S Series
Ultrasound System

User Guide

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SonoSite

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Ultrasound System

User Guide

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

SonoSite Ltd
Alexander House
40A Wilbury Way
Hitchin
Herts SG4 0AP
UK
T: +44-1462-444800
F: +44-1462-444801

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

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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 must be performed in a specific order.
- Bulleted lists present information in list format but do not imply a sequence.

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 & Service.
Europe Service Center:	+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 S-Cath™ ultrasound system, S-FAST™ ultrasound system, S-ICU™ ultrasound system, and the S-Nerve™ 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 38. On occasion, a software upgrade may be required. SonoSite provides a USB device containing the software. One USB device can upgrade multiple systems.

To use the ultrasound system

1. Turn the system on. (For power switch location, see "System controls" on page 7.)
2. Attach a transducer.
3. Press **Patient**, and complete the patient information form.
4. Press an imaging-mode control key: **2D** or **Color**.

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.

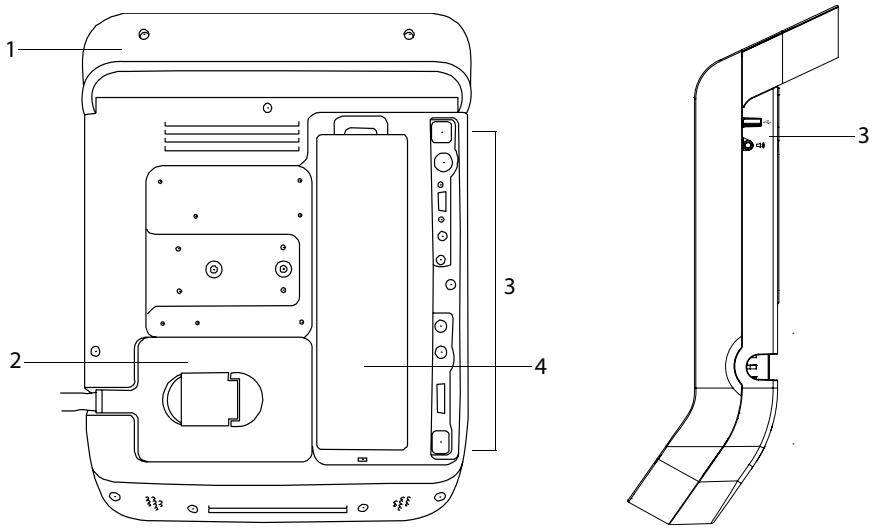


Figure 1.1 System Back (Left) and Side (Right):

1	Handle
2	Transducer
3	Connectors (See the table "Connectivity Symbols on Back and Side of System")
4	Battery compartment

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

Connectivity Symbols on Back and Side of System

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

* Not currently supported

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. Push down on the locking lever at the top of the battery to secure the battery.

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.

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 87.

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 1.1 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 7.)

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 18.

❖ 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 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.

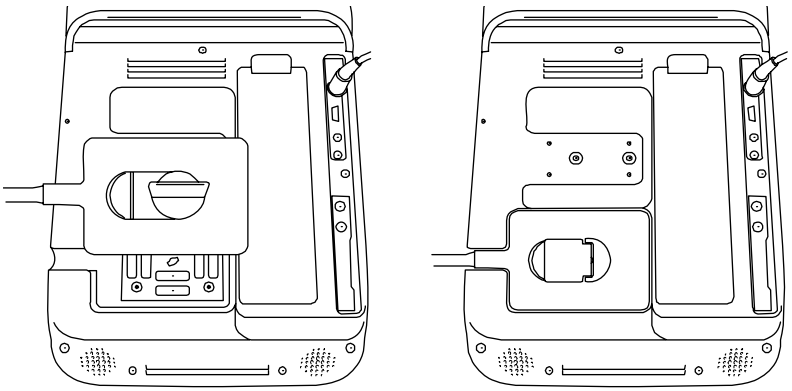


Figure 1.2 Connect the Transducer

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.

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 1.1 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 20.

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

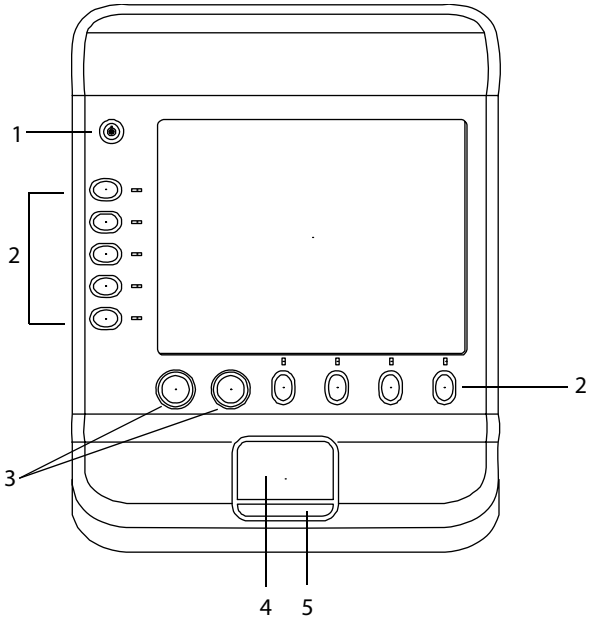


Figure 1.3 System Controls:

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, ROI box, and brightness. Sometimes perform an action. Are turned or pressed.
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

