S Series
Ultrasound System

User Guide

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SonoSite
FUJIFILM

S Series
Ultrasound System

User Guide

Manufacturer

FUJIFILM SonoSite, Inc.

21919 30th Drive SE

Bothell, WA 98021 USA

T: 1-888-482-9449 or 1-425-951-1200

F: 1-425-951-1201

EC Authorized Representative

FUJIFILM SonoSite B.V.

Joop Geesinkweg 140

1114 AB Amsterdam,

The Netherlands

Australia Sponsor

FUJIFILM SonoSite Australasia Pty Ltd

114 Old Pittwater Road

BROOKVALE, NSW, 2100

Australia

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

The SonoSite ultrasound system(s) referenced in this document may be covered by one or more of the following U.S. patents: 5722412, 5817024, 5893363, 6135961, 6203498, 6364839, 6371918, 6383139, 6416475, 6447451, 6471651, 6569101, 6648826, 6575908, 6604630, 6817982, 6835177, 6962566, 7169108, 7449640, 7534211, 7549961, 7588541, 7591786, 7604596, 7643040, D456509, D461895, D509900, D538432, D544962, D558351, D559390, D591423, D592750, D592760, and by the following counterpart foreign patents: AU727381, AU730822, CA2372158, CA2373065, CN ZL 97113678.5, CN ZL 98106133.8, CN ZL 98108973.9, CN ZL 200830007734.8, DE60021552.0, DE60029777.2, DE60034670.6, DE69730563.5, DE6980539.6, DE69831698.3, DE60 2004 23 816.3-08, FR0815793, FR0875203, FR0881492, FR1175713, FR1180970, FR1589878, GB0875203, GB0881492, GB1175713, GB1180970, GB1180971, GB1589878, IT0815793, IT0881492, IT1175713, IT1589878, KR528102, KR532359, NO326202, NO326814, NZ542968, RCD000897368-0001, SP0815793, SP0881492, SP1589878. Patents pending.

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Introduction

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

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

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

Conventions

The user guide follows these conventions:

- A **WARNING** describes precautions necessary to prevent injury or loss of life.
- A **Caution** describes precautions necessary to protect the products.
- Numbered steps in procedures must be performed in order.
- Items in bulleted lists do not require a sequence.
- Single-step procedures begin with ❖.

Symbols and terms used on the system and transducer are explained in Chapter 1, Chapter 6, and Glossary.

Customer comments

Questions and comments are encouraged. SonoSite is interested in your feedback regarding the system and the user guide. Please call SonoSite at 888-482-9449 in the US. Outside the US, call the nearest SonoSite representative. You can also e-mail SonoSite at comments@sonosite.com.

For technical support, please contact SonoSite as follows:

SonoSite Technical Support

Phone (US or Canada):	877-657-8118
Phone (Outside US and Canada):	425-951-1330 Or call your local representative.
Fax:	425-951-6700
E-mail:	service@sonosite.com
Web site:	www.sonosite.com Click Support.

Europe Service Center

Phone	+44-(0)1462-444-800
E-mail	uk.service@sonosite.com

Chapter 1: Getting Started

About the system

The SonoSite S Series ultrasound system is a portable, software-controlled device using all-digital architecture. The S Series includes the following:

- S-Cath™ ultrasound system
- S-FAST™ ultrasound system
- S-GYN™ ultrasound system
- S-ICU™ ultrasound system
- S-MSK™ ultrasound system
- S-Nerve™ ultrasound system
- S-Women's Health™ ultrasound system

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

Basic steps

1. Turn the system on. (For power switch location, see "System controls" on page 5.)
2. Attach a transducer.
3. Press **Patient**, and complete the patient information form.
4. If all imaging modes are licensed, press **Mode**, and select an imaging mode.

   By default, the system is in 2D imaging.

Preparing the system

Compartments and connectors

The back of the system has compartments for the battery and transducer as well as connectors for USB devices, power cords, cables, and more. The side has additional connectors. (See Figure 1 on page 2.)

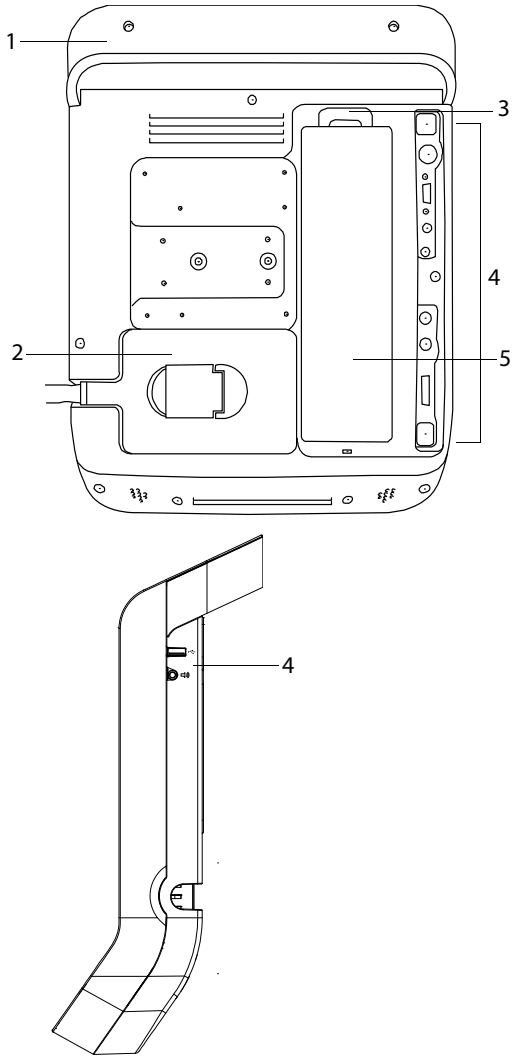

Figure 1 System Back (Top) and Side (Bottom)

1	Handle
2	Transducer
3	Locking lever for battery
4	Connectors (See the table "Connectivity Symbols on System.")
5	Battery

Each connector on the back and side of the system has a symbol that describes its use.

Connectivity Symbols on System

Symbol	Definition
	USB
	DC input
	RS-232 (DVD recorder or bar code scanner)
	Composite video out
	Print control
	S-video out
	S-video in
	DVI video out
	Ethernet
	Audio out

Installing or removing the battery

WARNING: To avoid injury to the operator and to prevent damage to the ultrasound system, inspect the battery for leaks prior to installing.

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

To install the battery

1 Disconnect the power supply from the ultrasound system.

2 Slide the two prongs at the bottom of the battery into the battery compartment on the back of the system.

3 Lower the battery into the compartment.

4 Firmly press the battery until the locking lever pops up.

To remove the battery

1 Disconnect the power supply from the ultrasound system.

2 Push down on the locking lever at the top of the battery, and lift the battery up.

Using AC power and charging the battery

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

The system can run on AC power and charge the battery if AC power is connected to the 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 "Electrical" on page 138.

To operate the system using AC power

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

2 Connect the AC power cord to the power supply and to a hospital-grade electrical outlet.

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 SonoSite or your local representative.

To turn the system on or off

❖ Press the power switch. (See "System controls" on page 5.)

To wake up the system

To conserve battery life while the system is on, the system goes into sleep mode if untouched for a preset time. To adjust the time for sleep delay, see "Audio, Battery setup" on page 14.

❖ Press a key, or touch the touchpad.

Connecting transducers

WARNING: To avoid injury to the patient, do not place the connector on the patient. Operate the ultrasound system in the S Series stand, the V-Universal™ stand, or on a convenient surface to allow air flow past the connector.

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

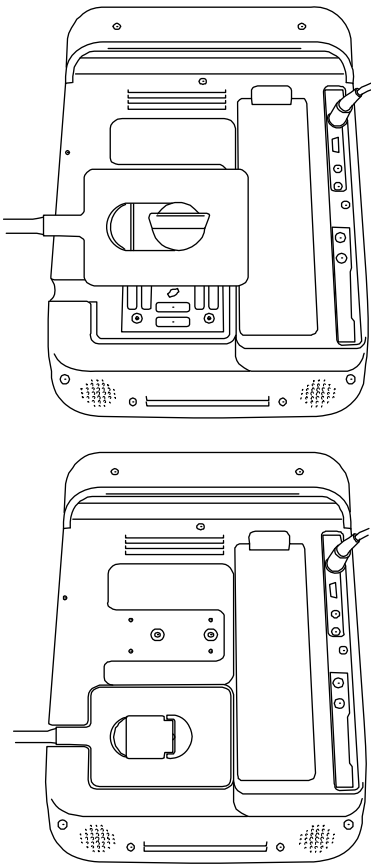

Figure 2 Connect the Transducer

To connect a transducer

1. Pull the transducer latch up, and rotate it clockwise.
2. Align the transducer connector with the connector on the back of the system.
3. Insert the transducer connector into 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, and rotate it clockwise.
2. Pull the transducer connector away from the system.

Inserting and removing USB storage devices

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

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

There are three USB ports on the system: two on the back, and one on the side. For additional USB ports, you can connect a USB hub into any USB port.

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

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

To insert a USB storage device

❖ Insert the USB storage device into a USB port on the system. See Figure 1 on page 2.

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

To view information about the device, see "USB Devices setup" on page 16.

To remove a USB storage device

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

1 Wait five seconds after the USB animation stops.

2 Remove the USB storage device from the port.

System controls

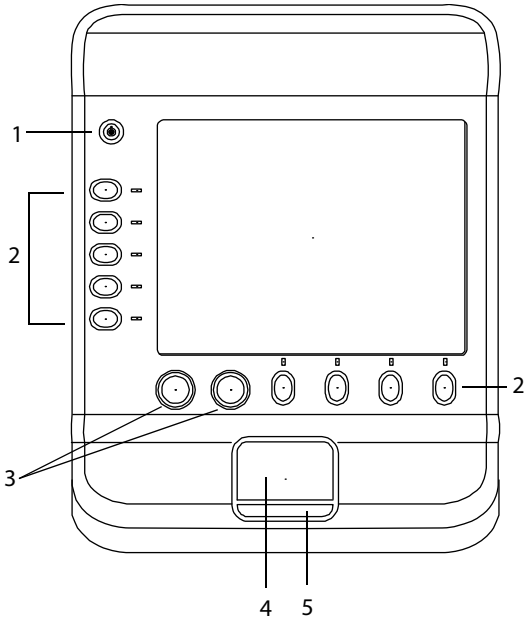

Figure 3 System Controls:

1	Power switch	Turns the system on and off.
2	Control keys	Perform an action or make a selection based on context. Current names appear on-screen adjacent to the keys.
3	Control knobs	Adjust gain, depth, cine buffer, brightness, and more. Can also perform an action. Are turned, pressed, or both, depending on context. Current names appear on-screen above the knobs.
4	Touchpad	Moves the pointer and other items.
5	Touchpad key	Works in conjunction with the touchpad. Is pressed to activate an item on-screen.

Screen layout

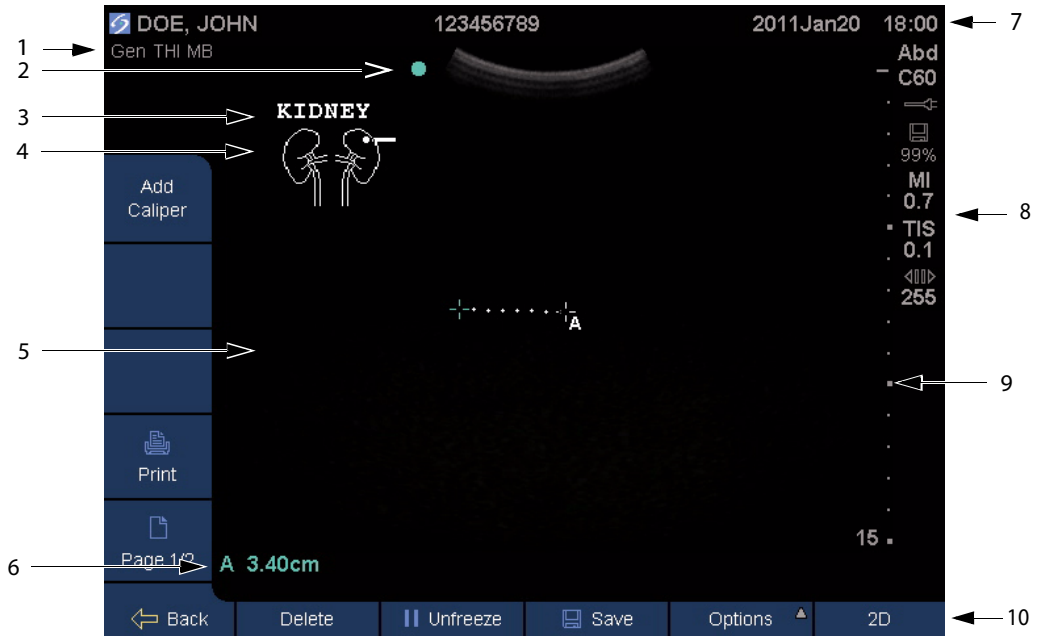

Figure 4 Screen Layout

1	Mode data area	Current imaging mode information and settings (for example, Gen, THI, MB). For definitions, see "Glossary."
2	Orientation marker	Provides indication for image orientation.
3	Text	Text entered using keyboard.
4	Picto	Pictograph to indicate anatomy and transducer position. You can select anatomy and screen location.
5	Image	Ultrasound image.
6	Measurement and calculations data area	Current data on measurements and calculations.
7	Patient header	Includes current patient name, patient ID number, institution, user, and date/time.
8	System status	Information on system status (for example, exam type, transducer, AC connected, battery charging, and USB).
9	Depth marker	Marks in .5 cm, 1 cm, and 5 cm increments depending on depth. To specify style, see "Presets setup" on page 16.
10	Controls	Names of controls available in the current context. (See also "Control keys and knobs" on page 7.)

General interaction

Touchpad

In forms and the setup pages, the touchpad is similar to a mouse on portable PCs. Using the touchpad, you move the pointer to an item and then *click* (press the key below the touchpad) to activate that item.

In other contexts, the touchpad adjusts and moves items on-screen: calipers, region of interest (ROI) box, and more. Clicking can toggle among selected items.

Control keys and knobs

The control keys and knobs change dynamically depending on context. For example, freezing an image may display the controls for zooming, performing measurements, and reviewing the cine buffer. The current name appears on-screen next to the key or knob.

To select a control key, press it. To select a control knob, press it, turn it, or both, depending on context.

Functionality

In general, a control functions in one of the following ways:

Knob or key

- Turns a feature on or off.
- Performs an action such as saving or returning to the previous screen.
- Displays additional controls.

Knob only

- Makes finer adjustments to gain, depth, PRF scale, gate size, and more.
- Scrolls through the cine buffer and saved images.

Key only

- Cycles through a list of settings.
- Displays a list from which to select. Identified by an arrow ▲. Pressing the key displays the list.
- Activates the right-hand knob. These keys are identified by a double circle ◉. When pressed, the key is outlined, along with the right-hand knob.

Page x/x displays additional controls.

Entering text

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

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

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

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

1 Click a text field.

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

2 Click each character you want to enter.

- The Äñ key displays and hides international characters.
- The SYMBOLS key displays symbols and punctuation.
- The CAPS LOCK key turns capital letters on and off.
- The SHIFT key turns capital letters on or off for the next letter entered.

- The DELETE key deletes the character right of the pointer.

3 (Optional) In forms, navigate among text fields:

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

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

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

Preparing transducers

WARNING: Some transducer sheaths contain natural rubber latex and talc, which can cause allergic reactions in some individuals. Refer to 21 CFR 801.437, User labeling for devices that contain natural rubber.

Some gels and sterilants can cause an allergic reaction on some individuals.

Caution: To avoid damage to the transducer, use only gels recommended by SonoSite. Using gels other than the one recommended by SonoSite can damage the transducer and void the warranty. If you have questions about gel compatibility, contact SonoSite or your local representative.

SonoSite recommends that you clean transducers after each use. See "Cleaning and disinfecting transducers" on page 58.

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

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

For information about preparing the TEEx transducer, see the *TEEx Transducer User Guide.*

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

To apply a transducer sheath

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

1 Place gel inside the sheath.

2 Insert the transducer into the sheath.

3 Pull the sheath over the transducer and cable until the sheath is fully extended.

4 Secure the sheath using the bands supplied with the sheath.

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.

Training videos

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

Note: Training videos are unavailable while the system is archiving or exporting data.

To display the list of videos

1 Insert the Education Key USB device into a USB port. (See "To insert a USB storage device.")

2 Press **Patient**.

3 Press **Review**. If there is an active exam, press **List**.

4 Click the **Videos** tab.

5 If the list does not appear, select the correct USB device:

   a Press **Select USB**.

   b In the **Select USB device for media playback** dialog box, select the Education Key USB device ("Training" appears under **Type**), and then click **Select**.

Note: Image Gallery is an unsupported feature.

To view a video

1 Display the list of videos.

2 Select the video.

3 Press **View**.

   The video begins playing.

4 Press any of the following, as needed:

- Adjusts the volume. The higher the number, the louder the sound. Zero is mute.
- **Back** Rewinds the video 10 seconds.
- **Pause** Pauses the video.
- **Play** Resumes playing of a paused video.
- **Forward** Advances the video 10 seconds.

To exit a video

❖ Press one of the following:

- **List** to return to the video list.
- **Done** to return to 2D imaging.

Intended uses

The system transmits ultrasound energy into various parts of the patient's body using 2D, color Doppler (Color), and color power Doppler (CPD) to obtain ultrasound images as follows.

For the intended transducer for each exam type, see "Imaging modes and exams available by transducer" on page 24.

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

Cardiac Imaging Applications You can assess the heart, cardiac valves, great vessels, surrounding anatomical structures, overall cardiac performance, and heart size for the presence or absence of pathology.

CPD imaging is not available in cardiac imaging

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

Interventional Imaging Applications You can use the system to provide ultrasound guidance for biopsy and drainage procedures, vascular line placement, peripheral nerve blocks, spinal nerve blocks and taps, amniocentesis, and other

obstetrical procedures and to 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, fetal hydrops, placental abnormalities, as well as maternal hypertension, diabetes, and lupus.

WARNING: 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 following:

- Detection of structural anomalies of the fetal heart
- Diagnosis of Intrauterine Growth Retardation (IUGR)

To avoid errors in fetal growth estimation, do not use the system as a fetal growth screening tool. The system does not provide fetal growth data.

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

Superficial Imaging Applications You can assess the breast, thyroid, testicle, lymph nodes, hernias, musculoskeletal structures, soft tissue structures, ophthalmic structures, and surrounding anatomical structures for the presence or absence of pathology. You can use the system to provide ultrasound guidance for biopsy and drainage procedures, vascular line placement, peripheral nerve blocks, and spinal nerve blocks and taps.

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

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

Chapter 2: System Setup

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

Displaying the setup pages

To display a setup page

1 Press **Options**, and then select **Setup**.

2 Click the setup page under **Setup Pages**.

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

Restoring default settings

To restore default settings for a setup page

❖ On the setup page, press **Reset**.

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 3.)

3 Simultaneously press the power key and the control key below it (the upper-left control key).

The system beeps several times.

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 display 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. (See "Entering text" on page 7.)

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

If you don't have the administrator password, contact SonoSite. (See "SonoSite Technical Support" on page vii.)

3 Click **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, click **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**, click **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 13.)
- Let users change their passwords: Select the **Password changes** check box.

4 Click **Save**.

User setup

To add a new user

1 Log in as Administrator.

2 Click **New**.

3 Under **User Information**, fill in the **Name**, **Password**, and **Confirm** boxes. (See "Choosing a secure password" on page 13.)

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

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

6 Click **Save**.

To modify user information

1 Log in as Administrator.

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

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

4 Click **Save**.

Any change to the user name replaces the previous name.

To delete a user

1 Log in as Administrator.

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

3 Click **Delete**.

4 Click **Yes**.

To change a user password

1 Log in as Administrator.

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

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

4 Click **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 Press **Export**. A list of USB devices appears.

4 Click the USB storage device, and click **Export**.

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

To import user accounts

1 Insert the USB storage device that contains the accounts.

2 Log in as Administrator.

3 Press **Import**.

4 Click the USB storage device, and click **Import**.

5 Click **Restart** in the dialog box that appears.

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

Exporting and clearing the Event log

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

To display the Event log

1 Log in as Administrator.

2 Press **Log**.

The Event log appears.

