVOT:
 - a On a frozen 2D image, press the **CALCS** key.
 - b From the calculations menu, select **LVOT D**.
 - c Position the calipers.
 - d Save the calculation as described in **“To save a calculation”** on page 5-8.
- 2 In Doppler, measure LVOT Vmax, and then measure AV Vmax. See **“To measure peak velocity”** on page 5-25. From the calculations menu, select **AV**, select sample site, and then select **Vmax**.

Note

Vmax can also be determined from the VTI measurement. See **“To calculate Velocity Time Integral (VTI)”** on page 5-25. From the calculations menu, select **AV**, select sample site, and then select **VTI**.

To calculate Qp/Qs

The Qp/Qs calculation requires two measurements in 2D and two measurements in Doppler. After the measurements are saved, the result appears in the patient report.

- 1 On a frozen 2D image, press the **CALCS** key.
- 2 Do the following to measure from LVOT D and again to measure from RVOT D:
 - a From the **Qp/Qs** calculations list, select **LVOT D** or **RVOT D**.
 - b Position the calipers.
 - c Save the calculation as described in **"To save a calculation"** on page 5-8.
- 3 On a frozen Doppler spectral trace, press the **CALCS** key.
- 4 Do the following to measure from LVOT VTI and again to measure from RVOT VTI:
 - a From the calculations menu, select **Qp/Qs** and then select **LVOT VTI** or **RVOT VTI**.
 - b Press the **SELECT** key to start the trace.
 - c Using the touchpad, trace the waveform.
 - d To make a correction, select **Undo** on-screen, backtrack with the touchpad, or press the **backspace** key.
 - e Press the **SET** key to complete the trace.
 - f Save the calculation as described in **"To save a calculation"** on page 5-8.

For information on the automatic trace tool, refer to **"To trace automatically in Doppler"** on page 5-6.

To calculate Stroke Volume (SV) or Stroke Index (SI)

The SV and SI calculations require a measurement in 2D and a measurement in Doppler. SI also requires Body Surface Area (BSA). After the measurements are saved, the result appears in the patient report.

- 1 (SI Only) Fill in the **Height** and **Weight** fields on the patient form. The BSA is calculated automatically (see **"To create a new patient information form"** on page 4-24).
- 2 Measure from LVOT (2D):
 - a On a frozen 2D image, press the **CALCS** key.
 - b From the calculations menu select **Ao/LA** then **LVOT D**.
 - c Position the calipers.
 - d Save the calculation as described in **"To save a calculation"** on page 5-8.
- 3 Measure from **LVOT** (Doppler). Refer to **"To calculate Velocity Time Integral (VTI)"** on page 5-25. From the calculations menu, select **AV** and then select **LVOT VTI**.

For information on the automatic trace tool, refer to **"To trace automatically in Doppler"** on page 5-6.

To calculate Cardiac Output (CO) or Cardiac Index (CI)

The CO and CI calculations require Stroke Volume (SV) and Heart Rate (HR) calculations. CI also requires Body Surface Area (BSA). After the measurements are saved, the result appears in the patient report.

- 1 (CI Only) Fill in the **Height** and **Weight** fields on the patient form. The BSA is calculated automatically (see **"To create a new patient information form"** on page 4-24).
- 2 Calculate SV as described in **"To calculate Stroke Volume (SV) or Stroke Index (SI)"** on page 5-27.
- 3 Calculate HR as described in **"To measure Heart Rate in Doppler"** on page 5-22.

To calculate Cardiac Output (CO) automatically

WARNINGS

- ▶ To avoid incorrect calculation results, make sure that the Doppler signal does not alias.

To avoid an incorrect diagnosis:

- ▶ Do not use automatic Cardiac Output calculations as the sole diagnostic criteria. Use them only in conjunction with other clinical information and patient history.
- ▶ Do not use automatic Cardiac Output calculations in neonatal patients.
- ▶ To avoid inaccurate velocity measurements if you use PW Doppler, make sure that Angle Correction is set to zero.

Make sure that the flow rate is 1 L/min or greater. The system can maintain accuracy of the measurements only if the flow rate is 1 L/min or greater.

- 1 Measure from LVOT:
 - a On a frozen 2D image, press the **CALCS** key.
 - b From the **CO** calculations menu, select **LVOT D**.
 - c Using the touchpad, position the calipers.
 - d Save the calculation as described in **"To save a calculation"** on page 5-8.
- 2 Trace automatically in Doppler. The automatic trace tool always measures the peak regardless of the Live Trace setting in Presets setup.
 - a Display the Doppler spectral trace (waveform).
 - b Select **Trace** on-screen, and then select **Above** or **Below** for the position of the automatic trace tool relative to the baseline.

Notes

- ▶ The automatic trace tool appears in yellow.
- ▶ The results appear at the bottom of the screen.

- c Freeze the image.
 - ▶ If you want to change the waveform measured, move each vertical caliper by pressing **SELECT** and then using the touchpad. Press **SET** to update the results.
 - ▶ If you invert the frozen image or move the baseline, results are cleared.
 - ▶ If you want to hide the results, select **Trace**.
- d Save the calculation.

To measure a Tissue Doppler Imaging (TDI) waveform

- 1 Ensure that TDI is on. Refer to **"PW Doppler controls"** on page 4-7.

- 2 On a frozen Doppler spectral trace, press the **CALCS** key.
- 3 From the calculations menu, select **TDI**, and then do the following for each measurement you want to take:
 - a From the calculations menu, select the measurement name.
 - b Position the calipers.
 - c Save the calculation as described in **"To save a calculation"** on page 5-8.

Gynecology (Gyn) calculations

Gynecology (Gyn) calculations include Uterus, Ovary, Follicle, and Volume. For instructions to calculate volume, refer to **"Volume calculation"** on page 5-11.

WARNINGS

- ▶ To avoid incorrect calculations, verify that the patient information, date, and time settings are accurate.
- ▶ To avoid misdiagnosis or harming the patient outcome, start a new patient information form before starting a new patient exam and performing calculations. Starting a new patient information form clears the previous patient's data. The previous patient's data will be combined with the current patient if the form is not first cleared. Refer to **"To create a new patient information form"** on page 4-24.

To measure uterus or ovary

- 1 On a frozen 2D image, press the **CALCS** key.
- 2 From the calculations menu, select **Gyn**.
- 3 Do the following for each measurement you want to take:
 - a Select the measurement name from the calculations menu.
 - b Position the calipers.
 - c Save the calculation as described in **"To save a calculation"** on page 5-8.

To measure follicles

On each side, you can save up to three distance measurements on a follicle, for up to 10 follicles. If you measure a follicle twice, the average appears in the report. If you measure a follicle three times, the average and a volume calculation appear in the report.

- 1 On a frozen 2D image, press the **CALCS** key.
- 2 From the calculations menu, select **Follicle**.
- 3 Do the following for each measurement you want to take:
 - a From the calculations menu, select the follicle number under **Right Fol** or **Left Fol**.
 - b Position the calipers. Refer to **"Working with calipers"** on page 5-1.
 - c Save the calculation as described in **"To save a calculation"** on page 5-8.

OB calculations

EFW is calculated only after appropriate measurements are completed. If any one of these parameters results in an EDD greater than what the OB tables provide, the EFW is not displayed.

WARNINGS

- ▶ To prevent injury or misdiagnosis, do not use this system for fetal growth screening if the advanced OB calculations and reports package is not available.
- ▶ Make sure that you have selected the OB exam type and the OB calculations author for the OB table you intend to use. Refer to **“System-defined OB calculations and table authors”** on page 5-30.
- ▶ Prior to use, verify that OB custom table data entries are correct. The system does not confirm the accuracy of the custom table data entered by the user.
- ▶ To avoid incorrect obstetrics calculations, verify with a local clock and calendar that the system’s date and time settings are correct before each use of the system. The system does not automatically adjust for daylight savings time changes.
- ▶ To avoid misdiagnosis or harming the patient outcome, start a new patient information form before starting a new patient exam and performing calculations. Starting a new patient information form clears the previous patient’s data. The previous patient’s data will be combined with the current patient if the form is not first cleared. Refer to **“To create a new patient information form”** on page 4-24.

System-defined OB calculations and table authors

The following table shows the system-defined measurements available for OB calculations by author. For definition of the acronyms, refer to **“Glossary”** on page A-1. To select authors, refer to **“OB Calculations setup”** on page 3-11.

If you change the calculation author during the exam, the common measurements are retained.

Table 5-4: OB calculations for system-defined measurements

Calculation Result	Gestational OB Measurements	Table Authors
Gestational Age ^a	YS	—
	GS	Hansmann, Nyberg, Tokyo U.
	CRL	Hadlock, Hansmann, Osaka, Tokyo U.
	BPD	Chitty, Hadlock, Hansmann, Osaka, Tokyo U.
	HC	Chitty, Hadlock, Hansmann
	AC	Hadlock, Hansmann, Tokyo U.
	FL	Chitty, Hadlock, Hansmann, Osaka, Tokyo U.
	HL	Jeanty
	Tibia	Jeanty
	TCD	—
	CM	—
	Lat V	—
	CxLen	—

^aThe Gestational Age is automatically calculated and displayed next to the OB measurement you selected. The average of the results is the AUA.

^bFor Tokyo U., APTD and TTD are used only to calculate EFW. No age or growth tables are associated with these measurements.

^cThe Estimated Fetal Weight calculation uses an equation that consists of one or more fetal biometry measurements. The author for the OB tables, which you choose on a system setup page, determines the measurements you must perform to obtain an EFW calculation. Refer to **"OB Calculations setup"** on page 3-11. Individual selections for Hadlock's EFW equations 1, 2, and 3 are not determined by the user. The selected equation is determined by the measurements that have been saved to the report with priority given to the order listed above.

^dThe Growth Analysis tables are used by the Report Graphs feature. Three growth curves are drawn using the table data for the selected growth parameter and published author. Growth tables are only available with a user-entered LMP or Estab. DD.

Table 5-4: OB calculations for system-defined measurements

Calculation Result	Gestational OB Measurements	Table Authors
Estimated Fetal Weight (EFW) ^c	HC, AC, FL	Hadlock 1
	BPD, AC, FL	Hadlock 2
	AC, FL	Hadlock 3
	BPD	Hansmann
	BPD, FL	Osaka U.
	BPD, AC	Shepard
	BPD, TTD, APTD, FL	Tokyo U.
Ratios	HC/AC	Campbell
	FL/AC	Hadlock
	FL/BPD	Hohler
	FL/HC	Hadlock
Amniotic Fluid Index	Q ¹ , Q ² , Q ³ , Q ⁴	Jeng

^aThe Gestational Age is automatically calculated and displayed next to the OB measurement you selected. The average of the results is the AUA.

^bFor Tokyo U., APTD and TTD are used only to calculate EFW. No age or growth tables are associated with these measurements.

^cThe Estimated Fetal Weight calculation uses an equation that consists of one or more fetal biometry measurements. The author for the OB tables, which you choose on a system setup page, determines the measurements you must perform to obtain an EFW calculation. Refer to **"OB Calculations setup"** on page 3-11. Individual selections for Hadlock's EFW equations 1, 2, and 3 are not determined by the user. The selected equation is determined by the measurements that have been saved to the report with priority given to the order listed above.

^dThe Growth Analysis tables are used by the Report Graphs feature. Three growth curves are drawn using the table data for the selected growth parameter and published author. Growth tables are only available with a user-entered LMP or Estab. DD.

Table 5-4: OB calculations for system-defined measurements

Calculation Result	Gestational OB Measurements	Table Authors
Growth Analysis Tables ^d	BPD	Chitty, Hadlock, Jeanty
	HC	Chitty, Hadlock, Jeanty
	AC	Chitty, Hadlock, Jeanty
	FL	Chitty, Hadlock, Jeanty
	EFW	Brenner, Hadlock, Jeanty
	HC/AC	Campbell

^aThe Gestational Age is automatically calculated and displayed next to the OB measurement you selected. The average of the results is the AUA.

^bFor Tokyo U., APTD and TTD are used only to calculate EFW. No age or growth tables are associated with these measurements.

^cThe Estimated Fetal Weight calculation uses an equation that consists of one or more fetal biometry measurements. The author for the OB tables, which you choose on a system setup page, determines the measurements you must perform to obtain an EFW calculation. Refer to **"OB Calculations setup"** on page 3-11. Individual selections for Hadlock's EFW equations 1, 2, and 3 are not determined by the user. The selected equation is determined by the measurements that have been saved to the report with priority given to the order listed above.

^dThe Growth Analysis tables are used by the Report Graphs feature. Three growth curves are drawn using the table data for the selected growth parameter and published author. Growth tables are only available with a user-entered LMP or Estab. DD.

To measure gestational growth (2D)

For each 2D OB measurement (except AFI), the system saves up to three individual measurements and their average. If you take more than three measurements, the earliest measurement is deleted.

- 1 In the patient information form, select **OB** exam type, and select **LMP** or **Estab.DD**. Select **Twins** if appropriate.
- 2 On a frozen 2D image, press the **CALCS** key.
- 3 Do the following for each measurement you want to take:
 - a From the calculations menu, select the measurement name.
 - b For twins, select **Twin A** or **Twin B**, and then select the measurement name.

Note

The caliper tool may change depending on the measurement selected, but the position remains constant.

- c Position the calipers.

d Save the calculation as described in “To save a calculation” on page 5-8.

To measure Fetal Heart Rate

- 1 On a frozen M Mode trace, press the **CALCS** key.
- 2 Select **FHR** from the calculations menu. A vertical caliper appears.
- 3 Using the touchpad, position the vertical caliper at the peak of the heartbeat.
- 4 Press the **SELECT** key. A second vertical caliper appears.
- 5 Using the touchpad, position the second vertical caliper at the peak of the next heartbeat.
- 6 Save the calculation as described in “To save a calculation” on page 5-8.

To calculate the S/D ratio, RI or PI of the Middle Cerebral Artery (MCA) or Umbilical Artery (UmbA)

Note | The system does not provide an MCA/UmbA ratio from the PI (Pulsatility Index).

- 1 Select **OB** exam type, and select **LMP** or **Estab.DD** in the patient information form.
- 2 On a frozen Doppler spectral trace, press the **CALCS** key.
- 3 Do the following for each measurement you need to take:
 - a From the calculations menu, select the measurement name under **MCA** (Middle Cerebral Artery) or **UmbA** (Umbilical Artery).
 - b Position the calipers:
 - ▶ For **S/D, RI**, position the first caliper at the peak systolic waveform. Press the **SELECT** key, and position the second caliper at the end diastole on the waveform.
 - ▶ For **S/D, RI, PI**, position the caliper at the beginning of the desired waveform, and press the **SELECT** key. Use the touchpad to manually trace the desired area. Press the **SET** key.

Note | If calipers are not positioned correctly, the calculation result is inaccurate.

c Save the calculation as described in “To save a calculation” on page 5-8.

Note | Only one calculation (**S/D, RI** or **S/D, RI, PI**) can be saved.

Required measurements for MCA or UmbA

Table 5-5: MCA or UmbA calculations and results

Calculation list	Measurement name	Results
MCA (Middle Cerebral Artery)	▶ S/D, RI	SD, RI
	▶ S/D, RI, PI*	SD, RI, PI, MDV
*Calculation requires a trace measurement.		

Table 5-5: MCA or UmbA calculations and results

Calculation list	Measurement name	Results
Umb A (Umbilical Artery)	▶ S/D, RI	SD, RI
	▶ S/D, RI, PI*	SD, RI, PI, MDV

*Calculation requires a trace measurement.

Small Parts and MSK calculations

WARNINGS

- ▶ To avoid incorrect calculations, verify that the patient information, date, and time settings are accurate.
- ▶ To avoid misdiagnosis or harming the patient outcome, start a new patient form before starting a new patient exam and performing calculations. Starting a new patient form clears the previous patient's data. The previous patient's data will be combined with the current patient if the form is not first cleared. See **"To create a new patient information form"** on page 4-24.

Small Parts calculations include volume, hip angle, and d:D ratio. MSK calculations include hip angle.

For instructions to calculate volume, see **"Volume calculation"** on page 5-11.

To calculate hip angle

- 1 On a frozen 2D image, press the **CALCS** key.
- 2 From the calculations menu, select **Right** or **Left**.
Select **Baseline** under **Hip Angle**. A baseline appears on-screen.
- 3 Position the baseline, and press the **SET** key. See **"Working with calipers"** on page 5-1.
Line A (alpha line) appears on-screen, and **Line A** is selected in the calculations menu.
- 4 Position Line A, and save the measurement. See **"To save a calculation"** on page 5-8.
Line B (beta line) appears on-screen, and **Line B** is selected in the calculations menu.
- 5 Position Line B, and save the measurement.

To calculate d:D ratio (Small Parts only)

- 1 On a frozen 2D image, press the **CALCS** key.
- 2 From the calculations menu, select **Right** or **Left**.
- 3 Under **d:D Ratio**, select **Fem Hd** (femoral head).
- 4 Using the touchpad, position and resize the circle. The **SELECT** key toggles between position and size.
Press the **SET** key. The baseline automatically appears with the left caliper active.
- 5 Position the caliper. See **"Working with calipers"** on page 5-1.

6 Save the measurement as described in **“To save a calculation”** on page 5-8.

Transcranial Doppler and Orbital calculations

WARNING

- ▶ To avoid injury to the patient, use only an Orbital (Orb) or Ophthalmic (Oph) exam type when performing imaging through the eye. The FDA has established lower acoustic energy limits for ophthalmic use. The system will not exceed these limits only if the Orbital or Ophthalmic exam type is selected.
- ▶ Verify that the patient information, date, and time settings are accurate.
- ▶ To avoid misdiagnosis or harming the patient outcome, start a new patient form before starting a new patient exam and performing calculations. Starting a new patient form clears the previous patient’s data. The previous patient’s data will be combined with the current patient if the form is not first cleared. See **“To create a new patient information form”** on page 4-24.

The following table shows the measurements available for Transcranial Doppler (TCD) and Orbital (Orb) calculations.

Table 5-6: Transcranial Doppler and Orbital calculations and results

Calculation list	Measurements	Results
TT MCA	<ul style="list-style-type: none"> ▶ Dist ▶ Mid ▶ Prox 	TAP PSV EDV MDV
	<ul style="list-style-type: none"> ▶ Bifur* ▶ ACA ▶ ACoA* ▶ TICA 	PI RI S/D Gate Size
TT	<ul style="list-style-type: none"> ▶ PCAp1 ▶ PCAp2 ▶ PCoA 	

*Available but not required.

Table 5-6: Transcranial Doppler and Orbital calculations and results (continued)

Calculation list	Measurements	Results
TO	<ul style="list-style-type: none"> ▶ OA ▶ Siphon 	TAP PSV EDV MDV PI RI S/D Gate Size
SM	ECICA	TAP PSV EDV MDV PI RI S/D Gate Size
FM FM BA	VA <ul style="list-style-type: none"> ▶ Prox ▶ Mid ▶ Dist 	TAP PSV EDV MDV PI RI S/D Gate Size
AL	ECVA	TAP PSV EDV MDV PI RI S/D Gate Size

*Available but not required.

To perform a Transcranial Doppler or Orbital calculation

- 1 Select the Orbital or Transcranial exam type.
 - ▶ **Orbital (Orb)** to measure Ophthalmic Artery and Siphon
 - ▶ **Transcranial (TCD)** for other measurements
 See **"To change the exam type"** on page 4-16.

- 2 On a frozen Doppler spectral trace, press the **CALCS** key.
- 3 On a frozen Doppler spectral trace, press the **CALCS** key.
- 4 From the calculations menu, select **Left** or **Right**.
- 5 Do the following for each measurement you want to take:
 - a From the calculations menu, select the measurement. (You may need to select **Next** or **Prev** to locate the measurement.)
 - b Do one of the following:
 - ▶ For a manual trace measurement, use the touchpad to position the caliper. Press the **SELECT** key. Use the touchpad to trace the waveform. If you need to make a correction, select **Undo** on-screen or press the **backspace** key.
 - ▶ For an auto trace measurement, select **Auto** on-screen, and use the touchpad to position the first caliper at the beginning of the waveform. Press the **SELECT** key, and position the second caliper at the end of the waveform.Confirm that the system-generated boundary is correct. If you are not satisfied with the trace, obtain a higher quality Doppler spectral trace image, or trace manually.
 - c Press the **SET** key.
 - d Save the calculation as described in **"To save a calculation"** on page 5-8.

Patient reports and worksheets

The patient report contains calculation results and patient information for the exam. For Arterial, Cardiac, OB, and TCD exams, the patient report has additional details and features.

The value for a calculation appears only if the calculation is performed. The pound symbol (**###**) indicates a value that is out of range (for example, too large or small). Calculation values that are out of range are not included in derived calculations (for example, mean).

You can display the patient report at any time during the exam. For a definition of terms in patient reports, refer to **"Glossary"** on page A-1.

To display the patient report

- 1 Press the **REPORT** key.
- 2 Do any of the following:
 - ▶ To display additional pages, select  **1/x** on-screen.
 - ▶ (Cardiac, Arterial, or TCD) Select **Details** or **Summary** on-screen. The mean of the detail entries is used in the summary.
- 3 (Optional) Press the **SAVE** key to save the current page of the patient report.
- 4 To exit the patient report and return to imaging, select **Done**.

Arterial and cardiac patient reports

To delete an arterial or cardiac measurement

- 1 On the **Details** page of the patient report, select the measurement by using the touchpad.
The selected measurement is highlighted.
- 2 Select **Delete** on-screen.

Note | Deleting some measurements also deletes related measurements. Deleted measurements are not included in the summary information.

To modify the ICA/CCA ratio (Arterial)

- ❖ In the **Ratio** list in the arterial patient report, select measurements for the ICA/CCA ratio for both the right and left sides.

To adjust the RA pressure

- ❖ On the **Summary** page of the cardiac patient report, select from the **RA** list.

Note | Changing the RA pressure from the default 5 affects the RVSP calculation result.

OB patient report

The OB patient report pages have a space for signing printed reports.

To display the OB Twins patient report

- ❖ On the OB patient report, select one of the following on-screen:
 - ▶ **Twin A/B** for individual twin patient reports
 - ▶ **Compare** for both twins in one patient report

To delete an OB measurement

- 1 On the OB patient report, select the OB measurement by using the touchpad. The selected measurement is highlighted.
- 2 Select **Delete** on-screen.
To delete all measurements, select the measurement label and press the **SELECT** key and then select **Delete** on-screen.

To fill out the OB anatomy checklist

You can document reviewed anatomy.

- 1 On the **Anatomy Checklist** page in the OB patient report, select the check boxes.
- 2 Press the **TAB** key to move between fields and the **spacebar** to select and deselect items in the checklist.

To complete the OB biophysical profile

- ❖ On page 2 of the OB patient report, select values under **BPP**. The total is calculated when values are selected. NST (non-stress test) is optional.