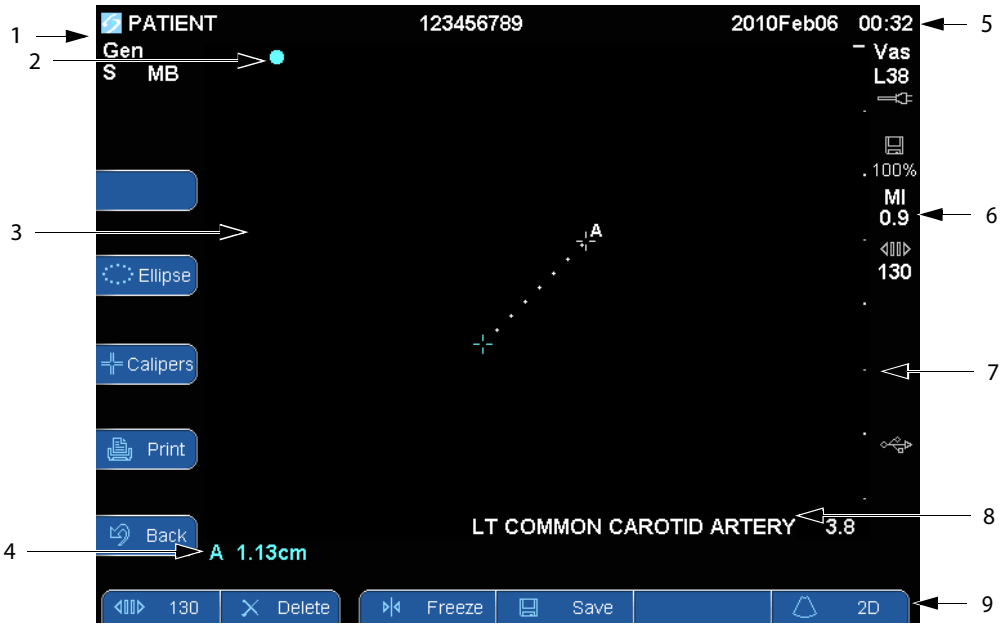


Figure 1.4 Screen Layout

1	Mode Data Area	Current imaging mode information (for example, Gen, S, THI). S and THI are on when available on the transducer and are not user-controlled. For definitions, see "Glossary."
2	Orientation Marker	Provides indication for image orientation.
3	Image	Ultrasound image.
4	Measurement Data Area	Current data on measurements.
5	Patient Header	Includes current patient name, patient ID number, institution, user, and date/time.
6	System Status	Information on system status (for example, exam type, transducer, AC connected, battery charging, and USB).
7	Depth Marker	Marks in .5 cm, 1 cm, and 5 cm increments depending on depth. To specify style, see "Presets setup" on page 19.
8	Exam label	Preset exam label from patient information form.
9	Control keys	Controls available in the current context. (See also "Control keys" on page 9.)

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.

Control keys

The control keys display forms, adjust settings, and perform actions such as freezing and zooming.The functionality depends on context. The current name appears on-screen next to the key. Control keys are usually pressed, but in forms you can also click them. The **Page x/x** control key displays additional control keys.

A control key functions in one of the following ways:

Cycle Moves through a list of settings.

On-Off Turns a feature on or off.

Action Performs an action such as saving a clip.

Figure 1.5 Control key names, lower screen (Color imaging shown)

Entering text

In forms, 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.

To enter text in text fields

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. If an external keyboard is connected, you can enter characters by typing.

- 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) 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 41.

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, install a transducer sheath.

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

To install 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.

Intended uses

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

Abdominal Imaging Applications This system transmits ultrasound energy into the abdomen of patients using 2D, SonoMB™ technology, color Doppler (Color), color power Doppler (CPD), and Tissue Harmonic Imaging (THI) to obtain ultrasound images. The liver, kidneys, pancreas, spleen, gallbladder, bile ducts, transplanted organs, abdominal vessels, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally.

Cardiac Imaging Applications This system transmits ultrasound energy into the thorax of patients using 2D, SonoMB technology, color Doppler (Color), and Tissue Harmonic Imaging (THI), to obtain ultrasound images. The heart, cardiac valves, great vessels, surrounding anatomical structures, overall cardiac performance, and heart size can be assessed for the presence or absence of pathology.

Gynecology and Infertility Imaging Applications This system transmits ultrasound energy in the pelvis and lower abdomen using 2D, SonoMB technology, color power Doppler (CPD), and color Doppler (Color) to obtain ultrasound images. The uterus, ovaries, adnexa, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally or transvaginally.

Interventional Imaging Applications This system transmits ultrasound energy into the various parts of the body using 2D, SonoMB technology, color Doppler (Color), color power Doppler (CPD), and Tissue Harmonic Imaging (THI) to obtain ultrasound images that provide guidance during interventional procedures. This system can be used 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 provide assistance during abdominal, breast, and neurological surgery.

Obstetrical Imaging Applications This system transmits ultrasound energy into the pelvis of pregnant women using 2D, SonoMB technology, color Doppler (Color), and color power Doppler (CPD) to obtain ultrasound images. The fetal anatomy, amniotic fluid, and surrounding anatomical structures can be assessed for the presence or absence of pathology transvaginally. CPD and color Doppler (Color) imaging is intended for high-risk pregnant women.

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 detection of structural anomalies of the fetal heart and as an adjunctive method, not as a screening tool for the diagnosis of Intrauterine Growth Retardation (IUGR).

Pediatric Imaging Applications This system transmits ultrasound energy into the pediatric patients using 2D, SonoMB multi-beam technology, color Doppler (Color), and color power Doppler (CPD) to obtain ultrasound images. The pediatric abdominal and pelvic anatomy, pediatric hips, and surrounding anatomical structures can be assessed for the presence or absence of pathology.

Superficial Imaging Applications This system transmits ultrasound energy into various parts of the body using 2D, SonoMB multi-beam technology, color Doppler (Color), and color power Doppler (CPD) to obtain ultrasound images. The breast, thyroid, testicle, lymph nodes, hernias, musculoskeletal structures, soft tissue structures, and surrounding anatomical structures can be assessed for the presence or absence of pathology. This system can be used to provide ultrasound guidance for biopsy and drainage procedures, vascular line placement, peripheral nerve blocks, and spinal nerve blocks and taps.

Vascular Imaging Applications This system transmits ultrasound energy into the various parts of the body using 2D, SonoMB, color Doppler (Color), and color power Doppler (CPD) to obtain ultrasound images. 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 can be assessed 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 In 2D imaging mode, do one of the following:

- Press **Patient**, and then press **Setup** on the horizontal row of control keys.
- Press **Setup** on the vertical row of control keys.

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 4.)

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 view the event log.

Security settings

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

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

To log in as Administrator

1 On the Administration setup page, type `Administrator` in the **Name** box. (See "Entering text" on page 9.)

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 viii.)

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 17.)
- 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 17.)

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. In the **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.

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 **Done** 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 view 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 View 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 14.)

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.

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.

Connectivity setup

On the Connectivity setup page, you select options for using devices and for alerts when internal storage is full.

To configure the system for a printer

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

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

To configure the system for a DVD recorder or 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**.
- In the **Serial Port** list, click the peripheral.

2 Click **Yes** to restart the system.

3 Attach a serial cable (RS-232) from the serial port 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 9.)
- 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, printer, and similar information.

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**, TCD is **TIC**, and all others are **TIS**.

Clip Length: Clip length in seconds.

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

Display Brightness: High displays brighter key names and icons and is suitable for a bright environment, such as daylight. **Low** 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.

System Information setup

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

See also "To enter a license key" on page 38.

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 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. Click a sort order under **Sort By**.

   The sort order specifies how exported files are organized.

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

Chapter 3: Imaging

Imaging modes

The system has a high-performance LCD and advanced image-optimization technology that greatly 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 possible image quality, properly adjust the display brightness, gain, depth settings, viewing angle, and exam type. Also, use an optimization setting that best matches your needs.

To display the 2D image

1 Do any of the following:

- Turn on the system.
- Press **2D**.

2 Adjust settings. See "2D settings."

2D settings

In 2D imaging, the following control keys adjust settings. See also "Adjusting depth and gain" on page 23.

2D settings

Control key	Icon	Description
Auto Gain		The gain adjusts each time you press the key. To adjust gain manually, see "Adjusting depth and gain" on page 23.
Brightness		Adjusts the display brightness. Press **Bright** and then turn the left-hand 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 19.) The display brightness affects battery life. To conserve battery life, adjust brightness to a lower setting.

2D settings (Continued)

Control key	Icon	Description
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.
Orientation		Select from four image orientations: **U/R** (Up/Right), **U/L** (Up/Left), **D/L** (Down/Left), **D/R** (Down/Right).
SonoMB (MB)		**MB On** and **MB Off** turn SonoMB technology on and off. When SonoMB is on, *MB* appears in the upper left-hand screen. SonoMB depends on transducer and exam type.
Page x/x		Indicates which page of options is displayed. Press to display the next page.

