FUJIFILM
Value from Innovation

SONOSITE SII

USER GUIDE

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

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Chapter 1

Introduction

This *SonoSite SII Ultrasound System User Guide* provides information on preparing and using the SonoSite SII 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
Centerline	Clarified centerline availability in **Cleaning and disinfecting**
Labeling symbols updated	Updated the **Labeling symbols** to comply with new definitions and regulations
Incorporated user guide supplement and errata	▸ P23649-01 ▸ 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 9-22 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 SII ultrasound system is a portable, software-controlled device using all-digital architecture. The SonoSite SII includes the following configurations:

- S-Total
- S-Vascular
- S-Vet

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 7-2. On occasion, a software upgrade may be required. FUJIFILM SonoSite provides a USB device containing the software. One USB device can upgrade multiple systems.

Basic steps

1. Turn the system on. For power switch location, refer to **Figure 2-1** on page 2-2.
2. Attach a transducer.
3. Tap **Patient**, and then tap **Information**.
4. Complete the patient information form.

   If all imaging modes are licensed, press **Mode**, and select an imaging mode.

   Note By default, the system is in 2D imaging.

Preparing the system

Components and connectors

The back of the system has compartments for the battery and two transducers as well as connectors for USB devices, power cord, network cable, and more. Refer to **Figure 2–1**.

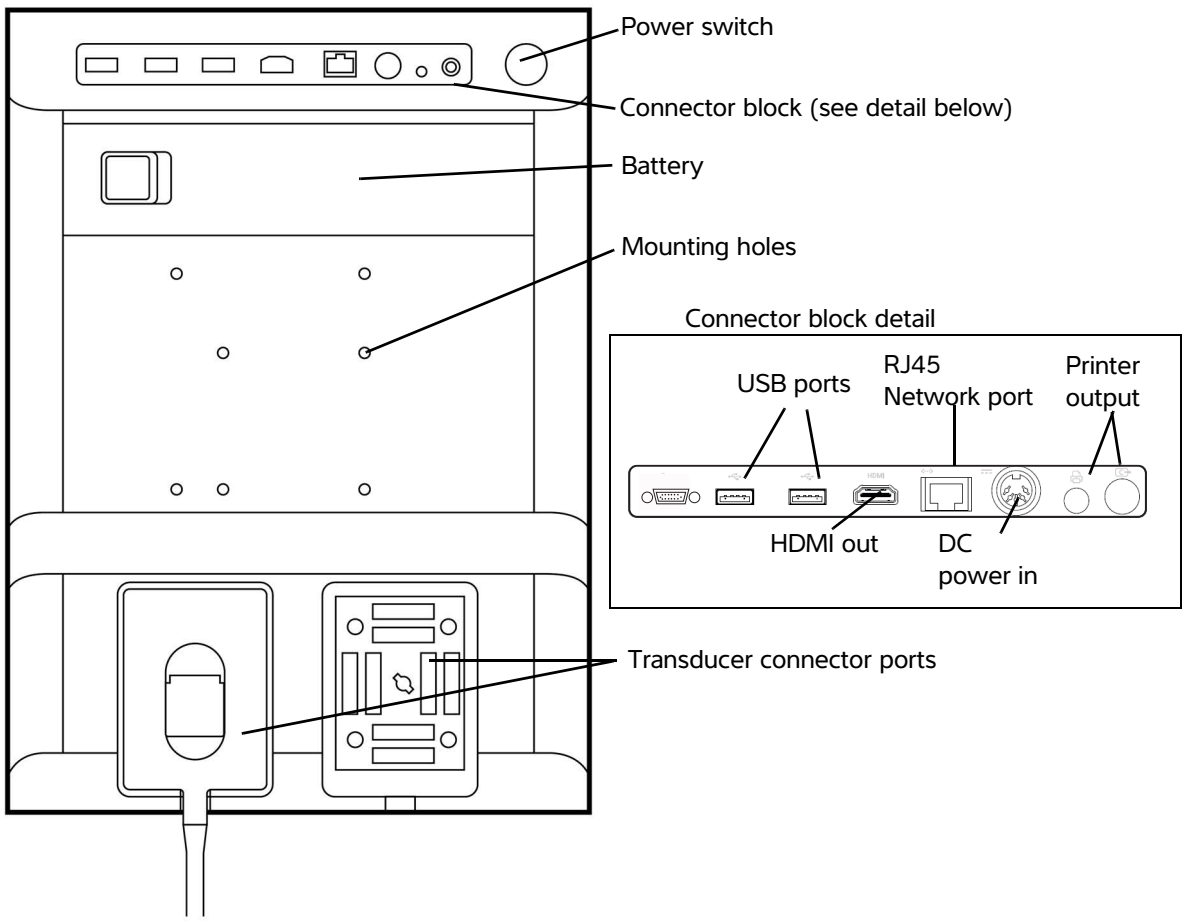


Figure 2–1 System Back

Each connector has a symbol that describes its use.

	USB
	DC input
	Composite video out
	Print control
	Ethernet
HDMI	HDMI video out

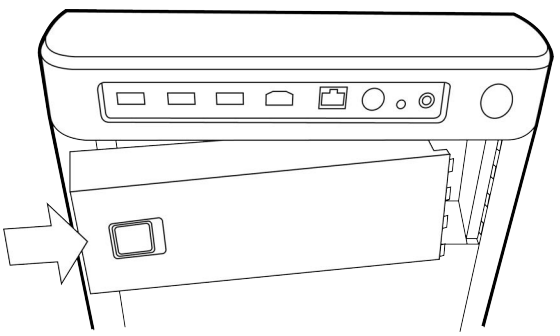
Installing or removing the battery

WARNINGS

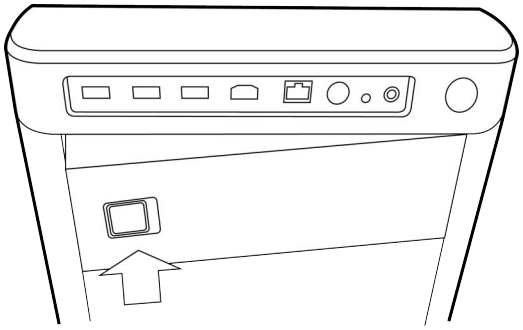
- To avoid injury to the operator and to prevent damage to the ultrasound system, inspect the battery for leaks prior to installing.
- To avoid data loss and to conduct a safe system shutdown, always keep a battery in the system.

To install the battery

1. Ensure the ultrasound system is turned off.
2. Disconnect the power supply.
3. At the back of the system, slide the four prongs on the end of the battery into the slots on the right side of the battery compartment.



4 Push the battery into the battery compartment and press until the latch engages.



To remove the battery

1 Ensure the ultrasound system is turned off.

2 Disconnect the power supply.

3 Slide the locking lever on the left side of the battery, and lift the battery up.

Using AC power and charging the battery

The battery charges when the system is connected to the AC power supply. A fully discharged battery recharges in less than five hours.

When the system is connected to AC power, the system can operate and charge the battery at the same time.

Depending on the imaging mode and the display brightness, the system can run on battery power for up to two hours. When running on battery power, the system may not restart if the battery charge is low. If the system will not start due to a low battery condition, connect the system to AC power.

WARNINGS

- Verify that the hospital supply voltage corresponds to the power supply voltage range. Refer to **"Electrical specifications"** on page 9-31.
- 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

> **Caution** Be sure to keep the battery inserted in the system even if the system is connected to the AC power supply.

1 Connect the DC power cable from the power supply to the power connector on the system. Refer to **Figure 2-1** on page 2-2.

2 Connect the AC power cord to the power supply, and then plug it in 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 stand base.

Turning the system on or off

> **Caution** Do not use the system if an error message appears on the display. Note the error code and turn off the system. Call FUJIFILM SonoSite or your local representative.

To turn the system on or off

❖ Press the power switch. Refer to **Figure 2-1** on page 2-2.

To wake up the system

To conserve battery life while the system is on, the system goes into sleep mode if untouched for a preset time. To adjust the time for sleep delay, refer to **"Audio, Battery settings"** on page 3-7.

❖ Press a key, or touch the touchpad.

Connecting transducers

WARNING To avoid injury to the patient, do not place the connector on the patient.

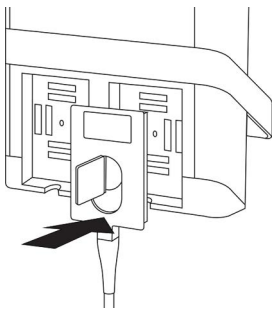
Caution To avoid damaging the transducer connector, do not allow foreign material in the connector.

To connect a transducer

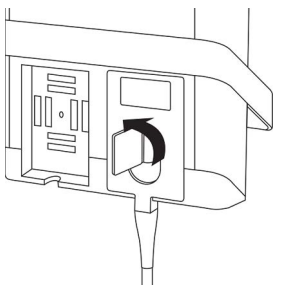
1 Pull the transducer latch up, and rotate it clockwise.

2 Align the transducer connector with the connector on the back of the system.

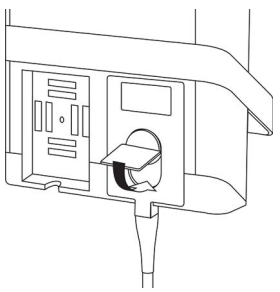
3 Insert the transducer connector into one of the transducer ports on the system.



4 Turn the latch counterclockwise.

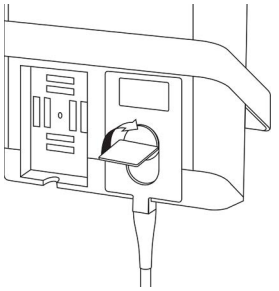


5 Press the latch down, securing the transducer connector to the system.



To remove a transducer

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



2 Pull the transducer connector away from the system.

Inserting and removing USB storage devices

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. Although the images and clips cannot be viewed from a USB storage device on the ultrasound system, you can remove the USB storage device and view the images on your PC.

You can also import and export user accounts and the Event log using a USB storage device.

There are three USB ports located on the back of the system near the top. For additional USB ports, you can connect a USB hub into any USB port.

WARNINGS 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.

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.

To insert a USB storage device

Insert the USB storage device into a USB port on the system. Refer to **Figure 2–1** on page 2–2. The USB storage device is ready when the USB icon appears.

To remove a USB storage device

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

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

System controls

1	Control knobs	Turn to adjust gain, depth, cine buffer, brightness, and more, depending on context. Current functions appear on-screen above the knobs.
2	Freeze key	Press and hold to freeze or unfreeze the image.
3	Touchpad	When the touchpad is lit, use it to control items displayed on the screen. Double-tap the touchpad to switch between functions.
4	Touchpad key	Works in conjunction with the touchpad. Tap to activate an item on-screen, or to switch between functions.
5	Print key	Available only when a printer is connected to the system. Tap to print from a live or frozen scan.
6	Save keys	Tap one of these keys to save an image or a clip.
7	Image mode	Tap one of these keys to change the imaging mode.
8	System controls	Change system settings, switch transducers, add labels, or see patient information.
9	Image and Doppler controls	Use these to adjust the image or select the Doppler imaging mode.
10	Touchscreen	Use the touchscreen the same way you would use the touchpad.

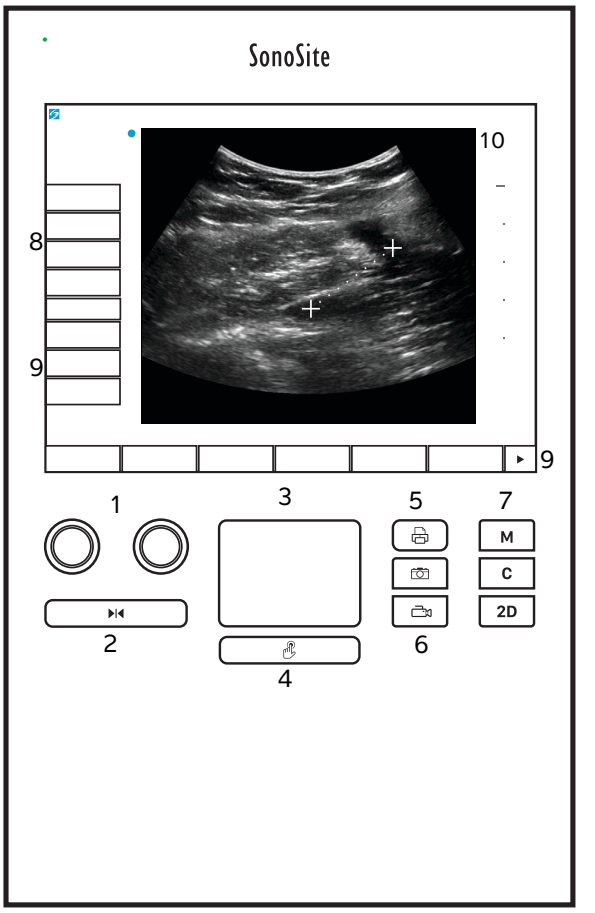


Figure 2-2 Control layout

Screen layout

The layout of the SonoSite SII system screen and the controls that appear on it change according to imaging mode or the specific task you are performing, such as measuring or annotating. During scanning, the following information is available:

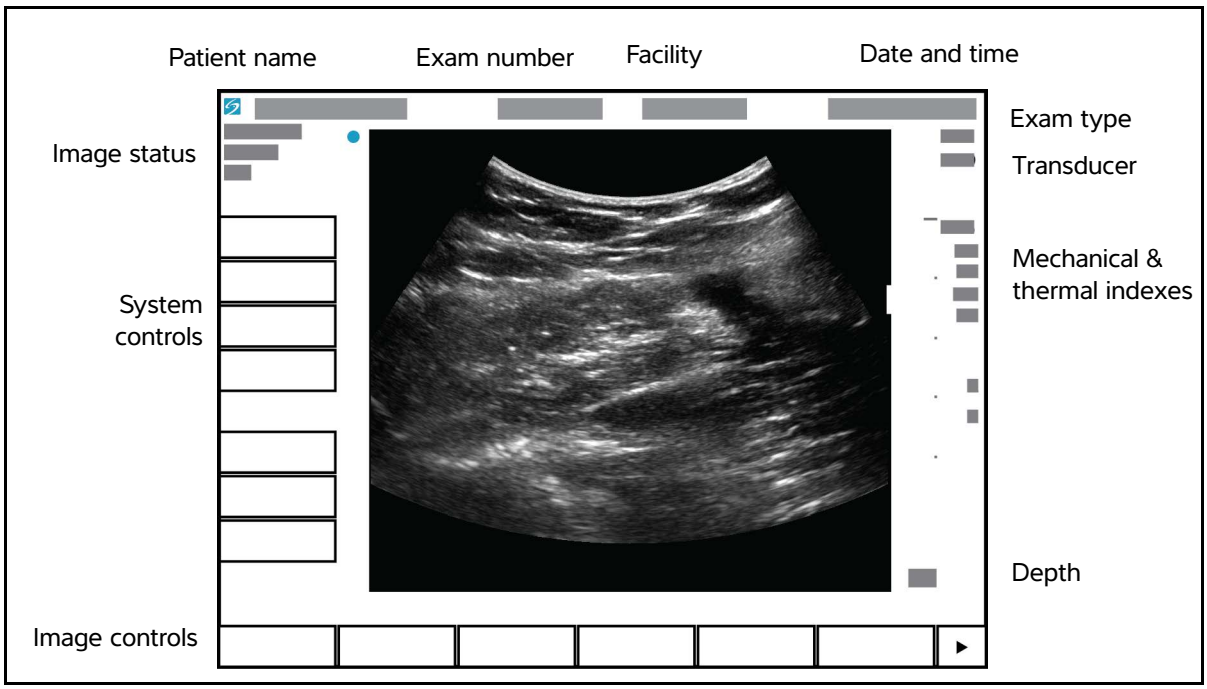


Figure 2-3 Screen layout

General interaction

Touchpad

The touchpad is an area centered below the screen that you can use as a pointing device. When the touchpad is active, drag your finger on the surface to move the item on screen.

