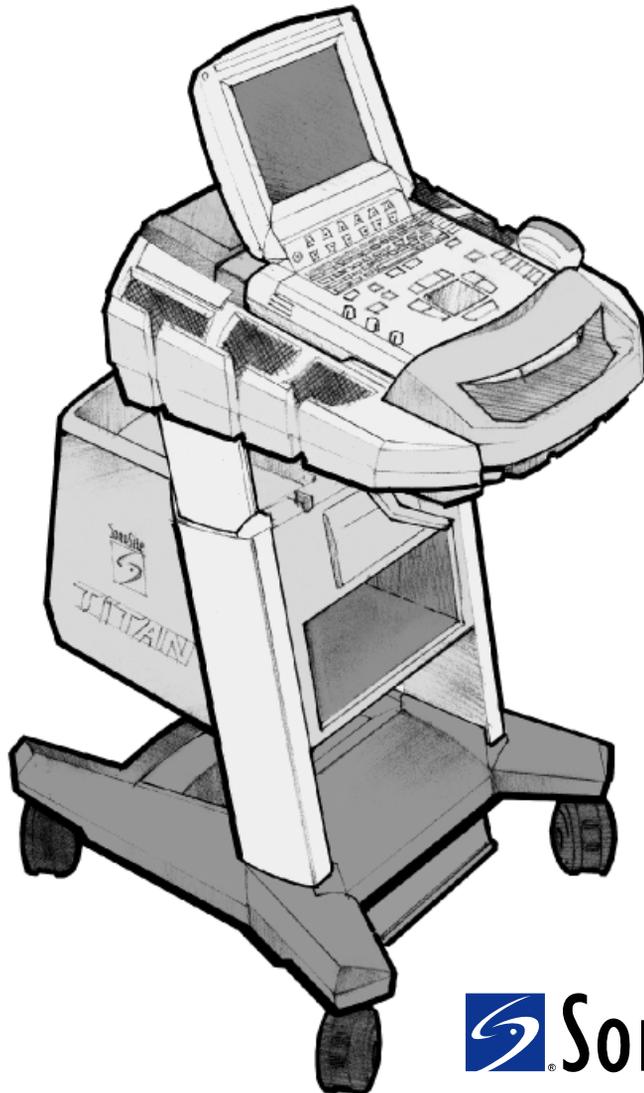

TITAN[®]

Ultrasound System User Guide



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 SonoSite[®]

TITAN[®]

Ultrasound System User Guide

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Chapter 1: Introduction

Please read the information in this user guide before using the *TITAN*[®] high-resolution ultrasound system. It applies to the ultrasound system, and transducers.

About the User Guide

This user guide is a reference for using the ultrasound system. It is designed 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.

The user guide covers the preparation, use, and maintenance of the ultrasound system, transducers, and accessories. Refer to the manufacturers' instructions for specific information about peripherals.

The user guide includes a table of contents and an index to help you find the information that you need. The user guide is divided into the following chapters:

| | | |
|-----------|-----------------------------------|---|
| Chapter 1 | "Introduction" | Contains general information about the user guide and the system. Customer assistance information is also included. |
| Chapter 2 | "Getting Started" | Contains information on healthy scanning practices, basic operation, and changing system settings. |
| Chapter 3 | "Imaging" | Contains detailed information about preparing for the exam, entering patient information, adjusting imaging modes, annotating images, saving images and reviewing patient images. |
| Chapter 4 | "Measurements and Calculations" | Contains information on performing measurements and calculations in the different imaging modes. |
| Chapter 5 | "DICOM Connectivity" | Contains instructions for configuring and using DICOM. |
| Chapter 6 | "Safety" | Contains information required by various regulatory agencies, including information about the ALARA (as low as reasonably achievable) principle, the output display standard, acoustic power and intensity tables, intended uses, and other safety information. |
| Chapter 7 | "Troubleshooting and Maintenance" | Contains information to assist in the correction of problems with system operation. Also contains information about proper care of the system, transducers, and accessories. |
| Chapter 8 | "References" | Contains information about measurement accuracy and the sources from which the system measurements and calculations are derived. |

| | | |
|------------|------------------|--|
| Chapter 9 | “Specifications” | Contains system and accessory specifications and agency approvals. Specifications for recommended peripherals can be found in the manufacturers’ instructions. |
| Chapter 10 | “Glossary” | Contains definitions of ultrasound system terms and features. |

Conventions Used in This User Guide

These conventions are used in this user guide:

- A **Warning** describes precautions necessary to prevent injury or loss of life.
- A **Caution** describes precautions necessary to protect the products.
- When the steps in the operating instructions must be performed in a specific order, the steps are numbered.
- Bulleted lists present information in list format, but they do not imply a sequence.
- The system handle is on the front of the system, and the battery compartment is on the back of the system.

Symbols and Terms Used in This User Guide

Symbols and terms used on the system, are explained in “Screen Layout” on page 16, Chapter 5, “DICOM Connectivity” and/or Chapter 10, “Glossary.”

Upgrades and User Guide Updates

SonoSite may offer software upgrades, new features, and improvements to the system performance. User guide updates accompany the upgrade software and provide detailed information on the enhancements.

Customer Comments

Questions and comments are encouraged. SonoSite is interested in your feedback regarding the system and the user guide. Please call SonoSite at **1-888-482-9449**. If you are outside the USA, call the nearest SonoSite representative. You can also send electronic mail (e-mail) to SonoSite at the following address: **comments@sonosite.com**.

About the System

The ultrasound system has multiple configurations and feature sets. All are described in this user guide but not every option may apply to your system. System features are dependent on your system configuration, transducer, and exam type.

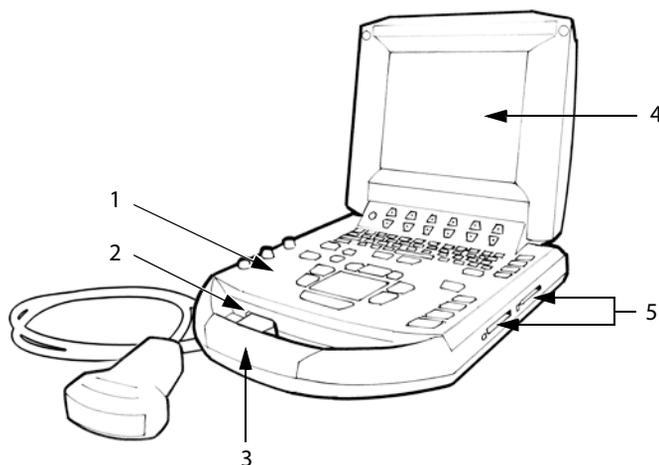


Figure 1 TITAN System Front View

Table 1: System Front Features

| Number | Feature |
|--------|---|
| 1 | Control panel |
| 2 | Transducer connection |
| 3 | Handle |
| 4 | Display |
| 5 | CompactFlash™ slots (front for image storage, back for system and transducers updates, import/export OB tables, user names/passwords, and DICOM configurations) |

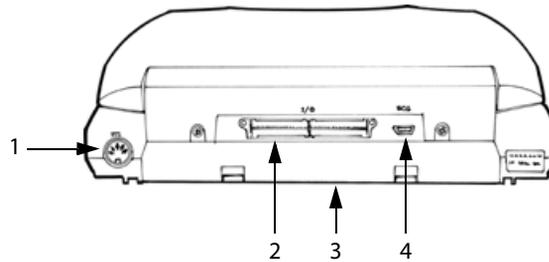


Figure 2 TITAN System Back View

Table 2: System Back Connectors

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

The TITAN system is a portable, software-controlled, ultrasound system using all-digital architecture. The system is used to acquire and display high-resolution, real-time ultrasound images: 2D, color power Doppler (CPD), directional color power Doppler (DCPD), Color Doppler (Color), Tissue Harmonic Imaging (THI), M Mode, pulsed wave (PW) Doppler, and continuous wave (CW) Doppler. The system has cine buffer, image zoom, labeling, biopsy, measurements, calculations, a USB connection for image transfer, image storage, image review, printing, recording, and the ability to archive Doppler with audio output to a videotape.

Currently, the system supports the following broadband transducers:

- C8/8-5 MHz 8 mm microcurved array
- C11/8-5 MHz 11 mm microcurved array
- C15/4-2 MHz 15 mm microcurved array
- C60/5-2 MHz 60 mm curved array
- HST/10-5 MHz 25 mm linear array
- ICT/8-5 MHz 11 mm intracavitary array
- L25/10-5 MHz 25mm linear array
- L38/10-5 MHz 38 mm linear array

System accessories include the following: *TITAN* mobile docking system, *TITAN* MDS Lite, *TITAN* mini-dock, Triple Transducer Connect, a power supply, a battery, ECG cable, video and printer cables, SiteLink Image Manager 2.2 software, and DICOM connectivity. See the *TITAN Accessory User Guide* for information on the accessories.

System peripherals include medical grade (conforming to the requirements of EN60601-1) and non-medical (commercial) grade products. System medical grade peripherals include a printer, VCR, and DVD. System non-medical grade peripherals include a CompactFlash card and a Kensington Security Cable. System setup instructions for the use of peripherals are covered in [Chapter 2, "System Setup" on page 21](#).

Manufacturer's instructions accompany each peripheral. Instructions for the use of peripherals with the system are covered in the *TITAN Accessory User Guide*.

About the System Software

The ultrasound system contains software that controls its operation. A software upgrade may be required. SonoSite will provide you with a CompactFlash card containing the software. Typically new software provides new capabilities. A single CompactFlash card can be used to update one or more systems. Software upgrades use the back CompactFlash slot on the right hand side of the system. CompactFlash cards installed in the front CompactFlash slot do not upgrade the system.

Chapter 2: Getting Started

This chapter contains information on healthy scanning practices, basic operation, and changing system settings.

Healthy Scanning Guidelines

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

Warning:

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 between the operator, the ultrasound system, and 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

To promote comfortable shoulder, arm and hand postures, consider the following:

- Use the TITAN mobile docking system to support the weight of the ultrasound system.

To minimize eye strain, consider the following:

- When the exam/procedure allows, position the system within reach.
- Adjust the angle of the system/display to minimize glare from overhead or outside lighting.

To minimize neck strain, consider the following:

- If using a stand, adjust the stand height such that the display is at or slightly below eye level.

Position Yourself

To support your back, consider the following:

- Use a chair that has support for your lower back.
- Use a chair that adjusts to your work surface height and promotes a natural body posture.
- Use a chair that allows for quick height adjustments.
- Always sit or stand in an upright manner. Avoid bending or stooping.

To minimize reaching and twisting, consider the following:

- Use a bed which 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.

To promote comfortable shoulder and arm postures for your scanning arm, consider the following:

- 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.

To minimize neck bending and twisting, consider the following:

- Position the ultrasound system/display directly in front of you.
- Provide an auxiliary monitor for patient viewing.

Go Lightly

To promote comfortable hand, wrist, and finger postures for your scanning arm, consider the following:

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

Take Breaks

Minimizing scanning time and taking breaks can be very effective in allowing your body to recover from physical activity, which can help you avoid any 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.

To vary your daily activities, consider the following:

- Plan your work so there are breaks in between ultrasound exams.
- Work efficiently when performing an ultrasound exam by using the software and hardware features correctly. Learn more about these features in [Chapter 3](#) of this guide.
- Keep moving. Avoid sustaining the same posture by varying your head, neck, body, arm, and leg positions.

Exercise

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.

System Preparation

Installing or Removing Battery

The battery comprises six lithium-ion cells plus electronics, a temperature sensor, and battery contacts.

If the battery is being installed for the first time, it will need to be charged.

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

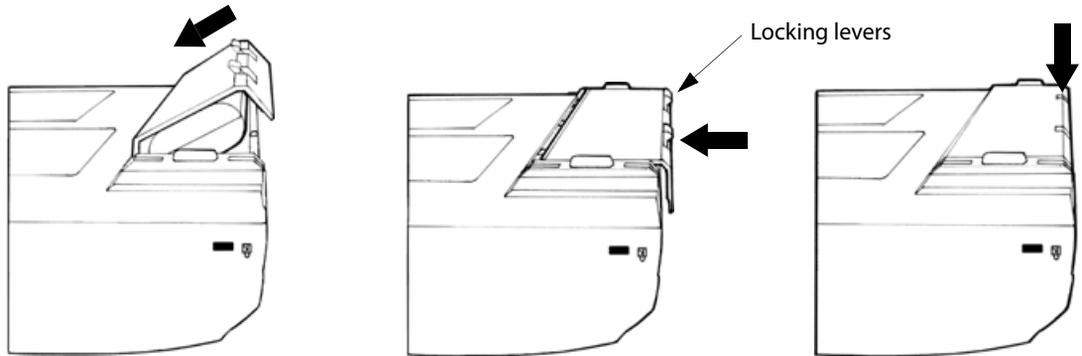


Figure 1 Insert Battery into System

To install the battery:

- 1 Turn the system upside down.
- 2 Place the battery into the battery compartment, at a slight angle. See [Figure 1](#).
- 3 Slide the battery forward until it locks into place.
- 4 Push down on the two locking levers to secure battery.

To remove battery:

- 1 Push up on the two locking levers.
- 2 Slide the battery back.
- 3 Lift the battery from the compartment.

Installing and Removing the CompactFlash Card

Images are saved to a CompactFlash card and are organized in a patient list. The images in the patient list are organized alphabetically by the patient name and ID. Images are archived from the system to a PC using a USB or Ethernet connection. Images on the CompactFlash card cannot be read directly from a CompactFlash card reader.

To install the CompactFlash card:

- 1 Verify the ejector pin is fully pushed in.
- 2 Insert the CompactFlash card into the front slot on the ultrasound system. See [Figure 1 on page 3](#).

The front slot is used to store images. The back slot is used to update systems/transducers and to import/export DICOM configuration information and OB Tables.

The CompactFlash card is ready to use when the save icon and the image memory counter, showing the remaining available memory, are displayed on the screen.

To remove the CompactFlash card:

Warning:

To prevent loss of data, loss of images, or damage to the CompactFlash card, turn the ultrasound system off before removing the CompactFlash card. When the CompactFlash card is removed before turning off the ultrasound system, the system must be restarted.

- 1 Turn off the ultrasound system before removing the card.
- 2 Press the ejector pin in the front card slot to position it to the outside of the system. See [Figure 1 on page 3](#).
- 3 Press in the ejector pin to eject the CompactFlash card.
Note: If the CompactFlash card does not eject properly, try a new card.
- 4 Remove the card.
- 5 Push in the ejector pin to avoid damaging the ejector pin.

Using AC Power/Charging Battery

The battery charges when the system is connected to the AC power supply. If the system is off and connected to AC power, a completely discharged battery will fully charge in 2.5 to 3.5 hours. If the system is on and connected to AC power, a completely discharged battery will fully charge in 5 to 6 hours.

The system can run on AC power and charge the battery in three ways.

- Connected directly to the system
- Connected to the mini-dock (See the *TITAN Accessory User Guide*.)
- Connected to the docking system (See the *TITAN Accessory User Guide*.)

To operate the system using AC power (directly to system):

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 the hospital supply voltage corresponds to the power supply voltage range. See “[Electrical](#)” on page 206.

- 1 Connect the DC power cable from the power supply to the connector on the system. See [Figure 2 on page 4](#).
- 2 Connect the AC power cord to the power supply and connect to a hospital-grade electrical outlet.

Turning System On/Off

To turn the system on/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.

- 1 Locate the **Power** key on the top left side of the system. See [Figure 3 on page 14](#).
- 2 Press the **Power** key once to turn on and once to turn off.

To wake up the system:

To conserve battery life, the system is configured to go into sleep mode. The system goes into sleep mode when the lid is closed or if the system has not been touched for a preset amount of time. Press any key, touch the touchpad, or open the lid to wake up the system. To adjust the time for sleep delay, see “[To set up Audio and Battery:](#)” on page 28.

Connecting and Removing the Transducer

Warning: The transducer connector can become hot during operation. This is normal. Operate the system in the docking system or on a flat, hard surface to allow air flow past the connector.

Caution: The electrical contacts inside the system transducer connector may be damaged by foreign material. Keep foreign material out of the connector.

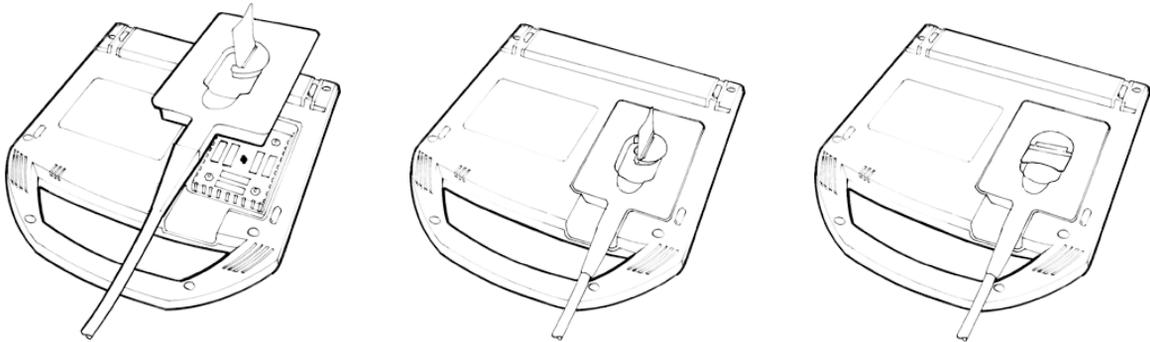


Figure 2 Connect the Transducer

To connect the transducer:

- 1 Turn the system upside down (if not in docking system).
- 2 Pull the transducer latch up and rotate it clockwise.
- 3 Align the transducer connector with the connector on the bottom of the system.
- 4 Insert the transducer connector into the system connector.
- 5 Turn the latch counterclockwise.
- 6 Press the latch down, securing the transducer connector to the system.

To remove the transducer:

- 1 Pull the latch up and rotate it clockwise.
- 2 Pull the transducer connector away from the system.

System Controls

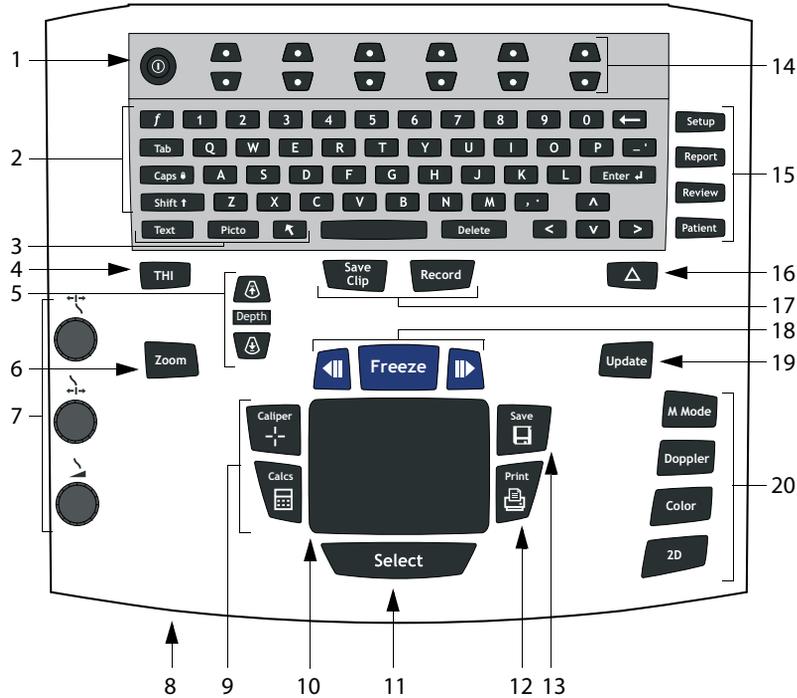


Figure 3 System Controls

Table 1: System Controls

| Number | System Control | Description | |
|--------|----------------|---|--|
| 1 | Power | Turns system on and off. | |
| 2 | Alphanumeric | Use to enter text and numbers. | |
| 3 | Annotation | Text Picto Arrow | Turns the keyboard on and off for text entry. Turns the pictographs/pictograph marker on and off. Displays an arrow that can be moved and rotated within the image area. |
| 4 | THI | Turns Tissue Harmonic Imaging on and off. | |
| 5 | Depth | Depth Depth Up Depth Down | Adjusts the imaging depth for 2D. Decreases imaging depth. Increases imaging depth. |

Table 1: System Controls (Continued)

| Number | System Control | Description |
|--------|--|--|
| 6 | Zoom | Magnifies image 2x. |
| 7 | Gain |  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. <i>Note: Some keyboards may have the words instead of the symbols.</i> |
| 8 | AC power indicator | A steady green light indicates AC power is connected. A flashing green light indicates the system is in sleep mode. |
| 9 | Caliper/Calcs | Caliper activates a measurement caliper on the screen. Calcs turns the calculation menu on and off. |
| 10 | Touchpad | Use to select, adjust, and move objects on the screen. |
| 11 | Select | Use to switch between frozen images in duplex and dual screens. color and Doppler menus, calipers for measurement (calipers), pictograph marker position/angle (picto), arrow position/orientation (arrow). |
| 12 | Print | Prints the active image to the printer. |
| 13 | Save | Saves an image to the CompactFlash card. Saves an image to the CompactFlash card and saves measurements/calculation to the report when configured in system setup. |
| 14 | Remappable controls | Controls features on the context menu which are adjusted based on the system state. |
| 15 | Forms | Setup Access to the system settings. Report Access to the patient report. Review Access to the patient list and saved patient images, and archive functions. Patient Access to patient information. |
| 16 |  (Delta key) | Use as a shortcut to existing functionality in the system. |
| 17 | Video recording | Record Turns VCR record on and off. Save Clip (Not available.) |

Table 1: System Controls (Continued)

| Number | System Control | Description |
|--------|----------------|---|
| 18 | Freeze Cine | Freeze Stops the live imaging and displays a frozen image. Cine Review images stored in the cine buffer; (back/forward) back/forward through last-in, first-out sequence. All mode images can be stored and reviewed in the cine buffer. |
| 19 | Update | Toggles between dual and duplex screens and image modes in M Mode and Doppler, e.g., between 2D Doppler sample line and Doppler spectral trace. |
| 20 | Modes | M Mode Turns M Mode on and toggles between M Mode sample line and the M Mode trace. Doppler Turns Doppler on and toggles between Doppler sample line and the Doppler trace. Color Turns CPD/DCPD/Color on and off. 2D Turns 2D on. |

Screen Layout

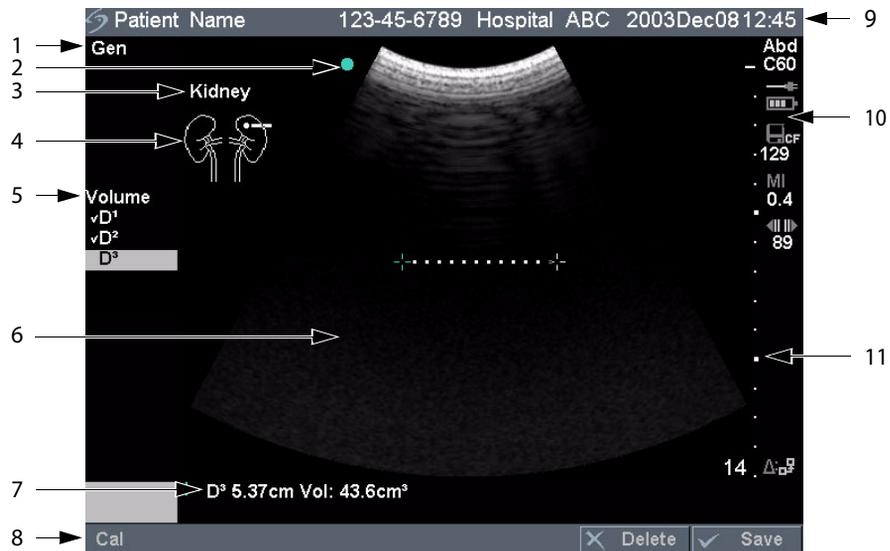


Figure 4 Screen Layout

Table 2: Screen Layout

| Number | Key | Description |
|---------------|----------------------------|---|
| 1 | Mode Data | Displays current imaging mode information, e.g., Gen, Res, THI, and PW. |
| 2 | Orientation Marker | Provides indication for image orientation. In dual and duplex images, the orientation marker is green on the active screen. |
| 3 | Text | Displays text entered using keyboard. |
| 4 | Picto | Displays pictograph to indicate anatomy and transducer position. |
| 5 | Calcs Menu | Displays available calculations. |
| 6 | Image | Displays ultrasound image. |
| 7 | Measurement and Calcs Data | Displays current measurement and calculation data. |
| 8 | Context Menu | Provides context sensitive controls based on the system state. |
| 9 | Patient Header | Displays current patient name, ID number, institution, sonographer, and date/time. |
| 10 | System Status | Displays information related to system status, e.g., exam type, transducer, and AC connected. |
| 11 | Depth Marker | Displays marks in .5 cm, 1 cm, and 5 cm increments depending on the depth. |

General Interaction

Touchpad

The touchpad is used to select, adjust, and move objects on the screen. For example, it controls the caliper position, CPD/DCPD/Color box position and size, floating cursor, and more.

Note: The arrow keys control much of the same functionality as the touchpad.

Context Menu

The context menu, located at the bottom of the screen, provides controls that can be adjusted based on the system state. For example, in 2D with a C60 transducer attached, the following options are available:

Table 3: Context Menu

| Icon | Description | Values | Types |
|--|-----------------------------------|---------------|---------|
|  Gen | Controls 2D image optimization | Res, Gen, Pen | Cycle |
|  L/R | Flips the image left or right | | Action |
|  U/D | Flips the image up or down | | Action |
|  Brightness | Controls display brightness | 1-10 | Up-Down |
|  Biopsy | Turns biopsy guidelines on or off | | On-Off |
|  Dual | Displays side-by-side images. | | On-Off |

Remappable Controls

The remappable controls consists of six sets of 2-button groups at the top of the control panel. They adjust the values of each control displayed in the context menu. The buttons function in one of four ways, depending on context.

Table 4: Remappable Control Options

| Control | Description |
|---------|---|
| Cycle | Moves through a list of values, then begins again when the bottom or top of the list is reached. |
| Up-Down | Stops at the top and bottom of a value list, not allowing user to go from the first to last or last to first value in one button press. |
| On-Off | Turns available features on or off depending on their current state. |
| Action | Performs some action related to an object on the screen. |

Annotation and Text

Keyboard Controls

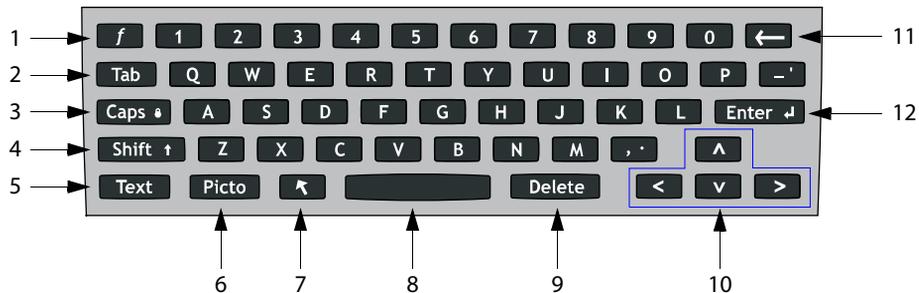


Figure 5 Keyboard Controls

Table 5: Keyboard Controls

| Number | Key | Description |
|--------|----------|--|
| 1 | <i>f</i> | Function key used with numbered key to display predefined text. |
| 2 | Tab | Moves cursor among fields in the forms and tabs between text position in dual screens. |
| 3 | Caps | Locks keyboard in caps mode. |
| 4 | Shift | Allows entry of capitalized characters and international characters. |
| 5 | Text | Turns the keyboard on and off for text entry. |

Table 5: Keyboard Controls (Continued)

| Number | Key | Description |
|--------|------------|--|
| 6 | Picto | Turns pictographs on and off. |
| 7 | Arrow | Displays an arrow that can be moved and rotated within the image area. |
| 8 | Spacebar | Turns the keyboard on for text entry or adds a space. |
| 9 | Delete | Removes one character to the right of the cursor during text entry. |
| 10 | Arrow keys | Moves highlighted selection in calculations menus, moves cursor one space when entering text, moves caliper position, and moves among pages in image review and reports. |
| 11 | Backspace | Removes one character to the left of the cursor in text entry mode. |
| 12 | Enter | Moves cursor among fields in forms and saves calculations to report. |

Symbols

Symbols/special characters can be entered in selected fields and forms:

- Patient Information: Last, First, Middle, ID, Accession, Indications, Procedure ID, Sonographer, Reading Dr., Referring Dr., and Institution.
- Connectivity (DICOM) Configure: Alias, AE Title.
- Delta Key, F Keys: f1 – f0.
- Text mode (Imaging): Annotation field.

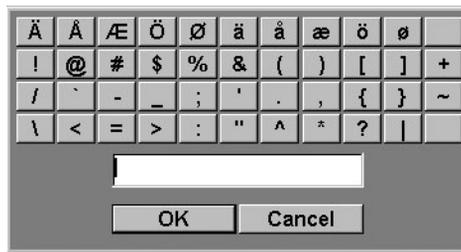


Figure 6 Symbols/Special Characters

To enter a symbol/special character:

- 1 Select the desired field and then select Symbols.
- 2 Click the desired symbol/character.
In the Symbols dialog box, the keyboard controls may also be used.
- 3 Click OK.

Forms

A floating cursor is available in the setup, patient, and report forms. The floating cursor allows interaction to occur using the touchpad and the **Select** key. For example, in the patient form, placing the floating cursor over the last name field and pressing the **Select** key will activate that field. Additionally, the floating cursor can be used to interact with the list and check boxes.

System Setup

System setup is used to customize the system. Press the **Setup** key to access and set up the following system functions:

| | |
|------------------------|--|
| Administration | Configure system to protect patient data by requiring users to log on and enter passwords. |
| Audio, Battery | Configure for type of Audio alert, Sleep delay, and Power delay. |
| Connectivity | Configure Printer, Video mode, Serial Port, and Transfer Mode: DICOM or SiteLink. (DICOM and SiteLink are optional features.) |
| Date and Time | Configure Date and Time functions. |
| Delta Key, F Keys | Configure existing system functionality as a shortcut and create predefined labels for images. |
| Display Information | Configure information displayed on image: patient information, mode data, and system status data. |
| OB Calculations | Select OB calculation authors. |
| OB Custom Measurements | Configure system for user defined measurements. (OB Custom Measurements are an optional feature.) |
| Presets | Configure Preset functions: Doppler Scale, Duplex, Live Trace, Thermal Index, and Save Key. |
| System Information | Displays system hardware and software versions. |

To set up 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.

SonoSite provides a comprehensive set of tools on the TITAN system that allows its customers to meet the applicable security requirements listed in the HIPAA standard. SonoSite's customers are ultimately responsible for ensuring the security and protection of all electronic protected health information collected, stored, reviewed and transmitted on the TITAN system.

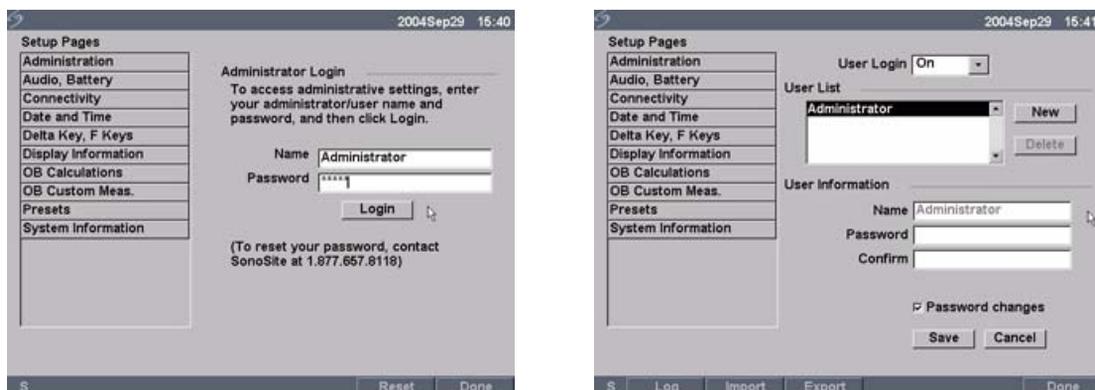


Figure 7 Setup Screens: Administration and Administrator Information

Administrator Login

- 1 Press the Setup key.
- 2 Select Administration.
- 3 In Administrator Login, type Administrator in the Name field.
- 4 Call SonoSite for the password (1-877-657-8118).
- 5 Select Login.

Change Administrator Password

- 1 In User Information, enter your new password in the Password field.
- 2 Enter the password again in the Confirm field.
To ensure passwords are secure, it is recommended that passwords contain characters from the following categories:
 - Upper case characters: A-Z
 - Lower case characters: a-z
 - Numbers: 0-9*Note: The password is case-sensitive.*
- 3 In Password changes, click on the check box to allow users access to change their password or leave unchecked to restrict access. (Optional)
- 4 Select Save.

User Login Setting

- 1 In the User Login list, select On or Off.
 - Selecting On restricts access to the *TITAN* system and requires the user to enter a user name and password.
 - Selecting Off allows access to the *TITAN* system and does not require the user to enter a user name and password.
 - 2 After making changes in the Administration setup, reboot the system to log off as administrator.
-

To add new users:

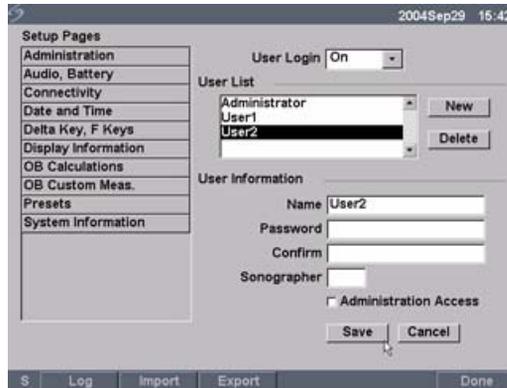


Figure 8 Setup Screen: User List Information

Add New User

- 1 Select New.
- 2 In User Information, enter information in Name, Password, and Confirm fields.

To ensure passwords are secure, it is recommended that passwords contain characters from the following categories:

- Upper case characters: A-Z
- Lower case characters: a-z
- Numbers: 0-9

Note: The name and password are case-sensitive.

- 3 In Sonographer, enter the user's initials to display the information in the patient header and the sonographer field in the Patient Information form. (Optional)
- 4 In Administration Access, click the check box to allow users access to all administration privileges or leave unchecked to restrict access. (Optional)
- 5 Select Save.

Modify User Information

- 1 In the User List, select desired user name.
- 2 Enter the new name.
- 3 Enter the new password and confirm.
- 4 Select Save.
Any change to the user name replaces the old name.

Delete User

- 1 In the User List, select the desired user name.
- 2 Select Delete.
A dialog is displayed.
- 3 Select Yes to delete or No to cancel.

-
- | | |
|-----------------------------|--|
| Change User Password | <ol style="list-style-type: none"> 1 In the User List, select the desired user name. 2 Enter the new password and confirm. 3 Select Save. |
|-----------------------------|--|
-

| | |
|-------------|----------------------------|
| Done | To return to live imaging. |
|-------------|----------------------------|

To export or import user accounts:

Note: Export and import are used to configure multiple systems and to back up user account information.

-
- | | |
|----------------------------|--|
| Export User Account | <ol style="list-style-type: none"> 1 Insert the CompactFlash card in the back slot of the TITAN system. See “Installing and Removing the CompactFlash Card” on page 11. 2 Press the Setup key. 3 Select Administration. 4 Select Export from the on-screen menu. All user names and passwords are copied to the CompactFlash card. 5 Remove the CompactFlash card. |
|----------------------------|--|
-

- | | |
|----------------------------|---|
| Import User Account | <ol style="list-style-type: none"> 1 Insert the CompactFlash card in the back slot of the TITAN system. See “Installing and Removing the CompactFlash Card” on page 11. 2 Press the Setup key. 3 Select Administration. 4 Select Import from the on-screen menu. A dialog box is displayed. 5 After all user names and passwords are imported, the system restarts. <p><i>Note: All user names and passwords currently on the system are replaced with the imported data.</i></p> |
|----------------------------|---|
-

| | |
|--------------|--|
| Reset | To return settings for this setup page to factory default, select Reset from the on-screen menu. |
|--------------|--|

To view, export, and clear event log:

The Event Log collects errors and events and can be exported to a CompactFlash card and read by a CompactFlash card reader.