CPD and color Doppler imaging

Color power Doppler (CPD) and color Doppler (Color) are optional features.

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

To display the CPD or Color image

1 Press **Color**.

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

2 Press **CPD** or **Color** on the left.

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

3 Using the touchpad, position the ROI box as needed.

A green outline shows the change.

Adjusting depth and gain

To adjust depth

You can adjust the depth in all imaging 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 19.

❖ Turn the **Depth** knob:

- Right increases the displayed depth.
- Left decreases the displayed depth.

To adjust gain manually

To adjust gain automatically in 2D, see "2D settings" on page 21.

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

- **Near**  adjusts the gain applied to the near field of the image.
- **Far**  adjusts the gain applied to the far field of the image.
- **Gain**  adjusts the overall gain applied to the entire image.

In CPD or Color imaging, the **Overall** setting affects the color gain applied to the region of interest (ROI) box. The **Near** and **Far** settings affect only the 2D image. (*Near* and *far* correspond to the time gain compensation [TGC] controls on other ultrasound systems.)

2 Turn the knob.

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 system status area.

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.

To zoom in on an image

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** again.

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

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

To exit zoom, press **Zoom** again.

Turning guidelines on and off

Guidelines are for needle guidance and are an optional feature.

To turn guidelines on or off

❖ On a 2D image, press one of the following control keys:

- **Biopsy** : This feature depends on transducer type. For more information, see *SonoSite Biopsy User Guide.*
- **Guide:** This feature depends on transducer and exam type. For more information, see *SonoSite Bracket and Needle Guide User Guide.*

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.

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:

- In 2D imaging, press **Exam**, and then click the exam type in the menu.
- On the patient information form, click the exam type in the **Exam** list. (See "Patient information form" on page 27.)

Imaging modes and exams available by transducer

Transducer	Exam Type[1]	S Series System	Imaging Mode		
			2D[2]	CPD	Color
C11x	Nrv	S-Nerve	X	X	X
	Vas	S-Nerve	X	X	X
C60x	Abd	S-Cath S-FAST S-ICU	X	X	X
	Nrv	S-Nerve	X	X	X
HFL38x	Bre	S-Cath	X	X	X
	Nrv	S-Nerve	X	X	X
	SmP	S-Cath S-FAST S-ICU	X	X	X
	Vas	S-Cath S-FAST S-ICU S-Nerve	X	X	X
	Ven	S-Cath S-FAST S-ICU	X	X	X
ICTx	Gyn	S-FAST	X	X	X
	OB	S-FAST	X	X	X

Imaging modes and exams available by transducer (Continued)

Transducer	Exam Type[1]	S Series System	Imaging Mode		
			2D[2]	CPD	Color
L25x	Nrv	S-Nerve	X	X	X
	Sup	S-Cath	X	X	X
	Vas	S-Cath S-ICU S-Nerve	X	X	X
	Ven	S-Cath S-ICU	X	X	X
L38x	Bre	S-Cath	X	X	X
	Nrv	S-Nerve	X	X	X
	SmP	S-Cath S-FAST S-ICU	X	X	X
	Vas	S-Cath S-FAST S-ICU S-Nerve	X	X	X
	Ven	S-Cath S-FAST S-ICU	X	X	X
P21x	Abd	S-Cath S-FAST S-ICU	X	X	X
	Crd	S-FAST S-ICU	X	—	X

1. Exam type abbreviations are as follows: Abd = Abdomen, Bre = Breast, Crd = Cardiac, Nrv = Nerve, OB = Obstetrical, SmP = Small Parts, Sup = Superficial, Vas = Vascular, Ven = Venous.

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

Patient information form

The patient information form lets you enter patient identification, exam, and clinical information for the patient exam.

When you create a new patient information form, all images and other data you save during the exam are linked to that patient. (See "Saving images and clips" on page 28.)

To create a new patient information form

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

2 Press **New**.

3 Fill in the form fields. See "Patient information form fields" on page 28 and "Entering text" on page 9.

4 Press **Done**.

To edit a patient information form

You can edit patient information during the exam. However, if you change the patient name or ID after saving an image, a new patient information form is created.

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

2 If you need to change the patient name or ID, save any data you want to keep.

3 Make changes as desired.

4 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 28.)

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

3 Do one of the following:

- Press **End Exam**.
- Press **New** to begin a new patient information form. (See "To create a new patient information form" on page 27.)

Patient information form fields

Field	Description
Last **First**	Patient name
ID	Patient identification number
Exam	Exam type
Exam label	Exam-specific label that appears in the lower-right screen
User	User initials, up to 3 characters. Appears in the patient list and image header.
Institution	Institution name. Appears in the image header.

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 18.)

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 18.

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

To save an image

❖ Press **Save**.

To save a clip

❖ Press **Clip**.

To specify clip length, see "Presets setup" on page 19.

Reviewing images and clips

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 viii.)

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

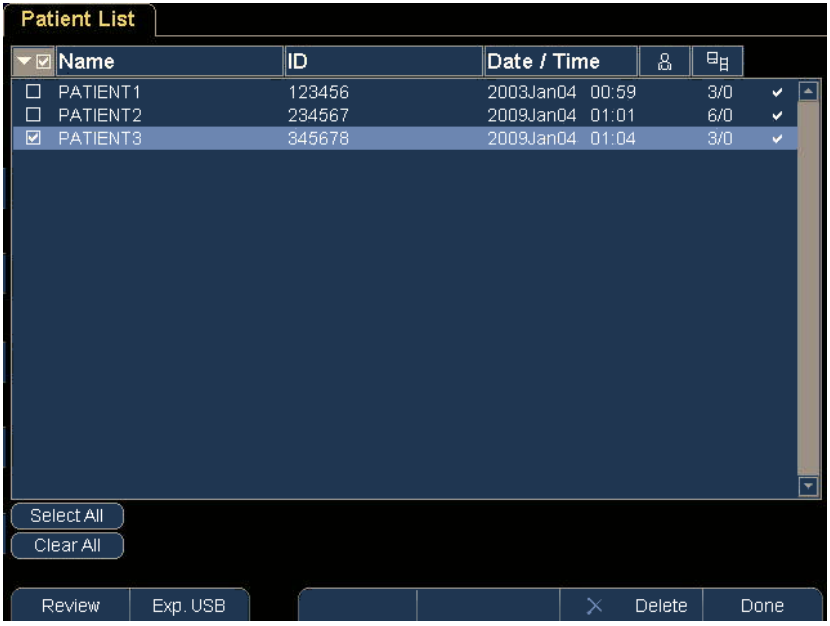


Figure 3.1 Patient List

To open 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 file 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 patients in the patient list

❖ Select the check box for one or more patients.

Clicking **Select All** selects all patients.

To deselect patients, clear checked boxes or click **Clear All**.