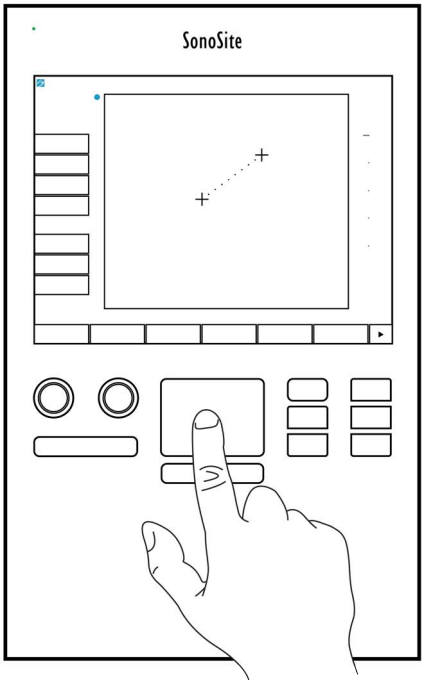


Figure 2-4 Using the touchpad

You can use the touchpad to do the following:

- Place labels
- Move calipers
- Move and shape region of interest (ROI) boxes
- Position the M-line
- Point to a text field in a form

Use the **Select** key below the touchpad to select or set the item after you have moved it.

Touch screen

As an alternative to the touchpad, you can move some items directly by dragging your finger on the screen.

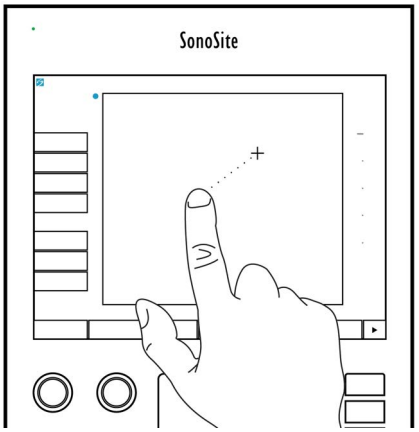


Figure 2–5 Using the touch screen

Control buttons and knobs

There are two types of controls on the SonoSite SII system:

- **Screen controls**

  The controls that appear on the touchscreen change dynamically depending on the context. For example, freezing an image may display the controls for zooming, performing measurements, and reviewing the cine buffer. Only the controls that are available in the current mode or function will appear. To select a control on the touchscreen, tap it once.

- **System controls**

  The buttons and knobs located below the touchscreen are persistent, but some may be disabled during certain modes or conditions. Controls are lighted when active and dark when disabled. The label for each knob appears on the screen just above it. The label and function of the knobs may change depending on the mode or condition.

Entering text

In forms and annotations, you can enter text in text fields using either the on-screen keyboard or an external USB keyboard connected to a USB port on the system.

If you are using an external USB keyboard, enter characters by typing. The TAB key navigates among text fields.

WARNING To avoid contamination, do not use the USB keyboard supplied by FUJIFILM SonoSite in a sterile environment. The USB keyboard is not sterilized and cannot withstand sterilization.

To enter text in text fields using the on-screen keyboard

1 Using the touchpad or the touchscreen, select a text field.

The on-screen keyboard appears with the text field at the top.

2 On the touchscreen, tap each character you want to enter.

- The **Äñ** key displays and hides international characters.
- The **Symbols** key displays symbols and punctuation.
- The Caps Lock key  turns capital letters on and off.
- The Shift key  turns capital letters on or off for the next letter entered.
- The **Delete** key deletes the character right of the pointer.
- The backspace key  deletes the character to the left of the pointer.

3 To navigate among text fields:

- Tap **Next** to advance to the next field.
- Tap **Prev** to return to the previous field.

4 To exit the keyboard, click one of the following:

- **OK** to save changes.
- **2D** to save changes and display 2D imaging.

Preparing 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 and disinfect transducers after each use. Refer to **"Cleaning and Disinfecting"** on page 8-1.

Acoustic coupling gel

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.

For general use, apply a liberal amount of gel between the transducer and the body. For invasive procedures, apply a transducer sheath.

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

To lessen the risk of contamination, install 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.

   Check for and eliminate bubbles between the face of the transducer and the sheath.

   Note

   Bubbles between the face of the transducer and the sheath may affect the ultrasound image.

5. Inspect the sheath to ensure that there are no holes or tears.

Intended uses

The SonoSite SII 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. Specific clinical applications and exam types include:

- Ophthalmic
- Fetal – OB/GYN
- Abdominal
- Pediatric
- Small Organ (breast, thyroid, testicle, prostate)
- Neonatal Cephalic
- Adult Cephalic
- Transrectal
- Transvaginal
- Musculoskeletal (Conventional)
- Musculoskeletal (Superficial)
- Cardiac Adult
- Cardiac Pediatric
- Peripheral Vessel

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.

For the intended transducer for each exam type, refer to **"Imaging modes and exams available by transducer"** on page 4-14.

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. Gynecology and infertility imaging applications

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 to provide ultrasound guidance for biopsy and drainage procedures, vascular line placement, peripheral nerve blocks, 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, 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. For more information, see **"Acoustic Output"** on page 10-1.
- 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 to provide ultrasound guidance for biopsy and drainage procedures, vascular line placement, and peripheral nerve blocks.

WARNING To avoid injury to the patient, use only an 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 Oph exam type is selected.

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.

Contraindications

The SonoSite SII ultrasound system has no known contraindications.

Chapter 3

System Setup

Use the Settings pages to customize the system and set preferences. The Settings pages are organized into the following categories:

- **Administration** – Control access to the system, including user accounts and passwords. See "Administration setup" on page 3-2
- **Annotations** – Create and customize predefined labels. See "Annotations settings" on page 3-6
- **Audio and battery** – Set audio alerts and power management settings. See "Audio, Battery settings" on page 3-7
- **Connectivity** – Manage connections and certificates to information storage services. See "Cardiac Calculations settings" on page 3-8
- **Date and time** – Set the system date and time. See "Date and Time settings" on page 3-9
- **Display information** – Control the amount of information that appears on-screen during imaging. See "Display Information settings" on page 3-10
- **Network** – View the status of your wireless network connection. See "Network Status settings" on page 3-10
- **OB calculations** – Select authors for OB gestational calculations. See "OB Calculations settings" on page 3-11
- **Presets** – Set general preferences. See "Presets settings" on page 3-11
- **System information** – View system hardware and software versions. See "System Information settings" on page 3-12
- **USB devices** – View information on all connected USB devices. See "USB Devices settings" on page 3-13

Displaying the Settings pages

To display a settings page

1 Tap **Settings**.

2 Under **Settings Pages**, select the page you want by tapping it.

3 To return to imaging from a setup page, tap **Done**.

Administration setup

On the **Administration** settings 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, import and export user accounts, disable USB export, and display the Event log.

To log in as Administrator

1 On the **Administration** settings page, type `Administrator` in the **Name** box. Refer to **"Entering text"** on page 2-12.

> **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 Tap **Login**.

To log out as Administrator

❖ Turn off or restart the system.

Security settings

> **WARNING** 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 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, tap **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**, tap **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 3-5.

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

5 Tap **Save**.

To limit USB export of exam data

1 Log in as Administrator.

2 Select **Disable USB Export**.

Administering users

These settings enable you to manage user information directly.

To add a new user

1 Log in as Administrator.

2 Tap **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 3-5.

- **(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 Tap **Save**.

To modify user information

1 Log in as Administrator.

2 Under **User List**, tap the user.

3 Under **User Information**, make changes as desired.

4 Tap **Save**. Any change to the user name replaces the previous name.

To delete a user

1 Log in as Administrator.

2 Under **User List**, tap the user.

3 Tap **Delete**.

4 Tap **Yes**.

To change a user password

1 Log in as Administrator.

2 Under **User List**, tap the user.

3 Type the new password in the **Password** box and **Confirm** box.

4 Tap **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 2-7.

2 Log in as Administrator.

3 Tap **Export**. A list of USB devices appears.

4 Tap the USB storage device, and then tap **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 2-7.

2 Log in as Administrator.

3 Tap **Import**.

4 Tap the USB storage device, and then tap **Import**.

5 Tap **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.

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 tap **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, tap **Guest**.

To change your password

1 Turn on the system.

2 In the **User Login** screen, tap **Password**.

3 Type your old and new passwords, confirm the new password, and then tap **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.

System setup

Annotations settings

On the **Annotations** settings 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 4-20.

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 4-21.

1. On the **Annotations** settings page, in the **Exam** list, select the exam type that includes the labels you want to specify.
2. Choose the label group associated with that exam. Next to **Group**, select **A**, **B**, or **C**. The preset labels for the selected group appear in the scroll list.
3. To add a custom label to the group:
   a. Tap **<New>** in the scroll list.
   b. Type the label in the **Text** box.
   c. Tap **Add**.
4. To rename a label:
   a. Tap the label
   b. Type the new name in the **Text** box
   c. Tap **Rename**.
5. To move a label within the group:
   a. Tap the label
   b. Tap the up or down arrow.
6. To delete a label from a group, tap the label, and then tap **Delete**.

   Refer to also **"Entering text"** on page 2-12.

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** settings 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, refer to **"To place an arrow on an image"** on page 4-21.

To export predefined label groups

1. Insert a USB storage device.
2. On the **Annotations** settings page, tap **Export**. A list of USB devices appears.
3. Select the USB storage device, and then tap **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** settings page, tap **Import**.
3. Select the USB storage device, and then tap **Import**.
4. Tap **OK** in the dialog box that appears.

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

Audio, Battery settings

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

Key click

Controls whether the controls make a clicking sound when tapped.

❖ 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 settings

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 settings

On the **Connectivity** settings page, select options for using devices and for alerts when internal storage is full. You also import wireless certificates and specify settings (including Transfer Mode and Location) for SiteLink Image Manager and DICOM, which are optional features. Refer to the SiteLink and DICOM documentation.

To configure the system for a printer

1. Set up the printer hardware. Refer to instructions included with the printer or stand.
2. On the **Connectivity** settings page, choose a printer from the **Printer** menu.
3. From the **Video Mode** list, choose the appropriate video standard: **NTSC** or **PAL**.
4. Plug the printer cable into the video output  on the system.

To connect to SiteLink

1. On the **Connectivity** settings page, choose **SiteLink** from the **Transfer mode** list.
2. Restart the system.
3. On the **Connectivity** settings page, tap **SiteLink setup**.

4 On the **SiteLink** page, choose the SiteLink account you want to use, and then tap **Save**.

5 To create a new account:

   a Tap **New**.

   b Enter the network settings for your new SiteLink account. Work with your network administrator to obtain the correct information.

   c Tap **Save**.

6 To import the SiteLink connection information:

   a Insert the USB storage device that contains the SiteLink connection information.

   b On the **SiteLink** page, tap **Import**.

   c Choose the USB storage device, and then tap **Import**.

7 To export your SiteLink connection information:

   a Insert a USB storage device.

   b On the **SiteLink** page, tap **Export**.

   c Choose the USB storage device, and then tap **Export**.

8 Tap **Done**.

To connect to DICOM

1 On the **Connectivity** settings page, choose **DICOM** from the **Transfer mode** list.

2 Restart the system.

3 On the **Connectivity** settings page, tap **DICOM setup**.

4 On the **DICOM** page, choose a location, and then choose the DICOM server you want to connect to.

5 Tap **Verify** and check that communication with the DICOM server is successful.

6 Tap **Done**.

To receive storage alerts

❖ On the **Connectivity** settings page, select **Internal Storage Capacity Alert**. The system displays a message if internal storage is near capacity when you end an exam.

Date and Time settings

To set the date and time

1 On the **Date and Time** settings page, do the following:

   a In the **Date** box, type the current date. Refer to **"Entering text"** on page 2-12.

b In the **Time** box, type the current time in 24 hour format (hours and minutes).

Display Information settings

On the **Display Information** settings 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 4-22.

Mode Data

Imaging information.

System Status

Power, battery, connectivity, and similar information.

Footswitch settings

On the Footswitch setup page, you can program the footswitch to perform common tasks.

❖ **Footswitch (L)**, **Footswitch (R)**. Set the left and right footswitches to: **Save Clip**, **Freeze**, **Save Image**, or **Print**.

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 a USB port on the back of the ultrasound system.

2 On the **Footswitch** setup page, select a function for the left and right footswitches.

Network Status settings

The **Network Status** settings 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 settings

On the **OB Calculations** settings page, you can select authors for OB gestational calculation tables. Refer to also **"OB calculations"** on page 5-32.

To specify gestational age

❖ On the **OB Calculations** settings page, select the desired OB authors (or select **None)** in the measurement lists under **Gestational Age**. Selecting an author places the associated measurement on the calculations menu.

Presets settings

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

Auto save Pat. Form

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

Clip Length

Choose the maximum clip length. Clip lengths are in seconds.

Depth Markers

- **Type 1**

  Displays an unnumbered depth scale to the right of the image, with the maximum depth number in the lower right screen.

- **Type 2**

  Displays a numbered depth scale to the right of the image.

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** velocity trace.

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.

Thermal Index

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

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

Units

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

System Information settings

The **System Information** settings 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** settings page, tap **Patents**.

USB Devices settings

On the **USB Devices** settings 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.

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 limit USB export of exam data"** on page 3-3

To specify a file format for exported images

The image format you specify affects only still images. Clips export in H.264 video format saved as MP4 files.

To export images

1 On the USB Devices setup page, tap **Export**.

2 Under SiteLink, select an image format. For JPEG image format, also select a JPEG compression.

> **Note** A high compression has a smaller file size but less detail.

3 Select a sort order under **Sort By**. The sort order specifies how exported files are organized.

4 To return to the previous screen, click **Devices**.

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 image between compressed and uncompressed is near 0
Medium	90%; Generally loss only to 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 SII system has a high-performance liquid crystal display (LCD) 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 4-14.

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 settings"** on page 3-11.

To display the 2D image

1 Do one of the following:

- Turn on the system.
- From another imaging mode, tap **2D**.

2 Adjust controls. For more information, see **"2D controls."**

2D controls

Note If the control you want does not appear on the screen, tap the More Controls arrow ▶ to view additional controls.

