
SonoSite M-Turbo Ultrasound System



User Guide

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The FUJIFILM SonoSite ultrasound system(s) referenced in this document may be covered by one or more of the following U.S. patents: Patents: US 9,895,133; US 9,671,491; US 9,151,832; US 8,861,822; US 8,500,647; US 8,398,408; US 8,213,467; US 8,137,278; US 8,088,071; US 8,066,642; US 7,849,250; US D625,015; US D625,014; US 7,740,586; US 7,591,786; US 7,588,541; US 7,534,211; US D559,390; US D544,962; US D538,432; US 7,169,108; US 6,962,566; US D509,900; US 6,648,826; US 6,569,101; US 6,471,651; US 6,364,839; CA 2372152; CA 2371711; CN ZL201180028132.X; CN ZL200880106592.8; EP 2187813 validated in FR and GB; EP 1589878 validated in DE, FR, and GB; EP 1552792 validated in DE, FR, and GB; EP 1180971 validated in DE and GB; EP 1180970 validated in DE, FR, and GB; JP 6258367; JP 5972258; JP 5894571; JP 5452491.

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CONTENTS

1. Introduction

Changes in this version	1-2
Document conventions	1-2
Getting help	1-3

2. Getting Started

About the system	2-1
Preparing the system	2-3
Installing or removing the battery	2-3
Using AC power and charging the battery	2-5
Turning the system on or off	2-6
Connecting transducers	2-6
Inserting and removing USB storage devices	2-8
System controls	2-9
Screen layout	2-11
Annotation and text	2-13
General interaction	2-14
Touchpad and cursor	2-14
On-screen options	2-14
Preparing transducers	2-16
Training videos	2-17
Intended uses	2-18

3. System Setup

Displaying the setup pages	3-1
Restoring default settings	3-1
A & B key and footswitch setup	3-1
Administration setup	3-2
Security settings	3-2
User setup	3-3
Exporting or importing user accounts	3-4
Exporting and clearing the event log	3-5
Logging in as user	3-6
Choosing a secure password	3-6
Annotations setup	3-6
Audio and battery setup	3-8

Cardiac calculations setup	3-8
Connectivity setup	3-8
Date and time setup	3-9
Display information setup	3-9
IMT calculations setup	3-10
Network status setup	3-10
OB calculations setup	3-10
OB custom measurements setup	3-11
OB custom tables setup	3-12
Presets setup	3-13
System information setup	3-14
USB devices setup	3-14
Specifying a file format for exported images	3-14
Including private tags	3-15
Limitations of JPEG format	3-15
eFilm Lite image-viewer	3-15

4. Imaging

Imaging modes	4-1
2D imaging	4-1
M Mode imaging	4-5
CPD and Color Doppler imaging	4-6
PW and CW Doppler imaging	4-7
Adjusting depth and gain	4-10
Freezing, viewing frames, and zooming	4-11
Needle visualization	4-12
About MBe	4-12
Imaging modes and exams available by transducer	4-14
Annotating images	4-17
Placing text on an image	4-17
Resetting the home position	4-18
Placing an arrow on an image	4-18
Placing a pictograph on an image	4-19
Patient information form	4-19
Images and clips	4-21
Saving images and clips	4-21
Reviewing patient exams	4-23
Printing, exporting, and deleting images and clips	4-26
ECG monitoring	4-27

5. Measurements and Calculations

Measurements	5-1
Working with calipers	5-2
2D measurements	5-2

M Mode measurements	5-4
Doppler measurements	5-5
General calculations	5-8
Unexpected data loss	5-8
Calculations menu	5-8
Performing and saving measurements in calculations	5-9
Displaying, repeating, and deleting saved measurements in calculations	5-9
EMED calculations	5-10
Percent reduction calculations	5-11
Volume calculations	5-13
Exam-based calculations	5-16
Measurement publications and terminology (cardiac)	5-30
Gynecology (Gyn) calculations	5-31
IMT calculations	5-32
OB calculations	5-36
Small parts calculations	5-40
Transcranial Doppler and orbital calculations	5-41
Vascular calculations	5-44
Patient report	5-45
Vascular and cardiac patient reports	5-46
TCD patient report	5-47
OB patient report	5-47
EMED worksheets	5-48
MSK worksheets	5-49

6. References

Measurement accuracy	6-1
Sources of measurement errors	6-3
Measurement publications and terminology	6-3
Cardiac references	6-4
Obstetrical references	6-12
Gestational age tables	6-13
Growth analysis tables	6-16
Ratio calculations	6-18
General references	6-18

7. Cleaning and Disinfecting

Before getting started	7-1
Determining the required cleaning and disinfecting level	7-2
Spaulding classifications	7-3
Clean and disinfect system and transducer to a high level (semi-critical uses)	7-3
Clean and disinfect system and transducer to a low level (non-critical uses)	7-8
Storing the transducer	7-10
Transporting the transducer	7-11

Cleaning the stand	7-12
Cleaning the footswitch	7-12
Cleaning and disinfecting accessories	7-13

8. Troubleshooting and Maintenance

Troubleshooting	8-1
Software licensing	8-2
Maintenance	8-4
Cleaning and disinfecting the battery	8-4

9. Safety

Ergonomic safety	9-1
Position the system	9-2
Position yourself	9-2
Take breaks, exercise, and vary activities	9-3
Electrical safety classification	9-4
Electrical safety	9-4
Equipment safety	9-7
Battery safety	9-8
Clinical safety	9-10
Hazardous materials	9-11
Electromagnetic compatibility	9-11
Separation distance	9-13
Compatible accessories and peripherals	9-14
Guidance and manufacturer's declaration	9-16
Manufacturer's declaration	9-16
ALARA principle	9-19
Applying ALARA	9-20
Direct controls	9-20
Indirect controls	9-21
Receiver controls	9-21
Acoustic artifacts	9-21
Guidelines for reducing MI and TI	9-22
Output display	9-23
MI and TI output display accuracy	9-25
Factors that contribute to display uncertainty	9-25
Related guidance documents	9-25
Transducer surface temperature rise	9-26
Acoustic output measurement	9-27
<i>In Situ</i> , derated, and water value intensities	9-27
Tissue models and equipment survey	9-28
Acoustic output tables	9-29
Terms used in the acoustic output tables	9-73
Acoustic measurement precision and uncertainty	9-74

Labeling symbols	9-75
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10. Specifications

Dimensions	10-1
System	10-1
Display	10-1
Supported transducers	10-1
Imaging modes	10-2
Image and clip storage	10-2
Accessories	10-2
Peripherals	10-3
Operating	10-3
Shipping and storage	10-3
Electrical	10-4
Battery	10-4
Standards	10-4
Electromechanical safety standards	10-4
EMC standards classification	10-5
Acoustic standards	10-5
Biocompatibility standards	10-5
Airborne equipment standards	10-5
DICOM standard	10-5
HIPAA	10-6

11. IT Network

Functions	11-1
Network for connecting the device	11-1
Specifications for the connection	11-1

A. Glossary

Terms	A-1
Abbreviations	A-3

B. Index

CHAPTER 1

Introduction

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

The user guide is written 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

Change	Description
Warnings and cautions	Updated and added warnings and cautions from compliance testing to the Safety chapter.
Cleaning and Disinfecting chapter	Added the Cleaning and Disinfecting chapter and removed the Cleaning section from the Troubleshooting and Maintenance chapter.
IT Network chapter	Added the new IT Network chapter.
EMC standard	Updated the EMC standards classification .
Incorporated User Guide Erratas and Supplements	<ul style="list-style-type: none">▶ P16206-02▶ P20052-03▶ P20272-08▶ P19888-02▶ P15653-06

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 ❖.

For a description of labeling symbols that appear on the product, see a **“Labeling symbols”** on page 9-75 in the user guide.

Getting help

For technical support, please contact FUJIFILM SonoSite as follows:

Phone (U.S. or Canada)	877-657-8118
Phone (outside U.S. or Canada)	425-951-1330, or call your local representative
Fax	425-951-6700
Email	ffss-service@fujifilm.com
Web	www.sonosite.com
Europe Service Center	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
Asia Service Center	+65 6380-5581

Printed in the U.S.

CHAPTER 2

Getting Started

About the system

The M-Turbo ultrasound system is a portable, software-controlled device using all-digital architecture. The system has multiple configurations and feature sets used to acquire and display high-resolution, real-time ultrasound images. Features available on your system depend on system configuration, transducer, and exam type.

A license key is required to activate the software. On occasion, a software upgrade may be required. FUJIFILM SonoSite provides a USB device containing the software. One USB device can be used to upgrade multiple systems.

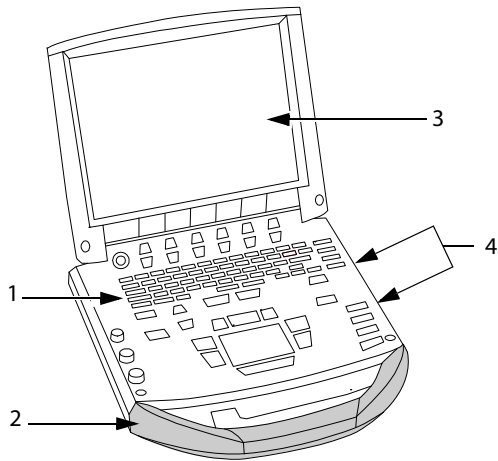


Figure 2-1 System front features: (1) Control panel, (2) Handle, (3) Display, (4) USB ports for storage, updates, importing, and exporting

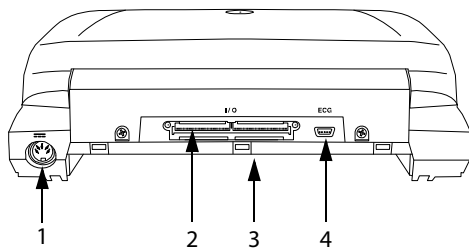


Figure 2-2 System back connectors: (1) DC input connector, (2) I/O connector, (3) Battery, and (4) ECG connector

To use the ultrasound system

- 1 Attach a transducer.
- 2 Turn the system on. (For power switch location, see [“System controls”](#) on page 2-9.)
- 3 Press the **Patient** key, and complete the patient information form.
- 4 Press an imaging mode key: **2D**, **M Mode**, **Color**, or **Doppler**

Preparing the system

Installing or removing the battery

To avoid data loss and conduct a safe system shutdown, always keep a battery in the system.

WARNINGS

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

To install the battery

- 1 Disconnect the power supply from the ultrasound system.
- 2 Remove the system from the mini-dock (if present) and turn it upside down.
- 3 Place the battery into the battery compartment, at a slight angle. See [Figure 2-3](#) on page 2-4.
- 4 Slide the battery forward until it locks into place.

5 Push down on the two locking levers to secure the battery.

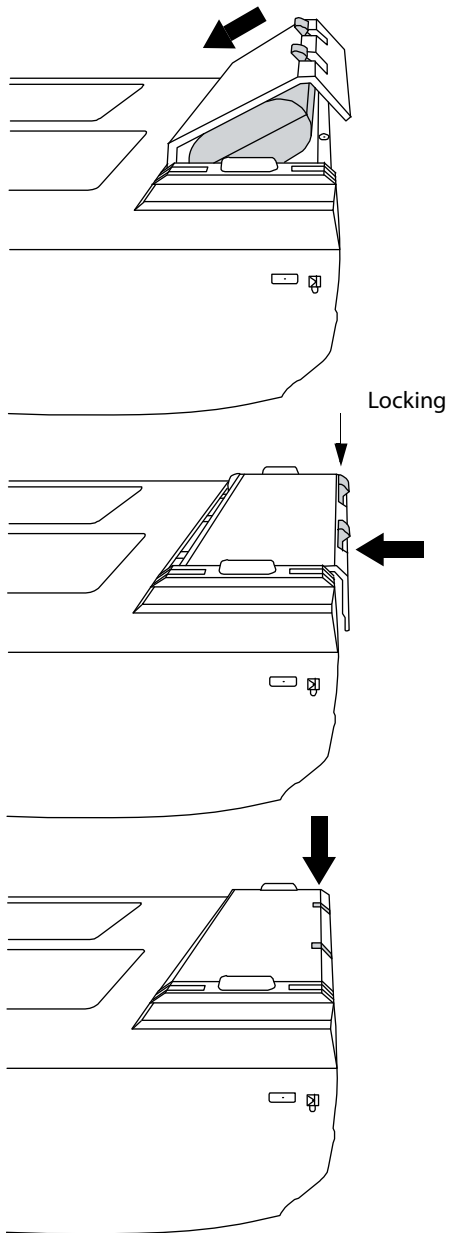


Figure 2-3 Install the battery

To remove the battery

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

Using AC power and charging the battery

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

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

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

WARNINGS

- ▶ Verify that the hospital supply voltage corresponds to the power supply voltage range. See “[Specifications](#)” on page 9-25.
- ▶ Plug the system only into a grounded hospital-grade outlet.
- ▶ Use only power cords provided by FUJIFILM SonoSite with the system.

To operate the system using AC power

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

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

Caution

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

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

Turning the system on or off

Caution

Do not use the system if an error message appears on the image display: Note the error code; call FUJIFILM SonoSite or your local representative; and turn off the system by pressing and holding the power key until the system powers down.

To turn the system on or off

- ❖ Press the power switch. (See “[System controls](#)” on page 2-9.)

To wake up the system

To conserve battery life while the system is on, the system goes into sleep mode if the lid is closed or if the system is untouched for a preset time. To adjust the time for sleep delay, see “[Audio and battery setup](#)” on page 3-8.

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

Connecting transducers

WARNING

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

Caution

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

To connect a transducer

- 1 Remove the system from the mini-dock (if present), and turn it upside down.
- 2 Pull the transducer latch up, and rotate it clockwise.

- 3 Align the transducer connector with the connector on the bottom of the system.
- 4 Insert the transducer connector into the system connector.
- 5 Turn the latch counterclockwise.
- 6 Press the latch down, securing the transducer connector to the system.

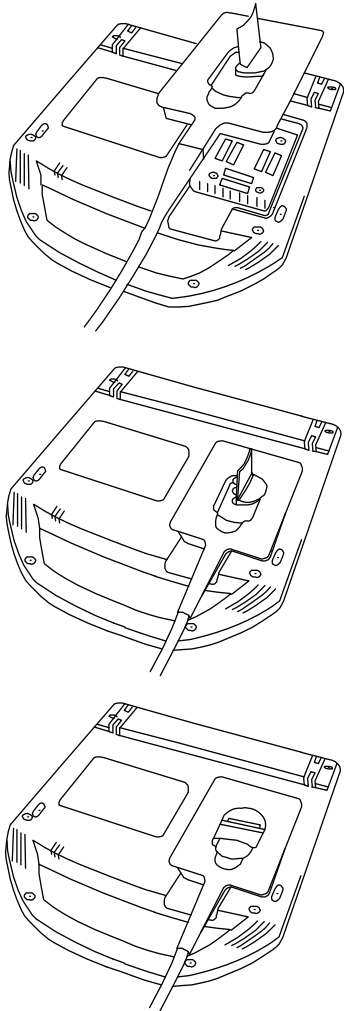


Figure 2-4 Connect the transducer

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

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

Note

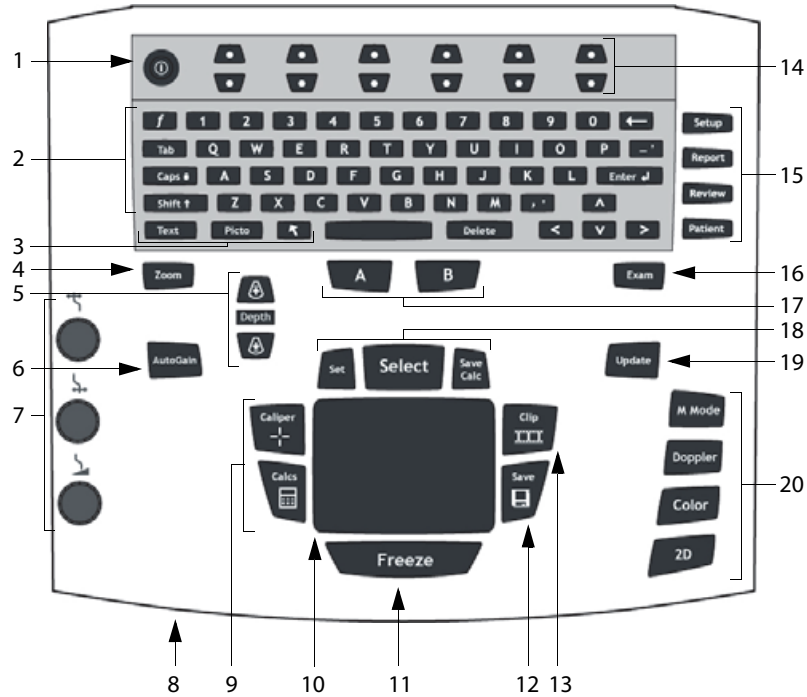
The system does not support password-protected USB storage devices. Make sure that the USB storage device you use does not have password protection enabled.

If you attach a USB device to the system, wait at least 30 seconds before removing it or attaching another USB device. Similarly, if you remove a USB device from the system, wait at least 30 seconds before reattaching it or attaching another USB device.

Attaching or removing USB devices (for example, a USB printer or USB storage device) too quickly may cause the system to stop responding and to display a blue screen with the **Maintenance**  and

Attention  icons.

System controls



1	Power switch	Turns system on and off.
2	Alphanumeric keys	Use to enter text and numbers.
3	Annotation keys	See "Alphanumeric keyboard" on page 2-13.
4	ZOOM	Magnifies the image 100%.
5	DEPTH UP, DEPTH DOWN	Decreases and increases imaging depth.
6	AUTO GAIN	Adjusts gain automatically.
7	Gain	
	Near	Adjusts the gain applied to the near field of the image.
	Far/ Angle correction	In live imaging, adjusts the gain applied to the far field of the image. On a frozen PW Doppler image, adjusts the angle.
	Gain/ Cine buffer	In live imaging, adjusts the overall gain applied to the entire image. On a frozen image, moves the cine buffer.

8	AC power indicator	A steady light indicates that AC power is connected. A flashing light indicates that the system is asleep.
9	CALIPER CALCS	Displays calipers on-screen for measuring. Turns the calculations menu on and off.
10	Touchpad	Selects, adjusts, and moves items on-screen.
11	FREEZE	Stops live imaging and displays a frozen image.
12	SAVE	Saves an image to internal storage. If configured, also saves calculations to the report. See “Presets setup” on page 3-13.
13	CLIP	Saves a clip to internal storage.
14	Control keys	Control on-screen options.
15	Forms	
	SETUP	Displays the system settings.
	REPORT	Accesses the patient report and EMED worksheets.
	REVIEW	Accesses the patient list, saved images, and archiving functions.
	PATIENT	Accesses patient information.
16	EXAM	Opens exam menu.
17	A & B shortcut keys	Keys that you can program to perform common tasks.
18	SET	Sets a trace measurement.
	SELECT	Used with the touchpad to select items on-screen. Also switches between Color and Doppler options, calipers for measurement, pictograph-marker position and angle, frozen images in duplex and dual screens, and arrow position and orientation.
	SAVE CALC	Saves calculations and their measurements to the patient report.
19	UPDATE	Toggles between dual and duplex screens and imaging modes in M Mode and Doppler (for example, between D-line and Doppler spectral trace).
20	Imaging modes	
	M MODE	Turns M Mode on, toggles between M-line and M Mode trace.
	DOPPLER	Turns Doppler on, toggles between D-line and Doppler trace.
	COLOR	Turns CPD/Color on and off.
	2D	Turns 2D on.

Screen layout

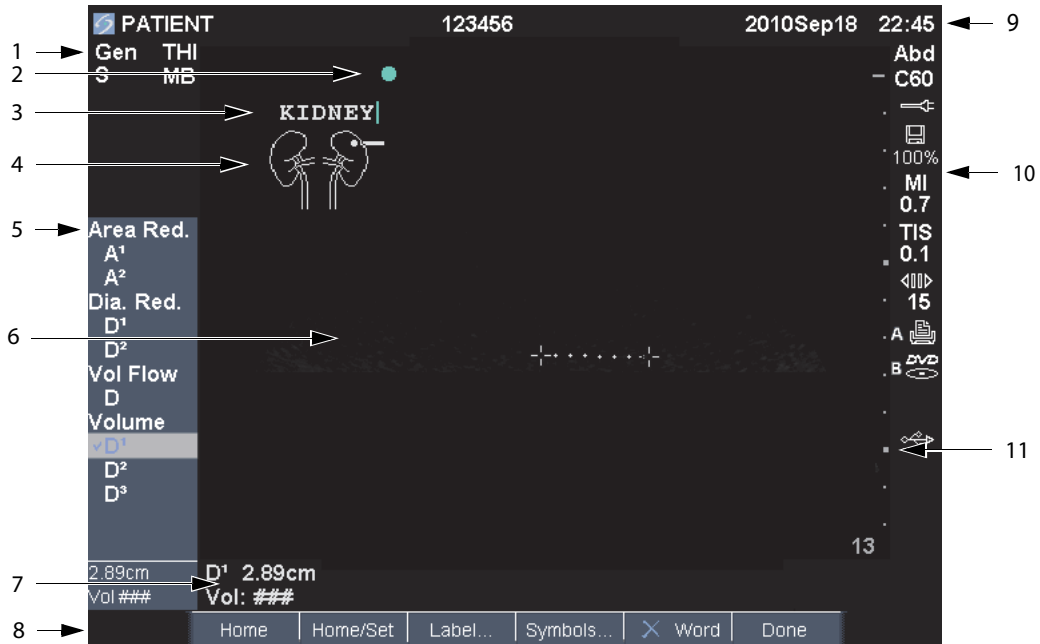


Figure 2-5 Screen layout

1	Mode data area	Current imaging mode information (for example, Gen, Res, TH1, and PW).
2	Orientation marker	Provides indication for image orientation. In dual and duplex images, the orientation marker is green on the active screen.
3	Text	Text entered using keyboard.
4	Pictograph	Pictograph to indicate anatomy and transducer position. You can select anatomy and screen location.
5	Calculations menu	Contains available measurements.
6	Image	Ultrasound image.
7	Measurement and calculations data area	Current data on measurements and calculations.
8	On-screen options	Options available in the current context.
9	Patient header	Includes current patient name, ID number, institution, user, and date/time.
10	System status	Information on system status (for example, exam type, transducer, AC connected, battery charging, and USB).
11	Depth marker	Marks in .5 cm, 1 cm, and 5 cm increments depending on depth.

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 password-protected. Turn the system off, and replace the device.

To insert a USB storage device

- ❖ Insert the USB storage device into any USB port on the system or mini-dock. See [Figure 2-1](#) on page 2-2.

The USB storage device is ready when the USB icon appears.

To view information about the device, see [“Inserting and removing USB storage devices”](#) on page 2-8.

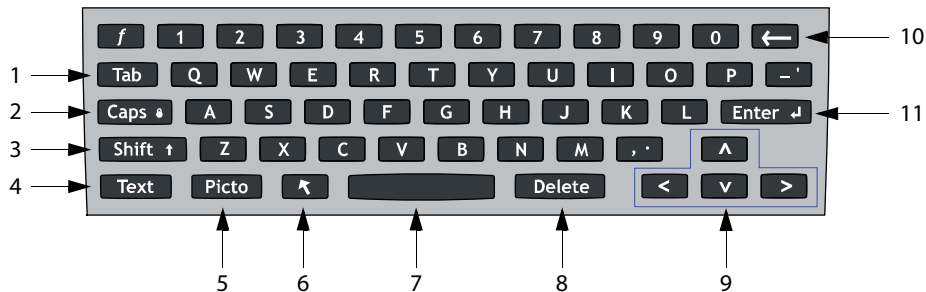
To remove a USB storage device

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

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

Annotation and text

Alphanumeric keyboard



1	TAB	Moves cursor among fields in the forms, and tabs between text position in dual screens.
2	CAPS LOCK	Sets the keyboard to capital letters.
3	SHIFT	Allows entry of capitalized characters and international characters.
4	TEXT	Turns the keyboard on and off for text entry.
5	PICTO	Turns pictographs on and off.
6	ARROW	Displays an arrow graphic that can be moved and rotated within the image area.
7	SPACEBAR	Turns the keyboard on for text entry. In text entry, adds a space.
8	DELETE	Removes all text from the screen during text entry and when not measuring.
9	ARROW KEYS	Moves highlighted selection in calculations menu, move cursor one space when entering text, move caliper position, move cine buffer forward and backward, and move among pages in image review and reports.
10	BACKSPACE	Removes the character left of the cursor in text-entry mode.
11	ENTER	Moves cursor among fields in forms and saves calculations to report.

General interaction

Touchpad and cursor

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

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

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

On-screen options

The on-screen options let you make adjustments and select settings. The options available depend on context.

Each option is controlled by the pair of keys below it. Depending on the option, the control keys function in one of four ways:

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

Up-Down Moves through a list of settings, stopping at the top or bottom. The upper control key moves upward. The lower control key moves downward. By default, a beep sounds when you reach either end of the range. (See **“Audio and battery setup”** on page 3-8.)

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

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



Figure 2-6 On-screen options (2D imaging shown)

Symbols

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

Patient information form: Last, First, Middle, Patient ID, Accession, Indications, Procedure ID, User, Reading Dr., Referring Dr., and Institution fields

DICOM or SiteLink configuration page: Alias and AE Title fields

A & B key, footswitch setup page: Text field

Text mode (imaging): Annotation field

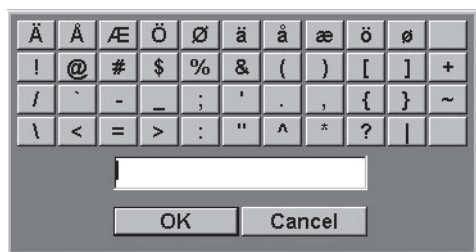


Figure 2-7 Symbols dialog box

To enter symbols or special characters

- 1 Select the field, and then select **Symbols**.
- 2 Select the desired symbol or character.

You can also press the keys on the keyboard.

- 3 Select **OK**.

Preparing 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 sterilants can cause an allergic reaction on some individuals.

Cautions

- ▶ To avoid damage to the transducer, use only gels recommended by FUJIFILM SonoSite. Using gels other than the one recommended by FUJIFILM SonoSite can damage the transducer and void the warranty. If you have questions about gel compatibility, contact FUJIFILM SonoSite or your local representative.
- ▶ FUJIFILM SonoSite recommends that you clean transducers after each use. See **“Cleaning and Disinfecting”** on page 7-1.

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 or surgical use, be sure to follow the sterilization instructions described in **“Cleaning and Disinfecting”** on page 7-1.

WARNING

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

To apply a transducer sheath

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

- 1 Place gel inside the sheath.
- 2 Insert the transducer into the sheath.
- 3 Pull the sheath over the transducer and cable until the sheath is fully extended.
- 4 Secure the sheath using the bands supplied with the sheath.

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

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

WARNING

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

Training videos

The FUJIFILM SonoSite® Education Key™ training videos are an optional feature.

To display the list of videos

- 1 Insert the Education Key USB device into a USB port on the system.
- 2 Press the REVIEW key.
- 3 If there is an active exam, select **List** on-screen.
- 4 Select the **Videos** tab.
- 5 If the list does not appear, select the correct USB device:
 - a Select **Select USB**.
 - b In the **Select USB device for media playback** dialog box, select the Education Key USB device (“Training” appears under **Type**), and then select **Select**.

Note


Image gallery is an unsupported feature.

To view a video

- 1 Display the list of videos.
- 2 Select the video.
- 3 Select **View** on-screen.

The video begins playing.

4 Select any of the following, as needed:

- ▶  Adjusts the volume. The higher the number, the louder the sound. Zero is mute.
- ▶ **Back** Rewinds the video 10 seconds.
- ▶ **Pause** Pauses the video.

- ▶ **Play** Resumes playing a paused video.
- ▶ **Forward** Advances the video 10 seconds.

To exit a video

- ❖ Select one of the following:
 - ▶ **List** to return to the video list.
 - ▶ **Done** to return to 2D imaging.

Intended uses

This system transmits ultrasound energy into various parts of the patient's body to obtain ultrasound images, as follows.

For the intended transducer and imaging modes for each exam type, see [“Imaging modes and exams available by transducer”](#) on page 4-14.

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, cardiac valves, great vessels, surrounding anatomical structures, overall cardiac performance, and heart size for the presence or absence of pathology.

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

You can obtain the patient's electrocardiogram (ECG). The ECG is used for timing of cardiac events.

WARNING

The ECG is not used to diagnose cardiac arrhythmias and is not designed for long term cardiac rhythm monitoring.

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

Interventional imaging applications You can use the system for ultrasound guidance in biopsy and drainage procedures, vascular line placement, peripheral nerve blocks, spinal nerve blocks and taps, ova harvesting, amniocentesis and other obstetrical procedures, and provide assistance during abdominal, breast, and neurological surgery.

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

WARNINGS

- ▶ 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 retardation (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, testicle, lymph nodes, hernias, musculoskeletal structures, soft tissue structures, ophthalmic structures, and surrounding anatomical structures for the presence or absence of pathology. You can use the system for ultrasound guidance in biopsy and drainage procedures, vascular line placement, peripheral nerve blocks, and spinal nerve blocks and taps.

WARNING

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

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

WARNING

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

Vascular 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.

CHAPTER 3

System Setup

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

Displaying the setup pages

To display a setup page

- 1 Press the **SETUP** key.
- 2 Select the setup page under **Setup Pages**.

To return to imaging from a setup page, select **Done** on-screen.

Restoring default settings

To restore default settings for a setup page

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

To restore all default settings

- 1 Turn the system off.
- 2 Connect the system to AC power. (See “**Electrical safety**” on page 9-4.)
- 3 Simultaneously press **1** and the power key.

The system beeps several times.

A & B key and footswitch setup

On the A & B key, footswitch setup page, you can program the shortcut keys and footswitch to perform common tasks. Select from the following lists:

A key, B key The function of the shortcut keys. By default, the A shortcut key is set to **Print** and the B shortcut key is set to **Record**. The shortcut keys are below the alphanumeric keypad.

Footswitch (L), Footswitch (R) The function of the left and right footswitches: **Save Clip, Record, 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 the USB port on the system or mini-dock.
- 2 On the A & B key, footswitch setup page, select a function for the left and right footswitches.

Administration setup

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

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 log in as administrator

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

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

If you don't have the administrator password, contact SonoSite. (See ["Getting help"](#) on page 1-3.)

3 Select **Login**.

To log out as administrator

❖ Turn off or restart the system.

To require user login

You can set the system to display the user login screen at startup.

1 Log in as Administrator.

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

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

To change the administrator password or let users change passwords

1 Log in as administrator.

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

3 Do any of the following:

- ▶ Change the administrator password: Under **User Information**, type the new password in the **Password** box and **Confirm** box. (See ["Choosing a secure password"](#) on page 3-6.)
- ▶ Let users change their passwords: Select the **Password changes** check box.

4 Select **Save**.

User setup

To add a new user

1 Log in as administrator.

2 Select **New**.

3 Under **User Information**, fill in the **Name**, **Password**, and **Confirm** boxes. (See ["Choosing a secure password"](#) on page 3-6.)

4 (Optional) In the **User** box, type the user's initials to display them in the patient header and the **User** field in the patient information form.

5 (Optional) Select the **Administration Access** check box to allow access to all administration privileges.

6 Select **Save**.

To modify user information

1 Log in as administrator.

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

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

4 Select **Save**.

Any change to the user name replaces the previous name.

To delete a user

1 Log in as administrator.

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

3 Select **Delete**.

4 Select **Yes**.

To change a user password

1 Log in as administrator.

2 In the **User List**, select the user.

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

4 Select **Save**.

Exporting or importing user accounts

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

To export user accounts

1 Insert a USB storage device.

2 Log in as administrator.

3 Select **Export** on-screen. A list of USB devices appears.

- 4 Select the USB storage device, and select **Export**.

All user names and passwords are copied to the USB storage device. Passwords are encrypted.

To import user accounts

- 1 Insert the USB storage device that contains the accounts.
- 2 Log in as administrator.
- 3 Select **Import** on-screen.
- 4 Select the USB storage device, and select **Import**.
- 5 Restart the system.

All user names and passwords on the system are replaced with the imported data.

Exporting and clearing the event log

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

To display the event log

- 1 Log in as administrator.
- 2 Select **Log** on-screen.

The event log appears.

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

To export the event log

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

- 1 Insert a USB storage device.
- 2 Select **Log** and then select **Export** on-screen.

A list of USB devices appears.

- 3 Select the USB storage device, and select **Export**.

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

To clear the event log

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

Logging in as user

If user login is required, the user login screen appears when you turn on the system.

To log in as user

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

To log in as guest

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

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

To change your password

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

Choosing a secure password

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

Annotations setup

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

For instructions to annotate images, see "[Annotating images](#)" on page 4-17.

To predefine a label group

You can specify which labels are available for an exam type when annotating an image. (See [“Annotating images”](#) on page 4-17.)

- 1 In the **Exam** list on the Annotations setup page, select the exam type whose labels you want to specify.
- 2 For **Group**, select **A**, **B**, or **C** for the label group you want associated with that exam.

The preset labels appear for the selected group.

- 3 Do any of the following:

- ▶ Add a custom label to the group: Type the label in the **Text** box, and select **Add**.
- ▶ Rename a label: Select the label, type the new name in the **Text** box, and select **Rename**.
- ▶ Move a label within the group: Select the label, and then select the on-screen up or down arrow.
- ▶ Delete a label from a group: Select the label, and select **Delete**.

You can use symbols in labels. See [“Annotation and text”](#) on page 2-13.

To specify text retention when unfreezing

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

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

The default setting is **Keep All Text**. For information on setting the home position, see [“Resetting the home position”](#) on page 4-18.

To export predefined label groups

- 1 Insert a USB storage device.
- 2 On the Annotations setup page, select **Export**.

A list of USB devices appears.
- 3 Select the USB storage device, and select **Export**.

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

To import predefined label groups

- 1 Insert the USB storage device that contains the label groups.
- 2 On the Annotations setup page, select **Import** on-screen.

3 Select the USB storage device, and then select **Import**.

4 Select **Done** in the dialog box that appears.

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

Audio and battery setup

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

Key click Select **On** or **Off** for keys to click when pressed.

Beep alert Select **On** or **Off** for the system to beep when saving, warning, starting, or shutting down.

Sleep delay Select **Off**, or **5** or **10** minutes to specify the period of inactivity before the system goes into sleep mode.

Power delay Select **Off**, or **15** or **30** minutes to specify the period of inactivity before the system automatically turns off.

Cardiac calculations setup

On the Cardiac Calculations setup page, you can specify measurement names that appear in the Tissue Doppler Imaging (TDI) calculations menu and on the report page.

See also “[Cardiac calculations](#)” on page 5-16.

To specify cardiac measurement names

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

Connectivity setup

On the Connectivity setup page, you specify options for using non-USB devices and for alerts when internal storage is full. You also import wireless certificates and specify settings (including Transfer Mode and Location) for SiteLink™ Image Manager and DICOM®, which are optional features. For SiteLink issues, refer to the SiteLink Image Manager user guide. For DICOM issues, such as storage commitment, archivers, and MPPS, refer to *Sending and Receiving DICOM Data on SonoSite Systems*.

To configure the system for a printer

1 Set up the printer hardware. (See instructions included with the printer or docking system.)

2 In the **Printer** list on the Connectivity setup page, select the printer.

To configure the system for a DVD recorder, PC, or serial bar code scanner

1 On the Connectivity setup page, do the following:

- ▶ (DVD recorder) In the **Video Mode** list, select the video standard: **NTSC** or **PAL**.
- ▶ In the **Serial Port** list, select the peripheral.