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

To export the Event log

The Event log has the file name (log.txt). Exporting the Event log to a USB storage device overwrites any existing log.txt file.

1 Insert a USB storage device.

2 Press **Log** and then press **Export**.

A list of USB devices appears.

3 Click the USB storage device, and click **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 Press **Clear**.

3 Click **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 12.)

To log in as user

1 Turn on the system.

2 In the **User Login** screen, type your name and password, and click **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, click **Guest**.

To change your password

1 Turn on the system.

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

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

Choosing a secure password

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

Annotations setup

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

For instructions to annotate images, see "Annotating images" on page 26.

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 26.)

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 for the selected group appear in the scroll list.

3 Do any of the following:

- Add a custom label to the group: Click **<New>** in the scroll list, and then type the label in the **Text** box. Click **Add**.
- Rename a label: Click the label, type the new name in the **Text** box, and click **Rename**.
- Move a label within the group: Click the label, and then click the up or down arrow.
- Delete a label from a group: Click the label, and click **Delete**.

See also "Entering text" on page 7.

To specify text retention when unfreezing

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

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

The default setting is **Keep All Text**. For information on setting the home position, see "To reset the home position" on page 27.

To export predefined label groups

1 Insert a USB storage device.

2 On the Annotations setup page, press **Export**.

A list of USB devices appears.

3 Select the USB storage device, and click **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, press **Import**.

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

4 Click **OK** in the dialog box that appears.

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

Audio, Battery setup

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

Key click: Click **On** or **Off** for keys to make a clicking sound when pressed.

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

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

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

Cardiac Calculations setup

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

See also "Cardiac calculations" on page 39.

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

To configure the system for a printer

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

2 On the Connectivity setup page, click the printer in the **Printer** list.

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

1 On the Connectivity setup page, do the following:

- (DVD recorder) In the **Video Mode** list, click the video standard: **NTSC** or **PAL**.
- (Bar code scanner) In the **Serial Port** list, click **Bar Code Scanner**.

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

2 Restart the system.

3 Attach a serial cable (RS-232) from the RS-232 connector on the back of the system to the peripheral.

To receive storage alerts

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

The system displays a message if internal storage is near capacity when you end an exam.

Date and Time setup

To set the date and time

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

- In the **Date** box, type the current date. (See "Entering text" on page 7.)
- In the **Time** box, type the current time in 24 hour format (hours and minutes).

Display Information setup

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

Patient Header: Information from the patient information form. (See "Patient information form" on page 27.)

Mode Data: Imaging information.

System Status: Power, battery, connectivity, and similar information.

Network Status setup

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

OB Calculations setup

On the OB Calculations setup page, you select authors for OB gestational calculation tables.

See also "OB calculations" on page 49.

To specify gestational age

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

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

Presets setup

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

Depth Markers: Type 1 displays unnumbered markers, with the maximum depth number in the lower right screen. **Type 2** displays markers with numbers.

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

Clip Length: Clip length in seconds.

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

Language: The system language. Changing the language requires restarting the system.

Display Brightness: Scheme 1 displays brighter key names and icons and is suitable for a bright environment, such as daylight. **Scheme 2** displays dimmer key names and icons and is suitable for a dark environment.

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

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

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

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

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

System Information setup

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

See also "To enter a license key" on page 56.

To display patents

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

USB Devices setup

On the USB Devices setup page, you can view information about connected USB devices, including space availability. You can also specify a file format for images in patient exams that you export to a USB storage device.

To specify a file format for exported images

The image format you specify affects only still images. Clips export in H.264 video saved as MP4 files. To view them, SonoSite recommends QuickTime 7.0 or later.

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

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

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

3 Select a sort order under **Sort By**.

The sort order specifies how exported files are organized.

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

To include private tags

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

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

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

Limitations of JPEG format

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

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

For more information on using lossy-compressed images, consult the industry literature, including the following references:

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

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

Chapter 3: Imaging

Imaging modes

The system has a high-performance LCD 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 24.

2D imaging

2D is the system's default imaging mode. The system displays echoes in two dimensions by assigning a brightness level based on the echo signal amplitude. To achieve the best image quality, properly adjust the display brightness, gain, depth settings, viewing angle, and exam type. Also, use a suitable optimization setting.

To display the 2D image

1 Do one of the following:

- Turn on the system.
- From another imaging mode, do one of the following, depending on your configuration:
  - Press **2D**.
  - Press **Mode** and select **2D**.

2 Adjust controls. See "2D controls."

2D controls

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

See also "Adjusting depth and gain" on page 23.

Auto Gain

The gain adjusts automatically each time you press the key.

To adjust gain manually, see "Adjusting depth and gain" on page 23.

Optimize

Settings are as follows:

Res provides the best possible resolution.

Gen provides a balance between resolution and penetration.

Pen provides the best possible penetration.

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

THI

Turns Tissue Harmonic Imaging on and off.

When on, *THI* appears in the mode data area. This feature depends on transducer and exam type.

SonoMB

Turns SonoMB® multi-beam imaging on and off. When on, *MB* appears in the mode data area.

Orientation

Select from four image orientations: **U/R** (Up/Right), **U/L** (Up/Left), **D/L** (Down/Left), **D/R** (Down/Right).

Guide 	Turns guidelines on and off. If using a variable angle needle guide, press **Guide** and then press again to select the angle: **A**, **B**, or **C**. The touchpad moves the depth cursor. See also *Bracket and Needle Guide User Guide* or *Bracket and Needle Guide for L25 Series User Guide*. Guidelines are for needle guidance, are an optional feature, and depend on transducer type.
Dual 	Displays side-by-side 2D images. Press **Dual**, and then press **Update** to display the second screen and to toggle between the screens. With both images frozen, press **Select** to toggle between the images. To return to full-screen 2D imaging, press **Dual**.
Brightness 	Adjusts the screen brightness. Press the **Brightness** key and then turn the **Brightness** knob. Settings range from **1** to **10**. (You can also adjust the brightness of only the key names and icons. See "Presets setup" on page 16.) The screen brightness affects battery life. To conserve battery life, adjust brightness to a lower setting.

M Mode imaging

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

To display the M-line

1. Press **Mode** and select **M Mode**.
2. Use the touchpad to position the M-line where desired.
3. Adjust controls as desired.

   Many optimization and depth settings available in 2D imaging are also available in M Mode imaging. See "2D controls" on page 19.

To display the M Mode trace

1. Display the M-line.
2. Adjust the depth if necessary. (See "To adjust depth" on page 23.)
3. Do either of the following:
   - Press **M Mode** on the left.
   - Press **Mode** and select **M Mode**.

   The time scale above the trace has small marks at 200 ms 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 **Update M Mode** and **Update 2D** to toggle between the M-line and M-Mode trace.
   - If using a duplex layout, press **Mode** and then select **M Mode** to toggle between the full-screen M-line and the duplex layout.

     To set a duplex layout, see "Presets setup" on page 16.

CPD and Color imaging

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. Do one of the following, depending on your configuration:
   - Press **Color**. For CPD, press **CPD** on the left.

- Press **Mode** and select **Color**. For CPD, press **CPD** on the left.

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

The current selection (Color or CPD) appears in the mode data area.

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

2 Using the touchpad, position or resize the ROI box as needed.

Pressing  **Position** and **Size** or clicking toggles between position and size. While you position or resize the ROI box, a green outline shows the change. For resizing, the outline is a dashed line.

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

CPD and Color controls

Flow Sensitivity 	The current setting appears below the icon: • **Low** optimizes the system for low flow states. • **Med** optimizes the system for medium flow states. • **High** optimizes the system for high flow states.
PRF Scale 	Select the desired PRF (pulse repetition frequency) Scale setting by pressing the key (if present) and then turning the knob. The available PRF Scale settings depend on the Flow Sensitivity setting. Available on select transducers.
Color Suppress 	Shows or hides color information. You can select **Show** or **Hide** while in live or frozen imaging.
Invert 	Switches the displayed direction of flow. Available in Color imaging.
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 22. Available on select transducers.
Wall Filter 	The current setting appears below the icon: **Low**, **Med**, or **High**. Available on select transducers.
Variance 	(Cardiac exam only) Turns variance on and off.

PW and CW Doppler imaging

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

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. Clicking cycles among color ROI box position; color ROI box size; the D-line and gate location; and (in PW Doppler) angle correction. The active selection is green.

To display the D-line

The default Doppler imaging mode is PW Doppler. In the cardiac exam, you can select CW Doppler.

1 Press **Mode** and select **Doppler**.

2 Do any of the following as needed:

- Adjust controls. See "PW Doppler controls" on page 22.
- 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:
  - Click, and then use the touchpad. Clicking toggles between the D-line and angle correction.
  - Freeze the image, and then turn the  **Angle** knob.

  You can adjust the angle in 2° increments from -74° to +74°.

To display the spectral trace

1 Display the D-line.

2 Do either of the following:

- Press **Doppler** on the left.
- Press **Mode** and select **Doppler**

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. See "Spectral trace controls" on page 23.
- Press **Update Doppler** and **Update 2D** to toggle between the D-line and spectral trace.
- If using a duplex layout, press **Mode** and select **Doppler** to toggle between the full-screen D-line and the duplex layout.

  To set a duplex layout, see "Presets setup" on page 16.

PW Doppler controls

CW, PW 	(Cardiac exam only) Toggles between PW Doppler and CW Doppler. The current selection appears in the mode data area.
Gate 	Press the button or turn the knob to select the gate size. Settings depend on transducer and exam type.
Angle 	Corrects the angle. Press to correct the angle to **0**°, **+60**°, or **-60**°. For a finer adjustment (2° increments from -74° to +74°), press the **Angle** key and then turn the **Angle** knob. The current setting appears in the mode data area. You can correct the angle whether the image is frozen or live. Available in PW Doppler.
PW/TDI	(Cardiac exam only) Turns tissue Doppler imaging on and off. When on, *TDI* appears in the mode data area. Available in PW Doppler.

Steering 	Press to select the desired steering angle setting. Settings available depend on the transducer. The PW Doppler angle automatically corrects to the optimum setting. • **-15** and **-20** have an angle correction of -60°. • **0** has an angle correction of 0°. • **+15** and **+20** have an angle correction of +60°. You can manually correct the angle after selecting a steering angle setting. Available on select transducers.

Spectral trace controls

Scale 	Select the desired PRF (pulse repetition frequency) Scale setting by pressing the key (if present) and then turning the knob. (To change the Doppler scale to cm/s or kHz, see "Presets setup" on page 16.)
Baseline 	Sets the baseline position. (On a frozen trace, you can set the baseline if **Live Trace** is off.)
Invert 	Vertically flips the spectral trace. (On a frozen trace, **Invert** is available if **Live Trace** is off.)
Volume 	Increases or decreases Doppler speaker volume (**0**-**10**).
Wall Filter 	Settings include **Low**, **Med**, **High**.
Sweep Speed 	Settings include **Slow**, **Med**, **Fast**.

Live Trace 	Displays a live trace of the peak or mean. (See "Presets setup" on page 16 to specify peak or mean.)

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. To change the style of depth markers, see "Presets setup" on page 16.

❖ Press the **Depth** button (if present), and then turn the **Depth** knob:

- Clockwise increases the displayed depth.
- Counter-clockwise decreases the displayed depth.

To adjust gain manually

To adjust gain automatically in 2D, see "2D controls" on page 19.

1 Press the left-hand knob to select a setting:

- **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** setting affects the color gain applied to the region of interest (ROI) box.

2 Turn the knob:

- Clockwise increases the gain.
- Counter-clockwise decreases the gain.

To revert to the default gain setting

❖ Press **Reset**.

Freezing, viewing frames, and zooming

To freeze or unfreeze an image

❖ Press **Freeze**.

On a frozen image, the cine icon and frame number appear in the lower left-hand corner.

To move forward or backward in the cine buffer

❖ On a frozen image, turn the cine knob.

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

You can also use the touchpad to move in the cine.

To zoom in on an image

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

1 Press **Zoom**. A ROI box appears.

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

3 Press **Zoom**.

The image in the ROI box is magnified by 100%, and the control key changes to **On**.

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

To exit zoom, press **On**.

Imaging modes and exams available by transducer

WARNING: To prevent misdiagnosis or harm to the patient, understand your system's capabilities prior to use. The diagnostic capability differs for each transducer, exam type, and imaging mode. In addition, transducers have been developed to specific criteria depending on their physical application. These criteria include biocompatability requirements.

To avoid injury to the patient, use only an 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 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 **Options** and select **Exam**. Then click the exam type in the menu.
- On the patient information form, click the exam type in the **Type** list under **Exam**. (See "Patient information form" on page 27.)

Imaging modes and exams available

S Series System	Transducer	Exam Type[1]	Imaging Mode: 2D[2]	M-Mode	CPD	Color	PW Doppler	CW Doppler
S-Cath	C60x[3]	Abd	✓	✓	✓	✓	✓	—
	HFL38x	Bre	✓	✓	✓	✓	✓	—
		SmP	✓	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	✓	—
		Ven	✓	✓	✓	✓	✓	—
	L25x	Sup	✓	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	✓	—
		Ven	✓	✓	✓	✓	✓	—
	L38x	Bre	✓	✓	✓	✓	✓	—
		SmP	✓	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	✓	—
		Ven	✓	✓	✓	✓	✓	—
	L38xi	Bre	✓	✓	✓	✓	✓	—
		SmP	✓	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	✓	—
		Ven	✓	✓	✓	✓	✓	—
	HFL50x	Bre	✓	✓	✓	✓	✓	—
		SmP	✓	✓	✓	✓	✓	—
	P10x	Abd	✓	✓	✓	✓	✓	—
		Crd	✓	✓	—	✓	✓	✓
		Neo	✓	✓	✓	✓	✓	—
	P21x[3]	Abd	✓	✓	✓	✓	✓	—
S-FAST	C60x[3]	Abd	✓	✓	✓	✓	✓	—
	HFL38x	SmP	✓	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	✓	—
		Ven	✓	✓	✓	✓	✓	—
	HFL50x	SmP	✓	✓	✓	✓	✓	—
	ICTx	Gyn	✓	✓	✓	✓	✓	—
		OB	✓	✓	✓	✓	✓	—
	L25x	Oph	✓	✓	✓	✓	✓	—
		Sup	✓	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	✓	—
		Ven	✓	✓	✓	✓	✓	—
	L38x	SmP	✓	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	✓	—
		Ven	✓	✓	✓	✓	✓	—
	L38xi	SmP	✓	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	✓	—
		Ven	✓	✓	✓	✓	✓	—
	P21x[3]	Abd	✓	✓	✓	✓	✓	—
		Crd	✓	✓	—	✓	✓	✓
		OB	✓	✓	✓	✓	✓	—
S-GYN	C60x[3]	Gyn	✓	✓	✓	✓	✓	—
		OB	✓	✓	✓	✓	✓	—
	HFL38x	Bre	✓	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	✓	—
	ICTx	Gyn	✓	✓	✓	✓	✓	—
		OB	✓	✓	✓	✓	✓	—
	L38x	Bre	✓	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	✓	—
	L38xi	Bre	✓	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	✓	—
	P21x[3]	OB	✓	✓	✓	✓	✓	—
S-ICU	C11x	Abd	✓	✓	✓	✓	✓	—
		Neo	✓	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	✓	—
	C60x[3]	Abd	✓	✓	✓	✓	✓	—
	HFL38x	SmP	✓	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	✓	—
		Ven	✓	✓	✓	✓	✓	—
	L25x	Vas	✓	✓	✓	✓	✓	—
		Ven	✓	✓	✓	✓	✓	—
	L38x	SmP	✓	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	✓	—
		Ven	✓	✓	✓	✓	✓	—

	L38xi	SmP	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	—
		Ven	✓	✓	✓	✓	—
	P10x	Abd	✓	✓	✓	✓	—
		Crd	✓	—	✓	✓	✓
		Neo	✓	✓	✓	✓	—
	P21x[3]	Abd	✓	✓	✓	✓	—
		Crd	✓	—	✓	✓	✓
S-MSK	C60x[3]	Abd	✓	✓	✓	✓	—
		Msk	✓	✓	✓	✓	—
		Nrv	✓	✓	✓	✓	—
	HFL38x	Msk	✓	✓	✓	✓	—
	HFL50x	Msk	✓	✓	✓	✓	—
	L25x	Msk	✓	✓	✓	✓	—
	L38xi	Msk	✓	✓	✓	✓	—
	SLAx	Msk	✓	✓	✓	✓	—
		Nrv	✓	✓	✓	✓	—
S-Nerve	C11x	Nrv	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	—
	C60x[3]	Nrv	✓	✓	✓	✓	—
	HFL38x	Nrv	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	—
	HFL50x	Nrv	✓	✓	✓	✓	—
	L25x	Nrv	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	—
	L38x	Nrv	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	—
	L38xi	Nrv	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	—
	SLAx	Nrv	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	—
S-Women's Health	C60x[3]	Gyn	✓	✓	✓	✓	—
		OB	✓	✓	✓	✓	—
	HFL38x	Bre	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	—
	HFL50x	Bre	✓	✓	✓	✓	—
	ICTx	Gyn	✓	✓	✓	✓	—
		OB	✓	✓	✓	✓	—
	L38x	Bre	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	—
	L38xi	Bre	✓	✓	✓	✓	—
		Vas	✓	✓	✓	✓	—
	P21x[3]	OB	✓	✓	✓	✓	—
n/a	TEEx[4]	Crd	✓	—	✓	✓	✓

1. Exam type abbreviations are as follows: Abd = Abdomen, Bre = Breast, Crd = Cardiac, Gyn = Gynecology, Msk = Musculoskeletal, Neo = Neonatal, Nrv = Nerve, OB = Obstetrical, Oph = Ophthalmic, SmP = Small Parts, Sup = Superficial, Vas = Vascular, Ven = Venous.
2. The optimization settings for 2D are Res, Gen, and Pen.
3. This transducer includes Tissue Harmonic Imaging. For more information, see "Glossary" on page 141.
4. The TEEx transducer is available for certain product configurations. Contact SonoSite or your SonoSite representative.

Annotating images

You can annotate live images as well as frozen images. (You cannot annotate a saved image.) You can place text (including predefined labels), an arrow, or a pictograph. To set preferences for annotations, see "Annotations setup" on page 13.

To place text on an image

You can place text manually or add a predefined label.

1. Press **Options** and select **Annotate**. A green cursor appears.
2. Move the cursor where desired, and then click.

   To move the cursor, use the touchpad, or press **Home** to move the cursor to the home position.

   The default home position depends on the imaging screen layout. You can reset the home position. See "To reset the home position."
3. Do one of the following:

- Click, and then type text. See "Entering text" on page 7.
- Press **Label**, and then press the desired label group: A, B, or C. Press the group again to select 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 13.

To return to the previous screen, press the **Back** knob.

To reset the home position

1. Press **Options** and select **Annotate**. A green cursor appears.
2. Using the touchpad, position the cursor where desired.
3. Press **Home/Set**.

To return to the previous screen, press the **Back** knob.

To place an arrow on an image

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

1. Press **Options** and select **Annotate**.
2. Press **Arrow**.
3. If you want to rotate the arrow, click and then use the touchpad. When the orientation is correct, click again.
4. Using the touchpad, position the arrow where desired.
5. Press **Back** or **2D** to set the arrow.

   The arrow changes from green to white.

To remove the arrow, press **Arrow** and then press **Hide**. Press **Show** to display it again.

To return to the previous screen, press the **Back** knob.

To place a pictograph on an image

The pictograph set available depends on transducer and exam type.

1. Press **Options** and select **Annotate**.
2. Press **Picto**.
3. Press **x/x** to display the desired pictograph, and then click.

   The first number shows which pictograph in the set is selected. The second number is the number of pictographs available.
4. Using the touchpad, position the pictograph marker.
5. If you want to rotate the pictograph marker, click and then use the touchpad.
6. Press a screen location for the pictograph: **U/L** (Up/Left), **D/L** (Down/Left), **D/R** (Down/Right), **U/R** (Up/Right).

To remove the pictograph, press **Hide**. Press **Show** to display it again.

To return to the previous screen, press the **Back** knob.

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 and other data you save during the exam are linked to that patient. (See "Patient report" on page 52.)

To create a new patient information form

Note: Creating a new patient information form removes any unsaved patient information, including

calculations and report page. To save this information, save the screen for each item.