To display OB graphs

You can display OB graphs if the **LMP** or **Estab. DD** fields are complete in the patient information form.

- 1 On the OB patient report, select **Graphs** on-screen.
In the **Graphs** list, select the desired measurement/author. The graph for the selected measurement appears. You can select another measurement/author or select  **1/x** on-screen.

Note

For twins, both measurement sets are plotted on the same graph.

- 2 (Optional) Press the **SAVE** key to save the current graph page.
- 3 Select one of the following on-screen:
 - ▶ **Report** to return to the previous patient report page
 - ▶ **Done** to return to live imaging.

TCD patient report

The maximum values for the TAP calculation appear on the summary page.

To delete a row of TCD measurements

- 1 On the **Details** page of the TCD patient report, select the row's TAP measurement using the touchpad. The selected measurement is highlighted.
- 2 Select **Delete** on-screen. Deleted measurements are not included in the summary information.

EMED and MSK worksheets

EMED and MSK (Musculoskeletal) worksheets are licensed features that include patient information, text boxes, and procedure information from the ultrasound system. EMED worksheets include results from measurements and calculations you perform from the EMED calculation lists.

To display an EMED worksheet

- 1 During or after the exam, press the **REPORT** key.
- 2 Select **EMED** on-screen.
- 3 Select the worksheet from the **Worksheet** list or by selecting  **x/x** on-screen.

To display an MSK worksheet

- 1 During or after the exam, press the **REPORT** key.
- 2 Select **MSK** on-screen.
- 3 Select the worksheet from the **Worksheet** list or by selecting  **x/x** on-screen.
 - a To display additional pages in the worksheet, select  **x/x** on-screen.

Each worksheet has its own Comments field, which remains on-screen even if you display another page in the worksheet.
 - b If you want to save a worksheet page, press the **SAVE** key.

CHAPTER 6

Measurement references

This section provides information about measurement accuracy, publications, and terminology.

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 6-1: ^{ac2D} 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

^aFull scale for distance implies the maximum depth of the image.

^bAn RMI 413a model phantom with 0.7 dB/cm MHz attenuation was used.

^cThe area accuracy is defined using the following equation:

$$\% \text{ tolerance} = ((1 + \text{lateral error}) * (1 + \text{axial error}) - 1) * 100 + 0.5\%$$

^dThe circumference accuracy is defined as the greater of the lateral or axial accuracy and by the following equation:

$$\% \text{ tolerance} = (\sqrt{2} (\text{maximum of 2 errors}) * 100) + 0.5\%$$

Table 6-2: 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
Time	< +/- 2% plus 1% of full scale ^c	Acquisition	Phantom ^d	0.01-10 sec

^aFull scale for distance implies the maximum depth of the image.

^bAn RMI 413a model phantom with 0.7 dB/cm MHz attenuation was used.

^cFull scale for time implies the total time displayed on the scrolling graphic image.

^dFUJIFILM SonoSite special test equipment was used.

Table 6-2: M Mode Measurement and Calculation Accuracy and Range

M Mode Measurement Accuracy and Range	System Tolerance	Accuracy By	Test Method	Range
Heart Rate	< +/- 2% plus (Full Scale ^c * Heart Rate/100)%	Acquisition	Phantom ^d	5-923 bpm

^aFull scale for distance implies the maximum depth of the image.

^bAn RMI 413a model phantom with 0.7 dB/cm MHz attenuation was used.

^cFull scale for time implies the total time displayed on the scrolling graphic image.

^dFUJIFILM SonoSite special test equipment was used.

Table 6-3: 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

^aFUJIFILM SonoSite special test equipment was used.

^bFull scale for frequency or velocity implies the total frequency or velocity magnitude, displayed on the scrolling graphic image.

^cFull 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.

Measurement publications and terminology

The following are the publications and terminology used for each calculation result.

Terminology and measurements comply with American Institute of Ultrasound in Medicine (AIUM) published standards.

Cardiac references

Acceleration (ACC) in cm/s^2

Zwiebel, W.J. *Introduction to Vascular Ultrasonography*. 4th ed., W.B. Saunders Company, (2000), p.52.

$\text{ACC} = \text{abs}(\text{delta velocity}/\text{delta time})$

Acceleration Time (AT) in msec

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Lippincott, Williams, and Wilkins, (2007), p.147-148.

$[\text{time a} - \text{time b}]$

where:

time a = early time;

time b = later time;

only valid when $[a] > [b]$

Aortic Valve Area (AVA) by Continuity Equation in cm^2

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Lippincott, Williams, and Wilkins, (2007), p.73 and p.191-195.

$$A_2 = A_1 * V_1/V_2$$

where:

A_2 = Ao valve area

A_1 = LVOT area;

V_1 = Peak LVOT velocity (Vmax) or LVOT VTI

V_2 = Peak Ao valve velocity (Vmax) or Ao VTI

LVOT = Left Ventricular Outflow Tract

Body Surface Area (BSA) in m^2

Grossman, W. *Cardiac Catheterization and Angiography*. Philadelphia: Lea and Febiger, (1980), p.90.

$$\text{BSA} = 0.007184 * \text{Weight}^{0.425} * \text{Height}^{0.725}$$

Weight = kilograms

Height = centimeters

Cardiac Index (CI) in l/min/m²

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Lippincott, Williams, and Wilkins, (2007), p.69-70.

$$CI = CO/BSA$$

where:

CO = Cardiac Output

BSA = Body Surface Area

Cardiac Output (CO) in l/min

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Lippincott, Williams, and Wilkins, (2007), p.69-70.

$$CO = (SV * HR)/1000$$

where:

CO = Cardiac Output

SV = Stroke Volume (ml)

HR = Heart Rate

Cross Sectional Area (CSA) in cm²

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Lippincott, Williams, and Wilkins, (2007), p.70-71.

$$CSA = 0.785 * D^2$$

where: D = diameter of the anatomy of interest

Deceleration Time in msec

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Lippincott, Williams, and Wilkins, (2007), p.73-74.

[time a - time b]

where:

time a = time associated with Vmax;

time b = when the line tangent to the envelope and through Vmax crosses the baseline

Delta Pressure: Delta Time (dP:dT) in mmHg/s

Otto, C.M. *Textbook of Clinical Echocardiography*. 2nd ed., W.B. Saunders Company, (2000), p.117-118.
32 mmHg/time interval in seconds

E:A Ratio in cm/sec

E:A = velocity E/velocity A

E/Ea Ratio

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), p.225.

E Velocity/Ea velocity

where:

E velocity = Mitral Valve E velocity

Ea = annular E velocity, also known as E prime

Effective Regurgitant Orifice (ERO) in mm²

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Lippincott, Williams, and Wilkins, (2007), p.73-76, p.210.

ERO = MV Flow Rate/ MR Vel * 100

Ejection Fraction (EF), percent

Hayashi, T., Kihara Y., et al. "The Terminology and Diagnostic Criteria Committee of The Japan Society of Ultrasonics in Medicine Standard measurement of cardiac function indexes." *J Med Ultrasonic* (2006), 33: p.123-127.

EF = [(LVEDV – LVESV)/LVEDV]* 100%

where:

EF = Ejection Fraction

LVEDV = Left Ventricular End Diastolic Volume

LVESV = Left Ventricular End Systolic Volume

Elapsed Time (ET) in msec

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Lippincott, Williams, and Wilkins, (2007), p.147, Figure 9-8.

ET = time between velocity cursors in milliseconds

Heart Rate (HR) in bpm

HR = 3 digit value input by user or measured on M Mode and Doppler image in one heart cycle

Interventricular Septum (IVS) Fractional Thickening, percent

Laurenceau, J. L., M.C. Malergue. *The Essentials of Echocardiography*. Le Hague: Martinus Nijhoff, (1981), p.71.

IVSFT = ((IVSS – IVSD)/IVSD) * 100%

where:

IVSS = Interventricular Septal Thickness at Systole

IVSD = Interventricular Septal Thickness at Diastole

Isovolumic Relaxation Time (IVRT) in msec

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), p.385.

[time a - time b]

where:

time a = mitral valve opening

time b = aortic valve closure

Lyon, M., N. Verma. "Ultrasound guided volume assessment using inferior vena cava diameter." *The Open Emergency Medicine Journal*. (2010), 3: p.22-24.

$(IVCd_{exp} - IVCd_{insp}) / IVCd_{exp}$

where:

expiration (exp) = maximum diameter (Max D)

inspiration (insp) = minimum diameter (Min D)

Left Atrium/Aorta (LA/Ao)

Feigenbaum, H. *Echocardiography*. Philadelphia: Lea and Febiger, (1994), p.206, Figure 4-49.

Left Atrial Area

Lopez, L. et al. "Recommendations for quantification methods during the performance of a pediatric echocardiogram: A report from the pediatric measurements writing group of the American Society of Echocardiography pediatric and congenital heart disease council." *J Am Soc Echocardiography*. (2010), 23: p.465-495.

Left Atrial Volume

Lang R. et al. "Recommendations for Cardiac Chamber Quantification: A report from the American Society of Echocardiography's Guidelines and Standards Committee and the Chamber Quantification Writing Group, Developed in Conjunction with the European Association of Echocardiography, a Branch of the European Society of Cardiology." *J Am Soc Echocardiography*. (2005), 18:1440-1463.

Lang R, Bierig M, Devereux R, et al. "Recommendations for Cardiac chamber Quantification by Echocardiography in Adults: An Update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging." *J Am Soc Echocardiography*. (2015), p.28:1-39.

$LA\ Vol = \pi/4(h) \Sigma(D1)(D2)$

where:

LA Vol = Left Atrial Volume in ml

h = Height of stacked oval disks making up the LA

D1 = Orthogonal minor axis

D2 = Orthogonal major axis

2-plane Simpson's rule (method of disks)

$$LA \text{ Vol} = \pi/4(h) \Sigma(D1)(D2)$$

Simpson's algorithm divides the LA into a series of stacked oval disks where h is the height of the stacked disks and D1 and D2 are the orthogonal minor and major axes

1-plane Simpson's rule (method of disks)

$$LA \text{ Vol} = \pi/4(h) \Sigma(D1)^2$$

Same as the 2-plane method of disks except there is an assumption that the stacked disks are circular.

The equation for the LA Vol Index is: LA Vol Index = LA Vol/BSA

Left Ventricular End Volumes (Teichholz) in ml

Teichholz, L.E., T. Kreulen, M.V. Herman, et al. "Problems in echocardiographic volume determinations: echocardiographic-angiographic correlations in the presence or absence of asynergy." *American Journal of Cardiology*. (1976) 37: p.7.

$$LVESV = (7.0 * LVDS^3)/(2.4 + LVDS)$$

where:

LVESV = Left Ventricular End Systolic Volume

LVDS = Left Ventricular Dimension at Systole

$$LVEDV = (7.0 * LVDD^3)/(2.4 + LVDD)$$

where:

LVEDV = Left Ventricular End Diastolic Volume

LVDD = Left Ventricular Dimension at Diastole

Left Ventricular Mass in gm for 2D

Schiller, N.B., P.M. Shah, M. Crawford, et al. "Recommendations for Quantitation of the Left Ventricle by Two-Dimensional Echocardiography." *J Am Soc Echocardiography*. September-October (1989), 2: p.364.

$$LV \text{ Mass} = 1.05 * \{[(5/6) * A1 * (a + d + t)] - [(5/6) * A2 * (a + d)]\}$$

where:

1.05 = Specific gravity of the myocardium

A1 = Short axis area, diastole (Epi)

A2 = Short axis area, diastole (Endo)

a = Long or semi major axis

d = Truncated semi major axis from the widest short axis diameter to mitral annulus plane.

t = Myocardial thickness

Left Ventricular Mass in gm for M Mode

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Philadelphia: Lippincott, Williams, and Wilkins, (2007), p.115.

$$LV \text{ Mass} = 1.04 [(LVID + PWT + IVST)^3 - LVID^3] * 0.8 + 0.6$$

where:

LVID = Internal Dimension
 PWT = Posterior Wall Thickness
 IVST = Interventricular Septal Thickness
 1.04 = Specific gravity of the myocardium
 0.8 = Correction factor

Left Ventricular Volume: Biplane Method in ml

Schiller, N.B., P.M. Shah, M. Crawford, et al. "Recommendations for Quantitation of the Left Ventricle by Two-Dimensional Echocardiography." *J Am Soc Echocardiography*. September-October (1989) 2: p.362.

$$V = \left(\frac{\pi}{4}\right) \sum_{i=1}^n a_i b_i \left(\frac{L}{n}\right)$$

Simpson's method is used to model the chamber as a stack of elliptical disks.

where:

V = Volume in ml
 a_i = Diameter of major axis of elliptical disk *i* in mm
 b_i = Diameter of minor axis of elliptical disk *i* in mm
 n = Number of disks (n=20)
 L = Length of the chamber
 i = Disk index

Left Ventricular Volume: Single Plane Method in ml

Schiller, N.B., P.M. Shah, M. Crawford, et al. "Recommendations for Quantitation of the Left Ventricle by Two-Dimensional Echocardiography." *J Am Soc Echocardiography*. September-October (1989) 2: p.362.

$$V = \left(\frac{\pi}{4}\right) \sum_{i=1}^n a_i^2 \left(\frac{L}{n}\right)$$

Simpson's method is used to model the chamber as a stack of circular disks.

where:

V = Volume
 a_i = Diameter of disk *i* in mm
 n = Number of disks (n=20)
 L = Length of chamber, measured from the midpoint of the line connecting the two opposite sides of the mitral ring and the most distant point (apex) of the chamber contour
 i = Disk index

Left Ventricular Dimension (LVD) Fractional Shortening, percent

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Philadelphia: Lippincott, Williams, and Wilkins, (2007), p.115.

$$LVDFS = [(LVDD - LVDS)/LVDD] * 100\%$$

where:

LVDD = Left Ventricle Dimension at Diastole

LVDS = Left Ventricle Dimension at Systole

LV Ejection Fraction

Schiller, N.B., Shah, P.M., Crawford, M., et al. "Recommendations for Quantification of the Left Ventricle by Two-Dimensional Echocardiography." *J Am Soc Echocardiography*. September-October (1989) 2: p.364.

$EF = ((\text{End Diastolic Volume} - \text{End Systolic Volume}) / \text{End Diastolic Volume}) * 100 (\%)$.

Left Ventricular Posterior Wall Fractional Thickening (LVPWFT), percent

Laurenceau, J. L., M.C. Malergue. *The Essentials of Echocardiography*. Le Hague: Martinus Nijhoff, (1981), p.71.

$LVPWFT = [(LVPWS - LVPWD) / LVPWD] * 100\%$

where:

LVPWS = Left Ventricular Posterior Wall Thickness at Systole

LVPWD = Left Ventricular Posterior Wall Thickness at Diastole

Mean Velocity (Vmean) in cm/s

Vmean = mean velocity

Mitral Valve Area (MVA) in cm²

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Philadelphia: Lippincott, Williams, and Wilkins, (2007), p.73-74.

$MVA = 220 / PHT$

where: PHT = pressure half time

220 is an empirical derived constant and may not accurately predict mitral valve area in mitral prosthetic heart valves. The mitral valve area continuity equation may be utilized in mitral prosthetic heart valves to predict effective orifice area.

MV Flow Rate in cc/sec

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Philadelphia: Lippincott, Williams, and Wilkins, (2007), p.73-76, p.210.

$\text{Flow} = PISA * Va$

where:

PISA = Proximal Isovelocity Surface Area

Va = aliasing Velocity

Pressure Half Time (PHT) in msec

Reynolds, Terry, *The Echocardiographer's Pocket Reference*, 2nd Edition, School of Cardiac Ultrasound, Arizona Heart Institute, (2000), p. 391.

$PHT = DT * 0.29$ (time required for the pressure gradient to fall half its maximum level)

where:

DT = deceleration time

Proximal Isovelocity Surface Area (PISA) in cm²

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Philadelphia: Lippincott, Williams, and Wilkins, (2007), p.74-76.

$$\text{PISA} = 2 \pi r^2$$

where:

r = aliasing radius

Qp/Qs

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Philadelphia: Lippincott, Williams, and Wilkins, (2007), p.70-72.

$$\text{Qp/Qs} = \text{SV Qp site} / \text{SV Qs site} = \text{RVOT SV} / \text{LVOT SV}$$

where:

$$\text{RVOT SV} = \text{RVOT CSA} * \text{RVOT VTI} = \pi/4 * \text{RVOT diameter}^2 * \text{RVOT VTI}$$

$$\text{LVOT SV} = \text{LVOT CSA} * \text{LVOT VTI} = \pi/4 * \text{LVOT diameter}^2 * \text{LVOT VTI}$$

Regurgitant Fraction (RF) in percent

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Philadelphia: Lippincott, Williams, and Wilkins, (2007), p.215-217.

$$\text{RF} = \text{RV} / \text{MV SV}$$

where:

RV = Regurgitant Volume

MV SV = Mitral Stroke Volume (Mitral CSA * Mitral VTI)

Mitral CSA = cross-sectional area calculated using annulus diameter

Regurgitant Volume (RV) in cc

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Lippincott, Williams, and Wilkins, (2007), p.215-217.

$$\text{RV} = \text{ERO} * \text{MR VTI} / 100$$

Right Atrial Area

Rudski L, Lai W, et al. "Guidelines for the echocardiographic assessment of the right heart in adults: a report from the American Society of Echocardiography." *J Am Soc Echocardiography*. (2010), p.685-713.

Right Atrial Volume

Lang, R., M. Bierig, R. Devereux, et al. "Recommendations for chamber quantification: a report from the American Society of Echocardiography's guidelines and standards committee and the chamber quantification writing group, Developed in conjunction with the European Association of

Echocardiography, a branch of the European Society of Cardiology." *J Am Soc Echocardiography*. (2005) 18: p.1440-1463.

$RA\ Vol = \pi/4 * \sum(ai) * ai * L/20$ for $i = 1$ to 20 (number of segments)

where:

RA Vol = Right Atrial Volume in ml

a_i = diameter of chamber view slice i

L = length of the chamber view

Right Atrial Volume Index

Wang, Y., J. Gutman, et al. "Atrial volume in a normal adult population by two-dimensional echocardiography." *Chest*. (1984), 86: p.595-601.

RA Vol Index = RA Vol/BSA (ml/L²)

Right Ventricular Systolic Pressure (RVSP) in mmHg

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Philadelphia: Lippincott, Williams, and Wilkins, (2007), p.66.

$RVSP = 4 * (V_{Max\ TR})^2 + RAP$

where:

RAP = Right Atrial Pressure

S/D

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), p.217.

S velocity/D velocity

where:

S velocity = Pulmonary vein S wave

D velocity = Pulmonary vein D wave

Stroke Index (SI) in cc/m²

Mosby's Medical, Nursing, & Allied Health Dictionary, 4th ed., (1994), p.1492.

SI = SV/BSA

where:

SV = Stroke Volume

BSA = Body Surface Area

Stroke Volume (SV) Doppler in ml

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Philadelphia: Lippincott, Williams, and Wilkins, (2007), p.69-71.

SV = (CSA * VTI)

where:

CSA = Cross Sectional Area of the orifice (LVOT area)

VTI = Velocity Time Integral of the orifice (LVOT VTI)

Stroke Volume (SV) 2D and M Mode in ml

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 2nd ed., Boston: Little, Brown and Company, (1994), p.44.

$SV = (LVEDV - LVESV)$

where:

SV = Stroke Volume

LVEDV = End Diastolic Volume

LVESV = End Systolic Volume

TAPSE

Rudski, L., W. Lai, et al. "Guidelines for the echocardiographic assessment of the right heart in adults: a report from the American Society of Echocardiography." *J Am Soc Echocardiography*. (2010), p.685-713.

M Mode distance measurement of systolic excursion of the right ventricle

Tricuspid Valve Area (TVA)

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Philadelphia: Lippincott, Williams, and Wilkins, (2007), p.73-74.

$TVA = 220 / PHT$

Velocity Time Integral (VTI) in cm

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), p.383.

$VTI = \text{sum of abs (velocities [n])}$

where:

Auto Trace – distance (cm) blood travels with each ejection period. Velocities are absolute values.

Obstetrical references

Amniotic Fluid Index (AFI)

Jeng, C. J. et al. "Amniotic Fluid Index Measurement with the Four Quadrant Technique During Pregnancy." *The Journal of Reproductive Medicine*, 35:7 (July 1990), p.674-677.

Average Ultrasound Age (AUA)

The system provides an AUA derived from the component measurements from the measurement tables.

Estimated Date of Delivery (EDD) by Average Ultrasound Age (AUA)

Results are displayed as month/day/year.

$EDD = \text{system date} + (280 \text{ days} - \text{AUA in days})$

Estimated Date of Delivery (EDD) by Last Menstrual Period (LMP)

The date entered into the patient information for LMP must precede the current date.

Results are displayed as month/day/year.

EDD = LMP date + 280 days

Estimated Fetal Weight (EFW)

Hadlock, F. et al. "Estimation of Fetal Weight with the Use of Head, Body, and Femur Measurements, A Prospective Study." *American Journal of Obstetrics and Gynecology*, 151:3 (February 1, 1985), p.333-337.

Hansmann, M. et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), p.154.

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), p.103-105.

Hansmann, M. et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), p.154.

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), p.103-105.

Shepard M.J., V. A. Richards, R. L. Berkowitz, et al. "An Evaluation of Two Equations for Predicting Fetal Weight by Ultrasound." *American Journal of Obstetrics and Gynecology*, 142:1 (January 1, 1982), p.47-54.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." *Japanese Journal of Medical Ultrasonics*, 23:12 (1996), p. 880, Equation 1.

Gestational Age (GA) by Last Menstrual Period (LMP)

The gestational age derived from the LMP date entered on the patient form.

Results are displayed in weeks and days, and is calculated as follows:

GA(LMP) = System date – LMP date

Gestational Age (GA) by Last Menstrual Period (LMPd) Derived from Established Due Date (EDD)

Same as GA by EDD.

The gestational age derived from the system derived LMP using the Established Due Date entered on the patient form.

Results are displayed in weeks and days, and is calculated as follows:

GA(LMPd) = System Date – LMPd

Last Menstrual Period Derived (LMPd) by Established Due Date (EDD)

Results are displayed as month/day/year.

LMPd(Estab. DD) = Estab. DD – 280 days

Gestational age tables

Abdominal Circumference (AC)

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), p.497-501.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), p.431.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." *Japanese Journal of Medical Ultrasonics*, 23:12 (1996), p.885.

WARNING

The gestational age calculated by your FUJIFILM SonoSite system does not match the age in the aforementioned reference at the 20.0 cm and 30.0 cm abdominal circumference (AC) measurements. The implemented algorithm extrapolates the gestational age from the slope of the curve of all table measurements, rather than decreasing the gestational age for a larger AC measurement indicated in the referenced table. This results in the gestational age always increasing with an increase in AC.

