

SonoSite EDGEII



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Caution

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

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Chapter 1: Introduction

About the SonoSite Edge II User Guide

The SonoSite Edge II Ultrasound System User Guide provides information about configuring and using the SonoSite Edge II ultrasound system including:

- Managing patient data
- ▶ Performing exams
- ▶ Taking measurements and calculations
- ▶ Cleaning and disinfecting the system

The information and procedures in this user guide apply to the SonoSite Edge II ultrasound system and its included accessories. Other accessories and third-party equipment are subject to their own instructions and restrictions.

The SonoSite Edge II Ultrasound System User Guide is intended for a user familiar with ultrasound. It does not provide training in sonography, ultrasound, or clinical practices. Before using the system, you must complete such training.

Document conventions

The document 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.

Getting help

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

▶ Instructional videos available on-line.

▶ FUJIFILM SonoSite Technical Support:

Phone 877-657-8118

(U.S. or Canada)

Phone 425-951-1330, or call your local representative

(outside U.S. or Canada)

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2 Getting help

Chapter 2: Getting Started

Use this section to help familiarize yourself with the SonoSite Edge II ultrasound system and its uses.

About the system

The SonoSite Edge II 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. See "Software licensing" on page 134. 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.

Intended use

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

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

The system transmits ultrasound energy into the patient's body to obtain ultrasound images as described below.

Abdominal Imaging Applications

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

Cardiac Imaging Applications

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

About the system 3

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, 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.

4 Intended use

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.

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.

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.

Note

For the intended transducer and imaging modes for each exam type, refer to "Imaging modes and exams available by transducer" on page 50.

Contraindications

The SonoSite Edge II ultrasound system has no known contraindications.

Intended use 5

Hardware features

The front of the system is shown in Figure 2-1.

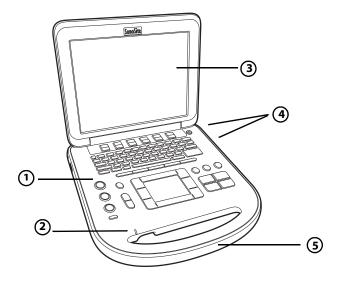


Figure 2-1 Front of the SonoSite Edge II Ultrasound System

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

The back of the system is shown in Figure 2-2.

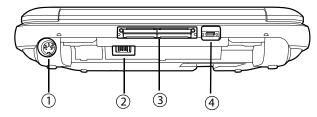


Figure 2-2 Back of the SonoSite Edge II Ultrasound System

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

6 Hardware features

Basic operating steps

- **1** Attach a transducer.
- 2 Turn the system on. For power switch location, see "System controls" on page 13.
- **3** Press the **PATIENT** key, and complete the patient information form.
- **4** Press an imaging mode key:
 - ▶ 2D
 - ▶ M MODE
 - ▶ **C** COLOR
 - **▶ D** DOPPLER

Preparing the system

Installing or removing the battery

WARNINGS

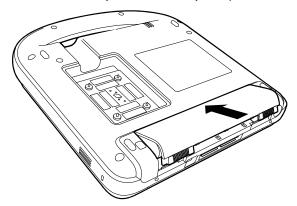
- ▶ To avoid injury to the operator and to prevent damage to the ultrasound system, inspect the battery for leaks prior to installing.
- ▶ To avoid data loss and to conduct a safe system shutdown, always keep a battery in the system.

See "Battery safety" on page 153.

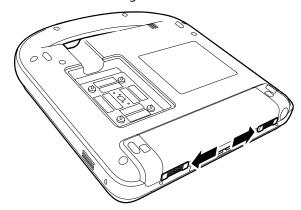
To install the battery

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

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



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



To remove the battery

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

Caution

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

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

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

To continue, connect the system to AC power.

WARNING

The equipment shall be connected to a center-tapped single phase supply circuit when users in the United States connect the equipment to a 240V supply system.

Caution

Verify that the hospital supply voltage corresponds to the power supply voltage range. See "Specifications" on page 170.

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.
- **2** Push the cable in firmly to ensure a secure connection.
- **3** Connect the AC power cord to the power supply and to a hospital-grade electrical outlet.

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

Note

Disconnecting only the DC power cable from the system or dock 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 display. Note the error code and turn off the system. Call FUJIFILM SonoSite or your local representative.

To turn the system on or off

❖ Press the power switch. See "System controls" on page 13.

To wake up the system

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

• Press a key, touch the touchpad, or open the lid.

To adjust the time for sleep delay

Refer to "Audio, Battery setup" on page 28.

Connecting transducers

NA.	1 A	N.	110	

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

Caution

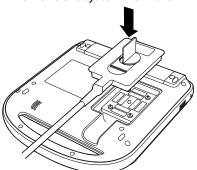
To avoid damaging the transducer connector, do not allow foreign material in the connector.

Note

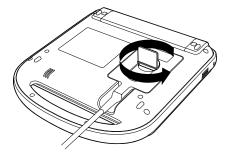
The system automatically checks for and notifies you of errors when connecting a transducer.

To connect a transducer

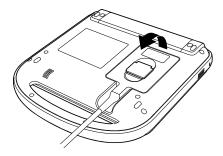
1 Remove the system from the mini-dock (if present), and turn it upside down.



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



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



To remove a transducer

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

Inserting and removing USB storage devices

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

Note

USB storage devices must be in FAT-32 format.

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

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

WARNING

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

To view information about the device

❖ Refer to "USB Devices setup" on page 34.

To remove a USB storage device

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

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

System controls

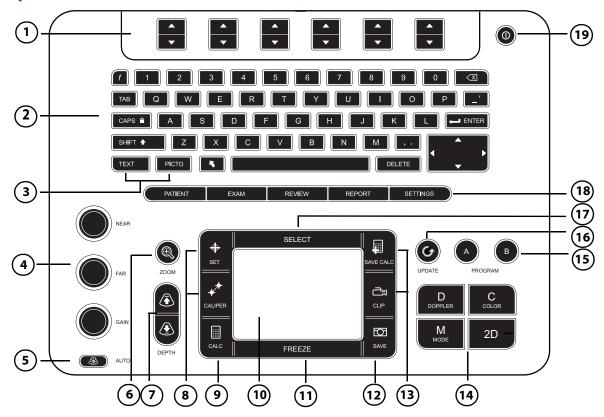


Table 2-1: Keyboard map

1	Control keys	Adjust on-screen controls.
2	Alphanumeric keys	Enter text and numbers.
3	Annotation keys	See "Alphanumeric keyboard" on page 17.
4	Gain	
	NEAR	Adjusts the gain applied to the near field of the image.
	FAR	In live imaging, adjusts the gain applied to the far field of the image. On a frozen PW Doppler image, adjusts the angle.
	GAIN	In live imaging, adjusts the overall gain applied to the entire image. On a frozen image, moves the cine buffer.

System controls 13

Table 2-1: Keyboard map (continued)

•	
AUTO	Adjusts gain automatically.
ZOOM	Magnifies the image 100%.
DEPTH UP, DEPTH DOWN	Decreases and increases imaging depth.
SET CALIPER	Sets a trace measurement. Displays calipers on-screen for measuring.
CALC	Turns the calculations menu on and off.
Touchpad	Selects, adjusts, and moves items on-screen.
FREEZE	Stops live imaging and displays a frozen image.
SAVE	Saves an image to internal storage. If configured, also saves calculations to the report. Refer to "Presets setup" on page 33.
SAVE CALC CLIP	Saves calculations and their measurements to the patient report. Saves a clip to internal storage.
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.
A & B shortcut keys	Keys that you can program to perform common tasks.
UPDATE	Toggles between dual and duplex screens and imaging modes in M Mode and Doppler (for example, between D-line and Doppler spectral trace).
SELECT	Used with the touchpad to select items on-screen. Also switches between Color and Doppler controls, calipers for measurement, pictograph-marker position and angle, frozen images in duplex and dual screens, and arrow position and orientation.
Forms	
PATIENT	Accesses patient information.
	ZOOM DEPTH UP, DEPTH DOWN SET CALIPER CALC Touchpad FREEZE SAVE SAVE CALC CLIP Imaging Modes M MODE DOPPLER COLOR 2D A & B shortcut keys UPDATE SELECT

14 System controls

Table 2-1: Keyboard map (continued)

	EXAM	Opens exam menu.
	REVIEW	Accesses the patient list, saved images, and archiving functions.
	REPORT	Accesses the patient report and EMED worksheets.
19	Power switch	Turns system on and off.

Screen layout

Sample screen:

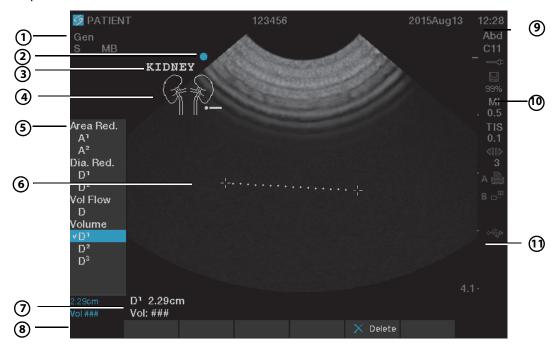


Table 2-2: Screen map

1	Mode Data Area	Current imaging mode information (for example, Gen, Res, THI, and PW).
2	Orientation Marker	Indication for image orientation.
3	Text	Text entered using keyboard.
4	Pictograph	Pictograph to indicate anatomy and transducer position. You can select anatomy and screen location.

Screen layout 15

Table 2-2: Screen map (continued)

Cala latin a Man	
Calculations Menu	Contains available measurements.
lmage	Ultrasound image.
Measurement and Calculations Data Area	Current data on measurements and calculations.
On-screen Controls	Controls available in the current context.
Patient Header	Header details such as current patient name, ID number, user, and date/time. Specified on the display information setup page.
System Status	Information on system status (for example, exam type, transducer, AC connected, battery charging, and USB).
	Marks in .5 cm, 1 cm, and 5 cm increments depending on depth.

General interaction

Touchpad and cursor

Caution

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

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

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

On-screen controls

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

16 General interaction

Cycle

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

Up-Down

Moves through a list of settings, stopping at the top or bottom. The upper key moves upward. The lower key moves downward. By default, a beep sounds when you reach either end of the range. Refer to "Audio, Battery setup" on page 28.

On-Off

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

Action

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

Annotation and text

Alphanumeric keyboard

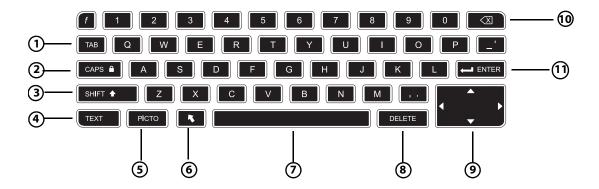


Table 2-3: Alphanumeric keyboard map

1	ТАВ	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.

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Table 2-3: Alphanumeric keyboard map (continued)

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

Symbols

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

Patient information form:

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

DICOM or SiteLink configuration page:

Alias and AE Title fields

A & B Key, Footswitch setup page:

Text field

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Text mode (imaging):

Annotation field



Figure 2-3 Symbols Dialog Box

To enter symbols or special characters

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

Preparing the transducers

WARNINGS

- ▶ Some transducer sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals. Refer to 21 CFR 801.437, User labeling for devices that contain natural rubber.
- ▶ Some gels and disinfectants can cause an allergic reaction 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. Refer to "Cleaning and disinfecting the system and transducer" on page 137.

Note

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

To use the transducer

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

WARNING

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

To apply a transducer sheath

❖ For invasive use, apply a transducer sheath.

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

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

Chapter 3: System Setup

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

Displaying the setup pages

To display a setup page

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

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

Restoring default settings

To restore default settings for a setup page

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

To restore all default settings

- **1** Turn the system off.
- 2 Connect the system to AC power. See "To operate the system using AC power" on page 9.
- 3 Simultaneously press 1 and the **power** key. The system beeps several times.

A & B Key, Footswitch setup

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

- Select from the following lists:
 - ▶ A Key, B Key. By default, the A shortcut key is set to **Print** and the B shortcut key is set to **none**. The shortcut keys are below the alphanumeric keypad.
 - ▶ Footswitch (L), Footswitch (R). Set the left and right footswitches to: Save Clip, Freeze, Save Image, or Print. See "To connect the footswitch" on page 22.

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.
 - a If you don't have the administrator password, contact FUJIFILM SonoSite. See "Getting help" on page 2.
- 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 26.
 - Let users change their passwords: Select the **Password changes** check box.
- 4 Select Save.

To enable encryption

- **1** Log in as Administrator.
- **2** Enter the encryption key in the text box.

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 26.
- **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.

Note

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 available 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

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**. Restart the system.

Note 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. See "To require user login" on page 23.

To log in as user

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

To log in as guest

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

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

To change your password

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

Choosing a secure password

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

Annotations setup

On the Annotations setup page, you can customize predefined labels and set the preference for managing text when unfreezing images. For instructions to annotate images, refer to "Annotating images" on page 55.

26 Annotations setup

To predefine a label group

You can specify which labels are available for an exam type when annotating an image. See "To place text on an image" on page 56.

- 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 "Symbols" on page 18.

To specify text retention when unfreezing

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

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

Note

The default setting is **Keep All Text**. For information on setting the home position, see "To reset the home position" on page 56.

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**.

Annotations setup 27

4 Select **Done** in the dialog box that appears. All predefined label groups for all exams are replaced with those from the USB storage device.

Audio, Battery setup

- ❖ On the Audio, Battery setup page, 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 "Cardiac calculations" on page 79.

To specify cardiac measurement names

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

Connectivity setup

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

To specify SiteLink settings

❖ See the SiteLink Image Manager User Guide.

To specify DICOM settings

See Sending and Receiving DICOM Data on SonoSite Systems.

To configure the system for a printer

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

28 Audio, Battery setup

To enable wireless connection

See Setting Up a Wireless Network.

To receive storage alerts

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

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

Date and Time setup

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

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.

- 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).

To enable the time server

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

Display Information setup

On the Display Information setup page, you can specify which details appear on-screen during imaging.

- Select settings in the following sections:
 - ▶ **Patient Header**. Information that appears in the patient header.
 - ▶ Mode Data. Imaging information.
 - ▶ **System Status**. System status information.

Date and Time setup 29

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 "OB calculations" on page 96.

To specify gestational age and growth analysis

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

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

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

Note

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

To export OB calculation tables

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

To import OB calculation tables

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

1 Insert the USB storage device that contains the tables.

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

OB Custom Measurements setup

On the OB Custom Measurements setup page, you can define measurements that appear in the OB calculations menu and OB report. OB Custom Measurements is an optional feature. See "OB calculations" on page 96.

To set up OB custom measurements

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

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

To delete an OB custom measurement

WARNING

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

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

OB Custom Tables setup

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

Gestational Age Table Measurements

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

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

Growth Analysis Table Measurements

The system provides growth graphs or curves for the following:

▶ BPD	▶ HC
▶ AC	▶ FL
▶ EFW	▶ 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 30.

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.

- 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
 - ▶ 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.

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- ▶ 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.

Note

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.
- ▶ 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. See "To enter a license key" on page 135.

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 as well as enable automatic exam export. You can also specify a file format for images and clips in patient exams that you export to a USB storage device. See "To export patient exams to a USB storage device" on page 64.

Note:

FAT32 formatting of the USB memory stick is required.

To specify a file format for exported images

- 1 On the USB Devices setup page, select **Export**.
- 2 Under **USB Export**, select an export type:
 - ▶ **SiteLink** organizes files in a SiteLink-style folder structure. Clips export in H.264 video saved as MP4 files. To view them, FUJIFILM SonoSite recommends QuickTime 7.0 or later.
 - ▶ **DICOM** creates files readable by a DICOM reader. DICOM is an optional feature.

3 Select an image format for your export type. For JPEG image format, also select a JPEG compression. Refer to "Limitations of JPEG format" on page 35

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

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

To enable automatic exam export

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

To include private tags

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

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

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

Limitations of JPEG format

When transferring or exporting images in JPEG format, the system uses lossy compression. Lossy compression may create images that have less absolute detail than BMP format and that don't render identically to the original images. In some circumstances, lossy-compressed images may be inappropriate for clinical use. For more information on using lossy-compressed images, consult the industry literature, including the following references:

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

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

USB Devices setup 35

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.

Note eFilm Lite is a licensed feature.

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. Refer to the *eFilm Lite User's Guide*, a PDF file in the eFilmLite folder.

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Chapter 4: Imaging

Imaging modes

The system has a high-performance display and advanced image-optimization technology that simplifies user controls. Imaging modes available depend on the transducer and exam type. See "Imaging modes and exams available by transducer" on page 50.

2D imaging

2D is the system's default imaging mode. The system displays echoes in two dimensions by assigning a brightness level based on the echo signal amplitude. To achieve the best possible image quality, properly adjust the 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 Adjust controls as desired as described in "2D controls."

2D controls

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

Table 4-1: 2D on-screen controls

Optimize

Settings are as follows:



- ▶ **Res** provides the best possible resolution.
- ▶ **Gen** provides a balance between resolution and penetration.
- ▶ **Pen** provides the best possible penetration.

Some of the parameters optimized to provide the best image include focal zones, aperture size, frequency (center and bandwidth), and waveform. They cannot be adjusted by the user.

Dynamic Range

Adjusts the grayscale range: -3, -2, -1, 0, +1, +2, +3.



Remember, the positive range increases the number of grays displayed, and the negative range decreases the number of grays displayed.

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

Clips

Table 4-1: 2D	On-screen controls (continued)
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 control. Use LVO for cardiac exams in 2D imaging mode. LVO lowers the mechanical index (MI) of the system. This control depends on transducer and exam type.
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.
Guide	Turns guidelines on and off. Guidelines are for needle guidance, are an optional feature, and depend on transducer type. For transducers with a single-angle or multi-angle bracket, the touchpad moves the depth cursor. 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: Select the angle again (A , B , or C). Exit angle selection and press Guide . See the needle guide's user documentation. Guide is not available when the ECG cable is connected.
Sector	(Cardiac exam) Specifies the sector width.
SonoMB (MB)	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. SonoMB depends on transducer and exam type.
SNP	Turns on Steep Needle Profiling™ technology. See "Needle visualization" on page 46. SNP depends on transducer and exam type.
ECG	Displays the ECG trace. Refer to "ECG Monitoring" on page 65. This feature is optional and requires a FUJIFILM SonoSite ECG cable.

38 Imaging modes

Displays the clip controls. Refer to "To capture and save a clip" on page 60.

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

ТНІ	Turns Tissue Harmonic Imaging on and off. When on, <i>THI</i> appears in the upper left-hand screen. This feature depends on transducer and exam type.
Centerline	Turns the centerline graphic on or off. See "Centerline" on page 49.
Page x/x	Indicates which page of controls is displayed. Select to display the next page.

M Mode imaging

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

To display the M-line

1 Press the M key.

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

2 Use the touchpad to position the M-line where desired.

Set controls as desired. Many optimization and depth controls available in 2D imaging are also available in M Mode imaging. See "2D controls" on page 37.

To display the M Mode trace

- **1** Display the M-line.
- 2 Adjust the depth if necessary. See "To adjust depth" on page 44.
- **3** Press the **M** key. The time scale above the trace has small marks at 200ms intervals and large marks at one-second intervals.
- **4** Do any of the following as needed:
 - ▶ Select the sweep speed → (Slow, Med, or Fast).
 - ▶ Press the **UPDATE** key to toggle between the M-line and M-Mode trace.
 - ▶ If using a duplex layout, press the **M** key to toggle between the full-screen M-line and the duplex layout.

To set a duplex layout

See "Presets setup" on page 33.

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 C key. A ROI box appears in the center of the 2D image.
- 2 Select CPD or Color.

Note 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.

Note

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

4 Adjust controls as desired. See "CPD and Color controls."

CPD and Color controls

In CPD or Color imaging, you can set the following on-screen controls.

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

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 4-2: CPD and Color on-screen controls (continued)

Flow The current setting appears on-screen. Sensitivity **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). PRF Available on select transducers. Wall Filter Settings include **Low**, **Med**, and **High**. Steering Select the steering angle setting of the color ROI box (-15, 0, or +15). If adding PW Doppler, see "PW Doppler controls" on page 43. 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 controls is displayed. Select to display the next page.

PW and CW Doppler imaging

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

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

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

To display the D-line

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

1 Press the **D** key.

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

- **2** Do any of the following as needed:
 - ▶ Adjust controls as described in "PW Doppler controls" on page 43.
 - Using the touchpad, position the D-line and gate where desired. Horizontal movements position the D-line. Vertical movements position the gate.

PW Doppler

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

To display the spectral trace

- **1** Display the D-line.
- 2 Press the **D** key. The time scale above the trace has small marks at 200 ms intervals and large marks at one-second intervals.
- **3** Do any of the following as needed:
 - ▶ Adjust controls. as described in "Spectral trace controls" on page 43.
 - ▶ Press the **UPDATE** key to toggle between the D-line and spectral trace.
 - If using a duplex layout, press the **D** key to toggle between the full-screen D-line and the duplex layout.

 To set a duplex layout, see "Presets setup" on page 33.

PW Doppler controls

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

Table 4-3: PW Doppler on-screen controls

PW, CW

CW applies to Cardiac exam only.



Toggle between PW Doppler and CW Doppler.

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

Angle

Corrects the angle to 0° , $+60^{\circ}$, or -60° .

Correction

You may also adjust the angle using the touchpad.



Gate Size

Settings depend on transducer and exam type.



In TCD or Orb exams, use the touchpad to specify the Doppler gate depth (the depth of the center of the gate in the Doppler image). The Doppler gate depth indicator is on the lower right-hand screen.

TDI On,

Select **TDI On** to turn on Tissue Doppler Imaging. When on, *TDI* 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.



- -15 and -20 have an angle correction of -60°.
- 0 has an angle correction of 0°.
- +15 and +20 have an angle correction of +60°.

You can manually correct the angle after selecting a steering angle setting. See "To display the D-line" on page 42.

Available on select transducers.

Page x/x

Indicates which page of controls is displayed. Select to display the next page.

Spectral trace controls

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

Table 4-4: Spectral trace on-screen controls

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 33.



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

Line	Sets the	baseline	positio

솧

(On a frozen trace, the baseline can be adjusted if **Live Trace** is off.)

Invert Vo

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 33 to specify peak or mean.

Page x/x

Indicates which page of controls is displayed. Select to display the next page.

Adjusting depth and gain

To adjust depth

You can adjust the depth in all imaging modes 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:
 - ▶ **DEPTH**UP key to decrease the displayed depth.
 - ▶ **DEPTH** DOWN key to increase the displayed depth.

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

To adjust gain automatically

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

To adjust gain manually

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

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

Freezing, viewing frames, and zooming

To freeze or unfreeze an image

❖ Press the **FREEZE** key.

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

To move forward or backward in the cine buffer

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

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

To zoom in on an image

You can zoom in 2D 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.)
- **5** To exit zoom, press the **ZOOM** key again.

Needle visualization

WARNING

To avoid incorrect needle placement when SNP is on:

- ▶ Using movement and fluid injection, verify the needle-tip location and trajectory. Steep Needle Profiling technology enhances linear structures within a selected angle range on the ultrasound plane. Linear structures outside the selected angle range or the ultrasound plane—such as a bent needle—may be less apparent.
- Note that linear structures are enhanced only in an outlined portion of the image. The area outside the outline remains unchanged.
- ▶ Note that the beam divergence of a curved array transducer may prevent a segment of the needle shaft from showing in the image. The needle tip may not show.

About Steep Needle Profiling technology

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

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

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

Table 4-5: Transducers and exam types available with SNP

Transducer	Arterial	Breast	Musculoskeletal	Nerve	Small Parts	Venous
rC60xi standard/armored	V	V	V	V	V	V
HFL38xi	V	V	\checkmark	V	V	V
HFL50x		V	\checkmark	V	V	
HSL25x	V		\checkmark	V		V
L25x	V		\checkmark	V		V
L38xi standard/armored				V		

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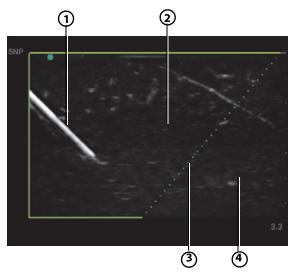


Figure 4-1 Image with SNP on (linear transducer)

- 1 Needle
- 2 Outlined area enhanced by SNP
- 3 Dotted line
- 4 Unenhanced area

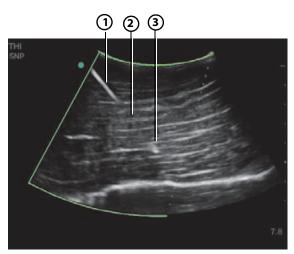


Figure 4-2 With a curved array transducer, only segments of the needle shaft may show

- 1 Upper needle shaft
- 2 Segment of needle shaft not shown (depends on specific image)

3 Needle tip

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Needle size and angle

Note

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

You can angle the needle up to 50° from the transducer surface as shown in Figure 4-3. Beyond 50°, the needle may be less enhanced.