1 In 2D, press **Patient**.

2 Press **New/End**.

3 Fill in the form fields. See "Patient information form fields" on page 28 and "Entering text" on page 7.

4 Press **Done**.

See also "To append images and clips to a patient exam" on page 30.

To edit a patient information form

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

Note: If Auto save Pat Form is set to On, an image saves when you start a new patient information form, preventing editing. See "Presets setup" on page 16.

See also "To edit patient information from the patient list" on page 30.

1 In 2D, press **Patient**.

2 Make changes as desired.

3 Press 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 "Images and clips" on page 29.)

2 In 2D, press **Patient.**

3 Press **New/End**.

A new patient information form appears.

Patient information form fields

Patient

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

Exam

- **Type** Exam types available depend on transducer. See "Imaging modes and exams available by transducer" on page 24. For the definition of abbreviations, see "Glossary" on page 141.
- **BP** (Cardiac or Vascular exam) Blood Pressure
- **HR** (Cardiac or Vascular exam) Heart Rate. Enter the beats per minute. Saving the heart rate using a measurement overwrites this entry.
- **Height** (Cardiac exam) The patient height in feet and inches or meters and centimeters. (To change the units, see "Presets setup" on page 16.)
- **Weight** (Cardiac exam) The patient weight in pounds or kilos. (To change the units, see "Presets setup" on page 16.)
- **BSA** (Cardiac exam) Body Surface Area. Automatically calculated after you enter height and weight.
- **LMP, Estab. DD** (OB or Gyn exam) In an OB exam, select **LMP** or **Estab. DD** and then enter either the date of the last menstrual period or

the established due date. In a Gyn exam, enter the date of the last menstrual period. The LMP date must precede the current system date.

- **Reading Dr.**
- **Referring Dr.**
- **Institution**

Images and clips

Saving images and clips

When you save an image or clip, it saves to internal storage. The system beeps afterward if Beep Alert is on, and the percentage icon flashes. (See "Audio, Battery setup" on page 14.)

The percentage icon shows the percentage of space used in internal storage. To receive alerts when storage is near capacity, see "To receive storage alerts" on page 15.

To access saved images and clips, open the patient list. See "Reviewing patient exams."

To save an image

❖ Press **Save**.

By default, the Save control key saves only the image. As a shortcut during calculations, the Save control key can save both the image to internal storage and the calculation to the patient report. See "Presets setup" on page 16.

To save a clip

❖ Press **Clip**.

To specify clip length, see "Presets setup" on page 16.

Reviewing patient exams

Caution: If the internal storage icon does not appear in the system status area, internal storage may be defective. Contact SonoSite Technical Support. (See "SonoSite Technical Support" on page vii.)

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

Figure 1 Patient List

To display the patient list

1 In 2D, press **Patient**.

2 Press **Review**.

3 If there is a current patient, press **List**.

To sort the patient list

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

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

Note: The selection column ☑ is sortable.

To select patient exams in the patient list

❖ Do one of the following:

- Select the check box for one or more patient exams.

  Clicking **Select All** selects all patient exams.

- If using a USB keyboard, press the UP ARROW or DOWN ARROW key to highlight the patient exam, and then press the SPACEBAR.

To deselect patient exams, clear checked boxes or click **Clear All**. On the USB keyboard, the SPACEBAR clears checked boxes.

To edit patient information from the patient list

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

1 In the patient list, select the patient exam.

2 Click **Edit**.

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

To append images and clips to a patient exam

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

1 In the patient list, select the patient exam.

2 Press **Append**.

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

To review images and clips

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

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

  The patient row is highlighted.

2 Press the **Review** knob.

  The icon on the knob changes to two numbers: the file displayed and the total files saved.

3 Turn the knob to cycle to the image or clip you want to review.

4 (Clip Only) Press the **Play** key.

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

  You can press the **Pause** key to freeze the clip and can turn the right-hand knob for a playback speed.

5 Turn the left-hand knob **x/x** to cycle to the next image or clip you want to view.

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

Printing, exporting, and deleting images and clips

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.

To print an image

1. Verify that a printer is selected. See "To configure the system for a printer" on page 15.
2. Do one of the following:
   - In the patient list, review the patient exam's images. Press **Print** when the image appears.
   - Freeze the image, and press **Print**.

To print multiple images

1. Verify that a printer is selected. See "To configure the system for a printer" on page 15.
2. Do one of the following:
   - Print all images for multiple patient exams: Select one or more patient exams in the patient list. Then press **Print**.
   - Print all images for one patient exam: Highlight the patient exam in the patient list, and press **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 28.)

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 16.

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

1. Insert the USB storage device. (See "Inserting and removing USB storage devices" on page 4.)
2. In the patient list, select the patient exams you want to export.
3. Press the **Exp. USB** knob. A list of USB devices appears.
4. Click the USB storage device. If you want to hide patient information, deselect **Include patient information on images and clips**.

   Only available USB devices are selectable.
5. Click **Export**.

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

To delete images and clips

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

To manually archive images and clips

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

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

2 Press **Archive.**

To display information about a patient exam

1 In the patient list, select the patient exam.

2 Click **Info**.

Chapter 4: Measurements and Calculations

You can measure for quick reference, or you can measure within a calculation.

Measurements are performed on frozen images. For references used, see Chapter 7, "References."

Measurements

You can perform basic measurements in any imaging mode. Options available depend on your configuration, transducer, and exam type.

About saving measurements

After performing a measurement, you can save the image with the measurements displayed. (See "To save an image" on page 29.) Some measurements can be saved to a calculation and the patient report.

If you prefer to select a measurement name before performing a measurement, start a calculation. See "Calculations" on page 37.

To save a measurement to a calculation and patient report

1 With the measurement active (green), press **Calcs**.

2 From the calculations menu, select a measurement name. (See "To select from the calculations menu" on page 38.)

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

3 Save the calculation. (See "To save a calculation" on page 38.)

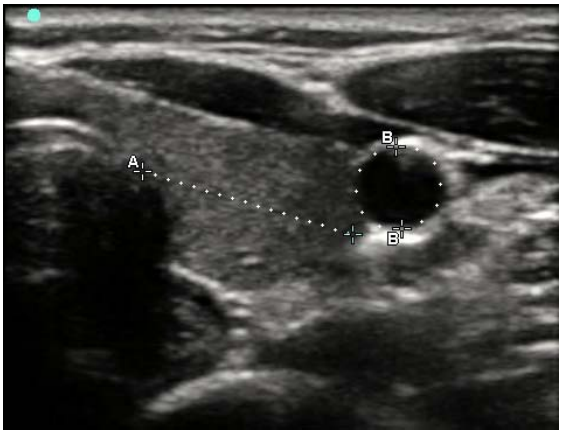

Figure 1 2D image with one distance and one circumference measurement

Working with calipers

When measuring, you work with calipers. 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.

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

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, click.

- To switch the active set, press **Switch**.

To delete or edit a measurement

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

- To delete, press the **Delete** knob.
- To edit, use the touchpad to move the calipers. You can edit only distance and area/circumference measurements.

To place calipers more precisely

❖ Do any of the following:

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

2D measurements

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

To measure distance

Distance is measured in cm.

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

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

2 Using the touchpad, position the first caliper, and then click.

The other caliper becomes active.

3 Using the touchpad, position the other caliper.

See also "To add calipers (2D)" on page 34 and "To save a measurement to a calculation and patient report" on page 33.

To measure area and circumference

Area and circumference measurements use an ellipse with calipers. Area is in cm^2, and Circumference is in cm.

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

2 Press **Ellipse**.

3 Use the touchpad to adjust the size and position of the ellipse. Clicking toggles between position and size.

See also "To add calipers (2D)" on page 34 and "To save a measurement to a calculation and patient report" on page 33.

To trace manually

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

2 Press **Manual**.

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

4 Using the touchpad, begin tracing.

To make a correction, press **Undo**.

5 Complete the trace, and then press **Set** or click.

The measurement is labeled **A**.

See also "To add calipers (2D)" on page 34 and "To save a measurement to a calculation and patient report" on page 33.

To add calipers (2D)

With a measurement active, you can add calipers to perform additional measurements.

❖ Press one of the following:

- **Add Caliper** to measure distance

- **Ellipse** to measure area and circumference
- **Manual** to trace manually

The second measurement is labeled **B**. The third is labeled **C**, and so on.

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 **Calipers**.

A single caliper appears.

2 Using the touchpad, position the caliper, and then click.

A second caliper appears.

3 Using the touchpad, position the second caliper.

See "To save a measurement to a calculation and patient report" on page 33.

To measure heart rate (M Mode)

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

2 Press **HR.**

A vertical caliper appears.

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

A second vertical caliper appears.

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

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

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

See also "To measure fetal heart rate (M Mode)" on page 51.

To add calipers (M Mode)

With a measurement active, you can add calipers to perform additional measurements.

❖ Press one of the following:

- **Add Caliper** to measure distance

  The second measurement is labeled **B**. The third is labeled **C**, and so on.

- **HR** to measure heart rate. Other measurements are cleared from the screen.

Doppler measurements

For Doppler measurements, the Doppler scale must be set to cm/s. See "Presets setup" on page 16.

To measure Velocity (cm/s) and Pressure Gradient (Doppler)

This measurement involves a single caliper from the baseline.

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

A single caliper appears.

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

See "To save a measurement to a calculation and patient report" on page 33.

To measure Velocities, Elapsed Time, Velocity Ratio (A/B), Resistive Index (RI), and Acceleration (Doppler)

Note: Resistive Index is measured in all available exams but the cardiac exam.

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

A single caliper appears.

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

A second caliper appears.

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

See also "To add calipers (Doppler)" on page 37 and "To save a measurement to a calculation and patient report" on page 33.

To measure time duration (Doppler)

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

2 Press **Time**.

A vertical caliper appears.

3 Using the touchpad, position the caliper where desired, and then click.

A second caliper appears.

4 Using the touchpad, position the second caliper where desired.

See also "To add calipers (Doppler)" on page 37.

To measure Pressure Half Time (Doppler)

1 On a frozen Doppler spectral trace in the Cardiac exam, press **Calipers**.

2 Press **PHT**.

A pair of calipers appears.

3 Position the calipers along the slope you want to measure. See "Working with calipers" on page 33.

See also"To save a measurement to a calculation and patient report" on page 33 and "To add calipers (Doppler)" on page 37.

To trace manually (Doppler)

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

2 Press **Manual**.

A single caliper appears.

3 Using the touchpad, position the caliper at the beginning of the desired waveform, and then click.

If you position calipers incorrectly, the results are inaccurate.

4 Using the touchpad, trace the waveform.

To make a correction, press **Undo**.

5 Click.

The measurement results appear.

See also"To save a measurement to a calculation and patient report" on page 33 and "To add calipers (Doppler)" on page 37.

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 36.)

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

2 Press **Auto**.

A vertical caliper appears.

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

A second vertical caliper appears.

If you position calipers incorrectly, the results are inaccurate.

4 Using the touchpad, position the second caliper at the end of the waveform and then press **Set**.

The measurement results appear.

See also "To add calipers (Doppler)" on page 37.

Trace results

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

- Velocity Time Integral (VTI)
- Peak Velocity (Vmax)
- Mean Pressure Gradient (PGmean)
- Peak Systolic Velocity (PSV)
- Time Average Mean (TAM)*
- +/× or Systolic/Diastolic (S/D)
- Pulsatility Index (PI)
- End Diastolic Velocity (EDV)
- Acceleration Time (AT)
- Resistive Index (RI)
- Maximum Pressure Gradient (PGmax)

To add calipers (Doppler)

With a measurement active, you can add calipers to perform additional measurements.

❖ Press one of the following:

- **Add Caliper** to measure velocity and pressure gradient
- **Time** to measure time duration
- **Manual** to trace manually
- **Auto** to trace automatically

The second measurement is labeled **B**. The third is labeled **C**, and so on.

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 52.

Calculation packages depend on exam type, transducer, and S Series system.

Calculations menu

The calculations menu contains measurements available for the imaging mode and exam type. After you perform and save a measurement, the result saves to the patient report. (See "Patient report" on page 52.) Also, a check mark appears next to the measurement name in the calculations menu. If you highlight the checked measurement name, the results appear below the menu. If you repeat the measurement, the results below the menu reflect either the last measurement or the average, depending on the measurement.

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

To select from the calculations menu

1 On a frozen image, press **Calcs**.

The calculations menu appears.

2 Using the touchpad, highlight the desired measurement name.

To display additional measurement names, highlight and click **Next**, **Prev**, or a measurement name that has ellipses (. . .).

Only measurement names available for the imaging mode are selectable.

3 Click the measurement name.

To close the calculations menu, press **Calcs**.

Performing and saving measurements in calculations

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

To save a calculation

❖ Do one of the following:

- Save the calculation only: Press **Save Calc**.

  The calculation saves to the patient report. To save the image with the measurements displayed, see "To save an image" on page 29.

- Save both the image and calculation: Press **Save** if the functionality is set to **Image/Calcs**. (See "Presets setup" on page 16.)

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

Displaying and deleting saved measurements in calculations

To display a saved measurement

❖ Do one of the following:

- Highlight the measurement name in the calculations menu. The result appears below the menu.
- Open the patient report. See "Patient report" on page 52.

To delete a saved measurement

1 Highlight the measurement name in the calculations menu.

2 Press **Delete**.

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

Some measurements can be deleted directly from the report pages. See "Patient report" on page 52.

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 27.

Systems and Exam Types for Cardiac Calculations

Exam Type	S Series System
Cardiac	S-Cath S-FAST S-ICU

The following table shows the measurements required to complete different cardiac calculations. For definitions of acronyms, see "Glossary" on page 163.

Cardiac Calculations

Menu Heading	Cardiac Measurements (Imaging Mode)	Calculation Results
LV…LVd	RVW (2D) RVD (2D) IVS (2D) LVD (2D) LVPW (2D)	CO EF SV LVESV LVEDV IVSFT LVPWFT LVDFS CI SI
…LVs	RVW (2D) RVD (2D) IVS (2D) LVD (2D) LVPW (2D) HRa needed for CO & CI	
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

Menu Heading	Cardiac Measurements (Imaging Mode)	Calculation Results
LV…LVd	RVW (M Mode) RVD (M Mode) IVS (M Mode) LVD (M Mode) LVPW (M Mode)	CO EF SV LVESV LVEDV IVSFT LVPWFT LVDFS CI SI LV Mass
…LVs	RVW (M Mode) RVD (M Mode) IVS (M Mode) LVD (M Mode) LVPW (M Mode)	
HR	HR[a]	
Area	AV (2D)	AV Area
	MV (2D)	MV Area
LV Vol (EF)	A4Cd (2D) A4Cs (2D) A2Cd (2D) A2Cs (2D)	LV Vol LV Area EF CO SV CI SI Biplane
LV mass	Epi (2D) Endo (2D) Apical (2D)	LV Mass Epi Area Endo Area D Apical

Menu Heading	Cardiac Measurements (Imaging Mode)	Calculation Results
PISA	Ann D (2D) Radius (Color) MR/VTI (Doppler) MV/VTI (Doppler)	PISA Area ERO MV Rate Regurgitant Volume Regurgitant Fraction
Qp/Qs	LVOT D (2D) RVOT D (2D) LVOT VTI (Doppler) RVOT VTI (Doppler)	D VTI VMax PGmax Vmean PGmean SV Qp/Qs
CO	LVOT D (2D) — (Doppler)	CO SV CI SI VTI HR LVOT D
TDI	(Wall) e′ and a′ (Doppler) (Wall) e′ and a′ (Doppler) (Wall) e′ and a′ (Doppler) (Wall) e′ and a′ (Doppler) (Wall) ‘e and a′ (Doppler)	E(MV)/e′ ratio

Menu Heading	Cardiac Measurements (Imaging Mode)	Calculation Results
P. Vein	A (Doppler)	VMax
	Adur (Doppler)	time
	S (Doppler)	VMax S/D ratio
	D (Doppler)	
MV	E (Doppler) A (Doppler)	E E PG A A PG E:A
	Adur (Doppler)	time
	PHT (Doppler)	PHT MVA Decel time
	VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
	IVRT (Doppler)	time
MV…MR	dP:dT[b] (CW Doppler)	dP:dT

Menu Heading	Cardiac Measurements (Imaging Mode)	Calculation Results
AV	Vmax (Doppler)	Vmax PGmax
	VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
	VTI or Vmax from LVOT (Doppler) VTI or Vmax from AV (Doppler)	AVA
Ao/LA	LVOT D (2D)	
AV	VTI (Doppler)	SV
Ao/LA	LVOT D (2D)	
AV	VTI (Doppler)	CO
Ao/LA	LVOT D (2D)	
HR	HR[a]	
LVOT	Vmax (Doppler)	Vmax PGmax
	VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
AV…AI	PHT (slope) (Doppler)	AI PHT AI slope

Menu Heading	Cardiac Measurements (Imaging Mode)	Calculation Results
TV	TRmax (Doppler)	Vmax PGmax
	E (Doppler) A (Doppler)	E E PG A A PG E:A
	PHT (Doppler)	PHT MVA Decel time
	VTI (Doppler)	VTI Vmax PGmax Vmean PGmean
	RA pressure[c]	RVSP
PV	Vmax (Doppler)	Vmax PGmax
	VTI (Doppler) AT (Doppler)	VTI Vmax PGmax Vmean PGmean AT

a. You can enter the HR measurement three ways: Patient information form, Doppler measurement (See "To calculate Heart Rate (HR)" on page 46), or M Mode measurement (See "To measure heart rate (M Mode)" on page 35).

b. Performed at 100 cm/s and 300 cm/s.

c. Specified on the cardiac patient report. See "Cardiac patient report" on page 52.

To measure LVd and LVs

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

2 From the calculations menu, select the measurement name.

3 Position the active (green) caliper at the starting point, and then click. (See "Working with calipers" on page 33.)

4 Position the second caliper, and then click.

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

5 Position the caliper, and then click. Repeat for each measurement name in the calculation group.

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

6 Save the calculation. (See "To save a calculation" on page 38.)

To measure Ao, LA, AAo, or LVOT D

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

2 From the calculations menu, select the measurement name.

3 Position the calipers. (See "Working with calipers" on page 33.)

4 Save the calculation. (See "To save a calculation" on page 38.)

To calculate LV Volume (Simpson's Rule)

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

2 Do the following for each measurement:

a From the calculations menu, select the desired view and phase.

b Position the caliper at the mitral annulus, and then click to start the trace.

c Using the touchpad, trace the left ventricular (LV) cavity.

To make a correction, press **Undo**.

d Complete the trace, and then click.

e Save the calculation. (See "To save a calculation" on page 38.)

To calculate MV or AV area

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

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 then click.

4 Using the touchpad, trace the desired area.

To make a correction, press **Undo**.

5 Complete the trace, and then press **Set**.

6 Save the calculation. (See "To save a calculation" on page 38.)

To calculate LV Mass

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

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 then click.

c Using the touchpad, trace the desired area.

To make a correction, press **Undo**.

d Complete the trace, and press **Set**.

e Save the calculation. (See "To save a calculation" on page 38.).

4 Select **Apical** from the calculations menu.

5 Positioning the calipers, measure the ventricular length. (See "Working with calipers" on page 33.)

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 **Calcs**.

2 From the calculations menu, select **MV**, **TV**, **TDI**, or **P. Vein**.

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

a Select the measurement name from the calculations menu.

b Position the calipers. (See "Working with calipers" on page 33.)

c Save the calculation. (See "To save a calculation" on page 38.)

To calculate Velocity Time Integral (VTI)

Note: This calculation computes other results in addition to VTI. See the table "Cardiac Calculations" on page 39.

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

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 then click to start the trace.

4 Using the touchpad, trace the waveform.

   To make a correction, press **Undo** or backtrack with the touchpad.

5 Press **Set** to complete the trace.

6 Save the calculation. (See "To save a calculation" on page 38.)

For information on the automatic trace tool, see "To trace automatically (Doppler)" on page 37.

To calculate Right Ventricular Systolic Pressure (RVSP)

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

2 From the calculations menu, select **TV** and then select **TRmax**.

3 Position the caliper. (See "Working with calipers" on page 33.)

4 Save the calculation. (See "To save a calculation" on page 38.)

5 To adjust the RA pressure, see "Cardiac patient report" on page 52.

   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 **Calcs**.

2 From the calculations menu, select **MV**, **AV**, or **TV**, and then select **PHT**.

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

   A second caliper appears.