Biparietal Diameter (BPD)

Chitty, L. S. and D.G. Altman. "New charts for ultrasound dating of pregnancy." *Ultrasound in Obstetrics and Gynecology* 10: (1997), p.174-179, Table 3.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), p.497-501.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), p.440.

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), p.98.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." *Japanese Journal of Medical Ultrasonics*, 23:12 (1996), p.885.

Crown Rump Length (CRL)

Hadlock, F., et al. "Fetal Crown-Rump Length: Re-evaluation of Relation to Menstrual Age (5-18 weeks) with High-Resolution, Real-Time Ultrasound." *Radiology*, 182: (February 1992), p.501-505.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), p.439.

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), p.20 and p.96.

Tokyo University. "Gestational Weeks and Computation Methods." *Ultrasound Imaging Diagnostics*, 12:1 (1982-1), p.24-25, Table 3.

Femur Length (FL)

Chitty, L. S. and D.G. Altman. "New charts for ultrasound dating of pregnancy." *Ultrasound in Obstetrics and Gynecology* 10: (1997), p.174-179, Table 8, 186.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), p.497-501.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), p.31.

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), p.01-102.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." *Japanese Journal of Medical Ultrasonics*, 23:12 (1996), p.886.

Fetal Trunk Cross-Sectional Area (FTA)

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), p.99-100.

Gestational Sac (GS)

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986).

Nyberg, D.A., et al. "Transvaginal Ultrasound." *Mosby Yearbook*, (1992), p.76.

Gestational sac measurements provide a fetal age based on the mean of one, two, or three distance measurements; however, Nyberg's gestational age equation requires all three distance measurements for an accurate estimate.

Tokyo University. "Gestational Weeks and Computation Methods." *Ultrasound Imaging Diagnostics*, 12:1 (1982-1).

Head Circumference (HC)

Chitty, L. S. and D.G. Altman. "New charts for ultrasound dating of pregnancy." *Ultrasound in Obstetrics and Gynecology* 10: (1997), 174-191, Table 5, p.182.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), p.497-501.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), p.431.

Humerus (HL)

Jeanty, P.; F. Rodesch; D. Delbeke; J. E. Dumont. "Estimate of Gestational Age from Measurements of Fetal Long Bones." *Journal of Ultrasound in Medicine*. 3: (February 1984), p.75-79

Occipito-Frontal Diameter (OFD)

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), p.431.

Tibia

Jeanty, P.; F. Rodesch; D. Delbeke; J. E. Dumont. "Estimate of Gestational Age from Measurements of Fetal Long Bones." *Journal of Ultrasound in Medicine*. 3: (February 1984), p.75-79.

Transverse Trunk Diameter (TTD)

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), p.431.

Growth analysis tables

Abdominal Circumference (AC)

Chitty, Lyn S. et al. "Charts of Fetal Size: 3. Abdominal Measurements." *British Journal of Obstetrics and Gynaecology*, 101: (February 1994), p.131, Appendix: AC-Derived.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), p.497-501.

Jeanty P, E. Coussaert, and F. Cantraine. "Normal Growth of the Abdominal Perimeter." *American Journal of Perinatology*, 1: (January 1984), p.129-135.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. *Ultrasound Diagnosis in Obstetrics and Gynecology*. Springer-Verlag, New York, (1986), p.179, Table 7.13.)

Biparietal Diameter (BPD)

Chitty, Lyn S. et al. "Charts of Fetal Size: 2. Head Measurements." *British Journal of Obstetrics and Gynaecology*, 101: (January 1994), p.43, Appendix: BPD-Outer-Inner.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), p.497-501.

Jeanty P, E. Coussaert, and F. Cantraine. "A Longitudinal Study of Fetal Limb Growth." *American Journal of Perinatology*, 1: (January 1984), p.136-144, Table 5.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. *Ultrasound Diagnosis in Obstetrics and Gynecology*. Springer-Verlag, New York, (1986), p.176, Table 7.8.

Estimated Fetal Weight (EFW)

Brenner, William E.; D. A. Edelman; C. H. Hendricks. "A standard of fetal growth for the United States of America," *American Journal of Obstetrics and Gynecology*, 126: 5 (November 1, 1976), p.555-564; Table II.

Hadlock F., et al. "In Utero Analysis of Fetal Growth: A Sonographic Weight Standard." *Radiology*, 181: (1991), p.129-133.

Jeanty, Philippe, F. Cantraine, R. Romero, E. Coussaert, and J. Hobbins. "A Longitudinal Study of Fetal Weight Growth." *Journal of Ultrasound in Medicine*, 3: (July 1984), p.321-328, Table 1.

(Also published in Hansmann, Hackeloer, Staudach, and Wittman. *Ultrasound Diagnosis in Obstetrics and Gynecology*. Springer-Verlag, New York, (1986), p.186, Table 7.20.)

Femur Length (FL)

Chitty, Lyn S. et al. "Charts of Fetal Size: 4. Femur Length." *British Journal of Obstetrics and Gynaecology*, 101: (February 1994), p.135.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), p.497-501.

Jeanty P, E. Coussaert, and F. Cantraine. "A Longitudinal Study of Fetal Limb Growth." *American Journal of Perinatology*, 1: (January 1984), p.136-144, Table 5.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. *Ultrasound Diagnosis in Obstetrics and Gynecology*. Springer-Verlag, New York, (1986), p.182, Table 7.17.)

Head Circumference (HC)

Chitty, Lyn S., et al. "Charts of Fetal Size: 2. Head Measurements." *British Journal of Obstetrics and Gynaecology*, 101: (January 1994), p.43, Appendix: HC-Derived.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), p.497-501.

Jeanty P, E. Cousaert, and F. Cantraine. "A longitudinal study of Fetal Head Biometry." *American J of Perinatology*, 1: (January 1984), p.118-128, Table 3.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. *Ultrasound Diagnosis in Obstetrics and Gynecology*. Springer-Verlag, New York, (1986), p.176, Table 7.8.)

Head Circumference (HC)/Abdominal Circumference (AC)

Campbell S., Thoms Alison. "Ultrasound Measurements of the Fetal Head to Abdomen Circumference Ratio in the Assessment of Growth Retardation," *British Journal of Obstetrics and Gynaecology*, 84: (March 1977), p.165-174.

Ratio calculations

FL/AC Ratio

Hadlock F.P., R. L. Deter, R. B. Harrist, E. Roecker, and S.K. Park. "A Date Independent Predictor of Intrauterine Growth Retardation: Femur Length/Abdominal Circumference Ratio," *American Journal of Roentgenology*, 141: (November 1983), p.979-984.

FL/BPD Ratio

Hohler, C.W., and T.A. Quetel. "Comparison of Ultrasound Femur Length and Biparietal Diameter in Late Pregnancy," *American Journal of Obstetrics and Gynecology*, 141:7 (Dec. 1 1981), p.759-762.

FL/HC Ratio

Hadlock F.P., R. B. Harrist, Y. Shah, and S. K. Park. "The Femur Length/Head Circumference Relation in Obstetric Sonography." *Journal of Ultrasound in Medicine*, 3: (October 1984), p.439-442.

HC/AC Ratio

Campbell S., Thoms Alison. "Ultrasound Measurements of the Fetal Head to Abdomen Circumference Ratio in the Assessment of Growth Retardation," *British Journal of Obstetrics and Gynaecology*, 84: (March 1977), p.165-174.

General references

+/x or S/D Ratio

$+/x = (\text{Velocity A}/\text{Velocity B})$

where:

A = velocity cursor +

B = velocity cursor x

Acceleration Index (ACC)

Zwiebel, W.J. *Introduction to Vascular Ultrasonography*, 4th ed., W.B. Saunders Company, (2000), p.52.

ACC = abs (delta velocity/delta time)

Elapsed Time (ET)

ET = time between velocity cursors in milliseconds

Hip Angle/d:D Ratio

Morin, C., Harcke, H., MacEwen, G. "The Infant Hip: Real-Time US Assessment of Acetabular Development." *Radiology* 177: p.673-677, December 1985.

Percent Area Reduction

Zwiebel W.J., J.A. Zagzebski, A.B. Crummy, et al. "Correlation of peak Doppler frequency with lumen narrowing in carotid stenosis." *Stroke*, 3: (1982), p.386-391.

% Area Reduction = $[1 - A2(\text{cm}^2)/A1(\text{cm}^2)] * 100$

where:

A1 = original area of the vessel in square cm

A2 = reduced area of the vessel in square cm

Percent Diameter Reduction

Handa, Nobuo et al., "Echo-Doppler Velocimeter in the Diagnosis of Hypertensive Patients: The Renal Artery Doppler Technique," *Ultrasound in Medicine and Biology*, 12:12 (1986), p.945-952.

% Diameter Reduction = $[1 - D2(\text{cm})/D1(\text{cm})] * 100$

where:

D1 = original diameter of the vessel in cm

D2 = reduced diameter of the vessel in cm

Pressure Gradient (PGr) in mmHG

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd ed., Philadelphia: Lippincott, Williams, and Wilkins, (2007), p.63-66.

$PGr = 4 * (\text{Velocity})^2$

Peak E Pressure Gradient (E PG)

$E PG = 4 * PE^2$

Peak A Pressure Gradient (A PG)

$A PG = 4 * PA^2$

Peak Pressure Gradient (PGmax)

$PGmax = 4 * VMax^2$

Mean Pressure Gradient (PGmean)

PGmean = Average pressure gradient during the flow period

Baumgartner, H., Hung, J., Bermejo, J., et al. "Echocardiographic Assessment of Valve Stenosis: EAE/ASE Recommendations for Clinical Practice". *Journal of American Society of Echocardiography*. January 2009, p. 4-5.

$$PG \text{ mean} = \sum(4v^2)/N$$

where:

v = peak velocity at interval n

N = the number of intervals in the Riemann sum

Pulsatility Index (PI)

Zwiebel, W. J. *Introduction to Vascular Ultrasonography*, 4th Edition, W.B. Saunders Company, (2000).

$$PI = (PSV - MDV)/V \text{ (no units)}$$

where:

PSV = peak systolic velocity

EDV = minimum diastolic velocity

V = TAP (Time Averaged Peak) flow velocity throughout the cardiac cycle

Resistive Index (RI)

Kurtz, A.B., W.D. Middleton. *Ultrasound-the Requisites*. Mosby Year Book, Inc., (1996), p.467.

$$RI = ((\text{Velocity A} - \text{Velocity B})/\text{Velocity A}) \text{ in measurements}$$

where:

A = velocity cursor +

B = velocity cursor x

Time Averaged Mean (TAM) in cm/s

$$TAM = \text{mean (mean Trace)}$$

Time Averaged Peak (TAP) in cm/s

$$TAP = \text{mean (peak Trace)}$$

Volume (Vol)

Beyer, W.H. *Standard Mathematical Tables*, 28th ed., CRC Press, Boca Raton, FL, (1987), p.131.

Volume Flow (VF) in ml/m

Robert J. Daigle, BA, RVT: *Techniques in Noninvasive Vascular Diagnosis; Second Edition*, (2002) p. 210. One of the following, depending on the Live Trace setting:

$$VF = CSA * TAM * 60$$

$$VF = CSA * TAP * 60$$

$$VF = CSA * TAV * 60 \text{ (When manual trace is used)}$$

CHAPTER 7

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. Refer to [“Getting help”](#) on page 1-2.

System does not turn on

- 1 Check all power connections.
- 2 Remove the DC input connector and battery, wait 10 seconds, and then reinstall them.
- 3 Ensure that the battery is charged.

System image quality is poor

- 1 Adjust the display to improve the viewing angle.
- 2 Adjust the brightness.
- 3 Adjust the gain.

No CPD image

- ❖ Adjust the gain.

No Color image

- ❖ Adjust the gain or the scale.

No OB measurement selections

- ❖ Select the OB exam type.

Print does not work

- 1 Select the printer on the Connectivity setup page. Refer to [“To configure the system for a printer”](#) on page 3-9.
- 2 Check the printer connections.

- 3 Ensure that the printer is turned on and set up properly. Refer to the printer manufacturer's instructions, if necessary.

System does not recognize the transducer

- ❖ Disconnect and reconnect the transducer.

System prompts you to "ensure the USB device is valid."

- ▶ Make sure that the USB storage device does not have password protection enabled and is not defective.
- ▶ Use the USB storage device included with the system.

System prompts you to "ensure the USB device contains valid data."

- 1 Make sure that the data are present on the USB storage device.
- 2 Reexport the original data onto the USB storage device.
- 3 Contact your system administrator.

System displays the alert "Incompatible power supply"

- ❖ Use the power supply that shipped with the system.

System displays the alert "The external video is not functional"

- ❖ Make sure that the system is securely attached to the dock.

System displays the alert "Maximum number of procedure entries reached" when trying to create a patient information form.

- ❖ Free up internal storage space by archiving or exporting patient exams and then deleting them from the system.

System displays the alert "Unable to save image or clip. You have reached the maximum number of images/clips allowed for a single patient."

- ❖ Delete any unwanted images or clips from the patient exam.

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 or transducer 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 a valid license key is entered.

To obtain a license key for your software, contact FUJIFILM SonoSite Technical Support. Refer to “[Getting help](#)” on page 1-2.

You need to provide the following information. Refer to “[System Information setup](#)” on page 3-15.

Table 7-1: License key required information

System Software	Transducer Software
Name of institution installing the upgrade	Name of institution installing the upgrade
Serial number (on bottom of system)	Serial number (on bottom of system)
ARM version	Transducer package version
PCBA serial number	PCBA serial number

After you obtain a license key, you must enter it into the system.

To enter a license key

- 1 Turn on the system. The license update screen appears.
- 2 Enter the license key in the **Enter license number** field.
- 3 Select **Done** on-screen.

Note

If you entered a valid license key but the license update screen appears, verify that you entered the license key correctly. If the license update screen still appears, contact FUJIFILM SonoSite Technical Support. Refer to “[Getting help](#)” on page 1-2.

- 4 If you upgraded a transducer package, the transducer package license update screen appears. Enter the transducer package license key, and then select **Done**.

Maintenance

WARNINGS

- ▶ No modification of this equipment, except as described in this manual or the *SonoSite Edge II Service Manual*, is allowed.
- ▶ 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. There are no internal components that require periodic testing or calibration. All maintenance requirements are described in this chapter and in the ultrasound system service manual.

Note

Performing maintenance procedures not described in the user guide or service manual may void the product warranty.

Contact FUJIFILM SonoSite Technical Support for any maintenance questions. Refer to **“Getting help”** on page 1-2.

Cleaning and disinfecting

Use the recommendations in **Chapter 8, “Cleaning and Disinfecting,”** when cleaning or disinfecting your ultrasound system, transducer, and accessories. Use the cleaning recommendations in the peripheral manufacturer’s instructions when cleaning or disinfecting your peripherals.

CHAPTER 8

Cleaning and Disinfecting

This chapter includes instructions for cleaning and disinfecting the ultrasound system, transducers, and accessories.

Use the FUJIFILM SonoSite recommendations when cleaning or disinfecting your ultrasound system, transducer, and accessories. Use the cleaning recommendations in the peripheral manufacturer's instructions when cleaning or disinfecting your peripherals.

See **Chapter 2, "Getting Started,"** for images of the ultrasound system.

See www.sonosite.com/products/transducers, for transducer images.

Notes

- ▶ The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.
- ▶ For cleaning the TEExi transducer, refer to the cleaning and disinfection instructions in the *TEExi User Guide*.
- ▶ FUJIFILM SonoSite defines ultrasound guided percutaneous procedures as non-critical use applications. Following percutaneous procedures, users should follow cleaning and disinfecting transducers for non-critical uses as outlined in the user guide for their device.^a

- a. "Disinfection of Ultrasound Transducers Used for Percutaneous Procedures. Intersocietal Position Statement." *American Institute of Ultrasound in Medicine | J Ultrasound Med.* February 16, 2021; 9999: p. 1-3.

Before getting started

- ▶ Follow the disinfectant manufacturer's recommendations regarding appropriate personal protective equipment (PPE), such as protective eyewear and gloves.
- ▶ Inspect the system and transducer to determine that they are free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.

- ▶ Confirm that cleaning and disinfecting materials are appropriate for your facility’s use. FUJIFILM SonoSite tests cleaners and disinfectants for use with the FUJIFILM SonoSite systems and transducers.
- ▶ Disinfectants and cleaning methods listed in this chapter are recommended by FUJIFILM SonoSite for efficacy and material compatibility with the products.
- ▶ Ensure that the disinfectant type and the solution strength and duration are appropriate for the equipment and application.
- ▶ Follow manufacturer recommendations and local regulations, when preparing, using and disposing of chemicals.

- WARNINGS**
- ▶ Ensure that cleaning and disinfecting solutions and wipes are not expired
 - ▶ Some cleaners and disinfectants can cause an allergic reaction in some individuals

- Caution**
- ▶ Do not allow cleaning solution or disinfectant into the system connectors, or transducer connector.
 - ▶ Do not use strong solvents such as thinner or benzene, or abrasive cleansers, since these will damage the exterior surfaces. Use only FUJIFILM SonoSite recommended cleaners or disinfectants.

Determining the required cleaning and disinfecting level

- WARNING** | The cleaning instructions contained in this chapter are based on requirements mandated by the American Food and Drug Administration (FDA). Failure to follow these instructions may result in cross contamination and patient infection.

The level of cleaning and disinfecting required for the system is dictated by the type of tissue it contacts during use. Use [Table 8-1](#) to determine the level of cleaning and disinfecting required.

Table 8-1: Choosing a cleaning and disinfecting method

Did any part of the system or transducer come in contact with broken skin or mucosal membranes?	
<p>YES</p> <p>Came in contact with broken skin or mucosal membranes.</p>	<p>→ Option A</p> <p>Go to “Clean and disinfect system and transducer to a high level (semi-critical uses)” on page 8-3.</p>
<p>OR</p>	

Table 8-1: Choosing a cleaning and disinfecting method

Did any part of the system or transducer come in contact with broken skin or mucosal membranes?	
NO	Did not come in contact with broken skin.
	→ Option B
	Go to “ Clean and disinfect system and transducer to a low level (non-critical uses) ” on page 8-8.

Spaulding classifications

Spaulding classifications (non-critical, semi-critical) determine the approach for cleaning and disinfecting medical equipment based on the device, the way it has been used, and the risk of infection. The system and transducers are designed for use within the Spaulding classifications of non-critical and semi-critical uses.

Option A Clean and disinfect system and transducer to a high level (semi-critical uses)

Use this procedure to clean and high-level disinfect the ultrasound system and transducer **whenever it has come into contact with broken skin or mucosal membranes.**

Follow the manufacturer's instructions when using cleaners and disinfectants. The cleaners and disinfectants listed in the procedure are both chemically compatible and have been tested for efficacy with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

- WARNINGS**
- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
 - ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not skip any steps or abbreviate the cleaning and disinfecting process in any way.
- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. This can damage the transducer and void the warranty.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non- recommended disinfecting solution or incorrect solution strength can damage the system and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.

Note

You must clean and disinfect both the ultrasound system and the transducer after each use, but only the transducer can be disinfecting to a high level.

To clean and disinfect the system and transducer

- 1 Turn off** the system by pressing the **Power button**.
- 2 Unplug** the power cord from the outlet.
- 3 Remove** the disposable transducer sheath, if applicable.
- 4 Disconnect** the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.
- 5 Clean** the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris. Use the following procedure:
 - Use either a pre-moistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from the list of approved cleaners.

Table 8-2: Approved cleaners/disinfectants for the ultrasound system

Cleaner/disinfectant	Minimum wet contact time ^a
SaniCloth AF3 ^b	3 minutes
SaniCloth Plus	3 minutes

^a For maximum effectiveness, the component being cleaned must remain wet with disinfectant for a minimum period of time.

^b Qualified for use as an intermediate-level disinfectant for mycobacteria.

Refer to the cleaners and disinfection tool available at www.sonosite.com/support/cleaners-disinfectants for a more complete list of approved cleaners and disinfectants. .

- b Remove** all gel and debris from the system.

- c With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.
 - d Observe the minimum wet contact time and refer to manufacturer’s instructions. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.
 - e Allow the ultrasound console to air dry in a clean, well-ventilated space.
- 6 Clean the ultrasound system **STAND** to remove any debris. For information about cleaning the stand, see the *Edge Stand and H-Universal Stand User Guide***
- 7 Clean the **TRANSDUCER CABLE AND BODY** to remove any debris. Use the following procedure:**
- a Use either a pre-moistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from the list of approved cleaners.

Table 8-3: Approved cleaners/disinfectants for the transducer

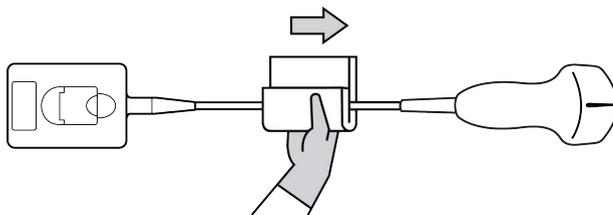
Product	Compatible Transducer	Minimum wet contact time ^a
Sani-Cloth AF3 ^b	C8x, C11x, C35x, HFL38xi, HFL50x, HSL25x, ICTx, L25x, L38xi, P10x, rC60xi, rP19x	3 minutes
Sani-Cloth Plus	HFL50x, L52x ^c	3 minutes

^a For maximum effectiveness, the component being cleaned must remain wet with disinfectant for a minimum period of time.

^b Qualified for use as an intermediate-level disinfectant for mycobacteria.

^c The L52x transducer is for veterinary use only. Refer to the cleaners and disinfection tool available at www.sonosite.com/support/cleaners-disinfectants for a more complete list of approved cleaners and disinfectants.

- b Remove all gel and debris from the transducer.
- c With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution | Do not allow moisture near the electronic components of the connector.

- d Observe the minimum wet contact time recommended by the manufacturer. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.

8 Verify that all gel and debris have been removed from the system and transducer. If necessary, repeat steps 5, 6, and 7 with a new wipe.

WARNING | Failure to remove all gel and debris could leave contaminants on the probe.

9 Examine the system, transducer and cable for damage, such as cracks or splitting where fluid can enter. If damage is evident, do not use. Instead, contact FUJIFILM SonoSite or your local representative.

10 Prepare the disinfectant for use.

- a Choose a high-level disinfectant from the list of approved disinfectants.

Table 8-4: High-level disinfectants compatible with SonoSite Edge II transducers

Disinfectant	Compatible transducers	Temperature	Disinfectant Soak Duration
Cidex	C8x, C11x, C35x, HFL38xi, HFL50x, HSL25x, ICTx, L25x, L38xi, P10x, rC60xi, rP19x	25°C, 77°F	45 minutes
Cidex OPA	C8x, C11x, HFL38xi, HFL50x, HSL25x, ICTx, L25x, L38xi, L52x ^b , P10x, rC60xi, rP19x	20°C, 68°F	12 minutes
Revital-OX Resert	C35x	20°C, 68°F	8 minutes

^b The L52x transducer is for veterinary use only. Refer to the cleaners and disinfection tool available at www.sonosite.com/support/cleaners-disinfectants for a more complete list of approved cleaners and disinfectants.