Steep Needle Profiling technology is intended for in-plane procedures only. Steep

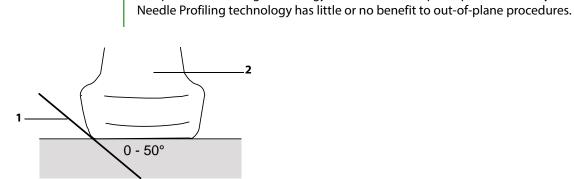


Figure 4-3 For best results, angle the needle only up to 50° from the transducer surface:

1 Needle 2 Transducer

SNP subcontrols

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

- ▶ **Shallow**, **Medium**, or **Steep** sets the outline's sloped edge, which is indicated by a dotted line. The current selection is highlighted.

Linear transducer: Use whichever setting best provides a perpendicular intersection with the dotted line. Within the enhancement area, the more perpendicular that a linear structure is to the dotted line, the more it is enhanced. Similarly, the less perpendicular (and more parallel) that a linear structure is to the dotted line, the less it is enhanced.

Curved array transducer: For a linear structure angled 30° or less from the transducer surface, use Shallow for best enhancement. For a linear structure angled 30-40°, use Medium. For a linear structure angled 40° or greater, use Steep.

 Off turns off SNP. Temporarily turning off SNP can help you identify artifacts and other structures not of interest.

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▶ **Back** returns to the previous screen. If Steep Needle Profiling technology is on, SNP is highlighted and SNP appears in the mode data area. Pressing SNP again redisplays the SNP controls.

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

Additional recommendations

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

If you use Steep Needle Profiling technology frequently, consider using a shortcut key to turn on the SNP control. For instructions to program a shortcut key, see "A & B Key, Footswitch setup" on page 21.

Centerline

The centerline graphic aligns with the center mark of the transducer and serves as a reference mark for the center of the displayed image.

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

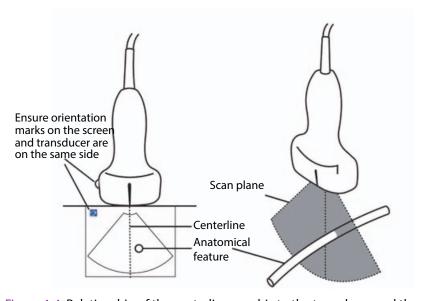


Figure 4-4 Relationship of the centerline graphic to the transducer and the ultrasound image.

Centerline 49

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

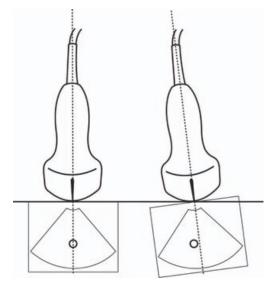


Figure 4-5 Relationship of the ultrasound image to the transducer angle or tilt.

Imaging modes and exams available by transducer

WARNINGS

- ▶ To prevent misdiagnosis or harm to the patient, understand your system's capabilities prior to use. The diagnostic capability differs for each transducer, exam type, and imaging mode. 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.

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

To change the exam type

- Do one of the following:
 - ▶ Press the **Exam** key, and select from the menu.

▶ On the patient information form, select from the **Type** list under **Exam**. See "Patient information form" on page 57.

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

			ı	lmaging m	ode	
Transducer	Exam Type ^a	2D ^b M Mode	CPD ^c	Color ^c	PW Doppler ^d	CW Doppler
C11x	Abd	√	V	V	V	
	Art	V	V	V	V	
	Neo	V	V	V	V	
	Nrv	V	V	V	V	
	Ven	V	V	V	V	
rC60xi standard/ armored	Abd	V	V	V	V	
	Gyn	V	V	V	V	
	Nrv	V	V	V	V	
	Msk	V	V	V	V	
	ОВ	V	V	V	V	

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

			lmaging mode				
Transducer	Exam Type ^a	2D ^b M Mode	CPD ^c	Color ^c	PW Doppler ^d	CW Doppler	
HFL38xi	Art	V	V	V	V		
	Bre	V	√	√	V		
	Lung	V	√	V	V		
	Msk	V	√	V	V		
	Nrv	\checkmark	\checkmark	V	V		
	SmP	\checkmark	√	V	V		
	Ven	V	V	V	V		
HFL50x	Bre	V	V	V	V		
	Msk	V	V	V	V		
	Nrv	V	V	V	V		
	SmP	V	V	V	V		

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

		Imaging mode				
Transducer	Exam Type ^a	2D ^b M Mode	CPD ^c	Color ^c	PW Doppler ^d	CW Doppler
HSL25x	Art	V	V	V	V	
	Lung	\checkmark	V	V	V	
	Msk	\checkmark	\checkmark	V	V	
	Nrv	\checkmark	V	V	✓	
	Oph	V	V	V	V	
	Sup	\checkmark	V	V	V	
	Ven	V	V	V	V	
ICTx	Gyn	V	\checkmark	V	V	
	ОВ	V	V	V	V	

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

		lmaging mode				
Transducer	Exam Type ^a	2D ^b M Mode	CPD ^c	Color ^c	PW Doppler ^d	CW Doppler
L25x	Art	√	V	V	V	
	Lung	V	√	√	V	
	Msk	V	√	V	V	
	Nrv	V	\checkmark	V	V	
	Oph	V	\checkmark	V	V	
	Sup	✓	\checkmark	√	V	
	Ven	√	\checkmark	V	V	
L38xi standard/ armored	Art	V	√	V	V	
	Lung	✓	√	√	V	
	Nrv	✓	\checkmark	V	V	
	SmP	✓	√	√	V	
	Ven	V	\checkmark	V	V	
P10x	Abd	√	√	V	V	
	Crd	√		√	V	√
	Neo	V	V	V	√	

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

				lmaging m	ode	
Transducer	Exam Type ^a	2D ^b M Mode	CPD ^c	Color ^c	PW Doppler ^d	CW Doppler
P11x ^e	Art	√	V	V		
	Ven	V	V	V		
rP19x standard/ armored	Abd	V	V	V	V	
	Crd	V		V	V	√
	Lung	V	V	V	V	
	ОВ	V	V	V	V	
	Orb	V	V	V	V	
	TCD	V	\checkmark	V	V	
TEExi ^f	Crd	V		V	V	√

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

Annotating images

You can annotate live images as well as frozen images. (You cannot annotate a saved image.) You can place text (including predefined labels), an arrow, or a pictograph. To set preferences for annotations, refer to "Annotations setup" on page 26.

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

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

d. For the cardiac exam type, PW TDI is also available. See "PW Doppler controls" on page 43.

e. For more information refer to the *P11x Transducer User Guide*, included with the P11x transducer.

f. For more information refer to the TEExi Transducer User Guide, included with the TEExi transducer.

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 highlighted cursor appears.
- 2 Move the cursor where desired:
 - ▶ Use the touchpad or arrow keys.
 - ▶ Select **Home** to move the cursor to the home position.

The default home position depends on the imaging screen layout. You can reset the home position as described in "To reset the home position" on page 56.

- **3** Using the keyboard, type text.
 - The arrow keys move the cursor left, right, up, and down.
 - ▶ The **DELETE** key deletes all text.
 - X Word removes a word.
 - ▶ **Symbols** lets you enter special characters. See "Symbols" on page 18.
- 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 26.

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

To reset the home position

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

To place an arrow on an image

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

1 Press the arrow key .

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

To place a pictograph on an image

The pictograph set available depends on transducer and exam type.

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

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

- **3** Using the touchpad, position the pictograph marker.
- **4** (Optional) If the image is frozen, use the touchpad or arrow keys to pan the image up, down, left, and right. You cannot pan in Dual. 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 106.

To create a new patient information form

- 1 Press the **PATIENT** key.
- 2 Select & New/End.

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- **3** Fill in the form fields as described in "Patient information form fields" on page 58.
- 4 Select Done.

See also "To append images and clips to a patient exam" on page 62.

To enable bar code lookup of patient data

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

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

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 "To edit patient information from the patient list" on page 62.

- 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 60
- 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 18.

Patient

- ▶ Last, First, Middle Patient name
- ▶ **ID** Patient identification number

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- 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. Refer to the document *Sending and Receiving DICOM Data on SonoSite Systems*.
- 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 50.
- ▶ **LMP or Estab. DD** (OB or Gyn exam)
 - ▶ In an OB exam, select **LMP** or **Estab. DD** and then enter either the date of the last menstrual period or the established due date.
 - In a Gyn exam, enter the date of the last menstrual period. The LMP date must precede the current system date.
- ▶ **Twins** (OB exam). Select the **Twins** check box to display Twin A and Twin B measurements on the calculations menu and for access to Twin A and Twin B screens for previous exam data.
- ▶ **Previous Exams (button)** (OB exam). Displays fields for five previous exams. The date for a previous exam must precede the current system date. For twins, select **Twin A/B** to toggle between Twin A and Twin B screens.

Note

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

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

- **BP** (Cardiac, Arterial, Orbital, or Transcranial exams) Blood Pressure
- ▶ **HR** (Cardiac, Arterial, Orbital, or Transcranial exams) Heart Rate. Enter the beats per minute. 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 33.
- ▶ **Weight** (Cardiac exam). The patient weight in pounds or kilos. To change the units, see "Presets setup" on page 33.
- ▶ BSA (Cardiac exam) Body Surface Area. Automatically calculated after you enter height and weight.
- ▶ Reading Dr.
- ▶ Referring Dr.

Patient information form 59

- **▶** Institution
- **▶** Department ID

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, Battery setup" on page 28.

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 save, and then delete them from the system to free up space. See "To delete images and clips" on page 64.

- ▶ To receive alerts when storage is near capacity, see "To receive storage alerts" on page 29.
- ▶ To access saved images and clips, open the patient list as described in "Reviewing patient exams" on page 61.

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 33.

To capture and save a clip

Clips lets you capture, preview, and save clips.

- 1 Set Clips controls as described in "To set Clips controls" on page 61.
- 2 Press the **CLIP** key.

One of the following occurs:

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

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

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

- ▶ **Delete** to delete the clip.
- **3** To stop saving a clip, press the **CLIP** key again. Data already acquired is saved.

To set Clips controls

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

- 1 In 2D imaging mode, select **Clips** on-screen.
- 2 Set controls as desired.

Clips controls

Table 4-7: Clip on-screen controls

Time, ECG

Time and **ECG** share the same location on-screen.



- 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,

PrevOn and **PrevOff** turn the preview feature on and off.

Preview Off

- With **Prev/On**, the captured clip automatically plays on-screen. The clip can be trimmed, saved, or deleted.
- With Prev/Off, the clip saves to internal storage, and the trim and delete controls are not available.

Prospective,

Pro and **Retro** determine how clips are captured:

Retrospective • 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 2.

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

To display the patient list

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

To sort the patient list

After the system starts, the patient list is arranged by date and time, with the most recent patient 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.

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 in the patient list

❖ 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 is ended but has not been exported or archived.

- 1 In the patient list, select the patient.
- 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 is 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 to display a new patient information form. 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 \(\bigcap \ni/\ni\) 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.

Note

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

- ▶ 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 28.
- **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 33.

To print multiple images

- 1 Verify that a printer is selected. See "To configure the system for a printer" on page 28.
- **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 58.

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 34.

- **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.

Note Only available USB devices are selectable.

5 Select **Export**.

The files finish 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 export patient exams automatically

To export patient exams automatically to a USB memory stick:

- 1 Make sure that automatic export is enabled. See "To specify a file format for exported images" on page 34.
- 2 Insert a USB memory stick into a USB port on the side of the system.
- **3** End the exam.

To stop in-progress exporting

Select Cancel Export.

To delete images and clips

- 1 In the patient list, do one of the following:
 - ▶ If deleting a single image or clip, display it. See "To review images and clips" on page 62.
 - ▶ If deleting entire patient exams, select them.

2 Select X Delete. A confirmation screen appears.

To manually archive images and clips

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

- 1 Select one or more patients in the patient list.
- 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 control 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.

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

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

ECG Monitoring 65

3 Adjust controls as desired.

ECG Monitoring controls

Table 4-8: ECG on-screen controls

Show/Hide	Turns on and off ECG trace.
4	
-∤-	
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 60.
Line	The position of the delay line on the ECG trace. The delay line indicates where the clip
∢ >	acquisition is triggered.
Save	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 controls.

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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, refer to Chapter 6, "Measurement References."

Measurements

You can perform basic measurements in any imaging mode and can save the image with the measurements displayed. Except for the M Mode HR measurement, the results do not automatically save to a calculation and the patient report. If you prefer, you can first begin a calculation and then measure. See "Performing and saving measurements" on page 74.

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

To save a measurement to a calculation and patient report

- 1 With the measurement active (highlighted), 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 as described in "To save a calculation" on page 74.

To start a calculation before measuring, see "Performing and saving measurements" on page 74.

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. A measurement is complete when you finish moving its calipers.

Within a calculation, calipers appear when you select from the calculations menu. Refer to "To select from the calculations menu" on page 73.

Note 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 cm²
- ▶ Circumference in cm

You can also measure area or circumference by tracing manually.

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 set of three calipers appears, connected by a dotted line.
- 2 Using the touchpad, position the first caliper, and then press the **SELECT** key. The second caliper becomes active.
- **3** Using the touchpad, position the second 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 67.

To measure area or circumference (2D)

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

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 67.

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 67.

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 67.

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 and press the **SELECT** key. A second vertical caliper appears.
- **4** 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 67.

Note

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

Doppler measurements

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

- Velocity (cm/s)
- ▶ Pressure Gradient
- Elapsed Time
- ▶ +/x Ratio

- Resistive Index (RI)
- Acceleration

You can also trace manually or automatically. For Doppler measurements, the Doppler scale must be set to cm/s. See "Presets setup" on page 33.

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 67.

To measure Velocities, Elapsed Time, +/x Ratio, Resistive Index (RI), and Acceleration (Doppler)

- RI appears only if the velocity associated with the first caliper is greater than the velocity associated with the second caliper.
- ▶ **ACC** appears only when the velocity associated with the second caliper is greater than the velocity associated with the first caliper.
- 1 On a frozen Doppler spectral trace, press the **CALIPER** key. A single caliper appears.
- **2** Using the touchpad, position the caliper to a peak 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 67.

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.

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

- **4** Using the touchpad, trace the waveform.
 - a To make a correction, select **Undo** on-screen, backtrack with the touchpad, or press the **backspace** key.
 - **b** Press the **SET** key. The measurement results appear. Refer to "To save a measurement to a calculation and patient report" on page 67.

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 71.

- 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.
 - **a** If calipers are not positioned correctly, the calculation result is inaccurate.
 - **b** Press the **SELECT** key. A second vertical caliper appears.
- **4** Using the touchpad, position the second caliper at the end of the waveform.
- **5** Press the **SET** key. The measurement results appear. Refer to "To save a measurement to a calculation and patient report" on page 67.

Automatic trace results

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

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

Peak Velocity (Vmax)Peak Systolic Velocity (PSV)

▶ Mean Pressure Gradient (PGmean)
▶ Time Average Mean (TAM)

▶ Mean Velocity on Peak Trace (Vmean)
▶ +/× or Systolic/Diastolic (S/D)

Pressure Gradient (PGmax)Pulsatility Index (PI)

► End Diastolic Velocity (EDV) Resistive Index (RI)

Acceleration Time (AT)

▶ 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 106.

Vote

Calculation packages depend on exam type and transducer.

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. Also, a check mark appears next to the measurement name in the calculations menu. If you highlight the checked measurement name, the results appear below the menu. If you repeat the measurement, the results below the menu reflect either the last measurement or the average, depending on the measurement.

Note

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

To select from the calculations menu

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

Performing and saving measurements

In 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 60.
 - 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 33.

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

Displaying, repeating, and deleting saved measurements

To display a saved measurement

- Do one of the following:
 - ▶ Highlight the measurement name in the calculations menu. The result appears below the menu.
 - ▶ Open the patient report as described in "Patient report" on page 106.

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 15. 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.

Note

Some measurements can be deleted directly from the patient report pages. See "Patient report" on page 106.

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.

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

For a list of exam types on each transducer, see "Imaging modes and exams available by transducer" on page 50.

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.
 - i To make a correction, select **Undo** on-screen or press the **backspace** key.
 - **d** Complete the trace, and press the **SET** key.
 - e Save the calculation as described in "To save a calculation" on page 74.

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 **D**¹ and then for **D**²:
 - a From the calculations menu, select the measurement name under Dia Red.
 - **b** Position the calipers.
 - **c** Save the calculation as described in "To save a calculation" on page 74.

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

Volume 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.

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

For a list of exam types on each transducer, see "Imaging modes and exams available by transducer" on page 50.

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.
 - iii Save the measurement as described in "To save a calculation" on page 74.

Volume flow 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.

Volume flow calculations are available in the following exam types: Abdomen, Arterial.

For a list of exam types on each transducer, see "Imaging modes and exams available by transducer" on page 50.

The following table shows the measurements required to complete the volume flow calculation. For definitions of acronyms, see the "Glossary" on page 237.

Calculation	Measurement (imaging mode)	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 33.

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
 - ▶ Precision in placing the caliper
 - Accuracy in angle correction
 - ▶ 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)
 - rC60xi and P10x transducer: 2, 3, 5, 7, 10, 12 Gate Size (mm)
 - ▶ HFL38xi and L25x: 1, 3, 5, 6, 7, 8, 10, 12 Gate Size (mm)
 - L38xi transducer: 1, 3, 5, 6, 7, 8, 10, 12 Gate Size (mm)

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

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.
 - **d** Save the calculation as described in "To save a calculation" on page 74.
- **2** Perform the Doppler measurement:
 - **a** On a frozen Doppler spectral trace, press the **CALCS** key.
 - **b** From the calculations menu, select **TAM** or **TAP** under **Vol Flow**. A vertical caliper appears.

c Using the touchpad, position the vertical caliper at the beginning of the waveform.

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

- **d** Press the **SELECT** key to display a second vertical caliper.
- **e** Using the touchpad, position the second vertical caliper at the end of the waveform.
- **f** Press the **SET** key to complete the trace and to display the results.
- **g** Save the calculation as described in "To save a calculation" on page 74.

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

Exam-based calculations

In addition to the general calculations, there are calculations specific to the Cardiac,(Crd) Gynecology (Gyn), , Obstetrical (OB), Orbital (Orb), Small Parts (SmP), Transcranial Doppler (TCD), and Aterial(Art) exam types.

Cardiac 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. See "To create a new patient information form" on page 57.

For a list of transducers available with the cardiac exam, see "Imaging modes and exams available by transducer" on page 50.

The following table shows the measurements required to complete different cardiac calculations. For definitions of acronyms, see the "Glossary" on page 237.

Table 5-1: Cardiac calculations and results

Calculation list	Measurement name (imaging mode)	Results
EFEF	LVDd (2D or M Mode)LVDs (2D or M Mode)	EF FS
LV Vol (EF)	 ▶ A4Cd (2D) ▶ A4Cs (2D) ▶ A2Cd (2D) ▶ A2Cs (2D) 	LV Vol LV Area EF CO SV CI SI Biplane
LVLVd	 ▶ RVW (2D) ▶ RVD (2D) ▶ IVS (2D) ▶ LVD (2D) ▶ LVPW (2D) 	CO EF SV LVESV LVEDV IVSFT LVPWFT LVDFS
LVs	 ▶ RVW (2D) ▶ RVD (2D) ▶ IVS (2D) ▶ LVD (2D) ▶ LVPW (2D) HR needed for CO & CI 	CI SI LV Mass (M Mode only)
HR ^a	HR (M Mode or Doppler)	HR

Table 5-1: Cardiac calculations and results (continued)

Calculation list	Measurement name (imaging mode)	Results
Ao/LA	► Ao (2D or M Mode)	Ao LA/Ao
	▶ AAo (2D)	AAo
	▶ LA (2D or M Mode)	LA LA/Ao
	▶ LVOT D (2D)	LVOT D LVOT area
	ACS (M Mode)	ACS
	▶ LVET (M Mode)	LVET
MV	▶ EF:Slope (M Mode)	EF SLOPE
	▶ EPSS (M Mode)	EPSS
	E (Doppler)A (Doppler)	E E PG A A PG E:A
	▶ PHT (Doppler)	PHT MVA Decel time
	▶ VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
	► IVRT (Doppler)	time
	Adur (Doppler)	time
MVMR	dP:dT^b (CW Doppler)	dP:dT

Table 5-1: Cardiac calculations and results (continued)

Calculation list	Measurement name (imaging mode)	Results
СО	LVOT D (2D)HR (Doppler)LVOT VTI (Doppler)	CO SV CI SI VTI HR LVOT D
IVC	Max D (2D or M Mode)Min D (2D or M Mode)	Collapse ratio
Atria	▶ LA A4C (2D)▶ LA A2C (2D)	LA Area LA Volume Biplane
	▶ RA (2D)	RA Area RA Volume
TAPSE	TAPSE (M Mode)	TAPSE cm
Area	▶ MV (2D)	MV Area
	▶ AV (2D)	AV Area
LV mass	Epi (2D)Endo (2D)Apical (2D)	LV Mass Epi Area Endo Area D Apical

Table 5-1: Cardiac calculations and results (continued)

Calculation list	Measurement name (imaging mode)	Results
AVAV	▶ Vmax (Doppler)	Vmax PGmax
	▶ VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
LVOT	▶ Vmax (Doppler)	Vmax PGmax
	▶ VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
Al	▶ PHT (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 TVA Decel time
	▶ VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
	▶ RA pressure ^c	RVSP

Table 5-1: Cardiac calculations and results (continued)

Calculation list	Measurement name (imaging mode)	Results
PV	▶ Vmax (Doppler)	Vmax PGmax
	▶ VTI (Doppler)	VTI Vmax
	▶ AT (Doppler)	PGmax Vmean PGmean AT
PISA	▶ Ann D (2D)	PISA Area ERO
	▶ Radius (Color)	MV Rate Regurgitant Volume
	MR VTI (Doppler)	Regurgitant Fraction
	► MV VTI (Doppler)	
Qp/Qs	▶ LVOT D (2D)	D VTI
	▶ RVOT D (2D)	VMax PGmax
	▶ LVOT VTI (Doppler)	Vmean PGmean
	▶ RVOT VTI (Doppler)	SV Qp/Qs
P. Vein	A (Doppler)	VMax
	▶ Adur (Doppler)	time
	▶ S (Doppler)	VMax S/D ratio
	▶ D (Doppler)	3,0 1000
TDI	▶ (Sep) e' and a' (Doppler)	E(MV)/e' ratio
	▶ (Lat) e' and a' (Doppler)	
	▶ (Inf) e' and a' (Doppler)	
	▶ (Ant) e' and a' (Doppler)	

Table 5-1: Cardiac calculations and results (continued)

a.	You can enter the HR meas	urement three ways: Patient information form, Doppl	er measurement. See "To calculate

- a. You can enter the HR measurement three ways: Patient information form, Doppler measurement. See "To calculate Heart Rate (HR)" on page 86, or M Mode measurement See "To measure heart rate (M Mode)" on page 70.
- b. dP:dT 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 106.

Measurement name (imaging mode)

To calculate EF

- 1 On a frozen 2D image or M Mode trace, press the CALCS key.
- **2** From the calculations menu, select the measurement name.

The distance between the default placement of the two calipers is displayed.

- 3 Use the touchpad to alter the calipers. Refer to "Working with calipers" on page 67
- **4** Save the calculation as described in "To save a calculation" on page 74.
- **5** Repeat with the next measurement.

To calculate LV Volume (Simpson's Rule)

- 1 On a frozen 2D image, press the **CALCS** key.
- **2** From the calculations menu, select **EF...**.to display the LV Vol (EF) menu.
- **3** 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 as described in "To save a calculation" on page 74.

To measure LVd and LVs

- 1 On a frozen 2D image or M Mode trace, press the **CALCS** key.
- **2** From the calculations menu, select the measurement name.
- 3 Position the active (highlighted) caliper at the starting point. Refer to "Working with calipers" on page 67.