Table 4–1: 2D controls

Control	Description
Gain	Adjusts the image brightness through signal amplification. To change the gain, rotate the **Gain** knob.
Depth	Adjusts the depth of the image. To change the depth, rotate the **Depth** knob.
Auto Gain	The gain adjusts automatically each time you press the key. To adjust gain manually, see **"PW and CW Doppler imaging"** on page 4-5.
Optimize	Settings are as follows: **Res** provides the best possible resolution. **Gen** provides a balance between resolution and penetration. **Pen** provides the best possible penetration. 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.
THI	Turns Tissue Harmonic Imaging on and off. When on, *THI* appears in the mode data area. This feature depends on transducer and exam type.
SonoMB	Turns SonoMB® multi-beam imaging on and off. When on, *MB* appears in the mode data area. This feature depends on transducer and exam type.
Orientation	Select from four image orientations: **U/R** (Up/Right), **U/L** (Up/Left), **D/L** (Down/Left), **D/R** (Down/Right).
Guide	Turns needle guidelines on. Guidelines can be used for needle guidance, and depend on transducer type. If using a variable angle needle guide, tap **Guide.** To select the angle, tap **A**, **B**, or **C**. To change the depth, move your finger on the touchscreen or the touchpad. To turn needle guidelines off, tap **A**, **B**, or **C** until the word **Guide** appears.
Dual	Displays side-by-side 2D images. Tap **Dual**, and then tap **Update** to display the second screen and to toggle between the screens. To return to full-screen 2D imaging, tap **Off**.
Monitor	Adjusts the screen brightness. Tap the ▶ button to show more controls, and then turn the **Monitor** knob. The default brightness value is **8**, but settings range from **1** to **10**. The screen brightness affects battery life. To conserve battery life, adjust brightness to a lower setting.

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 Tap **M**.

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

2 Drag your finger on either the touchpad or the touchscreen to position the M-line where desired.

3 Adjust controls as desired.

4 Tap **M** to start the M Mode trace.

M Mode controls

Table 4-2: M Mode controls

Control	Description
Gain	Adjusts the signal amplification. To change the gain, rotate the **Gain** knob.
Depth	Adjusts the depth of the scan. To change the depth, rotate the **Depth** knob.
M line position	Defines the area of interest so that movement can then be traced over time. To change the position of the M line, drag your finger on the touchpad or the touchscreen.
Scan speed	Controls the speed of the trace. Your options are **Fast**, **Med**, and **Slow**.

To display the M Mode trace

1 Display the M line.

2 Adjust the depth if necessary to show the structure you want to scan. For more information, see **"PW and CW Doppler imaging"** on page 4-5.

3 Using the touchpad or the touchscreen, move the M line to pass through the structures you want to scan.

4 To begin the trace, tap **M**.

A trace window appears. For information about changing the duplex layout, see **"Presets settings"** on page 3-11.

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

5 To change the sweep speed, tap **Slow**, **Med**, or **Fast** to cycle through each sweep speed.When the trace is frozen, you can change between the M-line and M-mode trace by tapping **Update**.

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 Tap **C** to enter Color mode.

A ROI box appears in the center of the 2D image. The current selection (**Color** or **CPD**) appears in the mode data area.

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

2 To change to CPD, tap **CPD**.

3 Using the touchpad or the touchscreen, you can change the position or size of the ROI box as needed.

Tapping **Position** or **Size**, or tapping  , switches between position and size. When resizing, the outline is a dashed line.

4 Adjust controls as desired. Refer to **"CPD and Color controls."**

CPD and Color controls

Table 4-3: CPD and Color controls

Control	Description
Flow	Choose one of the following: ▸ **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 PRF (pulse repetition frequency) Scale setting by tapping PRF, and then tapping either the up ▲ or down ▼ arrow. The available PRF Scale settings depend on the Flow Sensitivity setting. Available on select transducers.
Invert	Switches the displayed direction of flow. Available in Color imaging.

Table 4-3: CPD and Color controls

Control	Description
Steering	If using a linear array transducer, tap the **Steering** button to change the steering angle (for example: **-15**, **0**, or **+15**).
Wall Filter	A high wall filter can reduce excessive motion or noise, while a low wall filter displays more of the raw signal. Choose one of the following: ▸ **WF Low** ▸ **WF Med** ▸ **WF High**
Variance	(Cardiac exam only) Turns variance on and off.

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 or TDI Doppler on-screen control.

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

To display the D-line

1 Tap the **Doppler** control at the bottom of the touchscreen.

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.
- Drag your finger on the touchscreen or touchpad to position the D-line and gate where desired. Horizontal movements position the D-line. Vertical movements position the gate.
- To change the gate size, repeatedly press the right knob or tap the on-screen control above the knob until **Gate** appears, and then turn the knob to the gate size you want. To correct the angle, repeatedly press the right knob or tap the on-screen control above the knob until **Angle** appears, and then turn the knob to the correct angle.

WARNING | We do not recommend angle correction for the cardiac exam type.

To display the spectral trace

> **Note** Moving the baseline, scrolling, or inverting the trace while the image is frozen will clear displayed cardiac output results.

1 Tap **Doppler** to display the D-line.

2 Do one of the following:

- In PW Doppler – Tap **PW Dop**.
- In CW Doppler – Tap **CW Dop**.
- In TDI Doppler – Tap **TDI Dop**.
- In any Doppler mode – Tap **Update**.

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 the sweep speed (**Med**, **Fast**, **Slow**).
- Tap **Update** to toggle between the D-line and spectral trace.

Doppler controls

Table 4–4: Doppler on-screen controls

Control	Description
PW Dop, CW Dop, TDI Dop	Toggle between PW Doppler, CW Doppler, and TDI Doppler. The current selection appears in the upper left-hand screen. CW Doppler and TDI Doppler are available only in cardiac exams.
Gate	Settings depend on transducer and exam type. Use the right knob to adjust the Doppler gate size. The Doppler gate size indicator is on the upper left-hand screen.
Angle	Press the right knob to select **Angle**, and then turn the knob to choose between: **0°**, **+60°**, or **–60°**. We do not recommend angle correction for the cardiac exam type.
Steering	Select the desired steering angle setting. Settings available depend on the transducer. The PW Doppler angle correction automatically changes to the optimum setting. ▸ **-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°. You can manually correct the angle after selecting a steering angle setting. Available on select transducers.

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

Control	Description
Volume 	Increases or decreases Doppler speaker volume (**0**–**10**).
Zoom	Magnifies the image.

Spectral trace controls

Table 4-5: Spectral trace on-screen controls

Control	Description
Scale	Press the right knob to select **Scale**, and then turn the knob to choose the desired velocity setting [pulse repetition frequency (PRF)] in cm/s or kHz.
Line	Press the right knob to select **Line**, and then turn the knob to set the baseline position. (On a frozen trace, the baseline can be adjusted if **Trace** is off.)
Invert	Press the right knob to select **Invert**, and then turn the knob to vertically flip the spectral trace. (On a frozen trace, **Invert** is available if **Trace** is off.)
Volume 	Increases or decreases Doppler speaker volume (**0**–**10**).
Wall Filter 	Settings include **Low**, **Med**, **High**.
Sweep Speed 	Settings include **Slow**, **Med**, **Fast**.
Trace	Displays a live trace of the peak or mean. Specify peak or mean on the Presets setup page. Select **Above** or **Below** to position the trace above or below the baseline.

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.

❖ Turn the **Depth** knob:

- **Clockwise**

  Increases the displayed depth.

- **Counter-clockwise**

  Decreases the displayed depth.

To change the style of depth markers, see **"Presets settings"** on page 3-11.

To adjust gain automatically

❖ To adjust gain automatically in 2D, you can tap the **Auto Gain** button. For more information, see **"2D controls"** on page 4-1.

To adjust gain manually

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.

1 Turn the **Gain** knob:

- **Clockwise**

  Raises the gain.

- **Counter-clockwise**

  Lowers the gain.

2 To switch to near or far gain, tap the **Gain** button, or press the **Gain** knob.

Freezing, viewing frames, and zooming

To freeze or unfreeze an image

❖ Press and hold the **Freeze** button ( ).

When the image is frozen, the button color is blue. When the image is unfrozen, the button color is white.

On a frozen image, the cine icon ( ) and frame number appear above the left knob.

To move forward or backward in the cine buffer

❖ On a frozen image, do one of the following:

- Turn the Cine knob.
- Drag your finger on the touchscreen.

▸ Drag your finger on the touchpad.

The total number of frames appears next to the cine icon. The number changes to the current frame number as you move forward or backward.

WARNING To avoid loss of data, be careful not to touch the Freeze button ( ) while turning the Cine knob.

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 Tap **Zoom**. A ROI box appears.

2 Using the touchpad or the touchscreen, position the ROI box as desired.

3 Tap **Zoom**. The image in the ROI box is magnified by 100%.

4 (**Optional**) If the image is frozen, use the touchpad or the touchscreen to pan the image up, down, left, and right.

5 To exit zoom, tap **Zoom Off.**

Needle visualization

WARNINGS

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 4-6, "Transducers and exam types available with Steep Needle Profiling"** on page 4-10.
- 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 (formerly SonoMBe™ imaging), 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 4-11.

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 4-11. 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 4-6: Transducers and exam types available with Steep Needle Profiling

Transducer	Arterial	Breast	Musculoskeletal	Nerve	Small Parts	Spine	Venous
C35x			✓	✓		✓	
rC60xi standard/ armored			✓	✓			

Table 4-6: 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				✓			

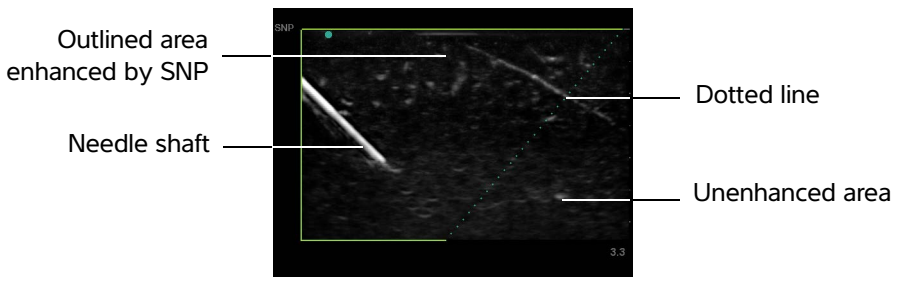


Figure 4-1 Image with SNP on (linear transducer)

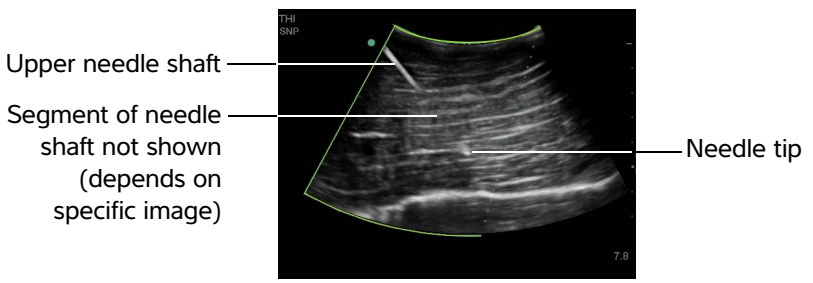


Figure 4-2 When using a curved-array transducer, only segments of the needle shaft may appear.

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 4-12. 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.

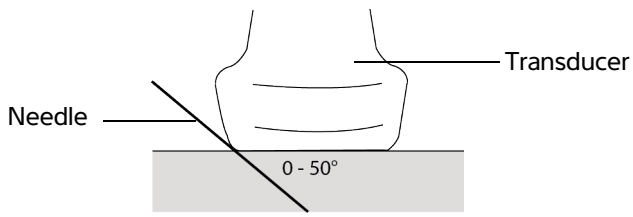


Figure 4-3 For best results, angle the needle only up to 50° from the transducer surface.

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 4-1.
- **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.

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.

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.

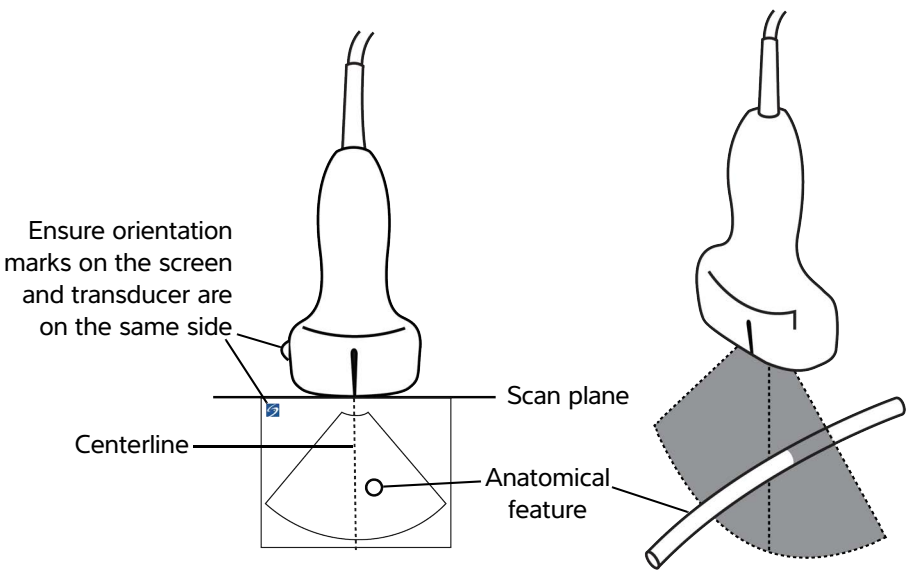


Figure 4-4 Relationship of the centerline graphic to the transducer and the ultrasound image.

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.

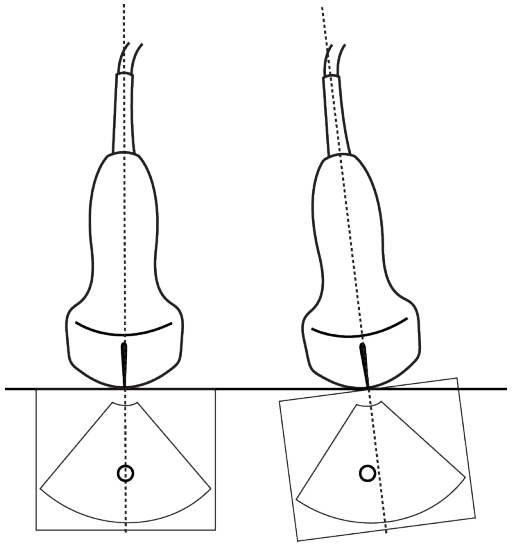


Figure 4–5 Relationship of the ultrasound image to the transducer angle or tilt.

Imaging modes and exams available by transducer

WARNINGS

- 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 biocompatability requirements. Understand the system's capabilities before using.
- To avoid injury to the patient, use only an Ophthalmic (Oph) exam type when performing imaging through the eye. The FDA has established lower acoustic energy limits for ophthalmic use. Only the Oph exam type is designed to not exceed these limits.

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 or exam types may be available.

To select a transducer

1 Tap **Transducer**.

The menu showing the current active transducer appears.

2 If another transducer is connected, you can change to that one by tapping **Switch**.

To change the exam type

❖ Do one of the following:

- Tap **Transducer**, and then choose an exam type from the list of available exams.
- Tap **Patient**, and then tap **Information**. Choose an exam type from the **Type** list in the **Exam** window. Refer to **"Patient information form"** on page 4-22.