- b Check the expiration date on the bottle to ensure the disinfectant has not expired.
- c Mix or check that the disinfection chemicals have the concentration recommended by the manufacturer (for example, a chemical strip test).
- d Check that the temperature of the disinfectant is within the manufacturer’s recommended limits.

11 Perform a high-level disinfection of the transducer. Use the following procedure:

- a Immerse the transducer in a high-level disinfectant solution.

WARNING | High-level disinfectants can cause harm to the patient if not completely removed from the transducer. Follow the manufacturer’s rinse instructions to remove chemical residue.

Cautions

- ▶ Do not soak the transducer longer than recommended by the chemical manufacturer.
- ▶ Do not immerse the transducer connector in any disinfectant solution.
- ▶ Use only FUJIFILM SonoSite recommended cleaners and disinfectants. Using a non- recommended disinfecting solution or incorrect solution strength can damage or discolor the transducer and void the warranty.

- b** Ensure that the connector and most of the cable remain out of the fluid. You may submerge 2 inches (5 cm) of the cable proximal to the transducer scanhead.

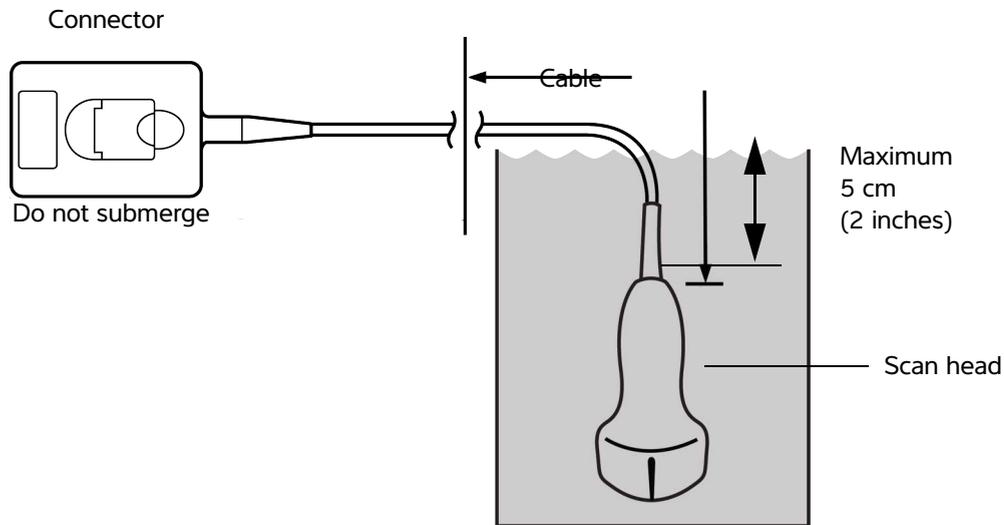


Figure 8-1 Transducer component names

- 12 Rinse** the transducer **three separate times** using the following procedure:

WARNING

High-level disinfectants can cause harm to the patient if not completely removed from the transducer. Follow the manufacturer's rinse instructions to remove chemical residue.

- Rinse the transducer in clean, running water according to the disinfectant manufacturer's instructions (at least one minute).
- Ensure that the connector and at least 12-18 inches (31-46 cm) of the cable from the connector remain dry.
- Repeat this step until the transducer has been rinsed three separate times.

- 13 Dry** the transducer with a sterile lint-free cloth.

- 14 Dispose** of the disinfectant according to the manufacturer's guidelines.

15 Examine the transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use of the transducer, and contact FUJIFILM SonoSite or your local representative.

Option **B** Clean and disinfect system and transducer to a low level (non-critical uses)

Use the following procedure to clean and disinfect the ultrasound system and transducer **if it has not come into contact with broken skin, or mucosal membranes.**

WARNING If the system or transducer has come into contact with any of the following, use the high-level cleaning and disinfection procedure. See “**Clean and disinfect system and transducer to a high level (semi-critical uses)**” on page 8-3:

- ▶ Broken skin
- ▶ Mucosal membranes

Follow the manufacturer's instructions when using cleaners and disinfectants. The cleaners and disinfectants listed in the procedure are both chemically compatible and have been tested for efficacy with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

WARNINGS

- ▶ To avoid electrical shock, before cleaning, disconnect the system from the power supply.
- ▶ Wear the appropriate personal protective equipment (PPE) recommended by the chemical manufacturer, such as eyewear and gloves.

Caution

- ▶ Do not spray cleaners or disinfectants directly on the system surfaces or on system and transducer connectors. Doing so may cause solution to leak into the system, damaging it and voiding the warranty.
- ▶ Use only FUJIFILM SonoSite-recommended cleaners and disinfectants. Using a non-recommended disinfecting solution or incorrect solution strength can damage the system and transducer and void the warranty. Follow the disinfectant manufacturer's recommendations for solutions strengths.
- ▶ Do not attempt to disinfect a transducer or transducer cable using a method or chemical that is not included here. Doing so can damage the transducer and void the warranty.

To clean and disinfect the system and transducer

- 1 Turn off** the system by pressing the **Power button**.
- 2 Unplug** the power cord from the outlet.

- 3 Remove** the transducer sheath, if applicable.
- 4 Disconnect** the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound system.
- 5 Clean** the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris. Use the following procedure:
 - a** Use either a pre-moistened wipe or a soft cloth dampened with cleaner and disinfectant. Choose a cleaner from the list of approved cleaners.

Table 8-5: Approved cleaners/disinfectants for the ultrasound system:

Cleaner/disinfectant	Minimum wet contact time ^a
SaniCloth AF3 ^b	3 minutes
SaniCloth Plus	3 minutes

^a For maximum effectiveness, the component being cleaned must remain wet with disinfectant for a minimum period of time.

^b Qualified for use as an intermediate-level disinfectant for mycobacteria.

Refer to the cleaners and disinfection tool available at www.sonosite.com/support/cleaners-disinfectants for a more complete list of approved cleaners and disinfectants.

- b** Remove all gel and debris from the system.
 - c** With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.
 - d** Observe the minimum wet contact time and refer to manufacturer's instructions. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.
- 6 Clean** the ultrasound system **STAND** to remove any debris. For information about cleaning the stand, see the *Edge Stand and H-Universal Stand User Guide*.

7 Clean the TRANSDUCER CABLE AND BODY to remove any debris. Use the following procedure:

- a** Use either a pre-moistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from the list of approved cleaners.

Table 8-6: Approved cleaners/disinfectants for the transducer:

Product	Compatible Transducer	Minimum wet contact time ^a
Sani-Cloth AF3 ^b	C8x, C11x, C35x, HFL38xi, HFL50x, HSL25x, ICTx, L25x, L38xi, P10x, rC60xi, rP19x	3 minutes
Sani-Cloth Plus	HFL50x, L52x ^c	3 minutes

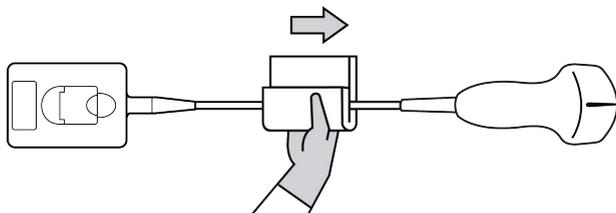
^a For maximum effectiveness, the component being cleaned must remain wet with disinfectant for a minimum period of time.

^b Qualified for use as an intermediate-level disinfectant for mycobacteria.

^c The L52x transducer is for veterinary use only.

Refer to the cleaners and disinfection tool available at www.sonosite.com/support/cleaners-disinfectants for a more complete list of approved cleaners and disinfectants.

- b** Remove all gel and debris from the transducer.
- c** With a new wipe, clean the cable and transducer, starting from the cable, wiping toward the scanhead. This method helps to avoid cross-contamination.



Caution | Do not allow moisture near the electronic components of the connector.

- d** Observe the minimum wet contact time recommended by the manufacturer. Monitor the transducer for wet appearance. Re-apply with a new wipe if no longer wet.
- 8 Verify** that all gel and debris have been removed from the system and transducer. If necessary, repeat steps 5, 6, and 7 with a new wipe.
- 9 Allow** the ultrasound system, including the console and transducer, to air dry in a clean, well-ventilated space.
- 10 Examine** the system, transducer and cable for damage, such as cracks or splitting where fluid can enter. If damage is evident, do not use. Instead, contact FUJIFILM SonoSite or your local representative.

Storing the transducer

To store the transducer

- 1 Make sure the transducer has been cleaned and disinfected as detailed in the previous section.
- 2 Store the transducer so that it hangs freely and vertically, and observe the following precautions:
 - ▶ Store the transducer away from any contaminated transducers.
 - ▶ Store the transducer in an environment that is safe and has good airflow. Do not store the transducer in closed containers or where condensation may occur.
 - ▶ Avoid direct sunlight and exposure to x-rays. Recommended storage temperature range is between 0° C (32° F) and +45° C (113° F).
 - ▶ If using a wall-mounted rack for storage, ensure that:
 - ▶ It is securely mounted.
 - ▶ The storage slots do not mar the transducer or cause damage to the cable.
 - ▶ The rack is sized and positioned to prevent the transducer from inadvertently falling.
 - ▶ Make sure the connector is supported and secure.

Transporting the transducer

When transporting the transducer, you must take precautions to protect the transducer from damage and avoid cross-contamination. Be sure to use a container approved by your organization.

To transport a soiled transducer for cleaning

A soiled transducer is one that has been contaminated and must be cleaned before using it in an exam.

- 1 Place the transducer in a clean, approved container.

WARNING

To prevent cross-contamination or unprotected exposure of personnel to biological material, containers used to transport contaminated transducers should carry an ISO biohazard label similar to the following:



Caution

Ensure the transducer is dry before placing it in a closed container. Condensation from a damp transducer can damage the connector.

- 2 Transport the transducer in the container to the point of processing. Do not open the container until the transducer is ready to be cleaned.

Caution | Do not leave the transducer in a sealed container for long periods of time.

To transport a clean transducer

A clean transducer is one that has completed the cleaning and disinfection process, has been stored properly, and is ready to be used in an examination.

- 1 Place the transducer in a clean, approved container. To identify the transducer as clean, containers used to transport clean transducers should carry a cleanliness verification sticker or certificate.
- 2 Transport the transducer in the container to the point of use. Do not open the container until the transducer is ready to be used.

To ship a transducer

WARNING | Whenever possible, avoid shipping a contaminated transducer. Before shipping, ensure the transducer has been cleaned and disinfected using the steps detailed in this chapter or according to special instructions received from FUJIFILM SonoSite. If you are returning the transducer to FUJIFILM SonoSite, document the disinfection on a "Declaration of Cleanliness," and attach it to the packing list.

- 1 Place the transducer in the shipping container and seal it. Do not allow any part of the transducer to protrude from the container.
- 2 Ship the transducer using the following precautions:
 - ▶ Clearly label the container as fragile.
 - ▶ Do not stack items on top of the shipping container.
 - ▶ Do not exceed the shipping temperature range: -35° C (-31° F) to +65° C (149° F).
 - ▶ Do not open the shipping container until it reaches its final destination.
 - ▶ After arrival, the transducer must be cleaned and disinfected before it can be used in an exam.

Cleaning the stand

For information about cleaning the stand, see the *Edge Stand and H-Universal Stand User Guide*.

Cleaning accessories

Clean accessories prior to disinfecting. You can disinfect the exterior surface of accessories using a recommended disinfectant. Refer to the cleaners and disinfection tool available at www.sonosite.com/support/cleaners-disinfectants.

To clean and disinfect accessories

- 1** If necessary, unplug the power supply, and detach any cables.
- 2** Clean the exterior surfaces of the accessory using a soft cloth lightly dampened in a mild soap or detergent cleaning solution to remove any particulate matter or body fluids.
Apply the solution to the cloth rather than the surface.
- 3** Mix the disinfectant solution compatible with the accessory, following disinfectant label instructions for solution strengths and disinfectant contact duration.
- 4** Wipe surfaces with the disinfectant solution. Follow the manufacturer's instructions for the disinfecting solution, including exposure time and temperature for effective disinfection.
- 5** Air dry or towel dry with a clean cloth.

Cleaning and disinfecting the ECG cable and slave cable

Caution | To avoid damaging the ECG cable, do not sterilize.

To clean and disinfect the ECG cables (wipe method)

- 1** Remove the cable from the system.
- 2** Examine the ECG cable for damage such as cracks or splitting.
- 3** Clean the surface using a soft cloth lightly dampened in a mild soap, cleaning solution, or pre-moistened wipe. Apply the solution to the cloth rather than the surface.
- 4** Wipe the surfaces with a FUJIFILM SonoSite Approved cleaner or disinfectant.
- 5** Air dry or dry with a clean cloth.

For more information on the ECG slave cable, refer to the *ECG Slave Cable User Guide*.

CHAPTER 9

Safety

This chapter contains information required by regulatory agencies, including electrical and clinical safety warnings, electromagnetic compatibility, and labeling. The information applies to the ultrasound system, transducer, accessories, and peripherals.

Ergonomic safety

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

WARNINGS

- ▶ To prevent musculoskeletal disorders, follow the guidelines in this section.
- ▶ Use of an ultrasound system may be linked to musculoskeletal disorders^{a,b,c}.
- ▶ Use of an ultrasound system is defined as the physical interaction among 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, promptly refer to a qualified health professional. Such symptoms can be linked with musculoskeletal disorders (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.

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 Health 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*. (May 1997), 357-362.

WARNING

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^a. This section provides guidelines that may help you work more comfortably and may reduce your risk of MSDs^{b,c}.

- a. 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.
- b. Habes, D.J. and S. Baron. "Health Hazard Report 99-0093-2749." *University of Medicine and Dentistry of New Jersey*. (1999).
- c. 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

Promote comfortable shoulder, arm, and hand postures

Use a stand to support the weight of the ultrasound system.

Minimize eye and neck strain

- ▶ If possible, position the system within reach.
- ▶ Adjust the angle of the system and display to minimize glare.
- ▶ If using a stand, adjust its height so that the display 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 for quick height adjustments.
- ▶ 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 ultrasound system 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.
- ▶ 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

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

The system complies with the standards as listed in the Standards section of this document. Refer to “Standards” on page 9-34

For maximum safety observe the following warnings and cautions.

WARNINGS

- ▶ To avoid discomfort or minor risk of patient injury, keep hot surfaces away from the patient.
- ▶ Under certain circumstances, parts of the enclosure can reach temperatures that exceed EN60601-1 limits for patient contact, therefore only the operator shall handle the system. This does not include the transducer face.
- ▶ To avoid the risk of injury, do not operate the system in the presence of flammable gases or anesthetics. Explosion can result.
- ▶ To avoid the risk of electrical shock or injury, do not open the system enclosures. All internal adjustments and replacements, except battery replacement, must be made by a qualified technician.

WARNING

- ▶ To avoid the risk of electrical shock:
 - ▶ Connect this equipment to a supply main with protective earth.
 - ▶ Use only properly grounded equipment. Shock hazards exist if the power supply is not properly grounded. Grounding reliability can be achieved only when equipment is connected to a receptacle marked "Hospital Only" or "Hospital Grade" or the equivalent. Do not remove or defeat the grounding wire.
 - ▶ When using the system in an environment where the integrity of the protective earth conductor arrangement is in doubt, operate the system on battery power only without using the power supply.
 - ▶ Do not allow any part of the system (including the bar code scanner, external mouse, power supply, power supply connector, external keyboard, and so on), except for the transducer or ECG leads, to touch the patient.
 - ▶ Do not touch the power supply and the patient at the same time. Do not touch any of the following: The ungrounded signal input/output connectors on the back of the ultrasound system.
 - ▶ The system battery contacts (inside the battery compartment).
 - ▶ The system transducer connector when the transducer or Triple Transducer Connect (TTC) is disconnected.
 - ▶ Any unused TTC transducer connector when the TTC is connected.

WARNINGS

- ▶ Do not connect the system's power supply or a docking system to a multiple portable socket outlet (MPSO) or extension cord.
- ▶ Before using the transducer, inspect the transducer face, housing, and cable. Do not use the transducer if the transducer or cable is damaged.
- ▶ Always disconnect the power supply from the system before cleaning the system.
- ▶ Do not use any transducer that has been immersed beyond the specified cleaning or disinfection level. Refer to [Chapter 8, "Cleaning and Disinfecting."](#)
- ▶ Use only accessories and peripherals recommended by FUJIFILM SonoSite, including the power supply. Connection of accessories and peripherals not recommended by FUJIFILM SonoSite could result in electrical shock. Contact FUJIFILM SonoSite or your local representative for a list of accessories and peripherals available from or recommended by FUJIFILM SonoSite.
- ▶ To avoid the risk of electrical shock and fire hazard:
 - ▶ Inspect the power supply, AC power cords, cables, and plugs on a regular basis. Ensure that they are not damaged.
 - ▶ The power cord set that connects the power supply of the ultrasound system or the stand to mains power must only be used with the power supply or docking system, and cannot be used to connect other devices to mains power.
- ▶ To prevent injury to the operator/bystander, the transducer must be removed from patient contact before the application of a high-voltage defibrillation pulse.
- ▶ 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 relevant installation requirements and safety standards.
- ▶ To avoid applying unsafe voltage levels to the patient while a device is connected to the external VGA or digital video out port, do not touch the ultrasound system and the patient simultaneously. Check the electrical safety of your system with a trained biomedical engineer.

Cautions

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

Electrical safety classification

Class I equipment

The ultrasound system is classified as Class I equipment when powered from the external power supply or mounted on the stand because the external power supply is a Class 1 protectively earthed power supply.

The stand has no protective earth. Ground bond testing is not applicable to the ultrasound system or the stand.

AC powered peripherals that may be used with the system are Class I and are individually protectively earthed. Ground bond testing may be conducted on each AC powered peripheral.

Internally powered equipment

Ultrasound system not connected to the power supply (battery only)

Type BF applied parts

Ultrasound transducers

Type CF applied parts

ECG module/ECG leads

IPX-7 (watertight equipment)

Ultrasound transducers

IPX-8 (watertight equipment)

Footswitch

Non AP/APG

Ultrasound system power supply, docking system, and peripherals. Equipment is not suitable for use in the presence of flammable anesthetics.

Equipment safety

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

Cautions

- ▶ Excessive bending or twisting of cables can cause a failure or intermittent operation.
- ▶ Improper cleaning or disinfecting of any part of the system can cause permanent damage. For cleaning and disinfecting instructions, refer to **Chapter 8, “Cleaning and Disinfecting.”**
- ▶ Do not submerge the transducer connector in solution. The cable is not liquid-tight beyond the transducer connector/cable interface.
- ▶ Do not use solvents such as thinner or benzene, or abrasive cleaners on any part of the system.
- ▶ Remove the battery from the system if the system is not likely to be used for some time.
- ▶ Do not spill liquid on the system.

Battery safety

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

WARNINGS

- ▶ The battery has a safety device. Do not disassemble or alter the battery.
- ▶ Charge the batteries only when the ambient temperature is between 0° and 40°C (32° and 104°F).
- ▶ Do not short-circuit the battery by directly connecting the positive and negative terminals with metal objects.
- ▶ Do not touch battery contacts.
- ▶ Do not heat the battery or discard it in a fire.
- ▶ Do not expose the battery to temperatures over 60°C (140°F). Keep it away from fire and other heat sources.
- ▶ Do not charge the battery near a heat source, such as a fire or heater.
- ▶ Do not leave the battery in direct sunlight.
- ▶ Do not pierce the battery with a sharp object, hit it, or step on it.
- ▶ Do not use a damaged battery.
- ▶ Do not solder a battery.
- ▶ The polarity of the battery terminals are fixed and cannot be switched or reversed. Do not force the battery into the system.
- ▶ Do not connect the battery to an electrical power outlet.
- ▶ Do not continue recharging the battery if it does not recharge after two successive six hour charging cycles.
- ▶ Do not ship a damaged battery without instructions from FUJIFILM SonoSite Technical Support. Refer to **“Getting help”** on page 1-2.
- ▶ If the battery leaks or emits an odor, remove it from all possible flammable sources.

Cautions

- ▶ Do not immerse the battery in water or allow it to get wet.
- ▶ Do not put the battery into a microwave oven or pressurized container.
- ▶ If the battery emits an odor or heat, is deformed or discolored, or in any way appears abnormal during use, recharging or storage, immediately remove it and stop using it. If you have any questions about the battery, consult FUJIFILM SonoSite or your local representative.
- ▶ Use only FUJIFILM SonoSite batteries.
- ▶ Periodically, check to make sure that the battery charges fully. If the battery fails to charge fully, replace it.
- ▶ Do not use or charge the battery with non-FUJIFILM SonoSite equipment. Only charge the battery with the system.

Clinical safety

WARNINGS

- ▶ Non-medical (commercial) grade peripheral monitors have not been verified or validated by FUJIFILM SonoSite as being suitable for diagnosis.
- ▶ FUJIFILM SonoSite does not recommend the use of high-frequency (HF) electromedical devices in proximity to its systems. FUJIFILM SonoSite equipment has not been validated for use with HF electrosurgical devices or procedures. Use of HF electrosurgical devices in proximity to its systems may lead to abnormal system behavior or shutdown of the system.
- ▶ To avoid the risk of a burn hazard, do not use the transducer with HF surgical equipment. Such a hazard may occur in the event of a defect in the HF surgical neutral electrode connection.
- ▶ The maximum temperature of the transducer scan head may be greater than 41 °C (105.8 °F), but is less than 43 °C (109.4 °F) when in contact with the patient. Special precautions should be considered when using the transducer on children or on other patients who are sensitive to higher temperatures.
- ▶ Do not use the system if it exhibits erratic or inconsistent behavior. Such behavior could indicate a hardware failure. Contact FUJIFILM SonoSite Technical Support.
- ▶ Some transducer sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals. Refer to 21 CFR 801.437, User labeling for devices that contain natural rubber.
- ▶ Perform ultrasound procedures prudently. Use the ALARA (as low as reasonably achievable) principle and follow the prudent use information concerning MI and TI.
- ▶ FUJIFILM SonoSite does not currently recommend a specific brand of acoustic standoff. If an acoustic standoff is used, it must have a minimum attenuation of .3dB/cm/MHz.
- ▶ 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 P10x or rP19x needle guide bracket on patients with pacemakers or medical electronic implants. The needle guide bracket for the P10x and rP19x transducers contains a magnet that is used to ensure the bracket is correctly oriented on the transducer. The magnetic field in direct proximity to the pacemaker or medical electronic implant may have an adverse effect.