- **4** Press the **SELECT** key, and position the second caliper.
- 5 Press the **SELECT** key. Another caliper appears, and the calculations menu highlights the next measurement name.
- **6** Position the caliper, and press the **SELECT** key. Repeat for each measurement name in the calculation group.

Note

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

7 Save the calculation as described in "To save a calculation" on page 74.

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.

From the calculations menu, select **HR**. A vertical caliper appears.

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

Press the **SELECT** key. A second vertical caliper appears. The active caliper is highlighted.

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

Save the calculation as described in "To save a calculation" **on page 74**.

To measure Ao, LA, AAo, or LVOT D

- 1 On a frozen 2D image or M Mode trace, press the **CALCS** key.
- **2** From the calculations menu, select the measurement name.
- **3** Position the calipers.
- **4** Save the calculation as described in "To save a calculation" on page 74.

To measure IVC collapse

- 1 On a frozen 2D image or M Mode trace, press the **CALCS** key.
- **2** From the calculations menu, select the measurement name.

- **3** Adjust the distance of the calipers using the touchpad.
- 4 Save the calculation as described in "To save a calculation" on page 74

To measure TAPSE

- 1 On a frozen M Mode trace, press the **CALCS** key.
- **2** From the calculations menu, select the measurement name.
- **3** Adjust the distance of the calipers using the touchpad.
- **4** Save the calculation as described in "To save a calculation" on page 74.

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.
 - **a** To make a correction, select **Undo** on-screen or press the **backspace** key.
- **5** Complete the trace, and press the **SET** key.
- **6** Save the calculation as described in "To save a calculation" on page 74.

To calculate Atrial areas and volumes

- 1 On a frozen 2D image, press the **CALCS** key.
- 2 In the calculations menu, locate **Atria**, and then select the measurement name.
- **3** Position the caliper where you want to begin the trace, and press the **SELECT** key.
- **4** Using the touchpad, trace the desired area.
 - **a** To make a correction, select **Undo** on-screen or press the **backspace** key.

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

5 Complete the trace, and press the **SET** key.

6 Save the calculation as described in "To save a calculation" on page 74.

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.
 - i To make a correction, select **Undo** on-screen or press the **backspace** key.
 - **d** Complete the trace, and press the **SET** key.
 - e Save the calculation.as described in "To save a calculation" on page 74.
- **4** Select **Apical** from the calculations menu.
- 5 Positioning the calipers, measure the ventricular length. See "Working with calipers" on page 67.
- **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.
 - **c** Save the calculation as described in "To save a calculation" on page 74.

To calculate Velocity Time Integral (VTI)

Note

This calculation computes other results in addition to VTI. Refer to Table 5-1 on page 80.

- 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.
 - a To make a correction, select **Undo** on-screen, backtrack with the touchpad, or press the **backspace** key.
- **5** Press the **SET** key to complete the trace.
- **6** Save the calculation as described in "To save a calculation" on page 74.

For information on the automatic trace tool, see "To trace automatically (Doppler)" on page 72.

To calculate Right Ventricular Systolic Pressure (RVSP)

- 1 On a frozen Doppler spectral trace, press the **CALCS** key.
- 2 From the calculations menu, select **TV** and then select **TRmax**.
- **3** Position the caliper. (Refer to "Working with calipers" on page 1.)
- **4** Save the calculation as described in "To save a calculation" on page 74.

To adjust the RA pressure, refer to "To delete a vascular or cardiac measurement" on page 106.

Note

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.

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

- **3** Position the second caliper:
 - ▶ In MV, position the caliper along the EF slope.

- In AV, position the caliper at the end diastole.
- **4** Save the calculation as described in "To save a calculation" on page 74.

To calculate Proximal Isovelocity Surface Area (PISA)

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

- 1 Measure from Ann D (2D):
 - **a** On a frozen 2D image, press the **CALCS** key.
 - **b** From the calculations menu, locate **PISA**, and then select **Ann D**.
 - **c** Position the calipers.
 - **d** Save the calculation as described in "To save a calculation" on page 74.
- **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.
 - i To make a correction, select **Undo** on-screen, backtrack with the touchpad, or press the **backspace** key.
 - **d** Press the **SET** key to complete the trace.
 - e Save the calculation.

For information on the automatic trace tool, refer to "To trace automatically (Doppler)" on page 72.

To calculate Isovolumic Relaxation Time (IVRT)

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

From the calculations menu, select **MV** and then select **IVRT**. A vertical caliper appears.

- **2** Using the touchpad, position the caliper at the aortic valve closure.
- **3** Press the **SELECT** key. A second vertical caliper appears.
- **4** Using the touchpad, position the second caliper at onset of mitral inflow.
- **5** Save the calculation as described in "To save a calculation" on page 74.

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

To perform the dP:dT measurements, the CW Doppler scale must include velocities of 300 cm/s or greater on the negative side of the baseline. See "Spectral trace controls" on page 43.

- 1 On a frozen CW Doppler spectral trace, press the **CALCS** key.
- **2** From the calculations menu, select **MV**, and then select **dP:dT**.

A horizontal dotted line with an active caliper appears at 100 cm/s.

- **3** Position the first caliper along the waveform at 100 cm/s.
- **4** Press the **SELECT** key.

A second horizontal dotted line with an active caliper appears at 300 cm/s.

- **5** Position the second caliper along the waveform at 300 cm/s.
- **6** Save the calculation as described in "To save a calculation" on page 74.

To calculate Aortic Valve Area (AVA)

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

- 1 In 2D, measure from LVOT:
 - **a** On a frozen 2D image, press the **CALCS** key.
 - **b** From the calculations menu, select **LVOT D**.
 - **c** Position the calipers.
 - **d** Save the calculation as described in "To save a calculation" on page 74.

2 In Doppler, measure LVOT Vmax, and then measure AV Vmax. See "To measure peak velocity" on page 88. From the calculations menu, select **AV**, select sample site, and then select **Vmax**.:

Note

Vmax can also be determined from the VTI measurement. See "To calculate Velocity Time Integral (VTI)" on page 89. From the calculations menu, select **AV**, select sample site, and then select **VTI**.

To calculate Qp/Qs

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

- 1 On a frozen 2D image, press the **CALCS** key.
- **2** Do the following to measure from LVOT D and again to measure from RVOT D:
 - a From the calculations menu, locate **Qp/Qs** and then select **LVOT D** or **RVOT D**.
 - **b** Position the calipers.
 - **c** Save the calculation as described in "To save a calculation" on page 74.
- **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 as described in "To save a calculation" on page 74.

For information on the automatic trace tool, refer to "To trace automatically (Doppler)" on page 72.

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

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

- 1 (SI Only) Fill in the **Height** and **Weight** fields on the patient information form. The BSA is calculated automatically. Refer to "To create a new patient information form" on page 57.
- **2** Measure from LVOT (2D):

- a On a frozen 2D image, press the CALCS key.
- **b** From the calculations menu select **Ao/LA** then **LVOT D**.
- **c** Position the calipers.
- **d** Save the calculation as described in "To save a calculation" on page 74.
- **3** Measure from **LVOT** (Doppler). Refer to "To calculate Velocity Time Integral (VTI)" on page 89. From the calculations menu, select **AV** and then select **LVOT VTI**.

For information on the automatic trace tool, refer to "To trace automatically (Doppler)" on page 72.

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 For CI Only: Fill in the **Height** and **Weight** fields on the patient information form. The BSA is calculated automatically. Refer to "To create a new patient information form" on page 57.
- 2 Calculate SV as described in "To calculate Stroke Volume (SV) or Stroke Index (SI)" on page 92.
- **3** Calculate HR as described in "To calculate Heart Rate (HR)" on page 86.

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.

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

- **4** 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.

d Save the calculation as described in "To save a calculation" on page 74.

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.

Notes

- The automatic trace tool appears in yellow.The results appear at the bottom of the screen.
- **c** Freeze the image.
 - If you want to change the waveform measured, move each vertical caliper by pressing **SELECT** and then using the touchpad. Press **SET** to update the results.
 - ▶ If you invert the frozen image or move the baseline, results are cleared.
 - If you want to hide the results, select **Trace**.
- **d** Save the calculation.

To measure a Tissue Doppler Imaging (TDI) waveform

- 1 Ensure that TDI is on. Refer to "PW Doppler controls" on page 43.
- 2 On a frozen Doppler spectral trace, press the CALCS key.
- 3 From the calculations menu, select **TDI**, and then do the following for each measurement you want to take:
 - **a** From the calculations menu, select the measurement name.
 - **b** Position the calipers.
 - **c** Save the calculation as described in "To save a calculation" on page 74.

Gynecology (Gyn) calculations

Gynecology (Gyn) calculations include Uterus, Ovary, Follicle, and Volume. For instructions to calculate volume, refer to "Volume calculations" on page 76.

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.

For a list of transducers available with the gynecological exam, see "Imaging modes and exams available by transducer" on page 50.

To measure uterus or ovary

- 1 On a frozen 2D image, press the CALCS key.
- 2 From the calculations menu, select **Gyn**.
- 3 Do the following for each measurement you want to take:
 - **a** Select the measurement name from the calculations menu.
 - **b** Position the calipers.
 - **c** Save the calculation as described in "To save a calculation" on page 74.

To measure follicles

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

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

- 1 On a frozen 2D image, press the CALCS key.
- 2 From the calculations menu, select Follicle.
- **3** Do the following for each measurement you want to take:
 - a From the calculations menu, select the follicle number under Right Fol or Left Fol.
 - **b** Position the calipers. Refer to "Working with calipers" on page 67.
- 4 Save the calculation as described in "To save a calculation" on page 74.

OB calculations

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

WARNINGS

- ▶ Make sure that you have selected the OB exam type and the OB author for the OB calculation table you intend to use. Refer to "" on page 97.
- ▶ 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.
- ▶ 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.

For a list of transducers available with the obstetrical exam, see "Imaging modes and exams available by transducer" on page 50.

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 the "Glossary" on page 237. To select authors, see "OB Calculations setup" on page 30.

See also "OB Custom Measurements setup" on page 31 and "OB Custom Tables setup" on page 31.

Table 5-2: 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
	НС	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	HC, AC, FL	Hadlock 1
(EFW) ^c	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.

Table 5-2: Results from System-Defined OB Measurements and Table Authors (continued)

Calculation Result	Gestational OB Measurements	Table Authors
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
Growth Analysis Tables ^d	BPD	Chitty, Hadlock, Jeanty
	НС	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 30. 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.
 - **b** For twins, select **Twin A** or **Twin B**, and then select the measurement name.

Note

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

- c Position the calipers.
- **d** Save the calculation as described in "To save a calculation" on page 74.

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 as described in "To save a calculation" on page 74.

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)

Moto

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

- 1 Select **OB** exam type, and select **LMP** or **Estab.DD** in the patient information form.
- **2** On a frozen Doppler spectral trace, press the **CALCS** key.
- **3** Do the following for each measurement you need to take:

- **a** From the calculations menu, select the measurement name under **MCA** (Middle Cerebral Artery) or **UmbA** (Umbilical Artery).
- **b** Position the calipers:
 - For **S/D**, **RI**, position the first caliper at the peak systolic waveform. Press the **SELECT** key, and position the second caliper at the end diastole on the waveform.

For **S/D**, **RI**, **PI**, position the caliper at the beginning of the desired waveform, and press the **SELECT** key. Use the touchpad to manually trace the desired area. Press the **SET** key.

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

c Save the calculation as described in "To save a calculation" on page 74.

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

Small Parts and MSK calculations

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

For instructions to calculate volume, see "Volume calculations" on page 76.

For a list of transducers available with the Small Parts and MSK exams, see "Imaging modes and exams available by transducer" on page 50.

To calculate hip angle

- 1 On a frozen 2D image, press the **CALCS** key.
- 2 From the calculations menu, select **Right** or **Left**.

Select **Baseline** under **Hip Angle**. A baseline appears on-screen.

3 Position the baseline, and press the **SET** key. See "Working with calipers" on page 67.

Line A (alpha line) appears on-screen, and **Line A** is selected in the calculations menu.

4 Position Line A, and save the measurement. See "To save a calculation" on page 74.

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

5 Position Line B, and save the measurement.

To calculate d:D ratio (Small Parts only)

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

- **2** From the calculations menu, select **Right** or **Left**.
- **3** Under **d:D Ratio**, select **Fem Hd** (femoral head).
- **4** Using the touchpad, position and resize the circle. The **SELECT** key toggles between position and size.
 - Press the **SET** key. The baseline automatically appears with the left caliper active.
- **5** Position the caliper. See "Working with calipers" on page 67.
- **6** Save the measurement as described in "To save a calculation" on page 74.

Transcranial Doppler and Orbital calculations

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 misdiagnosis or harming the patient outcome, start a new patient information form before starting a new patient exam and performing calculations. Starting a new patient information form clears the previous patient's data. The previous patient's data will be combined with the current patient if the form is not first cleared. Refer to "To create a new patient information form" on page 57.

The following table shows the measurements required to complete Transcranial Doppler (TCD) and Orbital (Orb) calculations. For definitions of acronyms, see the "Glossary" on page 237.

For a list of transducers available with the transcranial and orbital exams, see "Imaging modes and exams available by transducer" on page 50.

Table 5-3: 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
ТТ	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 5-3: Transcranial and Orbital calculations (continued)

Menu Heading	TCD and Orb Measurements	Results
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) exam type when performing imaging through the eye. The FDA has established lower acoustic energy limits for opthalmic 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 Opthalmic Artery and Siphon
 - ▶ Transcranial (TCD) for other measurements

See "To change the exam type" on page 50.

- 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.

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

- **c** Press the **SET** key.
- **d** Save the calculation as described in "To save a calculation" on page 74.

Vascular calculations

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. Refer to "To create a new patient information form" on page 57.
- ▶ To avoid incorrect calculations, verify that the patient information, date, and time settings are accurate.

For a list of transducers available with vascular (arterial) exams, see "Imaging modes and exams available by transducer" on page 50.

The vascular measurements that you can save to the patient report are listed in the following table. For definitions of acronyms, see the "Glossary" on page 237.

Table 5-4: Vascular calculations

Menu Heading	Vascular Measurement	Calculation Results
CCA	Prox	s (systolic), d (diastolic)
	Mid	s (systolic), d (diastolic)
	Dist	s (systolic), d (diastolic)
	Bulb	s (systolic), d (diastolic)
ICA	Prox	s (systolic), d (diastolic)
	Mid	s (systolic), d (diastolic)
	Dist	s (systolic), d (diastolic)
ECA	Prox	s (systolic), d (diastolic)
	Mid	s (systolic), d (diastolic)
	Dist	s (systolic), d (diastolic)
	VArty	s (systolic), d (diastolic)

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Table 5-5: Vascular measurements and results

Menu Heading	Vascular Measurement	Calculation Results
CCA	Prox	s (systolic), d (diastolic)
	Mid	s (systolic), d (diastolic)
	Dist	s (systolic), d (diastolic)
	Bulb	s (systolic), d (diastolic)
ICA	Prox	s (systolic), d (diastolic)
	Mid	s (systolic), d (diastolic)
	Dist	s (systolic), d (diastolic)
ECA	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.

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- **b** Using the touchpad, position the caliper at the peak systolic waveform.
 - Press the **SELECT** key. A second caliper appears.
- c Using the touchpad, position the second caliper at the end diastole on the waveform.
- **d** Save the calculation as described in "To save a calculation" on page 74.

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).

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**.

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 highlighted.
- 2 Select **Delete** on-screen.

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

To modify the ICA/CCA ratio (Vascular)

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

To adjust the RA pressure (Cardiac)

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

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

TCD patient report

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

To delete a row of TCD measurements

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

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

On the OB patient report, select the OB measurement by using the touchpad. The selected measurement is highlighted.

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

To fill out the OB anatomy checklist

You can document reviewed anatomy.

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

To complete the OB biophysical profile

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

To display OB graphs

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

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

In the Graphs list, select the desired measurement/author. The graph for the selected measuremen
appears. You can select another measurement/author or select 📋 1/x on-screen.

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

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

EMED and MSK worksheets

This feature is optional.

To display an EMED worksheet

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

- 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 **\(\bar{\text{L}} \) x/x** on-screen.

To display an MSK worksheet

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

- 1 During or after the exam, press the **REPORT** key.
- 2 Select MSK on-screen.
- 3 Select the worksheet from the Worksheet list.
 - **a** To display additional pages in the worksheet, select $\ \square$ **x/x** on-screen. Each worksheet has its own Comments field, which remains on-screen even if you display another page in the worksheet.
 - **b** If you want to save a worksheet page, press the **SAVE** key.

Chapter 6: Measurement References

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 6-1: 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 ²
Circumference ^d	< ±3% plus (1.4% of full scale/ smallest dimension) * 100 plus 0.5%	Acquisition	Phantom	0.01-96 cm

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

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Table 7: 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

a. Full scale for distance implies the maximum depth of the image.

Table 8: PW Doppler Mode measurement and calculation accuracy and range

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

a. FUJIFILM SonoSite special test equipment was used.

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.

b. An RMI 413a model phantom with 0.7 dB/cm MHz attenuation was used.

c. Full scale for time implies the total time displayed on the scrolling graphic image.

d. FUJIFILM SonoSite special test equipment was used.

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

c. Full scale for time implies the total time displayed on the scrolling graphic image.

▶ **Algorithmic Error** is 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/s²

Zwiebel, 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, and A.J. Tajik. *The Echo Manual*. 3rd Edition, Philadelphia: Lippincott, Williams, and Wilkins, (2007), 147-148.

|time a - time b|

Aortic Valve Area (AVA) by Continuity Equation in cm²

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

$$A_2 = A_1 * V_1/V_2$$

where:

 $A_2 = Ao valve area$

 $A_1 = LVOT$ area; $V_1 = LVOT$ velocity; $V_2 = Ao$ valve velocity

LVOT = Left Ventricular Outflow Tract

AVA $(PV_{IVOT}/PV_{AO}) * CSA_{IVOT}$

AVA (VTI_{LVOT}/VTI_{AO}) * CSA_{LVOT}

Body Surface Area (BSA) in m²

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

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

Weight = kilograms

Height = centimeters

Cardiac Index (CI) in I/min/m²

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

CI = CO/BSA

where:

CO = Cardiac Output

BSA = Body Surface Area

Cardiac Output (CO) in I/min

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

CO = (SV * HR)/1000

where:

CO = Cardiac Output

SV = Stroke Volume (ml)

HR = Heart Rate

Cross Sectional Area (CSA) in cm²

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

 $CSA = 0.785 * D^2$

where: D = diameter of the anatomy of interest

Deceleration Time in msec

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

|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

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

ERO = MV Flow Rate/MR Vel * 100

Ejection Fraction (EF), percent

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

EF = ((LVEDV - LVESV)/LVEDV) * 100%

where:

EF = Ejection Fraction

LVEDV = Left Ventricular End Diastolic Volume

LVESV = Left Ventricular End Systolic Volume

Elapsed Time (ET) in msec

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.

IVSFT = ((IVSS - IVSD)/IVSD) * 100%

where:

IVSS = Interventricular Septal Thickness at Systole

IVSD = Interventricular Septal Thickness at Diastole

Isovolumic Relaxation Time (IVRT) in msec

Oh, J. K., J. B. Seward, and A. J. Tajik. The Echo Manual. 3rd Edition. Philadelphia: Lippincott Williams and Wilkins, (2007), 123-124.

|time a - time b|

IVC Collapse

Lyon M, Verma N. "Ultrasound guided volume assessment using inferior vena cava diameter." *Open Emerg Med J.* (2010) 3:22-24.

(IVCd exp – IVCd insp)/IVCd exp

where:

expiration (exp) = maximum diameter (Max D)

inspiration (insp) = minimum diameter (Min D)

Left Atrium/Aorta (LA/Ao)

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

Left Atrial Volume

Lang R. et al. "Recommendations for Cardiac Chamber quantification by Echocardiography in Adults: An update from the American Society of Echocardiography and European Association of Cardiovascular Imaging." *J Am Soc Echocardiography*, January (2015), 20-28.

LA Vol = $\pi/4$ (h) Σ (D1)(D2)

where:

LA Vol = Left Atrial Volume in ml

h = Height of stacked oval disks making up the LA

D1 = Orthogonal minor axis

D2 = Orthogonal major axis

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 for 2D

Oh, J.K., J.B. Seward, and A.J. Tajik. *The Echo Manual*. 3rd Edition, Philadelphia: Lippincott Williams and Wilkins, (2007), 113-114.

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

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, and A.J. Tajik. *The Echo Manual*. 3rd Edition, Philadelphia: Lippincott Williams and Wilkins, (2007), 115.

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

where:

LVID = Internal Dimension

PWT = Posterior Wall Thickness

IVST = Interventricular Septal Thickness

1.04 = Specific gravity of the myocardium

0.8 = Correction factor

Left Ventricular Volume: Biplane Method in ml

Schiller, N.B., P.M. Shah, M. Crawford, et.al. "Recommendations for Quantitation of the Left Ventricle by Two-Dimensional Echocardiography." *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

Schiller, 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, and A.J. Tajik. *The Echo Manual*. 3rd Edition, Philadelphia: Lippincott Williams and Wilkins, (2007), 115.

LVDFS = ((LVDD - LVDS)/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. Malerque. The Essentials of Echocardiography. Le Hague: Martinus Nijhoff, (1981), 71.

LVPWFT = ((LVPWS - LVPWD)/LVPWD) * 100%

where:

LVPWS = Left Ventricular Posterior Wall Thickness at Systole

LVPWD = Left Ventricular Posterior Wall Thickness at Diastole

Mean Velocity (Vmean) in cm/s

Vmean = mean velocity

Mitral Valve Area (MVA) in cm²

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

MVA = 220/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

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

Flow = PISA * Va

where:

PISA = Proximal Isovelocity SurfaceArea

Va = aliasing velocity

Pressure Gradient (PGr) in mmHG

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

 $PGr = 4 * (Velocity)^2$

Peak E Pressure Gradient (E PG)

 $E PG = 4 * PE^2$

Peak A Pressure Gradient (A PG)

 $A PG = 4 * PA^2$

Peak Pressure Gradient (PGmax)

 $PGmax = 4 * PV^2$

Mean Pressure Gradient (PGmean)

PGmean = Average of pressure gradients/Duration of flow

Pressure Half Time (PHT) in msec

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

PHT = DT * 0.29

where: DT = deceleration time

Proximal Isovelocity Surface Area (PISA) in cm²

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

 $PISA = 2\pi r^2$

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), 70-72.

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

where:

RVOT SV = RVOT CSA* RVOT VTI = $\pi/4$ * RVOT diameter²* RVOT VTI LVOT SV = LVOT CSA * LVOT VTI = $\pi/4$ * LVOT diameter²* LVOT VTI

Regurgitant Fraction (RF) in percent

Oh, J.K., J.B. Seward, and A.J. Tajik. *The Echo Manual*. 3rd Edition, Boston: Philadelphia: Lippincott Williams and Wilkins, (2007), 73-76.

RF = RV / MV SV

where:

RV = Regurgitant Volume

MV SV = Mitral Stroke Volume (Mitral CSA * Mitral VTI)

Mitral CSA = cross-sectional area calculated using Annulas Diameter

Regurgitant Volume (RV) in cc

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

RV = ERO * MR VTI/100

Right Atrial Volume

Lang R, Bierig M, et al. "Recommendations for chamber quantification: a report from the American Society of Echocardiography's guidelines and standards committee and the chamber quantification writing group, Developed in conjunction with the European Association of Echocardiography, a branch of the European Society of Cardiology." *J Am Soc Echocardiography*. (2005), 18: 1440-1463.

Wang Y, Gutman J, et al. "Right atrial volume in a normal adult population by two-dimensional echocardiography." *Chest*, (1984), 86: 595-601.

RA Vol = $\pi/4$ (h) Σ (D1)2

RA Vol Index = RA Vol/BSA (ml/L2)

where:

RA Vol = Right Atrial Volume in ml h = Height of stacked circular disks making up the RA D1 = Orthogonal minor axis

Right Ventricular Systolic Pressure (RVSP) in mmHg

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

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

where: RAP = Right Atrial Pressure

S/D

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd Edition, 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 Edition, (1994), 1492.

SI = SV/BSA

where:

SV = Stroke Volume

BSA = Body Surface Area

Stroke Volume (SV) Doppler in ml

Oh, J.K., J.B. Seward, and A.J. Tajik. *The Echo Manual*. 3rd Edition, Philadelphia: Lippincott, Williams, and Wilkins, (2007), 69-71.