Table 4-7: 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	✓	✓	✓	✓	
C11x	Abd	✓	✓	✓	✓	
	Art	✓	✓	✓	✓	
	Neo	✓	✓	✓	✓	
	Nrv	✓	✓	✓	✓	
	Ven	✓	✓	✓	✓	

[a]Exam 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, Sup = Superficial, TCD = Transcranial Doppler, Ven = Venous.

[b]The optimization settings for 2D are Res, Gen, and Pen.

[c]The optimization settings for CPD and Color are low, medium, and high (flow velocity range) with a range of PRF settings for Color depending on the setting selected.

[d]For the cardiac exam type, PW TDI is also available. See **"Doppler controls" on page 4-6**.

[e]Needle guide-capable. For more information, refer to Using CIVCO Products with FUJIFILM SonoSite Systems.

Table 4–7: 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
C35x[e]	Abd	✓	✓	✓	✓	
	Msk	✓	✓	✓	✓	
	Nrv	✓	✓	✓	✓	
	OB	✓	✓	✓	✓	
	Spn	✓	✓	✓	✓	
rC60xi standard/ armored[e]	Abd	✓	✓	✓	✓	
	Gyn	✓	✓	✓	✓	
	Msk	✓	✓	✓	✓	
	Nrv	✓	✓	✓	✓	
	OB	✓	✓	✓	✓	

[a]Exam 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, Sup = Superficial, TCD = Transcranial Doppler, Ven = Venous.

[b]The optimization settings for 2D are Res, Gen, and Pen.

[c]The optimization settings for CPD and Color are low, medium, and high (flow velocity range) with a range of PRF settings for Color depending on the setting selected.

[d]For the cardiac exam type, PW TDI is also available. See **"Doppler controls" on page 4–6**.

[e]Needle guide–capable. For more information, refer to Using CIVCO Products with FUJIFILM SonoSite Systems.

Table 4-7: 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
HFL38xi standard/ armored[e]	Art	✓	✓	✓	✓	
	Bre	✓	✓	✓	✓	
	Lung	✓	✓	✓	✓	
	Msk	✓	✓	✓	✓	
	Nrv	✓	✓	✓	✓	
	Oph	✓	✓	✓	✓	
	SmP	✓	✓	✓	✓	
	Ven	✓	✓	✓	✓	
HFL50x[e]	Bre	✓	✓	✓	✓	
	Msk	✓	✓	✓	✓	
	Nrv	✓	✓	✓	✓	
	SmP	✓	✓	✓	✓	

[a]Exam 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, Sup = Superficial, TCD = Transcranial Doppler, Ven = Venous.

[b]The optimization settings for 2D are Res, Gen, and Pen.

[c]The optimization settings for CPD and Color are low, medium, and high (flow velocity range) with a range of PRF settings for Color depending on the setting selected.

[d]For the cardiac exam type, PW TDI is also available. See **"Doppler controls" on page 4-6**.

[e]Needle guide-capable. For more information, refer to Using CIVCO Products with FUJIFILM SonoSite Systems.

Table 4–7: 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
HSL25x	Art	✓	✓	✓	✓	
	Lung	✓	✓	✓	✓	
	Msk	✓	✓	✓	✓	
	Nrv	✓	✓	✓	✓	
	Oph	✓	✓	✓	✓	
	Sup	✓	✓	✓	✓	
	Ven	✓	✓	✓	✓	
ICTx[e]	Gyn	✓	✓	✓	✓	
	OB	✓	✓	✓	✓	

[a]Exam 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, Sup = Superficial, TCD = Transcranial Doppler, Ven = Venous.

[b]The optimization settings for 2D are Res, Gen, and Pen.

[c]The optimization settings for CPD and Color are low, medium, and high (flow velocity range) with a range of PRF settings for Color depending on the setting selected.

[d]For the cardiac exam type, PW TDI is also available. See **"Doppler controls" on page 4–6**.

[e]Needle guide-capable. For more information, refer to Using CIVCO Products with FUJIFILM SonoSite Systems.

Table 4-7: 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	✓	✓	✓	✓	

[a]Exam 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, Sup = Superficial, TCD = Transcranial Doppler, Ven = Venous.

[b]The optimization settings for 2D are Res, Gen, and Pen.

[c]The optimization settings for CPD and Color are low, medium, and high (flow velocity range) with a range of PRF settings for Color depending on the setting selected.

[d]For the cardiac exam type, PW TDI is also available. See **"Doppler controls" on page 4-6**.

[e]Needle guide-capable. For more information, refer to Using CIVCO Products with FUJIFILM SonoSite Systems.

Table 4–7: 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	✓	✓	✓	✓	

[a]Exam 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, Sup = Superficial, TCD = Transcranial Doppler, Ven = Venous.

[b]The optimization settings for 2D are Res, Gen, and Pen.

[c]The optimization settings for CPD and Color are low, medium, and high (flow velocity range) with a range of PRF settings for Color depending on the setting selected.

[d]For the cardiac exam type, PW TDI is also available. See **"Doppler controls" on page 4–6**.

[e]Needle guide-capable. For more information, refer to Using CIVCO Products with FUJIFILM SonoSite Systems.

Annotating images

You can annotate live images as well as frozen images. (You cannot annotate a saved image.) You can annotate an image using text (including predefined labels), an arrow, or a pictograph. To set preferences for annotations, refer to **"System setup"** on page 3–6.

To place text on an image

You can place text manually or add a predefined label.

1 Tap **Annotate**.

2 Tap **Label**.

3 Using the touchpad or touchscreen, move the cursor where desired.

4 To enter your own text, tap  or **Keyboard**.The on-screen keyboard appears, and you can type the label you want to add. For more information, see **"Entering text"** on page 2-12.

5 To add a preset label, tap the desired label group, **A**, **B**, or **C**, and then tap either the up arrow  or down arrow  to choose the label you want to add.

Next to each label group, the first number shows which label in the group is selected. The second number is the number of labels available. Refer to **"System setup"** on page 3-6.

6 Repeat steps 3 through 5 for each label you want to add.

7 Tap **Done**.

To place an arrow on an image

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

1 Tap **Annotate**.

2 Tap **Arrow**.

An arrow appears on the image.

3 Using the touchpad or the touchscreen, position the arrow in the desired location, and then double tap, or tap  .

4 Using the touchpad or the touchscreen, rotate the arrow to the desired angle.

5 Tap **Done**.

To place a pictograph on an image

The types of pictographs available depend on the transducer and exam type you have selected.

1 Tap **Annotate**.

2 Tap **Picto**.

A pictograph appears on the image.

3 Tap **X/X** to choose the pictograph you want to use.

The first number shows which pictograph in the set is selected. The second number is the number of pictographs available.

4 Using the touchpad or the touchscreen, position the pictograph marker, and then double-tap or tap  .

5 Using the touchpad or the touchscreen, rotate the pictograph marker to the desired angle.

6 Choose a screen location for the pictograph:

- **U/L** (Up/Left
- **D/L** (Down/Left)
- **D/R** (Down/Right)
- **U/R** (Up/Right)

7 Tap **Done**.

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. Refer to **"Tap Back to exit the calculation."** on page 5-35.

To create a new patient information form

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

1 Tap **Patient**, then **Information**.

The current patient information form appears.

2 Tap **End**.

A new patient information form appears.

3 Fill in the form fields. For more information, see **"Patient information form fields"** on page 4-24, and **"Entering text"** on page 2-12.

4 To return to the scan, tap **Done**. Refer to also **"To append images and clips to a patient exam"** on page 4-27.

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.

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

> **WARNING** After using the bar code scanner to retrieve patient records, take a moment to verify the patient information is correct. If the patient information retrieved using the bar code scanner is incorrect, enter the information manually.

❖ Plug the USB connector for the bar code scanner into the back of the ultrasound system. For more information about the bar code scanner, refer to the *Bar Code Scanner User Guide*.

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.

> **Note** If Auto save Pat Form is set to On, an image saves when you start a new patient information form, preventing editing. Refer to **"Presets settings"** on page 3-11.

Refer to **"To edit patient information from the patient list"** on page 4-27.

1 Tap **Patient**.

2 Tap **Information**

3 Make changes as desired. For more information about filling out forms, see **"Entering text"** on page 2-12.

4 Tap 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. Refer to **"Images and clips"** on page 4-25.

2 Tap **Patient.**

3 Tap **Information**.

4 Tap **End**. A new patient information form appears.

Patient information form fields

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)
- **Worklist** (button)[1]
- **Query** (button)

Exam

On the **Patient Information** page, in the **Exam** window, the following information fields are available:

- **Type**
  Exam types available depend on transducer. Refer to **"Imaging modes and exams available by transducer"** on page 4-14.

  Note | For the definition of abbreviations, refer to **"Glossary"** on page A-1.

- **BP**
  Blood Pressure (Cardiac or Vascular exam)
- **HR**
  Heart Rate. Enter the beats per minute. Using the system to measure heart rate overwrites this entry. (Cardiac or Vascular exam)

1. Available if the DICOM Worklist feature is licensed and configured. Refer to the DICOM user guide.

- **Height**

  The patient height in feet and inches or meters and centimeters. (Cardiac exam)

- **Weight**

  The patient weight in pounds or kilos. (Cardiac exam)

- **BSA** (Body Surface Area)

  Automatically calculated after you enter height and weight. (Cardiac exam)

- **LMP, Estab. DD**

  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. (OB or Gyn exam)

- **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 settings"** on page 3-7.

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 4-22.

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 4-26.

To save an image

❖ Tap  .

To save a clip

❖ Tap  .

For more information on setting the default clip length, see **"Presets settings"** on page 3-11.

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. Refer to **"Getting help"** on page 1-2.

The patient list lets you organize saved images and clips from a central location.

To display the patient list

1 Tap **Patient**.

2 Tap **Review**.

If a patient record appears, tap **List** to see the patient list.

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.

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

To select patient exams in the patient list

❖ Do one of the following:

- Select the check box for one or more patient exams.
- Tap **Select All** to select all patient exams.
- If using a USB keyboard, press the **up arrow** or **down arrow** key to highlight the patient exam, and then press the **spacebar**.

To deselect patient exams

❖ Do one of the following:

- Clear checked boxes.
- Tap **Clear All**.
- On the USB keyboard, the **spacebar** clears checked boxes.

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. Tap **Edit**.
3. Fill in the form fields, and then tap **Done**.

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. Tap **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. Tap **Review**. The icon on the knob changes to two numbers: the file displayed and the total files saved.
3. Turn the left knob to cycle to the image or clip you want to review.
4. To view a clip, tap **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:

   - Tap **Pause** to freeze the clip. Tap **Play** again to resume.
   - Turn the right knob to change the playback speed.
5. Turn the left knob to cycle to the next image or clip you want to view.
6. To return to the patient list, tap **List**.
7. To return to imaging, tap **Done**.

To review exported images or clips

1 Insert a USB memory stick containing the images and clips you want to view.

2 Tap **Patient**, and then tap **Review**.

3 Tap **List**, and then open the **Image Gallery** tab.

4 Tap **Select USB**.

5 Choose the USB memory stick that contains the images and clips you want to view, and then tap **Select**.

A list of available images and clips appears.

6 Tap the filename of the image or clip you want to view.

Printing, exporting, and deleting images and clips

WARNINGS 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 3-8.

2 Do one of the following:

- When reviewing a patient's exam images, tap  .
- In an exam, freeze the image, and then tap  .

To print multiple images

1 Verify that a printer is selected. For more information, see **"To configure the system for a printer"** on page 3-8.

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 tap  .

- To print all images for one patient exam, highlight the patient exam in the patient list, and then tap  . Each image appears briefly on-screen while printing.

To export patient exams to a USB storage device

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 4-23.

1. Insert the USB storage device. Refer to **"Inserting and removing USB storage devices"** on page 2-7.
2. In the patient list, select the patient exams you want to export.
3. Tap **Exp. USB**. 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. Tap **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, tap **Cancel Export**.

To delete images and clips

1. Select one or more patient exams in the patient list.
2. Tap **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 SonoSite Patient Data Archival Software (PDAS). DICOM and SonoSite PDAS are optional features. For more information about archiving, refer to the SonoSite PDAS and DICOM documentation.

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

2 Tap **Archive.**

To display information about a patient exam

1 In the patient list, select the patient exam.

2 Tap **Info**.

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 **"Measurement references"** on page 6-1

Measurements

You can perform basic measurements in any imaging mode. Options available 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, 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 5-3.

Working with calipers

Most measurements are performed using calipers, often in pairs, that you position by dragging. 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.

You can use either the touchpad or the touchscreen to move the calipers. You can adjust the position of the active caliper at any time. The active caliper is highlighted in yellow. On the touchpad, you can toggle between the calipers by tapping  .

The number and type of calipers that appear on the screen depends on the measurement type you have chosen. There are three types of calipers available:

- **Distance**

  Measures the straight-line distance between the two calipers. After selecting a distance measurement, two calipers appear on the screen. Drag the calipers to either side of the structure you want to measure.

- **Ellipse**

  Measures the circumference and surface area of an ellipse. After selecting an ellipse measurement, an ellipse with three calipers appears on the screen. Drag the calipers to define the size, position, and angle of the ellipse.

- **Trace**

  Measures the circumference and surface area of a shape you define. After selecting a trace measurement, a single caliper appears on the screen. Move the caliper to the start of the trace, lift your finger to set the location, and then drag the caliper to trace the shape.

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 create a set of calipers for measurement

1 On a frozen image, tap **Calipers**

  By default, a distance measurement appears.

2 To change to a different measurement, tap one of the following:

  - **Ellipse**
  - **Trace**

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 in yellow.

❖ Do one of the following:

- If you are using the touchpad, move the on-screen cursor to the caliper you want to move, and then tap  .
- If you are using the touchscreen, tap the caliper you want to move.

To delete or edit a measurement

If a measurement is no longer needed, or if you want to make room for a different measurement, you can delete it.

❖ With the measurement active (highlighted), do one of the following:

- Tap **Delete**.
- Use the touchpad or the touchscreen to reposition one or more of the calipers.

To place calipers more precisely

Use the following techniques to increase the precision of your measurements.

❖ 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.
- Minimize the depth.
- Zoom the image.

Saving measurements

After performing a measurement, you can save the image with the measurements displayed. Refer to **"To save an image"** on page 4-26. 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. Refer to **"Calculations"** on page 5-9.

To save a measurement to a calculation and patient report

1 With the measurement active, tap **Calcs**.

2 From the calculations menu, select a measurement name. Refer to **"To select from the calculations menu"** on page 5-9.

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

3 Save the calculation. Refer to **"To save a calculation"** on page 5-10.

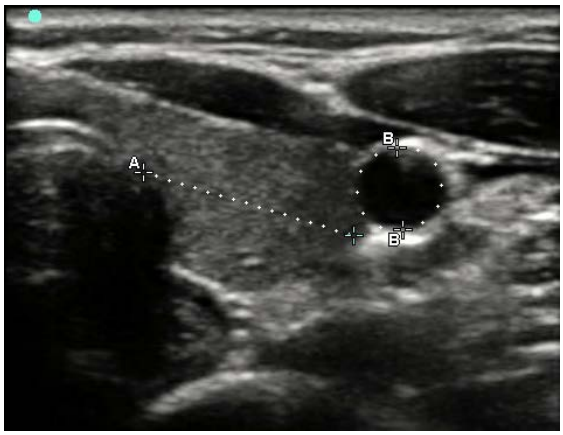


Figure 5-1 2D image with one distance and one circumference measurement

2D measurements

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

Note Distance is measured in cm.