Hazardous materials

WARNING

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

Electromagnetic compatibility

The ultrasound system has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2:2007 and IEC 60601-1-2:2014. The ultrasound system is suitable for use in the professional healthcare facility environment. Active HF surgical equipment causes high electromagnetic disturbances which may interfere with the ultrasound system operation. The ultrasound system should not be operated inside an RF-shielded room where magnetic resonance imagery is present, because it produces high electromagnetic disturbances which may interfere with the ultrasound system operation. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Note

The emissions characteristics of the SonoSite Edge II ultrasound system makes it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), the ultrasound system might not offer adequate protection to radio-frequency communication services. It may be necessary to take mitigation measures, such as relocating or reorienting the equipment.

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 9-16.

Cautions

- ▶ Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. Portable RF communications equipment (including peripherals, such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ultrasound system, including cables specified by FUJIFILM SonoSite. Portable and mobile RF communications equipment can affect the ultrasound system. Electromagnetic interference (EMI) from other equipment or interference sources could result in performance disruption of the ultrasound system. Evidence of disruption may include image degradation or distortion, erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site to determine the source of disruption, and take the following actions to eliminate the source(s).
 - ▶ Turn equipment in the vicinity off and on to isolate disruptive equipment.
 - ▶ Relocate or re-orient interfering equipment.
 - ▶ Increase distance between interfering equipment and your ultrasound system.
 - ▶ Manage use of frequencies close to ultrasound system frequencies.
 - ▶ Remove devices that are highly susceptible to EMI.
 - ▶ Lower power from internal sources within facility control (such as paging systems).
 - ▶ Label devices susceptible to EMI.
 - ▶ Educate clinical staff to recognize potential EMI-related problems.
 - ▶ Eliminate or reduce EMI with technical solutions (such as shielding).
 - ▶ Restrict use of personal communicators (cell phones, computers) in areas with devices susceptible to EMI.
 - ▶ Share relevant EMI information with others, particularly when evaluating new equipment purchases which may generate EMI.
 - ▶ Purchase medical devices that comply with IEC 60601-1-2 EMC Standards.
- ▶ 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 SonoSite Edge II ultrasound system implements two wireless solutions.

- ▶ Wireless USB Dongle (Panda) is a small wireless adapter that plugs into the USB port on the right side of the ultrasound system

- ▶ Wireless and Security Module (Laird) is a module that mounts on the lid of the ultrasound system and then plugs into the system with a right-angled USB cord

Refer to the information below for the transmission information for each one.

Wireless USB Dongle (Panda)

The Wireless USB Dongle uses the Industrial, Scientific, and Medical (ISM) frequency bands from 2.412 to 2.4835 GHz, depending on your country's regulation. The dongle implements the following methods of transmission:

- ▶ IEEE 802.11b with Direct Sequence Spread Spectrum (DSSS) at 19 dBm: Peak rate 54Mbps, Peak throughput: 27Mbps
- ▶ IEEE 802.11g with Orthogonal Frequency Division Multiplexing (OFDM) at 16 dBm: Peak rate 54Mbps, Peak throughput: 27Mbps
- ▶ IEEE 802.11n with Orthogonal Frequency Division Multiplexing (OFDM) at 15 dBm:
 - ▶ 1 T1 R. Peak rate: 150 Mbps, Peak throughput: 90 Mbps
 - ▶ 1 T2R. Peak rate: 300 Mbps, Peak throughput: Rx 160 Mbps
 - ▶ 2T2R. Peak rate: 300 Mbps, Peak throughput: Rx 260 Mbps

Wireless and Security Module (Laird)

The Wireless and Security Module uses the Industrial, Scientific, and Medical (ISM) frequency bands from 1.400 to 2.4835 GHz, and from 5.100 to 5.800 GHz. The module implements four different methods of transmission:

- ▶ IEEE 802.11a with Orthogonal Frequency Division Multiplexing (OFDM) at 11 dBm \pm 2 dBm @ 54 Mbps
- ▶ IEEE 802.11b with Direct Sequence Spread Spectrum (DSSS) at 16 dBm \pm 2.0 dBm @ 11 Mbps
- ▶ IEEE 802.11g with Orthogonal Frequency Division Multiplexing (OFDM) at 13 dBm \pm 2.0 dBm @ 54 Mbps
 - ▶ IEEE 802.11n with Orthogonal Frequency Division Multiplexing (OFDM) at 12 dBm \pm 2.0 dBm (802.11gn) @ MCS7

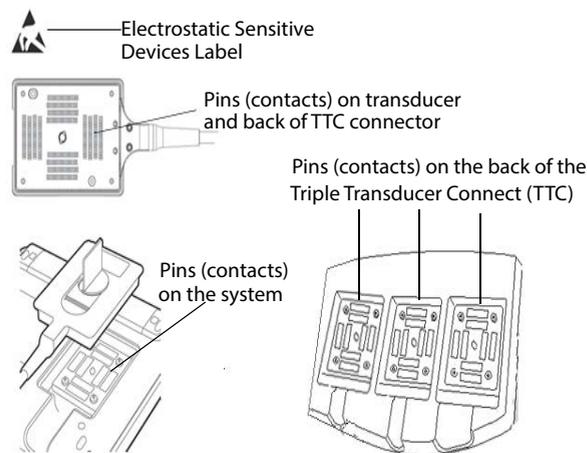
Electrostatic discharge

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 (such as the transducer connector):



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

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

Table 9-1: Recommended separation between portable and mobile RF communications equipment and the SonoSite Edge II ultrasound system

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.

Notes

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

Compatible accessories and peripherals

FUJIFILM SonoSite has tested the SonoSite Edge II Ultrasound System with the following accessories and peripherals and has demonstrated compliance to the requirements of IEC60601-1-2:2007 and IEC 60601-1-2:2014.

You may use these FUJIFILM SonoSite accessories and third-party peripherals with the SonoSite Edge II.

WARNINGS

- ▶ Use of the accessories with medical systems other than the SonoSite Edge II ultrasound system may result in increased emissions or decreased immunity of the medical system.
- ▶ Use of accessories other than those specified may result in increased emissions or decreased immunity of the ultrasound system.
- ▶ The ultrasound system should not be used in a domestic establishment or connected to the public mains network.
- ▶ If peripherals are connected to the system, ensure that the system and peripherals are connected to the same AC Mains branch circuit.

Table 9-2: Accessories and peripherals compatible with SonoSite Edge II ultrasound system

Description	Maximum Cable Length
C8x transducer	6.0 ft / 1.8 m
C11x transducer	6.0 ft/1.8 m
C35x transducer	5.5 ft / 1.7 m
rC60xi transducer standard/armored	5.5 ft/1.7 m
HFL38xi transducer standard/armored	5.5 ft/1.7 m
HFL50x transducer	5.7 ft/1.7 m
HSL25x transducer	8.0 ft/2.4 m
ICTx transducer	5.5 ft/1.7 m
L25x transducer standard/armored	7.5 ft/2.3 m
L38xi transducer standard/armored	5.5 ft/1.7 m
L52x transducer ^a	7.9 ft/2.4 m
P10x transducer	6.0 ft/1.8 m
rP19x transducer standard/armored	6.0 ft/1.8 m

For transducers, the maximum cable length is measured between the strain reliefs. The stated length do not include the lengths of cable in the following locations: underneath the strain reliefs, inside the transducer enclosure, and inside the transducer connector.

^aThe L52x transducer is for veterinary use only.

Table 9-2: Accessories and peripherals compatible with SonoSite Edge II ultrasound system

Description	Maximum Cable Length
TEExi transducer	7.2 ft/2.2 m
Bar code scanner	4.8 ft/1.5 m
Battery for PowerPack	—
Battery Pack	—
Battery PowerPack	—
Black & white printer	—
Black & white printer power cable	3.3 ft/1 m
Color printer	—
Color printer power cable	3.3 ft/1 m
Color printer video cable	6 ft/1.8 m
ECG lead wires	24 in/0.6 m
ECG module	5.8 ft/1.8 m
ECG slave cable	8 ft/2.4 m
SonoSite Edge II Dock	—
SonoSite Edge II Stand	—
Footswitch	9.8 ft/3 m
Petite mouse	6 ft /1.8 m
Power cord (system)	10 ft/3 m
Power supply with DC cable	6.8 ft/2 m
Power supply AC cable	39 in/1 m
PowerPark	—
Triple Transducer Connect	—
USB wireless adapter	—

For transducers, the maximum cable length is measured between the strain reliefs. The stated length do not include the lengths of cable in the following locations: underneath the strain reliefs, inside the transducer enclosure, and inside the transducer connector.

^aThe L52x transducer is for veterinary use only.

The tables in this section document the intended use environment and EMC compliance levels of the system. For maximum performance, ensure that the system is used in the environments described in this table.

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

Table 9-3: Manufacturer’s Declaration – Electromagnetic Emissions per IEC 60601-1-2:2007 and IEC 60601-1-2:2014

Emissions Test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The SonoSite Edge II ultrasound system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The SonoSite Edge II 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 9-4: Manufacturer’s Declaration – Electromagnetic Immunity per IEC 60601-1-2:2007

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.

Table 9-4: Manufacturer’s Declaration – Electromagnetic Immunity per IEC 60601-1-2:2007

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<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.
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 $d = 1.2 \sqrt{P}$

Table 9-4: Manufacturer’s Declaration – Electromagnetic Immunity per IEC 60601-1-2:2007

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2 \sqrt{P}$ 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 (10) according to the transmitter manufacturer and it is the recommended separation distance in meters (m). 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.		
<p>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.</p> <p>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Table 9-5: Manufacturer’s Declaration – Electromagnetic Immunity per IEC 60601-1-2:2014

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8.0KV, contact ± 2.0KV, ± 4.0KV, ± 8.0KV air, ± 15KV	± 8.0KV, ± 4.0KV, ± 8.0KV air, ± 15KV	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	0% U_T for 0.5 cycle 0% U_T for 5 cycles 70% U_T (30% dip in U_T) for 500 msec <5% U_T (>95% dip in U_T) for 5s	0% U_T for 0.5 cycle 0% U_T for 5 cycles 70% U_T (30% dip in U_T) for 500 msec <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.
Power Frequency Magnetic Field IEC 61000-4-8	30 A/m	30 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.

Table 9-5: Manufacturer’s Declaration – Electromagnetic Immunity per IEC 60601-1-2:2014

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands	3 Vrms 6 Vrms in ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the 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 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (10) according to the transmitter manufacturer and it is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol:  (IEC 60417 No. 417-IEC-5140: “Source of non-ionizing radiation”)
Proximity fields from wireless communications equipment	Per 60601-1-2:2014 Table 9	Per 60601-1-2:2014 Table 9	

Table 9-5: Manufacturer’s Declaration – Electromagnetic Immunity per IEC 60601-1-2:2014

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Note	<p>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.</p>		
<p>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.</p> <p>b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

FCC Caution: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Immunity testing requirements

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

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

Labeling symbols

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

Table 9-6: Standards labeling symbols

Symbol	Title	Standards development organization	Reference number	Description
	Manufacturer	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.1.1	Indicates the medical device manufacturer
	Date of manufacture	ISO 7000- Graphical symbols for Use on Equipment	5.1.3	To indicate the date on which a product was manufactured
	European community authorized representative	ISO 15223-1 Medical devices - symbols to be used with medical device labels, labelling and information to be supplied.	5.1.2	Indicates the Authorized representative in the European Community
	Serial number	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.1.7	Indicates the manufacturer’s serial number so that a specific medical device can be identified
	Catalog number	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.1.6	Indicates the manufacturer’s catalog number so that the medical device can be identified
	Caution	ISO 15223-1 Medical devices – symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements	5.4.4	Indicates that caution is necessary when operating the device or control close to where the symbol is placed

Table 9-6: Standards labeling symbols

Symbol	Title	Standards development organization	Reference number	Description
	Refer to instruction manual/booklet	IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	D.2-10	Follow instructions for use
	Consult instructions for use	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.4.3	Indicates that the operating instructions should be considered when operating the device or control close to where the symbol is placed
	Fragile handle with care	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.3.1	Indicates a medical device that can be broken or damaged if not handled carefully
	Keep dry	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.3.4	.Indicates a medical device that needs to be protected from moisture
	Temperature limit	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.3.7	Indicates the temperature limits to which the medical device can be safely exposed
	Atmospheric pressure limitations	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.3.9	Indicates the range of atmospheric pressure to which the medical device can be safely exposed

Table 9-6: Standards labeling symbols

Symbol	Title	Standards development organization	Reference number	Description
	Humidity limitation	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.3.8	Indicates the range of humidity to which the medical device can be safely exposed
	Degree of Ingress Protection Provided by Enclosure	IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance	D.3	Protected against the effects of temporary immersion in water. Submersible Protected against the effects of temporary immersion.
	Degree of Ingress Protection Provided by Enclosure	IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance	D.3	Protected against the effects of temporary immersion in water. Water-Tight Equipment Protected against the effects of extended immersion
	Alternating current	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	5032	Indicates on the rating plate, that the equipment is suitable for alternating current only, in order to identify appropriate terminals
	Direct current (DC)	—	—	—
	Dangerous voltage	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	5036	Indicates hazards arising from dangerous voltage
	Stacking limit by number	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	2403	Indicates that the items are not to be vertically stacked higher than the specified number of items

Table 9-6: Standards labeling symbols

Symbol	Title	Standards development organization	Reference number	Description
	Caution hot	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	5041	Indicates that the marked item can be hot and should not be touched without taking care
	Caution, static magnetic field hazard	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	6204	Identifies areas with potentially hazardous static magnetic fields and forces in an installation
	Type BF applied parts	IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	D.2-10	Identifies type BF applied part complying with IEC 60601-1
	Defibrillation-proof type CF applied part	IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	D.1-27	Identifies a defibrillation-proof type CF applied part complying with IEC 60601-1
	Electrostatic sensitive device	IEC 60417:2002 Graphical Symbols For Use On Equipment	5134	Indicates packages containing electrostatic sensitive devices, or identifies a device or a connector that has not been tested for immunity to electrostatic discharge
	Non-ionizing electromagnetic radiation	IEC 60601-1-2:2007 Medical Electrical Equipment Part 1-2: General requirements for basic safety and essential performance – collateral standard: electromagnetic compatibility	5.1.1	Indicates generally elevated, potentially hazardous levels of non-ionizing radiation, or to indicate equipment or systems e.g., in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment

Table 9-6: Standards labeling symbols

Symbol	Title	Standards development organization	Reference number	Description
	Medical Device	EU MDR	EU MDR Annex I, 23.2 (q)	Indicates the item the label is adhered to is categorized as a medical device per the MDR, Annex 1, 23.2, q.
	CE marking	—	—	Signifies European Technical Conformity
	Conformité Européenne Notified Body Reference No.: 2797	—	—	Indicates European technical conformity and identification of notified body responsible for implementation of the procedures set out in Annexes II, IV, V, and VI.
	UK Conformity Assessed	The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019	—	Mark that indicates conformity with the applicable requirements for products sold within Great Britain.
	UK Conformity Assessed with approved body number	The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019	—	Mark, including the approved body number, that indicates conformity with the applicable requirements for products sold within Great Britain.
	Regulatory Compliance Mark (RCM)	AS/NZS3820	—	Indicates C-Tick-Regulatory Compliance Mark for Australia and New Zealand Device complies with relevant Australian and New Zealand regulations for electronic devices.

Table 9-6: Standards labeling symbols

Symbol	Title	Standards development organization	Reference number	Description
	Batch code, date code, or lot code type of control number	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements	5.1.5	Indicates manufacturer's batch code so that the batch or lot can be identified
	Biological risk	ISO 7010 Graphical symbols -- Safety colors and safety signs	W009	To warn of biological Hazard
	INMETRO Safety Symbols	—	—	Indicates Brazil - Accredited certification body by the National Institute of Metrology Standardization and Industrial Quality (INMETRO)
	Canadian Standard Association Certification Mark	—	—	CSA certification mark signifying that the product complies with the applicable CSA and ANSI/UL requirements and is authorized for use in Canada and the US.
	Recycle: Electronic Equipment	BS EN 50419:2016 Marking of Electrical and Electronic Equipment in accordance with Directive 2012/19/EU for the Waste of Electrical and Electronic Equipment (WEEE) and Directive 2006/66/EC on Batteries and Accumulators and Waste Batteries and Accumulators	Annex IX	Do Not Throw in Trash
	Corrugated recycle	—	—	Shipping box is made of corrugated cardboard and should be recycled accordingly

Table 9-6: Standards labeling symbols

Symbol	Title	Standards development organization	Reference number	Description
	Resy- Recycling Symbol	—	—	Paper recycle
	21 Part 15	Federal Communications Commission (FCC) Declaration of conformity	—	FCC-Tested to Federal Communications Commission requirements Device complies with relevant FCC regulations for electronic devices
GEL	Gel	—	—	—
	—	—	—	Indicates handle with care
	—	—	—	Indicates follow manufacturer's instructions for disinfecting time
	—	—	—	
	—	—	—	Indicates disinfect transducer
	Sterilized using ethylene oxide	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General Requirements	5.2.3	Indicates a medical device that has been sterilized using ethylene oxide
	Sterilized using irradiation	ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General Requirements	5.2.4	Indicates a medical device that has been sterilized using irradiation

Table 9-6: Standards labeling symbols

Symbol	Title	Standards development organization	Reference number	Description
	Maximum weight load	IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance	7.2.21	Indicates total weight of the equipment, including the safe working load
	Underwriters Laboratories Certification Mark	—	—	Certification mark for electrical shock, fire, and mechanical hazards only
	UL Product Certification.	—	—	The product or company has successfully met stringent standards for product safety.
	China Pollution Control (10)	Ministry of Industry and Information Technology	—	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").	—	—	Compulsory safety mark for compliance to Chinese national standards for many products sold in the People's Republic of China.

Specifications

Dimensions

System

- ▶ **Length:** 13 in. (33 cm)
- ▶ **Width:** 12.4 in. (31.5 cm)
- ▶ **Height:** 2.5 in. (6.3 cm)
- ▶ **Weight:** 11.35 lbs. (4.6 kg) with the TEExi transducer and battery installed

Display

- ▶ **Length:** 9.7 in. (24.6 cm)
- ▶ **Height:** 7.3 in. (18.5 cm)
- ▶ **Diagonal:** 12.1 in. (30.7 cm)

Environmental limits

Note

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

Operating (system, battery and transducer)

- ▶ 10–40°C (50–104°F), 15–95% R.H.
- ▶ 700 to 1060hPa(0.7 to 1.05 ATM)

Mode of Operation

Continuous 40°C (104°F) or below

Shipping and storage (system and transducer)

- ▶ -35–65°C (-31–149°F), 15–95% R.H.
- ▶ 500 to 1060hPa (0.5 to 1.05 ATM)

Shipping and storage (battery)

- ▶ -20–60°C (-4–140°F), 15–95% R.H. (For storage longer than 30 days, store at or below room temperature.)
- ▶ 500 to 1060hPa (0.5 to 1.05 ATM)

Electrical specifications

- ▶ **Power Supply Input:** 100–240 VAC, 50–60 Hz, 2.0 A Max @ 100 VAC
- ▶ **Power Supply Output #1:** 15 VDC, 5.0 A Max
- ▶ **Power Supply Output #2:** 12 VDC, 2.3 A Max
- ▶ Combined output not exceeding 75 watts.

Battery specifications

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

Standards

Electromechanical safety standards

Standard	Description
ANSI/AAMI ES60601-1:2005/(R) 2012, and A1:2012	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance (Consolidated Edition 3.1)
CAN/CSA C22.2 No. 60601-1:2014 (Edition 3.1)	Medical electrical equipment – Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1:2012 (Edition 3.1)	Medical electrical equipment – Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-2-37:2015	Medical Electrical Equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-1-6:2013	Medical Electrical Equipment part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
JIS T0601-1:2013 (3rd Edition)	Japanese Industrial Standard, General Requirements for Safety of Medical Electrical Equipment

EMC standards classification

Standard	Description
IEC 60601-1-2:2014	Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance–Collateral Standard. Electromagnetic Compatibility. Requirements and Tests.
IEC 60601-1-2:2007	Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance–Collateral Standard. Electromagnetic Compatibility. Requirements and Tests.
CISPR 11:2009	Industrial, Scientific, and Medical (ISM) Radio-Frequency Equipment Electromagnetic Disturbance Characteristics–Limits and Methods of Measurement.

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

Biocompatibility standards

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

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

AAMI/ANSI/ISO 10993-10, Biological evaluation of medical devices—Part 10: Tests for irritation and delayed-type hypersensitivity (2002).

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

AAMI/ANSI/ISO 10993-12, Biological evaluation of medical devices—Part 12: Sample preparation and reference materials (2007).

Airborne equipment standards

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

DICOM standard

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

The system conforms to the DICOM standard as specified in the SonoSite Edge II 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 Portability and Accountability Act, Pub.L. No. 104-191 (1996). 45 CFR 160, General Administrative Requirements.

45 CFR 164, Security and Privacy.

CHAPTER 10

Acoustic Output

This chapter contains information required by regulatory agencies, including information about the ALARA (as low as reasonably achievable) principle, the output display standard, acoustic power and intensity tables, and other safety information. 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 that 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 (THI) 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 requires that patient exposure to ultrasound be limited to the lowest ultrasound output for the shortest time necessary to achieve acceptable diagnostic results. 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 IEC 60601-2-37: Particular requirement for the safety of ultrasound medical diagnostic and monitoring equipment. See **“Transducer surface temperature rise”** on page 10-9. 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 controls

The system does not exceed a spatial peak temporal average intensity (ISPTA) of 720 mW/cm^2 for all imaging modes. (For either the Ophthalmic or Orbital exam, the acoustic output is limited to the following values: ISPTA does not exceed 50 mW/cm^2 ; TI does not exceed 1.0, and MI does not exceed 0.23.) The mechanical index (MI) and thermal index (TI) may exceed values greater than 1.0 on some transducers in some imaging modes. One may monitor the MI and TI values and adjust the controls to reduce these values. See **“Guidelines for reducing MI and TI”** on page 10-3. Additionally, one means for meeting the ALARA principle is to set the MI or TI values to a low index value and then modifying this level until a satisfactory image or Doppler mode is obtained. For more information on MI and TI, refer to Medical Ultrasound Safety, AIUM and IEC 60601-2-37 Annex “Guidance on the interpretation of TI and MI to be used to inform the operator.”

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. Tissue attenuation is directly related to transducer frequency. The higher the PRF (pulse repetition frequency), the more output pulses occur over a period of time.

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
- ▶ Comet tails

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

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

Note

For L52x acoustic output information, refer to the *L52 Series Transducer User Guide*.

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 10-1: Guidelines for reducing MI

Transducer	Depth
C8x	↑
↓ Decrease or lower setting of parameter to reduce MI.	
↑ Increase or raise setting of parameter to reduce MI.	