SV = (CSA * VTI)

where:

CSA = Cross Sectional Area of the orifice (LVOT area)

VTI = Velocity Time Integral of the orifice (LVOT VTI)

Stroke Volume (SV) 2D and M Mode in ml

Oh, J.K., J.B. Seward, and A.J. Tajik. The Echo Manual. 2nd Edition, Boston: Little, Brown and Company, (1994), 44.

SV = (LVEDV - LVESV)

where:

SV = Stroke Volume

LVEDV = End Diastolic Volume

LVEDSV = End Systolic Volume

TAPSE

Rudski L, Lai W, et al. "Guidelines for the echocardiographic assessment of the right heart in adults: a report from the American Society of Echocardiography." *J Am Soc Echocardiogr.* (2010), 685-713.

Tricuspid Valve Area (TVA)

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

TVA = 220 / PHT

Velocity Time Integral (VTI) in cm

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

VTI = sum of abs (velocities [n])

where: Auto Trace – distance (cm) blood travels with each ejection period. Velocities are absolute values.

Obstetrical references

Amniotic Fluid Index (AFI)

Jeng, C. J., et al. "Amniotic Fluid Index Measurement with the Four Quadrant Technique During Pregnancy." *The Journal of Reproductive Medicine*, 35:7 (July 1990), 674-677.

Average Ultrasound Age (AUA)

The system provides an AUA derived from the component measurements from the measurement tables.

Estimated Date of Delivery (EDD) by Average Ultrasound Age (AUA)

Results are displayed as month/day/year.

EDD = system date + (280 days - AUA in days)

Estimated Date of Delivery (EDD) by Last Menstrual Period (LMP)

The date entered into the patient information for LMP must precede the current date.

Results are displayed as month/day/year.

EDD = LMP date + 280 days

Estimated Fetal Weight (EFW)

Hadlock, F., et al. "Estimation of Fetal Weight with the Use of Head, Body, and Femur Measurements, A Prospective Study." *American Journal of Obstetrics and Gynecology*, 151:3 (February 1, 1985), 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:

GA(LMP) = System date - 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:

GA(LMPd) = System Date - LMPd

Last Menstrual Period Derived (LMPd) by Established Due Date (Estab. DD)

Results are displayed as month/day/year.

LMPd(Estab. DD) = Estab. DD - 280 days

Gestational age tables

Abdominal Circumference (AC)

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." *Radiology*, 152: (1984), 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 = abs (Velocity A/Velocity B)

where:

A = velocity cursor +

B = velocity cursor x

Acceleration Index (ACC)

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

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.

% Area Reduction = $(1 - A2(cm^2)/A1(cm^2)) * 100$

where:

A1 = original area of the vessel in square cm

A2 = reduced area of the vessel in square cm

Percent Diameter Reduction

Handa, Nobuo et al., "Echo-Doppler Velocimeter in the Diagnosis of Hypertensive Patients: The Renal Artery Doppler Technique," *Ultrasound in Medicine and Biology*, 12:12 (1986), 945-952.

% Diameter Reduction = (1 - D2(cm)/D1(cm)) * 100

where:

D1 = original diameter of the vessel in cm

D2 = reduced diameter of the vessel in cm

Pressure Gradient (PGr) in mmHG

Oh, J.K., J.B. Seward, A.J. Tajik. The Echo Manual. 2nd ed., Lippincott, Williams, and Wilkins, (1999), 64.

4 * (Velocity)²

Peak E Pressure Gradient (E PG)

 $E PG = 4 * PE^2$

Peak A Pressure Gradient (A PG)

APG = 4 * PA2

Peak Pressure Gradient (PGmax)

PGmax = 4 * PV2

Mean Pressure Gradient (PGmean)

 $PGmean = 4 * Vmax^2$

Pulsatility Index (PI)

Kurtz, A.B., W.D. Middleton. Ultrasound-the Requisites. Mosby Year Book, Inc., (1996), 469.

PI = (PSV - EDV)/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.

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

where:

A = velocity cursor +

B = velocity cursor x

Time Averaged Mean (TAM) in cm/s

TAM = mean (mean Trace)

Time Averaged Peak (TAP) in cm/s

TAP = peak (peak Trace)

Volume (Vol)

Beyer, W.H. Standard Mathematical Tables, 28th ed., CRC Press, Boca Raton, FL, (1987), 131.

Volume cm³= $(4/3) * \pi * \text{Length/2} * \text{Width/2} * \text{Height/2}$

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: 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 2.

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 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.

Printing does not work.

- ▶ Select the printer on the Connectivity setup screen.
- ▶ Check the printer connections.
- ▶ Ensure that the printer is turned on and set up properly. See the printer manufacturer's instructions, if necessary.

System does not recognize the transducer.

Disconnect and reconnect the transducer.

System prompts you to "ensure the USB device is valid."

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- ▶ 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 are present on the USB storage device.
- ▶ Reexport the original data onto the USB storage device.
- ▶ Contact your system administrator.

System displays the alert "Incompatible power supply "

Use the power supply that shipped with the system.

System displays the alert "The external video is not functional"

Make sure that the system is securely attached to the dock.

System displays the alert "Maximum number of procedure entries reached" when trying to create a patient information form.

Free up internal storage space by archiving or exporting patient exams and then deleting them from the system.

System displays the alert "Unable to save image or clip. You have reached the maximum number of images/clips allowed for a single patient."

Delete any unwanted images or clips from the patient exam.

Software licensing

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

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

Caution

After the grace period expires, all system functions except licensing are unavailable until a valid license key is entered.

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To obtain a license key for your software, contact FUJIFILM SonoSite Technical Support. See "Getting help" on page 2. You need to provide the following information. Refer to "System Information setup" on page 34.

System Software	Transducer Software
Name of person installing the upgrade	Name of person installing the upgrade
Serial number (on bottom of system)	Serial number (on bottom of system)
ARM version	Transducer package version
PCBA serial number	PCBA serial number

After you obtain a license key, you must enter it into the system.

To enter a license key

- 1 Turn on the system. The license update screen appears.
- 2 Enter the license key in the Enter license number field.
- 3 Select Done on-screen.
- 4 If a transducer package upgrade was also performed, the transducer package license screen will appear.
- **5** Enter the transducer package license key in the **Enter license number** field.
- 6 Select **Done** on-screen.

Note

If you entered a valid license key but the license update screen appears, verify that you entered the license key correctly. If the license update screen still appears, contact FUJIFILM SonoSite Technical Support. See "Getting help" on page 2.

Maintenance

No periodic or preventive maintenance is required for the system, transducer, or accessories other than cleaning and disinfecting the transducer after every use. See Chapter 8, "Cleaning and Disinfecting.". There are no internal components that require periodic testing or calibration. All maintenance requirements are described in this user guide. Performing maintenance procedures not described in the user guide may void the product warranty.

Contact FUJIFILM SonoSite Technical Support for any maintenance questions.

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Chapter 8: Cleaning and Disinfecting

This chapter includes instructions for cleaning and disinfecting the ultrasound system, transducers, and accessories.

Use the FFSS 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.

Cleaning and disinfecting the system and transducer

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.

See Chapter 2, "Getting Started," for images of the ultrasound system.

See www.sonosite.com for transducer images.

Before getting started

- ▶ **Follow** the disinfectant manufacturer's recommendations regarding appropriate personal protective equipment (PPE), such as protective eyewear and gloves.
- ▶ **Inspect** the system to determine that it is free of any unacceptable deterioration, such as corrosion, discoloration, pitting, or cracked seals. If damage is evident, discontinue use, and contact FUJIFILM SonoSite or your local representative.
- ▶ **Confirm** that cleaning and disinfecting materials are appropriate for your facility's use. FUJIFILM SonoSite tests cleaners and disinfectants for use with the FUJIFILM SonoSite systems and transducers.
- ▶ **Verify** expiration dates, concentration, and efficacy of chemicals (for example, a chemical strip test). Disinfectants and cleaning methods listed 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 to 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 Sono Site recommended cleaners or disinfectants.

Determining the required cleaning and disinfecting level

Note

Be aware that you must perform both a cleaning as well as a disinfection for each component. For example, if a linear transducer was used in a procedure and has blood on it, it must go through the semi-critical work flow.

The level of cleaning and disinfecting required for the system is dictated by the type of tissue it contacts during use. Use Table 8-1 to determine the level of cleaning and disinfecting required.

Spaulding classifications

Spaulding classifications (non-critical, semi-critical) determine the approach for cleaning and disinfecting medical equipment based on the device, the way it has been used, and the risk of infection. The system and transducers are designed for use within the Spaulding classifications of non-critical and semi-critical uses. See Table 8-1.

Table 8-1: Cleaning and disinfecting guide

Did any part of the system or transducer come in contact with broken skin, blood, or bodily fluids?

A

YES

Came in contact with broken skin, blood, or bodily fluid



Option A

"Option A: Semi-critical cleaning of system and transducer and disinfecting of system and transducer (semi-critical uses)" on page 139

OR

Table 8-1: Cleaning and disinfecting guide (continued)

Did any part of the system or transducer come in contact with broken skin, blood, or bodily fluids?

B

NO

Did not come in contact with broken skin, blood, or bodily fluid



Option B

"Option B: Non-critical cleaning and low-level disinfecting of system and transducer (non-critical uses)" on page 143

Option A: Semi-critical cleaning of system and transducer and disinfecting of system and transducer (semi-critical uses)

Part 1 of 2: Cleaning of system and transducer and disinfecting of system for semi-critical contact

Follow the manufacturer's instructions when using cleaners and disinfectants. The materials listed in Table 8-2 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.

Table 8-2: Cleaner transducer compatibility and wet contact time

Product	Transducer	System	Wet Contact Time
SaniCloth AF3* (gray top)	C11x, HFL38xi, HFL50x, HSL25x, ICTx, L25x, L38xi, P10x, P11x, rC60xi, rP19x,	√	3 minutes
SaniCloth Plus (red top)	C11x, HFL38xi, HFL50x, HSL25x, ICTx, L25x, L38xi, P10x, P11x, rC60xi, rP19x	V	3 minutes
PI-Spray II	C11x, HFL38xi, HFL50x, HSL25x, ICTx, L25x, L38xi, P10x, P11x, rC60xi, rP19x	\checkmark	10 minutes

^{*}Qualified for use as an intermediate-level disinfectant for mycobacteria. For a more complete list, refer to the cleaners and disinfection document available at www.sonosite.com.

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.
- ▶ 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

Be aware that you must perform both a cleaning as well as a disinfection for each component. For example, if a linear transducer was used in a procedure and has blood on it, it must go through the semi-critical work flow.

To clean the system and transducer

- 1 **Turn off** the system by pressing the **Power button.**
- **2 Unplug** the power cord from the outlet.
- **3 Disconnect** the transducer from the system.
- **4 Remove** the disposable transducer sheath, if applicable.
- **5 Use** either a pre-moistened wipe or a soft cloth dampened with cleaner or disinfectant.

See Table 8-2, "Cleaner transducer compatibility and wet contact time" on page 139.

- **6 Clean** the exterior surfaces of the ultrasound system to remove any debris or bodily fluids, by **wiping** from clean areas to the soiled areas to avoid cross-contamination.
- **7 Clean** the cable and transducer body, by **wiping** the cable and transducer body, starting from the transducer cable, in a downward motion toward the scanhead.

Caution

Do not allow moisture near the electronic components of the connector.

8 Ensure that the system and transducer stay wet with the disinfectant for the wet contact time listed in Table 8-2, "Cleaner transducer compatibility and wet contact time" on page 139.

9 Verify that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 6, 7, and 8 with a new wipe.

WARNING

Failure to remove all gel, debris, and bodily fluid could leave contaminants on the transducer.

10 Examine the transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use of the transducer, and contact FUJIFILM SonoSite or your local representative.

Part 2 of 2: High-level disinfecting of transducer for semi-critical contact

WARNINGS

- ▶ Be sure to use the appropriate Personal Protective Equipment (PPE) whenever necessary.
- ▶ 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 skip any steps or abbreviate the disinfecting process in any way.
- ▶ Do not use unapproved disinfecting agents.
- ▶ 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.

Table 8-3: Compatible high-level disinfectants for immersing the transducer

Disinfectants	Transducer	Temperature	Disinfectant Soak Duration	Clean Water Soak Time
Cidex	C11x, HFL38xi, HFL50x, HSL25x, ICTx, L25x, L38xi, P10x, P11x, rC60xi, rP19x	23°C, 73°F	45 minutes	3 x 1 minute
Cidex OPA	C11x, HFL38xi, HFL50x, HSL25x, ICTx, L25x, L38xi, P10x, P11x, rC60xi, rP19x	23°C, 73°F	12 minutes	3 x 1 minute

For a more complete list, refer to the cleaners and disinfection document available at www.sonosite.com.

To disinfect the transducer

1 Immerse the transducer in the high-level disinfectant solution. Refer to Table 8-3, "Compatible high-level disinfectants for immersing the transducer" on page 141 for soak times. Ensure that the connector and most of the cable remain out of thefluid. You may submerge 2 inches (5 cm) of the cable proximal to the transducer scanhead. Refer to Figure 8-1.

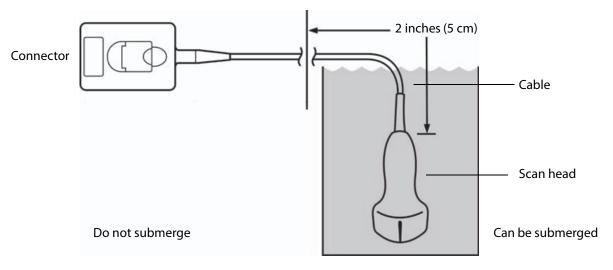


Figure 8-1 Transducer component names

2 Rinse by soaking the transducer in sterile or filtered water, according to the disinfectant manufacturer's instructions. Ensure that the connector and most of the cable remain out of the fluid. See Table 8-3, "Compatible high-level disinfectants for immersing the transducer" on page 141 for a list of sterile water soak times.

For example, Cidex OPA recommends a minimum1-minute soak repeated three times. This requires either replacing the water three times or having three bins with fresh water.

- **3 Dry** with a sterile lint-free cloth, or allow to air dry completely in a well-ventilated area.
- 4 Examine the transducer and cable for damage, such as cracks or splitting where fluid can enter.

If damage is evident, discontinue use of the transducer, and contact FUJIFILM SonoSite or your local representative.

Option B: Non-critical cleaning and low-level disinfecting of system and transducer (non-critical uses)

Follow the manufacturer's instructions when using cleaners and disinfectants. The materials listed in the table below are chemically compatible with the system and transducers. Confirm that the cleaners and disinfectants are appropriate for your facility's use.

Table 8-4: Cleaner transducer compatibility and wet contact time

Product	Transducer	System	Wet Contact Time
SaniCloth AF3* (gray top)	C11x, HFL38xi, HFL50x, HSL25x, ICTx, L25x, L38xi, P10x, P11x, rC60xi, rP19x	√	3 minutes
SaniCloth Plus (red top)	C11x, HFL38xi, HFL50x, HSL25x, ICTx, L25x, L38xi, P10x, P11x, rC60xi, rP19x	V	3 minutes
PI-Spray II	C11x, HFL38xi, HFL50x, HSL25x, ICTx, L25x, L38xi, P10x, P11x, rC60xi, rP19x	V	20 minutes

^{*}Qualified for use as an intermediate-level disinfectant for mycobacteria. For a more complete list, refer to the cleaners and disinfection document available at www.sonosite.com.

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 disinfect a transducer or transducer cable using a method or chemical that is not included here. Doing so can damager the transducer and void the warranty.

Note

Be aware that you must perform both a cleaning as well as a disinfection for each component. For example, if a linear transducer was used in a procedure and has blood on it, it must go through the semi-critical work flow.

To clean the system and transducer

- 1 Turn off the system by pressing the Power button.
- **2 Unplug** the power cord from the outlet.
- **3 Disconnect** the transducer from the system.
- **4 Remove** the transducer sheath, if applicable.
- **5 Use** either a pre-moistened wipe or a soft cloth dampened with cleaner and disinfectant.

See Table 8-4, "Cleaner transducer compatibility and wet contact time" on page 143 for a list of compatible materials.

- **6 Clean** the exterior surfaces of the ultrasound system to remove any debris or bodily fluids, by **wiping** from clean areas to the soiled areas to avoid cross-contamination.
- **7 Clean** the cable and transducer body, by **wiping** the cable and transducer body, starting from the transducer cable, in a downward motion toward the scanhead.

Caution Do not allow moisture near the electronic components of the connector.

8 Ensure that the system and transducer stay wet with the disinfectant for the wet time listed in Table 8-4, "Cleaner transducer compatibility and wet contact time" on page 143.

This may require reapplication to achieve the required wet time.

- **9 Verify** that all gel, debris, and bodily fluids have been removed from the system and transducer. If necessary, repeat steps 6, 7, and 8 with a new wipe.
- **10 Allow** the transducer and system to air dry in a clean, well-ventilated space.
- **11 Examine** the system, transducer and cable for damage, such as cracks or splitting where fluid can enter. If damage is evident, do not use the transducer. Instead, contact FuljiFilm SonoSite or your local representative.

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.

Vote

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.
- 4 Air dry.

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 the ECG cable and slave cable

Caution

To avoid damaging the ECG cable, do not sterilize.

To clean and disinfect the ECG cable (wipe method)

- **1** Remove the cable from the system.
- **2** Examine the EGC cable for damage such as cracks or splitting.

- **3** Clean the surface using a soft cloth lightly dampened in a mild soap, cleaning solution, or pre-moistened wipe. Apply the solution to the cloth rather than the surface.
- **4** Wipe the surfaces with a FUJIFILM SonoSite Approved cleaner or disinfectant
- **5** Air dry or dry with a clean cloth.

For more information on the ECG slave cable refer to the ECG Slave Cable User Guide.

Chapter 9: Safety

This chapter contains ergonomic, electrical, and clinical safety information required by regulatory agencies. The information applies to the ultrasound system, transducer, accessories, and peripherals. This chapter also defines labeling symbols, specifications, and standards.

For safety information regarding the ALARA principle and acoustic output, see Chapter 10, "Acoustic Output."

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 refer to 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.

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- 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*. (May1997), 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.
- 5. Habes, D.J. and S. Baron. "Health Hazard Report 99-0093-2749." *University of Medicine and Dentistry of New Jersey.* (1999).
- 6. Vanderpool, H.E., E.A. Friis, B.S. Smith, and K.L. Harms. "Prevalence of Carpal Tunnel Syndrome and Other Work-related Musculoskeletal Problems in Cardiac Sonographers." *Journal of Medicine*. 35:6 (1993), 605-610.

Position the system

Promote comfortable shoulder, arm, and hand postures

Use a stand to support the weight of the ultrasound system.

Minimize eye and neck strain

- ▶ If possible, position the system within reach.
- ▶ Adjust the angle of the system and display to minimize glare.
- If using a stand, adjust its height so that the display is at or slightly below eye level.

Position yourself

Support your back during an exam

- Use a chair that supports your lower back, that adjusts to your work surface height, that promotes a natural body posture, and that allows 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.

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▶ 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

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

The system complies with the standards as listed in the Standards section of this document. Refer to "Standards" on page 172.

For maximum safety observe the following warnings and cautions.

WARNINGS

- ▶ 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 discomfort or minor risk of patient injury, keep hot surfaces away from the patient.
- ▶ Under certain circumstances, parts of the enclosure can reach temperatures that exceed EN60601-1 limits for patient contact, therefore only the operator shall handle the system. This does not include the transducer face.
- ▶ To avoid the risk of injury, do not operate the system in the presence of flammable gases or anesthetics. Explosion can result.
- ▶ To avoid the risk of electrical shock or injury, do not open the system enclosures. All internal adjustments and replacements, except battery replacement, must be made by a qualified technician.

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WARNING

- ▶ 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 be achieved only 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 allow any part of the system (including the bar code scanner, external mouse, power supply, power supply connector, external keyboard, and so on), except for the transducer or ECG leads, to touch the patient.
 - ▶ Do not touch any of the following:
 - The power supply and the patient at the same time.
 - ▶ 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 TTC if no transducers are connected.

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WARNINGS

- ▶ Do not connect the system's power supply or a docking system to a multiple portable socket outlet (MPSO) or extension cord.
- ▶ Before using the transducer, inspect the transducer face, housing, and cable. Do not use the transducer if the transducer or cable is damaged.
- Always disconnect the power supply from the system before cleaning the system.
- Do not use any transducer that has been immersed beyond the specified cleaning or disinfection level. Refer to Chapter 8, "Cleaning and Disinfecting."
- Use only accessories and peripherals recommended by FUJIFILM SonoSite, including the power supply. Connection of accessories and peripherals not recommended by FUJIFILM SonoSite could result in electrical shock. Contact FUJIFILM SonoSite or your local representative for a list of accessories and peripherals available from or recommended by FUJIFILM SonoSite.
- ▶ To avoid the risk of electrical shock and fire hazard:
 - Inspect the power supply, AC power cords, cables, and plugs on a regular basis. Ensure that they are not damaged.
 - ▶ The power cord set that connects the power supply of the ultrasound system or the stand to mains power must only be used with the power supply or docking system, and cannot be used to connect other devices to mains power.
- ▶ To prevent injury to the operator/bystander, the transducer must be removed from patient contact before the application of a high-voltage defibrillation pulse.
- ▶ To avoid possible electrical shock or electromagnetic interference, verify proper operation and compliance with relevant safety standards for all equipment before clinical use. Connecting additional equipment to the ultrasound system constitutes configuring a medical system. FUJIFILM SonoSite recommends verifying that the system, all combinations of equipment, and accessories connected to the ultrasound system comply with relevant installation requirements and safety standards.

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.

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Electrical safety classification

Class I equipment The ultrasound system is classified as Class I equipment when pow-

ered 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 appli-

cable to the ultrasound system or the stand.

AC powered peripherals that may be used with the system are Class I and are individually protectively earthed. Ground bond testing may be conducted on

each AC powered peripheral.

only)

Type BF applied parts Ultrasound transducers

Type CF applied parts ECG module/ECG leads

IPX-7 (watertight equipment) Ultrasound transducers

IPX-8 (watertight equipment) Footswitch

Non AP/APG Ultrasound system power supply, docking system, and peripherals.

Equipment is not suitable for use in the presence of flammable

anesthetics.

Equipment safety

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

Cautions

- Excessive bending or twisting of cables can cause a failure or intermittent operation.
- Improper cleaning or disinfecting of any part of the system can cause permanent damage. For cleaning and disinfecting instructions, refer to Chapter 8, "Cleaning and Disinfecting."

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Battery safety

To prevent the battery from bursting, igniting, or emitting fumes and causing personal injury or equipment damage, observe the following precautions.

WARNINGS

- ▶ The battery has a safety device. Do not disassemble or alter the battery.
- ▶ Charge the batteries only when the ambient temperature is between 0° and 40°C (32° and 104°F).
- ▶ Do not short-circuit the battery by directly connecting the positive and negative terminals with metal objects.
- ▶ Do not touch battery contacts.
- ▶ Do not heat the battery or discard it in a fire.
- ▶ Do not expose the battery to temperatures over 60°C (140°F). Keep it away from fire and other heat sources.
- Do not charge the battery near a heat source, such as a fire or heater.
- ▶ Do not leave the battery in direct sunlight.
- Do not pierce the battery with a sharp object, hit it, or step on it.
- ▶ Do not use a damaged battery.
- ▶ Do not solder a battery.
- ▶ The polarity of the battery terminals are fixed and cannot be switched or reversed. Do not force the battery into the system.
- ▶ Do not connect the battery to an electrical power outlet.
- ▶ Do not continue recharging the battery if it does not recharge after two successive six hour charging cycles.
- ▶ Do not ship a damaged battery without instructions from FUJIFILM SonoSite Technical Support. Refer to "Getting help" on page 2.
- If the battery leaks or emits an odor, remove it from all possible flammable sources.
- ▶ Periodically, check to make sure that the battery charges fully. If the battery fails to charge fully, replace it.

Battery safety 153

To avoid the battery becoming damaged and causing equipment damage, observe the following precautions:

Caution

- ▶ Do not immerse the battery in water or allow it to get wet.
- ▶ Do not put the battery into a microwave oven or pressurized container.
- ▶ If the battery emits an odor or heat, is deformed or discolored, or in any way appears abnormal during use, recharging or storage, immediately remove it and stop using it. If you have any questions about the battery, consult FUJIFILM SonoSite or your local representative.
- ▶ Use only FUJIFILM SonoSite batteries.
- ▶ Do not use or charge the battery with non-FUJIFILM SonoSite equipment. Only charge the battery with the system.