Computer (PC) allows patient report data to be sent as ASCII text from the system to a PC. The PC must have third-party software to acquire, view, or format the data into a report. Check the compatibility of your software with SonoSite technical support.

Note

Because these peripherals use the same RS-232 connector on the mini-dock, you can connect only one of them at a time.

2 Restart the system.

3 Attach a serial cable (RS-232) from the serial port on the mini-dock or docking system to the peripheral.

To receive storage alerts

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

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

Date and time setup

WARNING

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

To set the date and time

❖ On the Date and Time setup page, do the following:

- ▶ In the **Date** box, type the current date.
- ▶ In the **Time** box, type the current time in 24 hour format (hours and minutes).

Display information setup

On the Display Information setup page, you can specify which details appear on-screen during imaging. You can select settings in the following sections:

Patient Header Information that appears in the patient header.

Mode Data Imaging information.

System Status System status information.

IMT calculations setup

On the IMT Calculations setup page, you can customize the IMT calculations menu. You can specify up to eight measurement names for both right side and left side calculations. The measurement names also appear in the patient report.

See also “[IMT calculations](#)” on page 5-32.

To customize the IMT calculations menu

- ❖ On the IMT Calculations setup page, do the following:
 - ▶ Under **IMT Calculations**, select measurement names from the lists, or select **None**.
The selected names appear in the calculations menu and in the patient report.
 - ▶ Type the desired width in the **Region width (mm)** box.

Network status setup

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

OB calculations setup

On the OB Calculations setup page, you select authors for OB calculation tables. You can also import or export additional OB calculation tables.

See also “[OB calculations](#)” on page 5-36.

To specify gestational age and growth analysis

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

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

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

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

To export OB calculation tables

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

All user-defined tables and measurements are copied to the USB storage device.

To import OB calculation tables

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

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

The system restarts.

OB custom measurements setup

On the OB Custom Measurements setup page, you can define measurements that appear in the OB calculations menu and OB report. OB custom measurements is an optional feature.

See also “[OB calculations](#)” on page 5-36.

To set up OB custom measurements

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

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

To delete an OB custom measurement

If you delete an OB custom measurement during an exam, the exam ends.

- 1 On the OB Custom Measurements setup page, highlight the measurement in the **Custom Measurements** list.
- 2 Select **Delete Last**.
- 3 Select **Yes**.

The exam ends, and any tables and report data associated with the measurement are removed from the system.

OB custom tables setup

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

Gestational Age Table Measurements The system provides gestational age measurements by selected authors for GS, CRL, BPD, OFD, HC, TTD, APTD, AC, FTA, FL, EFW, Tibia, HL, and 5 additional custom measurement labels.

Growth Analysis Table Measurements The system provides growth graphs or curves for BPD, HC, AC, FL, EFW, and HC/AC.

WARNING

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

To view OB tables

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

To create a new OB custom table

You can create two custom tables for each OB measurement.

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

6 Enter the data.

7 Select **Save** on-screen.

To display the measurement for the custom table in the calculations menu, see “[To specify gestational age and growth analysis](#)” on page 3-10.

To edit or delete an OB custom table

1 On the OB Calculations or OB Custom Measurements setup page, select **Tables** on-screen.

2 Select the OB custom table.

3 Select one of the following on-screen:

- ▶ **Edit** Enter data, and then select **Save** on-screen.
- ▶ **Delete** to remove the custom table. Select **Yes**.

Presets setup

The Presets setup page has settings for general preferences. You can select from the following lists:

Doppler Scale Select **cm/s** or **kHz**.

Duplex The layout for displaying M Mode trace and Doppler spectral trace: **1/3 2D, 2/3 Trace; 1/2 2D, 1/2 Trace**; or **Full 2D, Full Trace**.

Live Trace Select **Peak** or **Mean**.

Thermal Index You can select **TIS**, **TIB**, or **TIC**. The default setting is based on exam type: OB is **TIB**, TCD is **TIC**, and all others are **TIS**.

Save Key Behavior of the **SAVE** key. **Image Only** saves the image to internal storage. **Image/Calcs** saves the image to internal storage and saves the current calculation to the patient report.

Dynamic Range Settings include **-3, -2, -1, 0, +1, +2, or +3**. Negative numbers show higher contrast images, and positive numbers show lower contrast images.

Units Units for patient height and weight in cardiac exams: **in/ft/lbs** or **cm/m/kg**.

Language The system language. Changing the language requires restarting the system. If you need to change the language selection on the Presets setup page, make sure to first archive, transfer, or export all saved patient data you want to keep. The system may not correctly maintain the saved patient information after the language selection is changed.

Color Scheme The background color of the display.

Auto save Pat. Form Automatically saves the patient information form as an image in the patient's file.

System information setup

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

To display patents

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

USB devices setup

On the USB Devices setup page, you can view information about connected USB devices, including space availability. You can also specify a file format for images and clips in patient exams that you export to a USB storage device. (See "[Printing, exporting, and deleting images and clips](#)" on page 4-26.)

Specifying a file format for exported images

To specify a file format for exported images

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

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

For SiteLink export type, the image format affects only still images. For DICOM export type, the image format affects both still images and clips.

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

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

Including private tags

To include private tags

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

- ❖ 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 SonoSite software products. For more information, see M-Turbo System 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.

In some circumstances, lossy-compressed images may be inappropriate for clinical use. For example, if you use images in SonoCalc® IMT software, you should transfer or export them using BMP format. SonoCalc IMT software uses a sophisticated algorithm to measure images, and lossy compression may cause errors.

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

eFilm Lite image-viewer

You can include a copy of the eFilm Lite image-viewer with exams that you export to a USB memory stick in DICOM format. eFilm Lite lets you view DICOM-formatted images on a computer running Windows.

eFilm Lite is a licensed feature.

WARNING

Russian characters may appear incorrectly in eFilm Lite. FUJIFILM SonoSite recommends that you do not use the eFilm Lite image-viewer to view exams exported in Russian.

To start eFilm Lite image-viewer after exporting exams

- 1 Insert the USB memory stick into your computer.
- 2 Display the USB memory stick's contents.
- 3 Double-click **eFilmLite.bat**.

eFilmLite.bat starts the executable file in the eFilmLite folder. The eFilmLite folder contains the eFilm Lite software and related files. See also the *eFilm Lite User's Guide*, a PDF file in the eFilmLite folder.

Imaging

Imaging modes

The system has a high-performance display and advanced image-optimization technology that significantly simplifies user controls. Imaging modes available depend on the transducer and exam type. See “[Imaging modes and exams available by transducer](#)” on page 4-14.

2D imaging

WARNINGS

To avoid incorrect needle placement when MBe is on:

- ▶ Using movement and fluid injection, verify the needle-tip location and trajectory. MBe 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. (See [Figure 4-9](#) on page 4-13.)
- ▶ Note that the beam divergence of a curved array transducer may prevent a segment of the needle shaft from showing in the image. (See [Figure 4-10](#) on page 4-13.) The needle tip may not show.

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 possible image quality, properly adjust the display brightness, gain, depth settings, viewing angle, and exam type. Also, select an optimization setting that best matches your needs.

To display the 2D image

1 Do any of the following:

- ▶ Turn on the system.

- ▶ Press the 2D key.

2 Set options as desired.

2D options

In 2D imaging, you can select the following on-screen options.

Table 4-1: 2D options











Control	Description
Optimize 	Settings are as follows: <ul style="list-style-type: none"> ▶ Res provides the best possible resolution. ▶ Gen provides a balance between resolution and penetration. ▶ Pen provides the best possible penetration. 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.
Dynamic Range 	Adjusts the grayscale range: -3, -2, -1, 0, +1, +2, +3 . The positive range increases the number of grays displayed, and the negative range decreases the number of grays displayed.
Dual 	Displays side-by-side 2D images. Select Dual , and then press the UPDATE key to display the second screen and to toggle between the screens. With both images frozen, press the UPDATE key to toggle between the images. To return to full-screen 2D imaging, select Dual or press the 2D key.
LVO On, LVO Off 	LVO On turns on Left Ventricular Opacification. LVO Off turns off this option. Use LVO for cardiac exams in 2D imaging mode when using an imaging contrast agent. LVO lowers the mechanical index (MI) of the system to enhance visualization of the contrast agent and endocardial border. This option 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).
Brightness 	Adjusts the display brightness. Settings range from 1 to 10 . The display brightness affects battery life. To conserve battery life, adjust brightness to a lower setting.

Table 4-1: 2D options

Control	Description
<p>Guide</p> 	<p>Turns guidelines on and off. Guidelines are for needle guidance, are an optional feature, and depend on transducer type.</p> <p>For transducers with a single-angle or multi-angle bracket, the touchpad moves the depth cursor.</p> <p>If the transducer uses a multi-angle bracket, select Guide and then select the angle: A, B, or C. To exit angle selection, select Back. To clear the guides, do either of the following:</p> <ul style="list-style-type: none"> ▶ Select the angle again (A, B, or C). ▶ Exit angle selection and press Guide. <p>See also the needle guide’s user documentation.</p>
<p>Sector</p> 	<p>(Cardiac exam) Specifies the sector width.</p> <p>SonoMB On is available only for Sector Full.</p>
<p>SonoMB (MB)</p> 	<p>MB On and MB Off turn SonoMB™ multi-beam imaging technology on and off. When SonoMB is on, <i>MB</i> appears in the upper left-hand screen.</p> <p>SonoMB depends on transducer and exam type.</p>
<p>ECG</p>	<p>Displays the ECG trace. See “ECG monitoring” on page 4-27.</p> <p>This feature is optional and requires a FUJIFILM SonoSite ECG cable.</p>
<p>Clips</p>	<p>Displays the clips options. See “To capture and save a clip” on page 4-22.</p> <p>This feature is optional.</p>
<p>THI</p> 	<p>Turns Tissue Harmonic Imaging on and off.</p> <p>When on, <i>THI</i> appears in the upper left-hand screen. This feature depends on transducer and exam type.</p>
<p>Page x/x</p>	<p>Indicates which page of options is displayed. Select to display the next page.</p>

Notes

- ▶ If you use MBe frequently, use a shortcut key to turn on the MBe control.
- ▶ For instructions to program a shortcut key, see “**A & B key and footswitch setup**” on page 3-1.

2D controls

Table 4-2: 2D controls


Control	Description
<p>MBe</p>	<p>▶ Turns on 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 affected area. (See Figure 4-9 on page 4-13.)</p> <p>Note The MBe control is available in full-screen imaging only with the C60xi transducer.</p>
	<p>▶ For curved array transducers, MBe can help identify the direction of the needle, although only segments of the needle shaft may show in the image. (See Figure 4-10 on page 4-13.) Use movement and fluid injection to help verify the needle-tip location.</p>
	<p>▶ 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.</p>
	<p>▶ You can angle the needle up to 50° from the transducer surface. (See Figure 4-8 on page 4-12.) Beyond 50°, the needle may be less enhanced. (MBe has little or no benefit to out-of-plane procedures. MBe is intended for in-plane procedures only.)</p>
	<p>▶ Avoid setting the gain too high, as unnecessarily high gain can cause artifacts in the image. Also, respiratory and cardiac movement in the image may cause bright pulsating artifacts.</p>
	<p>When MBe is on, additional controls are available:</p> <p>▶ L/R Flip flips the affected area (the outline) horizontally on the image.</p> <p>For reorienting the entire image, use the orientation control .</p>
	<p>▶ Shallow, Medium, or Steep sets the outline's sloped edge, which is indicated by a dotted line.</p> <ul style="list-style-type: none"> ▶ Linear transducer: Use whichever setting provides best perpendicularity to the dotted line. Within the affected 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. <p>The current selection is highlighted green.</p>
	<p>▶ Off turns off MBe. Temporarily turning off MBe can help you identify artifacts and other structures not of interest.</p>

Table 4-2: 2D controls

Control	Description
	<p>▶ Back returns to the previous screen. If MBe is on, MBe is highlighted green and <i>MBe</i> appears in the mode data area. Pressing MBe again redisplay the MBe controls.</p> <p>Available in Breast, Musculoskeletal, Nerve, Small Parts, Vascular (L25x only), and Venous (L25x only) exams and in full-screen imaging only. If MBe is on, the MBe control is unavailable.</p>

M Mode imaging

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

To display the M-line

- 1 Press the M MODE key.

Note

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


- 2 Use the touchpad to position the M-line where desired.
- 3 Set options as desired.

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

To display the M Mode trace

- 1 Display the M-line.
- 2 Adjust the depth if necessary. (See ["To adjust depth"](#) on page 4-10.)
- 3 Press the M MODE key.

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

- 4 Do any of the following as needed:
 - ▶ Select the sweep speed  (**Slow**, **Med**, or **Fast**).
 - ▶ Press the UPDATE key to toggle between the M-line and M-Mode trace.
 - ▶ If using a duplex layout, press the M MODE key to toggle between the full-screen M-line and the duplex layout.

To set a duplex layout, see “[Presets setup](#)” on page 3-13.

CPD and Color Doppler imaging

Color Power Doppler (CPD) and Color Doppler (Color) are optional features.

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

To display the CPD or Color image

- 1 Press the **COLOR** key.

A ROI box appears in the center of the 2D image.

- 2 Select **CPD** or **Color**.

The current selection also appears in the upper left-hand screen.

The color indicator bar on the upper left-hand screen displays velocity in cm/s in color imaging mode only.

- 3 Using the touchpad, position or resize the ROI box as needed. Press the **SELECT** key to toggle between position and size.

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

- 4 Set options as desired. See “[CPD and Color options](#)” on page 4-6.

CPD and Color options

In CPD or color imaging, you can set the following on-screen options.

Table 4-3: CPD and Color options










Control	Description
Color, CPD 	Toggle between CPD and Color. The current selection appears in the upper left-hand screen.
Color Suppress 	Shows or hides color information. You can select Show or Hide while in live or frozen imaging. The setting shown on-screen is the current selection.

Table 4-3: CPD and Color options

Flow Sensitivity 	The current setting appears on-screen. ▶ Low optimizes the system for low flow states. ▶ Med optimizes the system for medium flow states. ▶ High optimizes the system for high flow states.
PRF Scale 	Select the desired pulse repetition frequency (PRF) setting by pressing the control keys. There is a wide range of PRF settings for each Flow Sensitivity setting (Low, Med, and High). Available on select transducers.
Wall Filter 	Settings include Low , Med , and High . Available on select transducers.
Steering 	Select the steering angle setting of the color ROI box (-15 , 0 , or +15). If adding PW Doppler, see “PW Doppler options” on page 4-9. Available on select transducers.
Variance 	Turns variance on and off. Available only for cardiac exam.
Invert 	Switches the displayed direction of flow. Available in Color imaging.
Sector 	(Cardiac exam) Specifies the sector width.
Page x/x	Indicates which page of options is displayed. Select to display the next page.

PW and CW Doppler imaging

Pulsed wave (PW) Doppler and continuous wave (CW) Doppler imaging modes are optional features.

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

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

To display the D-line


The default Doppler imaging mode is PW Doppler. In cardiac exams, you can select the CW Doppler on-screen option.

- 1 Press the DOPPLER key.

Note

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

- 2 Do any of the following as needed:

- ▶ Set options. See **"PW Doppler options"** on page 4-9.
- ▶ Using the touchpad, position the D-line and gate where desired. Horizontal movements position the D-line. Vertical movements position the gate.
- ▶ (PW Doppler) To correct the angle manually, do one of the following:
 - ▶ Press the SELECT key and then use the touchpad.
The SELECT key toggles between the D-line and angle correction.
 - ▶ Freeze the image, and then turn the  knob.
You can adjust the angle in 2° increments from -74° to +74°.

Cardiac imaging applications

You can identify the presence and location of fluid around the heart and lungs, use to assist in pericardiocentesis and thoracentesis procedures, visualize blood flow through cardiac valves, and detect normal lung motion for the presence or absence of pathology.

To display the spectral trace

- 1 Display the D-line.
- 2 Press the DOPPLER key.

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

- 3 Do any of the following as needed:





- ▶ Set options. See **"Spectral trace options"** on page 4-9.
- ▶ Press the UPDATE key to toggle between the D-line and spectral trace.
- ▶ If using a duplex layout, press the DOPPLER key to toggle between the full-screen D-line and the duplex layout.

To set a duplex layout, see **"Presets setup"** on page 3-13.

PW Doppler options

In PW Doppler imaging, you can set the following on-screen options.

Table 4-4: PW Doppler options

Control	Description
PW, CW 	(Cardiac exam only) Toggle between PW Doppler and CW Doppler. The current selection appears in the upper left-hand screen.
Angle Correction 	Corrects the angle to 0° , +60° , or -60° .
Gate Size 	Settings depend on transducer and exam type. In TCD or Orb exams, use the touchpad to specify the Doppler gate depth (the depth of the center of the gate in the Doppler image). The Doppler gate depth indicator is on the lower right-hand screen.
TDI On, TDI Off	Select TDI On to turn on tissue Doppler imaging. When on, <i>TDI</i> appears in the upper left-hand screen. The default is TDI off . Available only in cardiac exams.
Steering 	Select the desired steering angle setting. Settings available depend on the transducer. The PW Doppler angle correction automatically changes to the optimum setting. <ul style="list-style-type: none">▶ -15 and -20 have an angle correction of -60°.▶ 0 has an angle correction of 0°.▶ +15 and +20 have an angle correction of $+60^\circ$. You can manually correct the angle after selecting a steering angle setting. (See “To display the D-line” on page 4-8.) Available on select transducers.
Page x/x	Indicates which page of options is displayed. Select to display the next page.

Spectral trace options

In spectral trace imaging, you can set the following on-screen options.

Table 4-5: Spectral trace options








Control	Description
Scale 	Select the desired scale (pulse repetition frequency [PRF]) setting. (To change the Doppler scale to cm/s or kHz, see “Presets setup” on page 3-13.)

Table 4-5: Spectral trace options

Line 	Sets the baseline position. (On a frozen trace, the baseline can be adjusted if Live Trace is off.)
Invert 	Vertically flips the spectral trace. (On a frozen trace, Invert is available if Live 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 .
Live Trace 	Displays a live trace of the peak or mean. (See "Presets setup" on page 3-13 to specify peak or mean.)
Page x/x	Indicates which page of options is displayed. Select to display the next page.

Adjusting depth and gain

To adjust depth

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




- ❖ Press the following keys:
 - ▶ UP DEPTH key to decrease the displayed depth.
 - ▶ DOWN DEPTH key to increase the displayed depth.

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

To adjust gain automatically

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

To adjust gain manually

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


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

Freezing, viewing frames, and zooming

To freeze or unfreeze an image

- ❖ Press the FREEZE key.
 - On a frozen image, the cine icon and frame number appear in the system status area.

To move forward or backward in the cine buffer

- ❖ Freeze the image, and do one of the following:
 - ▶ Turn the  knob.
 - ▶ Use the touchpad. Right moves forward, and left moves backward.
 - ▶ Press the LEFT ARROW and RIGHT ARROW keys.

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

To zoom in on an image

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

- 1 Press the ZOOM key. A ROI box appears.
- 2 Using the touchpad, position the ROI box as desired.
- 3 Press the ZOOM key again.

The image in the ROI box is magnified by 100%.

- 4 (Optional) If the image is frozen, use the touchpad or arrow keys to pan the image up, down, left, and right. (You cannot pan in Dual.)

To exit zoom, press the ZOOM key again.

Needle visualization

About MBe

The MBe control is available in full-screen imaging only and is available on the C60xi transducer.

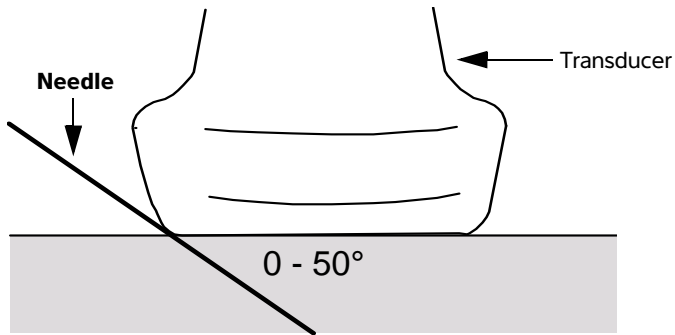


Figure 4-8 Transducer

Notes

- ▶ For best results, angle the needle only up to 50° from the transducer surface.
- ▶ If you use MBe frequently, use a shortcut key to turn on the MBe control.
- ▶ For instructions to program a shortcut key, see ["A & B key and footswitch setup"](#) on page 3-1.

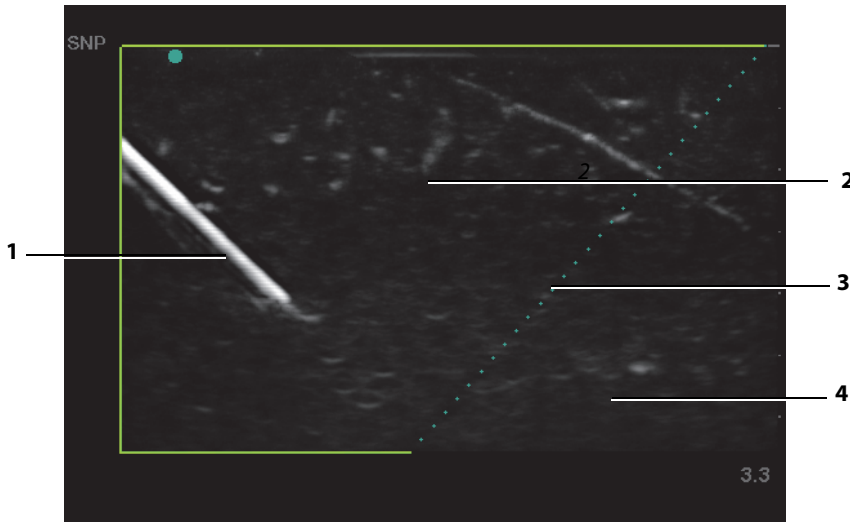


Figure 4-9 Image with MBe on (linear transducer)

1 Needle

2 Outlined area affected by MBe

3 Dotted line

4 Unenhanced area

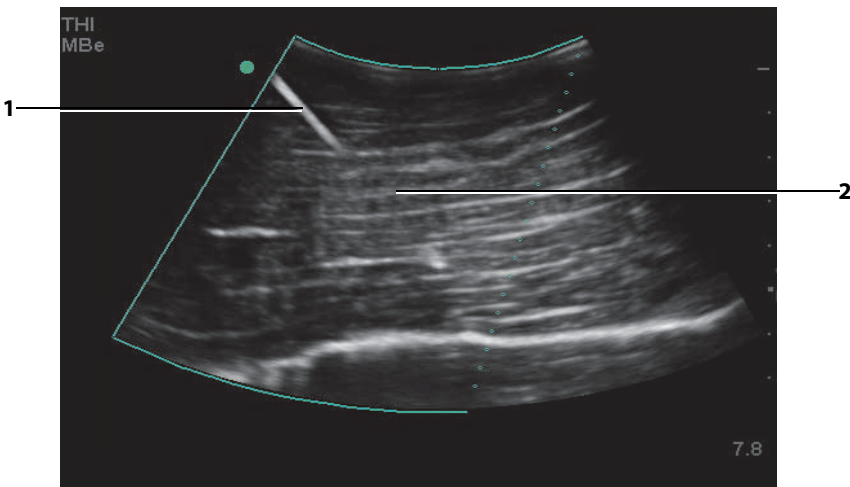


Figure 4-10 Curved array transducer

1 Upper needle shaft

2 Unshown segment of needle shaft
(unshown segment or segments depend
on specific image)

Note

With a curved array transducer, only segments of the needle shaft might show.

Imaging modes and exams available by transducer

The transducer you use determines which exam types are available. In addition, the exam type you select determines which imaging modes are available.

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. In addition, transducers have been developed to specific criteria depending on their physical application. These criteria include biocompatibility requirements.
- ▶ To avoid injury to the patient, use only an Orbital (Orb) or Ophthalmic (Oph) when performing imaging through the eye. The FDA has established lower acoustic energy limits for ophthalmic use. The system will not exceed these limits only if the Orb or Oph exam type is selected.

To change the exam type

- ❖ Do one of the following:
 - ▶ Press the EXAM key, and select from the menu.
 - ▶ On the patient information form, select from the **Type** list under **Exam**. (See **“Patient information form”** on page 4-19.).

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

Transducer	Imaging mode						
	Exam type ¹	2D ² M Mode	MBe	CPD ³	Color ³	PW Doppler ⁴	CW Doppler
C8X	Pros	✓	—	✓	✓	✓	—
C11x	Abd	✓	—	✓	✓	✓	—
	Neo	✓	—	✓	✓	✓	—
	Nrv	✓	—	✓	✓	✓	—
	Vas	✓	—	✓	✓	✓	—
C60x	Abd	✓	—	✓	✓	✓	—
	Gyn	✓	—	✓	✓	✓	—
	Msk	✓	✓	✓	✓	✓	—
	Nrv	✓	✓	✓	✓	✓	—
	OB	✓	—	✓	✓	✓	—
C60xi	Abd	✓	—	✓	✓	✓	—

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

Transducer	Imaging mode						
	Exam type ¹	2D ² M Mode	MBe	CPD ³	Color ³	PW Doppler ⁴	CW Doppler
	Gyn	✓	—	✓	✓	✓	—
	Msk	✓	✓	✓	✓	✓	—
	Nrv	✓	✓	✓	✓	✓	—
	OB	✓	—	✓	✓	✓	—
D2x	Crd	—	—	—	—	—	✓
HFL38x	Bre	✓	✓	✓	✓	✓	—
	IMT	✓	—	✓	✓	✓	—
	Msk	✓	✓	✓	✓	✓	—
	Nrv	✓	✓	✓	✓	✓	—
	SmP	✓	✓	✓	✓	✓	—
	Vas	✓	—	✓	✓	✓	—
	Ven	✓	—	✓	✓	✓	—
HFL50x	Bre	✓	✓	✓	✓	✓	—
	MSK	✓	✓	✓	✓	✓	—
	Nerve	✓	✓	✓	✓	✓	—
	SmP	✓	✓	✓	✓	✓	—

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

Transducer	Imaging mode						
	Exam type ¹	2D ² M Mode	MBe	CPD ³	Color ³	PW Doppler ⁴	CW Doppler
ICTx	Gyn	✓	—	✓	✓	✓	—
	OB	✓	—	✓	✓	✓	—
L25x	Msk	✓	✓	✓	✓	✓	—
	Nrv	✓	✓	✓	✓	✓	—
	Oph	✓	—	✓	✓	✓	—
	Sup	✓	—	✓	✓	✓	—
	Vas	✓	✓	✓	✓	✓	—
	Ven	✓	✓	✓	✓	✓	—
	Bre	✓	—	✓	✓	✓	—
L38x	IMT	✓	—	✓	✓	✓	—
	Nrv	✓	—	✓	✓	✓	—
	SmP	✓	—	✓	✓	✓	—
	Vas	✓	—	✓	✓	✓	—
	Ven	✓	—	✓	✓	✓	—
	Bre	✓	—	✓	✓	✓	—
L38xi	IMT	✓	—	✓	✓	✓	—
	Msk	✓	—	✓	✓	✓	—
	Nrv	✓	✓	✓	✓	✓	—
	SmP	✓	—	✓	✓	✓	—
	Vas	✓	—	✓	✓	✓	—
	Ven	✓	—	✓	✓	✓	—
	Bre	✓	—	✓	✓	✓	—
P10x	Abd	✓	—	✓	✓	✓	—
	Crd	✓	—	—	✓	✓	✓
	Neo	✓	—	✓	✓	✓	—
P21x	Abd	✓	—	✓	✓	✓	—
	Crd	✓	—	—	✓	✓	✓
	OB	✓	—	✓	✓	✓	—
	Orb	✓	—	✓	✓	✓	—
	TCD	✓	—	✓	✓	✓	—
	Nrv	✓	—	✓	✓	✓	—
	Sup	✓	—	✓	✓	✓	—
	Vas	✓	—	✓	✓	✓	—
Ven	✓	—	✓	✓	✓	—	
SLAx	Msk	✓	—	✓	✓	✓	—
	Nrv	✓	—	✓	✓	✓	—

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

Transducer	Imaging mode						
	Exam type ¹	2D ² M Mode	MBe	CPD ³	Color ³	PW Doppler ⁴	CW Doppler
	Sup	✓	—	✓	✓	✓	—
	Vas	✓	—	✓	✓	✓	—
	Ven	✓	—	✓	✓	✓	—
TEExi	Crd	✓	—	—	✓	✓	✓

1. Exam type abbreviations are as follows: Abd = Abdomen, Bre = Breast, Crd = Cardiac, Gyn = Gynecology, IMT = Intima Media Thickness, Msk = Musculoskeletal, Neo = Neonatal, Nrv = Nerve, OB = Obstetrical, Oph = Ophthalmic, Orb = Orbital, SmP = Small Parts, Sup = Superficial, TCD = Transcranial Doppler, Vas = Vascular, Ven = Venous., Pros = Prostate.
2. The optimization settings for 2D are Res, Gen, and Pen.
3. The optimization settings for CPD and Color are low, medium, and high (flow sensitivity) with a range of PRF settings for Color depending on the setting selected.
4. For the cardiac exam type, PW TDI is also available. See ["PW Doppler options"](#) on page 4-9.

Annotating images




You can annotate live images as well as frozen images. (You cannot annotate a saved image.) You can place text (including predefined labels), an arrow, or a pictograph. To set preferences for annotations, see ["Annotations setup"](#) on page 3-6.

Placing text on an image

To place text on an image

You can place text in the following imaging layouts: full-screen 2D, full-screen trace, dual, or duplex. You can place text manually or add a predefined label.

- 1 Press the TEXT key. A green cursor appears.
- 2 Move the cursor where desired:
 - ▶ Use the touchpad or arrow keys.
 - ▶ Select **Home** to move the cursor to the home position.
The default home position depends on the imaging screen layout. You can reset the home position. See ["To reset the home position"](#) on page 4-18.
- 3 Using the keyboard, type text.
 - ▶ The arrow keys move the cursor left, right, up, and down.

- ▶ The **DELETE** key deletes all text.
 - ▶ The **X Word** option removes a word.
 - ▶ Select **Symbols** to enter special characters. See “**Symbols**” on page 2-15.
- 4** (Optional) To add a predefined label, select **Label**, and then select the desired label group: , , or . Select the group again for the desired label.

The first number shows which label in the group is selected. The second number is the number of labels available. See “**Annotations setup**” on page 3-6.

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

Resetting the home position


To reset the home position

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

Placing an arrow on an image

To place an arrow on an image

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

- 1** Press the **ARROW** key .
- 2** If you need to adjust the arrow's orientation, press the **SELECT** key and then use the touchpad. When the orientation is correct, press the **SELECT** key again.
- 3** Using the touchpad, position the arrow where desired.
- 4** Press the **ARROW** key to set the arrow.

The arrow changes from green to white.

To remove the arrow, press the **ARROW** key and then select **Hide**.

Placing a pictograph on an image

To place a pictograph on an image

The pictograph set available depends on transducer and exam type.

- 1 Press the PICTO key.
- 2 Select  **x/x** to display the desired pictograph, and then press the SELECT key.

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

- 3 Using the touchpad, position the pictograph marker.
- 4 (Optional) To rotate the pictograph marker, press the SELECT key and then use the touchpad.
- 5 Select a screen location for the pictograph: **U/L** (Up/Left), **D/L** (Down/Left), **D/R** (Down/Right), **U/R** (Up/Right).

In a duplex layout, the pictograph is restricted to upper left. In Dual, all four positions are available.


To remove the pictograph, select **Hide**.

Patient information form

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

When you create a new patient information form, all images, clips, and other data you save during the exam are linked to that patient. (See **"Patient report"** on page 5-45.)

To create a new patient information form

- 1 Press the PATIENT key.
- 2 Select  **New/End**.
- 3 Fill in the form fields. See **"Patient information form fields"** on page 4-20.
- 4 Select **Done**.

See also **"Images and clips"** on page 4-21.


To edit a patient information form

You can edit patient information if the exam has not been archived or exported and if the information is not from a worklist.

See also “[Reviewing patient exams](#)” on page 4-23.

- 1 Press the **PATIENT** key.
- 2 Make changes as desired.
- 3 Select one of the following:
 - ▶ **Cancel** to undo changes and return to imaging.
 - ▶ **Done** to save changes and return to imaging.

To end the exam

- 1 Make sure that you have saved images and other data you want to keep. (See “[Saving images and clips](#)” on page 4-21.)
- 2 Press the **PATIENT** key.
- 3 Select  **New/End**.

A new patient information form appears.

Patient information form fields

The patient information form fields available depend on exam type. In some fields you can select Symbols to enter symbols and special characters. See “[Symbols](#)” on page 2-15.

Patient

- ▶ **Last, First, Middle** Patient name
- ▶ **ID** Patient identification number
- ▶ **Accession** Enter number, if applicable.
- ▶ **Date of birth**
- ▶ **Gender**
- ▶ **Indications** Enter desired text
- ▶ **User** User initials
- ▶ **Procedure (button)** Available if the DICOM Worklist feature is licensed and configured. See the DICOM user guide.
Select **Back** to save entries and return to the previous screen.

Exam

- ▶ **Type** Exam types available depend on transducer. See [“Imaging modes and exams available by transducer”](#) on page 4-14.
- ▶ **LMP Estab. DD** (OB or Gyn exam) In an OB exam, select **LMP** or **Estab. DD** and then enter either the date of the last menstrual period or the established due date. In a Gyn exam, enter the date of the last menstrual period. The LMP date must precede the current system date.
- ▶ **Twins** (OB exam) Select the **Twins** check box to display Twin A and Twin B measurements on the calculations menu and for access to Twin A and Twin B screens for previous exam data.
- ▶ **Previous Exams (button)** (OB exam) Displays fields for five previous exams. The date for a previous exam must precede the current system date. For twins, select **Twin A/B** to toggle between Twin A and Twin B screens. (If the **Twin A/B** option does not appear, select **Back**, and make sure that the **Twins** check box is selected.)
Select **Back** to save changes and return to the previous screen.
- ▶ **BP** (Cardiac, IMT, Orbital, Transcranial, or Vascular exam) Blood Pressure
- ▶ **HR** (Cardiac, Orbital, Transcranial, or Vascular exam) Heart Rate. Enter the beats per minute. Saving the heart rate using a measurement overwrites this entry.
- ▶ **Height** (Cardiac exam) The patient height in feet and inches or meters and centimeters. (To change the units, see [“Presets setup”](#) on page 3-13.)
- ▶ **Weight** (Cardiac exam) The patient weight in pounds or kilos. (To change the units, see [“Presets setup”](#) on page 3-13.)
- ▶ **BSA** (Cardiac exam) Body Surface Area. Automatically calculated after you enter height and weight.
- ▶ **Ethnicity** (IMT exam) Ethnic origin
- ▶ **Reading Dr.**
- ▶ **Referring Dr.**
- ▶ **Institution**

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. (See [“Audio and battery setup”](#) on page 3-8.) The percentage icon in the system status area shows the percentage of space used in internal storage. If you try to save an image or clip when no space remains, the system alerts you that internal storage is full. To resolve this issue, archive images and clips that you wish to keep, and then delete them from the system to free up space. To receive alerts when storage is near capacity, see [“To receive storage alerts”](#) on page 3-9. The percentage icon in the system status area shows the percentage of space *available* in internal storage.

To access saved images and clips, open the patient list. See [“Reviewing patient exams”](#) on page 4-23.

To save an image

- ❖ Press the **SAVE** key.

The image saves to internal storage.


By default, the **SAVE** key saves only the image. As a shortcut during calculations, the **SAVE** key can save both the image to internal storage and the calculation to the patient report. See “**Presets setup**” on page 3-13.