Table 10-1: Guidelines for reducing MI (continued)

Transducer	Depth
C11x	↑
C35x	↑
rC60xi standard/armored	↑
HFL38xi standard/armored	↑
HFL50x	↑
HSL25x	↑
ICTx	↑
L25x standard/armored	↑
L38xi standard/armored	↑
P10x	↑
rP19x standard/armored	↑
TEExi	↑
<p>↓ Decrease or lower setting of parameter to reduce MI.</p> <p>↑ Increase or raise setting of parameter to reduce MI.</p>	

Table 10-2: Guidelines for reducing TI

Transducer	CPD Settings						PW Settings
	Box Width	Box Height	Box Depth	PRF	Depth	Optimize	
C8x	↓				↑		↓ (Depth)
C11x			↑	↓	↑		↓ (Depth)
C35x	↑			↓	↑		↓ (Depth)
rC60xi standard/ armored	↓			↓	↑		↓ (PRF)
HFL38xi standard/ armored			↑	↑	↑		↓ (Depth)
HFL50x			↑	↑	↑		↓ (Depth)
HSL25x	↓				↑		↓ (PRF)
ICTx		↑	↑	↓		Exam Gyn	↓ (PRF)
L25x standard/ armored	↓				↑		↓ (PRF)
L38xi standard/ armored	↑	↑					↓ (Sample volume zone or size)
P10x			↑	↓			↓ (PRF)
rP19x standard/ armored				↓	↑		↓ (Depth)
TEExi				↓	↓		↓ (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 output display standard for MI and TI. See “[Related guidance documents](#)” on page 10-8. **Table 10-3** 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 10-3: TI or MI \geq 1.0

Transducer Model	Index	2D/M Mode	CPD/Color	PW Doppler	CW Doppler
C8x	MI	Yes	Yes	Yes	—
	TIC, TIB, or TIS	No	No	Yes	—
C11x	MI	No	No	No	—
	TIC, TIB, or TIS	No	No	Yes	—
C35x	MI	Yes	No	No	—
	TIC, TIB, or TIS	No	No	Yes	—
rC60xi/5-2 standard/armored	MI	Yes	Yes	Yes	—
	TIC, TIB, or TIS	Yes	Yes	Yes	—
HFL38xi standard/armored	MI	Yes	Yes	Yes	—
	TIC, TIB, or TIS	No	No	Yes	—
HFL50x	MI	Yes	Yes	Yes	—
	TIC, TIB, or TIS	No	No	Yes	—

Even when 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.

Table 10-3: TI or MI \geq 1.0 (continued)

Transducer Model	Index	2D/M Mode	CPD/Color	PW Doppler	CW Doppler
HSL25x	MI	Yes	Yes	No	—
	TIC, TIB, or TIS	No	No	Yes	—
ICTx	MI	No	No	No	—
	TIC, TIB, or TIS	No	No	Yes	—
L25x standard/armored	MI	Yes	Yes	No	—
	TIC, TIB, or TIS	No	No	Yes	—
L38xi standard/armored	MI	Yes	Yes	Yes	—
	TIC, TIB, or TIS	Yes	Yes	Yes	—
P10x	MI	No	No	Yes	No
	TIC, TIB, or TIS	No	Yes	Yes	Yes
rP19x standard/armored	MI	Yes	Yes	Yes	No
	TIC, TIB, or TIS	Yes	Yes	Yes	Yes
TEExi	MI	No	No	No	No
	TIC, TIB, or TIS	No	No	Yes	Yes

Even when 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.

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 10-71.

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, 2008.

Medical Ultrasound Safety, American Institute of Ultrasound in Medicine (AIUM), 2014.

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

IEC 60601-2-37: 2015, Particular requirements for the basic safety and essential performance of ultrasonic diagnostic and monitoring equipment.

Transducer surface temperature rise

Table 10-4 and Table 10-5 list the measured surface temperature rise from ambient ($23^{\circ}\text{C} \pm 3^{\circ}\text{C}$) of transducers used on the ultrasound system. The temperatures were measured in accordance with IEC 60601-2-37 with controls and settings positioned to give maximum temperatures.

Table 10-4: Transducer Surface Temperature Rise, External Use ($^{\circ}\text{C}$)

Test	C11x	C35x	rC60xi	HFL38xi	HFL50x	HSL25x	L25x	L38xi	P10x	rP19x
Still air	14.2	15.3	15.0	12.4	10.7	17.5	16.1	12.5	16.0	14.9
Simulated use	7.3	8.5	8.9	7.7	7.7	9.1	8.5	8.8	9.1	7.6

Table 10-5: Transducer Surface Temperature Rise, Non-External Use ($^{\circ}\text{C}$)

Test	ICTx	C8x	TEExi
Still air	9.2	11.3	8.6
Simulated use	5.2	5.5	4.7

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, the American Institute of Ultrasound in Medicine (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 IEC 60601-2-37: 2015, Particular requirements for the basic safety and essential performance of ultrasonic diagnostic and monitoring equipment. *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/cm². 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

The tables in this section 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, refer to “[Terms used in the acoustic output tables](#)” on page 10-70.

Transducer model: C8x Operating mode: 2D	10-14
Transducer model: C8x Operating mode: M mode	10-15
Transducer model: C8x Operating mode: Color/CPD	10-16
Transducer model: C8x Operating mode: PW Doppler	10-17
Transducer model: C11x Operating mode: PW Doppler	10-18
Transducer model: C35x Operating mode: 2D	10-19
Transducer model: C35x Operating mode: PW Doppler	10-20
Transducer model: HFL38xi (Ophthalmic use) Operating mode: 2D	10-21
Transducer model: HFL38xi (Ophthalmic use) Operating mode: M mode	10-22
Transducer model: HFL38xi (Ophthalmic use) Operating mode: Color/CPD	10-23
Transducer model: HFL38xi (Ophthalmic use) Operating mode: PW Doppler	10-24
Transducer model: HFL38xi Operating mode: 2D	10-25
Transducer model: HFL38xi Operating mode: M mode	10-26
Transducer model: HFL38xi Operating mode: Color/CPD	10-27
Transducer model: HFL38xi Operating mode: PW Doppler	10-28
Transducer model: HFL50x Operating mode: 2D	10-29
Transducer model: HFL50x Operating mode: M mode	10-30
Transducer model: HFL50x Operating mode: Color	10-31
Transducer model: HFL50x Operating mode: PW Doppler	10-32
Transducer model: HSL25x (Ophthalmic use) Operating mode: 2D	10-33
Transducer model: HSL25x (Ophthalmic use) Operating mode: M mode	10-34
Transducer model: HSL25x (Ophthalmic use) Operating mode: Color/CPD	10-35
Transducer model: HSL25x (Ophthalmic use) Operating mode: PW Doppler	10-36
Transducer model: HSL25x Operating mode: 2D	10-37
Transducer model: HSL25x Operating mode: Color/CPD	10-38
Transducer model: HSL25x Operating mode: PW Doppler	10-39
Transducer model: ICTx Operating mode: PW Doppler	10-40
Transducer model: L25x (Ophthalmic use) Operating mode: 2D	10-41
Transducer model: L25x (Ophthalmic use) Operating mode: M mode	10-42
Transducer model: L25x (Ophthalmic use) Operating mode: Color/CPD	10-43
Transducer model: L25x (Ophthalmic use) Operating mode: PW Doppler	10-44
Transducer model: L25x Operating mode: 2D	10-45
Transducer model: L25x Operating mode: Color/CPD	10-46
Transducer model: L25x Operating mode: PW Doppler	10-47
Transducer model: L38xi Operating mode: 2D	10-48
Transducer model: L38xi Operating mode: M mode	10-49

Transducer model: L38xi Operating mode: Color/CPD	10-50
Transducer model: L38xi Operating mode: PW Doppler	10-51
Transducer model: P10x Operating mode: Color	10-52
Transducer model: P10x Operating mode: CW Doppler	10-53
Transducer model: P10x Operating mode: PW Doppler	10-54
Transducer model: rC60xi Operating mode: 2D	10-55
Transducer model: rC60xi Operating mode: M mode	10-56
Transducer model: rC60xi Operating mode: Color/CPD	10-57
Transducer model: rC60xi Operating mode: PW Doppler	10-58
Transducer model: rP19x (Orbital use) Operating mode: 2D	10-59
Transducer model: rP19x (Orbital use) Operating mode: M mode	10-60
Transducer model: rP19x (Orbital use) Operating mode: Color/CPD	10-61
Transducer model: rP19x (Orbital use) Operating mode: PW Doppler	10-62
Transducer model: rP19x Operating mode: 2D	10-63
Transducer model: rP19x Operating mode: M mode	10-64
Transducer model: rP19x Operating mode: Color/CPD	10-65
Transducer model: rP19x Operating mode: CW Doppler	10-66
Transducer model: rP19x Operating mode: PW Doppler	10-67
Transducer model: TEExi Operating mode: CW Doppler	10-68
Transducer model: TEExi Operating mode: PW Doppler	10-69

Table 10-6: Transducer model: C8x Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.1	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.48					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	1.2					
	$z_{pii,\alpha}$ (cm)	1.2					
	f_{awf} (MHz)	5.53	#		#		#
Other information	prr (Hz)	9524					
	srr (Hz)	18.6					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	264					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	18.3					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	25.6					
	p_r at z_{pii} (MPa)	3.11					
Operating controls	Exam type	Pro					
	Optimization	Pen					
	Depth (cm)	2.5–3.2					
	MB	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 10-7: Transducer model: C8x Operating mode: M mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.3	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.91					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			#			
	z_b (cm)					#	
	z_{MI} (cm)	1.1					
	$z_{pii,\alpha}$ (cm)	1.1					
	f_{awf} (MHz)	5.07	#		#		#
Other information	pr (Hz)	800					
	srr (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	433					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	149					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	226					
	p_r at z_{pii} (MPa)	3.57					
Operating controls	Exam type	Pro					
	Optimization	Pen					
	Depth (cm)	4.2					

(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 10-8: Transducer model: C8x Operating mode: Color/CPD

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.2	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.68					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.8					
	$z_{pii,\alpha}$ (cm)	0.8					
	f_{awf} (MHz)	4.82	#		#		#
Other information	p_{rr} (Hz)	2548					
	s_{rr} (Hz)	26					
	n_{pps}	12					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	381					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sij,\alpha}$ (mW/cm ²)	132					
	I_{spta} at z_{pii} or z_{sij} (mW/cm ²)	176					
	p_r at z_{pii} (MPa)	3.1					
Operating controls	Exam type	Pro					
	Mode	CVD					
	2D optimization/depth (cm)	Pen/1.5–1.9					
	Color optimization/PRF (Hz)	High/any					
	Color box position/size	Narrow/any					

(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 10-9: Transducer model: C8x Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.0	(a)		1.4		(b)
Index component value			#	#	0.5	1.4	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.28					
	P (mW)		#		23.1		#
	$P_{1 \times 1}$ (mW)		#		23.1		
	z_s (cm)			#			
	z_b (cm)					1.0	
	z_{MI} (cm)	1.8					
	$z_{pii,\alpha}$ (cm)	1.8					
	f_{awf} (MHz)	4.80		#	4.80		#
Other information	pr (Hz)	1008					
	srr (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	263					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	334					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	616					
	p_r at z_{pii} (MPa)	3.1					
Operating controls	Exam type	Pro			Pro		
	Sample volume size (mm)	1			1		
	Sample volume position	Zone 4			Zone 4		
	PRF (Hz)	1008			1008		

(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 10-10: Transducer model: C11x Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		(a)	(a)		1.5		1.1
Index component value			#	#	0.5	1.5	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	#					
	P (mW)		#		24.6		21.7
	P_{1x1} (mW)		#		24.6		
	z_s (cm)			#			
	z_b (cm)					1.7	
	z_{MI} (cm)	#					
	$z_{pii,\alpha}$ (cm)	#					
	f_{awf} (MHz)	#	#		4.37		4.36
Other information	prr (Hz)	#					
	srr (Hz)	#					
	η_{pps}	#					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	#					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	#					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	#					
p_r at z_{pii} (MPa)	#						
Operating controls	Exam type				Nrv		Nrv
	Sample volume size (mm)				1		7
	Sample volume position				Zone 1		Zone 0
	PRF (Hz)				10417		6250

(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 10-11: Transducer model: C35x Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.0	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.8					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	3.3					
	$z_{pii,\alpha}$ (cm)	3.3					
	f_{awf} (MHz)	3.45	#		#		#
Other information	prr (Hz)	1021					
	srr (Hz)	7.98					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	250					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	8.6					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	16.5					
	p_r at z_{pii} (MPa)	2.61					
Operating controls	Exam type	Msk					
	Optimization	Res					
	Depth (cm)	8.3					
	MB	N/A					

(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 10-12: Transducer model: C35x Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		(a)	1.5		2.6		(b)
Index component value			1.5	1.0	1.0	2.6	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	#					
	P (mW)		72.8		47.1		#
	$P_{1 \times 1}$ (mW)		71.1		47.1		
	z_s (cm)			1.4			
	z_b (cm)					0.50	
	z_{MI} (cm)	#					
	$z_{pii,\alpha}$ (cm)	#					
	f_{awf} (MHz)	#	4.35		4.37		#
Other information	p_{rr} (Hz)	#					
	s_{rr} (Hz)	#					
	η_{pps}	#					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	#					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	#					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	#					
	p_r at z_{pii} (MPa)	#					
Operating controls	Exam type		Spine		Spine		
	Sample volume size (mm)		2		1		
	Sample volume position		Zone 5		Zone 0		
	PRF (Hz)		6250		15625		

(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 10-13: Transducer model: HFL38xi (Ophthalmic use) Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.17	0.007		0.007		(b)
Index component value			0.007	0.007	0.007	0.007	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.43					
	P (mW)		0.77		0.77		#
	$P_{1 \times 1}$ (mW)		0.21		0.21		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	2.1					
	$z_{pii,\alpha}$ (cm)	2.1					
	f_{awf} (MHz)	6.59	6.75		6.75		#
Other information	prr (Hz)	11339					
	srr (Hz)	19.7					
	η_{pps}	3					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	11.4					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	0.8					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	1.3					
	p_r at z_{pii} (MPa)	0.7					
Operating controls	Exam type	Oph	Oph		Oph		
	Optimization	Pen	Res		Res		
	Depth (cm)	4.9	4.9		4.9		
	MB	On	On		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 10-14: Transducer model: HFL38xi (Ophthalmic use) Operating mode: M mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.17	0.003		0.004		(b)
Index component value			0.003	0.002	0.002	0.004	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.44					
	P (mW)		0.087		0.064		#
	$P_{1 \times 1}$ (mW)		0.087		0.064		
	z_s (cm)			0.9			
	z_b (cm)					1.10	
	z_{MI} (cm)	1.0					
	$z_{pii,\alpha}$ (cm)	1.0					
	f_{awf} (MHz)	6.58	6.86		6.78		#
Other information	prr (Hz)	800					
	srr (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	10.3					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	1.0					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	1.7					
	ρ_r at z_{pii} (MPa)	0.55					
Operating controls	Exam type	Oph	Oph		Oph		
	Optimization	Pen	Res		Res		
	Depth (cm)	1.5	6.0		4.0		

(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.

Table 10-15: Transducer model: HFL38xi (Ophthalmic use) Operating mode: Color/CPD

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.17	0.02		0.02		(b)
Index component value			0.02	0.02	0.02	0.02	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.39					
	P (mW)		1.11		1.11		#
	$P_{1 \times 1}$ (mW)		0.75		0.75		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.9					
	$z_{pii,\alpha}$ (cm)	0.9					
	f_{awf} (MHz)	5.34	5.37		5.37		#
Other information	pr (Hz)	4537					
	srr (Hz)	13.5					
	η_{pps}	13					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	5.5					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	1.3					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	2.1					
Operating controls	p_r at z_{pii} (MPa)	0.46					
	Exam type	Oph	Oph		Oph		
	Mode	CVD	CVD		CVD		
	2D optimization/depth (cm)	Pen/1.5	Pen/4.9		Pen/4.9		
	Color optimization/PRF (Hz)	High/7813	High/6944		High/6944		
	Color box position/size	Bottom/small	Def/narrow		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 10-16: Transducer model: HFL38xi (Ophthalmic use) Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.18	0.09		0.17		(b)
Index component value			0.09	0.06	0.09	0.17	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.41					
	P (mW)		3.56		3.56		#
	$P_{1 \times 1}$ (mW)		3.56		3.56		
	z_s (cm)			1.1			
	z_b (cm)					1.64	
	z_{MI} (cm)	0.9					
	$z_{pii,\alpha}$ (cm)	0.9					
	f_{awf} (MHz)	5.34	5.33		5.33		#
Other information	prr (Hz)	1302					
	srr (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	6.6					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	10.9					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	15.0					
p_r at z_{pii} (MPa)	0.48						
Operating controls	Exam type	Oph	Oph		Oph		
	Sample volume size (mm)	1	10		10		
	Sample volume position	Zone 1	Zone 7		Zone 7		
	PRF (Hz)	1302	10417		10417		

(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 10-17: Transducer model: HFL38xi Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.3	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	3.05					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	1.2					
	$z_{pii,\alpha}$ (cm)	1.2					
	f_{awf} (MHz)	5.36		#		#	
Other information	prr (Hz)	2127					
	srr (Hz)	11.1					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	494					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	13.3					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	19.4					
	p_r at z_{pii} (MPa)	3.81					
Operating controls	Exam type	Ven					
	Optimization	Res					
	Depth (cm)	3.3					
	MB	N/A					
	Needle vision	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 10-18: Transducer model: HFL38xi Operating mode: M mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.2	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	3.14					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			#			
	z_b (cm)					#	
	z_{MI} (cm)	1.4					
	$z_{pii,\alpha}$ (cm)	1.4					
	f_{awf} (MHz)	6.75	#		#		#
Other information	prr (Hz)	1600					
	srr (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	388					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	163.2					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	333.3					
	p_r at z_{pii} (MPa)	4.35					
Operating controls	Exam type	Nrv					
	Optimization	Pen					
	Depth (cm)	4.0					

(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.

Table 10-19: Transducer model: HFL38xi Operating mode: Color/CPD

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.3	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	3.05					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	1.2					
	$z_{pii,\alpha}$ (cm)	1.2					
	f_{avf} (MHz)	5.36		#		#	
Other information	p_{rr} (Hz)	2223					
	s_{rr} (Hz)	3.3					
	n_{pps}	14					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	494					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	27.4					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	40.1					
	p_r at z_{pii} (MPa)	3.81					
Operating controls	Exam type	SmP					
	Mode	CVD					
	2D optimization/depth (cm)	Res/3.3					
	Color optimization/PRF (Hz)	Low/401					
	Color box position/size	Def/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 10-20: Transducer model: HFL38xi Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.2	1.1		2.2		(b)
Index component value			1.1	0.8	1.1	2.2	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.69					
	P (mW)		47.7		47.7		#
	$P_{1 \times 1}$ (mW)		47.7		47.7		
	z_s (cm)			1.1			
	z_b (cm)					1.10	
	z_{MI} (cm)	1.0					
	$z_{pii,\alpha}$ (cm)	1.0					
	f_{awf} (MHz)	5.34	4.86		4.86		#
Other information	prr (Hz)	1008					
	srr (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	308					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	102.8					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	210.0					
	p_r at z_{pii} (MPa)	3.23					
Operating controls	Exam type	Nrv	Art		Art		
	Sample volume size (mm)	1	1		1		
	Sample volume position	Zone 3	Zone 7		Zone 7		
	PRF (Hz)	1008	3125		3125		

(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 10-21: Transducer model: HFL50x Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.3	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	3.051					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	1.2					
	$z_{pii,\alpha}$ (cm)	1.2					
	f_{awf} (MHz)	5.36	#		#		#
Other information	pr (Hz)	2733					
	srr (Hz)	7.2					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	493					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	8.6					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	12.6					
	p_r at z_{pii} (MPa)	3.81					
Operating controls	Exam type	Any					
	Optimization	Any					
	Depth (cm)	3.3					
	Mbe	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 10-22: Transducer model: HFL50x Operating mode: M mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.2	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	3.14					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			#			
	z_b (cm)					#	
	z_{MI} (cm)	1.4					
	$z_{pii,\alpha}$ (cm)	1.4					
	f_{awf} (MHz)	6.75	#		#		#
Other information	prr (Hz)	1600					
	srr (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	388					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	163.2					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	333.3					
	p_r at z_{pii} (MPa)	4.35					
Operating controls	Exam type	Any					
	Optimization	Pen					
	Depth (cm)	4					

(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 10-23: Transducer model: HFL50x Operating mode: Color

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.3	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	3.05					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	1.2					
	$z_{pii,\alpha}$ (cm)	1.2					
	f_{avf} (MHz)	5.36		#		#	
Other information	p_{rr} (Hz)	8233					
	s_{rr} (Hz)	3.2					
	η_{pps}	14					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	494					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	26.8					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	39.2					
	p_r at z_{pii} (MPa)	3.81					
Operating controls	Exam type	Any					
	Mode	Any					
	Optimization/depth (cm)	Low/3.3					
	PRF (Hz)	Any					

(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 10-24: Transducer model: HFL50x Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.2	1.1		1.9		(b)
Index component value			1.1	0.7	1.1	1.9	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.69					
	P (mW)		42.6		42.6		#
	$P_{1 \times 1}$ (mW)		42.6		42.6		
	z_s (cm)			1.1			
	z_b (cm)					1.10	
	z_{MI} (cm)	1.0					
	$z_{pii,\alpha}$ (cm)	1.0					
	f_{awf} (MHz)	5.34	5.34		5.34		#
Other information	prr (Hz)	1008					
	srr (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	308					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	399.6					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	599.8					
	p_r at z_{pii} (MPa)	3.23					
Operating controls	Exam type	Any	Any		Any		
	Sample volume size (mm)	1	1		1		
	Sample volume position	Zone 3	Zone 7		Zone 7		
	PRF (Hz)	1008	1563–3125		1563–3125		

(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 10-25: Transducer model: HSL25x (Ophthalmic use) Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.17	0.02		0.02		(b)
Index component value			0.02	0.02	0.02	0.02	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.47					
	P (mW)		1.62		1.62		#
	$P_{1 \times 1}$ (mW)		0.70		0.70		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.8					
	$z_{pii,\alpha}$ (cm)	0.8					
	f_{awf} (MHz)	7.65	6.97		6.97		#
Other information	prr (Hz)	12580					
	srr (Hz)	12.3					
	η_{pps}	4					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	13.4					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	0.6					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	1.0					
	p_r at z_{pii} (MPa)	0.58					
Operating controls	Exam type	Oph	Oph		Oph		
	Optimization	Res	Pen		Pen		
	Depth (cm)	1.9	4.3		4.3		
	MB	On	On		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 10-26: Transducer model: HSL25x (Ophthalmic use) Operating mode: M mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.17	0.01		0.02		(b)
Index component value			0.010	0.009	0.013	0.020	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.47					
	P (mW)		0.45		0.45		#
	$P_{1 \times 1}$ (mW)		0.45		0.45		
	z_s (cm)			0.9			
	z_b (cm)					0.85	
	z_{MI} (cm)	1.0					
	$z_{pii,\alpha}$ (cm)	1.0					
	f_{awf} (MHz)	7.59	6.25		6.25		#
Other information	prr (Hz)	1600					
	srr (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	14.9					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	2.3					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	4.0					
	p_r at z_{pii} (MPa)	0.61					
Operating controls	Exam type	Oph	Oph		Oph		
	Optimization	Res	Pen		Pen		
	Depth (cm)	1.9	4.3		4.3		