4 Position the second caliper:

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

5 Save the calculation. (See "To save a calculation" on page 38.)

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 **Calcs**.

   b From the calculations menu, locate **PISA**, and then select **Ann D**.

   c Position the calipers. (See "Working with calipers" on page 33.)

   d Save the calculation. (See "To save a calculation" on page 38.)

2 Measure from Radius (Color):

   a On a frozen Color image, press **Calcs**.

   b From the calculations menu, select **Radius**.

   c Position the calipers.

   d Save the calculation.

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

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 then click to start the trace.

   c Using the touchpad, trace the waveform.

To make a correction, press **Undo** or backtrack with the touchpad.

d Press **Set** to complete the trace.

e Save the calculation.

For information on the automatic trace tool, see "To trace automatically (Doppler)" on page 37.

To calculate Isovolumic Relaxation Time (IVRT)

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

2 From the calculations menu, select **MV** and then select **IVRT**.

A vertical caliper appears.

3 Using the touchpad, position the caliper at the aortic valve closure, and then click.

A second vertical caliper appears.

4 Using the touchpad, position the second caliper at onset of mitral inflow.

5 Save the calculation. (See "To save a calculation" on page 38.)

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 23.)

1 On a frozen CW Doppler spectral trace, press **Calcs**.

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 Using the touchpad, position the first caliper along the waveform at 100 cm/s, and then click.

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

4 Using the touchpad, position the second caliper along the waveform at 300 cm/s.

5 Save the calculation. (See "To save a calculation" on page 38.)

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 Measure from LVOT (2D):

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

b From the calculations menu, select **Ao/LA**, and then select **LVOT D**.

c Position the calipers. (See "Working with calipers" on page 33.)

d Save the calculation. (See "To save a calculation" on page 38.)

2 Measure from LVOT, and then measure from AV (Doppler):

- For Vmax, see "To measure peak velocity" on page 43. From the calculations menu, select **AV**, select sample site, and then select **Vmax**.
- For VTI, see "To calculate Velocity Time Integral (VTI)" on page 43. 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 **Calcs**.

2 Do the following to measure from LVOT D and again to measure from RVOT D:

   a From the calculations menu, locate **Qp/Qs** and then select **LVOT D** or **RVOT D**.

   b Position the calipers. (See "Working with calipers" on page 33.)

   c Save the calculation. (See "To save a calculation" on page 38.)

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

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 Using the touchpad, position the caliper and then click.

   c Using the touchpad, trace the waveform.

   To make a correction, press **Undo** or backtrack with the touchpad.

   d Press **Set** to complete the trace.

   e Save the calculation. (See "To save a calculation" on page 38.)

For information on the automatic trace tool, see "To trace automatically (Doppler)" on page 37.

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. (See "To create a new patient information form" on page 27.)

2 Measure from LVOT (2D):

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

   b From the calculations menu, select **LVOT D**.

   c Position the calipers. (See "Working with calipers" on page 33.)

   d Save the calculation. (See "To save a calculation" on page 38.)

3 Measure from aorta (Doppler). See "To calculate Velocity Time Integral (VTI)" on page 43. From the calculations menu, select **AV** and then select **VTI**.

For information on the automatic trace tool, see "To trace automatically (Doppler)" on page 37.

To calculate Heart Rate (HR)

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 **Calcs**.

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

   A vertical caliper appears.

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

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

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

5 Save the calculation. (See "To save a calculation" on page 38.)

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

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

1 (CI Only) Fill in the **Height** and **Weight** fields on the patient information form. The BSA is calculated automatically. (See "To create a new patient information form" on page 27.)

2 Calculate SV. See "To calculate Stroke Volume (SV) or Stroke Index (SI)" on page 46.

3 Calculate HR. See "To calculate Heart Rate (HR)" on page 46.

To calculate Cardiac Output automatically

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

To avoid an incorrect diagnosis:

- Do not use automatic Cardiac Output calculations as the sole diagnostic criteria. Use them only in conjunction with other clinical information and patient history.
- Do not use automatic Cardiac Output calculations in neonatal patients.

To avoid inaccurate velocity measurements if you use PW Doppler, make sure that Angle Correction is set to zero.

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

1 Measure from LVOT (2D):

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

   b From the calculations menu, select **CO**, and then select **LVOT D**.

   c Position the calipers. (See "Working with calipers" on page 33.)

   d Save the calculation. (See "To save a calculation" on page 38.)

2 Trace automatically (Doppler):

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

   a Display the Doppler spectral trace (waveform).

   b For **Sweep Speed**, select **Slow** or **Med**.

   c Press **Trace**, and then press **Above** or **Below** for the position of the automatic trace tool relative to the baseline.

   The automatic trace tool appears in yellow.

   The results appear at the bottom of the screen.

   d Freeze the image.

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

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

   e Save the calculation.

To measure a Tissue Doppler Imaging (TDI) waveform

1 Ensure that TDI is on. (See "PW Doppler controls" on page 22.)

2 On a frozen Doppler spectral trace, press  **Calcs**.

3 From the calculations menu, select **TDI**, and then do the following for each measurement you want to take:

   a From the calculations menu, select the measurement name.

   b Position the calipers. (See "Working with calipers" on page 33.)

   c Save the calculation. (See "To save a calculation" on page 38.)

EMED calculations (S-FAST)

The results from EMED calculations automatically appear in the EMED worksheets. See "EMED worksheets (S-FAST)" on page 53. EMED calculations are available for all exams on any compatible transducer. (See "Imaging modes and exams available by transducer" on page 24.)

To perform an EMED calculation

1 On a frozen image, press  **Calcs**.

2 In the calculations menu, select the calculation name.

3 Perform a distance measurement. (See "To measure distance" on page 34.)

4 Save the measurement. See "To save a calculation" on page 38.

Gynecology (Gyn) calculations

Gynecology (Gyn) calculations include Uterus, Ovary, Follicle, and Volume. For instructions to calculate volume, see "Volume calculations" on page 51.

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 27.

Systems and Exam Types for Gynecology (Gyn) Calculations

Exam Type	S Series System
Gyn	S-FAST S-GYN S-Women's Health

To measure uterus or ovary

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

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

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

   a Select the measurement name from the calculations menu.

   b Position the calipers. (See "Working with calipers" on page 33.)

   c Save the calculation. (See "To save a calculation" on page 38.)

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 **Calcs**.

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

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

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

   b Position the calipers. (See "Working with calipers" on page 33.)

   c Save the calculation. (See "To save a calculation" on page 38.)

OB calculations

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

WARNING: Make sure that you have selected the OB exam type and the OB calculations author for the OB table you intend to use. See "System-defined OB calculations and table authors" on page 49.

To avoid incorrect obstetrics calculations, verify with a local clock and calendar that the system's date and time settings are correct before each use of the system. The system does not automatically adjust for daylight savings time changes.

To avoid misdiagnosis or harming the patient outcome, start a new patient information form before starting a new patient exam and performing calculations. Starting a new patient information form clears the previous patient's data. The previous patient's data will be combined with the current patient if the form is not first cleared. See "To create a new patient information form" on page 27.

Systems and Exam Types for OB Calculations

Exam Type	S Series System
OB	S-FAST S-GYN S-Women's Health

System-defined OB calculations and table authors

The following table shows the system-defined measurements available for OB calculations by author. For definition of the acronyms, see "Glossary" on page 141. To select authors, see "OB Calculations setup" on page 16.

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

Calculation Result	Gestational OB Measurements	Table Authors
Gestational Age[a]	YS	—
	GS	Hansmann, Nyberg, Tokyo U.
	CRL	Hadlock, Hansmann, Osaka, Tokyo U.
	BPD	Chitty, Hadlock, Hansmann, Osaka, Tokyo U.
	OFD	Hansmann
	HC	Chitty, Hadlock, Hansmann
	TTD	Hansmann, Tokyo U.[b]
	APTD	Tokyo U.[b]
	AC	Hadlock, Hansmann, Tokyo U.
	FTA	Osaka
	FL	Chitty, Hadlock, Hansmann, Osaka, Tokyo U.
	HL	Jeanty
	Tibia	Jeanty
	TCD	—
	CM	—
	Lat V	—
	CxLen	—
Estimated Fetal Weight (EFW)[c]	HC, AC, FL	Hadlock 1
	BPD, AC, FL	Hadlock 2
	AC, FL	Hadlock 3
	BPD, TTD	Hansmann
	BPD, FTA, FL	Osaka U.
	BPD, AC	Shepard
	BPD, TTD, APTD, FL	Tokyo U.
Ratios	HC/AC	Campbell
	FL/AC	Hadlock
	FL/BPD	Hohler
	FL/HC	Hadlock
Amniotic Fluid Index	Q^1, Q^2, Q^3, Q^4	Jeng

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 16.)
Individual selections for Hadlock's EFW equations 1, 2, and 3 are not determined by the user. The selected equation is determined by the measurements that have been saved to the report with priority given to the order listed above.

To measure gestational growth (2D)

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

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

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

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

a From the calculations menu, select the measurement name.

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

b Position the calipers. (See "Working with calipers" on page 33.)

c Save the calculation. (See "To save a calculation" on page 38.)

To measure fetal heart rate (M Mode)

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

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, and then click.

A second vertical caliper appears.

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

5 Save the calculation. (See "To save a calculation" on page 38.)

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. See "To create a new patient information form" on page 27.

Systems and Exam Types for Volume Calculations

Exam Types	S Series System
Bre	S-Cath S-GYN S-Women's Health
Gyn	S-FAST S-GYN S-Women's Health

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 **Calcs**.

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

i From the calculations menu, select the measurement name under **Volume**. (If **Volume** is not available in a Gyn exam, select **Gyn** and then select **Volume**.)

ii Position the calipers. (See "Working with calipers" on page 33.)

iii Save the measurement. (See "To save a calculation" on page 38.)

Patient report

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

The S-FAST system has EMED worksheets instead of a patient report. See "EMED worksheets (S-FAST)" on page 53.

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

You can display the patient report at any time during the exam. For a definition of terms in patient reports, see "Glossary" on page 141.

To display the patient report

1 After or during the exam, do one of the following:

- Press **Options**, and then select **Report**.
- Press **Patient**, and then press **Report**.

2 To display additional pages, press **x/x**.

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

OB patient report

To delete an OB measurement

1 Display the OB patient report.

2 Select the measurements to delete:

- Select one measurement by clicking it.
- Select all measurements by clicking the measurement name.

The selected measurements are highlighted green.

3 Press **Delete**.

Cardiac patient report

To delete a cardiac measurement

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

2 Select **Delete** on-screen.

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

To adjust the RA pressure

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

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

EMED worksheets (S-FAST)

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

To display an EMED worksheet

1. After or during the exam, press **Options** and select **Report**.
2. Select the worksheet from the **Worksheet** list or by pressing **x/x**.

MSK worksheets (S-MSK)

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

To display an MSK worksheet

1. After or during the exam, press **Options** and select **Report**.
2. Select the worksheet from the **Worksheet** list.

   To display additional pages in the worksheet, press **x/x**. Each worksheet has its own Comments field, which remains on-screen even if you display another page in the worksheet.
3. If you want to save a worksheet page, press **Save**.

Chapter 5: Troubleshooting and Maintenance

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

Troubleshooting

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

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 LCD screen to improve viewing angle.

Adjust the brightness.

Adjust the gain.

No CPD image Adjust the gain.

No Color image Adjust the gain or the scale.

No OB measurement selections Select the OB exam type.

MSK instead of EMED worksheets The system can display either MSK or EMED worksheets but not both. If MSK worksheets are licensed, EMED worksheets are unavailable. Contact SonoSite or your SonoSite representative.

Print does not work Select the printer on the Connectivity setup page. See "To configure the system for a printer" on page 15.

Check the printer connections.

Ensure that the printer is turned on and set up properly. See the printer manufacturer's instructions, if necessary.

DVD recorder does not record Check the DVD recorder connections.

Ensure that the DVD recorder is turned on and set up properly. See the applicable SonoSite accessory user guide and the manufacturers' instructions.

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

A maintenance icon  appears on the system screen System maintenance may be required. Record the number in parentheses on the C: line and contact SonoSite or your SonoSite representative.

Software licensing

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

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

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

To obtain a license key for your software, contact SonoSite Technical Support. (See "SonoSite Technical Support" on page vii.) You need to provide the following information. (See "System Information setup" on page 16.)

System Software	Transducer Software
Name of institution installing the upgrade	Name of institution installing the upgrade
Serial number (on bottom of system)	Transducer serial number
ARM version	Transducer part number (REF) or model number (for example, C60x)
PCBA serial number	Transducer bundle version

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

To enter a license key

1. Turn on the system.

   The license update screen appears.

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

3. Select **Done** on-screen.

   If you entered a valid license key but the license update screen appears, verify that you entered the license key correctly. If the license update screen still appears, contact SonoSite Technical Support. (See "SonoSite Technical Support" on page vii.)

Maintenance

Use the recommendations in this section 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.

No periodic or preventive maintenance is required for the system, transducer, or accessories other than cleaning and disinfecting the transducer after every use. (See "Cleaning and disinfecting transducers" on page 58.) There are no internal components that require periodic testing or calibration. All maintenance requirements are described in this chapter and in the ultrasound system service manual. Performing maintenance procedures not described in the user guide or service manual may void the product warranty.

Contact SonoSite Technical Support for any maintenance questions. (See "SonoSite Technical Support" on page vii.)

WARNING: Disinfectants and cleaning methods listed are recommended by SonoSite for compatibility with product materials, not for biological effectiveness. Refer to the disinfectant label instructions for guidance on disinfection efficacy and appropriate clinical uses.

The level of disinfection required for a device is dictated by the type of tissue it will contact during use. To avoid infection, ensure that the disinfectant type is appropriate for the equipment. For information, see the disinfectant label instructions and the recommendations of the Association for Professionals in Infection Control and Epidemiology (APIC) and the FDA.

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

Caution: 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.

Cleaning and disinfecting the ultrasound system

The exterior surface of the ultrasound system and the accessories can be cleaned and disinfected using a recommended cleaner or disinfectant. See Table 1, "Disinfectant Compatibility with System and Transducers" on page 60.

WARNING: To avoid electrical shock, before cleaning, disconnect the system from the power supply or remove it from the stand.

To avoid infection always use protective eyewear and gloves when performing cleaning and disinfecting procedures.

Caution: Do not spray cleaners or disinfectant directly on the system surfaces. Doing so may cause solution to leak into the system, damaging the system and voiding the warranty.

Do not use strong solvents such as thinner or benzene, or abrasive cleansers, since these will damage the exterior surfaces.

Use only recommended cleaners or disinfectants on system surfaces. Immersion-type disinfectants are not approved for use on system surfaces.

When you clean the system, ensure that the solution does not get inside the system controls or the battery compartment.

Do not scratch the LCD screen.

To clean the LCD screen

❖ Dampen a clean, non-abrasive, cotton cloth with an ethanolic-based liquid cleaner, and wipe the screen clean.

Apply the cleaner to the cloth rather than the surface of the screen.

To clean and disinfect system surfaces

1 Turn off the system.

2 Disconnect the system from the power supply, or remove it from the stand.

3 Clean the exterior surfaces using a soft cloth lightly dampened in a mild soap or detergent cleaning solution to remove any particulate matter or body fluids.

Apply the solution to the cloth rather than the surface.

4 Mix the disinfectant solution compatible with the system, following disinfectant label instructions for solution strengths and disinfectant contact duration.

5 Wipe surfaces with the disinfectant solution.

6 Air dry or towel dry with a clean cloth.

Cleaning and disinfecting transducers

To disinfect the transducer and its cable, use the immersion method or the wipe method. Immersible transducers can be disinfected only if the product labeling indicates they can be used with an immersion method.

See Table 1, "Disinfectant Compatibility with System and Transducers" on page 60.

WARNING: To avoid electrical shock, before cleaning, disconnect the transducer from the system.

To avoid injury, always use protective eyewear and gloves when performing cleaning and disinfecting procedures.

Caution: Transducers must be cleaned after every use. Cleaning transducers is necessary prior to effective disinfection. Ensure that you follow the manufacturer's instructions when using disinfectants.

Do not use a surgeon's brush when cleaning transducers. Even the use of soft brushes can damage a transducer. Use a soft cloth.

Using a non-recommended cleaning or disinfection solution, using incorrect solution strength, or immersing a transducer deeper or for a longer period of time than recommended can damage or discolor the transducer and void the transducer warranty.

Do not allow cleaning solution or disinfectant into the transducer connector.

Do not allow disinfectant to contact metal surfaces. Use a soft cloth lightly dampened in a mild soap or compatible cleaning solution to remove any disinfectant that remains on metal surfaces.

Attempting to disinfect a transducer or transducer cable using a method other than the one included here can damage the transducer and void the warranty.

To clean and disinfect a transducer (wipe method)

1 Disconnect the transducer from the system.

2 Remove any transducer sheath.

3 Clean the surface using a soft cloth lightly dampened in a mild soap or detergent cleaning solution to remove any particulate matter or body fluids.

Apply the solution to the cloth rather than the surface.

4 Rinse with water or wipe with water-dampened cloth, and then wipe with a dry cloth.

5 Mix the disinfectant solution compatible with the transducer, following disinfectant label instructions for solution strengths and disinfectant contact duration.

6 Wipe surfaces with the disinfectant solution.

7 Air dry or towel dry with a clean cloth.

8 Examine the transducer and cable for damage such as cracks, splitting, or fluid leaks.

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

To clean and disinfect a transducer (immersion method)

1. Disconnect the transducer from the system.
2. Remove any transducer sheath.
3. Clean the surface using a soft cloth lightly dampened in a mild soap or compatible cleaning solution to remove any particulate matter or body fluids.

   Apply the solution to the cloth rather than the surface.
4. Rinse with water or a wipe with water-dampened cloth, and then wipe with a dry cloth.
5. Mix the disinfectant solution compatible with the transducer, following disinfectant label instructions for solution strengths and disinfectant contact duration.
6. Immerse the transducer into the disinfection solution not more than 12-18 inches (31-46 cm) from the point where the cable enters the connector.

   Follow the instructions on the disinfectant label for the duration of the transducer immersion.
7. Using the instructions on the disinfectant label, rinse to the point of the previous immersion, and then air dry or towel dry with a clean cloth.
8. Examine the transducer and cable for damage such as cracks, splitting, or fluid leaks.

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

Cleaning and disinfecting the battery or USB keyboard

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 the battery (wipe method)

1. Remove the battery from the system.
2. Clean the surface using a soft cloth lightly dampened in a mild soap or detergent cleaning solution.

   Apply the solution to the cloth rather than the surface.
3. Wipe the surfaces with the disinfection solution. Sani-Cloth HB, Sani-Cloth Wipes, or 70% isopropyl alcohol is recommended.
4. Air dry or towel dry with a clean cloth.

To clean and disinfect the USB keyboard

1. Disconnect the USB keyboard from the system.
2. Wipe the surface with any of the following products:
   - Sani-Cloth Wipes.
   - Isopropyl alcohol
   - Hydrogen peroxide

Recommended disinfectants

Table 1 does not have the following regulatory information for disinfectants:

- EPA registration
- FDA 510(k) clearance (liquid sterilant, high level disinfectant)
- CE approval
- Before using a disinfectant, confirm that its regulatory status is appropriate for your jurisdiction and use. Verify expiration dates on chemicals.

When disposing of chemicals, follow manufacturer recommendations and EPA regulations.

See www.sonosite.com for updated cleaning and disinfectant information.