To capture and save a clip

Clips, an optional feature, lets you capture, preview, and save clips.

- 1 Set Clips options. (See “**To set clips options**” on page 4-23.)
- 2 Press the **CLIP** key.

One of the following occurs:

- ▶ If **Prev/Off** is selected, the clip saves directly to internal storage.
- ▶ If **Prev/On** is selected, the clip plays back in preview mode. You can select any of the following on-screen:
 - ▶ A playback speed  (**1x**, **1/2x**, **1/4x**)
 - ▶ **Pause** to interrupt playback
 - ▶ **Left: x** or **Right: x** to remove frames from the left or right sides of the clip (where x is the beginning or ending frame number)
 - ▶ **Save** to save the clip to internal storage
 - ▶ **Delete** to delete the clip




To set clips options

Setting clips options ensures that clips are captured to your specifications.

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

2 Set options as desired.

Table 4-7: Clips options

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

Reviewing patient exams

Caution

If the internal storage icon does not appear in the system status area, internal storage may be defective. Contact FUJIFILM SonoSite technical support. (See [“Getting help”](#) on page 1-3.)

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

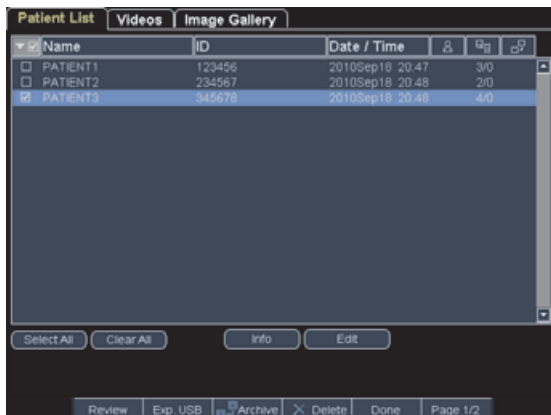


Figure 4-11 Patient List

To display the patient list

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

To sort the patient list

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

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

Note

The column heading is selectable.

To select patients in the patient list

- ❖ Using the touchpad, select the check box for one or more patients.
Select All selects all patients.

To deselect patients, select checked boxes or **Clear All**.

To edit patient information from the patient list

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

- 1 In the patient list, select the patient.
- 2 Select **Edit**.

3 Fill in the form fields, and select **OK**.

To append images and clips to a patient exam

Although you cannot add images and clips to a patient exam that has ended, 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 Select the exam in the patient list.

2 Select **Append** on-screen.


A new patient information form appears. The form has the same information as the exam you selected.

To review images and clips

You can review images and clips in only one patient exam at a time.

1 In the patient list, highlight the patient exam whose images and clips you want to review.

2 Select **Review** on-screen.

3 Select  **x/x** to cycle to the image or clip you want to review.

4 (Clip Only) Select **Play**.

The clip plays automatically after loading. The load time depends on clip length.

You can select **Pause** to freeze the clip and can select a playback speed  **1x, 1/2x, 1/4x**.

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

To return to the patient list, select **List**. To return to imaging, select **Done**.

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. See [“To configure the system for a printer”](#) on page 3-8.

2 Do one of the following:

- ▶ In the patient list, review the patient’s images. Select **Print** when the image appears.
- ▶ With the image displayed, press the A shortcut key.

By default, the A shortcut key prints. To reprogram the A and B shortcut keys, see [“Presets setup”](#) on page 3-13.

To print multiple images

1 Verify that a printer is selected. See [“To configure the system for a printer”](#) on page 3-8.

2 Do one of the following:

- ▶ Print all images for multiple patients: Select one or more patients in the patient list. Then select **Print**.
- ▶ Print all images for one patient: Highlight the patient in the patient list, and then select **Print**.

Each image appears briefly on-screen while printing.

To export patient exams to a USB storage device

You can export patient exams if they are ended. (See [“To end the exam”](#) on page 4-20.)

A USB storage device is for temporary storage of images and clips. Patient exams should be archived regularly. To specify file format, see [“USB devices setup”](#) on page 3-14.

1 Insert the USB storage device.

2 In the patient list, select the patient exams you want to export.

3 Select **Exp. USB** on-screen. A list of USB devices appears.

- 4 Select the USB storage device. If you want to hide patient information, deselect **Include patient information on images and clips**.

Only available USB devices are selectable.

- 5 Select **Export**.

The files are finished exporting approximately five seconds after the USB animation stops. Removing the USB storage device or turning off the system while exporting may cause exported files to be corrupted or incomplete. To stop in-progress exporting, select **Cancel Export**.

To delete images and clips

- 1 Select one or more patients in the patient list.
- 2 Select **Delete** to delete the selected patients. A confirmation screen appears.

To manually archive images and clips

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

- 1 Select one or more patients in the patient list.
- 2 Select **Archive**.

To display information about a patient exam

- 1 On the patient list, select the exam.
- 2 Select **Info**.

ECG monitoring

ECG monitoring is an optional feature and requires a FUJIFILM SonoSite ECG cable.

WARNINGS

- ▶ To prevent misdiagnosis, do not use the ECG trace to diagnose cardiac rhythms. The FUJIFILM SonoSite ECG option is a non-diagnostic feature.
- ▶ To avoid electrical interference with aircraft systems, do not use the ECG cable on aircraft. Such interference may have safety consequences.

Caution

- ▶ Use only accessories recommended by FUJIFILM SonoSite with the system. Your system can be damaged by connecting an accessory not recommended by FUJIFILM SonoSite.

Note

- ▶ If you defibrillate a patient while the ECG module is connected to the system, the ECG signal may display incorrectly, and the ECG module may need to be replaced.
- ▶ Biopsy guidelines are not available when ECG is connected. The ECG signal may take up to one minute to restabilize after defibrillator use on the patient.
- ▶ The ECG signal may take up to one minute to restabilize after defibrillator use on a patient.

To monitor ECG

- 1 Connect the ECG cable to the ECG connector on the ultrasound system, mini-dock, or docking system.

ECG monitoring turns on automatically.

Note

An external ECG monitor may cause a lag in the timing of the ECG trace, corresponding with the 2D image. Biopsy guidelines are not available when ECG is connected.

- 2 Select **ECG** on-screen. (**ECG** may be on another page. It appears only if the ECG cable is connected.)
- 3 Select options as desired.m

Table 4-8: ECG monitoring options





Show/Hide 	Turns on and off ECG trace.
Gain 	Increases or decreases ECG gain. Settings are 0-20 .
Position	Sets the position of the ECG trace.
Sweep Speed 	Settings are Slow, Med, and Fast .
Delay	Displays Line and Save for clip acquisition delay. (For instructions to capture clips, see "To capture and save a clip" on page 4-22.)

Table 4-8: ECG monitoring options

<p>Line</p> 	<p>The position of the delay line on the ECG trace. The delay line indicates where the clip acquisition is triggered.</p>
<p>Save</p>	<p>Saves the current position of the delay line on the ECG trace. (You can change the position of the delay line temporarily. Starting a new patient information form or cycling system power reverts the delay line to the most recently saved position.) Select Delay to display these options.</p>

CHAPTER 5

Measurements and Calculations

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

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

Measurements

You can perform basic measurements in any imaging mode and can save the image with the measurements displayed. (See [“Saving images and clips”](#) on page 4-21.) Except for the M Mode HR measurement, the results do not automatically save to a calculation and the patient report. If you prefer, you can first begin a calculation and then measure. See [“Performing and saving measurements in calculations”](#) on page 5-9.

Some options may not apply to your system. Options available depend on your configuration, transducer, and exam type.

To save a measurement to a calculation and patient report

- 1 With the measurement active (green), press the CALCS key.
- 2 From the calculations menu, select a measurement name.

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

- 3 Save the calculation. (See [“To save a calculation”](#) on page 5-9.)

To start a calculation before measuring, see [“Performing and saving measurements in calculations”](#) on page 5-9.

Working with calipers

When measuring, you work with calipers, often in pairs. Results based on the calipers' position appear at the bottom of the screen. The results update as you reposition the calipers by using the touchpad. In trace measurements, the results appear after you complete the trace.

Outside a calculation, you can add calipers by pressing the CALIPER key. You can have multiple sets of calipers and can switch from one set to another, repositioning them as needed. Each set shows the measurement result. The active calipers and measurement result are highlighted green. A measurement is complete when you finish moving its calipers.

Within a calculation, calipers appear when you select from the calculations menu. (See ["To select from the calculations menu"](#) on page 5-8.)

For an accurate measurement, accurate placement of calipers is essential.

To switch the active calipers

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

To delete or edit a measurement

- ❖ With the measurement active (highlighted), do one of the following:
 - ▶ To delete, select **Delete** on-screen.
 - ▶ To edit, use the touchpad to move the calipers.

Note

Trace measurements cannot be edited once set.

To improve precision of caliper placement

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

2D measurements

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

- ▶ Distance in cm

- ▶ Area in cm^2
- ▶ Circumference in cm

You can also measure area or circumference by tracing manually.

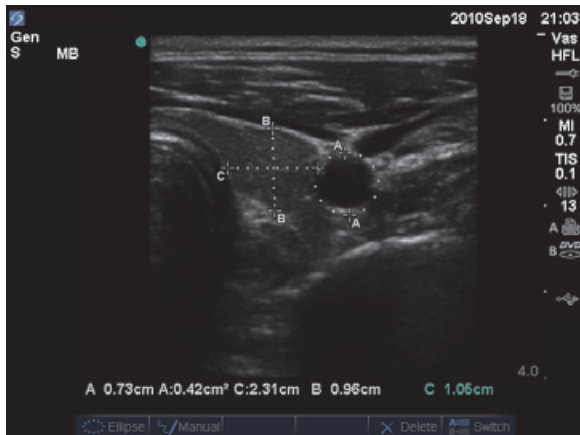


Figure 5-1 2D image with two distance and one circumference measurement

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

To measure distance (2D)

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

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

A pair of calipers appears, connected by a dotted line.

- 2 Using the touchpad, position the first caliper, and then press the SELECT key.

The other caliper becomes active.

- 3 Using the touchpad, position the other caliper.

If you move the calipers close together, they shrink and the dotted line disappears.

See [“To save a measurement to a calculation and patient report”](#) on page 5-1.

To measure area or circumference (2D)

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

2 Select **Ellipse** on-screen.

Note

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

3 Use the touchpad to adjust the size and position of the ellipse. The **SELECT** key toggles between position and size.

See **“To save a measurement to a calculation and patient report”** on page 5-1.

To trace manually (2D)

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

2 Select **Manual** on-screen.

Note

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

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

4 Press the **SELECT** key.

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

See **“To save a measurement to a calculation and patient report”** on page 5-1.

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, press the **CALIPER** key.

A single caliper appears.

2 Using the touchpad, position the caliper.

3 Press the **SELECT** key to display the second caliper.

4 Using the touchpad, position the second caliper.

See [“To save a measurement to a calculation and patient report”](#) on page 5-1.

To measure heart rate (M Mode)

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

2 Select **HR** on-screen.

A vertical caliper appears.

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

4 Press the SELECT key.

A second vertical caliper appears.

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

See [“To save a measurement to a calculation and patient report”](#) on page 5-1. Saving the heart rate measurement to the patient report overwrites any heart rate entered on the patient information form.

See also [“To measure fetal heart rate \(M Mode\)”](#) on page 5-39.

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), and Acceleration. You can also trace manually or automatically.

For Doppler measurements, the Doppler scale must be set to cm/s. See [“Presets setup”](#) on page 3-13.

To measure velocity (cm/s) and pressure gradient (Doppler)

1 On a frozen Doppler spectral trace, press the CALIPER key.

A single caliper appears.

2 Using the touchpad, position the caliper to a peak velocity waveform.

This measurement involves a single caliper from the baseline.

See [“To save a measurement to a calculation and patient report”](#) on page 5-1.

To measure velocities, elapsed time, +/- ratio, resistive index (RI), and acceleration (Doppler)

1 On a frozen Doppler spectral trace, press the CALIPER key.

A single caliper appears.

2 Using the touchpad, position the caliper to a peak systolic waveform.

3 Press the SELECT key.

A second caliper appears.

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

See **“To save a measurement to a calculation and patient report”** on page 5-1.

To measure time duration (Doppler)

1 On a Doppler spectral trace, press the CALIPER key.

2 Press **Time** on-screen.

A vertical caliper appears.

3 Using the touchpad, position the caliper where desired, and press the SELECT key.

A second caliper appears.

4 Using the touchpad, position the second caliper where desired, and press the SELECT key.

To trace manually (Doppler)

1 On a frozen Doppler spectral trace, press the CALIPER key.

2 Select **Manual** on-screen.

A single caliper appears.

3 Using the touchpad, position the caliper at the beginning of the desired waveform, and press the SELECT key.

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

4 Using the touchpad, trace the waveform.

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

5 Press the SET key.

The measurement results appear.

See [“To save a measurement to a calculation and patient report”](#) on page 5-1.

To trace automatically (Doppler)

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

1 On a frozen Doppler spectral trace, press the CALIPER key.

2 Select **Auto** on-screen.

A vertical caliper appears.

3 Using the touchpad, position the caliper at the beginning of the waveform.

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

4 Press the SELECT key.

A second vertical caliper appears.

5 Using the touchpad, position the second caliper at the end of the waveform.

6 Press the SET key.

The measurement results appear.

See [“To save a measurement to a calculation and patient report”](#) on page 5-1.

Automatic trace results

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

- ▶ Velocity time integral (VTI)
- ▶ Peak velocity (Vmax)
- ▶ Mean pressure gradient (PGmean)
- ▶ Mean velocity on peak trace (Vmean)
- ▶ Pressure gradient (PGmax)
- ▶ Cardiac output (CO)
- ▶ Peak systolic velocity (PSV)
- ▶ Time average mean (TAM)*
- ▶ +/× or systolic/diastolic (S/D)
- ▶ Pulsatility index (PI)
- ▶ End diastolic velocity (EDV)
- ▶ Acceleration time (AT)
- ▶ Resistive index (RI)

- ▶ Time average peak (TAP)
- ▶ Gate depth

General calculations

Within calculations, you can save measurement results to the patient report. You can display, repeat, and delete measurements from a calculation. Some measurements can be deleted directly from the patient report pages. See **“Patient report”** on page 5-45.

Calculation packages depend on exam type and transducer.

Unexpected data loss

Patient exam calculations on ultrasound workflows can be lost without warning or indication if certain settings change prior to ending any current (open) studies. See the following caution:

Caution

Changes made to any of the following settings will cause analysis values in the current (open) study to be cleared. These settings should not be changed before ending any open study on the system.

- ▶ Date and time
- ▶ OB tables or custom measurements
- ▶ Cardiac TDI labels
- ▶ IMT labels
- ▶ Doppler units

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. (See **“Patient report”** on page 5-45.) 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.

Menu items followed by ellipses (. . .) have sub-entries.

To select from the calculations menu

- 1 On a frozen image, press the CALCS key.

The calculations menu appears.

2 Using the touchpad or arrow keys, highlight the desired measurement name.

To display additional measurement names, highlight **Next**, **Prev**, or a measurement name that has ellipses (. . .). Then press the **SELECT** key.

Only measurement names available for the imaging mode are selectable.

3 Press the **SELECT** key.

To close the calculations menu, press the **CALCS** key once (if the menu is active) or twice (if the menu is inactive).

Performing and saving measurements in calculations

In performing a measurement within a calculation, you select from the calculations menu, position the calipers that appear, and then save the calculation. Unlike measurements performed outside a calculation, the calipers appear by selecting from the calculations menu, not by pressing the **CALIPER** key. The type of calipers that appear depends on the measurement.

To save a calculation

❖ Do one of the following:

▶ Save the calculation only: Press the **SAVE CALC** key, or select **Save** on-screen.

The calculation saves to the patient report. To save the image with the measurements displayed, see **“To save an image”** on page 4-22.

▶ Save both the image and calculation: Press the **SAVE** key if the **SAVE** key functionality is set to **Image/Calcs**. (See **“Presets setup”** on page 3-13.)

The calculation saves to the patient report, and the image saves to internal storage with the measurements displayed.

Displaying, repeating, 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. See **“Patient report”** on page 5-45.

To repeat a saved measurement

1 Highlight the measurement name in the calculations menu.

2 Press the **SELECT** key or the **CALIPER** key.

3 Perform the measurement again.

The new results appear on-screen in the measurement and calculations data area. (See “[Screen layout](#)” on page 2-11.) You can compare them to the saved results below the menu.

4 To save the new measurement, press the **SAVE CALC** key.

The new measurement saves to the patient report and overwrites the previously saved measurement.

To delete a saved measurement

1 Select the measurement name from the calculations menu.

2 Select **Delete** on-screen.

The measurement last saved is deleted from the patient report. If it is the only measurement, the check mark is deleted from the calculations menu.

Some measurements can be deleted directly from the patient report pages. See “[Patient report](#)” on page 5-45.

EMED calculations

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

To perform an EMED calculation:

1 Press the **CALCS** key.

2 Select **EMED** on-screen.

The calculations menu becomes the EMED calculations menu.

3 Select the calculation name.

4 Perform a distance measurement.

5 Save the measurement.

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

Percent reduction calculations

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 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.

Table 5-1: Transducers and exam types

Transducer	Exam types
C11x	Abdomen, Vascular
C60x	Abdomen, Msk
C60xi	Abdomen, Msk
HFL38x	IMT, Small Parts, Vascular
HFL50x	Msk, Small Parts
L25x	Msk, Vascular
L38x	IMT, Small Parts, Vascular
L38xi	IMT, Msk, Small Parts, Vascular
P10x	Abdomen
P21x	Abdomen
SLAx	Msk, Vascular

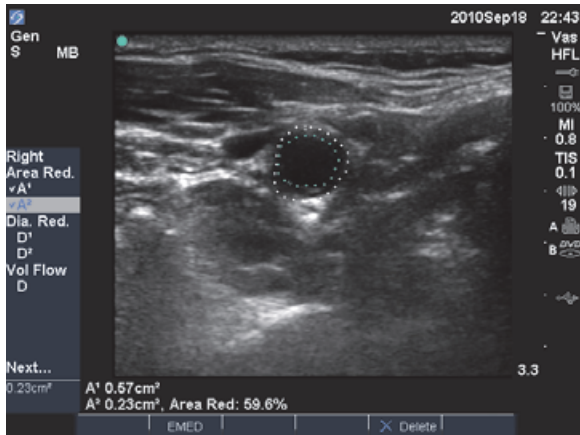


Figure 5-2 Percent area reduction calculation of right carotid bulb

To calculate percent area reduction

The percent area reduction calculation involves two manual trace measurements.

- 1 On a frozen 2D image, press the CALCS key.
- 2 Do the following for **A¹** and then for **A²**:
 - a From the calculations menu, select the measurement name under **Area Red.**
 - b Using the touchpad, move the caliper to the trace starting point, and press the SELECT key.
 - c Using the touchpad, trace the desired area.

To make a correction, select **Undo** on-screen or press the BACKSPACE key.
 - d Complete the trace, and press the SET key.
 - e Save the calculation. See [“To save a calculation”](#) on page 5-9.

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

To calculate percent diameter reduction

- 1 On a frozen 2D image, press the CALCS key.
- 2 Do the following for **D¹** and then for **D²**:
 - a From the calculations menu, select the measurement name under **Dia Red.**
 - b Position the calipers. (See [“Working with calipers”](#) on page 5-2.)
 - c Save the calculation. See [“To save a calculation”](#) on page 5-9.

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

Volume calculations

WARNINGS

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

Table 5-2: Transducers and exam types

Transducer	Exam types
C8x	Prostate
C11x	Abdomen, Neonatal, Nerve, Vascular,
C60x	Abdomen, Gyn, Msk, Nerve
C60xi	Abdomen, Gyn, Msk, Nerve
HFL38x	Breast, Nerve, Small Parts, Vascular
HFL50x	Breast, Msk, Nerve, Small Parts
ICTx	Gyn
L25x	Msk, Nerve, Superficial, Vascular
L38x	Breast, Nerve, Small Parts, Vascular
L38xi	Breast, Msk, Nerve, Small Parts, Vascular
P10x	Abdomen, Neonatal
P21x	Abdomen
SLAx	Msk, Nerve, Superficial, Vascular

Note

When performing volume flow measurements, the factor identified in the literature that affects the accuracy is difficulty ensuring uniform insonation of the vessel. The system is limited to the following sample volume sizes: C60xi transducer: 2, 3, 5, 7, 10, 12 Gate Size (mm).

To calculate volume

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

- ❖ Do the following for each image you need to measure:

- a On the frozen 2D image, press the calcs key.
- b Do the following for each measurement you need to take:
 - i From the calculations menu, select the measurement name under **Volume**. (If **Volume** is not available in a Gyn exam, select **Gyn** and then select **Volume**.)
 - ii Position the calipers. (See [“Working with calipers”](#) on page 5-2.)
 - iii Save the measurement. See [“To save a calculation”](#) on page 5-9.

Volume flow calculations

Table 5-3: Transducers and exam types

Transducer	Exam types
C11x	Abdomen, Vascular
C60x	Abdomen
C60xi	Abdomen
HFL38x	Vascular
L25x	Vascular
L38x	Vascular
L38xi	Vascular
P10x	Abdomen
P21x	Abdomen
SLAx	Vascular

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. See [“To create a new patient information form”](#) on page 4-19.

The following table shows the measurements required to complete the volume flow calculation. For definitions of acronyms, see [“Glossary”](#) on page A-1.

Table 5-4: Volume flow calculations

Menu heading	Measurement (Imaging mode)	Calculation result
Vol Flow	D (2D)* TAM or TAP (Doppler)	VF (Volume Flow ml/min)
* Required if measuring the diameter instead of using the gate size		

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.

The Doppler sample volume should completely insonate the vessel. You can measure either the time average mean or time average peak. To specify the live trace setting, see **“Presets setup”** on page 3-13.

Consider the following factors when performing volume flow measurements:

- ▶ Users should follow current medical practice for volume flow calculation applications.
- ▶ The accuracy of the volume flow calculation largely depends on the user.
- ▶ The factors identified in the literature that affect the accuracy are as follows:
 - ▶ Using the diameter method for 2D area
 - ▶ Difficulty ensuring uniform insonation of the vessel. The system is limited to the following sample volume sizes:
 - ▶ C11x transducer: 1, 2, 3 Gate Size (mm)
 - ▶ C60x and P10x transducers: 2, 3, 5, 7, 10, 12 Gate Size (mm)
 - ▶ C60xi transducer: 2, 3, 5, 7, 10, 12 Gate Size (mm)
 - ▶ HFL38x, L25x, and SLAx transducers: 1, 3, 5, 6, 7, 8, 10, 12 Gate Size (mm)
 - ▶ P21x transducer: 2, 3, 5, 7, 11.5, 14 Gate Size (mm)
 - ▶ Precision in placing the caliper
 - ▶ Accuracy in angle correction

The considerations and degree of accuracy for volume flow measurements and calculations are discussed in the following references:

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

To calculate volume flow

1 If measuring the diameter instead of using the gate size, perform the 2D measurement:

- a** On a frozen full-screen 2D image or duplex image, press the CALCS key.
- b** From the calculations menu, select **D** (distance) under **Vol Flow**.
- c** Position the calipers. (See **“Working with calipers”** on page 5-2.)

- d Save the calculation. See **“To save a calculation”** on page 5-9.
- 2 Perform the Doppler measurement:
- a On a frozen Doppler spectral trace, press the CALCS key.
 - b From the calculations menu, select **TAM** or **TAP** under **Vol Flow**.
A vertical caliper appears.
 - c Using the touchpad, position the vertical caliper at the beginning of the waveform.
If calipers are not positioned correctly, the calculation result is inaccurate.
 - d Press the SELECT key to display a second vertical caliper.
 - e Using the touchpad, position the second vertical caliper at the end of the waveform.
 - f Press the SET key to complete the trace and to display the results.
 - g Save the calculation. See **“To save a calculation”** on page 5-9.

Results appear at the bottom of the screen as well as save to the patient report.

Exam-based calculations

In addition to the general calculations, there are calculations specific to the Cardiac, Gynecology (Gyn), IMT, OB, Orbital, Small Parts, Transcranial Doppler (TCD), and Vascular exam types.

Cardiac calculations

Table 5-5: Transducers and exam types

Transducer	Exam type
D2x	Cardiac
P10x	Cardiac
P21x	Cardiac
TEEx	Cardiac
TEExi	Cardiac

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. See **"To create a new patient information form"** on page 4-19.

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

Table 5-6: Cardiac calculations

Menu heading	Cardiac measurements (Imaging mode)	Calculation results
LV...LVd	RVW (2D) RVD (2D) IVS (2D) LVD (2D) LVPW (2D)	CO EF SV LVESV LVEDV
...LVs	RVW (2D) RVD (2D) IVS (2D) LVD (2D) LVPW (2D) HR ^a needed for CO & CI	IVSFT LVPWFT LVDFS CI SI
Ao/LA	Ao (2D or M Mode) AAo (2D) LA (2D or M Mode) LVOT D (2D) ACS (M Mode) LVET (M Mode)	Ao LA/Ao AAo LA LA/Ao LVOT D LVOT area ACS LVET
MV	EF: Slope (M Mode) EPSS (M Mode)	EF SLOPE EPSS

Table 5-6: Cardiac calculations

Menu heading	Cardiac measurements (Imaging mode)	Calculation results
LV...LVd	RVW (M Mode) RVD (M Mode) IVS (M Mode) LVD (M Mode) LVPW (M Mode)	CO EF SV LVESV LVEDV
...LVs	RVW (M Mode) RVD (M Mode) IVS (M Mode) LVD (M Mode) LVPW (M Mode)	IVSFT LVPWFT LVDFS CI SI LV Mass
HR	HR ^a	
Area	AV (2D) MV (2D)	AV Area MV Area
LV Vol (EF)	A4Cd (2D) A4Cs (2D) A2Cd (2D) A2Cs (2D)	LV Vol LV Area EF CO SV CI SI Biplane
LV mass	Epi (2D) Endo (2D) Apical (2D)	LV Mass Epi Area Endo Area D Apical
PISA	Ann D (2D) Radius (Color) MR/VTI (Doppler) MV/VTI (Doppler)	PISA Area ERO MV Rate Regurgitant Volume Regurgitant Fraction
Qp/Qs	LVOT D (2D) RVOT D (2D) LVOT VTI (Doppler) RVOT VTI (Doppler)	D VTI VMax PGmax Vmean PGmean SV Qp/Qs

Table 5-6: Cardiac calculations

Menu heading	Cardiac measurements (Imaging mode)	Calculation results
CO	LVOT D (2D) — (Doppler)	CO SV CI SI VTI HR LVOT D
TDI	(Wall) e' and a (Doppler) (Wall) e' and a (Doppler) (Wall) e' and a (Doppler) (Wall) e' and a (Doppler) (Wall) e' and a (Doppler)	E(MV)/e' ratio

Table 5-6: Cardiac calculations

Menu heading	Cardiac measurements (Imaging mode)	Calculation results
P. Vein	A (Doppler)	VMax
	Adur (Doppler)	time
	S (Doppler)	VMax
	D (Doppler)	S/D ratio
MV	E (Doppler)	E
	A (Doppler)	E PG A A PG E:A
	Adur (Doppler)	time
	PHT (Doppler)	PHT MVA Decel time
	VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
	IVRT (Doppler)	time
MV...MR	dP:dT ^b (CW Doppler)	dP:dT
AV	Vmax (Doppler)	Vmax PGmax
	VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
	VTI or Vmax from LVOT (Doppler) VTI or Vmax from AV (Doppler)	AVA
Ao/LA	LVOT D (2D)	
AV	VTI (Doppler)	SV
Ao/LA	LVOT D (2D)	
AV	VTI (Doppler)	CO
Ao/LA	LVOT D (2D)	
HR	HR ^a	

Table 5-6: Cardiac calculations

Menu heading	Cardiac measurements (Imaging mode)	Calculation results
LVOT	Vmax (Doppler)	Vmax PGmax
	VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
AV...AI	PHT (slope) (Doppler)	AI PHT AI slope
TV	TRmax (Doppler)	Vmax PGmax
	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
	RA pressure ^c	RVSP
PV	Vmax (Doppler)	Vmax PGmax
	VTI (Doppler) AT (Doppler)	VTI Vmax PGmax Vmean PGmean AT

- a. You can enter the HR measurement three ways: Patient information form, Doppler measurement (See ["To calculate heart rate \(HR\)"](#) on page 5-28), or M Mode measurement (See ["To measure heart rate \(M Mode\)"](#) on page 5-5).
- b. Performed at 100 cm/s and 300 cm/s.
- c. Specified on the cardiac patient report. See ["To delete a vascular or cardiac measurement"](#) on page 5-46.

To measure LVd and LVs

- 1 On a frozen 2D image or M Mode trace, press the CALCS key.
- 2 From the calculations menu, select the measurement name.
- 3 Position the active (green) caliper at the starting point. (See “Working with calipers” on page 5-2.)
- 4 Press the SELECT key, and position the second caliper.
- 5 Press the SELECT key.

Another caliper appears, and the calculations menu highlights the next measurement name.

- 6 Position the caliper, and press the SELECT key. Repeat for each measurement name in the calculation group.

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

- 7 Save the calculation. (See “To save a calculation” on page 5-9.)

To measure Ao, LA, AAO, or LVOT D

- 1 On a frozen 2D image or M Mode trace, press the CALCS key.
- 2 From the calculations menu, select the measurement name.
- 3 Position the calipers. (See “Working with calipers” on page 5-2.)
- 4 Save the calculation. (See “To save a calculation” on page 5-9.)

To calculate LV Volume (Simpson’s Rule)

- 1 On a frozen 2D image, press the CALCS key.
- 2 Do the following for each measurement:
 - a From the calculations menu, select the desired view and phase.
 - b Position the caliper at the mitral annulus, and press the SELECT key to start the trace.
 - c Using the touchpad, trace the left ventricular (LV) cavity.

To make a correction, select **Undo** on-screen or press the BACKSPACE key.
 - d Complete the trace, and press the SET key.
 - e Save the calculation. (See “To save a calculation” on page 5-9.)

To calculate MV or AV area

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

- 2 In the calculations menu, locate **Area**, and then select **MV** or **AV**.
- 3 Position the caliper where you want to begin the trace, and press the SELECT key.
- 4 Using the touchpad, trace the desired area.

To make a correction, select **Undo** on-screen or press the BACKSPACE key.
- 5 Complete the trace, and press the SET key.
- 6 Save the calculation. (See **"To save a calculation"** on page 5-9.)

To calculate LV Mass

- 1 On a frozen 2D image, press the CALCS key.
- 2 In the calculations menu, locate **LV Mass**.
- 3 Do the following for **EPI** and then for **Endo**:
 - a Select the measurement name from the calculations menu.
 - b Position the caliper where you want to begin the trace, and press the SELECT key.
 - c Using the touchpad, trace the desired area.

To make a correction, select **Undo** on-screen or press the BACKSPACE key.
 - d Complete the trace, and press the SET key.
 - e Save the calculation. (See **"To save a calculation"** on page 5-9.).
- 4 Select **Apical** from the calculations menu.
- 5 Positioning the calipers, measure the ventricular length. (See **"Working with calipers"** on page 5-2.)
- 6 Save the calculation.

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 fifth one. If you delete a saved measurement from the patient report, the next measurement taken replaces the deleted one in the patient report. The most recently saved measurement appears at the bottom of the calculations menu.

- 1 On a frozen Doppler spectral trace, press the CALCS key.
- 2 From the calculations menu, select **MV**, **TV**, **TDI**, or **P. Vein**.

- 3 Do the following for each measurement you want to take:
 - a Select the measurement name from the calculations menu.
 - b Position the calipers. (See [“Working with calipers”](#) on page 5-2.)
 - c Save the calculation. (See [“To save a calculation”](#) on page 5-9.)

To calculate velocity time integral (VTI)

Note

This calculation computes other results in addition to VTI. See the table [“Cardiac calculations”](#) on page 5-16.

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

To make a correction, select **Undo** on-screen, backtrack with the touchpad, or press the BACKSPACE key.
- 5 Press the SET key to complete the trace.
- 6 Save the calculation. (See [“To save a calculation”](#) on page 5-9.)

For information on the automatic trace tool, see [“To trace automatically \(Doppler\)”](#) on page 5-7.

To calculate Right Ventricular Systolic Pressure (RVSP)

- 1 On a frozen Doppler spectral trace, press the CALCS key.
- 2 From the calculations menu, select **TV** and then select **TRmax**.
- 3 Position the caliper. (See [“Working with calipers”](#) on page 5-2.)
- 4 Save the calculation. (See [“To save a calculation”](#) on page 5-9.)
- 5 To adjust the RA pressure, see [“To delete a vascular or cardiac measurement”](#) on page 5-46.

Changing the RA pressure from the default 5 affects the RVSP calculation in the patient report.

To calculate pressure half time (PHT) in MV, AI, or TV

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

3 Position the first caliper at the peak, and press the **SELECT** key.

A second caliper appears.

4 Position the second caliper:

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

5 Save the calculation. (See **“To save a calculation”** on page 5-9.)

To calculate proximal isovelocity surface area (PISA)

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

1 Measure from Ann D (2D):

- a** On a frozen 2D image, press the **CALCS** key.
- b** From the calculations menu, locate **PISA**, and then select **Ann D**.
- c** Position the calipers. (See **“Working with calipers”** on page 5-2.)
- d** Save the calculation. (See **“To save a calculation”** on page 5-9.)

2 Measure from radius (Color):

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

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

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

- a** From the calculations menu, select **PISA** and then select **MR VTI** or **MV VTI**.
- b** Position the caliper at the start of the waveform, and press the **SELECT** key to start the trace.
- c** Using the touchpad, trace the waveform.
To make a correction, select **Undo** on-screen, backtrack with the touchpad, or press the **BACKSPACE** key.
- d** Press the **SET** key to complete the trace.
- e** Save the calculation.

For information on the automatic trace tool, see **“To trace automatically (Doppler)”** on page 5-7.

To calculate Isovolumic Relaxation Time (IVRT)

- 1 On a frozen Doppler spectral trace, press the **CALCS** key.
- 2 From the calculations menu, select **MV** and then select **IVRT**.
A vertical caliper appears.
- 3 Using the touchpad, position the caliper at the aortic valve closure.
- 4 Press the **SELECT** key.
A second vertical caliper appears.
- 5 Using the touchpad, position the second caliper at onset of mitral inflow.
- 6 Save the calculation. (See **"To save a calculation"** on page 5-9.)

To calculate delta pressure: delta time (dP:dT)

To perform the dP:dT measurements, the CW Doppler scale must include velocities of 300 cm/s or greater on the negative side of the baseline. (See **"Spectral trace options"** on page 3-32.)

- 1 On a frozen CW Doppler spectral trace, press the **CALCS** key.
- 2 From the calculations menu, select **MV**, and then select **dP:dT**.
A horizontal dotted line with an active caliper appears at 100 cm/s.
- 3 Position the first caliper along the waveform at 100 cm/s.
- 4 Press the **SELECT** key.
A second horizontal dotted line with an active caliper appears at 300 cm/s.
- 5 Position the second caliper along the waveform at 300 cm/s.
- 6 Save the calculation. (See **"To save a calculation"** on page 5-9.)

To calculate aortic valve area (AVA)

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

- 1 In 2D, measure from LVOT:
 - a On a frozen 2D image, press the **calcs** key.
 - b From the **Calculations** menu, select **AV** then **LVOT D**.

- c Position the calipers.
 - d Save the calculation.
- 2 In Doppler, select **AV**, measure LVOT, and then measure the AV.