Clinical safety

WARNINGS

- ▶ Non-medical (commercial) grade peripheral monitors have not been verified or validated by FUJIFILM SonoSite as being suitable for diagnosis.
- ▶ 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.
- Do not use the system if it exhibits erratic or inconsistent behavior.Discontinuities in the scanning sequence are indicative of a hardware failure that must be corrected before use.
- ▶ Some transducer sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals. Refer to 21 CFR 801.437, User labeling for devices that contain natural rubber.
- Perform ultrasound procedures prudently. Use the ALARA (as low as reasonably achievable) principle and follow the prudent use information concerning MI and TI.
- ▶ FUJIFILM SonoSite does not currently recommend a specific brand of acoustic standoff. If an acoustic standoff is used, it must have a minimum attentuation of .3dB/cm/MHz.
- ▶ Some FUJIFILM SonoSite transducers are approved for intraoperative applications if a market-cleared sheath is used.

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WARNINGS

- ▶ 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, guidewire misplacement, and risks normally associated with local or general anesthesia, surgery, and postoperative 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.

Hazardous materials 155

Electromagnetic compatibility

The ultrasound system has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2:2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

WARNING

To avoid the risk of increased electromagnetic emissions or decreased immunity, use only accessories and peripherals recommended by FUJIFILM SonoSite. Connection of accessories and peripherals not recommended by FUJIFILM SonoSite could result in malfunctioning of your ultrasound system or other medical electrical devices in the area. Contact FUJIFILM SonoSite or your local representative for a list of accessories and peripherals available from or recommended by FUJIFILM SonoSite. See "Compatible accessories and peripherals" on page 159.

Cautions

- ▶ Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. Portable and mobile RF communications equipment can affect the ultrasound system. Electromagnetic interference (EMI) from other equipment or interference sources could result in performance disruption of the ultrasound system. Evidence of disruption may include image degradation or distortion, erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site to determine the source of disruption, and take the following actions to eliminate the source(s).
 - ▶ Turn equipment in the vicinity off and on to isolate disruptive equipment.
 - ▶ Relocate or re-orient interfering equipment.
 - ▶ Increase distance between interfering equipment and your ultrasound system.
 - ▶ Manage use of frequencies close to ultrasound system frequencies.
 - ▶ Remove devices that are highly susceptible to EMI.
 - Lower power from internal sources within facility control (such as paging systems).
 - ▶ Label devices susceptible to EMI.
 - ▶ Educate clinical staff to recognize potential EMI-related problems.
 - ▶ Eliminate or reduce EMI with technical solutions (such as shielding).
 - ▶ Restrict use of personal communicators (cell phones, computers) in areas with devices susceptible to EMI.
 - ▶ Share relevant EMI information with others, particularly when evaluating new equipment purchases which may generate EMI.
 - ▶ Purchase medical devices that comply with IEC 60601-1-2 EMC Standards.
- ▶ Do not stack other equipment on the ultrasound system or use other equipment in close proximity and adjacent to the ultrasound system. If stacking or using other equipment in close proximity is unavoidable, then you must observe the system to verify normal operation.

Wireless transmission

The SonoSite Edge II ultrasound system contains an IEEE 802.11 transmitter that utilizes the ISM frequency bands from 2.412 to 2.484GHz and implements two methods of transmission:

- ▶ IEEE 802.11b with Complimentary Code Keying (CCK), Differential Quarternary Phase Shift Keying (DQPSK), and Differential Binary Phase Shift Keying (DBPSK) at 16 dB
- ▶ IEEE 802.11g with Orthogonal Frequency Division Multiplexing (ODFM) at 13 dBm

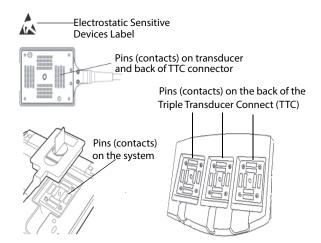
Electrostatic discharge

Caution

Electrostatic discharge (ESD), or static shock, is a naturally occurring phenomenon. ESD is common in conditions of low humidity, which can be caused by heating or air conditioning. ESD is a discharge of the electrical energy from a charged body to a lesser or non-charged body. The degree of discharge can be significant enough to cause damage to a transducer or an ultrasound system. The following precautions can help reduce ESD: anti-static spray on carpets, anti-static spray on linoleum, and anti-static mats.

WARNING

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



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

ESD precautionary procedures include the following:

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

Separation distance

Table 9-1: Recommended separation between portable and mobile RF communications equipment and the SonoSite Edge II ultrasound system

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

Rated maximum output power of	Separation distance according to frequency of transmitter m			
transmitter Watts	150 kHz to 80 MHz d=1.2 √P	80 MHz to 800 MHz d=1.2 √P	800 MHz to 2.5 GHz d=2.3 √P	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- ▶ These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Compatible accessories and peripherals

FUJIFILM SonoSite has tested the *SonoSite Edge II 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 Edge II ultrasound system.

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

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

Description	Maximum Cable Length
C11x transducer	6.0 ft/1.8 m
rC60xi transducer standard/armored	
HFL38xi transducer	5.5 ft/1.7 m
HFL50x transducer	5.7 ft/1.7 m
HSL25x transducer	8.0 ft/2.4 m
ICTx transducer	5.5 ft/1.7 m
L25x transducer	7.5 ft/2.3 m
L38xi transducer standard/armored	5.5 ft/1.7 m
L52x transducer	7.9 ft/2.4 m
P10x transducer	6.0 ft/1.8 m
P11x transducer	6.5 ft/2.0 m
rP19x transducer standard/armored	6.0 ft/1.8 m
TEExi transducer	7.2 ft/2.2 m
Bar code scanner	4.8 ft/1.5 m
Battery for PowerPack	_
Battery Pack	_
Battery PowerPack	_
Black & white printer	_
Black & white printer power cable	3.3 ft/1 m

Table 9-2: Accessories and peripherals compatible with SonoSite Edge II ultrasound system (continued)

Description	Maximum Cable Length
Color printer	_
Color printer power cable	3.3 ft/1 m
Color printer video cable	6 ft/1.8 m
ECG lead wires	24 in/0.6 m
ECG module	5.8 ft/1.8 m
ECG slave cable	8 ft/2.4 m
SonoSite Edge II Dock	_
SonoSite Edge II Stand	_
Footswitch	9.8 ft/3 m
Petite mouse	6 ft /1.8 m
Power cord (system)	10 ft/3 m
Power supply with DC cable	6.8 ft/2 m
Power supply AC cable	39 in/1 m
PowerPark	_
Triple Transducer Connect	_
USB wireless adapter	_

For transducers, the maximum cable length is measured between the strain reliefs. The stated length do not include the lengths of cable in the following locations: underneath the strain reliefs, inside the transducer enclosure, and inside the transducer connector.

Manufacturer's declaration

The tables in this section document the intended use environment and EMC compliance levels of the system. For maximum performance, ensure that the system is used in the environments described in this table.

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

Table 9-3: Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment	
RF emissions CISPR 11	Group 1	The SonoSite Edge II ultrasound system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class A	The SonoSite Edge II ultrasound system is suitable for use in all establishments other than domestic	
Harmonic emissions IEC 61000-3-2	Class A	and those directly connected to the public low-voltage power supply network which supplies buildings	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	used for domestic purposes.±	

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

Table 9-4: Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Floring Control of the Control of th
minimum y rest	IEC 00001 lest 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	\pm 2.0KV, \pm 4.0KV, \pm 6.0KV contact \pm 2.0KV, \pm 4.0KV, \pm 8.0KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient burst IEC 61000-4-4	± 2KV on the mains ± 1KV on signal lines	± 2KV on the mains ± 1KV on signal lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000- 4-5	± 1KV line(s) to line(s) ± 2KV line(s) to earth	± 1KV line(s) to line(s) ± 2KV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$<5\% U_T$ (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles $<5\% U_T$ (>95% dip in U_T) for 5s	$<5\% U_T$ (>95% dip in U _T) for 0.5 cycle 40% U _T (60% dip in U _T) for 5 cycles 70% U _T (30% dip in U _T) for 25 cycles $<5\% U_T$ (>95% dip in U _T) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FUJIFILM SonoSite ultrasound system requires continued operation during power mains interruptions, it is recommended that the FUJIFILM SonoSite ultrasound system be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	If image distortion occurs, it may be necessary to position the FUJIFILM SonoSite ultrasound system further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the Intended installation location to assure that it is sufficiently low.

Table 9-4: Manufacturer's Declaration - Electromagnetic Immunity (continued)

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	Portable and mobile RF communications equipment should be used no closer to any part of the FUJIFILM SonoSite ultrasound system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3 (continued)			Field strengths from fixed RF transmitters, as determined by an electromagnetic Site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: ((())) (IEC 60417 No. 417-IEC-5140: "Source of non-ionizing radiation")
Note	U _T is the AC mains voltage prior to application of the test level. At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

- a. Field strengths from fixed transmitters such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the FUJIFILM SonoSite ultrasound system is used exceeds the applicable RF compliance level above, the FUJIFILM SonoSite ultrasound system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the FUJIFILM SonoSite ultrasound system.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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

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

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

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

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

Labeling symbols

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

Table 9-5: Labels and symbols

Symbol	Definition
\sim	Alternating Current (AC)
C€	Class 1 device indicating manufacturer's declaration of conformance with Annex VII of 93/42/EEC

Table 9-5: Labels and symbols (continued)

Symbol	Definition
C€ 0086	Class 1 device requiring verification by the Notified Body of sterilization or measurement features, or to a Class IIa, IIb, or III device requiring verification or auditing by the Notified Body to applicable Annex(es) of 93/42/EEC
\triangle	Attention, refer to the user guide
	Device complies with relevant Australian regulations for electronic devices.
LOT	Batch code, date code, or lot code type of control number
	Biological risk
INMETRO OCP-0004	Device complies with relevant Brazilian regulations for electro-medical devices.
© us	Canadian Standards Association. The "C" and "US" indicators next to this mark signify that the product has been evaluated to the applicable CSA and ANSI/UL Standards, for use in Canada and the US, respectively.
REF	Catalog number
	Collect separately from other household waste (refer to European Commission Directive 93/86/EEC). Refer to local regulations for disposal.
Corrugated Recycles	Corrugated recycle
A	Dangerous voltage

Table 9-5: Labels and symbols (continued)

Symbol	Definition
M	Date of manufacture
***	Manufacturer
===	Direct Current (DC)
ず	Do not get wet.
2	Do not stack over 2 high.
5	Do not stack over 5 high.
10	Do not stack over 10 high.
	Electrostatic sensitive devices
FC	Device complies with relevant FCC regulations for electronic devices.
I	Fragile
GEL	Gel

Table 9-5: Labels and symbols (continued)

Symbol	Definition
STERILE R	Sterilized using irradiation
STERILE EO	Sterilized using ethylene oxide
<u>/</u>	Hot
	Device emits a static (DC) magnetic field.
	Non-ionizing radiation
	Paper recycle
SN	Serial number type of control number
orc err	Temperature limitation
+	Atmospheric pressure limitation
%	Humidity limitation
IPX7	Submersible. Protected against the effects of temporary immersion.
IPX8	Water-Tight Equipment. Protected against the effects of extended immersion.
V	Handle transducer with care.

Table 9-5: Labels and symbols (continued)

Symbol	Definition
	Follow manufacturer's instructions for disinfecting time.
	Disinfect transducer.
፟	Type BF patient applied part (B = body, F = floating applied part)
(*)	Defibrillator proof type CF patient applied part
(UL)	Underwriter's Laboratories labeling
10	Pollution Control Logo. (Applies to all parts/products listed in the China RoHS disclosure table. May not appear on the exterior of some parts/products because of space limitations.)
(C)	China Compulsory Certificate mark ("CCC Mark"). A compulsory safety mark for compliance to Chinese national standards for many products sold in the People's Republic of China.
WARNING: Connect Only Accessories and Peripherals Recommended by SonoSite	WARNING: Connect Only Accessories and Peripherals Recommended by FUJIFILM SonoSite
Ţ <u>i</u>	Follow instructions for use.
***	Manufacturer, or Manufacturer and date of manufacture
EC REP	Authorized representative in the European Community

Specifications

Dimensions

System

Length: 13 in. (33 cm)
Width: 12.4 in. (31.5 cm)
Height: 2.5 in. (6.3 cm)

▶ Weight: 11.35 lbs. (4.6 kg) with the TEExi transducer and battery installed

Display

Length: 9.7 in. (24.6 cm)
 Height: 7.3 in. (18.5 cm)
 Diagonal: 12.1 in. (30.7 cm)

Environmental limits

Note

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

Operating (system, battery, and transducer)

10-40°C (50-104°F), 15-95% R.H.

700 to 1060hPa (0.7 to 1.05 ATM)

Mode of Operation:

- Continuous 35°C or below
- ▶ Non-Continuous above 35°C (30 minutes on /30 minutes off)

Shipping and storage (system and transducer)