Figure 9 Event Log

Event Log

- 1 Press the **Setup** key.
- 2 Select Administration.
- 3 Select Log from the on-screen menu.
The Event Log is displayed.
- 4 Select Back to return to the previous menu.

Export Event Log

Note: The Event log and the DICOM network log have the same filename (log.txt). When you export either one to the same CF card, it will overwrite the existing log.txt file.

- 1 Insert the CompactFlash card in the back slot of the TITAN system.
- 2 Select Log and then Export from the on-screen menu.
- 3 View the files on a CompactFlash card reader.
The log is a text file that can be opened by a text file application, e.g., Microsoft Word or Notepad. The log file is named log.txt.

Clear Event Log

- 1 Select Clear from the on-screen menu.
- 2 Select Yes to delete or No to cancel.

To login to system as user:

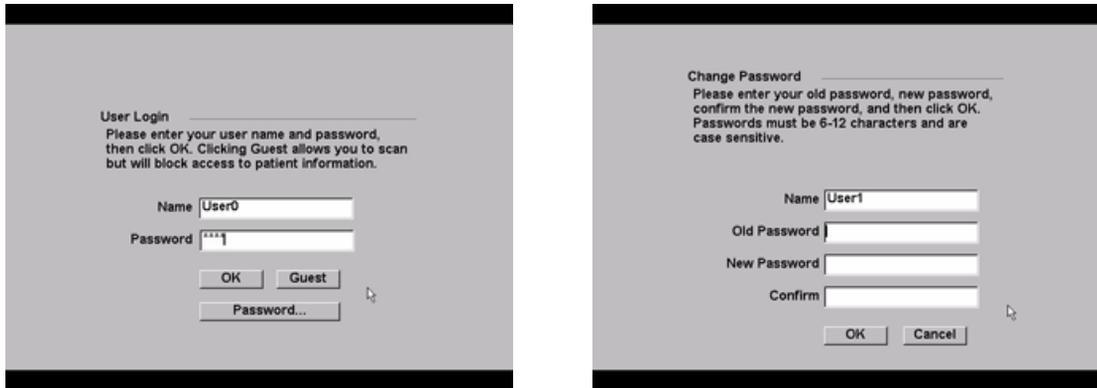


Figure 10 User Login and Change Password

Note: User Login is displayed when system access is turned on.

| | |
|------------------------|--|
| User Login | In User Login, enter Name and Password and click OK. |
| Guest Login | In User Login, select Guest. In Guest mode the user is able to scan but is restricted from accessing system setup and patient information. |
| Change Password | <ol style="list-style-type: none"> In User Login, select Password. Enter your old password, new password, confirm the new password and then click OK. To ensure passwords are secure, it is recommended that passwords contain characters from the following categories: <ul style="list-style-type: none"> • Upper case characters: A-Z • Lower case characters: a-z • Numbers: 0-9 <p><i>Note: The password is case-sensitive.</i></p> |

To set up Audio and Battery:

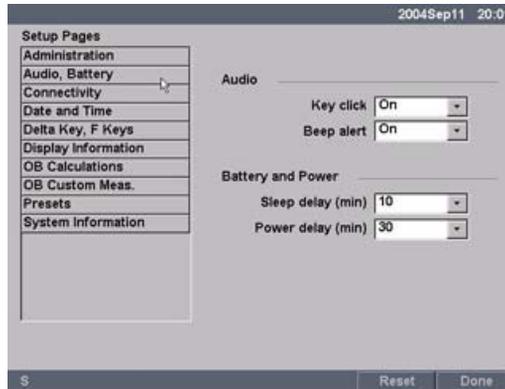


Figure 11 Setup Screen: Audio, Battery

| | |
|--------------------|--|
| Key click | <ol style="list-style-type: none"> 1 Press the Setup key. 2 Select Audio, Battery. 3 In the Key click list, select On or Off. |
| Beep alert | <ol style="list-style-type: none"> 1 Press the Setup key. 2 Select Audio, Battery. 3 In the Beep alert list, select On or Off. |
| Sleep delay | <ol style="list-style-type: none"> 1 Press the Setup key. 2 Select Audio, Battery. 3 In the Sleep delay list, select Off, 5, or 10 minutes. |
| Power delay | <ol style="list-style-type: none"> 1 Press the Setup key. 2 Select Audio, Battery. 3 In the Power delay list, select Off, 15, or 30 minutes. |
| Reset | To return settings for this setup page to factory default, select Reset from the on-screen menu. |

To set up Connectivity:

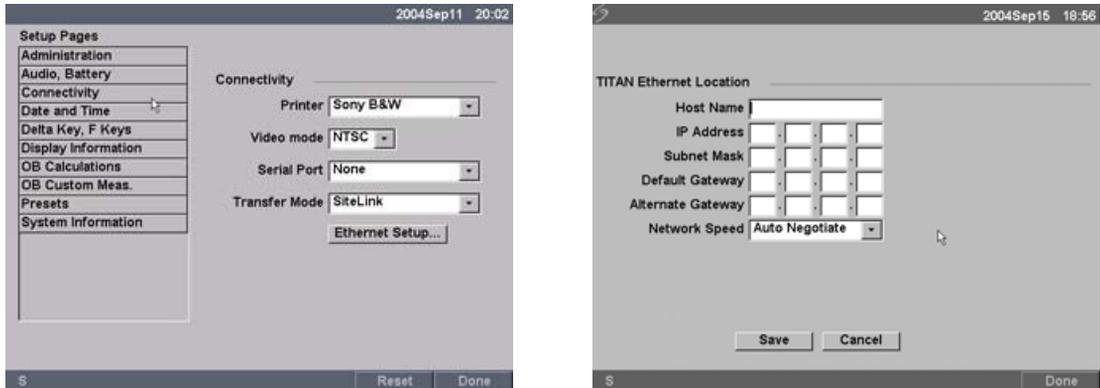


Figure 12 Setup Screens: Connectivity and Ethernet

Printer

- 1 Press the **Setup** key.
- 2 Select Connectivity.
- 3 In the Printer list, select the desired printer from the list of recommended printers.

Video mode

- 1 Press the **Setup** key.
- 2 Select Connectivity.
- 3 In the Video mode list, select NTSC or PAL for the desired mini-dock video output.

Serial Port

- 1 Press the **Setup** key.
- 2 Select Connectivity.
- 3 In the Serial Port list, select VCR, DVD, or Computer (PC).
- 4 Restart the system to activate VCR or DVD connectivity.
- 5 Attach a serial cable (RS-232) to the serial port from the TITAN mini-dock/TITAN docking system to the VCR, DVD, or PC.

Note: If PC is selected, the system allows report data to be sent as ASCII text from the TITAN system to a PC. Special third party software must be on the PC to acquire, view, or format the data into a report. Check the compatibility of your software with SonoSite technical support.

Transfer Mode

- 1 Press the **Setup** key.
- 2 Select Connectivity.
- 3 In the Transfer Mode list, select DICOM or SiteLink.
After changing connectivity, a dialog box is displayed to restart the system.

Note: The settings for SiteLink Image Manager and TITAN configurations must correspond. See the SiteLink Image Manager 2.2 User Guide.

| | |
|------------------------------|--|
| Ethernet Connectivity | <ol style="list-style-type: none">1 Press the Setup key.2 Select Connectivity.3 In the Transfer Mode list, select SiteLink. After changing connectivity, a dialog box is displayed to restart the system. |
| Ethernet Setup | <ol style="list-style-type: none">1 Press the Setup key.2 Select Connectivity.3 Select Ethernet Setup.4 Enter information in the following fields: (see DICOM chapter for definition of terms)<ul style="list-style-type: none">• Host Name• IP Address• Subnet Mask• Default Gateway• Alternate Gateway5 In the Network Speed list, select from the list.6 Select Save. |
| Reset | To return settings for this setup page to factory default, select Reset from the on-screen menu. |

To set Date and Time:

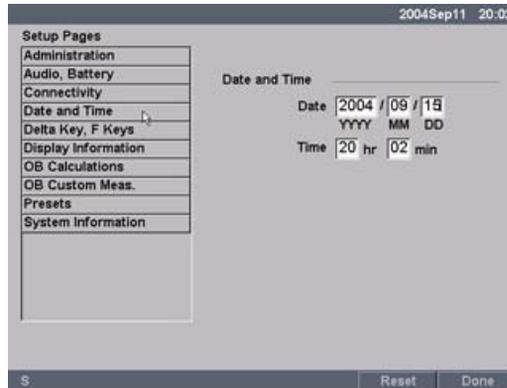


Figure 13 Setup Screen: Date and Time

Warning: An accurate date and time are critical for accurate obstetrics calculations. Verify that the date and time are accurate before each use of the system. The system does not automatically adjust for daylight savings time changes.

| | |
|--------------|--|
| Date | <ol style="list-style-type: none"> 1 Press the Setup key. 2 Select Date and Time. 3 In the Date field, enter the current date (year, month, and day). |
| Time | <ol style="list-style-type: none"> 1 Press the Setup key. 2 Select Date and Time. 3 In the Time field, enter the current time in 24 hour format (hours and minutes). |
| Reset | To return settings for this setup page to factory default, select Reset from the on-screen menu. |

To set up Delta Key and F Keys:

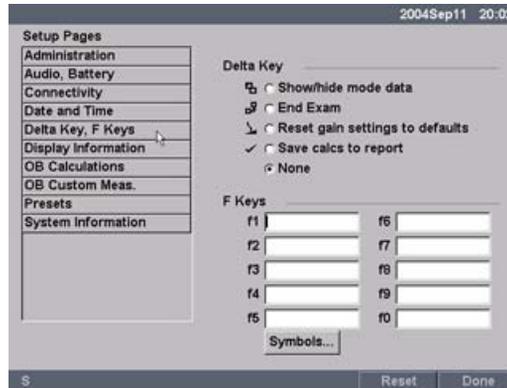


Figure 14 Setup Screen: Delta Key, F Keys

Delta Key

- 1 Press the **Setup** key.
- 2 Select Delta Key, F Keys.
- 3 Select desired functionality for the Delta key.
The Delta key will now control this function.

F Keys

- 1 Press the **Setup** key.
- 2 Select Delta Key, F Keys.
- 3 Type desired text. Use the **Backspace** key or **Delete** key to correct mistakes.

Reset

To return settings for this setup page to factory default, select Reset from the on-screen menu.

To set up Display Information:

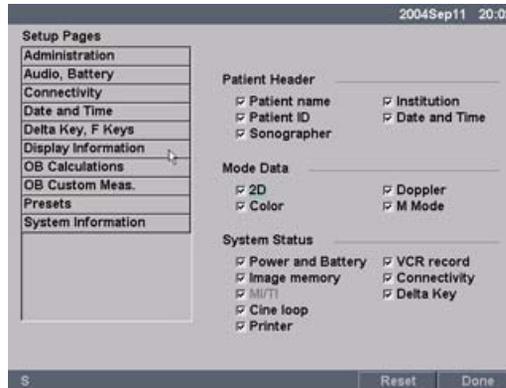


Figure 15 Setup Screen: Display Information

| | |
|-----------------------|--|
| Patient Header | <ol style="list-style-type: none"> 1 Press the Setup key. 2 Select Display Information. 3 Select the desired check boxes to display desired information in the patient header. |
| Mode Data | <ol style="list-style-type: none"> 1 Press the Setup key. 2 Select Display Information. 3 Select the desired check boxes to display imaging information on the screen. |
| System Status | <ol style="list-style-type: none"> 1 Press the Setup key. 2 Select Display Information. 3 Select the desired check boxes to display the system status on the screen. |
| Reset | To return settings for this setup page to factory default, select Reset from the on-screen menu. |

To set up OB calculations authors:

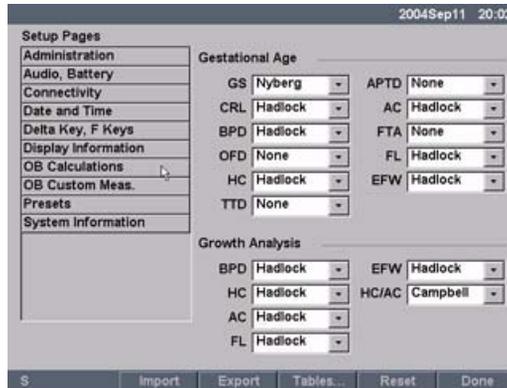


Figure 16 Setup Screen: OB Calculations

Gestational Age Growth Analysis

- 1 Press the **Setup** key.
- 2 Select OB Calculations.
- 3 In Gestational Age or Growth Analysis lists, select the desired OB authors.
Selecting an author places the measurement on the calculation menu and selecting None removes the measurement from the calculation menu.

More...

More... displays the list of user defined custom measurements and allows you to associate a custom table for the custom measurement. This is only available when a user defined custom table has been created for the custom measurement.

Export

- 1 Insert a blank CompactFlash card in the back slot of the TITAN system.
- 2 Press the **Setup** key.
- 3 Select OB Calculations.
- 4 Select Export from the on-screen menu.
All user defined tables and measurements are copied to the CompactFlash card.

| | |
|------------------|---|
| Import | <ol style="list-style-type: none">1 Insert the CompactFlash card in the back slot of the TITAN system.2 Press the Setup key.3 Select OB Calculations.4 Select Import from the on-screen menu.5 After all user defined tables and measurements are imported, the system restarts. <i>Note: All user defined tables and measurements currently on the system are replaced with imported data.</i>6 Select Done from the on-screen menu to return to live imaging. |
| Tables... | Tables... displays system OB tables or is used to create custom OB tables. See "To view and set up OB custom tables:" on page 37. |
| Reset | To return settings for this setup page to factory default, select Reset from the on-screen menu. |

To set up OB custom measurements:

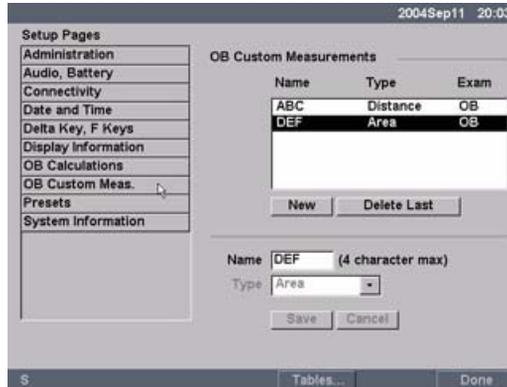


Figure 17 Setup Screen: OB Custom Measurements

OB Custom Measurements

- 1 Press the **Setup** key.
- 2 Select OB Custom Meas.
- 3 Select New.
- 4 In the Name field, enter a unique name.
- 5 In the Type list, select the desired measurement type.
- 6 Select Save.

The new measurement is displayed in the calculations menu and the OB report. Up to five custom measurements may be saved.

Delete OB Custom Measurement

- 1 Press the **Setup** key.
- 2 Select OB Custom Meas.
- 3 In the Custom Measurements list, highlight the last measurement.
- 4 Select Delete Last.

Note: If associated tables and report data exist for the measurement, they will be removed from the system.

Tables...

Select Tables... from the on-screen menu to create Gestational Age tables for a custom OB measurement. See [“To view and set up OB custom tables:”](#).

To view and set up OB custom tables:

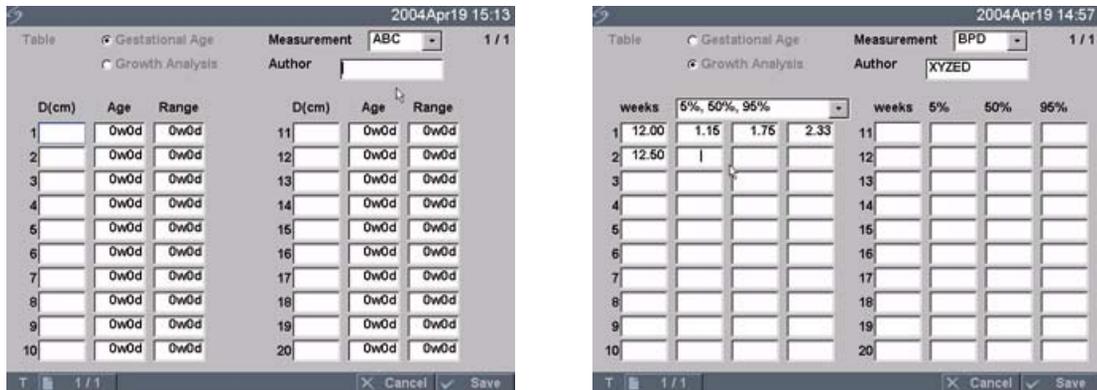


Figure 18 Setup Screen: OB Custom Table

Age Table Measurements: The system provides gestational age measurements by selected authors for the age table measurements listed in [Table 6](#).

Growth Analysis Table Measurements: The system provides growth graphs or curves for the growth table measurements listed in [Table 6](#).

Table 6: OB Custom Table Measurements

| | |
|------------------------------------|---|
| Age Table Measurements | GS, CRL, BPD, OFD, HC, TTD, AC, FTA, FL, 5 additional custom measurement labels |
| Growth Analysis Table Measurements | BPD, HC, AC, FL, EFW |

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

View OB Tables

- 1 Press the **Setup** key.
- 2 Select **OB Custom Meas.** or **OB Calculations**.
- 3 Select **Tables...** from the on-screen menu.
- 4 Select the desired table (**Age** or **Growth**) and measurement/author.

Create New OB Custom Tables

- 1 Press the **Setup** key.
- 2 Select OB Custom Meas. or OB Calculations.
- 3 Select Tables... from the on-screen menu.
- 4 Select the desired table (Age or Growth).
- 5 In the measurement list, select the desired measurement for the custom table.
- 6 Select New from the on-screen menu.
- 7 In the Author field, enter a unique name.
- 8 Enter the data.
- 9 Select Save from the on-screen menu.

Two custom tables may be created for each OB measurement.

Note: To display the measurement for the custom table in the calculation menu, see ["To set up OB calculations authors:"](#) on page 34 and select More...

Note: Growth analysis tables cannot be created for custom OB measurements.

Edit OB Custom Tables

- 1 Press the **Setup** key.
 - 2 Select OB Custom Meas. or OB Calculations.
 - 3 Select Tables... from the on-screen menu.
 - 4 Select the desired custom OB table.
 - 5 Select Edit and enter data and then select Save from the on-screen menu.
-

Delete OB Custom Tables

- 1 Press the **Setup** key.
 - 2 Select OB Custom Meas. or OB Calculations.
 - 3 Select Tables... from the on-screen menu.
 - 4 Select the desired custom OB table.
 - 5 Select Delete from the on-screen menu to remove the custom table from the system.
-

To set Presets:

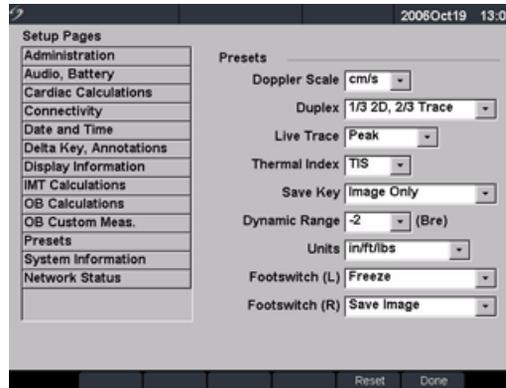


Figure 19 Setup Screen: Presets

| | |
|----------------------|--|
| Doppler Scale | <ol style="list-style-type: none"> 1 Press the Setup key. 2 Select Presets. 3 In the Doppler Scale list, select cm/s or kHz. |
| Duplex | <ol style="list-style-type: none"> 1 Press the Setup key. 2 Select Presets. 3 In the Duplex list, select desired image display. <ul style="list-style-type: none"> • Full 2D, Full Trace • 1/3 2D, 2/3 Trace • 1/2 2D, 1/2 Trace |
| Live Trace | <ol style="list-style-type: none"> 1 Press the Setup key. 2 Select Presets. 3 In the Live Trace list, select Peak or Mean. |
| Thermal Index | <ol style="list-style-type: none"> 1 Press the Setup key. 2 Select Presets. 3 In the Thermal Index list, select TIS, TIB, or TIC. |
| Save Key | <ol style="list-style-type: none"> 1 Press the Setup key. 2 Select Presets. 3 In the Save key list, select Image Only or Image/Calcs to designate the function of the Save key. <ul style="list-style-type: none"> • Selecting Image Only allows the Save key to save the image to the CF card. • Selecting Image/Calcs allows the Save Key to save the image to the CF card and to save the current calculation to the report. |

Reset

To return settings for this setup page to factory default, select Reset from the on-screen menu.

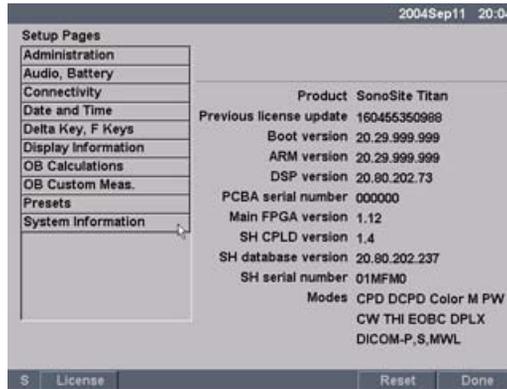
To view System Information:

Figure 20 Setup Screen: System Information

System Information

- 1 Press the Setup key.
- 2 Select System Information from the on-screen menu.

Note: To install a license key see “Installing a License Key” on page 170.

To change system setups to the default settings:

- 1 Turn the system off.
 - 2 Connect the system to AC power. See “To operate the system using AC power (directly to system):” on page 12.
 - 3 Simultaneously press and release 1 and the Power key.
- The system beeps several times and then the image display appears with all default settings.

Note: Default settings can not be changed by the user. Default settings are set at the factory.

Chapter 3: Imaging

Patient Information

The patient information form allows information to be entered into the system for the patient exam. Information which can be entered includes patient demographics, exam information, and clinical information. This information is automatically placed on the last page of the patient report. Once a patient is entered, all saved images will be linked to that patient. To end the exam, a New Patient can be created or End Exam can be selected.

*Note: Patient information can be edited during the exam by pressing the **Patient** key. However, if the patient name, ID, or Accession changes, a new patient is created.*

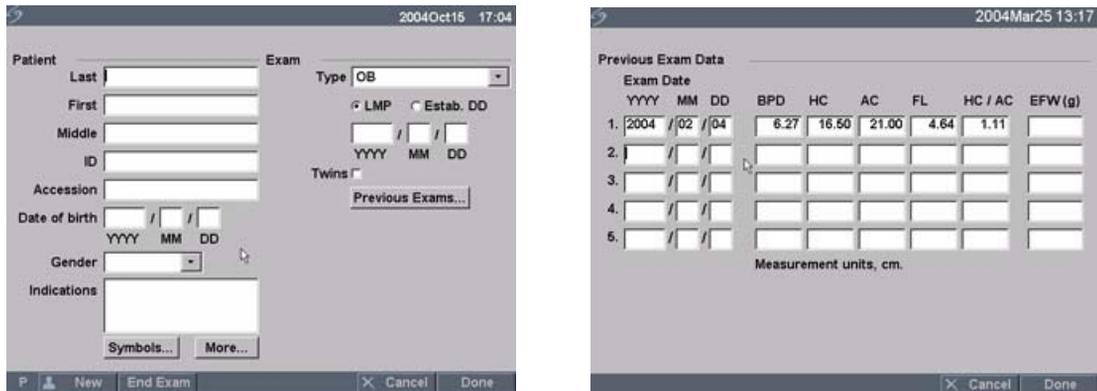


Figure 1 Patient Information Form

New Patient



- 1 Press the **Patient** key.
- 2 Select New from the on-screen menu.
This clears the existing patient information.
Note: New patient will erase any previously entered information, including any calculations and report pages. To save this information, save the screen for each item, e.g. report pages, patient information, calculations, and graphs.
- 3 Enter information into appropriate fields.
The patient information fields vary based on the selected exam type.
 - Patient
 - Patient: Enter Last, First, Middle, and ID.
 - Accession: Enter number, if applicable.
 - Date of birth: Enter (YYYY/MM/DD).
 - Gender: Select Female, Male, other, or leave blank.
 - Indications: Enter desired text.

New Patient (continued)

- Exam
 - Type: Select desired exam type.
 - LMP or Estab. DD: Enter either last menstrual period or established due date (YYYY/MM/DD). (Estab.DD only in OB exam.)
Note: The date for LMP must precede the current system date.
 - Twins: Select the Twins check box to display Twin A and Twin B measurements on the calculation menu (only in OB exam and report).
 - Previous Exams: Enter data from previous exams (only in OB exam).
 - HR: Enter the Heart Rate (only in vascular exam). If the heart rate is obtained and saved using M Mode, the values will override the number entered on the patient information screen.
 - BP: Enter blood pressure (only in vascular exam).
-

- Symbols (See [“Symbols” on page 20.](#))

- More...
 - Sonographer: Enter initials.
 - Reading Dr. and Referring Dr.: Enter names.
 - Institution: Enter name.

Note: All patient information can be edited up until the first image is saved. After the first image is saved, the Patient Name, ID, and Accession number cannot be modified. Modifying these fields closes the current patient exam and starts a new exam.

Select Done from the on-screen menu to save information and return to previous menu.

- Previous Exams...(only in OB exam).
 - Enter data from previous exams. Data from five previous exams may be entered.
 - For twins, select Twin A/B from the on-screen menu to enter data for each twin.

Note: The date for a previous exam must precede the current system date.

Select Done from the on-screen menu to save information and return to previous menu.

End Exam

- 1 Press the **Patient** key.
- 2 Select End Exam from the on-screen menu to close the current patient exam.

Note: Selecting End Exam, selecting New Patient, or modifying patient name or ID erases any previously entered information, including any calculations and report page. To save this information, save the screen for each item, e.g. report pages, patient information, calculations.

| | | |
|---------------|---|--|
| Cancel |  | Select Cancel from the on-screen menu to undo any changes to the patient information form and return to the previous imaging state. Pressing Cancel will not close the current patient exam. |
| Done | | Select Done from the on-screen menu to save information and return to the previous imaging state. Information is saved when exiting the patient information form unless Cancel is selected from the on-screen menu. <i>Note: If any changes are made to the current patient's name, ID, or accession number, that patient exam will be closed and a new one will be started.</i> |

Transducer, Exam Type, and Imaging Mode

The system has various configurations and options. All are described in this user guide and may not apply to your system. System features are dependent on your configuration, transducer, and exam type.

Warning: The diagnostic capability differs for each transducer, exam type, and imaging mode. Verify your system's capabilities prior to diagnosis.
Transducers have been developed to specific criteria depending on their application. This criteria includes biocompatibility requirements.

The following table describes the abbreviations for exam types.

Table 1: Exam Type Abbreviations

| Abbreviation | Exam Type |
|---------------------|------------------|
| Abd | Abdomen |
| Bre | Breast |
| Crd | Cardiac |
| Gyn | Gynecology |
| Msk | Muscle |
| Neo | Neonatal |
| Nrv | Nerve |
| OB | Obstetrical |
| Pro | Prostate |
| SmP | Small Parts |

Table 1: Exam Type Abbreviations (Continued)

| Abbreviation | Exam Type |
|--------------|-------------|
| Sup | Superficial |
| Vas | Vascular |

The following table describes the transducer's exam type, imaging mode, and optimization that may be available with your system.

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

The optimization settings for color power Doppler (CPD), directional color power Doppler (DCPD), and color Doppler (Color) are low, medium, and high (flow sensitivity) with a range of PRF settings for Color depending on the application.

Table 2: Transducer, Exam Type, and Imaging Mode

| Transducer | Exam Type | Imaging Mode | | | | | | | |
|------------|-------------|--------------|-----|-----|------|-------|--------|----|----|
| | | 2D | THI | CPD | DCPD | Color | M Mode | PW | CW |
| C8 | Prostate | X | | X | | | X | X | |
| | Gyn | X | | X | | | X | X | |
| | OB | X | | X | | | X | X | |
| C11 | Vascular | X | | X | | X | X | X | |
| | Cardiac | X | | | | X | X | X | X |
| | Neonatal | X | | X | | X | X | X | |
| | Abdomen | X | | X | | X | X | X | |
| C15 | Abdomen | X | X | X | | X | X | X | |
| | OB | X | X | X | | X | X | X | |
| | Cardiac | X | X | | | X | X | X | X |
| C60 | OB | X | X | X | | X | X | X | |
| | Gyn | X | X | X | | X | X | X | |
| | Abdomen | X | X | X | | X | X | X | |
| HST | Superficial | X | | X | X | | X | X | |
| | Muscle | X | | X | X | | X | X | |
| | Vascular | X | | X | X | | X | X | |

Table 2: Transducer, Exam Type, and Imaging Mode (Continued)

| Transducer | Exam Type | Imaging Mode | | | | | | | |
|------------|-------------|--------------|-----|-----|------|-------|--------|----|----|
| | | 2D | THI | CPD | DCPD | Color | M Mode | PW | CW |
| ICT | Gyn | X | | X | X | | X | X | |
| | OB | X | | X | X | | X | X | |
| L25 | Nerve | X | | X | | | | | |
| | Superficial | X | | X | | | | | |
| | Vascular | X | | X | | | | | |
| L38 | Breast | X | | X | | X | X | X | |
| | Small Parts | X | | X | | X | X | X | |
| | Vascular | X | | X | | X | X | X | |

Transducer Preparation

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.

Caution: Using gels not recommended for your transducer can damage it and void the warranty. If you have questions about gel compatibility, contact SonoSite or your local representative.

SonoSite recommends you clean transducers after each use. Refer to [“Cleaning and Disinfecting Transducers” on page 173](#) for cleaning and disinfecting procedures.

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 a sample is provided with the system.

General Use

| | |
|------------------|--|
| Apply Gel | Apply a liberal amount of gel between the transducer and the body. |
|------------------|--|

Invasive Use

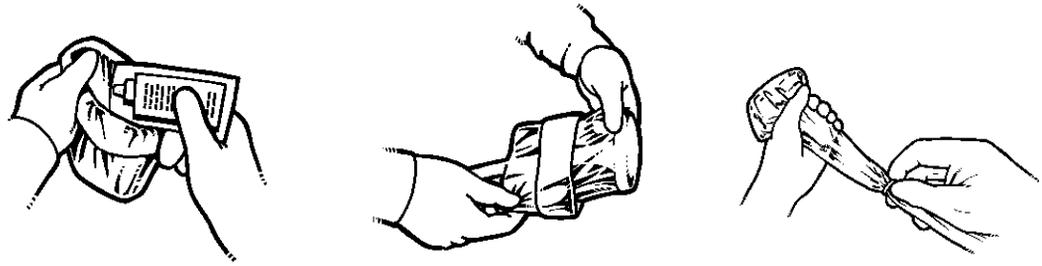


Figure 2 Install Transducer Sheath

Install Transducer Sheath

Note: SonoSite recommends the use of market-cleared, transducer sheaths for clinical applications of an invasive nature (such as transvaginal).

- 1 Place gel inside the sheath.
- 2 Insert the transducer into the sheath.

Note: To lessen the risk of contamination, install the sheath only when you are ready to perform the procedure.

- 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 footprint of the transducer and the sheath.

Note: If any bubbles are present between the footprint of the transducer and the sheath, the ultrasound image may be affected.

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

Modes

2D Imaging

The system has advanced image optimization technology that greatly simplifies user controls. To achieve the best possible image quality, it is important to properly adjust the display brightness, gain, depth settings, and exam type.

It is also important to select an optimization setting that best matches your needs.

The system has a high-performance, liquid crystal display (LCD). To optimize image quality, adjust the display for viewing angle, and brightness.

Each time you turn the system on, the 2D image is displayed. It displays echoes in two dimensions on the display by assigning a brightness level based on the echo signal amplitude. This is the system's default imaging mode. When imaging in another mode, you may return to 2D imaging by pressing the 2D key. If the system does not return to 2D imaging after pressing the 2D key, ensure the system is in live imaging.



Figure 3 2D Image

| | | |
|------------------------|---|---|
| Optimize |  | Select the desired optimization setting from the on-screen menu. <ul style="list-style-type: none">• Res provides the best possible resolution.• Gen provides a balance between resolution and penetration.• Pen provides the best possible penetration. <p><i>Note: Some of the parameters that are optimized to provide the best image include: focal zones, aperture size, frequency (center and bandwidth), dynamic range, and waveform. They cannot be adjusted by the user.</i></p> |
| Horizontal Flip |  | Select left or right flip from the on-screen menu to change image orientation. |
| Vertical Flip |  | Select up or down flip from the on-screen menu to change image orientation. |

| | | |
|--|---|--|
| Brightness |  | <p>Select the desired brightness setting from the on-screen menu to adjust display brightness (1-10).</p> <p><i>Note: The display brightness affects battery life. To conserve battery life, adjust brightness to a lower setting.</i></p> |
| Biopsy |  | <p>Select Biopsy from the on-screen menu to display biopsy guidelines. Select again to turn off. See “Biopsy” on page 59 and <i>Biopsy User Guide</i> for more information.</p> <p><i>Note: The feature is dependent on transducer and exam type.</i></p> <p><i>Note: Biopsy is not available when ECG cable is connected.</i></p> |
| Guide (L25 only) | | <p>Select Guide from the on-screen menu to display guide. Select again to turn off. See the <i>L25 Bracket and Needle Guide User Guide</i> for more information</p> <p><i>Note: The feature is dependent on transducer and exam type.</i></p> |
| ECG | | <p><i>Note: This option requires a SonoSite ECG cable.</i></p> <ol style="list-style-type: none"> 1 Connect the ECG cable. See the <i>TITAN Accessories User Guide</i>. 2 Select ECG from the on-screen menu to display the ECG trace. See “ECG Monitoring” on page 57. |
| Dual Images |  | <ol style="list-style-type: none"> 1 Select Dual from the on-screen menu to display side by side 2D images. 2 Press the Update key to display the second screen and to toggle between the screens. With both images frozen, press the Update key to toggle between the images, except if calipers, calcs, arrow, or picto are displayed. Select Dual from the on-screen menu or press the 2D key to return to full screen 2D imaging. |
| Gain | | <p>Turn the Near, Far, or Gain knobs (on the lower left side of the control panel) to increase or decrease the amount of gain applied to the near field, far field, or the overall image (near and far correspond to the time gain compensation (TGC) controls found on other ultrasound systems).</p> |
| Depth | | <p>Press the Depth key up to decrease or down to increase the displayed depth. As you adjust the depth, the maximum depth number changes in the lower right corner of the screen.</p> <p><i>Note: The vertical depth scale is marked in .5 cm, 1 cm, and 5 cm increments depending on the depth.</i></p> |
| Tissue Harmonic Imaging | | <p><i>Note: This is an optional feature and is dependent on transducer and exam type.</i></p> <ol style="list-style-type: none"> 1 Press the THI key to turn on THI. THI is displayed in the top left portion of the screen next to the optimization setting. 2 Press the THI key again to turn off THI. The THI icon is removed from the screen. |

Zoom

Note: Zoom is only available during real-time imaging. You cannot zoom on a frozen or saved image.

- 1 Press the **Zoom** key.
The image is magnified by a factor of two from the center of the image.
Note: You can change the depth while the image is zoomed.
 - 2 Press the **Zoom** key again to exit zoom.
-

Freeze

- 1 Press the **Freeze** key.
The cine icon and frame number are displayed in the system status area of the screen.
 - 2 Press the **Freeze** key again to return to live imaging.
The cine icon is removed from the system status area of the screen and live imaging begins.
-

Cine Buffer

On a frozen image, press the **Cine** keys to view individual frames in the cine buffer.

The frame number will change dynamically as the cine key is pressed.

Note: The total number of frames in the buffer is displayed in the system status under the freeze icon.

M Mode Imaging

The following instructions cover Motion mode (M Mode) imaging. Refer to “2D Imaging” on page 47 for instructions about depth and optimization.

M Mode Sample Line



Figure 4 M Mode Sample Line

Sample Line

- 1 Press the **M Mode** key for the M Mode sample line.
Note: If M Mode does not come on, make sure the system is in live imaging.
- 2 Use the touchpad to position the M Mode sample line over the area of interest on the image.
Note: Depth changes are not available in M Mode trace. Adjust the depth prior to activating the M Mode trace.