To calculate Qp/Qs

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

- 1 On a frozen 2D image, press the **CALCS** key.
- 2 Do the following to measure from LVOT D and again to measure from RVOT D:
 - a From the calculations menu, locate **Qp/Qs** and then select **LVOT D** or **RVOT D**.
 - b Position the calipers. (See **“Working with calipers”** on page 5-2.)
 - c Save the calculation. (See **“To save a calculation”** on page 5-9.)
- 3 On a frozen Doppler spectral trace, press the **CALCS** key.
- 4 Do the following to measure from LVOT VTI and again to measure from RVOT VTI:
 - a From the calculations menu, select **Qp/Qs** and then select **LVOT VTI** or **RVOT VTI**.
 - b Press the **SELECT** key to start the trace.
 - c Using the touchpad, trace the waveform.
To make a correction, select **Undo** on-screen, backtrack with the touchpad, or press the **BACKSPACE** key.
 - d Press the **SET** key to complete the trace.
 - e Save the calculation. (See **“To save a calculation”** on page 5-9.)

For information on the automatic trace tool, see **“To trace automatically (Doppler)”** on page 5-7.

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 Fill in the **Height** and **Weight** fields on the patient information form. The BSA is calculated automatically. (SI only.)
- 2 Measure from LVOT (2D).
 - a On a frozen 2D image, press the **calcs** key.
 - b From the 2D main menu, select **AO/LA**.

- c From the **Calculations** menu, select **LVOT D**.
 - d Position the calipers.
 - e Save the calculation.
- 3 Measure from LVOT (Doppler).
- a On a frozen Doppler image, press the **calcs** key.
 - b From the **Calculations** menu, select **AV**, and then select **LVOT VTI**.
 - c Position the calipers.
 - d Save the calculation.

For information on the automatic trace tool, see **“To trace automatically (Doppler)”** on page 5-7.

To calculate heart rate (HR)

Heart rate is available in all cardiac packages. The heart rate is not calculated using the ECG trace.

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

- 1 On a frozen Doppler spectral trace, press the **CALCS** key.
- 2 From the calculations menu, select **HR**.

A vertical caliper appears.

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

- 4 Press the **SELECT** key.

A second vertical caliper appears. The active caliper is highlighted green.

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

- 6 Save the calculation. (See **“To save a calculation”** on page 5-9.)

To calculate cardiac output (CO) or cardiac index (CI)

The CO and CI calculations require stroke volume and heart rate 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 information form. The BSA is calculated automatically. (See **“To create a new patient information form”** on page 4-19.)
- 2 Calculate SV. See **“To calculate stroke volume (SV) or stroke index (SI)”** on page 5-27.

3 Calculate HR. See **“To calculate heart rate (HR)”** on page 5-28.

To calculate cardiac output automatically

WARNINGS

- ▶ To avoid incorrect calculation results, make sure that the Doppler signal does not alias.
- ▶ To avoid an incorrect diagnosis:
 - ▶ Do not use automatic cardiac output calculations as the sole diagnostic criteria. Use them only in conjunction with other clinical information and patient history.
 - ▶ Do not use automatic cardiac output calculations in neonatal patients.
- ▶ To avoid inaccurate velocity measurements if you use PW Doppler, make sure that angle correction is set to zero.

The system can maintain the accuracy of automatic cardiac output measurements only if the flow rate is 1 L/min or greater.

1 Measure from LVOT (2D):

- a On a frozen 2D image, press the **CALCS** key.
- b From the calculations menu, select **CO**, and then select **LVOT D**.
- c Position the calipers. (See **“Working with calipers”** on page 5-2.)
- d Save the calculation. (See **“To save a calculation”** on page 5-9.)

2 Trace automatically (Doppler):

The automatic trace tool always measures the peak regardless of the Live Trace setting in Presets setup.

- a Display the Doppler spectral trace (waveform).
- b Select **Trace** on-screen, and then select **Above** or **Below** for the position of the automatic trace tool relative to the baseline.

The automatic trace tool appears in yellow.

The results appear at the bottom of the screen.

- c Freeze the image.

If you want to change the waveform measured, move each vertical caliper by pressing **SELECT** and then using the touchpad. Press **SET** to update the results.

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

If you want to hide the results, select **Trace**.

- d Save the calculation.

To measure a tissue Doppler imaging (TDI) waveform

- 1 Ensure that TDI is on. (See “PW Doppler options” on page 4-9.)
- 2 On a frozen Doppler spectral trace, press the CALCS key.
- 3 From the calculations menu, select **TDI**, and then do the following for each measurement you want to take:
 - a From the calculations menu, select the measurement name.
 - b Position the calipers. (See “Working with calipers” on page 5-2.)
 - c Save the calculation. (See “To save a calculation” on page 5-9.)

Measurement publications and terminology (cardiac)

The following are additional references for the cardiac exam type.

Left Ventricular Mass in gm for 2D

Schiller, N.B., P.M. Shah, M. Crawford, et.al. “Recommendations for Quantification of the Left Ventricle by Two-Dimensional Echocardiography.” *Journal of American Society of Echocardiography*. September-October 1998, 2:364.

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

where:
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*. 2nd Edition, Boston: Little, Brown and Company, (1999), 39.

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

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

Gynecology (Gyn) calculations

Gynecology (Gyn) calculations include Uterus, Ovary, Follicle, and Volume. For instructions to calculate volume, see [“Volume calculations”](#) on page 5-13.

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. See [“To create a new patient information form”](#) on page 4-19.

Table 5-7: Transducers and exam types

Transducer	Exam type
C60x	Gyn
C60xi	Gyn
ICTx	Gyn

To measure uterus or ovary

- 1 On a frozen 2D image, press the CALCS key.
- 2 From the calculations menu, select **Gyn**.
- 3 Do the following for each measurement you want to take:
 - a Select the measurement name from the calculations menu.
 - b Position the calipers. (See [“Working with calipers”](#) on page 5-2.)
 - c Save the calculation. (See [“To save a calculation”](#) on page 5-9.)

To measure follicles

On each side, you can save up to three distance measurements on a follicle, for up to 10 follicles.

If you measure a follicle twice, the average appears in the report. If you measure a follicle three times, the average and a volume calculation appear in the report.

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

- 2 From the calculations menu, select **Follicle**.
- 3 Do the following for each measurement you want to take:
 - a From the calculations menu, select the follicle number under **Right Fol** or **Left Fol**.
 - b Position the calipers. (See **“Working with calipers”** on page 5-2.)
 - c Save the calculation. (See **“To save a calculation”** on page 5-9.)

IMT calculations

Table 5-8: Transducers and exam types

Transducer	Exam type
L38x	IMT
L38xi	IMT
HFL38x	IMT

WARNINGS

- ▶ To ensure high quality images, all patient images must be obtained by qualified and trained individuals.
- ▶ To avoid patient injury, IMT results should not be used as a sole diagnostic tool. All IMT results should be interpreted in conjunction with other clinical information or risk factors.
- ▶ To avoid measurement errors, all measurements must be of the common carotid artery (CCA). This tool is not intended for measuring the bulb or the internal carotid artery (ICA).
- ▶ 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. See **“To create a new patient information form”** on page 4-19.

The following table shows available measurements for IMT calculations. The IMT measurement names are specified on the IMT setup page. See “[IMT calculations setup](#)” on page 3-10.

Table 5-9: IMT calculations (2D)

Menu heading	Available measurements
Right-IMT	Ant N (Anterior Near Wall)
Left-IMT	Ant F (Anterior Far Wall)
	Lat N (Lateral Near Wall)
	Lat F (Lateral Far Wall)
	Post N (Posterior Near Wall)
	Post F (Posterior Far Wall)
	IMT 1
	IMT 2
	IMT 3
	IMT 4
	IMT 5
	IMT 6
	IMT 7
	IMT 8
Plaque	Plaq 1
	Plaq 2

To calculate IMT automatically

- 1 On a frozen 2D image, press the CALCS key.
- 2 From the calculations menu, select the measurement.
- 3 Using the touchpad or arrow keys, position the IMT tool over the area of interest until the measurement results appear.
- 4 Adjust the tool, and edit as needed. See “[IMT tool options](#)” on page 5-33.
- 5 Save the calculation. (See “[To save a calculation](#)” on page 5-9.)

IMT tool options

When using the IMT tool, you can select the following options on-screen.

Table 5-10: Options






Option	Description
Hide 	Use to check results. Hides the measurement results and trace line. Select Show to redisplay them.

Table 5-10: Options

Option	Description
Move 	Repositions the tool horizontally by several pixels. The upper key moves the tool right, and the lower key moves the tool left.
Width 	Adjusts the tool width by 1 mm. The upper key increases the width, and the lower key decreases the width.
Edit	Displays Smooth , Adven , and Lumen .
Smooth	Adjusts the IMT line smoothing. Select Edit to display this option.
Adven 	Adjusts the adventitia-media line. The upper key moves the line upward. The lower key moves the line downward. Select Edit to display this option.
Lumen 	Adjusts the lumen-intima line. The upper key moves the line upward. The lower key moves the line downward. Each of the two IMT lines can be adjusted independently. Select Edit to display this option.

To trace IMT manually

In manually tracing IMT, the user defines the location.

- 1 On a frozen 2D image, press the CALCS key
- 2 From the calculations menu, select a measurement name.
- 3 Select **Edit** on-screen, and then select **Manual**, and then select **Sketch**.

A single caliper appears, and *Trace* appears next to the measurement.

- 4 Do the following for the desired adventitia-media boundary and then for the lumen-intima boundary:

- a Position the caliper at the beginning of the boundary, and press the SELECT key.
- b Using the touchpad, mark points by moving the caliper to the next desired point and pressing the SELECT key.

To make a correction, select **Undo** on-screen or press the BACKSPACE key to delete the last segment.

- c Press the SET key to complete the trace line.

- 5 Save the calculation. (See **"To save a calculation"** on page 5-9.)

To sketch IMT

The IMT sketch measurement involves two user-defined sketch lines that you can adjust manually.

- 1 On a frozen 2D image, press the **CALCS** key.
- 2 From the calculations menu, select a measurement name.
- 3 Select **Edit** on-screen, and then select **Manual**.

A single caliper appears on-screen, and *Sketch* appears next to the measurement.

- 4 Do the following for the desired adventitia-media boundary and then for the lumen-intima boundary:

- a Position the caliper at the beginning of the boundary and press the **SELECT** key.
- b Using the touchpad, mark points by moving the caliper to the next desired point and pressing the **SELECT** key.

To make a correction, select **Undo** on-screen or press the **BACKSPACE** key to delete the last segment.

- c Press the **SET** key to complete the trace line.
- d If necessary, adjust or edit the measurement. See [“IMT tool options”](#) on page 5-33.
- e Save the calculation. (See [“To save a calculation”](#) on page 5-9.)

OB calculations

WARNINGS

- ▶ Make sure that you have selected the OB exam type and the OB author for the OB calculation table you intend to use. See [“Results from system-defined OB measurements and table authors”](#) on page 5-37.
- ▶ 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 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. See [“To create a new patient information form”](#) on page 4-19.
- ▶ Prior to use, verify that OB custom table data entries are correct. The system does not confirm the accuracy of the custom table data entered by the user.

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

Table 5-11: Transducers and exam types

Transducer	Exam type
C60x	OB
C60xi	OB
ICTx	OB
P21x	OB

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

The following table shows the system-defined measurements available for OB calculations by author. For definition of the acronyms, see [“Glossary”](#) on page A-1. To select authors, see [“OB calculations setup”](#) on page 3-10.

See also [“OB custom measurements setup”](#) on page 3-11 and [“OB custom tables setup”](#) on page 3-12.

Results from system-defined OB measurements and table authors

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.
	OFD	Hansmann
	HC	Chitty, Hadlock, Hansmann
	TTD	Hansmann, Tokyo U. ^b
	APTD	Tokyo U. ^b
	AC	Hadlock, Hansmann, Tokyo U.
	FTA	Osaka
	FL	Chitty, Hadlock, Hansmann, Osaka, Tokyo U.
	HL	Jeanty
	Tibia	Jeanty
	TCD	—
	CM	—
	Lat V	—
	CxLen	—
Estimated Fetal Weight (EFW) ^c	HC, AC, FL	Hadlock 1
	BPD, AC, FL	Hadlock 2
	AC, FL	Hadlock 3
	BPD, TTD	Hansmann
	BPD, FTA, 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

Results from system-defined OB measurements and table authors

Calculation result	Gestational OB measurements	Table authors
Growth Analysis Tables ^d	BPD	Chitty, Hadlock, Jeanty
	HC	Chitty, Hadlock, Jeanty
	AC	Chitty, Hadlock, Jeanty
	FL	Chitty, Hadlock, Jeanty
	EFW	Brenner, Hadlock, Jeanty
	HC/AC	Campbell

- 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. (See "OB Calculations setup" on page 2-20.) 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 patient report with priority given to the order listed above.
- d. The growth analysis tables are used by the report graphs feature. Three growth curves are drawn using the table data for the selected growth parameter and published author. Growth tables are only available with a user-entered LMP or Estab. DD.

To measure gestational growth (2D)

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

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

The caliper tool may change depending on the measurement selected, but the position remains constant.
 - b Position the calipers. (See "**Working with calipers**" on page 5-2.)
 - c Save the calculation. (See "**To save a calculation**" on page 5-9.)

To measure fetal heart rate (M Mode)

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

2 Select **FHR** from the calculations menu.

A vertical caliper appears.

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

4 Press the SELECT key.

A second vertical caliper appears.

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

6 Save the calculation. (See **"To save a calculation"** on page 5-9 **"To save a calculation"** on page 5-9

Table 5-12: OB Doppler calculations

Menu heading	OB calculation	Results
MCA (Middle Cerebral Artery)	S/D, RI	SD RI
	S/D, RI, PI*	SD RI PI
Umb A (Umbilical Artery)	S/D, RI	SD RI
	S/D, RI, PI*	SD RI PI

*Calculation requires a trace measurement.

To calculate MCA or Umba (Doppler)

Note

The system does not provide an MCA/UmbA ratio from the PI (pulsatility index).

1 Select **OB** exam type, and select **LMP** or **Estab.DD** in the patient information form.

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

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

a From the calculations menu, select the measurement name under **MCA** (middle cerebral artery) or **UmbA** (umbilical artery).

b Position the calipers:

- ▶ For **S/D, RI**, position the first caliper at the peak systolic waveform. Press the SELECT key, and position the second caliper at the end diastole on the waveform.
 - ▶ For **S/D, RI, PI**, position the caliper at the beginning of the desired waveform, and press the SELECT key. Use the touchpad to manually trace the desired area. Press the SET key. If calipers are not positioned correctly, the calculation result is inaccurate.
- c Save the calculation. (See **“To save a calculation”** on page 5-9.)
- Only one calculation (**S/D, RI** or **S/D, RI, PI**) can be saved.

Small parts calculations

Small parts calculations include volume, hip angle, and d:D ratio. For instructions to calculate volume, see **“Volume calculations”** on page 5-13.

Table 5-13: Transducers and exam types

Transducer	Exam type
HFL38x	Small Parts
HFL50x	Small Parts
L38x	Small Parts
L38xi	Small Parts

To calculate hip angle

- 1 On a frozen 2D image, press the CALCS key.
- 2 From the calculations menu, select **Right** or **Left**.
- 3 Select **Baseline** under **Hip Angle**.

A baseline appears on-screen.
- 4 Position the baseline, and press the SET key. (See **“Working with calipers”** on page 5-2.)

Line A (alpha line) appears on-screen, and **Line A** is selected in the calculations menu.
- 5 Position Line A, and save the measurement. (See **“To save a calculation”** on page 5-9.)

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

To calculate d:D ratio

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

- 2 From the calculations menu, select **Right** or **Left**.
- 3 Under **d:D Ratio**, select **Fem Hd** (femoral head).
- 4 Using the touchpad, position and resize the circle. The SELECT key toggles between position and size.
- 5 Press the SET key.

The baseline automatically appears with the left caliper active.

- 6 Position the caliper. (See [“Working with calipers”](#) on page 5-2.)
- 7 Save the measurement. (See [“To save a calculation”](#) on page 5-9.)

Transcranial Doppler and orbital calculations

Table 5-14: Transducer and exam type

Transducer	Exam types
P21x	Transcranial (TCD), Orbital (Orb)

WARNINGS

- ▶ To avoid injury to the patient, use only an orbital (Orb) exam type when performing imaging through the eye.
- ▶ Verify that the patient information, date, and time settings are accurate.
- ▶ To avoid carrying over measurements from the previous patient, start a new patient information form for each new patient before you perform calculations on the new patient. See [“To create a new patient information form”](#) on page 4-19.

The following table shows the measurements required to complete transcranial Doppler (TCD) and orbital (Orb) calculations. For definitions of acronyms, see “[Glossary](#)” on page A-1.

Table 5-15: Transcranial and orbital calculations

Menu heading	TCD and Orb measurements	Results
TT MCA	Dist Mid Prox Bifur* ACA ACoA* TICA	TAP PSV EDV PI RI S/D Gate size
TT	PCAp1 PCAp2 PCoA	
TO	OA Siphon	TAP PSV EDV PI RI S/D Gate Size
SM	ECICA	TAP PSV EDV PI RI S/D Gate Size
FM FM BA	VA Prox Mid Dist	TAP PSV EDV PI RI S/D Gate size

Table 5-15: Transcranial and orbital calculations

AL	ECVA	TAP PSV EDV PI RI S/D Gate size
*Available but not required		

WARNING

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

To perform a transcranial Doppler or orbital calculation

1 Select the correct exam type:

- ▶ **Orbital (Orb)** to measure ophthalmic artery and siphon
- ▶ **Transcranial (TCD)** for other measurements

See **“To change the exam type”** on page 4-14.

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

3 From the calculations menu, select **Left** or **Right**.

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

a From the calculations menu, select the measurement. (You may need to select **Next** or **Prev** to locate the measurement.)

b Do one of the following:

- ▶ For a manual trace measurement, use the touchpad to position the caliper. Press the SELECT key. Use the touchpad to trace the waveform.

If you need to make a correction, select **Undo** on-screen or press the BACKSPACE key.

- ▶ For an auto trace measurement, select **Auto** on-screen, and use the touchpad to position the first caliper at the beginning of the waveform. Press the SELECT key, and position the second caliper at the end of the waveform.

Confirm that the system-generated boundary is correct. If you are not satisfied with the trace, obtain a higher quality Doppler spectral trace image, or trace manually.

- c Press the SET key.
- d Save the calculation. (See **“To save a calculation”** on page 5-9.)

Vascular calculations

Table 5-16: Transducers and exam types

Transducer	Exam type
C11x	Vascular
HFL38x	Vascular
L25x	Vascular
L38x	Vascular
L38xi	Vascular
SLAx	Vascular

WARNINGS

- ▶ 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. See **“To create a new patient information form”** on page 3-40.
- ▶ To avoid incorrect calculations, verify that the patient information, date, and time settings are accurate.

The vascular measurements that you can save to the patient report are listed in the following table. For definitions of acronyms, see **“Glossary”** on page A-1.

Table 5-17: Vascular calculations

Menu heading	Vascular measurement	Calculation results
CCA	Prox	s (systolic), d (diastolic)
	Mid	s (systolic), d (diastolic)
	Dist	s (systolic), d (diastolic)
ICA	Bulb	s (systolic), d (diastolic)
	Prox	s (systolic), d (diastolic)
	Mid	s (systolic), d (diastolic)
ECA	Dist	s (systolic), d (diastolic)
	Prox	s (systolic), d (diastolic)
	Mid	s (systolic), d (diastolic)
	Dist	s (systolic), d (diastolic)
	VArty	s (systolic), d (diastolic)

To perform a vascular calculation

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

- 1 On a frozen Doppler spectral trace, press the **CALCS** key.
- 2 From the calculations menu, select **Left** or **Right**.
- 3 Do the following for each measurement you want to take:
 - a From the calculations menu, select the measurement name.
 - b Using the touchpad, position the caliper at the peak systolic waveform.
 - c Press the **SELECT** key.
A second caliper appears.
 - d Using the touchpad, position the second caliper at the end diastole on the waveform.
 - e Save the calculation. (See **"To save a calculation"** on page 5-9.)

Table 5-18: Exam types and calculations for L38xi transducer

Exam type	Calculations
Bre	Volume
IMT	IMT Percent Reduction
Msk	Percent Reduction Volume
Nrv	Volume
SmP	Percent Reduction Small Parts Volume
Vas	Percent Reduction Vascular Volume Volume Flow

Patient report

The patient report contains calculation results and patient information. For Cardiac, OB, Transcranial, and Vascular exams, the patient report has additional details and features.


You can display the patient report at any time during the exam.

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).

If you transfer or export an exam from the ultrasound system, the following measurements do not appear in the exported patient report. If you need to record them, save the report as an image (press the **SAVE** key) before transferring or exporting, or write them manually into the patient record.

- ▶ GYN exam: Follicle
- ▶ Cardiac exam: Automatically calculated CO values (CO, SV, CI, SI, VTI, Vmax, Vmean, PGmax, PGmean, LVOT D, LVOT area)

To display a patient report

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

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

To send a patient report to a PC

You can send a patient report to a PC as a text file.

- 1 Ensure correct configuration. See ["To configure the system for a DVD recorder, PC, or serial bar code scanner"](#) on page 3-9.

Make sure to use the connection cable supplied by FUJIFILM SonoSite. Other connection cables may cause audio interference, including an inaudible Doppler signal.

- 2 Select **Send Rep.** on-screen.

Vascular and cardiac patient reports

To delete a vascular or cardiac measurement

- 1 On the **Details** page of the patient report, select the measurement by using the touchpad. (The selected measurement is green.)

2 Select **Delete** on-screen.

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

(Vascular) To modify the ICA/CCA ratio

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

(Cardiac) To adjust the RA pressure

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

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

TCD patient report

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

To delete a row of TCD measurements

1 On the **Details** page of the TCD patient report, select the row's TAP measurement using the touchpad. (The selected measurement is green.)

2 Select **Delete** on-screen.

Deleted measurements are not included in the summary information.

OB patient report

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

To display the OB Twins patient report

❖ On the OB patient report, select one of the following on-screen:

- ▶ **Twin A/B** for individual twin patient reports
- ▶ **Compare** for both twins in one patient report

To delete an OB measurement

1 On the OB patient report, select the OB measurement by using the touchpad.

The selected measurement is green.

2 Select **Delete** on-screen.

To delete all measurements, select the measurement label and press the SELECT key and then select **Delete** on-screen.

To fill out the OB anatomy checklist

You can document reviewed anatomy.

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

To complete the OB biophysical profile


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

To display OB graphs

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

1 On the OB patient report, select **Graphs** on-screen.

2 In the **Graphs** list, select the desired measurement/author.

The graph for the selected measurement appears. You can select another measurement/author or select  **1/x** on-screen.

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

3 (Optional) Press the SAVE key to save the current graph page.

4 Select one of the following on-screen:

- ▶ **Report** to return to the previous patient report page
- ▶ **Done** to return to live imaging.

EMED worksheets

EMED worksheets contain results from EMED calculations and checklists that you can complete.

To display an EMED worksheet

This feature is optional.

1 After or during the exam, press the REPORT key.

2 Select **EMED** on-screen.

3 Select the worksheet from the **Worksheet** list or by selecting  **x/x** on-screen.

MSK worksheets

MSK worksheets have lists from which you can select and a field for entering comments.


To display an MSK worksheet

This feature is optional.

1 After or during the exam, press the REPORT key.

2 Select **MSK** on-screen.

3 Select the worksheet from the **Worksheet** list.

To display additional pages in the worksheet, select  **x/x** on-screen. Each worksheet has its own comments field, which remains on-screen even if you display another page in the worksheet.

If you want to save a worksheet page, press the SAVE key.

References

Measurement accuracy

The measurements provided by the system do not define a specific physiological or anatomical parameter. Rather, the measurements 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 6-19: 2D Measurement accuracy and range

2D Measure 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
Circumference ^d	< ±3% plus (1.4% of full scale/ smallest dimension) * 100 plus 0.5%	Acquisition	Phantom	0.01-96 cm

Table 6-19: 2D Measurement accuracy and range (continued)

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

Table 6-20: 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
Heart Rate	< +/- 2% plus (Full Scale ^c * Heart Rate/ 100) %	Acquisition	Phantom ^d	5-923 bpm

^aFull scale for distance implies the maximum depth of the image.
^bAn RMI 413a model phantom with 0.7 dB/cm MHz attenuation was used.
^cFull scale for time implies the total time displayed on the scrolling graphic image.
^dFUJIFILM SonoSite special test equipment was used.

Table 6-21: PW Doppler mode measurement and calculation accuracy and range

Doppler mode measurement accuracy and range	System tolerance	Accuracy by	Test method ^a	Range
Velocity cursor	< +/- 2% plus 1% of full scale ^b	Acquisition	Phantom	0.01 cm/sec-550 cm/sec
Frequency cursor	< +/- 2% plus 1% of full scale ^b	Acquisition	Phantom	0.01kHz-20.8 kHz
Time	< +/- 2% plus 1% of full scale ^c	Acquisition	Phantom	0.01-10 sec

^aFUJIFILM SonoSite special test equipment was used.

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

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

Sources of measurement errors

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

▶ Acquisition error

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

▶ Algorithmic error

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

Measurement publications and terminology

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

Terminology and measurements comply with AIUM published standards.

Cardiac references

Acceleration (ACC) in cm/s^2

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

ACC = abs (delta velocity/delta time)

Acceleration time (AT) in msec

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 2nd ed., Lippincott, Williams, and Wilkins, (1999), 219.

Aortic valve area (AVA) by continuity equation in cm^2

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

$$A_2 = A_1 * V_1/V_2$$

where: A_2 = Ao valve area
 A_1 = LVOT area (CSA)
 V_1 = LVOT velocity (VMax)
 V_2 = Ao valve velocity (VMax)
LVOT = Left Ventricular Outflow Tract

Body Surface Area (BSA) in m^2

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

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

Weight = kilograms

Height = centimeters

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

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 2nd Edition, Boston: Little, Brown and Company, (1999), 59.

$$\text{CI} = \text{CO}/\text{BSA}$$

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*. 2nd ed., Lippincott, Williams, and Wilkins, (1999), 59.

$$\text{CO} = (\text{SV} * \text{HR})/1000$$

where: CO = Cardiac output
 SV = Stroke volume
 HR = Heart rate

Cross sectional area (CSA) in cm²

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 383.

$$\text{CSA} = 0.785 * \text{D}^2$$

where: D = diameter of the anatomy of interest

Deceleration time in msec

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 453.

|time a - time b|

Delta pressure: delta time (dP:dT) in mmHg/s

Otto, C.M. *Textbook of Clinical Echocardiography*. 2nd ed., W.B. Saunders Company, (2000), 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), 225.

E Velocity/Ea velocity

where: E velocity = Mitral valve E velocity
 Ea = annular E velocity, also known as: E prime

Effective regurgitant orifice (ERO) in mm²

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 455.

$$\text{ERO} = 6.28 (r^2) * \text{Va}/\text{MR Vel}$$

where: r = radius
 Va = aliasing velocity

Ejection fraction (EF), percent

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 2nd ed., Lippincott, Williams, and Wilkins, (1999), 40.

$$\text{EF} = ((\text{LVEDV} - \text{LVESV})/\text{LVEDV}) * 100\%$$

where: EF = Ejection fraction
 LVEDV = Left ventricular end diastolic volume
 LVESV = Left ventricular end systolic volume

Elapsed time (ET) in msec

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), 71.

$$\text{IVSFT} = ((\text{IVSS} - \text{IVSD})/\text{IVSD}) * 100\%$$

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*. School of Cardiac Ultrasound, Arizona Heart Institute, (1993), 146.

|time a - time b|

Left atrium/aorta (LA/Ao)

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), 37:7.

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

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

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 2nd Edition, Boston: Little, Brown and Company, (1999), 39.

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

where: LVID = Internal dimension
PWT = Posterior wall thickness
IVST = Interventricular septal thickness
1.04 = Specific gravity of the myocardium
0.8 = Correction factor

Left ventricular volume: Biplane method in ml

N.B., P.M. Shah, M. Crawford, et.al. "Recommendations for Quantitation of the Left Ventricle by Two-Dimensional Echocardiography." *Journal of American Society of Echocardiography*. September-October 1989, 2:362.

$$V = \left(\frac{\pi}{4}\right) \sum_{i=1}^n a_i b_i \left(\frac{L}{n}\right)$$

where: V = Volume in ml
a = Diameter
b = Diameter

n = Number of segments (n=20)

L = Length

i = Segment

Left ventricular volume: Single plane method in ml

N.B., P.M. Shah, M. Crawford, et.al. "Recommendations for Quantitation of the Left Ventricle by Two-Dimensional Echocardiography." *Journal of American Society of Echocardiography*. September-October 1989, 2:362.

$$V = \left(\frac{\pi}{4}\right) \sum_{i=1}^n a_i^2 \left(\frac{L}{n}\right)$$

where: V = Volume
a = Diameter
n = Number of segments (n=20)
L = Length
i = Segment

Left ventricular dimension (LVD) fractional shortening, percent

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. Boston: Little, Brown and Company, (1994), 43-44.

$$\text{LVDFS} = ((\text{LVDD} - \text{LVDS})/\text{LVDD}) * 100\%$$

where: LVDD = Left ventricle dimension at diastole
LVDS = Left ventricle dimension at systole

Left ventricular posterior wall fractional thickening (LVPWFT), percent

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

$$\text{LVPWFT} = ((\text{LVPWS} - \text{LVPWD})/\text{LVPWD}) * 100\%$$

where: LVPWS = Left ventricular posterior wall thickness at systole
LVPWD = Left ventricular posterior wall thickness at diastole

Mean velocity (Vmean) in cm/s

Vmean = mean velocity

Mitral valve area (MVA) in cm²

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 391, 452.

$$\text{MVA} = 220/\text{PHT}$$

where: PHT = pressure half time

Note

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

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 396.

$$\text{Flow} = 6.28 (r^2) * V_a$$

where: r = radius

V_a = aliasing Velocity

Pressure gradient (PGr) in mmHG

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 3rd Edition, Philadelphia: Lippincott, Williams, and Wilkins, (2007), p.63-66.

$$\text{PGr} = 4 * (\text{Velocity})^2$$

Peak E pressure gradient (E PG)

$$\text{E PG} = 4 * \text{PE}^2$$

Peak A pressure gradient (A PG)

$$\text{A PG} = 4 * \text{PA}^2$$

Peak pressure gradient (PGmax)

$$\text{PGmax} = 4 * \text{PV}^2$$

Mean pressure gradient (PGmean)

Echocardiographic Assessment of Valve Stenosis: EAE/ASE Recommendations for Clinical Practice Journal of American Society of Echocardiography, (January, 2009), 4-5.

$$\text{PG mean} = \text{sum}(4v^2)/N$$

where:

v = peak velocity at interval n

N = the number of intervals in the Riemann sum

Pressure half time (PHT) in msec

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 391.

$$\text{PHT} = \text{DT} * 0.29$$

where: DT = deceleration time

Proximal isovelocity surface area (PISA) in cm²

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 2nd ed., Boston: Little, Brown and Company, (1999), 125.

$$\text{PISA} = 2\pi r^2$$

where: $2\pi = 6.28$
r = aliasing radius

Qp/Qs

Oh, J.K., J.B. Seward, and A.J. Tajik. *The Echo Manual*. 3rd Edition, Boston: Philadelphia: Lippincott Williams and Wilkins, (2007), p.70-72.

$$\text{Qp/Qs} = \text{SV Qp site} / \text{SV Qs site} = \text{RVOT SV} / \text{LVOT SV}$$

where:

$$\begin{aligned} \text{RVOT SV} &= \text{RVOT CSA} * \text{RVOT VTI} = \pi/4 * \text{RVOT diameter}^2 * \text{RVOT VTI} \\ \text{LVOT SV} &= \text{LVOT CSA} * \text{LVOT VTI} = \pi/4 * \text{LVOT diameter}^2 * \text{LVOT VTI} \end{aligned}$$

Regurgitant fraction (RF) in percent

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. Boston: Little, Brown and Company, (1999), 125.

$$\text{RF} = \text{RV} / \text{MV SV}$$

where: RV = Regurgitant Volume
MV SV = Mitral Stroke Volume

Regurgitant volume (RV) in cc

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 396, 455.

$$\text{RV} = \text{ERO} * \text{MR VTI}$$

Right ventricular systolic pressure (RVSP) in mmHg

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. School of Cardiac Ultrasound, Arizona Heart Institute, (1993), 152.

$$\text{RVSP} = 4 * (\text{Vmax TR})^2 + \text{RAP}$$

where: RAP = Right atrial pressure

S/D

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 217.

S velocity/ D velocity

where: S velocity = Pulmonary vein S wave
D velocity= Pulmonary vein D wave

Stroke index (SI) in cc/m²

Mosby's Medical, Nursing, & Allied Health Dictionary, 4th ed., (1994), 1492.

$$\text{SI} = \text{SV}/\text{BSA}$$

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 Edition, Boston: Philadelphia: Lippincott Williams and Wilkins, (2007), p.69-71.

$$\text{SV} = (\text{CSA} * \text{VTI})$$

where
CSA = Cross sectional area of the orifice (LVOT area)
VTI = Velocity time integral of the LVOT

Tricuspid valve area (TVA)

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 55, 391, 452.

$$\text{TVA} = 220 / \text{PHT}$$

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), 44.

$$SV = (LVEDV - LVESV)$$

where: SV = Stroke volume
 LVEDV = End diastolic volume
 LVESV = End systolic volume

Velocity time integral (VTI) in cm

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 383.

$$VTI = \text{sum of abs (velocities [n])}$$

where: Auto trace – distance (cm) blood travels with each ejection period. Velocities are absolute values.

Obstetrical references

Amniotic fluid index (AFI)

Jeng, C. J., et al. "Amniotic Fluid Index Measurement with the Four Quadrant Technique During Pregnancy." *The Journal of Reproductive Medicine*, 35:7 (July 1990), 674-677.

Average ultrasound age (AUA)

The system provides an AUA derived from the component measurements from the measurement tables.

Estimated date of delivery (EDD) by average ultrasound age (AUA)

Results are displayed as month/day/year.

$$EDD = \text{system date} + (280 \text{ days} - \text{AUA in days})$$

Estimated date of delivery (EDD) by last menstrual period (LMP)

The date entered into the patient information for LMP must precede the current date.

Results are displayed as month/day/year.

$$EDD = \text{LMP date} + 280 \text{ days}$$

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), 333-337.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 154.

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), 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), 47-54.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." *Japanese Journal of Medical Ultrasonics*, 23:12 (1996), 880, Equation 1.

Gestational age (GA) by last menstrual period (LMP)

The gestational age derived from the LMP date entered on the patient information form.

Results are displayed in weeks and days, and is calculated as follows:

$$\text{GA(LMP)} = \text{System date} - \text{LMP date}$$

Gestational age (GA) by last menstrual period (LMPd) derived from established due date (Estab. DD)

Same as GA by Estab. DD.

The gestational age derived from the system derived LMP using the established due date entered on the patient information form.

Results are displayed in weeks and days, and is calculated as follows:

$$\text{GA(LMPd)} = \text{System date} - \text{LMPd}$$

Last menstrual period derived (LMPd) by established due date (Estab. DD)

Results are displayed as month/day/year.

$$\text{LMPd(Estab. DD)} = \text{Estab. DD} - 280 \text{ days}$$

Gestational age tables

Abdominal circumference (AC)

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 431.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." *Japanese Journal of Medical Ultrasonics*, 23:12 (1996), 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), 174-179, Table 3.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 440.

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), 98.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." *Japanese Journal of Medical Ultrasonics*, 23:12 (1996), 885.