To review images and clips

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

1 In the patient list, click the patient 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 18.

2 Do one of the following:

- In the patient list, review the patient'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 18.

2 Do one of the following:

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

  Each image appears briefly on-screen while printing.

To export images and clips to a USB storage device

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 20. A patient exam must be ended before you can export its images and clips. See "To end the exam."

1. Insert the USB storage device. (See "Inserting and removing USB storage devices" on page 6.)
2. In the patient list, select the patients whose images and clips you want to export.
3. Select **Exp. USB** on-screen. A list of USB devices appears.
4. Select the USB storage device, and select **Export**.

   Only available USB devices (for example, not password-protected) are selectable.

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

To delete images and clips

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

Chapter 4: Measurements

You can perform distance, area, and circumference measurements in any imaging mode. Measurements are performed on frozen images.

You can perform multiple measurements at one time: up to eight distance measurements or four area/circumference measurements or a combination; for example, six distance measurements and one area/circumference measurement.

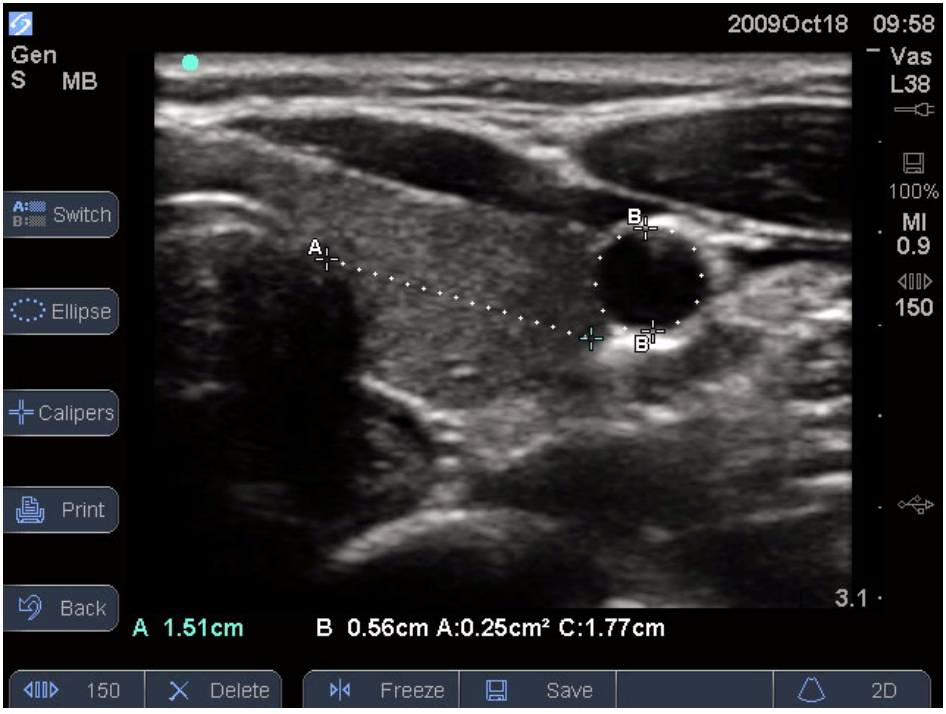


Figure 4.1 2D image with one distance and one circumference measurement

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.

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. 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.

To improve precision of caliper placement

❖ Do any of the following:

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

Distance measurements

Distance is measured in cm.

To measure distance

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

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

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

The other caliper becomes active.

3 Using the touchpad, position the other caliper.

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

To save the image with the measurements displayed, see "To save an image" on page 28.

Area and circumference measurements

Area and circumference measurements use an ellipse with calipers. You can measure the following:

- Area in cm^2
- Circumference in cm

To measure area or circumference

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

2 Press **Ellipse**.

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

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

To save the image with the measurements displayed, see "To save an image" on page 28.

Measurement accuracy

The measurements provided by the system do not define a specific physiological or anatomical parameter. Rather, the measurements are of a physical property such as distance for evaluation by the clinician. The accuracy values require that you can place the calipers over one pixel. The values do not include acoustic anomalies of the body.

The 2D linear distance measurement results are displayed in centimeters with one place past the decimal point, if the measurement is ten or greater; two places past the decimal point, if the measurement is less than ten.

The linear distance measurement components have the accuracy and range shown in the following tables.

Table 1: 2D Measurement Accuracy and Range

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

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

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

c.The area accuracy is defined using the following equation:
% tolerance = ((1 + lateral error) * (1 + axial error) – 1) * 100 + 0.5%.

d.The circumference accuracy is defined as the greater of the lateral or axial accuracy and by the following equation:

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

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.

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 table to help troubleshoot the problem. If the problem persists, contact SonoSite Technical Support. (See "SonoSite Technical Support" on page viii.)

Troubleshooting

Symptom	Solution
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.
Print does not work.	Select the printer on the Connectivity setup page. See "To configure the system for a printer" on page 18. 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 viii.) You need to provide the following information. (See "System Information setup" on page 20.)

Software License Key Information

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 viii.)

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 41.) 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 viii.)

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 U.S. Food and Drug Administration (FDA).

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, "Disinfectants Compatible with System and Transducers" on page 44.

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.

To avoid infection, ensure that the solution expiration date has not passed.

To avoid infection, the level of disinfection required for a product is dictated by the type of tissue it contacts during use. Ensure that the solution strength and duration of contact are 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 FDA.

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, "Disinfectants Compatible with System and Transducers" on page 44.

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.

To avoid infection, ensure that the solution expiration date has not passed.

To avoid infection, the level of disinfection required for a transducer is dictated by the type of tissue it contacts during use. Ensure that the solution strength and duration of contact are appropriate for the equipment. SonoSite tests products for compatibility of materials only. SonoSite does not test for biological effectiveness. For information, see the disinfectant label instructions and the recommendations of the Association for Professionals in Infection Control and Epidemiology (APIC) and FDA.

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, 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, 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

Caution: To avoid damaging the battery, do not allow cleaning solution or disinfectant to come in contact with the battery terminals.

To clean and disinfect a battery (wipe method)

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

   Apply the solution to the cloth rather than the surface.
3. Wipe the surfaces with the disinfection solution. Theracide disinfectant is recommended.
4. Air dry or towel dry with a clean cloth.

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

- EPA Registration
- FDA 510(k) clearance (liquid sterilant, high level disinfectant)
- CE approval

Prior to use, confirm that the regulatory status of the disinfectant is appropriate for your jurisdiction and use.

See www.sonosite.com for updated cleaning and disinfectant information. Click **Quick Link**, and then click **Documentation**.