For cleaning and disinfecting the TEEx transducer, see the *TEEx Transducer User Guide.*

Table 1: Disinfectant Compatibility with System and Transducers

Disinfection and Cleaning Solutions	Country of Origin	Type	Active Ingredient	C60x ICTx L38x P10x P21x SLAx	HFL38x	HFL50x	C11x L25x	L38xi	System Surfaces
AbcoCide 14	USA	Liquid	Glutaraldehyde	✓	✓	—	✓	—	—
Accel Plus	CAN	Wipe	Hydrogen Peroxide	⃠	⃠	—	⃠	—	—
Accel TB	CAN	Wipe	Hydrogen Peroxide	⃠	⃠	—	⃠	—	—
Accel Wipes	CAN	Wipe	Hydrogen Peroxide	✓	✓	—	✓	—	—
Aidal Plus	AUS	Liquid	Glutaraldehyde	✓	✓	—	✓	—	—
Airkem A-33	USA	Liquid	Quat. Ammonia	—	—	—	—	✓	—
Alcohol, Ethyl	USA	Liquid	Denatured Ethyl Alcohol 3A	—	—	—	—	✓	—
Alcohol, Isopropanol (100%)	ALL	Liquid	Alcohol	⃠	⃠	⃠	⃠	⃠	—

Table 1: Disinfectant Compatibility with System and Transducers (continued)

Disinfection and Cleaning Solutions	Country of Origin	Type	Active Ingredient	C60x ICTx L38x P10x P21x SLAx	HFL38x	HFL50x	C11x L25x	L38xi	System Surfaces
Alkacide	FRA	Liquid	Glutaraldehyde	✓	✓	—	✓	—	—
Alkazyme	FRA	Liquid	Quat. Ammonia	✓	✓	—	✓	—	—
Anioxy-Twin	FRA	Liquid	Peracetic Acid	⃠	⃠	—	⃠	—	—
Anioxyde 1000	FRA	Liquid	Peracetic Acid	⃠	⃠	—	⃠	⃠	—
Aquatabs (1000)	IRL	Tablet	Sodium Dichloroisocyanurate	✓	⃠	—	✓	—	—
Aquatabs (2000)	IRL	Tablet	Sodium Dichloroisocyanurate	✓	⃠	—	✓	—	—
Aquatabs (5000)	IRL	Tablet	Sodium Dichloroisocyanurate	⃠	⃠	—	⃠	—	—
Ascend	USA	Liquid	Quat Ammonia	✓	✓	—	✓	—	—
Asepti-HB	USA	Liquid	Quat Ammonia	✓	✓	✓	✓	✓	—
Asepti-Steryl	USA	Spray	Ethanol	✓	✓	—	✓	—	⃠
Asepti-Wipes	USA	Wipe	Propanol (Isopropyl Alcohol	✓	✓	—	✓	—	✓
Bacillocid rasant	DEU	Liquid	Glut./Quat. Ammonia	✓	✓	—	✓	—	—
Bacoban	DEU	Liquid	Ethanol Isopropanol	✓	✓	—	✓	—	⃠
Bacoban WB	DEU	Liquid	Benzalkonium chloride Diethylenglycol	✓	✓	—	✓	—	✓
Banicide	USA	Liquid	Glutaraldehyde	✓	—	—	✓	—	—
Bleach	USA	Liquid	NaCl Hypochlorite	✓	✓	—	✓	—	—

Table 1: Disinfectant Compatibility with System and Transducers (continued)

Disinfection and Cleaning Solutions	Country of Origin	Type	Active Ingredient	C60x ICTx L38x P10x P21x SLAx	HFL38x	HFL50x	C11x L25x	L38xi	System Surfaces
Cavicide	USA	Liquid	Isopropyl	✓	✓	—	✓	—	—
Caviwipes	USA	Wipes	Isopropanol	✓	✓	✓	⃠	✓	—
Chlor-Clean	GBR	Liquid	Sodium Dichloroisocyanurate	✓	⃠	—	✓	—	—
Cidalkan	FRA	Liquid	Alkylamine, isopropanol	✓	✓	—	✓	—	⃠
Cidalkan Lingettes	FRA	Wipes	Ethyl Alcohol	✓	✓	—	—	—	—
Cidex	USA	Liquid	Glutaraldehyde	✓	✓	—	✓	—	✓
Cidex OPA	USA	Liquid	Ortho-phthaldehyde	✓	✓	✓	✓	✓	—
Cidex Plus	USA	Liquid	Glutaraldehyde	✓	✓	—	✓	—	✓
Cleanisept	DEU	Wipes	Quat Ammonia	✓	✓	—	✓	—	✓
Clorox Wipes	USA	Wipes	Isopropanol	✓	✓	—	✓	—	—
Control III	USA	Liquid	Quat. Ammonia	✓	✓	—	⃠	—	—
Coverage Spray	USA	Spray	Quat. Ammonia	✓	✓	—	⃠	✓	⃠
Denatured Alcohol	USA	Liquid	Ethanol	⃠	⃠	—	⃠	—	—
DentaSept	FRA	Liquid	Quat. Ammonia	⃠	⃠	—	⃠	—	—
DisCide Wipes	USA	Wipes	Isopropyl Alcohol	✓	✓	—	✓	—	—
DisOPA	JPN	Liquid	Ortho-phthaldehyde	✓	✓	—	✓	—	—
Dispatch	USA	Spray	NaCl Hypochlorite	✓	✓	—	✓	—	—

Table 1: Disinfectant Compatibility with System and Transducers (continued)

Disinfection and Cleaning Solutions	Country of Origin	Type	Active Ingredient	C60x ICTx L38x P10x P21x SLAx	HFL38x	HFL50x	C11x L25x	L38xi	System Surfaces
Dynacide PA	FRA	Liquid	Peracetic Acid	✓	✓	—	✓	—	—
Echo Clean Lingettes	FRA	Wipe	Alkylamine, Isopropyl Alcohol	—	—	—	—	⃠	—
End-Bac II	USA	Liquid	Quat. Ammonia	✓	✓	—	✓	—	⃠
Endosporine	FRA	Liquid	Gluteraldehyde	—	—	✓	—	✓	—
Endozime AW Plus	FRA	Liquid	Propanol	✓	✓	—	✓	—	—
Envirocide	USA	Liquid	Isopropyl	✓	—	⃠	⃠	✓	—
Enzol	USA	Cleaner	Ethylene Glycol	✓	✓	—	✓	—	—
Expose	USA	Liquid	Isopropyl	✓	✓	—	✓	—	—
Gigasept AF	DEU	Liquid	Quat. Ammonia	✓	✓	—	✓	—	—
Gigasept FF	DEU	Liquid	Bersteinsaure	⃠	⃠	—	⃠	—	—
Gluteraldehyde SDS	USA	Liquid	Glutaraldehyde	✓	—	—	✓	—	—
Hexanios	FRA	Liquid	Polyhexanide/Quat. Ammonia	✓	✓	—	✓	—	—
Hi Tor Plus	USA	Liquid	Chloride	✓	✓	—	⃠	—	—
Hibiclens	USA	Cleaner	Chlorhexidine	✓	✓	—	✓	—	—
Hydrogen Peroxide (3%)	USA	Liquid	Hydrogen Peroxide	✓	✓	✓	✓	✓	—
Kodan Tücher	DEU	Liquid	Propanol	✓	✓	—	✓	—	—
Kohrsolin ff	DEU	Liquid	Glutaraldehyde	✓	—	—	✓	—	—

Table 1: Disinfectant Compatibility with System and Transducers (continued)

Disinfection and Cleaning Solutions	Country of Origin	Type	Active Ingredient	C60x ICTx L38x P10x P21x SLAx	HFL38x	HFL50x	C11x L25x	L38xi	System Surfaces
Korsolex basic	DEU	Liquid	Glutaraldehyde	⃠	⃠	—	⃠	—	—
Korsolex extra	DEU	Liquid	Ethanol/Propanol	✓	✓	—	✓	—	—
Lem-O-Quat	USA	Liquid	Alkyl/Chloride	⃠	⃠	—	⃠	—	—
LpHse	USA	Liquid	O-phenylphenol	✓	✓	—	✓	—	—
Lysol	USA	Spray	Ethanol	⃠	⃠	—	⃠	—	⃠
Lysol IC	USA	Liquid	O-phenylphenol	✓	⃠	—	✓	—	—
Madacide 1	USA	Liquid	Isopropanol	✓	✓	✓	⃠	✓	✓
Matar	USA	Liquid	O-phenylphenol	✓	—	—	✓	—	—
MetriCide 14	USA	Liquid	Glutaraldehyde	✓	✓	—	✓	—	—
MetriCide 28	USA	Liquid	Glutaraldehyde	✓	✓	—	✓	—	—
Metricide OPA Plus	USA	Liquid	Ortho-phthaldehyde	—	—	✓	—	✓	—
MetriZyme	USA	Cleaner	Propylene Glycol	✓	✓	—	✓	—	—
Mikrobak forte	DEU	Liquid	Ammonium Chloride	✓	✓	—	✓	—	—
Mikrozid Wipes	DEU	Wipe	Ethanol/Propanol	✓	✓	—	✓	—	—
Nuclean	FRA	Spray	Alcohol/Biguanide	✓	✓	—	✓	—	—
Precise	USA	Spray	O-phenylphenol	⃠	⃠	—	⃠	—	—
Prevention	CAN	Liquid	Hydrogen Peroxide	⃠	⃠	—	⃠	—	—
Reagent alcohol	n/a	Liquid	Denatured Ethyl Alcohol 3A	—	—	✓	—	—	—

Table 1: Disinfectant Compatibility with System and Transducers (continued)

Disinfection and Cleaning Solutions	Country of Origin	Type	Active Ingredient	C60x ICTx L38x P10x P21x SLAx	HFL38x	HFL50x	C11x L25x	L38xi	System Surfaces
Rely+On™ PeraSafe™	GBR	Liquid	Paracetic Acid	—	—	⊘	—	⊘	—
Ruthless	USA	Spray	Quat. Ammonia	✓	✓	—	⊘	—	—
Sagrosept Wipe	DEU	Wipe	Propanol	✓	✓	—	✓	—	—
Salvanios pH 7	FRA	Liquid	Quat. Ammonia	✓	✓	—	✓	—	—
Sani-Cloth HB	USA	Wipe	Quat. Ammonia	✓	✓	✓	⊘	✓	✓
Sani-Cloth Plus	USA	Wipe	Quat. Ammonia	✓	✓	✓	✓	⊘	✓
Sekusept	DEU	Liquid	Glutaraldehyde	✓	✓	—	✓	—	—
Sklar	USA	Liquid	Isopropanol	✓	✓	—	⊘	—	—
Sporicidin	USA	Liquid	Phenol	✓	✓	—	✓	⊘	⊘
Sporicidin Wipes	USA	Wipe	Phenol	✓	✓	—	✓	—	✓
Staphene	USA	Spray	Ethanol	✓	⊘	—	✓	—	—
Steranios	FRA	Liquid	Glutaraldehyde	✓	✓	—	✓	—	—
Steranios 20%	FRA	Liquid	Gluteraldehyde	—	—	✓	—	⊘	—
Super Sani-Cloth	USA	Wipe	Isopropyl Alcohol	⊘	⊘	⊘	⊘	⊘	⊘
T-Spray	USA	Spray	Quat. Ammonia	✓	✓	—	⊘	✓	⊘
T-Spray II	USA	Spray	Alkyl/Chloride	✓	✓	—	✓	✓	—
TASK 105	USA	Spray	Quat. Ammonia	✓	✓	—	✓	—	—
TBQ	USA	Liquid	Quat. Ammonia	✓	✓	—	✓	—	—

Table 1: Disinfectant Compatibility with System and Transducers (continued)

Disinfection and Cleaning Solutions	Country of Origin	Type	Active Ingredient	C60x ICTx L38x P10x P21x SLAx	HFL38x	HFL50x	C11x L25x	L38xi	System Surfaces
Tor	USA	Liquid	Quat. Ammonia	✓	✓	—	⃠	—	—
Transeptic	USA	Cleaner	Alcohol	⃠	⃠	—	⃠	—	—
Tristel	GBR	Liquid	Chlorine Dioxide	✓	✓	—	✓	—	—
Tristel Duo	GBR	Foam	Chlorine Dioxide	⃠	⃠	—	⃠	—	—
Tristel Solo	GBR	Foam	Hexamethylenebiguanide	✓	✓	—	✓	✓	—
Tristel Wipes	GBR	Wipe	Chlorine Dioxide	⃠	⃠	—	⃠	—	⃠
Vesphene II	USA	Liquid	Sodium/ o-Phenylphenate	✓	✓	—	✓	—	—
Virex II 256	USA	Liquid	Ammonium Chloride	✓	✓	✓	✓	✓	—
Virex TB	USA	Liquid	Quat. Ammonia	✓	✓	✓	⃠	✓	⃠
Virox 5	CAN	Wipe	Hydrogen Peroxide	✓	✓	—	✓	✓	—
Virufen	FRA	Liquid	Alkyl Ammonium Chloride	✓	✓	—	✓	—	—
Wavicide -01	USA	Liquid	Glutaraldehyde	⃠	⃠	—	⃠	—	—
Wavicide -06	USA	Liquid	Glutaraldehyde	✓	✓	—	✓	—	—
Wet Wipe Disinfection	DNK	Wipe	Guanidinium-chloride	—	✓	—	✓	—	—
Wex-Cide	USA	Liquid	O-phenylphenol	✓	✓	—	✓	—	—

✓ = Acceptable

⃠ = Not acceptable (Do not use)

— = Untested (Do not use)

Chapter 6: Safety

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

Ergonomic safety

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

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

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

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

When using an ultrasound system, as with many similar physical activities, you may experience occasional discomfort in your hands, fingers, arms, shoulders, eyes, back, or other parts of your body. However, if you experience symptoms such as constant or recurring discomfort, pain, throbbing, aching, tingling, numbness, burning sensation, or stiffness, promptly see a qualified health professional. Such symptoms can be linked with musculoskeletal disorders (MSDs). MSDs can be painful and may result in potentially disabling injuries to the nerves, muscles, tendons, or other parts of the body. Examples of MSDs include carpal tunnel syndrome and tendonitis.

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

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b. Craig, M. "Sonography: An Occupational Hazard?" *Journal of Diagnostic Medical Sonography.* 3 (1985), 121-125.

c. Smith, C.S., G.W. Wolf, G. Y. Xie, and M. D. Smith. "Musculoskeletal Pain in Cardiac Ultrasonographers: Results of a Random Survey." *Journal of American Society of Echocardiography.* (May1997), 357-362.

d. Wihlidal, L.M. and S. Kumar. "An Injury Profile of Practicing Diagnostic Medical Sonographers in Alberta." *International Journal of Industrial Ergonomics*. 19 (1997), 205-216.

e. Habes, D.J. and S. Baron. "Health Hazard Report 99-0093-2749." *University of Medicine and Dentistry of New Jersey.* (1999).

f. Vanderpool, H.E., E.A. Friis, B.S. Smith, and K.L. Harms. "Prevalence of Carpal Tunnel Syndrome and Other Work-related Musculoskeletal Problems in Cardiac Sonographers." *Journal of Medicine.* 35:6 (1993), 605-610.

Position the system

Promote comfortable shoulder, arm, and hand postures

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

Minimize eye and neck strain

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

Position yourself

Support your back during an exam

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

Minimize reaching and twisting

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

Promote comfortable shoulder and arm postures

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

Promote comfortable hand, wrist, and finger postures

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

Take breaks, exercise, and vary activities

- Minimizing scanning time and taking breaks can effectively allow your body to recover from physical activity and help you avoid MSDs. Some ultrasound tasks may require longer

or more frequent breaks. However, simply changing tasks can help some muscle groups relax while others remain or become active.

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

Electrical safety classification

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

Electrical safety

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

This system complies with the applicable medical equipment requirements published in the Canadian Standards Association (CSA), European Norm Harmonized Standards, and Underwriters Laboratories (UL) safety standards. See Chapter 8, "Specifications."

For maximum safety observe the following warnings and cautions.

WARNING: To avoid discomfort or minor risk of patient injury, keep hot surfaces away from the patient.

Under certain circumstances, the transducer connector and back of the display enclosure can reach temperatures that exceed EN60601-1 limits for patient contact, therefore only the operator shall handle the system. This does not include the transducer face.

To avoid discomfort or minor risk of operator injury when handling the transducer connector, the system should not be operated for more than 60 minutes continuously in a live-scan mode (as opposed to freeze or sleep modes).

To avoid the risk of injury, do not operate the system in the presence of flammable gasses or anesthetics. Explosion can result.

To avoid the risk of electrical shock or injury, do not open the system enclosures. All internal adjustments and replacements, except battery replacement, must be made by a qualified technician.

To avoid the risk of electrical shock:

- Use only properly grounded equipment. Shock hazards exist if the power supply is not properly grounded. Grounding reliability can only be achieved when equipment is connected to a receptacle marked "Hospital Only" or "Hospital Grade" or the equivalent. The grounding wire must not be removed or defeated.
- When using the system in an environment where the integrity of the protective earth conductor arrangement is in doubt, operate the system on battery power only without using the power supply.
- Do not touch any of the following:
  - The ungrounded signal input/output connectors on the back of the ultrasound system
  - The system battery contacts (inside the battery compartment)
  - The system transducer connector when the transducer is disconnected
- Do not connect either of the following to an MPSO or extension cord:
  - System power supply
  - Auxiliary mains outlet receptacles on the S Series stand or the V-Universal stand

- Before using the transducer, inspect the transducer face, housing, and cable. Do not use the transducer if the transducer or cable is damaged.
- Always disconnect the power supply from the system before cleaning the system.
- Do not use any transducer that has been immersed beyond the specified cleaning or disinfection level. See Chapter 5, "Troubleshooting and Maintenance."
- Use only accessories and peripherals recommended by SonoSite, including the power supply. Connection of accessories and peripherals not recommended by SonoSite could result in electrical shock. Contact SonoSite or your local representative for a list of accessories and peripherals available from or recommend by 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, S Series stand, or V-Universal stand to mains power must only be used with the power supply or stand, and cannot be used to connect other devices to mains power.

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. SonoSite recommends verifying that the system, all combinations of equipment, and accessories connected to the ultrasound system comply with JACHO installation requirements and/or safety standards such as AAMI-ES1, NFPA 99 OR IEC Standard 60601-1-1 and electromagnetic compatibility standard IEC 60601-1-2 (Electromagnetic compatibility), and are certified according to IEC Standard 60950 (Information Technology Equipment (ITE)).

Caution: Do not use the system if an error message appears on the image display: note the error code; call 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 back of the system.

Equipment safety

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

Caution:

Excessive bending or twisting of cables can cause a failure or intermittent operation.

Improper cleaning or disinfecting of any part of the system can cause permanent damage. For cleaning and disinfecting instructions, see Chapter 5, "Troubleshooting and Maintenance."

Do not submerge the transducer connector in solution. The cable is not liquid-tight beyond the transducer connector/cable interface.

Do not use solvents such as thinner or benzene, or abrasive cleaners on any part of the system.

Remove the battery from the system if the system is not likely to be used for some time.

Do not spill liquid on the system.

Battery safety

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

WARNING:

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 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.

WARNING: Do not continue recharging the battery if it does not recharge after two successive six hour charging cycles.

If the battery leaks or emits an odor, remove it from all possible flammable sources.

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 SonoSite or your local representative.

Store the battery between -20°C (-4°F) and 60°C (140°F).

Use only SonoSite batteries.

Do not use or charge the battery with non-SonoSite equipment. Only charge the battery with the system.

Clinical safety

WARNING: Non-medical (commercial) grade peripheral monitors have not been verified or validated by 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.

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 SonoSite transducers are approved for intraoperative applications if a market-cleared sheath is used.

Hazardous materials

WARNING: The liquid crystal display (LCD) contains mercury. Dispose of the LCD properly in accordance with local regulations.

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.

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

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

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

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. Static shock 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.

Manufacturer's declaration

Table 1 and Table 2 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 1: Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	The SonoSite 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 ultrasound system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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

Table 2: Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	2.0KV, 4.0KV, 6.0KV contact 2.0KV, 4.0KV, 8.0KV air	2.0KV, 4.0KV, 6.0KV contact 2.0KV, 4.0KV, 8.0KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient burst IEC 61000-4-4	2KV on the mains 1KV on signal lines	2KV on the mains 1KV on signal lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	0.5KV, 1.0KV, 2.0KV on AC power lines to ground 0.5KV, 1.0KV on AC power lines to lines	0.5KV, 1.0KV, 2.0KV on AC power lines to ground 0.5KV, 1.0KV on AC power lines to lines	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles *70*% U_T (30% dip in U_T) for 25 cycles >5% U_T (>95% dip in U_T) for 5s	>5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles *70*% U_T (30% dip in U_T) for 25 cycles >5% U_T (>95% dip in U_T) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SonoSite ultrasound system requires continued operation during power mains interruptions, it is recommended that the SonoSite ultrasound system be powered from an uninterruptible power supply or a battery.

Table 2: Manufacturer's Declaration - Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Power Frequency Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	If image distortion occurs, it may be necessary to position the SonoSite ultrasound system further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the Intended installation location to assure that it is sufficiently low.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the SonoSite ultrasound system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 Vim 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).