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-35-65°C (-31-149°F), 15-95% R.H.
```

500 to 1060hPa (0.5 to 1.05 ATM)

Shipping and storage (battery)

-20-60°C (-4-140°F), 15-95% R.H. (For storage longer than 30 days, store at or below room temperature.)

500 to 1060hPa (0.5 to 1.05 ATM)

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Electrical specifications

Power Supply Input: 100-240 VAC, 50/60 Hz, 2.0 A Max @ 100 VAC

Power Supply Output #1: 15 VDC, 5.0 A Max

Power Supply Output #2: 12 VDC, 2.3 A Max

Combined output not exceeding 75 watts.

Battery specifications

The battery comprises six lithium-ion cells plus electronics, a temperature sensor, and battery contacts. Run time is up to two hours, depending on imaging mode and display brightness.

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Standards

Electromechanical safety standards

Table 9-6: Electromechanical safety standards

Standard	Description
AAMI ES60601-1:2005 + C1(2009) + A2(2010)	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance (3 rd edition plus Corrigendum 1 and Amendment A2)
CSA C22.2 No. 60601- 1-08 + TC 2(2011)	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (3 rd edition plus Corrigendum 2)
IEC 60601-1:2005 + C1(2006) + C2(2007)	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance (3 rd edition plus Corrigendum 1 and Corrigendum 2)
CSA C22.2 60601-2- 37:08	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasound medical diagnostic and monitoring equipment
IEC 60601-2-37 (ed. 2.0)	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasound medical diagnostic and monitoring equipment
CSA C22.2 60601-6-07	Medical Electrical Equipment part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability.
IEC 60601-1-6:2010	Medical Electrical Equipment part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability

EMC standards classification

Table 9-7: 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, docking system, accessories, and peripherals when configured together is: Group 1, Class A.

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Biocompatibility standards

AAMI/ANSI/ISO 10993-1:2009, Biological evaluation of medical devices—Part 1: Evaluation and testing (2009).

AAMI/ANSI/ISO 10993-5, Biological evaluation of medical devices—Part 5: Tests for In Vitro cytotoxicity (2009).

AAMI/ANSI/ISO 10993-10, Biological evaluation of medical devices—Part 10: Tests for irritation and delayed-type hypersensitivity (2002).

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

AAMI/ANSI/ISO 10993-12, Biological evaluation of medical devices—Part 12: Sample preparation and reference materials (2007).

Airborne equipment standards

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

DICOM standard

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

The system conforms to the DICOM standard as specified in the X-Porte DICOM Conformance Statement, available at www.sonosite.com. This statement provides information about the purpose, characteristics, configuration, and specifications of the network connections supported by the system.

HIPAA standard

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

The Health Insurance and Portability and Accountability Act, Pub.L. No. 104-191 (1996). 45 CFR 160, General Administrative Requirements.

45 CFR 164, Security and Privacy.

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Chapter 10: Acoustic Output

This chapter contains safety information required by regulatory agencies pertaining to acoustic output. The information applies to the ultrasound system, transducer, accessories, and peripherals.

ALARA principle

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

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

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

Applying the ALARA principle

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

Prudent use of ultrasound requires that patient exposure to ultrasound be limited to the lowest ultrasound output for the shortest time necessary to achieve acceptable diagnostic results. Decisions that support prudent use are based on the type of patient, exam type, patient history, ease or difficulty of obtaining diagnostically useful information, and potential localized heating of the patient due to transducer surface temperature.

ALARA principle 175

The system has been designed to ensure that temperature at the face of the transducer will not exceed the limits established in Section 42 of EN 60601-2-37: Particular requirement for the safety of ultrasound medical diagnostic and monitoring equipment. See "Transducer surface temperature rise" on page 182. 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 177. Additionally, one means for meeting the ALARA principle is to set the MI or TI values to a low index value and then modifying this level until a satisfactory image or Doppler mode is obtained. For more information on MI and TI, refer to BS EN 60601-2-37:2001: Annex HH.

Indirect controls

The controls that indirectly affect output are controls affecting imaging mode, freeze, and depth. The imaging mode determines the nature of the ultrasound beam. 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

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- Reverberations
- Comet tails

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

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

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.

Note

For guidelines for reducing MI or TI for the P11x transducer, refer to the *P11x Transducer User Guide*, included with the P11x transducer.

Table 10-1: Guidelines for reducing MI

Transducer	Depth
C11x	1
rC60xi standard/armored	1
HFL38xi	1
HFL50x	1
HSL25x	1
ICTx	1

Table 10-1: Guidelines for reducing MI (continued)

Transducer	Depth
L25x	1
L38xi standard/armored	1
P10x	1
rP19x standard/armored	1
TEExi	1
Decrease or lower setting of parameter to reduce	e MI.
increase or raise setting of parameter to reduce	MI.

Table 10-2: Guidelines for reducing TI

Transducer	Box Width	Box Height	Box Depth	PRF	Depth	Optimize	PW Settings		
C11x			1	1	1		(Depth)		
rC60xi standard/ armored		1		1	1		(PRF)		
HFL38xi			1	1			(Depth)		

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

			CPD	Settings					
Transducer	Box Width	Box Height	Box Depth	PRF	Depth	Optimize	PW Settings		
HFL50x			1	1			(Depth)		
HSL25x	1				1		(PRF)		
ICTx		1	1	1		Exam Gyn	(PRF)		
L25x	1				1		(PRF)		
L38xi standard/ armored	1	1					(Sample volume zone or size)		
P10x			1	1			(PRF)		
rP19x standard/ armored				+	1		(Depth)		
TEExi				•	•		(PRF)		
	Decrease or lower setting of parameter to reduce TI. Increase or raise setting of parameter to reduce TI.								

Output display

The system meets the AIUM output display standard for MI and TI. See "Related guidance documents" on page 182. Table 10-3 indicates for each transducer and operating mode when either the TI or MI is greater than or equal to a value of 1.0, thus requiring display.

Table 10-3: TI or MI ≥ 1.0

Transducer Model	Index	2D/ M Mode	CPD/ Color	PW Doppler	CW Doppler
C11x/8-5	MI	No	No	No	_
	TIC,TIB, or TIS	No	No	Yes	_
rC60xi/5-2 standard/	MI	Yes	Yes	Yes	_
armored	TIC,TIB, or TIS	Yes	Yes	Yes	_
HFL38xi/13-6	MI	Yes	Yes	Yes	_
	TIC, TIB, or TIS	No	No	Yes	_
HFL50x/15-6	MI	Yes	Yes	Yes	_
	TIC, TIB, or TIS	No	No	Yes	_
HSL25x/13-6	MI	Yes	Yes	No	_
	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	Yes	No	_
	TIC, TIB, or TIS	No	No	Yes	_
L38xi/10-5 standard/armored	MI	Yes	Yes	Yes	_
	TIC, TIB, or TIS	Yes	Yes	Yes	_
P10x/8-4	MI	No	No	Yes	No
	TIC, TIB, or TIS	No	Yes	Yes	Yes
rP19x/5-1	MI	Yes	Yes	Yes	No
standard/armored	TIC, TIB, or TIS	Yes	Yes	Yes	Yes

Table 10-3: TI or MI ≥ 1.0 (continued)

Transducer Model	Index	2D/ M Mode	CPD/ Color	PW Doppler	CW Doppler
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. Refer to "Related guidance documents" on page 182.

Note

For output display information for the P11x transducer, refer to the *P11x Transducer User Guide*, included with the P11x transducer.

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 234.

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

Output display 181

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), 1994. (A copy is included with each system.)

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

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

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

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

Transducer surface temperature rise

Table 10-4 and Table 10-5 list the measured surface temperature rise from ambient ($23^{\circ}C \pm 3^{\circ}C$) 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.

Note

For information about surface temperature rise for the P11x transducer, refer to the *P11x Transducer User Guide*, included with the P11x transducer.

Table 10-4: Transducer Surface Temperature Rise, External Use (°C)

Test	C11x	rC60xi	HFL38xi	HFL50x	HSL25x	L25x	L38xi	P10x	rP19x
Still air	14.2	15.0	12.4	10.7	17.5	16.1	12.5	16.0	14.9
Simulated Use	7.3	8.9	7.7	7.7	9.1	8.5	8.8	9.1	7.6

Table 10-5: Transducer Surface Temperature Rise, Internal Use (°C)

Test	ICTx	TEExi
Still air	9.2	8.6
Simulated Use	5.2	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:

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).

Table 10-6 through Table 10-51 indicate the acoustic output for the system and transducer combinations with a TI or MI equal to or greater than one. These tables are organized by transducer model and imaging mode. For a definition of terms used in the tables, refer to "Terms used in the acoustic output tables" on page 233.

Note

For acoustic output information for the P11x transducer, refer to the P11x Transducer User Guide, included with the P11x transducer.

Table 10-6: Transducer Model: C11x **Operating Mode:** PW Doppler

					TIS		TIB	
	Index Label		M.I.		Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		(a)	_	(a)	_	1.5	1.1
	p _{r.3}	(MPa)	#					
	W_0	(mW)		_	#		24.6	21.7
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
Acou ter	Z _{bp}	(cm)				_		
ciated Acol Parameter	Z_{sp}	(cm)					1.70	
Associated Acoustic Parameter	z@PII _{.3max}	(cm)	#					
Asso	$d_{eq}(Z_{sp})$	(cm)					0.23	
1	F _c	(MHz)	#	_	#	_	4.37	4.36
	Dim of A _{aprt}	X (cm)		_	#	_	0.64	0.40
	·	Y (cm)		_	#	_	0.50	0.50
	PD	(µsec)	#					
o	PRF	(Hz)	#					
nati	p _r @PII _{max}	(MPa)	#					
forr	d _{eq} @PII _{max}	(cm)					0.22	
r I	Focal Length	FL _x (cm)		_	#	_		1.52
Other Information		FL _y (cm)		_	#	_		4.40
J	I _{PA.3} @MI _{max}	(W/cm ²)	#					
ט צ							Nrv	Nrv
Operating Control Conditions							1 mm	7 mm
peratin Control	Control 3: Sample Volume	Position					Zone 1	Zone 0
ð 3	Control 4: PRF						10417	6250

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-7: Transducer Model: rC60xi standard/armored **Operating Mode:** 2D

					TIS		TIB	
	Index Label		MI		Non-	-scan	N	TIC
				Scan	A _{aprt} <1	A _{aprt} >1	TIB Non-scan — — — — — — — — — — — — — — — — — —	
Global N	Maximum Index Value		1.5	(a)	_	_	_	(b)
	p _{r.3}	(MPa)	2.31					
	W_0	(mW)		#	_		_	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
Ë	z ₁	(cm)				_		
ousi	Z _{bp}	(cm)				_		
l Ac	Z_{sp}	(cm)					_	
atec aran	z@PII _{.3max}	(cm)	4.3					
Soci P	$d_{eq}(Z_{sp})$	(cm)					_	
Ass	F _c	(cm)	2.36	#	_	_	_	#
	Z _{bp}	(MHz)		#	_	_	_	#
	Dim of A _{aprt}	X (cm)		#	_	_	_	#
		Y (cm)						
	PD	(µsec)	0.680					
	PRF	(Hz)	3.584					
ion	p _r @PII _{max}	(MPa)	3.29					
ther mat	d _{eq} @PII _{max}	(cm)					_	
Other Associated Acoust Information Barameter S Parameter S P P P P P P P P P P P P P P P P P P	Focal Length	FL _x (cm)		#	_	_		#
<u> </u>		FL _y (cm)		#	_	_		#
	I _{PA.3} @MI _{max}	(W/cm ²)	356					
	Control 1: Exam Type		Abd					
ing ol ons			Res					
perating Control ondition	Control 3: Depth		11 cm					
Ope Co	Control 4: MB		Off					
9 0	Control 5: Needle Vision		On					

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

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

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

[—] Data are not applicable for this transducer/mode.

Table 10-8: Transducer Model: rC60xi standard/armored **Operating Mode:** M Mode

					TIS		TIB	
	Index Label		MI		Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	TIB Non-scan 1.0 69.8 4.20 0.69 2.89 2.25 1.20 0.49 Msk Pen 9.2 cm Off	
Global N	Maximum Index Value		1.3	_	_	(a)	1.0	(b)
	p _{r.3}	(MPa)	2.18					
	W_0	(mW)		_	_		69.8	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
. <u>∺</u>	z ₁	(cm)				_		
ousi	Z _{bp}	(cm)				_		
l Ac	Z_{sp}	(cm)					4.20	
ciated Aco Parameter	z@PII _{.3max}	(cm)	4.3					
Associated Acoustic	$d_{eq}(Z_{sp})$	(cm)					0.69	
Ass	F _c	(cm)	2.66	_	_	#	2.89	#
	Z _{bp}	(MHz)		_	_	#	2.25	#
	Dim of A _{aprt}	X (cm)		_	_	#	1.20	#
	7.1	Y (cm)						
	PD	(µsec)	0.620					
	PRF	(Hz)	800					
. ioi	p _r @PII _{max}	(MPa)	3.25					
Other	d _{eq} @PII _{max}	(cm)					0.49	
Other nformation	Focal Length	FL _x (cm)		_	_	#		#
<u> </u>		FL _y (cm)		_	_	#		#
	I _{PA.3} @MI _{max}	(W/cm^2)	290					
ص	Control 1: Exam Type		Abd				Msk	
trol tion	Control 2: Optimization		Pen				Pen	
Operating Control Conditions	Control 3: Depth		6.6cm					
<u> </u>	Control 4: THI		Off				Off	

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

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

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

Data are not applicable for this transducer/mode.

Table 10-9: Transducer Model: rC60xi standard/armored Operating Mode: CPD/Color

					TIS		TIB	
	Index Label		MI	6	Non-	scan	N	TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	al Maximum Index Value		1.5	1.2	_	_	_	(b)
	p _{r.3}	(MPa)	2.21					
	W_0	(mW)		107.5	_		_	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
cou ter	Z _{bp}	(cm)				_		
ed A	Z_{sp}	(cm)					_	
ciat. Para	z@PII _{.3max}	(cm)	4.3					
1550	$d_{eq}(Z_{sp})$	(cm)					_	
⋖	F _C	(MHz)	2.22	2.21	_	_	_	#
Perating Other Associated Acoustic Control Information Parameter	Dim of A _{aprt}	X (cm)		0.66	_	_	_	#
	up.t	Y (cm)		1.20	_	_	_	#
	PD	(µsec)	0.729					
	PRF	(Hz)	1265					
ion	p _r @PII _{max}	(MPa)	3.07					
ther mat	d _{eq} @PII _{max}	(cm)					_	
Of	Focal Length	FL _x (cm)		2.50	_	_		#
=		FL _y (cm)		6.50	_	_		#
	I _{PA.3} @MI _{max}	(W/cm ²)	342					
	Control 1: Exam Type		Abd	Abd				
	Control 2: Mode		CVD	CVD				
ating trol tions	Control 3: 2D Optimization/	Control 3: 2D Optimization/Depth/THI						
per? Con: Indi	Control 4: Color Optimization	on / PRF	Low/342	High/3125				
ō~3	Control 5: Color Box Positio	n/Size	Bottom/ Tall- Narrow	Bottom/ Tall- Narrow				

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-10: Transducer Model: rC60xi standard/armored **Operating Mode:** PW Doppler

					TIS		TIB	
	Index Label		M.I.		Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		1.2	_	_	2.0	4.0	(b)
	p _{r.3}	(MPa)	1.73					
	W_0	(mW)		_	_		291.8	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				187.5		
ıstic	z ₁	(cm)				4.0		
\cou	Z _{bp}	(cm)				4.0		
Associated Acoustic Parameter	Z _{sp}	(cm)					3.60	
ciat Par	z@PII _{.3max}	(cm)	4.5					
\sso	$d_{eq}(Z_{sp})$	(cm)					0.94	
4	F _c	(MHz)	2.20	_	_	2.23	2.23	#
	Dim of A _{aprt}	X (cm)		_	_	4.77	3.28	#
	·	Y (cm)		_	_	1.20	1.20	#
	PD	(µsec)	1.153					
o	PRF	(Hz)	1302					
nati	p _r @PII _{max}	(MPa)	2.43					
forr	d _{eq} @PII _{max}	(cm)					0.54	
r L	Focal Length	FL _x (cm)		_	_	17.97		#
Other Information		FL _y (cm)		_	_	6.50		#
O	I _{PA.3} @MI _{max}	(W/cm ²)	267					
g _ su	Control 1: Exam Type		Abd			Abd		Abd
Operating Control Conditions	Control 2: Sample Volume	e Size	3 mm			7 mm		7 mm
peratin Control ondition	Control 3: Sample Volume	e Position	Zone 3			Zone 6		Zone 5
ð 3	Control 2: Sample Volume Control 3: Sample Volume Control 4: PRF		1302			2604		2604

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-11: Transducer Model: *HFL38xi* **Operating Mode:** *2D*

					TIS		TIB	
	Index Label		MI	_	Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		1.3	(a)	_	_	_	(b)
	p _{r.3}	(MPa)	3.05					
	W_0	(mW)		#	_		_	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
. <u>∪</u>	z ₁	(cm)				_		
oust	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z _{sp}	(cm)					_	
ated Iran	z@PII _{.3max}	(cm)	1.2					
Associated Acoustic Parameter	$d_{eq}(Z_{sp})$	(cm)					_	
Ass	F _c	(cm)	5.36	#	_	_	_	#
	Z _{bp}	(MHz)		#	_	_	_	#
	Dim of A _{aprt}	X (cm)		#	_	_	_	#
	ирге	Y (cm)						
	PD	(µsec)	0.521					
	PRF	(Hz)	2127					
ion	p _r @PII _{max}	(MPa)	3.81					
Other formati	d _{eq} @PII _{max}	(cm)					_	
Other nformation	Focal Length	FL _x (cm)		#	_	_		#
		FL _y (cm)		#	_	_		#
	I _{PA.3} @MI _{max}	(W/cm ²)	494					
	Control 1: Exam Type		Ven					
ing ol ons	Control 2: Optimization		Res					
Operating Control Conditions	Control 3: Depth		3.3 cm					
900	Control 4: MB		N/A					
J	Control 5: Needle Vision		On					

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

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

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

[—] Data are not applicable for this transducer/mode.

Table 10-12: Transducer Model: *HFL38xi* **Operating Mode:** *M Mode*

					TIS		TIB	
	Index Label		MI		Non	-scan	i	TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		1.2	_	(a)	_	(a)	(b)
	p _{r.3}	(MPa)	3.14					
	W_0	(mW)		_	#		#	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
. <u>∪</u>	z ₁	(cm)				_		
ous! r	Z _{bp}	(cm)				_		
l Aco	Z_{sp}	(cm)					#	
ciated Aco Parameter	z@PII _{.3max}	(cm)	1.4					
Associated Acoustic Parameter	$d_{eq}(Z_{sp})$	(cm)					#	
Ass	F _c	(cm)	6.75	_	#	_	#	#
	Z _{bp}	(MHz)		_	#	_	#	#
	Dim of A _{aprt}	X (cm)		_	#	_	#	#
	·	Y (cm)						
	PD	(µsec)	0.263					
	PRF	(Hz)	1600					
_ ioi:	p _r @PII _{max}	(MPa)	4.35					
Other formati	d _{eq} @PII _{max}	(cm)					#	
Other Information	Focal Length	FL _x (cm)		_	#	_		#
=		FL _y (cm)		_	#	_		#
	I _{PA.3} @MI _{max}	(W/cm^2)	388					
gr _ sn	Control 1: Exam Type		Nrv					
atir otro litio	Control 2: Optimization		Pen					
Operating Control Conditions	Control 1: Exam Type Control 2: Optimization Control 3: Depth		4.0 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 10-13: Transducer Model: HFL38xi **Operating Mode:** CPD/Color

					TIS		TIB	
	Index Label		MI	_	Non	-scan	Non-	TIC
				Scan	A _{aprt} <1	A _{aprt} >1	scan	
Global M	laximum Index Value		1.3	(a)	_	_	_	(b)
	p _{r.3}	(MPa)	3.05					
	W_0	(mW)		#	_		_	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
COL ter	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					_	
ciat _e Para	z@PII _{.3max}	(cm)	1.2					
Associated Acoustic Parameter	$d_{eq}(Z_{sp})$	(cm)					_	
4	F _c	(MHz)	5.36	#	_	_	_	#
	Dim of A _{aprt}	X (cm)		#	_	_	_	#
	·	Y (cm)		#	_	_	_	#
	PD	(µsec)	0.521					
	PRF	(Hz)	2223					
0	p _r @PII _{max}	(MPa)	3.81					
Other formation	d _{eq} @PII _{max}	(cm)					_	
Other Information	Focal Length	FL _x (cm)		#	_	_		#
=		FL _y (cm)		#	_	_		#
	I _{PA.3} @MI _{max}	(W/cm ²)	494					
	Control 1: Exam Type		SmP					
10	Control 2: Mode		CVD					
S	Control 3: 2D Optimization/Depth		Res/ 3.3 cm					
O O O	Control 4: Color Optimization / Depth/PRF		Low/401					
	Control 5: Color Box Position	n/Size	Def/Def					

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-14: Transducer Model: HFL38xi Operating Mode: PW Doppler

					TIS		TIB	
	Index Label		MI		Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		1.2	_	1.1	_	2.2	(b)
	p _{r.3}	(MPa)	2.69					
	W_0	(mW)		_	47.7		47.7	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
\cou	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					1.10	
ciat Para	z@PII _{.3max}	(cm)	1.0					
Associated Acoustic Parameter	$d_{eq}(Z_{sp})$	(cm)					0.34	
4	F _c	(MHz)	5.34	_	4.86	_	4.86	#
	Dim of A _{aprt}	X (cm)		_	1.08	_	1.08	#
	·	Y (cm)		_	0.40	_	0.40	#
	PD	(µsec)	1.288					
	PRF	(Hz)	1008					
ion	p _r @PII _{max}	(MPa)	3.23					
Other	d _{eq} @PII _{max}	(cm)					0.25	
Other nformation	Focal Length	FL _x (cm)		_	3.72	_		#
_		FL _y (cm)		_	2.44	_		#
	I _{PA.3} @MI _{max}	(W/cm ²)	308					
D S	Control 1: Exam Type		Nrv		Art		Art	
Operating Control	Control 2: Sample Volume	Size	1 mm		1 mm		1 mm	
Son' Ton' Indi	Control 3: Sample Volume	Position	Zone 3		Zone 7		Zone 7	
500	I _{PA.3} @MI _{max} Control 1: Exam Type Control 2: Sample Volume Control 3: Sample Volume Control 4: PRF		1008		3125		3125	

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-15: Transducer Model: *HFL50x* **Operating Mode:** *2D*

					TIS		TIB	
	Index Label		MI		Non	-scan	N	TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	laximum Index Value		1.3	(a)	_	_	_	(b)
	p _{r.3}	(MPa)	3.051					
	W_0	(mW)		#	_		_	#
()	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
\cot	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					_	
Õ	z@PII _{.3max}	(cm)	1.2					
	$d_{eq}(Z_{sp})$	(cm)					_	
*	F _c	(MHz)	5.36	#	_	_	_	#
	Dim of A _{aprt}	X (cm)		#	_	_	_	#
		Y (cm)		#	_	_	_	#
	PD	(µsec)						
	PRF	(Hz)	2733					
ion	p _r @PII _{max}	(MPa)	3.81					
Other formatic	d _{eq} @PII _{max}	(cm)					_	
Other nformation	Focal Length	FL _x (cm)		#	_	_		#
=		FL _y (cm)		#	_	_		#
	I _{PA.3} @MI _{max}	(W/cm ²)	493					
g Sr	Control 1: Exam Type		Any	_	_	_	_	_
atin trol tior	Control 2: Optimization		Any	_	_	_	_	_
æ = =	Control 3: Depth		3.3	_	_	_	_	_
0 0	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 10-16: Transducer Model: HFL50x Operating Mode: M Mode

					TIS		TIB Non-scan (a) (b) # # # # # # # # # # # # # # #	
	Index Label		M.I.	Scan	Non-	-scan	Non ssan	TIC
				Scall	A _{aprt} <1	A _{aprt} >1	NOII-SCAII	
Global N	Maximum Index Value		1.2	_	(a)	_	(a)	(b)
	p _{r.3}	(MPa)	3.14					
	W_0	(mW)		_	#		#	#
ţi	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ousi r	z ₁	(cm)				_		
ciated Acou Parameter	Z _{bp}	(cm)				_		
ated	Z _{sp}	(cm)	1.4				#	
Associated Acoustic Parameter	$d_{eq}(Z_{sp})$	(cm)					#	
As	F _c	(MHz)	6.75	_	#	_	#	#
	Dim of A _{aprt}	X (cm)		_	#	_	#	#
		Y (cm)		_	#	_	#	#
	PD	(µsec)	0.263					
o	PRF	(Hz)	1600					
nati	p _r @PII _{max}	(MPa)	4.35					
forr	d _{eq} @PII _{max}	(cm)					#	
r I	Focal Length	FL _x (cm)		_	#	_		#
Other Information		FL _y (cm)		_	#	_		#
J	I _{PA.3} @MI _{max}	(W/cm ²)	388					
gr sn	Control 1: Exam Type		Any					
peratin Control onditior	Control 2: Optimization		Pen					
Operating Control Conditions	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 10-17: Transducer Model: HFL50x **Operating Mode:** CPD/Color

					TIS		TIB	
	Index Label		M.I.	Scan	Non-	-scan	Non-scan	TIC
				Scall	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		1.3	(a)	_	_	_	(b)
	p _{r.3}	(MPa)	3.05					
	W_0	(mW)		#	_		_	#
Ë	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ousi	z ₁	(cm)				_		
d Ac nete	Z _{bp}	(cm)				_		
Associated Acoustic Parameter	Z_{sp}	(cm)	1.2				_	
soci Pe	$d_{eq}(Z_{sp})$	(cm)					_	
As	F _c	(MHz)	5.36	#	_	_	_	#
	Dim of A _{aprt}	X (cm)		#	_	_	_	#
	·	Y (cm)		#	_	_	_	#
	PD	(µsec)	0.521					
o	PRF	(Hz)	8233					
nati	p _r @PII _{max}	(MPa)	3.81					
forr	d _{eq} @PII _{max}	(cm)					_	
r n	Focal Length	FL _x (cm)		#	_	_		#
Other Information		FL _y (cm)		#	_	_		#
0	I _{PA.3} @MI _{max}	(W/cm ²)	494					
D 2	Control 1: Mode		Any					
tion	Control 2: Exam Type		Any					
Operating Control Conditions	Control 1: Mode Control 2: Exam Type Control 3: Optimization/D Control 4: PRF	epth	Low/3.3					