Table 1: Disinfectants Compatible with System and Transducers

Disinfection and Cleaning Solutions	Country of Origin	Type	Active Ingredient	C60x/ICTx/ L38x/P21x	HFL38x	C11x/ L25x	System Surfaces
AbcoCide 14	USA	Liquid	Gluteraldehyde	A	A	A	U
Accel Wipes	CAN	Wipe	Hydrogen Peroxide	A	A	A	U
Accel Plus	CAN	Wipe	Hydrogen Peroxide	N	N	N	U
Accel TB	CAN	Wipe	Hydrogen Peroxide	N	N	N	U
Aidal Plus	AUS	Liquid	Gluteraldehyde	A	A	A	U
Alkacide	FRA	Liquid	Gluteraldehyde	A	A	A	U
Alkazyme	FRA	Liquid	Quat. Ammonia	A	A	A	U
Anioxy-Twin	FRA	Liquid	Peracetic Acid	N	N	N	U
Aquatabs (1000)	IRL	Tablet	Sodium Dichloroisocyanurate	A	N	A	U
Aquatabs (2000)	IRL	Tablet	Sodium Dichloroisocyanurate	A	N	A	U

Table 1: Disinfectants Compatible with System and Transducers (Continued)

Disinfection and Cleaning Solutions	Country of Origin	Type	Active Ingredient	C60x/ICTx/ L38x/P21x	HFL38x	C11x/ L25x	System Surfaces
Aquatabs (5000)	IRL	Tablet	Sodium Dichloroisocyanurate	N	N	N	U
Anioxyde 1000	FRA	Liquid	Peracetic Acid	N	N	N	U
Ascend	USA	Liquid	Quat Ammonia	A	A	A	U
Asepti-HB	USA	Liquid	Quat Ammonia	A	A	A	U
Asepti-Steryl	USA	Spray	Ethanol	A	A	A	N
Asepti-Wipes	USA	Wipe	Propanol (Isopropyl Alcohol	A	A	A	A
Bacillocid rasant	DEU	Liquid	Glut./Quat. Ammonia	A	A	A	U
Banicide	USA	Liquid	Gluteraldehyde	A	U	A	U
Bleach	USA	Liquid	NaCl Hypochlorite	A	A	A	U
Cavicide	USA	Liquid	Isopropyl	A	A	A	U
Caviwipes	USA	Wipes	Isopropanol	A	A	N	U
Chlor-Clean	GBR	Liquid	Sodium Dichloroisocyanurate	A	N	A	U
Cidalkan Lingettes	FRA	Wipes	Ethyl Alcohol	A	A	U	U
Cidex	USA	Liquid	Gluteraldehyde	A	A	A	A
Cidex OPA	USA	Liquid	Ortho-phthaldehyde	A	A	A	U
Cidex Plus	USA	Liquid	Gluteraldehyde	A	A	A	A
Cleanisept	DEU	Wipes	Quat Ammonia	A	A	A	A
Clorox Wipes	USA	Wipes	Isopropanol	A	A	A	U

Table 1: Disinfectants Compatible with System and Transducers (Continued)

Disinfection and Cleaning Solutions	Country of Origin	Type	Active Ingredient	C60x/ICTx/ L38x/P21x	HFL38x	C11x/ L25x	System Surfaces
Control III	USA	Liquid	Quat. Ammonia	A	A	N	U
Coverage Spray	USA	Spray	Quat. Ammonia	A	A	N	N
DentaSept	FRA	Liquid	Quat. Ammonia	N	N	N	U
Denatured Alcohol	USA	Liquid	Ethanol	N	N	N	U
DisCide Wipes	USA	Wipes	Isopropyl Alcohol	A	A	A	U
DisOPA	JPN	Liquid	Ortho-phthaldehyde	A	A	A	U
Dispatch	USA	Spray	NaCl Hypochlorite	A	A	A	U
Dynacide PA	FRA	Liquid	Peracetic Acid	A	A	A	U
End-Bac II	USA	Liquid	Quat. Ammonia	A	A	A	N
Endozime AW Plus	FRA	Liquid	Propanol	A	A	A	U
Envirocide	USA	Liquid	Isopropyl	A	U	N	U
Enzol	USA	Cleaner	Ethylene Glycol	A	A	A	U
Expose	USA	Liquid	Isopropyl	A	A	A	U
Gigasept AF	DEU	Liquid	Quat. Ammonia	A	A	A	U
Gigasept FF	DEU	Liquid	Bersteinsaure	N	N	N	U
Gluteraldehyde SDS	USA	Liquid	Gluteraldehyde	A	U	A	U
Hexanios	FRA	Liquid	Polyhexanide/Quat. Ammonia	A	A	A	U
Hi Tor Plus	USA	Liquid	Chloride	A	A	N	U
Hibiclens	USA	Cleaner	Chlorhexidine	A	A	A	U

Table 1: Disinfectants Compatible with System and Transducers (Continued)

Disinfection and Cleaning Solutions	Country of Origin	Type	Active Ingredient	C60x/ICTx/ L38x/P21x	HFL38x	C11x/ L25x	System Surfaces
Hydrogen Peroxide	USA	Liquid	Hydrogen Peroxide	A	A	A	U
Isopropanol Alcohol	ALL	Liquid	Alcohol	N	N	N	U
Kodan Tücher	DEU	Liquid	Propanol	A	A	A	U
Kohrsolin ff	DEU	Liquid	Gluteraldehyde	A	U	A	U
Korsolex basic	DEU	Liquid	Gluteraldehyde	N	N	N	U
Korsolex extra	DEU	Liquid	Ethanol/Propanol	A	A	A	U
Lem-O-Quat	USA	Liquid	Alkyl/Chloride	N	N	N	U
LpHse	USA	Liquid	O-phenylphenol	A	A	A	U
Lysol	USA	Spray	Ethanol	N	N	N	N
Lysol IC	USA	Liquid	O-phenylphenol	A	N	A	U
Madacide 1	USA	Liquid	Isopropanol	A	A	N	A
Matar	USA	Liquid	O-phenylphenol	A	U	A	U
MetriCide 14	USA	Liquid	Gluteraldehyde	A	A	A	U
MetriCide 28	USA	Liquid	Gluteraldehyde	A	A	A	U
MetriZyme	USA	Cleaner	Propylene Glycol	A	A	A	U
Mikrobak forte	DEU	Liquid	Ammonium Chloride	A	A	A	U
Mikrozid Wipes	DEU	Wipe	Ethanol/Propanol	A	A	A	U
Nuclean	FRA	Spray	Alcohol/Biguanide	A	A	A	U
Precise	USA	Spray	O-phenylphenol	N	N	N	U
Prevention	CAN	Liquid	Hydrogen Peroxide	N	N	N	U

Table 1: Disinfectants Compatible with System and Transducers (Continued)