M Mode Trace



Figure 5 M Mode Trace Image

| | |
|---------------------|--|
| M Mode Trace | <ol style="list-style-type: none"> 1 Press the M Mode key again to acquire the M Mode trace. <i>Note: The time scale at the top of the trace has small marks at 200 ms intervals and large marks at one second intervals.</i> 2 Press the Update key to toggle between the sample line and trace. 3 In duplex, press the M Mode key to return to the full screen M Mode sample line. <i>Note: You can set up three screen layouts. For duplex imaging see “Duplex” on page 39.</i> |
| Sweep Speed |  Select the desired sweep speed from the on-screen menu (slow, med, fast). |
| Gain | Turn the Near , Far , or Gain knobs (on the lower left side of the control panel) to increase or decrease the amount of gain applied to the near field, far field, or the overall image (near and far correspond to the time gain compensation (TGC) controls found on other ultrasound systems). |
| Freeze | <ol style="list-style-type: none"> 1 Press the Freeze key. 2 Press the Freeze key again to return to live imaging. The cine icon is removed from the system status area of the screen and live imaging begins. <i>Note: Press the M Mode or Update key to display the associated frozen 2D image with the M Mode sample line.</i> |
| Cine Buffer |  On a frozen image, press the Cine keys to view the trace at different points in time. |
| 2D Imaging | Press the 2D key to return to 2D imaging. |

Color Doppler Imaging

Note: Color power Doppler (CPD), directional color power Doppler (DCPD), and color Doppler (Color) are optional features and are dependent on transducer and exam type.

The following instructions cover CPD, DCPD, and Color imaging.

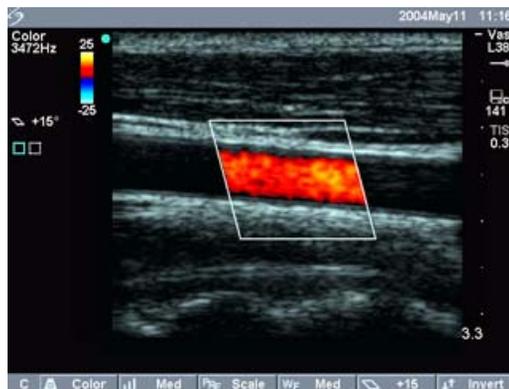


Figure 6 Color Image

| | | |
|---|---|--|
| CPD, DCPD, or Color |  | <ol style="list-style-type: none"> 1 Press the Color key for CPD, DCPD, or Color. A region of interest (ROI) box is displayed in the center of the 2D image. 2 Select CPD, DCPD, or Color from the on-screen menu. The current setting is displayed in the upper left corner of the screen and in the on-screen menu. In DCPD and Color mode, the color indicator bar is displayed in the upper left corner of the screen. The color bar displays velocity in cm/s. |
| Flow Sensitivity |  | <p>Select the desired flow sensitivity from the on-screen menu.</p> <ul style="list-style-type: none"> • Low optimizes the system for low flow states. • Med optimizes the system for medium flow states. • High optimizes the system for high flow states. <p>The current setting is displayed in the top left portion of the screen and in the on-screen menu.</p> |
| PRF Scale (Color only) |  | <p>Select the desired pulse repetition frequency (PRF) setting from the on-screen menu.</p> <p><i>Note: There is a wide range of PRF settings for each flow sensitivity selection.</i></p> |
| Wall Filter (Color only) |  | <p>Select the desired wall filter setting from the on-screen menu (low, med, high).</p> |

| | | |
|--|--|---|
| Steering (L38 and HST only) | | <p>Select the desired steering angle setting from the on-screen menu. This automatically changes pulsed wave (PW) Doppler angle correction to the optimum setting.</p> <ul style="list-style-type: none"> Steering angle of -15 degrees has an angle correction of -60 degrees. Steering angle of 0 degrees has an angle correction of 0 degrees. Steering angle of +15 degrees has an angle correction of +60 degrees. <p><i>Note: If two modes are active (CPD/DCPD/Color and PW Doppler) press the Select key to toggle between the on-screen menus.</i></p> |
| Variance (Cardiac only) | | <p>Select variance from the on-screen menu to turn on.</p> |
| Invert | | <p>Select Invert from the on-screen menu to switch the displayed direction of flow.</p> <p><i>Note: Invert is only displayed when DCPD/Color is selected.</i></p> |
| ROI Box | | <ol style="list-style-type: none"> Use the touchpad to position or change the size of the region of interest (ROI) box. While you are moving or changing the size of the ROI box, you will see a green outline of the new position or the new size as it moves on the display. Press the Select key to toggle between the position and size of the ROI box. The ROI box indicator on the left side of the screen is highlighted green to show which function the touchpad is controlling. |
| Gain | | <p>Turn the Gain knob (on the lower left side of the control panel) to increase or decrease the amount of color gain applied to the CPD, DCPD, or Color ROI box.</p> <p><i>Note: While in CPD, DCPD, or Color imaging, Near and Far knobs affect only the 2D image.</i></p> |
| 2D Imaging | | <p>Press the 2D or Color key to return to 2D imaging.</p> <p><i>Note: If two modes are active (CPD/DCPD/Color and PW Doppler) press the Select key to toggle between context menus.</i></p> |

Pulsed Wave (PW) and Continuous Wave (CW) Doppler Imaging

Note: PW Doppler and CW Doppler are optional features and are dependent on transducer and exam type. The following instructions cover PW and CW Doppler imaging.

Doppler Sample Line

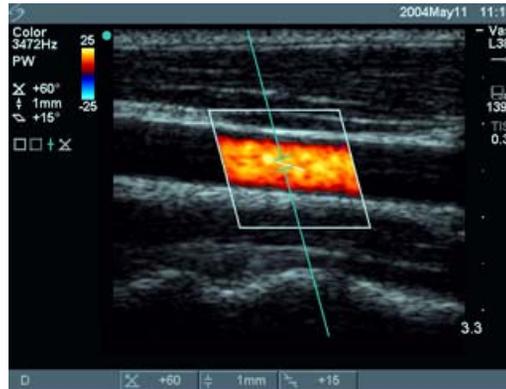


Figure 7 Doppler with Sample Line Image and ROI Box

| | | |
|----------------------|---|---|
| Sample Line | + | <ol style="list-style-type: none"> 1 Press the Doppler key for the Doppler sample line. 2 Use the touchpad to position the Doppler sample line over the area of interest on the image. 3 Press the Select key to set sample line and to toggle between Doppler sample line and Angle Correction. An indicator on the left side of the screen is highlighted green to show which function the touchpad is controlling. <p>Note: If PW or CW Doppler mode does not come on, make sure the system is in live imaging.</p> <p>Note: The color ROI box is tied to the PW or CW sample line.</p> |
| PW/CW Doppler | | <ol style="list-style-type: none"> 1 Press the Doppler key. 2 Select PW from the on-screen menu to toggle between PW Doppler and CW Doppler (CW Doppler only in cardiac exams). |

Angle Correction (PW only)

There are two ways to adjust the angle correction in PW Doppler imaging.

Select Angle Correction from the on-screen menu to adjust the angle correction to 0, +60, or -60 degrees.

OR

- 1 Press the **Select** key to highlight the angle correction icon displayed on the left side of the screen.
The indicator is highlighted green to show which function the touchpad is controlling.
- 2 Use the touchpad to adjust the angle in two degree increments from -74 to +74 degrees.
- 3 Press the **Select** key again to set the desired angle.

Gate Size (PW only)

Select the desired gate size setting from the on-screen menu.

Note: Gate size options vary with transducer and exam type.

Steering (L38 and HST only)

Select the desired steering angle setting from the on-screen menu.

This automatically changes PW angle correction to the optimum setting.

- Steering angle of -15 degrees has an angle correction of -60 degrees.
- Steering angle of 0 degrees has an angle correction of 0 degrees.
- Steering angle of +15 degrees has an angle correction of +60 degrees.

Note: The angle correction can be adjusted manually after steering has been selected. (See "Angle Correction (PW only).")

*Note: If two modes are active (CPD/DCPD/Color and PW/CW Doppler) press the **Select** key to toggle between on-screen menus.*

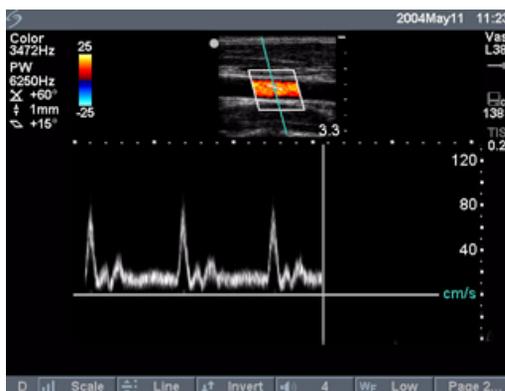
Doppler Spectral Trace

Figure 8 Doppler Trace Image

| | | |
|-----------------------|---|---|
| Spectral Trace | <ol style="list-style-type: none"> 1 Press the Doppler key again to acquire the Doppler trace. 2 Press the Update key to toggle between the 2D/sample line and trace. 3 In duplex, press the Doppler key to return to the full screen Doppler sample line. | |
| | <p>The on-screen menu options for Doppler spectral trace are:</p> <ul style="list-style-type: none"> • Scale • Baseline • Invert • Volume • Wall Filter • Sweep Speed • Live Trace (peak or mean) <p><i>Note: The time scale at the top of the trace has small marks at 200 ms intervals and large marks at one second intervals.</i></p> <p><i>Note: You can set up three screen layouts. For duplex imaging see “Duplex” on page 39.</i></p> | |
| Scale |  | Select the desired scale/pulse repetition frequency (PRF) setting from the on-screen menu. |
| Line |  | <p>Select the desired baseline position from the on-screen menu.</p> <p><i>Note: Baseline can be adjusted on a frozen trace, if Live Trace is not displayed.</i></p> |
| Invert |  | <p>Select Invert from the on-screen menu to vertically flip the spectral trace.</p> <p><i>Note: Invert can be adjusted on a frozen trace, if Live Trace is not displayed.</i></p> |
| Volume |  | Select the desired Doppler volume setting from the on-screen menu to increase or decrease Doppler speaker volume (0-10). |
| Wall Filter |  | Select the desired wall filter setting from the on-screen menu (low, med, high). |
| Sweep Speed |  | Select the desired sweep speed from the on-screen menu (slow, med, fast). |
| Live Trace |  | Select Trace from the on-screen menu to display a live trace of the peak or mean. See “Live Trace” on page 39. |
| Gain | | Turn the Gain knob to increase or decrease the amount of Doppler gain. |
| Freeze | | <ol style="list-style-type: none"> 1 Press the Freeze key. In 2D mode the cine icon is displayed in the system status area of the screen. 2 Press the Freeze key again to return to live imaging. The cine icon is removed from the system status area of the screen and live imaging begins. |

| | | |
|--------------------|---|---|
| Cine Buffer |  | On a frozen image, press the Cine keys to view the trace at different points in time. |
|--------------------|---|---|

| | |
|-------------------|---|
| 2D Imaging | Press the 2D key to return to 2D imaging. |
|-------------------|---|

ECG Monitoring

Note: This option requires a SonoSite ECG cable.

- Warning:** To prevent misdiagnosis, do not use the ECG trace to diagnosis cardiac rhythms. The SonoSite ECG option is a non-diagnostic feature.
- To prevent misdiagnosis, do not use the SonoSite ECG option for long term cardiac rhythm monitoring.
- Caution:** Use only accessories recommended by SonoSite with the system. Your system can be damaged by connecting an accessory not recommended by SonoSite.

| | |
|------------|--|
| ECG | <i>Note: This menu option is displayed only when the ECG cable is connected.</i> |
| | 1 Connect the ECG cable to the ECG connector on the docking system/mini-dock/TITAN system. See the <i>TITAN Accessories User Guide</i> . |
| | <i>Note: When the ECG cable is connected, ECG monitoring turns on automatically.</i> |
| | <i>Note: Biopsy guidelines are not available when ECG is connected.</i> |
| | 2 Select ECG from the on-screen menu. |

| | | |
|------------------|---|--|
| Show/Hide |  | Select show/hide from the on-screen menu to turn on/off ECG trace. |
|------------------|---|--|

| | | |
|-------------|---|--|
| Gain |  | Select the desired gain from the on-screen menu to increase or decrease ECG gain (1-20). |
|-------------|---|--|

| | | |
|-----------------|--|---|
| Position | | Select the desired position of the ECG trace from the on-screen menu. |
|-----------------|--|---|

| | | |
|--------------------|---|---|
| Sweep Speed |  | Select the desired sweep speed from the on-screen menu (slow, med, fast). |
|--------------------|---|---|

Annotation

Note: In a single image, you can only enter annotation in one row across the top of a frozen or live image. In Dual image you can only enter text in one row across the bottom of each section of the screen. Annotation is available in both live imaging and on a frozen image. You cannot annotate on a saved image.

Enter Text

- 1 Press the **Text** key or the **Spacebar** key.
In a single image a green data entry cursor is displayed in the upper left corner.
- 2 Use the keyboard to enter, delete, or modify text.
 - Press the **Backspace** key to delete characters to the left of the cursor.
 - Press the **Space** key to add spaces between words or replace characters with blank spaces to the right of the cursor.
 - Press the **Arrow** keys to move the cursor to the left or right.
 - Press the **Enter** key to return the cursor to the beginning of the line of text.
 - Press the **Delete** key to delete characters to the right of the cursor.
 - Select Delete Line from the on-screen menu to remove the entire line of text.
 - Select Symbols from the on-screen menu to enter special characters. See [“Symbols” on page 20](#).
 - Press the **Text** key to turn off text entry.

Arrow

- 1 Press the **Arrow** key.
Use the arrow as a pointer to bring attention to a specific part of the image.
 - 2 Use the touchpad to move the arrow over the image.
 - 3 Press the **Select** key to switch the arrow’s orientation and then use the touchpad to adjust the arrow’s orientation.
 - 4 Press the **Select** key again to set the arrow’s orientation and then use the touchpad to move the arrow over the image.
 - 5 Press the **Arrow** key to set the arrow.
The arrow changes from green to white.
To remove the arrow from the image, press the **Arrow** key and then select Hide from the on-screen menu.
-

| | |
|-------------------|--|
| Pictograph | <ol style="list-style-type: none"> 1 Press the Picto key to turn on the pictograph. The on-screen options for pictograph are: <ul style="list-style-type: none"> •  Show/Hide • Number (e.g., 1/18) • Done 2 Select the desired pictograph. The first number changes to show which pictograph in a set of pictographs has been selected. The second number shows the total number of pictographs available. <i>Note: The pictograph set that is available is dependent on transducer and exam type.</i> 3 Use the touchpad to position the pictograph marker. 4 Press the Select key and then use the touchpad to rotate the pictograph marker. 5 Select Hide from the on-screen menu to remove the pictograph. |
| F keys | <ol style="list-style-type: none"> 1 Press the Text key or the Spacebar key. A green flashing data entry cursor is displayed in the upper left corner. 2 Press the <i>f</i> key and then a number key to enter predefined text. See “To set up Delta Key and F Keys:” on page 32. |

Biopsy

The ultrasound system is equipped with a biopsy feature. Biopsy guides are used to assist in the guidance of a biopsy needle. The system generates guidelines that represent the anticipated path of the biopsy needle. The echoes of the anatomical target and the needle are displayed on the system display and assist in guiding the biopsy needle to the target. For detailed instructions on the use of the system and biopsy guide accessories, and a list of compatible transducers, please refer to the *Biopsy User Guide*.

Note: The feature is dependent on transducer and exam type.

Image Storage

Save to CompactFlash

Images are saved to the CompactFlash card. The images in the patient list are organized alphabetically by the patient name and ID. If a name is not entered in the patient name field, a patient exam is created and identified as (_No_Name_). If an ID number is not entered in the ID field, the ID number is identified as (_No_ID_).

To review saved images, see [“Image Review” on page 61](#). The images saved on the CompactFlash card cannot be opened and viewed on a PC. Images may be archived from the ultrasound system using DICOM Image Transfer or to a PC using SiteLink Image Manager 2.2. See [“DICOM Connectivity” on page 105](#) or the *SiteLink User Guide*.

The number of images saved to the CompactFlash card varies depending on the storage capacity of the card.

Warning: To prevent loss of data, loss of images, or damage to the CompactFlash card, turn the ultrasound system off before removing the CompactFlash card. When the CompactFlash card is removed before turning off the ultrasound system, the system must be restarted.

Save Image



- 1 Verify the CompactFlash card is inserted into the front slot on the ultrasound system. See [Figure 1 on page 3](#).
- 2 Turn system on.
The CompactFlash card is ready to use when the save icon and the image memory counter, showing the remaining available memory, are displayed on the screen.
Note: It may take a few seconds for the image memory counter to display the available memory.
Note: If the CompactFlash card is inserted into the back slot, the save icon and number are not displayed.
- 3 Press the **Save** key to save an image to the CompactFlash card. After the audible beep is heard, the next image may be saved. It may take a few seconds for the image memory counter to display the available memory.
The image memory indicator decreases by one.
Note: Ensure that there is sufficient memory available on the CompactFlash card before saving additional images.

Print to Local Printer

Ensure the printer is properly set up for operation with the system. See [“Printer” on page 29](#) for system setting and the *TITAN Accessory User Guide* for hardware setup.

Print Image

Press the **Print** key.

Image Review

The patient list displays all the patients who have images saved on the CompactFlash card. Image review is comprised of two parts: the patient list and the patient images. The patient images display images for the current patient or the patient selected from the patient list.

Patient List

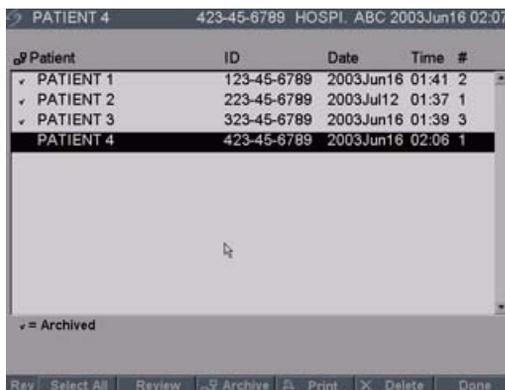


Figure 9 Patient List

| | | |
|-----------------------------|---|--|
| Patient List | | Press the Review key. If there is a current patient, select List from the on-screen menu. |
| Select All, Deselect | | Select All from the on-screen menu to highlight all the entries within the patient list. Deselect removes the highlight from all the entries and highlights the previously selected patient. <i>Note: Review is disabled when all entries in the list are selected.</i> |
| Review Images | | Select Review from the on-screen menu to review the images for the currently selected patient. |
| Archive |  | Select Archive from the on-screen menu to send the selected patient exams to a PC using SiteLink or to a DICOM printer or archiver. See “Transfer Mode” on page 29 . <i>Note: SiteLink and DICOM are optional features.</i> |
| Print All Images |  | <ol style="list-style-type: none"> 1 Verify a printer is selected. See “Printer” on page 29. 2 Press the Review key. 3 Select List from the on-screen menu. 4 Highlight the desired patient. <i>Note: An individual patient or all patients may be selected.</i> 5 Select Print from the on-screen menu to print all images. Each image will display briefly on the screen before printing starts. |

| | | |
|---------------|---|--|
| Delete |  | Select Delete from the on-screen menu to delete the selected patient exam. A confirmation screen is displayed. |
| Done | | Select Done from the on-screen menu to exit the patient list and return to the previous imaging state. |

Patient Images



Figure 10 Patient Images

| | | |
|-------------------------------|---|---|
| Patient Images | | Press the Review key. If there is not a current patient, highlight the desired patient and select Review from the on-screen menu. |
| Next or Previous Image |  | Select the Next or Previous Image (1/x) from the on-screen menu to view image. |
| Patient List |  | Select List from the on-screen menu to display the patient list. |
| Print Image |  | <ol style="list-style-type: none"> 1 Verify a printer is selected. See “Printer” on page 29. 2 Select Print from the on-screen menu to print the displayed image. |
| Delete |  | Select Delete from the on-screen menu to delete the displayed image. A confirmation screen is displayed. |
| Done | | Select Done from the on-screen menu to exit patient images and return to the previous imaging state. |

Chapter 4: Measurements and Calculations

Measurements

Measurements and calculations are performed on frozen images. The following sections explain how to perform basic measurements in each imaging mode. Based on the measurements performed, the SonoSite system automatically calculates specific information and displays the results. Some of the options described in the user guide may not apply to your system. System features are dependent on your configuration, transducer, and exam type.

2D Measurements

The basic measurements that can be performed in 2D are:

- Distance in cm
- Area in cm^2
- Circumference in cm



Figure 1 2D Measurement with One Linear and Ellipse

Distance Measurement

- 1 On a frozen 2D image, press the **Caliper** key.
A set of calipers is displayed on the screen and the following on-screen menu options are available:

- ⊕ First caliper set
- ✕ Second caliper set
- Ellipse (circumference/area)
- ✕ Delete

Note: The two calipers are connected by a dotted line. When the calipers get close together, they decrease in size and the caliper line is removed.

Note: No additional calipers are available on Dual screens.

- 2 Use the touchpad to position the first caliper.
The active caliper is highlighted green.
 - 3 Press the **Select** key to activate the second caliper.
 - 4 Use the touchpad to position the second caliper.
The result is displayed in the measurement and calculation data area and is updated as the caliper moves. The measurement is complete when you finish moving the calipers.
 - 5 If desired, press the **Save** key to save the image with the measurements displayed.
-

Second Distance Measurement

- 1 Press the **Caliper** key or select the second set of calipers from the on-screen menu.
A second set of calipers is displayed. The active caliper is highlighted green.
 - 2 Use the touchpad and the **Select** key as described in the preceding steps to complete the second measurement.
 - 3 If desired, press the **Save** key to save the image with the measurements displayed.
-

| | |
|--|---|
| Area/ Circumference Measurement | <ol style="list-style-type: none"> 1 On a frozen 2D image, press the Caliper key. 2 Select Ellipse from the on-screen menu. 3 Press the Select key and use the touchpad to adjust the position of the first caliper. The active caliper is highlighted green. 4 Press the Select key and use the touchpad to adjust the position of the second caliper. 5 Press the Select key and use the touchpad to adjust the size of the ellipse. The results are displayed in the measurement and calculation data area and are updated as the caliper moves. The measurement is complete when you finish moving the calipers. <i>Note: When an ellipse measurement is performed, only one distance measurement is available.</i> 6 If desired, press the Save key to save the image with the measurements displayed. 7 Select Ellipse again from the on-screen menu to turn off the ellipse. |
| Delete Measurement | <ol style="list-style-type: none"> 1 Select first or second caliper set or Ellipse from the on-screen menu. 2 Select Delete from the on-screen menu. This will remove the active set of calipers from the screen. |

M Mode Measurements

The basic measurements and calculations that can be performed in M Mode are:

- Distance in cm
- Time in seconds
- Heart Rate (HR) in beats per minute (bpm)

Note: The time scale at the top of the trace has small marks at 200 ms intervals and large marks at one second intervals.

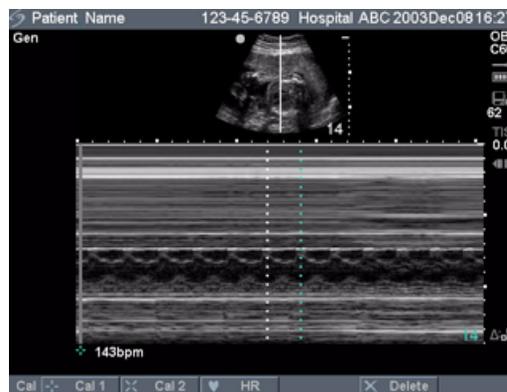


Figure 2 M Mode Trace Image with Heart Rate

**Distance
Measurement**

- 1 On a frozen M Mode trace, press the **Caliper** key.
A single caliper is displayed on the screen and the following on-screen menu options are available:
 - ⊕ First caliper set
 - ⊗ Second caliper set
 - ♥ Heart rate
 - ✕ Delete
 - 2 Use the touchpad to position the first caliper.
 - 3 Press the **Select** key to activate the second caliper.
 - 4 Use the touchpad to position the second caliper.
The active caliper is highlighted green.
The results are displayed in the measurement and calculation data area and are updated as the caliper moves. The measurement is complete when you finish moving the calipers.
 - 5 If desired, press the **Save** key to save the image with the measurements displayed.
-

**Heart Rate (HR)
Fetal Heart Rate
(FHR)**

- 1 On a frozen M Mode trace, press the **Caliper** key or press the **Calcs** key for FHR (OB exam only).
The following on-screen menu options are available:
 - ⊕ First caliper set
 - ⊗ Second caliper set
 - ♥ Heart rate
 - ✕ Delete
 - ✓ Save (only available when heart rate measurement can be saved to report)
- 2 Select HR from the on-screen menu or select FHR from the calculation menu.
A vertical caliper is displayed on the screen.
- 3 Use the touchpad to position the first vertical caliper at the peak of the heart beat.
- 4 Press the **Select** key.
A second vertical caliper is displayed on the screen. The active caliper is highlighted green.
- 5 Use the touchpad to position the second vertical caliper at the peak of the next heart beat.
The result is displayed in the measurement and calculation data area and is updated as the caliper moves. The measurement is complete when you finish moving the calipers.
- 6 Select **Save** from the on-screen menu to save the heart rate measurement to the patient report.
Note: This will overwrite the previous heart rate value entered under exam/patient information.
Note: In OB exam, only the fetal heart rate can be saved to the report.
- 7 If desired, press the **Save** key to save the image with the measurements displayed.

**Delete
Measurement**

- 1 Select the first or second caliper set from the on-screen menu.
 - 2 Select **Delete** from the on-screen menu.
This will remove the active set of calipers from the screen.
-

Doppler Measurements

Note: The Doppler scale must be set to cm/s for the following measurements. See “System Setup” on page 21.

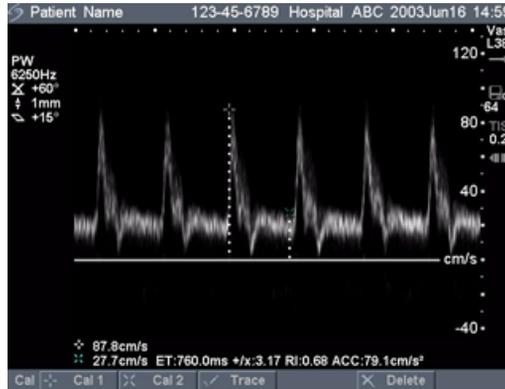


Figure 3 Doppler Trace with Two Velocity Measurements

Velocity (cm/s), Pressure Gradient

- 1 On a frozen Doppler spectral trace, press the **Caliper** key. A single caliper is displayed on the screen with the following on-screen menu options:
 - + First caliper
 - X Second caliper
 - Manual
 - X Delete
- 2 Use the touchpad to position the active green caliper to a peak systolic wave form. This is a single caliper from the baseline. The results are displayed in the measurement and calculation data area. They are updated as the caliper moves and are completed when you finish moving the calipers.
- 3 If desired, press the **Save** key to save the image with the measurements displayed.

Note: The measurements cannot be saved to the patient report.

**Velocities,
Elapsed Time,
+/ \times Ratio,
Resistive
Index (RI),
Acceleration**

- 1 On a frozen Doppler spectral trace, press the **Caliper** key.
A single caliper is displayed on-screen with the following menu options:
 -  First caliper
 -  Second caliper
 -  Manual
 -  Delete
- 2 Use the touchpad to position the first caliper to a peak systolic wave form.
- 3 Press the **Caliper** key or select the second caliper from the on-screen menu.
A second caliper is displayed on the screen.
- 4 Use the touchpad to position the second caliper at the end diastole on the wave form.
The results are displayed in the measurement and calculation data area. They are updated as the caliper moves and are completed when you finish moving the calipers.
Note: A measurement taken with the second caliper provides a second velocity, elapsed time, +/ \times ratio, RI, and acceleration.
- 5 If desired, press the **Save** key to save the image with the measurements displayed.
Note: The measurements cannot be saved to the patient report.

The following table shows the trace results displayed by exam type:

Table 1: Trace Calculations by Exam Type

| | Cardiac | Vascular | OB/Gyn | Abdominal and Other |
|---|----------------|-----------------|---------------|----------------------------|
| Velocity Time Integral (VTI) | X | | | |
| Peak Velocity (Vmax) | X | X | X | X |
| Mean Pressure Gradient (PGmean) | X | | | |
| Mean Velocity on Peak Trace (Vmean) | X | | | |
| Pressure Gradient (PGmax) | X | | | |
| Time Average Mean (TAM)* | | X | | X |
| +/ \times or Systolic/Diastolic (S/D) | | X | X | X |
| Pulsatility Index (PI) | | X | X | X |
| End Diastolic Velocity (EDV) | | X | | |

Table 1: Trace Calculations by Exam Type (Continued)

| | Cardiac | Vascular | OB/Gyn | Abdominal and Other |
|------------------------|---------|----------|--------|---------------------|
| Acceleration Time (AT) | X | | | X |
| Resistive Index (RI) | | X | X | X |

*Note: The automatic trace tool must be used to calculate the TAM.**

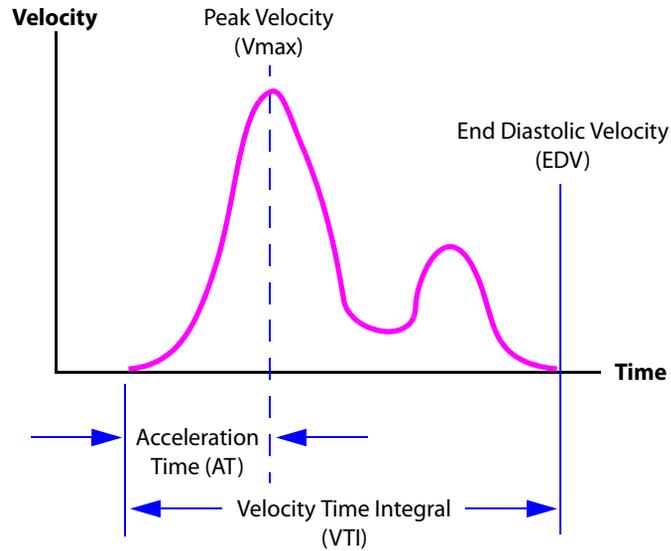


Figure 4 Trace Calculations of the Doppler Wave Form

Manual Trace

- 1 On a frozen Doppler spectral trace, press the **Caliper** key.
- 2 Select Manual from the on-screen menu.
A single caliper is displayed on the screen. This caliper is used to mark points on the trace.
- 3 Position the caliper at the beginning of the desired wave form and press the **Select** key.
Note: If calipers are not placed in the correct position, the calculation will not be performed accurately.
- 4 Use the touchpad to move the caliper to the next desired point on the wave form.
- 5 Continue marking points by pressing the **Select** key.
The last point must be placed at the end of the wave form.
Note: If an error is made, use the backspace key to delete the previous position.
- 6 Select Set from the on-screen menu to complete the trace and to display the results.
- 7 Press the **Save** key to save an image of the trace with the results displayed.
- 8 If performing a VTI, TAM, or S/D ratio, select Save from the on-screen menu.

Automatic Trace

Note: The optimum trace location is provided when live trace is turned on.

- 1 On a frozen Doppler spectral trace, press the **Caliper** key.
- 2 Select Auto from the on-screen menu.
A vertical caliper is displayed.
- 3 Use the touchpad to position the first caliper at the beginning of the wave form.
- 4 Press the **Select** key.
A second vertical caliper is displayed.
Note: If calipers are not placed in the correct position, the calculation will not be performed accurately.
- 5 Use the touchpad to position the second vertical caliper at the end of the wave form.
- 6 Select Set from the on-screen menu to complete the trace and to display the results.
- 7 Press the **Save** key to save an image of the trace with the results displayed.
- 8 If performing a VTI, TAM, or S/D ratio, select Save from the on-screen menu.

Calculations

Percent Reduction Calculations

Percent reduction calculations may be performed and saved to the patient report. The following table shows the transducers and exam types that provide vascular percent reduction calculations.

Table 2: Transducer and Exam Types for Percent Reduction

| Transducer | Exam Types |
|------------|-----------------------|
| C11 | Vascular |
| C15 | Abdominal |
| C60 | Abdominal |
| HST | Muscle, Vascular |
| L25 | Vascular |
| L38 | Small Parts, Vascular |

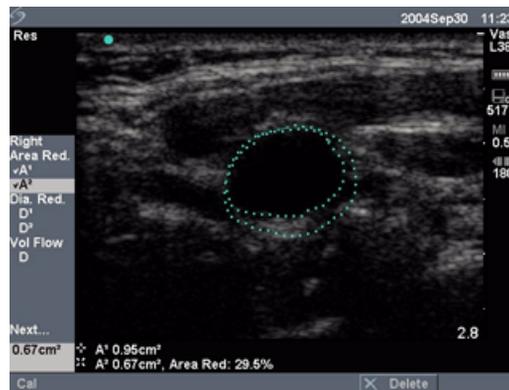


Figure 5 Percent Area Reduction Measurement

**Percent Area
Reduction
Measurement**

- 1 On a frozen 2D image, press the **Calcs** key.
 - 2 Highlight the desired measurement from the calculation menu and press the **Select** key.
 - 3 To perform the first trace, move the caliper to the desired starting point and press the **Select** key to start the tracing function.
 - 4 Use the touchpad to trace the desired area.
Note: If an error is made, select Undo from the on-screen menu to delete the previous position.
 - 5 Complete the trace and select **Set** from the on-screen menu or press the **Select** key.
The measurement is displayed in the measurement and calculation data area and is updated as the caliper moves.
 - 6 Select **Save** from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.
The saved measurement is shown at the bottom of the calculation menu and a check mark is put in front of the measurement.
 - 7 Highlight the next measurement and press the **Select** key.
 - 8 Perform the next trace.
 - 9 Complete the trace and select **Set** from the on-screen menu or press the **Select** key.
 - 10 Select **Save** from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.
The percent area reduction result is displayed in the measurement and calculation data area and in the patient report.
-

**Percent Diameter
Reduction
Measurement**

- 1 On a frozen 2D image, press the **Calcs** key.
 - 2 Highlight the desired measurement from the calculation menu and press the **Select** key.
 - 3 Perform the measurement.
The measurement is displayed in the measurement and calculation data area and is updated as the caliper moves. The measurement is complete when you finish moving the calipers.
 - 4 Select **Save** from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.
The saved measurement is shown at the bottom of the calculation menu and a check mark is put in front of the measurement.
 - 5 Highlight the next measurement and press the **Select** key.
 - 6 Perform the next measurement.
 - 7 Select **Save** from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.
The percent diameter reduction result is displayed in the measurement and calculation data area and in the patient report.
-

Volume Calculation

Warning: Verify the patient information, date, and time settings are accurate.
Before starting a new calculation, start a new patient exam to delete the previous measurements. See “New Patient” on page 41.

The following table shows the transducers and exam types that provide a volume calculation.

Table 3: Transducers and Exam Types for Volume

| Transducer | Exam Types |
|------------|------------------------------------|
| C8 | Gyn, Prostate |
| C11 | Vascular, Neonatal, Abdomen |
| C15 | Abdomen |
| C60 | Gyn, Abdomen |
| HST | Vascular, Superficial, Muscle |
| L25 | Superficial, Vascular, Small Parts |
| ICT | Gyn |
| L38 | Breast, Small Parts, Vascular |

The following measurements D^1 D^2 D^3 (2D distance) are required to complete the volume calculation. Volume measurements are performed in 2D mode.



Figure 6 2D Image with Volume Calculation

Volume Calculation

Note: D^1 , D^2 , and D^3 are required to complete a volume calculation.

- 1 On a frozen 2D image, press the **Calcs** key.
- 2 Use the touchpad to highlight the desired measurement from the calculations menu and press the **Select** key.
- 3 Perform the measurement.
The selected measurement is displayed in the measurement and calculation data area and is updated as the caliper moves. The measurement is complete when you finish moving the calipers.
- 4 Select **Save** from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.
The saved measurement is shown at the bottom of the calculation menu and a check mark is put in front of the measurement.

*Note: The Δ key or **Save** Key can be assigned in system setup to save calculations to the report. See ["Delta Key" on page 32](#) or ["Save Key" on page 39](#).*

If desired, press the **Save** key to save the image with the measurements displayed.

- 5 Repeat these steps until all measurements have been performed.
-

View or Repeat Saved Measurement

- 1 Use the touchpad to highlight the desired measurement from the calculations menu.
The saved measurement is shown at the bottom of the calculation menu.
- 2 Press the **Select** key or the **Caliper** key to select the measurement.
- 3 Repeat the measurement.
The new results appear in the measurement and calculation data area. You can compare the active measurement to the saved measurement.
- 4 To save the new measurement, select **Save** from the on-screen menu, or press the **Enter** key.

Note: This will save the new measurement to the patient report and overwrite the previously saved measurement.