1 On a frozen 2D image, tap **Calipers**. A pair of calipers appears, connected by a dotted line and labeled **A**.

2 Using the touchpad or the touchscreen, position the first caliper.

If you are using the touchpad, tap  to make the other caliper active.

3 Using the touchpad or the touchscreen, 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. Area is in cm^2, and Circumference is in cm.

1 On a frozen 2D image, tap **Calipers**.

2 Tap **Ellipse**.

3 Using the touchpad or the touchscreen, move the first caliper to the feature you want to measure.

If you are using the touchpad, tap  to make the other caliper active.

4 Using the touchpad or the touchscreen, position the other caliper so that the size, shape, and angle of the ellipse accurately matches the feature.

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 trace a shape

1 On a frozen 2D image, tap **Calipers**.

2 Tap **Trace**.

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

4 If you are using the touchscreen, lift your finger from the screen momentarily. If you are using the touchpad, tap  .

The trace feature becomes active.

5 Using the touchpad or the touchscreen, begin tracing the feature you want to measure.

If you want to make a correction, tapping **Undo** will move the trace backward incrementally. Then you can resume the trace.

6 When you are done, tap **Set**. The two ends of the trace are joined automatically.

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 (M Mode)

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

1 On a frozen M Mode trace, tap **Calipers**.

A single caliper appears.

2 Using the touchscreen, position the caliper.

   If you are using the touchpad, tap  . A second caliper appears.

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

Refer to **"To save a measurement to a calculation and patient report"** on page 5-3.

To measure heart rate (M Mode)

1 On a frozen M Mode trace, tap **Calipers**.

2 Tap **HR**.

   A vertical caliper appears.

3 Using the touchscreen, position the vertical caliper at the peak of the heartbeat

   If you are using the touchpad, tap  to set the position. A second vertical caliper appears.

4 Using the touchpad or the touchscreen, position the second vertical caliper at the peak of the next heartbeat.

5 (Cardiac exam) If you want to save the measurement to the patient report, tap **Save HR**.

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

Refer to also **"To measure fetal heart rate (M Mode)"** on page 5-35.

Doppler measurements

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

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

You can also trace manually or automatically. For Doppler measurements, the Doppler scale must be set to cm/s on the Presets setup page.

To measure Velocity (cm/s) and Pressure Gradient

This measurement involves a single caliper from the baseline.

1 On a frozen Doppler spectral trace, tap **Calipers**.

A single caliper appears.

2 Drag your finger on either the touchpad or the touchscreen to position the caliper to a peak velocity waveform.

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

1 On a frozen Doppler spectral trace, tap **Calipers**.

A single vertical caliper appears.

2 Using the touchpad or the touchscreen, position the caliper to a peak velocity waveform. Tap  to set the position.

A second vertical caliper appears.

3 Drag your finger on either the touchpad or the touchscreen to position the second vertical caliper at the end diastole on the waveform, and then tap  .

To make a correction, tap **Delete** above the right knob or press the right knob.

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.

If the absolute value of the earlier velocity is less than that of the later velocity identified by the calipers, Acceleration is calculated; otherwise, in non-cardiac exams, RI is calculated.

To measure time duration

1 On a frozen Doppler spectral trace, tap **Calipers**.

2 Navigate to the second page by tapping the arrow.

3 Select **Time**  .

A vertical caliper appears.

4 Using the touchpad or the touchscreen, position the caliper where desired, and then tap  .

A second vertical caliper appears.

5 Using the touchpad or the touchscreen, position the second caliper where desired.

To perform manual trace measurements in Doppler

1 On a frozen Doppler spectral trace, tap **Calipers**.

2 Navigate to the second page by tapping the arrow.

3 Tap **Manual** .

A single caliper appears.

4 Using the touchpad or the touchscreen, position the caliper at the beginning of the desired waveform, and then tap to activate the trace.

5 Using the touchpad or the touchscreen, trace the waveform, and then tap **Set** or .

To make a correction, tap **Undo** or **Delete**.

WARNING

When using the touchpad to trace a shape, be careful not to touch until you are finished with the trace. Doing so may complete the trace prematurely, causing an incorrect measurement and delay of care.

To perform automatic trace measurements in Doppler

1 On a frozen Doppler spectral trace, tap **Calipers**.

2 Navigate to the second page by tapping the arrow.

3 Tap **Auto** .

A vertical caliper appears.

4 Using the touchpad or the touchscreen, position the caliper at the beginning of the desired waveform, and then tap .

A second vertical caliper appears.

5 Using the touchpad or the touchscreen, position the caliper at the end of the desired waveform, and then tap **Set**.

To make a correction, tap **Undo** or **Delete**.

Automatic trace results

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

- Velocity Time Integral (VTI)
- Cardiac Output (CO)

- 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
- Peak Systolic Velocity (PSV)
- Time Average Mean (TAM)
- +/x or Systolic/Diastolic (S/D)
- Pulsatility Index (PI)
- Resistive Index (RI)
- Time Average Peak (TAP)
- Minimum Diastolic Velocity (MDV)

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. Refer to **"Patient report"** on page 5-35.

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. Refer to **"Patient report"** on page 5-35. Also, 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. Tap the menu item to see additional options.

To select from the calculations menu

1 On a frozen image, tap **Calcs**. The calculations menu appears.

The list of calculations or measurements can be too long to fit on a page. To see the next page of calculations or measurements, tap **Next**. To see the previous page, tap **Previous**.

2 To start a calculation, tap the name of the calculation you want to make.

Note Only calculations and measurements that are compatible with the current imaging mode are shown.

Many calculations include more than one measurement. The measurements for each calculation appear under the calculation name. You can perform the measurements in any order.

3 To perform a measurement within a calculation, tap the measurement name.

4 To save the completed calculation, tap **Save Calc**.

5 To close the calculations menu, tap **Back**.

Tapping **Back** will not save your calculation.

Performing and saving measurements in calculations

Calculations usually involve more than one measurement. Instead of tapping **Calipers**, as you would for a single measurement, tapping **Calcs** 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 by tapping **Save**.

To save a calculation

❖ When all of the measurements are complete and the final calculation is displayed, tap **Save Calc**.

Displaying and deleting saved measurements in calculations

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 report"** on page 5-35.

To delete a saved measurement

1 Highlight the measurement name in the calculations menu.

2 Tap **Delete**. 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.

Some measurements can be deleted directly from the report pages. Refer to **"Patient report"** on page 5-35.

General calculations

Percent reduction calculations

WARNING

- 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.

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

To calculate percent area reduction

The percent area reduction calculation involves two manual trace measurements.

1 On a frozen 2D image, tap **Calcs**.

2 Do the following for **A**^{1} and then for **A**^{2}:

a From the calculations menu, select the measurement name under Area Red.

b Using the touchpad or the touchscreen, position the caliper where you want to begin the trace.

c If you are using the touchscreen, lift your finger from the screen momentarily to activate the trace. If you are using the touchpad, tap  to activate the trace.

To make a correction, tap **Undo**, or tap the measurement name to restart the measurement.

d Using the touchpad or the touchscreen, trace the desired area, and then tap **Set**.

WARNING

When using the touchpad to trace a shape, be careful not to touch  until you are finished with the trace. Doing so may complete the trace prematurely, causing an incorrect measurement and delay of care.

e Tap **Save Calc** to save the calculation.

A check mark appears next to the saved measurement.

To calculate percent diameter reduction

1 On a frozen 2D image, tap **Calcs**.

2 Do the following for **D**^{1} and then for **D**^{2}:

   a From the calculations menu, select the measurement name under **Dia Red**.

   b Using the touchpad or the touchscreen, position the calipers.

   c Tap **Save Calc** to save the calculation.

   A check mark appears next to the saved measurement.

Volume calculation

WARNING

- 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.

The volume calculation involves three 2D distance measurements: D1, D2, and D3. 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, Venous, and Superficial.

To calculate volume

Do the following for each image you need to measure:

1 On a frozen 2D image, tap **Calcs**.

2 Do the following for each measurement you need to take:

   a From the calculations menu, under **Volume,** select the measurement name.

   If **Volume** is not available in a Gyn exam, select **Gyn** and then select **Volume**.

   b Using the touchpad or the touchscreen, position the calipers

   c Tap **Save Calc** to save the calculation.

   A check mark appears next to the saved measurement.

3 To save a picture of the finished calculation, tap  .

4 Tap **Back** to exit the calculation.

Volume flow calculation

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

Both a 2D and a Doppler measurement are required for the volume flow calculation. 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. Using this option may result in significant error.

The Doppler sample volume should completely insonate the vessel. You can measure either the time average mean (TAM) or time average peak (TAP).

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.

In the Arterial exam, you can calculate ICA/CCA ratio, volume, volume flow, and percent reduction. The Arterial calculations that you can perform are listed in the following table.

Table 5-1: Arterial calculations

Calculation list	Measurement name	Results
CCA	▸ Prox (Proximal) ▸ Mid (Middle) ▸ Dist (Distal) ▸ Bulb	s (systolic), d (diastolic)
ICA	▸ Prox (Proximal) ▸ Mid (Middle) ▸ Dist (Distal)	s (systolic), d (diastolic)

Table 5-1: Arterial calculations

Calculation list	Measurement name	Results
ECA	▸ 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, tap **Calcs**.

2 Do the following for each measurement you want to take:

   a Under **Left** or **Right**, select the measurement name.

   b Using the touchpad or touchscreen, position the caliper at the peak systolic waveform, and then tap  .

   A second caliper appears.

   c Using the touchpad, position the second caliper at the end diastole point on the waveform.

3 Tap **Save Calc** to save the calculation.

4 To save a picture of the finished calculation, tap  .

5 Tap **Back** to exit the calculation.

Cardiac calculations

WARNING To avoid incorrect calculations, verify that the patient information, date, and time settings are accurate.

WARNING 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 4-22.

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 three different ways:

- Manual entry in the patient information form
- Doppler measurement
- M-Mode measurement
-

The following table shows the measurements required to complete different cardiac calculations. For definitions of acronyms, refer to **"Glossary"** on page A-1.

Table 5-2: Cardiac calculations and results

Calculation list	Measurement name (imaging mode)	Results
EF EF LV Vol (EF)	▸ LVDd (2D or M Mode) ▸ LVDs (2D or M Mode)	EF LVDFS
	▸ A4Cd (2D) ▸ A4Cs (2D) ▸ A2Cd (2D) ▸ A2Cs (2D)	A4C EF A2C EF LV Vol CO[a] SV CI[a] SI

[a]HR needed for CO and CI. You can enter the HR measurement on the patient form, or obtain it by measuring in M Mode or Doppler.
[b]dP:dT performed at 100 cm/s and 300 cm/s.
[d]Specified on the cardiac patient report.
[e]Need to measure E (MV measurement) to get E/e´ ratio.

Table 5-2: Cardiac calculations and results

Calculation list	Measurement name (imaging mode)	Results
IVC	▸ Max D (2D or M Mode) ▸ Min D (2D or M Mode)	Collapse ratio
LV LVd	▸ RVW (2D) ▸ RVD (2D) ▸ IVS (2D) ▸ LVD (2D) ▸ LVPW (2D)	EF LVDFS CO[a] SV LVESV LVEDV IVSFT LVPWFT CI[a] SI LV Mass (M Mode only)
LVs	▸ RVW (2D) ▸ RVD (2D) ▸ IVS (2D) ▸ LVD (2D) ▸ LVPW (2D)	
HR[a]	HR (M Mode or Doppler)	HR
CO	▸ LVOT D (2D) ▸ HR (Doppler) ▸ LVOT VTI (Doppler)	CO[a] SV CI[a] SI VTI HR LVOT D

[a]HR needed for CO and CI. You can enter the HR measurement on the patient form, or obtain it by measuring in M Mode or Doppler.
[b]dP:dT performed at 100 cm/s and 300 cm/s.
[d]Specified on the cardiac patient report.
[e]Need to measure E (MV measurement) to get E/e´ ratio.

Table 5–2: Cardiac calculations and results

Calculation list	Measurement name (imaging mode)	Results
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
	▸ E (Doppler) ▸ A (Doppler)	E E PG A A PG E:A
	▸ PHT (Doppler)	PHT MVA Decel time
	▸ VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
	▸ IVRT (Doppler)	time
	▸ Adur (Doppler)	time
MV MR	▸ dP:dT[b] (CW Doppler)	dP:dT

[a]HR needed for CO and CI. You can enter the HR measurement on the patient form, or obtain it by measuring in M Mode or Doppler.

[b]dP:dT performed at 100 cm/s and 300 cm/s.

[d]Specified on the cardiac patient report.

[e]Need to measure E (MV measurement) to get E/e´ ratio.

Table 5-2: Cardiac calculations and results

Calculation list	Measurement name (imaging mode)	Results
Area	▸ MVA (2D)	MV Area
	▸ AVA (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
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

[a]HR needed for CO and CI. You can enter the HR measurement on the patient form, or obtain it by measuring in M Mode or Doppler.

[b]dP:dT performed at 100 cm/s and 300 cm/s.

[d]Specified on the cardiac patient report.

[e]Need to measure E (MV measurement) to get E/e´ ratio.

Table 5–2: Cardiac calculations and results

Calculation list	Measurement name (imaging mode)	Results
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
	▸ VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
PV	▸ Vmax (Doppler)	Vmax PGmax
	▸ PVVTI (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

[a]HR needed for CO and CI. You can enter the HR measurement on the patient form, or obtain it by measuring in M Mode or Doppler.

[b]dP:dT performed at 100 cm/s and 300 cm/s.

[d]Specified on the cardiac patient report.

[e]Need to measure E (MV measurement) to get E/e´ ratio.

Table 5–2: Cardiac calculations and results

Calculation list	Measurement name (imaging mode)	Results
PISA	▸ Radius (Color) ▸ MRVTI (Doppler) ▸ Ann D (2D) ▸ MVVTI (Doppler)	PISA Area ERO MV Rate Regurgitant Volume Regurgitant Fraction
Qp/Qs	▸ LVOT D (2D) ▸ RVOT D (2D) ▸ LVOTVTI (Doppler) ▸ RVOTVTI (Doppler)	D VTI Vmax PGmax Vmean PGmean SV Qp/Qs
TDI	▸ 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/e' ratio[e]
TAPSE	TAPSE (M Mode)	TAPSE cm

[a]HR needed for CO and CI. You can enter the HR measurement on the patient form, or obtain it by measuring in M Mode or Doppler.
[b]dP:dT performed at 100 cm/s and 300 cm/s.
[d]Specified on the cardiac patient report.
[e]Need to measure E (MV measurement) to get E/e' ratio.

To measure Ao, LA, AAo, or LVOT D

1 On a frozen 2D image or M Mode trace, tap **Calcs**.

2 From the calculations menu, tap **Ao/LA**.

3 From the **Ao/LA** menu, select the measurement you want to take.

4 Position the calipers by dragging.

For more information, see **"Working with calipers"** on page 5-1.