Table 2: Manufacturer's Declaration - Electromagnetic Immunity (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment
Radiated RF IEC 61000-4-3 (continued)			Field strengths from fixed RF transmitters, as determined by an electromagnetic Site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:  (IEC 60417 No. 417-IEC-5140: "Source of non-ionizing radiation")

Note: U_T is the AC mains voltage prior to application of the test level.
At 80 MHz and 800 MHz, the higher frequency range applies.
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

ALARA principle

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

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

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

Applying ALARA

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

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

The system has been designed to ensure that temperature at the face of the transducer will not exceed the limits established in Section 42 of EN 60601-2-37: Particular requirement for the safety of ultrasound medical diagnostic and monitoring equipment. See "Transducer surface temperature rise" on page 85. In the event of a device malfunction, there are redundant controls that limit transducer power. This is accomplished by an electrical design that limits both power supply current and voltage to the transducer.

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

Direct controls

The system does not exceed a spatial peak temporal average intensity (ISPTA) of 720 mW/cm^2 for all imaging modes. (For the Ophthalmic 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 81. Additionally, one means for meeting the ALARA principle is to set the MI or TI values to a low index value and then modifying this level until a satisfactory image or Doppler mode is obtained. For more information on MI and TI, see BS EN 60601-2-37:2001: 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
- Reverberations
- Comet tails

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

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

Guidelines for reducing MI and TI

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

Table 3: MI

Transducer	Depth
C11x	↑
C60x	↑
HFL38x	↑
HFL50x	↑
ICTx	↑
L25x	↑
L38x	↑
L38xi	↑
P10x	↑
P21x	↑
SLAx	↑
TEEx	↑

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

Table 4: TI (TIS, TIC, TIB)

Transducer	CPD Settings						PW Settings
	Box Width	Box Height	Box Depth	PRF	Depth	Optimize	
C11x			↑	↓	↑		↓ (Depth)
C60x	↓		↑	↓	↑		↓ (PRF)
HFL38x			↑	↑	↑		↓ (Depth)
HFL50x			↑	↑	↑		↓ (Depth)
ICTx		↑	↑	↓		Exam Gyn	↓ (PRF)
L25x	↓				↑		↓ (PRF)
L38x				↓			↓ (Depth)
L38xi				↓			↓ (PRF)
P10x	—	—	↑	↓	—	—	↓ (PRF)
P21x		↓		↓	↑		↓ (PRF)
SLAx	↑	—	—	↓	↑	—	↓ (PRF)
TEEx	—	—	—	↓	↓	—	↓ (PRF)

↓ Decrease or lower setting of parameter to reduce TI.
↑ Increase or raise setting of parameter to reduce TI.
— Data are not applicable.

Output display

The system meets the AIUM output display standard for MI and TI (see last reference in "Related guidance documents" below). Table 5 indicates for each transducer and operating mode if either the TI or MI is greater than or equal to a value of 1.0, thus requiring display.

Table 5: TI or MI is ≥ 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	Yes	Yes	—
C60x/5-2	MI	Yes	No	No	—
	TIC, TIB, or TIS	No	No	Yes	—
HFL38x/13-6	MI	No	Yes	Yes	—
	TIC, TIB, or TIS	No	No	Yes	—
HFL50x/15-6	MI	Yes	Yes	Yes	—
	TIC, TIB, or TIS	No	No	Yes	—
ICTx/8-5	MI	No	No	No	—
	TIC, TIB, or TIS	No	No	Yes	—
L25x/13-6	MI	No	No	No	—
	TIC,TIB, or TIS	No	No	Yes	—
L38x/10-5	MI	No	Yes	Yes	—
	TIC, TIB, or TIS	No	Yes	Yes	—
L38xi/10-5	MI	Yes	Yes	Yes	—
	TIC, TIB, or TIS	Yes	Yes	Yes	—
P10x/8-4	MI	No	Yes	Yes	No
	TIC, TIB, or TIS	No	Yes	Yes	Yes
P21x/5-1	MI	Yes	Yes	Yes	No
	TIC, TIB, or TIS	Yes	Yes	Yes	Yes
SLAx/13-6	MI	No	No	No	—
	TIC, TIB, or TIS	No	No	Yes	—

Table 5: TI or MI is ≥ 1.0 (Continued)

Transducer Model	Index	2D M Mode	CPD/ Color	PW Doppler	CW Doppler
TEEx/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. SonoSite provides a copy of *AIUM Medical Ultrasound Safety*, which contains guidance on determining which TI is appropriate (See "Related guidance documents" on page 85).

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 121.

The displayed MI and TI values are based on calculations that use a set of acoustic output measurements that were made using a single reference ultrasound system with a single reference transducer that is representative of the population of transducers of that type. The reference system and transducer are chosen from a sample population of systems and transducers taken from early production units, and they are selected based on having an acoustic output that is representative of the nominal expected acoustic output for all transducer/system combinations that might occur. Of course every transducer/system

combination has its own unique characteristic acoustic output, and will not match the nominal output on which the display estimates are based. This variability between systems and transducers introduces an error into displayed value. By doing acoustic output sampling testing during production, the amount of error introduced by the variability is bounded. The sampling testing ensures that the acoustic output of transducers and systems being manufactured stays within a specified range of the nominal acoustic output.

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

Related guidance documents

- Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, 1997.
- Medical Ultrasound Safety, American Institute of Ultrasound in Medicine (AIUM), 1994. (A copy is included with each system.)
- Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, NEMA UD2-2004.
- Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine, 1993.
- Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, NEMA UD3-2004.
- Guidance on the interpretation of TI and MI to be used to inform the operator, Annex HH, BS EN 60601-2-37 reprinted at P05699.

Transducer surface temperature rise

Table 6 lists the measured surface temperature rise from ambient (23°C ± 3°C) of transducers used on the ultrasound system. The temperatures were measured in accordance with EN 60601-2-37 section 42 with controls and settings positioned to give maximum temperatures.

Table 6: Transducer Surface Temperature Rise

Test	External Use (°C)									Internal Use (°C)		
	C11x	C60x	HFL38x	HFL50x	L25x	L38x	L38xi	P10x	P21x	ICTx	SLAx	TEEx
Still air	17.6	16.2	15.5	10.7	16.1	16.3	12.5	15.6	16.8	9.2	9.5	9.3
Simulated Use	9.1	8.8	7.9	7.7	8.5	9.6	8.8	9.8	9.0	5.2	4.8	5.8

Acoustic output measurement

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

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

In Situ, derated, and water value intensities

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

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

where:

In Situ = *In Situ* intensity value

Water = Water intensity value

e = 2.7183

a = attenuation factor (dB/cm MHz)

Attenuation factor (a) for various tissue types:

brain = 0.53

heart = 0.66

kidney = 0.79

liver = 0.43

muscle = 0.55

l = skinline to measurement depth in cm

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

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

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

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

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

Tissue models and equipment survey

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

A homogeneous tissue model with attenuation coefficient of 0.3 dB/cm MHz throughout the beam path is commonly used when estimating exposure levels. The model is conservative in that it overestimates the *In Situ* acoustic exposure when the path between the transducer and site of interest is composed entirely of soft tissue. When the path contains significant amounts

of fluid, as in many first and second-trimester pregnancies scanned transabdominally, this model may underestimate the *In Situ* acoustic exposure. The amount of underestimation depends upon each specific situation.

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

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

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

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

Acoustic output tables

Table 7 through Table 31 indicate the acoustic output for the system and transducer combinations with a TI or MI equal to or greater than one. These tables are organized by transducer model and imaging mode. For a definition of terms used in the tables, see "Terms used in the acoustic output tables" on page 119.

Table 7: Transducer Model: *C11x* **Operating Mode: *CPD/Color***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			(a)	(a)	—	—	—	1.0
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	#					
	W_0	(mW)		#	—		—	38.8
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	#	#	—	—	—	4.37
	Dim of A_{aprt}	X (cm)		#	—	—	—	1.12
		Y (cm)		#	—	—	—	0.50
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		#	—	—		4.29
		FL_y (cm)		#	—	—		4.40
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Control 1: Mode							Any
	Control 2: Exam Type							Abd
	Control 3: PRF							3676
	Control 4: Optimization/Depth							Low/5.1
	Control 5: Color Box Position/ Size							Top/ Short & Narrow

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

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

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

— Data are not applicable for this transducer/mode.

Table 8: Transducer Model: *C11x* **Operating Mode: *PW Doppler***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			(a)	—	1.0	—	1.7	1.8
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	#					
	W_0	(mW)		—	46.0		24.9	25.4
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				1.06	
	$d_{eq}(z_{sp})$	(cm)					0.24	
	f_c	(MHz)	#	—	4.36	—	4.37	4.36
	Dim of A_{aprt}	X (cm)		—	1.76	—	0.28	0.20
		Y (cm)		—	0.50	—	0.50	0.50
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.23	
	Focal Length	FL_x (cm)		—	6.37	—		0.77
		FL_y (cm)		—	4.40	—		4.40
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Control 1: Exam Type				Any		Any	Any
	Control 2: Sample Volume				2 mm		1 mm	1 mm
	Control 3: PRF				3906		10417	20833
	Control 4: Sample Volume Position				Zone 7		Zone 1	Zone 0

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

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

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

— Data are not applicable for this transducer/mode.

Table 9: Transducer Model: *C60x* **Operating Mode: *2D***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.0	(a)	—	—	—	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	1.69					
	W_0	(mW)		#	—		—	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	4.7				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	2.84	#	—	—	—	#
	Dim of A_{aprt}	X (cm)		#	—	—	—	#
		Y (cm)		#	—	—	—	#
Other Information	PD	(µsec)	0.579					
	PRF	(Hz)	5440					
	p_r@PII_{max}	(MPa)	2.679					
	d_{eq}@PII_{max}	(cm)					—	
	Focal Length	FL_x (cm)		#	—	—		#
		FL_y (cm)		#	—	—		#
	$I_{PA.3}$@MI_{max}	(W/cm^2)	197.7					
Operating Control Conditions	Control 1: Exam Type		Abd/OB					
	Control 2: Optimization		Any					
	Control 3: Depth		11/ 13 cm					
	Control 4: THI		On					
	Control 5: MB (Multi Beam)		On					

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

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

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

— Data are not applicable for this transducer/mode.

Table 10: Transducer Model: *C60x* **Operating Mode: *M Mode***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.0	—	(a)	—	(a)	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	1.62					
	W_0	(mW)		—	#		#	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	4.7				#	
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	2.85	—	#	—	#	#
	Dim of A_{aprt}	X (cm)		—	#	—	#	#
		Y (cm)		—	#	—	#	#
Other Information	PD	(µsec)	0.577					
	PRF	(Hz)	800					
	$p_r@PII_{max}$	(MPa)	2.576					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	184.3					
Operating Control Conditions	Control 1: Exam Type		Any					
	Control 2: Optimization		Pen					
	Control 3: Depth		7.8 cm					
	Control 4: MB (Multi Beam)		Off or On					

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

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

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

— Data are not applicable for this transducer/mode.

Table 11: Transducer Model: *C60x* **Operating Mode: *PW Doppler***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			(a)	—	(a)	—	3.1	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	#					
	W_0	(mW)		—	#		85.64	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				1.255	
	$d_{eq}(z_{sp})$	(cm)					0.51	
	f_c	(MHz)	#	—	#	—	2.233	#
	Dim of A_{aprt}	X (cm)		—	#	—	0.6552	#
		Y (cm)		—	#	—	1.3	#
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.415	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Control 1: Exam Type						Abd	
	Control 2: PRF						Any	
	Control 3: Sample Volume						12 mm	
	Control 4: Sample Volume Position						Zone 1	

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

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

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

— Data are not applicable for this transducer/mode.

Table 12: Transducer Model: *HFL38x* **Operating Mode: *CPD/Color***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.1	(a)	—	—	—	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.556					
	W_0	(mW)		—	—		—	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.2				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	5.328	—	—	—	—	#
	Dim of A_{aprt}	X (cm)		—	—	—	—	#
		Y (cm)		—	—	—	—	#
Other Information	PD	(µsec)	0.525					
	PRF	(Hz)	2597					
	$p_r@PII_{max}$	(MPa)	3.187					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		—	—	—		#
		FL_y (cm)		—	—	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	325.5					
Operating Control Conditions	Control 1: Mode		Color					
	Control 2: Exam Type		Any					
	Control 3: Optimization/Depth/PRF		Low/3.3 cm/393					
	Control 4: Color Box Position/Size		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 13: Transducer Model: *HFL38x* **Operating Mode: *PW Doppler***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.0	—	1.2	—	2.2	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.37					
	W_0	(mW)		—	46.55		46.55	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	0.9				1.1	
	$d_{eq}(z_{sp})$	(cm)					0.33	
	f_c	(MHz)	5.32	—	5.33	—	5.33	#
	Dim of A_{aprt}	X (cm)		—	1.04	—	1.04	#
		Y (cm)		—	0.4	—	0.4	#
Other Information	PD	(µsec)	1.29					
	PRF	(Hz)	1008					
	$p_r@PII_{max}$	(MPa)	2.404					
	$d_{eq}@PII_{max}$	(cm)					0.46	
	Focal Length	FL_x (cm)		—	3.72	—		#
		FL_y (cm)		—	2.5	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	323.35					
Operating Control Conditions	Control 1: Exam Type		Bre/Vas SmP/IMT		Vas/Ven/ IMT		Vas/Ven/IMT	
	Control 2: Sample Volume		1 mm		12 mm		12 mm	
	Control 3: PRF		1008		10417		10417	
	Control 4: Sample Volume Position		Zone 2		Zone 7		Zone 7	

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

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

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

— Data are not applicable for this transducer/mode.

Table 14: Transducer Model: HFL50x **Operating Mode: 2D**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.2	(a)	—	—	—	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	3.14					
	W_0	(mW)		#	—		—	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.4				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	6.75	#	—	—	—	#
	Dim of A_{aprt}	X (cm)		#	—	—	—	#
		Y (cm)		#	—	—	—	#
Other Information	PD	(µsec)	0.263					
	PRF	(Hz)	7653					
	$p_r@PII_{max}$	(MPa)	4.35					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		#	—	—		#
		FL_y (cm)		#	—	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	388					
Operating Control Conditions	Control 1: Exam Type		Any					
	Control 2: Optimization		Pen					
	Control 3: Depth		4.0					
	Control 4: MB		Off					

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

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

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

— Data are not applicable for this transducer/mode.

Table 15: Transducer Model: HFL50x **Operating Mode: M Mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.2	—	(a)	—	(a)	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	3.14					
	W_0	(mW)		—	#		#	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.4				#	
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	6.75	—	#	—	#	#
	Dim of A_{aprt}	X (cm)		—	#	—	#	#
		Y (cm)		—	#	—	#	#
Other Information	PD	(µsec)	0.263					
	PRF	(Hz)	1600					
	$p_r@PII_{max}$	(MPa)	4.35					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	388					
Operating Control Conditions	Control 1: Exam Type		Any					
	Control 2: Optimization		Pen					
	Control 3: Depth		4.0					

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

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

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

— Data are not applicable for this transducer/mode.

Table 16: Transducer Model: HFL50x **Operating Mode: CPD/Color**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.3	(a)	—	—	—	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	3.05					
	W_0	(mW)		#	—		—	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.2				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	5.36	#	—	—	—	#
	Dim of A_{aprt}	X (cm)		#	—	—	—	#
		Y (cm)		#	—	—	—	#
Other Information	PD	(µsec)	0.521					
	PRF	(Hz)	8233					
	$p_r@PII_{max}$	(MPa)	3.81					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		#	—	—		#
		FL_y (cm)		#	—	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	494					
Operating Control Conditions	Control 1: Mode		Any					
	Control 2: Exam Type		Any					
	Control 3: Optimization/Depth		Low/3.3					
	Control 4: PRF		Any					

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

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

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

— Data are not applicable for this transducer/mode.

Table 17: Transducer Model: HFL50x **Operating Mode: PW Doppler**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.2	—	1.1	—	1.9	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.69					
	W_0	(mW)		—	42.6		42.6	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.0				1.1	
	$d_{eq}(z_{sp})$	(cm)					0.33	
	f_c	(MHz)	5.34	—	5.34	—	5.34	#
	Dim of A_{aprt}	X (cm)		—	1.08	—	1.08	#
		Y (cm)		—	0.40	—	0.40	#
Other Information	PD	(µsec)	1.29					
	PRF	(Hz)	1008					
	$p_r@PII_{max}$	(MPa)	3.23					
	$d_{eq}@PII_{max}$	(cm)					0.22	
	Focal Length	FL_x (cm)		—	3.72	—		#
		FL_y (cm)		—	2.44	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	308					
Operating Control Conditions	Control 1: Exam Type		Any		Any		Any	
	Control 2: Sample Volume		1 mm		1 mm		1 mm	
	Control 3: PRF		1008		1563 - 3125		1563 - 3125	
	Control 4: Sample Volume Position		Zone 3		Zone 8		Zone 8	

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

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

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

— Data are not applicable for this transducer/mode.

Table 18: Transducer Model: *ICTx* **Operating Mode: *PW Doppler***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			(a)	—	(a)	—	1.2	(a)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	#					
	W_0	(mW)		—	#		16.348	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				1.6	
	$d_{eq}(z_{sp})$	(cm)					0.192	
	f_c	(MHz)	#	—	#	—	4.36	#
	Dim of A_{aprt}	X (cm)		—	#	—	0.6	#
		Y (cm)		—	#	—	0.5	#
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.187	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Control 1: Exam Type						Any	
	Control 2: Sample Volume						3 mm	
	Control 3: PRF						Any	
	Control 4: Sample Volume Position						Zone 1	

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

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

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

— Data are not applicable for this transducer/mode.

Table 19: Transducer Model L25x **Operating Mode: PW Doppler**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			(a)	—	(a)	—	1.4	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	#					
	W_0	(mW)		—	#		28.3	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				0.8	
	$d_{eq}(z_{sp})$	(cm)					0.31	
	f_c	(MHz)	#	—	#	—	6.00	#
	Dim of A_{aprt}	X (cm)		—	#	—	0.76	#
		Y (cm)		—	#	—	0.30	#
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.23	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Control 1: Exam Type						Vas/Ven/ Nrv	
	Control 2: Sample Volume						6 mm	
	Control 3: PRF						10417	
	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 20: Transducer Model: *L38x* **Operating Mode: *CPD/Color***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.3	1.0	—	—	—	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.89					
	W_0	(mW)		66.6	—		—	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.1				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	4.91	4.91	—	—	—	#
	Dim of A_{aprt}	X (cm)		0.54	—	—	—	#
		Y (cm)		0.4	—	—	—	#
Other Information	PD	(µsec)	0.529					
	PRF	(Hz)	9547					
	$p_r@PII_{max}$	(MPa)	3.48					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		1.5	—	—		#
		FL_y (cm)		2.5	—	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	439.3					
Operating Control Conditions	Control 1: Mode		Color	CPD				
	Control 2: Exam Type		Any	Bre				
	Control 3: PRF		393	2137				
	Control 4: Optimization/Depth		Any/3.1	Med/3.1				
	Control 5: Color Box Position/Size		Any	Def/Def/ Def				

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

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

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

— Data are not applicable for this transducer/mode.

Table 21: Transducer Model: *L38x* **Operating Mode: *PW Doppler***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.0	—	2.0	—	2.6	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.345					
	W_0	(mW)		—	84.94		84.94	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	0.8				1.3	
	$d_{eq}(z_{sp})$	(cm)					0.4685	
	f_c	(MHz)	5.01	—	5.05	—	5.05	#
	Dim of A_{aprt}	X (cm)		—	1.80	—	1.80	#
		Y (cm)		—	0.4	—	0.4	#
Other Information	PD	(µsec)	1.29					
	PRF	(Hz)	1008					
	$p_r@PII_{max}$	(MPa)	2.693					
	$d_{eq}@PII_{max}$	(cm)					0.2533	
	Focal Length	FL_x (cm)		—	5.54	—		#
		FL_y (cm)		—	2.5	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	284.5					
Operating Control Conditions	Control 1: Exam Type		Any		Vas		Vas	
	Control 2: Sample Volume		1 mm		12 mm		12 mm	
	Control 3: PRF		1008		Any		Any	
	Control 4: Sample Volume Position		Zone 0 (top)		Zone 7		Zone 7	

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

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

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

— Data are not applicable for this transducer/mode.