Delete Measurement

- 1 Use the touchpad to highlight the measurement.
 - 2 Select **Delete** from the on-screen menu.
This will remove the last saved measurement from the patient report.
-

Volume Flow Calculation

Warning: Verify the patient information, date, and time settings are accurate.
Before starting a new calculation, start a new patient exam to delete the previous measurements. See “New Patient” on page 41.

The following table shows the transducers and exam types that provide a volume flow calculation.

Table 4: Transducers and Exam Types for Volume Flow

| Transducer | Exam Types | Gate Sizes (mm) |
|------------|------------|--------------------|
| C60 | Abdomen | 2, 3, 5, 8, 10, 12 |
| L38/HST | Vascular | 1, 3, 5, 7, 10, 12 |

The following table shows the measurements required to complete the volume flow calculation.

Table 5: Volume Flow Calculation

| Measurement | Calculation Result |
|---|--------------------|
| D (2D distance) TAM (Doppler auto trace) | VF (Volume Flow) |

Volume flow measurements are done in 2D and Doppler. Both measurements are required for the volume flow calculation. The Doppler sample volume should completely insonate the vessel.

Note: The following factors should be considered when acquiring volume flow measurements:

- Users should follow current medical practice for volume flow calculation applications.
- The accuracy of the volume flow calculation is largely dependent on the user.
- The factors identified in the literature that affect the accuracy are:
 - Using the diameter method for 2D area
 - Difficulty ensuring uniform insonation of the vessel – The TITAN system is limited to the sample volume sizes listed in [Table 4](#).
 - Precision in placing the caliper
 - Accuracy in angle correction

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

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

Volume Flow Calculation
2D measurement

- 1 On a frozen full screen 2D image or duplex image, press the **Calcs** key.
- 2 Select Volume Flow and highlight D (distance).
- 3 Perform the measurement.

The selected measurement is displayed in the measurement and calculation data area and is updated as the caliper moves. The measurement is complete when you finish moving the calipers.

- 4 Select **Save** from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.

The saved measurement is shown at the bottom of the calculation menu and a check mark is put in front of the measurement.

*Note: The Δ key or **Save** Key can be assigned in system setup to save calculations to the report. See “Delta Key” on page 32 or “Save Key” on page 39.*

If desired, press the **Save** key to save the image with the measurements displayed.

Volume Flow Calculation**Doppler measurement**

- 1 On a frozen Doppler spectral trace or duplex image, press the **Calcs** key.
- 2 Use the touchpad to highlight Volume Flow and then highlight TAM.
- 3 Press the **Select** key to display the first vertical caliper.
- 4 Use the touchpad to position the first vertical caliper at the beginning of the wave form.
- 5 Press the **Select** key to display the second vertical caliper.

Note: If calipers are not placed in the correct position, the calculation will not be performed accurately.

- 6 Use the touchpad to position the second vertical caliper at the end of the wave form.
- 7 Select **SET** from the on-screen menu to complete the trace and to display the results.
- 8 Select **Save** from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.

The saved measurement is shown at the bottom of the calculation menu and a check mark is put in front of the measurement.

To view the volume flow calculation, go to the report. See “Patient Report” on page 101.

If desired, press the **Save** key to save the image with the measurements displayed.

Gyn Calculations

Warning: Verify the patient information, date, and time settings are accurate.
Before starting a new calculation, start a new patient exam to delete the previous measurements. See “New Patient” on page 41.

References for measurements and calculations are in [Chapter 8, “References.”](#) The following table shows the transducers and exam types that provide Gyn calculations.

Table 6: Transducers and Exam Type

| Transducer | Exam Type |
|------------|-----------|
| C8 | Gyn |
| C60 | Gyn |
| ICT | Gyn |

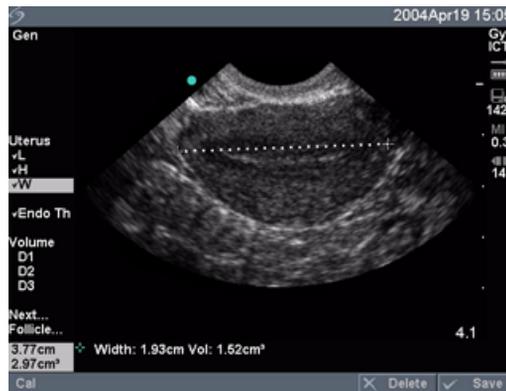


Figure 7 Gyn Measurements

| | |
|---|--|
| Gyn Calculation | <ol style="list-style-type: none"> 1 Select Gyn exam type. 2 On a frozen 2D image, press the Calcs key. 3 Select Gyn. 4 Highlight the desired measurement from the calculations menu and press the Select key. 5 Perform the measurement. 6 Select Save from the on-screen menu, or press the Enter key to save the measurement to the patient report. The saved measurement is shown at the bottom of the calculation menu and a check mark is put in front of the measurement. If desired, press the Save key to save the image with the measurements displayed. 7 Highlight the next measurement and press the Select key. 8 Repeat these steps until all measurements have been performed. |
| View or Repeat Saved Measurement | <ol style="list-style-type: none"> 1 Highlight the desired measurement from the calculations menu. The saved measurement is shown at the bottom of the calculation menu. 2 Press the Select key or the Caliper key to select the measurement. 3 Repeat the measurement. The new results are displayed in the measurement and calculation data area. You can compare the active measurement to the saved measurement. 4 To save the new measurement, select Save from the on-screen menu, or press the Enter key. <i>Note: This will save the new measurement to the patient report and overwrite the previously saved measurement.</i> |
| Delete Measurement | <ol style="list-style-type: none"> 1 Highlight the measurement. 2 Select Delete from the on-screen menu. This will remove the last saved measurement from the patient report. |



Figure 8 Follicle Measurement

Follicle Measurement

Note: You may save up to six follicular measurements. One distance measurement is provided for each follicle.

- 1 Select Gyn exam type.
- 2 On a frozen 2D image, press the **Calcs** key.
- 3 Select Follicle.
- 4 Highlight the desired measurement from the calculations menu and press the **Select** key.
- 5 Perform the measurement on the first follicle.
The measurement is displayed in the measurement and calculation data area and is updated as the caliper moves. The measurement is complete when you finish moving the calipers.
- 6 Select **Save** from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.
The saved measurement is shown at the bottom of the calculation menu and a check mark is put in front of the measurement.
If desired, press the **Save** key to save the image with the measurements displayed.
- 7 Highlight the next measurement and press the **Select** key.
- 8 Repeat these steps until all measurements have been performed.

| | | |
|---|---|---|
| View or Repeat Saved Measurement | 1 | Highlight the desired measurement from the calculations menu. The saved measurement is shown at the bottom of the calculation menu. |
| | 2 | Press the Select key or the Caliper key to select the measurement. |
| | 3 | Repeat the measurement. The new results are displayed in the measurement and calculation data area. You can compare the active measurement to the saved measurement. |
| | 4 | To save the new measurement, select Save from the on-screen menu, or press the Enter key. <i>Note: This will save the new measurement to the patient report and overwrite the previously saved measurement.</i> |
| Delete Measurement | 1 | Highlight the measurement. |
| | 2 | Select Delete from the on-screen menu. This will remove the last saved measurement from the patient report. |
| | | |

OB Calculations

| | |
|-----------------|---|
| Warning: | Make sure you have selected the OB exam type and the OB calcs author for the OB table you intend to use. See Table 9, “System Defined OB Calculations and Table Authors” on page 83. |
| | In OB exams, an accurate date and time are critical for accurate obstetrics calculations. Verify that the date and time are accurate before each use of the system. The system does not automatically adjust for daylight savings time changes. |
| | Verify the patient information, date, and time settings are accurate. |
| | Before starting a new calculation, start a new patient exam to delete the previous measurements. See “New Patient” on page 41. |
| | Prior to use, verify OB custom table data entries are correct. The system does not confirm the accuracy of the custom table data entered by the user. |

References for measurements and calculations are in [Chapter 8, “References.”](#) The following table shows the transducers and exam types that provide OB calculations.

Table 7: Transducers and Exam Type

| Transducer | Exam Type |
|------------|-----------|
| C8 | OB |
| C15 | OB |
| C60 | OB |
| ICT | OB |

The following terms describe the measurements and calculations performed by the system. References for measurements and calculations are in [Chapter 8, “References.”](#)

Table 8: OB Calculation Terms

| Acronym | Definition |
|----------------|--|
| AUA | The AUA (Average Ultrasound Age) is calculated by averaging the individual ultrasound ages for the fetal biometry measurements performed during the exam. The measurements used to determine the AUA are based on the selected OB calculation authors. |
| EDD by AUA | The EDD by AUA (Estimated Date of Delivery by Average Ultrasound Age) is the estimated date of delivery calculated from the measurements performed during the exam. |
| EDD by LMP | The EDD by LMP (Estimated Date of Delivery by Last Menstrual Period) is the due date calculated from the user entered LMP. |
| EFW | The EFW (Estimated Fetal Weight) is calculated from the measurements performed during the exam. The measurements used to determine EFW are defined by the currently selected EFW calculation author. |
| Estab. DD | The Estab. DD (Established Due Date) is a user entered due date based on previous exam data or other available information. The LMP is derived from the Established Due Date and is listed in the patient report as LMPd. |
| GA by LMP | The GA (Gestational Age by Last Menstrual Period) is the fetal age calculated using the date of the Last Menstrual Period (LMP). |
| GA by LMPd | The GA (Gestational Age by derived Last Menstrual Period) is the fetal age calculated using the Last Menstrual Period (LMPd) derived from the Established Due Date. |
| LMP | The LMP (Last Menstrual Period) is the first day of the Last Menstrual Period and is used to calculate gestational age and EDD. |
| LMPd | The LMPd (derived Last Menstrual Period) is calculated from the user entered Established Due Date (Estab. DD). |
| UA | The UA (Ultrasound Age) is calculated on the mean measurements taken for a particular fetal biometry. |

If you change the calculation author during the exam, the common measurements are retained. The following table shows the system defined measurements available for OB calculations by author. For descriptions of the acronyms, see [“Acronyms” on page 211](#).

Table 9: System Defined OB Calculations and Table Authors

| Calculation Result | Gestational OB Measurements | Table Authors |
|---------------------------------|-----------------------------|--|
| Gestational Age (See note 1) | GS | Hansmann Nyberg Tokyo U. |
| | CRL | Hadlock Hansmann Osaka Tokyo U. |
| | BPD | Chitty Hadlock Hansmann Osaka Tokyo U. |
| | OFD | Hansmann |
| | HC | Chitty Hadlock Hansmann |
| | TTD | Hansmann Tokyo U.* |
| | APTD | Tokyo U.* |
| | AC | Hadlock Hansmann Tokyo U. |
| | FTA | Osaka |
| | FL | Chitty Hadlock Hansmann Osaka Tokyo U. |

* For Toyko U, APTD and TTD are only used to calculate EFW. No age or growth tables are associated with these measurements.

Table 9: System Defined OB Calculations and Table Authors (Continued)

| Calculation Result | Gestational OB Measurements | Table Authors |
|--|---|-----------------------------|
| Estimated Fetal Weight (EFW) (See note 2 and 3) | HC, AC, FL | Hadlock 1 |
| | BPD, AC, FL | Hadlock 2 |
| | AC, FL | Hadlock 3 |
| | BPD, TTD | Hansmann |
| | BPD, FTA, FL | Osaka U. |
| | BPD, AC | Shepard |
| | BPD, TTD, APTD, FL | Tokyo U. |
| Ratios | HC/AC | Campbell |
| | FL/AC | Hadlock |
| | FL/BPD | Hohler |
| | FL/HC | Hadlock |
| Amniotic Fluid Index | Q ¹ , Q ² , Q ³ , Q ⁴ | Jeng |
| Growth Analysis Tables (See note 4) | BPD | Chitty Hadlock Jeanty |
| | HC | Chitty Hadlock Jeanty |
| | AC | Chitty Hadlock Jeanty |
| | FL | Chitty Hadlock Jeanty |
| | EFW | Hadlock Jeanty |
| | HC/AC | Campbell |

Note 1: The Gestational Age is automatically calculated and displayed next to the OB measurement you selected. The average of the results is the AUA.

Note 2: The Estimated Fetal Weight calculation uses an equation that consists of one or more fetal biometry measurements. The author for the OB tables, which you choose in system setup, determines the measurements you must perform to obtain an EFW calculation. See ["To set up OB calculations authors:"](#) on page 34, if necessary.

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

Note 4: The Growth Analysis tables are used by the Report Graphs feature. Three growth curves are drawn using the table data for the selected growth parameter and published author. Growth tables are only available with a user entered LMP or Estab. DD.

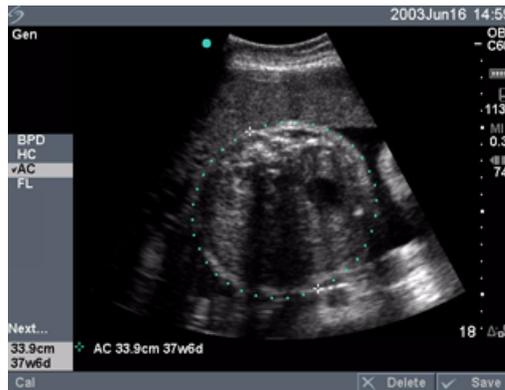


Figure 9 OB Measurement

| | |
|---|--|
| OB Calculation | <ol style="list-style-type: none"> 1 Select OB exam type, and enter either the LMP or Estab.DD in the patient information form. 2 On a frozen 2D image, press the Calcs key. 3 Highlight the desired measurement from the calculations menu and press the Select key. For twin calculations, select Twin A or Twin B and then highlight the desired measurement from the calculations menu and press the Select key. As you navigate through the measurements on the calculation menu, the caliper tool may change. However, the caliper position remains. 4 Perform the measurement. 5 Select Save from the on-screen menu, or press the Enter key to save the measurement to the patient report. For each 2D OB measurement (except AFI), the system stores up to three individual measurements and their average. If more than three measurements are made, the oldest measurement is deleted. The average measurement and ultrasound age are shown at the bottom of the calculation menu and a check mark is put in front of the measurement. <i>Note: The Δ key or Save Key can be assigned in system setup to save calculations to the report. See "Delta Key" on page 32 or "Save Key" on page 39.</i> If desired, press the Save key to save the image with the measurements displayed. 6 Highlight the next measurement and press the Select key. 7 Repeat these steps until all measurements have been performed. |
| View or Repeat Saved Measurement | <ol style="list-style-type: none"> 1 Use the touchpad to highlight the desired measurement from the calculations menu. The saved measurement is shown at the bottom of the calculation menu. 2 Press Select key or the Caliper key to select the measurement. 3 Repeat the measurement. The new results are displayed in the measurement and calculation data area. You can compare the active measurement to the saved measurement. 4 To save a new measurement, select Save from the on-screen menu, or press the Enter key. <i>Note: For measurements that are not averaged, this will save the new measurement to the patient report and overwrite the previously saved measurement.</i> |
| Delete Measurement | <ol style="list-style-type: none"> 1 Use the touchpad to highlight the measurement. 2 Select Delete from the on-screen menu. This will remove the last saved measurement from the patient report. |

The following table lists the ratios available for OB Doppler calculations.

Table 10: OB Doppler Calculations

| Measurement | Description | S/D | RI | PI* |
|-------------|------------------------|-----|----|-----|
| MCA | Middle Cerebral Artery | X | X | X |
| Umb A | Umbilical Artery | X | X | X |

*Calculation requires a trace.

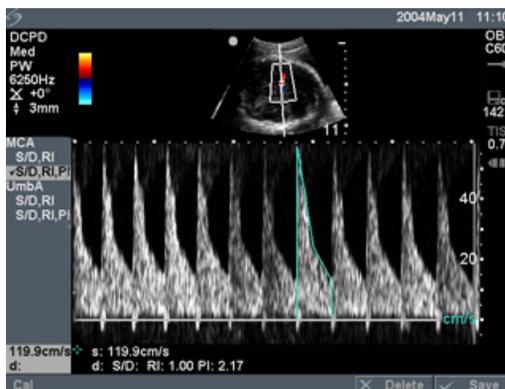


Figure 10 OB Doppler Calculation

OB Doppler Calculations

MCA (Middle Cerebral Artery)

UmbA (Umbilical Artery)

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

- 1 Select OB exam type, and enter either the LMP or Estab.DD into the patient information form.
- 2 On a frozen Doppler spectral trace, press the **Calcs** key.
- 3 Highlight the desired measurement from the calculation menu and press the **Select** key.
- 4 Perform the measurement.

Caliper Function

If S/D, RI is selected, the caliper function is activated.

- Position the first caliper at the peak systolic waveform. Press the **Select** key and position the second caliper at end diastole on the waveform.

OR

Manual Trace

If S/D, RI, PI is selected, the manual trace function is activated.

- Position the caliper at the beginning of the desired waveform and press the **Select** key. Use the touchpad to move the caliper to the next desired point on the wave form.
- Continue marking points by pressing the **Select** key. The last point must be placed at the end of the waveform.
- Select **Set** from the on-screen menu to complete the trace and display the results.

Note: If calipers are not placed in the correct position, the calculation will not be performed accurately.

- 5 Select **Save** from the on-screen menu, or press the **Enter** key to save the measurements to the patient report. The results are displayed at the bottom of the calculation menu and a check mark is put in front of the measurement. If desired, press the **Save** key to save the image with the measurements displayed.

Note: This will save the new measurement to the patient report and overwrite the previously saved measurement.

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

- 6 Repeat these steps until all measurements have been performed.

| | | |
|---|---|--|
| View or Repeat Saved Measurement | 1 | Highlight the desired measurement from the calculations menu. The saved measurement is shown at the bottom of the calculation menu. |
| | 2 | Press Select key or the Caliper key to select the measurement. |
| | 3 | Repeat the measurement. The new results are displayed in the measurement and calculation data area. You can compare the active measurement to the saved measurements. |
| | 4 | To save a new measurement, select Save from the on-screen menu, or press the Enter key. <i>Note: This will save the new measurement to the patient report and overwrite the previously saved measurement.</i> |
| Delete Measurement | 1 | Highlight the measurement. |
| | 2 | Select Delete from the on-screen menu. This will remove the last saved measurement from the patient report. |

Vascular Calculations

Warning: Verify the patient information, date, and time settings are accurate. Before starting a new calculation, start a new patient exam to delete the previous measurements. See [“New Patient” on page 41](#).

Vascular Measurements

The following table shows the transducers and exam types that provide vascular measurements.

Table 11: Transducer and Exam Types for Vascular

| Transducer | Exam Types |
|------------|------------|
| C11 | Vascular |
| HST | Vascular |
| L25 | Vascular |
| L38 | Vascular |

Carotid vascular measurements may be performed and saved to the patient report. The specific measurements that can be stored to the patient report are provided in the following table. For definitions of acronyms, see [“Acronyms” on page 211](#).

Table 12: Carotid Vascular Measurements

| Vascular Measurement | Systolic | Diastolic |
|----------------------|----------|-----------|
| PCCA | X | X |
| MCCA | X | X |
| DCCA | X | X |
| Bulb | X | X |
| PICA | X | X |
| MICA | X | X |
| DICA | X | X |
| PECA | X | X |
| MECA | X | X |
| DECA | X | X |
| VArty | X | X |

Note: After vascular measurements are performed, values used in the ICA/CCA ratio are selectable on the vascular report page.



Figure 11 Vascular Measurement

| | |
|---|--|
| Label Vascular Measurement | <ol style="list-style-type: none"> 1 On a frozen Doppler spectral trace, press the Calcs key. Use the touchpad to highlight Left or Right from the calculation menu. 2 Press the Select key. 3 Use the touchpad to highlight the desired measurement from the calculation menu. 4 Press the Select key. 5 Use the touchpad to position the caliper at the peak systolic wave form. 6 Press the Select key. A second caliper is displayed on the screen. The active caliper is highlighted green. 7 Use the touchpad to position the second caliper at end diastole on the waveform. The results are displayed in the measurement and calculation data area and are updated as the caliper moves. 8 Select Save from the on-screen menu, or press the Enter key to save the measurement to the patient report. The saved measurement is displayed at the bottom of the calculation menu and a check mark is put in front of the measurement. If desired, press the Save key to save the image with the measurements displayed. <i>Note: The Δ key or Save Key can be assigned in system setup to save calculations to the report. See "Delta Key" on page 32 or "Save Key" on page 39.</i> 9 Repeat these steps until all measurements have been performed. |
| View or Repeat Saved Measurement | <ol style="list-style-type: none"> 1 Use the touchpad to highlight the desired measurement from the calculations menu. The saved measurement is shown at the bottom of the calculation menu. 2 Press the Select key or the Caliper key to select the measurement. 3 Repeat the measurement. The new results appear in the measurement and calculation data area. You can compare the active measurement to the saved measurement. 4 To save a new measurement, select Save from the on-screen menu, or press the Enter key. <i>Note: This will save the new measurement to the patient report and overwrite the previously saved measurement.</i> <i>Note: You must remeasure systolic measurement to remeasure diastolic measurement.</i> |
| Delete Measurement | <ol style="list-style-type: none"> 1 Use the touchpad to highlight the measurement. 2 Select Delete from the on-screen menu. This will remove the last saved measurement from the patient report. |

Cardiac Calculations

Warning: Verify the patient information, date, and time settings are accurate. Before starting a new calculation, start a new patient exam to delete the previous measurements. See “New Patient” on page 41.

References for measurements and calculations are in [Chapter 8, “References.”](#) The following table shows the transducers and exam types that provide cardiac calculations.

Table 13: Transducer and Exam Types for Cardiac

| Transducer | Exam Types |
|------------|------------|
| C11 | Cardiac |
| C15 | Cardiac |

2D and M Mode Cardiac Calculations

The following table shows the measurements required to complete the desired cardiac calculation. The cardiac measurements are done in 2D and M Mode. For definition of acronyms, see “Acronyms” on page 211.

Table 14: Cardiac Calculations in 2D and M Mode

| Imaging Mode | Anatomy | Cardiac Measurement | Calculation Result |
|--------------|---------|-------------------------|--------------------|
| 2D/M Mode | LV | RVWs | CO |
| | | RVDs | EF |
| | | IVSs | SV |
| | | LVDs | LVESV |
| | | LVPWs | LVEDV |
| | | RVWd | IVSFT |
| | | RVDd | LVPWF |
| | | IVSd | LVDFS |
| | | LVDd | |
| | | LVPWd | |
| | | HR in M Mode or Doppler | |
| | Ao | Ao | Ao LA/Ao |
| | LA | LA | LA LA/Ao |

Table 14: Cardiac Calculations in 2D and M Mode (Continued)

| Imaging Mode | Anatomy | Cardiac Measurement | Calculation Result |
|---------------------|----------------|---|-------------------------------------|
| | LV Vol | A4Cd A4Cs A2Cd A2Cs (Biplane) | LV Vol LV Area EF CO SV |
| | LVOT D | LVOT D | LVOT D LVOT area |
| M Mode | | ACS | ACS |
| | | LVET | LVET |
| | | EF:SLOPE | EF:SLOPE |
| | | EPSS | EPSS |

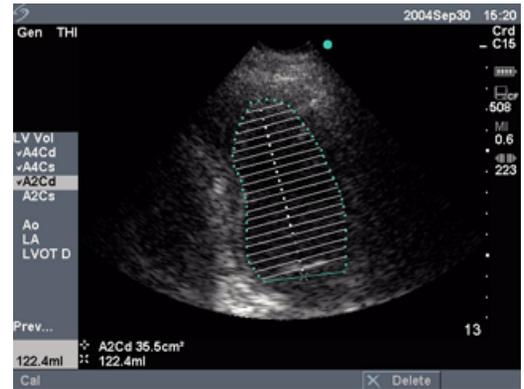
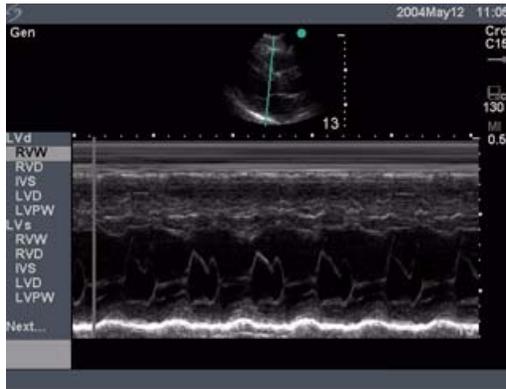


Figure 12 Cardiac M Mode and LV Volume

Cardiac Calculation (2D and M Mode)

- 1 On a frozen 2D image or M Mode trace, press the **Calcs** key.
- 2 Highlight the desired calculation package and press the **Select** key.
- 3 Select the measurement and press the **Select** key.
Note: As you advance through the LV measurements, the top caliper will automatically reposition to help you proceed with the next selected measurement.
- 4 Perform the measurement.
- 5 Select **Save** from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.
 The saved measurement is displayed at the bottom of the calculation menu and a check mark is put in front of the measurement.
 If desired, press the **Save** key to save the image with the measurements displayed.
*Note: The Δ key or **Save** Key can be assigned in system setup to save calculations to the report. See "[Delta Key](#)" on page 32 or "[Save Key](#)" on page 39.*
- 6 Highlight the next measurement and press the **Select** key.
- 7 Repeat these steps until all measurements have been performed.

**LV Volume
(Simpson's Rule)**

- 1 On a frozen 2D image, press the **Calcs** key.
 - 2 Highlight the desired calculation package and press the **Select** key.
 - 3 To perform the first measurement, select A4Cd and press the **Select** key.
 - 4 Position the caliper at the medial mitral annulus and press the **Select** key to start the tracing function.
 - 5 Use the touchpad to trace the left ventricular (LV) cavity.
Note: If an error is made, select Undo from the on-screen menu to delete the previous position.
 - 6 Complete the trace and select Set from the on-screen menu or press the **Select** key.
The measurement is displayed in the measurement and calculation data area and is updated as the caliper moves. Adjust the caliper position if needed.
 - 7 Select Save from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.
The saved measurement is displayed at the bottom of the calculation menu and a check mark is put in front of the measurement.
If desired, press the **Save** key to save the image with the measurements displayed.
Note: The Δ key or Save Key can be assigned in system setup to save calculations to the report. See "Delta Key" on page 32 or "Save Key" on page 39.
 - 8 Highlight the next measurement and press the **Select** key.
 - 9 Repeat these steps until all measurements have been performed.
-

**View or Repeat
Saved
Measurement**

- 1 Use the touchpad to highlight the desired measurement from the calculations menu.
The saved measurement is shown at the bottom of the calculation menu.
 - 2 Press the **Select** key or the **Caliper** key to select the measurement.
 - 3 Repeat the measurement.
The new results appear in the measurement and calculation data area. You can compare the active measurement to the saved measurement.
 - 4 To save a new measurement, select Save from the on-screen menu, or press the **Enter** key.
Note: This will save the new measurement to the patient report and overwrite the previously saved measurement.
-

**Delete
Measurement**

- 1 Use the touchpad to highlight the measurement.
 - 2 Select Delete from the on-screen menu.
This will remove the last saved measurement from the patient report.
-

Doppler Cardiac Calculations

The following table shows the measurements required to complete the desired cardiac calculation. The cardiac measurements are done in PW Doppler and CW Doppler mode. For definitions of acronyms, see “Acronyms” on page 211.

Table 15: Cardiac Calculations in Doppler

| Anatomy | Cardiac Measurement | Calculation Result |
|---------------------------------------|---|---|
| MV (Mitral Valve) | E | E |
| | A | E PG A A PG E:A |
| | PHT (deceleration time) | PHT MVA |
| LVOT (Left Ventricular Outflow Tract) | dP:dT | dP:dT |
| | VTI | VTI Vmax PGmax Vmean PGmean |
| AV (Aortic Valve) | Vmax or VTI | Vmax PGmax |
| | VTI | VTI Vmax PGmax Vmean PGmean |
| TV (Tricuspid Valve) | LVOT D in 2D VTI or Vmax from LVOT VTI or Vmax from aorta | AVA |
| | VTI LVOT D in 2D | SV |
| | VTI HR LVOT D in 2D | CO |
| | TRmax | TRmax PGmax |
| | dP:dT | dP:dT |

Table 15: Cardiac Calculations in Doppler (Continued)

| Anatomy | Cardiac Measurement | Calculation Result |
|-------------------------------------|---|---|
| PV (Pulmonic Valve) | VTI | VTI Vmax PGmax Vmean PGmean |
| | Vmax or VTI | Vmax PGmax |
| E, A, VMax, and TRmax | <ol style="list-style-type: none"> On a frozen Doppler spectral trace, press the Calcs key. Highlight the desired calculation package and press the Select key. Select the desired measurement and press the Select key. Perform the measurement. Select Save from the on-screen menu, or press the Enter key to save the measurement to the patient report. The saved measurement is displayed at the bottom of the calculation menu and a check mark is put in front of the measurement. If desired, press the Save key to save the image with the measurements displayed. <p><i>Note: The Δ key or Save Key can be assigned in system setup to save calculations to the report. See “Delta Key” on page 32 or “Save Key” on page 39.</i></p> <ol style="list-style-type: none"> Highlight the next measurement and press the Select key. Repeat these steps until all measurements have been performed. | |
| Velocity Time Integral (VTI) | <p><i>Note: In addition to VTI results, this calculation will compute other results. See Table 15.</i></p> <ol style="list-style-type: none"> On a frozen Doppler spectral trace, press the Calcs key. Highlight the LVOT, AV, or PV and press the Select key. Select VTI and press the Select key. Perform manual or automatic trace. See “Manual Trace” on page 71 and “Automatic Trace” on page 71. Select Save from the on-screen menu, or press the Enter key to save the measurement to the patient report. The saved measurement is displayed at the bottom of the calculation menu and a check mark is put in front of the measurement. If desired, press the Save key to save the image with the measurements displayed. | |

Pressure Half Time (PHT)

Note: PHT is calculated by measuring deceleration time from peak to baseline.

- 1 On a frozen Doppler spectral trace, press the **Calcs** key.
- 2 Highlight MV and press the **Select** key.
- 3 Select PHT.
- 4 Position the first caliper at the peak and press the **Select** key.
A second caliper is displayed.
Position the second caliper along the EF slope.
- 5 Select **Save** from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.
The saved measurement is displayed at the bottom of the calculation menu and a check mark is put in front of the measurement.
If desired, press the **Save** key to save the image with the measurements displayed.

**Delta Pressure:
Delta Time (dP:dT)**

Note: To perform the dP:dT measurements, the Doppler scale must include velocities of 300 cm/s or greater on the negative side of the baseline.

- 1 On a frozen Doppler spectral trace, press the **Calcs** key.
 - 2 Highlight MV or TV and press the **Select** key.
 - 3 Select dP:dT and press the **Select** key.
A horizontal dotted line with an active caliper is displayed at 100 cm/s.
 - 4 Position the first caliper along the beginning of the wave form at 100 cm/s.
 - 5 Press the **Select** key.
A second horizontal dotted line with an active caliper is displayed at 300 cm/s.
 - 6 Position the second caliper along the beginning of the wave form at 300 cm/s.
 - 7 Select **Save** from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.
The saved measurement is displayed at the bottom of the calculation menu and a check mark is put in front of the measurement.
If desired, press the **Save** key to save the image with the measurements displayed.
-

Aortic Valve Area (AVA)

Note: This calculation requires a measurement taken in 2D and two measurements taken in Doppler. After the three measurements are completed and saved, the result is displayed in the patient report.

2D measurement from LVOT

- 1 On a frozen 2D image, press the **Calcs** key.
- 2 Highlight LVOT D and press the **Select** key.
- 3 Perform the measurement.
- 4 Select Save from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.

The saved measurement is displayed at the bottom of the calculation menu and a check mark is put in front of the measurement.

If desired, press the **Save** key to save the image with the measurements displayed.

Doppler measurement from LVOT

- 1 On a frozen Doppler spectral trace, press the **Calcs** key.
- 2 Highlight LVOT and press the **Select** key.
- 3 Select VTI or Vmax and press the **Select** key.
- 4 Perform the measurement.
See [“Manual Trace” on page 71](#) or [“Automatic Trace” on page 71](#).
- 5 Select Save from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.

The saved measurement is displayed at the bottom of the calculation menu and a check mark is put in front of the measurement.

If desired, press the **Save** key to save the image with the measurements displayed.

Doppler measurement from aorta

- 1 On a frozen Doppler spectral trace, press the **Calcs** key.
- 2 Highlight AV and press the **Select** key.
- 3 Select VTI or Vmax and press the **Select** key.
- 4 Perform the measurement.
See [“Manual Trace” on page 71](#) or [“Automatic Trace” on page 71](#).
- 5 Select Save from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.

The saved measurement is displayed at the bottom of the calculation menu and a check mark is put in front of the measurement.

If desired, press the **Save** key to save the image with the measurements displayed.

Stroke Volume (SV)

Note: This calculation requires a measurement taken in 2D and one measurement taken in Doppler. After the measurements are completed and saved, the result is displayed in the patient report.

2D measurement from LVOT

- 1 On a frozen 2D image, press the **Calcs** key.
- 2 Highlight LVOT D and press the **Select** key.
- 3 Perform the measurement.
- 4 Select Save from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.
The saved measurement is displayed at the bottom of the calculation menu and a check mark is put in front of the measurement.
If desired, press the **Save** key to save the image with the measurements displayed.

Doppler measurement from aorta

- 1 On a frozen Doppler spectral trace, press the **Calcs** key.
 - 2 Highlight AV and press the **Select** key.
 - 3 Select VTI and press the **Select** key.
 - 4 Perform the measurement.
See [“Manual Trace” on page 71](#) or [“Automatic Trace” on page 71](#).
 - 5 Select Save from the on-screen menu, or press the **Enter** key to save the measurement to the patient report.
The saved measurement is displayed at the bottom of the calculation menu and a check mark is put in front of the measurement.
If desired, press the **Save** key to save the image with the measurements displayed.
-

Cardiac Output (CO)

Note: This calculation requires a stroke volume and a heart rate. After the measurements are completed and saved, the result is displayed in the patient report.

- 1 On a frozen Doppler spectral trace, press the **Calcs** key.
 - 2 Perform the calculation for SV.
See [“Stroke Volume \(SV\)” on page 100](#).
 - 3 Perform the calculation for HR.
See [“Heart Rate \(HR\)” on page 67](#).
-

Heart Rate (HR)

Note: The Heart Rate is not calculated using the ECG trace.

- 1 On a frozen Doppler spectral trace, press the **Calcs** key.
 - 2 Select desired cardiac calculation package.
Heart Rate is available in all cardiac packages.
 - 3 Select HR and press the **Select** key.
See [“Heart Rate \(HR\)” on page 67](#).
-

Patient Report



Figure 13 Example of Vascular Report Screen and Cardiac Report

Patient Reports

- 1 Press the **Report** key.
The current patient report is shown with the following on-screen menu options:
 - ▢ Next Page (1/x)
 - Done

Note: The pound symbol (###) is displayed on the patient report when an entry is out of range, e.g., too large or small.

Note: The value for a calculation is displayed only when the calculation has been performed.
- 2 Select Next Page (1/x) from the on-screen menu to view additional pages of the patient report.
The last page of the patient report contains patient information. In the OB report pages, a signature space is available for signing printed reports.
- 3 Press the **Save** key to save the current page of the patient report.
- 4 Select Done from the on-screen menu to exit patient report and return to the previous imaging state.

Vascular Report

- 1 At the end of a vascular exam, press the **Report** key.
- 2 In the Ratio list, select the desired measurements for the ICA/CCA ratio for both the right and left sides.

OB Twins Report (Individual)

- 1 At the end of an OB exam, press the **Report** key.
- 2 Select Twin A/B from the on-screen menu to view individual twin reports.

OB Twins Report (Combined)

- 1 At the end of an OB exam, press the **Report** key.
- 2 Select Compare from the on-screen menu to view both twins in a single report.