Disinfection and Cleaning Solutions	Country of Origin	Type	Active Ingredient	C60x/ICTx/ L38x/P21x	HFL38x	C11x/ L25x	System Surfaces
Ruthless	USA	Spray	Quat. Ammonia	A	A	N	U
Sagrosept Wipe	DEU	Wipe	Propanol	A	A	A	U
Salvanios pH 7	FRA	Liquid	Quat. Ammonia	A	A	A	U
Sani-Cloth HB	USA	Wipe	Quat. Ammonia	A	A	N	A
Sani-Cloth Plus	USA	Wipe	Quat. Ammonia	A	A	A	A
Sekusept	DEU	Liquid	Gluteraldehyde	A	A	A	U
Sklar	USA	Liquid	Isopropanol	A	A	N	U
Sporicidin	USA	Liquid	Phenol	A	A	A	N
Sporicidin Wipes	USA	Wipe	Phenol	A	A	A	A
Staphene	USA	Spray	Ethanol	A	N	A	U
Steranios	FRA	Liquid	Gluteraldehyde	A	A	A	U
Super Sani-Cloth	USA	Wipe	Isopropyl Alcohol	N	N	N	N
T-Spray	USA	Spray	Quat. Ammonia	A	A	N	N
T-Spray II	USA	Spray	Alkyl/Chloride	A	A	A	U
TASK 105	USA	Spray	Quat. Ammonia	A	A	A	U
TBQ	USA	Liquid	Quat. Ammonia	A	A	A	U
Theracide Plus	USA	Liquid	Quat. Ammonia	A	A	A	U
Theracide Plus Wipes	USA	Wipe	Quat. Ammonia	A	A	A	A
Tor	USA	Liquid	Quat. Ammonia	A	A	N	U

Table 1: Disinfectants Compatible with System and Transducers (Continued)

Disinfection and Cleaning Solutions	Country of Origin	Type	Active Ingredient	C60x/ICTx/ L38x/P21x	HFL38x	C11x/ L25x	System Surfaces
Transeptic	USA	Cleaner	Alcohol	N	N	N	U
Tristel	GBR	Liquid	Chlorine Dioxide	A	A	A	U
Tristel Wipes	GBR	Wipe	Chlorine Dioxide	N	N	N	N
Vesphene II	USA	Liquid	Sodium/ o-Phenylphenate	A	A	A	U
Virex II 256	USA	Liquid	Ammonium Chloride	A	A	A	U
Virex TB	USA	Liquid	Quat. Ammonia	A	A	N	N
Virox 5	CAN	Wipe	Hydrogen Peroxide	A	A	A	U
Virufen	FRA	Liquid	Alkyl Ammonium Chloride	A	A	A	U
Wavicide -01	USA	Liquid	Gluteraldehyde	N	N	N	U
Wavicide -06	USA	Liquid	Gluteraldehyde	A	A	A	U
Wex-Cide	USA	Liquid	O-phenylphenol	A	A	A	U

A = Acceptable

N = Not acceptable (Do not use)

U = 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, do not ignore these warning signs. Promptly see a qualified health professional. Symptoms such as these 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 chapter provides guidelines that may help you work more comfortably and may reduce your risk of MSDs[e,f].

a.Magnavita, N., L. Bevilacqua, P. Mirk, A. Fileni, and N. Castellino. "Work-related Musculoskeletal Complaints in Sonologists." *Occupational Environmental Medicine*. 41:11 (1999), 981-988.

b.Craig, M. "Sonography: An Occupational 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

- When the exam or procedure allows, position the system within reach.
- Adjust the angle of the system and display to minimize glare from overhead or outside lighting.
- 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 has support for your lower back, that adjusts to your work surface height, that promotes a natural body posture, and that allows for quick height adjustments.
- Always sit or stand in an upright manner. 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.

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.

Minimize neck bending and twisting

Position the ultrasound system directly in front of you.

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. One way of taking a break is to stop and relax. 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	Ultrasound system powered from power supply or part of the S Series stand.
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, 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 7, “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 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 injury, do not operate the system in the presence of flammable gasses or anesthetics. Explosion can result.

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.

To avoid the risk of electrical shock, 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.

To avoid the risk of electrical shock, do not connect the system’s power supply or the S Stand’s auxiliary mains outlet receptacles to an MPSO or extension cord.

To avoid the risk of electrical shock, before using the transducer, inspect the transducer face, housing, and cable. Do not use the transducer if the transducer or cable is damaged.

To avoid the risk of electrical shock, always disconnect the power supply from the system before cleaning the system.

To avoid the risk of electrical shock, do not use any transducer that has been immersed beyond the specified cleaning or disinfection level. See Chapter 5, “Troubleshooting and Maintenance.”

To avoid the risk of electrical shock and fire hazard, inspect the power supply, AC power cord, and plug on a regular basis. Ensure they are not damaged.

To avoid the risk of electrical shock and fire hazard, the power cord set that connects the power supply of the ultrasound system or S Series stand to mains power must only be used with the power supply or S Series stand, and cannot be used to connect other devices to mains power.

WARNING: To avoid the risk of electrical shock, 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, inspect cables and power cords used within the system on a regular basis for damage.

To avoid the risk of electrical shock to the patient/subject, do not touch the system battery contacts while simultaneously touching a patient/subject.

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: To avoid the battery bursting, igniting, or emitting fumes from the battery and causing equipment damage, observe the following precautions:

Do not immerse the battery in water or allow it to get wet.

Do not put the battery into a microwave oven or pressurized container.

If the battery emits an odor or heat, is deformed or discolored, or in any way appears abnormal during use, recharging or storage, immediately remove it and stop using it. If you have any questions about the battery, consult 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

Observe the following precautions related to 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.

WARNING: 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.

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.

Caution: 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.

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 68. 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. 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 64. 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, then the best results may be achieved by minimizing these parameters simultaneously. In some modes changing these parameters will not affect MI or TI. Changes to other parameters may also result in MI and TI reductions. Please note the 'MI' or 'TI' read out on the right side of the LCD screen.

"↓" means to decrease or lower setting of parameter to reduce MI or TI.

"↑" means to raise or increase setting of parameter to reduce MI or TI

Table 3: MI

Transducer	Depth
C11x	↑
C60x	↑
HFL38x	↑
ICTx	↑
L25x	↑
L38x	↑
P21x	↑

Table 4: TI (TIS, TIC, TIB)

Transducer	Color Power Doppler Settings					
	Box Width	Box Height	Box Depth	PRF	Depth	Optimize
C11x			↑	↓	↑	
C60x	↓		↑	↓	↑	
HFL38x			↑	↑	↑	
ICTx		↑	↑	↓		Exam Gyn
L25x	↓				↑	
L38x				↓		
P21x		↓		↓	↑	

Output display

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

Table 5: Cases Where Either a Thermal or Mechanical Index is ≥ 1.0

Transducer Model	Index	2D	CPD/ Color
C11x/8-5	MI	No	No
	TIC,TIB, or TIS	No	Yes
C60x/5-2	MI	Yes	No
	TIC, TIB, or TIS	No	No
HFL38x/13-6	MI	No	Yes
	TIC, TIB, or TIS	No	Yes
ICTx/8-5	MI	No	No
	TIC, TIB, or TIS	No	No
L25x/13-6	MI	No	No
	TIC,TIB, or TIS	No	No
L38x/10-5	MI	No	Yes
	TIC, TIB, or TIS	No	Yes
P21x/5-1	MI	Yes	Yes
	TIC, TIB, or TIS	Yes	Yes

Even when MI is less than 1.0, the system provides a continuous real-time display of MI whenever a transducer is operated in a 2D imaging mode. The index is displayed in increments of 0.1.

The system meets the output display standard for TI. A continuous real-time display of TI is provided for the operator whenever a transducer is operated in a CPD or Color imaging mode. The index is displayed in increments of 0.1.