903	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 10-18: Transducer Model: *HFL50x* **Operating Mode:** *PW Doppler*

					TIS		TIB	
	Index Label		MI		Non-	scan	N	TIC
				Scan -	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global M	laximum Index Value		1.2	_	1.1	_	1.9	(b)
	p _{r.3}	(MPa)	2.69					
	W_0	(mW)		_	42.6		42.6	#
Ë	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ous	z ₁	(cm)				_		
d Ac	Z _{bp}	(cm)				_		
Associated Acoustic Parameter	Z_{sp}	(cm)	1.0				1.1	
Socie P	$d_{eq}(Z_{sp})$	(cm)					0.33	
Ass	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	#
	PD	(µsec)	1.29					
	PRF	(Hz)	1008					
ion	p _r @PII _{max}	(MPa)	3.23					
Other formatic	d _{eq} @PII _{max}	(cm)					0.22	
Other Information	Focal Length	FL _x (cm)		_	3.72	_		#
		FL _y (cm)		_	2.44	_		#
	I _{PA.3} @MI _{max}	(W/cm ²)	308					
	Control 1: Exam Type		Any	_	Any	_	Any	_
ing ol ons	Control 2: Sample Volume		1 mm	_	1 mm	_	1 mm	_
≥ <u>.</u>	Control 3: PRF		1008	_	1563 - 3125	_	1563 - 3125	_
0	Control 4: Sample Volume	Position	Zone 3	_	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 10-19: Transducer Model: *HSL25x* **Operating Mode:** *2D*

					TIS		TIB Non-scan — — — — — — — — — — — — — — — — —	
	Index Label		M.I.	_	Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		1.2	(a)	_	_	_	(b)
	p _{r.3}	(MPa)	2.87					
	W_0	(mW)		#	_		_	#
Ë	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ous	z ₁	(cm)				_		
ciated Acor Parameter	Z _{bp}	(cm)				_		
atec arar	Z_{sp}	(cm)	0.8				_	
Associated Acoustic Parameter	$d_{eq}(Z_{sp})$	(cm)					_	
As	F _c	(MHz)	6.11	#	_	_	_	#
	Dim of A _{aprt}	X (cm)		#	_		_	#
		Y (cm)		#	_	_	_	#
	PD	(µsec)	0.630					
o	PRF	(Hz)	1061					
nati	p _r @PII _{max}	(MPa)	3.39					
Other Information	d _{eq} @PII _{max}	(cm)					_	
ır In	Focal Length	FL _x (cm)		#	_	_		#
Othe		FL _y (cm)		#	_	_		#
O	I _{PA.3} @MI _{max}	(W/cm ²)	478					
ng lo	Control 1: Exam Type		Nrv/Msk/ Ven/Art	_	_	_	_	_
peratin Control	Control 2: Optimization		Any	_	_	_	_	_
Operating Control Conditions	Control 3: Depth		1.9 - 2.2	_	_	_	_	_
0	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 10-20: Transducer Model: HSL25x **Operating Mode:** CPD/Color

					TIS		TIB	
	Index Label		M.I.	_	Non	-scan	Non-scan	TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		1.0	(a)	_	_	_	(b)
	p _{r.3}	(MPa)	2.35					
	W_0	(mW)		#	_		_	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
COU ter	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					_	
ciat Para	z@PII _{.3max}	(cm)	0.8					
Assoc	$d_{eq}(Z_{sp})$	(cm)					_	
	F _c	(MHz)	6.11	#	_	_	_	#
	Dim of A _{aprt}	X (cm)		#	_	_	_	#
	·	Y (cm)		#	_	_	_	#
	PD	(µsec)	0.630					
on	PRF	(Hz)	3079					
nati	p _r @PII _{max}	(MPa)	2.78					
forr	d _{eq} @PII _{max}	(cm)					_	
r I	Focal Length	FL _x (cm)		#	_	_		#
Other Information		FL _y (cm)		#	_	_		#
O	I _{PA.3} @MI _{max}	(W/cm ²)	276					
	Control 1: Exam Type		Sup					
	Control 2: Mode		CVD					
Operating Control Conditions	Control 3: 2D Optimization/Depth		Pen/ 3.1 cm					
	Control 4: Color Optimization / Depth/PRF		Low/401					
	Control 5: Color Box Posit	ion/Size	Def/Def					

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-21: Transducer Model: *HSL25x* **Operating Mode:** *PW Doppler*

					TIS		TIB	
	Index Label		M.I.	_	Non-	-scan		TIC
				Scan	A _{aprt} ≤1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		(a)	_	(a)	_	1.5	(b)
	p _{r.3}	(MPa)	#					
	W_0	(mW)		_	#		28.1	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ustic	z ₁	(cm)				_		
Acou	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					0.75	
ciat	z@PII _{.3max}	(cm)	#					
Associated Acoustic Parameter	$d_{eq}(Z_{sp})$	(cm)					0.30	
_	F _c	(MHz)	#	_	#	_	6.00	#
	Dim of A _{aprt}	X (cm)		_	#	_	0.76	#
		Y (cm)		_	#	_	0.30	#
	PD	(µsec)	#					
o	PRF	(Hz)	#					
nati	p _r @PII _{max}	(MPa)	#					
forr	d _{eq} @PII _{max}	(cm)					0.21	
r In	Focal Length	FL _x (cm)		_	#	_		#
Other Information		FL _y (cm)			#	_		#
O	I _{PA.3} @MI _{max} Control 1: Exam Type Control 2: Sample Volume Control 3: Sample Volume Control 4: PRF	(W/cm ²)	#					
D S	Control 1: Exam Type						Nrv	
trol tion	Control 2: Sample Volume	Size					8 mm	
Operating Control	Control 3: Sample Volume	Position					Zone 7	
ō 3	Control 4: PRF						1953	

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

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

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

Data are not applicable for this transducer/mode.

Table 10-22: Transducer Model: HSL25x Ophthalmic Use **Operating Mode:** 2D

					TIS	TIS		
	Index Label				Non-scan			TIC
	Global Maximum Index Value			Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		0.17	0.02	_	_	_	(b)
	p _{r.3}	(MPa)	0.47					
	W_0	(mW)		0.70	_		_	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
\cou	Z _{bp}	(cm)				_		
ed /	Z_{sp}	(cm)					_	
Associated Acoustic Parameter	z@PII _{.3max}	(cm)	0.8					
	$d_{eq}(Z_{sp})$	(cm)					_	
4	F _c	(MHz)	7.65	6.97	_	_	_	#
	Dim of A _{aprt}	X (cm)		0.96	_	_	_	#
		Y (cm)		0.30	_	_	_	#
	PD	(µsec)	0.101					
on	PRF	(Hz)	12580					
nati	p _r @PII _{max}	(MPa)	0.58					
forr	d _{eq} @PII _{max}	(cm)					_	
r L	Focal Length	FL _x (cm)		3.80	_	_		#
)the		FL _y (cm)		2.70	_	_		#
O	I _{PA.3} @MI _{max}	(W/cm^2)	13.4					
D 2	Control 1: Exam Type		Oph	Oph				
trol tio	Control 2: Optimization		Res	Pen				
Sont onti	Control 3: Depth		1.9 cm	4.3 cm				
perating Other Information Control	Control 4: MB		On	On				

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-23: Transducer Model: HSL25x Ophthalmic Use **Operating Mode:** M Mode

					TIS		TIB	
	Index Label				Non-scan			TIC
				Scan A _{aprt}		A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		0.17	_	0.01	_	0.02	(b)
	p _{r.3}	(MPa)	0.47					
	W_0	(mW)		_	0.45		0.45	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ustic	z ₁	(cm)				_		
Associated Acoustic Parameter	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					0.85	
ciat	z@PII _{.3max}	(cm)	1.0					
Asso	$d_{eq}(Z_{sp})$	(cm)					0.35	
_	F _c	(MHz)	7.59	_	6.25	_	6.25	#
	Dim of A _{aprt}	X (cm)		_	0.96	_	0.96	#
		Y (cm)		_	0.30	_	0.30	#
	PD	(µsec)	0.098					
o	PRF	(Hz)	1600					
nati	p _r @PII _{max}	(MPa)	0.61					
Other Information	d _{eq} @PII _{max}	(cm)					0.27	
r I	Focal Length	FL _x (cm)		_	3.80	_		#
Othe		FL _y (cm)		_	2.70	_		#
J	I _{PA.3} @MI _{max}	(W/cm^2)	14.9					
gr _ sn	Control 1: Exam Type		Oph		Oph		Oph	
atir ntro itio	Control 2: Optimization		Res		Pen		Pen	
Operating Control Conditions	Control 3: Depth		1.9 cm		4.3 cm		4.3 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 10-24: Transducer Model: HSL25x Ophthalmic Use Operating Mode: CPD/Color

					TIS		TIB	
	Index Label				Non-scan			TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Naximum Index Value		0.17	0.06	_	_	_	(b)
	p _{r.3}	(MPa)	0.42					
	W_0	(mW)		1.9	_		_	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
ted Acous ameter	Z _{bp}	(cm)				_		
	Z_{sp}	(cm)					_	
ciat Para	z@PII _{.3max}	(cm)	0.7					
\sso	$d_{eq}(Z_{sp})$	(cm)					_	
¥	F _C	(MHz)	6.11	6.10	_	_	_	#
	Dim of A _{aprt}	X (cm)		0.52	_	_		#
	·	Y (cm)		0.30	_	_	_	#
	PD	(µsec)	0.628					
uo	PRF	(Hz)	3096					
nati	p _r @PII _{max}	(MPa)	0.49					
forr	d _{eq} @PII _{max}	(cm)					_	
r n	Focal Length	FL _x (cm)		2.80	_	_		#
)th		FL _y (cm)		2.70	_	_		#
J	I _{PA.3} @MI _{max}	(W/cm ²)	7.5					
	Control 1: Exam Type		Oph	Oph				
	Control 2: Mode		CVD	CVD				
rating ntrol ditions	Control 3: 2D Optimization/Depth		Pen/ 1.9 cm	Pen/ 5.1 cm				
Spe One	Control 4: Color Optimiza	tion/PRF	Low/401	Med/4167				
erating Other Information Assontrol ditions	Control 5: Color Box Posit	ion/Size	Def/Def	Top/ Short-Wide				

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-25: Transducer Model: HSL25x Ophthalmic Use Operating Mode: PW Doppler

				TIS	TIS			
	Index Label			M.I.	Non-	-scan	No.	TIC
				Scan	A _{aprt} ≤1	A _{aprt} >1	Non-scan	
Global N	Global Maximum Index Value		0.18	_	0.12	_	0.21	(b)
	p _{r.3}	(MPa)	0.44					
	W_0	(mW)		_	4.0		4.0	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z_1	(cm)				_		
Acou ter	Z _{bp}	(cm)				_		
Associated Acoustic Parameter	Z_{sp}	(cm)					0.80	
ciat Par	z@PII _{.3max}	(cm)	1.2					
Asso	$d_{eq}(Z_{sp})$	(cm)					0.32	
1	F _c	(MHz)	6.03	_	6.03	_	6.03	#
	Dim of A _{aprt}	X (cm)		_	0.76	_	0.76	#
		Y (cm)		_	0.30	_	0.30	#
	PD	(µsec)	1.275					
ion	PRF	(Hz)	1953					
nat	p _r @PII _{max}	(MPa)	0.56					
forr	d _{eq} @PII _{max}	(cm)					0.23	
r n	Focal Length	FL _x (cm)		_	3.80	_		#
Other Information		FL _y (cm)		_	2.70			#
J	I _{PA.3} @MI _{max}	(W/cm ²)	7.4					
g Sc	Control 1: Exam Type		Oph		Oph		Oph	
Operating Control Conditions	Control 2: Sample Volume	Size	1 mm		1 mm		1 mm	
peratin Control	Control 3: Sample Volume	Position	Zone 7		Zone 7		Zone 7	
ō 0	Control 4: PRF		1953		5208		5208	

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-26: Transducer Model: ICTx Operating Mode: PW Doppler

					TIS		TIB	
Index Label		M.I.	M.I.	Non-	-scan	Non-scan	TIC	
	Global Maximum Index Value			Scan	Scan A _{aprt} ≤1 A _{aprt}			
Global N	Maximum Index Value		(a)	_	(a)	_	1.2	(a)
	p _{r.3}	(MPa)	#					
	W_0	(mW)		_	#		16.348	#
Ë	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ousi	z ₁	(cm)				_		
ciated Acoi Parameter	Z _{bp}	(cm)				_		
atec aran	Z_{sp}	(cm)	#				1.6	
Associated Acoustic Parameter	$d_{eq}(Z_{sp})$	(cm)					0.192	
As	F _c	(MHz)	#	_	#	_	4.36	#
	Dim of A _{aprt}	X (cm)		_	#	_	0.6	#
	·	Y (cm)		_	#	_	0.5	#
	PD	(µsec)	#				0.5	
ion	PRF	(Hz)	#					
nati	p _r @PII _{max}	(MPa)	#					
forr	d _{eq} @PII _{max}	(cm)					0.187	
r In	Focal Length	FL _x (cm)		_	#	_		#
Other Information		FL _y (cm)		_	#	_		#
)	I _{PA.3} @MI _{max}	(W/cm ²)	#					
D S	Control 1: Exam Type						Any	
atin trol tion	Control 2: Sample Volume						3 mm	
Operating Control	Control 3: PRF						Any	
<u>0</u> 0	Control 1: Exam Type Control 2: Sample Volume Control 3: PRF 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 10-27: Transducer Model: *L25x* **Operating Mode:** *2D*

				TIS		TIB	TIC	
	Index Label			_	Non-	-scan		
Global Maximum Index Value				Scan	Scan A _{aprt} ≤1 A _{aprt} >		Non-scan	
Global N	Maximum Index Value		1.2	(a)	_	_	_	(b)
	p _{r.3}	(MPa)	2.87					
	W_0	(mW)		#	_		_	#
Ë	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ousi	z ₁	(cm)				_		
d Ac	Z _{bp}	(cm)				_		
Associated Acoustic Parameter	Z_{sp}	(cm)	0.8				_	
soci Pe	$d_{eq}(Z_{sp})$	(cm)					_	
As	F _c	(MHz)	6.11	#	_	_	_	#
	Dim of A _{aprt}	X (cm)		#	_	_	_	#
		Y (cm)		#	_	_	_	#
	PD	(µsec)	0.630					
e o	PRF	(Hz)	1061					
nati	p _r @PII _{max}	(MPa)	3.39					
forr	d _{eq} @PII _{max}	(cm)					_	
r L	Focal Length	FL _x (cm)		#	_	_		#
Other Information		FL _y (cm)		#	_	_		#
O	I _{PA.3} @MI _{max}	(W/cm ²)	478					
ng lc sns	Control 1: Exam Type		Nrv/Msk/ Ven/Art	-	_	_	_	-
peratin Control onditior	Control 2: Optimization		Any	_	_	_	_	_
Operating Control	Control 3: Depth		1.9 - 2.2	_	_	_	_	_
9 0	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 10-28: Transducer Model: L25x **Operating Mode:** CPD/Color

TIC
can
(b)
#
#
#
#
#
#

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

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

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

[—]Data are not applicable for this transducer/mode.

 Table 10-29: Transducer Model: L25x Operating Mode: PW Doppler

				TIS TIB		TIB		
	Index Label			_	Non-	-scan		TIC
				Scan	A _{aprt} ≤1	A _{aprt} >1	Non-scan	
Global Maximum Index Value		(a)	_	(a)	_	1.7	(b)	
	p _{r.3}	(MPa)	#					
	W_0	(mW)		_	#		32.1	#
tic	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ous	z ₁	(cm)				_		
ciated Acoi Parameter	Z _{bp}	(cm)				_		
atec arar	Z_{sp}	(cm)	#				0.75	
Associated Acoustic Parameter	$d_{eq}(Z_{sp})$	(cm)					0.30	
As	F _c	(MHz)	#		#		6.00	#
	Dim of A _{aprt}	X (cm)		_	#	_	0.76	#
		Y (cm)		_	#	_	0.30	#
	PD	(µsec)	#					
o	PRF	(Hz)	#					
nati	p _r @PII _{max}	(MPa)	#					
Other Information	d _{eq} @PII _{max}	(cm)					0.21	
r n	Focal Length	FL _x (cm)		_	#	_		#
Othe		FL _y (cm)		_	#	_		#
J	I _{PA.3} @MI _{max}	(W/cm^2)	#					
ng lo sns	Control 1: Exam Type		_	_	_	_	Art/Ven/ Nrv	_
Operating Control Conditions	Control 2: Sample Volume		_	_	_	_	8 mm	_
Spe Co Sono	Control 3: PRF		_	_	_	_	1953	_
0	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 10-30: Transducer Model: L25x Ophthalmic Use **Operating Mode:** 2D

					TIS		TIB	
	Index Label		M.I.		Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Naximum Index Value		0.17	0.02	_	_	_	(b)
	p _{r.3}	(MPa)	0.47					
	W_0	(mW)		0.70	_		_	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
Acou ter	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					_	
Associated Acoustic Parameter	z@PII _{.3max}		0.8					
Asso	$d_{eq}(Z_{sp})$	(cm)					_	
4	F _c	(MHz)	7.65	6.97	_	_	_	#
	Dim of A _{aprt}	X (cm)		0.96	_	_	_	#
	·	Y (cm)		0.30	_	_	_	#
	PD	(µsec)	0.101					
on	PRF	(Hz)	12580					
nati	p _r @PII _{max}	(MPa)	0.58					
forr	d _{eq} @PII _{max}	(cm)					_	
r L	Focal Length	FL _x (cm)		3.80	_	_		#
Other Information		FL _y (cm)		2.70	_	_		#
O	I _{PA.3} @MI _{max}	(W/cm ²)	13.4					
g S	Control 1 Francis		Oph	Oph				
atin trol tior	Control 2: Optimization		Res	Pen				
\mathcal{L}	Control 3: Depth		1.9 cm	4.3 cm				
	Control 4: MB		On	On				

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-31: Transducer Model: L25x Ophthalmic Use **Operating Mode:** M Mode

					TIS		0.02 0.45 0.85 0.35 6.25 0.96 0.30 0.27	
	Index Label		м.і.		Non	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		0.17	_	0.01	_	0.02	(b)
	p _{r.3}	(MPa)	0.47					
	W_0	(mW)		_	0.45		0.45	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ustic	z ₁	(cm)				_		
Associated Acoustic Parameter	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					0.85	
ciat	z@PII _{.3max}	(cm)	1.0					
Asso	$d_{eq}(Z_{sp})$	(cm)					0.35	
_	F _c	(MHz)	7.59	_	6.25	_	6.25	#
	Dim of A _{aprt}	X (cm)		_	0.96	_	0.96	#
		Y (cm)		_	0.30	_	0.30	#
	PD	(µsec)	0.098					
o	PRF	(Hz)	1600					
nati	p _r @PII _{max}	(MPa)	0.61					
Other Information	d _{eq} @PII _{max}	(cm)					0.27	
r I	Focal Length	FL _x (cm)		_	3.80	_		#
Othe		FL _y (cm)		_	2.70	_		#
J	I _{PA.3} @MI _{max}	(W/cm^2)	14.9					
gr _ sn	Control 1: Exam Type Control 2: Optimization Control 3: Depth		Oph		Oph		Oph	
atir ntro itio			Res		Pen		Pen	
Operating Control Conditions	Control 3: Depth		1.9 cm		4.3 cm		4.3 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 10-32: Transducer Model: L25x Ophthalmic Use **Operating Mode:** CPD/Color

					TIS		TIB	
	Index Label		M.I.		Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		0.17	0.06	_	_	_	(b)
	p _{r.3}	(MPa)	0.42					
	W_0	(mW)		1.9	_		_	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
COL ter	Z _{bp}	(cm)				_		
ed A	Z_{sp}	(cm)					_	
ciat Para	z@PII _{.3max}		0.7					
Iformation Associated Acou	$d_{eq}(Z_{sp})$	(cm)					_	
	F _C	(MHz)	6.11	6.10	_	_	_	#
	Dim of A _{aprt}	X (cm)		0.52	_	_		#
	·	Y (cm)		0.30	_	_	_	#
	PD	(µsec)	0.628					
uo	PRF	(Hz)	3096					
nati	p _r @PII _{max}	(MPa)	0.49					
forr	d _{eq} @PII _{max}	(cm)					_	
r In	Focal Length	FL _x (cm)		2.80	_	_		#
Othe		FL _y (cm)		2.70	_	_		#
O	I _{PA.3} @MI _{max}	(W/cm ²)	7.5					
	Control 1: Exam Type		Oph	Oph				
	Control 2: Mode		CVD	CVD				
_ s	Control 3: 2D Optimization/Depth		Pen/ 1.9 cm	Pen/ 5.1 cm				
Ope Ono	Control 4: Color Optimiza	tion/PRF	Low/401	Med/4167				
5 0	Control 5: Color Box Posit	ion/Size	Def/Def	Top/ Short-Wide				

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-33: Transducer Model: L25xOphthalmic Use **Operating Mode:** PW Doppler

					TIS		TIB Non-scan 0.21 4.0 0.80 0.32 6.03 0.76 0.30 0.23	
	Index Label		M.I.	C	Non-	-scan	N	TIC
				Scan	A _{aprt} ≤1	A _{aprt} >1	Non-scan	
Global N	Naximum Index Value		0.18	_	0.12	_	0.21	(b)
	p _{r.3}	(MPa)	0.44					
	W_0	(mW)		_	4.0		4.0	#
C)	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
Associated Acoustic Parameter	Z_{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					0.80	
ciat	z@PII _{.3max}		1.2					
Asso	$d_{eq}(Z_{sp})$	(cm)					0.32	
_	F _c	(MHz)	6.03	_	6.03	_	6.03	#
	Dim of A _{aprt}	X (cm)		_	0.76	_	0.76	#
		Y (cm)		_	0.30	_	0.30	#
	PD	(µsec)	1.275					
on	PRF	(Hz)	1953					
nati	p _r @PII _{max}	(MPa)	0.56					
forr	d _{eq} @PII _{max}	(cm)					0.23	
Other Information	Focal Length	FL _x (cm)		_	3.80	_		#
)the		FL _y (cm)		_	2.70	_		#
_	I _{PA.3} @MI _{max}	(W/cm ²)	7.4					
D SI	Control 1: Evam Type		Oph		Oph		Oph	
is de la fin	Control 2: Sample Volume	Size	1 mm		1 mm		1 mm	
Operating Control	Control 3: Sample Volume	Position	Zone 7		Zone 7		Zone 7	
ð 3	Control 4: PRF		1953		5208		5208	

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-34: Transducer Model: *L38xi standard/armored* **Operating Mode:** *2D*

					TIS		TIB	
	Index Label		M.I.		Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		1.5	(a)	_	_	_	(b)
	p _{r.3}	(MPa)	3.30					
	W_0	(mW)		#	_		_	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
\cou	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					_	
ciat _e Para	z@PII _{.3max}	(cm)	0.8					
Associated Acoustic Parameter	$d_{eq}(Z_{sp})$	(cm)					_	
4	F _c	(MHz)	4.82	#	_	_	_	#
	Dim of A _{aprt}	X (cm)		#	_	_	_	#
	·	Y (cm)		#	_	_	_	#
	PD	(µsec)	0.544					
CO	PRF	(Hz)	1312					
nati	p _r @PII _{max}	(MPa)	3.79					
forr	d _{eq} @PII _{max}	(cm)					_	
7	Focal Length	FL _x (cm)		#	_	_		#
Other Information		FL _y (cm)		#	_	_		#
J	I _{PA.3} @MI _{max}	(W/cm^2)	605					
	Control 1: Exam Type		Nrv					
ing ol ons	Control 2: Optimization		Res					
peratin Control	Control 2: Optimization Control 3: Depth Control 4: MB		2.0 cm					
Operating Control Conditions	Control 4: MB		N/A					
	Control 5: Needle Vision		On					

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-35: Transducer Model: *L38xi standard/armored* **Operating Mode:** *M Mode*

					TIS		TIB	
	Index Label		M.I.	.	Non-	Non-scan	TIC	
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global I	Maximum Index Value		1.5	_	(a)	_	1.2	(b)
	p _{r.3}	(MPa)	3.54					
	W_0	(mW)		_	#		37.1	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z_1	(cm)				_		
\cou	Z _{bp}	(cm)				_		
ed /	Z_{sp}	(cm)					0.90	
Associated Acoustic Parameter	z@PII _{.3max}	(cm)	1.0					
Asso	$d_{eq}(Z_{sp})$	(cm)					0.49	
4	F _c	(MHz)	5.76	_	#	_	5.20	#
	Dim of A _{aprt}	X (cm)		_	#	_	1.86	#
		Y (cm)		_	#	_	0.40	#
	PD	(µsec)	0.146					
on	PRF	(Hz)	1600					
nati	p _r @PII _{max}	(MPa)	4.32					
forr	d _{eq} @PII _{max}	(cm)					0.49	
Other Information	Focal Length	FL _x (cm)		_	#	_		#
Ç		FL _y (cm)		_	#	_		#
9	I _{PA.3} @MI _{max}	(W/cm ²)	776					
ons	Control 1: Exam Type		Art				Art	
peratin Control onditior	Control 2: Optimization		Gen				Pen	
Operating Control Conditions	Control 3: Depth		4.7 cm				7.3 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 10-36: Transducer Model: L38xi standard/armored **Operating Mode:** CPD/Color

					TIS		TIB	
	Index Label		M.I.		Non	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global I	Maximum Index Value		1.5	1.1	_	_	_	(b)
	p _{r.3}	(MPa)	3.30					
	W_0	(mW)		49.0	_		_	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z_1	(cm)				_		
\cou	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					_	
Associated Acoustic Parameter	z@PII _{.3max}	(cm)	0.8					
1850	$d_{eq}(Z_{sp})$	(cm)					_	
4	F _c	(MHz)	4.82	483	_	_	_	#
	Dim of A _{aprt}	X (cm)		0.54	_	_	_	#
		Y (cm)		0.40	_	_	_	#
	PD	(µsec)	0.544					
uo	PRF	(Hz)	2190					
nati	p _r @PII _{max}	(MPa)	3.79					
forr	d _{eq} @PII _{max}	(cm)					_	
r n	Focal Length	FL _x (cm)		1.50	_	_		#
Other Information		FL _y (cm)		1.50	_	_		#
O	I _{PA.3} @MI _{max}	(W/cm ²)	605					
	Control 1: Exam Type		Art	Ven				
g Sc	Control 2: Mode Control 3: 2D Optimization		CVD	CVD				
atin trol tion	Control 3: 2D Optimization	on/Depth	Pen/2.0 cm	Pen/3.1 cm				
Operating Control Conditions	Control 4: Color Optimiza Control 5: Color Box Posi	ation/PRF	Low/393	Low/2315				
ō 0	Control 5: Color Box Posi	tion/Size	Def/Def	Bottom/ Short-Narrow				

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-37: Transducer Model: L38xi standard/armored **Operating Mode:** PW Doppler

					TIS		TIB	
	Index Label		M.I.		Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		1.3	_	2.6	_	3.7	(b)
	p _{r.3}	(MPa)	2.59					
	W_0	(mW)		_	114.5		114.5	#
	$min of [W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
Acou ter	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					1.20	
Associated Acoustic Parameter	z@PII _{.3max}	(cm)	0.7					
Asso	$d_{eq}(Z_{sp})$	(cm)					0.49	
4	F _c	(MHz)	4.06	_	4.78	_	4.78	#
	Dim of A _{aprt}	X (cm)		_	1.86	_	1.86	#
		Y (cm)		_	0.40	_	0.40	#
	PD	(µsec)	1.230					
o	PRF	(Hz)	1008					
nati	p _r @PII _{max}	(MPa)	2.86					
forr	d _{eq} @PII _{max}	(cm)					0.46	
r In	Focal Length	FL _x (cm)		_	5.54	_		#
Other Information		FL _y (cm)		_	1.50	_		#
O	I _{PA.3} @MI _{max}	(W/cm ²)	323					
L S	Control 1: Exam Type		Art		Nrv		Nrv	
Operating Control Conditions	Control 2: Sample Volume	Size	1 mm		1 mm		1 mm	
perating Control andition	Control 3: Sample Volume		Zone 0		Zone 7		Zone 7	
909	Control 4: PRF		1008		10417		10417	

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

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

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

Data are not applicable for this transducer/mode.

Table 10-38: Transducer Model: P10x **Operating Mode:** CPD/Color

					TIS		TIB	
	Index Label		M.I.	_	Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		(a)	(a)	_	_	_	1.1
	p _{r.3}	(MPa)	#					
	W_0	(mW)		#	_		_	42.2
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z_1	(cm)				_		
Associated Acoustic Parameter	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					_	
ciat Para	z@PII _{.3max}	(cm)	#					
1550	$d_{eq}(Z_{sp})$	(cm)					_	
Ä	F _c	(MHz)	#	#	_	_	_	3.89
	Dim of A _{aprt}	X (cm)		#	_	_	_	0.99
	артс	Y (cm)		#	_	_	_	0.70
	PD	(µsec)	#					
o	PRF	(Hz)	#					
nati	p _r @PII _{max}	(MPa)	#					
forr	d _{eq} @PII _{max}	(cm)					_	
r L	Focal Length	FL _x (cm)		#	_	_		6.74
Other Information		FL _y (cm)		#	_	_		5.00
O	I _{PA.3} @MI _{max}	(W/cm ²)	#					
	Control 1: Exam Type							Crd
	Control 2: Mode							CVD
Operating Control Conditions	Control 2: Mode Control 3: 2D Optimization Sector Width Control 4: Color Optimization	on/Depth /						Pen/8.9 cm/ Narrow
900	Control 4: Color Optimiza	ition/PRF						Low/2033
- 0	Control 5: Color Box Posit	ion/Size						Top/ Short- Wide

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-39: Transducer Model: P10x Operating Mode: PW Doppler

					TIS		TIB	
	Index Label		M.I.	_	Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		1.0	_	1.1	_	1.9	1.5
	p _{r.3}	(MPa)	1.92					
	W_0	(mW)		_	34.4		31.9	26.9
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
Associated Acoustic Parameter	z_1	(cm)				_		
\cou	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					0.80	
ciat. Para	z@PII _{.3max}	(cm)	2.1					
\sso	$d_{eq}(Z_{sp})$	(cm)					0.31	
4	F _c	(MHz)	3.87	_	6.86	_	3.84	3.86
	Dim of A _{aprt}	X (cm)		_	0.99	_	0.42	0.22
		Y (cm)		_	0.70	_	0.70	0.70
	PD	(µsec)	1.277					
o	PRF	(Hz)	1562					
nati	p _r @PII _{max}	(MPa)	2.54					
forn	d _{eq} @PII _{max}	(cm)					0.24	
r L	Focal Length	FL _x (cm)		_	6.74	_		0.92
Other Information		FL _y (cm)		_	5.00	_		5.00
O	I _{PA.3} @MI _{max}	(W/cm ²)	200					
	Control 1: Exam Type		Crd		Crd		Abd	Crd
ng ol	Control 2: Sample Volume	Size	1 mm		7 mm		12 mm	1 mm
perating Control ondition	Control 3: Sample Volume	Position	Zone 2		Zone 6		Zone 1	Zone 0