-
- | | |
|--|--|
| Delete Measurement (OB Report only) | <ol style="list-style-type: none"> 1 At the end of an OB exam, press the Report key. 2 Use the cursor to point to the desired OB measurement and press the Select key. The selected measurement is highlighted green. 3 Select Delete from the on-screen menu. To delete all measurements, select the measurement label and press the Select key then select Delete from the on-screen menu. |
|--|--|
-
- | | |
|--------------------|---|
| Send Report | <ol style="list-style-type: none"> 1 Ensure the printer is configured for serial port data export. See “To set up Connectivity:” on page 29. 2 Select Send Rep. from the on-screen menu. Data is sent to the computer as a text file. <p><i>Note: This function can be used for all reports.</i></p> |
|--------------------|---|
-

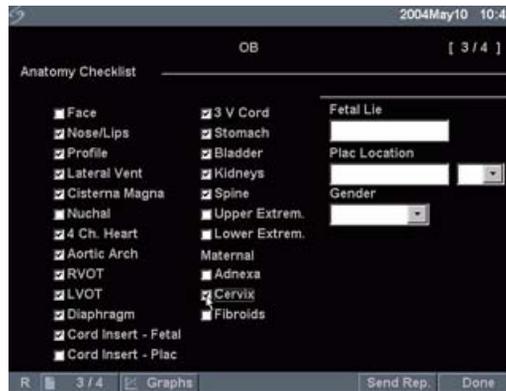


Figure 14 Anatomy Demonstrated

-
- | | |
|-----------------------------|---|
| Anatomy Demonstrated | <ol style="list-style-type: none"> 1 At the end of an OB exam, press the Report key. 2 On the page for Anatomy Demonstrated, select the check boxes to document reviewed anatomy. <i>Note: Use the Tab key to move between fields and the Space Bar to check and uncheck items from the checklist.</i> |
|-----------------------------|---|
-
- | | |
|----------------------------|--|
| Biophysical Profile | <ol style="list-style-type: none"> 1 At the end of an OB exam, press the Report key. 2 On page 2 of the report, select a value for the biophysical profile (0, 1, 2). The total score is calculated when values are entered. NST (non-stress test) is optional. |
|----------------------------|--|
-

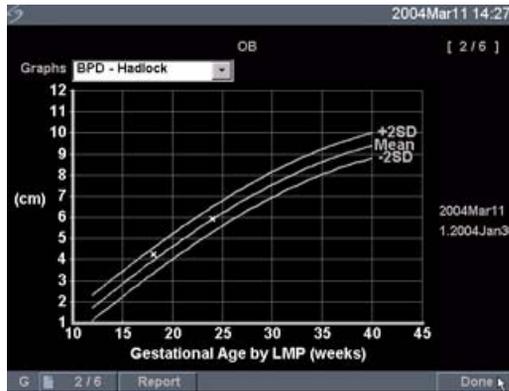


Figure 15 OB Graphs

OB Graphs

Note: OB Graphs may only be viewed when LMP or Estab. DD is entered in the patient information screen.

- 1 At the end of an OB exam, press the **Report** key.
- 2 Select **Graphs** from the on-screen menu.
- 3 In the **Graphs** list, select the desired measurement/author.
The graph for the selected measurement is displayed. If desired, select another measurement/author or select **Next Page** from the on-screen menu.
If desired, press the **Save** key to save the current graph page.
- 4 Select **Report** from the on-screen menu to return to the previous report page or **Done** to return to live imaging.

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

Chapter 5: DICOM Connectivity

DICOM (Digital Imaging and Communications in Medicine) is an optional data-transfer feature that allows the TITAN system to connect over a local area network (LAN) to PACS archivers, to film printers, and to worklist servers. This chapter contains instructions for configuring and using DICOM.

TITAN System Setup for DICOM

To set up the TITAN system for DICOM connectivity:

- 1 Press the **Setup** key.
- 2 Select **Connectivity**.
- 3 In the **Transfer Mode** list, select **DICOM**.
A dialog box is displayed to restart the system.

Ethernet Connection

To connect to a LAN:

Connect the Ethernet cable to the Ethernet interface cable and then connect to the Ethernet connection on the docking system/mini-dock. See *TITAN Accessories User Guide*.

With the system on, check the LAN link light (green LED) next to the Ethernet connector to verify physical connection to LAN.

DICOM Setting Backup

Before configuring the TITAN system, SonoSite highly recommends saving the DICOM factory settings to a CompactFlash card and storing the card in a secure location.

To create DICOM settings backup:

- 1 Insert a blank CompactFlash card in the back slot. See [“Installing and Removing the CompactFlash Card” on page 11](#).
- 2 Press the **Setup** key and select **Connectivity** and then **DICOM Setup**.
- 3 Select **Config** from the on-screen menu.
- 4 Select **Export** from the on-screen menu.
- 5 Remove the CompactFlash card when complete.

DICOM Configuration

The TITAN system provides configuration pages for setting up DICOM devices for network connectivity. The DICOM configuration pages are typically configured by network administrators or PACS managers.

| | |
|-----------|--|
| Locations | List of locations for the TITAN system. |
| Archivers | Devices for storing patient images. |
| Printers | Film printers for printing patient exam images. |
| Worklist | List of scheduled patient procedures used to enter patient data in the Patient Information form. |
| Procedure | List of system and user defined procedures. |

Configuring Locations

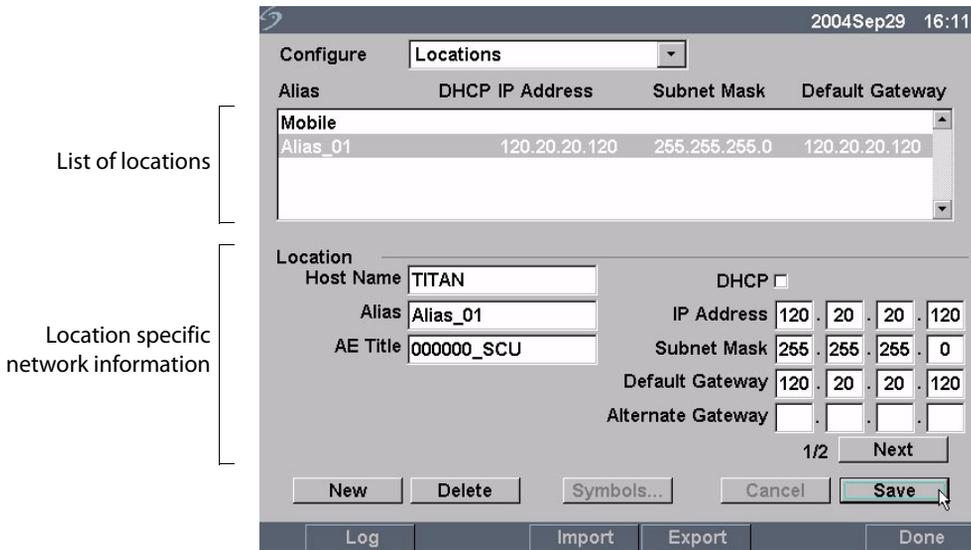


Figure 1 Locations Configuration (Page 1)

| | |
|-----------|--|
| Host Name | Unique network host name for the TITAN system. The default host name is TITAN. |
| Alias | Personalized name for the TITAN system. |
| AE Title | TITAN system DICOM Application Entity Title. |
| DHCP | Dynamic Host Configuration Protocol: A protocol for automating and managing the network configuration of the TITAN system. |

| | |
|-------------------|---|
| IP Address | Unique identifier of the TITAN system location. |
| Subnet Mask | Identifies a network subdivision. The default value is "255.255.0.0". |
| Default Gateway | IP address where the network connects to another network. |
| Alternate Gateway | Alternate location where the network connects to another network. |

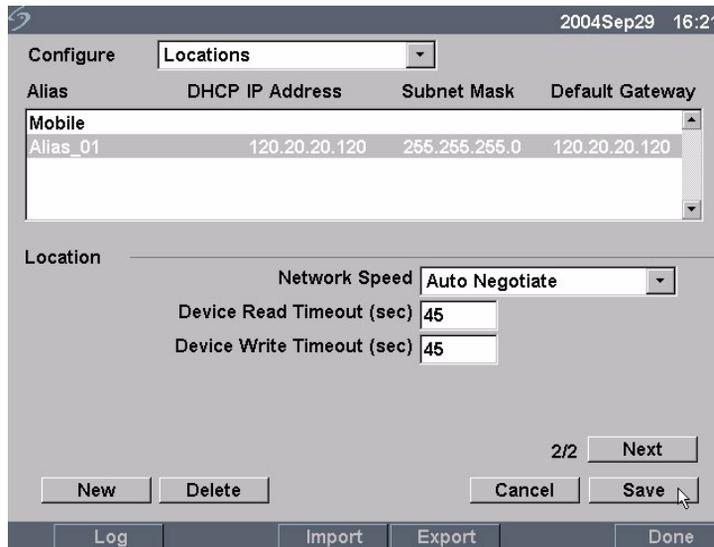


Figure 2 Locations Configuration (Page 2)

| | |
|----------------------|---|
| Network Speed | Speed at which the network is transferring data. |
| Device Read Timeout | Length of time the TITAN system will keep the network line open when receiving information. |
| Device Write Timeout | Length of time the TITAN system will keep the network line open when sending information. |

To configure a new location:

- 1 Ensure the TITAN system is set up for DICOM connectivity. See [“To set up the TITAN system for DICOM connectivity:” on page 105](#).
- 2 Press the **Setup** key and select Connectivity and then DICOM Setup.
- 3 Select Config from the on-screen menu.
- 4 Select New.
- 5 Enter network information in the fields (pages 1 and 2).
 - Each host name must have a unique name, contain only alphanumeric characters, and start with an alpha character. The host name cannot contain symbols/special characters or spaces (underscore symbol).
 - The Alias and AE Title may contain special characters.
 - The IP address must be entered before the information is saved.

Note: To use special characters, select Symbols. See [“To enter a symbol/special character:” on page 20](#).

Note: Use the space bar on the keyboard to enter the underscore symbol.

Select Cancel to undo last change.

If using Dynamic Host Configuration Protocol (DHCP), select the DHCP check box. When DHCP is selected, the IP Address, Subnet Mask, Default Gateway, and Alternate Gateway are inactive.

Note: The IP Address, Default Gateway, and Alternate Gateway cannot have values from “127.0.0.0” to “127.0.0.8”. An invalid value reverts back to the original value after information is saved.

- 6 Select Save.
- 7 Complete all configuration information and then select Done from the on-screen menu. A dialog box is displayed to restart the system.

To delete a location:

- 1 Select the name of the location from the list of locations.
- 2 Select Delete.
A dialog box is displayed.
- 3 Select Yes to delete and No to cancel.
- 4 Complete all configuration information and then select Done from the on-screen menu. A dialog box is displayed to restart the system.

Configuring Archivers

2004Sep29 16:13

Configure Archivers

| Alias | Model | IP Address | Port | AE Title |
|----------|----------------|---------------|------|--------------|
| Alias_02 | _Secondary_Cap | 120.20.20.120 | 104 | New_AE_Title |

Archiver

Name: New_Name IP Address: 120 . 20 . 20 . 120

Alias: Alias_02 Port: 104

Model: _Secondary_Cap AE Title: New_AE_Title

Ping 1/2 Next

New Delete Symbols... Cancel Save

Log Import Export Done

Figure 3 Archivers Configuration (Page 1)

| | |
|------------|---|
| Name | Network hostname for an archiver. |
| Alias | Personalized name for an archiver. |
| Model | List of generic archiver models based on capture type. |
| IP Address | Unique identifier for the archiver. |
| Port | Device port number. (IP port 104 is normally assigned for DICOM.) |
| AE Title | Archiver DICOM Application Entity Title. |
| Ping | Utility to determine whether a specific IP address is accessible. |

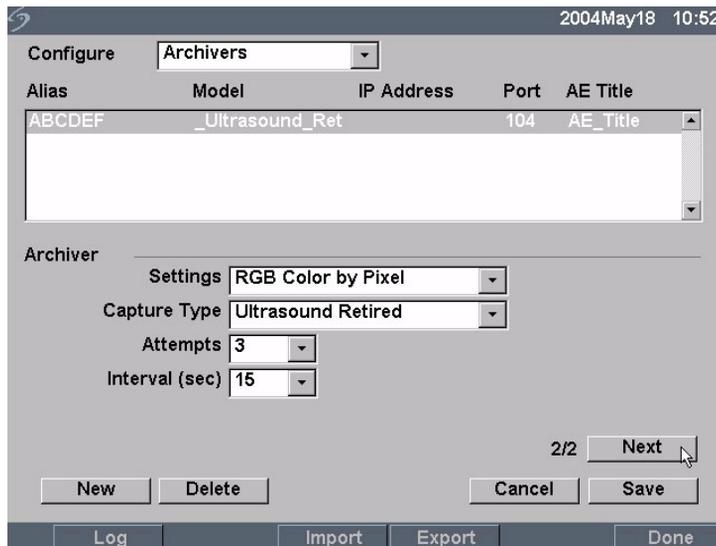


Figure 4 Archivers Configuration (Page 2)

| | |
|--------------|---|
| Settings | Defines how images are sent to the archiver, either as Color (RGB) or Monochrome images. |
| Capture Type | Type of DICOM image sent to the archiver (Ultrasound, Ultrasound Retired, Secondary Capture). |
| Attempts | Number of times the TITAN system tries to resend a failed file transfer. |
| Interval | Amount of time between attempts. |

To configure a new archiver:

- 1 Ensure the TITAN system is set up for DICOM connectivity. See [“To set up the TITAN system for DICOM connectivity:” on page 105](#).
- 2 Press the **Setup** key and select Connectivity and then DICOM Setup.
- 3 Select Config from the on-screen menu.
- 4 In the Configure list, select Archivers.
- 5 Select New.
- 6 Enter information in the fields (pages 1 and 2).
 - The Name cannot contain special characters.
 - The Alias and AE Title may contain special characters.
 - The IP address and port must be entered before the information is saved.

Note: To use special characters, select Symbols. See [“To enter a symbol/special character:” on page 20](#).

Note: Use the space bar on the keyboard to enter the underscore symbol.

Select Cancel to undo last change.

- 7 Select Save.
- 8 Complete all configuration information and then select Done from the on-screen menu.
A dialog box is displayed to restart the system.

To delete an archiver:

- 1 Select the name of the device from the list of archivers.
- 2 Select Delete.
A dialog box is displayed.
- 3 Select Yes to delete and No to cancel.
- 4 Complete all configuration information and then select Done from the on-screen menu.
A dialog box is displayed to restart the system.

Configuring Printers

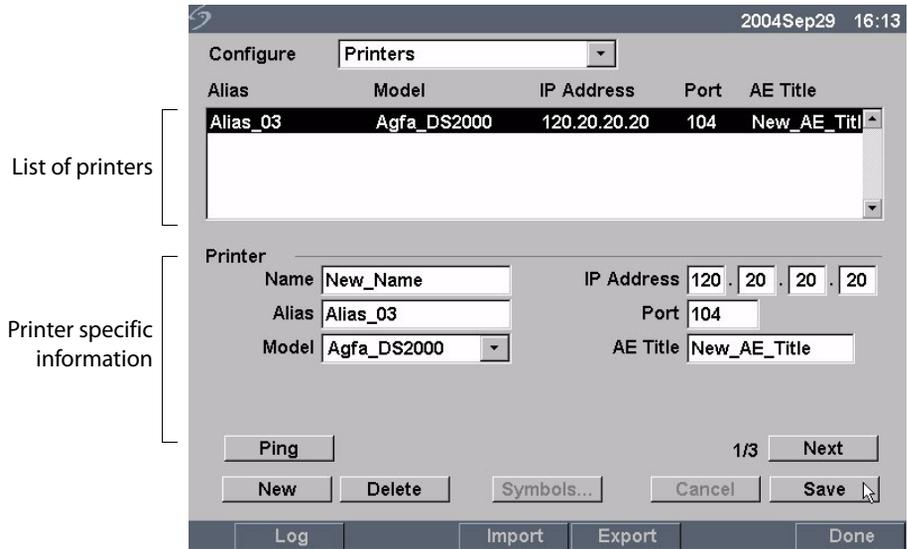


Figure 5 Printers Configuration (Page 1)

| | |
|------------|---|
| Name | Network hostname for a printer. |
| Alias | Personalized name for a printer. |
| Model | List of Agfa, Codonics, and Kodak printer models. If a specific model is not listed, choose one of the generic models at the end of the list. |
| IP Address | Unique identifier for the printer. |
| Port | Device port number. (IP port 104 is normally assigned for DICOM.) |
| AE Title | Printer DICOM Application Entity Title. |
| Ping | Utility to determine whether a specific IP address is accessible. |

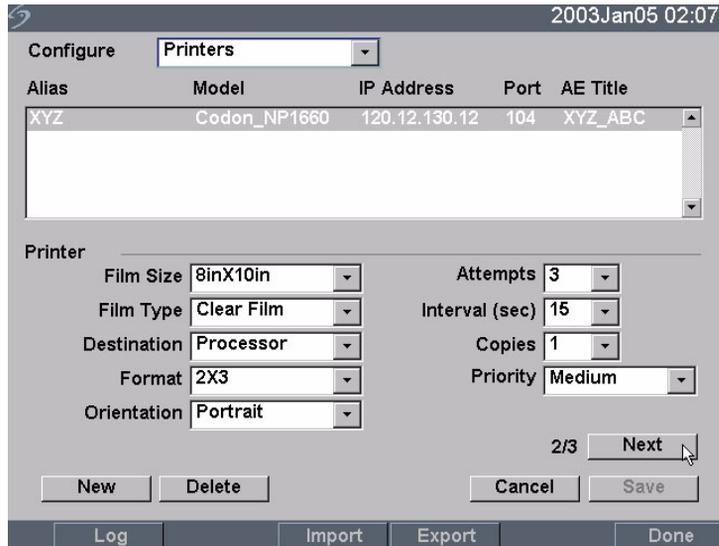


Figure 6 Printers Configuration (Page 2)

| | |
|-------------|---|
| Film Size | Film sizes supported by the printer. |
| Film Type | Film medium supported by the printer. |
| Destination | Location film is placed after it is printed. |
| Format | Number of columns and rows in the image printout. |
| Orientation | Film layout. |
| Attempts | Number of times the TITAN system tries to resend a failed image transfer. |
| Interval | Amount of time between attempts. |
| Copies | Number of copies to print for each image. |
| Priority | Importance of the print job. |

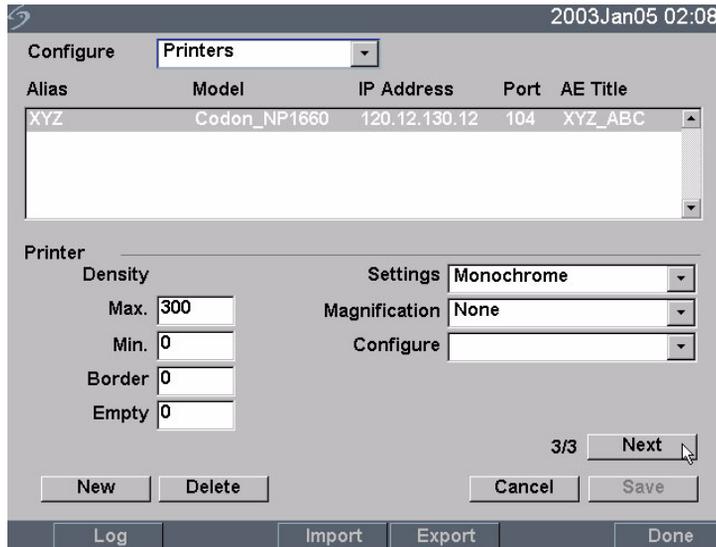


Figure 7 Printers Configuration (Page 3)

| | |
|----------------|--|
| Max. Density | Maximum density of the black value.* |
| Min. Density | Minimum density of the white value.* |
| Border Density | Density of the areas surrounding and between film images.* |
| Empty Density | Empty image density.* |
| Settings | Defines how images are sent to the printer, either as Color (RGB) or Monochrome images. |
| Magnification | Type of interpolation used during printing. |
| Configure | Printer-specific configuration value. If using generic printer settings, no configuration strings are available. |

* In hundredths of optical density (OD)

To configure a new printer:

- 1 Ensure the TITAN system is set up for DICOM connectivity. See [“To set up the TITAN system for DICOM connectivity:” on page 105](#).
- 2 Press the **Setup** key and select Connectivity and then DICOM Setup.
- 3 Select Config from the on-screen menu.
- 4 In the Configure list, select Printers.
- 5 Select New.
- 6 Enter information in the fields (pages 1, 2, and 3).
 - The Name cannot contain special characters.
 - The Alias and AE Title may contain special characters.
 - The IP address and port must be entered before the information is saved.

Note: To use special characters, select Symbols. See [“To enter a symbol/special character:” on page 20](#).

Note: Use the space bar on the keyboard to enter the underscore symbol.

Select Cancel to undo last change.

- 7 Select Save.
- 8 Complete all configuration information and then select Done from the on-screen menu.
A dialog box is displayed to restart the system.

To delete a printer:

- 1 Select the name of the device from the list of printers.
- 2 Select Delete.
A dialog box is displayed.
- 3 Select Yes to delete and No to cancel.
- 4 Complete all configuration information and then select Done from the on-screen menu.
A dialog box is displayed to restart the system.

Configuring Worklist Servers

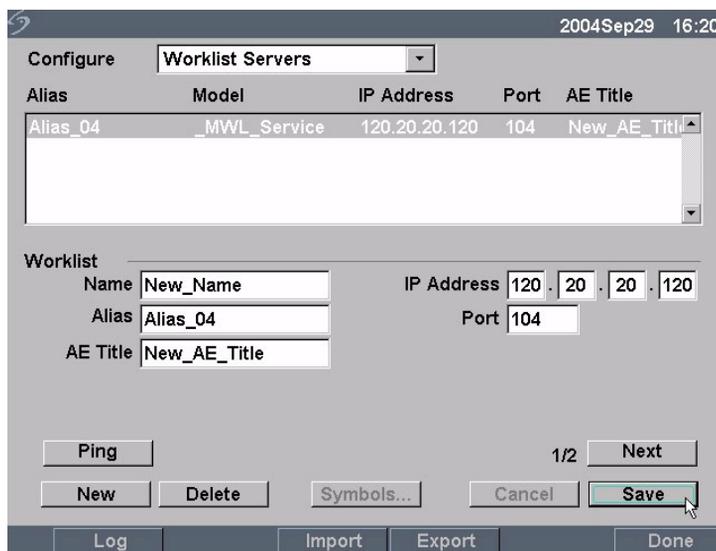


Figure 8 Worklist Configuration (Page 1)

| | |
|------------|---|
| Name | Network hostname for a worklist server. |
| Alias | Personalized name for a worklist server. |
| AE Title | Application Entity Title. |
| IP Address | Unique identifier for the worklist server. |
| Port | Device port number. (IP port 104 is normally assigned for DICOM.) |

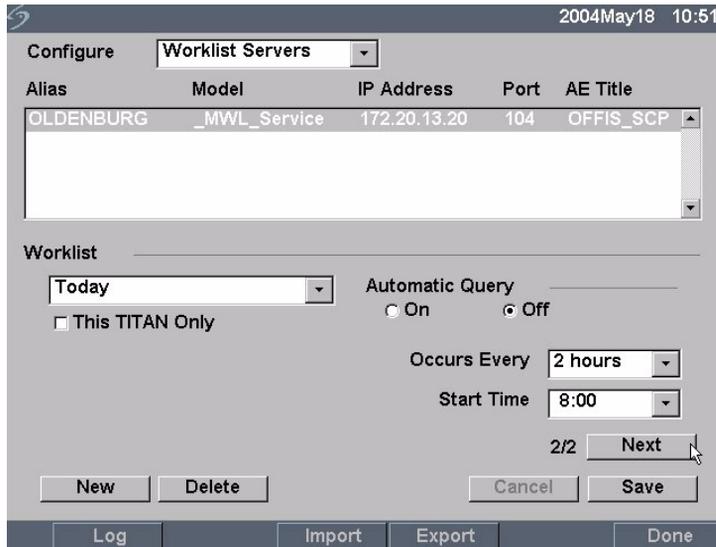


Figure 9 Worklist Configuration (Page 2)

| | |
|-----------------|---|
| Date Range | Defines the date range for manual or automatic queries. |
| This TITAN Only | Restricts the query to patient procedures that are scheduled for the TITAN based on its AE Title. |
| Automatic Query | Turns automatic query on/off. |
| Occurs Every | An option for an automatic query to select the length of time between automatic updates. |
| Start Time | An option for an automatic query to select the start time for the automatic update (displayed in 24 hour time). |

The following table identifies the parameters used for worklist queries.

Table 1: Manual and Automatic Query Parameters

| Item | Manual Patient Query | Manual Update from Worklist | Automatic Query Update |
|------------------------|----------------------|-----------------------------|------------------------|
| Patient data | X | | |
| Date Range | X | X | X |
| This TITAN Only | | X | X |
| Automatic Query On/Off | | | X |
| Occurs Every | | | X |
| Start Time | | | X |

To configure a new worklist server:

- 1 Ensure the TITAN system is set up for DICOM connectivity. See [“To set up the TITAN system for DICOM connectivity:” on page 105](#).
- 2 Press the **Setup** key and select Connectivity and then DICOM Setup.
- 3 Select Config from the on-screen menu.
- 4 In the Configure list, select Worklist Servers.
- 5 Select New.
- 6 Enter information in the fields (pages 1 and 2).
 - The Name cannot contain special characters.
 - The Alias and AE Title may contain special characters.
 - The IP address and port must be entered before the information is saved.

Note: To use special characters, select Symbols. See [“To enter a symbol/special character:” on page 20](#).

Note: Use the space bar on the keyboard to enter the underscore symbol.

Select Cancel to undo last change.
- 7 Select Save.
- 8 Complete all configuration information and then select Done from the on-screen menu. A dialog box is displayed to restart the system.

To set up an automatic query update:

- 1 Press the **Setup** key and select Connectivity and then DICOM Setup.
- 2 Select Config from the on-screen menu.
- 3 In the Configure list, select Worklist Servers.
- 4 In Automatic Query (page 2), select On.
- 5 In the Occurs Every list, select the desired length of time between automatic updates.
- 6 In the Start Time list, select the start time for the automatic updates.
- 7 Select Done from the on-screen menu. A dialog box is displayed to restart the system.

To delete a worklist server:

- 1 Select the name of the device from the worklist.
- 2 Select Delete.
A dialog box is displayed.
- 3 Select Yes to delete and No to cancel.
- 4 Complete all configuration information and then select Done from the on-screen menu.
A dialog box is displayed to restart the system.

Configuring Procedures

Procedures are automatically added to the procedure list when new exam types from the patient procedures are selected from the worklist.

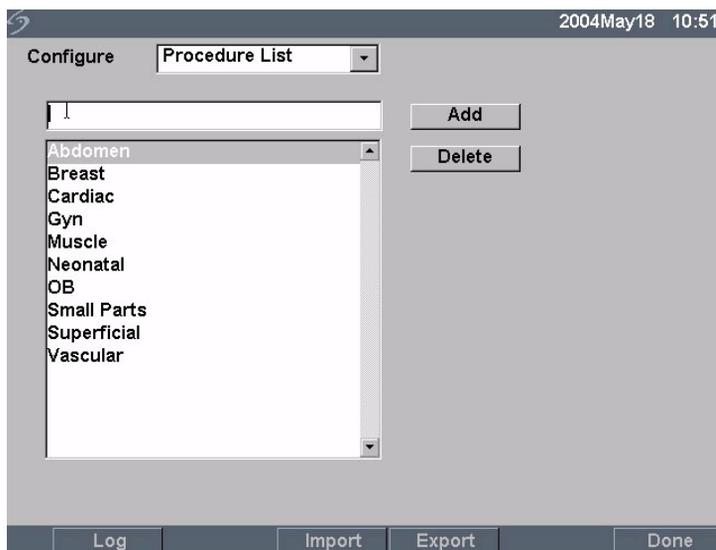


Figure 10 Procedure Configuration

To add a new procedure:

- 1 Ensure the TITAN system is set up for DICOM connectivity. See [“To set up the TITAN system for DICOM connectivity:” on page 105](#).
- 2 Press the **Setup** key and select Connectivity and then DICOM Setup.
- 3 Select Config from the on-screen menu.
- 4 In the Configure list, select Procedure List.
- 5 Type desired text.
- 6 Select Add.
- 7 Select Done from the on-screen menu.

To delete a procedure:

- 1 Select the name of the procedure from the list of procedures.
- 2 Select Delete.

Importing and Exporting Configurations

All configuration data for the locations (except IP addresses and AE titles), archivers, printers, and worklists can be imported and exported. This allows you to share configuration data between TITAN systems. The import and export functions are accessed on any DICOM configuration page.

To export configurations data:

- 1 Complete all pages of the configuration for one TITAN system.
- 2 Insert a blank CompactFlash card in the back slot. See [“Installing and Removing the CompactFlash Card” on page 11](#).
- 3 Press the **Setup** key and select Connectivity and then DICOM Setup.
- 4 Select Config from the on-screen menu.
- 5 Select Export from the on-screen menu.
All configuration data for the locations, archivers, printers, and worklists except TITAN location IP addresses, are copied to the CompactFlash card.
- 6 Remove the CompactFlash card.

To import configurations data:

- 1 Insert the CompactFlash card in the back slot of the TITAN system. See [“Installing and Removing the CompactFlash Card” on page 11](#).
- 2 Press the **Setup** key and select Connectivity and then DICOM Setup.
- 3 Select Config from the on-screen menu.
- 4 Select Import from the on-screen menu.
- 5 After all files are imported, the system restarts.
Note: All configurations currently on the system will be replaced with imported data.
Manually enter the IP addresses and AE titles for locations on the receiving TITAN system.
- 6 Complete all configuration information and then select Done from the on-screen menu.
A dialog box is displayed to restart the system.

Reviewing the Network Log

The Network Log function is accessible on any DICOM configuration page. The log collects network errors and events, typically to support diagnostics and can be exported to a CompactFlash card and read by a CompactFlash card reader. The log contents are saved when the TITAN system is turned off. The log has a finite amount of space and writes over existing information when it is full.

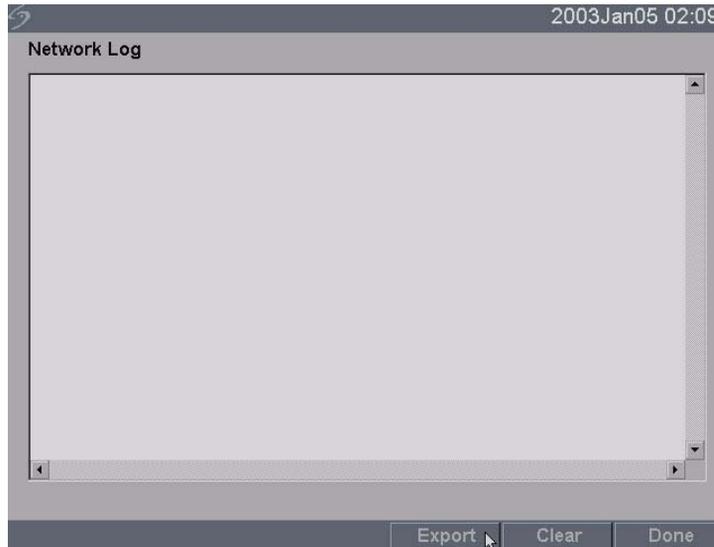


Figure 11 Network Log

| | |
|--------|--|
| Clear | Deletes all entries from the log. |
| Export | Copies the contents of the log to the CompactFlash card (back slot). The log file is named log.txt on the CompactFlash card. |
| Done | Returns to the previous page. |

To export log:

Note: The Event log and the DICOM network log have the same filename (log.txt). When you export either one to the same CF card, it will overwrite the existing log.txt file.

- 1 Insert the CompactFlash card in the back slot of the TITAN system.
- 2 Press the **Setup** key and select Connectivity and then DICOM Setup.
- 3 Select Log and then Export from the on-screen menu.
- 4 View the files on a CompactFlash card reader.
The log is a text file that can be opened by a text file application, e.g, Microsoft Word or Notepad. The log file is named log.txt.

To clear log:

- 1 Press the **Setup** key and select Connectivity and then DICOM Setup.
- 2 Select Log from the on-screen menu.
- 3 Select Clear from the on-screen menu to delete all text.
A dialog box is displayed.
- 4 Select Yes to delete or No to cancel.
- 5 Select Done to return to the previous menu.

DICOM Usage

The TITAN system can be connected through a LAN to send images from single or multiple network locations to single or multiple devices (printers, archivers, or worklists). The system can be configured to recognize a maximum of 16 printers, 16 archivers, and 16 worklist servers. From each location, you may select a maximum of two printers, four archivers, and one worklist server. Each device selected will receive the files that you transfer.

Based on your connectivity needs, TITAN DICOM can be configured in the following ways:

- Stationary TITAN system location transferring to a single device or to multiple devices.
- Mobile TITAN system locations (user selects between multiple locations within the facility) transferring to a single device or to multiple devices.



Figure 12 DICOM Main Screen

Location

Geographical location which identifies the network where the TITAN is connected. Network and DICOM device settings can be independently configured for each defined location.

| | |
|----------|--|
| AE Title | Refers to the Application Entity, the name by which the DICOM devices on the LAN knows the TITAN system. |
| Type | Type of device: archiver, printer, or worklist server. |
| Device | Name by which TITAN knows the printer, archiver, or worklist server. |
| Status | Indication of whether the device is available for use. |
| Verify | Test to ensure that the selected devices can communicate to the devices and servers. |
| Log | Log file for troubleshooting DICOM problems. (See “Reviewing the Network Log” on page 121.) |
| Config | Access to a series of pages for configuring network devices. (See “DICOM Configuration” on page 106.) |
| Done | Returns to the previous page if no changes are made or restarts the system if changes are made. |

To select a location, archiver, printer, or worklist server:

Note: The system must be configured before using DICOM. See [“DICOM Configuration” on page 106.](#)

- 1 Press the **Setup** key and select Connectivity and then DICOM Setup.
- 2 In the Location list, select the current location of the TITAN system.
- 3 In the Device list, select one or more archivers, printers, or worklist servers.
A check mark is displayed next to each device selected. A maximum of two printers, four archivers, and one worklist server may be selected for each location.
Select the device again to deselect.
- 4 Complete all configuration information and then select Done from the on-screen menu.
A dialog box is displayed to restart the system.

To verify status of an archiver, printer, or worklist server:

- 1 Press the **Setup** key and select Connectivity and then DICOM Setup.
- 2 From the Device list, select the desired device or devices.
- 3 Select Done from the on-screen menu.
A dialog box is displayed to restart the system.
The system restarts.
- 4 Press the **Setup** key and select Connectivity and then DICOM Setup.
- 5 Select Verify to confirm that a printer, archiver or worklist server is connected.

The connection status of the device is identified in the Device list. If the verify button is disabled, restart the system.



Figure 13 DICOM Main Screen Post Verify

| | |
|---------|---|
| Failed | DICOM communication with the selected device was unsuccessful. |
| Success | DICOM communication with the selected device was accomplished. |
| Unknown | DICOM device does not support the C-ECHO (i.e., verify query command) |

DICOM Image Archive and Print

Images are sent from the TITAN ultrasound system to a PACS server or printer using an Ethernet connection. The images are automatically sent when the TITAN system detects an Ethernet connection.



This icon is present and animated when the ultrasound system is connected and images are archiving

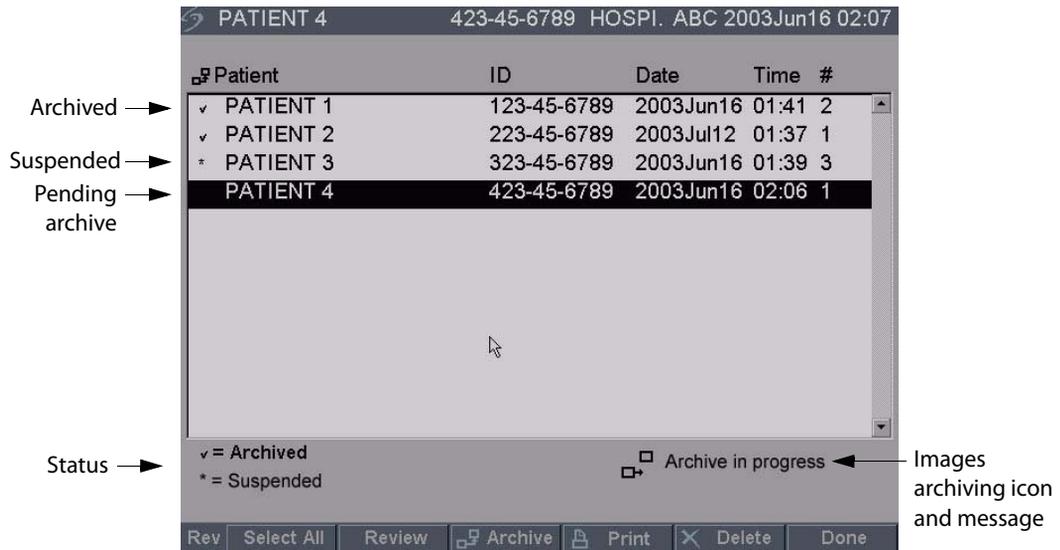


Figure 14 Patient List

To automatically archive or print images:

Images are automatically transferred to the selected devices. Pending exams are archived or printed starting at the top of the list. The network connection icon in the system status area is animated during DICOM network activity.