Cisterna magna (CM)

Mahony, B.; P. Callen, R. Filly, and W. Hoddick. "The fetal cisterna magna." *Radiology*, 153: (December 1984), 773-776.

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), 501-505.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 439.

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), 20 and 96.

Tokyo University. "Gestational Weeks and Computation Methods." *Ultrasound Imaging Diagnostics*, 12:1 (1982-1), 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), 174-179, Table 8, 186.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 431.

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), 101-102.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." *Japanese Journal of Medical Ultrasonics*, 23:12 (1996), 886.

Fetal trunk cross-sectional area (FTA)

Osaka University. *Ultrasound in Obstetrics and Gynecology*. (July 20, 1990), 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), 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, 182.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 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), 75-79.

Occipito-frontal diameter (OFD)

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 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), 75-79.

Transverse trunk diameter (TTD)

Hansmann, M., et al. *Ultrasound Diagnosis in Obstetrics and Gynecology*. New York: Springer-Verlag, (1986), 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), 131, Appendix: AC-Derived.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Jeanty P, E. Cousaert, and F. Cantraine. "Normal Growth of the Abdominal Perimeter." *American Journal of Perinatology*, 1: (January 1984), 129-135.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. *Ultrasound Diagnosis in Obstetrics and Gynecology*. Springer-Verlag, New York, (1986), 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), 43, Appendix: BPD-Outer-Inner.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Jeanty P, E. Cousaert, and F. Cantraine. "A Longitudinal Study of Fetal Limb Growth." *American Journal of Perinatology*, 1: (January 1984), 136-144, Table 5.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. *Ultrasound Diagnosis in Obstetrics and Gynecology*. Springer-Verlag, New York, (1986), 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), 555-564; Table II.

Hadlock F., et al. "In Utero Analysis of Fetal Growth: A Sonographic Weight Standard." *Radiology*, 181: (1991), 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), 321-328, Table 1.

(Also published in Hansmann, Hackeloer, Staudach, and Wittman. *Ultrasound Diagnosis in Obstetrics and Gynecology*. Springer-Verlag, New York, (1986), 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), 135.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Jeanty P, E. Cousaert, and F. Cantraine. "A Longitudinal Study of Fetal Limb Growth." *American Journal of Perinatology*, 1: (January 1984), 136-144, Table 5.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. *Ultrasound Diagnosis in Obstetrics and Gynecology*. Springer-Verlag, New York, (1986), 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), 43, Appendix: HC-Derived.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 497-501.

Jeanty P, E. Cousaert, and F. Cantraine. "A longitudinal study of Fetal Head Biometry." *American J of Perinatology*, 1: (January 1984), 118-128, Table 3.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. *Ultrasound Diagnosis in Obstetrics and Gynecology*. Springer-Verlag, New York, (1986), 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), 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), 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), 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), 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), 165-174.

General references

+/x or S/D ratio

$+/x = \text{abs}(\text{Velocity A}/\text{Velocity B})$

where A = velocity cursor +
 B = velocity cursor x

Acceleration index (ACC)

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

ACC = abs (delta velocity/delta time)

Elapsed time (ET)

ET = time between velocity cursors in milliseconds

Hip angle/d:D ratio

Graf, R. "Fundamentals of Sonographic Diagnosis of Infant Hip Dysplasia." *Journal of Pediatric Orthopedics*, Vol. 4, No. 6: 735-740, 1984.

Morin, C., Harcke, H., MacEwen, G. "The Infant Hip: Real-Time US Assessment of Acetabular Development." *Radiology* 177: 673-677, December 1985.

Intima media thickness (IMT)

Howard G, Sharrett AR, Heiss G, Evans GW, Chambless LE, Riley WA, et al. "Carotid Artery Intima-Medial Thickness Distribution in General Populations As Evaluated by B-Mode Ultrasound." ARIC Investigators. Atherosclerosis Risk in Communities. *Stroke*. (1993), 24:1297-1304.

O'Leary, Daniel H., MD and Polak, Joseph, F., MD, et al. "Use of Sonography to Evaluate Carotid Atherosclerosis in the Elderly. The Cardiovascular Health Study." *Stroke*. (September 1991), 22,1155-1163.

Redberg, Rita F., MD and Vogel, Robert A., MD, et al. "Task force #3—What is the Spectrum of Current and Emerging Techniques for the Noninvasive Measurement of Atherosclerosis?" *Journal of the American College of Cardiology*. (June 4, 2003), 41:11, 1886-1898.

Percent area reduction

Taylor K.J.W., P.N. Burns, P. Breslau. *Clinical Applications of Doppler Ultrasound*, Raven Press, N.Y., (1988), 130-136.

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), 386-391.

$$\% \text{ Area reduction} = (1 - A2(\text{cm}^2)/A1(\text{cm}^2)) * 100$$

where: A1 = original area of the vessel in square cm
 A2 = reduced area of the vessel in square cm

Percent diameter reduction

Handa, Nobuo et al., "Echo-Doppler Velocimeter in the Diagnosis of Hypertensive Patients: The Renal Artery Doppler Technique," *Ultrasound in Medicine and Biology*, 12:12 (1986), 945-952.

$$\% \text{ Diameter reduction} = (1 - D2(\text{cm})/D1(\text{cm})) * 100$$

where: D1 = original diameter of the vessel in cm
 D2 = reduced diameter of the vessel in cm

Pressure gradient (PGr) in mmHG

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 2nd ed., Lippincott, Williams, and Wilkins, (1999), 64.

$$4 * (\text{Velocity})^2$$

Peak E pressure gradient (E PG)

$$\text{E PG} = 4 * \text{PE}^2$$

Peak A pressure gradient (A PG)

$$\text{A PG} = 4 * \text{PA}^2$$

Peak pressure gradient (PGmax)

$$\text{PGmax} = 4 * \text{PV}^2$$

Mean pressure gradient (PGmean)

$$\text{PGmean} = 4 * \text{Vmax}^2$$

Pulsatility index (PI)

Kurtz, A.B., W.D. Middleton. *Ultrasound-the Requisites*. Mosby Year Book, Inc., (1996), 469.

$$\text{PI} = (\text{PSV} - \text{EDV})/\text{V}$$

where PSV = peak systolic velocity
 EDV = end diastolic velocity
 V = mean flow velocity throughout the entire cardiac cycle

Resistive index (RI)

Kurtz, A.B., W.D. Middleton. *Ultrasound-the Requisites*. Mosby Year Book, Inc., (1996), 467.

$$\text{RI} = \text{abs} ((\text{Velocity A} - \text{Velocity B})/\text{Velocity A}) \text{ in measurements}$$

where A = velocity cursor +
 B = velocity cursor x

Time averaged mean (TAM) in cm/s

TAM = mean (mean Trace)

Time averaged peak (TAP) in cm/s

TAP = peak (peak trace)

Volume (Vol)

Beyer, W.H. *Standard Mathematical Tables*, 28th ed., CRC Press, Boca Raton, FL, (1987), 131.

Volume $cm^3 = (4/3) * Length/2 * Width/2 * Height/2$

Volume flow (VF) in ml/m

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

One of the following, depending on the Live Trace setting:

$VF = CSA * TAM * .06$

$VF = CSA * TAP * .06$

CHAPTER 7

Cleaning and Disinfecting

This chapter includes instructions for cleaning and disinfecting the ultrasound system, transducers, and accessories.

Use the FUJIFILM SonoSite recommendations when cleaning or disinfecting your ultrasound system, transducer, and accessories. Use the cleaning recommendations in the peripheral manufacturer's instructions when cleaning or disinfecting your peripherals.

See **Chapter 2, "Getting Started,"** for images of the ultrasound system.

See www.sonosite.com/transducers, for transducer images.

Note

- ▶ The system and transducers must be cleaned and disinfected after each exam. It is important to follow these cleaning and disinfecting instructions without skipping any steps.
- ▶ For cleaning the TEE*xi* transducer, refer to the cleaning and disinfection instructions in the *TEE*xi* User Guide*.

Before getting started

- ▶ Follow the disinfectant manufacturer's recommendations regarding appropriate personal protective equipment (PPE), such as protective eyewear and gloves.
- ▶ Inspect the system and transducer to determine that they are free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.
- ▶ Confirm that cleaning and disinfecting materials are appropriate for your facility's use. FUJIFILM SonoSite tests cleaners and disinfectants for use with the FUJIFILM SonoSite systems and transducers.
- ▶ Disinfectants and cleaning methods listed in this chapter are recommended by FUJIFILM SonoSite for efficacy and material compatibility with the products.
- ▶ Ensure that the disinfectant type and the solution strength and duration are appropriate for the equipment and application.

- ▶ Follow manufacturer recommendations and local regulations, when preparing, using and disposing of chemicals.

WARNINGS

- ▶ Ensure that cleaning and disinfecting solutions and wipes are not expired
- ▶ Some cleaners and disinfectants can cause an allergic reaction in some individuals

Cautions

- ▶ 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 U.S. 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 7-22](#) to determine the level of cleaning and disinfecting required.

Table 7-22: Choosing a cleaning and disinfecting method

Did any part of the system or transducer come in contact with broken skin, blood, mucosal membranes, or bodily fluids?		
YES	Came in contact with broken skin, blood, mucosal membranes, or bodily fluids.	 <p>Option A</p> <p>Go to “Clean and disinfect system and transducer to a high level (semi-critical uses)” on page 7-3.</p>
OR		
NO	Did not come in contact with broken skin, blood, or bodily fluids.	 <p>Option B</p> <p>Go to “Clean and disinfect system and transducer to a low level (non-critical uses)” on page 7-8.</p>

Spaulding classifications

Spaulding classifications (non-critical, semi-critical) determine the approach for cleaning and disinfecting medical equipment based on the device, the way it has been used, and the risk of infection. The system and transducers are designed for use within the Spaulding classifications of non-critical and semi-critical uses.

Option **A** Clean and disinfect system and transducer to a high level (semi-critical uses)

Use this procedure to clean and high-level disinfect the ultrasound system and transducer **whenever it has come into contact with blood, broken skin, mucosal membranes, or bodily fluids**.

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 disinfecting to a high level.

To clean and disinfect the system and transducer

- 1 Turn off** the system by pressing the **Power button**.

- 2 **Unplug** the power cord from the outlet.
- 3 **Remove** the disposable transducer sheath, if applicable.
- 4 **Disconnect** the transducer from the system. Temporarily place it where it will not cross-contaminate clean equipment or surfaces while you clean the ultrasound console.
- 5 **Clean** the exterior surfaces of the **ULTRASOUND SYSTEM** to remove any debris or bodily fluids. 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 7-23: Approved cleaners/disinfectants for the ultrasound system

Cleaner/disinfectant	Compatible systems	Minimum wet contact time ¹
SaniCloth Plus	SonoSite Edge	3 minutes
PI-Spray II	SonoSite M-Turbo SonoSite S Series	10 minutes

¹For maximum effectiveness, the component being cleaned must remain wet with disinfectant for a minimum period of time.

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, debris, and bodily fluids 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 recommended by the manufacturer. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.
 - e Allow the ultrasound system to air dry in a clean, well-ventilated space.
- 6 Clean the ultrasound system **STAND** to remove any debris or bodily fluids. For information about cleaning the stand, see the H-Universal Stand User Guide.
- 7 Clean the **TRANSDUCER CABLE AND BODY** to remove any debris or bodily fluids. 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 7-24: Approved cleaners/disinfectants for the transducer

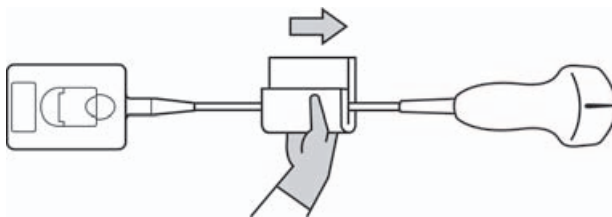
Product	Compatible transducer	Minimum wet contact time ¹
Sani-Cloth AF3 ²	C11x, C60x, C60xi, C8x, HFL38x, HFL50x, ICTx, L25x, L38xi, P10x, P21x	3 minutes
Sani-Cloth Plus	HFL50x	3 minutes
PI-Spray II	C11x, C60x, C60xi, C8x, HFL38x, HFL50x, ICTx, L25x, L38xi, P10x, P21x	10 minutes

¹For maximum effectiveness, the component being cleaned must remain wet with disinfectant for a minimum period of time.

² 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, debris, and bodily fluids 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, debris, and bodily fluids 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, debris, and bodily fluid could leave contaminants on the probe.

- 9 Examine** the system, transducer and cable for damage, such as cracks or splitting where fluid can enter. If damage is evident, discontinue use and contact FUJIFILM SonoSite or your local representative.
- 10 Prepare** the disinfectant for use.

- a Choose a high-level disinfectant from the list of approved disinfectants.

Table 7-25: High-level disinfectants compatible with SonoSite M-Turbo transducers

Disinfectant	Compatible transducers	Temperature	Disinfectant soak duration
Cidex	C11x, C60x, C60xi, C8x, HFL38x, HFL50x, ICTx, L25x, L38xi, P10x, P21x	25°C, 77°F	45 minutes
Cidex OPA	C11x, C60x, C60xi, C8x, HFL38x, HFL50x, L25x, L38xi, P10x, P21x	20°C, 68°F	12 minutes

Refer to the cleaners and disinfection tool available at www.sonosite.com/support/cleaners-disinfectants for a more complete list of the most current 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.

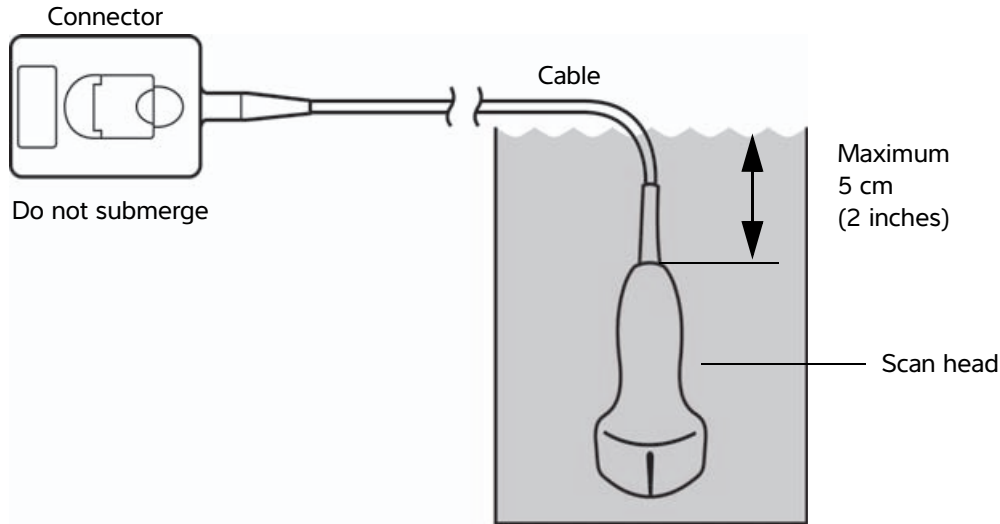


Figure 7-3 Transducer component names

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 one 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 the transducer with a sterile lint-free cloth.

14 Dispose of the disinfectant according to the manufacturer's guidelines.

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 blood, broken skin, mucosal membranes, or bodily fluids.**

WARNING

If the system or transducer has come into contact with any of the following, use the high-level cleaning and disinfection procedure. See “**Clean and disinfect system and transducer to a high level (semi-critical uses)**” on page 7-3:

- ▶ Blood
- ▶ Broken skin
- ▶ Mucosal membranes
- ▶ Bodily fluids

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 7-26: Approved cleaners/disinfectants for the ultrasound system:

Cleaner/disinfectant	Compatible systems	Minimum wet contact time ¹
SaniCloth Plus	SonoSite Edge	3 minutes
PI-Spray II	SonoSite M-Turbo SonoSite S Series	10 minutes

¹For maximum effectiveness, the component being cleaned must remain wet with disinfectant for a minimum period of time.

Refer to the cleaners and disinfection tool available at www.sonosite.com/support/cleaners-disinfectants for a more complete list of the most current approved cleaners and disinfectants.

- b** Remove all gel and debris from the system.
 - c** With a new wipe, clean the system, including the display, by wiping from clean areas to the soiled areas. This method helps to avoid cross-contamination.
 - d** Observe the minimum wet contact time and refer to manufacturer’s instructions. Monitor the system for wet appearance. Re-apply with a new wipe if no longer wet.
- 6 Clean** the ultrasound system **STAND** to remove any debris. For information about cleaning the stand, see the *Edge Stand and H-Universal Stand User Guide*.
 - 7 Clean** the **TRANSDUCER CABLE AND BODY** to remove any debris. Use the following procedure:
 - a** Use either a pre-moistened wipe or a soft cloth dampened with cleaner or disinfectant. Choose a cleaner from the list of approved cleaners.

Table 7-27: Approved cleaners/disinfectants for the transducer:

Product	Compatible transducer	Minimum wet contact time ¹
Sani-Cloth AF3 ²	C11x, C60x, C60xi, C8x, HFL38x, HFL50x, ICTx, L25x, L38xi, P10x, P21x	3 minutes
Sani-Cloth Plus	HFL50x	3 minutes

¹For maximum effectiveness, the component being cleaned must remain wet with disinfectant for a minimum period of time.

² 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 the most current approved cleaners and disinfectants.

Table 7-27: Approved cleaners/disinfectants for the transducer:

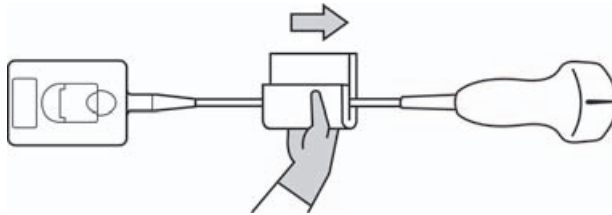
Product	Compatible transducer	Minimum wet contact time ¹
PI-Spray II	C11x, C60x, C60xi, C8x, HFL38x, HFL50x, ICTx, L25x, L38xi, P10x, P21x	10 minutes

¹For maximum effectiveness, the component being cleaned must remain wet with disinfectant for a minimum period of time.

² 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 the most current 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. **Allow** the ultrasound system to air dry in a clean, well-ventilated space.

WARNING | Failure to remove all gel and debris could leave contaminants on the probe.

- 9 Examine** the system, transducer and cable for damage, such as cracks or splitting where fluid can enter. If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative..

Storing the transducer

To store the transducer

- 1** Make sure the transducer has been cleaned and disinfected as detailed in the previous section.
- 2** Store the transducer so that it hangs freely and vertically, and observe the following precautions:
 - ▶ Store the transducer away from any contaminated transducers.

- ▶ Store the transducer in an environment that is safe and has good airflow. Do not store the transducer in closed containers or where condensation may occur.
- ▶ Avoid direct sunlight and exposure to x-rays. Recommended storage temperature range is between 0° C (32° F) and +45° C (113° F).
- ▶ If using a wall-mounted rack for storage, ensure that:
 - ▶ It is securely mounted.
 - ▶ The storage slots do not mar the transducer or cause damage to the cable.
 - ▶ The rack is sized and positioned to prevent the transducer from inadvertently falling.
 - ▶ Make sure the connector is supported and secure.

Transporting the transducer

When transporting the transducer, you must take precautions to protect the transducer from damage and avoid cross-contamination. Be sure to use a container approved by your organization.

To transport a soiled transducer for cleaning

A soiled transducer is one that has been contaminated and must be cleaned before using it in an exam.

- 1 Place the transducer in a clean, approved container.

WARNING

To prevent cross-contamination or unprotected exposure of personnel to biological material, containers used to transport contaminated transducers should carry an ISO biohazard label similar to the following:



Caution

Ensure the transducer is dry before placing it in a closed container. Condensation from a damp transducer can damage the connector.

- 2 Transport the transducer in the container to the point of processing. Do not open the container until the transducer is ready to be cleaned.

Caution

Do not leave the transducer in a sealed container for long periods of time.

To transport a clean transducer

A clean transducer is one that has completed the cleaning and disinfection process, has been stored properly, and is ready to be used in an examination.

- 1 Place the transducer in a clean, approved container. To identify the transducer as clean, containers used to transport clean transducers should carry a cleanliness verification sticker or certificate.
- 2 Transport the transducer in the container to the point of use. Do not open the container until the transducer is ready to be used.

To ship a transducer

WARNING

Whenever possible, avoid shipping a contaminated transducer. Before shipping, ensure the transducer has been cleaned and disinfected using the steps detailed in this chapter or according to special instructions received from FUJIFILM SonoSite. If you are returning the transducer to FUJIFILM SonoSite, document the disinfection on a "Declaration of Cleanliness," and attach it to the packing list.

- 1 Place the transducer in the shipping container and seal it. Do not allow any part of the transducer to protrude from the container.
- 2 Ship the transducer using the following precautions:
 - ▶ Clearly label the container as fragile.
 - ▶ Do not stack items on top of the shipping container.
 - ▶ Do not exceed the shipping temperature range: -35° C (-31° F) to +65° C (149° F).
 - ▶ Do not open the shipping container until it reaches its final destination.
 - ▶ After arrival, the transducer must be cleaned and disinfected before it can be used in an exam.

Cleaning the stand

For information about cleaning the stand, see the *H-Universal Stand User Guide*.

Cleaning the footswitch

Caution

To avoid damaging the footswitch, do not sterilize. It is not intended for use in a sterile environment.

To clean the footswitch

- 1 Dampen a non-abrasive cloth with one of the following products:
 - ▶ Isopropyl alcohol
 - ▶ Soap and water
 - ▶ Cidex
 - ▶ Sodium Hypochlorite 5.25% (Bleach) diluted 10:1
- 2 Wring out cloth until slightly wet and then gently rub soiled area until clean.

Cleaning and disinfecting accessories

To clean and disinfect the ECG slave cable, refer to the *ECG Slave Cable User Guide*.

CHAPTER 8

Troubleshooting and Maintenance

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

Troubleshooting

If you encounter difficulty with the system, use the following list to help troubleshoot the problem. If the problem persists, contact FUJIFILM SonoSite technical support. (See “[Getting help](#)” on page 1-3.)

System does not turn on. Check all power connections.

Remove the DC input connector and battery, wait 10 seconds, and then reinstall them.

Ensure that the battery is charged.

System displays the alert “Incompatible power supply . . . ” Use the power supply that shipped with the system. See “[Compatible accessories and peripherals](#)” on page 9-14.

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

Adjust the brightness.

Adjust the gain.

No CPD image. Adjust the gain.

No Color image. Adjust the gain or the PRF scale.

No OB measurement selections. Select the OB exam type.

System displays the alert “Maximum number of procedure entries reached” when trying to create a patient information form. Free up internal-storage space by archiving or exporting patient exams and then deleting them from the system.

System displays the alert “Unable to save image or clip. You have reached the maximum number of images/clips allowed for a single patient.” Delete any unwanted images or clips from the patient exam.

Print does not work. Select the printer on the Connectivity setup page. See [“To configure the system for a printer”](#) on page 3-8.

Check the printer connections.

Ensure that the printer is turned on and set up properly. See the printer manufacturer’s instructions, if necessary.

DVD recorder does not record. Check the DVD recorder connections.

Ensure that the DVD recorder is turned on and set up properly. See the applicable FUJIFILM SonoSite accessory user guide and the manufacturers’ instructions.

External monitor does not work. Check the monitor connections. Check the monitor to ensure that it is turned on and set up properly. See the monitor manufacturers’ instructions, if necessary.

System displays the alert “The external video is not functional . . .” Make sure that the system is securely attached to the dock.

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


System prompts you to “ensure the USB device is valid.” Make sure that the USB storage device does not have password protection enabled and is not defective.

Use the USB storage device included with the system.

System prompts you to “ensure the USB device contains valid data.” Make sure that the data is present on the USB storage device.

Reexport the original data onto the USB storage device.

Contact your system administrator.

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

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. (See [“Getting help”](#) on page 1-3.) You need to provide the following information. (See [“System information setup”](#) on page 3-14.)

Table 8-28: System and transducer software

System software	Transducer software
Name of person installing the upgrade	Name of person installing the upgrade
Serial number (on bottom of system)	Transducer serial number
ARM version	Transducer part number (REF) or model number (for example, C60x)
PCBA serial number	Transducer bundle version

After you obtain a license key, you must enter it into the system.

To enter a license key

1 Turn on the system.

The license update screen appears.

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

3 Select **Done** on-screen.

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. (See [“Getting help”](#) on page 1-3.)

Maintenance

WARNINGS

- ▶ No modification of this equipment, except as described in this manual or the FUJIFILM SonoSite M-Turbo 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 1-3.

Cleaning and disinfecting the battery

Caution

To avoid damaging the battery, do not allow cleaning solution or disinfectant to come in contact with the battery terminals.

To clean and disinfect a battery (wipe method)

- 1 Remove the battery from the system.
- 2 Clean the surface using a soft cloth lightly dampened in a mild soap or detergent cleaning solution.

Apply the solution to the cloth rather than the surface.

- 3 Wipe the surfaces with the disinfection solution. Sani-Cloth HB, Sani-Cloth Wipes, or 70% isopropyl alcohol is recommended.
 - ▶ Air dry.

CHAPTER 9

Safety

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.

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 (MSDs)^{1,2,3}.
- ▶ Use of an ultrasound system is defined as the physical interaction between the operator, the ultrasound system, and the transducer.
- ▶ When using an ultrasound system, as with many similar physical activities, you may experience occasional discomfort in your hands, fingers, arms, shoulders, eyes, back, or other parts of your body. However, if you experience symptoms such as constant or recurring discomfort, pain, throbbing, aching, tingling, numbness, burning sensation, or stiffness, do not ignore these warning signs. Promptly see a qualified health professional. Symptoms such as these can be linked with MSDs. MSDs can be painful and may result in potentially disabling injuries to the nerves, muscles, tendons, or other parts of the body. Examples of MSDs include carpal tunnel syndrome and tendonitis.

▶ While researchers are not able to definitively answer many questions about MSDs, there is a general agreement that certain factors are associated with their occurrence including preexisting medical and physical conditions, overall health, equipment and body position while doing work, frequency of work, duration of work, and other physical activities that may facilitate the onset of MSDs⁴. This chapter provides guidelines that may help you work more comfortably and may reduce your risk of MSDs^{5,6}.

1. 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.
2. Craig, M. "Sonography: An Occupational Hazard?" *Journal of Diagnostic Medical Sonography*. 3 (1985), 121-125.
3. Smith, C.S., G.W. Wolf, G. Y. Xie, and M. D. Smith. "Musculoskeletal Pain in Cardiac Ultrasonographers: Results of a Random Survey." *Journal of American Society of Echocardiography*. (May 1997), 357-362.
4. 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.
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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 quick height adjustments.
- ▶ Always sit or stand upright. Avoid bending or stooping.

Minimize reaching and twisting

- ▶ Use a bed that is height adjustable.

- ▶ Position the patient as close to you as possible.
- ▶ Face forward. Avoid twisting your head or body.
- ▶ Move your entire body front to back, and position your scanning arm next to or slightly in front of you.
- ▶ Stand for difficult exams to minimize reaching.
- ▶ Position the ultrasound system or display directly in front of you.
- ▶ Provide an auxiliary monitor for patient viewing.

Promote comfortable shoulder and arm postures

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

Promote comfortable hand, wrist, and finger postures

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

Take breaks, exercise, and vary activities

- ▶ Minimizing scanning time and taking breaks can effectively allow your body to recover from physical activity and help you avoid MSDs. Some ultrasound tasks may require longer or more frequent breaks. However, simply changing tasks can help some muscle groups relax while others remain or become active.
- ▶ Work efficiently by using the software and hardware features correctly.
- ▶ Keep moving. Avoid sustaining the same posture by varying your head, neck, body, arm, and leg positions.
- ▶ Do targeted exercises. Targeted exercises can strengthen muscle groups, which may help you avoid MSDs. Contact a qualified health professional to determine stretches and exercises that are right for you.

Electrical safety classification

Class I equipment The ultrasound system is classified as Class I equipment when powered from the external power supply or mounted on the stand because the external power supply is a Class 1 protectively earthed power supply. The stand has no protective earth. Ground bond testing is not applicable to the ultrasound system or the stand.

Note AC powered peripherals that may be used with the system are Class I and are individually protectively earthed. Ground bond testing may be conducted on each AC powered peripheral.

Internally powered equipment	Ultrasound system not connected to the power supply (battery only)
Type BF applied parts	Ultrasound transducers
Type CF applied parts	ECG module/ECG leads
IPX-7 (watertight equipment)	Ultrasound transducers
IPX-8 (watertight equipment)	Footswitch
Non AP/APG	Ultrasound system power supply, docking system, and peripherals. Equipment is not suitable for use in the presence of flammable anesthetics.

Electrical safety

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

This system complies with the applicable medical standards as listed in the Standards section of this document. Refer to “**Standards**” on page 10-4

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.

- ▶ Avoid patient contact with any part of the system other than the transducer or ECG leads.
- ▶ Under certain circumstances, the transducer connector and back of the display enclosure can reach temperatures that exceed EN60601-1 limits for patient contact, therefore only the operator shall handle the system. This does not include the transducer face.
- ▶ To avoid discomfort or minor risk of operator injury when handling the transducer connector, the system should not be operated for more than 60 minutes continuously in a live-scan mode (as opposed to freeze or sleep modes).
- ▶ 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.
- ▶ To avoid the risk of electrical shock, do not allow any part of the system (including the bar code scanner, external mouse, power supply, power supply connector, external keyboard, and so on), except for the transducer or ECG leads, to touch the patient.

To avoid the risk of electrical shock:

- ▶ This equipment must be connected only to a supply mains with protective earth.
- ▶ Use only properly grounded equipment. Shock hazards exist if the power supply is not properly grounded. Grounding reliability can only be achieved when equipment is connected to a receptacle marked "Hospital Only" or "Hospital Grade" or the equivalent. The grounding wire must not be removed or defeated.
- ▶ 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 any of the following:
 - ▶ The ungrounded signal input/output connectors on the back of the ultrasound system.
 - ▶ The system battery contacts (inside the battery compartment).
 - ▶ The system transducer connector when the transducer or Triple Transducer Connect (TTC) is disconnected.
 - ▶ The system transducer connector on the triple transducer connector if no transducers are connected.

- ▶ Do not connect the system's power supply or a docking system to an MPSO or extension cord.
- ▶ Before using the transducer, inspect the transducer face, housing, and cable. Do not use the transducer if the transducer or cable is damaged.
- ▶ Always disconnect the power supply from the system before cleaning the system.
- ▶ Do not use any transducer that has been immersed beyond the specified cleaning or disinfection level. See **Chapter 7, "Cleaning and Disinfecting."**
- ▶ Use only accessories and peripherals recommended by FUJIFILM SonoSite, including the power supply. Connection of accessories and peripherals not recommended by FUJIFILM SonoSite could result in electrical shock. Contact FUJIFILM SonoSite or your local representative for a list of accessories and peripherals available from or recommended by FUJIFILM SonoSite.
- ▶ Use commercial grade peripherals recommended by FUJIFILM SonoSite on battery power only. Do not connect these products to AC mains power when using the system to scan or diagnose a patient/subject. Contact FUJIFILM SonoSite or your local representative for a list of the commercial grade peripherals available from or recommended by FUJIFILM SonoSite.

To avoid the risk of electrical shock and fire hazard:

- ▶ Inspect the power supply, AC power cords, cables, and plugs on a regular basis. Ensure that they are not damaged.
- ▶ The power cord set that connects the power supply of the ultrasound system or MDS to mains power must only be used with the power supply or docking system, and cannot be used to connect other devices to mains power.
- ▶ To prevent injury to the operator/bystander, the transducer must be removed from patient contact before the application of a high-voltage defibrillation pulse.
- ▶ To avoid possible electrical shock or electromagnetic interference, verify proper operation and compliance with relevant safety standards for all equipment before clinical use.
- ▶ Connecting additional equipment to the ultrasound system constitutes configuring a medical system. FUJIFILM SonoSite recommends verifying that the system, all combinations of equipment, and accessories connected to the ultrasound system comply with the safety standards and installation requirements as applicable at the site of installation.
- ▶ Do not use shielded Ethernet cables with metal connector housings, as they may increase system touch current when connected to other equipment.

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

Cautions

- ▶ Do not use the system if an error message appears on the image display: note the error code; call FUJIFILM SonoSite or your local representative; turn off the system by pressing and holding the power key until the system powers down.
- ▶ To avoid increasing the system and transducer connector temperature, do not block the airflow to the ventilation holes on the side of the system.

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, see [Chapter 7, “Cleaning and Disinfecting.”](#)
- ▶ Do not submerge the transducer connector in solution. The cable is not liquid-tight beyond the transducer connector/cable interface.
- ▶ Do not use solvents such as thinner or benzene, or abrasive cleaners on any part of the system.
- ▶ Remove the battery from the system if the system is not likely to be used for some time.
- ▶ Do not spill liquid on the system.

Battery safety

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

WARNINGS

- ▶ Periodically, check to make sure that the battery charges fully. If the battery fails to charge fully, replace it.
- ▶ Do not ship a damaged battery without instructions from FUJIFILM SonoSite Technical Support.
- ▶ 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.
- ▶ If the battery leaks or emits an odor, remove it from all possible flammable sources.

Cautions

To avoid the battery becoming damaged and causing equipment damage, observe the following precautions:

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

Clinical safety

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 electromedical devices in proximity to its systems. FUJIFILM SonoSite equipment has not been validated for use with high-frequency electrosurgical devices or procedures. Use of high-frequency electrosurgical devices in proximity to its systems may lead to abnormal system behavior or shutdown of the system.
- ▶ To avoid the risk of a burn hazard, do not use the transducer with high frequency surgical equipment. Such a hazard may occur in the event of a defect in the high frequency surgical neutral electrode connection.
- ▶ 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 attenuation of .3dB/cm/MHz.
- ▶ Some FUJIFILM SonoSite transducers are approved for intraoperative applications if a market-cleared sheath is used.

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 and intraoperative procedures.
- ▶ Appropriate training in Interventional and Intraoperative procedures as dictated by current relevant medical practices as well as in proper operation of the ultrasound system and transducer is required. During vascular access, the potential exists for serious complications including without limitation the following: pneumothorax, arterial puncture, guide-wire misplacement, and risks normally associated with local or general anesthesia, surgery, and post-operative recovery.
- ▶ To avoid device damage or patient injury, do not use the P10x, P17x, or P21x needle guide bracket on patients with pacemakers or medical electronic implants. The needle guide bracket for the P10x, P17x, and P21x transducers contains a magnet that is used to ensure the bracket is correctly oriented on the transducer. The magnetic field in direct proximity to the pacemaker or medical electronic implant may have an adverse effect.

Hazardous materials

WARNING

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

Electromagnetic compatibility

The ultrasound system has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Cautions

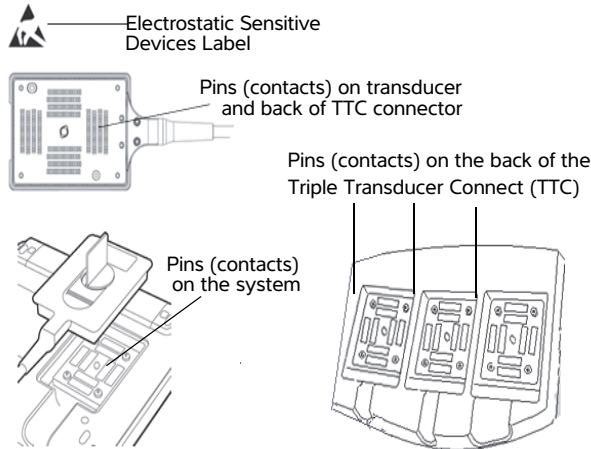
- ▶ Electrostatic discharge (ESD), or static shock, is a naturally occurring phenomenon. ESD is common in conditions of low humidity, which can be caused by heating or air conditioning. ESD is a discharge of the electrical energy from a charged body to a lesser or non-charged body. The degree of discharge 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.