(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 10-27: Transducer model: HSL25x (Ophthalmic use) Operating mode: Color/CPD

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.17	0.06		0.06		(b)
Index component value			0.06	0.06	0.06	0.06	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.42					
	P (mW)		2.9		2.9		#
	$P_{1 \times 1}$ (mW)		1.9		1.9		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.7					
	$z_{pii,\alpha}$ (cm)	0.7					
	f_{awf} (MHz)	6.11	6.10		6.10		#
Other information	p_{rr} (Hz)	3096					
	s_{rr} (Hz)	8.1					
	η_{pps}	14					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	7.5					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	1.1					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	1.6					
	p_r at z_{pii} (MPa)	0.49					
Operating controls	Exam type	Oph	Oph		Oph		
	Mode	CVD	CVD		CVD		
	2D optimization/depth (cm)	Pen/1.9	Pen/5.1		Pen/5.1		
	Color optimization/PRF (Hz)	Low/401	Med/4167		Med/4167		
	Color box position/size	Def/def	Top/short-wide		Top/short-wide		

(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 10-28: Transducer model: HSL25x (Ophthalmic use) Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.18	0.12		0.21		(b)
Index component value			0.12	0.08	0.12	0.21	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.44					
	P (mW)		4.0		4.0		#
	$P_{1 \times 1}$ (mW)		4.0		4.0		
	z_s (cm)			0.9			
	z_b (cm)					0.80	
	z_{MI} (cm)	1.2					
	$z_{pii,\alpha}$ (cm)	1.2					
	f_{awf} (MHz)	6.03	6.03		6.03		#
Other information	prr (Hz)	1953					
	srr (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	7.4					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	18.4					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	44.9					
p_r at z_{pii} (MPa)	0.56						
Operating controls	Exam type	Oph	Oph		Oph		
	Sample volume size (mm)	1	1		1		
	Sample volume position	Zone 7	Zone 7		Zone 7		
	PRF (Hz)	1953	5208		5208		

(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 10-29: Transducer model: HSL25x Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.2	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.87					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.8					
	$z_{pii,\alpha}$ (cm)	0.8					
	f_{avf} (MHz)	6.11	#		#		#
Other information	p_{rr} (Hz)	1061					
	s_{rr} (Hz)	13.0					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	478					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	12.2					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	16.4					
	p_r at z_{pii} (MPa)	3.39					
Operating controls	Exam type	Nrv/Msk/ Ven/Art					
	Optimization	Any					
	Depth (cm)	1.9–2.2					
	Mbe	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 10-30: Transducer model: HSL25x Operating mode: Color/CPD

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.0	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.35					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.8					
	$z_{pii,\alpha}$ (cm)	0.8					
	f_{avf} (MHz)	6.11		#		#	
Other information	p_{rr} (Hz)	3079					
	s_{rr} (Hz)	8.0					
	n_{pps}	14					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	276					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	47.6					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	63.9					
	p_r at z_{pii} (MPa)	2.78					
Operating controls	Exam type	Sup					
	Mode	CVD					
	2D optimization/depth (cm)	Pen/3.1					
	Color optimization/PRF (Hz)	Low/401					
	Color box position/size	Def/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 10-31: Transducer model: HSL25x Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		(a)	(a)		1.5		(b)
Index component value			#	#	0.8	1.5	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	#					
	P (mW)		#		28.1		#
	$P_{1 \times 1}$ (mW)		#		28.1		
	z_s (cm)			#			
	z_b (cm)					0.75	
	z_{MI} (cm)	#					
	$z_{pii,\alpha}$ (cm)	#					
	f_{awf} (MHz)	#	#		6.00		#
Other information	prr (Hz)	#					
	srr (Hz)	#					
	η_{pps}	#					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	#					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	#					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	#					
	p_r at z_{pii} (MPa)	#					
Operating controls	Exam type				Nrv		
	Sample volume size (mm)				8		
	Sample volume position				Zone 7		
	PRF (Hz)				1953		

(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 10-32: Transducer model: ICTx Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		(a)	(a)		1.2		(b)
Index component value			#	#	0.3	1.2	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	#					
	P (mW)		#		16.3		#
	P_{1x1} (mW)		#		16.3		
	z_s (cm)			#			
	z_b (cm)					1.60	
	z_{MI} (cm)	#					
	$z_{pii,\alpha}$ (cm)	#					
	f_{awf} (MHz)	#	#		4.36		#
Other information	prr (Hz)	#					
	srr (Hz)	#					
	η_{pps}	#					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	#					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	#					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	#					
	p_r at z_{pii} (MPa)	#					
Operating controls	Exam type				Any		
	Sample volume size (mm)				3		
	Sample volume position				Zone 1		
	PRF (Hz)				Any		

(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 10-33: Transducer model: L25x (Ophthalmic use) Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.17	0.02		0.02		(b)
Index component value			0.02	0.02	0.02	0.02	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.47					
	P (mW)		1.62		1.62		#
	$P_{1 \times 1}$ (mW)		0.70		0.70		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.8					
	$z_{pii,\alpha}$ (cm)	0.8					
	f_{awf} (MHz)	7.65	6.97		6.97		#
Other information	prr (Hz)	12580					
	srr (Hz)	12.3					
	η_{pps}	4					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	13.4					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	0.6					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	1.0					
	p_r at z_{pii} (MPa)	0.58					
Operating controls	Exam type	Oph	Oph		Oph		
	Optimization	Res	Pen		Pen		
	Depth (cm)	1.9	4.3		4.3		
	MB	On	On		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 10-34: Transducer model: L25x (Ophthalmic use) Operating mode: M mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.17	0.01		0.02		(b)
Index component value			0.010	0.009	0.013	0.020	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.47					
	P (mW)		0.45		0.45		#
	$P_{1 \times 1}$ (mW)		0.45		0.45		
	z_s (cm)			0.9			
	z_b (cm)					0.85	
	z_{MI} (cm)	1.0					
	$z_{pii,\alpha}$ (cm)	1.0					
	f_{awf} (MHz)	7.59	6.25		6.25		#
Other information	prr (Hz)	1600					
	srr (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	14.9					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	2.3					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	4.0					
	p_r at z_{pii} (MPa)	0.61					
Operating controls	Exam type	Oph	Oph		Oph		
	Optimization	Res	Pen		Pen		
	Depth (cm)	1.9	4.3		4.3		

(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 10-35: Transducer model: L25x (Ophthalmic use) Operating mode: Color/CPD

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.17	0.06		0.06		(b)
Index component value			0.06	0.06	0.06	0.06	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.42					
	P (mW)		2.9		2.9		#
	$P_{1 \times 1}$ (mW)		1.9		1.9		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.7					
	$z_{pii,\alpha}$ (cm)	0.7					
	f_{avf} (MHz)	6.11	6.10		6.10		#
Other information	pr (Hz)	3096					
	srr (Hz)	8.1					
	n_{pps}	14					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	7.5					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	1.1					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	1.6					
	p_r at z_{pii} (MPa)	0.49					
Operating controls	Exam type	Oph	Oph		Oph		
	Mode	CVD	CVD		CVD		
	2D optimization/depth (cm)	Pen/1.9	Pen/5.1		Pen/5.1		
	Color optimization/PRF (Hz)	Low/401	Med/4167		Med/4167		
	Color box position/size	Def/def	Top/short-wide		Top/short-wide		

(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 10-36: Transducer model: L25x (Ophthalmic use) Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.18	0.12		0.21		(b)
Index component value			0.12	0.08	0.12	0.21	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.44					
	P (mW)		4.0		4.0		#
	$P_{1 \times 1}$ (mW)		4.0		4.0		
	z_s (cm)			0.9			
	z_b (cm)					0.80	
	z_{MI} (cm)	1.2					
	$z_{pii,\alpha}$ (cm)	1.2					
	f_{awf} (MHz)	6.03	6.03		6.03		#
Other information	p_{rr} (Hz)	1953					
	s_{rr} (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	7.4					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	18.4					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	44.9					
p_r at z_{pii} (MPa)	0.56						
Operating controls	Exam type	Oph	Oph		Oph		
	Sample volume size (mm)	1	1		1		
	Sample volume position	Zone 7	Zone 7		Zone 7		
	PRF (Hz)	1953	5208		5208		

(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 10-37: Transducer model: L25x Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.2	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.87					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.8					
	$z_{pii,\alpha}$ (cm)	0.8					
	f_{awf} (MHz)	6.11		#		#	
Other information	p_{rr} (Hz)	1061					
	s_{rr} (Hz)	13.0					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	478					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	12.2					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	16.4					
	p_r at z_{pii} (MPa)	3.39					
Operating controls	Exam type	Nrv/Msk/ Ven/Art					
	Optimization	Any					
	Depth (cm)	1.9–2.2					
	Mbe	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 10-38: Transducer model: L25x Operating mode: Color/CPD

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.0	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.35					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.8					
	$z_{pii,\alpha}$ (cm)	0.8					
	f_{avf} (MHz)	6.11	#		#		#
Other information	p_{rr} (Hz)	5261					
	s_{rr} (Hz)	13.7					
	n_{pps}	14					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	276					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	81.5					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	109.5					
	p_r at z_{pii} (MPa)	2.78					
Operating controls	Exam type	Ven					
	Mode	CVD					
	2D optimization/depth (cm)	Pen/3.1					
	Color optimization/PRF (Hz)	Low/779					
	Color box position/size	Def/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 10-39: Transducer model: L25x Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		(a)	(a)		1.7		(b)
Index component value			#	#	0.9	1.7	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	#					
	P (mW)		#		32.1		#
	$P_{1 \times 1}$ (mW)		#		32.1		
	z_s (cm)			#			
	z_b (cm)					0.75	
	z_{MI} (cm)	#					
	$z_{pii,\alpha}$ (cm)	#					
	f_{awf} (MHz)	#	#		#		#
Other information	pr (Hz)	#					
	srr (Hz)	#					
	η_{pps}	#					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	#					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	#					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	#					
	p_r at z_{pii} (MPa)	#					
Operating controls	Exam type				Vas/Ven/Nrv		
	Sample volume size (mm)				8		
	Sample volume position				Zone 7		
	PRF (Hz)				1953		

(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 10-40: Transducer model: L38xi Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.5	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	3.3					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.8					
	$z_{pii,\alpha}$ (cm)	0.8					
	f_{awf} (MHz)	4.82	#		#		#
Other information	prr (Hz)	1312					
	srr (Hz)	10.3					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	605					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	10.2					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	13.5					
	p_r at z_{pii} (MPa)	3.79					
Operating controls	Exam type	Nrv					
	Optimization	Res					
	Depth (cm)	2.0					
	MB	N/A					
	Needle vision	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 10-41: Transducer model: L38xi Operating mode: M mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.5	(a)		1.2		(b)
Index component value			#	#	0.9	1.2	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	3.54					
	P (mW)		#		37.1		#
	$P_{1 \times 1}$ (mW)		#		37.1		
	z_s (cm)			#			
	z_b (cm)					0.9	
	z_{MI} (cm)	1.0					
	$z_{pii,\alpha}$ (cm)	1.0					
	f_{awf} (MHz)	5.76	#		5.20		#
Other information	pr (Hz)	1600					
	srr (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	776					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	181.8					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	280.5					
	p_r at z_{pii} (MPa)	4.32					
Operating controls	Exam type	Art			Art		
	Optimization	Gen			Pen		
	Depth (cm)	4.7			7.3		

(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 10-42: Transducer model: L38xi Operating mode: Color/CPD

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.5	1.1		1.1		(b)
Index component value			1.1	1.1	1.1	1.1	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	3.3					
	P (mW)		64.7		64.7		#
	$P_{1 \times 1}$ (mW)		49.0		49.0		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.8					
	$z_{pii,\alpha}$ (cm)	0.8					
	f_{awf} (MHz)	4.82	4.83		4.83		#
Other information	p_{rr} (Hz)	2190					
	s_{rr} (Hz)	4.5					
	η_{pps}	16					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	605					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	35.6					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	47.4					
	p_r at z_{pii} (MPa)	3.79					
Operating controls	Exam type	Art	Ven		Ven		
	Mode	CVD	CVD		CVD		
	2D optimization/depth (cm)	Pen/2.0	Pen/3.1		Pen/3.1		
	Color optimization/PRF (Hz)	Low/393	Low/2315		Low/2315		
	Color box position/size	Def/def	Bottom/short-narrow		Bottom/short-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 10-43: Transducer model: L38xi Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.3	2.6		3.7		(b)
Index component value			2.6	1.8	2.6	3.7	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.59					
	P (mW)		114.5		114.5		#
	$P_{1 \times 1}$ (mW)		114.5		114.5		
	z_s (cm)			1.2			
	z_b (cm)					1.2	
	z_{MI} (cm)	0.7					
	$z_{pii,\alpha}$ (cm)	0.7					
	f_{awf} (MHz)	4.06	4.78		4.78		#
Other information	p_{rr} (Hz)	1008					
	s_{rr} (Hz)	—					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	32.3					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	399.8					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	495.1					
	p_r at z_{pii} (MPa)	2.86					
Operating controls	Exam type	Art	Nrv		Nrv		
	Sample volume size (mm)	1	1		1		
	Sample volume position	Zone 0	Zone 7		Zone 7		
	PRF (Hz)	1008	10417		10417		

(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 10-44: Transducer model: P10x Operating mode: Color

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		(a)	(a)		(a)		1.1
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	#					
	P (mW)		#		#		42.2
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	#					
	$z_{pii,\alpha}$ (cm)	#					
	f_{awf} (MHz)	#	#		#		3.89
Other information	p_{rr} (Hz)	#					
	s_{rr} (Hz)	#					
	η_{pps}	#					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	#					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	#					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	#					
p_r at z_{pii} (MPa)	#						
Operating controls	Exam type						Crd
	Mode						CVD
	2D optimization/depth (cm)/sector width						Pen/8.9/narrow
	Color optimization/PRF (Hz)						Low/2033
	Color box position/size						Top/short-wide

(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 10-45: Transducer model: P10x Operating mode: CW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		(a)	(a)		1.8		1.7
Index component value			#	#	0.7	1.8	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	#					
	P (mW)		#		34.8		25.7
	$P_{1 \times 1}$ (mW)		#		34.8		
	z_s (cm)			#			
	z_b (cm)					0.70	
	z_{MI} (cm)	#					
	$z_{pii,\alpha}$ (cm)	#					
	f_{awf} (MHz)	#	#		4.00		4.00
Other information	pr (Hz)	#					
	srr (Hz)	#					
	η_{pps}	#					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	#					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	#					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	#					
	p_r at z_{pii} (MPa)	#					
Operating controls	Exam type				Crd		Crd
	Sample volume position				Zone 3		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.

Table 10-46: Transducer model: P10x Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.0	1.1		1.9		1.5
Index component value			1.1	0.6	0.6	1.9	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.92					
	P (mW)		34.4		31.9		26.9
	$P_{1 \times 1}$ (mW)		34.4		31.9		
	z_s (cm)			1.4			
	z_b (cm)					0.90	
	z_{MI} (cm)	2.1					
	$z_{pii,\alpha}$ (cm)	2.1					
	f_{awf} (MHz)	3.87	6.86		3.84		3.86
Other information	p_{rr} (Hz)	1562					
	s_{rr} (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	200					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	400.0					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	729.9					
	p_r at z_{pii} (MPa)	2.54					
Operating controls	Exam type	Crd	Crd		Abd		Crd
	Sample volume size (mm)	1	7		12		1
	Sample volume position	Zone 2	Zone 6		Zone 1		Zone 0
	PRF (Hz)	1562	1008		1953		15625
	TDI	Off	On		Off		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 10-47: Transducer model: rC60xi Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.5	(a)		(a)		(b)
Index component value			#	#	#	#	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.31					
	P (mW)		#		#		#
	$P_{1 \times 1}$ (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	4.3					
	$z_{pii,\alpha}$ (cm)	4.3					
	f_{awf} (MHz)	2.36	#		#		#
Other information	pr (Hz)	3584					
	srr (Hz)	28.0					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	356					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	24.1					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	44.9					
	p_r at z_{pii} (MPa)	3.29					
Operating controls	Exam type	Abd					
	Optimization	Res					
	Depth (cm)	11					
	MB (multi beam)	Off					
	THI	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 10-48: Transducer model: rC60xi Operating mode: M mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.3	(a)		1.0		(b)
Index component value			#	#	0.36	1.00	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.18					
	P (mW)		#		69.8		#
	$P_{1 \times 1}$ (mW)		#		25.9		
	z_s (cm)			#			
	z_b (cm)					4.2	
	z_{MI} (cm)	4.3					
	$z_{pii,\alpha}$ (cm)	4.3					
	f_{awf} (MHz)	2.66	#		2.89		#
Other information	p_{rr} (Hz)	800					
	s_{rr} (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	290					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	144.2					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	328.2					
	p_r at z_{pii} (MPa)	3.25					
Operating controls	Exam type	Abd			Msk		
	Optimization	Pen			Pen		
	Depth (cm)	6.6			9.2		
	THI	Off			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 10-49: Transducer model: rC60xi Operating mode: Color/CPD

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.5	1.2		1.2		(b)
Index component value			1.2	1.2	1.2	1.2	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.21					
	P (mW)		185.8		185.8		#
	$P_{1 \times 1}$ (mW)		107.5		107.5		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	4.3					
	$z_{pii,\alpha}$ (cm)	4.3					
	f_{awf} (MHz)	2.22	2.21		2.21		#
Other information	p_{rr} (Hz)	1265					
	s_{rr} (Hz)	9.89					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	342					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	8.9					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	15.8					
	p_r at z_{pii} (MPa)	3.07					
Operating controls	Exam type	Abd	Abd		Abd		
	Mode	CVD	CVD		CVD		
	2D optimization/depth (cm)/THI	Gen/11 / On	Gen/4.7 /Off		Gen/4.7 /Off		
	Color optimization/PRF (Hz)	Low/342	High/3125		High/3125		
	Color box position/size	Bottom/ tall-narrow	Bottom/tall-narrow		Bottom/tall-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 10-50: Transducer model: rC60xi Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.2	2.0		4.0		(b)
Index component value			0.7	2.0	0.8	4.0	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.73					
	P (mW)		386.5		291.8		#
	$P_{1 \times 1}$ (mW)		67.5		74.2		
	z_s (cm)			4.0			
	z_b (cm)					3.6	
	z_{MI} (cm)	4.5					
	$z_{pii,\alpha}$ (cm)	4.5					
	f_{awf} (MHz)	2.2	2.23		2.23		#
Other information	prr (Hz)	1302					
	srr (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	267					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	399.7					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	793.3					
	p_r at z_{pii} (MPa)	2.43					
Operating controls	Exam type	Abd	Abd		Abd		
	Sample volume size (mm)	3	7		7		
	Sample volume position	Zone 3	Zone 6		Zone 5		
	PRF (Hz)	1302	2604		2604		

(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 10-51: Transducer model: rP19x (Orbital use) Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.17	0.03		0.03		0.07
Index component value			0.03	0.03	0.03	0.03	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.25					
	P (mW)		4.4		4.4		4.7
	$P_{1 \times 1}$ (mW)		2.9		2.9		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	3.4					
	$z_{pii,\alpha}$ (cm)	3.4					
	f_{awf} (MHz)	2.06	2.06		2.06		1.90
Other information	pr (Hz)	6413					
	srr (Hz)	15.6					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	4.1					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	0.4					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	0.6					
	p_r at z_{pii} (MPa)	0.31					
Operating controls	Exam type	Orb	Orb		Orb		Orb
	Optimization	Res	Res		Res		Gen
	Depth (cm)	4.7	4.7		4.7		16
	MB	Off	Off		Off		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 10-52: Transducer model: rP19x (Orbital use) Operating mode: M mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.17	0.009		0.020		0.021
Index component value			0.006	0.009	0.006	0.020	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.25					
	P (mW)		1.34		1.34		1.34
	$P_{1 \times 1}$ (mW)		0.67		0.67		
	z_s (cm)			2.5			
	z_b (cm)					3.15	
	z_{MI} (cm)	3.4					
	$z_{pii,\alpha}$ (cm)	3.4					
	f_{awf} (MHz)	2.06	1.83		1.83		1.83
Other information	prr (Hz)	800					
	srr (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	4.05					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	1.7					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	2.7					
	p_r at z_{pii} (MPa)	0.31					
Operating controls	Exam type	Orb	Orb		Orb		Orb
	Optimization	Res	Gen		Gen		Gen
	Depth (cm)	4.7	35		35		35

(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 10-53: Transducer model: rP19x (Orbital use) Operating mode: Color/CPD

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.17	0.09		0.09		0.23
Index component value			0.09	0.09	0.09	0.09	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.25					
	P (mW)		15.47		15.47		15.50
	$P_{1 \times 1}$ (mW)		9.50		9.50		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	0.7					
	$z_{pii,\alpha}$ (cm)	0.7					
	f_{awf} (MHz)	2.14	2.11		2.11		2.11
Other information	prr (Hz)	5443					
	srr (Hz)	15.9					
	η_{pps}	16					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	1.82					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	3.2					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	3.5					
	p_r at z_{pii} (MPa)	0.26					
Operating controls	Exam type	Orb	Orb		Orb		Orb
	Mode	CVD	CVD		CVD		CVD
	2D optimization/depth (cm)	Gen/4.7	Gen/24		Gen/24		Gen/24
	Color optimization/PRF (Hz)	Low/1157	Low/3125		Low/3125		Low/3125
	Color box position/size	Def/def	Top/short-wide		Top/short-wide		Top/short-wide

(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 10-54: Transducer model: rP19x (Orbital use) Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		0.18	0.27		0.59		0.57
Index component value			0.19	0.27	0.18	0.59	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	0.27					
	P (mW)		37.4		35.3		37.4
	$P_{1 \times 1}$ (mW)		17.5		17.0		
	z_s (cm)			2.5			
	z_b (cm)					3.35	
	z_{MI} (cm)	3.5					
	$z_{pii,\alpha}$ (cm)	3.5					
	f_{awf} (MHz)	2.23	2.23		2.23		2.23
Other information	prr (Hz)	1953					
	srr (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	2.49					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	28.9					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	69.3					
	p_r at z_{pii} (MPa)	0.36					
Operating controls	Exam type	Orb	Orb		Orb		Orb
	Sample volume size (mm)	5	14		14		14
	Sample volume position	Zone 6	Zone 7		Zone 5		Zone 7
	PRF (Hz)	1953	1953		1953		1953