- 1 Ensure the current location is selected in the DICOM main screen.
- 2 Ensure connection to LAN. See [“Ethernet Connection” on page 105](#).
With the system on, check the LAN link light (green LED) next to the mini-dock connector to verify physical connection to LAN.
- 3 Verify patient exam is closed. See [“Patient Information” on page 41](#).

Note: Images saved on the TITAN ultrasound system are stored on a CF. See [“Image Storage” on page 60](#). Images transferred to DICOM devices are automatically sent from the CF after you end the exam. All images in the patient exams are sent at once to the DICOM devices, rather than the individual images. The DICOM formatted files are not saved to the CF card. File transfer of pending patient exams occurs only when you end the exam or create a new patient.

To verify images are sent:

Press the **Review** key.

The Patient List indicates the status of image transfer. See [Figure 14 on page 125](#).

- Patient exams that are checked are archived.
- Patient exams that are not checked are pending archive.
- Patient exams that are identified with an asterisk are suspended.

Transfer of images is suspended when the TITAN system executes the number of Attempts and Interval configured in the configuration setup. These exams need to be manually archived.

To manually archive or print images:

- 1 Verify the ultrasound system is turned on and the correct location is selected.
With the system on, check the LAN link light (green LED) next to the mini-dock connector to verify physical connection to LAN.
The network connection icon in the system status area is animated during DICOM network activity when images are transferred.
- 2 Press the **Review** key on the ultrasound system.
or,
If there is a current patient, select List from the on-screen menu.
- 3 Select an individual patient exam or Select All from the on-screen menu.
- 4 Select Archive from the on-screen menu. (Any check marks or asterisks will be removed.)
Once archived, a check mark reappears to the left of the selected patient's name.

Patient Information

The patient information form is used to enter patient data into the system. See [“Patient Information” on page 41](#) for information on completing fields on the form. The options listed below are only available in DICOM Worklist.

| | | |
|-----------------------|---|---|
| New Patient |  | <ol style="list-style-type: none">1 Press the Patient key.2 Select New from the on-screen menu. This ends the current patient procedure. <i>Note: New patient will erase any previously entered information, including any calculations and report pages. To save this information, save the screen for each item, e.g. report pages, patient information, calculations, and graphs.</i>3 Enter information into appropriate fields. |
| Procedure Type | | Select the procedure type (only available when DICOM Worklist feature is licensed and configured). |
| Procedure ID | | Enter desired identification information. The field is editable when performing a manual patient query. |
| Query | | <p>The Query on-screen menu is displayed when the following is set up:</p> <ul style="list-style-type: none">• Data is entered in the following fields:<ul style="list-style-type: none">• Patient: Last, First, Middle• Patient ID• Accession• Procedure ID• TITAN is connected to a LAN• Worklist server is active <p>See “To perform a manual patient query:” on page 127.</p> |

| | | |
|-----------------|---|--|
| Worklist | 1 | Press the Patient key. |
| | 2 | Select Worklist from the on-screen menu to view all scheduled patient procedures that have been queried by the system. |

DICOM Worklists

DICOM worklist provides the ability to import patient data from the Hospital Information System or Radiology Information System. The patient information form also provides the ability to enter specific patient data and query the worklist server for a matching patient procedure.

The system's worklist capability functions only when the following is set up:

- The system is configured before using DICOM. See [“DICOM Configuration” on page 106](#).
- The system is connected to a LAN. See [“To connect to a LAN:” on page 105](#).
- A worklist server has been configured for the active location.

To perform a manual patient query:

- 1 Ensure that a worklist server is configured and is communicating with the TITAN, by selecting Verify on the main DICOM configuration screen.
- 2 Press the **Patient** key.
- 3 Select New from the on-screen menu.
This ends the current patient procedure.

Note: New patient will end the existing exam and will erase any previously entered information, including any calculations and report pages. To save this information, save the screen for each item, e.g. report pages, patient information, calculations, and graphs.

- 4 Enter data in any of the following six fields: Patient: Last, First, Middle; Accession Number, Patient ID, or Procedure ID.
A query is made on the character or characters, e.g., searching for Smith will return Smith, Smithson, Smithy.
- 5 Select Query from the on-screen menu.
After the query has completed, the total number of patient procedures matching the query is displayed in the lower right corner of the screen.
- 6 Use the touchpad to highlight the desired patient procedure and then Select from the on-screen menu.
The information is displayed on the Patient Information form.
- 7 In the Type list, edit the desired procedure type, if required.
- 8 Select More... to enter information on page 2.
- 9 Select Done from the on-screen to return to previous page.

To perform a manual worklist update:

- 1 Press the **Patient** key.
- 2 Select Worklist from the on-screen menu and then select Update from the on-screen menu.

To perform an automatic worklist update:

- 1 Ensure TITAN system is turned on and connected to the LAN. See [“To connect to a LAN:” on page 105.](#)
- 2 Ensure TITAN system is set up for an automatic worklist query. See [“To set up an automatic query update:” on page 118.](#)
The worklist is automatically updated.
- 3 Verify the current system date and time.

To sort a worklist:

- 1 Press the **Patient** key.
- 2 Select Worklist from the on-screen menu.
- 3 Select the desired column heading (Name, ID, Accession, Procedure, or Date).
The worklist is sorted in ascending order.

Chapter 6: Safety

Read this information before using the ultrasound system. The information in this guide applies to the ultrasound system, transducer, accessories, and peripherals. This chapter contains information required by various 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.

A **Warning** describes precautions necessary to prevent injury or loss of life.

A **Caution** describes precautions necessary to protect the products.

Ergonomic Safety

Warning: To prevent musculoskeletal disorders, follow the “[Healthy Scanning Guidelines](#)” found in [Chapter 2](#) of this user guide.

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 9](#), “[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.

Warning:

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, 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 7, “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, 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, use commercial grade peripherals recommended by SonoSite on battery power only. Do not connect these products to AC mains power when using the system to scan or diagnose a patient/subject. Contact SonoSite or your local representative for a list of the commercial grade peripherals available from or recommended 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 side 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 7, "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 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.

Warning: Do not use a damaged battery.
Do not solder a battery.
The polarity of the battery terminals are fixed and cannot be switched or reversed.
Do not force the battery into the system.
Do not connect the battery to an electrical power outlet.
Do not continue recharging the battery if it does not recharge after two successive six hour charging cycles.

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 leaks or emits an odor, remove it from all possible flammable sources.
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 TITAN system.

Biological Safety

Observe the following precautions related to biological safety.

Warning: Non-medical (commercial) grade peripheral monitors have not been verified or validated by SonoSite as being suitable for diagnosis.
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.
Do not use the system if it exhibits artifacts on the LCD screen, either within the clinical image or in the area outside of the clinical image. Artifacts are indicative of hardware and/or software errors 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.

Warning: Perform ultrasound procedures prudently. Use the ALARA (as low as reasonably achievable) principle.

SonoSite does not currently recommend a specific brand of acoustic standoff.

Electromagnetic Compatibility (EMC)

The TITAN 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 (3V/meter EMI immunity, limit interference level to 0.0014 V/meter).

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 *TITAN 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 TITAN 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 TITAN 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 TITAN ultrasound system requires continued operation during power mains interruptions, it is recommended that the SonoSite TITAN ultrasound system be powered from an uninterruptible power supply or a battery. |
| Power Frequency Magnetic Field IEC 61000-4-8 | 3 A/m | 3 A/m | If image distortion occurs, it may be necessary to position the SonoSite TITAN ultrasound system further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the Intended installation location to assure that it is sufficiently low. |

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

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment |
|---|-----------------------------|------------------|---|
| Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | <p>Portable and mobile RF communications equipment should be used no closer to any part of the SonoSite TITAN ultrasound system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended Separation Distance $d = 1,2 \sqrt{P}$</p> |
| Radiated RF IEC 61000-4-3 | 3 Vim 80 MHz to 2.5 GHz | 3 V/m | <p>$d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz</p> <p>$d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> |
| Radiated RF IEC 61000-4-3 (continued) | | | <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div> <p>(IEC 60417 No. 417-IEC-5140: “Source of non-ionizing radiation”)</p> |

Note: U_T is the AC mains voltage prior to application of the test level.

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: 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 TITAN ultrasound system is used exceeds the applicable RF compliance level above, the SonoSite TITAN 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 TITAN ultrasound system.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

The 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; DCPD 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 and direction 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 41°C (106°F). 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 selection of exam type limits acoustic output through default. The acoustic output parameters that are set at default levels based on exam type are the mechanical index (MI) and the spatial peak temporal average intensity (ISPTA). The system does not exceed an MI of 1.0 or an ISPTA of 720 mW/cm² for all imaging modes. Thermal index (TI) values greater than 1.0 occur on some transducers in some imaging modes. See [Table 3](#).

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.

Output Display

The system meets the AIUM output display standard for MI and TI (see last reference listed in “[Related Guidance Documents](#)” below). [Table 3](#) indicates for each transducer and operating mode whether either the TI or MI is greater than a value of 1.0, thus requiring display.

Table 3: Cases Where Either a Thermal or Mechanical Index is > 1.0

| Transducer Model | Index | 2D/ M Mode | CPD/DCPD /Color | PW Doppler | CW Doppler |
|------------------|------------------|---------------|--------------------|---------------|---------------|
| C8/8-5 MHz | MI | No | No | No | – |
| | TIC, TIB, TIS | No | Yes | Yes | – |
| C11/8-5 | MI | No | No | No | No |
| | TIC, TIB, or TIS | No | No | Yes | No |
| C15/4-2 | MI | No | No | No | No |
| | TIC, TIB, or TIS | No | Yes | Yes | No |
| C60/5-2 | MI | No | No | No | – |
| | TIC, TIB, or TIS | No | No | Yes | – |
| HST/10-5 | MI | No | No | No | – |
| | TIC, TIB, or TIS | No | No | No | – |
| ICT/8-5 | MI | No | No | No | – |
| | TIC, TIB, or TIS | No | No | Yes | – |
| L25/10-5 | MI | No | No | – | – |
| | TIC, TIB, or TIS | No | No | – | – |
| L38/10-5 | MI | No | No | No | – |
| | TIC, TIB, or TIS | No | No | Yes | – |

Regardless that an MI of greater than 1.0 never occurs, 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, DCPD, Color, M Mode, or PW Doppler 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](#)” below).

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 UD2-1998.
- 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, American Institute of Ultrasound in Medicine, 1998.

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 UD 2-1998), and the “Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment” (AIUM and NEMA 1998).

In Situ, Derated, and Water Value Intensities

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

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

where:

In Situ = *In Situ* intensity value

Water = Water intensity value

$e = 2.7183$

a = attenuation factor (dB/cm MHz)

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

brain = 0.53

heart = 0.66

kidney = 0.79

liver = 0.43

muscle = 0.55

l = skinline to measurement depth in cm

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

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

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

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

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

Tissue Models and Equipment Survey

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

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

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

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

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

- A survey of 1990-equipment models yielded MI values between 0.1 and 1.0 at their highest output settings. Maximum MI values of approximately 2.0 are known to occur for currently available equipment. Maximum MI values are similar for real-time 2D and M Mode imaging.
- Computed estimates of upper limits to temperature elevations during transabdominal scans were obtained in a survey of 1988 and 1990 pulsed Doppler equipment. The vast majority of models yielded upper limits less than 1° and 4°C (1.8° and 7.2°F) for exposures of first-trimester fetal tissue and second-trimester fetal bone, respectively. The largest values obtained were approximately 1.5°C (2.7°F) for first-trimester fetal tissue and 7°C (12.6°F) for second-trimester fetal bone. Estimated maximum temperature elevations given here are for a “fixed path” tissue model and are for devices having I_{SPTA} values greater than 500 mW/cm². The temperature elevations for fetal bone and tissue were computed based on calculation procedures given in Sections 4.3.2.1-4.3.2.6 in “Bioeffects and Safety of Diagnostic Ultrasound” (AIUM, 1993).

Intended Uses

The intended uses for each exam type are contained here. See the intended transducer for exam type in [Table 2, “Transducer, Exam Type, and Imaging Mode” on page 44.](#)

Abdominal Imaging Applications

This system transmits ultrasound energy into the abdomen of patients using 2D, M Mode, color Doppler (Color), color power Doppler (CPD), Tissue Harmonic Imaging (THI), and pulsed wave (PW) Doppler 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, M Mode, color Doppler (Color), Tissue Harmonic Imaging (THI), pulsed wave (PW) Doppler, and continuous wave (CW) Doppler 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. The heart can be imaged transthoracic.

The patient’s electrocardiogram (ECG) may be obtained and is used for accurate timing of diastolic and systolic function.

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

Gynecology and Infertility Imaging Applications

This system transmits ultrasound energy in the pelvis and lower abdomen using 2D, M Mode, color power Doppler (CPD), directional color power Doppler (DCPD), Tissue Harmonic Imaging (THI), and pulsed wave (PW) Doppler 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 and Intraoperative Imaging Applications

This system transmits ultrasound energy into the various parts of the body using 2D, color Doppler (Color), color power Doppler (CPD), directional color power Doppler (DCPD), Tissue Harmonic Imaging (THI), and pulsed wave (PW) Doppler to obtain ultrasound images that provide guidance during interventional and intraoperative procedures. This system can be used to provide ultrasound guidance for biopsy and drainage procedures, vascular line placement, peripheral nerve blocks, ova harvesting, amniocentesis and other obstetrical procedures, and provide assistance during abdominal and vascular intraoperative procedures.

Warning: This system is not intended for use in providing guidance for central nerve blocks, i.e., the brain and spinal cord, or for ophthalmic applications.

Obstetrical Imaging Applications

This system transmits ultrasound energy into the pelvis of pregnant women using 2D, M Mode, color Doppler (Color), color power Doppler (CPD), directional color power Doppler (DCPD), Tissue Harmonic Imaging (THI), and pulsed wave (PW) Doppler to obtain ultrasound images. The fetal anatomy, viability, estimated fetal weight, gestational age, amniotic fluid, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally or transvaginally. CPD, color Doppler (Color), and DCPD imaging is intended for high-risk pregnant women. High-risk pregnancy indications include, but are not limited to, multiple pregnancy, fetal hydrops, placental abnormalities, as well as maternal hypertension, diabetes, and lupus.

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, DCPD, or Color images can be used as an adjunctive method, not as a screening tool, for the detection of structural anomalies of the fetal heart and as an adjunctive method, not as a screening tool for the diagnosis of Intrauterine Growth Retardation (IUGR).

Pediatric and Neonatal Imaging Applications

This system transmits ultrasound energy into the pediatric or neonatal patients using 2D, M Mode, color Doppler (Color), color power Doppler (CPD), pulsed wave (PW) Doppler, and continuous wave (CW) Doppler to obtain ultrasound images. The pediatric abdominal, pelvic and cardiac anatomy, pediatric hips, neonatal heads, and surrounding anatomical structures can be assessed for the presence or absence of pathology.

Prostate Imaging Applications

This system transmits ultrasound energy into the prostate of an adult male using 2D, M Mode, color power Doppler (CPD), and pulsed wave (PW) Doppler to obtain ultrasound images. The prostate gland 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, M Mode, color Doppler (Color), color power Doppler (CPD), directional color power Doppler (DCPD), and pulsed wave (PW) Doppler 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, and peripheral nerve blocks.

Warning: This system is not intended for use in providing guidance for central nerve blocks, i.e., the brain and spinal cord, or for ophthalmic applications.

Vascular Imaging Applications

This system transmits ultrasound energy into the various parts of the body using 2D, M Mode, color Doppler (Color), color power Doppler (CPD), directional color power Doppler (DCPD), and pulsed wave (PW) Doppler to obtain ultrasound images. The carotid arteries, deep veins 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.

About the Acoustic Output Table

Transducer Model is the SonoSite transducer model.

Table 4: 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. |
| $I_{pa,3}@MI_{max}$ | Derated pulse average intensity at the maximum MI in units of W/cm ² . |
| TIS | (Soft tissue thermal index) is a thermal index related to soft tissues. TIS scan is the soft tissue thermal index in an auto-scanning mode. TIS non-scan is the soft tissue thermal index in the non-autoscanning mode. |

Table 4: Acoustic Output Terms and Definitions (Continued)

| Term | Definition |
|--|--|
| 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). |
| W_o | 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}(z₁) | Derated ultrasonic power at axial distance z ₁ in units of milliwatts. |
| I_{SPTA.3}(z₁) | Derated spatial-peak temporal-average intensity at axial distance z ₁ (milliwatts per square centimeter). |
| z₁ | Axial distance corresponding to the location of maximum [min(W _{.3} (z), I _{TA.3} (z) x 1 cm ²)], where z ≥ z _{bp} in centimeters. |
| z_{bp} | $1.69 \sqrt{A_{aprt}}$ in centimeters. |
| z_{sp} | For MI, it is the axial distance at which p _{r.3} is measured. For TIB, it is the axial distance at which TIB is a global maximum (i.e., z _{sp} = z _{b.3}) in centimeters. |
| d_{eq}(z) | Equivalent beam diameter as a function of axial distance z, and is equal to $\sqrt{(4/(\pi))((W_o)/(I_{TA}(z)))}$, 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. |

Table 4: Acoustic Output Terms and Definitions (Continued)

| Term | Definition |
|--------------------|---|
| $p_r@PII_{max}$ | 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 Output Tables

Table 5 indicates the acoustic output for all system and transducer combinations for those imaging modes with a thermal index and mechanical index less than one.

Table 5: Acoustic Output

| Transducer Model | Imaging Modes | $I_{SPTA.3}$ | TI Type | TI Value | MI | $I_{pa.3@MI_{max}}$ |
|------------------|-----------------------------------|--------------|---------|----------|-----|---------------------|
| C8/8-5 MHz | 2D, M Mode | 78 | TIC | 0.2 | 0.8 | 130.4 |
| C11/8-5 MHz | 2D, CPD/Color, M Mode, CW Doppler | 73 | TIC | 0.4 | 0.5 | 16.47 |
| C15/4-2 MHz | 2D, M Mode, CW Doppler | 289 | TIC | 0.7 | 0.7 | 45.03 |
| C60/5-2 MHz | 2D, CPD/Color, M Mode | 60 | TIC | 0.7 | 0.6 | 37.66 |
| HST/10-5 MHz | All | 182 | TIB | 0.4 | 0.3 | 8.89 |
| ICT/8-5 MHz | 2D, CPD/DCPD, M Mode | 67 | TIC | 0.4 | 0.5 | 21.51 |
| L25/10-5 MHz | 2D, CPD/Color | 108 | TIC | 0.7 | 0.7 | 40.42 |
| L38/10-5 MHz | 2D, CPD/Color, M Mode | 256 | TIC | 0.9 | 0.7 | 109.9 |

Table 6 through Table 13 indicate the acoustic output for the system and transducer combinations with a thermal index equal to or greater than one.

Table 6: Transducer Model: C8/8-5

Operating Mode: PW Doppler

| Index Label | | M.I. | TIS | | | TIB | TIC | |
|----------------------------------|--|-------------|------|-------------------|----------------|----------|-------|---|
| | | | Scan | Non-scan | | Non-scan | | |
| | | | | $A_{aprt} \leq 1$ | $A_{aprt} > 1$ | | | |
| Global Maximum Index Value | | (a) | — | (a) | — | 1.5 | (b) | |
| Associated Acoustic Parameter | $P_{r,3}$ (MPa) | # | | | | | | |
| | W_0 (mW) | | — | # | | 24.67 | # | |
| | min of $[W_{,3}(z_1), I_{TA,3}(z_1)]$ (mW) | | | | — | | | |
| | z_1 (cm) | | | | — | | | |
| | z_{bp} (cm) | | | | — | | | |
| | z_{sp} (cm) | # | | | | 2.3 | | |
| | $d_{eq}(z_{sp})$ (cm) | | | | | 0.23 | | |
| | f_c (MHz) | # | — | # | — | 5.33 | # | |
| | Dim of A_{aprt} | X (cm) | | — | # | — | 0.768 | # |
| Y (cm) | | | — | # | — | 0.4 | # | |
| Other Information | PD (μ sec) | # | | | | | | |
| | PRF (Hz) | # | | | | | | |
| | $p_r@PII_{max}$ (MPa) | # | | | | | | |
| | $d_{eq}@PII_{max}$ (cm) | | | | | 0.179 | | |
| | Focal Length | FL_x (cm) | | — | # | — | | # |
| | | FL_y (cm) | | — | # | — | | # |
| $I_{PA,3}@MI_{max}$ (W/cm^2) | | # | | | | | | |
| Operating Control Conditions | Control 1: Exam Type | | | | | Any | | |
| | Control 2: Sample Volume | | | | | 3 mm | | |
| | Control 3: PRF | | | | | 3125 | | |
| | Control 4: Sample Vol. Position | | | | | zone 6 | | |

(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 is not applicable for this transducer/mode.

Table 7: Transducer Model: C8/8-5

Operating Mode: Color Power Doppler

| Index Label | | M.I. | TIS | | TIB | TIC | | |
|----------------------------------|--|-------------|------|-------------------|----------------|-----|---------------------|---|
| | | | Scan | Non-scan | | | Non-scan | |
| | | | | $A_{aprt} \leq 1$ | $A_{aprt} > 1$ | | | |
| Global Maximum Index Value | | (a) | (a) | — | — | (a) | (b) | |
| Associated Acoustic Parameter | $P_{r,3}$ (MPa) | # | | | | | | |
| | W_0 (mW) | | # | — | | # | # | |
| | 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) | # | # | — | — | # | # | |
| | Dim of A_{aprt} | X (cm) | | # | — | — | # | # |
| Y (cm) | | | # | — | — | # | # | |
| Other Information | PD (μ sec) | # | | | | | | |
| | PRF (Hz) | # | | | | | | |
| | $p_r@PII_{max}$ (MPa) | # | | | | | | |
| | $d_{eq}@PII_{max}$ (cm) | | | | | # | | |
| | Focal Length | FL_x (cm) | | # | — | — | | # |
| | | FL_y (cm) | | # | — | — | | # |
| $I_{PA,3}@MI_{max}$ (W/cm^2) | | # | | | | | | |
| Operating Control Conditions | Control 1: Exam Type | | | | | | OB & Pro | |
| | Control 2: Optimization | | | | | | Low | |
| | Control 3: Depth | | | | | | 2.5 | |
| | Control 4: Color Box Position and Size | | | | | | Bottom/wide & 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 is not applicable for this transducer/mode.

Table 8: Transducer Model: C11/8-5

Operating Mode: PW Doppler

| Index Label | | M.I. | TIS | | | TIB | TIC | |
|--|--|----------------------|------|-------------------|----------------|----------------|------|---|
| | | | Scan | Non-scan | | Non-scan | | |
| | | | | $A_{aprt} \leq 1$ | $A_{aprt} > 1$ | | | |
| Global Maximum Index Value | | (a) | — | (a) | — | 1.0 | (a) | |
| Associated Acoustic Parameter | $P_{r,3}$ (MPa) | # | | | | | | |
| | W_0 (mW) | | — | # | | 12.693 | # | |
| | min of $[W_{.3}(z_1), I_{TA,3}(z_1)]$ (mW) | | | | — | | | |
| | z_1 (cm) | | | | — | | | |
| | z_{bp} (cm) | | | | — | | | |
| | z_{sp} (cm) | # | | | | 1.4 | | |
| | $d_{eq}(z_{sp})$ (cm) | | | | | 0.2119 | | |
| | f_c (MHz) | # | — | # | — | 4.39 | # | |
| | Dim of A_{aprt} | X (cm) | | — | # | — | 0.40 | # |
| Y (cm) | | | — | # | — | 0.50 | # | |
| Other Information | PD (μ sec) | # | | | | | | |
| | PRF (Hz) | # | | | | | | |
| | $p_r@PII_{max}$ (MPa) | # | | | | | | |
| | $d_{eq}@PII_{max}$ (cm) | | | | | 0.1989 | | |
| | Focal Length | FL _x (cm) | | — | # | — | | # |
| | | FL _y (cm) | | — | # | — | | # |
| $I_{PA,3}@MI_{max}$ (W/cm ²) | | # | | | | | | |
| Operating Control Conditions | Control 1: Exam Type | | | | | Any | | |
| | Control 2: Sample Volume | | | | | 1 mm | | |
| | Control 3: PRF | | | | | 15625 or 20833 | | |
| | Control 4: Sample Vol. Position | | | | | zone 2 | | |

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

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

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

— Data is not applicable for this transducer/mode.

Table 9: Transducer Model: C15/4-2

Operating Mode: PW Doppler

| Index Label | | M.I. | TIS | | | TIB | TIC | |
|----------------------------------|--|-------------|------|-------------------|----------------|-------------|--------|---|
| | | | Scan | Non-scan | | Non-scan | | |
| | | | | $A_{aprt} \leq 1$ | $A_{aprt} > 1$ | | | |
| Global Maximum Index Value | | (a) | — | (a) | — | 3.2 | (b) | |
| Associated Acoustic Parameter | $P_{r,3}$ (MPa) | # | | | | | | |
| | W_0 (mW) | | — | # | | 88.846 | # | |
| | min of $[W_{,3}(z_1), I_{TA,3}(z_1)]$ (mW) | | | | — | | | |
| | z_1 (cm) | | | | — | | | |
| | z_{bp} (cm) | | | | — | | | |
| | z_{sp} (cm) | # | | | | 0.8 | | |
| | $d_{eq}(z_{sp})$ (cm) | | | | | 0.5487 | | |
| | f_c (MHz) | # | — | # | — | 2.17 | # | |
| | Dim of A_{aprt} | X (cm) | | — | # | — | 0.5138 | # |
| Y (cm) | | | — | # | — | 1.3 | # | |
| Other Information | PD (μ sec) | # | | | | | | |
| | PRF (Hz) | # | | | | | | |
| | $p_r@PII_{max}$ (MPa) | # | | | | | | |
| | $d_{eq}@PII_{max}$ (cm) | | | | | 0.5221 | | |
| | Focal Length | FL_x (cm) | | — | # | — | | # |
| | | FL_y (cm) | | — | # | — | | # |
| $I_{PA,3}@MI_{max}$ (W/cm^2) | | # | | | | | | |
| Operating Control Conditions | Control 1: Exam Type | | | | | Any | | |
| | Control 2: Sample Volume | | | | | 5 mm | | |
| | Control 3: PRF | | | | | ≥ 3125 | | |
| | Control 4: Sample Vol. Position | | | | | zone 0 | | |

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

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

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

— Data is not applicable for this transducer/mode.

Table 10: Transducer Model: C15/4-2

Operating Mode: Color

| Index Label | | M.I. | TIS | | | TIB | TIC | |
|--|--|----------------------|------|-------------------|----------------|----------|--------------|--------|
| | | | Scan | Non-scan | | Non-scan | | |
| | | | | $A_{aprt} \leq 1$ | $A_{aprt} > 1$ | | | |
| Global Maximum Index Value | | (a) | — | — | (a) | (a) | 1.2 | |
| Associated Acoustic Parameter | $P_{r,3}$ (MPa) | # | | | | | | |
| | W_0 (mW) | | — | — | | # | 95.48 | |
| | 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) | # | — | — | # | # | 2.27 | |
| | Dim of A_{aprt} | X (cm) | | — | — | # | # | 1.7616 |
| Y (cm) | | | — | — | # | # | 1.3 | |
| Other Information | PD (μ sec) | # | | | | | | |
| | PRF (Hz) | # | | | | | | |
| | $p_r@PII_{max}$ (MPa) | # | | | | | | |
| | $d_{eq}@PII_{max}$ (cm) | | | | | # | | |
| | Focal Length | FL _x (cm) | | — | — | # | | 6.2 |
| | | FL _y (cm) | | — | — | # | | 7.0 |
| $I_{PA,3}@MI_{max}$ (W/cm ²) | # | | | | | | | |
| Operating Control Conditions | Control 1: Exam Type | | | | | | Cardiac | |
| | Control 2: Optimization | | | | | | Low | |
| | Control 3: Harmonics | | | | | | TH on | |
| | Control 4: Depth | | | | | | 13 | |
| | Control 5: PRF | | | | | | 1000 Hz | |
| | Control 6: Color Box Size | | | | | | Wide & 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 is not applicable for this transducer/mode.

Table 11: Transducer Model: C60/5-2

Operating Mode: PW Doppler

| Index Label | | M.I. | TIS | | | TIB | TIC | |
|-------------------------------|--|----------------------|------|----------------------|----------------------|----------|-----|---|
| | | | Scan | Non-scan | | Non-scan | | |
| | | | | A _{aprt} ≤1 | A _{aprt} >1 | | | |
| Global Maximum Index Value | | (a) | — | 1.26 | — | 3.23 | (b) | |
| Associated Acoustic Parameter | P _{r,3} (MPa) | # | | | | | | |
| | W ₀ (mW) | | — | 88.606 | | 71.984 | # | |
| | min of [W _{.3} (z ₁), I _{TA,3} (z ₁)] (mW) | | | | — | | | |
| | z ₁ (cm) | | | | — | | | |
| | z _{bp} (cm) | | | | — | | | |
| | z _{sp} (cm) | # | | | | 1.0 | | |
| | d _{eq} (z _{sp}) (cm) | | | | | 0.4717 | | |
| | f _c (MHz) | # | — | 2.99 | — | 2.99 | # | |
| | Dim of A _{aprt} | X (cm) | | — | 0.625 | — | 0.5 | # |
| Y (cm) | | | — | 1.3 | — | 1.3 | # | |
| Other Information | PD (μsec) | # | | | | | | |
| | PRF (Hz) | # | | | | | | |
| | p _r @P _{II} _{max} (MPa) | # | | | | | | |
| | d _{eq} @P _{II} _{max} (cm) | | | | | 0.4378 | | |
| | Focal Length | FL _x (cm) | | — | 1.825 | — | | # |
| | | FL _y (cm) | | — | 5.0 | — | | # |
| | I _{PA,3} @M _I _{max} (W/cm ²) | # | | | | | | |
| Operating Control Conditions | Control 1: Exam Type | | | Any | | Any | | |
| | Control 2: Sample Volume | | | 5 mm | | 5 mm | | |
| | Control 3: PRF | | | ≥ 6250 | | Any | | |
| | Control 4: Sample Vol. Position | | | zone 1 | | zone 0 | | |

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

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

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

— Data is not applicable for this transducer/mode.

Table 12: Transducer Model: ICT/8-5

Operating Mode: PW Doppler

| Index Label | | M.I. | TIS | | TIB | TIC | | |
|----------------------------------|---|-------------|------|-------------------|----------------|----------------|----------|---|
| | | | Scan | Non-scan | | | Non-scan | |
| | | | | $A_{aprt} \leq 1$ | $A_{aprt} > 1$ | | | |
| Global Maximum Index Value | | (a) | — | (a) | — | 1.0 | (a) | |
| Associated Acoustic Parameter | $P_{r,3}$ (MPa) | # | | | | | | |
| | W_0 (mW) | | — | # | | 12.693 | # | |
| | min of [$W_{,3}(z_1), I_{TA,3}(z_1)$] | | | | — | | | |
| | z_1 (cm) | | | | — | | | |
| | z_{bp} (cm) | | | | — | | | |
| | z_{sp} (cm) | # | | | | 1.4 | | |
| | $d_{eq}(z_{sp})$ (cm) | | | | | 0.2119 | | |
| | f_c (MHz) | # | — | # | — | 4.39 | # | |
| | Dim of A_{aprt} | X (cm) | | — | # | — | 0.40 | # |
| Y (cm) | | | — | # | — | 0.50 | # | |
| Other Information | PD (μ sec) | # | | | | | | |
| | PRF (Hz) | # | | | | | | |
| | $P_r@PII_{max}$ (MPa) | # | | | | | | |
| | $d_{eq}@PII_{max}$ (cm) | | | | | 0.1989 | | |
| | Focal Length | FL_x (cm) | | — | # | — | | # |
| | | FL_y (cm) | | — | # | — | | # |
| $I_{PA,3}@MI_{max}$ (W/cm^2) | | # | | | | | | |
| Operating Control Conditions | Control 1: Exam Type | | | | | Any | | |
| | Control 2: Sample Volume | | | | | 1 mm | | |
| | Control 3: PRF | | | | | 15625 or 20833 | | |
| | Control 4: Sample Vol. Position | | | | | zone 2 | | |

- (a) This index is not required for this operating mode; value is <1.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed. (Reference Global Maximum Index Value line.)
- Data is not applicable for this transducer/mode.

Table 13: Transducer Model: L38/10-5

Operating Mode: PW Doppler

| Index Label | | M.I. | TIS | | TIB | TIC | | |
|----------------------------------|--|-------------|------|-------------------|----------------|----------|----------|---|
| | | | Scan | Non-scan | | | Non-scan | |
| | | | | $A_{aprt} \leq 1$ | $A_{aprt} > 1$ | | | |
| Global Maximum Index Value | | (a) | — | (a) | — | 1.73 | (b) | |
| Associated Acoustic Parameter | $P_{r,3}$ (MPa) | # | | | | | | |
| | W_0 (mW) | | — | # | | 34.73 | # | |
| | min of $[W_{.3}(z_1), I_{TA,3}(z_1)]$ (mW) | | | | — | | | |
| | z_1 (cm) | | | | — | | | |
| | z_{bp} (cm) | | | | — | | | |
| | z_{sp} (cm) | # | | | | 1.1 | | |
| | $d_{eq}(z_{sp})$ (cm) | | | | | 0.287 | | |
| | f_c (MHz) | # | — | # | — | 5.33 | # | |
| | Dim of A_{aprt} | X (cm) | | — | # | — | 1.02 | # |
| Y (cm) | | | — | # | — | 0.4 | # | |
| Other Information | PD (μ sec) | # | | | | | | |
| | PRF (Hz) | # | | | | | | |
| | $p_r@PII_{max}$ (MPa) | # | | | | | | |
| | $d_{eq}@PII_{max}$ (cm) | | | | | 0.2 | | |
| | Focal Length | FL_x (cm) | | — | # | — | | # |
| | | FL_y (cm) | | — | # | — | | # |
| $I_{PA,3}@MI_{max}$ (W/cm^2) | | # | | | | | | |
| Operating Control Conditions | Control 1: Exam Type | | | | | Vascular | | |
| | Control 2: Sample Volume | | | | | 10 mm | | |
| | Control 3: PRF | | | | | Any | | |
| | Control 4: Sample Vol. Position | | | | | zone 7 | | |

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

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

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

— Data is not applicable for this transducer/mode.

Global Maximum Derated I_{SPTA} and MI Values

The following values represent worst-case values of the $I_{SPTA,3}$ and MI for each transducer and each mode, over all operating conditions for that mode. These tables fulfill the requirements of Appendix G, Section C2, of the September 30, 1997 issue of the FDA document, "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers."