- ▶ Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources, could result in performance disruption of the ultrasound system. Evidence of disruption may include image degradation or distortion, erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site to determine the source of disruption, and take the following actions to eliminate the source(s).
- ▶ Turn equipment in the vicinity off and on to isolate disruptive equipment.
- ▶ Relocate or re-orient interfering equipment.
- ▶ Increase distance between interfering equipment and your ultrasound system.
- ▶ Manage use of frequencies close to ultrasound system frequencies.
- ▶ Remove devices that are highly susceptible to EMI.
- ▶ Lower power from internal sources within facility control (such as paging systems).
- ▶ Label devices susceptible to EMI.
- ▶ Educate clinical staff to recognize potential EMI-related problems.
- ▶ Eliminate or reduce EMI with technical solutions (such as shielding).
- ▶ Restrict use of personal communicators (cell phones, computers) in areas with devices susceptible to EMI.
- ▶ Share relevant EMI information with others, particularly when evaluating new equipment purchases which may generate EMI.
- ▶ Purchase medical devices that comply with IEC 60601-1-2 EMC Standards.
- ▶ To avoid the risk of increased electromagnetic emissions or decreased immunity, use only accessories and peripherals recommended by FUJIFILM SonoSite. Connection of accessories and peripherals not recommended by FUJIFILM SonoSite to the ultrasound system may result in malfunction of the ultrasound system or other medical electrical devices in the area. Contact FUJIFILM SonoSite or your local representative for a list of accessories and peripherals available from or recommended by FUJIFILM SonoSite. See the FUJIFILM SonoSite accessories user guide.
- ▶ The SonoSite M-Turbo ultrasound system should not be used adjacent to or stacked with other equipment. If such use occurs, verify that the SonoSite M-Turbo ultrasound system operates normally in that configuration.

WARNINGS

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 (such as the transducer connector):



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

Separation distance

The SonoSite M-Turbo 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 M-Turbo ultrasound system can help prevent electromagnetic interference by maintaining a minimum distance

between portable and mobile RF communications equipment (transmitters) and the SonoSite M-Turbo ultrasound system as recommended below, according to the maximum output power of the communications equipment.

Table 9–29: Recommended separation distances between portable and mobile RF communications equipment and the SonoSite M-Turbo ultrasound system

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

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

Note

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Compatible accessories and peripherals

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

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

WARNINGS

- ▶ Use of the accessories with medical systems other than the SonoSite M-Turbo 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.

Table 9–30: Accessories and peripherals compatible with SonoSite M-Turbo ultrasound system

Description	Maximum Cable Length
C8x transducer ^a	6.0 ft /-1.8 m
C11x transducer ^a	6.0 ft/1.8 m
C60x transducer ^a	5.5 ft/1.7 m
C60xi transducer ^{a,b}	5.5 ft/1.7 m
D2x transducer ^a	5.5 ft/1.7 m
HFL38x transducer ^a	5.5 ft/1.7 m
HFL50x transducer ^a	5.7 ft/1.7 m
ICTx transducer ^a	5.5 ft/1.7 m
L25x transducer ^a	7.5 ft/2.3 m
L38xi transducer ^a	5.5 ft/1.7 m
L52x ^a	7.9 ft/2.4 m
P10x transducer ^a	6.0 ft/1.8 m
P21x transducer ^a	6.5 ft/2.0 m
SLAx transducer ^a	8.0 ft/2.4 m
TEExi transducer ^a	11.8 ft/3.6 m
Bar code scanner	4.8 ft/1.5 m
Battery for PowerPack	—
Battery Pack	—
Battery PowerPack	—
Black & white printer	—
Black & white printer cable	3.3 ft/1 m
Black & white printer USB cable	10.8 ft/3.3 m
Color printer	—
Color printer power cable	3.3 ft/1 m
Color printer video cable	6.0 ft/-1.8 m
ECG lead wires	24 in/ 0.6 m
ECG module	5.8 ft/1.8 m
Footswitch	9.8 ft/3.0 m
H-Universal Stand	—
M-Turbo Dock	—
Petite mouse	6 ft /1.8 m
Power cord (system)	10 ft/3 m
Power supply with DC cable	6.8 ft/-2 m

Table 9-30: Accessories and peripherals compatible with SonoSite M-Turbo ultrasound system

Power supply AC cable	39 in/ 1 m
PowerPark	—
Triple Transducer Connect	—
USB keyboard	—
USB wireless adapter	—

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 This transducer supports a multi-angle biopsy guide.

Guidance and manufacturer’s declaration

WARNING

Other equipment, even equipment that complies with CISPR emission requirements, can interfere with the SonoSite M-Turbo ultrasound system.

The SonoSite M-Turbo ultrasound system contains an IEEE 802.11 receiver and transmitter that utilizes the ISM frequency band from 2.412 to 2.4835 GHz and implements three methods of transmission:

- ▶ IEEE 802.11b with Complementary Code Keying (CCK), Differential Quaternary Phase Shift Keying (DQPSK), and Differential Binary Phase Shift Keying (DBPSK) at 17 dBm
- ▶ IEEE 802.11g with Orthogonal Frequency Division Multiplexing (OFDM) at 14 dBm
- ▶ IEEE 802.11n with OFDM at 14 dBm

Manufacturer’s declaration

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

Table 9-31: Guidance and manufacturer’s declaration - electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	The SonoSite M-Turbo ultrasound system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.


Table 9-31: Guidance and manufacturer’s declaration – electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Class A	The SonoSite M-Turbo 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	

Table 9-32: Guidance and manufacturer’s declaration – electromagnetic environment

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 for power supply lines ±1KV for input/output lines	±2KV for power supply lines ±1KV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1KV line(s) to line(s) ±2KV line(s) to earth	±1KV line(s) to line(s) ±2KV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SonoSite M-Turbo ultrasound system requires continued operation during power mains interruptions, it is recommended that the Sonosite M-Turbo ultrasound system be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 9-32: Guidance and manufacturer’s declaration – electromagnetic environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the SonoSite M-Turbo ultrasound system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended Separation Distance</p> $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 Vim 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ <p>80 MHz to 800 MHz</p> $d = 2.3 \sqrt{P}$ <p>800 MHz to 2,5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). 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:</p> 

^aField 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.

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

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.

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

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

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

Immunity testing requirements

The SonoSite M-Turbo ultrasound system complies with the essential performance requirements specified in IEC 60601-1-2 and IEC 60601-2-37:2008+A1:2015. Results of immunity testing show that the SonoSite M-Turbo ultrasound system meets these requirements and is free from the following:

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

ALARA principle

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

A thorough knowledge of the imaging modes, transducer capability, system setup and scanning technique is necessary. The imaging mode determines the nature of the ultrasound beam. A stationary beam results in a more concentrated exposure than a scanned beam, which spreads that exposure over that area. The

transducer capability depends upon the frequency, penetration, resolution, and field of view. The default system presets are reset at the start of each new patient. It is the scanning technique of the qualified ultrasound user along with patient variability that determines the system settings throughout the exam.

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

Applying ALARA

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

Prudent use of ultrasound 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 Section 42 of EN 60601-2-37:2008+A1:2015: Particular requirement for the safety of ultrasound medical diagnostic and monitoring equipment. See **“Transducer surface temperature rise”** on page 9-26. 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/cm² 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/cm²; 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 9–22. 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, see BS EN 60601-2-37:2008+A1:2015: Annex HH.

Indirect controls

The controls that indirectly affect output are controls affecting imaging mode, freeze, and depth. The imaging mode determines the nature of the ultrasound beam. 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, see the following reference:

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

Guidelines for reducing MI and TI

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

Table 9-33: MI

Transducer	Depth
C8x	↑
C11x	↑
C60x	↑
C60xi	↑
HFL38x	↑
HFL50x	↑
ICTx	↑
L25x	↑
L38x	↑
L38xi	↑
P10x	↑
P21x	↑
SLAx	↑
TEEx	↑
TEExi	↑

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

Table 9-34: TI (TIS, TIC, TIB)

Transducer	Color Power Doppler settings						PW settings
	Box width	Box height	Box depth	PRF	Depth	Optimize	
C8x	↓	—	—	—	↑	—	↓ (Depth)
C11x	—	—	↑	↓	↑	—	↓ (Depth)
C60x	↓	—	↑	↓	↑	—	↓ (PRF)
C60xi	↓	—	↑	↓	↑	—	↓ (PRF)
HFL38x	—	—	↑	↑	↑	—	↓ (Depth)
HFL50x	—	—	↑	↑	↑	—	↓ (Depth)
ICTx	—	↑	↑	↓	—	Exam Gyn	↓ (PRF)
L25x	↓	—	—	—	↑	—	↓ (PRF)
L38x	—	—	—	↓	—	—	↓ (Depth)

Table 9-34: TI (TIS, TIC, TIB)

Transducer	Color Power Doppler settings						PW settings
	Box width	Box height	Box depth	PRF	Depth	Optimize	
L38xi	↑	↑	—	—	—	—	↓ (Sample volume zone or size)
P10x	—	—	↑	↓	—	—	↓ (PRF)
P21x	—	↓	—	↓	↑	—	↓ (PRF)
SLAx	—	—	↑	↓	↑	—	↓ (PRF)
TEEx	—	—	—	↓	↓	—	↓ (PRF)
TEExi	—	—	—	↓	↓	—	↓ (PRF)

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

Output display

The system meets the AIUM output display standard for MI and TI (see last reference in Related guidance documents below). **Table 9-35** 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.

Note

The D2x transducer has a static continuous wave (CW) output. This output is fixed. Therefore, TI and MI values cannot be changed by any system controls available to the user.

Table 9-35: Modes in which a TI or MI \geq 1.0

Transducer model	Index	2D/ M Mode	CPD/ Color	PW Doppler	CW Doppler
C8x	MI	Yes	Yes	Yes	==
	TIC, TIB, or TIS	No	No	Yes	==
C11x/8-5	MI	No	No	No	—
	TIC, TIB, or TIS	No	Yes	Yes	—
C60x/5-2	MI	Yes	No	No	—
	TIC, TIB, or TIS	No	No	Yes	—
C60xi/5-2	MI	Yes	No	No	—
	TIC, TIB, or TIS	No	No	Yes	—
D2x/2	MI	—	—	—	No
	TIC, TIB, or TIS	—	—	—	Yes

Table 9-35: Modes in which a TI or MI \geq 1.0 (continued)

Transducer model	Index	2D/ M Mode	CPD/ Color	PW Doppler	CW Doppler
HFL38x/13-6	MI	Yes	Yes	Yes	—
	TIC, TIB, or TIS	No	Yes	Yes	—
HFL50x/15-6	MI	Yes	Yes	Yes	—
	TIC, TIB, or TIS	No	No	Yes	—
ICTx/8-5	MI	No	No	No	—
	TIC, TIB, or TIS	No	No	Yes	—
L25x/13-6	MI	Yes	No	No	—
	TIC, TIB, or TIS	No	No	Yes	—
L38x/10-5	MI	No	Yes	Yes	—
	TIC, TIB, or TIS	No	Yes	Yes	—
L38xi/10-5	MI	Yes	Yes	Yes	—
	TIC, TIB, or TIS	No	Yes	Yes	—
P10x/8-4	MI	No	Yes	Yes	No
	TIC, TIB, or TIS	Yes	Yes	Yes	Yes
P21x/5-1	MI	Yes	Yes	Yes	No
	TIC, TIB, or TIS	Yes	Yes	Yes	Yes
SLAx/13-6	MI	No	No	No	—
	TIC, TIB, or TIS	No	No	Yes	—
TEEx/8-3	MI	No	No	No	No
	TIC, TIB, or TIS	No	No	Yes	Yes
TEExi/8-3	MI	No	No	No	No
	TIC, TIB, or TIS	No	No	Yes	Yes

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

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

The TI consists of three user-selectable indices, and only one of these is displayed at any one time. In order to display TI properly and meet the ALARA principle, the user selects an appropriate TI based on the specific exam being performed. FUJIFILM SonoSite provides a copy of *AIUM Medical Ultrasound Safety*, which contains guidance on determining which TI is appropriate (See “[Related guidance documents](#)” on page 9-25).

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 9-74.

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. (A copy is included with each system.)

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

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

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

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

Transducer surface temperature rise

Table 9-36 and **Table 9-37** list the measured surface temperature rise from ambient ($23^{\circ}\text{C} \pm 3^{\circ}\text{C}$) of transducers used on the ultrasound system. The temperatures were measured in accordance with EN 60601-2-37 section 42 with controls and settings positioned to give maximum temperatures.

For information about surface temperature rise for the TEExi transducer, refer to the *TEExi Transducer User Guide*, included with the TEExi transducer.

Table 9-36: Transducer surface temperature rise, external use ($^{\circ}\text{C}$)

Test	C11x	C60x	C60xi	D2	HFL38x	HFL50x	L25x	L38x
Still air	14.3	16.2	14.8	8.3	12.8	11.3	14.5	16.3
Simulated use	7.1	8.2	7.6	1.9	8.2	6.9	8.6	9.6
Test	L38xi	P10x	P21x					
Still air	13	16.1	17.2					
Simulated use	8.3	8.9	8.5					

Table 9-37: Transducer surface temperature rise, internal use ($^{\circ}\text{C}$)

Test	C8x	ICTx	SLAx	TEEx	TEExi
Still air	9.2	8.3	9.5	9.3	8.6
Simulated Use	4.4	4.7	4.8	5.8	4.7

Acoustic output measurement

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

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

In Situ, derated, and water value intensities

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

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

where:

In Situ = *In Situ* intensity value

Water = Water intensity value

e = 2.7183

a = attenuation factor (dB/cm MHz)

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

brain = 0.53

heart = 0.66

kidney = 0.79

liver = 0.43

muscle = 0.55

l = skinline to measurement depth in cm

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

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

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

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

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

Tissue models and equipment survey

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

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

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

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

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

- ▶ A survey of 1990-equipment models yielded MI values between 0.1 and 1.0 at their highest output settings. Maximum MI values of approximately 2.0 are known to occur for currently available equipment. Maximum MI values are similar for real-time 2D and M Mode imaging.
- ▶ Computed estimates of upper limits to temperature elevations during transabdominal scans were obtained in a survey of 1988 and 1990 pulsed Doppler equipment. The vast majority of models yielded upper limits less than 1° and 4°C (1.8° and 7.2°F) for exposures of first-trimester fetal tissue and second-trimester fetal bone, respectively. The largest values obtained were approximately 1.5°C (2.7°F) for first-trimester fetal tissue and 7°C (12.6°F) for second-trimester fetal bone. Estimated maximum temperature elevations given here are for a “fixed path” tissue model and are for devices having I_{SPTA} values greater than 500 mW/cm². The temperature elevations for fetal bone and tissue were computed based on calculation procedures given in Sections 4.3.2.1–4.3.2.6 in “Bioeffects and Safety of Diagnostic Ultrasound” (AIUM, 1993).

Acoustic output tables

Table 9–38 through **Table 9–80** indicate the acoustic output for the system and transducer combinations with a TI or MI equal to or greater than one. These tables are organized by transducer model and imaging mode. For a definition of terms used in the tables, see “**Terms used in the acoustic output tables**” on page 9–73.

For acoustic output tables for the TEE_{xi} transducer, refer to the *TEE_{xi} Transducer User Guide*, included with the TEE_{xi} transducer.

Table 9-38: Transducer model: C8x Operating mode: 2D

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.1	(a)	—	—	(b)	
Associated acoustic parameter	$P_{r,3}$	(MPa)	2.48		—	—		
	W_0	(mW)		#	—	—	#	
	min of [$W_{.3}(z_1), I_{TA.3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.2			—		
	$d_{eq}(z_{sp})$	(cm)				—		
	f_c	(MHz)	5.53	#	—	—	—	#
	Dim of A_{aprt}	X (cm)		#	—	—	—	#
	Y (cm)		#	—	—	—	#	
Other information	PD	(μ sec)	0.239					
	PRF	(Hz)	9524					
	$p_r@PII_{max}$	(MPa)	3.11					
	$d_{eq}@PII_{max}$	(cm)				—		
	Focal Length	FL_x (cm)		#	—	—		#
		FL_y (cm)		#	—	—		#
	$I_{PA.3}@MI_{max}$	(W/cm ²)	264					
Operating control conditions	Control 1: Exam Type		Pro	—	—	—	—	—
	Control 2: Optimization		Pen	—	—	—	—	—
	Control 3: Depth		2.5 - 3.2	—	—	—	—	—
	Control 4: 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 is 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 is not applicable for this transducer/mode.

Table 9–39: Transducer model: C8x Operating mode: M Mode

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.4	—	(a)	—	(a)	(b)
Associated acoustic parameter	Pr.3	(MPa)	3.16					
	W_0	(mW)		—	#		#	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.1				#	
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	5.07	—	#	—	#	#
	Dim of A_{aprt}	X (cm)		—	#	—	#	#
	Y (cm)		—	#	—	#	#	
Other information	PD	(μ sec)	0.427					
	PRF	(Hz)	800					
	$p_r@PII_{max}$	(MPa)	3.83					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA.3}@MI_{max}$	(W/cm ²)	482					
Operating control conditions	Control 1: Exam Type		Pro	—	—	—	—	—
	Control 2: Optimization		Pen	—	—	—	—	—
	Control 3: Depth		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 is 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 is not applicable for this transducer/mode.

Table 9–40: Transducer model: C8x Operating mode: Color

Index label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.4	(a)	—	—	—	(b)
Associated acoustic parameter	$P_{r,3}$	(MPa)	3.18					
	W_0	(mW)		#	—		—	#
	min of [$W_{.3}(z_1), I_{TA.3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	0.8				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	4.82	#	—	—	—	#
	Dim of A_{aprt}	X (cm)		#	—	—	—	#
	Y (cm)		#	—	—	—	#	
Other information	PD	(μ sec)	0.694					
	PRF	(Hz)	2548					
	$p_r@PII_{max}$	(MPa)	3.63					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL _x (cm)		#	—	—		#
		FL _y (cm)		#	—	—		#
	$I_{PA.3}@MI_{max}$	(W/cm ²)	555					
Operating control conditions	Control 1: Exam Type		Pro	—	—	—	—	—
	Control 2: Mode		CVD	—	—	—	—	—
	Control 3: 2D Optimization/Depth		Pen / 1.5 - 1.9	—	—	—	—	—
	Control 4: Color Optimization/PRF		High / Any	—	—	—	—	—
	Control 5: Color Box Position/Size		Short & 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 is 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 is not applicable for this transducer/mode.

Table 9-41: Transducer model: C8x Operating mode: PW Doppler

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.2	—	(a)	—	2.0	(b)
Associated acoustic parameter	$P_{r,3}$	(MPa)	2.59					
	W_0	(mW)		—	#		36.0	#
	min of [$W_{,3}(z_1), I_{TA,3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.1				1.10	
	$d_{eq}(z_{sp})$	(cm)					0.28	
	f_c	(MHz)	4.79	—	#	—	4.79	#
	Dim of A_{aprt}	X (cm)		—	#	—	1.12	#
	Y (cm)		—	#	—	0.40	#	
Other information	PD	(μ sec)	1.131					
	PRF	(Hz)	1008					
	$p_r@PII_{max}$	(MPa)	3.10					
	$d_{eq}@PII_{max}$	(cm)					0.28	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA,3}@MI_{max}$	(W/cm^2)	296					
Operating control conditions	Control 1: Exam Type		Pro	—	—	—	Pro	—
	Control 2: Sample Volume Size		1 mm	—	—	—	1 mm	—
	Control 3: Sample Volume Position		Zone 5	—	—	—	Zone 5	—
	Control 4: PRF		1008	—	—	—	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 is 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 is not applicable for this transducer/mode.

Table 9-42: Transducer model: C11x Operating mode: CPD/Color

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			(a)	(a)	—	—	1.0	
Associated acoustic parameter	$P_{r,3}$	(MPa)	#		—	—		
	W_0	(mW)		#	—	—	38.8	
	min of [$W_{,3}(z_1), I_{TA,3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	#	#	—	—	—	4.37
	Dim of A_{aprt}	X (cm)		#	—	—	—	1.12
Y (cm)			#	—	—	—	0.50	
Other information	PD	(μ sec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		#	—	—		4.29
		FL_y (cm)		#	—	—		4.40
$I_{PA,3}@MI_{max}$	(W/cm ²)	#						
Operating control conditions	Control 1: Mode						Any	
	Control 2: Exam Type						Abd	
	Control 3: PRF						3676	
	Control 4: Optimization/Depth						Low/ 5.1	
	Control 5: Color Box Position/Size						Top/ 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 9-43: Transducer model: C11x Operating mode: PW Doppler

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			(a)	—	1.0	—	1.7	1.8
Associated acoustic parameter	$P_{r,3}$	(MPa)	#					
	W_0	(mW)		—	46.0		24.9	25.4
	min of [$W_{,3}(z_1), I_{TA,3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				1.06	
	$d_{eq}(z_{sp})$	(cm)					0.24	
	f_c	(MHz)	#	—	4.36	—	4.37	4.36
	Dim of A_{aprt}	X (cm)		—	1.76	—	0.28	0.20
	Y (cm)		—	0.50	—	0.50	0.50	
Other information	PD	(μ sec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.23	
	Focal Length	FL_x (cm)		—	6.37	—		0.77
		FL_y (cm)		—	4.40	—		4.40
	$I_{PA,3}@MI_{max}$	(W/cm ²)	#					
Operating control conditions	Control 1: Exam Type				Any		Any	Any
	Control 2: Sample Volume				2 mm		1 mm	1 mm
	Control 3: PRF				3906		10417	20833
	Control 4: Sample Volume Position				Zone 7		Zone 1	Zone 0

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

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

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

— Data are not applicable for this transducer/mode.

Table 9-44: Transducer model: C60x Operating mode: 2D

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.0	(a)	—	—	(b)	
Associated acoustic parameter	$P_{r,3}$	(MPa)	1.69					
	W_0	(mW)		#	—	—	#	
	min of [$W_{,3}(z_1), I_{TA,3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	4.7				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	2.84	#	—	—	—	#
	Dim of A_{aprt}	X	(cm)		#	—	—	—
Y		(cm)		#	—	—	—	#
Other information	PD	(μ sec)	0.579					
	PRF	(Hz)	5440					
	$p_r@PII_{max}$	(MPa)	2.679					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x	(cm)		#	—	—	#
		FL_y	(cm)		#	—	—	#
$I_{PA,3}@MI_{max}$	(W/cm^2)	197.7						
Operating control conditions	Control 1: Exam Type		Abd/ OB					
	Control 2: Optimization		Any					
	Control 3: Depth		11/ 13 cm					
	Control 4: THI		On					
	Control 5: MB (Multi Beam)		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 9–45: Transducer model: C60x Operating mode: M Mode

Index label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.0	—	(a)	—	(a)	(b)
Associated acoustic parameter	Pr.3	(MPa)	1.62					
	W_0	(mW)		—	#		#	#
	min of [$W_{.3}(z_1), I_{TA.3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	4.7				#	
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	2.85	—	#	—	#	#
	Dim of A_{aprt}	X (cm)		—	#	—	#	#
	Y (cm)		—	#	—	#	#	
Other information	PD	(μ sec)	0.577					
	PRF	(Hz)	800					
	$p_r@PII_{max}$	(MPa)	2.576					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA.3}@MI_{max}$	(W/cm ²)	184.3					
Operating control conditions	Control 1: Exam Type		Any					
	Control 2: Optimization		Pen					
	Control 3: Depth		7.8 cm					
	Control 4: MB (Multi Beam)		Off or 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 9-46: Transducer model: C60x Operating mode: PW Doppler

Index label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			(a)	—	(a)	—	3.1	(b)
Associated acoustic parameter	$P_{r,3}$	(MPa)	#					
	W_0	(mW)		—	#		85.64	#
	min of [$W_{.3}(z_1), I_{TA,3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				1.255	
	$d_{eq}(z_{sp})$	(cm)					0.51	
	f_c	(MHz)	#	—	#	—	2.233	#
	Dim of A_{aprt}	X (cm)		—	#	—	0.6552	#
	Y (cm)		—	#	—	1.3	#	
Other information	PD	(μ sec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.415	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA,3}@MI_{max}$	(W/cm ²)	#					
Operating control conditions	Control 1: Exam Type						Abd	
	Control 2: PRF						Any	
	Control 3: Sample Volume						12 mm	
	Control 4: Sample Volume Position						Zone 1	

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

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

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

— Data are not applicable for this transducer/mode.

Table 9-47: Transducer model: C60xi Operating mode: 2D

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.0	(a)	—	—	(b)	
Associated acoustic parameter	P _{r,3}	(MPa)	1.69					
	W ₀	(mW)		#	—	—	#	
	min of [W _{,3} (z ₁), I _{TA,3} (z ₁)]		(mW)			—		
	z ₁	(cm)				—		
	z _{bp}	(cm)				—		
	z _{sp}	(cm)	4.7				—	
	d _{eq} (z _{sp})	(cm)					—	
	f _c	(MHz)	2.84	#	—	—	—	#
	Dim of A _{aprt}	X	(cm)		#	—	—	—
Y		(cm)		#	—	—	—	#
Other information	PD	(μsec)	0.579					
	PRF	(Hz)	5440					
	p _r @P _{II} _{max}	(MPa)	2.679					
	d _{eq} @P _{II} _{max}	(cm)				—		
	Focal Length	FL _x	(cm)		#	—	—	#
		FL _y	(cm)		#	—	—	#
I _{PA,3} @M _I _{max}	(W/cm ²)	197.7						
Operating control conditions	Control 1: Exam Type		Abd/ OB					
	Control 2: Optimization		Any					
	Control 3: Depth		11/ 13 cm					
	Control 4: THI		On					
	Control 5: MB (Multi Beam)		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 9-48: Transducer model: C60xi Operating mode: M Mode

Index label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.0	(a)	—	—	(a)	(b)
Associated acoustic parameter	$P_{r,3}$	(MPa)	1.62					
	W_0	(mW)		#	—		#	#
	min of [$W_{,3}(z_1), I_{TA,3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	4.7				#	
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	2.85	—	#	—	#	#
	Dim of A_{aprt}	X (cm)		—	#	—	#	#
	Y (cm)		—	#	—	#	#	
Other information	PD	(μ sec)	0.577					
	PRF	(Hz)	800					
	$p_r@PII_{max}$	(MPa)	2.576					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA,3}@MI_{max}$	(W/cm ²)	184.3					
Operating control conditions	Control 1: Exam Type		Any					
	Control 2: Optimization		Pen					
	Control 3: Depth		7.8 cm					
	Control 4: MB (Multi Beam)		Off or 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 9-49: Transducer model: C60xi Operating mode: PW Doppler

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			(a)	—	(a)	—	3.1	(b)
Associated acoustic parameter	$P_{r,3}$	(MPa)	#					
	W_0	(mW)		—	#		85.64	#
	min of [$W_{,3}(z_1), I_{TA,3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				1.255	
	$d_{eq}(z_{sp})$	(cm)					0.51	
	f_c	(MHz)	#	—	#	—	2.233	#
	Dim of A_{aprt}	X (cm)		—	#	—	0.6552	#
Y (cm)			—	#	—	1.3	#	
Other information	PD	(μ sec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.415	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
$I_{PA,3}@MI_{max}$	(W/cm^2)	#						
Operating control conditions	Control 1: Exam Type						Abd	
	Control 2: PRF						Any	
	Control 3: Sample Volume						12 mm	
	Control 4: Sample Volume Position						Zone 1	

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

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

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

— Data are not applicable for this transducer/mode.

Table 9–50: Transducer model: D2x Operating mode: CW Doppler

Index label			M.I.	TIS		TIB	TIC		
				Scan	Non-scan			Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$			
Global maximum index value			(a)	—	(a)	—	2.6	(b)	
Associated acoustic parameter	$P_{r,3}$	(MPa)	#						
	W_0	(mW)		—	#		90.52	#	
	min of [$W_{.3}(z_1), I_{TA,3}(z_1)$]	(mW)				—			
	z_1	(cm)				—			
	z_{bp}	(cm)				—			
	z_{sp}	(cm)	#				1.1		
	$d_{eq}(z_{sp})$	(cm)					0.66		
	f_c	(MHz)	#	—	#	—	2.00	#	
	Dim of A_{aprt}	X (cm)		—	#	—	0.8	#	
Y (cm)			—	#	—	0.4	#		
Other information	PD	(μ sec)	#						
	PRF	(Hz)	#						
	$p_r@PII_{max}$	(MPa)	#						
	$d_{eq}@PII_{max}$	(cm)					0.54		
	Focal Length	FL_x (cm)			—	#	—		#
		FL_y (cm)			—	#	—		#
$I_{PA,3}@MI_{max}$	(W/cm ²)	#							
Operating control conditions	Control 1: Exam Type						Crd		
	Control 2: Depth						Fixed		
	Control 3: Zone						Fixed		

(a) This index is not required for this operating mode; value is <1.
 (b) This transducer is not intended for transcranial or neonatal cephalic uses.
 # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)
 — Data are not applicable for this transducer/mode

Table 9-51: Transducer model: HFL38x/13-6 Operating mode: 2D

Index label			MI	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.1	(a)	—	—	(b)	
Associated acoustic parameter	$P_{r,3}$	(MPa)	2.56		—	—		
	W_0	(mW)		#	—	—	#	
	min of [$W_{.3}(z_1), I_{TA,3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)				—		
	$z@PII_{.3max}$		1.2					
	$d_{eq}(z_{sp})$	(cm)				—		
	f_c	(MHz)	5.33	#	—	—	—	#
Other information	Dim of A_{aprt}			#	—	—	—	#
		X (cm)		#	—	—	—	#
		Y (cm)		#	—	—	—	#
	PD	(μ sec)	0.525					
	PRF	(Hz)	2450					
	$p_r@PII_{max}$	(MPa)	3.19					
Operating control conditions	$d_{eq}@PII_{max}$	(cm)				—		
	Focal Length	FL_x (cm)		#	—	—		#
		FL_y (cm)		#	—	—		#
	$I_{PA,3}@MI_{max}$	(W/cm ²)	325.3					
	Control 1: Exam Type		Nrv/Bre/SmP/Msk		—	—	—	—
	Control 2: Optimization		Any		—	—	—	—
Control 3: Depth		3.3 cm		—	—	—	—	
Control 4: 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.

— Data are not applicable for this transducer/mode.

Table 9-52: Transducer model: HFL38x Operating mode: CPD/Color

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.1	1.0	—	—	(b)	
Associated acoustic parameter	$P_{r,3}$	(MPa)	2.556					
	W_0	(mW)		37.69	—		#	
	min of [$W_{,3}(z_1), I_{TA,3}(z_1)$]		(mW)			—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.2				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	5.328	5.324	—	—	—	#
	Dim of A_{aprt}	X	(cm)		0.44	—	—	—
Y		(cm)		0.4	—	—	—	#
Other information	PD	(μ sec)	0.525					
	PRF	(Hz)	2597					
	$p_r@PII_{max}$	(MPa)	3.187					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x	(cm)		1.32	—	—	#
		FL_y	(cm)		2.5	—	—	#
$I_{PA,3}@MI_{max}$	(W/cm^2)	325.5						
Operating control conditions	Control 1: Mode		Color	Color	—	—	—	—
	Control 2: Exam Type		Any	Ven	—	—	—	—
	Control 3: Optimization/Depth/PRF		Low/3.3 cm/ Any	Med/ 2.7 cm/ 2841	—	—	—	—
	Control 4: Color Box Position/Size		Any	Top/ Short	—	—	—	—

(a) This index is not required for this operating mode; value is <1.
 (b) This transducer is not intended for transcranial or neonatal cephalic uses.
 # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)
 — Data are not applicable for this transducer/mode

Table 9–53: Transducer model: HFL38x Operating mode: PW Doppler

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.0	—	1.1	—	2.0	(b)
Associated acoustic parameter	$P_{r,3}$	(MPa)	2.37					
	W_0	(mW)		—	43.01		43.01	#
	min of [$W_{,3}(z_1), I_{TA,3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	0.9				1.1	
	$d_{eq}(z_{sp})$	(cm)					0.33	
	f_c	(MHz)	5.32	—	5.30	—	5.30	#
Dim of A_{aprt}	X (cm)		—	1.04	—	1.04	#	
	Y (cm)		—	0.4	—	0.4	#	
Other information	PD	(μ sec)	1.29					
	PRF	(Hz)	1008					
	$p_r@PII_{max}$	(MPa)	2.404					
	$d_{eq}@PII_{max}$	(cm)					0.21	
	Focal Length	FL_x (cm)		—	3.72	—		#
		FL_y (cm)		—	2.5	—		#
$I_{PA,3}@MI_{max}$	(W/cm^2)	323.35						
Operating control conditions	Control 1: Exam Type		Bre/Vas SmP/IMT		Any	—	Any	—
	Control 2: Sample Volume		1 mm		1 mm	—	1 mm	—
	Control 3: PRF		1008		6250	—	6250	—
	Control 4: Sample Volume Position		Zone 2		Zone 7	—	Zone 7	—

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

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

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

— Data are not applicable for this transducer/mode

Table 9-54: Transducer model: HFL50x Operating mode: 2D

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.3	(a)	—	—	(b)	
Associated acoustic parameter	$P_{r,3}$	(MPa)	3.051		—	—		
	W_0	(mW)		#	—	—	#	
	min of $[W_{.3}(z_1), I_{TA,3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.2			—		
	$d_{eq}(z_{sp})$	(cm)				—		
	f_c	(MHz)	5.36	#	—	—	—	#
	Dim of A_{aprt}	X (cm)		#	—	—	—	#
	Y (cm)		#	—	—	—	#	
Other information	PD	(μ sec)	0.5.21					
	PRF	(Hz)	2733					
	$p_r@PII_{max}$	(MPa)	3.81					
	$d_{eq}@PII_{max}$	(cm)				—		
	Focal Length	FL_x (cm)		#	—	—		#
		FL_y (cm)		#	—	—		#
	$I_{PA,3}@MI_{max}$	(W/cm ²)	493					
Operating control conditions	Control 1: Exam Type		Any	—	—	—	—	
	Control 2: Optimization		Any	—	—	—	—	
	Control 3: Depth		3.3	—	—	—	—	
	Control 4: MB		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 9–55: Transducer model: HFL50x Operating mode: M Mode

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.2	—	(a)	—	(a)	(b)
Associated acoustic parameter	$P_{r,3}$	(MPa)	3.14					
	W_0	(mW)		—	#		#	#
	min of [$W_{.3}(z_1), I_{TA,3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.4				#	
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	6.75	—	#	—	#	#
	Dim of A_{aprt}	X (cm)		—	#	—	#	#
	Y (cm)		—	#	—	#	#	
Other information	PD	(μ sec)	0.263					
	PRF	(Hz)	1600					
	$p_r@PII_{max}$	(MPa)	4.35					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
Operating control conditions	Control 1: Exam Type		Any					
	Control 2: Optimization		Pen					
	Control 3: Depth		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 9-56: Transducer model: HFL50x Operating mode: CPD/Color

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.3	(a)	—	—	(b)	
Associated acoustic parameter	$P_{r,3}$	(MPa)	3.05					
	W_0	(mW)		#	—	—	#	
	min of [$W_{.3}(z_1), I_{TA,3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.2				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	5.36	#	—	—	—	#
	Dim of A_{aprt}	X (cm)		#	—	—	—	#
	Y (cm)		#	—	—	—	#	
Other information	PD	(μ sec)	0.521					
	PRF	(Hz)	8233					
	$p_r@PII_{max}$	(MPa)	3.81					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		#	—	—		#
		FL_y (cm)		#	—	—		#
Operating control conditions	$I_{PA,3}@MI_{max}$		(W/cm^2)	494				
	Control 1: Mode			Any				
	Control 2: Exam Type			Any				
	Control 3: Optimization/Depth			Low/3.3				
Control 4: PRF			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 9-57: Transducer model: HFL50x Operating mode: PW Doppler

Index label			M.I.	TIS		TIB	TIC		
				Scan	Non-scan			Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$			
Global maximum index value			1.2	—	1.1	—	1.9	(b)	
Associated acoustic parameter	Pr.3	(MPa)	2.69						
	W_0	(mW)		—	42.6		42.6	#	
	min of [$W_{.3}(z_1), I_{TA.3}(z_1)$]		(mW)				—		
	z_1	(cm)					—		
	z_{bp}	(cm)					—		
	z_{sp}	(cm)	1.0					1.1	
	$d_{eq}(z_{sp})$	(cm)						0.33	
	f_c	(MHz)	5.34	—	5.34	—	5.34	#	
	Dim of A_{aprt}	X (cm)		—	1.08	—	1.08	#	
Y (cm)			—	0.40	—	0.40	#		
Other information	PD	(μ sec)	1.29						
	PRF	(Hz)	1008						
	$p_r@PII_{max}$	(MPa)	3.23						
	$d_{eq}@PII_{max}$	(cm)					0.22		
	Focal Length	FL_x (cm)		—	3.72	—		#	
		FL_y (cm)		—	2.44	—		#	
$I_{PA.3}@MI_{max}$	(W/cm ²)	308							
Operating control conditions	Control 1: Exam Type		Any	—	Any	—	Any	—	
	Control 2: Sample Volume		1 mm	—	1 mm	—	1 mm	—	
	Control 3: PRF		1008	—	1563 - 3125	—	1563 - 3125	—	
	Control 4: Sample Volume Position		Zone 4	—	Zone 8	—	Zone 8	—	

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

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

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

— Data are not applicable for this transducer/mode.