The thermal index consists of three user selectable indices, and only one of these is displayed at any one time. In order to display properly and meet the ALARA principle, the user selects an appropriate TI based on the specific exam being performed. SonoSite provides the AIUM Medical Ultrasound Safety reference which contains guidance on how to determine which TI is appropriate (see second reference listed in "Related guidance documents" on page 67).

Mechanical and thermal indices output display accuracy

The accuracy result for the mechanical index (MI) is stated statistically. With 90% confidence, 90% of the measured MI values will be within +16% to –31% of the displayed MI value, or +0.2 of the displayed value, whichever value is larger.

The accuracy result for the thermal index (TI) is stated statistically. With 90% confidence, 90% of the measured TI values will be within +26% to –50% 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 79.

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 and Table 7 list the measured surface temperature rise from ambient* of transducers used on the ultrasound system. The temperatures were measured in accordance with EN 60601-2-37 section 42 where controls and settings were positioned to give maximum temperatures

Test 1: The transducer surface temperature test on tissue mimicking material (TMM) is based on the following standard: 42.3(a) 1, Test Method B (IEC 60601-2-37, Amendment 1). The limit is a 10°C rise from ambient, as measured on the TMM.

Test 2: The transducer surface temperature test in air is based on the following standard: 42.3(a) 2 (IEC 60601-2-37, Amendment 1). The limit is a 27°C rise from ambient.

Test 3: The transducer surface temperature test on TMM is based on the following standard: 42.3(a) 1, Test Method B (IEC 60601-2-37, Amendment 1). The limit is a 6°C rise from ambient, as measured on the TMM.

*The ambient temperature shall be 23°C ± 3°C.

Table 6: Transducer Surface Temperature Rise EN 60601-2-37 (External Use)

Test	C11x	C60x	HFL38x	L25x	L38x	P21x
1	9.2°C	9.0°C	9.5°C	9.5°C	9.6°C	9.0°C
2	19.0°C	18.0°C	19.0°C	18.2°C	20.0°C	20.0°C

Table 7: Transducer Surface Temperature Rise IEC 60601-2-37 (Internal Use)

Test	ICTx
3	5.5°C
2	12.0°C

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 prepared by its Bioeffects Committee (Bioeffects Considerations for the Safety of Diagnostic Ultrasound, J Ultrasound Med., Sept. 1988: Vol. 7, No. 9 Supplement), sometimes referred to as the Stowe Report, which 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 the "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (NEMA UD2-2004), and the "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment" (NEMA UDe3-2004).

In Situ, derated, and water value intensities

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

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

where:

In Situ = *In Situ* intensity value

Water = Water intensity value

e = 2.7183

a = attenuation factor (dB/cm MHz)

Attenuation factor (a) for various tissue types are given below:

brain = 0.53

heart = 0.66

kidney = 0.79

liver = 0.43

muscle = 0.55

l = skinline to measurement depth in cm

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

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

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

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

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

Tissue models and equipment survey

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

A homogeneous tissue model with attenuation coefficient of 0.3 dB/cm MHz throughout the beam path is commonly used when estimating exposure levels. The model is conservative in that it overestimates the *In Situ* acoustic exposure when the path between the transducer and site of interest is composed entirely of soft tissue. When the path contains significant amounts of fluid, as in many first and second-trimester pregnancies scanned transabdominally, this model may underestimate the *In Situ* acoustic exposure. The amount of underestimation depends upon each specific situation.

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

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

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

- A survey of 1990-equipment models yielded MI values between 0.1 and 1.0 at their highest output settings. Maximum MI values of approximately 2.0 are known to occur for currently available equipment. Maximum MI values are similar for real-time 2D and M Mode imaging.

- Computed estimates of upper limits to temperature elevations during transabdominal scans were obtained in a survey of 1988 and 1990 pulsed Doppler equipment. The vast majority of models yielded upper limits less than 1° and 4°C (1.8° and 7.2°F) for exposures of first-trimester fetal tissue and second-trimester fetal bone, respectively. The largest values obtained were approximately 1.5°C (2.7°F) for first-trimester fetal tissue and 7°C (12.6°F) for second-trimester fetal bone. Estimated maximum temperature elevations given here are for a "fixed path" tissue model and are for devices having I_{SPTA} values greater than 500 mW/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 8 through Table 13 indicate the acoustic output for the system and transducer combinations with a thermal index or mechanical index 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 78.

Table 8: Transducer Model: *C11x/8-5* **Operating Mode: *CPD/Color***

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			(a)	(a)	—	—	—	1.2
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	#					
	W_0	(mW)		#	—		—	40.50
	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)	#	#	—	—	—	4.38
	Dim of A_{aprt}	X (cm)		#	—	—	—	0.36
		Y (cm)		#	—	—	—	0.5
Other Information	PD	(µsec)	#					
	PRF	(Hz)	#					
	$p_r@PII_{max}$	(MPa)	#					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		#	—	—		1.56
		FL_y (cm)		#	—	—		2.5
	$I_{PA.3}@MI_{max}$	(W/cm^2)	#					
Operating Control Conditions	Control 1: Mode							CPD
	Control 2: Exam Type							Vas
	Control 3: PRF							2841
	Control 4: Optimization/Depth							Med/2.0
	Control 5: Color Box Position/ Size							Top/ Short

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

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

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

— Data are not applicable for this transducer/mode.

Table 9: Transducer Model: *C60x/5-2* **Operating Mode: *2D***

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.0	(a)	—	—	—	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	1.59					
	W_0	(mW)		#	—		—	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	5.3				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	2.86	#	—	—	—	#
	Dim of A_{aprt}	X (cm)		#	—	—	—	#
		Y (cm)		#	—	—	—	#
Other Information	PD	(µsec)	0.579					
	PRF	(Hz)	7923					
	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		Any					
	Control 2: Optimization		Pen					
	Control 3: Depth		6.6 cm					
	Control 4: THI		On					

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

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

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

— Data are not applicable for this transducer/mode.

Table 10: Transducer Model: *HFL38x/13-6* **Operating Mode: *CPD/Color***

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.1	1.0	—	—	—	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.556					
	W_0	(mW)		53.49	—		—	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.2				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	5.328	5.324	—	—	—	#
	Dim of A_{aprt}	X (cm)		0.44	—	—	—	#
		Y (cm)		0.4	—	—	—	#
Other Information	PD	(µsec)	0.525					
	PRF	(Hz)	2597					
	p_r@PII_{max}	(MPa)	3.187					
	d_{eq}@PII_{max}	(cm)					—	
	Focal Length	FL_x (cm)		1.32	—	—		#
		FL_y (cm)		2.5	—	—		#
	$I_{PA.3}$@MI_{max}	(W/cm^2)	325.5					
Operating Control Conditions	Control 1: Mode		Color	Color				
	Control 2: Exam Type		Any	Any				
	Control 3: Optimization/Depth/PRF		Low/3.3 cm/ 393	Med/ 2.7 cm/ 1938				
	Control 4: Color Box Position/Size		Any	Top/ Short				

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

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

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

— Data are not applicable for this transducer/mode.