5 Tap **Save Calcs**.

6 To save a picture of the finished calculation, tap .

7 Tap **Back** to exit the calculation.

To calculate MV or AV area

1 On a frozen 2D image, tap **Calcs**.

2 In the calculations menu, tap **Area.**

3 In the **Area** menu, select **MV** or **AV**.

4 If you are using the touchscreen, lift your finger from the screen momentarily to activate the trace. If you are using the touchpad, tap to set the position.

The trace feature becomes active.

5 Using the touchpad or the touchscreen, trace the desired area.

To make a correction, tap **Undo**, or tap the measurement name to restart the measurement.

WARNING

When using the touchpad to trace a shape, be careful not to touch until you are finished with the trace. Doing so may complete the trace prematurely, causing an incorrect measurement and delay of care.

6 When you are done, tap **Set**. The two ends of the trace are joined automatically.

7 Tap **Save Calc** to save the calculation.

For more information, see **"To save a calculation"** on page 5-10.

8 To save a picture of the finished calculation, tap .

9 Tap **Back** to exit the calculation.

To calculate LV mass

1 On a frozen 2D image, tap **Calcs**.

2 In the calculations menu, tap **LV mass**.

3 Do the following for these cardiac measurements, **Epi** and **Endo**:

a Select the measurement name from the **LV mass** menu.

b Using the touchpad or the touchscreen, position the caliper where you want to begin the trace.

c If you are using the touchscreen, lift your finger from the screen momentarily to activate the trace. If you are using the touchpad, tap  to activate the trace.

To make a correction, tap **Undo**, or tap the measurement name to restart the measurement.

d Using the touchpad or the touchscreen, trace the desired area, and then tap **Set**.

WARNING

When using the touchpad to trace a shape, be careful not to touch  until you are finished with the trace. Doing so may complete the trace prematurely, causing an incorrect measurement and delay of care.

e Tap **Save Calc** to save the calculation.

A check mark appears next to the saved measurement.

4 Select **Apical** from the **LV mass** menu.

5 Positioning the calipers, measure the ventricular length.

For more information, see **"Working with calipers"** on page 5-1.

6 Tap **Save Calc** to save the calculation.

7 To save a picture of the finished calculation, tap  .

8 Tap **Back** to exit the calculation.

To measure LVd and LVs

1 On a frozen 2D image or M Mode trace, tap **Calcs**.

2 Tap **LVd** or **LVs**.

3 Repeat the following for each measurement you want to take:

a On the **LVd** or **LVs** calculation list, tap the measurement you want to take.

b Position the calipers by dragging.

For more information, see **"Working with calipers"** on page 5-1.

c Tap **Save Calc** to save the calculation.

A check mark appears next to the saved measurement.

4 To save a picture of the finished calculation, tap  .

5 Tap **Back** to exit the calculation.

To measure Inferior Vena Cava (IVC) Collapse

1 On a frozen 2D image or M Mode trace, tap **Calcs**.

2 Tap **IVC**.

3 Do the following for both **Max D** and **Min D** measurements.

   a On the **IVC** calculations list, tap the measurement you want to take

   b Position the calipers by dragging.

   For more information, see **"Working with calipers"** on page 5-1.

   c Tap **Save Calc** to save the calculation.

   A check mark appears next to the saved measurement.

4 To save a picture of the finished calculation, tap .

5 Tap **Back** to exit the calculation.

To measure Ejection Fraction (EF)

1 On a frozen M Mode trace, tap **Calcs**.

2 Tap **EF**.

3 Do the following for both **LVDd** and **LVDs** measurements.

   a On the **EF** calculations list, tap the measurement that you want to take.

   b Position the calipers by dragging.

   For more information, see **"Working with calipers"** on page 5-1.

   c Tap **Save Calc** to save the calculation.

   A check mark appears next to the saved measurement.

4 To save a picture of the finished calculation, tap .

5 Tap **Back** to exit the calculation.

To measure Tricuspid Annular Plane Systolic Excursion (TAPSE)

1 On a frozen M Mode trace, tap **Calcs**.

2 In the calculations menu, tap **TAPSE**.

3 Position the calipers by dragging.

4 Tap **Save Calc** to save the calculation.

5 To save a picture of the finished calculation, tap .

6 Tap **Back** to exit the calculation.

To measure heart rate in Doppler

> **Note** 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, tap **Calcs**.

2 From the calculations menu, tap **HR**.

A vertical caliper appears.

3 Drag the first vertical caliper to the peak of the heartbeat, and then tap  to set the caliper position.

A second vertical caliper appears and is active.

4 Drag the second vertical caliper to the peak of the next heartbeat.

5 Tap **Save Calc** to save the calculation.

6 To save a picture of the finished calculation, tap  .

7 Tap **Back** to exit the calculation.

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:

- **a** On a frozen 2D image, tap **Calcs**.
- **b** On the calculations menu, tap **PISA**.
- **c** On the **PISA** calculations list, tap **Ann D**.
- **d** Position the calipers by dragging.
- **e** Tap **Save Calc** to save the calculation.

  A check mark appears next to the saved measurement.

2 Measure from Radius:

- **a** On a frozen Color image, tap **Calcs**.
- **b** On the calculations menu, tap **Radius**.
- **c** Position the calipers by dragging.
- **d** Tap **Save Calc** to save the calculation.

  A check mark appears next to the saved measurement.

3 On a frozen Doppler spectral trace, tap **Calcs**.

4 On the calculations menu, tap **PISA**.

5 Do the following for both **MRVTI** and **MVVTI**:

   a On the **PISA** calculations list, select the measurement you want to make.

   b Use the automatic trace tool to trace the waveform. See **"To perform automatic trace measurements in Doppler"** on page 5-8.

   c Tap **Save Calc** to save the calculation.

6 To save a picture of the finished calculation, tap  .

7 Tap **Back** to exit the calculation.

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, tap **Calcs**.

2 On the calculations menu, tap **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 by dragging.

   c Tap **Save Calc** to save the calculation.

   A check mark appears next to the saved measurement.

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, tap **Calcs**.

2 On the calculations menu, tap **VTI** under **MV**, **AV**, **TV**, or **PV**.

3 Use the automatic trace tool to trace the waveform. See **"To perform automatic trace measurements in Doppler"** on page 5-8.

4 Tap **Save Calc** to save the calculation.

5 To save a picture of the finished calculation, tap  .

6 Tap **Back** to exit the calculation.

To calculate Right Ventricular Systolic Pressure (RVSP)

1 On a frozen Doppler spectral trace, tap **Calcs**.

2 On the calculations menu, tap **TV** and then **TRmax**.

3 Position the caliper by dragging.

4 Tap **Save Calc** to save the calculation.

> **Note:** This calculation requires the RA pressure. If RA pressure has not been adjusted, the default value of 5 mmHg is used. Adjust the RA pressure in the Cardiac patient report.

5 To save a picture of the finished calculation, tap  .

6 Tap **Back** to exit the calculation.

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

1 On a frozen Doppler spectral trace, tap **Calcs**.

2 On the calculations menu, tap **MV**, **AV**, or **TV**, and then **PHT**.

Position the first caliper at the peak, and then tap  . 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 Tap **Save Calc** to save the calculation.

5 To save a picture of the finished calculation, tap  .

6 Tap **Back** to exit the calculation.

To calculate Isovolumic Relaxation Time (IVRT)

1 On a frozen Doppler spectral trace, tap **Calcs**.

On the calculations menu, tap **MV,** and then **IVRT**. A vertical caliper appears.

2 Position the caliper at the aortic valve closure.

3 Tap  . A second vertical caliper appears.

4 Position the second caliper at onset of mitral inflow.

5 Tap **Save Calc** to save the calculation.

6 To save a picture of the finished calculation, tap  .

7 Tap **Back** to exit the calculation.

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.

1 On a frozen Doppler spectral trace, tap **Calcs**.

2 On the calculations menu, tap **MV**, and then **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 Tap  .

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.Tap **Save Calc** to save the calculation.

6 To save a picture of the finished calculation, tap  .

7 Tap **Back** to exit the calculation.

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:

- **a** On a frozen 2D image, tap **Calcs**.
- **b** On the calculations menu, tap **Ao/LA**.
- **c** From the **Ao/LA** calculation list, select **LVOT D**.
- **d** Position the calipers.
- **e** Tap **Save Calc** to save the calculation.

2 In PW Doppler, measure either LVOT Vmax or LVOT VTI.

- **Vmax** – Tap **AV**, then tap the **Vmax** measurement under **LVOT**. Position the caliper, and then save the measurement.
- **VTI** – Tap **AV**, then tap the **VTI** measurement under **LVOT**. Use the automatic trace tool to trace the waveform, and then save the measurement.

Notes If **VTI** is chosen, the Vmax value derived from the trace is used as input to the AVA calculation.

3 In CW Doppler, measure either AV Vmax or AV VTI.

- **Vmax** – Tap **AV**, and then **Vmax**. Position the caliper, and then save the measurement.

- **VTI** – Tap **AV** and then **VTI**. Use the automatic trace tool to trace the waveform, and then save the measurement.

Notes

- If **VTI** is chosen, the Vmax value derived from the trace is used as input to the AVA calculation.
- If VTI measurements are made for both LVOT and AV, a second AVA result is provided.

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, tap **Calcs**.
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. Tap **Save Calc** to save the calculation.
3. On a frozen Doppler spectral trace, tap **Calcs**.
4. Do the following to measure from LVOT VTI and again to measure from RVOT VTI:
   a. On the calculations menu, tap **Qp/Qs** and then **LVOTVTI** or **RVOTVTI**.
   b. Use the automatic trace tool to trace the waveform. See **"To perform automatic trace measurements in Doppler"** on page 5-8.
   c. Tap **Save Calc** to save the calculation.

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.
2. Measure from LVOT (2D):
   a. On a frozen 2D image, tap **Calcs**.
   b. On the calculations menu, tap **Ao/LA** then **LVOT D**.
   c. Position the calipers.
   d. Tap **Save Calc** to save the calculation.
3. Measure from **LVOT** (Doppler). Refer to **"To calculate Velocity Time Integral (VTI)"** on page 5-25. On the calculations menu, tap **AV** and then **LVOTVTI**.

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.

2 Calculate SV as described in **"To calculate Stroke Volume (SV) or Stroke Index (SI)"** on page 5-28.

3 Calculate HR as described in **"To measure heart rate in Doppler"** on page 5-24.

To calculate Cardiac Output (CO) automatically

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.

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 or pediatric patients.
  - To avoid inaccurate velocity measurements if you use PW Doppler, make sure that the angle is set to zero

1 Measure from LVOT:
   - **a** On a frozen 2D image, tap **Calcs**.
   - **b** On the **CO** calculations menu, tap **LVOT D**.
   - **c** Position the calipers by dragging.
   - **d** Tap **Save Calc** to save the calculation.

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 live Doppler spectral trace.
   - **b** Tap the arrow to navigate to the next page.
   - **c** Tap **Trace**, and then select **Above** or **Below** to position the automatic trace tool relative to the baseline.
   - **d** Freeze the image, then tap **Calipers**.
   - **e** Tap **Auto**  .

     A vertical caliper appears.
   - **f** Using the touchpad or the touchscreen, position the caliper at the beginning of the desired waveform, and then tap  .

     A second vertical caliper appears

g Using the touchpad or the touchscreen, position the caliper at the end of the desired waveform, and then tap **Set**.

> **Note** If you invert the frozen image or move the baseline, results are cleared.

h Tap **Save Calc** to save the calculation.

To measure a Tissue Doppler Imaging (TDI) waveform

1. Ensure that TDI is on.
2. On a frozen Doppler spectral trace, tap **Calcs**.
3. Tap **TDI** on the calculations menu, and then do the following for each measurement you want to take:
   - **a** On the calculations menu, select the measurement name.
   - **b** Position the calipers.
   - **c** Tap **Save Calc** to save the calculation.

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.

The MSK calculations include hip angle and hip ratio.

To calculate hip angle

1. On a frozen 2D image, tap **Calcs**.
2. Do the following under **Right** and again under **Left**:
   - **a** Under **Hip Angle**, select **Baseline**.

     A baseline with calipers appears.
   - **b** Using the touchpad or the touchscreen, position the baseline.

     Line A (alpha line) appears, and **Line A** is selected in the calculations menu.
   - **c** Position Line A, and save the measurement.

     Line B (beta line) appears, and **Line B** is selected in the calculations menu.
   - **d** Position Line B, and save the measurement.

To calculate hip ratio

1 On a frozen 2D image, tap **Calcs**.

2 Do the following under **Right** and again under **Left**:

   a Under **d:D Ratio**, select **Fem Hd** (femoral head).

   An ellipse with calipers appears.

   b Using the touchpad or the touchscreen, position and resize the ellipse.

   The  key toggles between position and size.

   c Tap **Set**.

   The baseline appears automatically with the left caliper active.

   d Position the caliper.

Save the calculation

Gynecology (Gyn) calculations

Gynecology (Gyn) calculations include Uterus, Ovary, Follicle, and Volume. For instructions to calculate volume, refer to **"Patient report"** on page 5-35.

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 4-22.

To measure uterus or ovary

1 On a frozen 2D image, tap **Calcs**.

2 Tap the name of the structure you want to measure: **Uterus**, **R Ovary**, or **L Ovary**.

3 Do the following for each of the length, height, and width measurements:

   a Select the measurement name from the calculations menu.

   b Position the calipers.

   For more information, see **"Working with calipers"** on page 5-1.

   c Tap **Save Calc** to save the calculation.

A check mark appears next to the saved measurement.

4 To save a picture of the finished calculation, tap .

5 Tap **Back** to exit the calculation.

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, tap **Calcs**.

2 From the calculations menu, select **Follicle**.

3 Do the following for each follicle you want to measure:

   a From the calculations menu, select the measurement name under **Right Fol** or **Left Fol**.

   b Position the calipers.

   For more information, see **"Working with calipers"** on page 5-1.

   c Tap **Save Calc** to save the calculation.

   A check mark appears next to the saved measurement.

4 To save a picture of the finished calculation, tap .

5 Tap **Back** to exit the calculation.

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

- 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 5-33.
- 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 4-22.

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 settings" on page 3-11.

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

Table 5-3: 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	—

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

[b]For Tokyo U., APTD and TTD are used only to calculate EFW. No age or growth tables are associated with these measurements.

[c]The 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 settings" 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.

Table 5-3: 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

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

[b]For Tokyo U., APTD and TTD are used only to calculate EFW. No age or growth tables are associated with these measurements.

[c]The 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 settings"** 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.

To measure gestational growth (2D)

For each 2D OB measurement (except CxLen and YS), 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 enter the **LMP** or **Estab.DD** for the patient, if known.

2 On a frozen 2D image, tap **Calcs**.

3 Do the following for each measurement you want to take:

a From the calculations menu, select the measurement name.

Note The caliper tool may change depending on the measurement selected.

b Position the calipers.

For more information, see **"Working with calipers"** on page 5-1.

c Tap **Save Calc** to save the calculation.

A check mark appears next to the saved measurement.