(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 10-55: Transducer model: rP19x Operating mode: 2D

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.5	1.0		1.0		2.7
Index component value			1.0	1.0	1.0	1.0	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.1					
	P (mW)		152.6		152.6		177.8
	$P_{1 \times 1}$ (mW)		96.1		96.1		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	4.8					
	$z_{pii,\alpha}$ (cm)	4.8					
	f_{awf} (MHz)	1.99	2.08		2.08		1.53
Other information	pr (Hz)	6186					
	srr (Hz)	48.3					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	184					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	25.4					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	38.6					
	p_r at z_{pii} (MPa)	2.92					
Operating controls	Exam type	Abd	Crd		Crd		Crd
	Optimization	Gen	Res		Res		Pen
	Depth (cm)	10	10		10		4.7
	MB/THI	Off/Off	Off/On		Off/On		Off/On
	Sector width	N/A	Narrow		Narrow		N/A

(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 10-56: Transducer model: rP19x Operating mode: M mode

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.5	(a)		1.7		1.0
Index component value			#	#	0.2	1.7	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.1					
	P (mW)		#		55.0		62.1
	$P_{1 \times 1}$ (mW)		#		28.5		
	z_s (cm)			#			
	z_b (cm)					4.33	
	z_{MI} (cm)	4.8					
	$z_{pii,\alpha}$ (cm)	4.8					
	f_{awf} (MHz)	1.99		#		1.81	1.77
Other information	p_{rr} (Hz)	800					
	s_{rr} (Hz)	—					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	184					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	73.5					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	140.8					
	p_r at z_{pii} (MPa)	2.92					
Operating controls	Exam type	TCD			Abd		Abd
	Optimization	Gen			Res		Res
	Depth (cm)	7.5			10		16
	THI	Off			On		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 10-57: Transducer model: rP19x Operating mode: Color/CPD

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.5	1.2		1.2		2.5
Index component value			1.2	1.2	1.2	1.2	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.1					
	P (mW)		128.0		128.0		170.5
	$P_{1 \times 1}$ (mW)		115.6		115.6		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	4.8					
	$z_{pii,\alpha}$ (cm)	4.8					
	f_{awf} (MHz)	1.99	2.14		2.14		2.12
Other information	p_{rr} (Hz)	505					
	s_{rr} (Hz)	7.9					
	η_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	184					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	2.1					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	3.2					
	p_r at z_{pii} (MPa)	2.92					
Operating controls	Exam type	Abd	TCD		TCD		Crd
	Mode/THI	CVD/Off	CVD/Off		CVD/Off		CVD/On
	2D optimization/depth (cm)/sector width	Gen/10/N/A	Pen/7.5 /N/A		Pen/7.5 /N/A		Gen/16/narrow
	Color optimization/PRF (Hz)	Low/300	Low/3125		Low/3125		High/5208
	Color box position/size	Def/def	Def/narrow		Def/narrow		Def/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 10-58: Transducer model: rP19x Operating mode: CW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		(a)	1.2		4.0		4.0
Index component value			1.2	1.1	1.2	4.0	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	#					
	P (mW)		125.4		125.4		125.4
	$P_{1 \times 1}$ (mW)		125.4		125.4		
	z_s (cm)			0.9			
	z_b (cm)					0.9	
	z_{MI} (cm)	#					
	$z_{pii,\alpha}$ (cm)	#					
	f_{awf} (MHz)	#	2.00		2.00		2.00
Other information	prr (Hz)	#					
	srr (Hz)	#					
	η_{pps}	#					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	#					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	#					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	#					
	p_r at z_{pii} (MPa)	#					
Operating controls	Exam type		Crd		Crd		Crd
	Sample volume position		Zone 0		Zone 0		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.

Table 10-59: Transducer model: rP19x Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		1.3	1.8		4.0		3.9
Index component value			1.3	1.8	1.2	4.0	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	1.94					
	P (mW)		253.7		240.2		251.1
	$P_{1 \times 1}$ (mW)		118.6		116.0		
	z_s (cm)			2.5			
	z_b (cm)					3.35	
	z_{MI} (cm)	3.0					
	$z_{pii,\alpha}$ (cm)	3.0					
	f_{avf} (MHz)	2.14		2.23		2.23	2.10
Other information	p_{rr} (Hz)	1562					
	s_{rr} (Hz)	—					
	n_{pps}	1					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	180					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	374.9					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	594.7					
	p_r at z_{pii} (MPa)	2.42					
Operating controls	Exam type	Crd	Crd		Crd		Crd
	Sample volume size (mm)	1	12		1		1
	Sample volume position	Zone 1	Zone 7		Zone 5		Zone 5
	PRF (Hz)	1562	1562		39062		39062
	TDI	Off	Off		Off		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 10-60: Transducer model: TEExi Operating mode: CW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		(a)	(a)		1.7		(b)
Index component value			#	#	0.7	1.7	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	#					
	P (mW)		#		34.4		#
	$P_{1 \times 1}$ (mW)		#		34.4		
	z_s (cm)			#			
	z_b (cm)					1.10	
	z_{MI} (cm)	#					
	$z_{pii,\alpha}$ (cm)	#					
	f_{awf} (MHz)	#	#		4.00		#
Other information	prr (Hz)	#					
	srr (Hz)	#					
	η_{pps}	#					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm ²)	#					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm ²)	#					
	I_{spta} at z_{pii} or z_{sii} (mW/cm ²)	#					
	p_r at z_{pii} (MPa)	#					
Operating controls	Exam type				Crd		
	Sample volume				Zone 2		

(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 10-61: Transducer model: TEExi Operating mode: PW Doppler

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	At surface
Maximum index value		(a)	(a)		1.4		(b)
Index component value			#	#	0.7	1.4	
Acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	#					
	P (mW)		#		35.8		#
	$P_{1 \times 1}$ (mW)		#		35.8		
	z_s (cm)			#			
	z_b (cm)					2.57	
	z_{MI} (cm)	#					
	$z_{pii,\alpha}$ (cm)	#					
	f_{awf} (MHz)	#	#		3.81		#
Other information	prr (Hz)	#					
	srr (Hz)	#					
	η_{pps}	#					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	#					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	#					
	I_{spta} at z_{pii} or z_{sii} (mW/cm^2)	#					
	p_r at z_{pii} (MPa)	#					
Operating controls	Exam type				Crd		
	Sample volume size (mm)				1		
	Sample volume position				Zone 3		
	PRF (Hz)				2604		

(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.

Terms used in the acoustic output tables

Table 10-62: Terms used in the acoustic output tables

Term	Definition
α	Attenuation coefficient used for derating. Equal to 0.3 dB/cm/MHz ² .
f_{awf}	Acoustic working frequency.
$I_{pa,\alpha}$	Attenuated pulse-average intensity.
I_{spta}	Spatial-peak temporal-average intensity.
$I_{spta,\alpha}$	Attenuated spatial-peak temporal-average intensity.
MI	Mechanical index.
P	Output power.
$P_{1 \times 1}$	Bounded-square output power.
$p_{r,\alpha}$	Attenuated peak-rarefactional acoustic pressure.
p_r	Peak-rarefactional acoustic pressure.
pii	Pulse-intensity integral.
pii,α	Attenuated pulse-intensity integral.
n_{pps}	Number of pulses per ultrasonic scan line.
prr	Pulse repetition rate.
srr	Scan repetition rate.
TI	Thermal index.
TIB	Bone thermal index.
TIC	Cranial-bone thermal index.
TIS	Soft-tissue thermal index.
z_b	Depth for TIB.
z_{MI}	Depth for mechanical index.
z_{pii}	Depth for peak pulse-intensity integral.
$z_{pii,\alpha}$	Depth for peak attenuated pulse-intensity integral.

Table 10-62: Terms used in the acoustic output tables

Term	Definition
Z_{sij}	Depth for peak sum of pulse-intensity integrals.
$Z_{sij,\alpha}$	Depth for peak sum of attenuated pulse-intensity integrals.
Z_s	Depth for TIS.

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 10-63: Acoustic measurement precision and uncertainty

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

IT Network

Functions

This device can be connected to an IT network to perform the following functions:

- ▶ Storing the examination data (static images, clips) acquired by this device in a Picture Archiving and Communication System (PACS) by DICOM communication.
- ▶ Querying examination orders from the Modality Worklist (MWL) server by DICOM communication and starting them.
- ▶ Uploading images to the SonoSite Patient Data Archival Software (PDAS) or SiteLink Image Manager.
- ▶ Setting the time of this device by interrogating the network time service.
- ▶ Communicating procedure status via the Modality Performed Procedure Step (MPPS) service.
- ▶ Requesting transfer of responsibility for image ownership to another system via the Storage Commitment service.

Network for connecting the device

To ensure safety, use an IT network that is isolated from the external environment by a firewall.

Specifications for the connection

Hardware specification

- ▶ 802.11 b/g/n
- ▶ Ethernet 100BASE-TX/10BASE-T using RJ45 port with patch cable

Software specifications

- ▶ This device is connected to PACS and MWL by the DICOM standard. Refer to the DICOM Conformance Statement of this device for details.
- ▶ When available, this device connects to the network time server at startup.

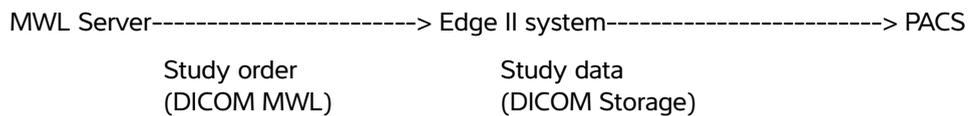
- ▶ The system conforms to the DICOM standard as specified in the *SonoSite Edge II, SonoSite SII DICOM Conformance Statement*, available at www.sonosite.com. This statement provides information about the purpose, characteristics, configuration, and specifications of the network connections supported by the system.

Security

- ▶ The port for DICOM communication (specified by the user in the system settings; typically port 104, 2762, or 11112) is used for outgoing communication to the network.
- ▶ Anti-virus software is not installed on this device.
- ▶ This device has a single configurable listening port for the purposes of DICOM Echo and Storage Commitment.

Data flow

DICOM



Please refer to the *SonoSite Edge II, SonoSite SII DICOM Conformance Statement (D18493)* for details.

Caution

- 1 Connection of equipment to an IT network that includes other systems, could result in previously unidentified risks to patients, operators or third parties. Before connecting the equipment to an uncontrolled IT Network, make sure that all potential risks resulting from such connections, were identified and evaluated, and suitable countermeasures were put in place. IEC 80001-1:2010 provides guidance for addressing these risks.
- 2 When a setting of the IT network to which this device is connected has been changed, check that the change does not affect this device and take measures if necessary. Changes to the IT network include:
 - ▶ Changes in network configuration (IP address, router etc.)
 - ▶ Connection of additional items
 - ▶ Disconnection of items
 - ▶ Update of equipment
 - ▶ Upgrade of equipment

Any changes to the IT network could introduce new risks requiring additional evaluation to be performed as per item 1 above.

Glossary

Terms

For ultrasound terms not included in this glossary, refer to *Recommended Ultrasound Terminology, Third Edition*, published in 2011 by the American Institute of Ultrasound in Medicine (AIUM).

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, rC60xi.
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.
linear array transducer	Identified by the letter L (linear) and a number (38). The number corresponds to the length of the array expressed in millimeters. The transducer elements are electrically configured to control the characteristics and direction of the acoustic beam. For example, L38xi.
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 10, “Acoustic Output,” for a more complete description of MI.
MI/TI	Refer to <i>mechanical index (MI)</i> and <i>thermal index (TI)</i> .
phased array transducer	A transducer designed primarily for cardiac scanning. Forms a sector image by electronically steering the beam direction and focus. For example, rP19x.
skinline	A depth on the display that corresponds to the skin/transducer interface.
SonoMB	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.
Tissue Doppler Imaging (TDI)	A pulsed wave Doppler technique used to detect myocardial motion.

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 10, “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 Harmonic Imaging (THI)	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.

Abbreviations

Table 1: Abbreviations in user interface

Abbreviation	Definition
+/×	“+” Caliper/“×” Caliper Ratio
A	“A” Wave Peak Velocity
A PG	“A” Wave Peak Pressure Gradient
A2Cd	Apical 2 Chamber diastolic
A2Cs	Apical 2 Chamber systolic
A4Cd	Apical 4 Chamber diastolic
A4Cs	Apical 4 Chamber systolic
AAA	Abdominal Aortic Aneurysm

Table 1: Abbreviations in user interface (continued)

Abbreviation	Definition
AAo	Ascending Aorta
Abd	Abdomen
abs	Absolute value
AC	Abdominal Circumference
ACA	Anterior Cerebral Artery
ACC	Acceleration Index
ACoA	Anterior Communicating Artery
ACS	Aortic Valve Cusp Separation
Adur	“A” wave duration
AFI	Amniotic Fluid Index
AI	Aortic Insufficiency
AI PHT	Aortic Insufficiency Pressure Half Time
AL	Atlas Loop
Ann D	Annulus Diameter
ANT F	Anterior Far
ANT N	Anterior Near
Ao	Aorta
AoD	Aortic Root Diameter
Apical	Apical View
APTD	Anteroposterior Trunk Diameter
Art	Arterial
AT	Acceleration (Deceleration) Time
AUA	Average Ultrasound Age Calculated by averaging the individual ultrasound ages for the fetal biometry measurements performed during the exam. The measurements used to determine the AUA are based on the selected OB calculation authors.

Table 1: Abbreviations in user interface (continued)

Abbreviation	Definition
AV	Aortic Valve
AV Area	Aortic Valve Area
AVA	Aortic Valve Area
BA	Basilar Artery
Bifur	Bifurcation
BP	Blood Pressure
BPD	Biparietal Diameter
BPM	Beats per Minute
Bre	Breast
BSA	Body Surface Area
CCA	Common Carotid Artery
CI	Cardiac Index
CM	Cisterna Magna
CO	Cardiac Output
CPD	Color Power Doppler
Crd	Cardiac
CRL	Crown Rump Length
CSA	Cross Sectional Area
CVD	Color Velocity Doppler
CW	Continuous Wave Doppler
CxLen	Cervix Length
D	Diameter
D Apical	Distance Apical
DCCA	Distal Common Carotid Artery
DECA	Distal External Carotid Artery

Table 1: Abbreviations in user interface (continued)

Abbreviation	Definition
Decel	Deceleration time
DICA	Distal Internal Carotid Artery
Dist	Distal
dP:dT	Delta Pressure: Delta Time
E	"E" Wave Peak Velocity
E PG	"E" Wave Peak Pressure Gradient
E:A	E:A Ratio
E/e'	E velocity = Mitral Valve E velocity divided by the annular e' velocity
ECA	External Carotid Artery
ECG	Electrocardiogram
ECICA	Extracranial Internal Carotid Artery
ECVA	Extracranial Vertebral Artery
EDD	Estimated Date of Delivery
EDD by AUA	Estimated Date of Delivery by Average Ultrasound Age The estimated date of delivery calculated from the measurements performed during the exam.
EDD by LMP	Estimated Date of Delivery by Last Menstrual Period The due date calculated from the user-entered LMP.
EDV	End Diastolic Velocity
EF	Ejection Fraction
EF:SLOPE	E-F Slope
EFW	Estimated Fetal Weight Calculated from the measurements performed during the exam. The measurements used to determine EFW are defined by the currently selected EFW calculation author.
Endo	Endocardial
Epi	Epicardial
EPSS	"E" Point Septal Separation

Table 1: Abbreviations in user interface (continued)

Abbreviation	Definition
Estab. DD	Established Due Date A user-entered due date based on previous exam data or other available information. The LMP is derived from the Established Due Date and is listed in the patient report as LMPd.
ET	Elapsed Time
FAC	Fractional Area Change
FH	Femoral Head
FHR	Fetal Heart Rate
FL	Femur Length
FM	Foramen Magnum (same as SO)
FS	Fractional Shortening
FTA	Fetal Trunk Area
GA	Gestational Age
GA by LMP	Gestational Age by Last Menstrual Period The fetal age calculated using the date of the Last Menstrual Period (LMP).
GA by LMPd	Gestational Age by derived Last Menstrual Period The fetal age calculated using the Last Menstrual Period (LMPd) derived from the Estab. DD.
Gate	Depth of Doppler Gate
GS	Gestational Sac
Gyn	Gynecology
HC	Head Circumference
HL	Humerus Length
HR	Heart Rate
ICA	Internal Carotid Artery
IVC	Inferior Vena Cava
IVRT	Iso Volumic Relaxation Time

Table 1: Abbreviations in user interface (continued)

Abbreviation	Definition
IVS	Interventricular Septum
IVSd	Interventricular Septum Diastolic
IVSFT	Interventricular Septum Fractional Thickening
IVSs	Interventricular Septum Systolic
LA	Left Atrium
LA/Ao	Left Atrium/Aorta Ratio
LAT F	Lateral Far
LAT N	Lateral Near
Lat V	Lateral Ventricle
LMP	Last Menstrual Period
LMP	Last Menstrual Period The first day of the last menstrual period. Used to calculate gestational age and EDD.
LMPd	derived Last Menstrual Period Calculated from the user-entered Estab. DD.
LV	Left Ventricular
LV Area	Left Ventricular Area
LV mass	Left Ventricular mass
LV Volume	Left Ventricular Volume
LVd	Left Ventricular diastolic
LVD	Left Ventricular Dimension
LVDd	Left Ventricular Dimension Diastolic
LVDFS	Left Ventricular Dimension Fractional Shortening
LVDs	Left Ventricular Dimension Systolic
LVEDV	Left Ventricular End Diastolic Volume
LVESV	Left Ventricular End Systolic Volume
LVET	Left Ventricular Ejection Time

Table 1: Abbreviations in user interface (continued)

Abbreviation	Definition
LVO	Left Ventricular Opacification
LVOT	Left Ventricular Outflow Tract
LVOT Area	Left Ventricular Outflow Tract Area
LVOT D	Left Ventricular Outflow Tract Diameter
LVOT VTI	Left Ventricular Outflow Tract Velocity Time Integral
LVPW	Left Ventricular Posterior Wall
LVPWd	Left Ventricular Posterior Wall Diastolic
LVPWFT	Left Ventricular Posterior Wall Fractional Thickening
LVPWs	Left Ventricular Posterior Wall Systolic
LVs	Left Ventricular systolic
MB	SonoMB technology
MCA	Middle Cerebral Artery
MCCA	Mid Common Carotid Artery
MDV	Minimum diastolic velocity
MECA	Mid External Carotid Artery
MI	Mechanical Index
MICA	Mid Internal Carotid Artery
Mid	Middle
MM	M Mode
MR PISA	Mitral Regurgitation Proximal Iso Velocity Surface Area
MR/VTI	Mitral Regurgitation/Velocity Time Integral
Msk	Musculoskeletal
MV	Mitral Valve
MV Area	Mitral Valve Area
MV Regurgitant Fraction	Mitral Valve Regurgitant Fraction

Table 1: Abbreviations in user interface (continued)

Abbreviation	Definition
MV Regurgitant Volume	Mitral Valve Regurgitant Volume
MV/VTI	Mitral Valve/Velocity Time Integral
MVA	Mitral Valve Area
MV ERO	Mitral Valve Effective Regurgitant Orifice
MV PISA Area	Mitral Valve Proximal Isovelocity Surface Area
MV Rate	Mitral Valve Rate
Neo	Neonatal
Nrv	Nerve
NST	Non-stress test
NTSC	National Television Standards Committee
OA	Ophthalmic Artery
OB	Obstetrical
OFD	Occipital Frontal Diameter
Oph	Ophthalmic
Orb	Orbital
PAL	Phase Alternating Line
PCAp	Posterior Cerebral Artery Peak
PCCA	Proximal Common Carotid Artery
PCoA	Posterior Communicating Artery
PECA	Proximal External Carotid Artery
PGmax	Maximum Pressure Gradient
PGmean	Mean Pressure Gradient
PGr	Pressure Gradient
PHT	Pressure Half Time
PI	Pulsatility Index

Table 1: Abbreviations in user interface (continued)

Abbreviation	Definition
PICA	Proximal Internal Carotid Artery
PISA	Proximal Isovelocity Surface Area
Plaq	Plaque
POST F	Posterior Far
POST N	Posterior Near
PRF	Pulse Repetition Frequency
Pro	Prostate
Prox	Proximal
PSV	Peak Systolic Velocity
PV	Pulmonic Valve
P. Vein	Pulmonary Vein
PW	Pulsed Wave Doppler
Qp/Qs	Pulmonary blood flow divided by systemic blood flow
RA	Right Atrial (pressure)
RI	Resistive Index
RVD	Right Ventricular Dimension
RVDd	Right Ventricular Dimension Diastolic
RVDs	Right Ventricular Dimension Systolic
RVOT D	Right Ventricular Outflow Tract Diameter
RVOT VTI	Right Ventricular Outflow Tract Velocity Time Integral
RVSP	Right Ventricular Systolic Pressure
RVW	Right Ventricular Free Wall
RVWd	Right Ventricular Free Wall Diastolic
RVWs	Right Ventricular Free Wall Systolic
S'	Tricuspid Lateral Annular Systolic Velocity (TDI measurement)

Table 1: Abbreviations in user interface (continued)

Abbreviation	Definition
S/D	Systolic/Diastolic Ratio
SI	Stroke Index
Siphon	Siphon (internal carotid artery)
SM	Submandibular
SmP	Small Parts
SNP	Steep Needle Profiling
SO	Suboccipital
Spn	Spine
Sup	Superficial
SV	Stroke Volume
TAM	Time Average Mean
TAP	Time Average Peak
TAPSE	Tricuspid Annular Plane Systolic Excursion: M Mode distance measurement of systolic excursion of the right ventricle
TCD	Trans-cerebellum Diameter (OB measurement) Transcranial Doppler (exam type)
TDI	Tissue Doppler Imaging
THI	Tissue Harmonic Imaging
TI	Thermal Index
TICA	Terminal Internal Carotid Artery
TO	Transorbital
TRmax	Tricuspid Regurgitation (peak velocity)
TT	Transtemporal
TTD	Transverse Trunk Diameter
TV	Tricuspid Valve
TVA	Tricuspid Valve Area

Table 1: Abbreviations in user interface (continued)

Abbreviation	Definition
UA	Ultrasound Age Calculated on the mean measurements taken for a particular fetal biometry.
Umb A	Umbilical Artery
VA	Vertebral Artery
VArty	Vertebral Artery
Vas	Vascular
Ven	Venous
VF	Volume Flow
Vmax	Peak Velocity
Vmean	Mean Velocity
Vol	Volume
VTI	Velocity Time Integral
YS	Yolk Sac

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