Table 9–58: Transducer model: ICTx Operating mode: PW Doppler

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			(a)	—	(a)	—	1.2	(a)
Associated acoustic parameter	$P_{r,3}$	(MPa)	#	—	—	—	—	—
	W_0	(mW)		—	#	—	16.348	#
	min of [$W_{.3}(z_1), I_{TA,3}(z_1)$]	(mW)		—	—	—	—	—
	z_1	(cm)		—	—	—	—	—
	z_{bp}	(cm)		—	—	—	—	—
	z_{sp}	(cm)	#	—	—	—	1.6	—
	$d_{eq}(z_{sp})$	(cm)		—	—	—	0.192	—
	f_c	(MHz)	#	—	#	—	4.36	#
	Dim of A_{aprt}	X (cm)		—	#	—	0.6	#
	Y (cm)		—	#	—	0.5	#	
Other information	PD	(μ sec)	#	—	—	—	—	—
	PRF	(Hz)	#	—	—	—	—	—
	$p_r@PII_{max}$	(MPa)	#	—	—	—	—	—
	$d_{eq}@PII_{max}$	(cm)		—	—	—	0.187	—
	Focal Length	FL_x (cm)		—	#	—	—	#
		FL_y (cm)		—	#	—	—	#
	$I_{PA,3}@MI_{max}$	(W/cm ²)	#	—	—	—	—	—
Operating control conditions	Control 1: Exam Type			—	—	—	Any	—
	Control 2: Sample Volume			—	—	—	3 mm	—
	Control 3: PRF			—	—	—	Any	—
	Control 4: Sample Volume Position			—	—	—	Zone 1	—

(a) This index is not required for this operating mode; value is <1.
 (b) This transducer is not intended for transcranial or neonatal cephalic uses.
 # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)
 — Data are not applicable for this transducer/mode.

Table 9–59: Transducer model: L25x Operating mode: 2D

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.2	(a)	—	—	(b)	
Associated acoustic parameter	Pr.3	(MPa)	2.87		—	—		
	W_0	(mW)		#	—	—	#	
	min of [$W_{.3}(z_1), I_{TA.3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	0.8			—		
	$d_{eq}(z_{sp})$	(cm)				—		
	f_c	(MHz)	6.11	#	—	—	—	#
	Dim of A_{aprt}	X (cm)		#	—	—	—	#
	Y (cm)		#	—	—	—	#	
Other information	PD	(μ sec)	0.630					
	PRF	(Hz)	1061					
	$p_r@PII_{max}$	(MPa)	3.39					
	$d_{eq}@PII_{max}$	(cm)				—		
	Focal Length	FL _x (cm)		#	—	—		#
		FL _y (cm)		#	—	—		#
	$I_{PA.3}@MI_{max}$	(W/cm ²)	478					
Operating control conditions	Control 1: Exam Type		Nrv/Msk/ Ven/Vas	—	—	—	—	—
	Control 2: Optimization		Any	—	—	—	—	—
	Control 3: Depth		1.9 - 2.2	—	—	—	—	—
	Control 4: 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 9–60: Transducer model L25x Operating mode: PW Doppler

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			(a)	—	(a)	—	1.7	(b)
Associated acoustic parameter	$P_{r,3}$	(MPa)	#					
	W_0	(mW)		—	#		32.1	#
	min of [$W_{.3}(z_1), I_{TA.3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				0.75	
	$d_{eq}(z_{sp})$	(cm)					0.30	
	f_c	(MHz)	#	—	#	—	6.00	#
	Dim of A_{aprt}	X (cm)		—	#	—	0.76	#
	Y (cm)		—	#	—	0.30	#	
Other information	PD	(μ sec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.21	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA.3}@MI_{max}$	(W/cm ²)	#					
Operating control conditions	Control 1: Exam Type		—	—	—	—	Vas/Ven/Nrv	—
	Control 2: Sample Volume		—	—	—	—	8 mm	—
	Control 3: PRF		—	—	—	—	1953	—
	Control 4: Sample Volume Position		—	—	—	—	Zone 7	—

(a) This index is not required for this operating mode; value is <1.
 (b) This transducer is not intended for transcranial or neonatal cephalic uses.
 # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)
 —Data are not applicable for this transducer/mode.

Table 9-61: Transducer model: L38x Operating mode: CPD/Color

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.3	1.0	—	—	(b)	
Associated acoustic parameter	P _{r,3}	(MPa)	2.89					
	W ₀	(mW)		64.88	—	—	#	
	min of [W _{,3} (z ₁), I _{TA,3} (z ₁)]		(mW)			—		
	z ₁	(cm)				—		
	z _{bp}	(cm)				—		
	z _{sp}	(cm)	1.1				—	
	d _{eq} (z _{sp})	(cm)					—	
	f _c	(MHz)	4.91	4.91	—	—	—	#
	Dim of A _{aprt}	X	(cm)		0.54	—	—	—
Y		(cm)		0.4	—	—	—	#
Other information	PD	(μsec)	0.529					
	PRF	(Hz)	9547					
	p _r @P _{II} _{max}	(MPa)	3.48					
	d _{eq} @P _{II} _{max}	(cm)					—	
	Focal Length	FL _x	(cm)		1.5	—	—	#
		FL _y	(cm)		2.5	—	—	#
I _{PA,3} @M _I _{max}	(W/cm ²)	439.3						
Operating control conditions	Control 1: Mode		Color	CPD				
	Control 2: Exam Type		Any	Bre				
	Control 3: PRF		331	2137				
	Control 4: Optimization/Depth		Any/3.1	Med/ 3.1				
	Control 5: Color Box Position/Size		Any	Def/ 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 9–62: Transducer model: L38x Operating mode: PW Doppler

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.04	—	2.0	—	2.6	(b)
Associated acoustic parameter	$P_{r,3}$	(MPa)	2.345					
	W_0	(mW)		—	84.94		84.94	#
	min of [$W_{.3}(z_1), I_{TA,3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	0.8				1.3	
	$d_{eq}(z_{sp})$	(cm)					0.4685	
	f_c	(MHz)	5.01	—	5.05	—	5.05	#
	Dim of A_{aprt}	X (cm)		—	1.80	—	1.80	#
Y (cm)			—	0.4	—	0.4	#	
Other information	PD	(μ sec)	1.29					
	PRF	(Hz)	1008					
	$p_r@PII_{max}$	(MPa)	2.693					
	$d_{eq}@PII_{max}$	(cm)					0.2533	
	Focal Length	FL_x (cm)		—	5.54	—		#
		FL_y (cm)		—	2.5	—		#
$I_{PA,3}@MI_{max}$	(W/cm ²)	284.5						
Operating control conditions	Control 1: Exam Type		Any		Vas		Vas	
	Control 2: Sample Volume		1 mm		12 mm		12 mm	
	Control 3: PRF		1008		Any		Any	
	Control 4: Sample Volume Position		Zone 0 (top)		Zone 7		Zone 7	

(a) This index is not required for this operating mode; value is <1.
 (b) This transducer is not intended for transcranial or neonatal cephalic uses.
 # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)
 — Data are not applicable for this transducer/mode.

Table 9–63: Transducer model: L38xi/10–5 Operating mode: 2D

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.5	(a)	—	—	(b)	
Associated acoustic parameter	$P_{r,3}$	(MPa)	3.54					
	W_0	(mW)		#	—	—	#	
	min of [$W_{.3}(z_1), I_{TA,3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.0			—		
	$d_{eq}(z_{sp})$	(cm)				—		
	f_c	(MHz)	5.76	#	—	—	—	#
	Dim of A_{aprt}	X (cm)		#	—	—	—	#
	Y (cm)		#	—	—	—	#	
Other information	PD	(μ sec)	0.146					
	PRF	(Hz)	7551					
	$p_r@PII_{max}$	(MPa)	4.32					
	$d_{eq}@PII_{max}$	(cm)				—		
	Focal Length	FL_x (cm)		#	—	—		#
		FL_y (cm)		#	—	—		#
	$I_{PA,3}@MI_{max}$	(W/cm ²)	776					
Operating control conditions	Control 1: Exam Type		Any	—	—	—	—	—
	Control 2: Optimization		Gen/Pen	—	—	—	—	—
	Control 3: Depth		2.0 cm	—	—	—	—	—
	Control 4: MB		On/Off	—	—	—	—	—

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

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

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

— Data are not applicable for this transducer/mode.

Table 9-64: Transducer model: L38xi/10-5 Operating mode: M Mode

Index label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.5	—	(a)	—	1.2	(b)
Associated acoustic parameter	$P_{r,3}$	(MPa)	3.54					
	W_0	(mW)		—	#		37.1	#
	min of [$W_{.3}(z_1), I_{TA,3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.0				0.9	
	$d_{eq}(z_{sp})$	(cm)					0.49	
	f_c	(MHz)	5.76	—	#	—	5.20	#
	Dim of A_{aprt}	X (cm)		—	#	—	1.86	#
	Y (cm)		—	#	—	0.40	#	
Other information	PD	(μ sec)	0.146					
	PRF	(Hz)	1600					
	$p_r@PII_{max}$	(MPa)	4.32					
	$d_{eq}@PII_{max}$	(cm)					0.49	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA,3}@MI_{max}$	(W/cm ²)	776					
Operating control conditions	Control 1: Exam Type		Any	—	—	—	Any	—
	Control 2: Optimization		Gen	—	—	—	Pen	—
	Control 3: Depth		4.7 cm	—	—	—	7.3–9.0 cm	—

(a) This index is not required for this operating mode; value is <1.
 (b) This transducer is not intended for transcranial or neonatal cephalic uses.
 # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)
 — Data are not applicable for this transducer/mode.

Table 9–65: Transducer model: L38xi/10–5 Operating mode: CPD/Color

Index label			M.I.	TIS			TIB	TIC	
				Scan	Non-scan		Non-scan		
					$A_{aprt} \leq 1$	$A_{aprt} > 1$			
Global maximum index value			1.5	1.1	—	—	—	(b)	
Associated acoustic parameter	Pr.3	(MPa)	3.30						
	W ₀	(mW)		47.5	—		—	#	
	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]		(mW)				—		
	z ₁	(cm)					—		
	z _{bp}	(cm)					—		
	z _{sp}	(cm)	0.8						
	d _{eq} (z _{sp})	(cm)							
	f _c	(MHz)	4.82	4.82	—	—	—	#	
	Dim of A _{aprt}	X (cm)			0.66	—	—	—	#
Y (cm)				0.40	—	—	—	#	
Other information	PD	(μsec)	0.544						
	PRF	(Hz)	2885						
	p _r @PII _{max}	(MPa)	3.79						
	d _{eq} @PII _{max}	(cm)					—		
	Focal Length	FL _x (cm)			1.86	—	—		#
		FL _y (cm)			1.50	—	—		#
I _{PA.3} @MI _{max}	(W/cm ²)	605							
Operating control conditions	Control 1: Mode		CVD/CPD	CVD	—	—	—	—	
	Control 2: Exam Type		Any	Bre	—	—	—	—	
	Control 3: 2D Optimization/Depth		Any/2.0–2.5 cm	Any/3.8 cm	—	—	—	—	
	Control 4: Color Optimization/PRF		Any/Any	Low/1323	—	—	—	—	
	Control 5: Color Box Position/Size		Any/Any	Any/Default	—	—	—	—	

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

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

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

— Data are not applicable for this transducer/mode.

Table 9-66: Transducer model: L38xi/10-5 Operating mode: PW Doppler

Index label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.1	—	2.6	—	3.7	(b)
Associated acoustic parameter	$P_{r,3}$	(MPa)	2.56					
	W_0	(mW)		—	114.5		114.5	#
	min of $[W_{.3}(z_1), I_{TA,3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.19				0.8	
	$d_{eq}(z_{sp})$	(cm)					0.49	
	f_c	(MHz)	4.88	—	4.79	—	4.79	#
	Dim of A_{aprt}	X (cm)		—	1.86	—	1.86	#
Y (cm)			—	0.40	—	0.40	#	
Other information	PD	(μ sec)	1.22					
	PRF	(Hz)	1008					
	$p_r@PII_{max}$	(MPa)	2.97					
	$d_{eq}@PII_{max}$	(cm)					0.45	
	Focal Length	FL_x (cm)		—	5.54	—		#
		FL_y (cm)		—	1.50	—		#
$I_{PA,3}@MI_{max}$	(W/cm^2)	342						
Operating control conditions	Control 1: Exam Type		Bre/Vas	—	Bre/Vas	—	Bre/Vas	—
	Control 2: Sample Volume		1 mm	—	1 mm	—	1 mm	—
	Control 3: PRF		1008	—	10417	—	10417	—
	Control 4: Sample Volume Position		Zone 1	—	Zone 7	—	Zone 7	—

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

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

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

— Data are not applicable for this transducer/mode.

Table 9–67: Transducer model: P10x Operating mode: 2D Mode

Index label			M.I.	TIS			TIB	TIC	
				Scan	Non-scan		Non-scan		
					$A_{aprt} \leq 1$	$A_{aprt} > 1$			
Global maximum index value			(a)	(a)	—	—	—	1.0	
Associated acoustic parameter	$P_{r,3}$	(MPa)	#						
	W_0	(mW)		#	—		—	35.24	
	min of [$W_{.3}(z_1), I_{TA,3}(z_1)$]	(mW)				—			
	z_1	(cm)				—			
	z_{bp}	(cm)				—			
	z_{sp}	(cm)	#				—		
	$d_{eq}(z_{sp})$	(cm)					—		
	f_c	(MHz)	#	#	—	—	—	4.84	
	Dim of A_{aprt}	X (cm)		#	—	—	—	0.416	
	Y (cm)		#	—	—	—	0.7		
Other information	PD	(μ sec)	#						
	PRF	(Hz)	#						
	$p_r@PII_{max}$	(MPa)	#						
	$d_{eq}@PII_{max}$	(cm)					—		
	Focal Length	FL_x (cm)			#	—	—		1.67
		FL_y (cm)			#	—	—		5.0
	$I_{PA,3}@MI_{max}$	(W/cm ²)	#						
Operating control conditions	Control 1: Exam Type							Neo	
	Control 2: Optimization							Gen	
	Control 3: Depth							2.0	
	Control 4: MB/SonoHD							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 9–68: Transducer model: P10x Operating mode: Color

Index label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.0	(a)	—	—	—	1.3
Associated acoustic parameter	Pr.3	(MPa)	2.02					
	W_0	(mW)		#	—		—	41.38
	min of [$W_{.3}(z_1), I_{TA.3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	2.4				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	3.90	#	—	—	—	3.91
	Dim of A_{aprt}	X (cm)		#	—	—	—	0.608
Y (cm)			#	—	—	—	0.7	
Other information	PD	(μ sec)	0.70					
	PRF	(Hz)	2772					
	$p_r@PII_{max}$	(MPa)	2.80					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL _x (cm)		#	—	—		2.48
		FL _y (cm)		#	—	—		5.0
$I_{PA.3}@MI_{max}$	(W/cm ²)	252						
Operating control conditions	Control 1: Mode		Color					Color
	Control 2: Exam Type		Neo					Abd
	Control 3: Optimization/Depth/PRF		Low/ 3.7/ 772					Med/ 2.0/ 2315
	Control 4: Color Box Pos/Size		Any/ Tall					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 9–69: Transducer model: P10x Operating mode: PW Doppler

Index label		M.I.	TIS			TIB	TIC
			Scan	Non-scan		Non-scan	
				$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value		1.0	—	1.2	—	2.0	1.8
Associated acoustic parameter	Pr.3 (MPa)	2.03	—	—	—	—	—
	W_0 (mW)	—	—	36.25	—	34.4	31.5
	min of [$W_{.3}(z_1), I_{TA.3}(z_1)$] (mW)	—	—	—	—	—	—
	z_1 (cm)	—	—	—	—	—	—
	z_{bp} (cm)	—	—	—	—	—	—
	z_{sp} (cm)	2.1	—	—	—	0.8	—
	$d_{eq}(z_{sp})$ (cm)	—	—	—	—	0.32	—
	f_c (MHz)	3.87	—	6.86	—	3.84	3.86
	Dim of A_{aprt}	X (cm)	—	0.992	—	0.416	.224
	Y (cm)	—	0.7	—	0.7	0.7	
Other information	PD (μ sec)	1.28	—	—	—	—	—
	PRF (Hz)	1563	—	—	—	—	—
	$p_r@PII_{max}$ (MPa)	2.70	—	—	—	—	—
	$d_{eq}@PII_{max}$ (cm)	—	—	—	—	0.25	—
	Focal Length	FL_x (cm)	—	6.74	—	—	0.92
		FL_y (cm)	—	5.0	—	—	5.0
	$I_{PA.3}@MI_{max}$ (W/cm^2)	233	—	—	—	—	—
Operating control conditions	Control 1: Exam Type	Crd	—	Crd	—	Neo	Crd
	Control 2: Sample Volume	1 mm	—	7 mm	—	12 mm	1 mm
	Control 3: PRF/TDI	1563/ Off	—	Any/ On	—	15625/ Off	5208/ Off
	Control 4: Sample Volume Position	Zone 3	—	Zone 6	—	Zone 2	Zone 1

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

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

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

— Data are not applicable for this transducer/mode.

Table 9-70: Transducer model: P10x Operating mode: CW Doppler

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			(a)	—	(a)	—	2.1	2.0
Associated acoustic parameter	$P_{r,3}$	(MPa)	#					
	W_0	(mW)		—	#		40.72	30.00
	min of [$W_{.3}(z_1), I_{TA,3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				0.7	
	$d_{eq}(z_{sp})$	(cm)					0.36	
	f_c	(MHz)	#	—	#	—	4.00	4.00
	Dim of A_{aprt}	X (cm)		—	#	—	0.320	0.16
	Y (cm)		—	#	—	0.7	0.7	
Other information	PD	(μ sec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.27	
	Focal Length	FL_x (cm)		—	#	—		0.92
		FL_y (cm)		—	#	—		5.0
	$I_{PA,3}@MI_{max}$	(W/cm ²)	#					
Operating control conditions	Control 1: Exam Type						Card	Card
	Control 2: Depth						Any	Any
	Control 3: Zone						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 9-71: Transducer model: P21x Operating mode: 2D

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.5	(a)	—	—	2.3	
Associated acoustic parameter	Pr.3	(MPa)	2.03					
	W_0	(mW)		#	—	—	171.53	
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$		(mW)			—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	3.4			—		
	$d_{eq}(z_{sp})$	(cm)				—		
	f_c	(MHz)	1.83	#	—	—	—	1.94
	Dim of A_{aprt}	X (cm)		#	—	—	—	1.9
Y (cm)			#	—	—	—	1.3	
Other information	PD	(μ sec)	1.03					
	PRF	(Hz)	4444					
	$p_r@PII_{max}$	(MPa)	2.53					
	$d_{eq}@PII_{max}$	(cm)				—		
	Focal Length	FL_x (cm)		#	—	—		18.46
		FL_y (cm)		#	—	—		9.0
$I_{PA.3}@MI_{max}$	(W/cm^2)	194						
Operating control conditions	Control 1: Exam Type		Card				Card	
	Control 2: Optimization		Gen/ Pen				Pen	
	Control 3: Depth		4.7 cm				27 cm	
	Control 4: THI		On				Off	
	Control 5: Sector Width		Any				Narrow	

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

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

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

— Data are not applicable for this transducer/mode.

Table 9-72: Transducer model: P2 1x Operating mode: M Mode

Index label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.5	—	(a)	—	1.4	1.1
Associated acoustic parameter	$P_{r.3}$	(MPa)	2.10					
	W_0	(mW)		—	#		40.08	29.71
	min of [$W_{.3}(z_1), I_{TA.3}(z_1)$]	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	3.645				4.9	
	$d_{eq}(z_{sp})$	(cm)					0.343	
	f_c	(MHz)	1.93	—	#	—	1.93	1.94
	Dim of A_{aprt}	X (cm)		—	#	—	1.835	1.9
	Y (cm)		—	#	—	1.3	1.3	
Other information	PD	(μ sec)	0.904					
	PRF	(Hz)	800					
	$p_r@PII_{max}$	(MPa)	2.679					
	$d_{eq}@PII_{max}$	(cm)					0.341	
	Focal Length	FL_x (cm)		—	#	—		18.46
		FL_y (cm)		—	#	—		5.5
	$I_{PA.3}@MI_{max}$	(W/cm^2)	237.4					
Operating control conditions	Control 1: Exam Type		Abd/ OB				Abd/OB	Abd/OB /Card
	Control 2: Optimization		Any				Gen/Res	Pen
	Control 3: Depth		7.5 cm				10/13 cm	27 cm
	Control 4: THI		On				On	Off
	Control 5: MB		On				On or Off	On or 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 9-73: Transducer model: P2 1x Operating mode: CPD/Color

Index label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.5	1.3	—	—	—	2.5
Associated acoustic parameter	Pr,3	(MPa)	2.03					
	W ₀	(mW)		136.91	—		—	116.5
	min of [W ₃ (z ₁), I _{TA,3} (z ₁)]	(mW)				—		
	z ₁	(cm)				—		
	z _{bp}	(cm)				—		
	z _{sp}	(cm)	3.4				—	
	d _{eq} (z _{sp})	(cm)					—	
	f _c	(MHz)	1.83	2.16	—	—	—	2.17
Dim of A _{aprt}	X (cm)		0.918	—	—	—	0.46	
	Y (cm)		1.3	—	—	—	1.30	
Other information	PD	(μsec)	1.032					
	PRF	(Hz)	2038					
	p _r @PII _{max}	(MPa)	2.53					
	d _{eq} @PII _{max}	(cm)					—	
	Focal Length	FL _x (cm)		3.68	—	—		1.55
		FL _y (cm)		9.00	—	—		9.00
I _{PA,3} @MI _{max}	(W/cm ²)	194						
Operating control conditions	Control 1: Mode		Color	CPD				Color/CPD
	Control 2: Exam Type		Crđ	OB				TCD
	Control 3: PRF/Depth		Any/4.7	850/7.5				≤2016/4.7
	Control 4: Color Optimization		Any	Med				Low
	Control 5: THI		On	Off				Off
	Control 6: Color Box Size		Any	Short and Narrow				Short and Narrow

(a) This index is not required for this operating mode; value is <1.
 (b) This transducer is not intended for transcranial or neonatal cephalic uses.
 # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)
 — Data are not applicable for this transducer/mode.

Table 9-74: Transducer model: P21x Operating mode: PW Doppler

Index label			M.I.	TIS		TIB	TIC	
				Scan	Non-scan			Non-scan
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			1.2	—	—	1.3	4.0	2.8
Associated acoustic parameter	$P_{r,3}$	(MPa)	1.73					
	W_0	(mW)		—	—		95.55	200.7
	min of $[W_{.3}(z_1), I_{TA,3}(z_1)]$	(mW)				124.4		
	z_1	(cm)				3.1		
	z_{bp}	(cm)				2.8		
	z_{sp}	(cm)	5.0				0.6	
	$d_{eq}(z_{sp})$	(cm)					0.49	
	f_c	(MHz)	2.15	—	—	2.22	2.23	2.12
	Dim of A_{aprt}	X (cm)		—	—	1.97	0.459	1.97
	Y (cm)		—	—	1.3	1.3	1.30	
Other information	PD	(μ sec)	1.182					
	PRF	(Hz)	1562					
	$p_r@PII_{max}$	(MPa)	2.50					
	$d_{eq}@PII_{max}$	(cm)					0.49	
	Focal Length	FL_x (cm)		—	—	13.84		18.46
		FL_y (cm)		—	—	9.0		9.00
	$I_{PA,3}@MI_{max}$	(W/cm ²)	216					
Operating control conditions	Control 1: Exam Type		Card			Card	TCD	Card
	Control 2: Sample Volume		1mm			3mm	14mm	1mm
	Control 3: PRF		1563			3906	12500	3125
	Control 4: Sample Volume Position		Zone 2			Zone 4	Zone 0	Zone 5

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

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

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

— Data are not applicable for this transducer/mode.

Table 9-75: Transducer model: P2 1x Operating mode: CW Doppler

Index label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			(a)	—	—	1.0	3.5	3.0
Associated acoustic parameter	$p_{r,3}$	(MPa)	#					
	W_0	(mW)		—	—		90.1	104.9
	min of [$W_{,3}(z_1), I_{TA,3}(z_1)$]		(mW)				104.9	
	z_1	(cm)				1.20		
	z_{bp}	(cm)				1.31		
	z_{sp}	(cm)	#				1.255	
	$d_{eq}(z_{sp})$	(cm)					0.49	
	f_c	(MHz)	#	—	—	2.00	2.00	2.00
	Dim of A_{aprt}	X (cm)		—	—	0.46	0.655	0.459
Y (cm)			—	—	1.30	1.30	1.30	
Other information	PD	(μ sec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.45	
	Focal Length	FL_x (cm)		—	—	1.55		1.55
		FL_y (cm)		—	—	9.00		9.00
$I_{PA,3}@MI_{max}$	(W/cm^2)	#						
Operating control conditions	Control 1: Exam Type					Card	Card	Card
	Control 2: Zone					Zone 0	Zone 1	Zone 0

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

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

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

— Data are not applicable for this transducer/mode.

Table 9-76: Transducer Model: SLAx Operating Mode: PW Doppler

Index Label			M.I.	TIS		TIB	TIC		
				Scan	Non-scan			Non-scan	
					A _{aprt} ≤1	A _{aprt} >1			
Global Maximum Index Value			(a)	—	(a)	—	1.3	(b)	
Associated acoustic parameter	Pr.3	(MPa)	#	—	—	—	—	—	
	W ₀	(mW)	—	—	#	—	11.3	#	
	min of [W ₃ (z ₁), I _{TA,3} (z ₁)]		(mW)	—	—	—	—	—	—
	z ₁	(cm)	—	—	—	—	—	—	
	z _{bp}	(cm)	—	—	—	—	—	—	
	z _{sp}	(cm)	#	—	—	—	0.72	—	
	d _{eq} (z _{sp})	(cm)	—	—	—	—	0.15	—	
	f _c	(MHz)	#	—	#	—	6.00	#	
	Dim of A _{aprt}	X (cm)	—	—	#	—	0.32	#	
Y (cm)		—	—	#	—	0.30	#		
Other information	PD	(μsec)	#	—	—	—	—	—	
	PRF	(Hz)	#	—	—	—	—	—	
	p _r @PII _{max}	(MPa)	#	—	—	—	—	—	
	d _{eq} @PII _{max}	(cm)	—	—	—	—	0.14	—	
	Focal Length	FL _x (cm)	—	—	#	—	—	#	
		FL _y (cm)	—	—	#	—	—	#	
I _{PA,3} @MI _{max}	(W/cm ²)	#	—	—	—	—	—		
Operating control conditions	Control 1: Exam Type		—	—	—	—	Vas, Nrv, Ven	—	
	Control 2: Sample Volume		—	—	—	—	6 mm	—	
	Control 3: PRF		—	—	—	—	20833	—	
	Control 4: Sample Vol. Position		—	—	—	—	Zone 2	—	

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

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

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

- Data are not applicable for this transducer/mode.

Table 9-77: Transducer model: TEE_x Operating mode: PW Doppler

Index Label			M.I.	TIS			TIB	TIC	
				Scan	Non-scan		Non-scan		
					A _{aprt} ≤1	A _{aprt} >1			
Global Maximum Index Value			(a)	—	(a)	—	1.7	(b)	
Associated acoustic parameter	Pr.3	(MPa)	#	—	—	—	—	—	
	W ₀	(mW)	—	—	#	—	29.29	#	
	min of [W _{.3} (z ₁), I _{TA.3} (z ₁)]		(mW)	—	—	—	—	—	—
	z ₁	(cm)	—	—	—	—	—	—	
	z _{bp}	(cm)	—	—	—	—	—	—	
	z _{sp}	(cm)	#	—	—	—	0.6	—	
	d _{eq} (z _{sp})	(cm)	—	—	—	—	0.34	—	
	f _c	(MHz)	#	—	#	—	3.84	#	
	Dim of A _{aprt}	X (cm)	—	—	#	—	0.261	#	
Y (cm)		—	—	#	—	0.9	#		
Other information	PD	(μsec)	#	—	—	—	—	—	
	PRF	(Hz)	#	—	—	—	—	—	
	p _r @PII _{max}	(MPa)	#	—	—	—	—	—	
	d _{eq} @PII _{max}	(cm)	—	—	—	—	0.34	—	
	Focal Length	FL _x (cm)	—	—	#	—	—	—	#
		FL _y (cm)	—	—	#	—	—	—	#
I _{PA.3} @MI _{max}	(W/cm ²)	#	—	—	—	—	—	—	
Operating control conditions	Control 1: Exam Type		—	—	—	—	Crd	—	
	Control 2: Sample Volume		—	—	—	—	1 mm	—	
	Control 3: PRF		—	—	—	—	≥ 2604	—	
	Control 4: Sample Volume Position		—	—	—	—	Zone 1	—	

(a) This index is not required for this operating mode; value is <1.
 (b) This transducer is not intended for transcranial or neonatal cephalic uses.
 # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)
 - Data are not applicable for this transducer/mode.

Table 9-78: Transducer model: TEE_x Operating mode: CW Doppler

Index label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			(a)	—	(a)	—	1.2	(b)
Associated acoustic parameter	$P_{r,3}$	(MPa)	#					
	W_0	(mW)		—	#		27.23	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				1.1	
	$d_{eq}(z_{sp})$	(cm)					0.39	
	f_c	(MHz)	#	—	#	—	4.00	#
	Dim of A_{aprt}	X (cm)		—	#	—	0.435	#
		Y (cm)		—	#	—	0.9	#
PD	(μ sec)	#						
Other information	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.34	
	Focal Length	FL _x (cm)		—	#	—		#
		FL _y (cm)		—	#	—		#
$I_{PA.3}@MI_{max}$	(W/cm ²)	#						
Operating control conditions	Control 1: Exam type						Crd	
	Control 2: Depth						Any	
	Control 3: Zone						Zone 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 9-79: Transducer model: TEExi Operating mode: PW Doppler

Index label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global maximum index value			(a)	-	(a)	-	1.4	(b)
Associated acoustic parameter	$P_{r,3}$	(MPa)	#					
	W_0	(mW)		-	#		35.8	#
	min of $W_{.3}(z_1), I_{TA,3}(z_1)$	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)					2.57	
	$z@PII_{.3max}$	(cm)	#					
	$d_{eq}(z_{sp})$	(cm)					0.29	
	f_c	(MHz)	#	-	#	-	3.81	#
	Dim of A_{aprt}	X (cm)		-	#	-	0.90	#
	Y (cm)		-	#	-	0.90	#	
Other information	PD	(μ sec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.28	
	Focal Length	FL_x (cm)		-	#	-		#
		FL_y (cm)		-	#	-		#
	$I_{PA,3}@MI_{max}$	(W/cm ²)	#					
Operating control conditions	Control 1: Exam type						Card	
	Control 2: Sample volume size						1mm	
	Control 3: Sample volume position						Zone 3	
	Control 4: PRF						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 9-80: Transducer model: TEExi Operating mode: CW Doppler

Index label		M.I.	TIS			TIB	TIC	
			Scan	Non-scan		Non-scan		
				$A_{\text{aprt}} \leq 1$	$A_{\text{aprt}} > 1$			
Global maximum index value		(a)	-	(a)	-	1.7	(b)	
Associated acoustic parameter	$P_{r,3}$ (MPa)	#						
	W_0 (mW)		-	#		34.4	#	
	min of $W_{.3}(z_1), I_{TA.3}(z_1)$ (mW)				-			
	z_1 (cm)				-			
	z_{bp} (cm)				-			
	z_{sp} (cm)					1.1		
	$z@PII_{.3\text{max}}$ (cm)	#						
	$d_{\text{eq}}(z_{\text{sp}})$ (cm)					0.34		
	f_c (MHz)	#	-	#	-	4.00	#	
	Dim of A_{aprt}	X (cm)		-	#	-	0.43	#
		Y (cm)		-	#	-	0.90	#
Other information	PD (μsec)	#						
	PRF (Hz)	#						
	$p_r@PII_{\text{max}}$ (MPa)	#						
	$d_{\text{eq}}@PII_{\text{max}}$ (cm)					0.34		
	Focal Length	FL_x (cm)		-	#	-		#
		FL_y (cm)		-	#	-		#
$I_{PA.3}@MI_{\text{max}}$ (W/cm^2)	#							
Operating control conditions	Control 1: Exam type					Card		
	Control 2: Sample volume					Zone 2		
	Control 3:							
	Control 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.