Operating Control Conditions	Control 2: Sample Volume Control 3: Sample Volume Control 4: PRF		1562		1008		1953	15625
9 0	Control 5: TDI		Off		On		Off	Off

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

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

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

Data are not applicable for this transducer/mode.

Table 10-40: Transducer Model: P10x **Operating Mode:** CW Doppler

					TIS		TIB Non-scan 1.8 34.8 0.70 0.36 4.00 0.32 0.70 0.27	
	Index Label		M.I.	_	Non-sca	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		(a)	_	(a)	_	1.8	1.7
	p _{r.3}	(MPa)	#					
	W_0	(mW)		_	#		34.8	25.7
U	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z_1	(cm)				_		
\cot	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					0.70	
Associated Acoustic Parameter	z@PII _{.3max}	(cm)	#					
Asso	$d_{eq}(Z_{sp})$	(cm)					0.36	
	F _c	(MHz)	#	_	#	_	4.00	4.00
	Dim of A _{aprt}	X (cm)		_	#	_	0.32	0.16
		Y (cm)		_	#	_	0.70	0.70
	PD	(µsec)	#					
on	PRF	(Hz)	#					
nati	p _r @PII _{max}	(MPa)	#					
forn	d _{eq} @PII _{max}	(cm)					0.27	
r l	Focal Length	FL _x (cm)		_	#	_		0.92
Other Information		FL _y (cm)		_	#	_		5.00
0	I _{PA.3} @MI _{max}	(W/cm ²)	#					
gr _ sn	Control 1: Exam Type						Crd	Crd
Control 1: Exam Type Control 2: Sample Volume Position Control 2: Sample Volume Position						Zone 3	Zone 0	

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-41: Transducer Model: rP19x standard/armored **Operating Mode:** 2D

					TIS		TIB Non-scan — — — — — — — — — — — — — — — — — —	
	Index Label		M.I.		Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	- Non-scan	
Global N	Maximum Index Value		1.5	1.0	_	_	_	2.7
	p _{r.3}	(MPa)	2.10					
	W_0	(mW)		96.1	_		_	177.8
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)						
\cou	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					_	
ciat Para	z@PII _{.3max}	(cm)	4.8					
Associated Acoustic Parameter	$d_{eq}(Z_{sp})$	(cm)					_	
4	F _c	(MHz)	1.99	2.08	_	_	_	1.53
	Dim of A _{aprt}	X (cm)		1.44	_	_	_	0.54
	·	Y (cm)		1.15	_	_	_	1.15
	PD	(µsec)	0.492					
CO	PRF	(Hz)	6186					
nati	p _r @PII _{max}	(MPa)	2.92					
forr	d _{eq} @PII _{max}	(cm)					_	
r n	Focal Length	FL _x (cm)		6.43	_	_		1.55
Other Information		FL _y (cm)		9.00	_	_		9.00
O	I _{PA.3} @MI _{max}	(W/cm ²)	184					
	Control 1: Exam Type		Abd	Crd				Abd
ing ol ons	Control 2: Optimization		Gen	Res				Pen
Operating Control Conditions	Control 3: Depth		10 cm	10 cm				4.7 cm
90 Co	Control 2: Optimization Control 3: Depth Control 4: MB/THI		Off/Off	Off/Off				Off/On
	Control 5: Sector Width		N/A	Narrow				N/A

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-42: Transducer Model: rP19x standard/armored **Operating Mode:** M Mode

					TIS		TIB	
	Index Label		M.I.		Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global Maximum Index Value		1.5	_	(a)	_	1.7	1.0	
	p _{r.3}	(MPa)	2.10					
	W_0	(mW)		_	#		55.0	62.1
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
Associated Acoustic Parameter	z ₁	(cm)				_		
Acou	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					4.33	
ciat Par	z@PII _{.3max}	(cm)	4.8					
Asso	$d_{eq}(Z_{sp})$	(cm)					0.43	
_	F _c	(MHz)	1.99	_	#	_	1.81	1.77
	Dim of A _{aprt}	X (cm)		_	#	_	1.68	1.74
		Y (cm)		_	#	_	1.15	1.15
	PD	(µsec)	0.492					
on	PRF	(Hz)	800					
nati	p _r @PII _{max}	(MPa)	2.92					
forr	d _{eq} @PII _{max}	(cm)					0.42	
r l	Focal Length	FL _x (cm)		_	#	_		9.82
Other Information		FL _y (cm)		_	#	_		9.00
O	I _{PA.3} @MI _{max}	(W/cm ²)	184					
D SI	Control 1: Exam Type		TCD				Abd	Abd
rin trol tion	Control 2: Optimization		Gen				Res	Res
Operating Control Conditions	Control 3: Depth		7.5 cm				10 cm	16 cm
5°3	Control 4: THI		Off				On	On

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-43: Transducer Model: rP19x standard/armored **Operating Mode:** CPD/Color

					TIS		TIB	
	Index Label		M.I.	6	Non-	-scan	N	TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global	Maximum Index Value		1.5	1.2	_	_	_	2.5
	$p_{r,3}$	(MPa)	2.10					
	W_0	(mW)		115.6	_		_	170.5
<u>ب</u>	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				-		
oust	z_1	(cm)				_		
Acc	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					_	
Associated Acoustic Parameter	z@PII _{.3max}	(cm)	4.8					
Ass	$d_{eq}(Z_{sp})$	(cm)					_	
	F _c	(MHz)	1.99	2.14	_	_	_	2.12
	Dim of A _{aprt}	X (cm)		0.78	_	_	_	1.80
		Y (cm)		1.15	_	_	_	1.15
	PD	(µsec)	0.492					
uo	PRF	(Hz)						
nati	p _r @PII _{max}	(MPa)	2.92					
forr	d _{eq} @PII _{max}	(cm)					_	
느	Focal Length	FL _x (cm)		3.68	_	_		9.82
Other Information		FL _y (cm)		9.00	_	_		9.00
O	I _{PA.3} @MI _{max}	(W/cm^2)	184					
	Control 1: Exam Type		Abd	TCD				Crd
	Control 2: Mode/THI		CVD/Off	CVD/Off				CVD/On
Operating Control	Control 3: 2D Optimize Depth/Sector Control 4: Color Optimize PRF	ation/	Gen/10 cm/ N/A	Pen/7.5 cm/ N/A				Gen/16 cm/ Narrow
Oper			Low/300	Low/3125				High/5208
() TI:	Control 5: Color Box P		Def/Def	Def/Narrow				Def/Def

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-44: Transducer Model: rP19x standard/armored **Operating Mode:** PW Doppler

					TIS		TIB	
	Index Label		M.I.		Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global I	Maximum Index Value		1.3	_	_	1.8	4.0	3.9
	p _{r.3}	(MPa)	1.94					
	W_0	(mW)		_	_		240.2	251.1
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				173.7		
ıstic	z ₁	(cm)				2.5		
\cou	Z _{bp}	(cm)				2.5		
ciated Aco Parameter	Z_{sp}	(cm)					3.35	
Associated Acoustic Parameter	z@PII _{.3max}	(cm)	3.0					
\sso	$d_{eq}(Z_{sp})$	(cm)					0.80	
4	F _c	(MHz)	2.14	_	_	2.23	2.23	2.10
	Dim of A _{aprt}	X (cm)		_	_	1.86	1.80	1.80
	·	Y (cm)		_	_	1.15	1.15	1.15
	PD	(µsec)	1.334					
uo	PRF	(Hz)	1562					
Other Information	p _r @PII _{max}	(MPa)	2.42					
forn	d _{eq} @PII _{max}	(cm)					0.62	
r L	Focal Length	FL _x (cm)		_	_	29.82		18.46
Othe		FL _y (cm)		_	_	9.00		9.00
O	I _{PA.3} @MI _{max}	(W/cm ²)	180					
	Control 1: Exam Type		Crd			Crd	Crd	Crd
و د	Control 2: Sample Volum	e Size	1 mm			12 mm	12 mm	1mm
rtin trol tior	Control 3: Sample Volume Position		Zone 1			Zone 7	Zone 5	Zone 5
Operating Control Conditions	Control 2: Sample Volum Control 3: Sample Volum Control 4: PRF		1562 Hz			1562 Hz	1562 Hz	3906 Hz
	Control 5: TDI		Off			Off	Off	Off

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-45: Transducer Model: rP19x standard/armored Operating Mode: CW Doppler

					TIS		TIB	
	Index Label		M.I.	_	Non-	scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		(a)	_	1.2	_	4.0	4.0
	p _{r.3}	(MPa)	#					
	W_0	(mW)		_	125.4		125.4	125.4
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
Associated Acoustic Parameter	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					0.90	
ciat	z@PII _{.3max}	(cm)	#					
Asso	$d_{eq}(Z_{sp})$	(cm)					0.64	
	F _c	(MHz)	#	_	2.00	_	2.00	2.00
	Dim of A _{aprt}	X (cm)		_	0.42	_	0.42	0.42
		Y (cm)		_	1.15	_	1.15	1.15
	PD	(µsec)	#					
o	PRF	(Hz)	#					
nati	p _r @PII _{max}	(MPa)	#					
Other Information	d _{eq} @PII _{max}	(cm)					0.61	
r n	Focal Length	FL _x (cm)		_	1.55	_		1.55
Othe		FL _y (cm)		_	9.00	_		9.00
J	I _{PA.3} @MI _{max}	(W/cm ²)	#					
gr I	Control 1: Exam Type					Crd	Crd	Crd
Operating Control Conditions	Se Control 1: Exam Type Control 2: Zone Control 2: Zone					Zone 0	Zone 0	Zone 0

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-46: Transducer Model: rP19x Orbital Use standard/armored **Operating Mode:** 2D

					TIS		TIB	
	Index Label		M.I.	_	Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		0.17	0.03	_	_	_	0.07
	p _{r.3}	(MPa)	0.25					
	W_0	(mW)		2.9	_		_	4.7
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z_1	(cm)				_		
\cot	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					_	
Associated Acoustic Parameter	z@PII _{.3max}	(cm)	3.4					
Asso	$d_{eq}(Z_{sp})$	(cm)					_	
1	F _c	(MHz)	2.06	2.06	_	_	_	1.90
	Dim of A _{aprt}	X (cm)		0.84	_	_	_	1.74
		Y (cm)		1.15	_	_	_	1.15
	PD	(µsec)	0.511					
on	PRF	(Hz)	6413					
nati	p _r @PII _{max}	(MPa)	0.31					
forr	d _{eq} @PII _{max}	(cm)					_	
r l	Focal Length	FL _x (cm)		3.68	_	_		13.84
Other Information		FL _y (cm)		9.00	_	_		9.00
J	I _{PA.3} @MI _{max}	(W/cm ²)	4.1					
D SI	Control 1: Exam Type		Orb	Orb				Orb
Operating Control Conditions	Control 2: Optimization		Res	Res				Gen
peratin Control onditior	Control 3: Depth		4.7 cm	4.7 cm				16 cm
ō 0	Control 4: MB		Off	Off				Off

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-47: Transducer Model: rP19x Orbital Use standard/armored Operating Mode: M Mode

					TIS		TIB	
	Index Label		M.I.		Non-	scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		0.17	_	_	0.01	0.02	0.02
	p _{r.3}	(MPa)	0.25					
	W_0	(mW)		_	_		1.34	1.34
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				1.0		
ıstic	z ₁	(cm)				2.5		
Associated Acoustic Parameter	Z _{bp}	(cm)				2.4		
ciated Aco Parameter	Z_{sp}	(cm)					3.15	
ciat Para	z@PII _{.3max}	(cm)	3.4					
Asso	$d_{eq}(Z_{sp})$	(cm)					0.43	
4	F _c	(MHz)	2.06	_	_	1.83	1.83	1.83
	Dim of A _{aprt}	X (cm)		_	_	1.74	1.74	1.74
	·	Y (cm)		_	_	1.15	1.15	1.15
	PD	(µsec)	0.511					
o	PRF	(Hz)	800					
nati	p _r @PII _{max}	(MPa)	0.31					
forn	d _{eq} @PII _{max}	(cm)					0.81	
r n	Focal Length	FL _x (cm)		_	_	29.82		29.82
Other Information		FL _y (cm)		_	_	9.00		9.00
0	I _{PA.3} @MI _{max}	(W/cm ²)	4.05					
g _ sn	Control 1: Exam Type		Orb			Orb	Orb	Orb
peratin Control onditior	Control 2: Optimization		Res			Gen	Gen	Gen
Operating Control Conditions	Control 3: Depth		4.7 cm			35 cm	35 cm	35 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 10-48: Transducer Model: rP19x Orbital Use standard/armored **Operating Mode:** CPD/Color

					TIS		TIB	
	Index Label		M.I.		Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global	Maximum Index Value		0.17	0.09	_	_	_	0.23
	p _{r.3}	(MPa)	0.25					
	W_0	(mW)		9.5	_		_	15.5
ij	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				-		
oust	z ₁	(cm)				_		
Acc	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					_	
Associated Acoustic Parameter	z@PII _{.3max}	(cm)	0.7					
Ass	$d_{eq}(Z_{sp})$	(cm)					_	
	F _c	(MHz)	2.14	2.11	_	_	_	2.11
	Dim of A _{aprt}	X (cm)		1.80	_	_	_	1.80
	·	Y (cm)		1.15	_	_	_	1.15
	PD	(µsec)	1.325					
uo	PRF	(Hz)	5443					
nati	p _r @PII _{max}	(MPa)	0.26					
forr	d _{eq} @PII _{max}	(cm)					_	
Other Information	Focal Length	FL _x (cm)		13.84	_	_		13.84
Othe		FL _y (cm)		9.00	_	_		9.00
O	I _{PA.3} @MI _{max}	(W/cm^2)	1.82					
	Control 1: Exam Type		Orb	Orb				Orb
	Control 2: Mode		CVD	CVD				CVD
ating trol	Control 3: 2D Optimiz Depth	ration/	Gen/4.7 cm	Gen/24 cm				Gen/24 cm
Operating Control	Control 4: Color Optir PRF	Control 1: Exam Type Control 2: Mode Control 3: 2D Optimization/ Depth Control 4: Color Optimization/ PRF		Low/3125				Low/3125
	Control 5: Color Box F Size	osition/	Def/Def	Top/ Short- Wide				Top/ Short- Wide

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-49: Transducer Model: rP19x Orbital Use standard/armored **Operating Mode:** PW Doppler

					TIS		TIB	
	Index Label		M.I.		Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		0.18	_	_	0.27	0.59	0.57
	p _{r.3}	(MPa)	0.27					
	W_0	(mW)		_	_		35.3	37.4
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				25.3		
ıstic	z ₁	(cm)				2.5		
Cou	Z _{bp}	(cm)				2.5		
ciated Aco Parameter	Z_{sp}	(cm)					3.35	
Associated Acoustic Parameter	z@PII _{.3max}	(cm)	3.5					
\sso	$d_{eq}(Z_{sp})$	(cm)					0.81	
4	F _c	(MHz)	2.23	_	_	2.23	2.23	2.23
	Dim of A _{aprt}	X (cm)		_	_	1.86	1.80	1.86
	·	Y (cm)		_	_	1.15	1.15	1.15
	PD	(µsec)	6.557					
on	PRF	(Hz)	1953					
nati	p _r @PII _{max}	(MPa)	0.36					
forr	d _{eq} @PII _{max}	(cm)					0.64	
r In	Focal Length	FL _x (cm)		_	_	29.82		29.82
Other Information		FL _y (cm)		_	_	9.00		9.00
0	I _{PA.3} @MI _{max}	(W/cm ²)	2.49					
D S	Control 1: Exam Type		Orb			Orb	Orb	Orb
Operating Control Conditions	Control 2: Sample Volume Size		5 mm			14 mm	14 mm	14 mm
Deratin Control	Control 3: Sample Volume	Position	Zone 6			Zone 7	Zone 5	Zone 7
903	Control 4: PRF		1953			1953	1953	1953

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

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

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

[—]Data are not applicable for this transducer/mode.

Table 10-50: Transducer Model: TEExi **Operating Mode:** PW Doppler

					TIS		TIB	
	Index Label		M.I.		Non-	-scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Maximum Index Value		(a)	_	(a)	_	1.4	(b)
	p _{r.3}	(MPa)	#					
	W_0	(mW)		_	#		35.8	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
\cou	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					2.57	
Associated Acoustic Parameter	z@PII _{.3max}	(cm)	#					
Asso	$d_{eq}(Z_{sp})$	(cm)					0.29	
4	F _c	(MHz)	#	_	#	_	3.81	#
	Dim of A _{aprt}	X (cm)		_	#	_	0.90	#
		Y (cm)		_	#	_	0.90	#
	PD	(µsec)	#					
on	PRF	(Hz)	#					
nati	p _r @PII _{max}	(MPa)	#					
forr	d _{eq} @PII _{max}	(cm)					0.28	
r n	Focal Length	FL _x (cm)		_	#	_		#
Other Information		FL _y (cm)		_	#	_		#
J	I _{PA.3} @MI _{max}	(W/cm^2)	#					
D 2	Control 1: Exam Type						Crd	
Operating Control	Control 1: Exam Type Control 2: Sample Volume Control 3: Sample Volume Control 4: PRF	Size					1 mm	
peratin Control	Control 3: Sample Volume	Position					Zone 3	
500	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 10-51: Transducer Model: TEExi **Operating Mode:** CW Doppler

					TIS		TIB	
	Index Label		M.I.		Non-	·scan		TIC
				Scan	A _{aprt} <1	A _{aprt} >1	Non-scan	
Global N	Global Maximum Index Value		(a)	_	(a)	_	1.7	(b)
	p _{r.3}	(MPa)	#					
	W_0	(mW)		_	#		34.4	#
	min of $[W_{.3}(z_1),I_{TA.3}(z_1)]$	(mW)				_		
ıstic	z ₁	(cm)				_		
Associated Acoustic Parameter	Z _{bp}	(cm)				_		
ciated Aco Parameter	Z_{sp}	(cm)					1.1	
ciat	z@PII _{.3max}	(cm)	#					
Asso	$d_{eq}(Z_{sp})$	(cm)					0.34	
_	F _c	(MHz)	#	_	#	_	4.00	#
	Dim of A _{aprt}	X (cm)		_	#	_	0.43	#
		Y (cm)		_	#	_	0.90	#
	PD	(µsec)	#					
on	PRF	(Hz)	#					
nati	p _r @PII _{max}	(MPa)	#					
Other Information	d _{eq} @PII _{max}	(cm)					0.34	
er In	Focal Length	FL _x (cm)		_	#	_		#
Ç		FL _y (cm)		_	#	_		#
	I _{PA.3} @MI _{max}	(W/cm^2)	#					
gr I	Control 1: Exam Type						Crd	
Operating Control Conditions	Control 2: Sample Volume 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.

Terms used in the acoustic output tables

Term	Definition
Ispta.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.
lpa.3@Mlmax	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.
Aaprt	Area of the active aperture measured in cm ² .
Pr.3	Derated peak rarefactional pressure associated with the transmit pattern giving rise to the value reported under MI (Megapascals).
Wo	Ultrasonic power, except for ${\sf TIS}_{\sf scan}$, in which case it is the ultrasonic power passing through a one centimeter window in units of milliwatts.
W.3(z1)	Derated ultrasonic power at axial distance z ₁ in units of milliwatts.
ISPTA.3(z1)	Derated spatial-peak temporal-average intensity at axial distance z_1 (milliwatts per square centimeter).
z1	Axial distance corresponding to the location of maximum [min(W $_3$ (z), I $_{TA.3}$ (z) x 1 cm 2)], where z \geq zbp in centimeters.
zbp	1.69 $\sqrt{(A_{aprt})}$ in centimeters.
zsp	For MI, the axial distance at which $p_{r,3}$ is measured. For TIB, the axial distance at which TIB is a global maximum (for example, $z_{sp} = z_{b,3}$) in centimeters.

Term	Definition
deq(z)	Equivalent beam diameter as a function of axial distance z, and is equal to $\sqrt{(4/(\pi))((Wo)/(ITA(z)))}$, where $I_{TA}(z)$ is the temporal-average intensity as a function of z in centimeters.
fc	Center frequency in MHz.
Dim. of Aaprt	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.
PRF	Pulse repetition frequency associated with the transmit pattern giving rise to the reported value of MI in Hertz.
p _r @Pllmax	Peak rarefactional pressure at the point where the free-field, spatial-peak pulse intensity integral is a maximum in Megapascals.
deq@PIImax	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.

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

Quantity	Precision (% of standard deviation)	Uncertainty (95% confidence)
PII _{.3}	3.2%	+13.47 to -17.5%

Glossary

Terms

For ultrasound terms not included in this glossary, refer to *Recommended Ultrasound Terminology, Third Edition,* published in 2011 by the American Institute of Ultrasound in Medicine (AIUM).

as low as reasonably achievable (ALARA)

The guiding principle of ultrasound use, which states that you should keep patient exposure to ultrasound energy as low as reasonably achievable for

diagnostic results.

curved array transducer Identified by the letter C (curved or curvilinear) and a number (60). The number corresponds to the radius of curvature of the array expressed in millimeters. The transducer elements are electrically configured to control the characteristics and direction of the acoustic beam. For example, C11x.

depth Refers to the depth of the display. A constant speed of sound of

1538.5 meters/second is assumed in the calculation of echo position in the

image.

in situ In the natural or original position.

LCD liquid crystal display

linear array transducer Identified by the letter L (linear) and a number (38). The number corresponds

to the length of the array expressed in millimeters. The transducer elements are electrically configured to control the characteristics and direction of the

acoustic beam. For example, L38xi.

mechanical index (MI) An indication of the likelihood of mechanical bioeffects occurring: the higher

the MI, the greater the likelihood of mechanical bioeffects. See Chapter 10,

"Acoustic Output," for a more complete description of MI.

MI/TI Refer to mechanical index (MI) and thermal index (TI).

NTSC National Television Standards Committee. A video format setting. Refer to

PAL.

PAL Phase Alternating Line. A video format setting. Refer to *NTSC*.

phased array transducer A transducer designed primarily for cardiac scanning. Forms a sector image by electronically steering the beam direction and focus. For example, rP19x.

skinline A depth on the display that corresponds to the skin/transducer interface.

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SonoHD2[™] Imaging Technology A subset of the 2D imaging mode in which the 2D image is enhanced by reducing speckle noise artifact at tissue margins and improving contrast resolution by reducing artifacts and improving visualization of texture patterns within the image.

SonoMB technology, Steep Needle Profiling technology

A subset of the 2D imaging mode in which the 2D image is enhanced by looking at a target from multiple angles and then merging or averaging the scanned data together to improve overall image quality and, in parallel, reducing noise and artifacts.

Tissue Doppler Imaging

A pulsed wave Doppler technique used to detect myocardial motion.

thermal index (TI)

The ratio of total acoustic power to the acoustic power required to raise tissue temperature by 1°C under defined assumptions. See Chapter 10, "Acoustic Output," for a more complete description of TI.

TIB (bone thermal index)

A thermal index for applications in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.

TIC (cranial bone thermal index)

A thermal index for applications in which the ultrasound beam passes through bone near the beam entrance into the body.

TIS (soft tissue thermal index)

A thermal index related to soft tissues.

Tissue Harmonic Imaging 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.

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Table 11-1: Abbreviations in user interface

Abbreviation	Definition
+/×	"+" Caliper/"×" Caliper Ratio
A	"A" Wave Peak Velocity
A PG	"A" Wave Peak Pressure Gradient
A2Cd	Apical 2 Chamber diastolic
A2Cs	Apical 2 Chamber systolic
A4Cd	Apical 4 Chamber diastolic
A4Cs	Apical 4 Chamber systolic
AAA	Abdominal Aortic Aneurysm
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
Al	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 11-1: 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
ВА	Basilar Artery
Bifur	Bifurcation
ВР	Blood Pressure
BPD	Biparietal Diameter
BPM	Beats per Minute
Bre	Breast
BSA	Body Surface Area
CCA	Common Carotid Artery
Cl	Cardiac Index
CM	Cisterna Magna
СО	Cardiac Output
CPD	Color Power Doppler
Crd	Cardiac
CRL	Crown Rump Length

Table 11-1: 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
Е	"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 11-1: Abbreviations in user interface (continued)

Abbreviation	Definition
EFW	Estimated Fetal Weight Calculated from the measurements performed during the exam. The measurements used to determine EFW are defined by the currently selected EFW calculation author.
Endo	Endocardial
Ері	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)
FS	Fractional Shortening
FTA	Fetal Trunk Area
GA	Gestational Age
GA by LMP	Gestational Age by Last Menstrual Period The fetal age calculated using the date of the Last Menstrual Period (LMP).
GA by LMPd	Gestational Age by derived Last Menstrual Period The fetal age calculated using the Last Menstrual Period (LMPd) derived from the Estab. DD.
Gate	Depth of Doppler Gate
GS	Gestational Sac
Gyn	Gynecology
HC	Head Circumference

Table 11-1: Abbreviations in user interface (continued)

Abbreviation	Definition
HL	Humerus Length
HR	Heart Rate
ICA	Internal Carotid Artery
IVC	Inferior Vena Cava
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

Table 11-1: Abbreviations in user interface (continued)

Abbreviation	Definition
LVDFS	Left Ventricular Dimension Fractional Shortening
LVDs	Left Ventricular Dimension Systolic
LVEDV	Left Ventricular End Diastolic Volume
LVESV	Left Ventricular End Systolic Volume
LVET	Left Ventricular Ejection Time
LVO	Left Ventricular Opacification
LVOT	Left Ventricular Outflow Tract
LVOT Area	Left Ventricular Outflow Tract Area
LVOT D	Left Ventricular Outflow Tract Diameter
LVOT VTI	Left Ventricular Outflow Tract Velocity Time Integral
LVPW	Left Ventricular Posterior Wall
LVPWd	Left Ventricular Posterior Wall Diastolic
LVPWFT	Left Ventricular Posterior Wall Fractional Thickening
LVPWs	Left Ventricular Posterior Wall Systolic
LVs	Left Ventricular systolic
MB	SonoMB technology
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 11-1: 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
ОВ	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 11-1: 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 11-1: 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
TAPSE	M Mode distance measurement of systolic excursion of the right ventricle
TCD	Trans-cerebellum Diameter (OB measurement) Transcranial Doppler (exam type)
TDI	Tissue Doppler Imaging
THI	Tissue Harmonic Imaging
TI	Thermal Index
TICA	Terminal Internal Carotid Artery
ТО	Transorbital
TRmax	Tricuspid Regurgitation (peak velocity)
TT	Transtemporal
TTD	Transverse Trunk Diameter
TV	Tricuspid Valve
TVA	Tricuspid Valve Area

Table 11-1: Abbreviations in user interface (continued)

Abbreviation	Definition
UA	Ultrasound Age Calculated on the mean measurements taken for a particular fetal biometry.
Umb A	Umbilical Artery
VA	Vertebral Artery
VArty	Vertebral Artery
Vas	Vascular
Ven	Venous
VF	Volume Flow
Vmax	Peak Velocity
Vmean	Mean Velocity
Vol	Volume
VTI	Velocity Time Integral
YS	Yolk Sac



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