Table 22: Transducer Model: L38xi/10-5 **Operating Mode: 2D**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	(a)	—	—	—	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	3.54					
	W_0	(mW)		#	—		—	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.0				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	5.76	#	—	—	—	#
	Dim of A_{aprt}	X (cm)		#	—	—	—	#
		Y (cm)		#	—	—	—	#
Other Information	PD	(µsec)	0.146					
	PRF	(Hz)	7551					
	$p_r@PII_{max}$	(MPa)	4.32					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		#	—	—		#
		FL_y (cm)		#	—	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	776					
Operating Control Conditions	Control 1: Exam Type		Any					
	Control 2: Optimization		Gen/Pen					
	Control 3: Depth		2.0 cm					
	Control 4: MB		On/Off					

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

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

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

— Data are not applicable for this transducer/mode.

Table 23: Transducer Model: L38xi/10-5 **Operating Mode: M Mode**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	—	(a)	—	1.1	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	3.54					
	W_0	(mW)		—	#		37.1	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.0				0.9	
	$d_{eq}(z_{sp})$	(cm)					0.49	
	f_c	(MHz)	5.76	—	#	—	5.20	#
	Dim of A_{aprt}	X (cm)		—	#	—	1.86	#
		Y (cm)		—	#	—	0.40	#
Other Information	PD	(µsec)	0.146					
	PRF	(Hz)	1600					
	$p_r@PII_{max}$	(MPa)	4.32					
	$d_{eq}@PII_{max}$	(cm)					0.49	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	776					
Operating Control Conditions	Control 1: Exam Type		Any				Any	
	Control 2: Optimization		Gen				Pen	
	Control 3: Depth		4.7 cm				7.3 - 9.0 cm	

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

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

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

— Data are not applicable for this transducer/mode.

Table 24: Transducer Model: L38xi/10-5 **Operating Mode: CPD/Color**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	1.1	—	—	—	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	3.30					
	W_0	(mW)		47.5	—		—	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	0.8					
	$d_{eq}(z_{sp})$	(cm)						
	f_c	(MHz)	4.82	4.82	—	—	—	#
	Dim of A_{aprt}	X (cm)		0.66	—	—	—	#
		Y (cm)		0.40	—	—	—	#
Other Information	PD	(µsec)	0.544					
	PRF	(Hz)	2885					
	$p_r@PII_{max}$	(MPa)	3.79					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		1.86	—	—		#
		FL_y (cm)		1.50	—	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	605					
Operating Control Conditions	Control 1: Mode		CVD/CPD	CVD				
	Control 2: Exam Type		Any	Bre				
	Control 3: 2D Optimization/Depth		Any/2.0-2.5 cm	Any/3.8 cm				
	Control 4: Color Optimization/PRF		Any/Any	Low/ 1323				
	Control 5: Color Box Position/Size		Any/Any	Any/ Default				

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

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

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

— Data are not applicable for this transducer/mode.

Table 25: Transducer Model: L38xi/10-5 **Operating Mode: PW Doppler**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.1	—	2.6	—	3.7	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.56					
	W_0	(mW)		—	114.5		114.5	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.19				0.8	
	$d_{eq}(z_{sp})$	(cm)					0.49	
	f_c	(MHz)	4.88	—	4.79	—	4.79	#
	Dim of A_{aprt}	X (cm)		—	1.86	—	1.86	#
		Y (cm)		—	0.40	—	0.40	#
Other Information	PD	(µsec)	1.22					
	PRF	(Hz)	1008					
	$p_r@PII_{max}$	(MPa)	2.97					
	$d_{eq}@PII_{max}$	(cm)					0.45	
	Focal Length	FL_x (cm)		—	5.54	—		#
		FL_y (cm)		—	1.50	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	342					
Operating Control Conditions	Control 1: Exam Type		Bre/Vas		Bre/Vas		Bre/Vas	
	Control 2: Sample Volume		1 mm		1 mm		1 mm	
	Control 3: PRF		1008		10417		10417	
	Control 4: Sample Volume Position		Zone 1		Zone 7		Zone 7	

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

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

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

— Data are not applicable for this transducer/mode.

Table 26: Transducer Model: *P10x* **Operating Mode: *Color***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.0	(a)	—	—	—	1.3
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.02					
	W_0	(mW)		#	—		—	41.38
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	2.4				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	3.90	#	—	—	—	3.91
	Dim of A_{aprt}	X (cm)		#	—	—	—	0.608
		Y (cm)		#	—	—	—	0.7
Other Information	PD	(µsec)	0.70					
	PRF	(Hz)	2772					
	$p_r@PII_{max}$	(MPa)	2.80					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		#	—	—		2.48
		FL_y (cm)		#	—	—		5.0
	$I_{PA.3}@MI_{max}$	(W/cm^2)	252					
Operating Control Conditions	Control 1: Mode		Color					Color
	Control 2: Exam Type		Neo					Abd
	Control 3: Optimization/Depth/PRF		Low/ 3.7/ 772					Med/ 2.0/ 2315
	Control 4: Color Box Pos/Size		Any/ Tall					Short/ Narrow

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

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

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

— Data are not applicable for this transducer/mode.

Table 27: Transducer Model: *P10x* **Operating Mode: *PW Doppler***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.0	—	1.2	—	2.0	1.8
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.03					
	W_0	(mW)		—	36.25		34.4	31.5
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	2.1				0.8	
	$d_{eq}(z_{sp})$	(cm)					0.32	
	f_c	(MHz)	3.87	—	6.86	—	3.84	3.86
	Dim of A_{aprt}	X (cm)		—	0.992	—	0.416	.224
		Y (cm)		—	0.7	—	0.7	0.7
Other Information	PD	(µsec)	1.28					
	PRF	(Hz)	1563					
	$p_r@PII_{max}$	(MPa)	2.70					
	$d_{eq}@PII_{max}$	(cm)					0.25	
	Focal Length	FL_x (cm)		—	6.74	—		0.92
		FL_y (cm)		—	5.0	—		5.0
	$I_{PA.3}@MI_{max}$	(W/cm^2)	233					
Operating Control Conditions	Control 1: Exam Type		Crd		Crd		Neo	Crd
	Control 2: Sample Volume		1 mm		7 mm		12 mm	1 mm
	Control 3: PRF/TDI		1563/Off		Any/ On		15625/ Off	5208/ Off
	Control 4: Sample Volume Position		Zone 3		Zone 6		Zone 2	Zone 1

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

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

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

— Data are not applicable for this transducer/mode.

Table 28: Transducer Model: *P10x* **Operating Mode: *CW Doppler***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			(a)	—	(a)	—	2.1	2.0
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	#					
	W_0	(mW)		—	#		40.72	30.00
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				0.7	
	$d_{eq}(z_{sp})$	(cm)					0.36	
	f_c	(MHz)	#	—	#	—	4.00	4.00
	Dim of A_{aprt}	X (cm)		—	#	—	0.320	0.16
		Y (cm)		—	#	—	0.7	0.7
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.27	
	Focal Length	FL_x (cm)		—	#	—		0.92
		FL_y (cm)		—	#	—		5.0
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Control 1: Exam Type						Crd	Crd
	Control 2: Depth						Any	Any
	Control 3: Zone						Zone 3	Zone 0

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

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

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

— Data are not applicable for this transducer/mode.

Table 29: Transducer Model: *P21x* **Operating Mode: *2D***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	(a)	—	—	—	2.1
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.03					
	W_0	(mW)		#	—		—	155.2
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	3.4				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	1.83	#	—	—	—	1.94
	Dim of A_{aprt}	X (cm)		#	—	—	—	1.9
		Y (cm)		#	—	—	—	1.3
Other Information	PD	(µsec)	.842					
	PRF	(Hz)	4444					
	$p_r@PII_{max}$	(MPa)	2.53					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		#	—	—		18.46
		FL_y (cm)		#	—	—		5.5
	$I_{PA.3}@MI_{max}$	(W/cm^2)	194					
Operating Control Conditions	Control 1: Exam Type		Crd					Crd
	Control 2: Optimization		Gen/ Pen					Pen
	Control 3: Depth		4.7 cm					27 cm
	Control 4: THI		On					Off

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

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

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

— Data are not applicable for this transducer/mode.

Table 30: Transducer Model: *P21x* **Operating Mode: *M Mode***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	—	(a)	—	1.4	1.1
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.10					
	W_0	(mW)		—	#		40.08	79.71
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	3.645				4.9	
	$d_{eq}(z_{sp})$	(cm)					0.343	
	f_c	(MHz)	1.93	—	#	—	1.93	1.94
	Dim of A_{aprt}	X (cm)		—	#	—	1.835	1.9
		Y (cm)		—	#	—	1.3	1.3
Other Information	PD	(µsec)	0.904					
	PRF	(Hz)	800					
	$p_r@PII_{max}$	(MPa)	2.679					
	$d_{eq}@PII_{max}$	(cm)					0.341	
	Focal Length	FL_x (cm)		—	#	—		18.46
		FL_y (cm)		—	#	—		5.5
	$I_{PA.3}@MI_{max}$	(W/cm^2)	237.4					
Operating Control Conditions	Control 1: Exam Type		Abd/OB				Abd/OB	Abd/OB /Crd
	Control 2: Optimization		Any				Gen/Res	Pen
	Control 3: Depth		7.5 cm				10/13 cm	27 cm
	Control 4: THI		On				On	Off
	Control 5: MB		On				On or Off	On or Off

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

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

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

— Data are not applicable for this transducer/mode.

Table 31: Transducer Model: *P21x* **Operating Mode: *CPD/Color***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	1.1	—	—	—	2.5
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.03					
	W_0	(mW)		135.05	—		—	126.57
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	3.4				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	1.83	2.16	—	—	—	2.17
	Dim of A_{aprt}	X (cm)		0.918	—	—	—	0.46
		Y (cm)		1.3	—	—	—	1.30
Other Information	PD	(µsec)	1.032					
	PRF	(Hz)	2038					
	$p_r@PII_{max}$	(MPa)	2.53					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		3.68	—	—		1.55
		FL_y (cm)		9.00	—	—		9.00
	$I_{PA.3}@MI_{max}$	(W/cm^2)	194					
Operating Control Conditions	Control 1: Mode		Color	CPD				Color/CPD
	Control 2: Exam Type		Crd	OB				OB
	Control 3: PRF/Depth		4.7	2016/4.7				1524/ 4.7
	Control 4: Color Optimization		Any	Med				Med
	Control 5: THI		On	Off				Off
	Control 6: Color Box Size		Any	Short and Narrow				Short and Narrow

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

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

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

— Data are not applicable for this transducer/mode.

Table 32: Transducer Model: *P21x* **Operating Mode: *PW Doppler***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.2	—	—	1.3	3.9	2.8
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	1.73					
	W_0	(mW)		—	—		93.28	200.7
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				124.4		
	z_1	(cm)				3.1		
	z_{bp}	(cm)				2.8		
	z_{sp}	(cm)	5.0				0.6	
	$d_{eq}(z_{sp})$	(cm)					0.49	
	f_c	(MHz)	2.15	—	—	2.22	2.23	2.12
	Dim of A_{aprt}	X (cm)		—	—	1.97	0.459	1.97
		Y (cm)		—	—	1.3	1.3	1.30
Other Information	PD	(µsec)	1.182					
	PRF	(Hz)	1562					
	$p_r@PII_{max}$	(MPa)	2.50					
	$d_{eq}@PII_{max}$	(cm)					0.49	
	Focal Length	FL_x (cm)		—	—	13.84		18.46
		FL_y (cm)		—	—	9.0		9.00
	$I_{PA.3}@MI_{max}$	(W/cm^2)	216					
Operating Control Conditions	Control 1: Exam Type		Crd			Crd	Crd	Crd
	Control 2: Sample Volume		1mm			3mm	14mm	1mm
	Control 3: PRF		1563			3906	10417	3125
	Control 4: Sample Volume Position		Zone 2			Zone 4	Zone 0	Zone 5

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

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

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

— Data are not applicable for this transducer/mode.

Table 33: Transducer Model: *P21x* **Operating Mode: *CW Doppler***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			(a)	—	—	1.0	3.5	3.0
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	#					
	W_0	(mW)		—	—		90.1	104.9
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				104.9		
	z_1	(cm)				1.20		
	z_{bp}	(cm)				1.31		
	z_{sp}	(cm)	#				1.255	
	$d_{eq}(z_{sp})$	(cm)					0.49	
	f_c	(MHz)	#	—	—	2.00	2.00	2.00
	Dim of A_{aprt}	X (cm)		—	—	0.46	0.655	0.459
		Y (cm)		—	—	1.30	1.30	1.30
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.45	
	Focal Length	FL_x (cm)		—	—	1.55		1.55
		FL_y (cm)		—	—	9.00		9.00
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Control 1: Exam Type					Crd	Crd	Crd
	Control 2: Zone					Zone 0	Zone 1	Zone 0

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

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

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

— Data are not applicable for this transducer/mode.

Table 34: Transducer Model: SLAx **Operating Mode: PW Doppler**

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			(a)	—	(a)	—	1.1	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	#					
	W_0	(mW)		—	#		12.45	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				1.2	
	$d_{eq}(z_{sp})$	(cm)					0.15	
	f_c	(MHz)	#	—	#	—	6.00	#
	Dim of A_{aprt}	X (cm)		—	#	—	0.48	#
		Y (cm)		—	#	—	0.30	#
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.15	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Control 1: Exam Type						Vas	
	Control 2: Sample Volume						5 mm	
	Control 3: PRF						1953	
	Control 4: Sample Vol. Position						Zone 5	

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

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

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

— Data are not applicable for this transducer/mode.

Table 35: Transducer Model: *TEEx* **Operating Mode: *PW Doppler***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			(a)	—	(a)	—	1.7	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	#					
	W_0	(mW)		—	#		29.29	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				0.6	
	$d_{eq}(z_{sp})$	(cm)					0.34	
	f_c	(MHz)	#	—	#	—	3.84	#
	Dim of A_{aprt}	X (cm)		—	#	—	0.261	#
		Y (cm)		—	#	—	0.9	#
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.34	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Control 1: Exam Type						Crd	
	Control 2: Sample Volume						1 mm	
	Control 3: PRF						≥ 2604	
	Control 4: Sample Volume Position						Zone 1	

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

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

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

— Data are not applicable for this transducer/mode.

Table 36: Transducer Model: *TEEx* **Operating Mode: *CW Doppler***

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			(a)	—	(a)	—	1.2	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	#					
	W_0	(mW)		—	#		27.23	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	#				1.1	
	$d_{eq}(z_{sp})$	(cm)					0.39	
	f_c	(MHz)	#	—	#	—	4.00	#
	Dim of A_{aprt}	X (cm)		—	#	—	0.435	#
		Y (cm)		—	#	—	0.9	#
Other Information	PD	(μsec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					0.34	
	Focal Length	FL_x (cm)		—	#	—		#
		FL_y (cm)		—	#	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Control 1: Exam Type						Crd	
	Control 2: Depth						Any	
	Control 3: Zone						Zone 3	

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

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

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

— Data are not applicable for this transducer/mode.

Terms used in the acoustic output tables

Table 37: Acoustic Output Terms and Definitions

Term	Definition
$I_{SPTA.3}$	Derated spatial peak, temporal average intensity in units of milliwatts/cm^2.
TI type	Applicable thermal index for the transducer, imaging mode, and exam type.
TI value	Thermal index value for the transducer, imaging mode, and exam type.
MI	Mechanical index.
$I_{pa.3}$@MImax	Derated pulse average intensity at the maximum MI in units of W/cm^2.
TIS	(Soft tissue thermal index) is a thermal index related to soft tissues. TIS scan is the soft tissue thermal index in an auto-scanning mode. TIS non-scan is the soft tissue thermal index in the non-autoscanning mode.
TIB	(Bone thermal index) is a thermal index for applications in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone. TIB non-scan is the bone thermal index in the non-autoscanning mode.
TIC	(Cranial bone thermal index) is the thermal index for applications in which the ultrasound beam passes through bone near the beam entrance into the body.
A_{aprt}	Area of the active aperture measured in cm^2.
$P_{r.3}$	Derated peak rarefactional pressure associated with the transmit pattern giving rise to the value reported under MI (Megapascals).
Wo	Ultrasonic power, except for TIS_{scan}, in which case it is the ultrasonic power passing through a one centimeter window in units of milliwatts.
$W_{.3}(z_1)$	Derated ultrasonic power at axial distance z_1 in units of milliwatts.
$I_{SPTA.3}(z_1)$	Derated spatial-peak temporal-average intensity at axial distance z_1 (milliwatts per square centimeter).
z_1	Axial distance corresponding to the location of maximum [min($W_{.3}(z)$, $I_{TA.3}(z)$ x 1 cm^2)], where $z \geq$ zbp in centimeters.
z_{bp}	$1.69 \sqrt{(A_{aprt})}$ in centimeters.
z_{sp}	For MI, the axial distance at which $p_{r.3}$ is measured. For TIB, the axial distance at which TIB is a global maximum (for example, $z_{sp} = z_{b.3}$) in centimeters.

Table 37: Acoustic Output Terms and Definitions (Continued)

Term	Definition
$d_{eq}(z)$	Equivalent beam diameter as a function of axial distance z, and is equal to $\sqrt{(4/(\pi))((Wo)/(I_{TA}(z)))}$, where $I_{TA}(z)$ is the temporal-average intensity as a function of z in centimeters.
fc	Center frequency in MHz.
Dim. of A_{aprt}	Active aperture dimensions for the azimuthal (x) and elevational (y) planes in centimeters.
PD	Pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of MI.
PRF	Pulse repetition frequency associated with the transmit pattern giving rise to the reported value of MI in Hertz.
p_r@PII_{max}	Peak rarefactional pressure at the point where the free-field, spatial-peak pulse intensity integral is a maximum in Megapascals.
d_{eq}@PII_{max}	Equivalent beam diameter at the point where the free-field, spatial-peak pulse intensity integral is a maximum in centimeters.
FL	Focal length, or azimuthal (x) and elevational (y) lengths, if different measured in centimeters.

Acoustic measurement precision and uncertainty

All table entries have been obtained at the same operating conditions that give rise to the maximum index value in the first column of the table. Measurement precision and uncertainty for power, pressure, intensity, and other quantities that are used to derive the values in the acoustic output table are shown in the table below. In accordance with Section 6.4 of the Output Display Standard, the following measurement precision and uncertainty values are determined by making repeat measurements and stating the standard deviation as a percentage.

Table 38: Acoustic Measurement Precision and Uncertainty

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

Labeling symbols

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

Table 39: Labeling Symbols

Symbol	Definition
	Alternating Current (AC)
	Class 1 device indicating manufacturer's declaration of conformance with Annex VII of 93/42/EEC
	Class 1 device requiring verification by the Notified Body of sterilization or measurement features, or to a Class IIa, IIb, or III device requiring verification or auditing by the Notified Body to applicable Annex(es) of 93/42/EEC
	Attention, see the user guide
	Device complies with relevant Australian regulations for electronic devices.
	Batch code, date code, or lot code type of control number
	Biological risk
	Device complies with relevant Brazilian regulations for electro-medical devices.
	Canadian Standards Association. 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.
	Catalog number
	Collect separately from other household waste (see European Commission Directive 93/86/EEC). Refer to local regulations for disposal.
	Contents sterilized using ethylene oxide process.

Table 39: Labeling Symbols (Continued)

Symbol	Definition
	Corrugated recycle
	Dangerous voltage
	Date of manufacture
	Direct Current (DC)
	Do not get wet.
	Do not stack over n high, where n represents the number on the label.
	Electrostatic sensitive devices
	Device complies with relevant FCC regulations for electronic devices.
	Fragile
GEL STERILE R	Gel sterilized by radiation.
	Hot
	Indoor use only
	Device emits a static (DC) magnetic field.

Table 39: Labeling Symbols (Continued)

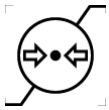
Symbol	Definition
	Non-ionizing radiation
	Paper recycle
SN	Serial number type of control number
	Temperature limitation
	Atmospheric pressure limitation
	Humidity limitations
IPX7	Submersible. Protected against the effects of temporary immersion.
IPX8	Water-Tight Equipment. Protected against the effects of extended immersion.
	Handle transducer with care.
	Type BF patient applied part (B = body, F = floating applied part)
	Underwriter's Laboratories labeling
	Pollution Control Logo. (Applies to all parts/products listed in the China RoHS disclosure table. May not appear on the exterior of some parts/products because of space limitations.)
	China Compulsory Certificate mark ("CCC Mark"). A compulsory safety mark for compliance to Chinese national standards for many products sold in the People's Republic of China.
	Contains mercury. (Applies to the LCD and may apply to other components in the ultrasound system.)