Table 14: C8/8-5 Transducer

| Transducer Model | Imaging Mode | Derated I_{SPTA} | MI |
|------------------|--------------|--------------------|-----|
| C8/8-5 MHz | 2D | 10 | 0.8 |
| | CPD | 362 | 0.9 |
| | M Mode | 78 | 0.8 |
| | PW Doppler | 474 | 0.9 |

Table 15: C11/8-5 Transducer

| Transducer Model | Imaging Mode | Derated I_{SPTA} | MI |
|------------------|--------------|--------------------|------|
| C11/8-5 MHz | 2D | 3 | 0.4 |
| | CPD/Color | 58 | 0.5 |
| | M Mode | 21 | 0.4 |
| | PW Doppler | 340 | 0.5 |
| | CW Doppler | 73 | <0.1 |

Table 16: C15/4-2 Transducer

| Transducer Model | Imaging Mode | Derated I_{SPTA} | MI |
|------------------|--------------|--------------------|-----|
| C15/4-2 MHz | 2D | 12 | 0.7 |
| | CPD/Color | 137 | 0.7 |
| | M Mode | 73 | 0.7 |
| | PW Doppler | 423 | 0.7 |
| | CW Doppler | 289 | 0.1 |

Table 17: C60/5-2 Transducer

| Transducer Model | Imaging Mode | Derated I_{SPTA} | MI |
|------------------|--------------|--------------------|-----|
| C60/5-2 MHz | 2D | 2 | 0.6 |
| | CPD/Color | 60 | 0.6 |
| | M Mode | 20 | 0.6 |
| | PW Doppler | 496 | 0.6 |

Table 18: HST/10-5 Transducer

| Transducer Model | Imaging Mode | Derated I_{SPTA} | MI |
|------------------|--------------|--------------------|-----|
| HST/10-5 MHz | 2D | 2 | 0.2 |
| | CPD/DCPD | 17 | 0.3 |
| | M Mode | 5 | 0.2 |
| | PW Doppler | 182 | 0.3 |

Table 19: ICT/8-5 Transducer

| Transducer Model | Imaging Mode | Derated I_{SPTA} | MI |
|------------------|--------------|--------------------|-----|
| ICT/8-5 MHz | 2D | 3 | 0.4 |
| | CPD/DCPD | 67 | 0.5 |
| | M Mode | 20 | 0.4 |
| | PW Doppler | 353 | 0.5 |

Table 20: L25/10-5 Transducer

| Transducer Model | Imaging Mode | Derated I_{SPTA} | MI |
|------------------|--------------|--------------------|-----|
| L25/10-5 MHz | 2D | 13 | 0.7 |
| | CPD/Color | 108 | 0.7 |

Table 21: L38/10-5 Transducer

| Transducer Model | Imaging Mode | Derated I _{SPTA} | MI |
|------------------|--------------|---------------------------|-----|
| L38/10-5 MHz | 2D | 7 | 0.6 |
| | CPD/Color | 256 | 0.7 |
| | M Mode | 121 | 0.7 |
| | PW Doppler | 552 | 0.7 |

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 22: 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% |
| P _{II} | 3.2% | +12.5 to -16.8% |
| P _{II,3} | 3.2% | +13.47 to -17.5% |

Labeling Symbols

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

Table 23: Labeling Symbols

| Symbol | Definition |
|---|---|
|  | Alternating Current (AC) |
|  | Affixed to a Class 1 device indicating manufacturer's declaration of conformance with Annex VII of 93/42/EEC. |
|  | Affixed to a 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 |
|  | Batch code, date code, or lot code type of control number |
|  | Canadian Standards Association |
| REF | Catalog number |
|  | Collect separately from other household waste (see European Commission Directive 93/86/EEC). Refer to local regulations for disposal. |
|  | Corrugated recycle |
|  | Date of manufacture |
|  | Direct Current (DC) |
|  | Do not get wet |

Table 23: Labeling Symbols (Continued)

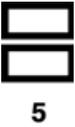
| Symbol | Definition |
|---|--|
|  | Do not stack over 2 high |
|  | Do not stack over 5 high |
|  | Do not stack over 10 high |
|  | Electrostatic sensitive devices |
|  | Fragile |
|  | Indoor use only |
|  | Non-ionizing radiation |
|  | Paper recycle |
| SN | Serial number type of control number |
|  | Storage temperature conditions |
| IPX7 | Submersible. Protected against the effects of temporary immersion. |
| TITAN Mobile Docking System Input: 100 - 240V ~ 50 - 60Hz 4 - 2A | |

Table 23: Labeling Symbols (Continued)

| Symbol | Definition |
|--|---|
|  | Type BF patient applied part (B = body, F = floating applied part) |
|  | Underwriter's Laboratories labeling |
| <p>WARNING: Connect Only Accessories and Peripherals Recommended by SonoSite to Convenience Receptacles.</p> | |

Chapter 7: Troubleshooting and Maintenance

This chapter contains information to help you correct problems with system operation and provides instructions on the proper care of the system, transducer, and accessories.

Troubleshooting

If you encounter difficulty with the system, use the information in this chapter to help correct the problem. If the problem is not covered here, contact SonoSite technical support at the following numbers or addresses:

| | |
|----------------------------------|---|
| Technical support | 1-877-657-8118 |
| International technical support: | Contact your local representative or call 425-951-1330 |
| Technical support fax: | 1-425-951-6700 |
| Technical support e-mail: | service@sonosite.com |
| SonoSite website: | www.sonosite.com and select Products & Solutions and then Technical Support |

Table 1: Troubleshooting

| Symptom | Solution |
|-------------------------------|---|
| System will not power on. | Check all power connections. Perform the following sequence: remove DC input connector and battery; wait 10 seconds; connect DC input or install battery; press the power key. Ensure the battery is charged. |
| System image quality is poor. | Adjust the LCD screen to improve viewing angle. Adjust the brightness, as necessary, to improve image quality. Adjust the gain. |
| Zoom does not work. | Press Freeze key. Zoom does not work when the image is frozen. |
| No CPD image. | Adjust the gain. |
| No DCPD image. | Adjust the gain. |
| No Color image. | Adjust the gain. |

Table 1: Troubleshooting (Continued)

| Symptom | Solution |
|---|--|
| No OB measurement selections. | Select the OB exam type. |
| Print does not work. | Set the correct printer in system setup. Check the printer connections. Check the printer to ensure that it is turned on and set up properly. See the printer manufacturer's instructions, if necessary. |
| VCR does not record. | Check the VCR connections. Check the VCR to ensure that it is turned on and set up properly. See the VCR manufacturers' instructions, if necessary. |
| External monitor does not work. | Check the monitor connections. Check the monitor to ensure that it is turned on and set up properly. See the monitor manufacturers' instructions, if necessary. |
| Unexpected labels using the function keys. | Ensure labels have been assigned to the function keys. |
| Inaccurate fetal age calculation. | Ensure that the patient information, date, and time are set accurately. |
| System does not recognize the transducer. | Disconnect and reconnect the transducer. |
| Text cursor does not move when touchpad or arrows are selected. | Text cursor is constrained to one line. |
| A maintenance icon  displays on the system screen. | This icon indicates that 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, which is obtained from SonoSite or from its authorized representatives. You must obtain one key for each system or transducer that will use the new software. See [“Obtaining a License Key” on page 169](#).

The software may be installed and will operate for a short period of time without requiring a valid license key. We refer to this period of time as the “grace period.” The grace period is variable.

When you first install your software, your SonoSite system prompts you for a license key. If you have not yet obtained a valid license key, you can elect to use the software as long as the grace period time has not been fully consumed.

When a system is running in the grace period, all system functions are available. As you use the system, the grace period is slowly consumed. When the grace period has expired, the system will not be usable until a valid license key has been entered. Grace period time is not consumed while the system is powered off or when it is in “sleep” mode. Whenever a system is running in the grace period, the grace period time remaining is available on the license update screen.

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

Upgrading the System and Transducer Software

As described in [Chapter 1 “About the System Software” on page 5](#), software upgrades are provided on CompactFlash cards, which are installed in the back CompactFlash slot on the right hand side of the system. Upgrades provided may be required or optional.

Whenever you install a CompactFlash card containing a newer version of software into the system, the system will determine the level of software, prepare the system for the upgrade, and then install the new software onto the system.

When a CompactFlash card contains new transducer software and the transducer that requires a software upgrade is connected, the system prompts the user that the transducer requires the upgrade.

To upgrade the system software:

- 1 Remove any transducer or Triple Transducer Connect from the TITAN system.
- 2 Connect the TITAN system directly to the power supply or through the docking system/mini-dock. See the *TITAN Accessories User Guide*.
- 3 Insert the CompactFlash card into the back slot.
The system displays the following message:



Figure 1 Upgrade System Software

- 4 Select **Yes** to accept or **No** to cancel the upgrade.
When you accept the system software upgrade, the system begins to load the new software and prepare for the upgrade and displays the following message:



Figure 2 System Software Loading

When the software upgrade has prepared the system for upgrade, the system displays the following message:



Figure 3 System Software Step 1 Restart

5 Select **Restart**.

After restart, there is a short delay before the system goes into the upgrade process. Do not turn the system off. The system displays the following message:



Figure 4 System Software Installation

When the upgrade is completed, the system displays the following message:

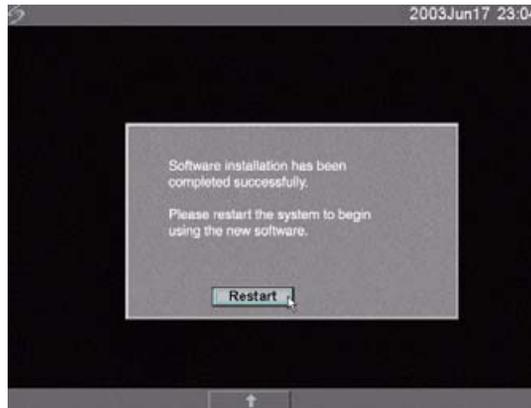


Figure 5 System Software Step 2 Restart

6 Select **Restart**.

When the operating software has been replaced, the system presents you with the license update screen so that you may license the software. If upgrading a transducer, press Cancel from the on-screen menu.



Figure 6 System Software License Key

At this point, the software upgrade process is complete, but the software is not yet licensed. See "[Obtaining a License Key](#)" on page 169.

Note: If you are upgrading a system and one or more transducers, it is recommended to upgrade all items before calling SonoSite Technical Support for your license keys. To postpone obtaining a license key, press Cancel from the on-screen menu.

To upgrade transducer software:

- 1 Turn the system off and remove the CompactFlash card from the back slot.
- 2 Connect the transducer for the upgrade.
- 3 Turn the system on.
- 4 Wait approximately 10 seconds and then insert the upgrade CompactFlash card.

Note: XXX identifies the current software version.

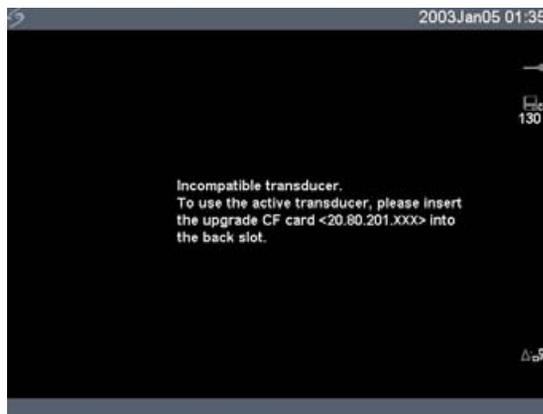


Figure 7 Incompatible Transducer Update

This screen is not displayed for compatible transducers.

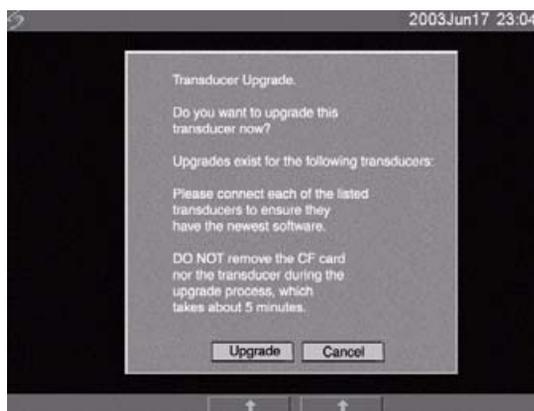


Figure 8 Upgrade Transducer Software

- 5 Select **Yes** to accept or **No** to cancel the upgrade.
When you accept the transducer software upgrade, the system loads the new software and displays the following message:



Figure 9 Transducer Software Loading

When the upgrade is completed, the system displays the following message.



Figure 10 Transducer Software Installation

6 Select **Restart**.

When the transducer software has been replaced, the system presents you with the license update screen so that you may license the software for your transducer. Upgrade all transducers before obtaining license keys. Repeat all steps in “[To upgrade transducer software:](#)”

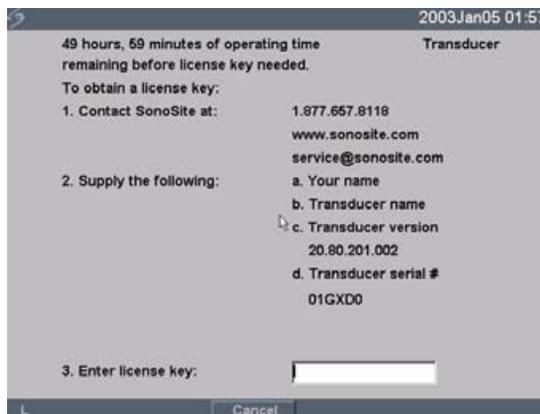


Figure 11 Transducer License Screen

At this point, the software upgrade process is complete, but the software is not yet licensed. The following section “[Obtaining a License Key](#)” explains how to license your system and transducer software.

Note: If you are upgrading additional transducers, it is recommended to upgrade all items before calling SonoSite Technical Support for your license keys. To postpone obtaining a license key, press Cancel from the on-screen menu.

Obtaining a License Key

A license key is required to update your system. It may be obtained by contacting SonoSite, Inc. Technical Support Department.

| | |
|----------------------------------|---|
| Technical support | 1-877-657-8118 |
| International technical support: | Contact your local representative or call 425-951-1330 |
| Technical support fax: | 1-425-951-6700 |
| Technical support e-mail: | service@sonosite.com |
| SonoSite website: | www.sonosite.com and select Products & Solutions and then Technical Support |

To receive your license key, you will need to provide the following information, which is displayed on the system information screen of your system:

Table 2: Software License Key Information

| System Software | Transducer Software |
|--|---|
| Name of the person installing the upgrade | Name of the person installing the upgrade |
| Serial number (located on the bottom of your system) | Serial number |
| ARM version | REF number |
| PCBA serial number | SH database version |

Installing a License Key

When you have obtained a license key for your software, you must enter it into the system. Once a valid license key has been entered, the system remains licensed until the next time the system software is upgraded.

To install a license key:

- 1 Turn on the system.

If the software is not yet licensed, the license update screen displays.

The license update screen displays the following information: how to contact SonoSite, the required information to obtain the license key, and the grace period (time remaining) on your system.



Figure 12 System and Transducer License Screens

- 2 Enter your license key in the license number field.
- 3 Select Done from the on-screen menu to install the license key and license your software.

Note: If you have entered a valid license key and you cannot complete the licensing procedure, verify that the license key has been entered correctly. The license key should be exactly 12 digits (for example, 123348990552) with no other characters or punctuation.

Note: If after confirming correct entry of the license key, you are still unable to license your system, call SonoSite technical support. USA/Canada customers call 1-877-657-8118. International customers call your local representative or 1-425-951-1330.

Maintenance

This section is intended to assist in effective cleaning and disinfection. It is also intended to protect the system and transducers against damage during cleaning or disinfection. 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.

For more information about cleaning or disinfection solutions or ultrasound gels used with the transducer, contact SonoSite or your local representative. For information about a specific product, contact the product manufacturer.

There is no recommended periodic or preventive maintenance required for the system, transducer, or accessories. There are no internal adjustments or alignments that require periodic testing or calibration. All maintenance requirements are described in the *TITAN Ultrasound System User Guide* and *TITAN Ultrasound System Service Manual*. Performing maintenance activities not described in the User Guide or Service Manual may void the product warranty.

Contact SonoSite Technical Support for any maintenance questions.

Recommended Disinfectant

See the [Table 3, "Disinfectants Compatibility with System and Transducers"](#) on page 177.

Safety

Please observe the following warnings and cautions when using cleaners, disinfectants, and gels. More specific warnings and cautions are included in the product literature and in the procedures later in this chapter.

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.

Warning: The level of disinfection required for a device is dictated by the type of tissue it will contact during use. To avoid infection, ensure 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 FDA.

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

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.

Warning: To avoid electrical shock, before cleaning, disconnect the system from the power supply or remove from the docking system/mini-dock.

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

To avoid infection, if a pre-mixed disinfection solution is used, observe the solution expiration date, and ensure that the 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 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 tested for use on system surfaces.

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

Do not scratch the LCD screen.

To clean the LCD screen:

Dampen a clean, non-abrasive, cotton cloth with an ammonia-based window cleaner, and wipe the screen clean. It is recommended to apply the cleaning solution to the cloth rather than the surface of the screen.

To clean and disinfect the system surfaces:

- 1 Turn off the system.
- 2 Disconnect the system from the power supply or remove from the docking system/ mini-dock.
- 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, use the immersion method or the wipe method. Immersible transducers can be disinfected only if the product labeling of the compatible disinfectant you are using indicates it can be used with an immersion method.

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, if a pre-mixed disinfection solution is used, observe the solution expiration date, and ensure that the 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 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:

Transducers must be cleaned after every use. Cleaning transducers is necessary prior to effective disinfection. Ensure 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.

Caution: 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.

To clean and disinfect a transducer using the 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 using the 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, 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 transducer.
- 7 Follow the instructions on the disinfectant label for the duration of the transducer immersion.
- 8 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.
- 9 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.

Sterilizable Transducers

The only method of sterilizing SonoSite transducers is liquid sterilants. See [Table 3, “Disinfectants Compatibility with System and Transducers” on page 177](#).

Cleaning and Disinfecting Transducer Cables

The transducer cable can be disinfected using a recommended wipe or immersion disinfectant. Before disinfecting, orient the cable to ensure that the transducer and system do not get immersed.

Warning: To avoid infection, if a pre-mixed disinfection solution is used, observe the solution expiration date, and ensure that the date has not passed.

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

To clean and disinfect the transducer cable using the 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 cable, 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 the transducer cable using the immersion method:

- 1 Disconnect the transducer from the system.
- 2 Remove any transducer sheath.
- 3 Clean the transducer cable 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, then wipe with a dry cloth.
- 5 Mix the disinfectant solution compatible with the transducer cable, following disinfectant label instructions for solution strengths and disinfectant contact duration.
- 6 Immerse the transducer cable into the disinfection solution.
- 7 Follow the instructions on the disinfectant label for the duration of the transducer cable immersion.
- 8 Using the instructions on the disinfectant label, rinse the transducer cable, and then air dry or towel dry with a clean cloth.
- 9 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

To clean and disinfect the battery using the wipe method:

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

- 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 3: Disinfectants Compatibility with System and Transducers

| Disinfection and Cleaning Solutions | Country of Origin | Type | Active Ingredient | C60/L38 | C15/C11 | ICT | HST | C8 | L25 | System Surfaces |
|-------------------------------------|-------------------|--------|-------------------------------------|---------|---------|------|------|------|------|-----------------|
| 105 Spray | USA | Spray | Quat. Ammonia | T, C | T, C | N | N | T, C | T, C | A |
| AbcoCide (4) | USA | Liquid | Gluteraldehyde | T | T | T | U | U | U | U |
| AbcoCide 28 (4) | USA | Liquid | Gluteraldehyde | T | U | T | U | U | U | U |
| Aidal Plus | Australia | Liquid | Gluteraldehyde | T, C | T, C | T, C | N | T, C | T, C | N |
| Alkacide | France | Liquid | Gluteraldehyde | T, C | T, C | T, C | U | T, C | T, C | A |
| Alkalingettes (3) | France | Liquid | Alkylamine, Isopropanol | U | U | N | T, C | U | U | U |
| Alkaspray GSA (3) | France | Spray | Isopropyl Alcohol | U | U | U | N | U | U | U |
| Alkazyme | France | Liquid | Quat. Ammonia | T, C | T, C | N | T | T, C | T, C | A |
| Ampholysine Basique (3) | France | Liquid | Biguanide/Quat. Ammonia | U | U | N | T | U | U | U |
| Ampholysine plus | France | Liquid | Quat. Ammonia | U | U | N | N | U | U | U |
| Amphospray 41(3) | France | Spray | Ethanol | U | U | N | N | U | U | U |
| Amphyl (4) | USA | Liquid | O-phenylphenol | U | U | N | N | U | U | U |
| Aniosyme P.L.A. | France | Liquid | Quat. Ammonia | U | U | U | N | U | U | U |
| Anioxyde 1000 | France | Liquid | Hydrogen Peroxide Peracetic Acid | U | U | U | N | U | U | U |
| Ascend (4) | USA | Liquid | Quat Ammonia | T, C | T, C | N | U | T, C | T, C | A |
| Asepti-HB | USA | Liquid | Quat Ammonia | T, C | T, C | N | U | T, C | T, C | N |
| Asepti-Steryl 14 or 28 (4) | USA | Liquid | Gluteraldehyde | U | U | U | T, C | U | U | U |

Table 3: Disinfectants Compatibility with System and Transducers (Continued)

| Disinfection and Cleaning Solutions | Country of Origin | Type | Active Ingredient | C60/ L38 | C15/ C11 | ICT | HST | C8 | L25 | System Surfaces |
|-------------------------------------|-------------------|--------|--------------------------------|-------------|-------------|------|------|------|------|-----------------|
| Asepti-Steryl | USA | Spray | Ethanol | T, C | N | N | T, C | T, C | T, C | A |
| Asepti-Wipes | USA | Wipe | Propanol (Isopropyl Alcohol) | T, C | T, C | N | U | T, C | T, C | A |
| Aseptosol | Germany | Liquid | Gluteraldehyde | U | U | U | N | U | U | U |
| Autoclave (Steam) | | System | Steam/Heat | N | N | N | N | N | N | N |
| Bacillocid rasant | Germany | Liquid | Glut./Quat. Ammonia | T, C | T, C | N | N | T, C | T, C | N |
| Bacillol 25 | Germany | Liquid | Ethanol/Propanol | U | U | U | N | U | U | U |
| Bacillol Plus | Germany | Spray | Propanol/Glut. | T, C | N | N | N | T, C | N | A |
| Bactylisine | France | Liquid | Quat. Ammonia | U | U | U | N | U | U | U |
| Baktobod | Germany | Liquid | Glut. Quat. Ammonia | U | U | U | N | U | U | U |
| Banicide (4) | USA | Liquid | Gluteraldehyde | T, C | T, C | T, C | U | T, C | T, C | N |
| Betadine | USA | Liquid | Providone-Iodine | N | N | N | N | N | N | N |
| Biotensid | Germany | Spray | 2-Propanol | U | U | U | N | U | U | U |
| Biospray | France | Spray | Ethanol/Aldehyde | U | U | U | N | U | U | U |
| Bioxal M (3) | France | Liquid | Hydrogen Peroxide, Acetic Acid | U | U | U | N | U | U | U |
| Bleach (4) | USA | Liquid | NaCl Hypochlorite | T, C | T, C | N | N | T, C | T, C | N |
| Bodedex | France | Liquid | Quat. Ammonia | U | U | N | N | U | U | U |
| Cavicide (4) | USA | Liquid | Isopropyl | T, C | N | N | N | T, C | T, C | A |

Table 3: Disinfectants Compatibility with System and Transducers (Continued)

| Disinfection and Cleaning Solutions | Country of Origin | Type | Active Ingredient | C60/L38 | C15/C11 | ICT | HST | C8 | L25 | System Surfaces |
|-------------------------------------|-------------------|---------|-------------------------|---------|---------|------|------|------|------|-----------------|
| Cetavlon | France | Liquid | Cetrimide | U | U | N | N | U | U | U |
| Chlorispray | France | Spray | Gluteraldehyde | U | U | N | N | U | U | U |
| Cidalkan (3) | France | Liquid | Alkylamine, isopropanol | U | U | U | N | U | U | U |
| Cidex (2) (4) (5) | USA | Liquid | Gluteraldehyde | T, C | T, C | T, C | T, C | T, C | T, C | A |
| Cidex OPA (2) (3) (4) (5) | USA | Liquid | ortho-phthaldehyde | T, C | T, C | T, C | T, C | T, C | T, C | A |
| Cidex Plus (2) (4) (5) | USA | Liquid | Gluteraldehyde | T, C | T, C | T, C | T | U | T, C | U |
| Cidezyme | USA | Cleaner | Ethylene Glycol | U | U | U | N | U | U | U |
| Coldspor Spray | USA | Spray | Gluteraldehyde | U | U | N | N | U | U | U |
| Control III (4) | USA | Liquid | Quat. Ammonia | T, C | T, C | N | N | T, C | N | A |
| Coverage Spray (4) | USA | Spray | Quat. Ammonia | T, C | T, C | N | N | T, C | N | A |
| Cutasept F | Germany | Spray | 2-Propanol | U | U | N | N | U | U | U |
| Dentured Alcohol | USA | Liquid | Ethanol | N | N | N | N | N | N | N |
| Dismonzon pur | Germany | Liquid | Hexahydrate | T, C | T, C | N | N | T, C | T, C | A |
| Dispatch (4) | USA | Spray | NaCl Hypochlorite | T, C | T, C | N | N | T, C | T, C | N |
| End-Bac II | USA | Liquid | Quat. Ammonia | T, C | N | N | N | T, C | T, C | A |
| Endo FC | France | Liquid | Gluteraldehyde | U | U | U | T, C | U | U | U |
| Endozime AW Plus | France | Liquid | Propanol | T, C | T, C | N | N | T, C | T, C | A |
| Envirocide (4) | USA | Liquid | Isopropyl | T, C | T, C | N | N | T, C | N | A |
| Enzol | USA | Cleaner | Ethylene Glycol | T, C | T, C | N | N | T, C | T, C | A |

Table 3: Disinfectants Compatibility with System and Transducers (Continued)

| Disinfection and Cleaning Solutions | Country of Origin | Type | Active Ingredient | C60/ L38 | C15/ C11 | ICT | HST | C8 | L25 | System Surfaces |
|-------------------------------------|-------------------|---------|-------------------------------|-------------|-------------|------|------|------|------|-----------------|
| Enzy-Clean | USA | Cleaner | Amylase/Protease Complex | U | U | U | T, C | U | U | U |
| Epizyme Rapid | Australia | Cleaner | Citric Acid | U | U | U | T, C | U | U | U |
| Esculase 388 | France | Liquid | Quat. Ammonia | U | U | U | N | U | U | U |
| Ethylene Oxide (EtO) (4) | | System | Ethylene Oxide | N | N | N | N | N | N | N |
| Expose | USA | Liquid | Isopropyl | T, C | T, C | N | N | T, C | T, C | A |
| Foam Insurance | USA | Spray | n-Alkyl | U | U | U | N | U | U | U |
| Gercid 90 | France | Liquid | Quat. Ammonia | U | U | U | N | U | U | U |
| Gigasept AF (3) | Germany | Liquid | Quat. Ammonia | T, C | T, C | N | N | T, C | T, C | N |
| Gigasept FF | Germany | Liquid | Bersteinsäure | N | N | N | N | N | N | N |
| Gluteraldehyde SDS | USA | Liquid | Gluteraldehyde | U | U | U | U | T | T | A |
| Helipur H+N (3) | Germany | Liquid | Gluteraldehyde/ Propanol | U | U | U | N | U | U | U |
| Hexanios | France | Liquid | Polyhexanide/Quat. Ammonia | T, C | T, C | N | N | T, C | T, C | A |
| Hi Tor Plus | USA | Liquid | Chloride | T, C | T, C | N | N | T, C | N | N |
| Hibiclens | USA | Cleaner | Chlorhexidine | T, C | T, C | N | N | T, C | T, C | A |
| Hydrogen Peroxide | USA | Liquid | Hydrogen Peroxide | T, C | T, C | T, C | U | T, C | T, C | N |
| Incides | Germany | Wipe | Alcohol | U | U | U | N | U | U | U |
| Incidine | Germany | Spray | Aldehydes | U | U | U | N | U | U | U |
| Incidur | Germany | Liquid | Gluteraldehyde | U | U | U | N | U | U | U |

Table 3: Disinfectants Compatibility with System and Transducers (Continued)

| Disinfection and Cleaning Solutions | Country of Origin | Type | Active Ingredient | C60/L38 | C15/C11 | ICT | HST | C8 | L25 | System Surfaces |
|-------------------------------------|-------------------|-----------|--|---------|---------|-----|------|------|------|-----------------|
| Incidur Spray | Germany | Spray | Ethanol | U | U | U | N | U | U | U |
| Instruzyme | France | Liquid | Quat. Ammonia | U | U | U | T | U | U | U |
| Kawason | Australia | | | U | U | U | N | U | U | U |
| Kleen-aseptic b (4) | USA | Spray | Isopropanol | U | U | U | N | U | U | U |
| Klenzyme | USA | Cleaner | Proteolytic Enzymes | U | U | U | T | U | U | U |
| Kodan | Germany | Spray | Propanol/Alcohol | U | U | U | N | U | U | U |
| Kohrsolin ff | Germany | Liquid | Gluteraldehyde | N | N | N | T | N | N | A |
| Kohrsolin iD | Germany | Liquid | Gluteraldehyde | U | U | U | T | U | U | U |
| Korsolex (3) | Germany | Liquid | Gluteraldehyde | U | U | U | T, C | U | U | U |
| Korsolex basic (3) | Germany | Liquid | Gluteraldehyde | N | N | N | T, C | N | N | A |
| Korsolex Concentrate (3) | Germany | Liquid | Gluteraldehyde | N | N | N | N | T | U | A |
| Korsolex FF | Germany | Liquid | Gluteraldehyde | T | T | T | U | T | N | A |
| Korsolex pret a l'emploi | Germany | Liquid | Gluteraldehyde | U | U | U | T, C | U | U | U |
| Kutasept | Germany | | | U | U | U | N | U | U | U |
| Linget'anios | France | Towelette | Quat. Ammonia | U | U | U | N | U | U | U |
| LpHse (4) | USA | Liquid | O-phenylphenol | T, C | N | N | N | T, C | N | A |
| Lysertol V Neu (3) | Germany | Liquid | Gluteraldehyde, Formaldahyde, Quat. Ammonium chloride | U | U | U | T | U | U | U |
| Lysol IC (4) | USA | Liquid | O-phenylphenol | T, C | N | N | N | T, C | T, C | A |

Table 3: Disinfectants Compatibility with System and Transducers (Continued)

| Disinfection and Cleaning Solutions | Country of Origin | Type | Active Ingredient | C60/L38 | C15/C11 | ICT | HST | C8 | L25 | System Surfaces |
|-------------------------------------|-------------------|---------|---------------------|---------|---------|------|------|------|------|-----------------|
| Lysol Spray | USA | Spray | Ethanol | U | U | U | U | T, C | U | A |
| Madacide (4) | USA | Liquid | Isopropanol | T, C | N | N | N | T, C | N | N |
| Matar (4) | USA | Liquid | O-phenylphenol | T, C | T, C | N | N | T, C | T, C | N |
| Medi-Swab | Sweden | Wipe | Isopropyl/Alcohol | U | U | U | N | U | U | U |
| Medside Medallion | USA | Liquid | Quat. Ammonia | U | U | U | N | U | U | U |
| MetriCide 14 (2) (4) (5) | USA | Liquid | Gluteraldehyde | T | T | T | T | U | U | U |
| MetriCide 28 (2) (4) (5) | USA | Liquid | Gluteraldehyde | T, C | N | T, C | T | T, C | U | A |
| MetriCide Plus 30 (4) (5) | USA | Liquid | Gluteraldehyde | T, C | T, C | T, C | U | U | T, C | U |
| MetriGuard (4) | USA | Liquid | Ammonium Chloride | U | U | N | T | U | U | U |
| MetriZyme | USA | Cleaner | Propylene Glycol | T, C | T, C | N | U | T, C | T, C | A |
| Mikrobak forte | Germany | Liquid | Ammonium Chloride | T, C | T, C | N | T | T, C | T, C | A |
| Mikrozid Tissues (3) | Germany | Wipe | Ethanol/Propanol | T, C | N | N | N | T, C | T, C | A |
| Milton | Australia | Liquid | Sodium Hypochlorite | U | U | U | N | U | U | U |
| New Ger (3) | Spain | Liquid | n-Duopropenide | U | U | U | N | U | U | U |
| Nuclean | France | Spray | Alcohol/Biguanide | T, C | T, C | N | N | T, C | T, C | N |
| Omega (4) | USA | Liquid | Isopropyl | U | U | U | N | U | U | U |
| Peract 20 (1) (2) (3) (5) | USA | Liquid | Hydrogen Peroxide | U | U | U | N | U | U | U |
| Phagocide D (3) | France | Liquid | Gluteraldehyde | U | U | U | T, C | U | U | U |

Table 3: Disinfectants Compatibility with System and Transducers (Continued)

| Disinfection and Cleaning Solutions | Country of Origin | Type | Active Ingredient | C60/ L38 | C15/ C11 | ICT | HST | C8 | L25 | System Surfaces |
|-------------------------------------|-------------------|-----------|---|-------------|-------------|-----|------|------|------|-----------------|
| Phagolase ND NFLE (3) | France | Cleaner | Quaternary Ammonium, Alkylamine, Enzyme proteolytique | U | U | U | T, C | U | U | U |
| Phagolase pH Basique | France | Liquid | Gluteraldehyde | U | U | U | T, C | U | U | U |
| Phagolingelette D 120 (3) | France | Towelette | Alcohol, Biguanide, Quaternary Ammonium | U | U | U | N | U | U | U |
| Phagosept Spray (3) | France | Spray | Alcohol, Biguanide, Quaternary Ammonium | U | U | U | N | U | U | U |
| Phagozyme ND (3) | France | Liquid | Quaternary Ammonium Enzymes | U | U | U | T, C | U | | U |
| PowerQuat | Canada | Liquid | Quat. Ammonia | U | U | U | N | U | U | U |
| Precise (4) | USA | Spray | O-phenylphenol | N | N | N | N | N | N | N |
| Presept | USA | Liquid | NaCl Dichlorite | U | U | U | N | U | U | U |
| Prontocid N (3) | Germany | Liquid | Formaldahyde/ Gluteraldehyde | U | U | U | N | U | U | U |
| Pyobactene | France | Liquid | Aldehydes | U | U | U | N | U | U | U |
| Rivascop | France | Liquid | Quat. Ammonia | U | U | U | N | U | U | U |
| Ruthless | USA | Spray | Quat. Ammonia | T, C | N | N | N | T, C | N | A |
| Sagrosept | Germany | Liquid | Propanol | N | N | N | N | U | U | U |
| Sagrosept | Germany | Wipe | Proponal | T, C | N | N | U | T, C | T, C | N |

Table 3: Disinfectants Compatibility with System and Transducers (Continued)

| Disinfection and Cleaning Solutions | Country of Origin | Type | Active Ingredient | C60/ L38 | C15/ C11 | ICT | HST | C8 | L25 | System Surfaces |
|-------------------------------------|-------------------|--------|---|-------------|-------------|-----|------|------|------|-----------------|
| Salvanios pH 10 | France | Liquid | Quat. Ammonia | U | U | U | T, C | U | U | U |
| Sani-Cloth (4) | USA | Wipe | Quat. Ammonia | U | U | U | N | U | U | U |
| Sani-Cloth Plus | USA | Wipe | Quat. Ammonia | T, C | T, C | N | N | T, C | T, C | N |
| Seku Extra | Germany | Liquid | Gluteraldehyde | U | U | U | T | U | U | U |
| Sekucid | France | Liquid | Gluteraldehyde | U | U | U | T, C | U | U | U |
| Sekucid N (3) | France | Liquid | Gluteraldehyde | U | U | U | T, C | U | U | U |
| Sekulyse | France | Liquid | Biguanide | U | U | U | T | U | U | U |
| Sekusept Extra | Germany | Liquid | Glyoxal/Glut. | U | U | U | N | U | U | U |
| Sekusept forte | Germany | Liquid | Formaldahyde | U | U | U | N | U | U | U |
| Sekusept forte S | Germany | Liquid | Formaldehyde/ Glyoxal/ Gluteraldehyde/ Quat. Ammonia | U | U | U | N | U | U | U |
| Sekusept Plus | Germany | Liquid | Glucoprotamin | U | U | U | N | U | U | U |
| Sekusept Pulver | Germany | Liquid | Natriumperborat | U | U | U | N | U | U | U |
| Sklar (4) | USA | Liquid | Isopropanol | T, C | T, C | N | N | T, C | N | N |
| Softasept N | Germany | Spray | Ethanol | U | U | U | N | U | U | U |
| Sporadyne | France | Liquid | Didecyldimethyl | U | U | U | T | U | U | U |
| Sporadyne pret a l'emploi (3) | France | Liquid | Gluteraldehyde | U | U | U | T | U | U | U |
| Sporicidin (2) (4) | USA | Liquid | Phenol | T, C | T, C | N | N | T, C | T, C | N |

Table 3: Disinfectants Compatibility with System and Transducers (Continued)

| Disinfection and Cleaning Solutions | Country of Origin | Type | Active Ingredient | C60/L38 | C15/C11 | ICT | HST | C8 | L25 | System Surfaces |
|-------------------------------------|-------------------|--------|--------------------------------|---------|---------|------|------|------|------|-----------------|
| Sporicidin (2) (4) | USA | Wipe | Phenol | T, C | T, C | N | N | T, C | T, C | N |
| Sporicidin Sterilant (2) (4) (5) | USA | Liquid | Phenol, Sodium Phenate, Glute. | U | U | U | T, C | U | U | U |
| Sporox II (4) | USA | Liquid | Hydrogen Peroxide | U | U | U | T, C | U | U | U |
| Staphene (4) | USA | Spray | Ethanol | T, C | N | N | N | T, C | T, C | A |
| Steam sterilization | USA | Gas | Water | N | N | N | N | N | N | N |
| Steranios | France | Liquid | Gluteraldehyde | T, C | T, C | T, C | U | T, C | T, C | A |
| STERIS (4) | USA | Liquid | Peracetic Acid | U | U | U | N | U | U | U |
| Surfaces Hautes (3) | France | Spray | Quat. Ammonia | U | U | U | N | U | U | U |
| Surg L Kleen | USA | Liquid | | U | U | U | N | U | U | U |
| T-Spray | USA | Spray | Quat. Ammonia | T, C | T, C | N | N | T, C | N | A |
| T-Spray II | USA | Spray | Alkyl/Chloride | T, C | T, C | N | N | T, C | T, C | A |
| TBQ (4) | USA | Liquid | Alkyl | T, C | T, C | N | N | T, C | T, C | N |
| Theracide | USA | Liquid | Quat. Ammonia | T, C | T, C | N | N | U | U | U |
| Theracide | USA | Wipe | Quat. Ammonia | T, C | T, C | N | N | U | U | U |
| Thericide Plus | USA | Liquid | Quat. Ammonia | T, C | T, C | N | N | T, C | T, C | A |
| Thericide Plus | USA | Wipe | Quat. Ammonia | T, C | T, C | N | N | T, C | T, C | A |
| Tor (4) | USA | Liquid | Quat. Ammonia | T, C | T, C | N | N | T, C | N | N |
| Tor Spray | USA | Spray | Butoxyethanol Alkane | N | N | N | U | N | N | N |

Table 3: Disinfectants Compatibility with System and Transducers (Continued)

| Disinfection and Cleaning Solutions | Country of Origin | Type | Active Ingredient | C60/L38 | C15/C11 | ICT | HST | C8 | L25 | System Surfaces |
|-------------------------------------|-------------------|---------|-----------------------------|---------|---------|------|-----|------|------|-----------------|
| Transeptic | USA | Cleaner | Alcohol | T | N | N | N | T | N | A |
| Tristel | UK | Liquid | Chlorine Dioxide | T, C | N | T, C | U | T, C | T, C | N |
| Ultra Swipes | USA | Wipe | Ethanol | U | U | U | N | U | U | U |
| Vaposeptol | Germany | Spray | Biguanide | U | U | U | T | U | U | U |
| Vesphene II (4) | USA | Liquid | Sodium/ o-Phenylphenate | T, C | T, C | N | N | T, C | T, C | A |
| Virex (4) | USA | Liquid | Quat. Ammonia | T, C | T, C | N | N | T, C | N | N |
| Virkon | Australia | Liquid | Potassium Monopersulfate | U | U | U | N | U | U | U |
| VP 483 | Germany | Liquid | Unknown | U | U | U | N | U | U | U |
| VP 483/2H | Germany | Liquid | Unknown | U | U | U | N | U | U | U |
| Wavicide -01 (2) (4) (5) | USA | Liquid | Gluteraldehyde | N | N | N | N | N | N | A |
| Wavicide -06 (4) | USA | Liquid | Gluteraldehyde | T, C | N | T, C | N | T, C | T, C | N |
| Wavicide -06 Plus (4) | USA | Liquid | Gluteraldehyde | U | U | U | U | U | U | U |
| Wex-Cide (4) | USA | Liquid | O-phenylphenol | T, C | T, C | N | N | T, C | T, C | A |
| Ytdesinfektion Plus | Sweden | Liquid | Isopropanol | U | U | U | N | U | U | U |

(1) Compatible but no EPA Registration

(2) Has FDA 510(k)

(3) Has CE Mark

(4) EPA Registered

(5) FDA 510(k) cleared liquid sterilant or high level disinfectant

Table 3: Disinfectants Compatibility with System and Transducers (Continued)

| Disinfection and Cleaning Solutions | Country of Origin | Type | Active Ingredient | C60/ L38 | C15/ C11 | ICT | HST | C8 | L25 | System Surfaces |
|---|-------------------|------|-------------------|-------------|-------------|-----|-----|----|-----|-----------------|
| <p>A = Acceptable for use N = No (do not use) T = Transducer only T, C = Transducer and Cable U = Untested (do not use)</p> | | | | | | | | | | |

Chapter 8: References

This section includes information about clinical measurements that can be made with the system, the accuracy of each measurement, and factors affecting measurement accuracy.