Table 11: Transducer Model: *L38x/10-5* **Operating Mode: *CPD/Color***

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.3	1.0	—	—	—	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.89					
	W_0	(mW)		64.88	—		—	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	1.1				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	4.91	4.91	—	—	—	#
	Dim of A_{aprt}	X (cm)		0.54	—	—	—	#
		Y (cm)		0.4	—	—	—	#
Other Information	PD	(µsec)	0.529					
	PRF	(Hz)	9547					
	$p_r@PII_{max}$	(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		331	2137				
	Control 4: Optimization/Depth		Any/3.1	Med/3.1				
	Control 5: Color Box Position/Size		Any	Def/ Def/Def				

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

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

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

— Data are not applicable for this transducer/mode.

Table 12: Transducer Model: *P21x/5-1* **Operating Mode: *2D***

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.3	1.1	—	—	—	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	1.83					
	W_0	(mW)		122.87	—		—	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	5.1				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	1.84	1.88	—	—	—	#
	Dim of A_{aprt}	X (cm)		0.590	—	—	—	#
		Y (cm)		1.3	—	—	—	#
Other Information	PD	(µsec)	0.963					
	PRF	(Hz)	4421					
	$p_r@PII_{max}$	(MPa)	2.574					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		1.55	—	—		#
		FL_y (cm)		5.5	—	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	209.0					
Operating Control Conditions	Control 1: Exam Type		Card	Abd/OB				
	Control 2: Optimization		Pen/ Gen	Any				
	Control 3: Depth		4.7/7.6 cm	4.7				
	Control 4: THI		On	On				

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

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

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

— Data are not applicable for this transducer/mode.

Table 13: Transducer Model: *P21x/5-1* **Operating Mode: *CPD/Color***

Index Label			M.I.	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.5	1.3	—	—	—	(b)
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.19					
	W_0	(mW)		136.91	—		—	#
	min of $[W_{.3}(z_1), I_{TA.3}(z_1)]$	(mW)				—		
	z_1	(cm)				—		
	z_{bp}	(cm)				—		
	z_{sp}	(cm)	4.5				—	
	$d_{eq}(z_{sp})$	(cm)					—	
	f_c	(MHz)	2.15	2.16	—	—	—	#
	Dim of A_{aprt}	X (cm)		0.918	—	—	—	#
		Y (cm)		1.3	—	—	—	#
Other Information	PD	(µsec)	1.20					
	PRF	(Hz)	1063					
	$p_r@PII_{max}$	(MPa)	2.574					
	$d_{eq}@PII_{max}$	(cm)					—	
	Focal Length	FL_x (cm)		3.68	—	—		#
		FL_y (cm)		5.5	—	—		#
	$I_{PA.3}@MI_{max}$	(W/cm^2)	330.4					
Operating Control Conditions	Control 1: Mode		Color	CPD				
	Control 2: Exam Type		Abd/ OB	OB				
	Control 3: PRF/Depth		300/10	850/7.5				
	Control 4: Color Optimization		Any	Med				
	Control 5: THI		On	Off				
	Control 6: Color Box Size		Any	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.

Terms used in the acoustic output tables

Table 14: 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 14: 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 15: 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%

Table 15: Acoustic Measurement Precision and Uncertainty (Continued)

Quantity	Precision (% of standard deviation)	Uncertainty (95% confidence)
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 16: Labeling Symbols

Symbol	Definition
	Alternating Current (AC)
	Class 1 device indicating manufacturer's declaration of conformance with Annex VII of 93/42/EEC
 0086	Class 1 device requiring verification by the Notified Body of sterilization or measurement features, or to a Class IIa, IIb, or III device requiring verification or auditing by the Notified Body to applicable Annex(es) of 93/42/EEC
	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.

Table 16: Labeling Symbols (Continued)

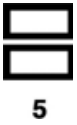
Symbol	Definition
REF	Catalog number
	Collect separately from other household waste (see European Commission Directive 93/86/EEC). Refer to local regulations for disposal.
STERILE EO	Contents sterilized using ethylene oxide process.
	Corrugated recycle
	Dangerous voltage
	Date of manufacture
	Direct Current (DC)
	Do not get wet.
	Do not stack over 2 high.
	Do not stack over 5 high.
	Do not stack over 10 high.
	Electrostatic sensitive devices
	Device complies with relevant FCC regulations for electronic devices.

Table 16: Labeling Symbols (Continued)

Symbol	Definition
	Fragile
GEL STERILE R	Gel sterilized by radiation.
	Hot
	Indoor use only
	Device emits a static (DC) magnetic field.
	Non-ionizing radiation
	Paper recycle
SN	Serial number type of control number
	Storage temperature conditions
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

Table 16: Labeling Symbols (Continued)

Symbol	Definition
	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.)
WARNING: Connect Only Accessories and Peripherals Recommended by SonoSite	WARNING: Connect Only Accessories and Peripherals Recommended by SonoSite

Chapter 7: 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)
- 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)
- P21x/5-1 MHz(6 ft/1.8 m)

Imaging modes

- 2D (256 gray shades)
- Color power Doppler (CPD) (256 colors)
- Color Doppler (Color) (256 colors)

Images and clips storage

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

Accessories

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

- Battery
- Biopsy Guide
- Needle Guide
- Power supply
- System AC power cord (10 ft/3.1 m)
- S Series stand

Peripherals

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

Medical grade	• Black-and-white printer Recommended sources for printer paper: Contact Sony at 800-686-7669 or www.sony.com/professional to order supplies or to find the local distributor. • DVD recorder
Non-medical grade	• Kensington Security Cable • USB keyboard

Temperature and humidity limits

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

Table 1: Operating Limits

System	Battery	Transducer
10–40°C (50–104°F), 15–95% R.H. 700 to 1060hPa (0.7 to 1.05 ATM)	10–40°C (50–104°F), 15–95% R.H. 700 to 1060hPa (0.7 to 1.05 ATM)	10–40°C (50–104°F), 15–95% R.H.

Table 2: Shipping and Storage Limits

System without Battery	Battery	Transducer
-35–65°C (-31–149°F), 15–95% R.H. 500 to 1060hPa (0.5 to 1.05 ATM)	-20–60°C (-4–140°F), 15–95% R.H.* 500 to 1060hPa (0.5 to 1.05 ATM)	-35–65°C (-31–149°F), 15–95% R.H.

* For storage longer than 30 days, store at or below room temperature.

Electrical

Power Supply Input	100-240 VAC, 50/60 Hz, 2.0 A Max @ 100 VAC
Power Supply Output #1	15 VDC, 5.0 A Max
Power Supply Output #2	12 VDC, 2.3 A Max

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 A1:2005, 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 (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
Abd	Abdomen
Bre	Breast
CPD	Color Power Doppler
Crd	Cardiac
MB	SonoMB
MI	Mechanical Index
Msk	Musculoskeletal
Nrv	Nerve
NTSC	National Television Standards Committee
OB	Obstetrical
S	SonoHD imaging technology
SmP	Small Parts
THI	Tissue Harmonic Imaging
TI	Thermal Index
Vas	Vascular
Ven	Venous

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Numerics

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