Table 39: Labeling Symbols (Continued)

Symbol	Definition
WARNING: Connect Only Accessories and Peripherals Recommended by SonoSite	WARNING: Connect Only Accessories and Peripherals Recommended by SonoSite

Chapter 7: 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 table.

Table 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[c]	< ±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%.

Sources of measurement errors

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

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

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

Measurement publications and terminology

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

Terminology and measurements comply with AIUM published standards.

Cardiac references

Acceleration (ACC) in cm/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, A.J. Tajik. *The Echo Manual*. 2nd ed., Lippincott, Williams, and Wilkins, (1999), 219.

Aortic Valve Area (AVA) by Continuity Equation in cm²

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 393, 442.

$A_2 = A_1 * V_1/V_2$

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 $(PV_{LVOT}/PV_{AO}) * CSA_{LVOT}$

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 l/min/m²

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

CI = CO/BSA

where: CO = Cardiac Output

BSA = Body Surface Area

Cardiac Output (CO) in l/min

Oh, J.K., J.B. Seward, A.J. Tajik *The Echo Manual*. 2nd ed., Lippincott, Williams, and Wilkins, (1999), 59.

CO = (SV * HR)/1000

where: CO = Cardiac Output

SV = Stroke Volume

HR = Heart Rate

Cross Sectional Area (CSA) in cm²

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

$CSA = 0.785 * D^2$

where: D = diameter of the anatomy of interest

Deceleration Time in msec

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

|time a - time b|

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

Otto, C.M. *Textbook of Clinical Echocardiography.* 2nd ed., W.B. Saunders Company, (2000), 117, 118.

32 mmHg/time interval in seconds

E:A Ratio in cm/sec

E:A = velocity E/velocity A

E/Ea Ratio

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

E Velocity/Ea velocity

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

Effective Regurgitant Orifice (ERO) in mm²

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

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

where: r = radius
Va = aliasing velocity

Ejection Fraction (EF), percent

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

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

Reynolds, Terry. *The Echocardiographer's Pocket Reference*. School of Cardiac Ultrasound, Arizona Heart Institute, (1993), 146.

|time a - time b|

Left Atrium/Aorta (LA/Ao)

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

Left Ventricular End Volumes (Teichholz) in ml

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

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

where: LVESV = Left Ventricular End Systolic Volume
LVDS = Left Ventricular Dimension at Systole

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

where: LVEDV = Left Ventricular End Diastolic Volume
LVDD = Left Ventricular Dimension at Diastole

Left Ventricular Mass in gm

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

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

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

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

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. Malergue. *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 cm^2

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

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

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

Flow = 6.28 (r^2) * Va

where: r = radius
Va = aliasing Velocity

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.

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 ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 391.

PHT = DT * 0.29

where: DT = deceleration time

Proximal Isovelocity Surface Area (PISA) in cm^2

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

PISA = $2\pi r^2$

where: 2π = 6.28
r = aliasing radius

Qp/Qs

Reynolds, Terry. *The Echocardiographer's Pocket Reference.* 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 400.

Qp/Qs = SV Qp site/SV Qs site

SV sites will vary depending upon the location of the shunt.

Regurgitant Fraction (RF) in percent

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

RF = RV/ MV SV

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

Regurgitant Volume (RV) in cc

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

RV = ERO * MR VTI

Right Ventricular Systolic Pressure (RVSP) in mmHg

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

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

where: RAP = Right Atrial Pressure

S/D

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

S velocity/ D velocity

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

Stroke Index (SI) in cc/m²

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

SI = SV/BSA

where: SV = Stroke Volume
BSA = Body Surface Area

Stroke Volume (SV) Doppler in ml

Oh, J.K., J.B. Seward, A.J. Tajik. *The Echo Manual*. 2nd ed., Lippincott, Williams, and Wilkins, (1999), 40, 59, 62.

SV = (CSA * VTI)

where CSA = Cross Sectional Area of the orifice (LVOT area)
VTI = Velocity Time Integral of the aortic valve

Tricuspid Valve Area (TVA)

Reynolds, Terry. *The Echocardiographer's Pocket Reference.* 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 55, 391, 452.

TVA = 220 / PHT

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

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

SV = (LVEDV – LVESV)

where: SV = Stroke Volume
LVEDV = End Diastolic Volume
LVEDSV = End Systolic Volume

Velocity Time Integral (VTI) in cm

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

VTI = 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, (1985), 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, (1985), 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 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.

Anteroposterior Trunk Diameter (APTD)

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." *Japanese Journal of Medical Ultrasonics*, 23:12 (1996), 885.

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, (1985), 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.

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, (1985), 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, (1985), 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, (1985).

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, (1985), 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, (1985), 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, (1985), 431.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." *Japanese Journal of Medical Ultrasonics*, 23:12 (1996), 885.

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

Volume (Vol)

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

Chapter 8: Specifications

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

Supported transducers

- C11x/8-5 MHz (6 ft/1.8 m)
- C60x/5-2 MHz (5.5 ft/1.7 m)
- HFL38x/13-6 MHz (5.6 ft/1.7 m)
- HFL50x/15-6 MHz (5.5 ft/1.7 m)
- ICTx/8-5 MHz (5.5 ft/1.7 m)
- L25x/13-6 MHz (7.5 ft/2.3 m)
- L38x/10-5 MHz (5.5 ft/1.7 m)
- L38xi/10-5 MHz (5.5 ft/1.7 m)
- P10x/8-4 MHz (6 ft/1.8 m)
- P21x/5-1 MHz (6 ft/1.8 m)
- SLAx/13-6 MHz (6 ft/1.8 m)
- TEEx/8-3 MHz (7.2 ft./2.2 m)

Imaging modes

- 2D (256 gray shades)
- Color power Doppler (CPD) (256 colors)
- Color Doppler (Color) (256 colors)
- M Mode
- Pulsed wave (PW) Doppler
- Continuous wave (CW) Doppler
- Tissue Doppler Imaging (TDI)
- Tissue Harmonic Imaging (THI)

Images and clips storage

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

Accessories

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

- Battery
- Biopsy Guide
- Education keys
- Mobile docking system
- Needle Guide
- Power supply
- SiteLink Image Manager
- System AC power cord (10 ft/3.1 m)
- SonoRemote control

Peripherals

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

Medical grade

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

- DVD recorder

Non-medical grade

- Kensington Security Cable
- USB keyboard

Temperature and humidity limits

Operating

System, battery, and transducer

10–40°C (50–104°F), 15–95% R.H.

700 to 1060hPa(0.7 to 1.05 ATM)

Shipping and storage

System and transducer

-35–65°C (-31–149°F), 15–95% R.H.

500 to 1060hPa (0.5 to 1.05 ATM)

Battery

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

500 – 1060hPa (0.5 – 1.05 ATM)

Electrical

Power Supply Input 100 – 240 VAC, 50/60 Hz, 2.0 – 1.0 A

Power Supply Output #1 15 VDC, 5.0 A

Power Supply Output #2 12 VDC, 2.3 A

Combined output not exceeding 75 watts.

Battery

The battery comprises six lithium-ion cells plus electronics, a temperature sensor, and battery contacts.

Run time is up to two hours, depending on imaging mode and display brightness.

Electromechanical safety standards

EN 60601-1:1997, European Norm, Medical Electrical Equipment–Part 1. General Requirements for Safety.

EN 60601-1-1:2001, European Norm, Medical Electrical Equipment–Part 1. General Requirements for Safety–Section 1-1. Collateral Standard. Safety Requirements for Medical Electrical Systems.

EN 60601-2-37:2001 + Amendment A1:2004 + Amendment A2:2005, European Norm, Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.

CAN/CSA C22.2, No. 601.1-M90, Canadian Standards Association, Medical Electrical Equipment–Part 1. General Requirements for Safety (including CSA 601.1 Supplement 1:1994 and CSA 601.1 Amendment 2:1998).

CEI/IEC 61157:1992, International Electrotechnical Commission, Requirements for the Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment.

UL 60601-1 (1st Edition), Underwriters Laboratories, Medical Electrical Equipment-Part 1: General Requirements for Safety.

EMC standards classification

EN 60601-1-2:2001, European Norm, Medical Electrical Equipment. General Requirements for Safety-Collateral Standard. Electromagnetic Compatibility. Requirements and Tests.

CISPR11:2004, International Electrotechnical Commission, International Special Committee on Radio Interference. Industrial, Scientific, and Medical (ISM) Radio-Frequency Equipment Electromagnetic Disturbance Characteristics-Limits and Methods of Measurement.

The Classification for the ultrasound system, stand, accessories, and peripherals when configured together is: Group 1, Class A.

Airborne equipment standards

RTCA/DO-160E:2004, Radio Technical Commission for Aeronautics, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21.0 Emission of Radio Frequency Energy, Category B.

HIPAA standard

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.

Glossary

Terms

For ultrasound terms not included in this glossary, refer to *Recommended Ultrasound Terminology, Second Edition,* published in 1997 by the American Institute of Ultrasound in Medicine (AIUM).

as low as reasonably achievable (ALARA)	The guiding principle of ultrasound use, which states that you should keep patient exposure to ultrasound energy as low as reasonably achievable for diagnostic results.
curved array transducer	Identified by the letter C (curved or curvilinear) and a number (60). The number corresponds to the radius of curvature of the array expressed in millimeters. The transducer elements are electrically configured to control the characteristics and direction of the acoustic beam. For example, C15, C60e.
depth	Refers to the depth of the display. A constant speed of sound of 1538.5 meters/second is assumed in the calculation of echo position in the image.
in situ	In the natural or original position.
LCD	liquid crystal display
linear array transducer	Identified by the letter *L* (linear) and a number (for example, 38). The number corresponds to the radius of width of the array expressed in millimeters. The transducer elements are electrically configured to control the characteristics and direction of the acoustic beam. For example, L38.
mechanical index (MI)	An indication of the likelihood of mechanical bioeffects occurring: the higher the MI, the greater the likelihood of mechanical bioeffects. See Chapter 6, "Safety," for a more complete description of MI.
MI/TI	See *mechanical index (MI)* and *thermal index (TI)*.
NTSC	National Television Standards Committee. A video format setting. See also *PAL*.
PAL	Phase Alternating Line. A video format setting. See also *NTSC*.
phased array	A transducer designed primarily for cardiac scanning. Forms a sector image by electronically steering the beam direction and focus.

skinline	A depth on the display that corresponds to the skin/transducer interface.
SonoHD™ imaging technology	A subset of the 2D imaging mode in which the 2D image is enhanced by reducing speckle noise artifact at tissue margins and improving contrast resolution by reducing artifacts and improving visualization of texture patterns within the image.
SonoMB technology	A subset of the 2D imaging mode in which the 2D image is enhanced by looking at a target from three angles and then merging or averaging the scanned data together to improve overall image quality and, in parallel, reducing noise and artifacts.
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 6, "Safety," for a more complete description of TI.
TIB (bone thermal index)	A thermal index for applications in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.
TIC (cranial bone thermal index)	A thermal index for applications in which the ultrasound beam passes through bone near the beam entrance into the body.
TIS (soft tissue thermal index)	A thermal index related to soft tissues.
Tissue Harmonic Imaging	Transmits at one frequency and receives at a higher harmonic frequency to reduce noise and clutter and improve resolution.
transducer	A device that transforms one form of energy into another form of energy. Ultrasound transducers contain piezoelectric elements, which when excited electrically, emit acoustic energy. When the acoustic energy is transmitted into the body, it travels until it encounters an interface, or change in tissue properties. At the interface, an echo is formed that returns to the transducer, where this acoustic energy is transformed into electrical energy, processed, and displayed as anatomical information.

Abbreviations

Abbreviations in User Interface

Abbreviation	Definition
A	"A" Wave Peak Velocity
A PG	"A" Wave Peak Pressure Gradient
A/B	A Caliper/B Caliper: Ratio
A2Cd	Apical 2 Chamber diastolic
A2Cs	Apical 2 Chamber systolic
A4Cd	Apical 4 Chamber diastolic
A4Cs	Apical 4 Chamber systolic
AAA	Abdominal Aortic Aneurysm
AAo	Ascending Aorta
Abd	Abdomen
abs	Absolute value
ACC	Acceleration Index
ACS	Aortic Valve Cusp Separation
Adur	"A" wave duration
AI	Aortic Insufficiency
AI PHT	Aortic Insufficiency Pressure Half Time
Ann D	Annulus Diameter
ANT F	Anterior Far
ANT N	Anterior Near
Ao	Aorta
AoD	Aortic Root Diameter
Apical	Apical View
AT	Acceleration (Deceleration) Time

Abbreviations in User Interface (Continued)

Abbreviation	Definition
AUA	Average Ultrasound Age Calculated by averaging the individual ultrasound ages for the fetal biometry measurements performed during the exam. The measurements used to determine the AUA are based on the selected OB calculation authors.
AV	Aortic Valve
AV Area	Aortic Valve Area
AVA	Aortic Valve Area
BA	Basilar Artery
Bifur	Bifurcation
BP	Blood Pressure
BPD	Biparietal Diameter
BPM	Beats per Minute
Bre	Breast
BSA	Body Surface Area
CCA	Common Carotid Artery
CI	Cardiac Index
CM	Cisterna Magna
CO	Cardiac Output
CPD	Color Power Doppler
Crd	Cardiac
CW	Continuous Wave Doppler
CxLen	Cervix Length
D	Diameter
D Apical	Distance Apical
DCCA	Distal Common Carotid Artery
DECA	Distal External Carotid Artery

Abbreviations in User Interface (Continued)

Abbreviation	Definition
DICA	Distal Internal Carotid Artery
Dist	Distal
dP:dT	Delta Pressure: Delta Time
E	"E" Wave Peak Velocity
E PG	"E" Wave Peak Pressure Gradient
E:A	E:A Ratio
E/e'	E velocity = Mitral Valve E velocity divided by the annular e' velocity
ECA	External Carotid Artery
ECICA	Extracranial Internal Carotid Artery
ECVA	Extracranial Vertebral Artery
EDD by AUA	Estimated Date of Delivery by Average Ultrasound Age The estimated date of delivery calculated from the measurements performed during the exam.
EDD by LMP	Estimated Date of Delivery by Last Menstrual Period The due date calculated from the user-entered LMP.
EDV	End Diastolic Velocity
EF	Ejection Fraction
EF:SLOPE	E-F Slope
EFW	Estimated Fetal Weight Calculated from the measurements performed during the exam. The measurements used to determine EFW are defined by the currently selected EFW calculation author.
Endo	Endocardial
Endo Th	Endometrial thickness
Epi	Epicardial
EPSS	"E" Point Septal Separation

Abbreviations in User Interface (Continued)

Abbreviation	Definition
Estab. DD	Established Due Date A user-entered due date based on previous exam data or other available information. The LMP is derived from the Established Due Date and is listed in the patient report as LMPd.
ET	Elapsed Time
FM (Right and Left)	Foramen Magnum (same as SO)
GA by LMP	Gestational Age by Last Menstrual Period The fetal age calculated using the date of the Last Menstrual Period (LMP).
GA by LMPd	Gestational Age by derived Last Menstrual Period The fetal age calculated using the Last Menstrual Period (LMPd) derived from the Estab. DD.
Gate	Depth of Doppler Gate
Gyn	Gynecology
HL	Humerus Length
HR	Heart Rate
IVRT	Iso Volumic Relaxation Time
IVS	Interventricular Septum
IVSd	Interventricular Septum Diastolic
IVSFT	Interventricular Septum Fractional Thickening
IVSs	Interventricular Septum Systolic
LA	Left Atrium
LA/Ao	Left Atrium/Aorta Ratio
Lat V	Lateral Ventricle
LMP	Last Menstrual Period The first day of the last menstrual period. Used to calculate gestational age and EDD.
LMPd	derived Last Menstrual Period Calculated from the user-entered Estab. DD.

Abbreviations in User Interface (Continued)

Abbreviation	Definition
LV	Left Ventricular
LV Area	Left Ventricular Area
LV mass	Left Ventricular mass
LV Volume	Left Ventricular Volume
LVd	Left Ventricular diastolic
LVD	Left Ventricular Dimension
LVDd	Left Ventricular Dimension Diastolic
LVDFS	Left Ventricular Dimension Fractional Shortening
LVDs	Left Ventricular Dimension Systolic
LVEDV	Left Ventricular End Diastolic Volume
LVESV	Left Ventricular End Systolic Volume
LVET	Left Ventricular Ejection Time
LVO	Left Ventricular Opacification
LVOT	Left Ventricular Outflow Tract
LVOT Area	Left Ventricular Outflow Tract Area
LVOT D	Left Ventricular Outflow Tract Diameter
LVOT VTI	Left Ventricular Outflow Tract Velocity Time Integral
LVPW	Left Ventricular Posterior Wall
LVPWd	Left Ventricular Posterior Wall Diastolic
LVPWFT	Left Ventricular Posterior Wall Fractional Thickening
LVPWs	Left Ventricular Posterior Wall Systolic
LVs	Left Ventricular systolic
MB	SonoMB
MI	Mechanical Index
MM	M Mode

Abbreviations in User Interface (Continued)

Abbreviation	Definition
MR PISA	Mitral Regurgitation Proximal Iso Velocity Surface Area
MR/VTI	Mitral Regurgitation/Velocity Time Integral
Msk	Musculoskeletal
MV	Mitral Valve
MV Area	Mitral Valve Area
MV Regurgitant Fraction	Mitral Valve Regurgitant Fraction
MV Regurgitant Volume	Mitral Valve Regurgitant Volume
MV/VTI	Mitral Valve/Velocity Time Integral
MVA	Mitral Valve Area
MV ERO	Mitral Valve Effective Regurgitant Orifice
MV PISA Area	Mitral Valve Proximal Iso Velocity Surface Area
MV Rate	Mitral Valve Rate
Neo	Neonatal
Nrv	Nerve
NTSC	National Television Standards Committee
OB	Obstetrical
Oph	Ophthalmic
P. Vein	Pulmonary Vein
PGmax	Maximum Pressure Gradient
PGmean	Mean Pressure Gradient
PGr	Pressure Gradient
PHT	Pressure Half Time
PI	Pulsatility Index
PICA	Proximal Internal Carotid Artery
PISA	Proximal Isovelocity Surface Area

Abbreviations in User Interface (Continued)

Abbreviation	Definition
PRF	Pulse Repetition Frequency
PSV	Peak Systolic Velocity
PV	Pulmonic Valve
PW	Pulsed Wave Doppler
Qp/Qs	Pulmonary blood flow divided by systemic blood flow
RA	Right Atrial (pressure)
RI	Resistive Index
RVD	Right Ventricular Dimension
RVDd	Right Ventricular Dimension Diastolic
RVDs	Right Ventricular Dimension Systolic
RVOT D	Right Ventricular Outflow Tract Diameter
RVOT VTI	Right Ventricular Outflow Tract Velocity Time Integral
RVSP	Right Ventricular Systolic Pressure
RVW	Right Ventricular Free Wall
RVWd	Right Ventricular Free Wall Diastolic
RVWs	Right Ventricular Free Wall Systolic
S/D	Systolic/Diastolic Ratio
SI	Stroke Index
SmP	Small Parts
Sup	Superficial
SV	Stroke Volume
TAM	Time Average Mean
TAP	Time Average Peak
TCD	Trans-cerebellum Diameter (OB measurement) Transcranial Doppler (exam type)
TDI	Tissue Doppler Imaging

Abbreviations in User Interface (Continued)

Abbreviation	Definition
THI	Tissue Harmonic Imaging
TI	Thermal Index
TRmax	Tricuspid Regurgitation (peak velocity)
TV	Tricuspid Valve
TVA	Tricuspid Valve Area
UA	Ultrasound Age Calculated on the mean measurements taken for a particular fetal biometry.
VA	Vertebral Artery
VArty	Vertebral Artery
Vas	Vascular
Ven	Venous
Vmax	Peak Velocity
Vmean	Mean Velocity
VTI	Velocity Time Integral
YS	Yolk Sac

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