Display Size

The precision with which a caliper can be placed in an image can be improved by making sure the area of interest fills as much of the screen as possible.

In 2D imaging, the distance measurement is improved by minimizing the display depth.

Caliper Placement

When making a measurement, accurate placement of the caliper is essential.

To improve caliper placement precision: adjust the display for maximum sharpness; use leading edges (closest to the transducer) or borders for start and stop points; and maintain a consistent transducer orientation for each type of measurement.

When the calipers are positioned farther apart, they get larger. When the calipers are moved closer together, they get smaller. The caliper line disappears as the calipers get closer together.

2D Measurements

The measurements provided by the system do not define a specific physiological or anatomical parameter. Rather, what is provided is a measurement 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) ^c |
|-------------------------------|-------------------------------|-------------|--------------------------|-------------------------|
| 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 |

Table 1: 2D Measurement Accuracy and Range (Continued)

| 2D Measure Accuracy and Range | System Tolerance ^a | Accuracy By | Test Method ^b | Range (cm) ^c |
|-------------------------------|--|-------------|--------------------------|--------------------------|
| Diagonal Distance | < ±2% plus 1% of full scale | Acquisition | Phantom | 0-44 cm |
| Area ^d | < ±4% plus (2% of full scale/smallest dimension) * 100 plus 0.5% | Acquisition | Phantom | 0.01-720 cm ² |
| Circumference ^e | < ±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. Based upon C15 imaging at maximum depth with calipers in rectangular imaging area.

d. The area accuracy is defined using the following equation:

$$\% \text{ tolerance} = ((1 + \text{lateral error}) * (1 + \text{axial error}) - 1) * 100 + 0.5\%.$$

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

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

Table 2: M Mode Measurement and Calculation Accuracy and Range

| M Mode Measurement Accuracy and Range | System Tolerance | Accuracy By | Test Method | Range |
|---------------------------------------|--|-------------|----------------------|-------------|
| Distance | < +/- 2% plus 1% of full scale ^a | Acquisition | Phantom ^b | 0-26 cm |
| Time | < +/- 2% plus 1% of full scale ^c | Acquisition | Phantom ^d | 0.01-10 sec |
| Heart Rate | < +/- 2% plus (Full Scale ^c * Heart Rate/100) % | Acquisition | Phantom ^d | 5-923 bpm |

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

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

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

d. SonoSite special test equipment was used.

Table 3: PW Doppler Mode Measurement and Calculation Accuracy and Range

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

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

Sources of Measurement Errors

In general, two types of errors can be introduced into the measurement: acquisition error and algorithmic error.

Acquisition Error

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

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

Terminology and Measurement Publications

Terminology and measurements comply with AIUM published standards.

Cardiac References

Left Atrium/Aorta (LA/Ao)

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

Acceleration (ACC) in cm/s²

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

ACC = abs (delta velocity/delta time)

Acceleration Time (AT) in msec

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

See [Figure 4 on page 70](#).

Aortic Valve Area (AVA) by Continuity Equation in cm²

Reynolds, Terry. The Echocardiographer's Pocket Reference. 2nd ed., School of Cardiac Ultrasound, Arizona Heart Institute, (2000), 383, 442.

$$A_2 = A_1 * V_1 / V_2$$

where: A_2 = Ao valve area

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

LVOT = Left Ventricular Outflow Tract

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

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

Cardiac Output (CO) in l/min

Oh, J.K., J.B. Seward, A.J. Tajik The Echo Manual. 2nd ed., Lippincott, Williams, and Wilkins, (1999), 59.

$$CO = (SV * HR) / 1000$$

where: CO = Cardiac Output

SV = Stroke Volume

HR = Heart Rate

Cross Sectional Area (CSA) in cm²

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

$$CSA = 0.785 * D^2$$

where: D = diameter of the anatomy of interest

Delta Pressure: Delta Time (dP:dT) in mmHg/s

Otto, C.M. Textbook of Clinical Echocardiography. 2nd ed., W.B. Saunders Company, (2000), 117, 118.

32 mmHg/time interval in seconds

E:A ratio in cm/sec

E:A = velocity E/velocity A

Ejection Fraction (EF), percent

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

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

where: EF = Ejection Fraction
LVEDV = Left Ventricular End Diastolic Volume
LVESV = Left Ventricular End Systolic Volume

Elapsed Time (ET) in msec

ET = time between velocity cursors in milliseconds

Heart Rate (HR) in bpm

HR = 3 digit value input by user or measured on M Mode and Doppler image in one heart cycle

Interventricular Septum (IVS) Fractional Thickening, percent

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

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

where: IVSS = Interventricular Septal Thickness at Systole
IVSD = Interventricular Septal Thickness at Diastole

Left Ventricular End Volumes (Teichholz) in ml

Teichholz, L.E., T. Kreulen, M.V. Herman, et. al. "Problems in echocardiographic volume determinations: echocardiographic-angiographic correlations in the presence or absence of asynergy." American Journal of Cardiology, (1976), 37:7.

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

where: LVESV = Left Ventricular End Systolic Volume
LVDS = Left Ventricular Dimension at Systole

$$LVEDV = (7.0 * LVDD^3)/(2.4 + LVDD)$$

where: LVEDV = Left Ventricular End Diastolic Volume
LVDD = Left Ventricular Dimension at Diastole

Left Ventricular Volume: Biplane Method in ml

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

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

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

Left Ventricular Volume: Single Plane Method in ml

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

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

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

Left Ventricular Dimension (LVD) Fractional Shortening, percent

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

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

where: LDD = Left Ventricle Dimension at Diastole
LVDS = Left Ventricle Dimension at Systole

Left Ventricular Posterior Wall Fractional Thickening (LVPWFT), percent

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

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

where: LVPWS = Left Ventricular Posterior Wall Thickness at Systole
LVPWD = Left Ventricular Posterior Wall Thickness at Diastole

Mean Velocity (Vmean) in cm/s

Vmean = mean velocity

Mitral Valve Area (MVA) in cm²

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

$$MVA = 220/PHT$$

where: PHT = pressure half time

Note: 220 is an empirical derived constant and may not accurately predict mitral valve area in mitral prosthetic heart valves. The mitral valve area continuity equation may be utilized in mitral prosthetic heart valves to predict effective orifice area.

Pressure Gradient (PGr) in mmHG

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

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

Peak E Pressure Gradient (E PG)

$$E PG = 4 * PE^2$$

Peak A Pressure Gradient (A PG)

$$A PG = 4 * PA^2$$

Peak Pressure Gradient (PGmax)

$$PGmax = 4 * PV^2$$

Mean Pressure Gradient (PGmean)

$$PGmean = 4 * Vmax^2$$

Pressure Half Time (PHT) in msec

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

$$PHT = DT * 0.29$$

where: DT = deceleration time

Stroke Volume (SV) Doppler in ml

Oh, J.K., J.B. Seward, A.J. Tajik. The Echo Manual. 2nd ed., Lippincott, Williams, and Wilkins, (1999), 40, 59, 62.

$$SV = (CSA * VTI)$$

CSA = Cross Sectional Area of the LVOT

VTI = Velocity Time Integral of the aortic valve

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

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

$$SV = (LVEDV - LVESV)$$

where: SV = Stroke Volume
LVEDV = End Diastolic Volume
LVESV = End Systolic Volume

Velocity Time Integral (VTI) in cm

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

VTI = sum of abs (velocities [n])

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

Obstetrical References

Amniotic Fluid Index (AFI)

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

Average Ultrasound Age (AUA)

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

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

Results are displayed as month/day/year.
EDD = system date + (280 days - AUA in days)

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

The date entered into the patient information for LMP must precede the current date.
Results are displayed as month/day/year.
EDD = LMP date + 280 days

Estimated Fetal Weight (EFW)

Hadlock, F., et al. "Estimation of Fetal Weight with the Use of Head, Body, and Femur Measurements, A Prospective Study." American Journal of Obstetrics and Gynecology, 151:3 (February 1, 1985), 333-337.

Hansmann, M., et al. Ultrasound Diagnosis in Obstetrics and Gynecology. New York: Springer-Verlag, (1986), 154.

Osaka University. Ultrasound in Obstetrics and Gynecology. (July 20, 1990), 103-105.

Shepard M.J., V. A. Richards, R. L. Berkowitz, et al. "An Evaluation of Two Equations for Predicting Fetal Weight by Ultrasound." American Journal of Obstetrics and Gynecology, 142:1 (January 1, 1982), 47-54.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." Japanese Journal of Medical Ultrasonics, 23:12 (1996), 880, Equation 1.

Gestational Age (GA) by Last Menstrual Period (LMP)

The gestational age derived from the LMP date entered on the patient information form.

Results are displayed in weeks and days, and is calculated as follows:

$GA(LMP) = \text{System date} - \text{LMP date}$

Gestational Age (GA) by Last Menstrual Period (LMPd) Derived from Established Due Date (Estab. DD)

Same as GA by Estab. DD.

The gestational age derived from the system derived LMP using the Established Due Date entered on the patient information form.

Results are displayed in weeks and days, and is calculated as follows:

$GA(LMPd) = \text{System Date} - \text{LMPd}$

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

Results are displayed as month/day/year.

$LMPd(\text{Estab. DD}) = \text{Estab. DD} - 280 \text{ days}$

Gestational Age Tables

Abdominal Circumference (AC)

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." Radiology, 152: (1984), 497-501.

Hansmann, M., et al. Ultrasound Diagnosis in Obstetrics and Gynecology. New York: Springer-Verlag, (1986), 431.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." Japanese Journal of Medical Ultrasonics, 23:12 (1996), 885.

Warning:

The gestational age calculated by your SonoSite system does not match the age in the aforementioned reference at the 20.0 cm and 30.0 cm abdominal circumference (AC) measurements. The implemented algorithm extrapolates the gestational age from the slope of the curve of all table measurements, rather than decreasing the gestational age for a larger AC measurement indicated in the referenced table. This results in the gestational age always increasing with an increase in AC.

Anteroposterior Trunk Diameter (APTD)

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." Japanese Journal of Medical Ultrasonics, 23:12 (1996), 885.

Biparietal Diameter (BPD)

Chitty, L. S. and D.G. Altman. "New charts for ultrasound dating of pregnancy." Ultrasound in Obstetrics and Gynecology 10: (1997), 174-179, Table 3.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." Radiology, 152: (1984), 497-501.

Hansmann, M., et al. Ultrasound Diagnosis in Obstetrics and Gynecology. New York: Springer-Verlag, (1986), 440.

Osaka University. Ultrasound in Obstetrics and Gynecology. (July 20, 1990), 98.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." Japanese Journal of Medical Ultrasonics, 23:12 (1996), 885.

Crown Rump Length (CRL)

Hadlock, F., et al. "Fetal Crown-Rump Length: Re-evaluation of Relation to Menstrual Age (5-18 weeks) with High-Resolution, Real-Time Ultrasound." Radiology, 182: (February 1992), 501-505.

Hansmann, M., et al. Ultrasound Diagnosis in Obstetrics and Gynecology. New York: Springer-Verlag, (1986), 439.

Osaka University. Ultrasound in Obstetrics and Gynecology. (July 20, 1990), 20 and 96.

Tokyo University. "Gestational Weeks and Computation Methods." Ultrasound Imaging Diagnostics, 12:1 (1982-1), 24-25, Table 3.

Femur Length (FL)

Chitty, L. S. and D.G. Altman. "New charts for ultrasound dating of pregnancy." Ultrasound in Obstetrics and Gynecology 10: (1997), 174-179, Table 8, 186.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." Radiology, 152: (1984), 497-501.

Hansmann, M., et al. Ultrasound Diagnosis in Obstetrics and Gynecology. New York: Springer-Verlag, (1986), 431.

Osaka University. Ultrasound in Obstetrics and Gynecology. (July 20, 1990), 101-102.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." Japanese Journal of Medical Ultrasonics, 23:12 (1996), 886.

Fetal Trunk Cross-Sectional Area (FTA)

Osaka University. Ultrasound in Obstetrics and Gynecology. (July 20, 1990), 99-100.

Gestational Sac (GS)

Hansmann, M., et al. Ultrasound Diagnosis in Obstetrics and Gynecology. New York: Springer-Verlag, (1986).

Nyberg, D.A., et al. "Transvaginal Ultrasound." Mosby Yearbook, (1992), 76.

Gestational sac measurements provide a fetal age based on the mean of one, two, or three distance measurements; however, Nyberg's gestational age equation requires all three distance measurements for an accurate estimate.

Tokyo University. "Gestational Weeks and Computation Methods." Ultrasound Imaging Diagnostics, 12:1 (1982-1).

Head Circumference (HC)

Chitty, L. S. and D.G. Altman. "New charts for ultrasound dating of pregnancy." Ultrasound in Obstetrics and Gynecology 10: (1997), 174-191, Table 5, 182.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." Radiology, 152: (1984), 497-501.

Hansmann, M., et al. Ultrasound Diagnosis in Obstetrics and Gynecology. New York: Springer-Verlag, (1986), 431.

Occipito-Frontal Diameter (OFD)

Hansmann, M., et al. Ultrasound Diagnosis in Obstetrics and Gynecology. New York: Springer-Verlag, (1986), 431.

Transverse Trunk Diameter (TTD)

Hansmann, M., et al. Ultrasound Diagnosis in Obstetrics and Gynecology. New York: Springer-Verlag, (1986), 431.

University of Tokyo, Shinozuka, N. FJSUM, et al. "Standard Values of Ultrasonographic Fetal Biometry." Japanese Journal of Medical Ultrasonics, 23:12 (1996), 885.

Growth Analysis Tables

Abdominal Circumference (AC)

Chitty, Lyn S. et al. "Charts of Fetal Size: 3. Abdominal Measurements." British Journal of Obstetrics and Gynaecology 101: (February 1994), 131, Appendix: AC-Derived.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." Radiology, 152: (1984), 497-501.

Jeanty P., E. Cousaert, and F. Cantraine. "Normal Growth of the Abdominal Perimeter." American Journal of Perinatology, 1: (January 1984), 129-135.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. Ultrasound Diagnosis in Obstetrics and Gynecology. Springer-Verlag, New York, (1986), 179, Table 7.13.)

Biparietal Diameter (BPD)

Chitty, Lyn S. et al. "Charts of Fetal Size: 2. Head Measurements." British Journal of Obstetrics and Gynaecology 101: (January 1994), 43, Appendix: BPD-Outer-Inner.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." Radiology, 152: (1984), 497-501.

Jeanty P., E. Cousaert, and F. Cantraine. "A Longitudinal Study of Fetal Limb Growth." American Journal of Perinatology, 1: (January 1984), 136-144, Table 5.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. Ultrasound Diagnosis in Obstetrics and Gynecology. Springer-Verlag, New York, (1986), 176, Table 7.8.)

Estimated Fetal Weight (EFW)

Hadlock F., et al. "In Utero Analysis of Fetal Growth: A Sonographic Weight Standard." Radiology, 181: (1991), 129-133.

Jeanty, Philippe, F. Cantraine, R. Romero, E. Cousaert, and J. Hobbins. "A Longitudinal Study of Fetal Weight Growth." Journal of Ultrasound in Medicine, 3: (July 1984), 321-328, Table 1.

(Also published in Hansmann, Hackeloer, Staudach, and Wittman. Ultrasound Diagnosis in Obstetrics and Gynecology. Springer-Verlag, New York, (1986), 186, Table 7.20.)

Femur Length (FL)

Chitty, Lyn S. et al. "Charts of Fetal Size: 4. Femur Length." British Journal of Obstetrics and Gynaecology 101: (February 1994), 135.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." Radiology, 152: (1984), 497-501.

Jeanty P, E. Cousaert, and F. Cantraine. "A Longitudinal Study of Fetal Limb Growth." American Journal of Perinatology, 1: (January 1984), 136-144, Table 5.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. Ultrasound Diagnosis in Obstetrics and Gynecology. Springer-Verlag, New York, (1986), 182, Table 7.17.)

Head Circumference (HC)

Chitty, Lyn S., et al. "Charts of Fetal Size: 2. Head Measurements." British Journal of Obstetrics and Gynaecology 101: (January 1994), 43, Appendix: HC-Derived.

Hadlock, F., et al. "Estimating Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." Radiology, 152: (1984), 497-501.

Jeanty P, E. Cousaert, and F. Cantraine. "A longitudinal study of Fetal Head Biometry." American J of Perinatology, 1: (January 1984), 118-128, Table 3.

(Also published in Hansmann, Hackeloer, Staudach, Wittman. Ultrasound Diagnosis in Obstetrics and Gynecology. Springer-Verlag, New York, (1986), 176, Table 7.8.)

Head Circumference (HC)/Abdominal Circumference (AC)

Campbell S., Thoms Alison. "Ultrasound Measurements of the Fetal Head to Abdomen Circumference Ratio in the Assessment of Growth Retardation," British Journal of Obstetrics and Gynaecology, 84: (March 1977), 165-174.

Ratio Calculations

FL/AC Ratio

Hadlock F.P., R. L. Deter, R. B. Harrist, E. Roecker, and S.K. Park. "A Date Independent Predictor of Intrauterine Growth Retardation: Femur Length/Abdominal Circumference Ratio," American Journal of Roentgenology, 141: (November 1983), 979-984.

FL/BPD Ratio

Hohler, C.W., and T.A. Quetel. "Comparison of Ultrasound Femur Length and Biparietal Diameter in Late Pregnancy," American Journal of Obstetrics and Gynecology, 141:7 (Dec. 1 1981), 759-762.

FL/HC Ratio

Hadlock F.P., R. B. Harrist, Y. Shah, and S. K. Park. "The Femur Length/Head Circumference Relation in Obstetric Sonography." Journal of Ultrasound in Medicine, 3: (October 1984), 439-442.

HC/AC Ratio

Campbell S., Thoms Alison. "Ultrasound Measurements of the Fetal Head to Abdomen Circumference Ratio in the Assessment of Growth Retardation," British Journal of Obstetrics and Gynaecology, 84: (March 1977), 165-174.

General References

+/x or S/D Ratio

$+/x = \text{abs (Velocity A/Velocity B)}$
where A = velocity cursor +
 B = velocity cursor x

Acceleration Index (ACC)

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

ACC = abs (delta velocity/delta time)

Elapsed Time (ET)

ET = time between velocity cursors in milliseconds

Percent Area Reduction

Taylor K.J.W., P.N. Burns, P. Breslau. Clinical Applications of Doppler Ultrasound, Raven Press, N.Y., (1988), 130-136.

Zwiebel W.J., J.A. Zagzebski, A.B. Crummy, et al. "Correlation of peak Doppler frequency with lumen narrowing in carotid stenosis." Stroke, 3: (1982), 386-391.

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

where: A1 = original area of the vessel in square cm
 A2 = reduced area of the vessel in square cm

Percent Diameter Reduction

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

% Diameter Reduction = $(1 - D2(\text{cm})/D1(\text{cm})) * 100$

where: D1 = original diameter of the vessel in cm
 D2 = reduced diameter of the vessel in cm

Pressure Gradient (PGr) in mmHG

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

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

Peak E Pressure Gradient (E PG)

$$E PG = 4 * PE^2$$

Peak A Pressure Gradient (A PG)

$$A PG = 4 * PA^2$$

Peak Pressure Gradient (PGmax)

$$PGmax = 4 * PV^2$$

Mean Pressure Gradient (PGmean)

$$PGmean = 4 * Vmax^2$$

Pulsatility Index (PI)

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

$$PI = (PSV - EDV)/V$$

where

PSV = peak systolic velocity

EDV = end diastolic velocity

V = mean flow velocity throughout the entire cardiac cycle

Resistive Index (RI)

Kurtz, A.B., W.D. Middleton. Ultrasound-the Requisites. Mosby Year Book, Inc., (1996), 467.

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

where

A = velocity cursor +

B = velocity cursor x

Time Averaged Mean (TAM) in cm/s

$$TAM = \text{mean (mean Trace)}$$

Volume (Vol)

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

Volume Flow (VF) in l/m

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

$$VF = CSA * TAM * .06$$

Chapter 9: Specifications

This chapter contains system and accessory specifications and agency approvals. The specifications for recommended peripherals can be found in the manufacturers' instructions.

System Dimensions

Length: 11.8 in. (29.97 cm)

Width: 10.9 in. (27.69 cm)

Depth: 3.0 in. (7.62 cm)

Weight: 8.3 lbs. (3.76 kg) with the C60 transducer and battery installed

Display Dimensions

Length: 5.1875 in. (13.18 cm)

Width: 6.75 in. (17.15 cm)

Diagonal: 8.5 in. (21.59 cm)

Transducers

- C8/8-5 MHz 8 mm curved array (5 ft./1.5 m)
- C11/8-5 MHz 11 mm microcurved array (5 ft./1.5 m)
- C15/4-2 MHz 15 mm microcurved array (5.5 ft./1.7 m)
- C60/5-2 MHz 60 mm curved array (5 ft./1.5 m)
- HST/10-5 MHz 25 mm linear array (8 ft./2.1 m)
- ICT/8-5 MHz 11 mm intracavitary array (5 ft./1.5 m)
- L25/10-5 MHz 25mm linear array (5.5 ft./1.7 m)
- L38/10-5 MHz 38 mm linear array (5.5 ft./1.7 m)

Imaging Modes

2D (256 gray shades)

Color power Doppler (CPD) (256 colors)

Color Doppler (Color) (256 colors)

Directional color power Doppler (DCPD) (256 colors)

M Mode

Pulsed wave (PW) Doppler

Continuous Wave (CW) Doppler

Tissue Harmonic Imaging

Applications

- Abdominal Imaging
- Cardiac Imaging
- Gynecology and Infertility Imaging
- Interventional and Intraoperative Imaging Applications
- Obstetrical Imaging
- Pediatric and Neonatal Imaging
- Prostate Imaging
- Superficial Imaging
- Vascular Imaging

Image Storage

The number images saved to the CompactFlash card vary depending on the card storage capacity.
Cine buffer

Accessories

Hardware, Software, and Documentation

- AIUM Ultrasound Medical Safety Guidance Document
- Battery
- Biopsy Guide
- Carry case
- External display
- MDS Lite
- Mobile Docking System (MDS)
- Mini-Dock
- Power supply
- Quick Reference Guide
- SiteLink Image Manager 2.2
- System User Guide
- Triple Transducer Connect, MDS
- Triple Transducer Connect, MDS Lite
- Ultrasound gel

Cables

ECG cable (6 ft./1.8 m)

System AC power cord (10 ft./3.1 m)

Peripherals

See the manufacturer's specifications for the following peripherals.

Medical Grade

Black-and-white printer

Recommended sources for printer paper: Contact Sony at 1-800-686-7669 or www.sony.com/professional to order supplies or to obtain the name and number of the local distributor.

Color printer

Video cassette recorder

Non-Medical Grade

Kensington Security Cable

Temperature, Pressure, and Humidity Limits

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

Operating Limits: System

10–40°C (50–104°F), 15–95% R.H.

700 to 1060hPa (0.7 to 1.05 ATM)

Shipping/Storage Limits: System without Battery

-35–65°C (-31–149°F), 15–95% R.H.

500 to 1060hPa (0.5 to 1.05 ATM)

Operating Limits: Battery

10–40°C (50–104°F), 15–95% R.H.

Shipping/Storage Limits: Battery

-20–60°C (-4–140°F), 0–95% R.H.*

500 to 1060hPa (0.5 to 1.05 ATM)

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

Operating Limits: Transducer

10–40°C (50–104°F), 15–95% R.H.

Shipping/Storage Limits: Transducer

-35–65°C (-31–149°F), 15–95% R.H.

Electrical

Power Supply Input: 100-240 VAC, 50/60 Hz, 1.2 A Max @ 100 VAC.

| | |
|-----------------------------------|---|
| Power Supply Output (system on): | (1) 15 VDC, 2.7A Max (system) |
| | (2) 12.6 VDC, 0.8A Max (battery charging) |
| Power Supply Output (system off): | (1) 15 VDC, 2.0A Max (system) |
| | (2) 12.6 VDC, 1.8A Max (battery charging) |
| | Combined output not exceeding 52W. |

Battery

6-cell, 11.25 VDC, 4.4 amp-hours, rechargeable lithium ion battery pack.

Run time is 2 hours or more, 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.

C22.2, No. 601.1:1990, Canadian Standards Association, Medical Electrical Equipment–Part 1. General Requirements for Safety.

CEI/IEC 61157:1992, International Electrotechnical Commission, Requirements for the Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment.

UL 2601-1:1997, Second 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.

CISPR11:97, 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 SonoSite system, SiteStand, accessories, and peripherals when configured together is: Group 1, Class A.

Airborne Equipment Standards

RTCA/DO160D:1997, Radio Technical Commission for Aeronautics, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21.0 Emission of Radio Frequency Energy, Category B.

DICOM Standard

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

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.

Chapter 10: Glossary

This glossary includes an alphanumeric listing of terms.

The American Institute of Ultrasound in Medicine (AIUM) has published, *Recommended Ultrasound Terminology, Second Edition*, 1997. Refer to it for ultrasound terms not contained in this glossary.

Terms

| | |
|---|---|
| 2D (two-dimensional) image | A way to display echoes in two dimensions on a video display. Video pixels are assigned a brightness level based on echo signal amplitude. See also CPD image, Color Doppler (Color) image, and DCPD image. |
| 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. |
| Color Power Doppler (CPD) image | A Doppler imaging mode used to visualize the presence of detectable blood flow. See also 2D image, Color image, and DCPD image. |
| Color Doppler (Color) image | A Doppler imaging mode used to visualize the presence, velocity, and direction of blood flow in a wide range of flow states. See 2D image, CPD image, and DCPD image. |
| continuous wave (CW) Doppler mode | A Doppler recording of blood flow velocities along the length of the beam. |
| 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. E.g., C15, C60. |
| depth | A menu item used to adjust 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. |
| Directional Color Power Doppler (DCPD) image | A Doppler imaging mode used to visualize the presence of detectable blood flow and the direction of blood flow. See also 2D image, Color image, and CPD image. |
| in situ | In the natural or original position. |
| 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. E.g, L38. |

| | |
|---|--|
| M Mode | Motion Mode showing the phasic motions of the cardiac structures. A single beam of ultrasound is transmitted and reflected signals are displayed as dots of varying intensities, which create lines across the screen. |
| 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 and thermal index. |
| NTSC | National Television Standards Committee. A video format setting. See also PAL. |
| PAL | Phase Alternating Line. A video format setting. See also NTSC. |
| pulsed wave (PW) Doppler mode | A Doppler recording of blood flow velocities in a range specific area along the length of the beam. |
| skinline | A depth on the display that corresponds to the skin/transducer interface. |
| 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. |

variance

Displays a variation in Color Doppler flow imaging within a given sample. Variance is mapped to the color green and is used to detect turbulence

Acronyms

Acronyms used in the user interface are listed below.

Table 1: Acronyms

| Acronym | Description |
|----------------|--|
| +/ \times | "+" Caliper/" \times " Caliper Ratio |
| A | "A" Wave Peak Velocity |
| A4Cd | Apical 4 Chamber diastolic |
| A4Cs | Apical 4 Chamber systolic |
| A2Cd | Apical 2 Chamber diastolic |
| A2Cs | Apical 2 Chamber systolic |
| A PG | "A" Wave Peak Pressure Gradient |
| abs | Absolute value |
| AC | Abdominal Circumference |
| ACC | Acceleration Index |
| AFI | Amniotic Fluid Index |
| Ao | Aorta |
| AoD | Aortic Root Diameter |
| ACS | Aortic Valve Cusp Separation |
| APTD | Anteroposterior Trunk Diameter |
| AT | Acceleration (Deceleration) Time |
| AUA | Average Ultrasound Age |
| AV | Aortic Valve |
| AVA | Aortic Valve Area |
| BPD | Biparietal Diameter |

Table 1: Acronyms (Continued)

| Acronym | Description |
|----------------|--|
| BPM | Beats per Minute |
| CO | Cardiac Output |
| CCA | Common Carotid Artery |
| CPD | Color Power Doppler |
| CRL | Crown Rump Length |
| CW | Continuous Wave Doppler |
| D | Diameter |
| DCCA | Distal Common Carotid Artery |
| DCPD | Directional Color Power Doppler |
| DECA | Distal External Carotid Artery |
| DICA | Distal Internal Carotid Artery |
| dP:dT | Delta Pressure: Delta Time |
| E | "E" Wave Peak Velocity |
| E PG | "E" Wave Peak Pressure Gradient |
| E:A | E:A Ratio |
| ECA | External Carotid Artery |
| ECG | Electrocardiogram |
| EDD | Estimated Date of Delivery |
| EDD by AUA | Estimated Date of Delivery by Average Ultrasound Age |
| EDD by LMP | Estimated Date of Delivery by Last Menstrual Period |
| EF | Ejection Fraction |
| EF:SLOPE | E-F Slope |
| EFW | Estimated Fetal Weight |
| EPSS | "E" Point Septal Separation |
| Estab. DD | Established Due Date |

Table 1: Acronyms (Continued)

| Acronym | Description |
|----------------|--|
| ET | Elapsed Time |
| FHR | Fetal Heart Rate |
| FL | Femur Length |
| FTA | Fetal Trunk Area |
| GA | Gestational Age |
| GS | Gestational Sac |
| HC | Head Circumference |
| HR | Heart Rate |
| ICA | Internal Carotid Artery |
| IVS | Interventricular Septum |
| IVSd | Interventricular Septum Diastolic |
| IVSs | Interventricular Septum Systolic |
| IVSFT | Interventricular Septum Fractional Shortening |
| LA | Left Atrium |
| LA/Ao | Left Atrium/Aorta Ratio |
| LMP | Last Menstrual Period |
| LMPd | derived Last Menstrual Period |
| LV Volume | Left Ventricular Volume |
| LV Area | Left Ventricular Area |
| LVD | Left Ventricular Dimension |
| LVDd | Left Ventricular Dimension Diastolic |
| LVDs | Left Ventricular Dimension Systolic |
| LVDfS | Left Ventricular Dimension Fractional Shortening |
| LVEDV | Left Ventricular End Diastolic Volume |
| LVESV | Left Ventricular End Systolic Volume |

Table 1: Acronyms (Continued)

| Acronym | Description |
|----------------|---|
| LVET | Left Ventricular Ejection Time |
| LVOT | Left Ventricular Outflow Tract |
| LVOT area | Left Ventricular Outflow Tract Area |
| LVOT D | Left Ventricular Outflow Tract Diameter |
| LVPW | Left Ventricular Posterior Wall |
| LVPWd | Left Ventricular Posterior Wall Diastolic |
| LVPWFT | Left Ventricular Posterior Wall Fractional Thickening |
| LVPWs | Left Ventricular Posterior Wall Systolic |
| MCA | Middle Cerebral Artery |
| MCCA | Mid Common Carotid Artery |
| MECA | Mid External Carotid Artery |
| MI | Mechanical Index |
| MICA | Mid Internal Carotid Artery |
| MV | Mitral Valve |
| MVA | Mitral Valve Area |
| NTSC | National Television Standards Committee |
| OFD | Occipital Frontal Diameter |
| PAL | Phase Alternating Line |
| PCCA | Proximal Common Carotid Artery |
| PECA | Proximal External Carotid Artery |
| PGr | Pressure Gradient |
| PGmax | Maximum Pressure Gradient |
| PGmean | Mean Pressure Gradient |
| PHT | Pressure Half Time |
| PI | Pulsatility Index |

Table 1: Acronyms (Continued)

| Acronym | Description |
|--------------------|---|
| PICA | Proximal Internal Carotid Artery |
| PV | Pulmonic Valve |
| PW | Pulsed Wave Doppler |
| RI | Resistive Index |
| RVD | Right Ventricular Dimension |
| RVDd | Right Ventricular Dimension Diastolic |
| RVDs | Right Ventricular Dimension Systolic |
| RVW | Right Ventricular Free Wall |
| RVWd | Right Ventricular Free Wall Diastolic |
| RVWs | Right Ventricular Free Wall Systolic |
| S/D | Systolic/Diastolic Ratio |
| SV | Stroke Volume |
| TAM | Time Average Mean |
| THI | Tissue Harmonic Imaging |
| TI | Thermal Index |
| TRmax | Tricuspid Regurgitation (peak velocity) |
| TTD | Transverse Trunk Diameter |
| TV | Tricuspid Valve |
| Umb A | Umbilical Artery |
| VA _{rt} y | Vertebral Artery |
| V _{max} | Peak Velocity |
| V _{mean} | Mean Velocity |
| Vol | Volume |
| VF | Volume Flow |
| VTI | Velocity Time Integral |

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