4 To save a picture of the finished calculation, tap .

5 Tap **Back** to exit the calculation.

To measure fetal heart rate (M Mode)

1 On a frozen M Mode trace, tap **Calcs**.

2 Select **FHR** from the calculations menu. A vertical caliper appears.

3 Position the vertical caliper at the peak of the heartbeat.

If you are using the touchpad, tap  . A second vertical caliper appears.

4 Position the second vertical caliper at the peak of the next heartbeat.

If you are using the touchpad, tap  .

5 Tap **Save Calc** to save the calculation.

6 To save a picture of the finished calculation, tap .

7 Tap **Back** to exit the calculation.

Patient report

The patient report contains calculation results and patient information for the exam. For OB and Cardiac 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 After or during the exam, tap **Patient**, and then tap **Report**.

2 To display additional pages, tap **x/x**, or turn the left knob.

3 To exit the patient report and return to imaging, tap **Done**.

To save a report to a study

❖ In an open patient report, tap **Save** on each page that you want to save.

To delete an OB measurement

1 In the OB patient report, select the measurements to delete by tapping it.

The selected measurement turns yellow.

2 Tap **Delete**.

To delete a cardiac measurement

1 In the Cardiac patient report, tap **Details** to open the **Details** page.

2 Select the measurement to delete.

The selected measurement turns yellow.

3 Tap **Delete**. Deleting some measurements also deletes related measurements. Deleted measurements are not included in the summary information.

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.

MSK worksheets

To display an MSK worksheet

The MSK worksheets have lists from which you can select and a field for entering comments. Saved MSK worksheets become part of the patient report.

1 After or during the exam, tap **Patient** and then tap **MSK**.

2 Select a specific body area from the **Worksheet** list.

3 To display additional pages in the worksheet, tap **x/x**, or turn the left knob.

Each worksheet has its own **Comments** field, which remains on-screen even if you display another page in the worksheet.

4 To save a worksheet page, tap **Save**.

5 To exit the MSK worksheet, tap **Done**.

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: 2D Measurement Accuracy and Range

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

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

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

Table 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

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

Table 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

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

Sources of measurement errors

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

- **Acquisition Error:** Includes errors introduced by the ultrasound system electronics relating to signal acquisition, signal conversion, and signal processing for display. Additionally, computational and display errors are introduced by the generation of the pixel scale factor, application of that factor to the caliper positions on the screen, and the measurement display.
- **Algorithmic Error:** The error introduced by measurements, which are input to higher order calculations. This error is associated with floating-point versus integer-type math, which is subject to errors introduced by rounding versus truncating results for display of a given level of significant digit in the calculation.

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.

ACC = abs (delta velocity/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.

[time a – 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.

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

Weight = kilograms

Height = centimeters

Cardiac Index (CI) in l/min/m^2

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 cm^2

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 mm^2

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 closureIVC Percentage Collapse

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 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 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 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.

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

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 =((End Diastolic Volume - End Systolic Volume)/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 cm^2

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.

Flow = PISA * Va

where:

PISA = Proximal Isovelocity SurfaceArea

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 cm^2

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual.* 3rd ed., Philadelphia: Lippincott, Williams, and Wilkins, (2007), p.74-76.

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.

Qp/Qs = SV Qp site/SV Qs site = RVOT SV/LVOT SV

where:

RVOT SV = RVOT CSA* RVOT VTI = $\pi/4$ * RVOT diameter^2 * RVOT VTI

LVOT SV = LVOT CSA * LVOT VTI = $\pi/4$ * LVOT diameter^2 * 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.

RF = RV/ 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.

RV = ERO * 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 = π/4 * Σ(ai) * ai * L/20 for i = 1 to 20 (number of segments)

where:

RA Vol = Right Atrial Volume in ml

ai = 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.

$RVSP = 4 * (VMax\ TR)^2 + RAP$

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/m^2

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
LVEDSV = 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 = 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 = system date + (280 days – 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. Cousaert, 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. Cousaert, 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. Cousaert, 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. Cousaert, 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 = (Velocity A/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(cm^2)/A1(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(cm)/D1(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 * $(Velocity)^2$

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 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 (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 = ((Velocity A – Velocity B)/Velocity A) in measurements

where:

A = velocity cursor +
B = velocity cursor x

Time Averaged Mean (TAM) in cm/s

TAM = mean (mean Trace)

Time Averaged Peak (TAP) in cm/s

TAP = 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 (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 LCD screen to improve 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 3-8.

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.

A maintenance icon  appears on the system screen

System maintenance may be required. Record the number in parentheses on the C: line and contact FUJIFILM SonoSite or your local representative.

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 settings" on page 3-12.

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 Tap **Done**.

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 tap **Done**.

Maintenance

WARNINGS

- No modification of this equipment, except as described in this manual or the *SonoSite SII 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 **"Cleaning and Disinfecting"** on page 8-1 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 **"Getting Started"** on page 2-1 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.
- 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 it is 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.

WARNING

- 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?		
YES	Came in contact with broken skin or mucosal membranes.	→ **Option A** Go to **"Clean and disinfect system and transducer to a high level (semi-critical uses)"** on page 8-3
OR		

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. See **Table 8-1**.

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.

Cautions

- 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 disinfected 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 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 or disinfectant. Choose a cleaner from the list of approved cleaners. Remove all gel and debris from the system.

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 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.

c 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.

d Allow the ultrasound system 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 *SonoSite SII 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.

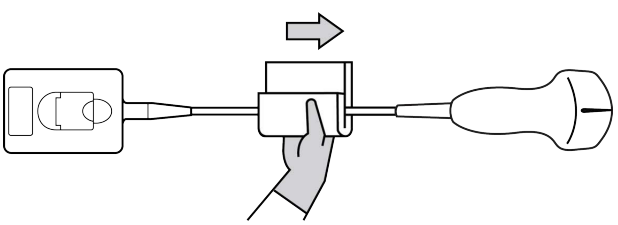
[b] Qualified for use as an intermediate-level disinfectant for mycobacteria.

[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. 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.

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 SII 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[a], P10x, rC60xi, rP19x	20°C, 68°F	12 minutes
Revital-OX Resert	C35x	20°C, 68°F	8 minutes

[a] 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.

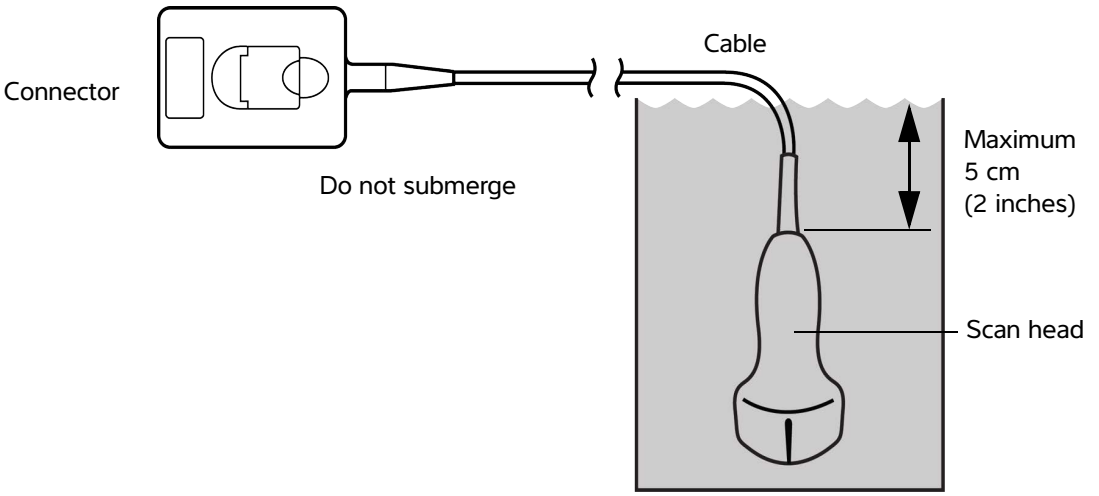


Figure 8-1 Transducer component names

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.

a Rinse the transducer in clean, running water according to the disinfectant manufacturer's instructions (at least 1 minute).

b Ensure that the connector and at least 12-18 inches (31-46 cm) of the cable from the connector remain dry.

c Repeat this step until the transducer has been rinsed three separate times.

13 Dry 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 Option A, **"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.

Cautions

- 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 *SonoSite SII 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.

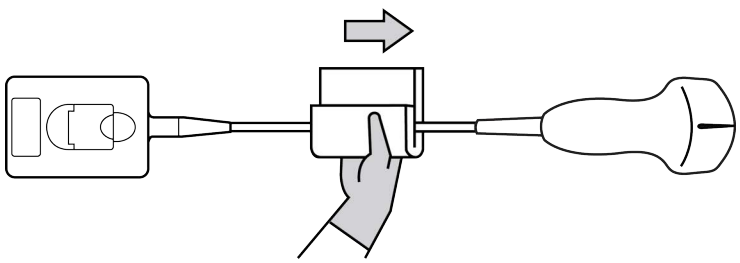
[b] Qualified for use as an intermediate-level disinfectant for mycobacteria.

[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 transducer and system 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 the transducer. 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^{o} C (32^{o} F) and $+45^{o}$ C (113^{o} 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 *SonoSite SII 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.

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*. (May1997), 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 classification

Class I equipment	The ultrasound system is classified as Class I equipment when powered from the external power supply or mounted on the stand because the external power supply is a Class 1 protectively earthed power supply. The stand has no protective earth. Ground bond testing is not applicable to the ultrasound system or the stand. Note: AC powered peripherals that may be used with the system are Class I and are individually protectively earthed. Ground bond testing may be conducted on each AC powered peripheral.
Internally powered equipment	Ultrasound system not connected to the power supply (battery only)
Type BF applied parts	Ultrasound transducers
IPX-7 (watertight equipment)	Ultrasound transducers
IPX-8 (watertight equipment)	Footswitch
Non AP/APG	Ultrasound system power supply, SonoSite SII stand, and peripherals. Equipment is not suitable for use in the presence of flammable anaesthetics.

Electrical safety

This system meets EN60601-1, Class I/internally-powered equipment requirements and Type BF 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 9-32

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.
- To avoid the risk of injury, do not operate the system in the presence of flammable gasses 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.

WARNINGS

To avoid the risk of electrical shock:

- Connect this equipment to a supply main with protective earth.
- 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, to touch the patient.
- Use only properly grounded equipment. Shock hazards exist if the power supply is not properly grounded. Grounding reliability can only be achieved when equipment is connected to a receptacle marked "Hospital Only" or "Hospital Grade" or the equivalent. 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 touch the power supply and the patient at the same time.
- Do not touch any of the following:
  - The signal input/output connectors on the back of the ultrasound system
  - The system battery contacts (inside the battery compartment)
  - The system transducer connectors when the transducers are disconnected
- Do not connect either of the following to an MSO or extension cord:
  - System power supply
  - Auxiliary mains outlet receptacles on the SonoSite SII stand
- 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 **"Troubleshooting and Maintenance"** on page 7-1
- Use only accessories and peripherals recommended by FUJIFILM SonoSite, including the power supply. Connection of accessories and peripherals not recommended by FUJIFILM SonoSite could result in electrical shock. Contact FUJIFILM SonoSite or your local representative for a list of accessories and peripherals available from or recommend by FUJIFILM SonoSite.

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, SonoSite SII stand to mains power must only be used with the power supply or stand, and cannot be used to connect other devices to mains power.

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

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 button until the system powers down.
- To avoid increasing the system and transducer connector temperature, do not block the airflow to the ventilation holes.

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 **"Troubleshooting and Maintenance"** on page 7-1
- 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.
- Periodically, check to make sure that the battery charges fully. If the battery fails to charge fully, replace it.

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.
- 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. Discontinuities in the scanning sequence are indicative of a hardware failure that must be corrected before use.
- 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 attentuation 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.
- 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 transducer 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 of 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.

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 9-13.

Note The emissions characteristics of the SonoSite SII 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.

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 ultrasound system implements two wireless solutions.

- Wireless USB Dongle (Panda) is a small wireless adapter that plugs into the USB port on the upper back of the ultrasound system.

- Wireless and Security Module (Laird) is a module that mounts on the transducer holder arm of the ultrasound system and then plugs into the system with a 12 inch 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 throuohput: 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 ± 2 dBm @ 54 Mbps
- IEEE 802.11b with Direct Sequence Spread Spectrum (DSSS) at 16 dBm ± 2.0 dBm @ 11 Mbps
- IEEE 802.11g with Orthogonal Frequency Division Multiplexing (OFDM) at 13 dBm ±2.0 dBm @ 54 Mbps
- IEEE 802.11n with Orthogonal Frequency Division Multiplexing (OFDM) at 12 dBm ± 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.

WARNINGS

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:

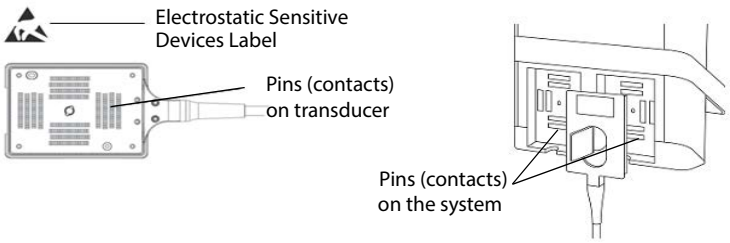


Figure 1 The transducer connector is an example of an electrostatically-sensitive device.

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

Table 9-1: Recommended separation between portable and mobile RF communications equipment and the SonoSite SII 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 √P	80 MHz to 800 MHz d=1.2 √P	800 MHz to 2.5 GHz d=2.3 √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 SII 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 SII ultrasound system.

WARNINGS

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

Description	Maximum Cable Length[a]
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	7.5 ft/2.3 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[b]	7.9 ft/2.4 m
P10x transducer	6.0 ft/1.8 m
rP19x transducer standard/armored	6.0 ft/1.8 m
Bar code scanner	4.8 ft/1.5 m
Battery for PowerPack	—
Battery Pack	—
Battery PowerPack	—

Table 9-2: Accessories and peripherals compatible with SonoSite SII ultrasound system

Description	Maximum Cable Length[a]
Black & white printer	—
Black & white printer power cable	3.3 ft/1 m
Black & white printer control cable	6.0 ft/1.8 m
Black & white printer video cable	6.2 ft/1.9 m
Footswitch	9.8 ft/3 m
Footswitch USB extension cable	6.5 ft/2 m
SonoSite SII Stand	—
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	—
USB wireless adapter	—
USB memory drive	—

[a]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.

[b]The L52x transducer is for veterinary use only.

Manufacturer's declaration

The tables in this section document the intended use environment and EMC compliance levels of the system. For maximum performance, ensure that the system is used in the environments described in 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 SII ultrasound system uses RF energy only for their internal functions. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The SonoSite SII ultrasound system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

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.		

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

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

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	U_T is the AC mains voltage prior to application of the test level. At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
a. Field strengths from fixed transmitters such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the FUJIFILM SonoSite ultrasound system is used exceeds the applicable RF compliance level above, the FUJIFILM SonoSite ultrasound system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the FUJIFILM SonoSite ultrasound system. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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

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

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
	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
	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

Table 9-6: Standards labeling symbols

Symbol	Title	Standards development organization	Reference number	Description
	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
	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
	Medical Device	EU MDR	EU MDR Annex I, 23.2 (q)	Indicates that the device is a medical device
	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
	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

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
	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
	CE marking	—	—	Signifies European Technical Conformity
	Conformité Européene Notified Body Reference No.: 0086	—	—	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.