Terms used in the acoustic output tables

Table 9–81: Acoustic output terms and definitions

Term	Definition
$I_{\text{SPTA},3}$	Derated spatial peak, temporal average intensity in units of milliwatts/cm ² .
TI type	Applicable thermal index for the transducer, imaging mode, and exam type.
TI value	Thermal index value for the transducer, imaging mode, and exam type.
MI	Mechanical index.
$I_{\text{pa},3}@\text{MI}_{\text{max}}$	Derated pulse average intensity at the maximum MI in units of W/cm ² .
TIS	(Soft tissue thermal index) is a thermal index related to soft tissues. TIS scan is the soft tissue thermal index in an auto-scanning mode. TIS non-scan is the soft tissue thermal index in the non-autoscanning mode.
TIB	(Bone thermal index) is a thermal index for applications in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone. TIB non-scan is the bone thermal index in the non-autoscanning mode.
TIC	(Cranial bone thermal index) is the thermal index for applications in which the ultrasound beam passes through bone near the beam entrance into the body.
A_{aprt}	Area of the active aperture measured in cm ² .
$P_{r,3}$	Derated peak rarefactional pressure associated with the transmit pattern giving rise to the value reported under MI (Megapascals).
Wo	Ultrasonic power, except for TIS_{scan} , in which case it is the ultrasonic power passing through a one centimeter window in units of milliwatts.
$W_{.3}(z_1)$	Derated ultrasonic power at axial distance z_1 in units of milliwatts.
$I_{\text{SPTA},3}(z_1)$	Derated spatial-peak temporal-average intensity at axial distance z_1 (milliwatts per square centimeter).
z_1	Axial distance corresponding to the location of maximum $[\min(W_{.3}(z), I_{\text{TA},3}(z) \times 1 \text{ cm}^2)]$, where $z \geq z_{\text{bp}}$ in centimeters.
z_{bp}	$1.69 \sqrt{(A_{\text{aprt}})}$ in centimeters.
z_{sp}	For MI, the axial distance at which $p_{r,3}$ is measured. For TIB, the axial distance at which TIB is a global maximum (for example, $z_{\text{sp}} = z_{\text{b},3}$) in centimeters.
$d_{\text{eq}}(z)$	Equivalent beam diameter as a function of axial distance z , and is equal to $\sqrt{(4/(\pi))((Wo)/(I_{\text{TA}}(z)))}$, where $I_{\text{TA}}(z)$ is the temporal-average intensity as a function of z in centimeters.
fc	Center frequency in MHz.
Dim. of A_{aprt}	Active aperture dimensions for the azimuthal (x) and elevational (y) planes in centimeters.
PD	Pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of MI.

Table 9-81: Acoustic output terms and definitions (continued)

Term	Definition
PRF	Pulse repetition frequency associated with the transmit pattern giving rise to the reported value of MI in Hertz.
$p_r@PII_{max}$	Peak rarefactional pressure at the point where the free-field, spatial-peak pulse intensity integral is a maximum in Megapascals.
$d_{eq}@PII_{max}$	Equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum in centimeters.
FL	Focal length, or azimuthal (x) and elevational (y) lengths, if different measured in centimeters.

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 9-82: Acoustic measurement precision and uncertainty

Quantity	Precision (% of standard deviation)	Uncertainty (95% confidence)
Pr	1.9%	$\pm 11.2\%$
Pr_3	1.9%	$\pm 12.2\%$
Wo	3.4%	$\pm 10\%$
fc	0.1%	$\pm 4.7\%$
PII	3.2%	+12.5 to -16.8%
PII_3	3.2%	+13.47 to -17.5%

Labeling symbols

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

Table 9-83: 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, as EU directives 90/385/EEC, 93/42/EEC and 98/79/EC
	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 9-83: Standards labeling symbols (continued)







Symbol	Title	Standards development organization	Reference number	Description
	Caution	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.4.4	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions, that cannot for a variety of reasons, be presented on the medical device itself
	Fragile handle with care	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.3.1	Indicates a medical device that can be broken or damaged if not handled carefully
	Keep dry	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.3.4	.Indicates a medical device that needs to be protected from moisture
	Temperature limit	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.3.7	Indicates the temperature limits to which the medical device can be safely exposed
	Atmospheric pressure limitations	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	5.3.9	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
	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 9-83: Standards labeling symbols (continued)







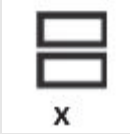
Symbol	Title	Standards development organization	Reference number	Description
	Degree of ingress protection provided by enclosure	IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	D.3	Protected against the effects of temporary immersion
	Refer 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 (used in accordance with IEC 60601-1)
	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 the need for the user to consult the instructions for use
	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
	Equipment mass	IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	7.2.21	Total equipment mass including its safe working load
	Dangerous voltage	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	5036	Indicates hazards arising from dangerous voltage
	Stacking limit by number	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	2403	Indicates that the items are not to be vertically stacked higher than the specified number of items

Table 9-83: Standards labeling symbols (continued)






Symbol	Title	Standards development organization	Reference number	Description
	Caution hot	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	5041	Indicates that the marked item can be hot and should not be touched without taking care
	Caution, static magnetic field hazard	ISO 7000 / IEC 60417 Graphical symbols for use on equipment	6204	Identifies areas with potentially hazardous static magnetic fields and forces in an installation
	Type BF applied parts	IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	D.2-10	Identifies type BF applied part complying with IEC 60601-1
	Defibrillation-proof type CF applied part	IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	D.1-27	Identifies a defibrillation-proof type CF applied part complying with IEC 60601-1
	Electrostatic sensitive device	IEC 60417:2002 Graphical Symbols For Use On Equipment	5134	Indicates packages containing electrostatic sensitive devices, or identifies a device or a connector that has not been tested for immunity to electrostatic discharge

Table 9-84: FDA Recognition numbers for Table 9-83

FDA recognition number	Standards development organization (SDO)
5-118	ISO 15223-1:2016 Medical devices – symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements
5-103	ISO 7000:2014 Graphical symbols used on equipment
19-4	AAMI/ANSI ES60601-1:2005 Medical electrical equip. – Part 1: General requirements for basic safety and essential performance
19-2	AAMI/ANSI/IEC 60601-1-2:2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance

Table 9-85: Other Symbols


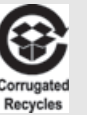









Symbol	Title	Standards development organization	Reference number	Description
	CSA mark	—	—	Indicates CSA mark for Canadian Standards Association. The “C” and “US” indicators next to this mark signify that the product has been evaluated to the applicable CSA and ANSI/UL standards, for use in Canada and the U.S., respectively
	Corrugated recycle	—	—	Indicates shipping box is made of corrugated cardboard and should be recycled accordingly
	—	—	—	FCC-Tested to Federal Communications Commission requirements Device complies with relevant FCC regulations for electronic devices
	RESY – recycling symbol	—	—	Indicates paper recycle

Table 9-85: Other Symbols

	CE Marking	Council Directive 93/42/EEC	Article 17 Annex XII	Indicates European technical conformity and identification of notified body responsible for implementation of the procedures set out in Annexes II, IV, V, and VI.
	Regulatory Compliance Mark (RCM)	AS/NZS3820	—	C-Tick—Regulatory Compliance Mark for Australia and New Zealand device complies with relevant Australian and New Zealand regulations for electronic devices.
	Recycle: Electronic Equipment	BS EN 50419:2016 Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	—	Indicates do not throw in trash
	INMETRO safety symbols	—	—	Indicates Brazil - accredited certification body by the National Institute of Metrology Standardization and Industrial Quality (INMETRO)
				Handle with care
				Follow manufacturer's instructions for disinfecting time
				Indicates disinfect transducer

CHAPTER 10

Specifications

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

Dimensions

System

Length: 11.8 in. (29.97 cm)

Width: 10.8 in. (27.43 cm)

Height: 3.1 in. (7.87 cm)

Weight: 8.5 lbs. (3.9 kg) with the C60xi transducer and battery installed

Display

Length: 8.4 in. (21.34 cm)

Height: 6.3 in. (16 cm)

Diagonal: 10.4 in. (26.4 cm)

Supported transducers

- ▶ C8x/8-5 MHz (6 ft/1.8 m)
- ▶ C11x/8-5 MHz (6 ft/1.8 m)
- ▶ C60x/5-2 MHz (5.5 ft/1.7 m)
- ▶ C60xi/5-2 MHz (5.5 ft/1.7 m)
- ▶ D2x/2 MHz (5.5 ft/1.7 m)
- ▶ HFL38x/13-6 MHz (5.5 ft/1.7 m)
- ▶ HFL50x/15-6 MHz (5.5 ft/1.7 m)
- ▶ ICTx/8-5 MHz (5.7 ft/1.7 m)
- ▶ L25x/13-6 MHz (7.5 ft/2.3 m)

- ▶ L38x/10-5 MHz (5.5 ft/1.7 m)
- ▶ L38xi/10-5 MHz (5.5 ft/1.7 m)
- ▶ P10x/8-4 MHz (6 ft/1.8 m)
- ▶ P21x/5-1 MHz(6 ft/1.8 m)
- ▶ SLAx/13-6 MHz (7.5 ft/2.3 m)
- ▶ TEEEx/8-3 MHz (11.8 ft./3.6 m)
- ▶ TEEExi/8-3 MHz (11.8 ft./3.6 m)

Imaging modes

- ▶ 2D (256 gray shades)
- ▶ Color Power Doppler (CPD) (256 colors)
- ▶ Color Doppler (Color) (256 colors)
- ▶ M Mode
- ▶ Pulsed Wave (PW) Doppler
- ▶ Continuous Wave (CW) Doppler
- ▶ Tissue Doppler Imaging (TDI)
- ▶ Tissue Harmonic Imaging (THI)

Image and clip 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
- ▶ Carry case
- ▶ ECG cable (6 ft/1.8 m)
- ▶ Education keys
- ▶ Footswitch
- ▶ Mini-Dock
- ▶ Mobile docking system
- ▶ Power supply
- ▶ System AC power cord (10 ft/3.1 m)
- ▶ Triple Transducer Connect

Peripherals

See the manufacturer's specifications for the following peripherals.

Medical grade

- ▶ Bar code scanner, USB
- ▶ Black-and-white printer

Recommended sources for printer paper: Contact Sony at 800-686-7669 or www.sony.com/professional to order supplies or to find the local distributor.

- ▶ Color printer

Non-medical grade

- ▶ Kensington security cable
- ▶ USB storage device temperature and humidity 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)

Battery

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

500 to 1060hPa (0.5 to 1.05 ATM)

Electrical

Power Supply Input: 100–240 VAC, 50/60 Hz, 2.0 A Max @ 100 VAC

Power Supply Output #1: 15 VDC, 5.0 A Max

Power Supply Output #2: 12 VDC, 2.3 A Max

Combined output not exceeding 75 watts.

Battery

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

Standards

Electromechanical safety standards

Standard	Description
ANSI/AAMI ES60601-1:2005/(R) 2012, and A1:2012	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance (Consolidated Edition 3.1)
CAN/CSA C22.2 No. 60601-1:2014 (Edition 3.1)	Medical electrical equipment–Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1:2012 (Edition 3.1)	Medical electrical equipment–Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-2-37:2007	Medical Electrical Equipment–Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 60601-1-6:2013	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

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.

Acoustic standards

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

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

Biocompatibility standards

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

Airborne equipment standards

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

DICOM standard

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

The system conforms to the DICOM standard as specified in the SonoSite Edge II DICOM Conformance Statement, available at www.sonosite.com. This statement provides information about the purpose, characteristics, configuration, and specifications of the network connections supported by the system.

HIPAA

The system includes security settings that help you to meet the applicable security requirements listed in the HIPAA regulation listed below. 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), section 45 CFR 164.312, Security and Privacy.

IT Network

Functions

This device can be connected to an IT network to perform the following functions:

- ▶ Storing the examination data (static images, clips) acquired by this device in a Picture Archiving and Communication System (PACS) by DICOM communication.
- ▶ Querying examination orders from the Modality Worklist (MWL) server by DICOM communication and starting them.
- ▶ Uploading images to the FUJIFILM SonoSite Patient Data Archival Software (PDAS) or SiteLink Image Manager.
- ▶ Setting the time of this device by interrogating the network time service.
- ▶ Communicating procedure status via the Modality Performed Procedure Step (MPPS) service.
- ▶ Requesting transfer of responsibility for image ownership to another system via the Storage Commitment service.

Network for connecting the device

To ensure safety, use an IT network that is isolated from the external environment by a firewall.

Specifications for the connection

Hardware specification

- ▶ 802.11 b/g/n
- ▶ Ethernet 100BASE-TX/10BASE-T using RJ45 port with patch cable

Software specifications

- ▶ This device is connected to PACS and MWL by the DICOM standard. Refer to the DICOM Conformance Statement of this device for details.
- ▶ When available, this device connects to the network time server at startup.

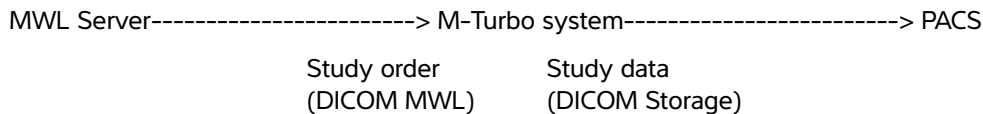
The system conforms to the DICOM standard as specified in the *SonoSite M-Turbo and S Series DICOM Conformance Statement*, available at www.sonosite.com. This statement provides information about the purpose, characteristics, configuration, and specifications of the network connections supported by the system.

Security

- ▶ The port for DICOM communication (specified by the user in the system settings; typically port 104, 2762, or 11112) is used for outgoing communication to the network.
- ▶ Antivirus software is not installed on this device.
- ▶ This device has a single configurable listening port for the purposes of DICOM Echo and Storage Commitment.

Data flow

DICOM



Please refer to the *Turbo DICOM Conformance Statement (D05690)* for details.

Caution

- 1 Connection of equipment to an IT network that includes other systems, could result in previously unidentified risks to patients, operators or third parties. Before connecting the equipment to an uncontrolled IT Network, make sure that all potential risks resulting from such connections, were identified and evaluated, and suitable countermeasures were put in place. IEC 80001-1:2010 provides guidance for addressing these risks.
- 2 When a setting of the IT network to which this device is connected has been changed, check that the change does not affect this device and take measures if necessary. Changes to the IT network include:
 - ▶ Changes in network configuration (IP address, router etc.)
 - ▶ Connection of additional items
 - ▶ Disconnection of items
 - ▶ Update of equipment
 - ▶ Upgrade of equipment

Any changes to the IT network could introduce new risks requiring additional evaluation to be performed as per item 1 above.

Glossary

Terms

For ultrasound terms not included in this glossary, refer to *Recommended Ultrasound Terminology, 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, C15, C60e.
depth	Refers to the depth of the display. A constant speed of sound of 1538.5 meters/second is assumed in the calculation of echo position in the image.
in situ	In the natural or original position.
LCD	liquid crystal display
linear array transducer	Identified by the letter L (linear) and a number (38). The number corresponds to the radius of width of the array expressed in millimeters. The transducer elements are electrically configured to control the characteristics and direction of the acoustic beam. For example, L38.
mechanical index (MI)	An indication of the likelihood of mechanical bioeffects occurring: the higher the MI, the greater the likelihood of mechanical bioeffects. See Chapter 9, "Safety," for a more complete description of MI.
MI/TI	See <i>mechanical index (MI)</i> and <i>thermal index (TI)</i> .
NTSC	National Television Standards Committee. A video format setting. See also <i>PAL</i> .
PAL	Phase Alternating Line. A video format setting. See also <i>NTSC</i> .
phased array	A transducer designed primarily for cardiac scanning. Forms a sector image by electronically steering the beam direction and focus.
skinline	A depth on the display that corresponds to the skin/transducer interface.

SonoHD™ 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.
SonoMBe 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 (TDI)	A pulsed wave Doppler technique used to detect myocardial motion.
thermal index (TI)	The ratio of total acoustic power to the acoustic power required to raise tissue temperature by 1°C under defined assumptions. See Chapter 9, “Safety,” 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-86: Abbreviations in user interface

Abbreviation	Definition
+/x	“+” Caliper/“x” Caliper Ratio
A	“A” Wave Peak Velocity
A PG	“A” Wave Peak Pressure Gradient
A2Cd	Apical 2 Chamber diastolic
A2Cs	Apical 2 Chamber systolic
A4Cd	Apical 4 Chamber diastolic
A4Cs	Apical 4 Chamber systolic
AAA	Abdominal Aortic Aneurysm
AAo	Ascending Aorta
Abd	Abdomen
abs	Absolute value
AC	Abdominal Circumference
ACA	Anterior Cerebral Artery
ACC	Acceleration Index
ACoA	Anterior Communicating Artery
ACS	Aortic Valve Cusp Separation
Adur	“A” wave duration
AFI	Amniotic Fluid Index
AI	Aortic Insufficiency
AI PHT	Aortic Insufficiency Pressure Half Time
AL	Atlas Loop
Ann D	Annulus Diameter
ANT F	Anterior Far
ANT N	Anterior Near

Table A-86: Abbreviations in user interface (continued)

Abbreviation	Definition
Ao	Aorta
AoD	Aortic Root Diameter
Apical	Apical View
APTD	Anteroposterior Trunk Diameter
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
CPD	Color Power Doppler
Crd	Cardiac
CRL	Crown Rump Length

Table A-86: Abbreviations in user interface (continued)

Abbreviation	Definition
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
ECG	Electrocardiogram
ECICA	Extracranial Internal Carotid Artery
ECVA	Extracranial Vertebral Artery
EDD	Estimated Date of Delivery
EDD by AUA	Estimated Date of Delivery by Average Ultrasound Age The estimated date of delivery calculated from the measurements performed during the exam.
EDD by LMP	Estimated Date of Delivery by Last Menstrual Period The due date calculated from the user-entered LMP.
EDV	End Diastolic Velocity
EF	Ejection Fraction
EF:SLOPE	E-F Slope

Table A-86: 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
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
FH	Femoral Head
FHR	Fetal Heart Rate
FL	Femur Length
FM (Right and Left)	Foramen Magnum (same as SO)
FTA	Fetal Trunk Area
GA	Gestational Age
GA by LMP	Gestational Age by Last Menstrual Period The fetal age calculated using the date of the Last Menstrual Period (LMP).
GA by LMPd	Gestational Age by derived Last Menstrual Period The fetal age calculated using the Last Menstrual Period (LMPd) derived from the Estab. DD.
Gate	Depth of Doppler Gate
GS	Gestational Sac
Gyn	Gynecology
HC	Head Circumference
HL	Humerus Length

Table A-86: Abbreviations in user interface (continued)

Abbreviation	Definition
HR	Heart Rate
ICA	Internal Carotid Artery
IMT	Intima Media Thickness
IVRT	Iso Volumic Relaxation Time
IVS	Interventricular Septum
IVSd	Interventricular Septum Diastolic
IVSFT	Interventricular Septum Fractional Thickening
IVSs	Interventricular Septum Systolic
LA	Left Atrium
LA/Ao	Left Atrium/Aorta Ratio
LAT F	Lateral Far
LAT N	Lateral Near
Lat V	Lateral Ventricle
LMP	Last Menstrual Period
LMP	Last Menstrual Period The first day of the last menstrual period. Used to calculate gestational age and EDD.
LMPd	derived Last Menstrual Period Calculated from the user-entered Estab. DD.
LV	Left Ventricular
LV Area	Left Ventricular Area
LV mass	Left Ventricular mass
LV Volume	Left Ventricular Volume
LVd	Left Ventricular diastolic
LVD	Left Ventricular Dimension
LVDd	Left Ventricular Dimension Diastolic
LVDFS	Left Ventricular Dimension Fractional Shortening

Table A-86: Abbreviations in user interface (continued)

Abbreviation	Definition
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
LVPWs	Left Ventricular Posterior Wall Systolic
LVs	Left Ventricular systolic
MBe	SonoMBe technology
MBe	MultiBeam enhancement
MCA	Middle Cerebral Artery
MCCA	Mid Common Carotid Artery
MECA	Mid External Carotid Artery
MI	Mechanical Index
MICA	Mid Internal Carotid Artery
Mid	Middle
MM	M Mode
MR PISA	Mitral Regurgitation Proximal Iso Velocity Surface Area
MR/VTI	Mitral Regurgitation/Velocity Time Integral

Table A-86: Abbreviations in user interface (continued)

Abbreviation	Definition
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
NST	Non-stress test
NTSC	National Television Standards Committee
OA	Ophthalmic Artery
OB	Obstetrical
OFD	Occipital Frontal Diameter
Oph	Ophthalmic
Orb	Orbital
PAL	Phase Alternating Line
PCAp	Posterior Cerebral Artery Peak
PCCA	Proximal Common Carotid Artery
PCoA	Posterior Communicating Artery
PECA	Proximal External Carotid Artery
PGmax	Maximum Pressure Gradient

Table A-86: Abbreviations in user interface (continued)

Abbreviation	Definition
PGmean	Mean Pressure Gradient
PGr	Pressure Gradient
PHT	Pressure Half Time
PI	Pulsatility Index
PICA	Proximal Internal Carotid Artery
PISA	Proximal Isovelocity Surface Area
Plaq	Plaque
POST F	Posterior Far
POST N	Posterior Near
PRF	Pulse Repetition Frequency
Prox	Proximal
PSV	Peak Systolic Velocity
PV	Pulmonic Valve
P. Vein	Pulmonary Vein
PW	Pulsed Wave Doppler
Qp/Qs	Pulmonary blood flow divided by systemic blood flow
RA	Right Atrial (pressure)
RI	Resistive Index
RVD	Right Ventricular Dimension
RVDd	Right Ventricular Dimension Diastolic
RVDs	Right Ventricular Dimension Systolic
RVOT D	Right Ventricular Outflow Tract Diameter
RVOT VTI	Right Ventricular Outflow Tract Velocity Time Integral
RVSP	Right Ventricular Systolic Pressure
RVW	Right Ventricular Free Wall

Table A-86: Abbreviations in user interface (continued)

Abbreviation	Definition
RVWd	Right Ventricular Free Wall Diastolic
RVWs	Right Ventricular Free Wall Systolic
S	SonoHD technology
S/D	Systolic/Diastolic Ratio
SI	Stroke Index
Siphon	Siphon (internal carotid artery)
SM	Submandibular
SmP	Small Parts
SO	Suboccipital
Sup	Superficial
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
TICA	Terminal Internal Carotid Artery
TO	Transorbital
TRmax	Tricuspid Regurgitation (peak velocity)
TT	Transtemporal
TTD	Transverse Trunk Diameter
TV	Tricuspid Valve
TVA	Tricuspid Valve Area

Table A-86: Abbreviations in user interface (continued)

Abbreviation	Definition
UA	Ultrasound Age Calculated on the mean measurements taken for a particular fetal biometry.
Umb A	Umbilical Artery
VA	Vertebral Artery
VArty	Vertebral Artery
Vas	Vascular
Ven	Venous
VF	Volume Flow
Vmax	Peak Velocity
Vmean	Mean Velocity
Vol	Volume
VTI	Velocity Time Integral
YS	Yolk Sac

Index

- +/x measurement **5-6**
- 2D imaging **4-1**
- 2D options **4-2**
- A & B shortcut keys **3-1**
- abbreviations **A-3**
- abdominal, intended uses **2-18**
- AC
 - cord **2-5**
 - power **2-5**
- AC power indicator **2-10**
- acceleration (ACC) index **5-6**
- accessories
 - compatible **9-14**
- accessories list **10-2**
- acoustic measurement precision **9-74**
- acoustic output
 - measurement **9-27**
 - tables **9-29, 9-73**
- acquisition error **6-3**
- add new user **3-3**
- Administrator **3-2**
- age, gestational **5-37**
- airborne equipment standards **10-5**
- ALARA principle **9-19-9-20, A-1**
- alphanumeric keys **2-9**
- angle correction **4-8-4-9**
- annotations
 - keys **2-9**
 - place **4-17**
 - predefine label groups **3-7**
 - setup **3-6**
- aorta (Ao) **5-22**
- aortic valve area (AVA) **5-26**
- archivers **3-8**
- arrow graphic **4-18**
- ascending aorta (AAo) **5-22**
- audio **3-8**
- bar code scanner **3-9**
- baseline **4-10**
- battery
 - clean **8-4**
 - safety **9-8**
 - setup **3-8**
 - specifications **10-4**
- beeps **3-8**
- biological safety **9-10**
- bodymarker. See pictographs
- brightness **4-2**
- cables. See cords
- calculations
 - cardiac. See cardiac calculations
 - delete measurement **5-9-5-10**
 - general **5-8**
 - IMT **5-32**
 - menu **2-11, 5-8**
 - OB **5-36**
 - percent area **5-12**
 - percent diameter **5-12**
 - percent reductions **5-11**
 - perform measurement **5-9**
 - performing **5-9**
 - repeat measurement **5-9**
 - save **5-9**

- small parts **5-40**
- specialized **5-16**
- vascular **5-44**
- view measurement **5-9**
- volume **5-13**
- volume flow **5-14**
- calipers **5-2**
- cardiac calculations
 - AAo **5-22**
 - Ao **5-22**
 - AVA **5-26**
 - CI **5-28**
 - CO **5-28-5-29**
 - dP:dT **5-26**
 - HR **5-28**
 - IVRT **5-20**
 - LA **5-22**
 - LV volume (Simpson's Rule) **5-22**
 - LVd **5-22**
 - LVOT D **5-22**
 - LVs **5-22**
 - MV/AV area **5-22**
 - overview **5-16, 8-1, 9-1**
 - PHT **5-24**
 - PISA **5-18**
 - RVSP **5-24**
 - setup **3-8**
 - SV **5-27**
 - TDI **5-30**
 - VTI **5-24**
- cardiac imaging applications **4-8**
- cardiac index (CI) **5-28**
- cardiac output (CO) **5-28-5-29**
- cardiac references **6-4**
- cardiac, intended uses **2-18**
- cautions, definition **1-2**
- cine buffer **2-9, 4-11**
- clean
 - battery **8-4**
 - ECG cable **7-6, 7-10**
- cleaning
 - stand **7-12**
- clip acquisition delay **4-28**
- clips
 - See also images and clips
 - options **4-3, 4-23**
- color Doppler (Color) imaging **4-6**
- color power Doppler (CPD) imaging **4-6**
- color scheme, background **3-14**
- color suppress **4-6**
- Color. See color Doppler (Color) imaging
- compatible
 - accessories **9-14**
 - peripherals **9-14**
- connectivity setup, wireless certificates **3-8**
- continuous wave (CW) Doppler imaging **4-7, 4-9**
- controls
 - direct **9-20**
 - indirect **9-21**
 - receiver **9-21**
- cords
 - AC **2-5**
 - DC **2-5**
- CPD. See color power Doppler (CPD) imaging
- CW Doppler. See continuous wave (CW) Doppler imaging

- date **3-9**
- DC
 - cord **2-5**
- default settings **3-1**
- delta pressure:delta time (dP:dT) **5-26**
- depth
 - adjust **4-10**
 - definition **A-1**
 - keys **2-9**
 - marker **2-11**
- DICOM **3-8, 11-2**
 - eFilm Lite **3-15**
- disinfect
 - battery **8-4**
 - ECG cable **7-6, 7-10**
- display setup **3-9**
- distance measurements
 - 2D **5-3**
 - M mode **5-4**
- D-line **4-8**
- Doppler
 - Doppler gate depth **4-9**
 - measurements **5-5**
 - scale setup **3-13**
- dual images **4-2**
- duplex **3-13**
- DVD recorder **3-9, 8-2**
- Dynamic Range **3-13**
- ECG
 - Monitoring **4-3, 4-27**
- eFilm Lite image-viewer **3-15**
- elapsed time (ET) measurement **5-6**
- electrical
 - safety **9-4**
 - specifications **10-4**
- electromagnetic
 - emissions **9-16**
- electromagnetic compatibility **9-11**
- electromechanical safety standards **10-4**
- EMC classification standards **10-5**
- EMED worksheets **5-48-5-49**
- equipment safety **9-7**
- error message **9-7**
- errors
 - acquisition **6-3**
 - algorithmic **6-3**
 - measurement **6-3**
- estimated date of delivery (EDD) **6-12**
- estimated fetal weight (EFW) **6-13**
- Event log **3-5**
- exam
 - change type **4-14**
 - end **4-20**
 - type and transducer **4-14**
- export and import
 - OB calculation tables **3-11**
 - predefined label groups **3-7**
 - user accounts **3-4**
- far **2-9**
- fetal heart rate (FHR) **5-39**
- flow sensitivity **4-7**
- focal zones, optimize **4-2**
- footswitch setup **3-1**
- forms **2-10**
- freeze **4-11**
- gain

- adjust **4-10**
- ECG **4-28**
- knob **2-9**
- gate size **4-9**
- gestational age
 - setup **3-10**
 - tables, references **6-13**
- gestational growth, measure **5-38**
- grace period **8-2**
- growth analysis
 - setup **3-10**
 - tables, references **6-16**
- guidance documents, related **9-25**
- guideline **4-3**
- gynecology (Gyn)
 - intended uses **2-18**
- heart rate **4-21**
- heart rate (HR) **5-5, 5-28, 5-39**
- HIPAA standard **10-6**
- home position **4-18**
- humidity limits **10-3**
- image quality, poor **8-1**
- images and clips
 - archive **4-27**
 - delete **4-27**
 - export to USB **4-26**
 - review **4-25**
- imaging modes
 - list of **10-2**
 - transducer **4-14**
- import. See export and import
- IMT. See Intima Media Thickness (IMT)
- in situ, definition **A-1**
- include private tags, private tags **3-15**
- infertility, intended uses **2-18**
- intended uses **2-18-2-20**
- intensity
 - derated **9-27**
 - in situ **9-27**
 - water-value **9-27**
- interventional, intended uses **2-18**
- Intima Media Thickness (IMT)
 - calculations **3-10, 5-32**
 - sketch **5-35**
 - trace **5-35**
- intraoperative, intended uses **2-18**
- invert
 - Color **4-7**
 - spectral trace **4-10**
- iso volumic relaxation time (IVRT) **5-20**
- keys **2-9**
- knobs **2-9**
- labeling symbols **9-75**
- language **3-13**
- layout **3-13**
- LCD screen
 - output **9-25**
- left atrium (LA) **5-22**
- left ventricular diastolic (LVd) **5-22**
- left ventricular outflow tract diameter (LVOT D) **5-22**
- left ventricular systolic (LVs) **5-22**
- left ventricular volume (LV volume) **5-22**
- license key **8-3**
- live trace **3-13, 4-10**
- login

Administrator **3-2**
 user **3-3**
 LVO (Left Ventricular Opacification) **4-2**
 M Mode imaging **4-5**
 measurements
 +/- Ratio, Doppler **5-6**
 2D **5-2**
 Acceleration, Doppler **5-6**
 accuracy **5-2, 6-1**
 area, 2D **5-3**
 automatic trace, Doppler **5-7**
 circumference, 2D **5-3**
 delete **5-2**
 distance, 2D **5-3**
 distance, M Mode **5-4**
 Doppler **5-5**
 edit **5-2**
 Elapsed Time, Doppler **5-6**
 errors **6-3**
 fetal heart rate **5-39**
 heart rate **5-5, 5-39**
 M Mode **5-4**
 manual trace **5-4, 5-6**
 Pressure Gradient, Doppler **5-5**
 publications **6-3**
 Resistive Index, Doppler **5-6**
 save to calculation and report **5-1**
 terminology **6-3**
 vascular **5-44**
 Velocities, Doppler **5-6**
 mechanical index (MI) **9-25, A-1**
 mitral valve/aortic valve (MV/AV) **5-22**
 M-line **4-5**
 mode data **2-11, 3-9**
 modes, keys **2-10**
 MPPS **3-8**
 near **2-9**
 network **3-10**
 networking **11-1**
 note, definition **1-2**
 NTSC
 definition **A-1**
 option **3-9**
 OB
 calculations **3-10, 5-36**
 custom measurements setup **3-11**
 custom tables setup **3-12**
 graphs **5-48**
 intended uses **2-19**
 references **6-12**
 tables setup **3-12**
 on-screen controls **2-10**
 optimize **4-2**
 Orbital calculations **5-41**
 orientation
 marker **2-11**
 option **4-2**
 output display **9-25**
 PAL
 definition **A-1**
 option **3-9**
 password **3-3-3-4, 3-6**
 patient header **2-11, 3-9**
 patient information form **4-19, 4-24-4-25**
 patient list **4-23**
 patient report

- about **5-45**
- cardiac **5-46**
- general **5-46**
- OB **5-47**
- save measurement to **5-1**
- vascular **5-46**
- PC **3-9**
- pediatric, intended uses **2-19**
- percent reduction calculations **5-11**
- peripherals **10-3**
 - compatible **9-14**
- pictographs
 - PICTO key **2-11**
 - placing **4-19**
- power
 - AC **2-5**
 - cord **2-5**
 - DC **2-5**
- power delay **3-8**
- power key **2-9**
- precision, acoustic measurement **9-74**
- preferences **3-13**
- presets **3-13**
- pressure half time (PHT) **5-24**
- pressure limits **10-3**
- PRF **4-7, 4-9**
- print **4-26**
- printer
 - problem **8-2**
 - setup **3-8**
- probe. See transducer
- proximal isovelocity surface area (PISA) **5-18**
- pulsed wave (PW) Doppler imaging **4-7**
 - PW Doppler. See pulsed wave (PW) Doppler imaging
 - recording problem **8-2**
 - references
 - cardiac **6-4**
 - general **6-18**
 - gestational age tables **6-13**
 - growth analysis tables **6-16**
 - obstetrical **6-12**
 - ratio calculations **6-18**
 - report, patient **5-45**
 - resistive index (RI) measurement **5-6**
 - right ventricular systolic pressure (RVSP) **5-24**
 - safety
 - battery **9-8**
 - biological **9-10**
 - electrical **9-4**
 - electromagnetic compatibility **9-11**
 - equipment **9-7**
 - save
 - calculations **5-9**
 - image **2-10**
 - measurements **5-1**
 - SAVE key **3-13**
 - scale **4-9**
 - scanhead. See transducer
 - screen layout **2-11**
 - security **3-2**
 - separation distance **9-13**
 - serial port **3-9**
 - setup pages **3-1**
 - ship

- transducer **7-12**
- shipping specifications **10-3**
- shortcut keys **3-1**
- Simpson's Rule **5-22**
- skin line, definition **A-1**
- sleep delay **3-8**
- small parts calculations **5-40**
- software license **8-2**
- SonoHD **A-2**
- SonoMB **4-3, A-2**
- spectral trace **4-8**
- stand, clean and disinfect **7-12**
- standards
 - acoustic **10-5**
 - electromechanical **10-4**
 - EMC classification **10-5**
 - HIPAA **10-6**
- steering
 - CPD **4-7**
 - Doppler **4-9**
- storage commitment **3-8**
- storage specifications
 - equipment **10-3**
 - images **10-2**
- stroke volume (SV) **5-27**
- superficial, intended uses **2-19**
- sweep speed
 - Doppler **4-10**
 - ECG **4-28**
 - M Mode **4-5**
- symbols, labeling **9-75**
- system
 - controls **2-9**
 - status **2-11, 3-10**
 - wake up **2-6**
- temperature limits **10-3**
- text **4-17**
- text description **2-11**
- thermal index (TI) **3-13, 9-25, A-2**
- THI **4-3**
- time setup **3-9**
- tissue Doppler imaging (TDI) **4-9, 5-30**
- tissue models **9-28**
- touchpad **2-10, 2-14**
- Transcranial Doppler calculations **5-41**
- transcranial, intended uses **2-19**
- transducer
 - connect **9-13**
 - curved array **A-1**
 - definition **A-2**
 - exam type **4-14**
 - general use **2-16**
 - imaging modes **4-14**
 - invasive or surgical use **2-16**
 - linear array **A-1**
 - preparation **2-16**
 - problems **8-2**
 - ship **7-12**
 - specifications **10-1**
 - transport **7-11**
- transport
 - transducer **7-11**
- troubleshoot **1-3, 8-1**
- ultrasound terminology **A-1**
- unfreeze text **3-7**
- USB storage device, export to **4-26**

user account **3-4**
user guide
 conventions used **1-2**
 updates **1-2**
user setup **3-3**
uses, intended **2-18-2-20**
variance **4-7**
vascular
 calculations **5-44**
 intended uses **2-20**
velocity measurement **5-6**
velocity time integral (VTI) **5-24**
volume
 Doppler, adjust **4-10**
volume flow **5-14**
wall filter **4-7, 4-10**
warnings, definition **1-2**
worklist **11-1**
worksheets, EMED **5-48-5-49**
zoom **4-11**

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