Table 9-6: Standards labeling symbols

Symbol	Title	Standards development organization	Reference number	Description
	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
	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
	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
	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

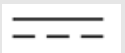
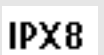
Symbol	Title	Standards development organization	Reference number	Description
	Date of manufacture	ISO 7000- Graphical symbols for Use on Equipment	5.1.3	To indicate the date on which a product was manufactured
	Direct current (DC)	—	—	—
	21 Part 15	Federal Communications Commission (FCC) Declaration of conformity	—	FCC-Tested to Federal Communications Commission requirements Device complies with relevant FCC regulations for electronic devices
GEL	Gel	—	—	—
	Resy- Recycling Symbol	—	—	Paper recycle
	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
	—	—	—	Indicates handle with care
	—	—	—	Indicates follow manufacturer's instructions for disinfecting time
	—	—	—	Indicates disinfect transducer

Table 9-6: Standards labeling symbols

Symbol	Title	Standards development organization	Reference number	Description
	—	—	—	To avoid tipping, do not move the system using the handle on the front of the SonoSite SII ultrasound system.
	—	—	—	When moving the system, push the stand using the tray assembly.
	Maximum weight load	IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic	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 (5)	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 someparts/ products because of space limitations.)
	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.)

Table 9-6: Standards labeling symbols

Symbol	Title	Standards development organization	Reference number	Description
	China Compulsory Certificate mark ("CCC Mark").	—	—	A compulsory safety mark for compliance to Chinese national standards for many products sold in the People's Republic of China.
	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
	For indoor use only	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	5957	Identifies electrical equipment designed primarily for indoor use

Specifications

This chapter contains system and accessory specifications and standards. The specifications for recommended peripherals are in the manufacturers' instructions.

System

- Dimensions
  - Height: 44.7 cm (17.6 inches)
  - Height with stand:
    - Max: 151 cm (59.5 inches)
    - Min:124.5 cm (49 inches)
  - Width: 28.7 cm (11.3 inches)
  - Depth: 12.2 cm (4.8 inches)

- Weight
  - System: 5.7 kg (12.5 lbs)
  - System with stand: 26.1 kg (57.5 lbs.)

Imaging modes

- 2D (256 gray shades)
- Color power Doppler (CPD) (256 colors)
- Color Doppler (Color) (256 colors)
- M Mode
- Tissue Harmonic Imaging (THI)

Images and clips storage

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

Accessories

The following items are either included with or available for use on the ultrasound system.

- Battery
- Biopsy Guide
- Needle Guide
- Power supply
- PDAS (SiteLink) Image Manager
- System AC power cord (10 ft/3.1 m)

Peripherals

Peripherals include medical grade (conforming to EN60601-1 requirements) and non-medical grade (commercial) products. Manufacturer's instructions accompany each peripheral.

Medical grade

- Bar code scanner, USB
- Black-and-white printer
  Recommended sources for printer paper:
  To order supplies or to find the local distributor, contact Sony at www.sony.com/digitalphotofinishing.

Non-medical grade

- Kensington Security Cable

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)

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 – 1060hPa (0.5 – 1.05 ATM)

Electrical specifications

- Power Supply Input: 100 – 240 VAC, 50–60 Hz, 2.0 – 1.0 A
- Power Supply Output #1: 15.0 VDC, 5.0 A maximum
- Power Supply Output #2: 9-12.6 VDC, 2.3 A maximum

Note 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

Table 9-7: 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 T0601-1:2012 (3rd Edition)	Japanese Industrial Standard, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

EMC standards classification

Table 9-8: EMC standards classification

Standard	Description
IEC 60601-1-2:2007	Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance-Collateral Standard. Electromagnetic Compatibility. Requirements and Tests.
CISPR 11:2009	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 (2014).

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

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

Airborne equipment standards

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

DICOM standard

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.

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	↑
C11x	↑
↓ 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
C35x	↑
rC60xi standard/armored	↑
HFL38xi standard/armored	↑
HFL50x	↑
HSL25x	↑
ICTx	↑
L25x standard/armored	↑
L38xi standard/armored	↑
P10x	↑
rP19x standard/armored	↑
↓ Decrease or lower setting of parameter to reduce MI. ↑ Increase or raise setting of parameter to reduce MI.	

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

Table 10-2: Guidelines for reducing TI (continued)

Transducer	CPD Settings						PW Settings
	Box Width	Box Height	Box Depth	PRF	Depth	Optimize	
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)
↓ 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 ≥ 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 ≥ 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

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 10-69.

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°C ± 3°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 (°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 (°C)

Test	ICTx	C8x
Still air	9.2	11.3
Simulated use	5.2	5.5

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/cm^2. The temperature elevations for fetal bone and tissue were computed based on calculation procedures given in Sections 4.3.2.1-4.3.2.6 in "Bioeffects and Safety of Diagnostic Ultrasound" (AIUM, 1993).

Acoustic output tables

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 10-68.

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_{1x1} (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					
	n_{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_{1x1} (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	prr (Hz)	800					
	srr (Hz)	—					
	n_{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_{1x1} (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)	2548					
	srr (Hz)	26					
	n_{pps}	12					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm^2)	381					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ (mW/cm^2)	132					
	I_{spta} at z_{pii} or z_{sii} (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_{1x1} (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	prr (Hz)	1008					
	srr (Hz)	—					
	n_{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)	#					
	n_{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_{1x1} (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					
	n_{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_{1x1} (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	prr (Hz)	#					
	srr (Hz)	#					
	n_{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_{1x1} (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					
	n_{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_{1x1} (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)	—					
	n_{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					
	p_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_{1x1} (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	prr (Hz)	4537					
	srr (Hz)	13.5					
	n_{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					
	p_r at z_{pii} (MPa)	0.46					
Operating controls	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_{1x1} (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)	—					
	n_{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_{1x1} (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					
	n_{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_{1x1} (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)	—					
	n_{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_{1x1} (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)	2223					
	srr (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_{1x1} (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)	—					
	n_{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_{1x1} (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)	2733					
	srr (Hz)	7.2					
	n_{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_{1x1} (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)	—					
	n_{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_{1x1} (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)	8233					
	srr (Hz)	3.2					
	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)	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_{1x1} (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)	—					
	n_{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_{1x1} (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					
	n_{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_{1x1} (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)	—					
	n_{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_{1x1} (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	prr (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 10-28: 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_{1x1} (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)	—					
	n_{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_{1x1} (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	prr (Hz)	1061					
	srr (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 10–30: 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_{1x1} (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	*prr* (Hz)	3079					
	srr (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_{1x1} (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)	#					
	n_{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)	#					
	n_{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_{1x1} (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					
	n_{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_{1x1} (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)	—					
	n_{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_{1x1} (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	prr (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_{1x1} (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)	—					
	n_{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_{1x1} (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	prr (Hz)	1061					
	srr (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_{1x1} (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	*prr* (Hz)	5261					
	srr (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_{1x1} (mW)		#		32.1		
	z_s (cm)			#			
	z_b (cm)					0.75	
	z_{MI} (cm)	#					
	$z_{pii,\alpha}$ (cm)	#					
	f_{awf} (MHz)	#	#		#		#
Other information	prr (Hz)	#					
	srr (Hz)	#					
	n_{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_{1x1} (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					
	n_{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_{1x1} (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	prr (Hz)	1600					
	srr (Hz)	—					
	n_{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_{1x1} (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	*prr* (Hz)	2190					
	srr (Hz)	4.5					
	n_{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_{1x1} (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	prr (Hz)	1008					
	srr (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_{1x1} (mW)		#		#		
	z_s (cm)			—			
	z_b (cm)					—	
	z_{MI} (cm)	#					
	$z_{pii,\alpha}$ (cm)	#					
	f_{awf} (MHz)	#	#		#		3.89
Other information	*prr* (Hz)	#					
	srr (Hz)	#					
	n_{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_{1x1} (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	prr (Hz)	#					
	srr (Hz)	#					
	n_{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_{1x1} (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	*prr* (Hz)	1562					
	srr (Hz)	—					
	n_{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_{1x1} (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	prr (Hz)	3584					
	srr (Hz)	28.0					
	n_{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_{1x1} (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	*prr* (Hz)	800					
	srr (Hz)	—					
	n_{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_{1x1} (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	*prr* (Hz)	1265					
	srr (Hz)	9.89					
	n_{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_{1x1} (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)	—					
	n_{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_{1x1} (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	prr (Hz)	6413					
	srr (Hz)	15.6					
	n_{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_{1x1} (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)	—					
	n_{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_{1x1} (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					
	n_{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_{1x1} (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)	—					
	n_{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_{1x1} (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	prr (Hz)	6186					
	srr (Hz)	48.3					
	n_{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_{1x1} (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	*prr* (Hz)	800					
	srr (Hz)	—					
	n_{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_{1x1} (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	prr (Hz)	505					
	srr (Hz)	7.9					
	n_{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_{1x1} (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)	#					
	n_{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_{1x1} (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_{awf} (MHz)	2.14	2.23		2.23		2.10
Other information	*prr* (Hz)	1562					
	srr (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.

Terms used in the acoustic output tables

Table 10-60: 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_{1x1}	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 10-60: Terms used in the acoustic output tables

Term	Definition
z_{sii}	Depth for peak sum of pulse-intensity integrals.
$z_{sii,\alpha}$	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 10-61: Acoustic measurement precision and uncertainty

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

Chapter 11

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 Picture Archiving and Communication System (PACS) by DICOM communication.
- Querying examination orders from the Modality Worklist (MWL) server by DICOM communication and starting them.
- Setting the time of this device by inquiring 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 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 WLAN.
- 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

MWL Server ----------> SonoSite SII ----------> PACS

Study order	Study data
(DICOM MWL)	(DICOM Storage)

Please refer to the *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.

Chapter A

Glossary

Terms

For ultrasound terms not included in this glossary, refer to *Recommended Ultrasound Terminology, Second Edition,* published in 1997 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.
LCD	liquid crystal display
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 **"Acoustic Output"** on page 10-1 for a more complete description of MI.
MI/TI	Refer to *mechanical index (MI)* and *thermal index (TI).*

NTSC	National Television Standards Committee. A video format setting. Refer to *PAL*.
PAL	Phase Alternating Line. A video format setting. Refer to *NTSC*.
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.
SonoHD2™ Imaging Technology	A subset of the 2D imaging mode in which the 2D image is enhanced by reducing speckle noise artifact at tissue margins and improving contrast resolution by reducing artifacts and improving visualization of texture patterns within the image.
SonoMB technology, Steep Needle Profiling technology	A subset of the 2D imaging mode in which the 2D image is enhanced by looking at a target from multiple angles and then merging or averaging the scanned data together to improve overall image quality and, in parallel, reducing noise and artifacts.
Tissue Doppler Imaging	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 **"Acoustic Output"** on page 10-1 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	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 A–1: Abbreviations in User Interface

Abbreviation	Definition
A	"A" Wave Peak Velocity
A PG	"A" Wave Peak Pressure Gradient
A/B	A Caliper/B Caliper: Ratio
A2Cd	Apical 2 Chamber diastolic
A2Cs	Apical 2 Chamber systolic
A4Cd	Apical 4 Chamber diastolic
A4Cs	Apical 4 Chamber systolic
AAA	Abdominal Aortic Aneurysm
AAo	Ascending Aorta
Abd	Abdomen
abs	Absolute value
ACC	Acceleration Index
ACS	Aortic Valve Cusp Separation
Adur	"A" wave duration

Table A-1: Abbreviations in User Interface (continued)

Abbreviation	Definition
AI	Aortic Insufficiency
AI PHT	Aortic Insufficiency Pressure Half Time
Ann D	Annulus Diameter
ANT F	Anterior Far
ANT N	Anterior Near
Ao	Aorta
AoD	Aortic Root Diameter
Apical	Apical View
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.
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

Table A-1: Abbreviations in User Interface (continued)

Abbreviation	Definition
CPD	Color Power Doppler
Crd	Cardiac
CW	Continuous Wave Doppler
CxLen	Cervix Length
D	Diameter
D Apical	Distance Apical
DCCA	Distal Common Carotid Artery
DECA	Distal External Carotid Artery
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
ECICA	Extracranial Internal Carotid Artery
ECVA	Extracranial Vertebral Artery
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

Table A-1: Abbreviations in User Interface (continued)

Abbreviation	Definition
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
Endo Th	Endometrial thickness
Epi	Epicardial
EPSS	"E" Point Septal Separation
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
FM (Right and Left)	Foramen Magnum (same as SO)
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
Gyn	Gynecology
HL	Humerus Length
HR	Heart Rate
IVRT	Iso Volumic Relaxation Time
IVS	Interventricular Septum
IVSd	Interventricular Septum Diastolic
IVSFT	Interventricular Septum Fractional Thickening
IVSs	Interventricular Septum Systolic
LA	Left Atrium

Table A-1: Abbreviations in User Interface (continued)

Abbreviation	Definition
LA/Ao	Left Atrium/Aorta Ratio
Lat V	Lateral Ventricle
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
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

Table A-1: Abbreviations in User Interface (continued)

Abbreviation	Definition
LVPWs	Left Ventricular Posterior Wall Systolic
LVs	Left Ventricular systolic
MB	SonoMB
MI	Mechanical Index
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
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 Iso Velocity Surface Area
MV Rate	Mitral Valve Rate
Neo	Neonatal
Nrv	Nerve
NTSC	National Television Standards Committee
OB	Obstetrical
Oph	Ophthalmic
P. Vein	Pulmonary Vein
PGmax	Maximum Pressure Gradient
PGmean	Mean Pressure Gradient

Table A–1: Abbreviations in User Interface (continued)

Abbreviation	Definition
PGr	Pressure Gradient
PHT	Pressure Half Time
PI	Pulsatility Index
PICA	Proximal Internal Carotid Artery
PISA	Proximal Isovelocity Surface Area
PRF	Pulse Repetition Frequency
PSV	Peak Systolic Velocity
PV	Pulmonic Valve
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/D	Systolic/Diastolic Ratio
SI	Stroke Index
SmP	Small Parts
Sup	Superficial

Table A-1: Abbreviations in User Interface (continued)

Abbreviation	Definition
SV	Stroke Volume
TAM	Time Average Mean
TAP	Time Average Peak
TCD	Trans-cerebellum Diameter (OB measurement) Transcranial Doppler (exam type)
TDI	Tissue Doppler Imaging
THI	Tissue Harmonic Imaging
TI	Thermal Index
TRmax	Tricuspid Regurgitation (peak velocity)
TV	Tricuspid Valve
TVA	Tricuspid Valve Area
UA	Ultrasound Age Calculated on the mean measurements taken for a particular fetal biometry.
VA	Vertebral Artery
VArty	Vertebral Artery
Vas	Vascular
Ven	Venous
Vmax	Peak Velocity
Vmean	Mean Velocity
VTI	Velocity Time Integral
YS	Yolk Sac

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